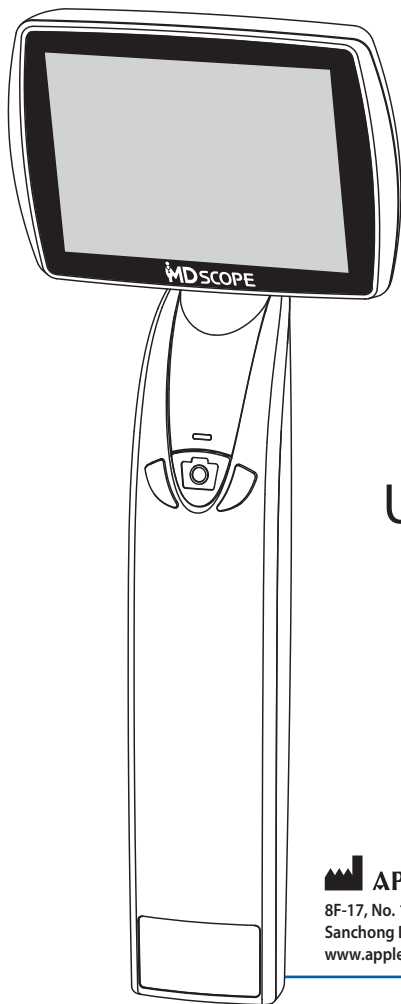




Digital Otoscope

MS102

User Manual



APPLE BIOMEDICAL INC.

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Sanchong Dist. New Taipei, 241406, Taiwan
www.applebiomed.com | info@applebiomed.com

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

U.S. Agent:
Anatomed, Inc.
1000 Lake Street, Building D
Ramsey, New Jersey 07446
USA



Medical Device Safety Service
GmbH
Schiffgraben 41, 30175
Hannover Germany

Thank you for choosing the MDSCOPE® Digital Otoscope. 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® Digital Otoscope, please contact your local dealer for the after-sales support. You may also contact the customer service at +886 2 2999-5505 or www.applebiomed.com

FDA listed:

D083901, D119968, D150295

IEC 60601-1, IEC 60601-1-2



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.

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1 Introduction

The MDSCOPE® Digital Otoscope is a hand-held medical device that includes a camera probe to capture image and video from external 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.

