

## ***SC-1001AR Quick Guide***

World First handheld 4.3 inch Touch Screen Display Portable Otoscope



















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# 1. Safety and Declaration of Conformity

## 1-1. Safety Considerations

	This symbol reminds the user should read instruction/manual carefully before operating this device.
	This symbol cautions the user that important information regarding the operation and / or maintenance of this equipment has been included. Information preceded by this symbol should be read carefully to avoid damage to the equipment or miss operation.
	This symbol denotes Type BF – Electrically connected to Patient but not directly to heart.
	Recycling Follow local governing ordinances and recycling plans regarding the recycling or disposal of this equipment.
	Safety Compliance This product meets the requirements of EN-60601-1 so as to conform to the Medical Device Directive 93/42/EEC and 2007/47/EC (general safety information).
	This symbol means Medical Device.
	This product meets or exceeds the safety requirements of Taiwan Bureau of Standards, Metrology and Inspection (BSMI).
	This product meets the requirements of Taiwan Food and Drug Administration (TFDA) for medical device
	This symbol means the manufacturer.
	This symbol means the manufacturer's European Community representative.
	This symbol indicates the date on which a product was manufactured.
	To identify the manufacturer's batch or lot code.
	To identify the product's serial number.
	This symbol means the power on/off.
	This symbol means the snap shot/video.
	This symbol means the Micro SD memory card.

## 1-2. Declaration of Conformity

### IEC:

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

## 2. Instruction

### 2-1. Intended Use

The Portable 4.3" TP ENT Endoscope is primary designed for ease of use and portability, enabling ENT (ear, nose, throat) medical inspection operations to be possible to be carried out in areas where no fixed power source is available.

This device is internally powered equipment to be used alone. The charging system (including AC adapter and Type C cable) is provided for charging the device while it is not in use. Follow the instruction of the manual and some useful tips of how to experience performance of the unit and ways to maintain it. Please read and retain this manual.

### 2-2. Intended User Profile

This device is intended for a licensed professionals trained in ENT Scopy.

Intended operator: any operator (mild reading vision impairment or vision corrected to log MAR 0.2 (6/9.5 or 20/32)) with minimum of 8 years of education. Person diagnosed by a doctor with unhealthy mental status is not allowed to use the device.

### 2-3. Intended Patient

This product does not apply to children under 12 years old.

### 2-4. Environment

- Indoor use only
- Physical :
  - Temperature range: 10 °C to +50 °C.
  - Relative humidity range: 30 % to 80 %, noncondensing.
  - Ambient pressure range: 700hPa~1060hPa.
  - Warm-up Time not required particularly.

### 2-5. Warnings and Precautions

Do not use this device in explosive environments such as where flammable anesthetics exit or inside an oxygen chamber with strong electronic and electromagnetic fields e.g., mobile phones.

