Horus+ Scope

EOC 100 Digital Otoscope
User Manual

DOC. No. 2014.02-A

MiiS

1. Category

Model Name	MiiS Horus+ Scope EOC 100
Product Name	Digital Otoscope
Accessory	1. Battery 2. Disposable Specula a.) adult x 8 b.) pediatric x 8 3. Power Adapter 4. USB Cable 5. AV Cable

2. Symbols

Caution must be taken. Read user's manual before use.

Type BF- Indicates the device is classified as a device with a Type BF applied part.

The operator is advised to read the instructions of user's manual.

Manufacturer.

Date of Manufacture.

CE mark.

European Authorized Representative.

This product is a rechargeable internal Class II power supply.

3. Warnings and Cautions

NOTE

Prior to installation and start-up of the device, carefully read the instructions provided here in! As with all technical devices, the proper function and safety operation of this device depend on the user's compliance with the safety recommendations which are presented in these operating instructions. Do not attempt to open the cover of the product, so as to avoid malfunction of product.

CAUTION

Always use the device in accordance with the directions and recommendations contained in this User Manual.

Operate the device, please take note that optical lens do not touch the eyes or nose of patient. Avoid harm to patient.

To prevent fire or electrical shock, do not expose these appliances to rain or moisture.

This device is not waterproof. If the optical lens and control unit get wet; do not attempt to dry with a heater, microwave, autoclave or UV light.

Avoid subjecting the device to vibration or shock. When the product is not in use, please disconnect the power plug and keep it in a safe place.

Avoid using the device in a dusty environment, and keep the power cord away from any heat source.

Before operation, please make sure the appearance is not damaged or broken. If there are breaks in the device cover or other visual defects, please contact manufacturer or manufacturer certified service facility.

Please do not charge the battery when the device is operated by the user.

Only use Li-ion Battery 3.7V @ 2600mAh which shall be provided by the manufacturer or distributors. The battery has designed the protection circuit. To ensure the safety of the product operation, if the battery reaches lifetime or failure, please contact the manufacturer or distributor to buy the spare battery.

If you purchase different memory capacity of Micro SD Card, must be preceded format to FAT32.

The eye can't be exposed to the illumination light of the product at operation.

Replace the disposable specula of Horus+ Scope EOC 100, Digital Otoscope, before each use for a new patient.

Gently insert the specula of Horus+ Scope EOC 100 into ear canal. To keep a safety distance between the specula and tympanic membrane. Do not make the specula contact with ear's tympanic membrane.

No modification of this device is allowed. The performance would be changed if modify this device by user. Modification to this device may cause hazardous radiation exposure.

CLASS 1 LED PRODUCT

This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 2007. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. If this device does cause harmful interference to other devices, which can be determined by turning the system 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 device
- Increase the separation between the system and other devices.
- Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.

- Consult the manufacturer or field service technician for help.

The International Electrotechnical Commission sets the essential requirements for electrical and electronic equipment that may disturb, or be disturbed by, other equipment.
The device complies with these requirements as shown in the tables in “15. (1) EMC (Electromagnetic Compatibility)” (Page 13-16). Follow the guidance in the tables for use of the device in an electromagnetic environment.

During installation and operation of the device, observe the following instructions about EMC (electromagnetic compatibility):

- Do not use the device simultaneously with other electronic equipment to avoid
- electromagnetic interference with the operation of the device.
- Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the device.
- Do not use the device in the same room as other electronic equipment such as life-support equipment, equipment that has major effects on the life of the patient and results of treatment, or any other measurement or treatment equipment that involves small electric current.

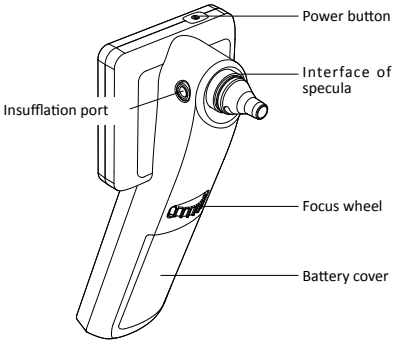
- Do not use the system with portable and mobile radio frequency communication systems because that may have an adverse effect on operation of the device.
- Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.
- Do not touch lens connecting pins of control unit, or signal pad of lenses without special precautions.

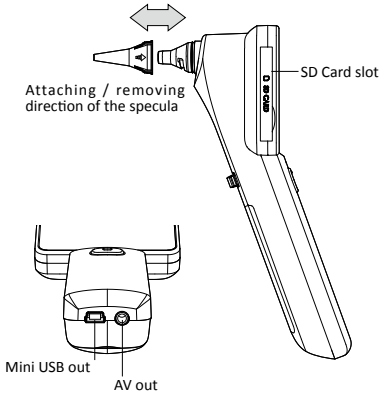
Users are responsible for managing captured image data. Manufacturer will not assume any responsibility for loss of data.

