

- After the scanner is connected correctly and capped with the scanner tip, the scanner tip will automatically be heated up when the indicator turns green.

## 5.2 Start using

### Connection

See more details in [Connection and disconnection](#).

### Registration and Login

If you already have an account, enter your username and password or use verification code to log in. If not, you need to register first.

### Activation

Activation is to ensure that the scanner is officially authorized. You have to activate the scanner to make it work properly.

When you use the scanner for the first time, you need to activate it. See more details of activation in the User Manual.

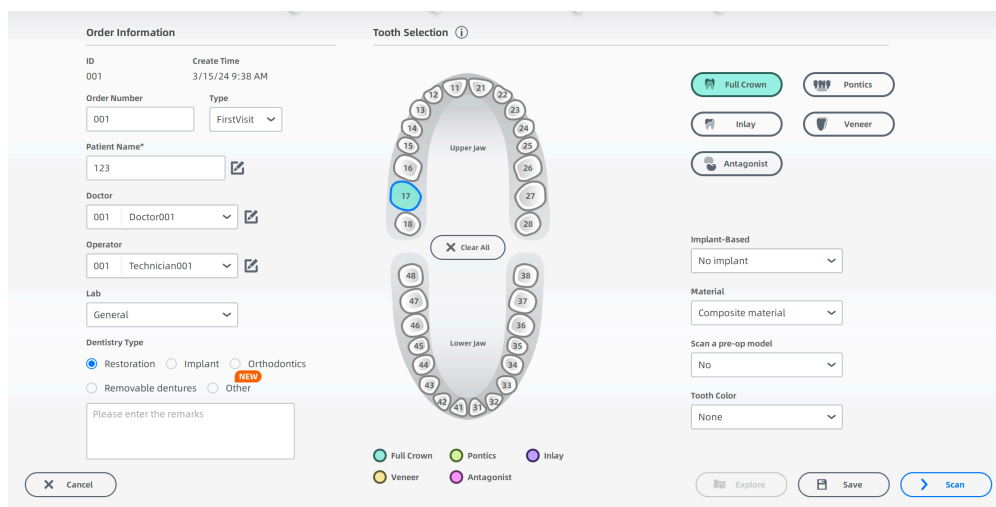
### Calibration

See more details in [Calibration](#).

### Order Creation

After a successful login, you can create a new order or import an order.

Click  on the left to create a new order. You can also select a patient in the patient list and click  to create a new order.



**Order Information**

ID: 001 | Create Time: 3/15/24 9:38 AM

Order Number: 001 | Type: FirstVisit

Patient Name\*: 123

Doctor: 001 | Doctor001

Operator: 001 | Technician001

Lab: General

Dentistry Type:
 

- ☒ Restoration
- ☐ Implant
- ☐ Orthodontics
- ☐ Removable dentures
- ☐ Other

Please enter the remarks

**Tooth Selection**

Upper jaw: 12, 13, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 26, 27, 28

Lower jaw: 48, 49, 46, 45, 44, 43, 42, 41, 38, 37, 36, 35, 34, 33, 32, 47, 46, 45, 44, 43, 42, 41, 38, 37, 36, 35, 34, 33, 32, 47

**Right Panel Settings:**

- Full Crown (selected), Pontics, Inlay, Veneer, Antagonist
- Implant-Based: No implant
- Material: Composite material
- Scan a pre-op model: No
- Tooth Color: None

**Legend:**

- Full Crown (green circle)
- Pontics (light green circle)
- Inlay (purple circle)
- Veneer (yellow circle)
- Antagonist (pink circle)

**Buttons:** Cancel, Explore, Save, Scan

Please fill in related information of the patient and the dentist, select dentistry type and tooth. Then the user can save the order for future use or start scanning.