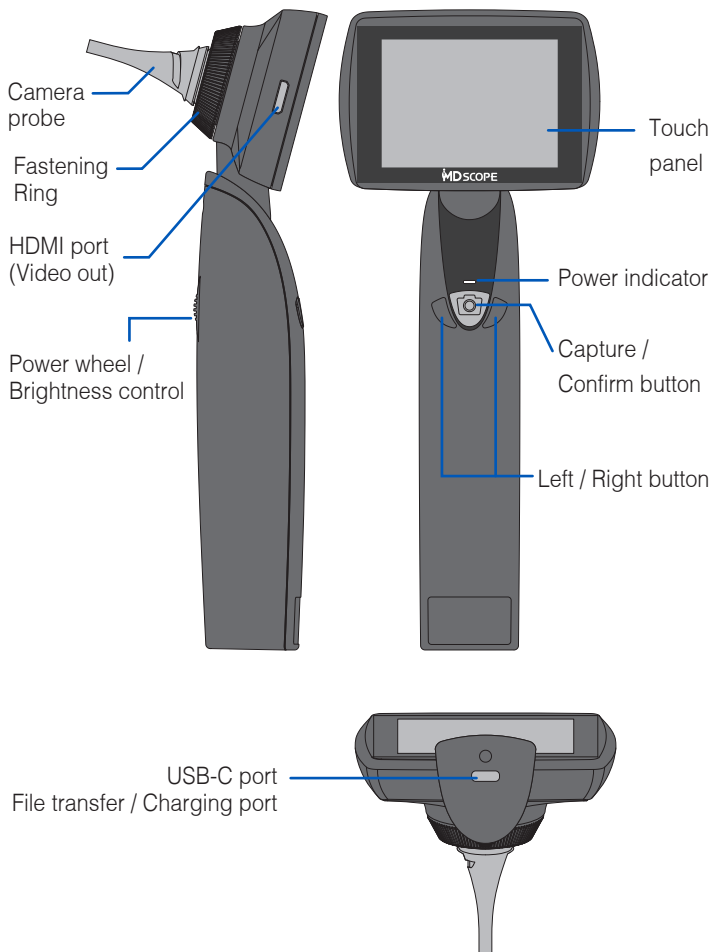
Intended Use

The MDSCOPE® Digital Otoscope is intended to allow inspection of the external ear, ear canal, and tympanic membrane under magnification.

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.

Figures



Symbols



Manufacturer



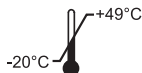
Use by date



Caution



Keep away
from rain



Temperature limits



Serial number



Non sterile



Non latex



Model number



Type BF



Unique device
identification

1 PC / BOX

Quantity per box



Follow instructions
for use

IPX0

Not protected against
the ingress of water



Symbol for "AUTHORIZED
REPRESENTATIVE IN THE
EUROPEAN COMMUNITY"



Meets European
Standards for
Safety and Quality



Medical Device



Catalogue number

Warnings and Cautions

To ensure optimal video performance and patient safety, it is essential to read this booklet thoroughly prior to the operation of your MDSCOPE® digital otoscope. For any technical or clinical inquiries regarding the use or maintenance of the digital otoscope, please contact our Customer Service Department.

Warnings

- Do not use in the presence of inflammable anesthetics.
- 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.

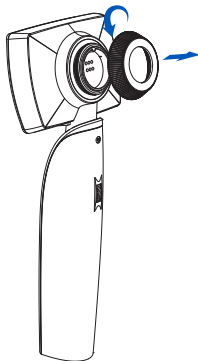
Cautions

- Do not replace the lithium battery without manufacture's authorization, it might cause the danger of explosion or fire.
- 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 attempt to disinfect the Video System using glutaraldehyde products, ethylene oxide gas, steam, or any other liquid or gas disinfectant.
- 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.
- 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 modify in any way. Doing so could lead to instrument failure or injury.

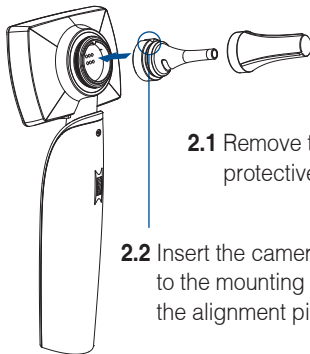
2 Operation

Setup

1. Remove the fastening ring.



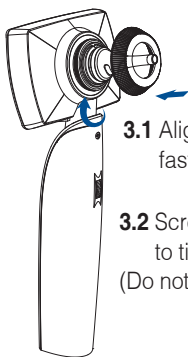
2. Align the camera probe to the mounting base.



2.1 Remove the protective cover.

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

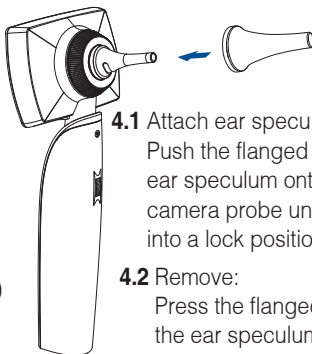
3. Screw on the fastening ring.



3.1 Align the fastening ring.

3.2 Screw clockwise to tighten.
(Do not over-tighten)

4. Put on new speculum before using



4.1 Attach ear speculum:
Push the flanged end of the ear speculum onto the camera probe until it clicks into a lock position.

