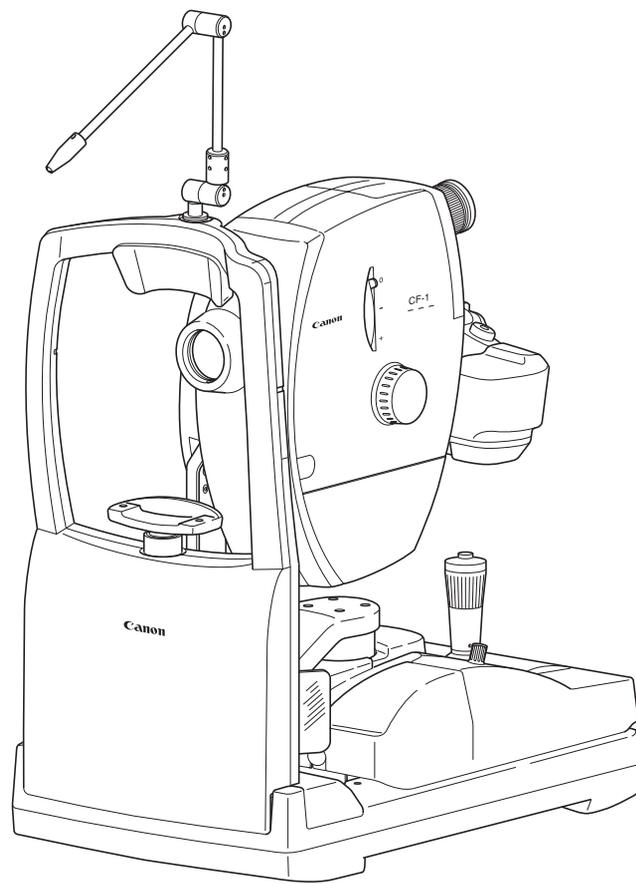


Canon

Digital Retinal Camera

CF-1

Operation Manual



MERCOFRAMES OPTICAL CORP

5555 Nw 74 Ave. Miami, Fl. 33166

Tel. 305-882-0120

ale@mercoframes.com

CE

Make sure you read this manual before using the instrument.
Keep this manual in a safe place so that you can use it in the future.

PLEASE NOTE

1. Please contact your sales representative or local Canon dealer to have the instruments installed.
2. The computer and monitor used in the CF-1 fundus imaging system must conform to IEC60601-1/UL60601-1 or IEC60950/UL60950.
Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. If in doubt, consult your sales representative or local Canon dealer.
Be sure to also use an isolation transformer conforming to IEC60601-1/UL60601-1 when a computer or monitor conforming to IEC60950/UL60950 is used.
3. The user is responsible for the use and maintenance of the product.
We suggest that a dedicated individual is assigned responsibility for maintenance to ensure that the product is kept in good condition and can be used safely.
Medical products must be used only by a doctor or a legally qualified person.
4. This product may malfunction due to electromagnetic waves caused by cellular phones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as these, which affect this product, brought near the product.
5. In no event will Canon be liable for direct or indirect consequential damage arising out of the use of this product. Canon will not be liable for loss of image data for any reason.
6. Reading of images and storage of data must be performed in accordance with the law of the country where the product is being used. Also, the user is responsible for maintaining the privacy of image data.
7. The power cable supplied is designed to be used solely with this camera. Do not use it for any other product.
8. Canon reserves the right to change the specifications, configuration and appearance of the product without prior notice.



European Union (and EEA*) only.

This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2002/96/EC) and your national law. 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 your household waste disposal service. For more information regarding return and recycling of WEEE products, please visit www.canon-europe.com/weee.

* EEA : Norway, Iceland and Liechtenstein

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Safety Information

Regulations

This instrument conforms to IEC 60601-1-2:2001/A1:2004 and IEC 60601-1-2:2007.

For USA and Canada

- When the CF-1 is going to be operated at a voltage of 240V in USA or Canada, be sure to connect the instrument to a center tapped voltage source.
- This instrument is CLASS I EQUIPMENT according to UL60601-1.

WITH RESPECT TO ELECTRICAL SHOCK, FIRE MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1, MEDICAL EQUIPMENT CERTIFIED FOR CANADA



MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1 <CONTROL NUMBER 41C4>

- Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade".
- The following mark indicates that the instrument is Type B Applied Parts (forehead rest and chin rest).



- The degree of protection against ingress of water is IPX0.
- This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
- The mode of operation is Continuous Operation.

For EU Countries

- The following mark shows compliance of the instrument with Directive 93/42/EEC.



- This instrument is CLASS I EQUIPMENT according to EN 60601-1:2006 and IEC 60601-1:2005.
- The following mark indicates that the instrument is Type B Applied Parts (forehead rest and chin rest) according to EN 60601-1.



- The degree of protection against ingress of water is IPX0.
- This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
- The mode of operation is Continuous Operation.

Für Deutschland

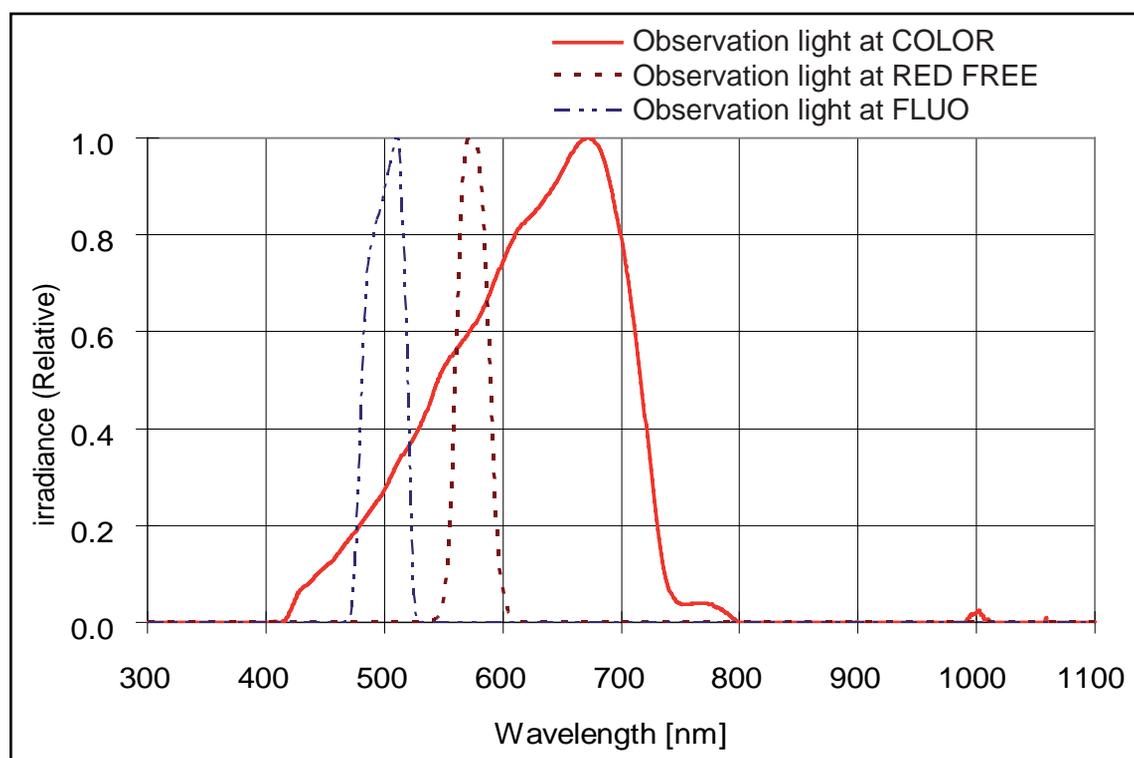
- Während des Betriebs liegt der Schalldruckpegel dieses Instruments bei 70 dB(A) oder weniger gemäß ISO 7779.

Safety Information

ISO15004

This report provides information about the hazard to the examinee's eyes in compliance with ISO15004 (1997).

1. The spectral characteristics of radiant flux exiting from this instrument are as follows:



2. Photochemical radiance

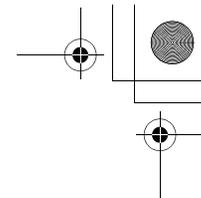
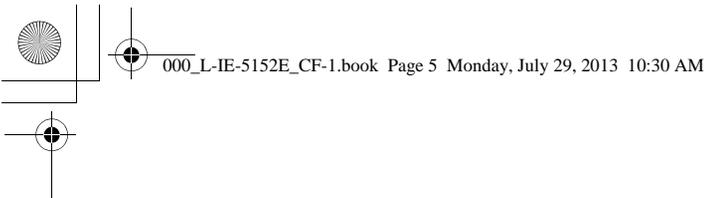
The photochemical radiances at each photography modes irradiated from this instrument to the examinee's eyes are indicated below. All the values in the following table were measured when the instrument was operating at maximum light intensity and maximum aperture.

	La [mW/cm ² /sr]	Lb [mW/cm ² /sr]
(1) Color	0.352	0.347
(2) Red Free	0.009	0.009
(3) Fluo	0.252	0.252

3. The above values are spectrally weighted radiance on the pupil of examinee's eyes in each wavelength.

La gives the measure for eyes in which the crystalline lens has been removed (aphakes) or for eyes of infants. Lb gives this measure for eyes in which the crystalline lens is in place except for infants'.

Spectrally weighted photochemical radiances La and Lb give a measure of the potential that exists for a beam of light to cause photochemical hazard to the retina.



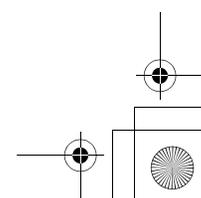
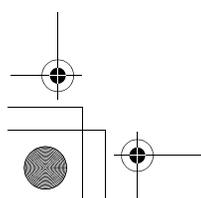
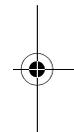
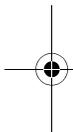
Safety Information

According to the American Conference of Governmental Industrial Hygienist (ACGIH) - Threshold Limit Values for Chemical Substances and Physical Agents (1995 - 1996 edition), at photochemical radiances L_a and L_b of $80 \text{ [mW/cm}^2\text{/sr]}$, 3 minutes irradiation would cause the retinal exposure dose level to attain the recommended exposure limit.

If the value of radiance was $40 \text{ [mW/cm}^2\text{/sr]}$, 6 minutes would be needed to reach the recommended limit.

That is, the retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time.

Since L_a and L_b of this instrument are extremely low, the risk of the photochemical hazard is also very low. While no acute optical radiation hazards have been identified for this instrument, it is recommended that the intensity of light directed into the examinee's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.



Safety Information

EMC (Electromagnetic Compatibility)

The CF-1 is designed and tested to comply with IEC 60601-1-2 (EN 60601-1-2), the applicable regulations regarding EMC for medical devices and must be installed and put into service according to the EMC information stated as follows.

If this equipment causes harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect this device into an outlet on a circuit different from that to which the other devices are connected.

If the problem cannot be solved with the above measures, stop using this equipment and consult your sales representative or local Canon dealer.

Precautions on EMC

1. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the manual.
2. Portable and mobile RF communications equipment can affect medical electrical equipment.
3. Information regarding the cable affecting EMC is as follows.

To maintain the optimum EMC performance, use only the designated cables.

Name	Type	Length	Remarks
AC Power cable	BH4-6217	3.0 m fixed-length	Supplied.
USB cable	KU20-3H (Shielded)	Max 3.0 m	Not Supplied.
USB cable	KU20-3H (Shielded)	Max 3.0 m	Not Supplied.

4. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by your sales representative or local Canon dealer as replacement parts for internal components, may result in increased emissions or decreased immunity of the CF-1.
5. The CF-1 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the CF-1 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration for EMC Directive

Electromagnetic Emissions

The CF-1 is intended for use in the electromagnetic environment specified below. The user of the CF-1 should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11 EN 55011	GROUP 1	The CF-1 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 CISPR 11 EN 55011	Class A	The CF-1 is suitable for use in all establishments other than domestic 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.

