

# Ori 3.0

## INTRAORAL SCANNER

### User Guide

Ori 3, intraoral scanner Instructions for use

© Ori, Inc.

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Pleasant Grove, UT 84062

Phone 801.367.2189

## For your information

Thank you for purchasing Ori, Inc. Ori 3 Intraoral Dental Scanner. Our Systems are the result of years of engineering, research, and development into producing consistent, high-quality devices.

This manual contains the instructions for safely using, cleaning, sterilizing, and maintaining the Ori System. Before using the Ori System, please thoroughly read the information contained in this manual, and keep it in a safe and accessible area. If you have any questions or comments about the Ori System or this manual, please contact Ori, Inc. customer service at: 801.367.2189.

Ori is a registered trademark of Ori, Inc. All images, text and descriptions are the intellectual property of Ori, Inc. and may not be reproduced or electronically distributed without written permission from the copyright holder.

## Definitions

**WARNING:** A warning indicates that the personal safety of the patient or physician may be compromised. Disregarding a warning may result in serious injury to the patient or physician. XE "Definitions:WARNING" XE "WARNING"

**Caution:** A caution indicates that the device may be damaged if the caution is disregarded. XE "Definitions:Caution" XE "Caution"

*Note: A note provides additional information regarding the safe operation of the instrument.*

## Warranty

Repairs, changes, or expansions which are not carried out by Ori, Inc. or by experts authorized by Ori, Inc. will invalidate all guarantees regarding the correct functioning of equipment or instruments which have been repaired by unauthorized third parties.

**Caution:** If the system has just been delivered from a cold environment, allow it to adjust to room temperature to avoid fogging the lens and to allow for proper calibration.

*Note: Any damage to the device resulting from incorrect operation is not covered by the manufacturer's warranty.*

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## Table of Contents

|                                       |    |
|---------------------------------------|----|
| For your information                  | i  |
| Definitions                           | i  |
| Warranty                              | i  |
| 1.0 Getting Started                   | 5  |
| Essential Performance                 | 6  |
| .....                                 | 6  |
| Product Labeling Symbols              | 7  |
| Ori Controls                          | 7  |
| Button Mode Indicators                | 8  |
| Ori Reusable Tip                      | 9  |
| Indications                           | 9  |
| 2.0 Setup and Installation            | 6  |
| Unpacking the Equipment               | 11 |
| What's Inside the Package             | 11 |
| Technical Specifications              | 11 |
| Computer Requirements                 | 12 |
| Setting up the Ori System             | 13 |
| 3.0 Quick Start Overview              | 14 |
| Creating a Patient Script             | 15 |
| Creating a New Case                   | 16 |
| Creating a Lab Order                  | 17 |
| Creating Scan                         | 18 |
| Scan Path                             | 20 |
| Taking a Scan                         | 22 |
| Bite Registration                     | 23 |
| Submitting Lab Cases                  | 28 |
| 4.0 Safety and Warnings               | 31 |
| Standard System Warnings and Cautions | 31 |
| Software Warnings and Cautions        | 31 |
| Training                              | 31 |
| Equipment Failure                     | 32 |

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|  |    |
|--|----|
| Mechanical Hazards                                   | 32 |
| Explosion Hazards                                    | 33 |
| Electrical Safety                                    | 33 |
| Eye Safety   | 36 |
| Hygiene  | 36 |
| Safety when Scanning                                 | 37 |
| Protection from Overheating                          | 37 |
| Environmental Conditions                             | 38 |
| 5.0 Cleaning, Disinfection, Maintenance and Disposal | 40 |
| Cleaning and Sterilizing the Scanner Tip             | 40 |
| Cleaning and Sterilizing Procedure                   | 42 |
| Cleaning and Disinfecting Other Parts of the System  | 42 |
| Additional Cleaning if Scan Quality is Poor          | 43 |
| Disposal of the Scanner Tip                          | 43 |
| Disposal of the Ori System                           | 43 |
| Technical Maintenance                                | 44 |
| Environmental Considerations                         | 44 |
| 6.0 EMC/EMI Tables                                   | 46 |

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Chapter

1

## 1.0 Getting Started

Ori, Inc. (hereafter referred to as Ori) thanks you for purchasing the Ori 2 Intraoral Scanner (hereafter referred to as Ori 2). This Guide describes the steps installing, using, and cleaning the Ori 2 as well as handling dental impressions. Conventions used in this Guide are described below.

**WARNING:** A warning indicates that the personal safety of the patient or physician may be compromised. Disregarding a warning may result in serious injury to the patient or physician. XE "Definitions:WARNING" XE "Definitions:WARNING" \t "See WARNING"

**Caution:** A caution indicates that the device may be damaged if the caution is disregarded.

*Note:* A note provides additional information regarding the safe operation of the instrument. XE "Definitions:Caution" \t "See Caution"

*Note:* The symbols and images in the manual are representations and may not match the images of your specific device. XE "Definitions:Caution" \t "See Caution"

## **Essential Performance**

### **Intended Use**

The Ori 2 is an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation. The three-dimensional (3D) model generated from the scan may be further used for the design and manufacturing of dental restorations.

### **Contraindications**

The Ori 2 scanner is not indicated for orthopedics or any indication beyond dentistry.

### **Physical description and mechanism of action**









The Ori 2 scanner is an optical system intended to obtain 3D images of the topographical characteristics of teeth. The system consists of a computer, proprietary software and a handheld dental “wand” for scanning the surface of the teeth. There is a removable tip on the wand which is changed between patients to prevent cross contamination.









Using the wand in close proximity to the teeth, the image of the teeth is communicated to the software and a 3D model is created by the software. The 3D model is then stored on disk along with pertinent patient information.

The scanning wand is a handheld optical device that captures high-resolution video images, in real time, as the patient is being scanned. The wand contains an optical system consisting of low intensity light emitting diodes (LEDs), a light sensor, a lens and supporting electronics. The wand is connected to the computer via a high-speed USB-C data transfer cable. The wand is designed to be easily maneuvered inside the patient's mouth and captures video imagery at 20 frames per second. Those images are converted to 3D data sets and displayed in real time.

*Note: The essential performance described above Is for EMC purposes. There Is no unacceptable risk to the operator or patient based on degradation of essential performance.*

## Product Labeling Symbols

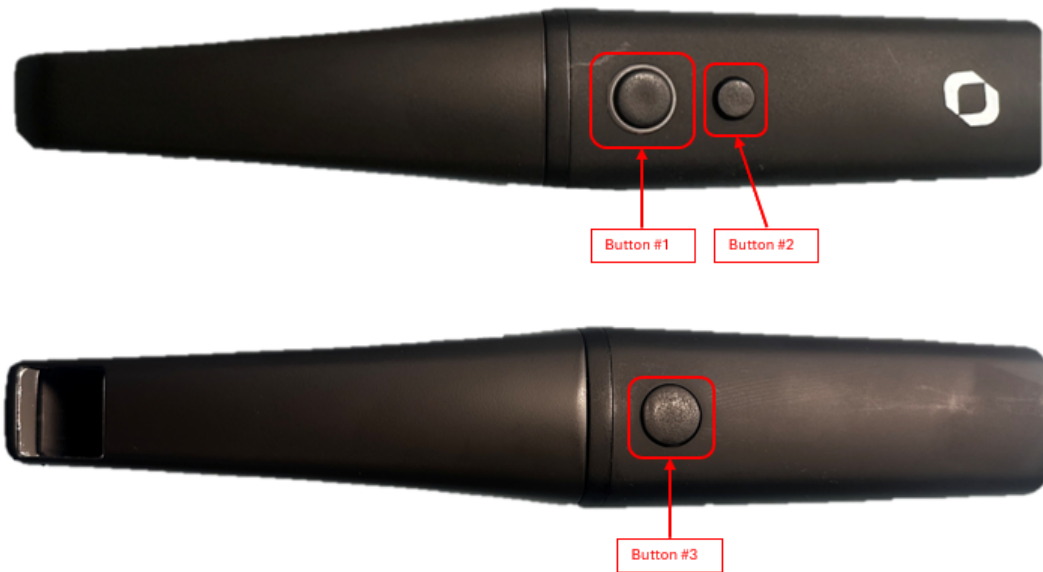
|  |  |
|--|--|
|  ORI, Inc | (01)00860008859549   |
| 1064 S North County Blvd #430  | (21)00101  |
| Pleasant Grove, UT 84062   |    |
| MODEL# Ori 3 Scanner   |    |
|  00101    |   IPX1  |
| Assembled in USA   |  |

| Table 1. Product Labeling Symbols   |  |
|---|--|
| Symbol  | Description  |
|    | Type B Applied Part  |
|  | Refer to instruction manual  |
|  | Manufacturer   |
|  | Serial number  |
|  | Federal law restricts this device to sale by or on the order of a physician. This symbol is located on the Product Identification Label. |
|  | Do not dispose of electronic products in the general waste stream  |
|  | Unique Device Identifier (QR Code). The code in this table does not match the code on your device.                                       |
|  | Class II electrical equipment  |

## Ori Controls

The Ori scanner is USB powered; it automatically turns on when the system is connected to laptop via USB 3.0 and software has been initialized. The Ori scanner is operated by 3 button controls to start/stop scan or advance to the next function.

Figure 1. Location of camera controls



**Control Buttons:**

Button 1 & 3: Start / Stop Scanning

Button 1 & 3: Long press enters remote control interface

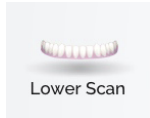
Button 2: Advance through workflow (Hands free button)

Button 2: Long press rotates 3D model

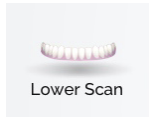
**Caution: Do not coil the cable around the body of the scanner. Coiling the cable in tight loops can result in damage to the internal electronics.**

**Caution: The Ori Scanner should be placed in the Ori Docking Station when not in use.**

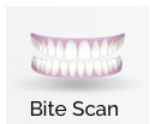
## Button Mode Indicators



Upper scan



Lower scan



Bite registration mode

## Ori Reusable Tip

The Ori 3 has a single tip designed to image downward facing. The tips are designed to be removed and autoclaved between uses. See section 8 of this Guide for more information.