4.2 Remove:
Press the flanged end of the ear speculum to remove and discard after use.

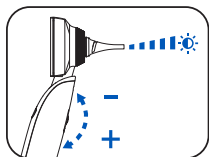
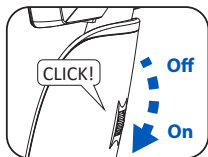
Power On / Power off

To turn on the device: Scroll down the power wheel all the way. The screen will then display “MDSCOPE” for 3 second and the power indicator will blink blue and amber once for system check.

To turn off the device: Scroll up the power wheel until a “click” sound is heard.

Brightness Adjustment

In live view mode, scroll down the power wheel to increase the brightness and up to decrease it.



Zoom in / Zoom out

At real time operation, you can zoom in or zoom out the image by pressing right or left buttons, or tapping + or – icon to adjust image size for capture or recording as needed.



Real Time



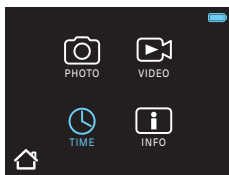
Zoom In



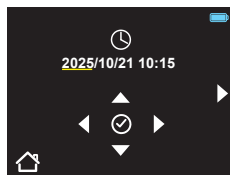
Zoom Out

Time Setting

- 1. Enter the main menu:** Press the left and right buttons simultaneously. Or, gently tap on the screen with three fingers .
- 2. Navigate to the time icon:** Use the left and right buttons to select the time icon. Once the time icon is highlighted in blue, click the capture button . Or, tap on the time icon with one finger.
- 3. Adjust the date and time:** Use the left and right buttons to select the desired change date or time. Press the capture button  once to enter the modify mode. Use the left button to decrease the digit and right button to increase the digit.
- 4. Confirm changes:** To save the changes, click the capture button  once to finish and press left and right button simultaneously to return to main menu.



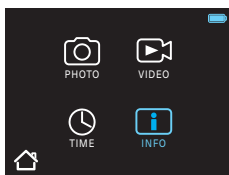
TIME



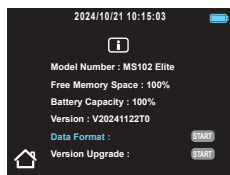
Current Status

Info Setting

1. Information page shows the current status and version of device.
2. When “Data Format” is executed, all saved data will be deleted permanently. Please operate the function with care, when needed.
3. Version Upgrade: this particular function is limited to be operated by authorized personnel only. Improper operation may cause temporary system failure. Contact your service center for assistance when you have questions.



INFO



Current Status

Image Capture

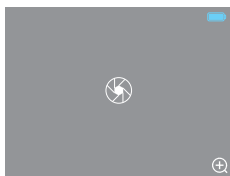
Carefully insert the tip of the camera probe into the ear canal until the tympanic membrane (eardrum) is clearly visible. Adjust brightness control as needed until a clear image is visible.

Capture with physical button

- 1. Capture Image:** Press capture button  once to take an image. After pressing, the device will enter the browsing mode and the screen will immediately display the captured image. The image will also be saved to the device.
- 2. Return to Live View:** To exit the browsing mode, press the capture button  again and the device will return to live view.

Capture with touch panel

- 1. Capture Image:** Gently tap the screen once with one finger  to take an image. After tapping, the device will immediately enter the browsing mode and the screen will display the captured image. The image will also be saved to the device.
- 2. Return to Live View:** To exit the browsing mode, press the return icon located at bottom half of the screen.



Capturing



Image Captured



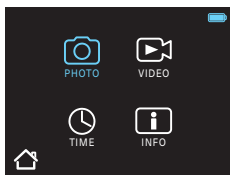
Return to live view

Image browsing and delete with physical button

- 1. Select the “PHOTO” option:** Press left and right buttons simultaneously to enter main menu. Using left or right button to navigate on high-lighted PHOTO icon, and press capture button  to review saved images.
- 2. Delete a saved image:** Using left and right buttons to navigate, and select the image. Press capture button  to initiate the deletion process. And press left button to continue delete or right button to abort.
- 3. Return to live view:** Press left and right buttons simultaneously to return to the main menu. Press both buttons again to return to live view.

