iMDSCOPE®

Video Otoscope

MS102

User's Manual

UM-AP1301-01-B

When there is a need to immediately report an adverse effect in connection with operation of the MDSCOPE® Video Otoscope, please contact the authorized representative or agent. You may also contact customer service at +886 2 2999-5505 or MDSCOPE@appleBMI.com

U.S. Agent:
Harvest Consulting Corp.
2904 N, Boldt Drive, Flagstaff
Arizona 86001, U.S.A.

EC REP

Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover
Germany

Thank you for choosing the MDSCOPE® Video Otoscope, the Video Otoscope choice for health care professionals. The operating and maintenance instructions found in this manual should be followed to ensure product reliability. Please read this manual carefully before using the product.

If you experience a technical problem related to operation of the MDSCOPE® Video Otoscope, please contact your local dealer for the after-sales support. You may also contact the customer service at +886 2 2999-5505 or MDSCOPE@appleBMI.com

FDA listed:
D083901, D119968, D150295
IEC 60601-1, IEC 60601-1-2

CE

The manufacturer declares on his/her sole responsibility that the product meets European Standards for Safety and Quality, and that the relevant conformity assessment procedures have been fulfilled.

Contents

Chapter 1 Introduction 04
Features 05
Symbols 07
Warnings and Cautions 08

Chapter 2 Operation 10
Setting up 10
Power On/Off 11
Brightness control 11
Image capture 12
Image browse 12
Image Zoom in / out 13
Battery status 13
Power Saving mode 14
File Transfer and Delete 14
Video Output Function 15
Battery Charging 16

Chapter 3 Specifications 18

Chapter 4 Cleaning and Storage 19

Chapter 5 Troubleshooting 20

Chapter 6 Accessories 22

Chapter 7 Limited Warranty 24

Appendix EMC Guidance and
Manufacturer's declaration 25

1 Introduction

The MDSCOPE® Video Otoscope is a hand-held medical device that includes a video camera to capture video image from outer ear canal and/or tympanic membrane. The image can be displayed on built-in screen, or on external display device through video-out port. Additional features include images storage, image zoom in/out, brightness adjustment. It is powered by a reliable lithium re-chargeable battery to support a 4 hours operation period.

Video imaging provides several advantages over direct visualization. Via capturing and image storage MDSCOPE® video otoscope records patient's medical history in real time, so as the health care professionals can review the clinical findings to enhance doctor-patient real-time interaction.

Indications For Use

The MDSCOPE® video otoscope is a medical device used to observe and inspect the outer ear canal and tympanic membrane through its advanced image technology.

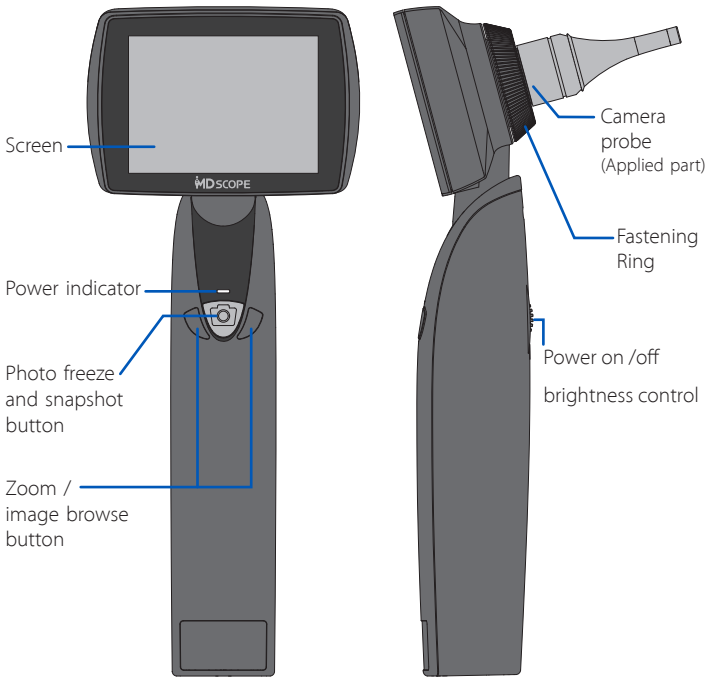
User Profile

Targeted and intended users includes GP or other health professionals in primary care (instead of optical otoscopes), or ENT specialists, Pediatricians and Audiologist in secondary care. The users require proper training with medical knowledge and qualification. It would be used for people with all ages who need ear examination. And it should not be used for any other purposes.

