

Intraoral Scanner

User Manual

Original User Manual

Model 001

Model 010



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1. About this guide

This User Manual is valid for the product life cycle of your device and its software unless a new manual is published within this period.

The provided instructions contain important information on the safe and appropriate use of your scanner and its software. Make sure to have read and understood this document prior to working with the device. In case of questions, contact your local distributor.

Please keep this document for future reference.

1.1 Disclaimer

This device is designed for use by persons who have appropriate knowledge in dentistry and dental laboratory technology.

The user of this device is solely responsible for determining whether or not this device is suitable for a particular patient case and circumstances. The user is solely responsible for the correctness, completeness and adequacy of all data entered into this device and the provided software. The user has to check the correctness and accuracy of the results and to assess each individual case.

Dental Wings products must be used in accordance with their accompanying instructions for use. Improper use or handling of Dental Wings products will void the warranty, if any, given for Dental Wings products. If you require additional information on the proper use of Dental Wings products, contact your local distributor. The user is not allowed to modify Dental Wings products.

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Updates to hardware and software components are made regularly. Therefore some of the instructions, specifications and pictures contained in the User Manual may differ slightly from your particular situation. Dental Wings reserves the right to revise or make changes or improvements to this product or documentation at any time without obligation to notify any person of such revisions or improvements.

Third party products and product data

When scanning and designing cases the user may work with third party products and/or product data. Dental Wings, its subsidiaries, or distribution partners disclaim any liability for damages in connection with or arising from such third party product data or products being used within this scope.

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Software license

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Availability

Some of the products and accessories mentioned in the User Manual may not be available in all countries.

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2. Introduction and overview

2.1 Intended use

The Intraoral Scanner is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.

2.2 Device description and features

The Intraoral Scanner consists of a computer with embedded software, a touch-screen monitor, and a handpiece that contains optical sensors.

Device variants and configuration

The Intraoral Scanner (Type: DW-IO) is delivered in two product variants (*see Identification of the scanner parts, p. 14*):

- Model 001 (cart model)
- Model 010 (portable model)

Moreover, the device is delivered in the following configurations:

- With the distributor logo and color
- With a distributor-specific set of accessories
- With a distributor-specific software configuration
- With a country-specific power cord

Principles of operation

Sensors in the handpiece of the Intraoral Scanner provide data, which is matched to each other in the processing unit to create a digital impression.

Novel features

The Intraoral Scanner does not contain novel features in relation to conventional dentistry. The software supports digital realization of conventional dental services in the area of restorative prosthetic.

2.3 Accessories and products used in combination

The use of the Intraoral Scanner requires accessories (surface coating, standard laboratory bottle, cleaning and disinfection products, standard packaging material). Moreover, it can be used in combination with other products (e.g. CAD/CAM software).

Dental Wings has validated the specific products given in chapter *Technical data and label* (see *Accessory parts*, p. 39), in *Appendix A - Reprocessing of the handpiece* (p.44) and *Appendix B - Reprocessing of scanner unit and accessories* (p.50). Others may be suitable as well if they meet the requirements below. However, the user has to validate their compatibility with the Intraoral Scanner.

Since Dental Wings is continuously validating other suitable accessories and products, you may also contact your local distributor for more information.

Scanning

Scanning with the Intraoral Scanner may require surface coating according to the surface reflectivity and opacity. Suitable coating shall be intended to be used for intra- or extra-oral application in digital dentistry for matting surfaces and enhancing contrast on objects to be scanned.

Reprocessing

The Intraoral Scanner requires reprocessing. The particular use, specific requirements, as well as validated products for the reprocessing material and equipment are found in Appendices A and B.

Standard Laboratory Bottle: The bottles are used for soaking the handpiece. They shall be resistant to the cleaning and disinfection agents and fit into the reprocessing station. They shall meet the following characteristics:

- Height: 146 mm
- Diameter: 60 mm
- Inner diameter of bottle mouth: 45 mm
- Capacity: 250 ml

Cleaning and disinfection products : The scanner requires reprocessing with specific detergents and disinfectants. They are specified in Appendices A and B.

Standard packaging material: Standard see-through sterilization pouch shall be used to protect the semicritical area of the handpiece after reprocessing. A size of 9 cm x 20 cm is required. In addition, a standard plastic bag may be used to store the complete handpiece. A minimum size of 25 cm x 40 cm is required.

Further use of 3D scans

3D scans from the Intraoral Scanner may be used with other software products. It is required that such products can handle open STL files. Dental Wings has validated the use of:

DWOS: 3D dental restorations design software

Straumann® CARES® Visual: 3D dental restorations design software

2.4 Indications

The scanner is an intraoral optical 3D scanning device intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations. The 3D scan is provided in a 3D geometry format. The device allows several scanner heads embedded in the handpiece to scan at once from multiple angles. It is intended to be used by dental professionals.

2.5 Contraindications

The device is not intended to create images of the internal structure of teeth or the supporting skeletal structure. It is not intended to be used for cases with more than four (4) subsequent edentulous tooth positions.

2.6 Precautions

This scanner is capable of very precise scanning. To achieve scanning accuracy, comply with all the given instructions .

This device is a protection class I device. To avoid risk of electric shock it shall only be connected to a power outlet with protective earth.

The scanner is suitable for use in laboratories, dental offices and equivalent environment. However, the protection against dust and water has not been specifically tested.

Install the scanner in accordance with the instructions. Before any maintenance action, unplug the scanner from the power outlet.

Keep the original packaging of the scanner for safe transportation in case of service, repair and disposal. Unpack and pack your scanner following the instructions.

The Intraoral Scanner is only compatible with Dental Wings handpieces. Make sure you are connected to the internet when plugging a handpiece for the first time.

Reprocessing shall be done before the first use, then after each use, as well as prior to service, repair and disposal to prevent cross-contamination.