Image browsing and delete with touch panel

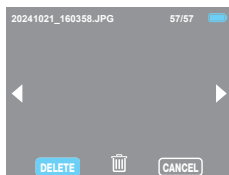
- 1. Enter Main Menu:** Gently tap on screen with 3 fingers  and then tap on PHOTO icon to review saved images.
- 2. Delete a saved image:** To remove an unwanted image from the device, navigate to it by clicking the left or right icons. Once the image is displayed on the screen, tap the trash icon to delete. Confirm the deletion by selecting the “COMFIRM” option on the screen. Or, cancel the request by tapping the “CANCEL” option from the screen.
- 3. Return to live view:** Gently tap the screen with three fingers to return to the main menu. Or, tap the house icon on the bottom left corner to return to the live view.



Select Photo



Delete Photo



Confirm Delete

Video Recording

Carefully insert the tip of the camera probe into the ear canal until the tympanic membrane (eardrum) is clearly visible. Adjust brightness control as needed until a clear image is visible.

Recording with physical button

- 1. Start Recording:** Long-press capture button  for 3 seconds. While the device is recording, a recording icon will blink at the bottom right corner of the screen to indicate the process is underway.
- 2. End Recording:** Press the capture button  once to stop the recording. The device will enter the browsing mode, and display the recorded video.
- 3. Return to Live View:** To exit the browsing mode, press the capture button  again and the device will return to live view.

Recording with touch panel

- 1. Start Recording:** Gently tap the screen once with two fingers . While recording, a record icon will be blinking at the bottom right corner of the screen to indicate the process.
- 2. End Recording:** To terminate the record, tap the screen again with two fingers . After ending the record, the device enter the browsing mode and display the latest recorded video.
- 3. Return to Live View:** To Exit the browsing mode, tap on the return icon located at the center of the bottom half of the screen.



Recording



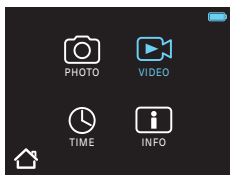
Recorded Video



Return to live view

Video browsing and delete with physical button

- 1. Select the “VIDEO” option:** press left and right buttons simultaneously to enter main menu. Using left or right button to navigate to high-lighted VIDEO icon, and press capture button  to review saved videos.
- 2. Play a saved video:** Navigate to the video with left and right button. Press the capture button  to start the streaming. Press the button again to pause the video.
- 3. Delete a saved video:** Navigate to the video with left and right button. Press left button to initiate the deletion and press left button again to confirm. Or, cancel the request with right button.
- 4. Return to live view:** Press left and right buttons simultaneously to return to the main menu. Press both buttons simultaneously again to return to live view.



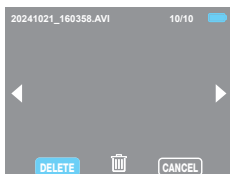
Video



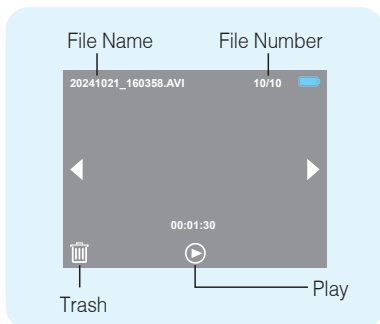
Play



Pause

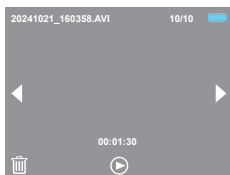


Delete

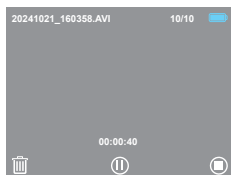


Video browsing and delete with touch panel

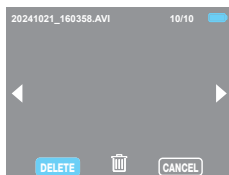
- 1. Select the “VIDEO” option:** gently tap on screen with 3 fingers  and then tap on VIDEO icon to review saved images.
- 2. Play a saved video:** Navigating to the video with left and right icons. Tap "Play" icon to start the streaming. Press the icon again to pause the video.
- 3. Delete a saved video:** Navigating to the video with left or right icon. Tap the trash icon at bottom half of the screen. To tap on "DELETE" sign for deletion or "CANCEL" sign to abort.
- 4. Return to live view:** Gently tap the screen with three fingers to return to the main menu. Or, tap the house icon on the bottom left corner to return to the live view.



