Canon

Full Auto Ref-Keratometer

RK-F3m

Instructions for Use

Manufacturer
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CE 2797

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Intended purpose

This device is intended to measure the refractive power of eyes objectively to measure the corneal curvature radius.

Intended Users and the Patient Target Group

This device is intended only for use by eye care professionals (e.g., doctors, optometrists).
The patient who is examined with this device are required to follow the instructions below:

Must be able to take a sitting position.
Must be able to answer questions given by eye care professionals (e.g., doctors, optometrists).

Accessories

Operation manual	:1	Model eye	:1	Power cord	:1	Printing paper	:3
Fuse	:2	Chin rest paper	:1	Chin rest paper pin	:2	Dust cover	:1

For more information, please contact your dealer.

Electronic Instructions for Use

Instructions for use are available on the website for viewing and download by customers.

・https://global.canon/en/ifu/medcom/index.html

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

Safety Symbols and Graphics

Before reading this manual, make sure you fully understand the following symbols and graphics and observe the instructions with these symbols and graphics.

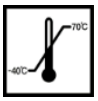
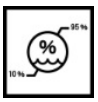
Description of symbols

Warning	Indicates a situation that may result in death or serious injury if ignored or handled improperly.
Caution	Indicates a situation that may result in injury or property damage if ignored or handled improperly.
NOTE	Indicates supplementary information to the main text that is important or that you should know.

Marks labeled on the exterior of the device

Mark	Description	Mark	Description
	General warning sign		Serial number
	Type B applied part		Alternating current
	See the operation manual.		Power OFF
			Power ON

Marks labeled on the packing box

Mark	Description
	Do Not Step On sign
	Fragile sign
	Face this side upwards.
	Do not stack more than 2 high.
	Keep Dry sign
	The left value indicates the lower limit atmospheric pressure, and the right value indicates the upper limit atmospheric pressure.
	The left value indicates the lower limit temperature, and the right value indicates the upper limit temperature.
	The left value indicates the lower limit humidity, and the right value indicates the upper limit humidity.
	WEEE Directive
	EU Battery Directive

Safety Considerations

⚠ Warning

1) If any problem is found (e.g., abnormal noise, smoke), immediately unplug the power cord from the power outlet and contact your distributor. Continued use could result in a fire or injury.
2) The power cord with protective earthing must be connected to an earthed three-prong AC outlet.
   Failure to do so could result in a fire or electric shock in case of electrical leakage.
3) When replacing a fuse, disconnect the power cord from the device before removing the fuse holder.
4) An attempt to remove the fuse holder without disconnecting the power cord could result in an electric shock.
   Never disassemble, modify, or repair the device. Doing so could result in an electric shock.
5) EMD (Electromagnetic Disturbances)
   This device complies with EMD standard IEC 60601-1-2, and the expected electromagnetic environment for the entire life cycle is the home healthcare environment.
   However, when used in hospitals, etc., except for near active HF surgical equipment and RF shielded rooms with an ME system for magnetic resonance imaging, where the intensity of electro-magnetic disturbances is high.
   RK-F3m or RK-F3m system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, RK-F3m or RK-F3m system should be observed to verify normal operation in the configuration in which it will be used.
   The use of the accessory, transducer or cable with RK-F3m and RK-F3m system other than those specified may result in increased emission or decreased immunity of RK-F3m or RK-F3m system.
   Do not use equipment that emits electromagnetic waves within 30 cm (12 inch) of any part of RK-F3m or RK-F3m system.
   It can result in reduced performance of RK-F3m or RK-F3m system.