## Indications

The Ori dental scanner supports the following indications:

- Implants (single abutments)
- 3-Unit implant bridges
- Inlays
- Onlays
- Orthodontics
- Post and core
- Single crowns
- Up to 5-unit bridges
- Veneers

Chapter

# 2

## 2.0 Setup and Installation

### Unpacking the Equipment

Examine the packaging for any shipping damage. Carefully unpack the system components and access the Ori components from their packaging. Check for any missing items. If your device is damaged due to shipping or any items are missing, please contact Ori Customer Service immediately.

**Caution: If the system has just been delivered from a cold environment, allow it to adjust to room temperature to avoid fogging the lens and to allow for proper calibration.**

**Caution: Inspect all parts of the system for physical damage, loose fasteners and cables, or signs of wear that could compromise proper use and device function.**

### What's Inside the Package

| Table 1. What's Inside the Package    |   |
|---------------------------------------|---|
| <b>Ori 3 Intraoral Scanner</b>        | Ori Intraoral Scanner   |
| <b>Ori 3 Laptop Computer</b>          | Control Computer  |
| <b>Scanner Tips</b>                   | Three (3) Scanner tips are included with the device                                     |
| <b>Computer Mouse</b>                 | Bluetooth computer mouse  |
| <b>Ori 3 Docking Station</b>          | Machined Aluminum / Silicone Cushion Docking Station                                    |
| <b>Ori 3 Scanner Protective Cover</b> | Protective scanner cover attaches to the scanner to keep optics clean from dust, debris |
| <b>Ori 3.0 USB Cable Assembly</b>     | Used to transfer the output signal from the scanner to the PC.                          |

### Technical Specifications

| Table 2. Technical Specifications |  |
|-----------------------------------|--|
| <b>Light Source</b>               | Ori uses LED light source. Do not view directly with optical instruments. The product complies with EN (IEC) 62471 (Photobiological safety of lamps and lamp systems). |
| <b>Sterilization Method</b>       | Scanner tips are autoclavable.   |
| <b>Power Input</b>                | Computer USB 3.2 Power 5 VDC, 900 mA   |

| <b>Table 3. Installing the Ori Dental Scanner Hardware</b> |                                  |                                   |
|--|----------------------------------|-----------------------------------|
| <b>Cable/Component</b>                                     | <b>Connects (first location)</b> | <b>Connects (second location)</b> |
| Device Mount   | To dental tray                   | Photo of Ori in mount.            |
| Ori 3 Cable  | Ori 3                            | Computer                          |
| Computer Power Supply                                      | Computer                         | 100-120 VAC Wall Outlet           |

| <b>Table 4. Applied Parts</b> |                       |  |
|-------------------------------|-----------------------|--|
| <b>Component</b>              | <b>Classification</b> | <b>Description</b>                                   |
| Scanner Tip                   | Type B                | No electrical contact with Patient and maybe earthed |

| <b>Table 5. Computer System Requirements</b> |   |  |
|--|---|--|
| <b>Item</b>                                  | <b>Recommended</b>  | <b>Minimum</b>                                 |
| CPU  | Intel Core i7-12700H /AMD Ryzen 7 6800H)                      | Intel Core i7-10750H /AMD Ryzen™ 7 PRO 4750U   |
| RAM  | 16 GB   | 16 GB  |
| Operating System                             | Windows 10/11 64bit Home/Pro/Corporate Edition                | Windows 10/11 64bit Home/Pro/Corporate Edition |
| USB Port                                     | Type-C, USB 3.0 or above                                      | Type-C, USB 3.0 or above                       |
| Video Card                                   | NVIDIA GeForce 3060 or above graphics with 6G or more memory) | NVIDIA GeForce 1660GTX or above, more than 6G  |
| Regulatory (Computer & Power Supply)         | Must meet IEC 62368-1 or IEC 60950-1                          | Must meet IEC 62368-1 or IEC 60950-1           |

### **Users of the Ori 3**

The Ori 3 may be operated only by trained dental professionals and qualified personnel. Using the Ori 3 for any purpose other than the “intended use” described above may damage the Ori 3 and harm operators and patients. Proper use of the Ori 3 includes following the operation and maintenance instructions, and observing warnings and caution descriptions in this user guide.

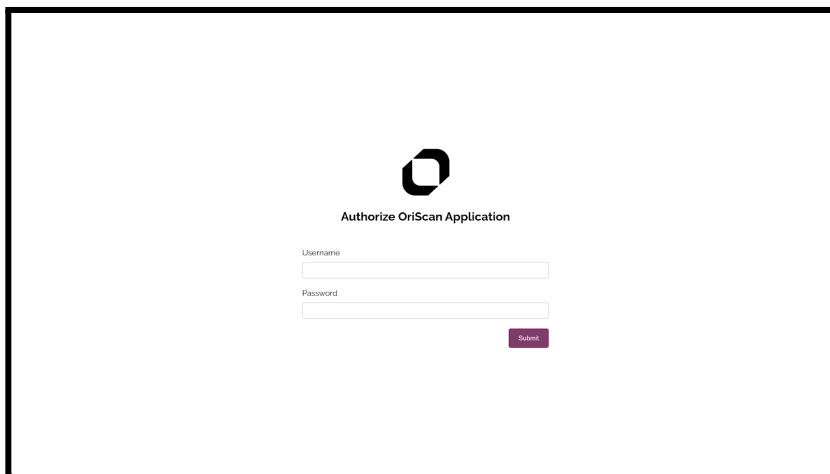
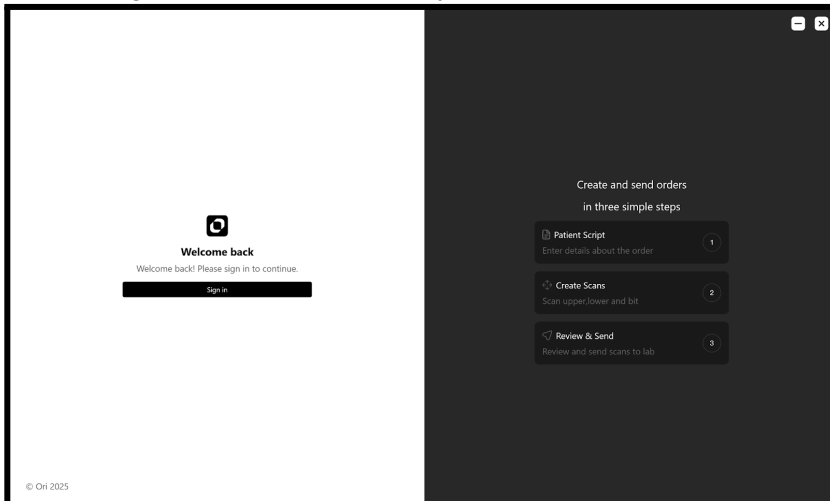
**WARNING:** The laptop computer is intended to be plugged into a proper wall socket during use. The Ori 3 scanner is not intended to be operated under computer battery power.

3

## 3.0 Quick Start Overview

### Ori Dental Scanner Overview

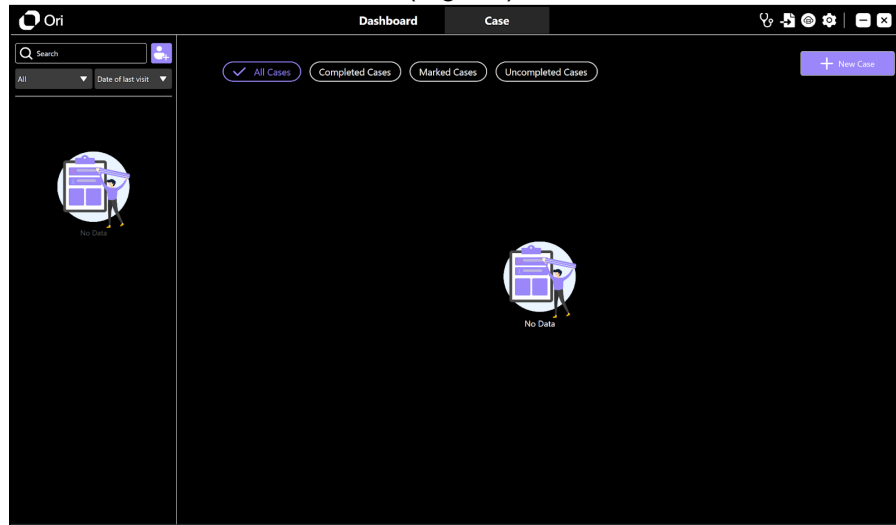
1. Login to Windows.
2. Locate and select the  icon on the desktop of the laptop.
3. Login to the software with your Ori username and password credentials.