Always ensure a biunique relationship between patient, scan and treatment case.

Backup your data at regular intervals. It is the responsibility of the user to perform and maintain data backups in order to prevent loss of data.

Use a strong password to reduce the risk of intrusion.

Do not install or uninstall software on the system.

The use of surface coating may be required on the patient's teeth. When indicated, apply a uniform and very thin layer to ensure teeth characteristics are not modified. Always comply with the instructions given by the surface coating manufacturer.

Always handle the handpiece with great care as it contains fragile components. Dropping the handpiece on the floor may damage it permanently.

The handpiece heats up over normal body temperature, but it does not pose a hazard to the patient due to short term exposure and small contact area.

Make sure the scanner is placed in a safe and stable position.

Never put any load on the scanner.

Do not dispose of this device as unsorted municipal waste. Collect separately.

2.7 Compatibility information

The device is compatible with the Intraoral Scanner software application version 1.5 and higher.

2.8 Further information

Dental Wings and its products are registered in the main markets. If you have any questions please contact your local distributor.

Radiation information

The Intraoral Scanner contains a gesture control module, which includes an infrared laser projector. It is rated *Class 1* according to applicable standards (see *Technical data and label, p. 35*).

The handpiece contains LEDs. They are rated *Exempt* according to applicable standards (see *Technical data and label, p. 35*).

Electromagnetic compatibility information

The Intraoral Scanner is suitable for use in professional healthcare facility environment and does not execute any essential performance function in the understanding of the applied product standards. Nevertheless, it had been tested for electromagnetic compatibility (EMC) and needs special precautions.

The Intraoral Scanner needs to be installed and put into service according to the Electromagnetic Compatibility Guideline (see *Appendix C - Electromagnetic Compatibility Guideline, p. 53*).

Caution

The use of accessories other than those specified in *Technical data and label* (see *Accessory parts, p. 39*) may result in increased emission or decreased immunity of the Intraoral Scanner.

The Intraoral Scanner allows for wireless network connection. However, it may be interfered with radio frequency (RF) sources in the vicinity of the device (e.g, electromagnetic security systems, cellular telephones, radio frequency identification (RFID) or other in-band transmitters), even if that other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements.

The Intraoral Scanner should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Intraoral Scanner should be observed to verify normal operation in the configuration in which it will be used.

Other portable radio frequency 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 Intraoral Scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

2.9 Disposal

Caution

Reprocess prior to disposal to prevent cross-contamination.

Electrical and electronic devices must be disposed of separately from normal household waste in order to promote reuse, recycling and other forms of recovery, to avoid adverse effects on the environment and human health as a result of the presence of hazardous substances in some of their components and to reduce the quantity of waste to be eliminated with a view to reducing landfill. This includes accessories such as remote controls, power cords, etc.



 **Caution**

Do not dispose of this device as unsorted municipal waste. Collect separately.

For details on how to dispose of your device and its packaging, please contact your local distributor.

3. Installation

⚠ Caution

Keep the original box and packaging material for safe transportation of the device in case of service, repair and disposal. Unpack and pack your scanner following the instructions.

For instructions on how to pack the scanner, see *Packing the scanner (p.32)*.

3.1 Unpacking the scanner

Store the shipping box in a safe place in case you need to transport or ship the scanner in the future.

