ShinChi
Technology Corp.

SC-2XXXX Quick Guide

World first digital dental root canal orifices detector

EN

Table of Contents

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 Dental Root Canal Orifices Detector is a patented product. Built-in LED light, this tiny detector enables dentist easily locate the root canal orifices. The compact and easy-to-hold design make it simple to allow patients to visually understand your diagnosis.
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 Dental Scopy.
Intended operator: any operator (mild reading vision impairment or vision corrected to log MAR 0.2 (6/9.5 or 20/32)) graduated from department of dentistry.

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 +40 °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.

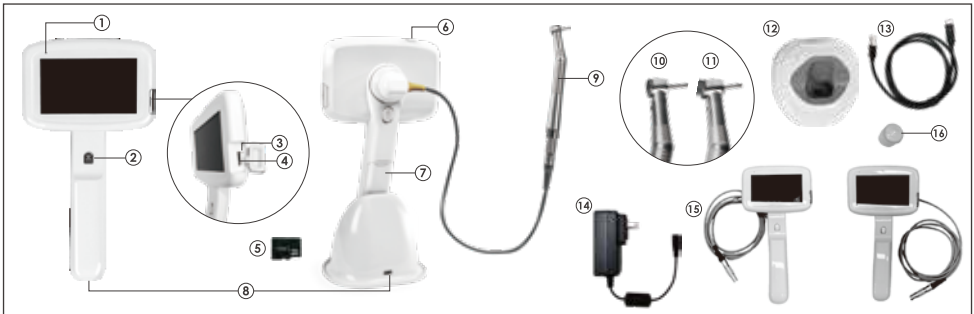
⚠ WARNING

- 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 battery other than it included with this device or replacement parts supplied by the manufacturer.
- To Charge the equipment, please use the adapter supplied and plug to the power outlet.
- 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 to avoid battery leakage problem and reduce unwanted battery self-discharge.
- Do not attempt to disinfect this device using glutaraldehyde products, ethylene oxide gas, steam or any other liquid or gas disinfectant.
- That before each use, the outer surface of the Handpiece PROBE, the applied part, should be checked to ensure there are no unintended rough surfaces sharp edges or protrusions which may cause HARM.
- That before each use or after a change of viewing modes / settings, the OPERATOR should check to ensure the view observed through the Equipment provides a live image (rather than a stored one) and has the correct image orientation.
- 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 power adapter to a position where it is difficult to disconnect the device.
- Only use the equipment with supplied accessories.
- Follow national requirements to dispose of the device.

3. Name and Function of Each Part



① LED indicator	⑤ 16 GB Micro SD Card	⑨ Dental Handpiece with Probe (Applied part)	⑬ USB type C to tape A cable
② Snap / Record	⑥ Power on / off	⑩ Half height specular	⑭ AC adapter with USB type A connector
③ Reset key	⑦ Battery Cover	⑪ Full height specular	⑮ SC-2001L / SC-2001R (Left / Right)
④ SD card slot	⑧ Charger (Type C connector)	⑫ Charger stand	⑯ Detal handpiece cap

* The type C charger slot is compatible with the enclosed type C cable only.
* 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

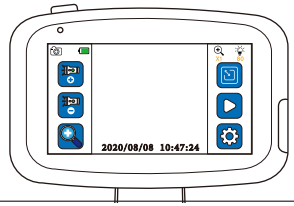
Battery capacity	File	Snap
SD 99% SD card memory capacity	SD card uninstall	Recording / Video file
X2 ZOOM	OUT OF MEMORY SD card uninstall or out of memory	AUTO White Balance
80 LED	Dental handpiece disconnect to device	

4-2. Quick Guide for Use

1. Fully charge device for the first time using.
2. Please avoid direct eye exposure to the probe directly, while LED is turned on.
3. Make sure the lens in front of the probe end is clean.
4. Remove the Dental Handpiece Cap.
5. Connect the Dental Handpiece with cable, make sure the connection is pin to pin, black arrow to red dot.
6. Turn on the device, display shown up to ensure the connection is successfully.
7. Detaching the dental handpiece from main device without turning off, the ⚠ will be shown on the screen. Re-install the handpeice, the device will power on automatically.

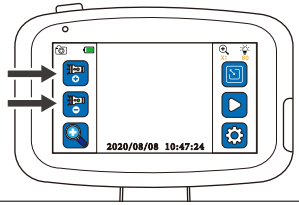
Power on

- Press the Power button on the left side of top for 3 seconds to turn on the device.
- LED on the distal tip of handpiece will be light up after **Power on**.
- LED will be pop up after **Power on**.