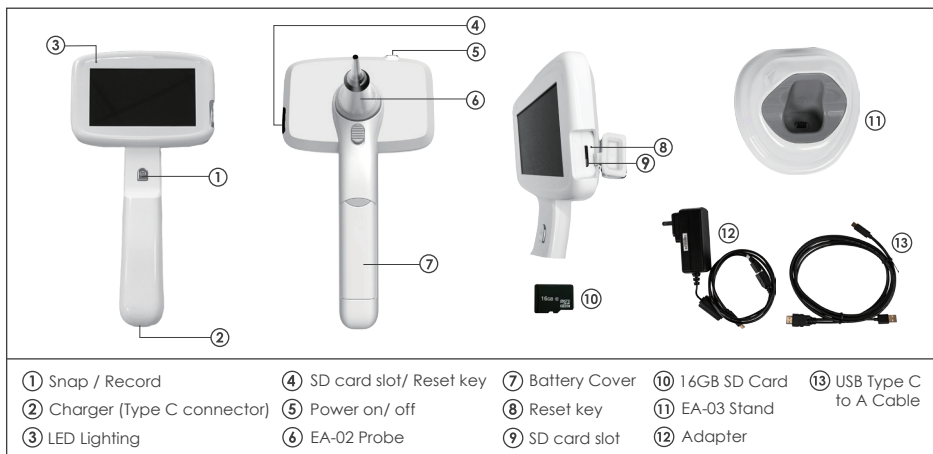
#### WARNING

- Use only provided AC adapter and Type C/USB cable to charge this device. Use of accessories other than those specified above and the use of unapproved replacement components may result in increased emissions or decreased immunity of this device.
- Do not use probe cover, battery other than it included with this device or replacement parts supplied by the manufacturer.
- Use a power cord that matches the voltage of the power outlet, which has been approved and complies with the safety standard of your particular country.
- No modification of this equipment is allowed.
- This device and accessories should not be used adjacent to or stacked with other equipment.
- Do not use this device while it is charging.
- Recharge the battery every 3 months to maintain the battery if this device is not likely to be used for some time.
- Do not attempt to disinfect this device using glutaraldehyde products, ethylene oxide gas, steam or any other liquid or gas disinfectant.
- If there is any other problem, please consult or return the device to your dealer/distributor. Do not try to repair a defective device.

#### CAUTION

- This device is for medical practitioner or medical trained personnel use only.
- This device may seriously be damaged after the device is dropped and the probe end hits the ground.
- The probe end will be slightly warm after the device has been operating continuously for a period of time.
- The maximum temperature of the end complies with medical device regulations and will not harm human skin.
- To fully disengage the power, please disconnect the AC adaptor from the power outlet.
- Do not position the AC inlet to a position where it is difficult to disconnect the device.
- Follow national requirements to dispose of the device.

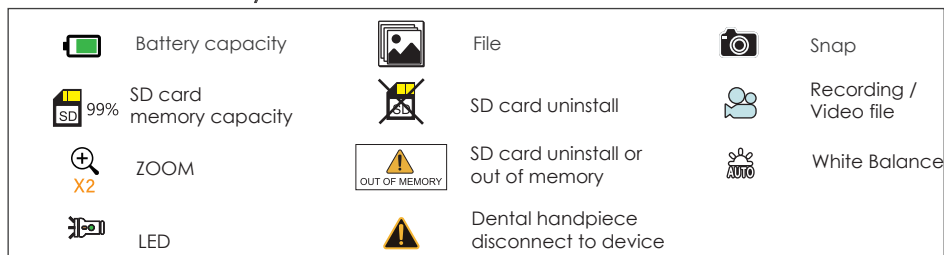
### 3. Name and Function of Each Part



- \* Only compatible with the enclose type C cable.
- \* The rechargeable battery is embedded and can only be replaced in authorized service center or dealer or distributor.
- \* Do not replace the battery yourself or it may cause device damage and no warranty.

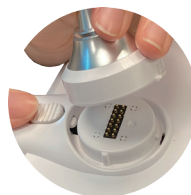
### 4. Operation and Maintenance

#### 4-1. Instructions For Symbol




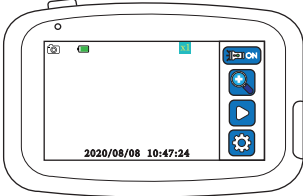
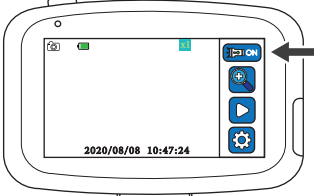


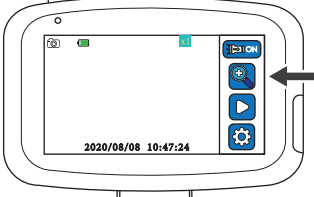

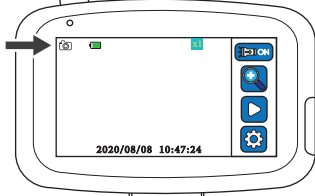


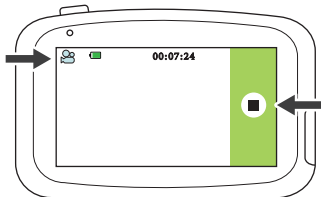



#### 4-2. Quick Guide for Use

1. Make sure the battery is fully charged.
2. Before using the device, make sure the probe cap is removed.
3. Make sure the lens in front of the end is clean.  
\* Clean the lens by using a soft cloth.
4. Please make sure the memory is correctly inserted
5. Attach the disposable probe cover by pushing onto the probe end. Reverse procedure to remove and discard the cover after each use.  
\*Suggested brand and specification of the cover :  
WelchAllyn 4.25mm Single-Use Adult tip.  
#52434-U (Purchase at your own)
6. Put on and take off the Probe
  - 6-1 Switch off the device, hold the probe and push the switch button down to remove the probe
  - 6-2 Insert the flange of the probe into the slot of the main device at an angle of 30 degrees, press the probe on the device. A snapping sound will be heard when the probe is firmly fixed to the device and then switch on the device.
7. The "⚠" will appear when taking off the probe without switching off the device. After putting on the probe, the device will be switched on.