## Creating a New Patient

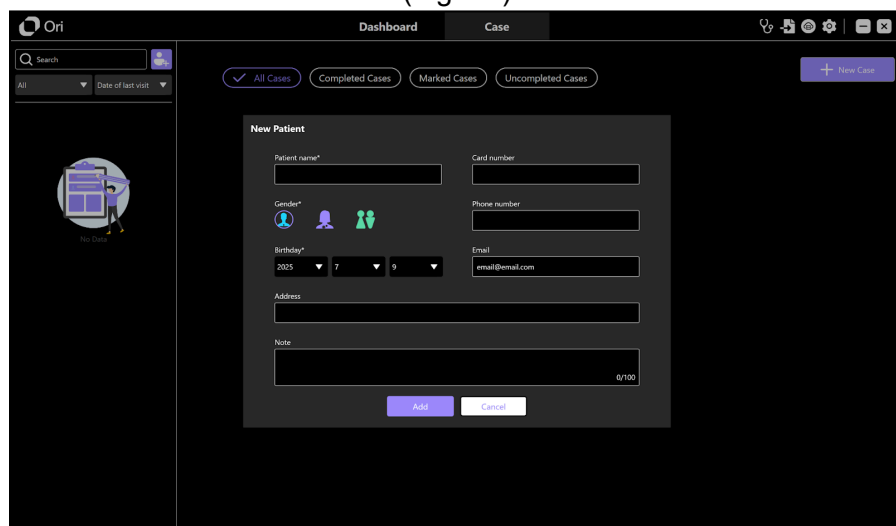
1. Select the purple “new patient” icon as shown in (Fig 1.1).

(Fig 1.1)



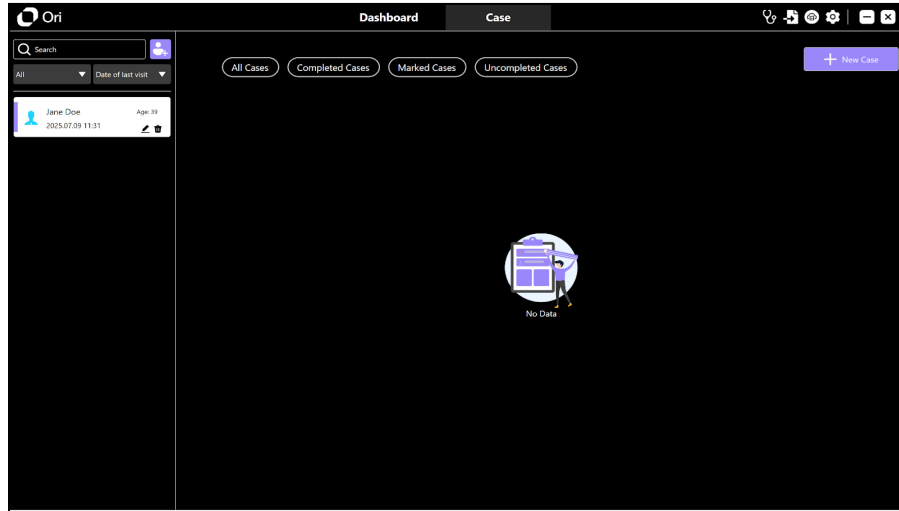
2. Enter the Patient’s name and any other relevant information. When completed select “Add” as shown in (Fig.1.2).

(Fig 1.2)



- Once the patient record has been created, it will be stored to the left of the screen under the patient search bar as shown in (Fig 1.3).

(Fig 1.3)



## Creating a New Case

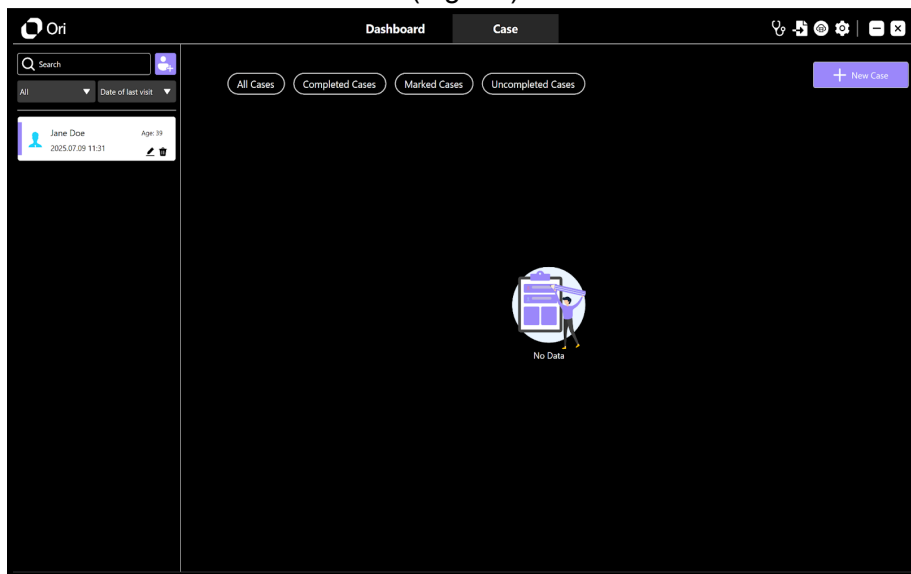
- To create a “New Case”, follow these steps as shown in (Fig 1.4).

**Step 1.** Select the patient to the left of the screen.

**Step 2.** Select the “New Case” icon to the right of the screen.

**Note:** To search for a patient, type in the Patients first and last name in the search bar.

(Fig 1.4)



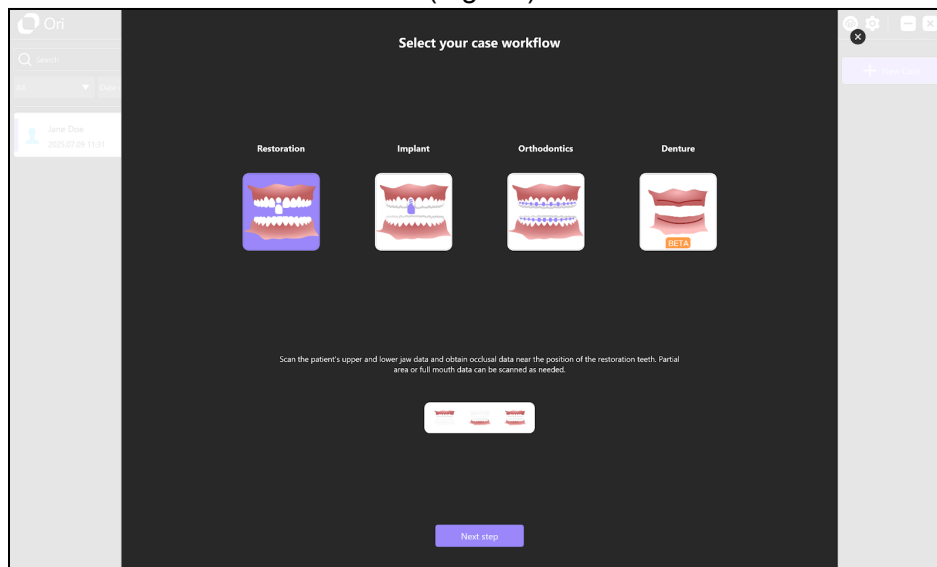
## Creating a Workflow

5. Select your “Case Workflow” from one of the following options as shown in (Fig 1.5).

1. **Restoration**
2. **Implant**
3. **Orthodontics**
4. **Denture**

Select (Next Step)

(Fig 1.5)



## Creating a Lab Order

6. Create a “Lab Order” by following the next steps.

**Step 1.** Select teeth by clicking on the teeth on the chart as shown in (Fig 1.5).

**Step 2.** Select the dentist.

- a. Under the doctor section, select the pen next to the dropdown menu. Doing so will allow you to add and save the dentist information for later use. This option is also available for dental assistants.

(Fig 1.5)



**Step 3.** Enter any comments related to the case in the comments section.

**Step 4.** Select “Save” to continue.

**As shown in (Fig 1.6)**

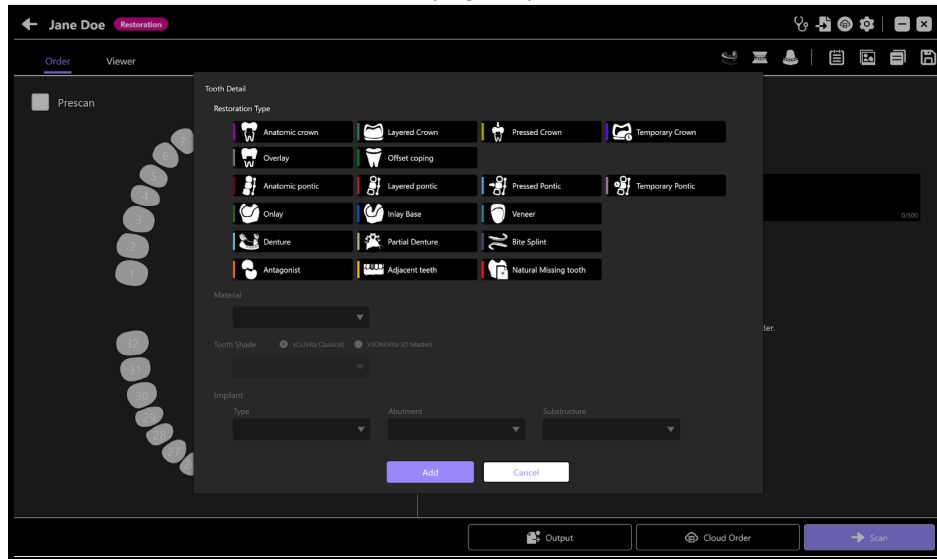
**Step 5.** Select a restoration by choosing one of the list of options.