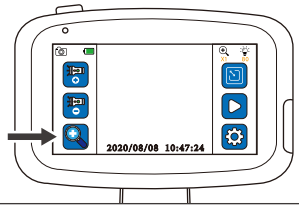
Preview

1. Preview mode
2. Display
   - Snapshot
   - Battery capacity
   - LED +/- adjustment (0~100)
   - Zoom in/out (x1, x1.5, x2)
   - Screen scale up (400x400 / 480x480)
   - Playback
   - Set up



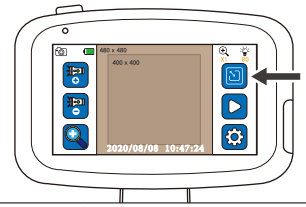
LED + / -

Touch the icon of LED to adjust the LED light from 0, 10, 20 to 100.



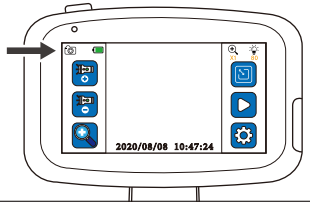
Zoom in/out

Touch Zoom in/out icon to adjust the zoom (x1, x1.5, x2)



Screen scale up

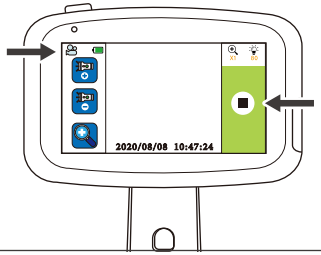
1. Touch the scale up icon to scale up the image 400 x 400 or 480 x 480.
2. Touch the screen to disappear the icons.



Take Pictures

Press snap button on the handle once for still image.

The flash once snapshot is ready.

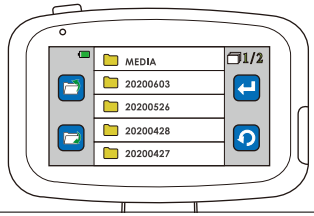


Video Record

- Long press snap button on the handle for video recording. Recording icon shown on the left of screen.
- Press snap button again or press the stop icon on the screen to return to preview mode.

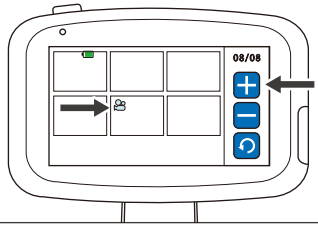
✱ The time display at the top of the screen indicates the remaining recordable time.

4. Operation and Maintenance



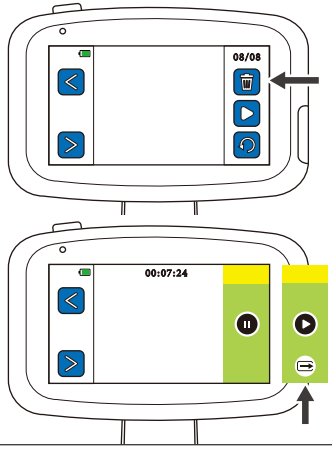
Playback

- Touch on the home page.
- Select folder by touching screen.
- Touch to enter the folder to review the pictures or video.
- Touch or for page up and down.



Playback Preview

- Touch can preview the last 9 pictures, and for next 9 pictures.
  (The file with icon is video file)
- Quick touch the picture for 2 times to enter full screen playback.
- Touch to return to home page.



Video playback & delete

- 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 or press to quit from the playing mode.
- Press Delete button to delete video file
- Press Return key to be back to file list.
- Press Return key to be back to folder
- Press the Return key again to be back to the preview page.

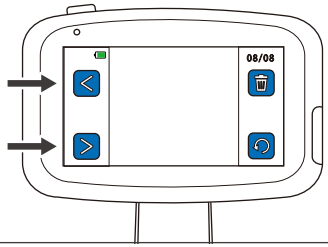
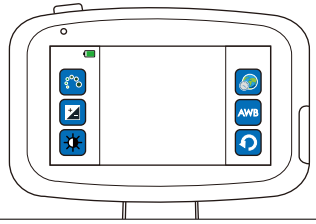


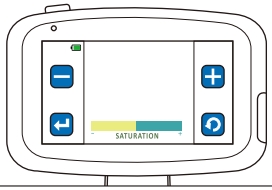
Photo playback & delete

- When a picture is under playback mode, touch the or for page up / down.
- Press Delete button to delete current file.
- Press Return key to be back to the folder
- Press the Return key again to be back to the preview page.



