



fundus link

model: 20D001



instructions manual

Product Description

Fundus Link is an adapter lens that can be clipped over the camera on smartphone, intended for examiner to place Fundus Link close to subject's eye for retinal imaging. It is an ultra-compact, ultra-wide field smartphone ophthalmoscope. Digital images of the back of the eye can be captured by the smartphone with Fundus Link. The images show the retina, the optic disc, and blood vessels which allow the health care professional (as ophthalmologist, or trained personnel) to evaluate the health of subject's eye.

Intended Use

Fundus Link is intended for the imaging of the back of the eye ("fundus") for the purposes of general visualization for the retina or back of the eye. It can be operated by health care professional, be used for patient as adult.

Contraindications

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. The Fundus Link is deemed to have a maximum safety exposure for use on a patient of One hours.

Fundus Link is safe for patients and health care professional (as ophthalmologist, or trained personnel) when using accordance with this Instruction for use, for the instruction and the warnings and cautions.

The Fundus Link is not intended to provide visualization for the purposes of diagnosis.

Warnings and Cautions



WARNING

- *No modifications to the Fundus Link hardware are permitted.*
- *To prevent fire or electrical shock. Do not expose or use the device in raining or moisture. The Fundus Link is not protected against the ingress of water and should not be used in the presence of liquids which may enter the device.*
- *Portable and mobile RF communications equipment can affect the Fundus Link performance.*
- *Exposure to flash light of Fundus Link, in rare cases, may contribute to migraines or temporary visual disturbances, particularly in patients with a history of light sensitivity or migraines. Multiple flashes per eye in a single exam may increase the likelihood of occurrence.*
- *Clean and disinfect the eyecup after each patient to avoid the risk of cross-contamination.*
- *The manufacturer declares that this medical device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (Radio Equipment Directive).*
- *Use only accessories belong to this instruction of use (IFU) mentioned. Using others then this IFU mentioned accessories with Fundus Link can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.*



CAUTION

- *Use only smartphone that are listed as compatible with the Fundus Link.*
- *The Fundus Link avoid using the device in a dusty environment.*
- *The Fundus Link avoid subjecting the device to vibration or shock.*
- *Do not sterilize the device.*
- *Keep the device away from any heat source.*
- *All servicing of this device is to be performed by C-MER RainsOptics Limited or by a centre approved by C-MER RainsOptics Limited*
- *Do not the device in direct sunlight. Strong ambient light may affect the results.*
- *Do not use automatic cleansing machines or sterilization.*
- *Consult the cleaning and disinfection agent manufacturer instructions for their proper use and germicidal efficacy, prior to their use.*
- *Consult your facility's procedures and the cleaning and disinfection agent manufacturer instructions for recommended Personal Protective Equipment and other safety precautions such as ventilation, etc.*

Eye Safety

The Fundus Link has been tested against BS EN ISO 15004-2:2007 – Ophthalmic Instruments – Fundamental requirements and test methods Part 2: Light hazard protection. The illumination levels of all supported Fundus Link implementations have been shown to comply with Group 1 classification as per the referenced standard. Group 1 classification of the Fundus Link product assumes a continuous light exposure time of less than 1 hours. Group 1 ophthalmic instruments require no external product labelling for light hazards.

Battery

Do not disassemble, modify, crush or destroy the battery pack. Doing so can cause battery fluid leakage, heat generation, burns, fire and/or explosion.

Do not replace of battery with an incorrect type that can defeat a safeguard.

Disposal of a battery into fire or a hot oven, or mechanically crushing or cutting of a battery, that can result in an explosion

Leaving a battery in an extremely high temperature surrounding environment that can result in an explosion or the leakage of flammable liquid or gas

A battery subjected to extremely low air pressure that may result in an explosion or the leakage of flammable liquid or gas

Use of an unrecommended charger may cause battery fluid leakage, overheating of the battery, or may cause the battery to explode.