Clinical use

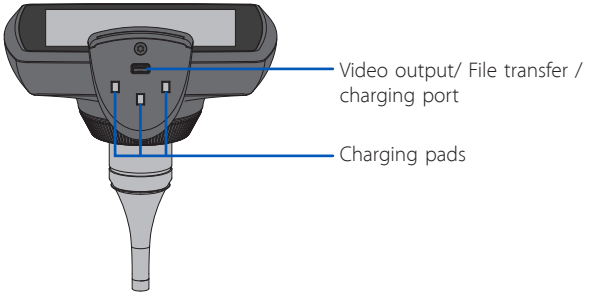
Otoscopy is a clinical procedure used to examine structures of the ear, particularly the external auditory canal, tympanic membrane, and middle ear. Clinicians use the process during routine wellness physical exams and the evaluation of specific ear complaints. Reference from https://www.ncbi.nlm.nih.gov/books/NBK556090

Features- Main Device MS102

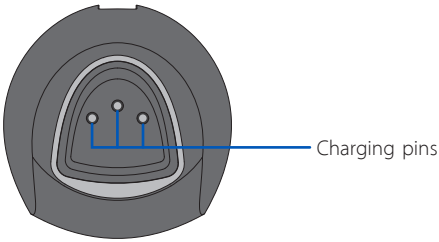


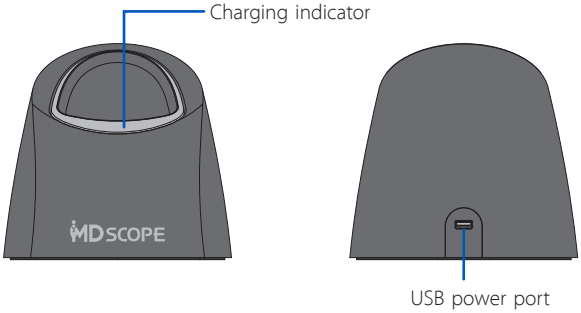
Series Models :

MS102(ELBP)-EU, MS102(ELBP)-US, MS102(VEB)-EU, MS102(VEB)-US, MS102(ELB)-EU, MS102(ELB)-US, MS102(DXB), MS102(DX3B), MS102-011T, MS102-002V, MS102-012V, MS102-013V, MS102-014V



Features- Charging Cradle





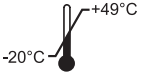
Symbols

Safety Symbols

Manufacturer

Use by date

Caution



Temperature limits

Serial number

Non sterile

Non latex

Not protected against the ingress of water

Keep away from rain

Quantity per box

Follow instructions for use

Type BF

Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

Meets European Standards for Safety and Quality

Medical Device

Catalogue number

Button Symbols

Image capture / snapshot

Image zoom / browser

Warnings and Cautions

In order to obtain optimum video performance and ensure patient safety, it is important that this booklet be read thoroughly prior to using the instrument. Any technical or clinical issues concerning the use or care of the video otoscope, please contact our Customer Service Department.

- Do not use in the presence of inflammable anesthetics.
- Do not modify in any way. Doing so could lead to instrument failure or injury.
- Images and records generated from this device are not intended for diagnostic purposes.
- Do not use this instrument for any purpose other than specified in this booklet. Doing so will invalidate the instrument's warranty.
- Do not use this instrument if you notice any signs of damage to the components of the system. Contact our Customer Service Department for immediate assistance.
- Do not immerse the camera probe into water, alcohol, or any other chemical solutions. Any liquid entering the lens will damage internal components.
- Do not attempt to disinfect the Video System using glutaraldehyde products, ethylene oxide gas, steam, or any other liquid or gas disinfectant.
- Do not replace the lithium battery without manufacture's authorization, it might cause the danger of explosion or fire.
- The signal output (USB Port) connector is intended for connection of device complying with IEC 60601-1 or other IEC standards appropriate to the device only.
- This product complies with current required standards for electromagnetic interference, IEC 60601-1-2, and should not present problems to other equipment or affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