Caution

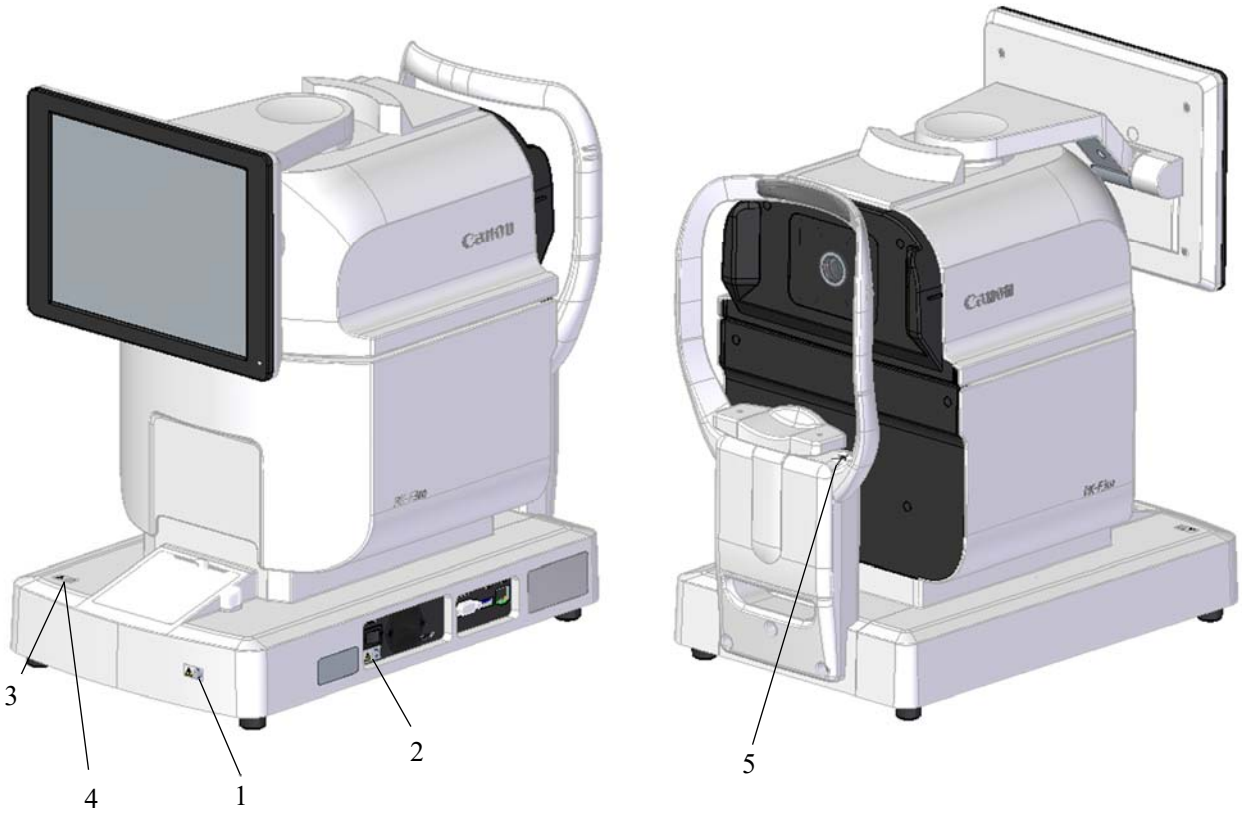
1) Fingerprints, dust, or other foreign matter on an optical part, such as the measuring window glass, affects measuring accuracy.
   Never touch the optical parts with your fingers and avoid dust adhering to the optical parts.
   If a fingerprint or dust adheres to an optical part, such as glass and lens, gently wipe it off with a soft cloth.
2) Do not install the device near wireless devices, such as televisions and radios. If doing so, the device may generate noise in the TV or radio.
3) If the device is exposed to a liquid or contains foreign matter, immediately unplug the power cord from the outlet and contact your distributor.
4) Never use organic solvents such as thinner as doing so causes the device surface to dissolve.
   Doing so could deteriorate and damage the cover, resulting in injury.
5) Do not install the device with the power cord connected.
   Doing so could cause the device to fall, resulting in injury.
6) Do not use the device at where the applicable power-supply voltage is not stable.
7) Avoid using the device at where temperature and humidity swing widely.
   Otherwise, it may affect the optical system because the water vapor becomes dew.
8) Unplug the power supply before changing the fuse.
   Otherwise, it may cause shock.
9) Do not hold the chinrest unit and the LCD unit when moving the device.

NOTE If a serious incident related to the device occurs, the manufacturer, user, and/or patient of the device are required to report it to the governing agency of each country.

Warning Labels and Their Locations

Warning instructions are labeled for ensuring the safety of the device.

Follow these instructions for correct use of the device. If any of the following labels are not found on the device, contact your distributor or us at the contact information provided on the back cover.



No.	Label	Meaning
1		Warning Do not open the cover. For repairs, contact service personnel. Failure to do so could result in an electric shock or injury.
2		Warning When replacing a fuse, disconnect the power cord from the device and replace the fuse with the designated one. Failure to do so could result in an electric shock or fire.
3		Caution During measurement, carefully observe the device from either side of the device. Failure to do so may result in contact between the measurement unit and patient's eye or nose.
4		Caution When operating the chin rest UP or DOWN button, be careful that the patient will not get their fingers caught in the chin rest. Otherwise, the patient could get injured.
5		Degree of protection against electrical shock: Type B applied part

Operation Procedure

1) Plug the power cord into an earthed three-prong AC outlet.
2) When connecting an external device, turn on that device.
3) Turn on the power switch on the device.
4) Have the patient sit in front of the device.
5) Press and hold the chin rest UP/DOWN button on the control panel to adjust the height of the chin rest so that the eye height of the patient aligns with the eye mark on the chin rest.
6) Have the patient put their forehead on the head rest.
7) Press and hold the screen to align the pupil center so that it is within the reticle.
8) Measurement starts automatically after alignment is completed.
9) Turn off the power switch after use.
10) If an external device is connected, turn off the external device.
11) Unplug the power cord from the earthed three-prong AC outlet.