**Step 6.** Use the dropdown menu to select a material from the list of options.

**Step 7.** Use the dropdown menu to select a shade from the list of options.

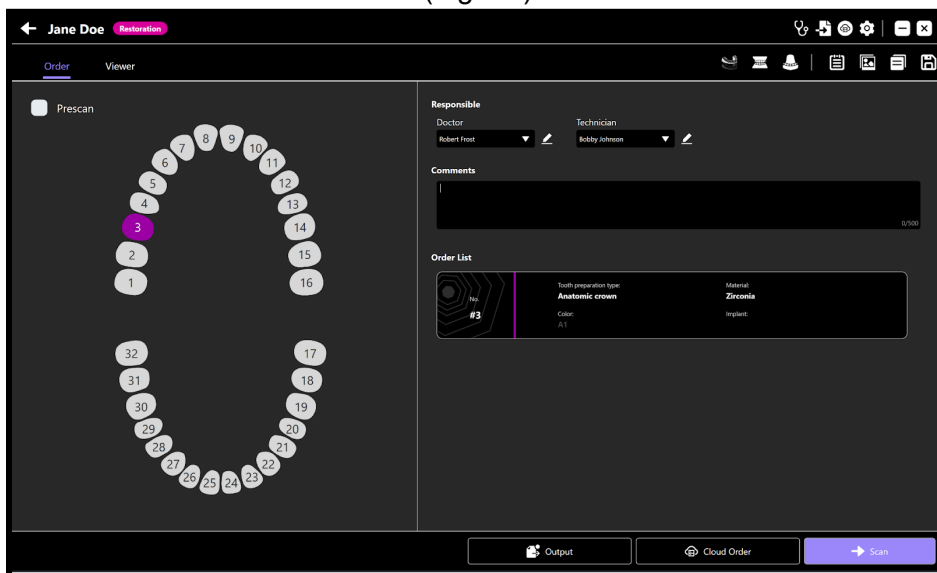
**Step 8.** Select “Add” to continue.

(Fig 1.6)



7. Double check to ensure the lab script is filled out completely and select “scan” as shown in (Fig 1.7).

(Fig 1.7)



## Creating Scans

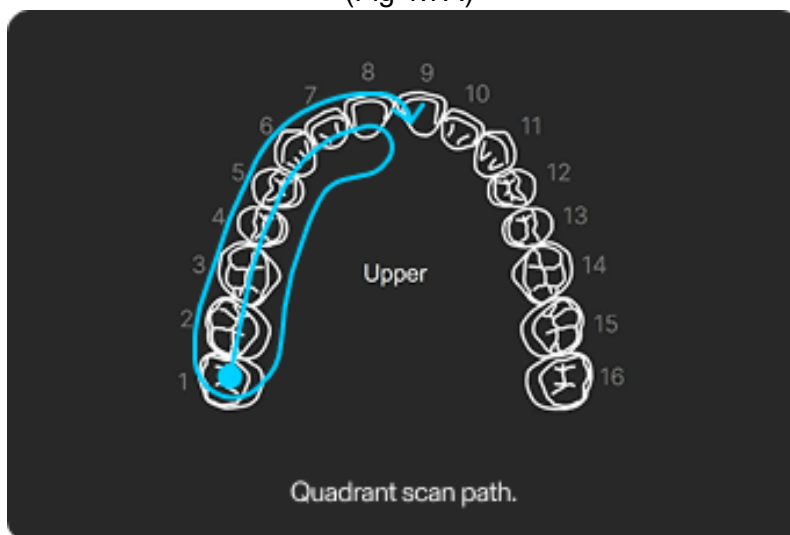
8. Select “Scan” as shown on (Fig 1.7) to move on to the scan page.

(Fig 1.7)



9. Prior to scanning, determine your scan path as seen in Figure 1.7A and Figure 1.7B.
- a. **Quadrant Scan Path** (Fig 1.7A)
- Start on the furthest molar and scan the occlusal surface.
  - Once you reach the midline rotate to the lingual and scan distally.
  - Slow roll over the furthest molar and wrap to the buccal and scan to the midline
  - Scan over any holes or voids.

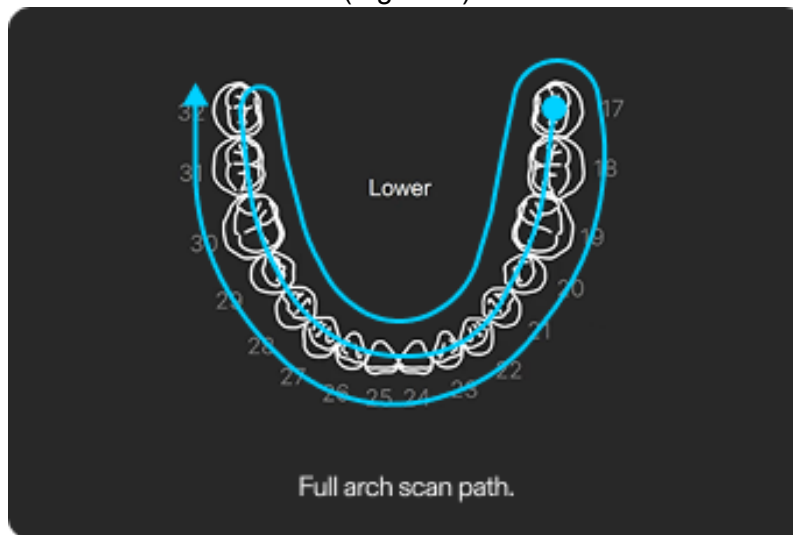
(Fig 1.7A)



**b. Quadrant Scan Path (Fig 1.7B)**

- i. Start directly on the furthest molar and complete a full arch occlusal scan.
- ii. Rotate lingually and complete full arch scan.
- iii. Rotate to the buccal and complete a full arch buccal scan.
- iv. Scan over any holes or voids.

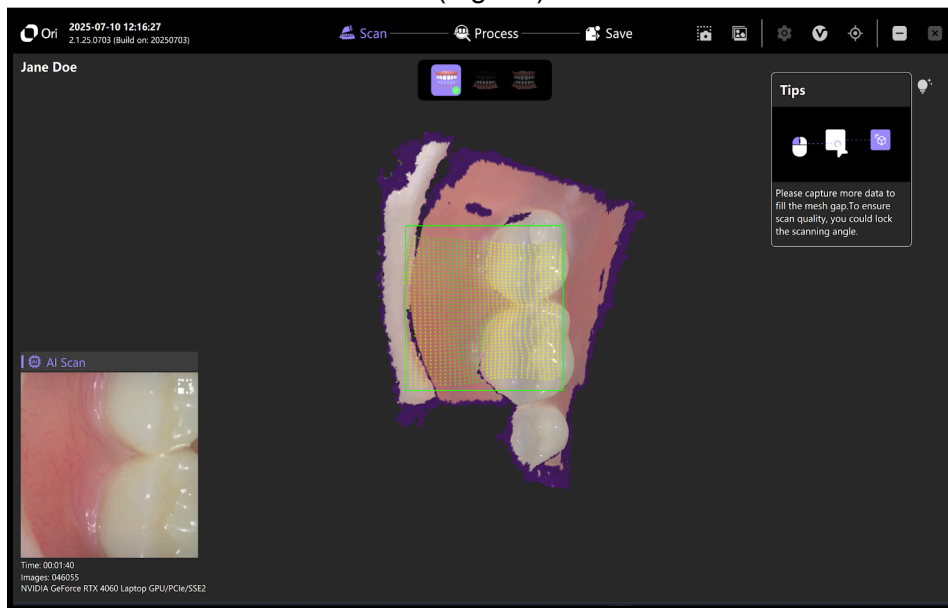
(Fig 1.7B)



10. To initiate the scan, do a quick press of the start button located on the top or the bottom of the scanner. Complete the recommended scan path for either a quadrant or full arch scan. Make sure to maintain a target distance of 5mm with a max distance of 15mm from the teeth being scanned.

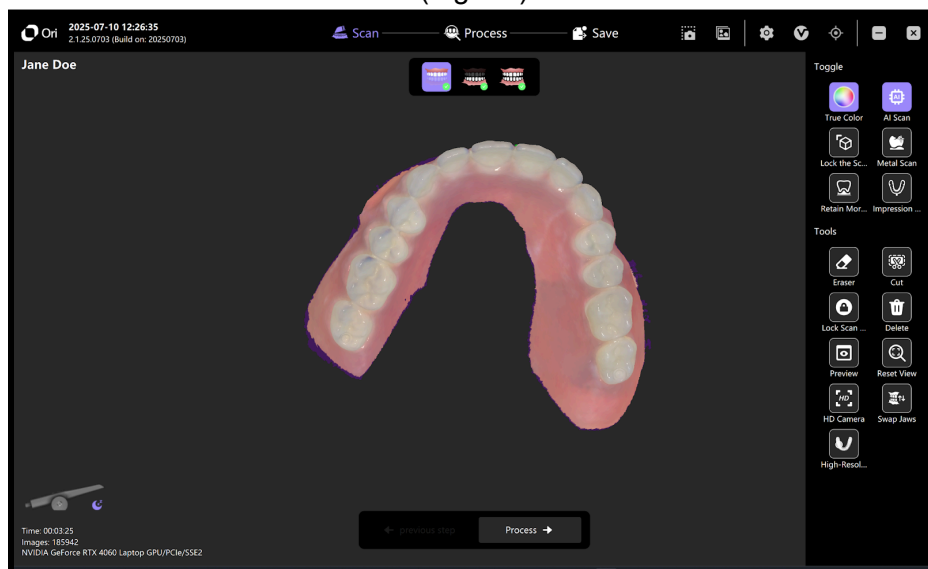
## Taking The Scans

(Fig 1.8)

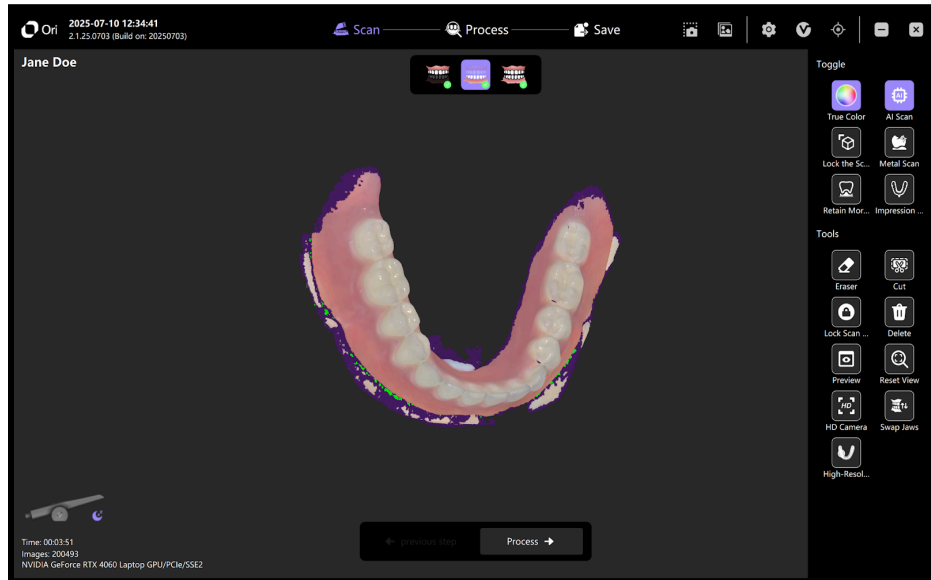


11. Once you have completed a scan, quickly press the mode button located on the top of the scanner under the start button. Doing this will allow you to proceed to the next step (arch).

