

# 3DISC

## 3DISC OVO3 IOS

# Safety, Regulatory & Technical Specifications User Guide



## 3DISC IOS Solutions

# 3DISC

Taking Digital Beyond

| Document | Software version | Date       |
|----------|------------------|------------|
| IU-13    | 5.0 and higher   | 04/23/2025 |

This document describes the Technical Specifications for the 3DISC OVO3 IOS Solution.

The original document is written in English.

For an overview of the features proposed by your 3DISC IOS Solution see the following documents:

- [OVO3 IOS Quick Guide](#) [IOS-FPQG-71-003\_EN]

For comprehensive information on using 3DISC products, visit:

- [3DISC Online Help](#)

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# 1. Conventions used in this guide

## Warnings and Symbols



**NOTE:** Represents information that is important to know but which does not affect the functionality of the system.



**IMPORTANT:** The functionality of the system will be limited in the case of incorrect use.



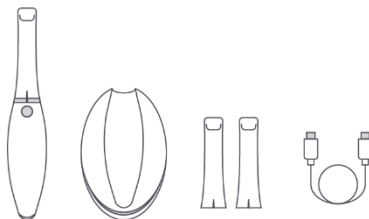
**WARNING:** General prohibition indication. The functionality of the system can be destroyed in the case of incorrect use. If unauthorized changes have been made to the delivered system and accessories, the warranty by 3DISC becomes void. 3DISC will not accept any responsibility or liability for the improper functioning of the product in such a case.

## 2. What's in the Box

The OVO3 IOS system is composed of the following hardware components\*:

### OVO3 IOS

1. OVO3 IOS Scanner
2. OVO3 IOS base
3. Removable autoclavable tips
4. USB C cable



| Hardware Component         | Part Number |
|----------------------------|-------------|
| OVO3 IOS (Includes 3 Tips) | FP-2        |
| USB C Cable                | OS-44       |
| OVO3 base                  | CM-035      |

**Save the Box:** It is highly recommended that you store the box in a safe place and do not throw it away. The box is optimal for any necessary transportation or shipment of your 3DISC IOS solution.

## 3. Certification and compliance

The system has been tested and conforms to the following standards:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances

- Requirements and tests:

- IEC 62471, Photobiological safety of lamps and lamp systems

### 3.1 Regulatory

The 3DISC OVO3 IOS solution is manufactured and marketed in accordance with US FDA Regulations and EU Medical Device Regulation 2017/745.

### 3.2 Intended Use

The 3DISC OVO3 IOS is an optical impression system. It is used to record the topographical characteristics of teeth, dental impressions, or stone models for use in the computer-aided design (CAD) and computer-aided manufacturing (CAM) of dental restorative prosthetic devices.



**CAUTION:** Rx only - Federal law restricts this device to be sold by or on the order of a Dentist.



**Warning:** The systems should only be sold and operated by a trained dental professional



**WARNING:** Unintended use of the system can result in physical injury to the patient and operator, and damage to the system.

### 3.3 Indications supported

The software enables you to select the following indications\* when filling out orders for restoration:

- Conventional crowns
- Anatomic crowns
- Copings
- Provisional crowns
- Anatomical pontics
- Reduced pontics
- Provisional pontics
- Inlays/Onlays
- Implant abutments
- Implant-based bridges
- Tooth-based bridges
- Orthodontic aligners
- Nightguards
- Splints
- Retainers
- Bleach trays
- Sleep appliances
- ...

\* Verify with your dental lab or service provider about their capabilities to produce different indications.

### 3.4 Contraindications

The intraoral scanning system is not intended to be used to create images of the internal structure of teeth or the supporting skeletal structure.

### 3.5 Classifications

The 3DISC OVO3 IOS system has the following classifications:

- Protection against electrical shock: Type B Applied Part
- Protection against harmful ingress of water: Ordinary equipment (IPX0)
- Safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

## 3DISC Privacy Policy and GDPR Privacy Statement

Your privacy and the privacy of the patient data managed by you is important to 3DISC.