Play



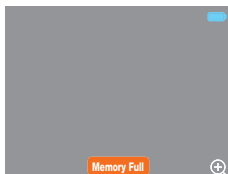
Pause



Delete

Memory Full

When device memory capacity is lower than 10%, an orange “Memory Full” sign will show at the bottom of screen, to remind memory capacity is low. It is suggested to delete or remove file to free up storage space for new images and videos.



Memory Full

Battery Status

On-Screen Battery Indicator: When the device is powered on, a battery icon is visible on the top-right corner, indicating the current battery status. The icon will appear in blue when the battery level exceeds 20%. The icon will appear in yellow when the battery level is between 19% - 6%. If the battery level falls below 5%, the icon will change to red, indicating that immediate charging is necessary.

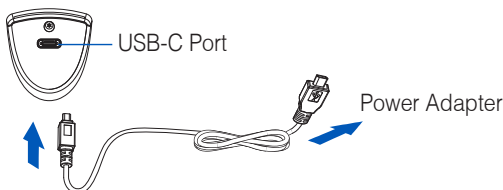
On Power Indicator: Upon turning on the your MDSCOPE® device, the power indicator will briefly blink blue and amber once as part of the system check. Following this, the indicator will remain solid blue, indicating that the battery level is above 20%. If the battery level falls below this threshold, the power indicator will begin to blink amber.

Charging

To charge your MDSCOPE® device, please follow these steps:

- 1. Turn off:** Ensure that the device is completely powered off.
- 2. Plug in:** Connect a USB-C cable to the device and plug the other end of the cable into your power adapter.
- 3. Charging:** During the charging process, the power indicator will display a solid amber light. Once fully charged, the indicator light will turn off.

If you attempt to charge your device while it is powered on, the screen will turn black immediately and the device will be inoperable for safety reasons.



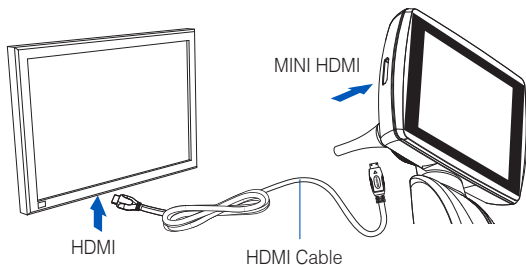
Power Saving Mode

- **Sleep Mode:** When your MDSCOPE® device remains inactive for 3 minutes, it will automatically enter sleep mode; indicated by a flashing blue status light. To reactivate the device, simply press any button or tap on the screen once.
- **Deep Sleep Mode:** If the device remains unused for over 5 minutes, the device will trigger deep sleep mode automatically. To restart the device, first scroll up the power wheel until you hear a "click" sound. Then proceed to operate the device as usual.

Video Output

No additional software is required for operation. When connecting to an external monitor, the display screen on your MDSCOPE® device will temporarily turn off for performance optimization. Once the cable is disconnected from the MDSCOPE® device or the external monitor, the device will automatically return to live view.

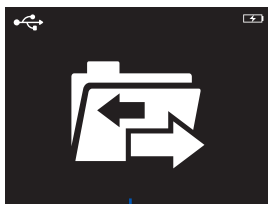
1. **Power On:** Ensure that both the MDSCOPE® device and the external monitor are powered on.
2. **Connect:** Plug in the mini HDMI end to the MDSCOPE® device and the HDMI end to the input port of external monitor.
3. **External Display:** A separate window will automatically appear on the external monitor, displaying the live view from the MDSCOPE® device. Please note that the screen of MDSCOPE® device will turn black during this process.



