Instructions for Use
for Fundus Camera

Product name: Fundus Camera
Model name: WFC-01

WikiOptics Inc.

205, 120, Heungdeokjungang-ro,
Giheung-gu, Yongin-si, Gyeonggi-do,
Republic of Korea

Tel. +82-70-4667-4271
contact@wikioptics.com

EC REP **JaviTech e.K.**

Sachesenhausener Str. 16, 65824
Schwalbach a. Ts., Germany

Tel. +49-6196-4021549
info@javitech.de

Contents

1. Device information

1.1 Device Name

Product Name: Fundus camera
Model Name: WFC-01

1.2 General Description

The WFC-01 is a medical device that observes and records the retina of humans or animals. Users can focus on the retinal surface by manually focusing the knob viewing with an IR light source and getting the visible image with a white LED flash. So there is no need to use any pupil dilation agent.
Using the user's Android OS smartphone, the user can view the retinal image and control the level of lighting, etc.

1.3 Intended Purpose

A medical device that illuminates the fundus by incident light on the pupil and records the fundus condition according to the reflected light in an image.

1.4 Performance Characteristics

1.4.1 NON MYDRIATIC

Focusing uses an IR light source and gets the retinal image with a white LED flash

1.4.2 WIDE FIELD OF VIEW

>45˚(horizontal), > 40˚(Vertical)

1.4.3 MANUAL FOCUS ADJUSTMENT

RANGE OF DIOPTER: -20D - +20D

1.4.4 Android OS SMARTPHONE

The nun+ App for Android is available so that it can conveniently manage the patient's retinal image and video.

1.5 Indications

- Glaucoma, diabetic retinopathy, macular degeneration, and retinal detachment

1.6 Contra-indications

- While any medical procedure has potential risks as well as benefits, more complicated examinations should not be performed for longer than three minutes within twenty-four hours.
- Since prolonged intense light exposure can cause ocular damage, the device should not be used for ocular examination for unnecessarily extended periods, and the brightness setting should be sufficient to provide a clear view of the target structures only. Infants, those with aphakia, or people with diseased eyes are at greater risk of ocular damage. The risk may also be increased if the person being examined has been exposed to the same or any other ophthalmic instrument using a visible light source during the past 24 hours.

1.7 Patient Target Group

From infants to old age

1.8 Intended Users

This medical device is intended for use by healthcare professionals only.

1.9 Residual Risks

After conducting risk management activities, there are no residual risks.

1.10 Precautions

• Do not use this device where there are flammable anesthetic mixtures, since it presents an explosive hazard.
• Do not drop the device or place heavy objects on top of it.
• Do not store the device near objects with strong magnetism, such as magnets, as it may lead to failure [of the device].
• Do not disassemble or recondition the battery pack as it presents an explosive hazard.
• Please use only the original battery pack with the protective circuit provided or one certified by WikiOptics and a battery charger certified as a medical device.
• Please do not charge a battery in an environment where the temperature is above 45℃ or below 0℃.
• When the battery is fully charged, unplug the DC power supply.
• Do not expose the battery pack to a temperatures above 55℃ or below -20℃.
• Please do not discharge the battery pack at temperature above 55℃ or below -20℃.

1.11 Warnings

• No acute optical radiation hazards have been identified in connection with use of the device. The intended use of this device is for routine ophthalmic examinations typically lasting less than 60 seconds per eye. While any medical procedure has risks as well as benefits, more complicated examinations should not exceed 3 minutes within 24 hours.

1.12 Specifications

1.12.1 Optical specification

Field of view (FOV): >45˚(Hor.), >40˚(Ver.),
Diopter: -20D to +20D (manual focus)
Light source: Infrared LEDs for focus, Natural White LEDs for flash, Fixation 7 LEDs for fixation target
Image format: JPEG
Image sensor: 13Mp
Image resolution: 2880x2160
USB connectivity: Mini USB2.0

1.12.2 User's smartphone system requirements for nun+ app

OS: Android 5.0 over
CPU: Quad-core 1.6GHz over
RAM: 2.0GB over
Display: 5.1inch display, 1080x1920 over

1.12.3 Dimensions

Fundus camera 'nun+', body - [L] 223.4mm x [W] 66.4mm x [H] 187mm
Cradle - [L] 224.6mm x [W] 79.7mm x [H] 87.9mm

1.12.4 Weight

Fundus camera 'nun+', body: 531g
Cradle: 224g

1.12.5 Rechargeable battery

3.6V 3500mAh protection circuit 18650
In IR preview mode with Flash 3 level every 5 minutes, the battery can be used for about 3~4 hours.