For information on 3DISC Privacy Policy, go to:

[Privacy policy - 3DISC](#)

To access 3DISC's GDPR Privacy Statement, go to:

[GDPR Privacy statement - 3DISC](#)

# 4. System Requirements and Specifications

## 4.1 OVO3 Scanner Specifications

|                                       |                                                                                         |
|---------------------------------------|-----------------------------------------------------------------------------------------|
| Scanner Type                          | Hand-held (chairside) scanner that creates optical impressions for dental restorations. |
| Design                                | Compact, lightweight, ergonomic – designed to be operated with little physical effort.  |
| Dimensions Base                       | Size: L 154mm, W 88mm, H 64mm                                                           |
| Dimensions Scanner                    | Weight: 190 grams                                                                       |
|                                       | Size: L 257mm, W 45mm, H 62mm                                                           |
|                                       | Cable length (scanner to computer): 2m                                                  |
| Power Requirement                     | 5V @ 1.5 A via USB-C                                                                    |
| Scanner Tip                           | Reusable up to 250 times, sterilize using steam autoclave                               |
| Scanner Tip Position                  | Rotatable tip. Four positions for acquiring data                                        |
| Heating Element                       | Ventilated. Prevents fog formation on optics                                            |
| Acquisition Method/Imaging technology | Hybrid technology: active stereo imaging and structured light                           |
| Sensor technology                     | CMOS                                                                                    |
| Color Scanning                        | 24-bit (10-bit per channel)                                                             |
| Scanning frequency                    | 50-70Hz                                                                                 |
| Imaging field-of-view                 | 12mm x 14mm                                                                             |
| Light sources                         | High-power LEDs                                                                         |



## 4.2 OVO3 Scanning Process

|                                               |                                                                         |
|-----------------------------------------------|-------------------------------------------------------------------------|
| Tooth Preparation                             | No powder or spray required                                             |
| Scanning Principle                            | Continuously scanning and accumulating (stitching) depth and color data |
| Distance Scanner - Tooth                      | -1mm – 19mm (20mm)                                                      |
| Possible contact duration by operator         | <10 min. Note: May vary with hardware configuration                     |
| Operator accessible part                      | Handpiece                                                               |
| Possible contact duration by patient          | $t \leq 10 \text{ min}$                                                 |
| Patient accessible part (Type B Applied Part) | Tip (autoclavable)                                                      |
| Computer – Scanner Interface                  | USB C                                                                   |

## 4.3 Software output and design software compatibility

|                                    |                                                                                          |
|------------------------------------|------------------------------------------------------------------------------------------|
| Output File Format                 | STL, PLY, OBJ                                                                            |
| Compatibility with CAD/CAM Systems | Open Architecture Output format STL, PLY, OBJ<br>Compatible with most Dental CAD systems |

## 4.4 OVO3 Environment Conditions

|                                                     |                                                                                                                           |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Operating Temperature                               | 10°C to 30°C                                                                                                              |
| Operating Relative Humidity                         | 10% to 80% (non-condensing)                                                                                               |
| Storage Temperature                                 | - 20°C to 60°C                                                                                                            |
| Storage Relative Humidity                           | 10% to 80% (non-condensing) Indoor use only                                                                               |
| Installation Category                               | 1                                                                                                                         |
| Pollution Degree                                    | 2                                                                                                                         |
| Ingress of Liquids                                  | IPXO                                                                                                                      |
| Protective Class                                    | Class IIIB                                                                                                                |
| Overvoltage category                                | II per IEC 60664-1                                                                                                        |
| Max. working condition                              | Continuous cycles with image capture and transmission from/to Notebook or non-medical grade PC.                           |
| Other possible accessories (IEC60601-1 3rd, Cl. 16) | Notebook with AC/DC Adapter.                                                                                              |
| Equipment Maintenance                               | No user maintenance is required, and no user service is allowed. Please contact technical support in case of problem.     |
| Cleaning                                            | Do not try to clean the inside of the device. Refer to section 10: Cleaning the Handpiece for cleaning and sterilization. |

# 4.5 OVO3 - Minimum Computer Requirements

**WARNING:** Computer or Laptop must be certified to IEC 60950/IEC 62368-1 or IEC 60601-1. Connecting to any other equipment may be hazardous.