Disposal of the System Components

Within the EU

Do not dispose of this product as unsorted municipal solid waste. Submit for separate collection as specified by Directive 2012/19/EU of the European Parliament and the Council of the European Union on Waste Electrical and Electronic Equipment (WEEE).

Outside the EU

When the product and its components reach end of life, recycle the product according to national, State, and local regulations.

Reporting of Incident to Manufacturer & Competent Authority

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the Member State in which the user and/or patient is established through the following contact information:

Manufacturer:

APPLE Biomedical Inc.

8F, No.12 Lane 609, Chong Shin Road Sec.5, New Taipei, 24159 Taiwan

TEL : +886 2 2999-5505 FAX : +886 2 2999-6605

E-mail: sls@applebmi.com

Website: www.applebmi.com

EU Authorized Representative:

Medical Device Safety Service GmbH

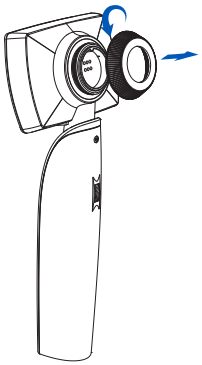
Schiffgraben 41, Hannover 30175 Germany

TEL : +49 511 6262 8630

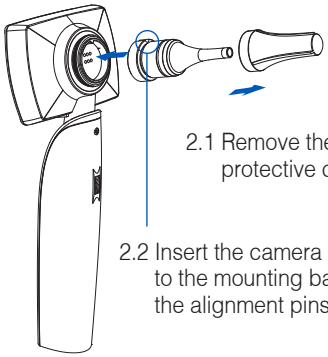
2 Operations

Setting up the Video Otoscope

1. Remove the fastening ring.



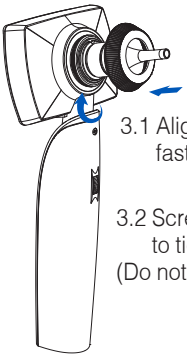
2. Align the camera probe to the mounting base.



2.1 Remove the protective cover.

2.2 Insert the camera probe to the mounting base via the alignment pins.

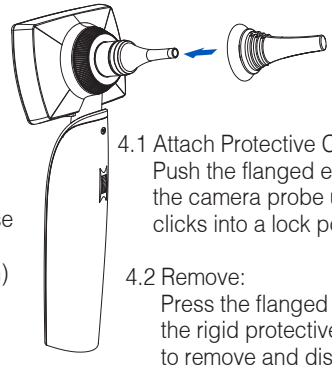
3. Screw on the fastening ring.



3.1 Align the fastening ring.

3.2 Screw clock-wise to tighten.
(Do not over-tighten)

4. Put on new speculum before using

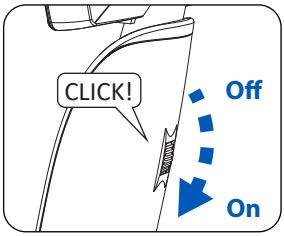


4.1 Attach Protective Cover:
Push the flanged end onto the camera probe until it clicks into a lock position.

4.2 Remove:
Press the flanged end of the rigid protective cover to remove and discard after use.

Power On / Power off

1. Scroll the wheel down until a “click“ is heard to power the unit ON.
2. After icon “ MDSCOPE “ is displayed on screen in 5 seconds,
   The device is on a preview mode and ready to use.
3. Scroll the wheel up until a “click” is heard to power the unit OFF.



Brightness Control

In preview mode, scroll the wheel down to increase the brightness, or to scroll up to decrease the brightness.