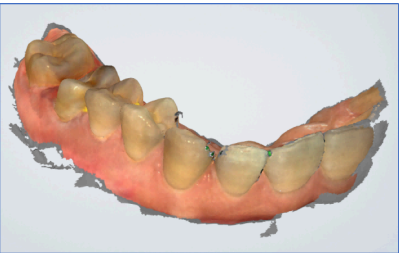
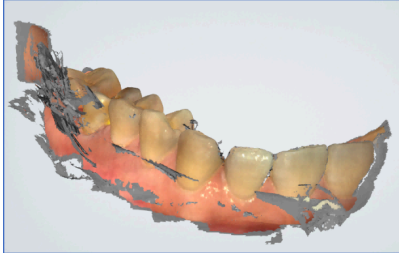
## 5.3 Scanning

### Note:

- Pay attention to the guidance and notes in the software interface.
- If necessary, ask the patient to keep the tongue still and move it to the other side, so as to avoid unnecessary influences.
- Hold the scanner steady on the tooth surface and keep the scan tip window 15 mm away from the teeth.
- When scanning, slowly move the scanner along with the dental arches and simultaneously check the scan results on the screen to ensure high-quality scanning.
- To scan the occlusal surface of the teeth, hold the scanner parallel to it; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45-degree angle.
- Please pay attention to the device and the patient's status. If there are abnormalities or warning messages, please stop scanning immediately and consult the technical support.
- When scanning, change the scanning angle to 35-55 degrees to create overlaps. It is important to achieve an overlap of at least 30% between each acquisition. If the overlap is small, the jaws may fail to align.
- A complete scan data of a single area includes the surfaces of occlusal, lingual, buccal, interproximal contacts of the adjacent teeth, and 2-3 mm buccal gingiva.
- A complete scan data of a single case includes the lower jaw, upper jaw, and bites.

### Scan upper jaw

1. Please ensure that the image of the camera window in the upper left corner of the software is displayed normally. Click  or press the Space key or press the scanner body button to start scanning.

| Function                                                                            | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Enabled during intraoral scanning. When it is enabled, miscellaneous data, including buccolingual data and soft tissues data, will be deleted automatically. When you use the software for the first time, it takes 1~2 minutes to initialize this function.</p> <p>Left image: Function disabled. Right image: Function enabled.</p> <div></div> |

### Note:

- The green box in the middle of the software interface indicates the data range of the current scanning. If the green box turns into red, the scanned position is incorrect. Please move the scanner tip to the position where displayed in the red frame.
- When the scanning is paused or finished, areas which are not been scanned on the model will turn into green. Users can rescan the corresponding areas according to the demand.

2. When the scanning is paused, you can click  to edit data.

3. Once enough data has been scanned, click  or long press the Space key or press the scanner body button to process and save the data.

When it is completed, the upper jaw icon is green and ticked with a , indicating that the scanning process is finished.

## Scan lower jaw

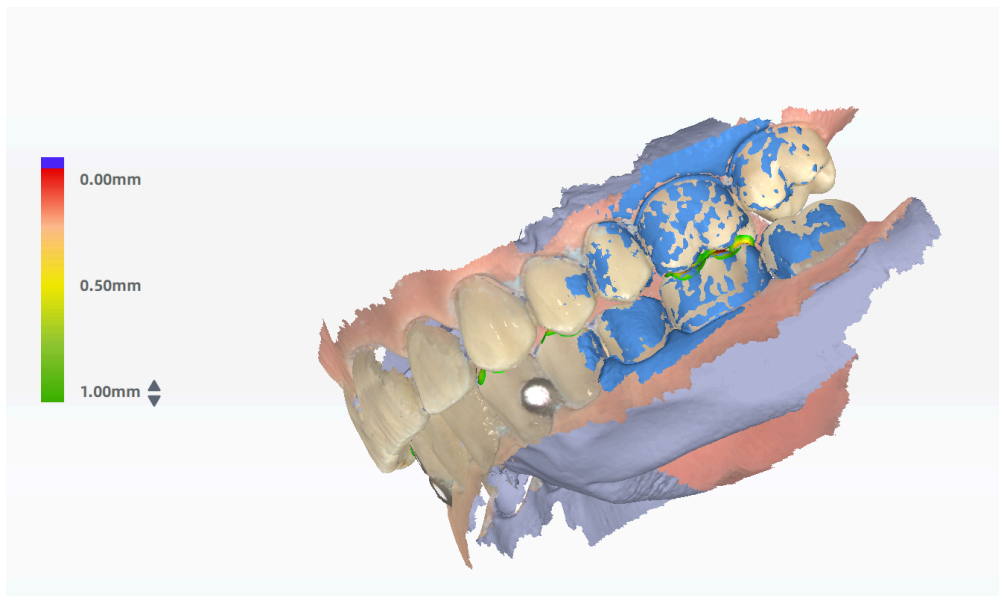
After the upper jaw scanning and the data processing are completed, the lower jaw scanning interface is automatically displayed. The procedure is the same as scanning the upper jaw.

