UP600

Dental Digital Impression System



User Manual



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CONTENTS

Safety Guidelines

1.1 Intended Use	01
1.2 Scope of Application	01
1.3 Exceptions	01
1.4 Precautions	02
1.5 Symbol Explanation – – – – – – – – – – – – – – – – – – –	03
1.6 Network Security Instructions	04
Product Overview	04

Installation

1	
3.1 System Requirements	 06
3.2 Hardware	 06
3.3 Software – – – – – – – – – – – – – – – – – – –	 11

| Dental Digital Impression System User Guide

4.1 Calibration	11
4.2 Scanning	12
4.3 Scanning Precautions	15

Operating Guide for Intra-oral Digital Impression Software

5.1 Working Conditions - <th>16 16</th>	16 16
Maintenance and upkeep	28
Cleaning and Sterilization/Disinfection	29
Main Safety Features of the Product	33
Electromagnetic Compatibility	34
Electrical Insulation Diagram	42
After-sales Service	43
Basic Information	44

01/Safety Guidelines

1.1 Intended Use

The product is intended for obtaining digital impressions of teeth, gums, mucosa, and other soft and hard tissues inside the oral cavity for dental restoration purposes.

1.2 Scope of Application

(1) Intended Use: Dental restoration(2) Indications: Single crowns, five-unit bridges, inlays, onlays, veneers, orthodontics, and implant restorations

(3) Applicable Population: Adults and/or children requiring dental restorations

(4) Expected Operating Environment

① Location:Dental clinics

② Environmental Conditions:

- Temperature Range: 15°C-30°C or 59 to 86 degrees Fahrenheit (maintain a constant temperature)

- Relative Humidity: 20%-80% (no condensation)

- Atmospheric Pressure Range: 70KPa-110KPa

- Prior to scanning, ensure sufficient saliva suction and blood cleaning to maintain oral dryness and avoid imaging issues or bubble formation due to light reflection.

- During data acquisition, move away from dental chair examination lights to prevent interference and errors in the oral digital impression imaging.

1.3 Exceptions

(1) Not suitable for cases with more than four consecutive missing teeth.(2) Caution is advised when used in patients with moderate or severe restricted mouth opening.

1.4 Precautions

(1) The provided instructions contain important safety information and guidance on the correct use of the oral digital impression system and its accompanying software. Before installing and operating the oral digital impression system, please ensure that you read and understand this user manual carefully.

(2) This oral digital impression system allows for highly accurate scanning. To achieve precise scanning results, follow the instructions completely.

(3) This device is classified as a Class I protection device. To avoid electric shock, it should only be connected to a power outlet with a protective grounding connection. The oral digital impression system is suitable for use in laboratories, dental clinics, and appropriate environments.

(4) Install the oral digital impression system according to the instructions. Before any maintenance steps, unplug the power plug of the oral digital impression system from the power outlet.

(5) Open the outer packaging and the oral digital impression system following the instructions. Retain the original packaging box of the oral digital impression system for safe transportation during servicing, maintenance, or disposal.

(6) Wear gloves for cleaning and disinfection before the first use, after each use, and before sending for repair, maintenance, or disposal to prevent cross-contamination and ensure hygiene and safety.

(7) The intraoral scanner contains fragile components. Handle with care when holding it. Avoid collisions that may cause permanent damage to the equipment.

(8) Ensure that the oral digital impression system is placed in a safe and stable location.

(9) Do not apply any load on the oral digital impression system.

(10) Do not dispose of the waste equipment as unclassified municipal waste. Dispose of separately.

(11) Only trained dental professionals and other technical personnel should operate the intraoral scanner.

(12) If repairs are needed, circuit diagrams can be provided to the repair personnel for reference.

(13) To prevent cross-contamination, the scanner head of the oral digital impression system should be used by one person and cleaned and sterilized (high-pressure steam sterilization) for single use. Regularly clean and disinfect the scanner to ensure hygiene and safety.

1.5 Symbol Explanation

Symbol	Explain
\triangle	General Warning - Caution
Ĩ	Transport Packaging - Fragile, Handle with Care
Ť	Transport Packaging - Keep Dry
<u>11</u>	Transport Packaging - Keep Upright
E.	Material Recycling
Ŕ	B-Type Applied Component Identification
8	Please refer to the user manual for reference.
	Caution: High temperature, risk of burns.

1.6 Network Security Instructions

(1) The dental digital impression system software is compatible with Windows 10 or
11 operating systems. When the dental digital impression system is connected to
the computer via USB 3.0, the software controls the data acquisition using the USB
3.0 protocol.

(2) User access control: Users need to log in with an account and password.

(3) Remote control is not allowed for this software.

02/Product Overview

(1) Product name: Dental Digital Impression System

The UP600 system utilizes a small-sized intra-oral optical scanning head to directly capture three-dimensional color and texture information of the teeth, gingiva, and oral mucosa surfaces inside the patient's mouth. It offers high precision, fast imaging, intuitive operation, and visual feedback, making oral examinations safe, comfortable, efficient, and accurate.

