

# Fundus On Phone Non Mydriatic

## FOP NM-10



### Instructions For Use



Remidio Innovative Solutions Pvt. Ltd.



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# Table of Contents

Table of Contents.....	5
Introduction.....	7
Package inclusions.....	7
The Fundus On Phone Device .....	9
Components.....	9
Description.....	10
Features .....	10
Set-up Instructions.....	11
Mounting the Smart phone to the Phone Holder .....	11
Mounting the Phone Holder to the FOP NM Device.....	13
Mounting the FOP Device to the Slit Lamp Fixture.....	15
Procedure for Viewing/Capturing Images of the Retina.....	17
Specifications.....	25
Warnings .....	27
Usage and Maintenance.....	29
Cleaning of the Lens.....	29
Trouble Shooting .....	30
Symbols.....	32
Warranty.....	33
Technical Support.....	34
Contacts .....	34



## Introduction

Remidio Fundus On Phone Non Mydriatic (FOP NM) device is the world's first smartphone enabled, high quality retinal imaging system which does not require dilation. The system uses high quality, precision optics to illuminate and capture images of the retina. The Remidio FOP NM device is intended to be used by certified optometrists, ophthalmologists and primary care physicians.

As part of the optical design, the device uses LED light source. This ensures a stress-free experience for the patient, unlike conventional non-mydriatic desktop fundus cameras.

The Remidio FOP NM device is to be used with the built in Remidio Fundus Software App to view the retina and it can capture digital images of the retina when used along with a smart phone with and without any dilation.

The optical design of the Remidio FOP gives the best Field of View (FoV) and magnification. A minimum 45° FoV gives up to 10x magnified view of the retina.

## Package inclusions

The contents of the package are listed below.

SL. No.	Name of the Unit	No. of Units
1	FOP NM Device	1
2	AC-Power Adapter	1
3	Slit lamp Slider Fixture	1
4	Phone Holder	1
5	Smart Phone	1

## Fundus on Phone Non Mydriatic FOP NM-10

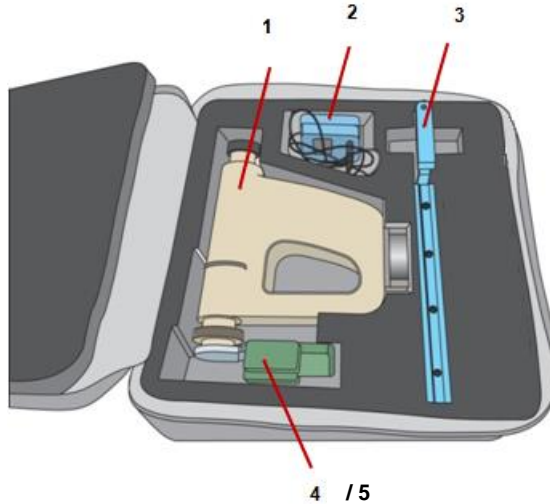


Figure 1-FOP NM Package

1. Fundus On Phone NM Device & Eye Cup
2. AC-Power Adapter
3. Slit lamp Slider Fixture
4. Phone Holder
5. Smart Phone

**Note:** If any of the item listed is missing or damaged, contact the dealer.

### WHAT TO DO BEFORE THE FIRST USE

Remove the Fundus On Phone NM device from the package and check that all the parts are intact.