(Fig 1.9)



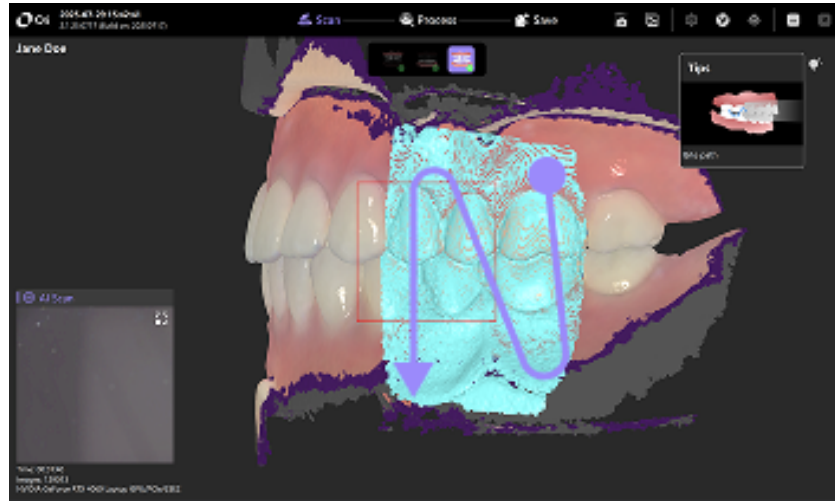
## 12. Scanning the opposing arch.



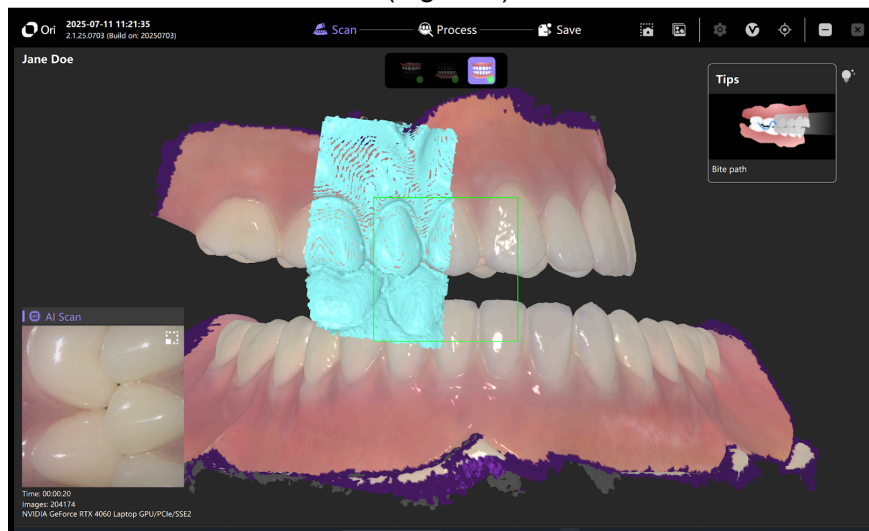
## Bite Registration

13. Once both arches are scanned, do a quick press of the mode button to proceed to the bite registration. To complete the bite registration follow these steps.
  - i. Step 1. Have the patient open and place the scanner in the patient's mouth.
  - ii. Step 2. Use the scanner to retract the patient's cheek.
  - iii. Step 3. Have the patient lightly bite together until the teeth are in occlusion.
  - iv. Step 4. Place the scanner 5mm away from the buccal teeth and activate the scanner by quickly pressing the start button.
  - v. Step 5. Without rotating the scanner, start on the maxillary teeth and scan in a "S" pattern moving downward to the mandible and back up to the maxillary as shown on (Fig 1.8).

(Fig 1.8)

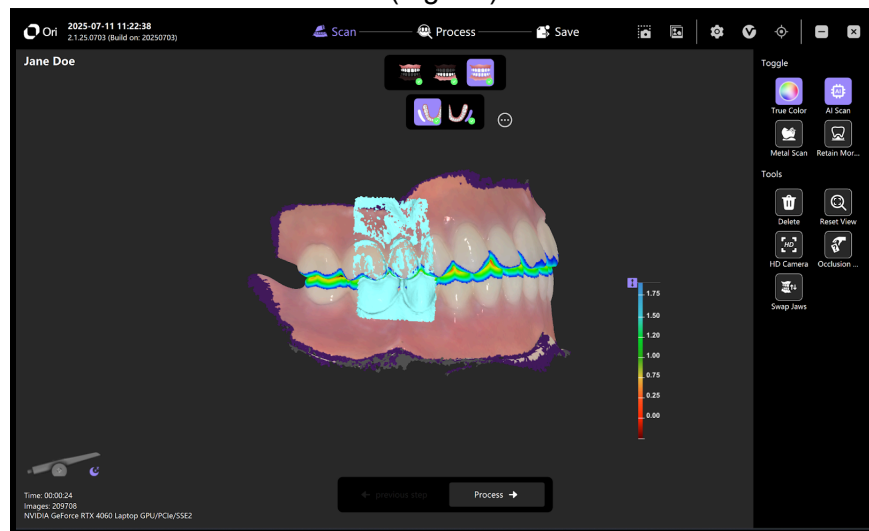


(Fig 1.8a)



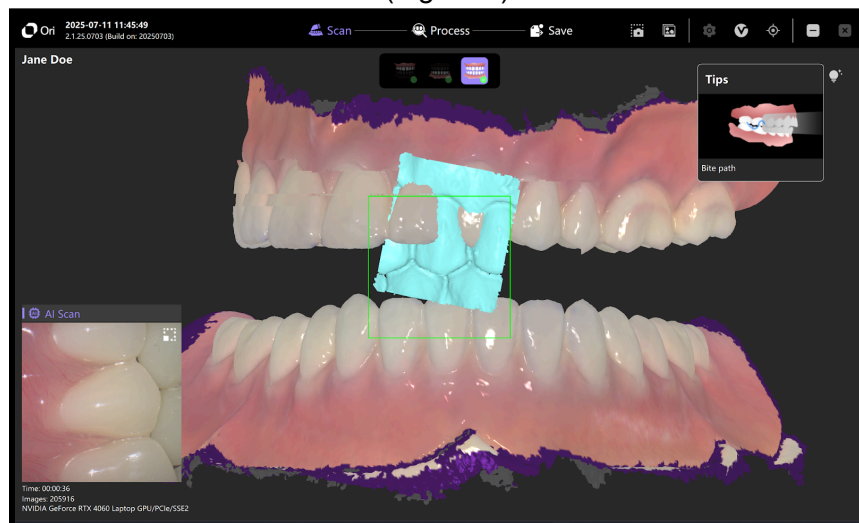
Once the bite registration is complete you will hear an indicating chime. (Fig 1.9)

(Fig 1.9)

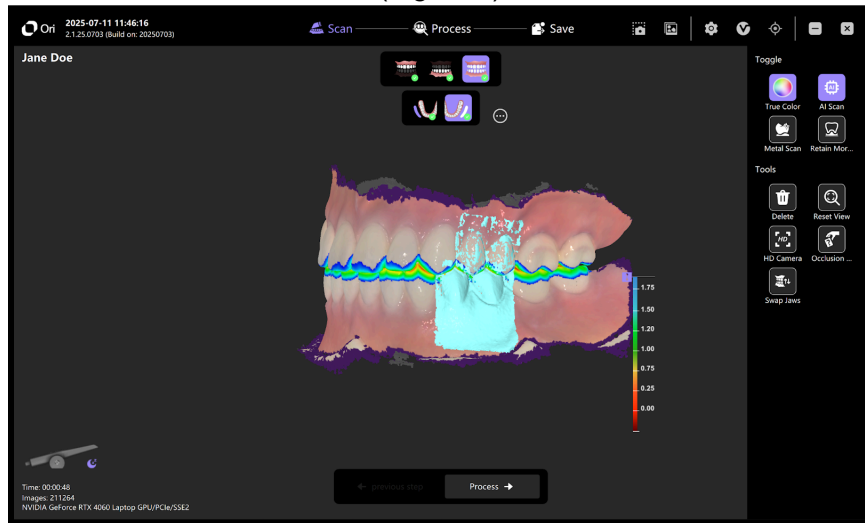


Step 6. If doing a full arch scan, quickly press the mode button to add an additional bite registration. Follow the same steps listed above.