## Scan bite

After the lower jaw scanning and the data processing are finished, the bite scanning interface is automatically displayed.

Click  or press the Space key or press the scanner body button to start scanning. After scanning some data, the software automatically performs dynamic bite alignment.

After the upper jaw and the lower jaw are successfully aligned to the bite, click  or press the Space key to pause the scanning and check the occlusion.



Click  or long press the Space key or the scanner body button for about 3 seconds to post-process the data.

See more details in User Manual.

## Coded scanbody scanning

Coded scanbody scanning is supported. After scanning the jaws and coded scanbody, the software will align the coded scanbody to the jaws.

## 5.4 Scanned data view

View scanned data in IntraoralScan.

### Check jaws

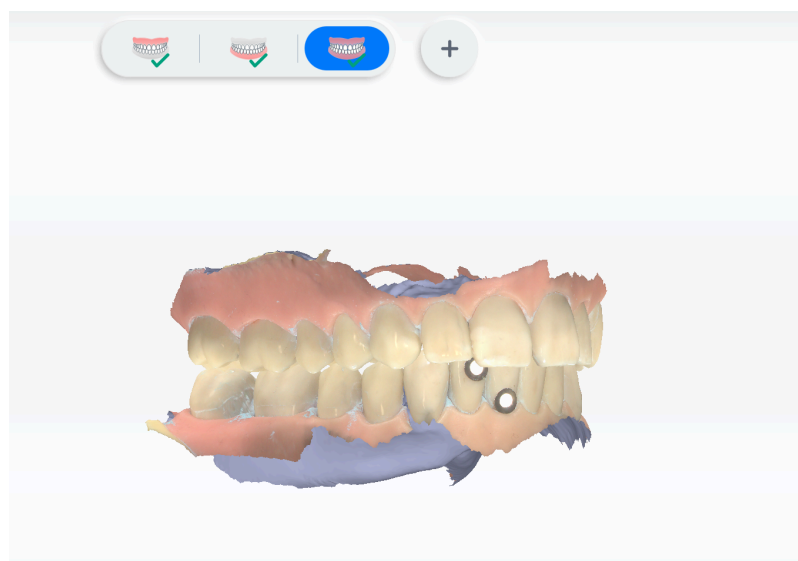


Upper jaw



Lower jaw

### Check the bite



| Name                                                                                                                                        | Description                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Tooth preparation<br/>dynamic depth<br/>monitoring</p> | <p>Tooth preparation is only supported for pre-op orders. By monitoring the prepared tooth, data will be saved during the grinding. It's convenient to compare multiple sets of tooth preparation data to standard model. After creating a pre-op order and scanning the models, click on the right side of the interface and make comparison. Click on the compared models to check the results.</p> |

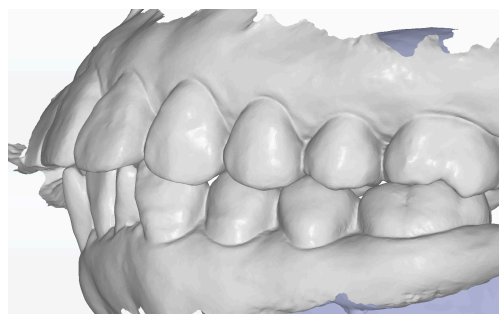
## 5.5 Pre-design

### Texture

View the texture of the model.



Enabled



Disabled

### Smooth

Clean the noise and improve the quality of the model.