## The Fundus On Phone Device

### Components

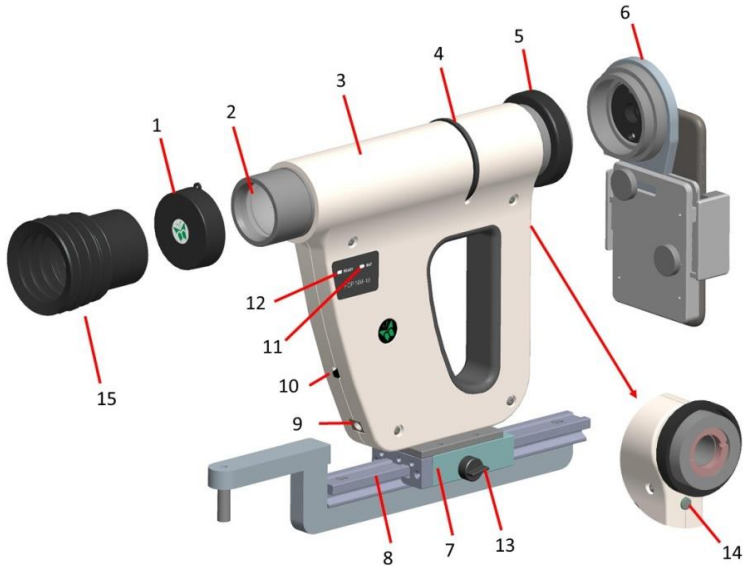


Figure 2-FOP NM Device

- |                             |                             |
|-----------------------------|-----------------------------|
| 1. Objective Lens Cap       | 2. Objective Lens           |
| 3. FOP NM Device            | 4. Focusing Knob            |
| 5. Locknut                  | 6. Phone Holder             |
| 7. Slider Guide             | 8. Slit lamp Slider Fixture |
| 9. AC-Power Adapter Port    | 10. Power ON/OFF Switch     |
| 11. Battery Level Indicator | 12. Ready Indicator         |
| 13. Slider Lock             | 14. Trigger Knob            |
| 15. Eye Cup                 |                             |

Detachable parts: Eye Cup, Objective Lens Cap, Phone Holder, Smart Phone, Slit lamp Slider Fixture.

Accessories: Phone Holder & Smart Phone

## Description

1. Objective Lens Cap – Protects the objective lens
2. Objective Lens - Magnifies the retina up to 10x times the original size
3. FOP NM Device –Captures the retinal images
4. Focusing Knob – Used for Diopter Correction, gives a clear view of the retina, when turned towards the plus (+) sign for far-sighted (hyperopic) eye or the minus (-) sign for near-sighted (myopic) eye
5. Locknut – Secures the smartphone holder to the FOP device
6. Phone Holder – Holds the smartphone
7. Slider Guide – Used to mount the FOP device on the slider
8. Slider – Used to mount the FOP device on the slit lamp fixture
9. AC-Power Adapter Port – Charge the battery using the AC-power adapter port
10. Power ON/OFF Switch – Switch ON/OFF the FOP device
11. Battery Level Indicator – Indicates the charge of the battery
12. Ready Indicator –System / device ready indicator
13. Slider Lock – Used to secure the FOP device on the slider
14. Trigger Knob – Additional switch to capture Retinal Images
15. Eye Cup –To be mounted while capturing Retinal Images

## Features

- Works as Mydriatic and Non Mydriatic system
- High quality images of the retina
- Wireless App based Intensity controls
- 45°field of view
- Li-ion rechargeable battery, up to 7 hours of backup when fully charged in Non-Mydriatic mode & 3 hours in Mydriatic mode
- Highly compact and portable

## Set-up Instructions

### Pre-requisites

Ensure that the battery is completely charged before the initial use. The battery requires approximately three hours of charging and the charge lasts up to 7 hours in Non-Mydriatic mode & 3 hours in Mydriatic mode.

### Mounting the Smart phone to the Phone Holder

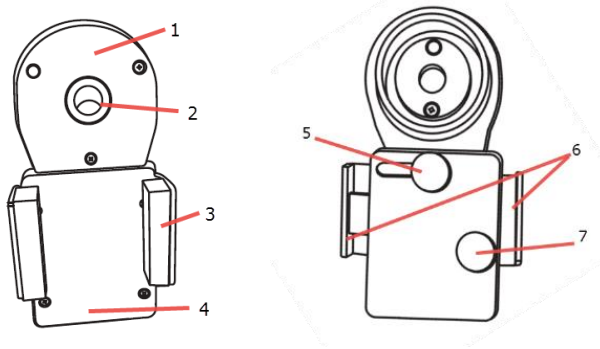


Figure 3- Phone Holder (front and rear view)