Precautions Regarding Connection

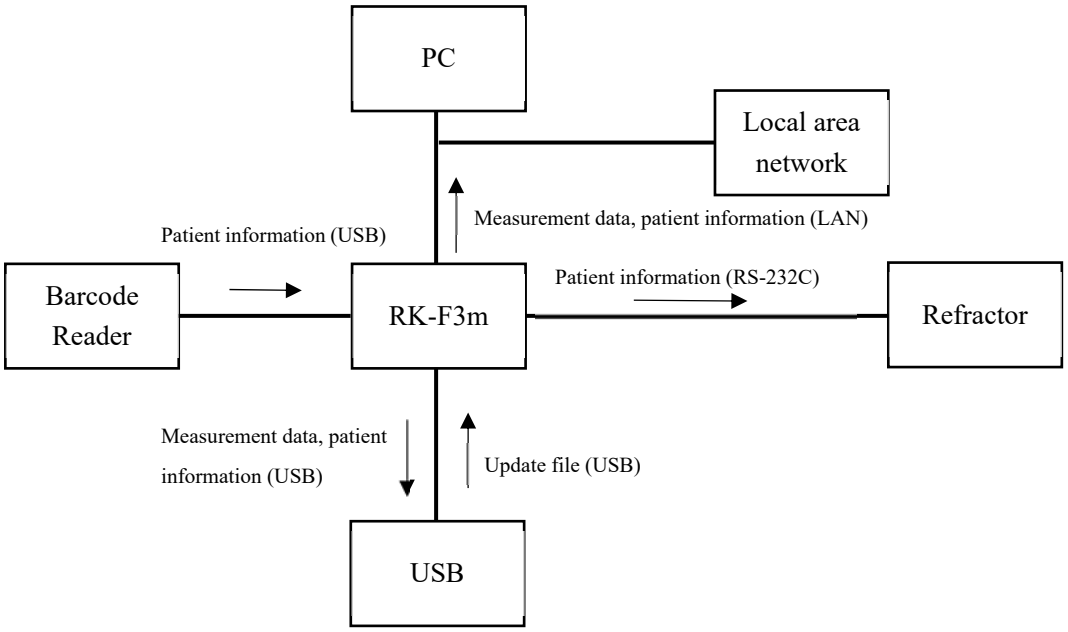
This device can be connected to a PC, refractor, and other devices via RS-232C or LAN.

Connection with Other Devices

Ensure that the devices connected to this device conform to the safety requirements of IEC60601-1 or IEC60950-1 and are provided with protective earthing or a separator.
If you have any questions about connections, consult with your distributor.

IT Networks

1) See the figure below for details on the properties, configuration, technical specifications, and output information and path to it when the device is connected to an IT network.
2) When connecting the device to an IT network, take appropriate measures according in order to prevent the infection of computer viruses and information leaks.
3) An IT-related failure is sometimes accompanied by several other troubles.
   • Due to a LAN, USB-A, or RS-232C communication failure, it may be impossible to output measurement data and patient information, resulting in the loss of result data.
   • Due to a USB-A communication failure, wrong patient information may be input with a barcode and used for measurement.
4) If the device is connected to an IT network containing other devices, unidentified risks to the patient, user, or a third person may arise.
5) The responsible organization must identify, analyze, assess, and control these risks.
6) A change to the IT network may raise new risks, which requires additional analysis.
7) Changes to the IT network include the following:
   • Making a change to the IT network configuration
   • Connecting an additional function to the IT network
   • Disconnecting a device from the IT network
   • Updating a device connected to the IT network
   • Upgrading a device connected to the IT network
8) For details on this device, consult with your distributor.



Maintenance

Check before Using

1) The device operates normally.
2) The optical parts such as the measuring window are free of fingerprints and dust.

Storage after Using

Check the items following in case that the device is not used or is stored for a long time.