Enabled



Disabled

### Bite detection

Click  under the "Pre-design" process to enter the occlusion detection interface.

- The green color indicates there is a distance between the two jaws.
- The red color indicates the touching area between the two jaws.

- The blue color indicates the bite-through area between the two jaws. Double-click on the point of the model to detect the occlusal gap at that point.

## Check undercut

Click  on the right side of the software to open the undercut interface. You can rotate the model to the appropriate view, double-click the view or choose to recalculate undercut area.

## Accudesign

On the pre-design interface, click  to enter the AccuDesign interface. AccuDesign is a model generation software. Use it to generate solid or hollow model out of the scanned data by 3D scanner. You can add attachments to the model, such as text, frame, and drain hole in a convenient way. And then export file for 3D printing. For more details, please check the AccuDesign User Manual.

## Orthodontic simulation

ConsulOS is an orthodontic simulation software specially used in face scan and intraoral scan. The software boasts many features:

- Simulates the face shape and dentition before and after the orthodontic tooth arrangement according to facial and intraoral scanned data.
- Supports a flexible switch between the face model and the tooth model to view different details.
- Improves the texture of teeth to simulate the patient's real intraoral conditions.
- Supports uploading multiple sets of plan and export multiple reports at once.

## Oral health report

When creating a new order, the doctor can select the case as "Check" to generate a report in the pre-design interface. Doctors can know relative information of the patient with the report.

See more details in User Manual.

## 5.6 Order storage and uploading

After scanning, you can check the current storage path of the order and upload it.

Order Information

ID

001

Order Number

001

Create Time

3/15/24 9:38 AM

Doctor

Doctor001

Operator

001 / Technician001

Patient

123

Dentistry Type

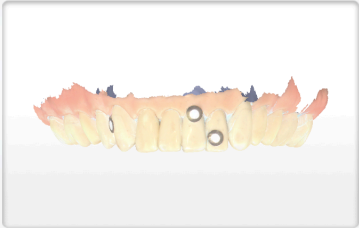
Restoration

Notes

Tooth Preview



Scanned Model



Do you need to send back the data?

☐

Pre-design

Tooth map

| No. | Type       | Tooth Color | Implant-Bas... | Material      |
|-----|------------|-------------|----------------|---------------|
| 17  | Full Crown |             | No implant     | Composite ... |

Send Settings

Target

My Cloud

From

qxrt成都医院

Attachment (Recommendation <50MB)

Institution

Export

Finish

Send

## 6. Storage and Transport

### 6.1 Requirements for daily and long-term storage

- Please store the scanner in a place free of water and moisture.
- Ensure the scanner is disinfected or sterilized and is completely dry before long-term storage.
- Do not store the scanner and accessories in areas of extreme temperatures or under direct sunlight.
- As for the temperature, humidity, and air pressure required during daily and long-term storage, please check the labels on the package.

### 6.2 Requirements for transportation

- Make sure that the scanner is clean before placing it back to the original carry box/package to avoid any possible contamination.
- Place each part of the product, e.g. the tip, scanner body, cradle, power adapter, in the original package carefully.
- Make sure that each cable is rolled up and tangle-free before placing it in the original carry box.
- Before sealing the package box, please make sure that no part of the product is sticking out of the package box.
- As for the temperature, humidity, and air pressure required during the transportation, check the labels on the package.

#### **Caution:**

- If transportation of the scanner is required, it is recommended that the users can retain the original package.
- If the original package is no longer accessible, please wrap all parts of the scanner with bubble wrap to prevent damage during transportation.

# 7. Safety Information

## 7.1 Electrical safety

Only trained medical personnel should operate this scanner. According to the standard *IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, anyone who creates or adjusts a medical electrical system by combining with other devices, is responsible for meeting the following requirements to ensure the safety of patients, operators and the environment, and the product complies with the following standards.