(Fig 1.10)

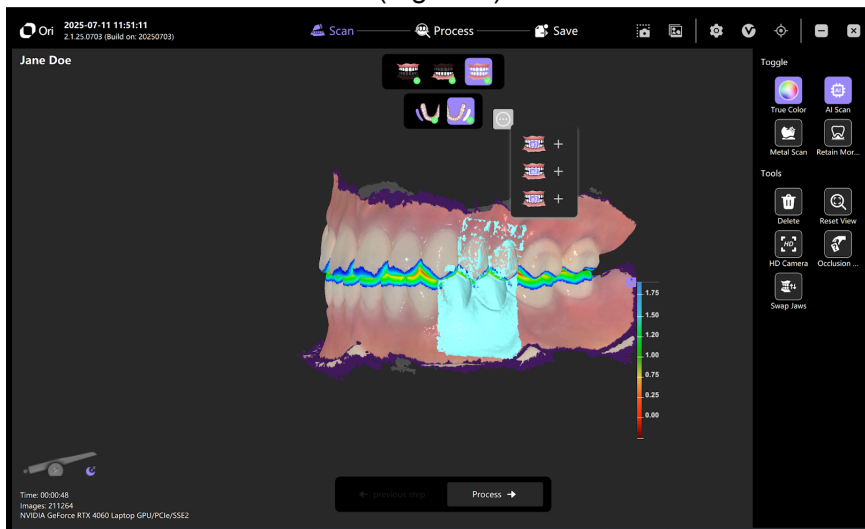


(Fig 1.11)



Note: To add additional bites, select the (...) next to the bite registrations as shown in (Fig 1.12).

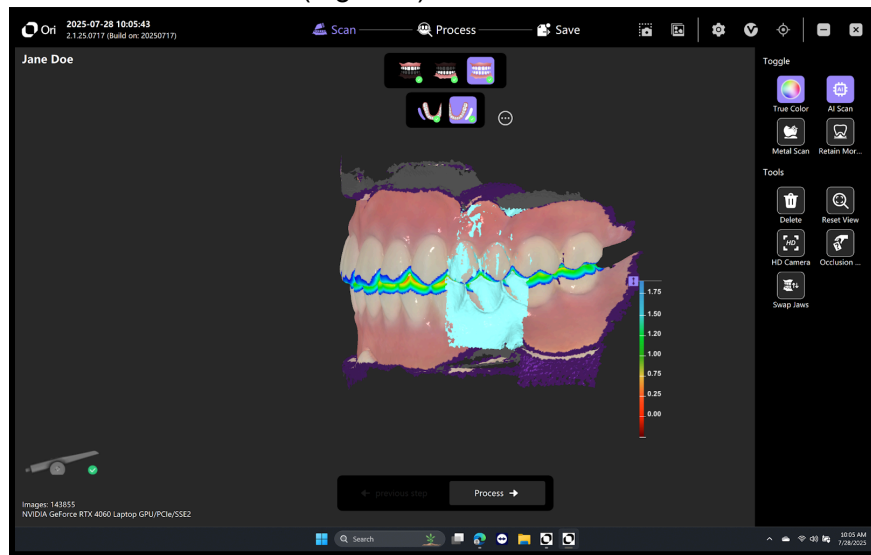
(Fig 1.12)



7. When all data has been collected select “Process” to finalize the case as shown on (Fig 1.13)

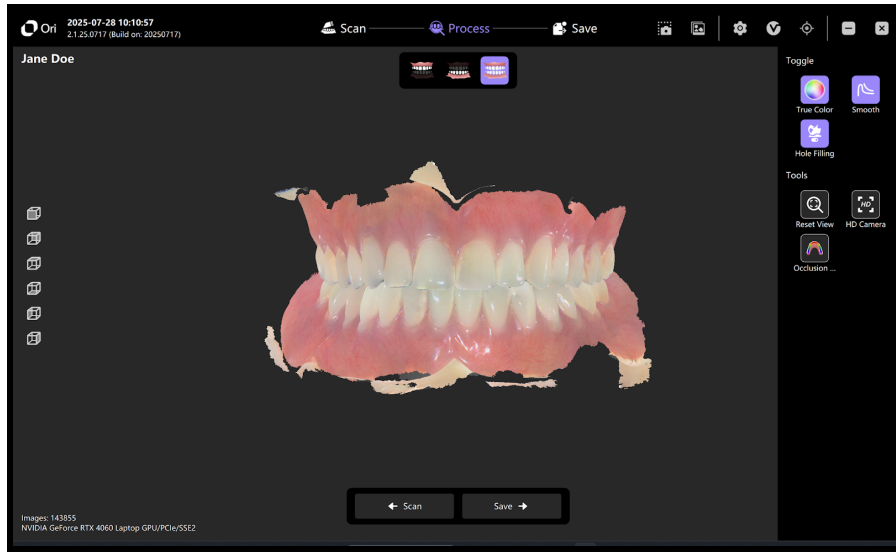
Note: If edits are needed you can select “Scan” to resume scanning.

(Fig 1.13)



8. If no adjustments are needed select “Save” as shown on (Fig 1.14)

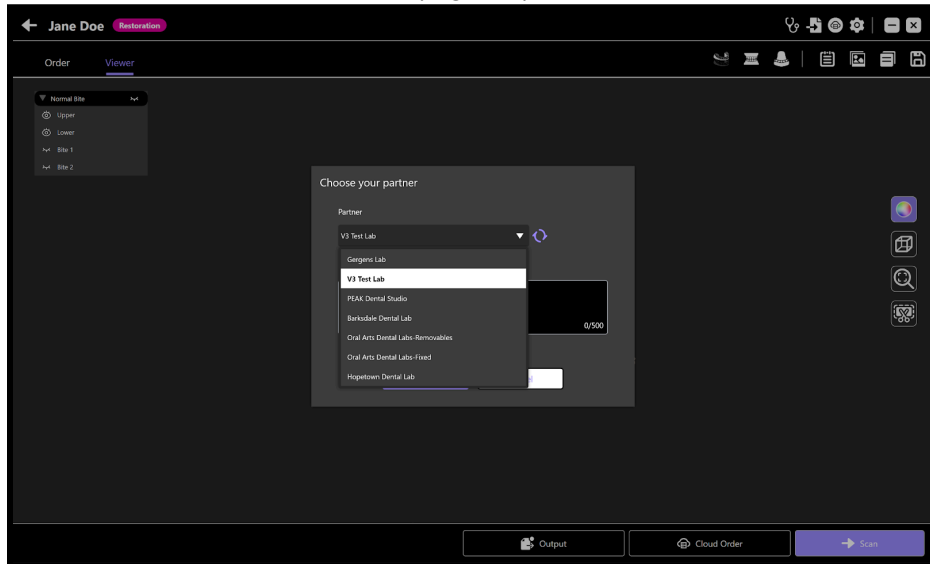
(Fig 1.14)



## Submitting Lab Cases

9. Select “Cloud Order” and select a lab from the list of choices as shown in (Fig 1.15).

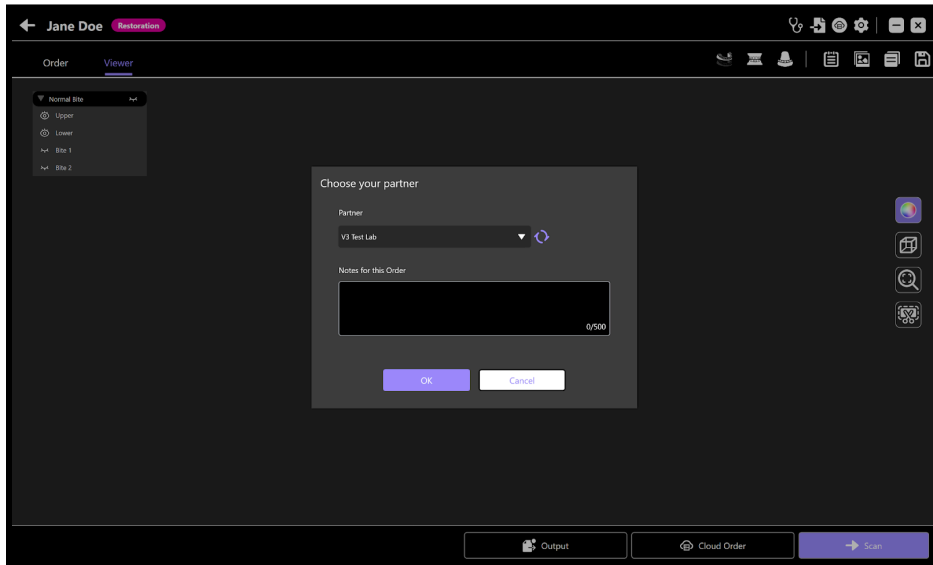
(Fig1.15)

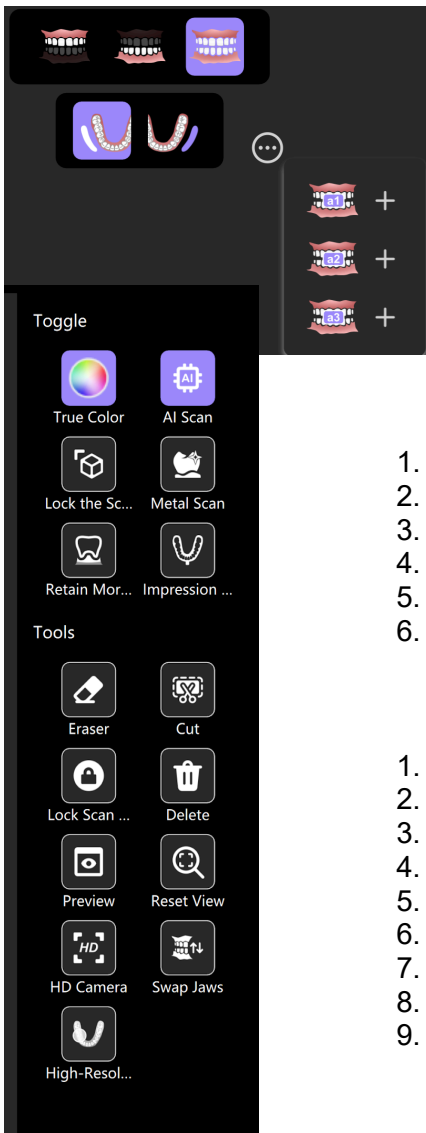


10. Once the lab has been selected, select “Ok” to submit the case as shown in (Fig 1.16).

(Fig 1.16)