- |                                |                  |
|--------------------------------|------------------|
| 1. Top Plate                   | 2. Locator Guide |
| 3. Clamp Spread                | 4. Bottom Plate  |
| 5. Top Plate Adjusting Knob    | 6. Sliders       |
| 7. Bottom Plate Adjusting Knob |                  |

1. Loosen the Bottom Plate Adjusting Knob [7] in figure 3) and expand the clamp spread [3] of the Phone Holder.

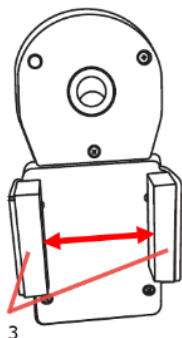


Figure 4-Phone Holder (front view)

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**Note:** This Phone Holder accommodates smart phones of width between 55mm to 75mm.

2. Mount the smartphone between the clamp spread of the bottom plate (Refer [4] in figure 3) and fix the slider (Refer [6] in figure 3).



Figure 5- Phone Holder (front view)

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3. Use the bottom plate adjusting knob [7] to secure the smart phone.

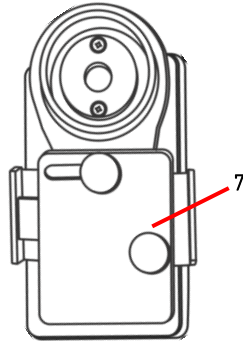


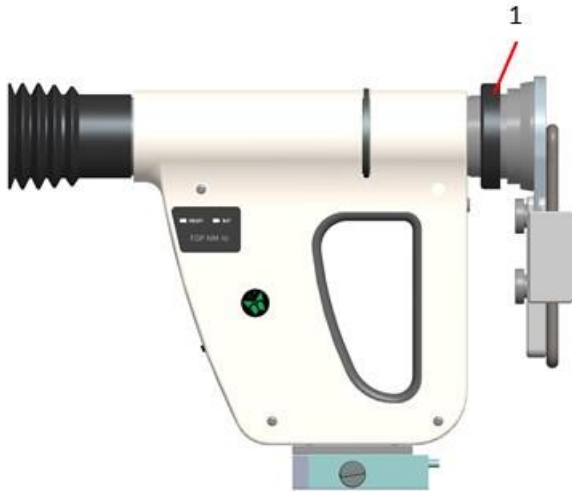
Figure 6-Phone Holder (rear view)

---

4. Align the smart phone camera to the locator guide (Refer [2] in figure 3) using top plate (Refer [1] in figure 3).
5. Secure the top plate (Refer [1] in figure 3) using top plate adjusting knob (Refer [5] in figure 3). Loosen the screw knob on the left hand side.

### Mounting the Phone Holder to the FOP NM Device

1. Ensure the smart phone is mounted to the Phone Holder.
2. Mount the Phone Holder to the FOP NM device, (figure 7).



---

1. Figure 7-FOP NM device and the Phone Holder

1. Lock Nut

Turn the locknut [1] in counter-clockwise direction to secure the Phone Holder.

**Note:**

Tighten the locknut by hand.



Avoid over tightening.

**Mounting of Eye Cup to the FOP NM Device**

Mount the Eye Cup on the FOP NM device as shown in Fig. 7 by sliding it in, for dismounting pull the Eye cup out.



Do not rotate the Eye cup while mounting or dismounting it.

## Using the FOP Device on the Slit Lamp Fixture

### Mounting the FOP Device to the Slit Lamp Fixture

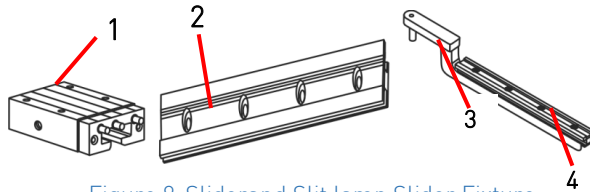


Figure 8-Slider and Slit Lamp Slider Fixture

1. Slider Guide 2. Slider Rail 3. Slider Pin 4. Slider Rail Support

1. Fix the slider pin (Refer [3] in figure 8) to the hinge point [1]. The Hinge point diameter may vary with Slit Lamps of different manufacturers. In case of any difficulty in inserting the slider pin, please contact the FOP NM distributor or manufacturer.