DO NOT place any equipment which does not comply with IEC 60601-1 in the immediate vicinity of the patient. Leave at least 1.5 meters distance between the patient and the equipment.

Refer to your computer's installation guide for details on the data processing system, computer, and monitor.  
Ensure there is enough space around the computer to allow for proper ventilation.

Place the screen so that light reflections from both internal and external sources are minimized to achieve the best image quality and ensure comfortable viewing.

|                           |                                                                                                                                                                                                                                                  |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Disk Space                | 100 GB or greater of free disk space                                                                                                                                                                                                             |
| Ports                     | At least 1 x USB C port (SuperSpeed)                                                                                                                                                                                                             |
| Nvidia Driver             | Nvidia Studio driver version 572.83 is currently required. Nvidia gamer-ready driver should not be used with the 3DiscClinic software.                                                                                                           |
| NVIDIA GPU Operation Mode | The PC must be able to ensure that the Nvidia GPU is the only GPU activated on the PC and that any Intel integrated GPU is disabled. (This is usually achieved using high level configuration tools or BIOS commands).                           |
| Screen resolution         | <b>Full HD (1920 x 1080) with DPI 100%</b><br><b>NOTE:</b> The use of 4K (3840 x 2160 pixels) or Ultra-Wide (3440 x 1440 pixels) resolutions is also possible, however the impact on performance has not been quantified by 3DISC at this stage. |
| Operating System          | Windows 11, Administrative rights required.                                                                                                                                                                                                      |

## 4.6 Software Configuration Recommendations

|                                 |                                                                                                                               |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Windows automatic updates       | 3DISC recommends deactivating all Windows automatic updates (except for security updates).                                    |
| Nvidia driver automatic updates | Nvidia driver automatic updates should be disabled.                                                                           |
| Windows Battery Settings        | On laptops, the battery setting in Windows should be configured to high performance mode only, with no battery saving option. |

## 4.7 Minimum Hardware Requirements

|                                   |                                                                                                                                                                                 |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CPU Type                          | Intel i7 or i9 with 12 - 13 - 14 generation.<br><br>Processors that do not have a minimum of 24 MB Intel® Smart Cache should be avoided.                                        |
| Memory                            | 32 GB of RAM or greater (DDR4 or better)                                                                                                                                        |
| GPU<br>(Graphics Processing Unit) | List of GPU* recommended by 3DISC:<br>*Laptop & desktop unless indicated otherwise. <ul style="list-style-type: none"><li>• RTX 4070, RTX 4080, RTX 4090, ...</li></ul>         |
| Graphics Card Memory              | 8GB of RAM minimum on the graphics card is needed. Below this, the software will not be launched: an error message will inform you that the minimum requirement is not reached. |

## 4.8 Calibration

The 3DISC OVO3 Intra-oral Scanner (IOS) is calibrated in the factory and therefore does not require calibration when installed.

If your 3DISC Intra-oral Scanner begins to have problems scanning and recognizing teeth models, contact your dealer or 3DISC Support technician. If the scanner cannot be recalibrated remotely, this may result in the system being returned for repair/calibration.

## 5. General Maintenance

### 5.1 Cleaning the Handpiece

The entire body, cord and base of the scanner must be wiped down using an approved disinfectant that is labeled and specified for tuberculocidal/mycobactericidal activity. Do not use disinfectant on



**IMPORTANT:** All components of the scanner (excluding the tips) must be wiped down and **not** sprayed. Avoid getting any moisture, alcohol or disinfectant inside the open scanner chamber.

the nozzle.

### Recommended and approved surface disinfectants

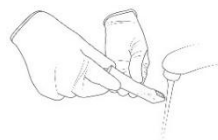
- Birex Wipes: TB Claim= 10 minutes-‘Phenolic (Dual) Water-Based’
- Prospray Wipes: TB Claim=10 minutes-‘Phenolic (Dual) Water-Based’
- Cavicide Wipes: TB Claim=3 minutes-‘Phenolics (Dual) Alcohol-Based’
- DisCide ULTRA Wipes: TB Claim=1 minute-‘Phenolics (Dual) Alcohol-Based’
- Maxiwipe Germicidal Cloth: TB Claim=5 minutes-‘Phenolics (Dual) Alcohol- Based’
- Ster 1 Plus: TB Claim=5 minutes-‘Quaternary ammonium and Alcohol-Based’



**WARNING:** Do not autoclave the handpiece of the device.

## 5.2 Cleaning and Sterilizing the Tip

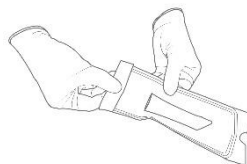
1. Clean the tip with soapy water, ensuring that the mirror is clean and free of smudges, stains, or any residue. Avoid using abrasive cloth materials as this will scratch the mirror.