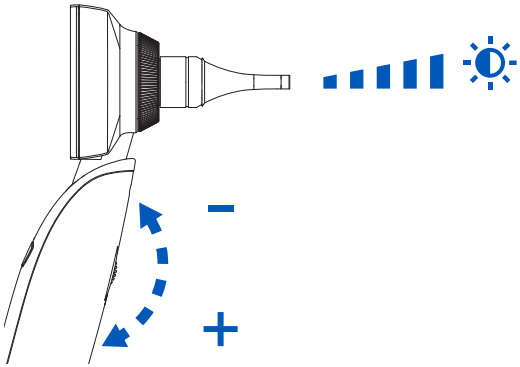
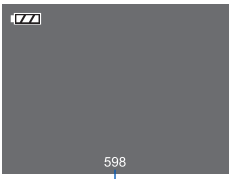
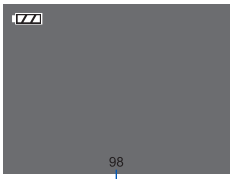


Image capture

1. After tuning on the power, press button to freeze and capture the image. This captured image will be stored directly to memory of the device.
2. Short click the button to get back to preview mode.
3. In preview mode, remaining image capacity will show at the middle bottom of screen, when it is below 100, the number turns to RED. When it becomes 0, the memory is full. At this point, device can no longer take any new images. Please see " File transfer and Delete" on page 14 to find out how to delete files and to free up memory.
4. To enter the browse mode, direct press the button for 2 seconds while in preview mode.



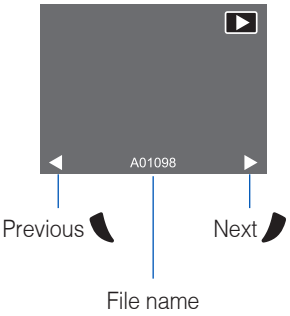
Balance images



Balance less than 100

How to browse image

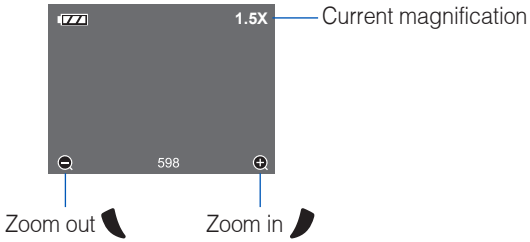
While in review mode, the file name is displayed at middle bottom of screen. To view image, briefly press the buttons : press right button to view next image, and press left button to view previous image. Press select buttons for 2 seconds to enter a quick review mode. Short click the button at center and get back to browse mode.



Zoom in / Zoom out

In preview mode, press button to zoom in image (right button), or to zoom out (left button). There are total three magnifications: **1X**, **1.5X** and **2X**.

***<Attention> image is always stored with 1X ratio to memory.**



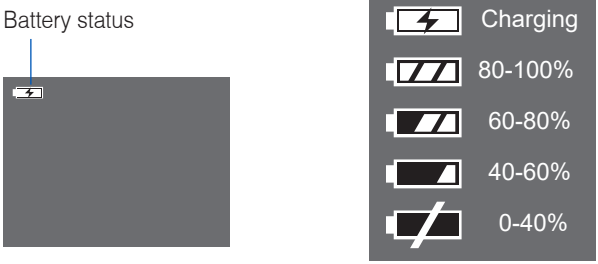
Battery Level

In preview mode, the battery status shows at top left screen.

1. When battery is low, the icon will flash, and turn to RED.

Please charge the battery.

2. When a lightning bolt is shown at center of the battery icon , the unit is in charging mode.
3. Battery status and capacity shown in the diagram below.

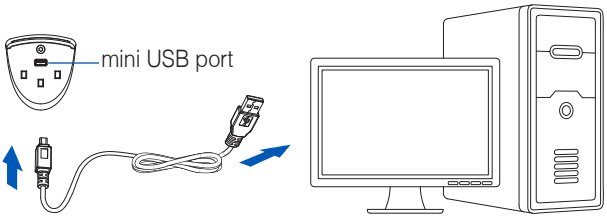


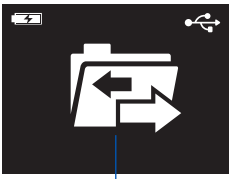
Power saving mode

If the device is idle for three minutes, the device enters a sleep mode to save power. The indicator remains under this condition. To awaken the device by simply holding up the handle, this device turns to ready mode for reuse.