Cart Model

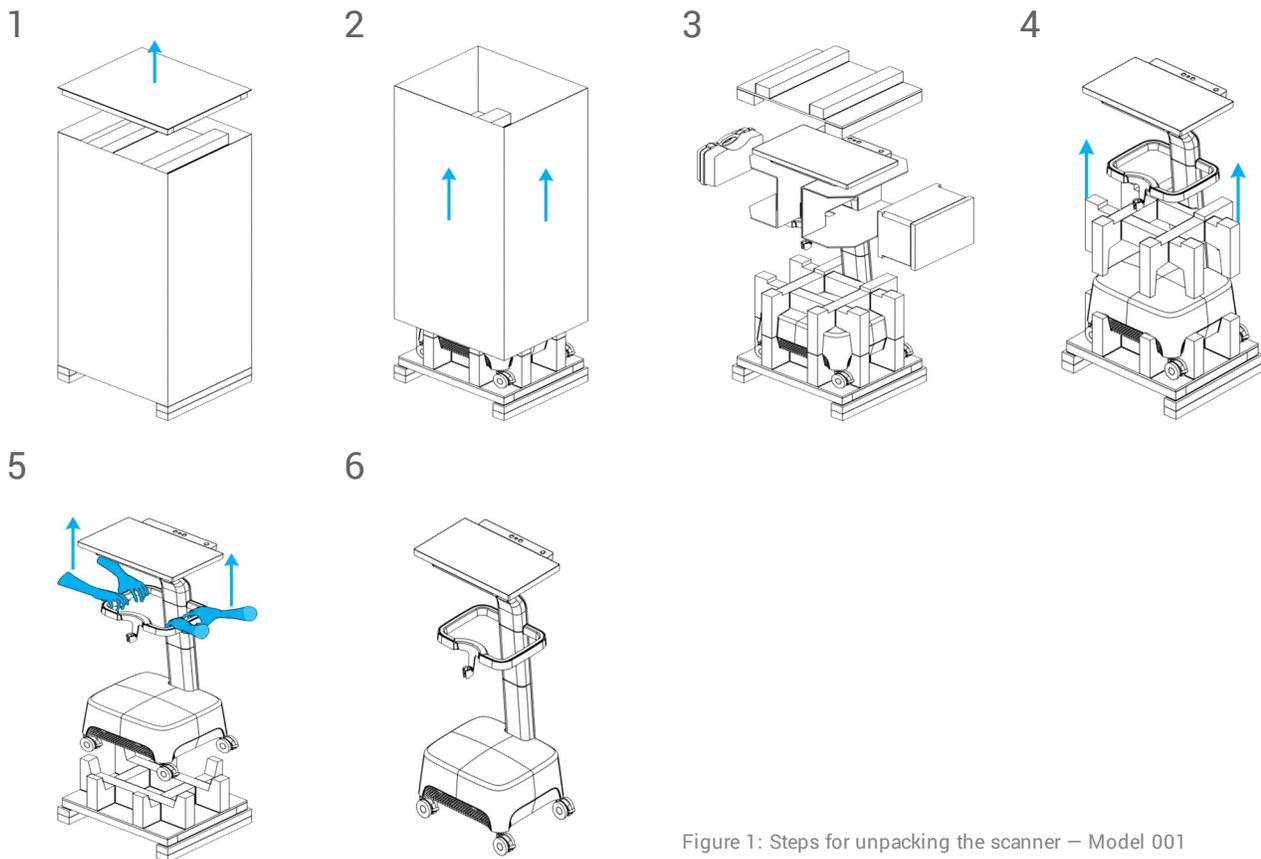


Figure 1: Steps for unpacking the scanner – Model 001

Portable Model

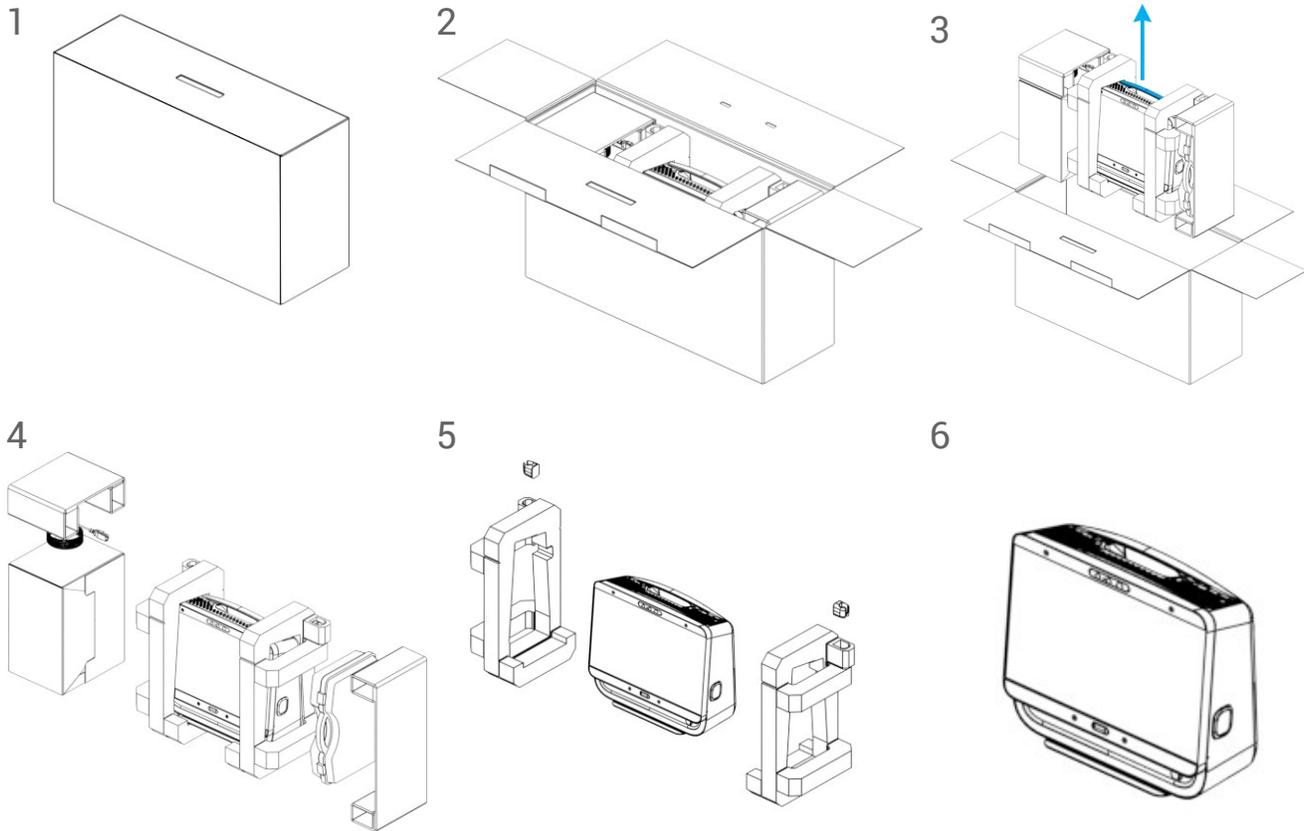


Figure 2: Steps for unpacking the scanner – Model 010

3.2 Setting up the scanner

⚠ Caution

Install the scanner in accordance with the manufacturer's instructions.

The scanner is suitable for use in laboratories, dental offices and equivalent environment. However, the protection against dust and water has not been specifically tested (see *Technical data and label*, p. 35).

Do not install the scanner in places with high temperature differences, near heat sources, in direct sunlight or in damp environment (e.g. exposed to splash water). Do not expose this device to rain or moisture. Do not install the scanner in dusty environment.

Do not block any ventilation openings.

The scanner must be turned off before plugging or unplugging any device or cable.

Always handle the handpiece with great care as it contains fragile components. Dropping the handpiece on the floor may damage it permanently.