Safety Information

Electromagnetic Immunity

The CF-1 is intended for use in the electromagnetic environment specified below.
The user of the CF-1 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) EN IEC 61000-4-2	$\pm(2, 4, 6)$ kV contact $\pm(2, 4, 8)$ kV air	$\pm(2, 4, 6)$ kV contact $\pm(2, 4, 8)$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CF-1 requires continued operation during power mains interruptions, it is recommended that the CF-1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF EN IEC 61000-4-6</p> <p>Radiated RF EN IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the CF-1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separations distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the CF-1 is used exceeds the applicable RF compliance level above, the CF-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CF-1.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Safety Information

Recommended Separation Distances

The CF-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the CF-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CF-1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

General Safety Information

Follow the safety instructions in this manual and all warnings and cautions printed on the warning labels. Ignoring such cautions or warnings while handling the product may result in injury or accident. Be sure to read and fully understand the manual before using this product. Keep this manual for future reference.

Meaning of Caution Signs

To protect the safety of users and others and to prevent accidents, this operation manual utilizes the symbols and text shown below in warnings and cautions. Read the meanings of these caution signs and the Safety Precautions (see page 12), and follow the safety instructions.

 WARNING	This indicates a potentially hazardous situation which, if not heeded, could result in death or serious injury to you or others.
 CAUTION	This indicates a hazardous situation which, if not heeded, may result in minor or moderate injury to you or others, or may result in machine damage.
NOTE	This is used to emphasize essential information. Be sure to read this information to avoid incorrect operation.

Safety Information

Safety Precautions

Be sure to follow the safety instructions below to ensure correct operation of the instrument.

Installation and Environment of Use

 WARNING	<p>Do not use or store the instrument near any flammable chemicals such as alcohol, thinner, or benzene. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the instruments. Also, some disinfectants are flammable. Be sure to exercise caution when using them.</p>
 CAUTION	<p>Do not use or store the instrument in a location with the conditions listed below. Otherwise, it may result in failure or malfunction, fall or cause fire or injury.</p> <ul style="list-style-type: none"> • 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.
 CAUTION	<p>Do not cover the vent holes on the cover. Otherwise, the temperature in the instrument may rise and cause fire.</p>
 CAUTION	<p>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.</p>

Installation Operation

 WARNING	<p>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.</p>
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Power Supply

 WARNING	<p>Only operate with the type of power supply indicated on the rating label. Otherwise, fire or electric shock may result.</p>
 WARNING	<p>Be sure to turn OFF the power before plugging or unplugging the cables as indicated in this manual. Also, do not handle the cables with wet hands. Otherwise, you may get an electric shock that may result in death or serious injury.</p>

Power Supply

 WARNING	Securely plug in the power cable into the AC outlet. If contact failure occurs, or if dust or a metal object comes in contact with the exposed metal prong of the plug, fire or electric shock may result.
 WARNING	Be sure to hold the plug to disconnect the power cable. If you pull the cable, the core wire may be damaged, resulting in fire or electric shock.
 WARNING	Do not cut or process the cables. Also, do not place anything heavy on the cables (including the instrument). Do not step on, pull bend, or bundle the cables. Otherwise, the cable may be damaged, which may result in fire or electric shock.
 WARNING	Do not get the power for more than one instrument from the same AC outlet. Otherwise, it may result in fire or electric shock.
 CAUTION	Before connecting or disconnecting the cables, be sure to hold the instrument firmly in order to ensure safety. Otherwise, the main unit may fall over, possibly causing injury.
 CAUTION	The instrument is shipped with a grounding type (three-core) power cable. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
 CAUTION	To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet.

Handling

 WARNING	Never disassemble or modify the product as it may result in fire or electric shock. Also, since the instrument incorporates high-voltage parts that may cause electric shocks and other hazardous parts, touching them may cause death or serious injury.
 WARNING	Do not place anything on top of the instrument. Otherwise, the object may fall and cause injury. Also, if metal objects such as a needle or clip falls into the instrument, or if liquid is spilled, it may result in fire or electric shock.
 WARNING	When the instrument is going to be moved, be sure to turn OFF the power, unplug the power cable from the AC outlet, and disconnect other cables. Otherwise, the cable may be damaged, which may result in fire or electric shock.
 WARNING	When the instrument is going to be carried, be sure to tighten the stage unit lock, hold the indentations for lifting at the left and right of the bottom panel and hold the instrument horizontally. Do not hold it by the digital camera or the head rest poles or other parts, as they may come off and result in injury.
 WARNING	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.

Safety Information

Handling

 CAUTION	To prevent the risk of infection, wipe the forehead rest with disinfectant ethanol 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.
 CAUTION	To ensure cleanliness, replace the chin rest paper for each patient.
 CAUTION	When adjusting the forward position of the main unit, be sure to move the main unit slowly toward the patient while looking from the side of the patient, to prevent accidental contact of the objective lens with the patient.
 CAUTION	Do not place your hands or fingers or allow the patient to place his/her hands or fingers between the stage and base. Otherwise, injury may occur.
 CAUTION	When the instrument is not going to be used, turn OFF the power. Also, unplug the power cable from the AC outlet when it is not going to be used for long periods of time.
 CAUTION	The instrument weighs approximately 26 kg (57 lbs). Be sure that at least two people lift the instrument to transport it and that it is lifted by gripping the indentations for lifting. Otherwise, injury may occur.

When Problem Occurs

 WARNING	<p>Should any of the following occur, immediately turn OFF the power of each instrument, unplug the power cable from the AC outlet, and contact your sales representative or local Canon dealer.</p> <ul style="list-style-type: none"> • When there is smoke, an odd smell or abnormal sound. • When liquid has been spilled into the instrument or a metal object has entered through an opening. • When the instrument has been dropped and it is damaged.
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Maintenance and Inspection

 WARNING	For safety reasons, be sure to turn OFF the power when the inspections indicated in this manual are going to be performed. Otherwise, electric shock may result.
 WARNING	When the instrument is going to be cleaned, be sure to turn OFF the power, and unplug the power cable from the AC outlet. Never use alcohol, benzene, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.
 WARNING	Clean the plug of the power cable periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth. If the cable is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture, and this could cause insulation failure which could result in a fire.

Maintenance and Inspection

 WARNING	The instrument must be repaired by a qualified engineer only. If it is not repaired properly, it may cause fire, electric shock, or accident.
 CAUTION	For safety reasons, be sure to inspect the instrument before using it.
 CAUTION	Always take a test image to check that there is no foreign matter present that can affect image readings before using the instrument (see page 44).

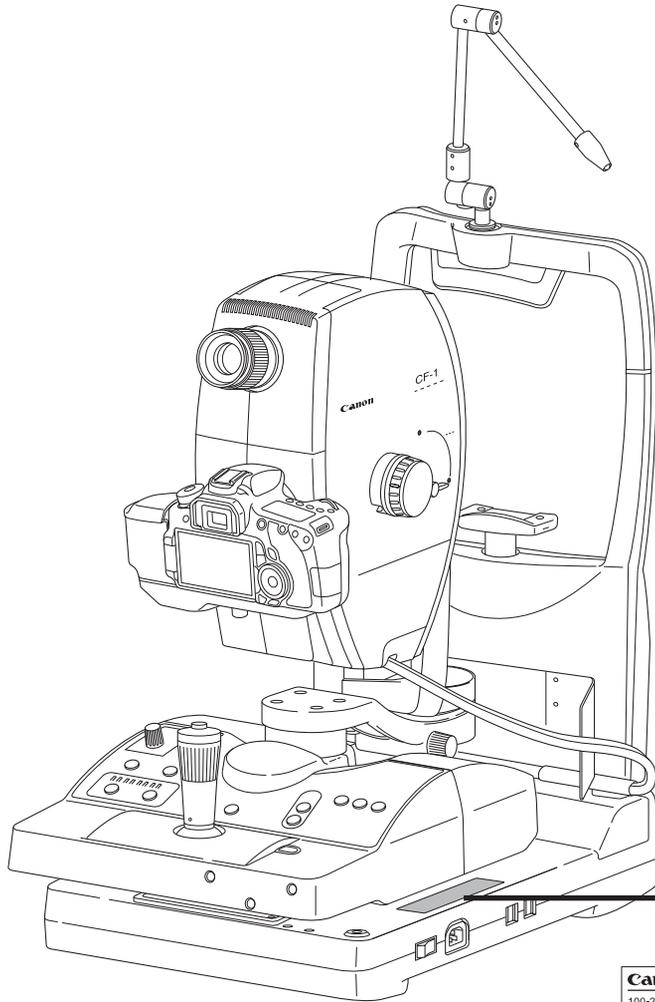
System Use

 WARNING	Do not place multiple portable socket-outlets on the floor. Otherwise, fire or electric shock may result.
 WARNING	Do not connect an additional multiple portable socket-outlet or extension cord to the system. Otherwise, fire or electric shock may result.
 WARNING	Do not connect instruments that are not specified as part of the system. Otherwise, fire or electric shock may result.
 WARNING	For the system, use a power transformer of 1000 VA of the maximum permitted load. Otherwise, fire or electric shock may result.
 WARNING	Use multiple portable socket-outlets only for supplying power to equipment that is intended to form part of the system. Otherwise, fire or electric shock may result.
 WARNING	Do not connect non-medical electrical equipment that has been supplied as a part of the system to any power socket other than the multiple socket-outlets for the system. Otherwise, electric shock may result.
 WARNING	Do not connect any electrical equipment that has not been supplied as a part of the system to the multiple portable socket-outlets for the system. Otherwise, fire or electric shock may result.
 WARNING	Do not simultaneously touch a patient and non-medical electrical equipment. Otherwise, electric shock may result.
 CAUTION	For cleaning equipment forming part of the system, follow the instruction manual for the equipment. Otherwise, it may cause failure, an accident, or fire.
 CAUTION	Install the system in a way that enables the user to achieve optimal use.

Safety Information

Labels and Markings on the Instrument

The CF-1 has a label on it.
The label contents and its position are indicated below.



Canon	Digital Retinal Camera CF-1	Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL GRADE".
100-240V ~	50/60Hz	7-3A
See Accompanying Documents		Rx only
MANUFACTURED:		CANON INC. 30-2, SHIMOMARUKO 3-CHOME, OHTA-KU, TOKYO, JAPAN
		NO. MADE IN JAPAN

For 110-120V Countries

Canon	Digital Retinal Camera CF-1	
100-240V ~	50/60Hz	7-3A
MANUFACTURED:		CANON INC. 30-2, SHIMOMARUKO 3-CHOME, OHTA-KU, TOKYO, JAPAN
		SN MADE IN JAPAN

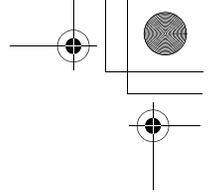
For 230-240V Countries

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1. Features

The Canon CF-1 digital retinal camera is used to observe the retinas of patients' eyes and take photographic images of them (in 4 modes: color, red-free, OPTION and fluorescein angiography). The camera has the following features:

Compact size and superior operability

The controller has been designed as a single integrated unit, offering a compact size and light weight. The system offers enhanced ease of operation, making it significantly more efficient and comfortable to assist patients. The alignment procedure has also been improved now that the main unit can be raised and lowered by the operation lever and the chin rest is motor driven.

Panning and tilting functions provided as standard features

Panning and tilting functions are provided as standard options. These functions make it possible to undertake focusing and panning or tilting at the same time.

Support for photographing small pupils

The camera can photograph small pupils when the pupils have a field angle of 50° and a diameter of 5.2 mm or greater.

If it is difficult to dilate the pupil of a patient's eye, the small pupil photography function enables photographs to be taken of pupils with a diameter of $\phi 4.3$ mm or greater.

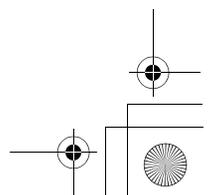
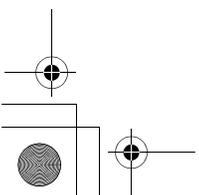
System optimized for digital photography

By using the Retinal imaging control software MYD (hereinafter called "control software"), the images photographed by the CF-1 can be browsed, processed, stored, output to the DICOM storage server, exported to DICOM files and output to an inkjet printer.

High-speed image transfer is enabled using the USB 2.0 interface. In addition, depending on whether color, red-free, OPTION or fluorescein angiography is established as the photography mode, the lighting system filter, flash intensity and EOS digital camera are automatically set and other steps are taken to optimize the photography workflow.