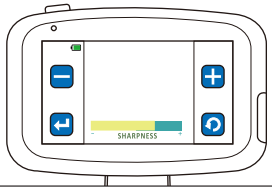
Set up

1. Saturation adjustment
2. Sharpness adjustment
3. Backlight adjustment
4. Language/ Date / Time / Battery Power Saving / Setting Reset set up
5. White Balance correction.



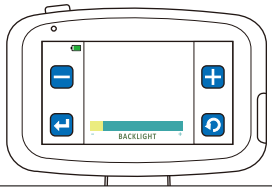
Saturation

1. Select + or − to up or down level.
2. Enter ↵



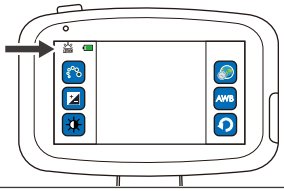
Sharpness

1. Select + or − to up or down level.
2. Enter ↵



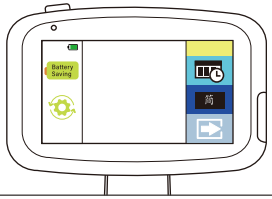
Backlight

1. Select + or − to up or down level.
2. Enter ↵



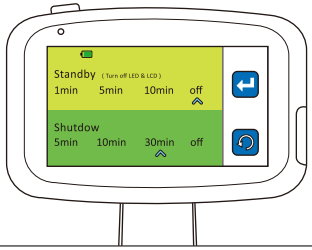
White Balance AWB

Select the white balance, AUTO will appear on the left upper screen and indicates that the automatic correction.



Language/ Date/ Time

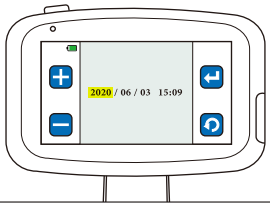
1. Battery Power saving mode
2. Date/ Time
3. Language Selection (English/ Simplified Chinese)
4. Setting Reset



Power Saving Mode Battery Saving

1. Standby timing: After 1min or 5min or 10min without any operation and then screen and LED off automatically.
2. After 5min or 10min or 30min without any operation and then device shut down automatically.
3. Select " Off " for non-saving mode.

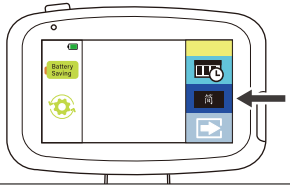
* Touch the screen or press any button to wake up the device. The default set up is Standby timing 5min.



Time Set Up

1. Select to set up Year/ Month/ Date/ Hour/ Minute
2. Enter ↵
3. Select ↺ to return.

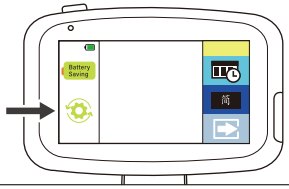
4. Operation and Maintenance



Language Set Up

Press 简 or ENG to select language,

English or Simplified Chinese.



Setting Reset

Press → to reset Saturation, Sharpness,

Backlight and Battery Saving to default.

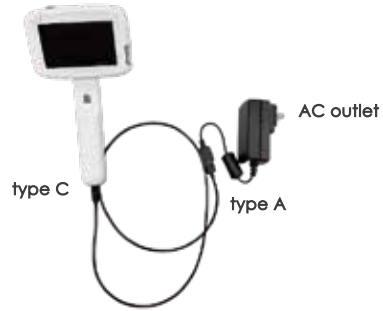
Turn off the device

Long press " Power " button until " Goodbye " shown on the LCD screen and release the button to turn off the device.

4-3. 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.

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



Battery capacity reference table

0%~20%	21%~40%	41%~60%	61%~80%	81%~100%

* For reference only. The battery capacity will get loss or fading gradually after charging and discharging cycles.

* Make sure plugging the Type C plug into the type C socket is in same direction; otherwise, it is not able to be plugged in or there is no image shown.
* 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.

4-4. 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.

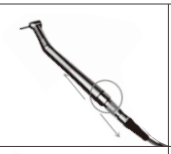
a. Connect to a monitor by using a USB TYPE C / A cable
b. A new folder pop up on the PC screen
c. Read photo/video data from new folder

4-5. Care and Maintenance

a. No calibration is needed.
b. Before clean and disinfection (High-level), please remove the dental handpiece from the connecting cable and wear the handpiece cap to the bottom of handpiece.
c. Clean: clean the front end of handpiece by using soft brush under running water.
d. Disinfection (High-Level): after clean the handpiece by running water, use soft tissue to wipe the handpiece and make sure the handpiece cap is in position tightly under 25°C room temperature. After then, immerse the handpiece in the "Metrex" High-level Disinfectant (Glutaraldehyde 2%) for 45 minutes at least. **(Note1 Note2)**
e. Clean the handpiece after high-level disinfection: After removing handpiece from the "Metrex" High-level Disinfectant (Glutaraldehyde 2%), rinse the handpiece by distilled water or sterile water and then wipe it by sterile tissue for next time use. If store the handpiece for a long time, please follow the clean and high-level disinfection procedure before using again.