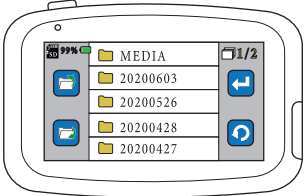




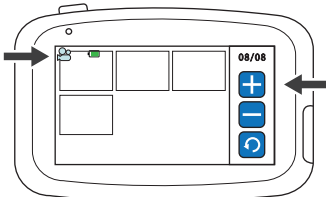




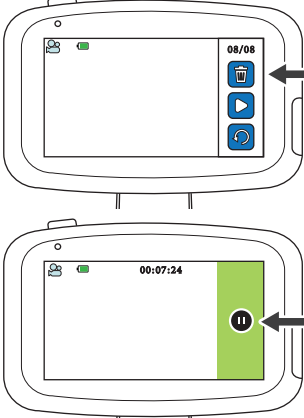






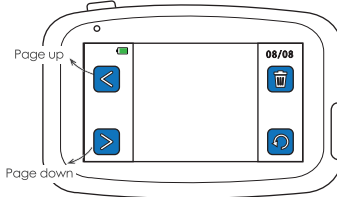







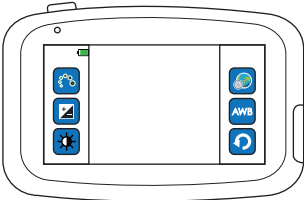
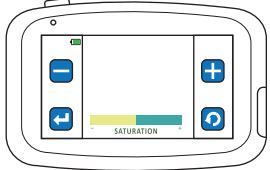




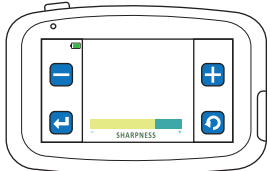




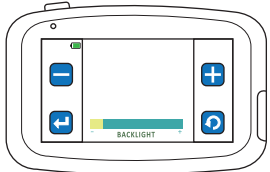




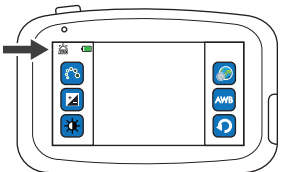


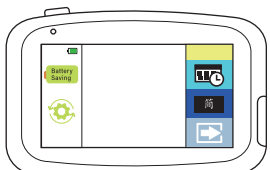
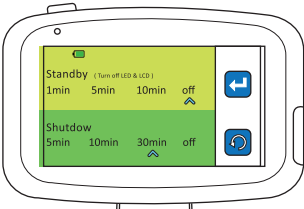

6-1

6-2

 <p>Power on/ off</p>	<p><b>Power on</b></p> <ul style="list-style-type: none"> <li>• Press the Power button on the left side of top for 3 seconds to turn on the device.</li> <li>• LED will be pop up after <b>Power on</b>.</li> </ul>
	<p><b>Preview</b></p> <ol style="list-style-type: none"> <li>1. Preview mode</li> <li>2. Display</li> </ol> <ul style="list-style-type: none"> <li>• Snapshot</li> <li>• Battery capacity</li> <li>• Zoom in/out (x1, x1.5, x2, x2.7 &amp; x4)</li> <li>• Playback</li> <li>• Date/Time</li> </ul>
	<p><b>LED on/off</b>  </p> <p>Touch the icon of LED on/off to switch LED on probe.</p>
	<p><b>Zoom in/out</b> </p> <p>Touch Zoom in/out icon to adjust the zoom (x1, x1.5, x2, x2.7 &amp; x4).</p>
	<p><b>Take Pictures</b></p> <p>Press snap  button on the handle once for still image.</p> <p>The  flash once snapshot is ready.</p>
	<p><b>Video Record</b></p> <ul style="list-style-type: none"> <li>• Long press snap  button on the handle for video recording. Recording icon  shown on the left of screen.</li> <li>• Press snap button again or press the stop icon  on the screen to return to preview mode.</li> </ul> <p>* The time display at the top of the screen indicates the remaining recordable time.</p>