(2) Model: UP600

(3) Technical specifications: [Please provide the specific technical specifications Scanning Head Size

for the UP600 system.

Structure	Desktop		
Workstation	Keypad-based		
Scanning Method	Powder-free, continuous video scanning, automatic stitching and reconstruction		
Reconstruction Speed	3D point cloud reconstruction speed > 16fps		
Supported Data Formats	STL、PLY、OBJ		
Data Interface Type	USB3.0		
Front-End Scanning Head Specifications	Detachable scanning head		
Scanning Head Size	20 (W) × 18.0 (H), unit: mm		
Scanning Window Size	14.5 (L) × 16 (W), unit: mm		
Accuracy and Precision	a) Single crown accuracy < 30μm, single crown precision < 50μm; b) Three-unit fixed bridge accuracy < 120μm, three-unit fixed bridge precision < 60μm; c) Full arch accuracy < 120μm, full arch precision < 60μm; d) Inlay accuracy < 60μm, inlay precision < 50μm.		
Light Source	Red, Green, Blue (RGB) LED light source		
Light Source Parameters	Wavelength: 617nm (R), 500~600nm (G), 455nm (B) Light Power: 0.4W (R), 1.0W (G), 0.6W (B)		
Imaging Characteristics	True color, real-time imaging		
Noise	≤70dB (under no-load operation)		
Scanning Head Sterilization Method	High-pressure steam sterilization method		

03 / Installation

3.1 System Requirements

To ensure a better user experience, please configure your computer according to the recommended specifications.

ltem	Recommended Specifications		
Operating System	Windows 10 or Windows 11, 64-bit Professional edition		
CPU	Intel Core 12th generation i7 or above		
Dedicated Graphics Card	NVIDIA GeForce RTX 30xx series (with at least 6GB VRAM, recommended 8GB)		
Memory	16GB RAM or above		
Hard Drive	Dual Drives: 256GB SSD (Solid State Drive) + 1TB HDD (7200 RPM)		
Motherboard	Choose a reputable manufacturer's motherboard (e.g., ASUS) with USB 3.0 support.		
\triangle	Ensure the presence of a dedicated graphics card. Sufficient availability of USB 3.0 ports (at least 2). For stability purposes, it is recommended to use a branded computer rather than a custom-built one.		

3.2 Hardware

3.2.1 Transportation

If you need to transport the equipment, it is recommended to keep the original packaging to ensure maximum safety during transportation.

If the original packaging is damaged, please use bubble wrap to package each part of the oral digital impression system, following the packaging specifications and standards strictly to prevent any potential damage during transportation. Transportation and Storage: 1. Before placing the oral digital impression system into the original packaging box, ensure that it is disinfected, clean, and the packaging box is intact.

2. Carefully place each part of the product in the original packaging and prevent the high-speed USB cable from tangling.

3. Prior to packing for transportation, ensure that no part of the product is protruding from the packaging.

Transportation Environment:

Temperature: -5°C to 45°C or 23 to 113 degrees Fahrenheit, Humidity: 20% to 80%, Atmospheric Pressure: 70KPa to 110KPa.

3.2.2 Accessories Checklist

Check the following items in the accessory box. If any items are missing or damaged, please contact your supplier immediately.

accessories	quan- tities	images	purposes	
Handpiece	1		Used in conjunction with the scanning head to scan the patient's teeth and surrounding tissues, creating a three -dimensional digital image.	
Scanning Head	4	0	Connects to the handpiece for scanning purposes.	
Stand (Base)	1	n	Used to hold the oral digital impressio scanner when not in use.	
alibration Cylinder	1		Used for calibrating the accuracy of the device (automatic calibration).	

accessories	quan- tities	images	purposes		
USB Flash Drive	1		Used for storing software installation files and other related materials.		
Power Adapter	ver 1 Supplies appropriate voltage oral digital impression sca		Supplies appropriate voltage to the oral digital impression scanner.		
Power Cable	1	\bigcirc	Used for powering the oral digital impression system.		
High-Speed USB Cable	1		Connects the handpiece to the computer for data transmission.		
Type-C Cable	1		Used to connect the calibration cylinder to the power port.		
Protective Cap	1		Used to protect the front end of the handpiece.		

3.2.3 Composition of the Intra-oral Digital Impression System

The intraoral digital impression system consists of a handpiece, scanner head, stand, power adapter, and software processing system.

(1)Scanner Head and Handpiece



Diagram of Scanner Head and Handpiece Assembly

The composition of the scanner head and handpiece is illustrated in the following table:

Component	Function	Remarks
Scanner Head	The scanner head, equipped with a reflection mirror, is the main component that comes into contact with the oral cavity. It is used to scan the upper jaw, lower jaw, or full arch.	It is detachable and reusable.
Scan Button	Pressing the button activates the intra-oral digital impression system and initiates the scanning process.	
Hand piece Casing	The casing provides protection for the internal components of the intra-oral digital impression scanner.	
Air Inlet	The air inlet allows for the circulation of cool air inside the main unit to prevent overheating of internal components.	
Cable Interface	The cable interface is used to transfer the scanned data to an external computer.	