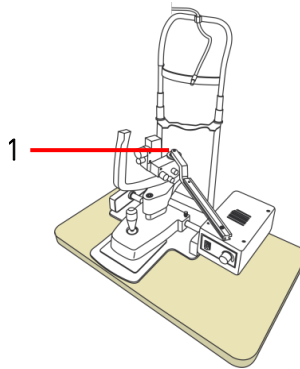


Figure 9-Slit Lamp Fixture

1. Hinge Point

2. Slide the FOP device slider guide [Refer [1] in figure 8] over the slider rail support [Refer [4] in figure 8].

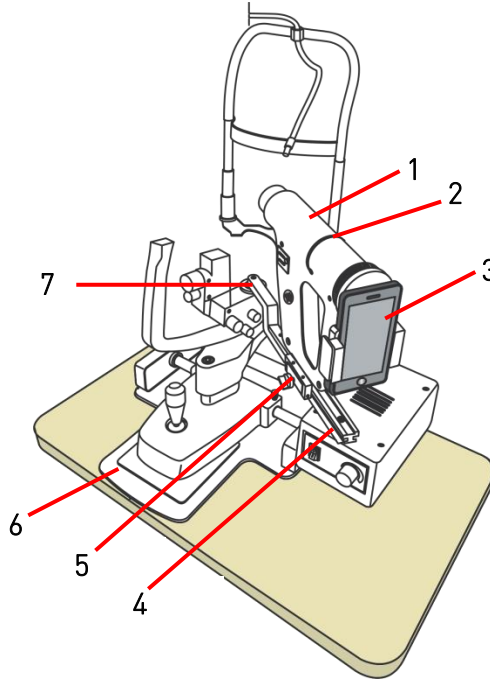


Figure 10- Slit Lamp Fixture with FOP Device (Phone Holder Mounted)

- |                  |                             |
|------------------|-----------------------------|
| 1. FOP NM Device | 2. Diopter Correction Wheel |
| 3. Smart phone   | 4. Slider Rail              |
| 5. Slider Lock   | 6. Slit Lamp Base           |
| 7. Hinge Point   |                             |

3. Rotate the slider lock [3] clockwise to secure the FOP NM device[1] on the slider[2].



## Procedure for Viewing/Capturing Images of the Retina

### 1. Preparing the Patient:

- Seat the patient in front of the Slit Lamp.
- Place the chin on the chinrest. Ensure that the forehead touches the forehead band.
- Align the FOP NM device to view the eye of the patient on the screen.

### 2. Capturing Images of the Retina:

- The Eye cup ensures the pupil is well dilated to get a better view of the retina.
- In case the pupil size is not getting enlarged when used with the Eye cup, please instruct the patient to close the other eye with his hand. In case this also does not work, please switch off all the lights in the room & take the retinal images.
- The Eye cup is to be cleaned with disinfectant before and after screening every patient.

***Note: Refer Figure 10 for more information.***

## Capturing images of the Retina using Smart Phone Camera

The images of the retina can be captured using smart phone with native camera and the pre-loaded Remidio Fundus app with or without dilation of the eye. The entire hardware control is driven by app interface on the phone. The images of the retina can be captured like any normal photograph after selecting either Non-Mydriatic (NM) mode or Mydriatic (M) mode.




Figure 11- Images of the Retina

1. Switching ON:  
Turn ON the FOP NM-10retinal Imaging System
2. App Signup and Sign In  
Start the **Fundus** app on the smart phone, signup and create the hospital profile for the first time and sign in for routine use



Figure 12 Remidio App start page screenshot

3. Patient Profile Creation:  
Create patient profile by touching the  in app. Fill in appropriate details in the fields and save.