High picture quality, high-definition diagnostic images

Diagnostic images with a high picture quality and high definition can be obtained by using an EOS digital camera that incorporates a large, high-definition CMOS sensor.



2. Notes for Using the Instrument

Before Use

- Take a daily test image to ensure that there is no foreign matter present that can affect image readings.
- Check and clean the objective lens before taking an image, as any stains or scratches on it will appear as white spots.
- Sudden heating of the room in cold areas will cause condensation to form on the objective lens or on optical parts inside the instrument. In this case, wait until condensation disappears before performing photography.
- Do not touch the lens of the main unit or the mirror of the digital camera when attaching and detaching the digital camera from the main unit.

If any dirt, fingerprints, dust, or other foreign objects attach to 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

- Turn OFF the power of the instrument. Place the cap over the objective lens, and place the dust cover over the instrument.
You will not be able to take a good picture when the objective lens is dirty.
- If the EOS digital camera is removed and left unattached, dust and other foreign objects can enter the main unit and the EOS digital camera. Always be sure to attach the caps to the respective mounts.

Cleaning and Disinfection

- Do not let the tip of a blower touch the objective lens.
- Do not wipe off or rub the objective lens when there is dust or other substances on it.
This could scratch the lens surface.
- Never wipe the objective lens with disinfecting ethanol, eyeglass lens cleaner, or cleaning paper containing silicon.
The lens surface could be damaged or the surface may not be completely wiped off.
- Do not clean the cover of the instrument with lens cleaner. The cover of the instrument could be damaged.
- Never use alcohol, benzene, thinner, or other solvents to clean the cover of the instrument. This could damage the cover of the instrument.
- Never use disinfecting ethanol, glutaraldehyde or other solvents to clean the cover of the instrument, except the forehead rest and the chin rest. This could damage the cover of the instrument.
- If the chin rest paper will not be used, be sure to disinfect the chin rest for each patient in the same manner as for the forehead rest.

2. Notes for Using the Instrument

Environment of Use

- Do not install or store the camera or leave it standing in an adverse environment such as where the temperature and humidity levels are high. Doing so may cause misoperation and/or malfunction. Be sure to follow the instructions on page 9 when selecting the installation location.
- Dust in the air will not only attach to the objective lens, also to the optical parts inside the instrument. You will not be able to take a good image when dust is on these parts. Please keep the room dust free.

Installation

- Please ask your sales representative or local Canon dealer to perform installation of this product.
- Please handle this product carefully. The adjustment can be altered if it is subjected to a strong shock or jolt.
- If this product will be transported in an automobile or shipped a long distance, protective measures need to be taken against vibrations and shocks. Ask your sales representative or local Canon dealer for more information.

Others

For USA

Rx only-Caution:

Federal law restricts this device to sale by or on the order of a licensed practitioner.

Intended Use:

CF-1 is intended to be used for taking digital images of the retina of human eye with a mydriatic.

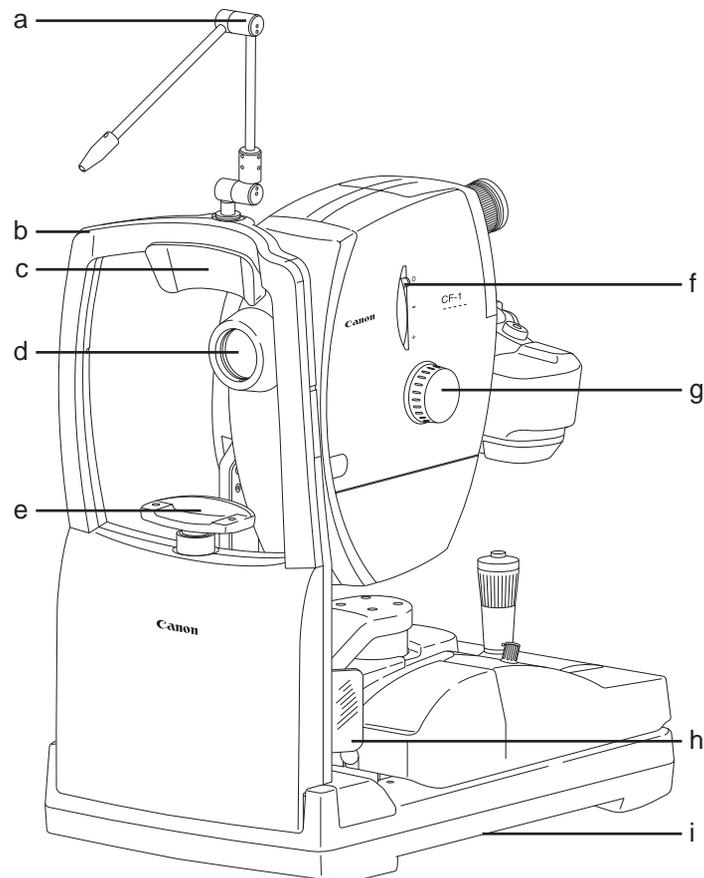
For European Union

Intended Use:

This medical device is intended to observe, image and record the retinal fundus through the pupil without contact with the subject's eye for the purpose of diagnosis by way of producing fundus image information.

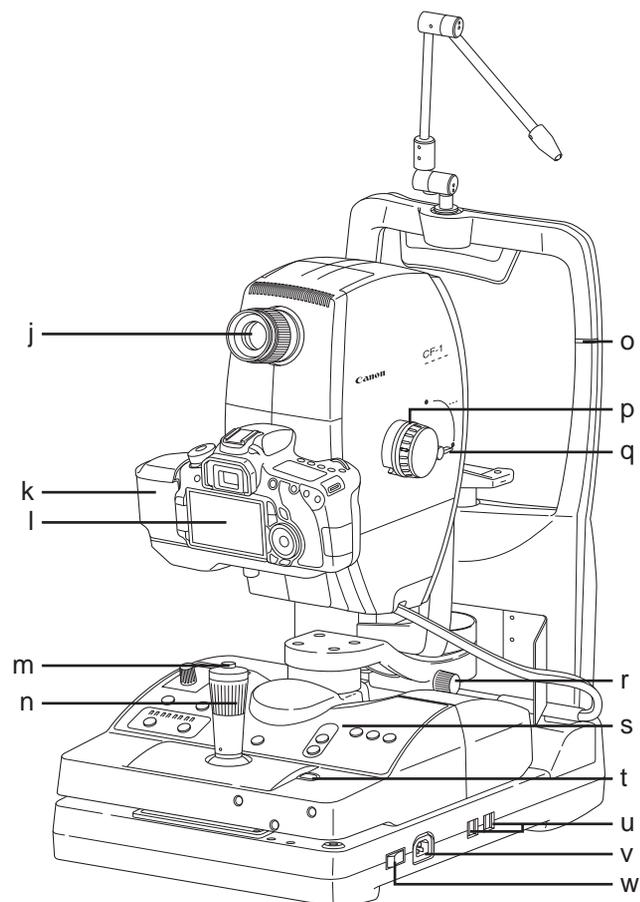
3. Description

3.1 Main Unit



Symbol	Name	Function
a	External eye fixation lamp	Used to guide the patient's eye and determine which area of the eye to photograph.
b	Head rest	Holds the patient's head in place.
c	Forehead rest	Place the patient's forehead against this rest.
d	Objective lens	Lens used for photography.
e	Chin rest	Place the patient's chin on this rest.
f	Diopter compensation lever	Used when the target is not brought into focus by turning the focus knob.
g	Focus knob	Used for focusing on the patient's eye.
h	Finger guard	This is a guard which prevents the patient from grasping the head rest.
i	Indentation for lift	To carry the camera, hold these parts at the left and right of the main unit's bottom panel.

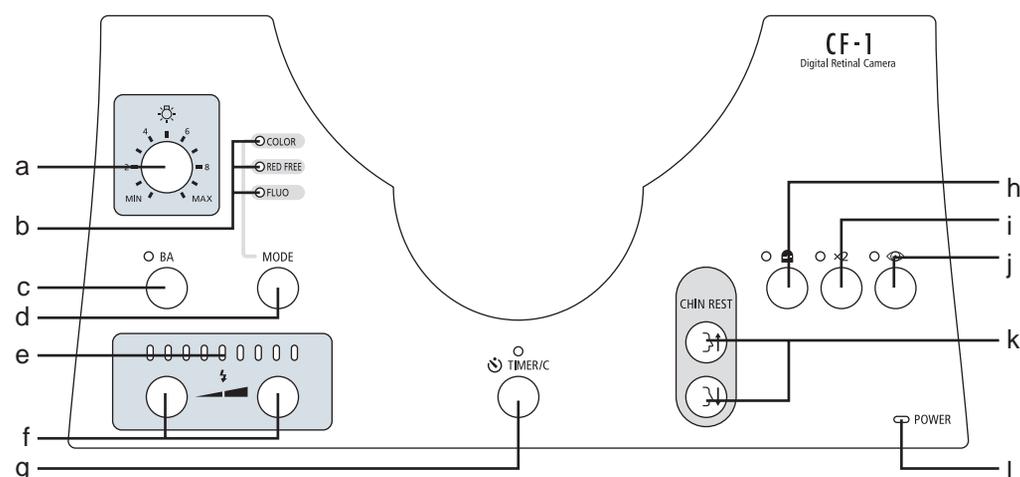
3. Description



Symbol	Name	Function
j	Viewfinder	Use this when positioning and focusing on the patient's eye.
k	Digital camera cover	Covers the terminal of the digital camera.
l	Digital camera	Takes fundus images (sold separately)
m	Shutter release button	Press this button to take an image.
n	Operation lever	Aligns the camera with the patient's eye.
o	Height adjustment mark	Adjust so that the height of the patient's eye is aligned with this mark. This is used for adjusting the height of the chin rest.
p	Pan-tilt grip	Use when adjusting the camera angle from side to side and up and down.
q	Tilting lock lever	Loosen this lever when adjusting the camera angle in the vertical direction.
r	Panning lock knob	Loosen this knob when adjusting the camera angle from side to side.
s	Operation panel	3.2 Operation Panel (see page 24)
t	Stage unit lock button	Locks and unlocks the stage unit.
u	USB connector	The USB cable is connected.
v	AC power connector	The supplied power cable is connected.
w	Power switch	The power turns ON when pressed to the I side, and the power turns OFF when pressed to the O side.

3. Description

3.2 Operation Panel



Symbol	Name	Function
a	Brightness adjuster	Used for adjusting brightness in field of view for observation.
b	Mode indicator lamp	The lamp for the selected photography mode turns ON. COLOR and FLUO light up when the OPTION is selected.
c	BA switch	Switch to insert the barrier filter or disengage it. The lamp lights brightly when the barrier filter is inserted.
d	MODE switch	Selects the photography mode. The mode is displayed in the following sequence: COLOR → RED FREE → OPTION → FLUO → COLOR.
e	Flash intensity indicator	Indicates the flash intensity setting.
f	Flash intensity switch	Pressing the left switch reduces the flash intensity. Pressing the right switch increases the flash intensity.
g	TIMER/C switch	Starts and stops the timer. When the timer has started, the buzzer sounds each second, and the lamp lights brightly. The elapsed time is displayed by the control software. Can be used only when fluorescein angiography mode is selected for the photography mode.
h	Focus indicator switch	Switch to use the focus indicator or not. The lamp lights brightly when the focus indicator is being used.
i	×2 switch	Switches the ×2 photography function ON and OFF. The lamp lights up when the function is ON.
j	Small pupil photography switch	Switches the function for photographing small pupil diameters ON and OFF. The lamp lights brightly when the function is ON.
k	CHIN REST switch	Pressing the top button raises the chin rest. Pressing the bottom button lowers the chin rest.
l	POWER lamp	Lights up when the power is ON.

4. Preparation



Concerning the power-saving function

The power-saving function is activated under the following circumstances:

- When none of the switches on the operation panel have been operated for 10 or more minutes while power is supplied to the camera
- When none of the switches on the operation panel have been operated for 1 or more minutes after the operation to stop the timer has been performed during fluorescein angiography photography

When the power-saving function has been activated, the POWER lamp on the operation panel blinks.

To restore normal operation, press any switch on the operation panel, move the stage to the left or right or operate the diopter compensation lever.