File transfer and Delete

1. Connect one end of Micro USB cable to MDSCOPE®, the other end to PC or Mac and turn on the power. When a transfer icon shows on screen, you can start moving files or deleting to release the memory.





File transfer icon

2. File Folder

2.1 “MD Scope”, is the folder images captured and stored via this device

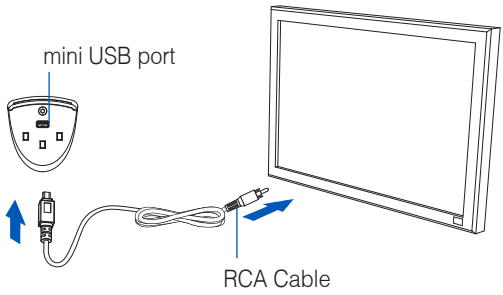
2.2 “Gallery”, is the folder of images that user pre-loaded, for demonstration or teaching purpose.

Please note File format is Jpeg 640x480 pixels.

***<ATTENTION> The MDSCOPE® may shut down if format is incorrect. Please remove the non-specified file format.**

Video Output

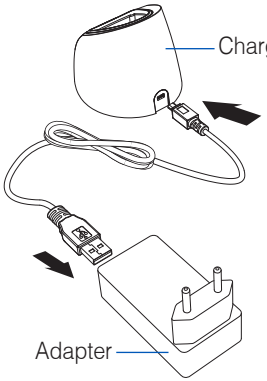
Connect one end of Micro USB cable to video out port, the other RCA end to Video-In port of a monitor, a simultaneous image can be displayed on the external screen.



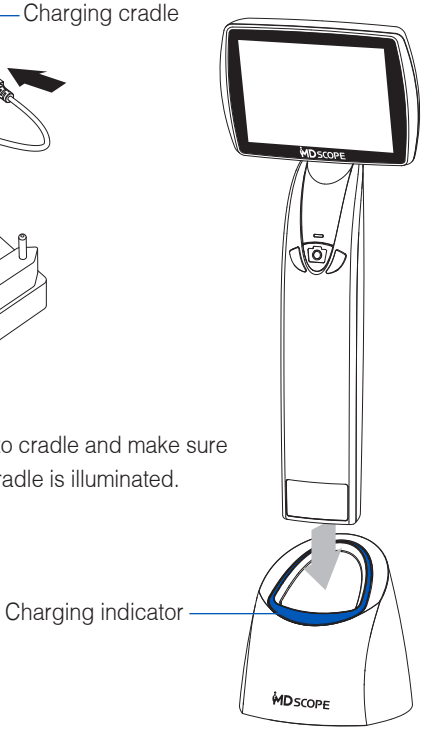
Battery charging (Please turn off the power before charging)

A. Quick charge (Using charging cradle)

1. Connect Micro USB plug to the charging port at rear of cradle, the other end of the cable to power adaptor. Plug the adaptor to power socket and turn on the power.



2. Insert MDSCOPE® onto cradle and make sure blue band on top of cradle is illuminated.

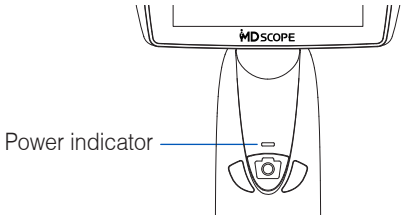


B. Standard Charging

Plug Micro USB cable to socket at bottom of device and connect the other end of cable to USB port of PC or adaptor. Turn on power to start charging.

C. Charging indicator

To follow procedure A or B, power indicator shows from RED start charging to OFF when battery is full.



D. Charging Time

Approximate time for full charge is 2.5 hours with quick charging procedure, and 5 hours with for standard charging. Charging time varies depending on battery status.