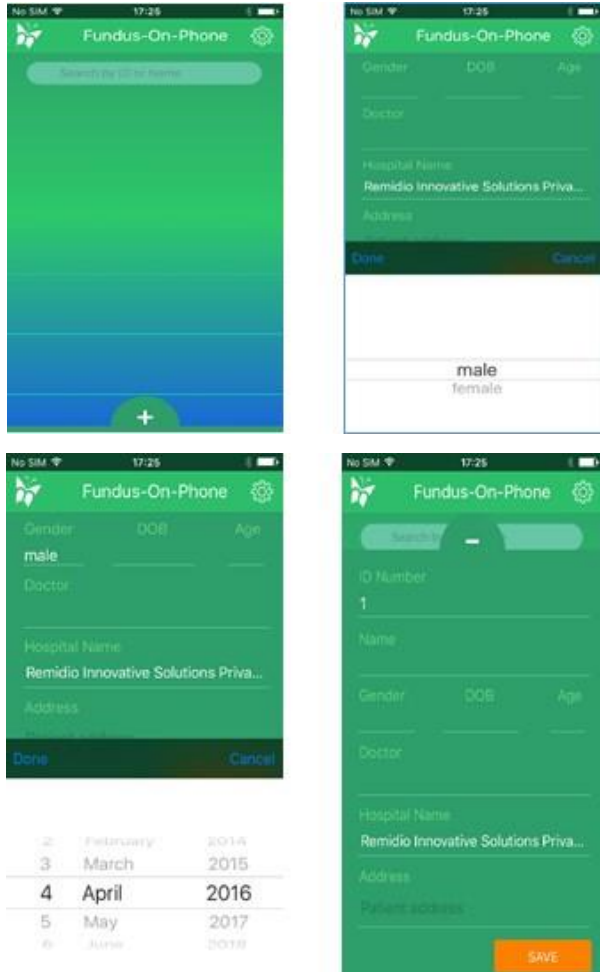


Figure 13- Patient profile creation screenshot

#### 4. Image Capture

Select the mode for mydriatic or non-mydriatic imaging. Toggle between the two modes by sliding the mode changing slider. In mydriatic mode only the white LED icon will appear. In the non mydriatic mode both the white as well as red LED icons will appear

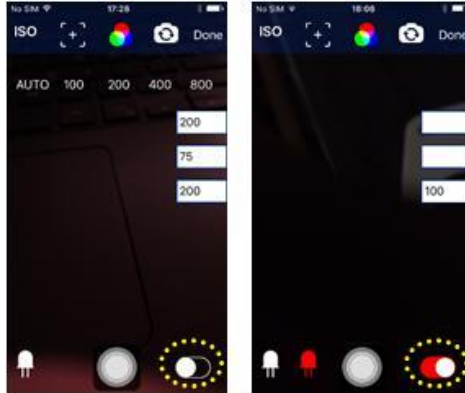


Figure 14- Myd and Non Myd mode toggle screenshot

Make desired changes to ISO, Tone, IR/ White LED Intensity settings to get a clear live view of the retina