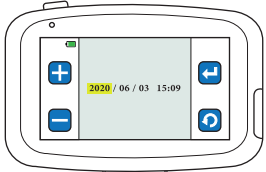



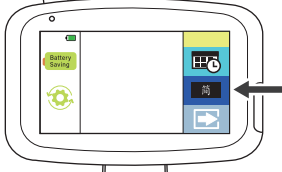


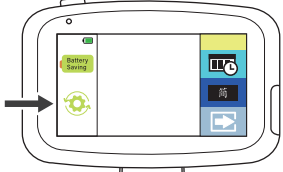



## 4. Operation and Maintenance

	<h3>Playback</h3> <ul style="list-style-type: none"> <li>• Touch  on the home page.</li> <li>• Select folder by touching screen.</li> <li>• Touch  to enter the folder to review the pictures or video.</li> <li>• Touch  or  for page up and down.</li> </ul>
	<h3>Playback Preview</h3> <ul style="list-style-type: none"> <li>• Touch  can preview the last 9 pictures, and  for next 9 pictures. (The file with  icon is video file)</li> <li>• Quick touch the picture for 2 times to enter full screen playback.</li> <li>• Touch  to return to home page.</li> </ul>
	<h3>Video playback &amp; delete</h3> <ul style="list-style-type: none"> <li>• Press the Video playback icon  to play video and press Pause icon  to stop playing video; Press the Playing button to proceed the rest video.</li> <li>• Press Delete button  to delete video file</li> <li>• Press Return key  to be back to file list.</li> <li>• Press Return key  to be back to folder</li> <li>• Press the Return key  again to be back to the preview page.</li> </ul>
	<h3>Photo playback &amp; delete</h3> <ul style="list-style-type: none"> <li>• When a picture is under playback mode, you can scroll the picture up/down by touching the left side of screen. You may see the page up/down icon  /  shown up for selection.</li> <li>• Press Delete button  to delete current file.</li> <li>• Press Return key  to be back to the folder</li> <li>• Press the Return key  again to be back to the preview page.</li> </ul>

	<p><b>Set up</b> <span style="float: right;">Contrast adjustment</span></p> <ol style="list-style-type: none"> <li>1. Saturation adjustment</li> <li>2. Sharpness adjustment</li> <li>3. Backlight adjustment</li> <li>4. Language/ Date/ Time/ Battery Power Saving/ Reset</li> <li>5. White Balance correction.</li> </ol>
	<p><b>Saturation</b> </p> <ol style="list-style-type: none"> <li>1. Select  or  to up or down level.</li> <li>2. Enter </li> </ol>
	<p><b>Sharpness</b> </p> <ol style="list-style-type: none"> <li>1. Select  or  to up or down level.</li> <li>2. Enter </li> </ol>
	<p><b>Backlight</b> </p> <ol style="list-style-type: none"> <li>1. Select  or  to up or down level.</li> <li>2. Enter </li> </ol>
	<p><b>White Balance</b> </p> <p>Select the white balance,  will appear on the left upper screen and indicate automatic correction is on.</p>
	<p><b>Language/ Date/ Time</b></p> <ol style="list-style-type: none"> <li>1. Battery Power saving mode</li> <li>2. Date/ Time</li> <li>3. Language Selection (English/ Simplified Chinese)</li> <li>4. Reset setting</li> </ol>
	<p><b>Power Saving Mode</b> </p> <ol style="list-style-type: none"> <li>1. Standby: The screen will be automatically off after 1min, 5min or 10min without any operation.</li> <li>2. Shutdown : The device will be automatically shutdown after 5min, 10min or 30min without any operation.</li> <li>3. Select "Off" for non "Power-Saving Mode"</li> </ol> <p>* Touch the screen or press any button to wake up the device. The default standby time is 5min.</p>