Component	Function
Stand (Base)	Allows placement of the handpiece when not in use

3.2.4 Connection

First, securely connect the scanner head to the front end of the handp iece as shown in the diagram. Insert the scanner head into the front end of the hand piece



Assembly Steps:

1. Take the hand piece out of the packaging. Note that the hand piece is connected to the HUB connection box via a cable. When handling the mouth digital impression device, be careful to protect the HUB connection box. Next, remove the scanner head from the packaging. Firmly attach it to the front end of the hand piece as shown in the diagram. The installation is now complete.



3. Connect the HUB connection box to the USB 3.0 port of the computer using the high-speed USB connection cable.

4. Connect the power adapter to the power port on the HUB connection box.

5. Finally, plug the power adapter into a power outlet. The assembly of the oral digital impression device is now complete.

6. Start the software for the oral digital impression device.

3.3 Software

(1)Before using the digital impression system, you need to install the Updental and Intra-oral Scanner software.

(2)Follow the instructions provided in the installation interface to complete the installation of all software.

(3)Once the software installation is complete, launch the scanning software through Updental.

04 /Dental Digital Impression System User Guide

4.1 Calibration

To ensure the quality of the scanning data, it is necessary to calibrate the dental digital impression system regularly (recommended every 1-2 weeks). Calibration is required in the following situations: (1)Initial setup of the scanner has been completed. (2)Scanning data is inaccurate compared to previous results.

(3)Environmental conditions such as temperature have changed.(4)The dental digital impression system has been accidentally dropped. (5) Switching between different devices.

How to calibrate the UP600 scanner

Automatic Calibration

•Connect the scanner to the computer and launch the Updental software to open the scanning application.

·Start the digital impression scanner through Updental.

In the user interface, go to the system configuration located in the upper right corner and click on "Calibration."

·Follow the software prompts and prepare the calibration tools.

During the calibration process, follow the software navigation for the operations.
Continue following the software navigation throughout the calibration process.
Once calibration is complete, return the calibration tools to their place.

4.2 Scanning

4.2.1 Scanning Technique

The scanning technique in the software has certain requirements. During the scanning process, maintain a steady scanning speed, and the model should be scanned before moving on to the next area. Additionally, it is important to have a certain degree of overlap between the scans of the facial surface, tongue side, and cheek side to minimize cumulative errors in the scanned model.

Scanning Steps

Upper Jaw

1.Start scanning from the facial surface of the terminal teeth on one side to the facial surface of the terminal teeth on the other side. (First position, then scan)

2.Transition from the posterior teeth on the facial surface to the tongue side for scanning, scanning to the opposite side of the tongue side, then transition back to the facial surface.

3. Transition from the posterior teeth on the facial surface to the cheek side for scanning, scanning to the opposite side of the cheek side, then transition back to the facial surface.

4.Tilt the scanning lens appropriately towards the tongue side for scanning the anterior teeth.

5.Check if the scan is complete and perform additional scanning on any incomplete areas.

The scanning path is shown in the diagram below:



Lower Jaw

1.Start scanning from the facial surface of the terminal teeth on one side to the facial surface of the terminal teeth on the other side. (First position, then scan)

2.Transition from the posterior teeth on the facial surface to the cheek side for tongue side scanning, scanning to the opposite side of the tongue side, then transition back to the facial surface.

3.Transition from the posterior teeth on the facial surface to the cheek side for cheek side scanning, scanning to the opposite side of the cheek side, then transition back to the facial surface.

4.Tilt the scanning lens appropriately towards the tongue side for scanning the anterior teeth.

5.Check if the scan is complete and perform additional scanning on any incomplete areas.

The scanning path is shown in the diagram below:



Occlusal Scanning

Perform an S-shaped scan from the posterior teeth on the buccal side to the anterior teeth on the labial side.

The scanning path is shown in the diagram below:



4.3 Scanning Precautions

(1)From the beginning of using the intra-oral scanner until the completion of the scan, it is necessary to wear surgical gloves to ensure a clean working environment and protect the patient's safety.

(2)Prior to scanning, the tooth surfaces should be dried and isolated to prevent moisture interference.

(3)When using the intra-oral scanner, avoid staring at the light source for prolonged periods or directing the light source towards others' eyes to prevent discomfort.

(4)If the scan quality deteriorates during the scanning process, check for interference such as fogging or saliva on the scanning tip, and if necessary, replace the scanning tip.

(5)During scanning, avoid interference from the tongue, cheeks, and lips. Auxiliary tools such as an intra-oral mirror, cotton swab, gloved finger, or mouth opener can be used for assistance in scanning.

05/Operating Guide for Intra-oral Digital Impression Software

5.1 Working Conditions

Please refer to "3.1 System Requirements" for detailed information.

5.2 Software Operation

5.2.1 Login

1.Log in to the account through the UPDENTAL software.

 \cdot Login with password.