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances– Requirements and tests
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment–Part 1-6: General requirements for basic safety and essential performance–Collateral standard: Usability
- IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 Medical electrical equipment–Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
- IEC 62366-1 2015+AMD1:2020 Medical devices–Part 1: Application of usability engineering to medical devices

## Main safety features of the product

- Type of protection against electric shock: Internal power supply
- The degree of protection against electric shock: Type BF applied part
- Enclosure protection: IPX0
- Degree of protection against incoming liquids: IPX0
- Level of safety when used with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non-AP/APG equipment.
- The mode of operation: Continuous operation
- Nominal voltage:
  - Cradle: 5 V;
  - Battery: DC 3.6 V;
- Input current:
  - Cradle: 3 A;
  - Battery: 5 A;
- Specification of the calibrator:

Nominal voltage: DC 5.0 V; Input current: 900 mA;

- Specification of the charging case:

Nominal voltage: DC 5.0 V; Input current: 2 A;

- Pollution degree: 2

#### **Caution:**

The product supplier can provide the circuit diagram, components list, illustrations, details of correction, or other materials that is necessary to help repair the component specified by the manufacturer.

#### **Warning:**

- To meet waterproof requirements, the sockets should not be placed on the ground.
- The supplied medical power adapter can only be used to connect the grounded outlet.
- To avoid risk of electrical shock hazards, always inspect the scanner and cable connections before use.
- Do not use the scanner when it is around or stacked with other equipment. If it is necessary, please make sure the scanner is working properly.
- Do not use the scanner in an environment with a high concentration of inflammable liquid and gas or oxygen.
- Only authorized technicians can replace internal parts of the scanner and modify the software configuration.
- If the scanner tip or cable is damaged, stop using it immediately and contact technical support to replace it.
- Do not cut, bend, reassemble or squeeze all types of cables in order to prevent the outside insulating material from being damaged, thus leading to a short circuit or even a fire accident.
- To prevent liquid and moisture from infiltrating into the device and lead to a short circuit, do not allow foreign objects (including all types of liquid) to enter the scanner and its cradle.
- The radiation characteristics of the scanner is suitable for use in all locations ,including domestic and direct connection to the residential public low-voltage supply grid for domestic use. (CISPR 11 Class B).

## 7.2 EMC notice

#### **Caution:**

- The scanner meets the EMC requirements.
- Users should install and use the product according to the EMC information provided in the attached file.
- A portable or mobile RF communication device might affect the performance of the scanner. When using the scanner, please keep the scanner away from strong ELECTROMAGNETIC interference, such as a mobile phone or microwave oven.
- The guidance and manufacturer's statement are shown in the attached table.

#### **Warning:**

- With the exception of cables sold by the manufacturer of the scanner as spare parts for internal components, the use of accessories and cables other than those specified may result in an increase in transmission power or a decrease in immunity of scanner.
- If the Essential Performance is lost or degraded due to electromagnetic disturbances, the users will need to stop scanning to wait for the software recovering, and resume scanning after recovery. This process takes no risk to the patient or user and does not affect the scanning data.

#### List of cables

| No. | Name                           | Length |
|-----|--------------------------------|--------|
| 1   | Type-C Cable (For the cradle)  | 1.0 m  |
| 2   | USB Cable (For the calibrator) | 1.5 m  |

#### Essential performance

None.

#### Electromagnetic emissions

Medical electrical equipment, such as the scanner, requires special precautions for electromagnetic compatibility. It must be installed and put into service according to the following electromagnetic tables.

The scanner is intended for use in specified electromagnetic environment. Customers or users of the scanner should assure that it is used in this environment.

| Guidance and manufacturer's statement - Electromagnetic emission                                                                                                                     |            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment: |            |
| Emission measurement                                                                                                                                                                 | Conformity |
| RF emissions CISPR 11                                                                                                                                                                | Group 1    |
| RF emissions CISPR 11                                                                                                                                                                | Class B    |
| Harmonic emissions IEC 61000-3-2                                                                                                                                                     | Class A    |
| Voltage fluctuations/flicker according to IEC 61000-3-3                                                                                                                              | Applicable |