Parts identification

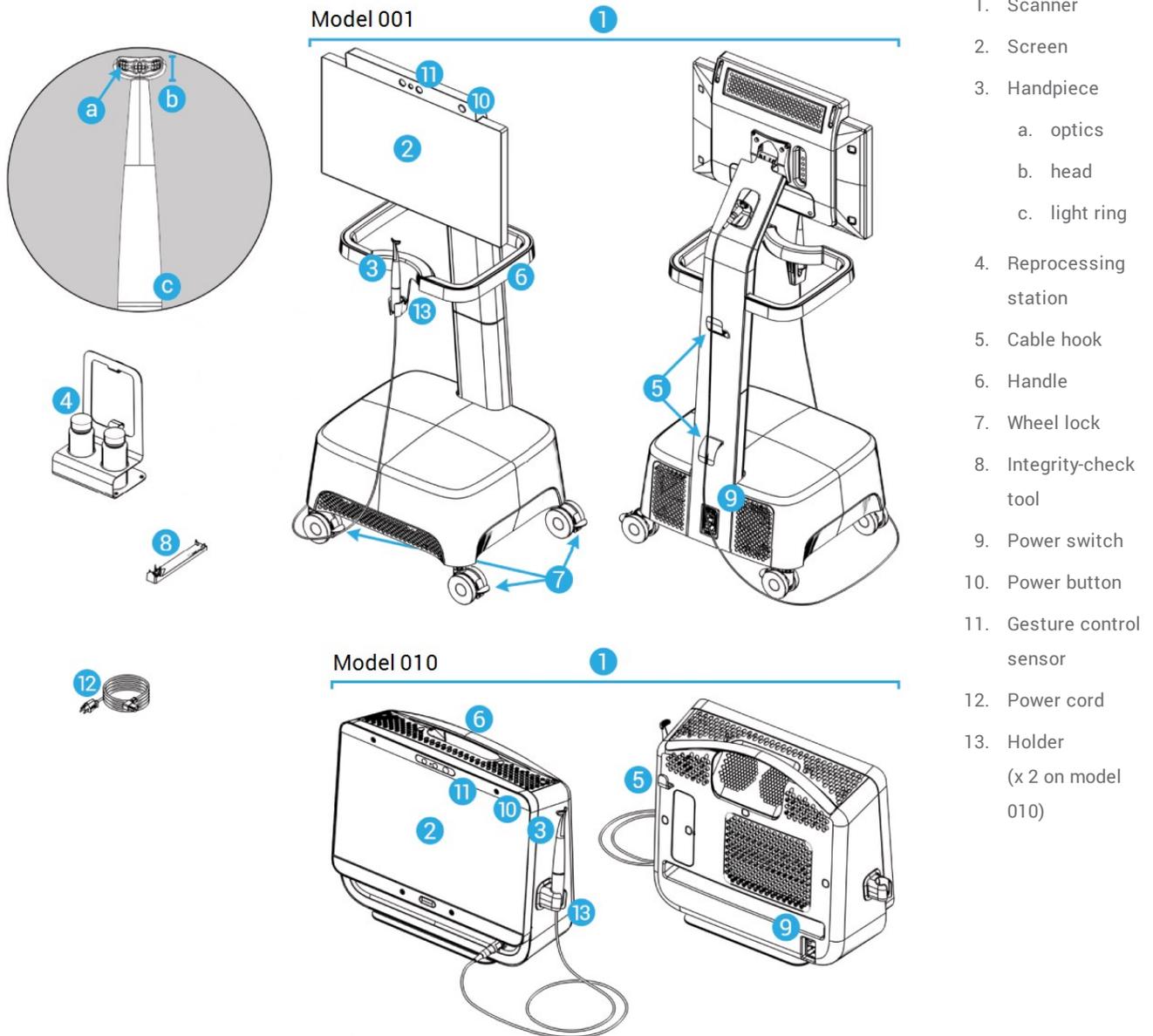


Figure 3: Identification of the scanner parts

Connecting the handpiece to the scanner

1. The arrows on the connector must be placed upward.
2. Insert the handpiece connector into the dedicated socket on the scanner.

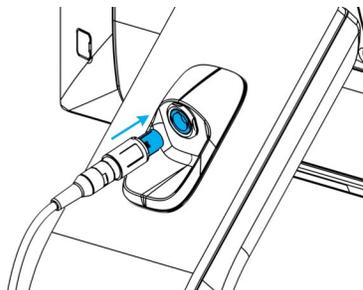


Figure 4: Connecting the handpiece to the back of the screen – Model 001

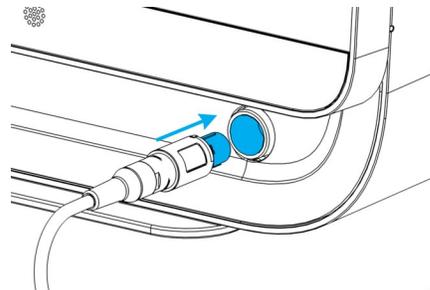


Figure 5: Connecting the handpiece below the screen – Model 010

Disconnecting the handpiece from the scanner

The device must be shut down first or the handpiece should be disconnected as follows

1. Select the *Settings* icon of the taskbar, then the *Handpiece Management* submenu.
2. Select the *Disconnect* button.
3. To release the cord, press both sides of the mobile cylinder and pull it towards you.
4. Then the cord can be released from the socket.

Installing holders for the handpiece

The holders must be installed on the scanner (portable model only). They are retained with a magnet. Placing one on each side is useful to accommodate both right- and left-handed users.

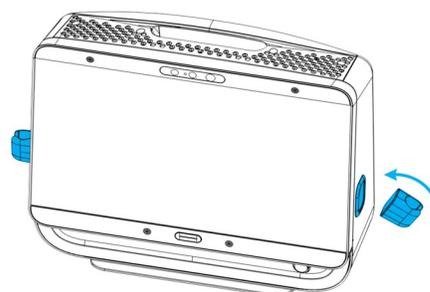


Figure 6: Installing the holders – Model 010

Caution

Never leave the handpiece elsewhere than in its dedicated holder.

Plugging the scanner

Caution

This device is a protection class I device. To avoid risk of electric shock it shall only be connected to a power outlet with protective earth.