· Verification Code Login:



Enter your account and password to access the software's main interface. Refer to the following figure:

Ø	Skip Order Celibrate	Scan Record		Please Enter t	he Patie Q Creation Start	→ Creation End
	Oral Scan 🔸	Patient Name	Scan Rod	Creator	Creation Time 0	Operate
3	Madellin	Unknown Patient	无	Tori	2023-06-05 08:47:21	a 6 6
(1)	House List	Unknown Patient	无	Tori	2023-06-04 22:21:03	1 8 8
•	x x T	tori15	无	Tori	2023-05-31 13:16:59	4 8 8
\$	No data for Now	Unknown Patient	无	JiuJiu	2023-05-22 16:41:35	a 🗅 🖸
	Model Preview					4 in Total < 1 >
	No data for Now					
•••						

5.2.2 Adding Intra-oral Scanning Information

1.Click on "New Order" on the software's main interface to enter the scene.

Q)	+ New Order	Order List	Pending	a Mill	sleted 🗌 My 📄 To-do	Please Enter Patie	nt Name/Case Numb Q
	Tooth map	Patient Name	Medical Record NO.	Status	Doctor	Last Modified ÷	Operate
		as		Tori-Scanning	2	023-06-08 11:50:10	(@) Scan
		15		To Nest	21	023-06-06 12:49:35	Nest
~	8 8	tori15		To Design	21	023-06-05 08:52:37	R Design
v	8			To Design	21	023-06-04 22:41:02	R Design
	-0000 ⁰ -	tori		To Nest	21	023-06-04 22:32:51	Nest
		tori		To Design	21	023-06-04 22:28:50	R Design
		tori15		To Design	2	023-06-04 22:26:55	Pa Design
		tori15		To Nest	2	023-06-04 20:50:28	Nest 🗸
					3	4 in Total < 1	2 > Go to
Ø	Skip Order Calibrate	Scan Record			Please Enter the PatieQ	Creation Start	→ Creation End
	Oral Scan 🔶	Patient Name	Scan Rod	C	Creator Creat	tion Time ≎	Operate
67	Model List	Unknown Patier	nt 无		Tori 2023-0	6-05 08:47:21	a 6 C

2.Fill in the patient information.

6	< <return< th=""><th></th><th></th><th></th><th></th></return<>				
	Patient Name		Doctor	Remarks	Drop Do V
	Please Enter the Patient's Name		Please Enter the Doctor in Charge	Please Enter Remark	
69	Medical Record NO.		Case Number		
	Please Enter the Patient's Medic	al Record Number	Please Enter the Case Number		Save as General Remarks
4	Unfold				
\$		Restoration	后全部修算关型		
				Save Only Save	and Scan Save and Send
		Oral Sca	n	X	
		Patient Name	Patient Name		
		Implant	teeth (scanning with a scanning	rod)	
		No more	prompts in the future, directly start th	e Involution	
			Cancel	Confirm	

Note: The patient's name is a required field. Fields marked with an asterisk (*) are mandatory.

3.Select the tooth position, restoration type, material, and shade, etc.



4.Click "Save and Scan" and select "Intra-oral Scanner".



5.Click "Confirm" to start the intra-oral scan.

6. If there are no scans for the order, you can enter the scanning process by clicking the "Scan" button on the order management interface.

Ð,	+ New Order	Order List	Pendin Create Orde	Successfully			
6	Tooth map	Patient Name	Medical Record NO.	Status	Doctor	Last Modified	Operate
63	00000	1		To Scan	JiuJiu	Time 2023-07-05 14:35:18	😥 Scan
		as		Tori-Scanning		2023-06-08 11:50:10	(Ø) Scan
9	8 8	15		To Nest		2023-06-06 12:49:35	🗎 Nest
~		tori15		To Design		2023-06-05 08:52:37	R Design
	-0000 ⁰ -			To Design		2023-06-04 22:41:02	Pa Design
		tori		To Nest		2023-06-04 22:32:51	🗎 Nest
		tori		To Design		2023-06-04 22:28:50	Ra Design
		tori15		To Design		2023-06-04 22:26:55	P2 Design ↓

5.2.3 Scan

5.2.3.1 User Interface



- Title Bar

	menu	System settings		
	Minimize	Minimize the scanning program		
Maximize		Maximize the scanning program		
	Restore	Restore the scanning program		
E Calibrate		Calibrate the data		
🔅 Settings		Set the background application		
× Exit		Close the program		

- Navigation Bar

Upper Jaw	Scan images of the upper jaw
Lower Jaw	Scan images of the lower jaw
Bite Alignment	Align the bite
Complete	Complete the scanning process and generate scan data

- Toolbar

Selection Tool	Select	Move	Delete
Lasso Tool			
Rectangle Tool			
Smoothing Tool			
		6	
iexture Display	Hide	Show	
Visible Region	Hide	Show	

Selection Tool	Select	Move	Note
Hole Filling	Before filling	After filling	
Concavity	Before concavity	After concavity	
Lock	Before locking	After locking	Rotate the model after locking to view the concavity before locking

	Specific Operations						
Operation	Purpose	Shortcut Keys					
Selection	Select and delete area	Left mouse button					
Deselect Deselect all selected areas		Ctrl+C key					
Subtract Selection	Subtract selected areas	Ctrl+Left mouse button					
Delete	Delete selected areas	Delete key					
Undo Undo deleted areas		Ctrl+Z key					
Redo Recover deleted areas		Ctrl+Y key					

