

LINKTOP

Otoscope

User Manual

(Model: NE20)

CE

(Version: 1.0)

Introduction

This user manual is a part of a medical product - the Otoscope. Please read through this brochure before use and keep them for future reference.

Linktop bears no liability and provides no guarantee with regard to damage (including indirect damage) arising due to this user manual not being complied with. Linktop reserves the right to make technical changes without notice in the interest of progress. Prior notices will not be given in case of any amendments within this manual.

Table of contents

1. Safety Information	1
2. Description	3
3. Using Instructions	6
4. Cleaning and Maintenance	8
5. Environment Conditions	8
6. Troubleshooting	9
7. Servicing	9
8. Warranty	9
9. Explanation of utilized symbols	10
10. Electromagnetic Compatibility	11

1. Safety Information

To assure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this manual.

1.1 Warnings

- Using this medical product is not a substitute for visiting a physician and may not delay obtaining medical assistance in sudden pathological conditions.
- This medical product can be operated by adults only.
- This medical product is not intended for diagnostics in emergency conditions! If you suspect any hazard to life or health (e.g. trouble breathing, impaired consciousness, significantly increased respiratory rate, panic), do not use this medical product! In such a situation, contact a doctor urgently.
- Keep the device out of the reach of unsupervised infants and children.
- The cable may constitute a strangulation hazard: any examination of children should be conducted under supervision.
- Use only original Otoscope parts, spare parts, and accessories.
- The correct and safe function of the device is only guaranteed if both the device used and its accessories are provided by Linktop.
- Do not perform examinations with the device or put it to the body while it is being charged.
- This medical product is non-sterile. Do not use on injured tissue.
- Do not shine light of the device directly into the eyes.
- Prior to commencing examination, please disconnect the charging cable from the device.
- Prior to using the device, make sure that it has no visible damage.

- Do not use the device where it may be exposed to flammable gas.
- The device is not allowed to enter or be used in areas with strong magnetic fields, e.g. MRI scanners.
- Do not attempt to replace the battery on your own.
- Do not disassemble or attempt to repair and modify the device or components. Repairs shall only be carried out by qualified persons.

1.2 Cautions

- This medical product is an Otoscope. It should be used solely for checking the details of the earhole, nasal. This medical product does not analyze the pictures recorded.
- A video shooting made using this medical product may be transmitted only via applications approved by Linktop. The videos made using any applications other than those specified below may not be reliable, which may lead to their content being interpreted incorrectly by a doctor and, in consequence, to incorrect diagnosis. The list of approved applications is available at the www.linktop.com website.
- In case of noticing any irregularities in functioning of the device or any damage to it, stop using it immediately and contact the manufacturer.
- Do not touch the lens directly by hand or something hard.
- The device should be stored in a clean and dry place.
- Protect this device from water, moisture, impact, dropping, direct sunlight, heat and fire.
- The device should be charged only by means of the charging cable included in the set supplied. In any other case, use a charger that meets the requirements described of this manual.
- When the product is being charged, all its functions, including data transmission, are blocked.
- The device does not include any parts that can be replaced by the user on their own.

2. Description

2.1 Intended Use

Linktop Otoscope is a portable, handheld optical magnifying device with short focal length camera, which is intended for the examination of the ear, the external auditory canal and the tympanum. The high resolution camera can provide great image and video quality, there are 6 LED lights on the tip of the camera which makes the light path and increase the visual field of view. It has rechargeable battery powered. It needs to be used with the USB cables to connect to Android system equipment and iPhone. By using visualization App, it enables capturing and transmission of video and still images. It can be used on any person undergoing a physical examination. It is suitable for adulthood and children over 3 years old.

2.2 Components

The main elements of the Otoscope are presented on Figure 1.

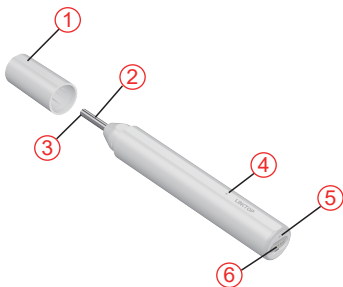





Figure 1

Description of each component	
①	Cover: Used to control device to automatically turn on and off by opening and closing the cover.
②	Camera: For video shooting and photos taking.
③	6 LED lights: Lighting for camera imaging, non-removable.
④	Reset hole: For resetting the device by inserting a thin rod into the reset hole to short press the reset key.
⑤	Indicator light: Two color LED light, used to indicate the operation, charging and low power status of the device.
⑥	Magnetic USB interface: For connecting charging cable, Android/ iOS device.

The table below includes the description of the LEDs on the Otoscope:

	Green led is on when the device is on and connected to an iOS device.
	Green led flashes slowly when the battery is below 20% (low power mode), and not be charged.
	Blue led is on when it is connected to an Android device.
	Blue light is on when it is charging.
	LED is off when it is fully charged.

2.3 Specifications

Product Name	Otoscope
Model	NE20
Power supply	Lithium-ion battery (non-removable)
Charging voltage /current	5V DC 2A/1A/500mA
Dimensions	<ul style="list-style-type: none">● Height: 5.3 inches (134.5mm)● Diameter: 0.7 inches (17.8 mm)
Weight	24.5 g
Battery life	Battery life
Camera	<ul style="list-style-type: none">● Diameter: 3.9mm● Pixel: 1,000,000 pixels● Resolution: 720p● Focal length: 1.5~2.0cm● Horizontal viewing angle: (FOV) 70°● Frame rate: 15fps
Protection class	IP22
Package Contents	<ul style="list-style-type: none">● Otoscope × 1● User manual × 1● Magnetic USB-C cable × 1● Magnetic iOS cable × 1● Micro USB adapter cable × 1● Magnetic USB charging cable × 1
Shelf Life	3 years

3. Using Instructions

3.1 Preparations for use

3.1.1 Application

Prior to using the Otoscope, it is necessary to confirm whether your mobile phone is supported by Otoscope. The available mobile phones are as follows:

- (1) Mobile phone or tablet with Android 6.0 or higher.
- (2) iPhone with iOS 9.0 or higher.