1.12.6 Waterproof grade

IPXØ: This product is NOT protected from any penetration of water.

1.12.7 Operating environment

Operating temperature: 15℃ - +45℃
Operating Humidity: 30% - 90%
Storage temperature: -20℃ - +55℃
Storage Humidity: 10% - 95%
Operating and Storage atmospheric pressure: 800 – 1060hPa

1.12.8 DC power supply (for charging)

IEC60601-1 Medical power supply, compliant with 2MOPP
- Model name: GTM46101-1005-USB
- Input: 100-240V, 50-60Hz, 0.3A
- Output: DC 5.0 V, 2.0A

The device is class II medical device / electrical equipment with internal power supply.

1.13 Storage Condition

• Storage temperature: -20℃~ 55℃
• Storage humidity: 10% ~ 95%
• Storage Atmospheric pressure: 800hPa ~ 1060hPa

1.14 Shelf-life

6 years

1.15 Sterile State and Method

This is a non-sterile medical device.

1.16 Single-Use

This medical device is not intended for single use.

1.17 Preparations

1.17.1 Steps for Charging Device

To charge the battery, connect the mini-USB connector on the mini-USB power cable to the fundus

camera charging cradle and connect the USB connector to a DC power adapter USB port that plugs into a PC or wall power socket.

Place the device on the cradle and set the main power switch to OFF"○" to charge. The charging indicator LED is amber during charging but turns green when charging is complete.

1.17.2 How to Replace the Battery

When the rechargeable battery cannot be recharged any longer, please replace it as follows.

- Ensure that the device is powered off when replacing the battery.
- Open the battery cover by sliding the battery cover release knob.
- Remove the old battery to be replaced. Insert the new 3.6V 3500mAh protection circuit 18650 battery in the correct polarity direction and press the cover firmly into place.
- Connect the user's smartphone to this unit and turn on the power to check the device is operating properly.

1.17.3 How to Replace the DC Power Supply and Mini-USB Power Cable

When the DC power supply and mini-USB power cable are no longer available, please replace them as follows;

- The Mini-USB power cable can be replaced by purchasing another new mini-USB power cable.
- The DC power supply be purchased from WikiOptics or its local distributors.

1.17.4 Eye Cup

It helps when blocking external light and guiding the patient's eyes with fixation LEDs.
Place the eye cup on the objective lens barrel of the device.

1.17.5 Attaching a Smartphone to the Device

Raise the clip to the smartphone on the device.
The Clip can accommodate smartphone up to 78mm wide.
Note) Galaxy™ Smartphone width:

-. Galaxy Note 9: 76.4mm, Galaxy Note10+: 77.2mm
-. Galaxy S20 ultra: 76mm, Galaxy S10+: 74.1mm

1.17.6 Calibration and Service

- The accuracy of this fundus camera has been carefully tested and designed to last long.
- Periodic inspections are recommended every two years to ensure proper operation and accuracy of the fundus camera “nun+”.
- If you have any questions or you need help, please contact the place where the device was purchased, or our head office.
- Preventive inspections to ensure continuous safe use;
  - Before using the fundus camera “nun+”, connect it to the smartphone, adjust the settings, check the image preview, and turn on the white LED to check the brightness level. Adjust the focus adjustment knob to check the focus status.