Note1: The preparation method and high-level disinfection time for the "Metrex" High-level Disinfectant (Glutaraldehyde 2%), please follow the instruction provided by the manufacturer of disinfectant. If sterilization is required in a high-risk situation, soak the device in the "Metrex" High-level Disinfectant (2% glutaraldehyde) for at least 10 hours.

Note2: When executing the high-level disinfection or sterilization by using the "Metrex" High-level Disinfectant (Glutaraldehyde 2%), be sure to follow the instructions or recommendations from the competent authorities, and take protective actions and infection control.

① Remove the handpiece from cable		③ Immerse the handpiece into the "Metrex" High-level Disinfectant (Glutaraldehyde 2%) at least 45 minutes under 25℃ room temperature	
② Wear the handpiece cap to the bottom of the handpiece		④ Clean the handpiece by distilled water or sterile water and then wipe it dry by sterile tissue	

f. Do NOT immerse the device in alcohol, any other liquid or subject to steam sterilization.
g. Always switch off the device when not use in for prolonged periods of time.
h. The device is not user-serviceable and should never be disassembled,
i. To order any replacement parts, contact the nearest dealer.
j. 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	Dental Handpiece does not connect with the cable properly.	Make sure the direction red mark of cable and handpiece each is at same direction.
5.2	Micro SD card does not insert into the device properly.	No functions but Preview function only.
5.3	Improper Operation.	Removing the Micro SD card or dental handpiece is not allowed during snap or recording.
5.4	Device shuts down or power off automatically while in playback mode.	Cause : Micro SD card may damage Solution : • Connect the device to PC first. • Check the Micro SD card file from PC and delete the bad file, which file capacity shows zero "0" . • Format the Micro SD card. Before formating the Micro SD card, please make sure to have files backup.
5.5	The device cannot be turned on.	• Make sure the battery is full charged before start up the device • Check and confirm the power button functional well.
5.6	The image is fuzzy.	• Make sure no dust or scratch in front of the camera. • Check LED light level has been adjusted to suitable brightness.
5.7	The function buttons can't be controlled or abnormal use causes device crash.	• Check and confirm the buttons can be press and depress easily. • Restart the device and try the function buttons again. • Use a pin to push the "reset" to re-start the device.
5.8	The device is not charged after connecting to USB adapter.	• Try to unplug the USB adapter and re-connect it again to make sure if the plug was installed properly. • Try to charge device with USB adapter again to check if the charging status LED will be pop up. • Switch on the device to see if the device is still working.

✱ 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.

6. Specifications

ITEM	DESCRIPTION
Camera module	
Camera resolution	CMOS sensor, 400 x 400
Frame Rate	30fps
Light Source	LED
Lens	Fixed Focus
Field of View (FoV)	110°
Lens F/No	F 5.0± 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 ~ +40°C (±10%) / 30% RH ~ 80% RH
Storage / Transportation environment	-20°C ~ +60°C (±10%) / 20% RH ~ 90% RH
Atmospheric pressure	700-1060 hPa

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 Dental Root Canal Orifices Detector is intended for use in the electromagnetic environment specified below. The customer or the user of The Dental Root Canal Orifices Detector 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 Dental Root Canal Orifices Detector, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 $\sqrt{P}$ d = 1,2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2,3 $\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2010		PASS	
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 Dental Root Canal Orifices Detector is used exceeds the applicable RF compliance level above, The Dental Root Canal Orifices Detector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating The Dental Root Canal Orifices Detector.

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 Dental Root Canal Orifices Detector is intended for use in the electromagnetic environment specified below. The customer or the user of The Dental Root Canal Orifices Detector 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 +A1: 2017		PASS	Mains power quality should be that of a typical commercial or hospital environment. If the user of The Dental Root Canal Orifices Detector requires continued operation during power mains interruptions, it is recommended that The Dental Root Canal Orifices Detector be powered from an uninterruptible power supply or a battery.
* NOTE UT is the a.c. mains voltage prior to application of the test level.			

8. Warranty and Service Program

The Dental Root Canal Orifices Detector 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 Dental Root Canal Orifices Detector 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-2001L / SC-2001R

Dealer's Name _____ Date of Purchase _____

SHINCHI TECHNOLOGY CORP.
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