Attention:

- Always use the most recent version of the application. You can use the mobile phone to download the application from Google Play or App Store.
- Please make sure that the app permissions of the mobile phone is open.

3.1.2 Charge the battery

When using the Otoscope for the first time, open the cover to turn it on. If the battery is low, it will not be able to start up. Use the supplied charging cable to connect the device (Figure 2) to a charger to charge it.



Figure 2

Attention:

- Use only the enclosed charging cable.
- In any other case the charging cable should be connected to a charger that meets the requirements described in this manual.
- When charging is complete, please unplug the charging cable.

3.2 How to Use

- (1) Open the cover of the Otoscope to turn it on.
- (2) Connect the Otoscope to the mobile phone using the appropriated cable for your phone type, either the iOS or the USB-C connector (Figure 3). If your phone has a micro-USB connector, use the provided Micro USB adapter with the USB-C cable.



Figure 3

- (3) Once you have connected the Otoscope to your mobile phone, open the application, the application will automatically bind the device.
- (4) Use the application to start to preview captured images.
- (5) Point the camera close to the specific spots you want to observe(Figure 4), and hold the Otoscope at each spot, use the application to take photos or shoot videos, until you have finalized the observation.
- (6) You can use the application to save and share the photos and videos.



Figure 4.

3.3 Turning the Otoscope off

If you do not use the Otoscope, you can remove the cable and close the cover to turn the Otoscope off.

Attention:

If the Otoscope is not turned off when it is not in use, it will run out of battery power.

4. Cleaning and Maintenance

The Otoscope should be cleaned after each use. It should be cleaned using a cotton pad or swab moistened with non-alcoholic disinfectant intended for medical products or personal use.

Attention:

- Do not soak, autoclave or let water or other liquids dip into the device.
- Do not clean it under running water.
The corrosive or polishing detergent is prohibited.
- Do not insert the device in alcohol.

5. Environment Conditions

5.1 Storage and transport conditions:

Temperature: -20 °C to 55 °C

Relative humidity: 10% to 95%

Atmospheric pressure: 700 hPa ~1060 hPa

5.2 Operation conditions:

Temperature: 5 °C to 35 °C

Relative humidity: 10% to 95%

Atmospheric pressure: 700 hPa ~1060 hPa

6. Troubleshooting

6.1 No image

- Check and make sure the cable connected to the phone and device are properly connected.
- Disconnect and reconnect the cable.
- Close the app and open it again.
- Check and make sure the app permissions of the mobile phone is open.
- Power down and restart the device.
- Check the battery level, and recharge the battery.

6.2 Image choppy or delayed

- Disconnect and reconnect the cable.
- Close the app and open it again.
- Power down and restart the device.

7. Servicing

In case of noticing any irregularities in functioning of the medical product, contact the maintenance service at the e-mail address:

support@linktop.com























Linktop bears no liability and provides no guarantee with regard to damage (including indirect damage) arising due to this user manual not being complied with.

8. Warranty

The warranty for the entire product is invalidated if non-genuine Linktop products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by Linktop. The product has a 2-year warranty. For more warranty-related information regarding warranty duration, its scope, its territorial range, and the rights in case of finding a defect are described in detail at the address: www.linktop.com.

9. Explanation of utilized symbols

The following symbols are used on the device or on the packaging:

1		Manufacturer
2		Batch code
3		Serial number
4		Date of manufacture
5		Use-by date
6		Unique Device Identifier
7		CE mark
8		Authorized representative in the European Community /European Union
9		Importer
10		Refer to instruction manual/booklet
11		Caution
12	IP22	IP classification
13		Type BF Applied Part
14		Medical device
15		Part recycled separately from other waste
16		Do not use if package is damaged
17		Fragile, handle with care
18		Humidity limitation
19		Atmospheric pressure limitation
20		Temperature limit
21		Keep away from sunlight
22		Keep dry
23		Direct current

10. Electromagnetic Compatibility

The Otoscope has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

- a) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in abnormal operation of the unit.
- b) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
- c) Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Manufacturer's declaration – electromagnetic emissions

The Otoscope is intended for use in the electromagnetic environments specified below. The customer or the user of the Otoscope should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Otoscope use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Otoscope is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage function /flicker emissions IEC 61000-3-3	Not applicable	


Manufacturer's declaration – electromagnetic immunity

The Oscope is intended for use in the electromagnetic environment specified below. The customer or the user of the Oscope should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, 4, 8, 15kV air	±8kV contact ±2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable (Battery operated device)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable (Battery operated device)	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 IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable (Battery operated device)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oscope requires continued operation during power mains interruptions, it is recommended that the Oscope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels

IEC 61000-4-8			characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration – electromagnetic

The Oscope is intended for use in the electromagnetic environment specified below. The customer or the user of the Oscope should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 10V/m 80MHz to 2.7GHz	Not applicable (Battery operated device) 10V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Oscope, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 12 \sqrt{p}$ $d = 12 \sqrt{p} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 23 \sqrt{p} \quad 80\text{MHz to } 2,7 \text{ GHz}$ <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 meter (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> <div style="text-align: right;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a Field strengths from 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 in which the Otoscope is used exceeds the applicable RF compliance level above. The Otoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Otoscope.

b Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 KHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE 13, 17 Band	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE 5 Band	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE 1, 3, 4, 25 Band, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						

2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE 7 Band	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0.3	9
5500						
5785						



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