To prevent fire or shock hazard, do not use the plug with an extension cord.

Protect the power cord from being walked on and from pinching.

1. Plug the power cord in the back of the scanner.
2. Plug the power cord into the power outlet.
3. Flip the power switch in the *power on position* (see *Scanner controls, p. 18*).
4. Press the power button (see *Scanner controls, p. 18*).

Refer to instructions for using the device (see *Basic principles and user interface, p. 18*).

Unplugging the scanner

Before any maintenance on the scanner, it should be unplugged as follows:

1. Turn off the device (see *Shutting down the device, p. 20*).
2. Flip the power switch in the "power off" position.
3. Unplug the power cord from the power outlet.
4. Loop the cord around the hook(s).

Integrity check

Caution

Make sure the integrity-check tool is reprocessed as required before and after it's use (see *Appendix B - Reprocessing of scanner unit and accessories, p. 50*).

To confirm correct installation of your device, proceed as follows:

1. Clean optics using a foam tip applicator soaked with alcohol.
2. Select the *Settings* icon of the taskbar, then *Handpiece Management* submenu.
3. Place the handpiece on the integrity-check tool, making sure both sides of the head fully rest on the tool (Figure 7).
4. Select the *Start test* button and wait for the confirmation and further instructions to display on the screen.

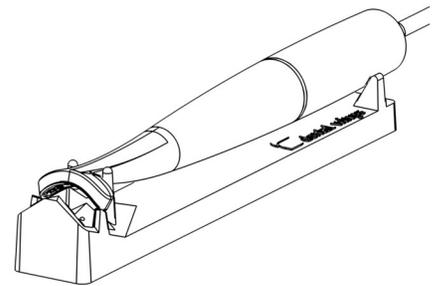


Figure 7: Using the integrity-check tool

Note

This procedure should also be performed if the handpiece was dropped or subject to a shock, to confirm that it is in good operating condition.

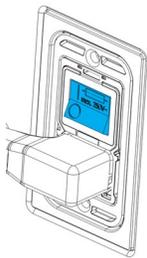
System language

The system language is preset. If this is not the case, contact your local distributor.

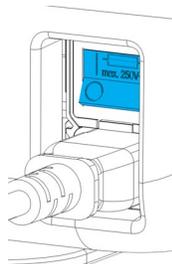
4. Basic principles and user interface

Scanner controls

Power switch : used to power on the scanner



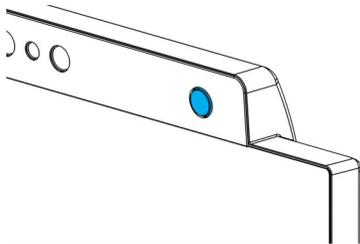
Model 001



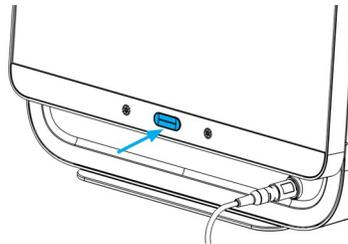
Model 010

| Position (down) | Scanner status |
|-----------------|----------------|
| I | Power on |
| O | Power off |

Power button: used to start up the scanner



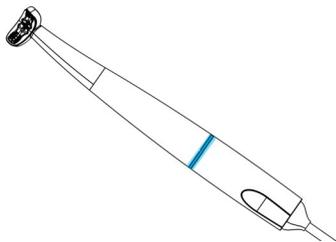
Model 001



Model 010

| Status | Scanner status |
|-----------|----------------|
| Light on | Turned on |
| Light off | Turned off |

Light ring: provides the user with a feedback of handpiece's status



| Color | Handpiece status |
|-------------------------|-------------------------------|
| Blinking, white to blue | Preheating |
| Blue | Preheated |
| Green | Scanning & acquiring data |
| Red | Scanning & not acquiring data |

Turning on the device

1. Press the power switch in the *power on* position.
2. Press the power button.
3. Select your user icon and type in your PIN.

First use

When the scanner is activated for the first time, a wizard pops up to assist the user with the basic settings: create administrator account, create users, set credentials to local network and other scanner settings.

User interface

The user interface is mainly icon-driven and provides direct instructions for performing the scans. Here are the main stations that you can access from the taskbar that is displayed on the left side of the screen:

- | | | | | | |
|---|-------------------------------------------------------------------------------------|-------------------------|---|--------------------------------------------------------------------------------------|------------------------------|
| 1 |  | Change user or shutdown | 4 |  | Case database |
| 2 |  | Workspace | 5 |  | Dentist and patient database |
| 3 |  | | 6 |  | Settings and Options |

Indicates the current workflow status of a case:
Plan, Scan, Align, Review or Export.

Data Transfer (WiFi)

The Intraoral Scanner can be used as a standalone device. It however allows for wireless data transfer on a local network, for sharing or back up purposes. For using a WiFi network, proceed as follows:

1. Starting outside of the screen, swipe your finger from the left side to the center of the screen.
2. You now have access to Windows menu and taskbar.
3. Follow manufacturer's instructions for managing wireless connections on Microsoft Windows 10.

Caution

Use protected WiFi setup and access. Keep a distance to other communication devices of 13 cm when you are using 2,4 GHz and 19 cm when you are using 5 GHz.

Shutting down the device

1. Select the top icon of the taskbar bar.
2. Select *Shutdown*.
3. Confirm (a warning pops up if a case is uploading to DWOS Connect).
4. Flip the power switch in the *power off* position if the power cord needs to be unplugged.