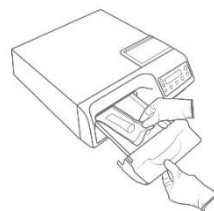
2. After drying the tip exterior, carefully dry the interior and mirror with lint free wipes ensuring you do not scratch the surface. The mirror should be free of any noticeable debris or water spots.



3. Insert and seal the tip into a sterilization pouch. Make sure the seal is airtight. Each tip should be packaged individually.



4. Sterilize the wrapped tip in a steam autoclave at following parameters:
  - 132°C (270°F) at 4 minutes
  - 134°C (273°F) at 4 minutes
  - 121°C (250°F) at 45 minutes



5. Ensure the dry cycle is complete prior to removing the tip from the autoclave. If the pouch is damp with moisture, proper sterilization cannot be guaranteed.



For more information, visit [3DISC Online Help](#)

## 5.3 Important Safety Notices



**WARNING:** Do not remove the pouch before the sterilizer completes its full dry cycle. If the pouch is wet or has any signs of moisture, this can potentially leave water spots on the mirror which can affect image quality during scanning.



**IMPORTANT:** Tips should **not** be placed in an ultrasonic cleaner or any cold sterile solutions. The sterilant solutions will leave a sticky residue or film on the mirror when drying



**WARNING:** Always autoclave the tip wrapped in a sealed sterilization pouch; failure to do so will result in permanent stains on the mirror.

## Disposal

Your 3DISC Intra-oral Scanner (IOS) is an electrical device with electronic components inside and should be disposed of in accordance with local environmental laws and regulations.

## Calibration

The 3DISC Intra-oral Scanner (IOS) is calibrated in the factory and therefore does not require calibration when installed.

If the 3DISC Intra-oral Scanner begins to have problems scanning and recognizing teeth models, contact your dealer or **3DISC Support** technician.



**WARNING:** Use extreme caution when cleaning the mirror as it is very delicate and is prone to scratching.

If the scanner cannot be recalibrated remotely, this may result in the system being returned for repair/calibration.

For more information, see below:

- [Chapter 7 - Support, Warranty and Repair Service](#)

# 6. Safety Guidelines and Warnings

## 6.1 General Guidelines

- Do not spill liquids on the body of the device
- Never operate the device in a wet environment.
- Keep the device away from radiators and heat sources.
- Use the device only with the accessories supplied.
- Do not alter the device or open enclosures.

If any of the following conditions occur, disconnect the device from the computer and contact authorized service personnel:

- The USB-C is damaged.
- The device has been exposed to water.
- The device has been damaged.
- The device does not operate correctly when the operating instructions are followed.

## 6.2 General Warnings

### System Modification



**WARNING:** Modifying the system may result in physical injury to the patient and operator, and damage to the system.

### Approved Software

The 3DISC Intra-oral Scanning device is designed to operate with the 3DiscClinic™ software.



**WARNING:** The 3DISC IOS scanner should only be used with approved, compatible software.

## Equipment Failure



**WARNING:** In case of *system* malfunction or failure, you should:

- Prevent any contact between the system and the patient.
- Unplug the system from the computer.
- Store the system away so it cannot be used by someone else.
- Contact service personnel.

## 6.3 Mechanical Hazards

### Moving Parts



**NOTE:** All moving parts are inside handheld scanner: do not open the unit.

### Dropped Equipment



**WARNING:** If the scanner tip is dropped, ensure that the mirror is not damaged and that it is not detached; if the tip is damaged it should be disposed of immediately. If the scanner handpiece is dropped or bumped, ensure that no part of the system is damaged as it could affect performance.