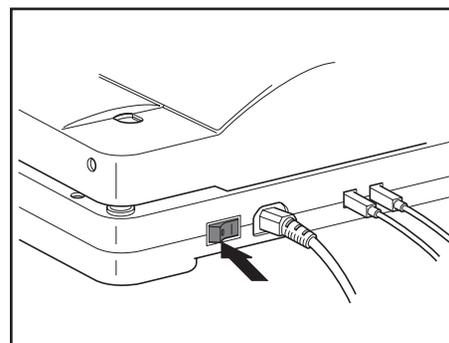
Concerning control software operations

For details on the control software operations, refer to the operation manual of the control software.

Note: Before preparing to take photographs, check the sections on the Power Cable Connections (see page 52), Attaching the EOS Digital Camera (see page 53) and Connecting the USB Cable (see page 56).

4.1 Turn ON the power.

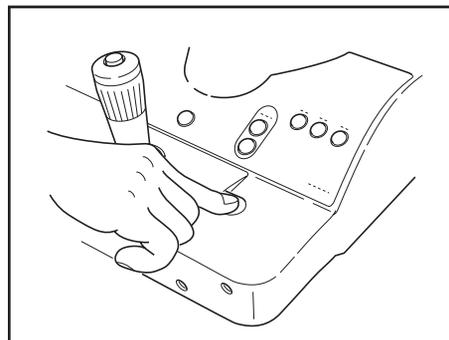
- 1 Turn ON the computer.
Turn ON the computer, and start the control software.
- 2 Turn ON the power of the main unit.
Press the power switch to the I side.



4. Preparation

4.2 Unlock the stage unit.

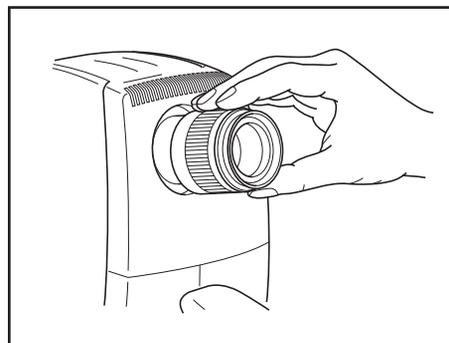
If the stage unit is locked, press the stage unit lock button to release the lock.



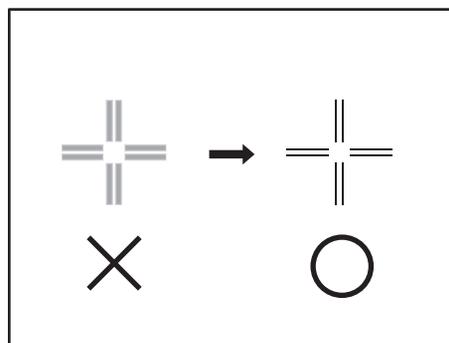
4.3 Adjust the viewfinder.

Note: Be sure to adjust the diopter of the viewfinder so it matches the diopter of the photographer's eye. Otherwise, focusing will not be able to be performed correctly.

Turn the viewfinder diopter compensation ring all the way counterclockwise until it stops.
Then look into the viewfinder with one eye, and look into the distance with the other eye.



Turn the diopter compensation ring all the way to the + side and then gradually turn toward the - side until the cross-hair lines in the field of view appear sharpest.



5. Photography



Concerning control software operations

For details on the control software operations, refer to the operating instructions of the control software.

5.1 Photography modes

Four photography modes are available in the CF-1.

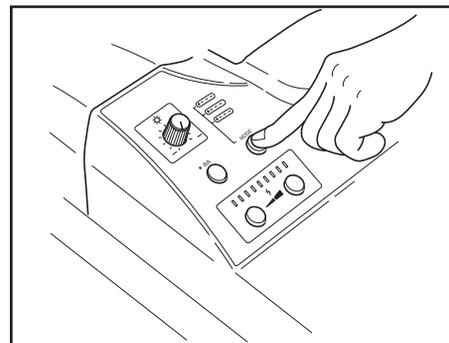
The mode can be selected with the **MODE** switch on the control panel or with the control software.

Photography mode	Features
Color photography (see page 28)	Select this mode to take color fundus images. The small pupil function can be used.
Red-free photography (see page 34)	Select this mode to take red-free fundus images. The small pupil function can be used.
OPTION photography (see page 35)	Select this mode to perform OPTION photography using the exciter filter for fluorescein angiography. The small pupil function can be used.
Fluorescein angiography (see page 36)	Select this mode to take fluorescein angiography images.

5. Photography

5.2 Color photography mode

- 1 Enter the study information into the computer.
Enter the study information with the control software.
- 2 Select color photography mode.
Select COLOR with the MODE switch.
Or select the photography mode with the control software.
The mode indicator lamp (COLOR) lights up.

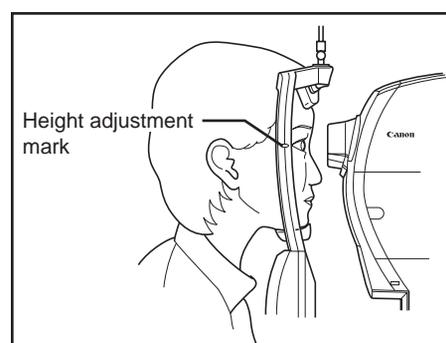


- 3 Disinfect the forehead rest and replace the chin rest paper.

 CAUTION	<p>To prevent the risk of infection, wipe the forehead rest with a disinfectant such as ethanol or glutaraldehyde for each patient. For details on the disinfection procedure, consult a specialist.</p>
 CAUTION	<p>To ensure cleanliness, replace the chin rest paper for each patient.</p>

If chin rest paper is not used, disinfect the chin rest.

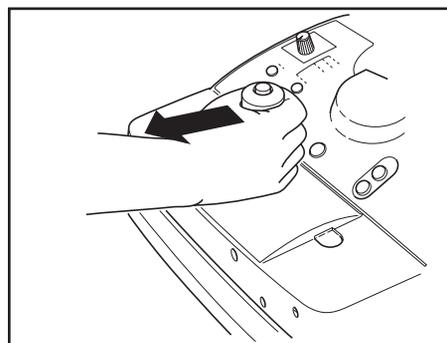
- 4 Have the patient sit down.
Have the patient place his or her chin against the chin rest and his or her forehead against the forehead rest.
- 5 Align the height of the patient's eye.
Move the chin rest up or down so that the patient's eye is aligned with the height adjustment mark.



6 Align the camera's main unit to the eye to be photographed.

 CAUTION	<p>Do not put your fingers or hands between the sliding part and base of the stage unit or on the panning and tilting sliding parts. Similarly, do not allow patients to put their hands in these places. Otherwise, your hands or fingers or theirs may be pinched, possibly resulting in injury.</p>
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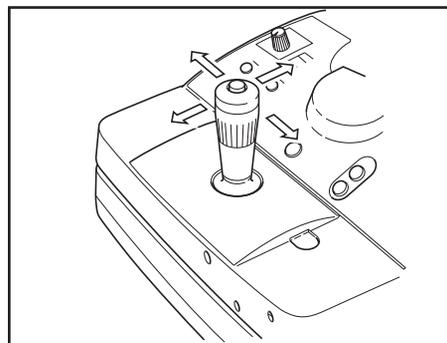
Hold the operation lever, pull it towards you, and then move it in the direction of the eye to be photographed.



7 Align the camera position.

 CAUTION	<p>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. You may injure the patient's eye if the objective lens makes contact with it.</p>
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Use the operation lever to approximately align the camera position.

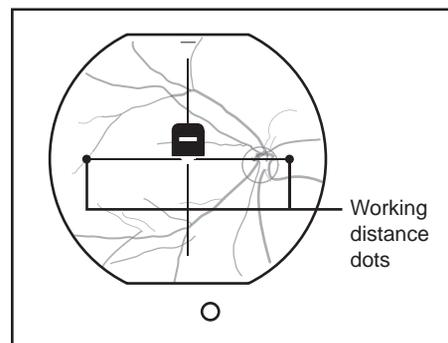


Direction	Operation
Height	Turn the operation lever.
Side movement	While holding the operation lever, pull it to the left and right to perform approximate adjustment; tilt it to the left and right to perform fine adjustment.
Forward/backward	While holding the operation lever, pull it forward and backward to perform approximate adjustment; tilt it forward and backward to perform fine adjustment.

Continued on the following page >>

5. Photography

The position where the working distance dots appear small is the optimum position.



When the split lines are not visible

Part of the split lines may not be visible if the pupil diameter is small.

In this case, press the small pupil photography switch to turn ON the small pupil photography function (see page 39).



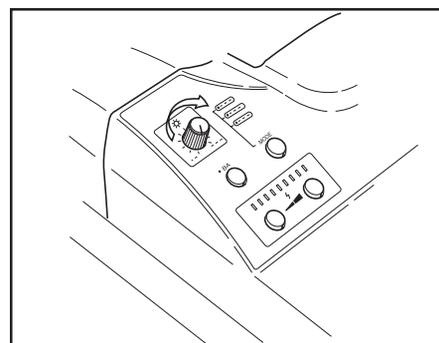
Concerning the linkup function of the working distance dot

Using a setting in the control software, the working distance dot and split line operations can be linked up.

For further details, refer to the operation manual of the control software.

8 Adjust brightness in field of view for observation.

Turning the brightness adjuster clockwise increases the brightness for observation, and turning it counter-clockwise reduces the brightness for observation.



Concerning the brightness for observation

Standard brightness is position 4 on the scale.

Keeping in mind the potential for strain on the patient's eye, select the lowest possible brightness level.

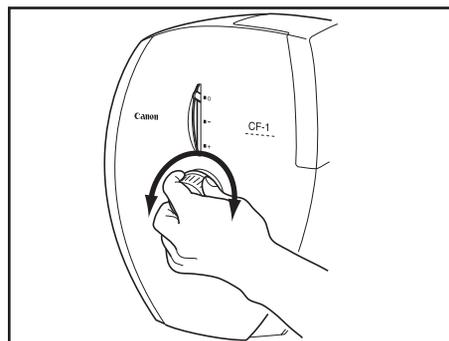
9 Determine the area to be photographed.

Have the patient look at the external eye fixation lamp so that you may guide the patient's eye.

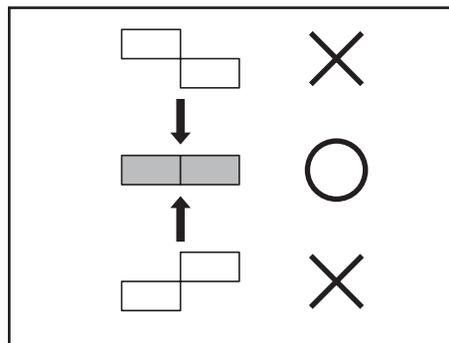
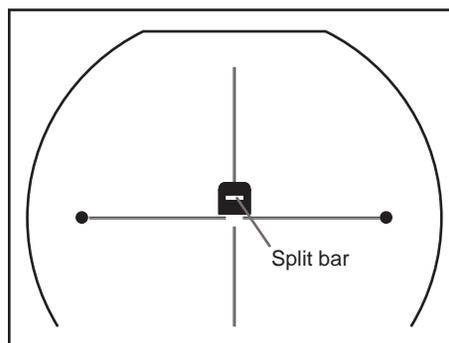
The panning function (see page 40) and tilting function (see page 40) can also be used to change the angle of the main unit.

10 Focus on the patient's eye.

Turn the focus knob to focus the image.



When using the focus indicator (see page 38), ensure that the split lines in the center are aligned into a single straight line.



MEMO When the split lines cannot be aligned
 If the patient diopter is not in the range of -10 to +15 (D), focusing cannot be performed using the focus indicator.
 In this case, use the diopter compensation function (see page 39) to focus with the cross-hair line in the viewfinder.

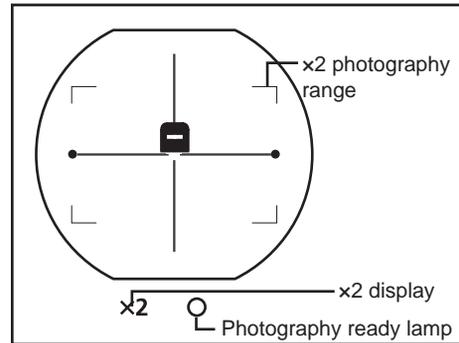
MEMO When bringing the target into exact focus
 When bringing the target into exact focus, the focus indicator serves as the general guideline for focusing.
 To bring it into focus even more exactly, focus on the target in such a way that the cross-hair lines in the viewfinder and fundus image can be clearly seen at the same time.