Gesture control

The scanner is equipped with a gesture control module. Its sensor is located above the screen as shown on Figure 3 (p. 14). Using gesture control instead of the touch-screen prevents cross-contamination during scanning.

| Step | Hand gesture | | Triggered action |
|------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1 | Place hand wide open in front of the sensor. |  | Activates the gesture control feature. |
| 2 | Point one finger upwards. |  | Displays contextual menu. |
| 3 | Move hand wide open from side to side. |  | To navigate inside the contextual menu. |
| 4 | Point one finger upwards. |  | Stops the navigation. You can therefore move your hand without affecting the selection. |
| 5 | Move hand towards the sensor while the finger is still pointing upwards. |  | Enters the selection. |
| 6 | Move hand wide open in any direction. |  | Moves the scan in 3D as if it was linked to your hand. |

Voice control

The scanner is equipped with a voice control module. Using voice control instead of the touch-screen prevents cross-contamination while enabling to perform all scans without moving your hands away from the patient or handpiece. The commands are listed below with their associated action.

| Voice command | Triggered action |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| io start | Launches the scan for the current element (upper, lower or occlusion). |
| io pause | Pauses the current scan (re-launch with the start command). |
| io next | Switches to the next step. |
| io reset | Erases the current data. |
| io undo | Removes surface data in a chronological fashion. |
| io redo | Restores surface data in a chronological fashion. |
| io lock | Protects the current scan against modification. The locked surfaces turn into a reddish color. |
| io unlock | Releases the locked surfaces so that they can again be modified. They turn back into their original color. |
| io screenshot | Takes a screenshot of the current view and attaches it to the order. |
| io take photo | Within the <i>Add Picture</i> feature of the <i>Plan Editor</i> : takes a photo from the screen built-in camera or from the handpiece camera, according to which one is active. |
| io powder | Switches to the scanning mode to be used when surface coating is applied. |
| io powder free | Switches to the scanning mode to be used when no surface coating is applied. |

5. Scanning

5.1 Accuracy

This scanner is capable of very precise scanning. For scanning accuracy as measured according to Dental Wings testing standard, see *Technical data and label (p.35)*.

Caution

To achieve scanning accuracy, comply with all given instructions.

Considering that the final accuracy and fit of the restoration highly depend upon the preciseness of the user's manipulations and judgment, the clinical outcome is easily influenced by the following factors ¹ :

- Scanning too fast
- Jaws shifting during occlusion scan
- Inadequate occlusion alignment
- Inadequate amount of surface coating
- Uneven application of surface coating

5.2 Step-by-step

Setup

Caution

Make sure the scanner has been reprocessed as described in *Reprocessing (p.26)*.

- Select a User or a Dentist;
- Enter security PIN;
- Select *New case*;
- Enter case description, including tooth number, restoration type, material and shade;
- Set *Appointment Date* for the preparation;
- Set *Due Date*, as the target delivery for the restoration at your clinic;
- Specify if a *Pre-Preparation Scan* is desired;

¹ Certain error sources can contribute with deviations in mm range.

- Select Patient (create or search);
- Add notes and attach files as desired;
- Select *Next*.

A short pre-heating must take place prior to scanning. When the light ring turns red or green, the handpiece is ready for scanning.

Caution

Always ensure a biunique relationship between patient, scan and treatment case.

Scan

Caution

The use of surface coating may be required on the patient's teeth. When indicated, apply a uniform and very thin layer to ensure teeth characteristics are not modified. Always comply with the instructions given by the surface coating manufacturer.

The handpiece will heat up over normal body temperature (*see Temperature limits, p. 35*), but it does not pose a hazard to the patient due to short term exposure and small contact area.

- Prepare the patient's mouth with surface coating if indicated (for scanning a full arch or due to surface characteristics);
- Lift the handpiece from its holder;
- Remove protective packaging from the handpiece, if any;
- Scan upper and lower arches as well as bite, following on-screen instructions;
- Select *Next* after each arch;
- Replace the handpiece on its holder.

Alignment

Caution

Verify that upper and lower arches are identified as such.

- Align upper and lower scans onto the bite scan, following on-screen instructions;
- If needed, invert upper and lower arches by selecting *Swap Arches*;
- If needed, switch quadrant by selecting *Switch Sides*;
- Adequate superimposition can be observed when the surface presents an evenly marbled pattern between both colors. Confirm by selecting *Next*.

Review

- Confirm complete occlusion by observing sufficient red areas.
- Identify planned preparations on the scanning data.
- Confirm adequate occlusal spacing on each preparation for restoration material using the gradient slider.
- Confirm absence of undercuts on each preparation by simulating the insertion axis.
- If desired, specify part or complete margin line on each preparation.

Export to DWOS Connect

- In the *Export* screen, verify the case overview;
- Select collaborating laboratory from the drop-down list;
- Review or complete attachments and notes;
- Select *Export*.

Back to the home screen, a progress bar is displayed until the case is sent. Wait until the progress is completed before turning off the device.

Export to STL

- Click the *Case database* icon from the taskbar;
- On the case to export, swipe your fingers towards the right side of the screen;
- Select *Export STL*;
- Select the destination folder.

6. Maintenance

6.1 Handling

Store the handpiece and scanner according to the given ambient conditions (*see Ambient conditions, p. 37*).

Use standard packaging material to protect the handpiece from contamination between uses (*see Accessories and products used in combination, p. 7*).

Unplug this device during lightning storms or when unused for long periods of time.

Note

The product warranty does not apply if damage to the product is the result of a lightning strike.

Caution

Position the scanner as such, that it can not move, tilt, wobble or fall.

The surface on which the portable model is placed shall be intended to carry the weight.

Always lock the wheels when not moving the cart model. Push down the red tabs for locking the wheels.

Before any maintenance action, unplug and reprocess the scanner.

To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.

Ensure that the packaging is large enough to contain the handpiece without excessively bending the cable.

Do not install or uninstall software on the system.