Battery Charger

Only connect the equipment to computers or laptops or battery charger that have passed the safety standard for information technology equipment IEC 60601-1, EN 60601-1, ANSI/AAMI ES 60601-1, IEC 62368-1, EN 62368-1 to ensure the safety of the USB electrical connection.

Electromagnetic compatibility

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer

than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services

This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation

Notice of compliance

The device complies with the FCC rules, Part 15. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference

received, including interference that may cause undesired operation.

FCC rules

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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 antenna.
- Increase the separation between equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

IC Radiation Exposure Statement:

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This equipment complies with Canada radiation exposure limits set forth for uncontrolled environments. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Déclaration d'IC sur l'exposition aux radiations:

Cet équipement est conforme aux limites d'exposition aux radiations définies par le Canada pour des environnements non contrôlés.

Cet émetteur ne doit pas être installé au même endroit ni utilisé avec une autre antenne ou un autre émetteur.

Trademarks

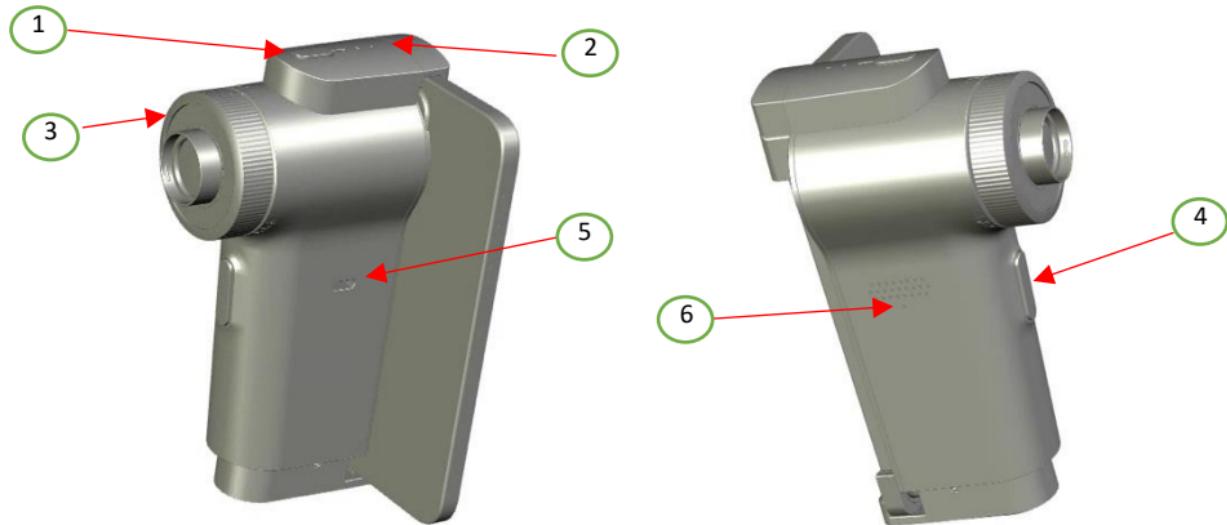
Bluetooth®

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by C-MER RainsOptics Limited is under license. Other trademarks and trade names are those of their respective owners.

Table of Contents

Product Description	1
Intended Use	1
Contraindications	1
Warnings and Cautions	2
Notice of compliance	6
Trademarks	8
Table of Contents	9
Parts and Feature of Fundus Link	10
Procedures for before use	12
Procedures for Mounting the Fundus Link onto the iPhone	14
Investigation	15
Cleaning Fundus Link	19
Fundus Link Care	21
Product Specification	22
Device Class	23
Troubleshooting	24
Important Symbols	25
Contact Information	27

Parts and Feature of Fundus Link



Part #	Part Name
1	Power On/Off button
2	Indicator: Power ON: Green LED indicator will be flashing Bluetooth Connection: Blue LED indicator will be constant on Preview Mode: Green LED indicator will be constant on Low battery: Amber LED indicator will be flashing Battery charging: Amber LED indicator will be constant on
3	Focus Ring
4	Shutter button
5	Battery charging socket
6	Reset