Continued on the following page >>

5. Photography

11 Select the photography range.

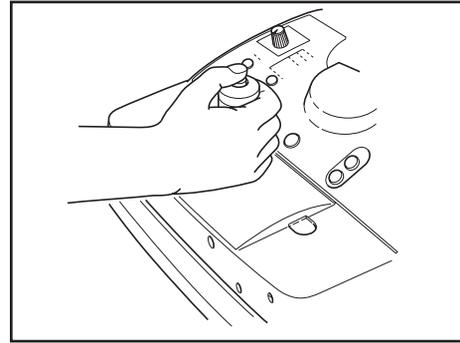
The ×2 photography function (see page 38) is turned ON and OFF each time the ×2 switch is pressed. When the ×2 photography function is ON, the lamp turns ON, and ×2 is displayed in the viewfinder.



12 Take the image.

Check that the photography ready lamp has lighted up green.

In a flare-free status, check the focus again, and press the shutter release button.



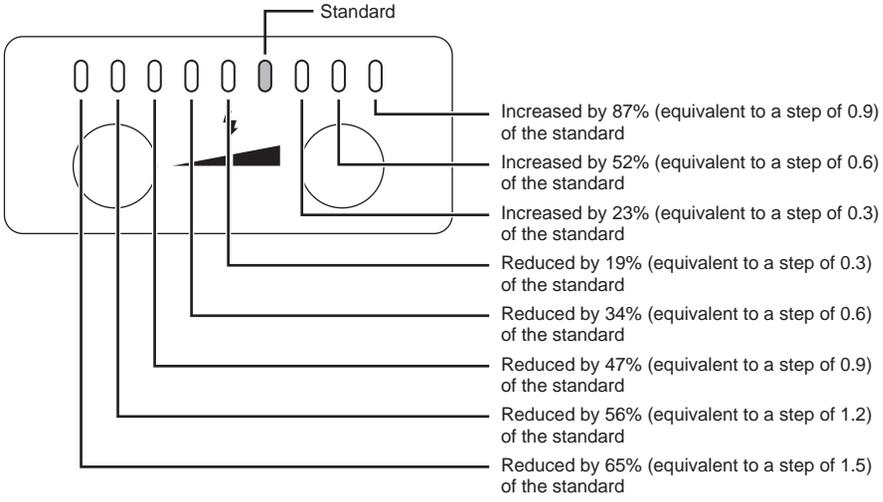
 **Concerning the photography ready lamp**

The ready status of the fundus camera is indicated by the color of the photography ready lamp. This status differs depending on the photography mode and image-taking conditions.

Color	Description
Green	Images can be taken. (Up to 10 images can be taken continuously when in the fluorescein angiography mode.)
Orange	Images can be taken, but if image-taking is continued, the getting ready status will soon be established.
Red	The camera is in the getting ready status (no images can be taken). Wait until the lamp lights up green or orange.

 **Concerning the adjustment of the flash intensity**

The flash intensity is already set to the standard level for each photography mode.
 To adjust the intensity, press the flash intensity switches.
 Each time one of these switches is pressed, the intensity is increased or reduced by steps of 0.3.
 The flash intensity selected is shown by the lighted area of the flash intensity indicator.



- 13** Review the image.
 The fundus images and study information are displayed in the control software. Check the images.
 To take more images, repeat steps 2 and following.
- 14** End the study.
 End the study with the control software.
- 15** Lock the stage unit.
 Press the stage unit lock button to lock the stage unit.

 **Concerning locking the stage unit**

When the stage unit lock button is pressed, the stage unit can be locked or unlocked in the following two places:

Lock position	Description
Locked at center	Center position of stage unit. (The unit is locked here upon completion of the examination.)
Lock at front right	Position where the stage unit has been drawn to the front right. (This protects the patient's eyes from unintended operations either while an examination is being undertaken or after an examination has been completed.)

- 16** Turn OFF the power of the main unit.
 Press the power switch to the O side.

5. Photography

5.3 Red-free Photography Mode

The steps with no explanation in the procedure below are the same as in the color photography mode. Refer to the procedure for the color photography mode (see page 28).

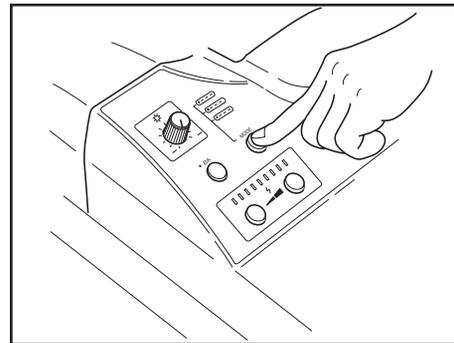
1 Enter the study information into the computer.

2 Select red-free photography mode.

Select RED FREE with the MODE switch.

Or select the photography mode in the control software.

Mode indicator lamp (RED FREE) lights up.



3 Disinfect the forehead rest and replace the chin rest paper.

4 Have the patient sit down.

5 Align the height of the patient's eye.

6 Align the camera to the eye to be photographed.

7 Align the camera position.

8 Adjust brightness in field of view for observation.

9 Determine the area to be photographed.

10 Focus on the patient's eye.

11 Select the photography range.

12 Take the image.

13 Review the image.

14 End the study.

15 Lock the stage unit.

16 Turn OFF the power of the camera main unit.

5.4 OPTION Photography Mode

In this mode, OPTION photography using the exciter filter for fluorescein angiography is possible. The control software must be set up in order to perform OPTION photography. For details on the settings, refer to the operating manual for the control software.

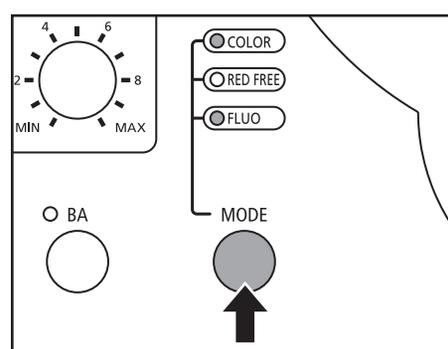
The steps with no explanation in the procedure below are the same as in the color photography mode. Refer to the procedure for the color photography mode (see page 28).

- 1 Enter the study information into the computer.
- 2 Select the OPTION photography mode.

Select OPTION with the MODE switch.

Or, select the photography mode in the control software.

The COLOR and FLUO mode indicator lamps light up.



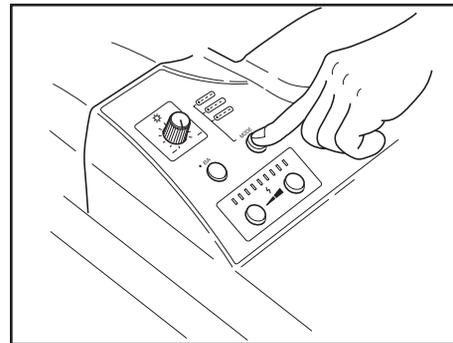
- 3 Disinfect the forehead rest and replace the chin rest paper.
- 4 Have the patient sit down.
- 5 Align the height of the patient's eye.
- 6 Align the camera to the eye to be photographed.
- 7 Align the camera position.
- 8 Adjust brightness in field of view for observation.
- 9 Determine the area to be photographed.
- 10 Focus on the patient's eye.
- 11 Select the photography range.
- 12 Take the image.
- 13 Review the image.
- 14 End the study.
- 15 Lock the stage unit.
- 16 Turn OFF the power of the camera main unit.

5. Photography

5.5 Fluorescein Angiography Mode

The steps with no explanation in the procedure below are the same as in the color photography mode. Refer to the procedure for the color photography mode (see page 28).

- 1 Enter the study information into the computer.
- 2 Select fluorescein angiography mode.
Select FLUO with the MODE switch.
Or select the mode in the control software.
Mode indicator lamp (FLUO) lights up.



- 3 Disinfect the forehead rest and replace the chin rest paper.
- 4 Have the patient sit down.
- 5 Align the height of the patient's eye.
- 6 Align the camera to the eye to be photographed.
- 7 Align the camera position.



MEMO

Concerning the barrier filter

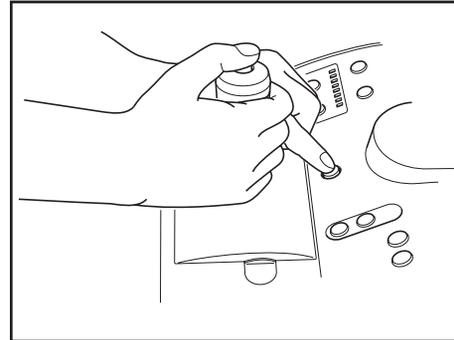
During retinal observations in the fluorescein angiography mode, each time the BA switch is pressed, the barrier filter is inserted or disengaged. However, while images are being taken, the filter is inserted automatically.

While the barrier filter is inserted, the lamp lights brightly.

- 8 Adjust brightness in field of view for observation.
- 9 Determine the area to be photographed.
- 10 Focus on the patient's eye.
- 11 Select the photography range.

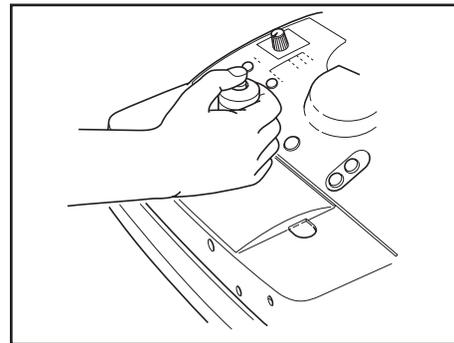
12 Start the timer.

Press the **TIMER/C** switch as soon as the fluorescein medium is injected. The buzzer sounds each second, the lamp lights brightly and the elapsed time is displayed in the control software.

**13** Take the image.

In a flare-free status, check the focus again, and press the shutter release button.

To take images continuously, hold down the shutter release button. Images can be taken continuously for up to 10 seconds at a rate of one frame per second.

**14** Review the image.**15** Stop the timer.

Press the **TIMER/C** switch. The elapsed time display is reset.

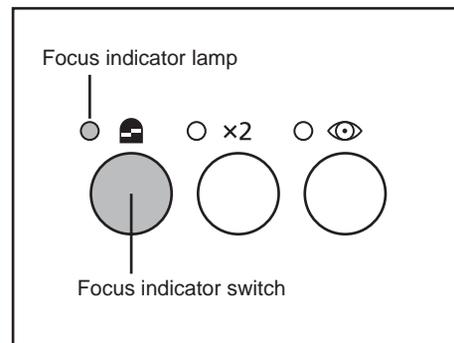
16 End the study.**17** Lock the stage unit.**18** Turn OFF the power of the main unit.

6. Photography auxiliary functions

6.1 Using the focus indicator

The focus indicator switch on the operation panel can be used to select whether or not to use the focus indicator.

When the focus indicator is being used, the focus indicator lamp lights brightly.



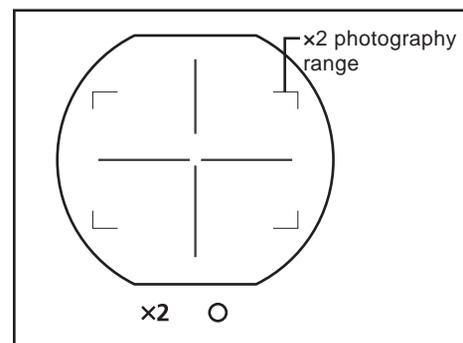
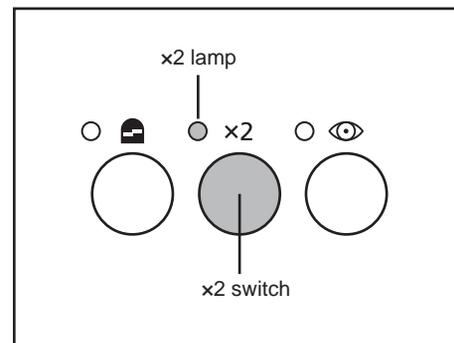
6.2 ×2 photography function

Press the ×2 switch. When the ×2 photography function is operational, the ×2 lamp lights up, and at the same time ×2 and a green display appear at the bottom inside the viewfinder.