#### Interference Immunity

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

| Guidance and manufacturer's statement - Electromagnetic emission                                                                                                                     |                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment: |                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                        |
| Immunity test                                                                                                                                                                        | IEC 60601 test levels                                                                                                                                                                                                                                  | Compliance level                                                                                                                                                                                                                                       |
| Electrostatic discharge (ESD) IEC 61000-4-2                                                                                                                                          | ±8 kV contact<br>±2, ±4, ±8, ±15 kV air                                                                                                                                                                                                                | ±8 kV contact<br>±2, ±4, ±8, ±15 kV air                                                                                                                                                                                                                |
| Electrical fast transient/burst IEC 61000-4-4                                                                                                                                        | ±2 kV for power supply lines                                                                                                                                                                                                                           | ±2 kV for power supply lines                                                                                                                                                                                                                           |
| Surge IEC 61000-4-5                                                                                                                                                                  | ±0.5, ±1 kV line(s) to line(s)                                                                                                                                                                                                                         | ±0.5, ±1 kV line(s) to line(s)                                                                                                                                                                                                                         |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11                                                                                  | 0% $U_T$ (100% dip in $U_T$ ) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ (100% dip in $U_T$ ) for 1 cycle and 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles At 0°<br>0% $U_T$ (100% dip in $U_T$ ) for 250/300 cycles | 0% $U_T$ (100% dip in $U_T$ ) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ (100% dip in $U_T$ ) for 1 cycle and 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles At 0°<br>0% $U_T$ (100% dip in $U_T$ ) for 250/300 cycles |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8                                                                                                                              | 30 A/m                                                                                                                                                                                                                                                 | 30 A/m                                                                                                                                                                                                                                                 |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.                                                                                                        |                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                        |

### Guidance and manufacturer's statement - Electromagnetic emission

The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:

| Immunity test                                             | IEC 60601 test levels                                                                                    | Compliance level                                                                                                           |
|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Radiated RF EM fields IEC 61000-4-3                       | 3V/m 10V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1 kHz                                                       | 3V/m 10V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1 kHz                                                                         |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V<br>0.15MHz to 80 MHz<br><br>6 V<br>in ISM bands between<br>0.15MHz and 80 MHz<br><br>80% AM at 1 kHz | 3 V<br>0.15MHz to 80 MHz<br><br>6 V<br>in ISM and amateur radio bands<br>between 0.15MHz and 80 MHz<br><br>80% AM at 1 kHz |

### Guidance and manufacturer's statement - Electromagnetic emission

The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strength 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 scanner is used exceeds the applicable RF compliance level above, the scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the scanner.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

#### Signal input/output parts PORT

| Phenomenon and standard                                   | Immunity test levels                                                                                  |                                                                                                                         |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
|                                                           | Professional healthcare facility environment                                                          | Home healthcare environment                                                                                             |
| Electrostatic discharge (ESD) IEC 61000-4-2               | ±8 kV contact<br>±2, ±4, ±8, ±15 kV air                                                               |                                                                                                                         |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V<br>0.15MHz to 80 MHz<br><br>6 V<br>in ISM bands between 0.15MHz and 80 MHz<br><br>80% AM at 1 kHz | 3 V<br>0.15MHz to 80 MHz<br><br>6 V<br>in ISM and amateur radio bands between 0.15MHz and 80 MHz<br><br>80% AM at 1 kHz |

#### Test specifications for enclosure port immunity to proximity magnetic fields

| Test frequency | Modulation                 | Immunity test level |
|----------------|----------------------------|---------------------|
| 30kHz          | CW                         | 8                   |
| 134,2KHz       | Pulse modulation<br>2.1kHz | 65                  |
| 13,56MHz       | Pulse modulation<br>50kHz  | 7.5                 |

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the scanner further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference.

Customers or the users of the scanner should operate the device under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

#### Separation distances

The scanner is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. Based on the maximum output power of the communications equipment, the customers or the users of the scanner can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the scanner, as recommended below.

The medical electrical equipment is suitable for the professional healthcare environment per IEC 60601-1-2. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except near HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging or other environments where the intensity of electromagnetic disturbances is high.