## 4. Operation and Maintenance

	<p><b>Time Set Up</b></p> <ol style="list-style-type: none"> <li>1. Select  to set up Year/ Month/ Date/ Hour/ Minute</li> <li>2. Enter </li> <li>3. Select  to return.</li> </ol>
	<p><b>Language Set Up</b></p> <p>Press  or  to select language, English or Simplified Chinese.</p>
	<p><b>Setting Reset</b></p> <p>Press  →  to reset Saturation, Sharpness, Backlight and Battery Saving to default.</p>
	<p><b>Turn off the device</b></p> <p>Long press "Power" button until "Goodbye" shown on the LCD screen and release the button to turn off the device.</p>


### 4-2. Pictures and Video Files Output by Connecting to a PC



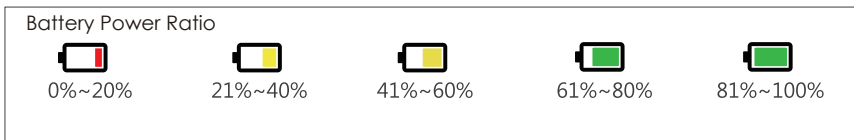
Turn on the device and connect to the computer by using the USB type C/A cable. Open "Windows Explorer" and find "New Folder Name" folder under the "Devices with Removable Storage". The pictures and videos in this folder can be copied, deleted and removed etc.

- a. Connect to a monitor by using a TYPE C/USB cable
- b. A new folder pop up on the PC screen
- c. Read photo/video data from new folder

#### 4-4. Battery Charge

When low battery  shows on the LCD screen, get USB type C/A cable and AC adaptor plug in power outlet. An orange LED on the left top of the LCD screen will be lighted up after the USB type C/A cable inserts to the device. The battery has reached full capacity once the LED light turned off automatically.

- Connect the device to USB port of PC by using USB type C/A cable.
- An orange LED lights up while power is charged and the light will be off when power charge is finished.



Adapter type: SINPRO, HPU26-102, INPUT 100-240V~47-63Hz, 0.7-0.4A

**\* NOTE :**

Ask an authorized dealer to replace battery when the battery is always running low after have been charged a few times.

#### 4-5. Care and Maintenance

- No calibration is needed. Even components exceed the life limitation, there is no aging problem.
- The device requests routine cleaning and inspection.
- Use a dry cloth to clean the device. Do NOT use any organic solvent (for example: antiseptic solution, etc.) to clean the device.
- Do NOT immerse the device in alcohol, any liquid or subject to steam sterilization.
- Use a 75% alcohol cotton to clean the tip of probe or attach the included disposable probe cover before operating the device.
- Always switch off the device when not use it in short period of time.
- The device is not user-serviceable and should never be disassembled.
- To order any replacement parts, contact the nearest dealer.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

## 5. Troubleshooting Section


	Problem	Solution
5.1	Micro SD card is not inserted into the device properly.	No Snap and record functions. Preview function only.
5.2	Improper Operation.	It is NOT allowed to remove the SD card during snapping or recording
5.3	Device shuts down or power off automatically while in playback mode.	Cause: Micro SD card might be damaged Solution: <ul style="list-style-type: none"> <li>• Connect the device to PC first.</li> <li>• Check the SD card files from PC and delete the bad files which show zero file capacity.</li> <li>• Format the SD card, please be sure to backup files before formatting.</li> </ul>
5.4	The device cannot be turned on	<ul style="list-style-type: none"> <li>• Make sure the battery is fully charged before starting up the device.</li> <li>• Check and confirm.</li> </ul>
5.5	The image is fuzzy	<ul style="list-style-type: none"> <li>• Make sure no dust or scratch in front of the camera.</li> <li>• Check if LED light level has been adjusted to the suitable brightness.</li> </ul>
5.6	The function buttons can't be controlled	<ul style="list-style-type: none"> <li>• Check and confirm the buttons can be pressed and depressed easily.</li> <li>• Restart the device and try the function buttons again.</li> </ul>
5.7	The device is not charged after connecting to USB adapter	<ul style="list-style-type: none"> <li>• Try to unplug the USB adapter and re-connect it again to make sure if the plug was installed properly.</li> <li>• Try to charge the device with USB adapter again to check if the charging status LED is on or not.</li> <li>• Switch on the device to see if the device is still working.</li> </ul>
<p>* Note : If the above recommended solutions do not solve the problem, please contact your local dealer for technical supports. Do not attempt to repair or open the device by yourself, as any attempt to do so will render warranty invalid.</p>		