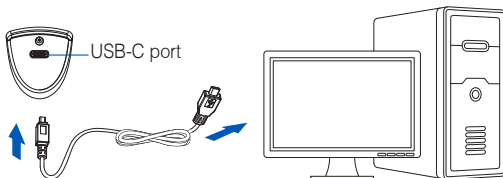
File Storage and Transfer

No additional software is required for operation. While transferring the file from your MDSCOPE® device to a PC/MAC, a file transfer icon will be displaying on your device. If the cable is disconnected from the device, the device will automatically return to live view.

- 1. Power On:** Ensure that both the MDSCOPE® device and the PC/MAC are powered on.
- 2. Connect:** Plug in the USB-C end to the MDSCOPE device and the other USB-C end to the PC/MAC.
- 3. Locate the Folder:** Access "My Computer" from the connected PC/MAC and find the "MS102" folder to browse saved images/videos.
- 4. Transfer and Delete:** To transfer photos or videos, click and drag the desired files from the "MS102" folder to your designated folder. To delete any unwanted files, right-click on the file and select the "Delete" option.



File transfer icon



3 Maintenance

Cleaning and Disinfection

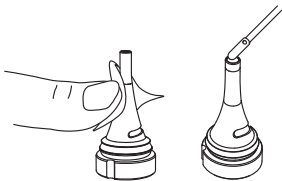
Cleaning main device:

- 1. Power Off:** Before beginning the cleaning process, ensure that the device is powered off.
- 2. Cleaning:** Use a cloth lightly dampened with water or a non-staining disinfectant to clean the device. Avoid spraying any liquids directly onto the device, and do not immerse it in any liquids.
- 3. Air dry:** Allow the device to rest in an open area for one minute to ensure complete evaporation of any residual moisture.

Cleaning camera probe:

Use an alcohol pre-pad to wipe the exterior of the camera probe, except the metal pad at the bottom of the camera probe.

For the tip of the camera probe, gently clean with a microfiber swab.



Storage

To ensure the longevity and optimal performance of MDSCOPE® device, it is recommended to clean the device after each use. Please adhere to the cleaning guidelines provided in the manual. After cleaning, store the device in its original carrying pouch or in a clean and dry environment. Avoid exposing the device to extreme temperatures, high humidity, or direct sunlight to prevent potential damage.

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: info@applebiomed.com
Website: www.applebiomed.com

EU Authorized Representative:

Medical Device Safety Service GmbH
Schiffgraben 41, Hannover 30175 Germany
TEL : +49 511 6262 8630

4 Specifications

Item	Specifications
Dimensions (approximate)	Length : 85mm (panel) Width : 78mm (including probe) Height : 210mm
Focal distance	8 to 80 mm
Weight	Approx. 250 grams (including camera probe)
Battery type	Rechargeable lithium battery 3.6V / 3350mAh
Display	2.8" VGA touch panel
Video-out format	1280 x 720 pixels (HD)
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

5 Troubleshooting

Device Freezing

Scroll up the power wheel until you hear a click sound, to turn off the power. Wait for 3 seconds to scroll down the wheel to turn on the power for device reboot.

No Image

1. Check if the protective cover is removed.
2. Detach camera probe from device, and re-attach it while making sure the probe ring is properly fastened.
3. Make sure the metal pads on bottom of camera probe is clean and not oxidized. Use rubber eraser to clean the surface as needed.

Blurry Image

Examine tip of the camera probe and remove if any foreign substances found, with a microfiber swab in the pouch.

No captured image or recorded video on device

1. Go to Info page and check if free memory space is available. To release space by deleting or removing files. Operate capture and record function again.
2. Check if the capture button can be properly operated. If it is stucked for uncertain reasons, contact your local distributor or manufacturer for technical support.