(Fig 1.16)





### Toggle

1. True Color
2. AI Scan
3. Lock Scan
4. Metal Scan
5. Retain More Tissue
6. Impression Scan

### Tools

1. Eraser
2. Cut
3. Lock Scan ...
4. Delete
5. Preview
6. Reset View
7. HD Camera
8. Swap Jaws
9. High Resolution

Chapter

# 4

## 4.0 Safety and Warnings

### Standard System Warnings and Cautions

**WARNING:** Read all instructions including all warnings and caution notices. You must comply with the warnings in this manual to prevent injury to persons and damage to the equipment. Proper functionality and safety can only be guaranteed if the safety precautions in this safety guide and on the Ori system are observed.

**Caution:** Please examine the Ori system for any mechanical damage on the enclosure, cables, and computer. Safety can only be guaranteed if no damage on the Ori system is found.

**Caution:** Modifications to the system which may affect operator, patient, or third-party safety are prohibited by law.

**Caution:** The Ori Scanner should be placed in the scanner mount when not in use.

### Software Warnings and Cautions

**Caution:** Use approved software only to prevent interference with the runtime reliability of the system and programs within it.

**Caution:** Installation of third party software onto the Ori Computer may cause unexpected performance issues including the ability to communicate with the Ori One scanner and/or operation of the Ori scanning software.

### Training

**WARNING:** All persons attempting to use the Ori scanner on patients should be trained in proper system use and have read and understood all sections of this Guide. All uses should be thoroughly familiar with the safe operation of the Ori system as described in this documentation.

## Equipment Failure

**WARNING: If the Ori system malfunctions, or if you suspect it is not working properly:**

**Remove the scanner from contact with the patient  
Shut down the system and unplug power from the wall outlet  
Prevent others from using the system  
Contact Ori Customer Service**

**WARNING: Do not attempt to open the enclosure or service the computer on the Ori system.**

## Mechanical Hazards

**WARNING: Avoid the following sources of injury:**

Do not lean on the system or scanner mount  
Movable parts can pinch body parts

**WARNING: If you drop an Ori scanner tip on the floor, you must dispose of it immediately and not use the same tip again for scanning. There is a high risk that the optics in the tip have come dislodged and can fall out.**

**WARNING: Always place the scanner on the scanner Dock when not in use. Place the cables carefully so that the patient/user do not get caught in the cables and accidentally cause injury or damage to the system.**

## Explosion Hazards

**WARNING:** The Ori system is not designed to be used in environments that are potentially explosive such as in close proximity to flammable liquids or gasses or in oxygen-rich environments.

**WARNING:** There is a potential explosion hazard if the Ori system is operated in the presence of flammable anesthetic.

## Electrical Safety

**WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply main with grounding/protective earth. The system is equipped with a three pin (US prongs) grounding/earth type plug. If you cannot insert the plug into your outlet, contact your electrician. Do not try to defeat or ignore the purpose of the grounding-type plug.

**WARNING:** There is a risk of electrical shock if you attempt to access the inside of any part of the system. Only authorized and qualified service personnel may access the inside of any part of the system.

**WARNING: Do not connect the Ori 3 to an ordinary power strip or extension cord because these may not be secure in relation to grounding. If the ground connection fails, these can cause the total leakage current for all connected equipment to exceed the limits specified in EN/IEC 60601-1, and the impedance of the ground connection could exceed the limits specified in EN/IEC 60601-1.**

**WARNING: Anyone who configures a connection of an IT network or connects other peripherals to the laptop is responsible for ensuring that any such system complies with EN/IEC 60601-1 requirements.**

**WARNING: All externally connected cables such as power cable, network cable, and the hand-held scanner cable connection must never be subjected to pulling stresses.**

**WARNING: Do not bring liquids such as beverages near the Ori system. Do not spill liquids on the system.**

**WARNING: Variations in temperature or humidity may cause water to condense inside the system, which can cause damage. Always allow the system to reach room temperature before plugging it into a power source. If the system has been subject to major temperature changes, wait at least 2 hours before plugging it into a power source. If there is visible evidence of condensation, wait at least 8 hours before plugging it into a power source.**

**WARNING:** There is no power ON/OFF switch; the system is powered ON/OFF with the computer. The only reliable way to disconnect the system from the main is to power the computer OFF and unplug the power cord. Do not position the system so that it is difficult to unplug the power cord. Please allow enough time to shut down the computer properly before unplugging the power cord.

**WARNING:** Only use the laptop and power supply provided with the system. There are two ways to set up the system: 1.) The system is standard equipment certified to IEC 60950-1 and is located at least 1.5 m away from the patient. In this configuration, you must not scan the patient and touch the laptop at the same time! You must not touch any corded peripherals, such as a wired mouse, or any of the accessible I/O ports while scanning a patient. Peripherals using a wireless connection (wireless mouse) may be used without this restriction. 2.) the laptop is a medical grade certified to IEC 60601-1. See the laptop's instructions for use and further details.

**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**WARNING:** 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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Eye Safety

**WARNING:** The scanner emits a bright light from its tip during operation. The scanner complies with EN (IEC) 62471 (Photobiological safety of lamps and lamp systems). However, we recommend caution when handling the scanner.

A brief glimpse of the light into the eye is not dangerous, but do not stare into the beam or view directly with optical instruments and do not aim the beam toward other people's eyes. Intense light sources have high secondary exposure potential due to their blinding effect. As is also true when viewing other bright light sources (headlights), temporary reduction in visual acuity and after images can occur, leading to irritation, annoyance, visual impairment, and even accidents, depending on the situation.

## Hygiene

Perform the following maintenance activities on your scanner and accessories regularly. To ensure maximum hygienic safety for the patient, carefully follow the instructions to prepare the scanner for use. After each patient, clean and sterilize the tip.

To minimize the risk for cross-contamination, after each patient:

- Clean and disinfect the scanner. See Section 8.
- Clean and sterilize the scanner tip.

**WARNING:** To maintain a clean work environment and the safety of the patient, wear clean surgical gloves when:

Handling the scanner tip during changing or adjusting angle.  
Handling the protection tip.  
Applying the Ori 3 to patients for scanning.  
Touching the Ori 3 system.

**WARNING:** The scanner unit and its optical window must always be cleaned and/or reprocessed before attaching a protection tip. Do not allow patient contact with the protection tip.

**WARNING:** Always have the scanner tip mounted when inserting the scanner into the patient's mouth or in any way in contact with the patient. Mounting the scanner tip is always required for maximal electrical safety and due to the risk of contamination.

### **Safety when Scanning**

**Caution:** The Ori scanner is a highly precise optical instrument and must be handled with care. Do not drop, shake or bump the scanner as these actions could cause it to break or malfunction.

Always return the handheld scanner to its docking station when not in use.

Do not bend or kink the cord attached to the scanner.

Do not submerge the scanner in liquids.

Do not place the scanner on heated or wet surfaces.

Grip the scanner firmly when in use and when engaging or disengaging with the mount.

**Caution:** The handheld scanner tip is fragile and contains sensitive optics. To avoid damage to the tip and optics, do not bump the tip into the patient's teeth or restorations.

### **Protection from Overheating**

**WARNING:** Ventilation openings on the laptop must never be blocked or obstructed. If overheated, the system could stop functioning.

## Environmental Conditions

| Components                                      | Environmental Requirements |
|---|----------------------------|
| Operating Temperature                           | +10 - 32 °C                |
| Transportation and Storage Temperature          | -5 - 45 °C                 |
| Operating Relative Humidity                     | 20 - 80% RH                |
| Transportation and Storage Relative Humidity    | 10 - 90% RH                |
| Operating Atmospheric Pressure                  | 700 - 1060 hPa             |
| Transportation and Storage Atmospheric Pressure | 600 - 1060 hPa             |

| Condition   | Classification   |
|---|--|
| Type of protection against electric shock             | Class II electrical equipment  |
| Degree of protection against electric shock           | Type B Applied Part (Scanner tip)  |
| Degree of protection against harmful ingress of water | IPX0<br><br>Note: After the tip is attached, the tip portion of the device is IPX1.  |
| Mode of operation                                     | Continuous operation   |
| Flammable anesthetics                                 | Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide. |

Chapter

# 5

## **5.0 Cleaning, Disinfection, Maintenance and Disposal**

### **Cleaning and Sterilizing the Scanner Tip**

The Ori 3 scanner tip is the part of the scanner that is inserted into the patient's mouth when scanning. The scanner tips are not pre-sterilized. New tips must be cleaned and sterilized before first use and before each subsequent use. If the scanner is visibly contaminated with bodily fluids, it must be cleaned before disinfection. The scanner tip can be reused up to 100 times but must be cleaned and reprocessed between patients. Ensure you have completed the previous scan and "Stop Scan" before removing the tip.