- Scan Information

0 FPS	Frame Rate	Display the current scan data acquisition frame rate
@ 0 P	Captured Images	Display the number of current scan captured images

- Device Status

Not Connected	Indicates that the intraoral scanner is not connected
Connected	Indicates that the intraoral scanner is connected and can be used

【应用栏】

	Start Scan	Start the scanning process. You can also use the scan button on the device to start the scan.		
	Stop Scan	Stop the scanning process. You can also use the scan button on the device to stop the scan.		
	Gingival Separation	Real-time separation of teeth and gums		
	Delete	Delete completed scan data		
(² ²	Triangulation	Point cloud data processing		
M	Manual Alignment	Manually align the bite		
	Export	Model export		

5.2.4.2 Scanning

⚠ Note:

(1)Before scanning, dry and isolate the surface of the teeth.

(2) To avoid interference and errors caused by other light sources during imaging with the intraoral scanner, move away the dental chair's operating light during scanning.

(3)During scanning, avoid interference from the tongue, cheek, and lips. You can use a mouth mirror, cotton swab, gloved finger, or mouth opener for assistance.

(4)Follow the instructions to properly and effectively connect the intraoral scanner, and check its connectivity.

1.Select the desired scanning position. Click on "Upper Jaw" in the Navigation Bar or press the scan button on the intraoral scanner, or click on the scan icon in the Application Bar 🕟 to start scanning the upper jaw.。

2.Align the scanning window of the scanner head with the surface of the teeth to be scanned. Slowly move the scanner head to perform the upper jaw scan. The user interface will display the scanned model data. The Camera Window will show real-time dynamic images of the oral cavity. See the diagram below:



3.After completing the scan, click on K the point cloud data processing in the interface to generate a 3D model. See the diagram below:



4.Click on the lower jaw in the navigation bar, briefly press the scan button on the oral digital impression device, or click on the scan icon in the application bar \bigcirc to start the lower jaw scan.

5.Align the scanning window of the scanner with the surface of the teeth to be scanned, and slowly move the scanner to perform the lower jaw scan. The user interface will display the scanned model data, and the 5.camera window will show real-time dynamic images of the oral cavity. Continue the scan until the upper jaw scan is completed. Click on \widehat{V}^* the point cloud data processing in the interface to generate a 3D model. See the diagram below:



6.Click on the bite alignment in the navigation bar, briefly press the scan button on the oral digital impression device, or click on the scan icon in the application bar \bigcirc to start the bite alignment.

7.Scan the bite relationship to complete the bite alignment. See the diagram below:



8.Once the bite alignment is confirmed, click on "Export" in the navigation bar to complete the scanning process and generate the scan data.

\land Note:

(1) After starting the scan, the scan icon in the application bar will switch to.
Click on O to stop the scan. You can also briefly press the scan button to stop the scan.

(2) After the 3D model is generated, hold the right mouse button and drag to rotate the model according to the mouse movement. Hold the middle mouse button and drag to translate the model. Scroll the mouse wheel up and down to zoom in and out of the model.

(3) In non-scan mode, click on 🔄 or 🕟 in the toolbar to select specific areas of the 3D model and delete redundant parts of the model.

(4) the generated 3D model is not satisfactory or for any other reason, click onin in the application bar to delete the current generated model data.

5.2.5 Close the software

click on the "Title Bar" and then click on the "Close" button. Confirm the action by clicking "OK." This will close the dental digital impression software.

06/Maintenance and upkeep

(1) When the dental digital impression system is not in use or after use, place it on the base and keep it away from the edge of the table to prevent it from falling.

(2) When the scanner and the handheld unit are separated, cover the front end of the handheld unit with a protective cap to prevent damage to the optical lens of the dental digital impression system and to keep out dust.

(3) Unplug the device's power when it is not being used or during thunderstorms or when it will not be used for an extended period of time.

(4) Avoid storing the dental digital impression system and its accessories in places with extreme temperatures or direct sunlight.

(5) When using the dental digital impression system, from the start of scanning to the completion of the process, it is necessary to wear surgical gloves to ensure a clean working environment and protect the patient's safety.

(6) If the scanning quality deteriorates during the scanning process, you can calibrate the dental digital impression system or clean the scanner.

(7) After each use, the scanner needs to be cleaned and disinfected before it can be used again.

(8) Before storing the scanner, make sure the scanner head, handheld unit, and base are completely dry.

(9) Storage environment: Temperature: -5°C to 45°C, humidity: 20% to 80%, atmospheric pressure: 70Kpa to 110Kpa.

07/Cleaning and Sterilization/Disinfection

To provide more protection for patients, it is necessary to clean and sterilize the scanner head before using the dental digital impression system. Refer to the following standards for cleaning and sterilization procedures: WS 310.2-2016 "Hospital Disinfection Supply Center Part 2: Technical Specifications for Cleaning, Disinfection, and Sterilization," Appendix B for cleaning methods of instruments and items; WS/T 367-2012 "Technical Specifications for Disinfection in Healthcare Institutions," Appendix C for requirements of common disinfection and sterilization methods; and WS 506-2016 "Technical Specifications for Disinfection and sterilization of Dental Instruments." We recommend using manual cleaning and high-temperature, high-pressure steam sterilization for cleaning and sterilization the scanner head.