### Base



**NOTE:** When not in use, always rest the handpiece on the Base. The Base may be mounted on the wall per provided instructions. Do not place the Base on a slanted surface. Place the USB-C cables where people cannot accidentally get caught in them and potentially damage the system.

## 6.4 Electrical Safety

### Electrical Shock



**WARNING:** There is a risk of electrical shock when opening or attempting to open any part of the system; only qualified service personal should open parts of the system.

### Stress on Cables



**WARNING:** Care should be taken not to apply unnecessary stress on the USB-C cables of the system.

### Eye Safety



**WARNING:** During operation, the system emits a bright, flashing light from its tip. Although the system complies with standard IEC 62471 (Photobiological safety of lamps and lamp systems), prolonged exposure to flashing light may result in discomfort, seizure or eye irritation.

### Hygiene



**WARNING:** In order to maintain safety for the patient, wear surgical gloves when handling any parts of the system. Always ensure that the tip is mounted on the handpiece before inserting it into the mouth of the patient. Before using the system with a new patient, ensure that the system is disinfected, and the tip is sterilized.

## 6.5 Precautions During Systems Operation



**WARNING:** The OVO3 IOS system contains delicate optical and mechanical elements and therefore should be handled carefully. Do not drop, bump, or shake the handpiece or the tip. Always place the handpiece on the Base when not in use. Do not put stress on the cable connecting the handpiece to the Base. Do not submerge the handpiece or the Base in any liquid. Do not place the handpiece or the Base on wet or heated surfaces. Hold the handpiece with a firm grip when handling it.



**WARNING:** In order to prevent over-heating of the system, the ventilation opening at the bottom of the handpiece should never be obstructed.

## Performance



**NOTE:** During operation of the system, the handpiece and the tip may get slightly warm; this is normal.

Under normal use, the 3DISC Intra-oral Scanner (IOS) solution should transmit images to the laptop/workstation with the installed image manipulation software and the video stream is visible in the bottom left corner of the screen. If not used properly, there may be loss of transmission of image information or slow transmission temporarily.



**WARNING:** Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the 3DISC Intra-oral Scanner (IOS) solution, including cables specified by the MANUFACTURER. Otherwise, performance degradation of this equipment may occur.

## Accessories

| Accessory   | 3DISC Part Number |
|-------------|-------------------|
| USB C Cable | OS-44             |
| OVO3 base   | CM-035            |

## 6.6 EMC Guidance and Declaration

3DISC Intra-oral Scanner (IOS) solutions are intended for use in a professional healthcare setting with electromagnetic environment specified below.



**WARNING:** Use of this equipment adjacent to or on other equipment must be avoided as it may result in improper operation. If this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally.

### Electromagnetic Emissions

| Emissions Test                                       | Compliance       | Electromagnetic Environment Guidance                                                                                                                                                                                                                     |
|------------------------------------------------------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF Emissions CISPR 11                                | Group 1, Class A | The 3DISC Intra-oral Scanner (IOS) solution 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.                                         |
| Harmonic emissions IEC 61000-3-2                     | Class A          |                                                                                                                                                                                                                                                          |
| Voltage Fluctuations/Flicker Emissions IEC 61000-3-3 | Complies         | The 3DISC Intra-oral Scanner (IOS) solution 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. |

### Electromagnetic Immunity

| Immunity Test                                  | Test Level                                                                                           | Compliance Level                                                                                     | Electromagnetic Environment Guidance                                                                                                            |
|------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD) IEC 61000-4-2    | $\pm 8$ kV /Contact<br>$\pm 2$ kV, $\pm 4$ kV,<br>$\pm 8$ kV, $\pm 15$ kV /air                       | $\pm 8$ kV /Contact<br>$\pm 2$ kV, $\pm 4$ kV,<br>$\pm 8$ kV, $\pm 15$ kV /air                       | Surface should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/ burst IEC 61000-4-4 | $\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines                                  | $\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines                                  | Mains power quality should be that of a typical professional healthcare facility environment.                                                   |
| Surge IEC 61000-4-5                            | $\pm 0.5$ kV, $\pm 1$ kV line(s) to line(s)<br>$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to earth | $\pm 0.5$ kV, $\pm 1$ kV line(s) to line(s)<br>$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to earth | Mains power quality should be that of a typical professional healthcare facility environment.                                                   |