4. Intended for Use

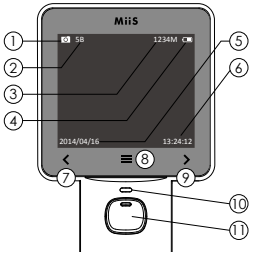
EOC 100 is a digital hand-held otoscope used to record digital photographs and video of the human ear's canal and tympanic membrane. EOC 100 can also be used at general Inspection of throat and nasal cavity and capture the photographs and video.

5. User Interface





6. Operating Instructions



1. Operation Mode:
   - Photo
   - Video
   - Display
2. Brightness indicator
3. Free memory of SD Card
4. Power indicator
5. Date indicator
6. Time indicator

7. Brightness decreasing/ Function selection
8. MENU
9. Brightness increasing/ Function selection
10. Status Indicator:
    Blue LED- Normal Operation
    Orange LED- In charging
11. Capture Button

7. Battery Charging and Photo Transferring

Battery Charging:
Step1. Connect the EOC 100 and power adapter via USB cable.
Step2. Insert the power adapter into the wall plug for charging.

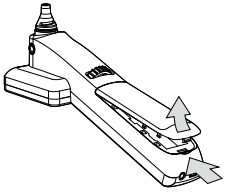
Photo Transferring:
Connect the EOC 100 and computer via USB cable. At normal situation, EOC 100 becomes a standard storage device, user can review or copy the photos from this device to the computer.

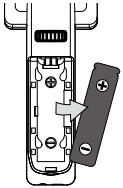
NOTE

EOC 100 can also operate at “UVC” mode. It means the pictures can be shown at LCD panel of EOC 100 and the screen of the computer if EOC 100 is connected to computer via USB cable.
User want to operate at “UVC” mode, please enter the menu to enable this function.

8. Battery Replacement

Battery Replacement





Open the battery cover by digging out the gap in the bottom of battery cover with a finger or something pointed.

- Tilt the battery cover and remove the battery cover by lifting it up.
- Remove the original battery and replace a new battery along the correct direction.
- Place the battery cover and secure it in place.

9. Cleaning and Disinfection

The device is a precision photoelectronic instrument that shall be handled with specific care. Please note following cleaning instructions:

- Power off device before cleaning it.
- Disinfect the product with the soft cloth with alcohol (70% ethyl alcohol).
- It is recommended to clean the optical lens with cleaning cloth or lens cleaning tissue such as THORLAB Inc., (www.thorlabs.com) Lens Cleaning Tissue.

If the replacement for new disposable specula, please contact with manufacturer or your own retailer.

NOTE

The device is not intended to be sterilized

10. Operation Environment

- Ambient temperature: 0°C to +35°C
- Relative humidity: 10% to 80%
- Atmospheric pressure: 700hPa ~ 1060hPa

11. Environment for Storage and Transportation

- Ambient temperature: -10°C to +40°C
- Relative humidity range: 10% to 95%

NOTE

It is recommended to remove the battery if the device is stored over 2 weeks.

12. Technical Description

- Focus Range 25~100 mm (Typical)
- Dimension 180 x 70 x 70 mm^3 (Typical)
- Weight 200 Grams (Typical)
- Camera / Video Natural White Light Emitting Diode (LED)

Focus:	Manual Focus
Camera Resolution:	1920 x 1080 pixels
Screen:	TFT-LCD
Image Format:	JPEG (Photograph) and H.264 (Video)
Interface:	Mini USB, AV out port
File Transfer:	Mini USB Port to PC
Dynamic Video Output:	Composite AV out, or USB live video enable from USB port
File storage:	SD Card, default 8GB. Supports 2G to 32GB by FAT32 Format
Power Source:	Rechargeable Lithium Battery 3.7V / 2600mAh

External Power:	Source: 100~240 VAC, 50/60 Hz
Power adapter output spec:	5V DC, 1.2A
Operating time:	3 hours at 2.5 Watt condition
Charging time:	5 hours
Expected service life: (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary

13. Liability

Manufacturer considers itself responsible for the effects on safety, reliability and performance of the device only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

14. Environment

- Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components. Especially when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD, or power cord, be sure to follow the local governing ordinances.
- Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.
- When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.
- Inappropriate disposal may contaminate the environment.
- When disposing of eye cup, follow the disposal procedures for medical waste such as needles, infusion tubes, metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

15. Standards

Electrical safety	IEC 60601-1: 2005 (EN 60601-1:2006)
EMC and regulatory compliance	IEC 60601-1-2: 2007 (EN 60601-1-2:2007)

- Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

EMC (Electromagnetic Compatibility)
The device complies with the International Electrotechnical Commission standards (IEC 6060112: 2007) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in an electromagnetic environment.

EMC (IEC 6060112: 2007)

Guidance and manufacturer's declaration electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The device uses 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100032	*1	
Voltage fluctuations/ Flicker emissions IEC 6100033	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 6100042	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 6100044	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100045	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 61000411	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 6100048	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 6100046 Radiated RF IEC 6100043	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms (V1=3) 3 V/m (E1=3)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 meters (m). 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]

			Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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Please visit www.miis.com.tw for more information.