The specific operating procedures are as follows:

(1) Disconnect the power of the dental digital impression system.

(2) Remove the scanner head and cover the handheld unit with a protective cap to prevent damage to the optical lens of the dental digital impression system and to keep out dust.

(3) Wear surgical gloves when cleaning and sterilizing the scanner head.

(4) Rinse the scanner head (including the scanning mirror) under flowing water at a temperature of 15°C to 30°C to remove initial contaminants.

(5) After rinsing, soak the scanner head in a cleaning basin filled with a medical detergent (neutral soapy water) for 2 to 3 minutes. Then, thoroughly brush and scrub the inner and outer sides of the scanner head using a soft-bristle brush.

(6) Carefully wipe the scanning mirror with a lint-free cloth.

(7) After thorough brushing and scrubbing, rinse and brush the inner and outer sides of the scanner head again under flowing water at a temperature of 15°C to 30°C.

(8) Finally, thoroughly rinse the inner and outer sides of the scanner head and the surface of the scanning mirror with purified water.

(9) After cleaning, use a clean, lint-free cloth or air gun to remove moisture from the surface of the scanner head. Alternatively, allow it to air dry naturally.

(10) Wipe the scanning mirror with a clean, lint-free cloth to remove moisture from the surface.

(11) Place the scanner head in a sterile bag and seal it.

(12) Put the sealed scanner head in a high-pressure steam sterilizer: sterilize at a high temperature of 121°C for 30 minutes.

(13) Allow the sterilized scanner head to dry for 15 minutes before opening the high-pressure sterilizer.

(14) Place the sterilized scanner head (including the bag) in the sterile storage area. The storage validity period is 180 days.

⚠ Note:

- The scanner head is a component that comes into contact with the patient's oral cavity during scanning. It can only be reused for a limited number of times but must be cleaned/sterilized before each reuse to prevent cross-infection.

- To avoid cross-infection, the scanner head should be assigned to one person and undergo cleaning and sterilization (high-pressure steam sterilization) before each use. - The scanner head can be sterilized with high temperature for up to 20 times. After undergoing 20 cycles of high-pressure steam sterilization, it is recommended to discard the scanner head.

- Proper disposal of the discarded scanner head should be done according to local regulations or the waste management system of the hospital or clinic. It should not be disposed of casually.

Cleaning and Disinfection of the Scanning Mirror

(1) Wipe the scanning mirror with a lint-free cloth soaked in ethanol solution.

(2) Wipe the scanning mirror with a clean, lint-free cloth.

(3) Repeat the wiping process until there is no dust, foreign objects, or stains on the scanning mirror.

⚠ Note:

- The cleanliness and surface condition of the scanning mirror directly affect the quality of the scanning data, so please take precautions to prevent foreign objects and stains on the scanning mirror.

Disinfection of the Handpiece

(1) Disconnect the power of the oral digital impression scanner.

(2) Remove the scanner head from the handpiece.

(3) Before disinfecting the handpiece, store the detached scanner head in a safe and clean place, such as a dental instrument tray.

(4) After removing the scanner head from the handpiece, cover the handpiece with a protective cap to prevent damage to the optical lens of the oral digital impression scanner and to isolate it from dust.

(5) When cleaning and disinfecting the device, it is necessary to wear surgical gloves and hold the handpiece with your hand.

(6) Wipe the surface of the handpiece body with a new gauze soaked in 75% concentration medical alcohol.

(7) After completion, store the handpiece in a clean and safe place.

Disinfection of the Base

(1) Disconnect the power of the oral digital impression scanner.

(2) Grip the base with your hand.

(3) Wipe the surface of the base with a new gauze soaked in 75% concentration medical alcohol.

(4) After completion, store the base in a clean and safe place.

08/Main Safety Features of the Product

A.1 Classification according to protection against electric shock: The oral digital impression scanner is classified as a Class I product.

A.2 Classification according to the degree of protection against electric shock: The handpiece of the oral digital impression scanner is classified as Type B applied part.

A.3 Classification according to the degree of protection against liquid ingress: The oral digital impression scanner has an IPX0 degree of liquid ingress protection for the main unit.

A.4 Classification according to the safety level when used with flammable anesthetic gases mixed with air or with oxygen or nitrous oxide: The oral digital impression scanner is classified as non-AP/APG type.

A.5 Classification according to the operating mode: The oral digital impression scanner operates in an intermittent mode.

A.6 Power supply: AC220V, 50Hz.

A.7 Input power: 35VA.

A.8 Whether it has protection against defibrillation discharge effects in the applied part: The oral digital impression scanner does not have protection against defibrillation discharge effects in the applied part.

A.9 Whether it has signal output or input parts: The oral digital impression scanner does not have signal output or input parts.