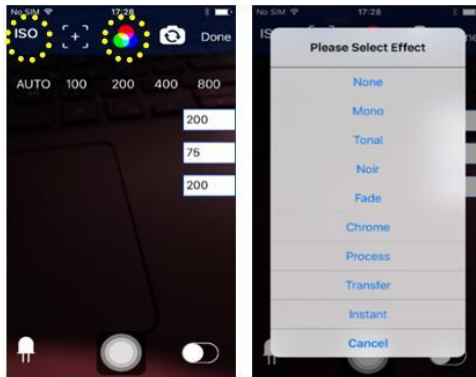


Figure 15- ISO and Tone setting screenshot

## Fundus on Phone Non Mydriatic FOP NM-10

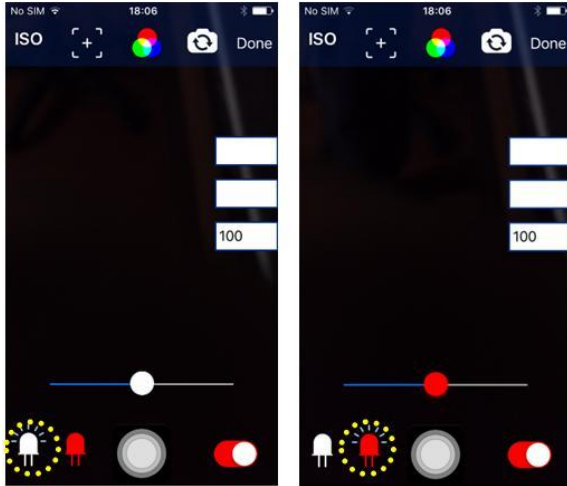


Figure 16- White and IR LED intensity setting Screenshot

Touch OR pinch zoom the desired area of the retinal image on the phone screen to auto-focus.

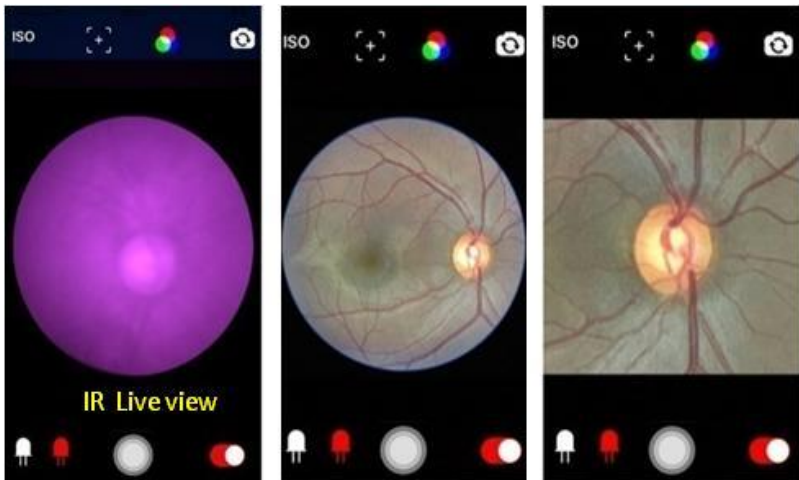


Figure 17- Images of the Retina on Smart Phone

## Fundus on Phone Non Mydriatic FOP NM-10

If required, adjust the diopter correction wheel of the FOP NM device till a clear focused and sharp view of the retina appears on the smart phone screen

Capture the photos using the capture toggle on the screen or with the trigger knob on the system. In case the image seems over or under exposed, vary the flash intensity using the White LED slider. To increase or decrease the infrared live view brightness, use the slider provided in the app with the red LED icon.

### 5. Image editing:

Images can be further modified for RGB colour and other edit functions such as Image rotate, focus, blurr, Crop or Draw.



Figure 18- Image RGB EDIT function Screenshot

## Fundus on Phone Non Mydriatic FOP NM-10

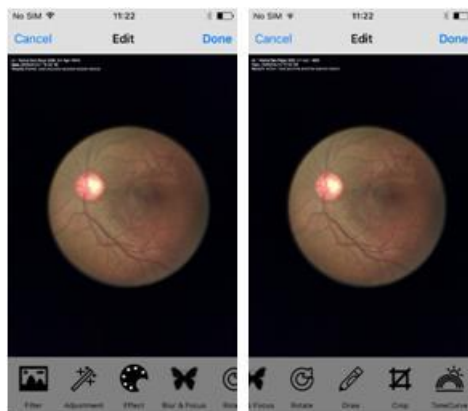


Figure 19- Image EDIT function Screenshot

- Image Print, Share, delete function:
- Transfer the captured images using USB connection. Touch and hold the image that needs to be shared.
- Image highlights upon selection, can be shared or deleted or printed as report. To create a PDF report, select printer symbol, add desired comment in the comment field and print. Print the report using wireless printer.