Procedures for before use

1. Charging the Fundus Link

- Fundus Link is delivered uncharged. Before the first use, you must fully recharge it for about **4 hours** with the supplied battery charger, or until the YELLOW indicator light turns off.
- The use of any other charger will automatically suspend the warranty.
- During subsequent charges, the charging should take approximately **4 hours**.
- Please connect the charger to the Fundus Link and to the mains. During the charging, the YELLOW indicator light is constant on. The YELLOW indicator light will turn off when the charging is completed.
- Do not let the device charge for more than 24 hours.

2. Power ON and OFF

Power ON:

- Press and Hold the POWER button for about 1sec until the GREEN indicator light is flashing.
- Release the POWER button.

Power OFF:

- Press and hold the POWER button for about 3sec until the GREEN and/or BLUE indicator light is off.
- Release the POWER button.

3. Bluetooth connection

Bluetooth connection is the process of linking two Bluetooth® devices, so that they can communicate.

The Bluetooth connection only needs to be done once. Afterwards, every time you power on your Fundus Link, it will automatically connect to your smartphone (Bluetooth® of smartphone is on and set to automatically connection).

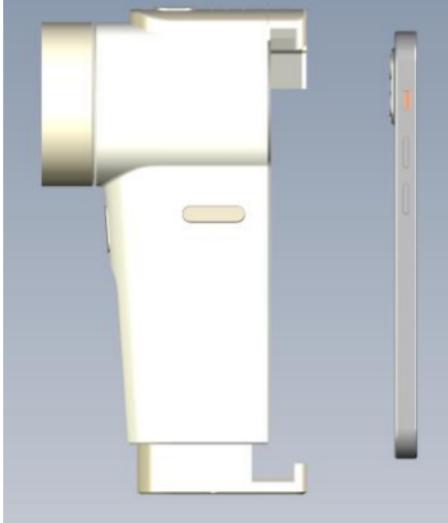
To initiate the Bluetooth connection, put both Fundus Link and the smartphone within 0.3 meter (1 foot) from each other.

1. Power on the Fundus Link, the GREEN indicator is flashing.
2. Switch on your smartphone and select the Bluetooth® discover mode on the smartphone (See the Bluetooth® smartphone user guide).

3. Once the smartphone detects the device, a message is displayed with the following information: “Fundus Link_xxxx”.
4. Follow the smartphone instructions to accept the connection.
5. When the connection is completed, the BLUE indicator will be constant on.

Procedures for Mounting the Fundus Link onto the iPhone

1



Pull out the bottom clamp

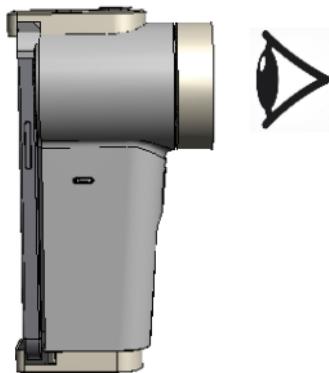
2



Insert the iPhone, and make sure the alignment bar on the mount have aligned to the side wall of the iPhone

Note: Make sure the camera on the iPhone is aligned to the designed aperture on the mount

Investigation



Open the “Camera” app in smartphone to start the investigation

- Do the investigation in a dark environment.
- The device is intended to be used in the population with the pupil size above 2.5mm without mydriasis. Dark environment allows pupils naturally dilated during investigation.