 **Warning:**

- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the scanner, including cables specified by the manufacturer. Otherwise, it could lead to degradation of the performance of this equipment.
- If immunity test level is higher than those specified in IEC60601-1-2, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

## 7.3 Biological safety

The scanner meets the following biological standard:

1. ISO10993-5: 2009 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity)
2. ISO10993-10: 2021 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization)
3. ISO10993-23: 2021 (Biological evaluation of medical devices — Part 23: Tests for irritation)

## 7.4 Laser protection



This product is a class 1 laser product and is only for maintenance, replacement and removal by professional personnel of the manufacturer or its designated agent (if necessary). If the device is not used, please disassemble the scanner or replace components as required. Otherwise, the scanner may not work properly and laser radiation may occur. If a laser component is faulty, please contact the manufacturer for help.

This product is a class 1 laser product according to "IEC 60825-1:2014 Safety of laser products-Part 1: Equipment classification and requirements". This product doesn't have harmful laser radiation. Users will not be exposed to laser radiation if they operate this product correctly according to the Instructions.

Users should be aware of optical radiation protection. Bright light is projected from the scanner tip during scanning. As with other light, there may be a temporary reduction in vision or visual residuals. Do not look directly into the light projected by the scanner tip or shine the light into the eyes of others.

## 7.5 Explosion prevention

- Do not charge the battery for a long time.
- Do not reverse the positive (+) and negative (-) terminals.
- Do not directly solder the battery terminals.
- Do not disassemble the battery and the charging case at will.
- Do not put the battery into a fire or apply direct heat to it.
- Do not place the battery in a microwave oven or pressurized container.
- Do not use or store the battery near sources of heat such as a fire or heater.
- Do not short-circuit the battery by connecting wires or other metal objects to the positive (+) and negative (-) terminals.
- Do not connect the battery directly to wall outlets or car cigarette-lighter sockets.
- Use the battery and the charging case supplied with the device. Do not change them at will.
- Replace the battery shell if it's damaged to prevent leak or fire accident.
- Do not put any objects on the charging case when it's charging the battery, in order to keep good ventilation and heat dissipation.
- Do not connect the charging case with power for a long time. Cut off the power after using the charging case to avoid safety hazards.
- Store the battery and the charging case in an environment that is clean, dry, and free of inflammable materials like powder, liquid, and metal scraps.
- Do not use the battery if it gives off an odor, generates heat, becomes discolored or deformed, or appears abnormal in any way. If the battery is in use or being recharged, remove it from the device or charger immediately and discontinue use.

## 8. Specifications

### 8.1 Specifications of the scanner

| Parameter  | Description              |
|------------|--------------------------|
| Type name  | Intraoral scanner        |
| Model name | Aoralscan Elite Wireless |

| Scanner                |                                                               |
|------------------------|---------------------------------------------------------------|
| Scanning depth         | 22 mm (-2 mm ~ 20 mm away from the window of the scanner tip) |
| Scanner size (L×W×H)   | 247±4 mm × 38±1 mm × 37±1 mm (with a standard tip)            |
| Scanner weight         | 194±15 g (with a standard tip and battery)                    |
| Scanner tip connection | Pluggable                                                     |
| Light source           | LED and laser                                                 |
| Wave length            | Blue laser: 450±10 nm<br>White LED: 400 nm-780 nm             |
| Output                 | STL、OBJ、PLY                                                   |
| Device Lifetime        | 8 years                                                       |

| Scanner tip                             |                                                                                                                                                    |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Scanner tip types                       | Big scanner tip, standard scanner tip and mini scanner tip                                                                                         |
| Scan field(L×W)                         | Big tip: 19 mm × 14 mm<br>Standard tip: 16 mm × 12 mm<br>Mini tip: 12 mm × 9 mm                                                                    |
| Scanner tip dimensions(L×W×H)           | Big scanner tip: 95±2 mm x 30±1 mm x 26±1 mm<br>Standard scanner tip: 93±2 mm x 30±1 mm x 26±1 mm<br>Mini scanner tip: 92±2 mm x 30±1 mm x 26±1 mm |
| Front end dimensions of the scanner tip | Big scanner tip: 23.0±1 × 18.0±1 mm<br>Standard scanner tip: 20.6±1 × 16.0±1 mm<br>Mini scanner tip: 17.7±1 × 14.3±1 mm                            |
| Scanner tip weight                      | Big scanner tip: 18.5±3 g<br>Standard scanner tip: 16.5±3 g<br>Mini scanner tip: 15.5±3 g                                                          |
| Scanner tip maintenance                 | Sterilized and disinfected by users (Maximum: 100 times)                                                                                           |