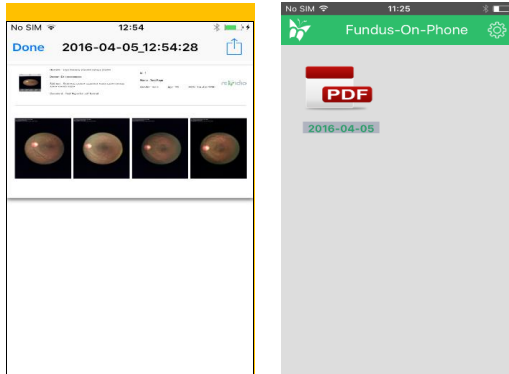


Figure 20- Image sharing, report and Print Screenshot

6. Data Backup procedure:  
 Go to patient folder and select the images that need to be transferred and select forward (📤), Screen will appear having save image option, Select Save # Image (📁) Images now will be present in Photo gallery (📷). Transfer the images to backup system through Data cable.

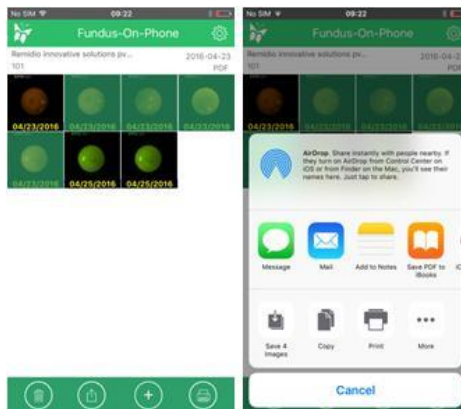


Figure 21- Image sharing, report and Print Screenshot



## Specifications

Parameter	Description
Imaging modalities	Non Mydriatic & Mydriatic
Photography modes	Color, Red free & Infrared
Field of view	45°
Optical magnification	10X (Eyepiece retinal view)
Diopter correction	-30D to +30D
Light Source	Infrared & Cool White LED Infrared LED Intensity 9000 to 12000 Lux; 855nm wavelength Cool white LED Intensity 6000 to 8000 Lux; 700 nm wavelength
Working Distance	33mm
Focus adjustment	Auto / Manual
ISO Range	ISO 100 to 800
Smart phone	Smart Phone with 8 MP camera and above
Environment	Storage Temperature -10°C to 70°C Operating Temperature 0°C to 45 °C Relative humidity 10% to 95% Atmospheric Pressure 700 to 1060 h Pa Operating Altitude upto 3000m
Power Supply	Medical grade external AC power adapter AC Input: 100-240 Vac 47-63 Hz DC Output: 9Vdc 2 Amps Power: 18W Max
Battery	7.4V, 1500mAH Li-ion rechargeable battery with 7 hours backup in Non-Mydriatic mode & 3 hours backup in Mydriatic mode, Model # 2S1P3SWS-003, Rajmane Telectric
Device dimensions (W x D x H)	68mm x 248mm x 234mm
Weight	1.5kg

# Fundus on Phone Non Mydriatic FOP NM-10

## Warnings

1. Do not use this device in close proximity to heat or open flames.
2. Do not use this device in close proximity less than 33 mm with the eye.
3. Keep away from dust and moisture.
4. Use only the AC-Power Adapter supplied with this device.
5. Do not use any solvent-based cleaners on the lens. Use only clean optical grade cloth to clean the lens.
6. Turn ON the FOP NM device before cleaning the lens.
7. Do not touch the lens. Lens temperature can go up to 46° C when the ambient temp is 45° C
8. Turn off the FOP NM device when it is not in use.
9. The adaptor has to be used on mains sockets with voltages as specified for the device use only.
10. The FOP NM device contains no user serviceable or replaceable parts. However, all the information for the Service Personnel would be shared on request.
11. Ensure that the illumination light is not brighter than necessary. Excessive discomfort may result in patient discomfort.
12. While using device on patients with media opacity, images may sometimes have artefacts. User may need to take images in different angles to ensure lack of clinical relevance of the artefacts.
13. Do not use mydriatic imaging on undilated eye as this will compromise the image quality.
14. AC Power adapter to be disconnected from mains to isolate the device.
15. Connect the FOP NM device to the AC power adapter when the Battery Level Indicator LED starts blinking RED.