1. Ensure the Bluetooth connection is well connected between Fundus Link and Smartphone (BLUE indicator is constant ON)
2. Press the SHUTTER button briefly to change to “PREVIEW” mode (GREEN indicator constant ON), a dim preview light will light up for focusing.
3. Adjust focus ring before examination

Clockwise

– Myopic refractive error



Anticlockwise

– Hyperopic refractive error



4. Examination



Holding the focus ring with your
LEFT hand;

Holding the device and pressing the shutter
with your **Right** hand;

Ask the patient to look at your
Right ear for fixation;

Touching the patient's forehead for
stabilization



Holding the focus ring with your
Right hand;

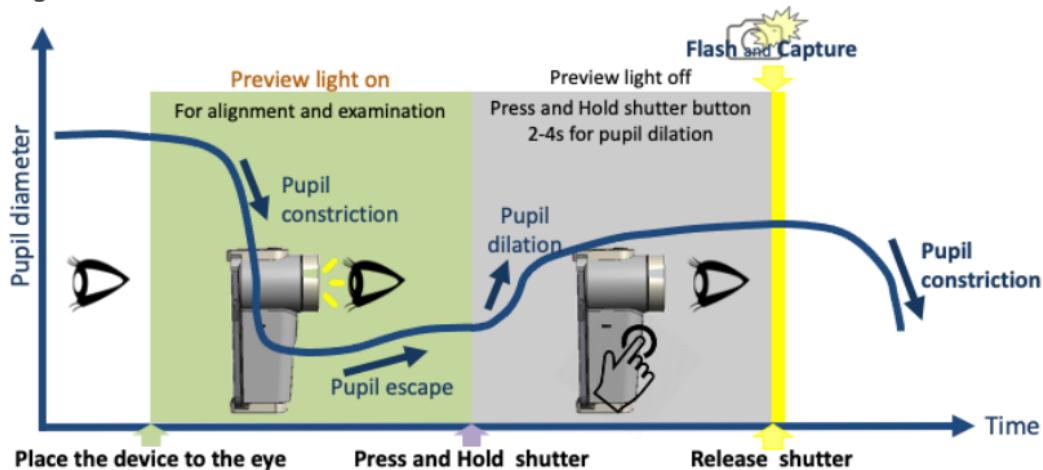
Holding the device and pressing the shutter
with your **Left** hand;

Ask the patient to look at your
Left ear for fixation;

Touching the patient's forehead for
stabilization

5. Adjust the distance between the eye and Fundus Link, and adjust the focus ring until the sharp image have been displayed on the smartphone screen.

6. Press and Hold the SHUTTER button 2-4 seconds to off the preview light for pupil dilation
7. Release the SHUTTER button for flash lighting and remote control the smartphone to capture the image.



CAUTION

Capturing failures could be due to limited pupil size, blinking and alignment issues. Repeat capturing is required. If repeat capturing still fails, it is recommended to capture after mydriasis.

Cleaning Fundus Link

When you perform the detailed cleaning steps, please note the following:

- Ensure the cleaning wipe is not dripping, but is saturated with cleaner solution.
- Always replace the wipe when visibly dust.

Fundus Link Body:

- Using a soft dry cotton cloth wipe the body gently.

Fundus Link Lens:

- Disconnect the USB cable from the device.
- Remove the eyecup from the device.
- Using a commercially blower to blow away dust when it adheres to the lens.
- And using a soft cotton cloth wipe the lens gently in a circular motion.

Fundus Link Eyecup:

- Recommend to clean the eyecup before each use on a new patient
- Disinfect the eyecup with a soft cloth moistened with alcohol (e.g. 70% ethanol); or
- Soak the eyecup in a glutaraldehyde-based solution or hydrogen peroxide and peracetic acid solution
- Rinse the eyecup under running water
- Dry the eyecup (e.g. with clean paper towel) before subsequent use

If a replacement eyecup is needed, please contact customer service or your local distributor. The eyecup should be replaced when:

- Discolored
- Deteriorated
- Shattered, cracked or disintegrated



CAUTION

Do not use cleaners that contain organic solvents to clean the Fundus Link body or lens.

Fundus Link is not intended to be sterilized

Ensure that no moisture penetrates the system during cleaning and disinfection.