| Cradle              |                               |
|---------------------|-------------------------------|
| Cradle size (L×W×H) | 119±3 mm × 93±2 mm × 101±2 mm |
| Cradle weight       | 340±50 g                      |

| Calibrator              |                              |
|-------------------------|------------------------------|
| Calibrator size (L×W×H) | 236±3 mm × 50±2 mm × 50±2 mm |
| Calibrator weight       | 431±30 g                     |

| Battery         |                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Battery type    | Rechargeable lithium-ion battery                                                                                                  |
| Nominal voltage | 3.6 V                                                                                                                             |
| Capacity        | 3250 mAh                                                                                                                          |
| Cycle life      | ≥400 cycles<br>(After 400 cycles of charging and discharging, the battery capacity is not less than 80% of its original capacity) |

## 8.2 Environmental requirements

### Operating and storage requirements

|                                     | Requirement                            |
|-------------------------------------|----------------------------------------|
| Operating temperature               | 10°C ~ 30°C (Recommended: 20°C ~ 30°C) |
| Operating Relative humidity         | 30%RH ~ 80%RH                          |
| Storage/Transport temperature       | -30°C ~ 60°C                           |
| Storage/Transport/Relative humidity | 30%RH ~ 90%RH                          |
| Air pressure                        | 70 kPa ~ 106 kPa                       |

### Battery storage requirements

| Storage time                     | Storage temperature |
|----------------------------------|---------------------|
| Short-term(less than 1 month)    | -20°C ~ 45°C        |
| Middle-term(1 month to 3 months) | -20°C ~ 35°C        |
| Long-term(3 months to 12 months) | -10°C ~ 25°C        |

- Relative humidity: 30%RH ~ 75%RH

# Appendix

## Wireless Compliance Notification

| Symbol                                                                            | Explanation                                                             |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|  | Japan Ministry of Internal Affairs and Communications Certificate (MIC) |
|  | Taiwan China National Communications Commission Certificate (NCC)       |
|  | Korea Certification (KC)                                                |

## FCC Compliance Statement

This device complies with the Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference;
2. This device must accept any interference received, including interference that may cause undesired operation.
  - The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.
  - This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    - Reorient or relocate the receiving antenna.
    - Increase the separation between the equipment and receiver.
    - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
    - Consult the dealer or an experienced radio/TV technician for help.

- This device complies with FCC radiation exposure limits set forth for an uncontrolled rolled environment. Cradle should be installed and operated with a minimum distance of 20cm between the radiator and your body (For the Cradle Only).
- This device for operation in the band 5150-5250 MHz is only for indoor use (For the Scanner Body and Cradle Only).

## ISED

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.
3. This equipment complies with RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body (For the Cradle Only).
4. The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems (For the Scanner Body and Cradle Only).

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement."
3. Pour se conformer aux exigences de conformité d'exposition RF du CNR 102, une distance de séparation d'au moins 20 cm doit être maintenue entre l'antenne de cet appareil et toutes les personnes.(pour berceau seulement)
4. L'appareil fonctionnant dans la bande 5150-5250 MHz est réservé uniquement à un usage interne afin de réduire le risque d'interférence nuisible aux systèmes satellites mobiles utilisant les mêmes canaux. (pour corps de Scanner et berceau seulement)

## NCC

無線操作特殊警示說明：

- 取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前述合法通信，指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。應避免影響附近雷達系統之操作。

## MIC

本機器は電波法に基づく工事設計認証を取得しています (技適マークが付いています) 5GHz 帯:W52/W53 屋内使用限定 (ただし登録局に接続される場合は除く)



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