Moving to another room

- Shut down according to instructions (*see Shutting down the device, p. 20*)
- Flip the power switch in the "power off" position.
- Unplug the cord from the power outlet and loop it around the hook(s).
- Unlock the wheels by lifting up the red tab on each one of them (cart model only).
- Move the device while holding it by the handle (*see Identification of the scanner parts, p. 14*).
- When arrived at destination lock each wheel by pushing down the red tab (cart model only).

Note

If the handpiece was dropped or subject to a shock, run the integrity check to confirm that it is in good operating condition (*see Integrity check, p. 16*).

Transportation

Always use the original packaging to transport the scanner. Refer to instructions for *Packing the scanner (p.32)* and *Unpacking the scanner (p.12)*.

6.2 Reprocessing

⚠ Warning

Reprocessing shall be done before the first use, then after each use, as well as prior to service, repair and disposal to prevent cross-contamination.

⚠ Caution

Before any reprocessing, unplug the scanner from power outlet.

Always handle the handpiece with great care as it contains fragile components. Dropping the handpiece on the floor may damage it permanently.

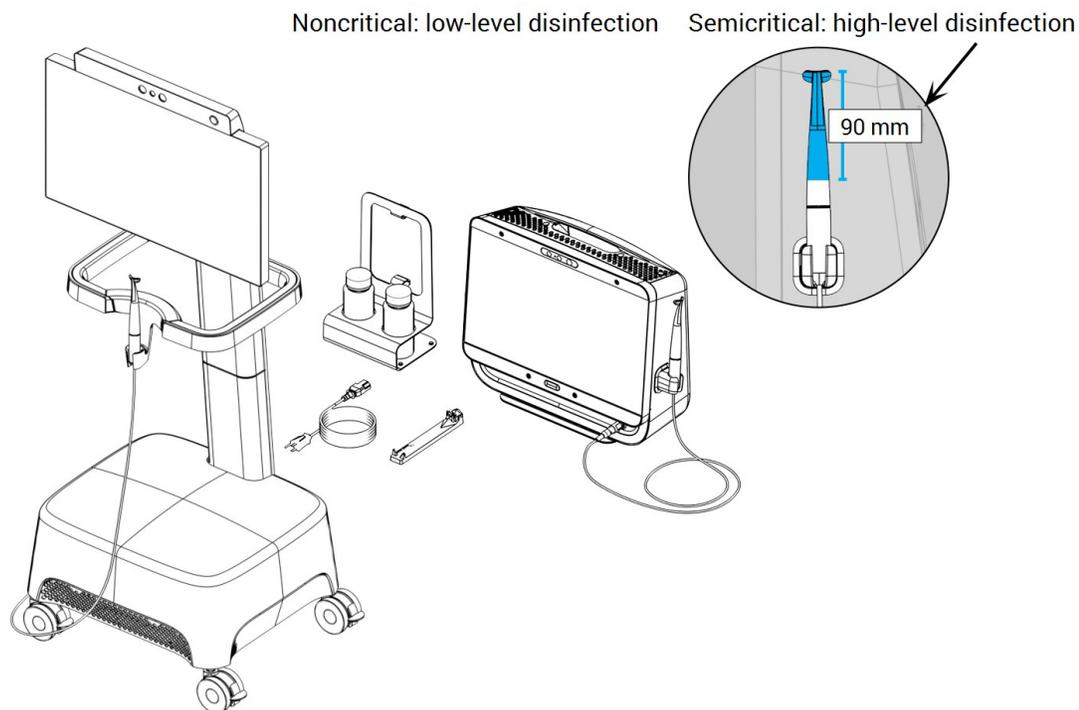


Figure 8: Disinfection levels of handpiece, scanner unit and accessories

The Intraoral Scanner consists of semicritical and noncritical areas. The materials used in the semicritical area are biocompatible. The semicritical area requires high-level disinfection¹. The noncritical area requires low-level disinfection¹.

Appendix A - Reprocessing of the handpiece and *Appendix B - Reprocessing of scanner unit and accessories* contain further details on how to reprocess the device.

The instructions given have been validated by Dental Wings² as being capable of preparing the Intraoral Scanner for re-use. It remains the responsibility of the user to ensure that the reprocessing as actually performed using equipment, material and personnel in the dental or reprocessing facility achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the instructions provided is performed under sole responsibility of the user and should be properly evaluated for effectiveness and potential adverse consequences.

6.3 Data backup

Caution

Backup your data at regular intervals. It is the responsibility of the user to perform and maintain data backups in order to prevent their loss.

Use a strong password to reduce the risk of intrusion.

The Intraoral Scanner performs automatic backups of the database, as long as you define a destination for it:

1. Log in as **Administrator**.
2. Select the **Settings** icon from the taskbar, then the **System Settings** submenu.
3. In the field **Backup target directory**, type in a location or click the folder icon to browse to the desired destination for storing the files created by the automatic backup feature.

¹ The term *high-level disinfection* is used in this manual to refer to the method used to reprocess semicritical areas, the term *low-level disinfection* is used to refer to the method used to reprocess noncritical areas. Both are known as *disinfection* in certain territories.

² Appendix A has also been validated by an independent, government accredited and recognized test laboratory.

6.4 Changing fine fuses

The Intraoral Scanner contains two fine fuses (see *Technical data and label, p. 35*). They are located at the back of the scanner, inside the power switch assembly (see *Identification of the scanner parts, p. 14*). If necessary, exchange them in the following way:

1. Using a small flathead screwdriver (approx. width 4 mm), lever out the insert.
2. Change the corresponding fine fuses.
3. Reassemble.