Fundus Link Care

- This Fundus Link is a precision instrument. Do not drop it or subject it to physical shock.
- The Fundus Link is not waterproof. If you accidentally drop the Fundus Link into water, promptly send the instrument back to C-MER RainsOptics Ltd. Wipe off any water droplets with a dry and clean cloth. If the Fundus Link has been exposed to salty air, wipe it with a well-wrung wet cloth.
- Do not leave the Fundus Link in excessive heat, such as in a car in direct sunlight.
- Use only a commercially-available blower to blow away dust when it adheres to the lens.
- To remove dirt, grease or fingerprints, clean with a soft cotton cloth rubbing in a circular motion. Use of coarse cloth or unnecessary rubbing may scratch the lens surface and eventually cause permanent damage.
- Do not use cleaners that contain organic solvents to clean the Fundus Link body or lens.
- If the Fundus Link is suddenly brought in from the cold into a warm room, condensation may form on the lens surface and internal parts. To prevent condensation, first put the Fundus Link in a sealed plastic bag and let it adjust to the warmer temperature before taking it out of the plastic bag.
- Avoid storing the Fundus Link where there are chemicals that result in rust and corrosion such as in a chemical lab.

Product Specification

Product Name / model	Fundus Link / 20D001
Service life	5 years
Width x Depth x Height:	51 mm x 106 mm x 160 mm
Weight	235 g
View Angle	30 Degree (Typical)
Diopter	-15 - +15D (Typical)
Minimal Pupil Diameter size	2.5 mm
Light source	Natural White Light Emitting Diode (LED)
Operating Environment	+ 10 °C to + 40 °C, 30 % to 75 %, 700 - 1060hpa
Storage / Transport Environment	- 10 °C to + 55 °C, 30 % to 75 %, 700 - 1060hpa
Compatible smartphones model	Apple iPhone 12
Power Source	Rechargeable Lithium Battery 3.7V / 2700 mAh
Battery charger (model no. UES06WNCPU-050100SPA)	Input: 100~240 VAC, 50/60 Hz, 0.2A; Output: 5.0V DC, 1.0A
Operating Time	35 hours
Charging Time	4 hours (through the charging adapter model no. UES06WNCPU-050100SPA)
Firmware version	V1.00
IP class	IPx5 (optical system only)

Accessories

- Eyecup
- Soft pouch
- Battery charger
- USB charging cable
- Instruction for use
- Soft cloth
- Dust sweeper
- Lens cover
- Activation Card

Device Class

This product has been tested to meet the requirements under ISO 15004-2:2007 as a Group I exempt product.

Troubleshooting

TBD

Important Symbols

Symbols	Descriptions
	Warning. The warning statement in this instruction for use identify conditions or practices that could lead to illness, injury, or death.
	Caution. Consult the instructions for use for important cautionary information. The user is advised of important operating and maintenance instructions.
	To identify electrical equipment designed primarily for indoor use.
	Symbol for "Consult Instructions for Use" or "Consult Instruction Manual"
	Symbol for "Follow instruction for use"
	Do not operate or leave this assembly in any environment that may exceed +10°C to 40°C.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates a medical device that needs protection from light sources
	Indicate the item is a medical device
	Indicates the model number
	Indicates the manufacturer's serial number so that the specific medical device can be identified.

UDI	Indicates a carrier that contains UDI information
	Indicates the medical device manufacturer, as defined in the EU Regulation (EU) 2017/745.
	To identify the country of manufacture of products
	Indicates the Authorized representative in the European Community.
	Mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Regulation.
	US Federal Communication Commission
	Waste Electrical and Electronic Equipment Directive
Rx only	Prescription only or "For Use by or on the order of a licensed medical professional

Symbols found in the electronic camera device are not included. For iPhone user, please visit www.apple.com to learn how to use your device. The iPhone user guides are available on the Apple website.

Contact Information



Manufacturer:

C-MER RainsOptics Limited

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