|                                                                                                     |                                                                                                                                                          |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0,5 cycle<br>40% UT (60% dip in UT) for 5 cycles<br>70 % UT (30% dip in UT) for 25 cycles<br><5% UT (>95% dip in UT) for 5 s | <5% UT (>95% dip in UT) for 0,5 cycle<br>40% UT (60% dip in UT) for 5 cycles<br>70 % UT (30% dip in UT) for 25 cycles<br><5% UT (>95% dip in UT) for 5 s | Mains power quality should be that of a typical professional healthcare facility environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8                                             | 30 A/m                                                                                                                                                   | 30 A/m                                                                                                                                                   | Power frequency magnetic fields should be at levels characteristic of a location in a typical professional healthcare facility environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Conducted RF IEC 61000-4-6                                                                          | 3V 0.15-80MHz<br>6V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1KHz                                                                           | 3V 0.15-80MHz<br>6V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1KHz                                                                           | <p>Portable and mobile RF communications equipment should be used no closer to any part of the 3DISC Intra-oral Scanner (IOS) system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = \left[ \frac{3.5}{\sqrt{f}} \right] \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[ \frac{3.5}{f^{1/4}} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{f^{1/4}} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| Radiated RF IEC 61000-4-3                                                                           | Table 9 in IEC-60601-1-2:2014<br><br>3V/m<br>80 MHz – 2.7 GHz<br>80% AM at 1 kHz                                                                         | Table 9 in IEC-60601-1-2:2014<br><br>3V/m<br>80 MHz – 2.7 GHz<br>80% AM at 1 kHz                                                                         | <p>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 IOS including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

# Separation distances

Recommended separation distances between portable and mobile RF communications equipment and the OVO™ IOS System that is not Life-Supporting

3DISC Intra-oral Scanner (IOS) System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3DISC Intra-oral Scanner (IOS) system as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | IEC 60601-1-2   |                 |
|-----------------------------------------------|---------------------------------------------------------------|-----------------|-----------------|
|                                               |                                                               | 80 MHz~800 MHz  | 800 MHz~2.5 GHz |
|                                               | 150 kHz~80 MHz<br>$d=1.2\sqrt{P}$                             | $d=1.2\sqrt{P}$ | $d=1.2\sqrt{P}$ |
| 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              |

For transmitters rated a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

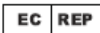
**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

| Guidance and Manufacturer’s Declaration - Electromagnetic Immunity                                                                                                             |            |                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------------------------------------|
| For the immunity to proximity fields from RF wireless communications equipment, the IOS is compliant with the test levels specified below, according to IEC60601-1-2 standard. |            |                                        |
| Test Frequency (MHz)                                                                                                                                                           | Band (MHz) | Immunity Test Levels                   |
| 385                                                                                                                                                                            | 380-390    | Pulse modulation 18Hz, 27V/m           |
| 450                                                                                                                                                                            | 430-470    | FM, ±5 kHz, deviation, 1kHz sine 28V/m |
| 710                                                                                                                                                                            | 704-787    | Pulse modulation 217Hz, 9V/m           |
| 745                                                                                                                                                                            |            |                                        |
| 780                                                                                                                                                                            |            |                                        |
| 810                                                                                                                                                                            | 800-960    | Pulse modulation 18Hz, 28V/m           |
| 870                                                                                                                                                                            |            |                                        |
| 930                                                                                                                                                                            |            |                                        |
| 1720                                                                                                                                                                           | 1700-1990  | Pulse modulation 217Hz, 28V/m          |

|      |           |                               |
|------|-----------|-------------------------------|
| 1845 |           |                               |
| 1970 |           |                               |
| 2450 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5280 | 5100-5800 | Pulse modulation 217Hz, 9V/m  |
| 5500 |           |                               |
| 5785 |           |                               |