3 Specifications

Item	Specifications
Dimensions (approximate)	Length : 9.5 cm (3.5") Width : 8.5 cm (3-3/8") Height : 21.0 cm (8-1/4")
Focal distance	1 to 4 cm
Weight	Approx. 250 grams
Battery type	Rechargeable Li-ion battery
Display	3" TFT color LCD
Video-out format	640x480 pixels, JPEG format
Operating conditions	
Temperature	+10° C to 30° C (+50° F to +86° F)
Relative humidity	30% to 75% non-condensing
Shipping / Storage conditions	
Temperature	-20° C to 49° C (-4° F to +120° F)
Relative humidity	95% Max. non-condensing
Minimum lifespan	2 years

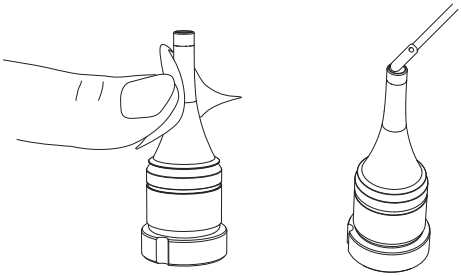
4 Cleaning and Storage

For cleaning of the camera probe

Step 1: Take out the alcohol prep-pad

Step 2: Clean and wipe the stainless steel part of the standard camera probe with alcohol prep-pad.

Step 3: Gently clean the camera lens with the microfiber swab.
Care should be taken not to scratch the lens of camera probe.
Do not use non-certified swab to clean the lens.



For cleaning of the main unit

The housing of the device can be cleaned with a cloth dampened with water, alcohol, or a non-staining disinfectant.
Liquids should not be dripped or spilled over the surfaces of the LCD module or handle as they are not watertight.

Storage

The camera probe and main device should be placed in the storage compartment of the carrying case.Unnecessary exposure to extremes in temperature and humidity should be avoided.
Keep device in cradle between procedures.

5 Troubleshooting

1. Why is MDSCOPE® video otoscope not powered ON?

☐ 1. Please confirm the battery is charged, and recharge the battery if necessary.

☐ 2. Please use the power adapter- O/P: DC5V 2A that original equipment manufacturer supplies.

☐ 3. Make sure power wheel is scrolled to “click” position.

☐ 4. Wait for at least 10 seconds, until the “MDSCOPE” icon is displayed on screen.

☐ 5. If the device is NOT switched ON by repeating the above steps, please contact your local dealer for technical support.

2. After the device is switched ON, the power indicator light is ON but no image is displayed or the image is unclear or unstable.

☐ 1. Confirm that camera probe is mounted properly.

☐ 2. Confirm that the fastening ring is tightened.

☐ 3. Confirm that there is no foreign substance on the metal contact and clean the surface of metal contacts with alcohol prep-pad.

☐ 4. Confirm image is displayed on screen by increasing the brightness control.

☐ 5. Confirm the lens on top of camera probe is clean. Use the supplied microfiber swab to clean the lens.

☐ 6. If the image is still NOT displayed properly after carrying out steps 1-5 above, please contact your local dealer for technical support.

3. The device is switched ON with image displayed but I can't take the photo.

☐ 1. Confirm the memory is not full: "0" is not in the middle of bottom.

☐ 2. Restart the device and try image capture function again.

☐ 3. Check and confirm the button can be depressed with ease, and repeat at least 10 times then restart the device.

☐ 4. Connect the device to computer, transfer or delete the files in the "MD Scope" folder. Format the folder.
<ATTENTION> The file name will be reset after format.

☐ 5. The device may be defective if the capture function does not work after repeating the above steps for several times. Please contact your local dealer for technical supports.