## Fundus on Phone Non Mydriatic FOP NM-10

16. Replacement of Li-ion battery by inadequately trained personnel could result in a hazard.
17. No modification of this equipment is allowed.
18. DO NOT USE more than one FOP NM device in the same room to prevent RF interference.
19. Do not overtighten the phone holder to avoid optical misalignment
20. Do not remove the front lens holder as it will result in dust on the inner lenses leading to loss of image clarity.
21. Please do not remove the lens cap to prevent fungal growth
22. Only mild / neutral cleaning detergents to be used for cleaning the plastic casing.

## Usage and Maintenance

### Cleaning of the Lens

1. Remove the lens cap.
2. Switch on the system so as to see the dust particles clearly.
3. Have in place cotton swab bud and acetone to clean the lens.
4. Dip the cotton swab in acetone and clean the lens by rotating circularly starting from the center to outer diameter of the lens.

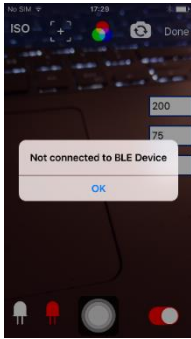



Figure 13- Images of the Retina on Smart Phone

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5. Continue cleaning till the dust particles are completely removed.

## Trouble Shooting

Effect	Cause	Trouble Shooting
Artifacts in the live view/saved images	Dust or Oil stains or thumb impressions or nose rubs on objective lens	Refer the procedure 'Cleaning of the Lens' in the section 'Usage and Maintenance'
Dark images	Improper placement of phone in the phone holder	Align the phone properly in the phone holder figure 4) to 6)
<p>"Not connected to BLE device"</p> 	Message is displayed when FOP-NM-10 is not connected to smart phone.	Please switch on the system and execute the app after two minutes
<p>Captured Image in Purple in colour</p> 	IR light not synchronized	Please contact the service provider

## Fundus on Phone Non Mydriatic FOP NM-10

### **Eye Safety:**

FOP NM-10 has been tested against ISO 15004-2:2007– Ophthalmic Instruments – Fundamental requirements and test methods Part 2: Light hazard protection. The illumination levels of the device implementations have been shown to comply with Group 1 classification as per the referenced standard. Group 1 ophthalmic instruments require no external product labelling for light hazards.

FOP NM 10 is a class IIa product in accordance with MDD Council Directive 93/42/EEC.

Symbols found in the Smartphone device are not included. Please visit the Smartphone manufacturer website for phone usage instructions.

### **FCC compliance statements:**

(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 Caution!!!**



- Any changes or modifications not expressly approved by the party

Responsible for compliance could void the user's authority to operate this

Equipment

## Symbols



Meets essential requirements of European Medical Device Directive 93/42/EEC.



EC Rep



Manufacturer



Mandatory to refer instructions for use



Warning



Type BF applied part – Eye Cup

Applied part, is a part of the medical device that in normal use necessarily comes into physical contact with the patient



Fragile, handle with care



Keep Dry



Waste Electrical and Electronics Equipment. Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Therefore, when disposing of this product, be absolutely certain to follow the procedure which conforms with the laws and regulations applicable to your area.



## Warranty

Remidio Innovative Solutions Pvt. Ltd. warrants the Fundus On Phone Non Mydriatic (FOP NM) to be free of original defects in material and workmanship and to perform in accordance with the manufacturer's specifications for a period of one year from the date of purchase. If this instrument or any component thereof is found to be defective or at variance with the manufacturer's specifications during the warranty period as solely determined by Remidio, Remidio will repair or replace the instrument or components at no extra cost to the purchaser.

This warranty only applies to the instruments purchased from Remidio or its authorized distributors or representatives. Return the instrument directly to Remidio or an authorized distributor. The shipping costs needs to be borne by the shipper.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping, Fungal growth on lens and is void if the instrument is not used in accordance with manufacturer's recommendations or if opened, repaired or serviced by any company other than Remidio or an authorized representative of Remidio.

No other express or implied warranty is given.

## Technical Support

For queries regarding the FOP NM Device, see  
<http://www.remidio.com/Contact.html>

## Contacts



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