When images are taken in this status, a range equivalent to one-fourth of the observation screen at the center (×2 photography range) is stored.

The stored images will be enlarged and displayed on the monitor by the control software.

Field angle is equivalent to 43°.



6. Photography auxiliary functions

6.3 Small pupil photography function

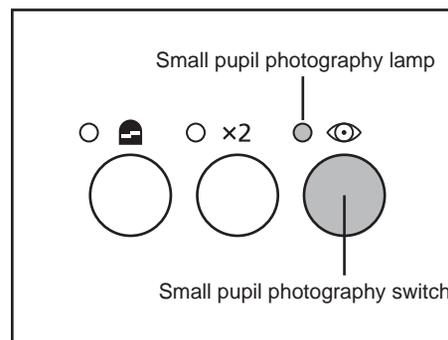
The small pupil photography function can be used in the color, red free or OPTION photography mode.

To activate this function, press the small pupil photography switch on the operation panel.

The small pupil photography lamp will light brightly.

During normal photography, the pupil diameter must be $\phi 5.2$ mm or more. When the small pupil photography function is operational, however, images of pupils can be taken if their diameter is $\phi 4.3$ mm or more.

In this case, however, flare may be visible around the edges of the images.



6.4 Diopter compensation function

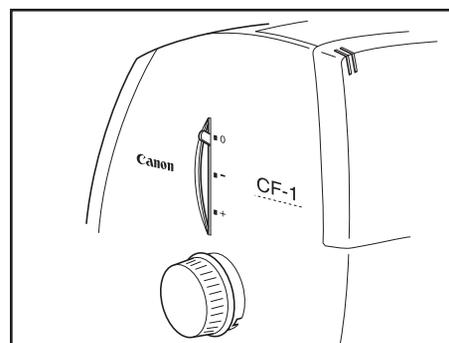
If the target cannot be brought into focus by turning the focus knob, use the diopter compensation lever to insert the diopter compensation lens, and take the photographs. Given below is the diopter range in which images can be photographed.

0 position: -10 to $+15$ D

$-$ position: -7 to -31 (D)

$+$ position: $+11$ to $+33$ (D)

However, since the focus indicator (see page 38) cannot be used when the diopter compensation lever is set to the $-$ or $+$ position, turn the focus knob to adjust to the position where the cross-hair lines and fundus image are clearly visible at the same time inside the viewfinder.



Note: When operating the diopter compensation lever, set it precisely to the 0, $-$ or $+$ position. If the lever is set to a position midway between two settings, fundus images will not be taken properly.

6. Photography auxiliary functions

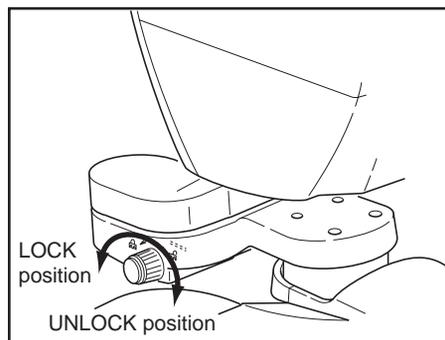
6.5 Panning function and tilting function

6.5.1 Panning function

This function is used to take photographs of edges in the side-to-side direction.

First, turn the panning lock knob to the  position, and then adjust the angle of the digital retinal camera main unit in the side-to-side right direction.

Before carrying the camera around, turn the panning lock knob to the  position.



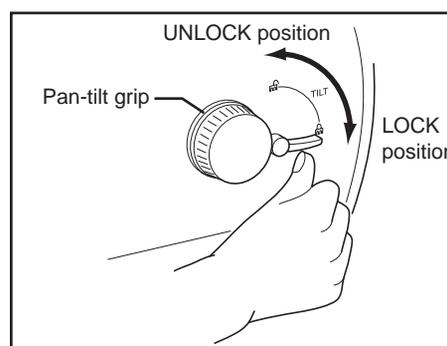
6.5.2 Tilting function

This function is used to take photographs of edges in the up/down direction.

First turn the tilting lock lever to the  position, and then adjust the angle of the digital retinal camera main unit in the vertical direction.

The lever clicks into position when it is at the horizontal setting so it is easy to check the horizontal position.

Before carrying the camera around, turn the tilting lock lever to the  position.



Note: Hold the pan-tilt grip when adjusting the camera angle by panning or tilting.

Note: To lock the camera at the tilt angle, turn the tilting lock lever precisely to the  position, and check that the camera is completely locked. If it is not completely locked, perform these steps again.

7. Daily Inspection and Maintenance

 WARNING	The instrument must be repaired by a qualified engineer only. If the instrument is not repaired properly, it may cause fire, electric shock, or accident.
 CAUTION	For safety reasons, be sure to inspect the instrument before using it.

7.1 Inspection

In order to ensure that the instrument is used safely and according to specifications, please be sure to inspect the instrument before use.

If the inspection finds a fault, and you are unable to correct the problem, please contact your sales representative or local Canon dealer.

It is recommended that you either copy the tables 7.1.1 and 7.1.2 on the following pages or create a separate checklist for recording the inspection results.

7. Daily Inspection and Maintenance

7.1.1 Before Turning ON the Power

 WARNING	For safety reasons, be sure to turn OFF the power when the following inspections are going to be performed. Otherwise, electric shock may result.
 WARNING	Clean the plug of the power cable periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth. If the cable is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture, and this could cause insulation failure which could result in a fire.

Location	Inspection	Result			Remedy
		Month Day	Month Day	Month Day	
Power cable	Check that the power cable is not damaged and the covering is not torn.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there is a problem.
	Check that the power cable is fully inserted into the connector on the main unit and the AC outlet. Also check the connections of the cables between the equipment.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Fully insert the power cable into the connector and the AC outlet with the power turned OFF. Also, be sure to plug in cables between equipments as far as they will go.
Main unit	Check that the cover and parts are not damaged or loose.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if the cover and parts are damaged or loose.
	Grasp the operation lever and tilt it back and forth and from left to right, checking that the stage unit moves smoothly. Check that the locking of the stage unit operates properly.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there is a problem.
	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.	Pass/ Fail	Pass/ Fail	Pass/ Fail	
	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.	Pass/ Fail	Pass/ Fail	Pass/ Fail	
	Check that there is no dust or other substances on the viewfinder.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Clean the viewfinder if it is dirty (see page 49).
	Disinfect the forehead rest. If the chin rest paper will not be used, be sure to disinfect the chin rest as well.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Disinfect the forehead rest for each patient (see page 49).

7. Daily Inspection and Maintenance

Location	Inspection	Result			Remedy
		Month Day	Month Day	Month Day	
EOS Digital camera	Check that the EOS digital camera is firmly attached and the cables are connected correctly.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there is a problem.

7.1.2 Turning ON the Power

Always perform the inspections shown in the following sections to ensure proper function before use.

 CAUTION	For safety reasons, be sure to inspect the instrument before using it.
--	--

7.1.2.1 Check Items on the Behaviors of the Equipment

Turn on the power of all the equipment that has been connected as a system and check the following items.

Location	Inspection	Result			Remedy
		Month Day	Month Day	Month Day	
Main unit	Check whether the POWER lamp lights.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if the POWER lamp fails to light even though the power cable is connected properly.
	Check that there is no dirt or scratches on the objective lens.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Clean the lens if it is dirty (see page 48). Contact your sales representative or local Canon dealer if it is scratched.
	Place a sheet of paper in front of the objective lens, turn the brightness adjuster, and check that the brightness for observation changes.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there are no changes.
	Place a sheet of paper in front of the objective lens and press the shutter release button to check that the flash is emitted.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if no flash is emitted.
	Set to fluorescein angiography mode and press the TIMER/C switch to check that the timer starts and stops properly.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there is a problem.

Continued on the following page >>

7. Daily Inspection and Maintenance

Location	Inspection	Result			Remedy
		Month Day	Month Day	Month Day	
Main unit	Check that the chin rest moves smoothly up and down when the CHIN REST switch is pressed.	Pass/ Fail	Pass/ Fail	Pass/ Fail	Contact your sales representative or local Canon dealer if there is a problem.

7.1.2.2 Check Items on the Image

Location	Inspection	Result			Remedy
		Month Day	Month Day	Month Day	
foreign matter on image	<p>Place a sheet of paper in front of the objective lens and take a test image in the following conditions.</p> <p>Conditions Flash intensity: Standard pos. Diopter comp. lever: 0 Focus knob: Turn the knob on the right (viewed from you) all the way clockwise.</p> <p>Then check that there is no foreign matter present on the image that can affect image readings.</p>	Pass/ Fail	Pass/ Fail	Pass/ Fail	Clean the objective lens (see page 48). If you cannot remove the foreign matter on the image, stop using the retinal camera and contact your sales representative or local Canon dealer.

7.2 Before Calling a Service Technician

Perform the appropriate remedy when any of the problems below appear in inspection or during operation or a warning is displayed in the control software.

If performing the remedy still does not fix the problem, or the warning is still displayed, turn OFF the power, and contact your sales representative or local Canon dealer.

Please be sure to describe the problem or warning message in detail.

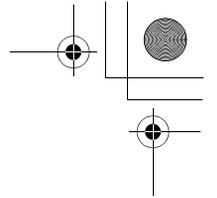
7.2.1 Troubleshooting

Problem	Cause	Remedy
When the retinal camera main unit is raised and lowered, its movement is stiff at the upper limit.	The camera was subjected to severe vibration while it was in transit.	Turn the operation lever, and move the main unit to the upper level by raising and lowering it several times.
The POWER lamp does not light up when the power is turned ON.	The power cable is disconnected.	Turn OFF the power to the main unit, and connect the cable properly.
	An indoor circuit breaker has been tripped.	Find and resolve the cause of the tripped circuit breaker, and reset the circuit breaker.
	The cable is cut.	Turn OFF the power to the main unit, and contact your sales representative or local Canon dealer.
When the power is turned on, 3 short beeps sound and the display lamps on the operation panel blink.	A system error has occurred.	Turn off the power to the main unit and contact your sales representative or local Canon dealer.
The external eye fixation lamp does not light up or flicker.	The external eye fixation lamp is not attached properly.	Insert the external eye fixation lamp fully into the connector on top of the head rest.
The external eye fixation lamp does not stop at the specified position.	The holding power has become weak.	Contact your sales representative or local Canon dealer.
The fundus image is still not visible even when increasing the brightness for observation with the brightness adjuster.	The lamp for observation is burnt out.	Contact your sales representative or local Canon dealer.
It is hard to see the split lines and working distance dots.	The brightness for observation is too strong.	Reduce the brightness for observation.
The working distance dots are not visible.	The positioning is not correct.	Perform positioning.
Flare is visible.		

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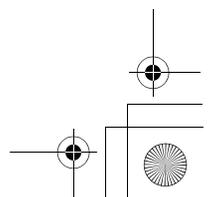
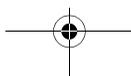
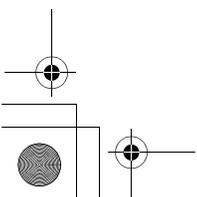
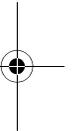
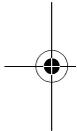
7. Daily Inspection and Maintenance

Problem	Cause	Remedy
The split lines are not visible.	The split bar is not displayed.	Press the focus indicator switch to display the split bar.
	The pupil is not dilated enough.	Dilate the patient's pupil. If the pupil is still too small, press the small pupil photography switch to activate the small pupil function.
	The positioning is not correct.	Perform positioning.
	Eyebrows or eyelashes are blocking the pupil.	Instruct the patient to open his or her eye wider.
	The patient's vitreous body is unclear.	Focusing cannot be performed with the split lines.
	The diopter compensation lever is set to the - side or + side.	Set to the no compensation position.
	The Internal Eye Fixation Target (sold separately) is used.	The split lines cannot be displayed. In this case, turn the focus knob to adjust to the position where the cross-hair lines and fundus image are clearly visible at the same time inside the viewfinder.
	The split lines display lamp is burned out.	Contact your sales representative or local Canon dealer.
The split lines do not align.	The diopter of the patient's eye is outside the range of -10 to +15 D.	Turn the focus knob to focus so that the cross-hair lines in the field of view and the fundus image can be seen clearly at the same time.
Sharp images cannot be taken.	The pupil is not dilated enough.	Dilate the patient's pupil. If the pupil is still too small, press the small pupil photography switch to activate the small pupil function.
	The positioning is not correct.	Perform positioning.
	The image is unfocused.	Focus the image.
	Eyebrows or eyelashes are blocking the pupil.	Instruct the patient to open his or her eye wider.
	The patient's eye is opaque.	A sharp image cannot be taken.
	The patient blinked when the image was taken.	Take another image.
	The flash intensity, diopter compensation lever, and viewfinder diopter compensation ring have not been adjusted.	Adjust the settings.
	The objective lens is dirty.	Clean the lens (see page 48).
Black spots appear on photographed images in the same area.	Dust or another substance is adhering to the surface of the objective lens.	Clean the lens (see page 48).
	Dust or another substance is adhering to the surface of the CMOS sensor of the EOS digital camera.	Clean the CMOS sensor by referring to the operation manual for the EOS digital camera.