# 6.7 Symbols on your 3DISC Scanner & Transport Case

| Symbol                                                                            | Description                                                                                                                                                |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Manufacturer's trade name and address (ISO 15223-1)                                                                                                        |
|  | Date of manufacture (ISO 15223-1)                                                                                                                          |
|  | Equipment Power On/Off (push/push)                                                                                                                         |
|  | Authorized Representative in the European Community                                                                                                        |
|  | European Conformity mark                                                                                                                                   |
|  | Medical Device                                                                                                                                             |
|  | Reference for the Device                                                                                                                                   |
|  | Unique Device Identifier                                                                                                                                   |
|  | User manuals are available electronically at the link provided ( <a href="https://docs.3disccloud.com/support/">https://docs.3disccloud.com/support/</a> ) |

# 7. Support, Warranty and Repair Service

## 7.1Support

If you have questions about the software, please consult the manual and Help menu in the software. If you are experiencing issues with your software, please check the list of common issues provided below prior to contacting a dealer. It could be simply a question of a minor issue that can be fixed quickly.

However, if you’re still experiencing problems after following the recommendations in this section, then please contact the dealer where you bought the equipment.

### Operating Issues Checklist

| Issue                                                                                               | Recommendation                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| There’s a memory full error message that pops up when the software is open.                         | Clear some space on the C Drive                                                                                                                                                       |
| The status in the Live view window is “Disconnected”.                                               | Check that the USB-C cables is connected to the Scanner and that the USB-C cable is connected to a USB-C Port.                                                                        |
| Scanning is very slow.                                                                              | Check that the Laptop is connected to an external power source.                                                                                                                       |
| The corners are cut in the live view window.                                                        | Check that the Tip is correctly mounted and when rotating it is locking in place with a click.                                                                                        |
| There is a red square in the scan window                                                            | Go back to a tooth that is scanned and start from there again                                                                                                                         |
| No images appear when scanned but everything else (e.g. live window image, sounds, FPS) works fine. | The scanner might need to be recalibrated. Please contact your local dealer for support.                                                                                              |
| There are spots on the Live view window.                                                            | Check and clean the mirror of the tip.                                                                                                                                                |
| Where can I get the 3DiscClinic software and manuals?                                               | Software and manuals can be downloaded in the Support section of the 3DISC website.<br>An Online Help is available at:<br><a href="https://docs.3disc.com">https://docs.3disc.com</a> |

## 7.2 Standard Warranty

3DISC warrants its non-consumable hardware products to be free from defects in materials and workmanship. The warranty covers the cost of parts and labor to repair the product.

Please keep the shipping container for future use. Products returned to the factory for repair should be properly packaged. To obtain warranty service, follow the procedure described in the Repair Service section. Failure to do so will cause delays and additional expense to the customer.

The warranty is valid when the product is used for its intended purpose and does not cover products which have been modified without written permission from **3D Imaging and Simulation Corp. Americas**, or which have been damaged by abuse, accident or connection to incompatible equipment.

This warranty is in lieu of all other warranties, expressed or implied.

## 7.3 Repair Service

The 3DISC Intra-oral Scanner (IOS) cannot be serviced locally. In the event of a hardware malfunction, contact your dealer to arrange for a swap unit (same model or newer) so your unit can be replaced, and work can continue. Some testing might be needed in order to verify the Hardware/Software error or malfunction.

The company reserves the right to cease providing repair, maintenance, parts and technical support for its non-consumable hardware products five years after a product is discontinued.

### Out of Warranty Repair Service

Out of warranty repair service is available in selected geographical locations. Contact the supplier for current terms and rates.

We hope this **Safety, Regulatory & Technical Specifications User Guide** was helpful to you.

For additional material and user information consult:  
OVO3 IOS Quick Guide

[3DISC Online Help](#)

For support requests, contact:

[3disc.com/support](http://3disc.com/support)

USA



### 3D Imaging and Simulation

Corp. Americas

365 Herndon Pkwy #18

Herndon, VA 20170 United States

Tel: +1 703 430 6080

Tel: +1 800 570 0363 (Toll free)

Contact 3DISC

[Info@3DISC.com](mailto:Info@3DISC.com)

Europe



### 3DISC Dental Connect

Tour CB21 16 Pl. de l'Iris

92400 Courbevoie FRANCE

Tel : +33 (0)1 42 25 73 98

Contact support

[support@3DISC.com](mailto:support@3DISC.com)