A.10 Whether it is a permanently installed or non-permanently installed device: The oral digital impression scanner is a non-permanently installed device. It uses a detachable power cord and electrical coupler.

A.11 Electrical insulation diagram and electrical insulation table: Refer to Figure A.1 and Table A.1 in the electrical insulation diagram.

A.12 Classification of electromagnetic compatibility: According to GB 4824, the oral digital impression scanner belongs to Group 1 Class B equipment.

09/Electromagnetic Compatibility

⚠ Note:

- The UP600 intraoral scanner complies with the requirements of the IEC 60601-1-2:2007 standard for electromagnetic compatibility.

- Users should install and use the device based on the electromagnetic compatibility information provided in the accompanying documentation.

- Portable and mobile RF communication devices may affect the performance of the UP600 intraoral scanner. Therefore, it is recommended to avoid strong electromagnetic interference, such as proximity to mobile phones, microwave ovens, etc.

- For detailed guidelines and manufacturer's statements, please refer to the attached documentation.

⚠ Warning:

- The UP600 intraoral scanner should not be used in close proximity or stacked with other devices. If it is necessary to use it in close proximity or stacked with other devices, it should be observed and verified that it can function properly in the given configuration.

- The use of cables other than those provided by the manufacturer of the UP600 intraoral scanner as spare parts for internal components may result in increased emissions or reduced immunity to interference.

- The use of non-specification cables with the UP600 intraoral scanner may result in increased emissions or reduced immunity to interference.

Cable Information:

Name	Cable Length (m)	Shielded	Remarks
Power Cord	1.5	NO	
High-Speed USB Cable	1	Yes	Interconnect Cable
Scanner Head Connection Cable	1.5	Yes	Interconnect Cable Non-detachable
Power Adapter Output Cable	1	NO	
Type-C Cable	1	NO	

Attachment:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The UP600 Intraoral Scanner is intended for use in the electromagnetic environments specified below. The purchaser or user of the UP600 Intraoral Scanner should ensure that it is used in such an environment:

Emissions Test	Compliance	Electromagnetic Environment - Guidance
GB 4824 RF Emissions	Group 1	The UP600 Intraoral Scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interfer- ence in nearby electronic equipment.
GB 4824 RF Emissions	Class B	
GB 17625.1 Harmonic Emissions	Class A	The UP600 Intraoral Scanner is suitable for use in all establishments, including residential environments and those direct-
GB 17625.2 Voltage Fluctuations/Flicker Emissions	Complian	ly connected to a low-voltage power supply network for residential use.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The UP600 Intraoral Scanner is intended to be used in the following specified electromagnetic environments. The purchaser or user of the UP600 Intraoral Scanner should ensure that it is used in such electromagnetic environments:

Immunity Test Electrostatic Discharge (ESD) GB/T 17626.2

IEC 60601 Test Level

±6 kV contact discharge ±8 kV air discharge

Compliance Level

±6 kV contact discharge ±8 kV air discharge

Electromagnetic Environment - Guidance

The ground should be wood, concrete, or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test Fast Transient Burst GB/T 17626.4

IEC 60601 Test Level

±2 kV for power supply lines ±1 kV for input/output lines

Compliance Level

±2 kV for power supply lines

Electromagnetic Environment - Guidance

The power supply should be of a quality suitable for typical commercial or hospital environments.

Immunity Test Surge GB/T 17626.5

IEC 60601 Test Level ±1 kV differential mode voltage ±2 kV common mode voltage

Compliance Level ±1 kV differential mode voltage ±2 kV common mode voltage

Electromagnetic Environment - Guidance

The power supply should be of a quality suitable for typical commercial or hospital environments.

Immunity Test

Voltage Dips, Short Interruptions, and Voltage Variations on Power Input Lines GB/T 17626.11

IEC 60601 Test Level

<5% UT, duration of 0.5 cycles (>95% dip in UT) 40% UT, duration of 5 cycles (60% dip in UT) 70% UT, duration of 25 cycles (30% dip in UT) <5% UT, duration of 5 seconds (>95% dip in UT)

Compliance Level

<5% UT, duration of 0.5 cycles (>95% dip in UT) 40% UT, duration of 5 cycles (60% dip in UT) 70% UT, duration of 25 cycles (30% dip in UT) <5% UT, duration of 5 seconds (>95% dip in UT)

Electromagnetic Environment - Guidance

The power supply should be of a quality suitable for typical commercial or hospital environments. If continuous operation of the UP600 Intraoral Scanner is required during power interruptions, it is recommended to use an uninterruptible power supply or battery power. Immunity Test Power Frequency Magnetic Field (50/60 Hz) GB/T 17626.8

IEC 60601 Test Level 3A/m

Compliance Level 3A/m,50Hz

Electromagnetic Environment - Guidance

The power frequency magnetic field should have the characteristics of a typical commercial or hospital environment.