7. Daily Inspection and Maintenance

Problem	Cause	Remedy
White spots appear on the photographed images.	The objective lens is dirty.	Clean the lens (see page 48).
	The patient's eyelashes have appeared on the images.	Instruct the patient to open his or her eye wider. Take another image.



7. Daily Inspection and Maintenance

7.3 Cleaning and Disinfection

7.3.1 Objective lens

Note: Do not wipe off or rub the objective lens when there is dust or other substances on it.
This could scratch the lens surface.

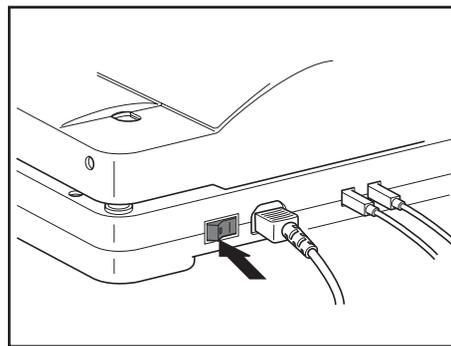
Note: Never wipe the objective lens with disinfecting ethanol, eyeglass lens cleaner, or cleaning paper containing silicon.
The lens surface could be damaged or the surface may not be completely wiped off.

Note: Do not let the tip of a blower touch the objective lens.

Use the procedure below to clean the objective lens when it is dirty.

Please order the lens cleaning paper, lens cleaner, and blower from your sales representative or local Canon dealer.

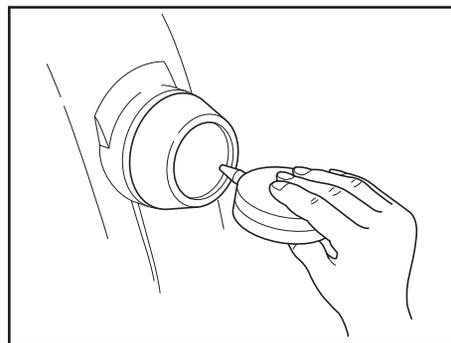
- 1 Turn ON the power of the main unit.
Press the power switch to the I side.



- 2 Adjust the brightness.
Set the brightness adjuster in the 8 to MAX range.

- 3 Check for any dust or dirt.
Look at the objective lens from the patient side to check for any dust or dirt.

- 4 Blow away any dust or dirt.
Remove the brush from the blower brush, and use the blower to blow away any dust or dirt on the objective lens.

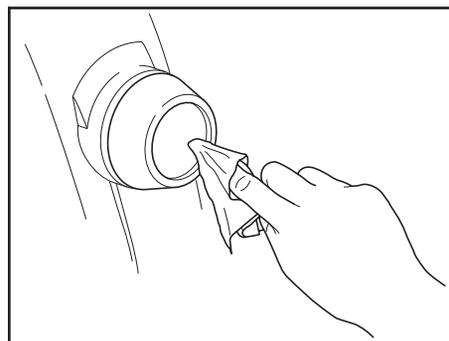


7. Daily Inspection and Maintenance

5 Wipe off the objective lens.

Gently wipe the lens with Canon-designated lens cleaning paper that has been wet with the Canon-designated lens cleaner.

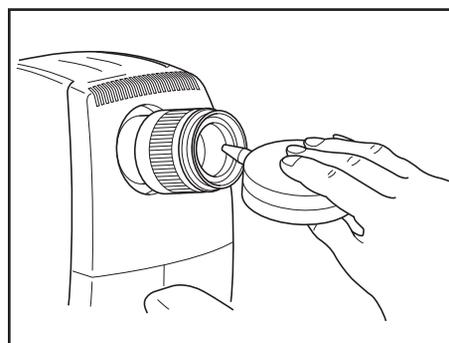
Starting from the center of the lens, wipe the lens in increasingly larger spirals toward the circumference. Change the paper, and wipe several times until the dirt is removed and the cleaner is completely wiped off.



7.3.2 Viewfinder

Note: Do not let the tip of a blower touch the viewfinder lens.

If the viewfinder is dirty, use the blower to blow off any dirt or dust on the lens surface.



7.3.3 Forehead rest



CAUTION

To prevent the risk of infection, wipe the forehead rest with disinfecting ethanol for each patient.
For more details on the disinfection procedure, please consult a specialist.

Disinfect the forehead rest for each patient.

7. Daily Inspection and Maintenance

7.3.4 Cover

 WARNING	When the instrument is going to be cleaned, be sure to turn OFF the power and unplug the power cable from the AC outlet. Never use alcohol, benzine, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.
--	--

Note: Do not clean the cover of the instrument with lens cleaner. The cover of the instrument could be damaged.

Use the procedure below to clean the cover when it is dirty.

- 1** Turn OFF the power of the main unit.
Press the power switch to the O side.
- 2** Unplug the power cable.
- 3** Wipe the instrument with cleanser.
Soak a soft cloth with diluted neutral cleanser and wring it out.
- 4** Wipe off the instrument with a rinsed cloth.
Wipe the instrument with a cloth that has been dipped in water and wrung out.

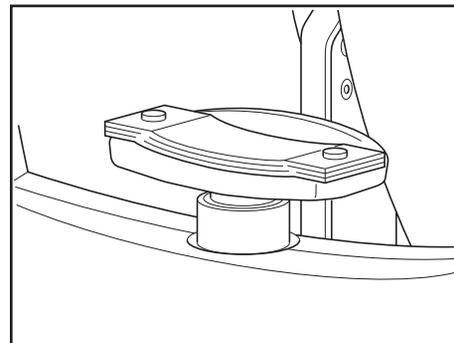
7.4 Refilling the Chin Rest Paper

Note: If the chin rest paper will not be used, be sure to disinfect the chin rest for each patient in the same manner as for the forehead rest.

- 1 Pull out the chin rest right and left holding pins.

- 2 Insert the holding pins in the chin rest paper.
Insert the holding pins in the right and left holes of the chin rest paper.
About 100 sheets of paper can be mounted.

- 3 Attach the chin rest paper to the chin rest.
Attach the chin rest paper with holding pins attached to the chin rest.

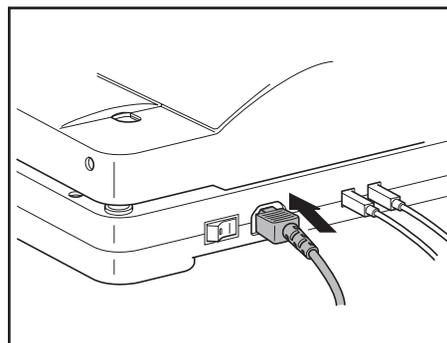


7. Daily Inspection and Maintenance

7.5 Power Cable Connections

⚠ WARNING	Be sure to operate this instrument using the power supply described in the specifications. Otherwise, it may result in fire or electric shock.
⚠ WARNING	Be sure to turn OFF the power before plugging or unplugging the cables as indicated in this manual. Also, do not handle the cables with wet hands. Otherwise, you may get an electric shock that may result in death or serious injury.
⚠ CAUTION	Before connecting or disconnecting the cables, be sure to hold the instrument firmly in order to ensure safety. Otherwise, the main unit may fall over, possibly causing injury.
⚠ CAUTION	Always use a grounded AC outlet with a 3-pin plug as the power outlet.

- 1 Turn OFF the power of the main unit.
Press the power switch to the O side.
- 2 Connect the power cable to the main unit.
Insert the power cable connector firmly into the AC power connector while holding down the main unit with your hand.



- 3 Insert the power plug into the AC outlet.
Insert the plug all the way into the AC outlet.

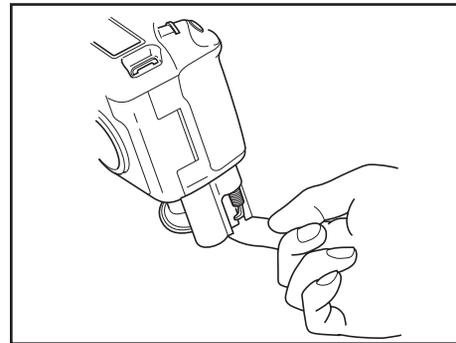
7.6 Installing and Removing the EOS Digital Camera

7.6.1 Installing the EOS Digital Camera

Note: Do not touch the lens of the main unit or the mirror of the digital camera when attaching and detaching the digital camera from the main unit. If any dirt, fingerprints, dust, or other foreign objects attach to the lens or mirror, you will not be able to take a good image.

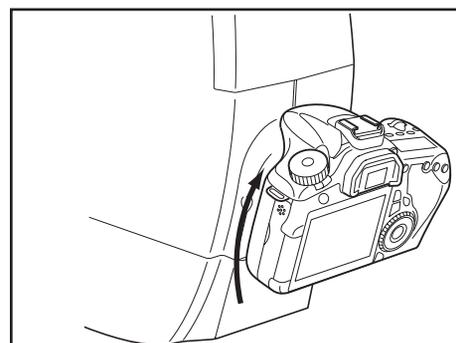
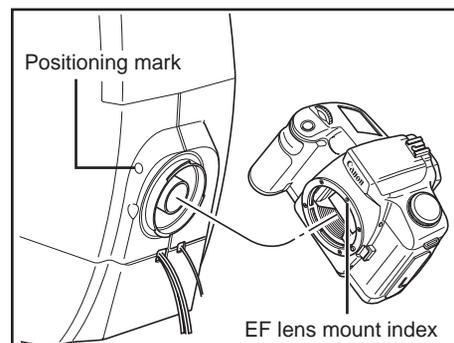
- 1 Turn OFF the power of the retinal camera.
Press the power switch of the retinal camera to the O side (OFF).
- 2 Remove the power plug from the AC outlet.
- 3 Attach the DC coupler to the EOS digital camera.

Open the battery compartment cover on the EOS digital camera and attach the DC coupler.
After attaching the DC coupler, pass the cord through the DC coupler cord hole and then close the battery compartment cover.



- 4 Mount the EOS digital camera to the main unit.
Align the EF lens mount index of the EOS digital camera with the CF-1 positioning mark.

Fit the lens mount of the EOS digital camera into the camera mount and turn the camera unit clockwise until it clicks into place.

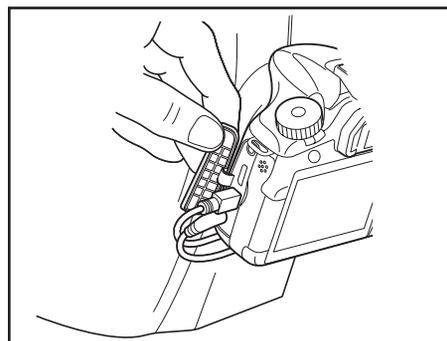


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7. Daily Inspection and Maintenance

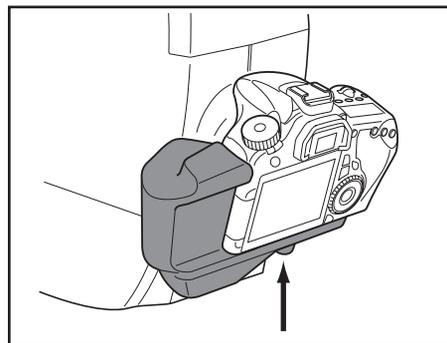
5 Attach the cable to the EOS digital camera.

Open the terminal cover of the EOS digital camera and connect the respective cables to the digital terminal and remote control terminal.