No synchronized image or video on external monitor

1. Check if the device is power on and the camera probe is securely attached to the device.
2. Check if mini HDMI end of the cable is well connected to the device, and the HDMI end is well connected to the external monitor.

Data Transfer Failure

1. Check if the device is power on and the camera probe is securely attached to the device.
2. Check if an USB-C cable is well connected to device and PC/MAC.
3. Re-plug USB-C cable to a different slot of PC/MAC if possible.

Contact your local distributor or manufacturer for technical support if you cannot find solution from above troubleshooting processes. Do not disassemble or repair the device without manufacturer's authorization.

6 Accessories

Basic Parts

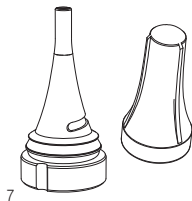
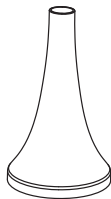
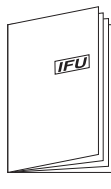
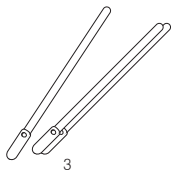
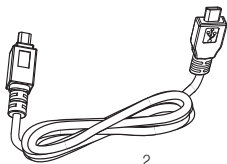
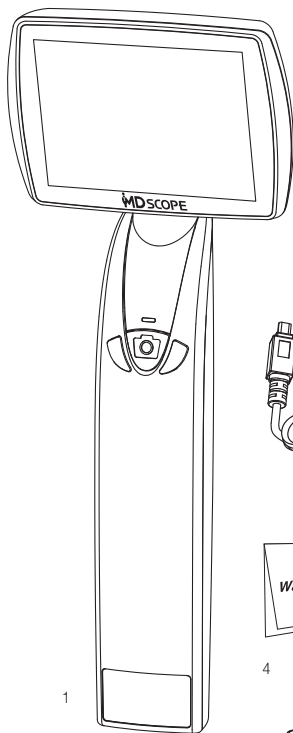
Number	Description	Quantity
1	Main device	1
2	USB-C to USB-C cable	1
3	Microfiber swab	12
4	Warranty card	1
5	User manual	1
6	Silicon specula	12
7	HD camera probe 47mm L	1

*Please secure the warranty card in the set.

Optional Parts

Number	Item	Description	Quantity
6	MS101-019	Silicon specula for MS102-M002	24
7	MS102-M002	HD camera probe 47mm L	1

List of Accessories



7 | Limited Warranty

Each MDSCOPE® digital otoscope is backed by a one-year manufacturer's warranty from the date of the device was delivered. This warranty covers repairs and, if necessary, the replacement of any unit that fails to perform due to defects in materials or workmanship. Repairs or replacements for defective products will be conducted at the manufacturer's discretion or through an authorized local technician or distributor, provided that all conditions are met. Failure to comply with these conditions may result in additional fees for repairs. The following special terms and conditions apply:

Non-Transferable Warranty

This warranty is non-transferable and applies solely to the original purchaser. The original proof of purchase might be requested by the manufacturer for verification.

Exclusions

The warranty does not extend to damages caused by negligence, accidents, abuse, misapplication, modifications, or repairs performed by unauthorized parties. If your MDSCOPE® digital otoscope is proven to have been repaired by an unauthorized party, the request for repair or replacement will be denied.

Shipping

Please note that any shipping costs associated with returning the device to a local dealer or authorized service provider are not covered by this warranty.

If the products are returned to Apple Biomedical, the original customer must obtain a RMA (Return Merchandise Authorization) number from Apple via email. The RMA number must be included on the package and the customer must prepay all freight charges to return any product to Apple.

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 <u>MS102</u> 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 <u>MS102</u> must 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-electromagnetic 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 61000-4-2 (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-electromagnetic 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 energy may cause malfunction or damage 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 actual modulation, it would be worse case.

- NOTE 1: If necessary to achieve the IMMUNITY TEST LEVEL, 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.