1) Set the device to packing mode and store it the packing box for the device.
   Packing mode can be selected with the Packing button in the Setup screen.
2) Avoid storage under the following conditions
   - Where dust accumulates
   - Where water may get on the unit
   - Where temperature and humidity out of the specified ranges
   - Where sunlight directly contacts
   - Unstable and high place

Cleaning

1) Head Rest and Chin Rest
   When the head rest and chin rest get dirty, clean them with the neutral cleanser.
   When reusing, for disinfecting the parts especially where the examinee may contact such as the chin rest and head rest, use the ethanol for disinfection.
2) External Cover
   When the external covers get dirty, gently wipe them with a dry cloth.
   For stubborn stains on the external covers, it is recommended to clean them with a little water or neutral cleanser.
3) LCD Touch Panel
   If dust is adhered, gently wipe it with monitor cleaner etc. after brushing it off with a soft brush etc.
   If a finger print etc. is put, gently wipe it with monitor cleaner etc.

4) Measuring Window Glass

If the measuring window glass gets dirty, auto alignment might not work. If it gets dirty, gently wipe it with a soft cloth. At this time, do not scratch it with great care.

Periodic Inspection by a Representative

To prevent malfunction and accidents and maintain to performance and reliability of the product, it is recommended to request your distributor for the periodical inspection and maintenance once a year.

Replacement of Consumables

1) Printing Paper

Press the printer cover open switch to open the cover.

While paying attention to the paper winding direction, pull one end of the paper toward you to set.

Close the printer cover. Close the cover until it clicks.

2) Fuse

Remove the power fuse holder.

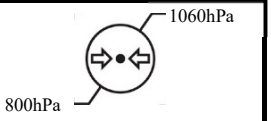
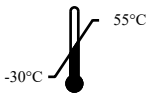
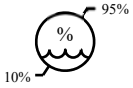
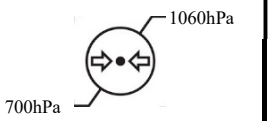
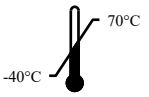
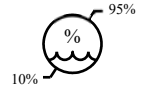
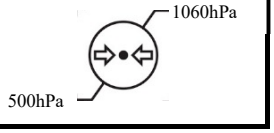
Replace with a fuse of the same rating as the built–in product.

Attach the fuse holder by squeezing it in.

3) Chin Rest Paper

When refilling the chin rest paper, pull out the chin rest paper pins and refill it. After that, fix it with the pins again.

Environmental Conditions

	Temperature	Humidity	Atmospheric pressure
Usage			
Storage			
Transportation			

Disposal

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

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

Only for the United Kingdom

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

Specifications

Refractive measurement range	Sphere (S)	-30D to +22D (In case of VD=12) (step: 0.01/0.12/0.25D)
	Cylinder (C)	0 to ±10D (step: 0.01/0.12/0.25D)
	Astigmatism axis angle (A)	0 to 180° (5/1°unit)
	Accuracy	According to EN ISO 10342:2010
Corneal curvature radius measurement	Corneal curvature radius	5.0 to 10.0 mm (step: 0.01 mm)
	Corneal refractivity	33.75 to 67.5D (However, corneal refractive n=1.3375) (step: 0.12/0.25D)
	Degree of corneal astigmatism	0 to ±10D (step: 0.12/0.25D)
	Astigmatism axis angle	0 to 180° (step: 5/1°)
	Peripheral measurement	φ7.0 mm
	Accuracy	According to EN ISO 10343:2014
Accommodation measurement	Measurement range	0 to +5.0D (step: 0.5D)
Vertex distance	0, 10, 12, 13.5, 15 mm	
Minimum pupil diameter	φ2.0 mm	
PD measurement	Measurement range	0 to 85 mm (step: 1 mm)
	Accuracy	within ±1 mm
Pupil diameter measurement	Measurement range	φ2.0 mm to 8.5 mm
	Display range	0.1 mm
	Accuracy	within ±0.1 mm
Corneal diameter measurement	Measurement range	φ2.0 to φ14 mm (diagonal measurement: φ14 mm)
	Display range	0.1 mm
	Accuracy	within ±0.2 mm
Measurement distance (WD)	44.0 mm	
Printer	The thermal line printer with auto cutter (paper width 58 mm)	
Internal monitor	10.4 inches color LCD monitor (TFT)	
Shifting range of the sliding body	back/forth ± 16 mm right/left ±43 mm up/down ±20 mm	
Vertical adj. range of chinrest	±30 mm	
Dimensions	(W) 277±1 mm (D) 431±1 mm (H) 482±5 mm	
Weight	23 kg or less	
External interface	Ethernet (10/100 Mbps) × 1 USB 2.0 Full Speed (HID/Mass Storage Class, HUB) × 1 Serial communication port × 1	
Power source	100 to 240 V 50/60 Hz	
Power rating	90 VA	
Power saving function	OFF, 3, 5, 10mins (switchable)	

The specification and design are changed without notice.