6 Attach the camera cover to the EOS digital camera.

Attach the camera cover to the EOS digital camera. Attach the camera cover screws to the tripod socket on the bottom of the EOS digital camera.



7.6.2 Removing the EOS Digital Camera

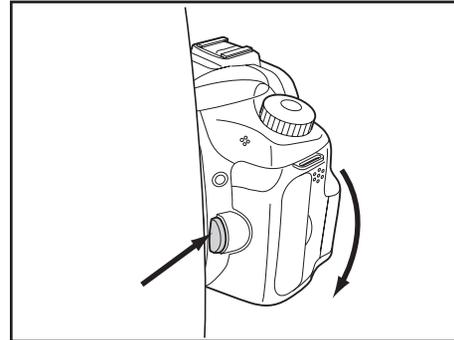
Note: If the EOS digital camera is removed and left unattached, dust and other foreign objects can enter the main unit and EOS digital camera. Be sure to always attach the caps to the respective mounts.

- 1 Turn OFF the power of the retinal camera.
Press the power switch of the retinal camera to the O side (OFF).
- 2 Remove the power plug from the AC outlet.
- 3 Remove the camera cover.
Loosen the screws of the camera cover to remove the cover.
- 4 Disconnect the cables.
Remove the respective cables from the digital terminal and remote control terminal.

7. Daily Inspection and Maintenance

5 Remove the EOS digital camera.

Turn the EOS digital camera counter-clockwise while holding down the lens release button on the EOS digital camera to detach the camera.



6 Remove the DC coupler.

Open the battery compartment cover on the EOS digital camera, and then slide the battery lock lever to remove the DC coupler.

After removing the DC coupler, close the battery compartment cover.

7 Attach the cap to the camera mount.

Attach the mount cap to the camera mount.

Also attach the body cap to the lens mount of the EOS digital camera.

7. Daily Inspection and Maintenance

7.7 Connecting the USB Cables

- 1 Turn OFF the power of the retinal camera.
Press the power switch of the retinal camera to the O side (OFF).
- 2 Remove the power plug from the AC outlet.
- 3 Connect the USB cables to the main unit.
Insert the USB cables connector firmly into the USB connectors while holding down the main unit with your hand.
- 4 Connect the USB connectors at the other end to the computer.
Connect the connector at the other end of the USB cable firmly into the computer's USB ports.

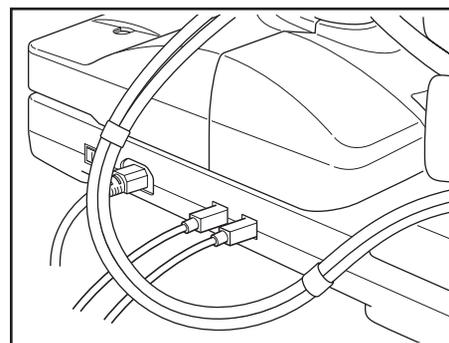
Note: Use the following type of USB cable. Communication may not be possible if any other kind of cable is used.

- Cable with type AB connector plug supporting USB 2.0 Hi-Speed, maximum length of 3 meters

For further details, contact your sales representative or local Canon dealer.

Note: When connecting the USB cable, pass it underneath the cables of the camera main unit, and connect.

If it is passed over the main unit cables, the USB cable may become disconnected by the image-taking operations of the main unit.



7.8 Carrying the instrument

Follow this procedure when carrying the instrument by hand:

<p> WARNING</p>	<p>When the instrument is going to be moved, be sure to turn OFF the power, unplug the power cable from the AC outlet, and disconnect other cables. Otherwise, the cable may be damaged, fire or electric shock may result. Also, when the instrument is going to be carried, be sure to tighten the stage unit lock, the panning lock knob and the tilting lock lever, grip the indentations for lift at the left and right of the bottom panel, and hold the instrument horizontally. Do not hold the instrument by the digital camera (sold separately) or the head rest poles or other parts, as they may come off and result in injury.</p>
<p> WARNING</p>	<p>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 being repaired.</p>

Note: If this product will be transported in an automobile or shipped a long distance, protective measures need to be taken against vibrations and shocks. Ask your sales representative or local Canon dealer for more information.

- 1 Turn OFF the power of the retinal camera.
Press the power switch of the retinal camera to the O side (OFF).
- 2 Remove the connected cables.
Remove all power cables and USB cables.
- 3 Remove the EOS digital camera.
See section 7.6.2 Removing the EOS Digital Camera (see page 54).
- 4 Secure the parts in place.
Tighten the panning lock knob, tilting lock lever and the stage unit lock.
- 5 Carry the main unit.
Hold the main unit by gripping the indentations for lift at the left and right of the bottom panel, and carry the unit horizontally.

8. Service Information

Repair

If a problem cannot be solved even after taking the measures indicated in Section 7, contact your sales representative or local Canon dealer for repair.

When requesting repair, please provide us with the following information by referring to the rating label on the main unit.

Name of the instrument: CF-1
Serial number of the instrument: 6-digit number indicated on the rating label
Problem: In detail.

Limit for Supplying Performance Parts for Repair

Performance parts (parts required to maintain the functioning of the product) will be stocked for eight years after discontinuance of production.

Expendable Parts Replaced by Service Person

The following parts are apt to become worn out or to deteriorate due to the characteristics of their material or structure.

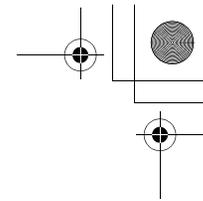
These parts cannot be replaced by the user. If these parts are found to be worn out or to have deteriorated during daily or regular inspection, contact your sales representative or local Canon dealer for repair.

- Halogen lamp for observation
- Strobe tube for photography
- Base board (USB connector)

9. Main Specifications

Type	Mydriatic type
Field angle	50°/43° (digital)
Magnification view	1.1× (Image size on the sensor)
Image magnification of observation	10×
Diameter of pupil required	ø5.2 mm or more ø4.3 mm or more (when using the small pupil function)
Working distance	35 mm
Patient's diopter 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)
Photographer's diopter compensation range	±5 D
Flash intensity	Linked to photography mode Can be set manually
Camera	Canon EOS digital camera (sold separately)
Eye fixation lamp	External eye fixation lamp Internal Eye Fixation Target (sold separately)
Working range	
Stage horizontal movement	110 mm side to side, 65 mm front and back
Main unit vertical movement	30 mm
Chin rest vertical movement	60 mm
Panning	30° to the right and left
Tilting	15° up and 10° down
Environment requirements	
Use	Temperature: 10°C to 35°C Humidity: 30% to 80% RH (no condensation) Atmospheric pressure: 800 hPa to 1060 hPa
Storage	Temperature: -10°C to 55°C Humidity: 10% to 95% RH (no condensation) Atmospheric pressure: 700 hPa to 1060 hPa
Transportation	Temperature: -30°C to 60°C Humidity: 10% to 60% RH (no condensation) Atmospheric pressure: 700 hPa to 1060 hPa
Rated power supply	AC 100 V to 240 V, 50/60 Hz, 7 to 3 A
Dimensions	320(W) × 531(L) × 576(H) mm
Mass	26 kg (including a EOS digital camera 0.8 kg)

Note: In the International System of Units (SI), the expression 1 D (diopter) = 1 m⁻¹.

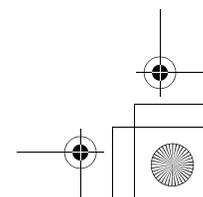
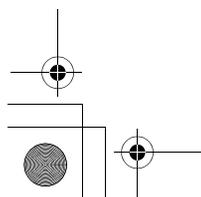


10. Components

CF-1 main unit.....	1
External eye fixation lamp.....	1
Power cable (3 m, Non-shielded)	1
Chin rest paper.....	100
Objective lens cap.....	1
Camera mount cap.....	1
Digital camera cover.....	1
Dust cover.....	1
CD-ROM (Retinal imaging control software MYD)	1
Operation manual (CF-1/control software)	1 each
DICOM conformance statement.....	1
Software license agreement.....	1
Warranty card (for USA model only).....	1
WEEE directive leaflet (for EU model only)	1
Installation report.....	1

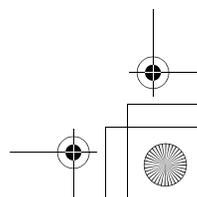
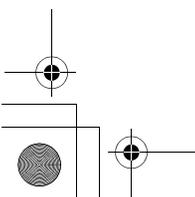
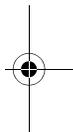
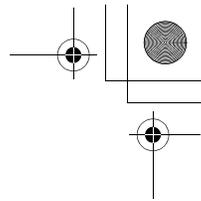
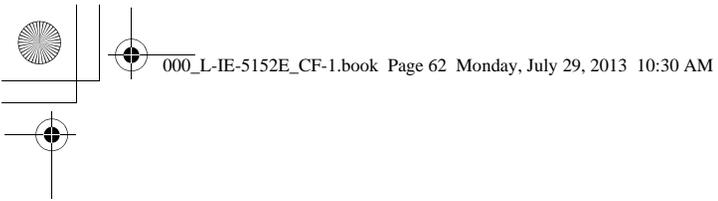
Optional Units

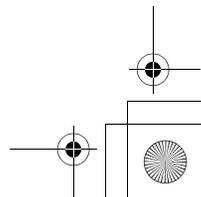
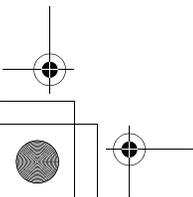
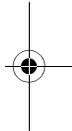
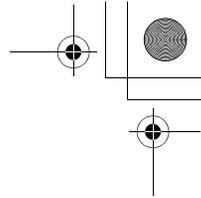
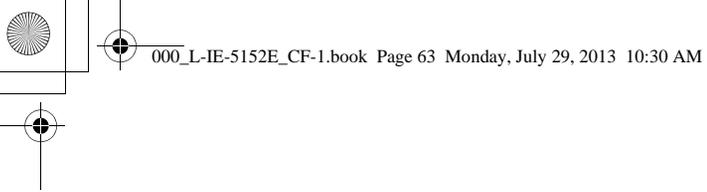
- Internal eye fixation target
- Stereo unit
- Chin rest paper (500 sheets)



11. EN IEC60601-1-6:2010 Equipment Application Specification CF-1

- | | |
|-----------------------------------|--|
| 1. Medical Purpose | |
| a) Device name | Retinal camera |
| b) Objective | Observation, photographing, and recording of the ocular fundus by passing through the pupil without making contact with the examined eye and providing fundus image information for diagnosis. |
| 2. Patient Group | |
| a) Patient type | Human |
| b) Age group | Infants to senior citizen |
| c) Sex | Male/female |
| d) Height | No restriction |
| e) Weight | No restriction |
| f) Nationality | No restriction |
| g) Health status | Various |
| h) Medical condition | Various (conscious state) |
| i) Patient's role | The patient is not the operator. |
| j) Miscellaneous | Patient contact with forehead rest and chin rest. |
| 3. Body Parts, Organs and Tissues | |
| a) Parts | Eye |
| b) Organs and tissues | Ocular fundus (retina, macular region, optic papilla, etc.) |
| 4. Intended Operator | |
| a) Age | None (someone having satisfied the appropriate educational and/or qualification level) |
| b) Sex | Male/female |
| c) Weight | No restriction |
| d) Educational level | General knowledge of ophthalmology |
| e) Skills/knowledge | Skills and knowledge to understand the information in the operation manual. No special training is required. |
| f) Language ability | Capable of understanding English vocabulary |
| g) Experience | Guided by an experienced technician many times |
| h) Disabilities | An operator having the use of both arms and legs is envisioned. |
| i) Maintenance | Carried out by a trained serviceman. |
| 5. Environment | |
| a) Location | Examination room. Not intended for outdoor use. |
| b) Illumination | Lighting environment where the pupil of the examined eye does not contract |
| c) Temperature and humidity | 10 to 35°C, 30 to 90% RH |
| 6. Frequency of Use | 50 shots per day are envisioned. |
| 7. Durable Years | 8 years |
| 8. Mobility | Desktop units |
| 9. Hygiene Maintenance | The forehead rest and chin rest are wiped clean with disinfecting ethanol. |
| 10. Technology (other devices) | None |







L-IE-5152E

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