6 Parts

Basic Parts

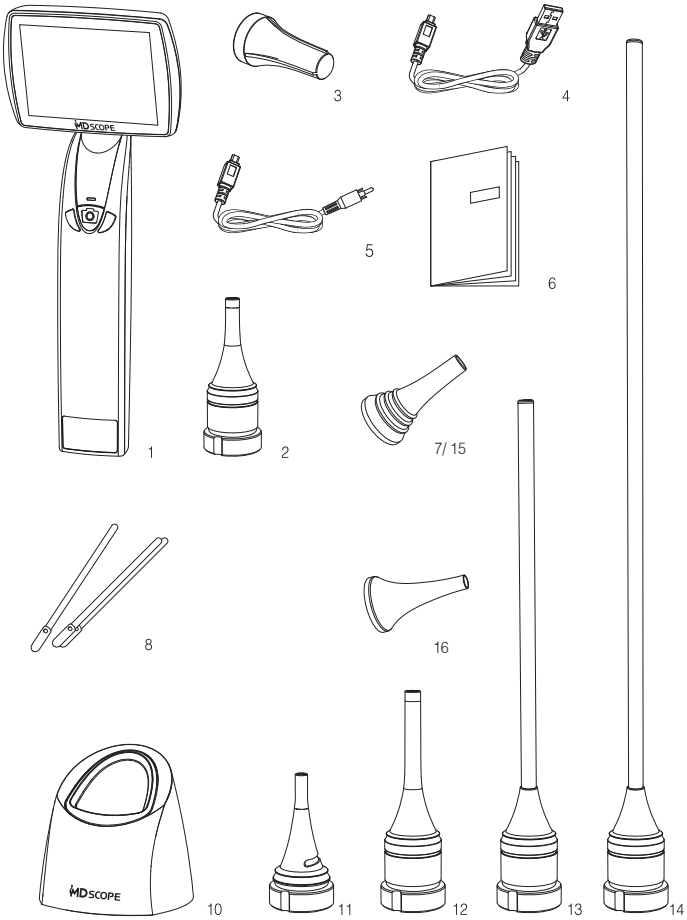
Item	Number	Description	Quantity
1	MS102-001	Main device	1
2	MS102-002V	VGA camera probe	1
3	MS102-003	Protective cover	1
4	MS102-004	File transferring / charging cable	1
5	MS102-005	Video out RCA cable	1
6	MS102-006	User manual	1
7	MS101-016	Disposable Speculum for MS102-002V	24
8	MS102-008	Microfiber swab	12
10	MS102-010	Charging cradle	1

*Please secure the warranty card in the set.

Optional Parts

Item	Number	Description	Quantity
11	MS102-011T	Pediatric camera probe (47mm)	1
12	MS102-012V	VGA long camera probe (75mm)	1
13	MS102-013V	VGA flexible camera probe (150mm)	1
14	MS102-014V	VGA flexible camera probe (300mm)	1
15	MS101-015	Disposable speculum for MS102-002V	250
16	MS101-019	Silicon specula for MS102-011	24

Parts List



7 Limited Warranty

Each of the MDSCOPE video otoscope comes with a one-year warranty, starting on the purchase date to cover repair and/or if necessary replacement of any product failure due to defects in materials and workmanship. Within the limited range of the warranty, defective products shall be repaired or replaced by Manufacturer or authorized technical and service groups at their discretion and in accordance with local laws.

This warranty is non transferable. Damages due to negligence, accident, abuse, misapplication, modification, or repairs not made by the Manufacturer, or authorized technical and service groups, are not covered by the warranty. Within the coverage of the warranty, the delivery fee for mailing to the local dealer or the direct store is not covered within the scope of the warranty.

EU Representative:
Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover
Germany

Manufacturer:
APPLE BioMedical Inc.
8th Floor, No.12, Lane 609, Chong Shin Road Sec.5,
New Taipei, 24159, Taiwan.
TEL : +886 2 2999 5505
FAX : +886 2 2999 6605
E-mail : MDSCOPE@appleBMI.com
Website : www.MDSCOPE.net

Appendix

Table 201
Guidance and manufacturer's declaration-electromagnetic emissions

The MS102 is intended for use in the electromagnetic environment specified below. The customer or the user of the MS102 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	■ Group 1	The MS102 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.(CISPR 11：2015 +A1：2016，Annex A)
RF emissions CISPR 11	□ Group 2	The MS102 imust emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. (CISPR 11：2015 +A1：2016，Annex A)
RF emissions CISPR 11	■ Class A □ Class B	
Harmonic current emissions IEC 61000-3-2	■ Class A / □ Class B □ Class C / □ Class D □ Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	■ Complies □ Not Applicable	