### **Cleaning the Scanner and Tip**

1. Dampen (do not soak) a lint-free cloth with lukewarm water.
2. Wipe/remove all bodily fluids and residue with the cloth.
3. Remove the reusable tip by gently pulling the tip away from the scanner body while avoiding pressing the scanner button.
4. Clean the tip manually using soap and water and a brush and/or dampened lint-free cloth. Inspect the optics in the tip after cleaning. If the mirror has stains or smudges, repeat cleaning with soap and water. Dry the optics carefully with a dry lint-free cloth.
5. Place the tip in a sterilization pouch and seal the pouch airtight. Self-adhesive or heat-sealed pouches are acceptable.

### **Disinfecting the Scanner**

The scanner must be thoroughly disinfected after each patient. Follow the disinfectant manufacturer's instructions for the appropriate contact time to ensure adequate disinfection.

**Caution:**

**Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner for reuse.**

**You must wear gloves while cleaning and disinfecting the scanner.**

**The scanner must be disinfected with an U.S. Environmental Protection Agency (EPA) registered or CE marked intermediate-level disinfectant solution with tuberculocidal activity between patients.**

**DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the scanner.**

**Never put the scanner in an autoclave device or immerse it in water or the disinfectant solution. Excessive fluids can damage the scanner. Do not use cotton, cloth or tissues soaked with disinfectant to disinfect the scanner.**

**Do not spray cleaning solutions directly onto the scanner, monitor or laptop.**

**XE "Definitions:Caution" XE "Caution"**

**Caution: Use only disinfectant wipes approved by the manufacturer. XE "Definitions:Caution" XE "Caution"**

1. Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time.
2. Thoroughly wiped all surfaces of the scanner.

**Caution: Do not rinse or submerge the scanner in water or any other cleaning or disinfecting agent. XE "Definitions:Caution" XE "Caution"**

1. Allow the scanner to air dry.
2. After the scanner has dried, use a clean, lint-free cloth dampened with water to remove residual disinfectant from the surface of the scanner.
3. Visually inspect the scanner for signs of deterioration, especially around the buttons and the cable. If damage is noted, do not use the scanner and contact your representative.

**Note: Over time, the cleaning and disinfecting of the scanner may cause discoloration. This discoloration does not affect the performance or safety of the Ori Scanner.**

### **Sterilizing the Scanner Tips**

The removable scanner tips are autoclavable up to 100 cycles. After 100 cycles, discard the tip. If you limit the exposure time at 134°C to not more than 4 minutes, you can autoclave the tip up to 100 cycles.

**WARNING: The scanner tips are not pre-sterilized. New tips must be cleaned and sterilized before first use and before each subsequent use.**

1. Place the cleaned tips, each prepared with a piece of folded gauze in the tip window, in an FDA cleared or CE mark sealed sterilization pouch.
1. Sterilize the wrapped tip in an autoclave with one of the two settings:

| Pre-Vacuum Autoclave   |                    |
|------------------------|--------------------|
| Exposure Time at 132°C | Drying Time        |
| Minimum 4 Minutes      | Minimum 20 Minutes |
|                        |                    |
| Gravity Autoclave      |                    |
| Exposure Time at 132°C | Drying Time        |
| Minimum 15 Minutes     | Minimum 20 Minutes |

Use an autoclave program that dries the wrapped tip before opening the autoclave. A number of wrapped and sterilized tips can be kept at a suitable place ready for use at your convenience.

**Caution: Never autoclave a tip that is not wrapped as this will stain the mirror permanently.**

**Caution: A class B Vacuum autoclave according to EN13060 is required for sterilization of the scanner tip.**

**Caution: The scanner tip can be re-sterilized up to 100 times and must be disposed of afterwards as described in the section Disposal.**

**Caution: the optics in the tip are sensitive. Clean and undamaged optics are essential to scan quality. The mirror should be handled with care; ensure there are no scratches or smudges before scanning a patient.**

- **Wear gloves when handling a contaminated scanner tip.**
- **Read and follow the warnings and personal protection instructions provided in the manufacturer's SDS for the detergent used to clean the scanner tip prior to sterilization.**
- **Do not soak the scanner tips in disinfectant for a long period.**
- **Dry the scanner tips thoroughly before mounting onto the scanner.**
- **Do not use an ultrasonic cleaning machine to clean the scanner tips.**

### **Additional Cleaning if Scan Quality is Poor**

During scanning, the tip mirror may become dirty or contain artifacts, resulting in poor scan quality. In this situation, you can clean the mirror.

1. Remove the scanner tip.
2. Apply alcohol to a clean cloth or cotton-tipped swab and wipe the mirror until it is clean. Use alcohol that is free of impurities to prevent staining the mirror. Ethanol or propanol can be used.
3. Wipe the tip mirror dry with a dry, lint free cloth to avoid leaving dust and fiber on the mirror.

**Caution: Do not use acetone or any oxidizing solutions to clean the tip mirror.**

If scan quality continues to be poor following secondary cleaning procedures, inspect the scanner's optical window for cleanliness and apply the same procedures if necessary.

### **Disposal of the Scanner Tip**

1. Sterilize the tip as described previously.
2. Dispose of the tip normally as other clinical waste.

**WARNING: The scanner tip must be sterilized before disposal.**

**Caution: Dispose the scanner tip as other clinical waste.**

### **Disposal of the Ori System**

Certain components of electronic devices may be considered hazardous due to heavy metal or other constituents; thus, the end-of-life handling of some electronic discards is regulated by either federal (Resource Conservation and Recovery Act--RCRA) or State (Health and Safety Code) hazardous waste laws, or both. Regulations in Title 14, Division 7 of the California Code of Regulations (CCR) were promulgated to implement the Electronic Waste Recycling Act of 2003, with primary departments being CalRecycle and Department of Toxic Substance Control (DTSC).

**WARNING: At the end of its useful operating life, dispose of the device as electronic scrap.**

Please ask either Ori or your sales representative for information on your local collection point. Within the scope of application of this Directive, Ori is responsible for the proper disposal of this device.

### **Technical Maintenance**

***Caution: All technical service and repair of the Ori system must be performed by an Ori authorized representative only.***

The user does not need to perform any regular maintenance other than cleaning, disinfection and sterilization as described. Preventative inspections and scheduled maintenance are not required.

### **Environmental Considerations**

The Ori scanner is designed to conform with the following directives:

- RoHS, Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (2002/95/EC).
- WEEE, Waste, Electrical and Electronic Equipment Directive (2002/96/EC).

Chapter

# 6

## EMC/EMI Tables

| Guidance and manufacture's declaration - electromagnetic emissions  |            |  |
|---|------------|--|
| The Intraoral Scanners intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic environment. |            |  |
| Emission Test   | Compliance | Electromagnetic environment - guide  |
| RF emission CISPR 11  | Group 1    | The Intraoral Scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.   |
| RF emission CISPR 11  | Class B    | The Intraoral Scanner is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emission IEC 61000-3-2   | Class A    |  |
| Voltage fluctuations/ flicker emission IEC 61000-3-3  | Applied    |  |

| Guidance & Manufacturer's Declaration-Electromagnetic Immunity  |  |                              |   |
|---|--|------------------------------|---|
| The Intraoral Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the intraoral Scanner should assure that it is used in such an electromagnetic environment: |  |                              |   |
| Immunity Test   | IEC60601 Test Level  | Compliance level             | Electromagnetic Environment-Guidance  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ±6 kV contact<br>±8 kV air                                   | ±6 kV contact<br>±8 kV air   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br>IEC 61000-4-4  | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment.   |


|  |  |  |   |
|--|--|--|---|
| Surge<br>IEC 61000-4-5   | ±1 kV<br>Differential<br>mode<br>±2 kV common<br>mode  | ±1 kV<br>Differential<br>mode<br>±2 kV common<br>mode  | Mains power quality should be that of a typical commercial or hospital environment.   |
| Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11 | <5 % UT<br>(>95% dip in UT) for 0.5 cycle<br>40% UT<br>(60% dip in UT) for 5 cycles<br>70% UT<br>(30% dip in UT) for 25 cycles<br><5 % UT<br>(95% dip in UT) for 5 sec | <5 % UT<br>{>95% dip in UT) for 0.5 cycle<br>40 % UT<br>(60% dip in UT) for 5 cycles<br>70 % UT<br>(30% dip in UT) for 25 cycles<br><5 % UT<br>(95% dip in UT) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intraoral Scanner requires continued operation during power mains interruption, it is recommended that the Intraoral Scanner be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8  | 3A/m   | 3A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.   |

Note: UT is the a.c. mains voltage prior to application of the test level.

**Guidance and manufacturer's declaration – electromagnetic immunity**

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

| IMMUNITY test  | IEC 60601 TEST LEVEL   | Compliance level          | Electromagnetic environment – guidance  |
|--|--|---------------------------|---|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>3 V/m</p> <p>80 MHz to 2.5 GHz</p> | <p>3 Vrms</p> <p>3V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Ori 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2 \sqrt{P}</math></p> <p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800MHz to 2.7 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended</p> |

|  |  |  |  |
|--|--|--|--|
|  |  |  | <p>separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
|--|--|--|--|

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.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ori 3 is used exceeds the applicable RF compliance level above, the Ori 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ori 3.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the Ori 2**

The Ori 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ori 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ori 2 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter<br>W | Separation distance according to frequency of transmitter<br>m |                   |                    |
|--|--|-------------------|--------------------|
|  | 150 kHz to 80 MHz  | 80 MHz to 800 MHz | 800 MHz to 2,7 GHz |
|  |  |                   |                    |

|   | $d = 1.2 \sqrt{P}$ | $d = 1.2 \sqrt{P}$ | $d = 2.3 \sqrt{P}$ |
|---|--------------------|--------------------|--------------------|
| 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                | 3.8                | 7.3                |
| 100   | 12                 | 12                 | 23                 |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> |                    |                    |                    |