⚠ Note:

UT refers to the alternating current mains voltage before the application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The UP600 Intraoral Scanner is intended to be used in the following specified electromagnetic environments. The purchaser or user of the UP600 Intraoral Scanner should ensure that it is used in such electromagnetic environments:

Immunity Test

RF Conducted GB/T 17625.6 RF Radiated GB/T 17626.3

IEC 60601 Test Level

3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz

Compliance Level

3 Vrms 3 V/m

Electromagnetic Environment - Guidance

Portable and mobile RF communication equipment should not be used closer to any part of the UP600 Intraoral Scanner, including cables, than the recommended separation distance. This distance should be calculated using the formula corresponding to the transmitter frequency.

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

In the given context, "P" represents the maximum rated output power of the transmitter provided by the transmitter manufacturer, measured in watts (W). "d" refers to the recommended isolation distance, measured in meters (m).

The field strength of fixed RF transmitters is determined through electromagnetic field surveys ("a"), and it should be lower than the compliance level in each frequency range ("b").

Interference may occur near devices marked with the following symbols.

🗥 Note 1:

For frequencies between 80MHz and 800MHz, the formula for the higher frequency range should be used.

🗥 Note 2:

These guidelines may not apply to all situations, as electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and human bodies.

a) The field strength of fixed transmitters, such as wireless (cellular/cordless) telephones, ground-based mobile radio stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, cannot be accurately predicted in theory. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic field survey should be conducted. If the field strength measured at the location of the UP600 oral digital scanner exceeds the RF compliance level of the aforementioned applications, the UP600 oral digital scanner should be observed to verify its proper functioning. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UP600 oral digital scanner.

b) In the frequency range of 150kHz to 80MHz, the field strength should be below 3 V/m.

Recommended Isolation Distance between Portable and Mobile RF Communication Devices and UP600 Oral Digital Scanner

The UP600 oral digital scanner is intended to be used in an electromagnetic environment where radiation from RF sources is controlled. Based on the maximum output power of the communication devices, the purchaser or user of the UP600 oral digital scanner can prevent electromagnetic interference by maintaining the minimum distance recommended below between portable and mobile RF communication devices (transmitters) and the UP600 oral digital scanner.

Rated Maximum	Isolation Distance for Different Frequencies of Transmitter (m)				
Output Power of Transmitter (W)	150 kHz ~ 80 MHz d = $1.2\sqrt{P}$	$80 \text{ MHz} \sim 800$ MHz d = 1.2 \sqrt{P}	800 MHz ~ 2,5 GHz d = $2.3\sqrt{P}$		
0,01	0,12	0,12	0,23		
0,1	0,38	0,38	0,73		
1	1,2	1,2	2,3		
10 3,8 100 12		3,8	7,3		
		12	23		

For rated maximum output powers of transmitters not listed in the table, the recommended isolation distance (d) in meters (m) can be determined using the formula provided in the corresponding transmitter frequency column, where P is the maximum output power rating of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: For frequencies between 80 MHz and 800 MHz, use the formula for the higher frequency range. Note 2: These guidelines may not apply to all situations, as electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and human bodies.

10/Electrical Insulation Diagram



Figure A.1 Electrical Insulation Diagram

序号	Insulation Path	Insulation Type	Reference Voltage (V)	Test Voltage (V)	Creepage Distance (mm)	Clearance (mm)
1	A-f	BI	a.c.220	a.c.1500	3.0	1.6
2	A-a1	BI	a.c.220	a.c.1500	4.0	2.5
3	A-a2	DI/RI	a.c.220	a.c.4000	8.0	5.0
4	B-a	DI/RI	a.c.220	a.c.4000	8.0	5.0

11/After-sales Service

Shenzhen Yunjia Technology Co., Ltd. guarantees that the products it manufactures comply with the specifications on the product label and are free from material and workmanship defects during the warranty period. The warranty period is defined as 24 months from the date of installation or 27 months from the date of product delivery (whichever comes first).

The following cases are not covered by the warranty:

a) Damages caused by transportation.

b) Damages caused by incorrect use and maintenance.

c) Damages caused by any unauthorized modification or repair by personnel not authorized by Shenzhen Yunjia Technology Co., Ltd.

d) Accidental damages.

e) Replacement or removal of product serial number labels or manufacturer labels.

12/Basic Information

Registered Name: Shenzhen Yunjia Technology Co., Ltd.

Registered Address: Building B, Nanshan Yungu Innovation Industrial Park, No. 4093 Liuxian Avenue, Pingshan Community, Nanshan District, Shenzhen City, Guangdong Province, China

Manufacturer Name: Shenzhen Yunjia Technology Co., Ltd.

Production Address: Floors 3 and 5, Building 4, Tangtou Third Industrial Zone, Shiyan Street, Bao'an District, Shenzhen City, Guangdong Province, China

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After-sales Service Unit: Shenzhen Yunjia Technology Co., Ltd.

Customer Service Hotline:

Production License Number: Guangdong Food and Drug Administration Medical Device Production License No. 20224692

Registration Certificate Number: Guangdong Medical Device Registration Certificate No. 20222170382

Product Technical Requirements Number: Guangdong Medical Device Registration No. 20222170382

Production Date: Refer to the product label for the production date

Expiration Date: 6 years

Instruction Manual Compilation and Revision Date: April X, 2023