NOTE 1: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 202
Guidance and manufacturer's declaration-electomagnetic conformity

The MS102 is intended for use in the electromagnetic environment specified below. The customer or the user of the MS102 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 1000-4-2 (ESD)	■ ± 8 kV contact ■ ± 2 kV,± 4 kV,± 8 kV,± 15 kV air	Not Complies	☐ Home Healthcare Environment ■ Professional healthcare facility environment ☐ Special Environment
Radiated RF EM Fields IEC 61000-4-3 (RS)	☐ 10V/m ■ 3V/m	Complies	☐ Home Healthcare Environment ■ Professional healthcare facility environment ☐ Special Environment
Proximity Fields From RF Wireless Communications Equipment IEC 61000-4-3 (RS)	■ Table 9	Complies	☐ Home Healthcare Environment ■ Professional healthcare facility environment ☐ Special Environment
Electrical fast transient/burst IEC 61000-4-4 (EFT)	■ ±2 kV For power supply lines ■ ±1 kV For input/output lines 100kHz	Complies	☐ Home Healthcare Environment ■ Professional healthcare facility environment ☐ Special Environment
Surge IEC 61000-4-5	■ ±1 kV Line(s) to line(s) ■ ±2 kV Line(s) to Ground	Complies	☐ Home Healthcare Environment ■ Professional healthcare facility environment ☐ Special Environment

Table 204
Guidance and manufacturer's declaration-electomagnetic conformity

The MS102 is intended for use in the electromagnetic environment specified below. The customer or the user of the MS102 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted Disturbances induced by RF Fields IEC 61000-4-6 (CS)	■ 3Vrms 0.15kHz~80MHz □ 6Vrms, in ISM and amateur radio bands between 0.15 and 80MHz ■ 6Vrms, in ISM bands between 0.15 and 80MHz	Complies	□ Home Healthcare Environment ■ Professional healthcare facility environment □ Special Environment
Voltage dips IEC 61000-4-11	■ Dip to 0% UT ; 0.5 Cycle (0°~360°, Step 45°) ■ Dip to 0% UT ; 1 Cycle (0°) ■ Dip to 70% UT ; 25/30 Cycles (0°)	Complies	□ Home Healthcare Environment ■ Professional healthcare facility environment □ Special Environment
Voltage interruptions IEC 61000-4-11	■ Residual 0% UT ; 250/300 Cycles	Complies	□ Home Healthcare Environment ■ Professional healthcare facility environment □ Special Environment
Rated Power Frequency Magnetic Fields (MS) (50/60 Hz) IEC 61000-4-8	■ 30 A/m	Complies	□ Home Healthcare Environment ■ Professional healthcare facility environment □ Special Environment

NOTE 1: UT is the a.c. mains voltage prior to application of the test level.

NOTE 2: MS102 provides limited electrostatic protection, overflow enegy may cause mulfunction or demage to device. Please discharge body electrostatic before use.

Table 206
Recommended separation distance between portable and mobile RF communications equipment and the MS102

The MS102 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MS102 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MS102 as recommended below Table, according to the maximum output power of the communications equipment.

IEC 60601-1-2 : 2014 , Table 9

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [a]	Maximum power (W)	Distance (M)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [c] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800 / 900 TETRA 800, iDEN 820 CDMA 850, LTE Band 5	Pulse modulation [c] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 / CDMA 1900 GSM 1900, DECT LTE Band 1,3, 4, 25 ; UMTS	Pulse modulation [c] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse modulation [c] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [c] 217 Hz	2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent qctual modulation, it would be worse case.

NOTE 1: If necessary to achieve the IMMUNITY TEST VELEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

NOTE 2: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 4: Massive body's static electricity in touch of metal pads on device bottom, may cause splash screen and restart. It is a normal phenomenon, and the device will resume working properly afterwards.