1.18 Verifications of the Software and Accessories

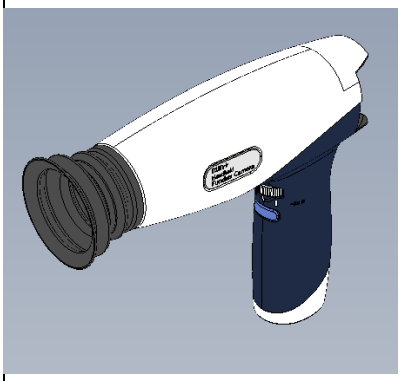
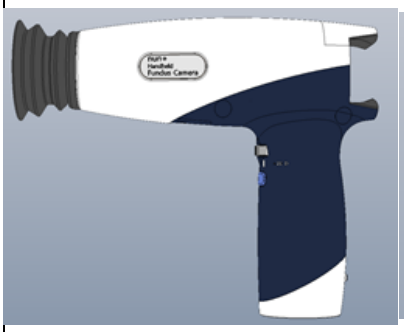
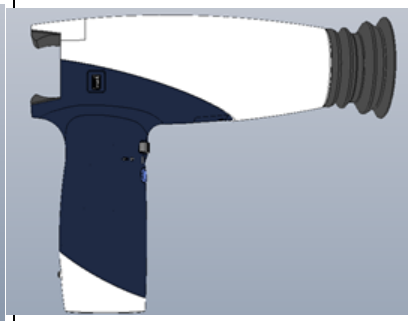
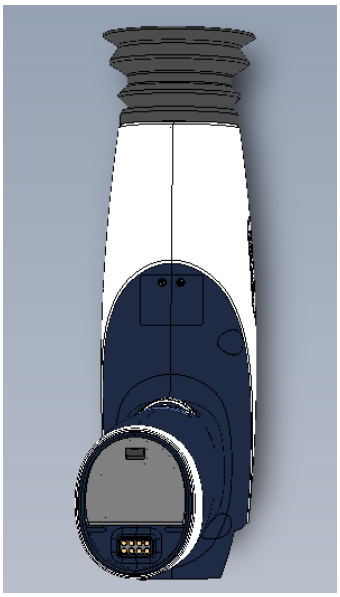
Since this medical device has an app as its accessory, it may be difficult to achieve its intended purpose if the user uses the device with another software.

1.19 Notice to Users/Patients

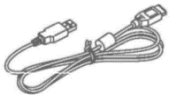
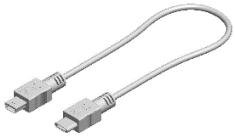
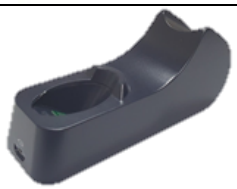
Any serious incident that has occurred in relation to the fundus camera (WFC-01) should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2. Device Configurations

2.1 Picture of Device

Whole	Front	Back
		
Right	**Left**	**Bottom**
		

2.2 Configurations of Device

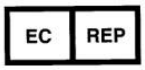
No.	Component	Picture of the component
1	nun+ App	
2	DC power supply & plug	
3	Mini USB power cable	
4	Eye cup	
5	OTG cable	
6	OTG gender	
7	Cradle for battery charging	
8	User manual (On line)	

3. How to Use

- Make sure that the examining room is as dark as possible when examining the retina.
- Hold the fundus camera handle with one hand and the eye cup with the other.
- Aligned the device so that it is level with the patient's eye.
- Guide the patient's eye to the fixation target light and ask them to cover their other eye with their hand.
- Approach slowly so the patient's retina can be seen (until the optical disk image is visible).
- When the optic disk is observed, adjust the focus with the manual focusing knob of the device.
- Let the retina image be fill the screen. The working distance between the objective lens and the cornea is about 25mm.
- If the patient's retinal image is well-focused, press the shot button to take a good retinal image.

- Tip for diopter
  - Hyperopia (farsighted eye): The device is focused to a distance by turning the manual focusing wheel toward (+) diopter.
  - Myopia (nearsighted eye): The device is focused closer by turning the manual focusing wheel toward (-) diopter.

4. Symbols on Packaging

Symbol	Description	Symbol	Description
	Caution: This symbol identifies a safety note. Ensure you understand the function of this control before using it. The control function is described in the appropriate service manual		To identify equipment meeting the safety requirements specified for Class II equipment according to IEC61140
	"ON" (Power) To indicate a connection to the mains		To indicate whether the battery is charging
	"OFF"(Power) To indicate disconnection from the mains		Indicates the USB connection
	Refer to the instruction manual/booklet	IPXØ	Degree of protection provided by enclosure (IP code)
	CE marking of conformity in accordance with Annex V of Regulation (EU) 2017/745		Indicates a medical device that can be broken or damaged if not handled carefully
	Indicates the date when the medical device was manufactured		Indicates a medical device that needs protection from light sources
	Indicates the medical device manufacturer		Indicates a medical device that needs to be protected from moisture
	Indicates the Authorized Representative in the European Community		Indicates the temperature range to which the medical device can be safely exposed
	Indicates the manufacturer's serial number so that a specific medical device can be identified		This symbol indicates the humidity limitation for operation, transport, and storage.
	Identifies a type B applied part complying with IEC 60601-1		The device is subject to European Directive 2012/19/EU for Waste Electrical and Electronic Equipment (WEEE). Do not dispose of the device as normal household waste, but rather dispose of it in an environmentally friendly manner via an officially approved disposal company.
	Indicates the item is a medical device		Indicates a carrier that contains a Unique Device Identifier information
	Indicates the entity importing the medical device into the locale		Indicates the entity distributing the medical device in the locale