## 6. Specifications

ITEM	DESCRIPTION
Camera resolution	720P CMOS sensor, default 960 x 720
Frame Rate	30fps
Light Source	LED x 4pcs
Lens	Fixed Focus
Field of View (FoV)	85°
Lens F/No	F 4.0± 5%
Depth of Field (DoF)	5mm~50mm
Control system	
Function Buttons	Power / Snap / Record / Reset
Output Interface	SD card slot / USB2.0 Mass Storage
Display	4.3" TFT-LCD + CTP
Display resolution	RGB 800 x 480
Auto Exposure Control (AEC)	Auto
White Balance	Manual
Image Format	JPEG
Video Format	MOV
Storage	Built-in 16 GB Micro SD card
UI features	Preview / Playback / LED / Zoom / Setting mode / Battery saving
Battery	3.6V, 3350mAh rechargeable lithium battery
Operating Temperature / Humidity	10°C ~ +50°C (±10%) / 30% RH ~ 80% RH
Storage / Transportation environment	-20°C ~ +60°C (±10%) / 20% RH ~ 90% RH
Atmospheric pressure	700-1060

## 7. Electromagnetic Compatibility (EMC) Tables

All medical electronic devices must conform to the requirements of IEC 60601-1-2. Precautions, adherences to the EMC guideline information provided in this manual and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other medical devices.

• Guidance and manufacturer's declaration – electromagnetic immunity			
The Portable 4.3" TP ENT Endoscope series is intended for use in the electromagnetic environment specified below. The customer or the user of the Portable 4.3" TP ENT Endoscope series should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated, Radio-frequency, electromagnetic field IEC 61000-4-3:2010	80MHz-2.7GHz 3V/m 80%, 1kHz AM	3V/m, 9V/m, 27V/m, 28V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Portable 4.3" TP ENT Endoscope series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 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).
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2010		PASS	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: 
Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013	0.15-80MHz 3V, 6V	0.15-80MHz 3V, 6V	
* Note1 : Applicable Limits: For radiated emissions at frequencies up to 1GHz (Class A, Group 1/2) & up to 1GHz (Class B, Group 1/2). * Note2 : 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 Portable 4.3" TP ENT Endoscope series is used exceeds the applicable RF compliance level above, the Portable 4.3" TP ENT Endoscope series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Portable 4.3" TP ENT Endoscope series. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			
• Guidance and manufacturer's declaration – electromagnetic immunity			
The Portable 4.3" TP ENT Endoscope series is intended for use in the electromagnetic environment specified below. The customer or the user of the Portable 4.3" TP ENT Endoscope series should assure that it is used in such an environment.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge IEC 61000-4-2:2008	Contact: ±8kV Air: ±2kV, ±4kV,±8kV, ±15kV	Contact: ±8kV Air: ±8kV, ±15kV	Floors 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 61000-4-4:2012	Input AC power ports: ±2kV	Input AC power ports: 0.5kV, 1kV, 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2014	Input AC power ports: ±0.5kV, ±1kV, ±2kV	Input AC power ports: 0.5kV, 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field IEC 61000-4-8:2009	50Hz or 60Hz 30A/m (rms)	50Hz or 60Hz 30A/m (rms)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips Voltage interruptions IEC 61000-4-11:2004 +A1: 2017		PASS	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Portable 4.3" TP ENT Endoscope series requires continued operation during power mains interruptions, it is recommended that the Portable 4.3" TP ENT Endoscope series be powered from an uninterruptible power supply or abattery.
* NOTE UT is the a.c. mains voltage prior to application of the test level.			

## 8. Warranty and Service Program

The Portable 4.3" TP ENT Endoscope series is warranted against any defects in materials and workmanship under normal use and service as follows:

1. Warranty extends to the original retail purchaser.
2. The entire Portable 4.3" TP ENT Endoscope series is warranted one (1) year from date of purchase.
3. Except in case of misuse, negligence, obvious abuse or accidental damage, if a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to our distributor.

Model No. SC-1001AR

Dealer's Name \_\_\_\_\_

Date of Purchase \_\_\_\_\_



**SHINCHI TECHNOLOGY CORP.**

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