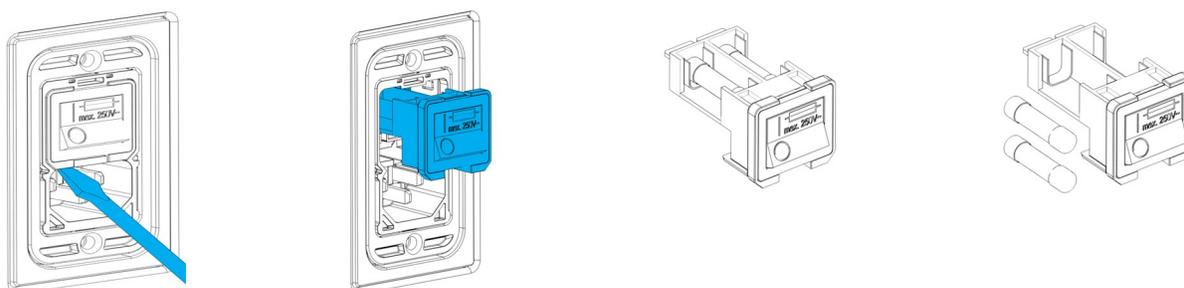


Figure 9: Instructions for changing fine fuses

6.5 Service

⚠ Caution

Reprocess prior to service to prevent cross-contamination.

To reduce the risk of electric shock, do not remove the cover. Refer servicing to authorized service personnel.

Do not replace components of the scanner without the prior authorization from your distributor. Refer servicing to authorized service personnel.

Service is required when the device has been damaged in any way, has been exposed to rain or moisture, does not operate normally, or has been dropped. Contact your local distributor.

The intraoral scanner does not require regular service. However, in certain countries it might be mandatory according national law. A risked based approach taking the amount of usage into account is acceptable. It shall be conducted according IEC 62353.

When returning your scanner for service or repair, pack the scanner as described in *Packing the scanner (p.32)*.

7. Troubleshooting

Find below a list of messages (some are abbreviated) that could appear while using the Intraoral Scanner, and the actions that should be taken to solve the problem.

| On-screen message | Required action |
|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Start up and log in | |
| Cannot start setup... ...credentials could not be verified. | Restart the device and try again. |
| It seems that there is no valid license to run this software on your system... | Contact your local distributor to obtain a license. |
| The scanner initialization failed. | Ensure that the handpiece is properly connected and restart the device. |
| Hardware and configuration | |
| Integrity check failed... | Restart the integrity check and ensure that you follow the procedure. |
| Integrity check failed again... | Contact your local distributor. |
| Integrity check failed because of an unforeseen error... | |
| An error has occurred. | Restart the device and try again. |
| No configuration file found for the connected handpiece. | |
| The configuration file does not match the connected handpiece. | <ol style="list-style-type: none"> 1. Check internet connection. 2. Click the <i>Settings</i> icon from the taskbar and select <i>Handpiece Management</i> submenu. In the Overview section, click on the download icon. |
| The connected handpiece has been qualified for demonstration only, not for clinical use. | The scan accuracy of the connected handpiece is not sufficient for patient cases. |

| On-screen message | Required action |
|-----------------------------------------------|-------------------------------------------------------------------|
| Database | |
| Case creation failed. | Restart the device and try again. |
| ... could not be computed/imported... | |
| Unable to save... | |
| Patient/Dentist update/deletion failed. | Try to export in a different folder and/or a different file name. |
| Database backup execution failed. | |
| Implant kit / ipflib file errors. | Select a valid implant kit file. |
| Software | |
| Server errors. | Restart the device and try again. |
| Error... loading 3D graphic resource. | |
| Unable to save the recorded message. | |
| Cannot recognize microphone. | |
| An error occurred while recording. | |
| Failed to convert case to XOrder... | |
| Dentist assignment failed. | Run the updater again. |
| Wrong client version. | |
| Case export failed. | Try to export in a different folder and/or a different file name. |
| Scanning | |
| Scanned area too small for meshing. | Scan more tooth surface before proceeding. |
| Unable to create mesh from scanned points. | Clear scan data and rescan. |
| Could not swap arches... | |
| ... Failed to create a temporary directory... | Clean up hard drive. |
| This case is not ready to export. | Complete the scan workflow before exporting the case. |
| No scan to save. | Complete the scan procedure and retry. |

| On-screen message | Required action |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| The scan has been interrupted to prevent overheating... | Wait one minute to let the handpiece cool down and then resume scanning. |
| DWOS Connect | |
| No internet connection... | Check internet connection. |
| Server not found/not reachable... | |
| Authentication to DWOS Connect failed. | Try again later. |
| Failed to authenticate on DWOS Connect... | Check DWOS Connect credentials. |
| Bad configuration for remote server. | Check that the DWOS Connect configurations are valid. |
| No remote server is configured. | Configure your case exchange server connection. |
| This case is not in queue. | Check if the case is in the upload queue in the workspace screen. If yes, restart the device and try again. |
| This case is already in queue. | Check if the case is in the upload queue in the workspace screen. If not, restart the device and try again. |
| Upload was canceled. | If you did not cancel the upload on purpose, restart the device and try again. |
| Please select a supplier... | Select a supplier in the export screen and export the case again. |
| Failed to upload case... Will automatically retry later. | Wait until it automatically retries. If it still fails, restart the device and try again. |
| Concurrent upload/multiple DWOS connect configurations not supported yet. | Contact your local distributor. |
| Internal server error (no token). | |
| A case cannot be exported twice. | Delete the case in DWOS Connect web interface and try again. |
| DWOS Connect configuration mismatch... | Use DWOS Connect web interface to delete the case. |

If the recommended action does not solve the problem, or for other on-screen messages, contact your local distributor.

8. Packing the scanner

Packing the scanner for transportation must be done as follows:

- Shut down the device;
- Flip the power switch in the "power off" position;
- Unplug the power cord, wind it carefully and place it inside one of the packaging inserts;
- Remove the handpiece holders by pulling them to release the magnet (portable model only);
- Place the handpiece in its plastic case;
- Pack the scanner in its original box and packaging material as shown in the pictures below.

Cart Model

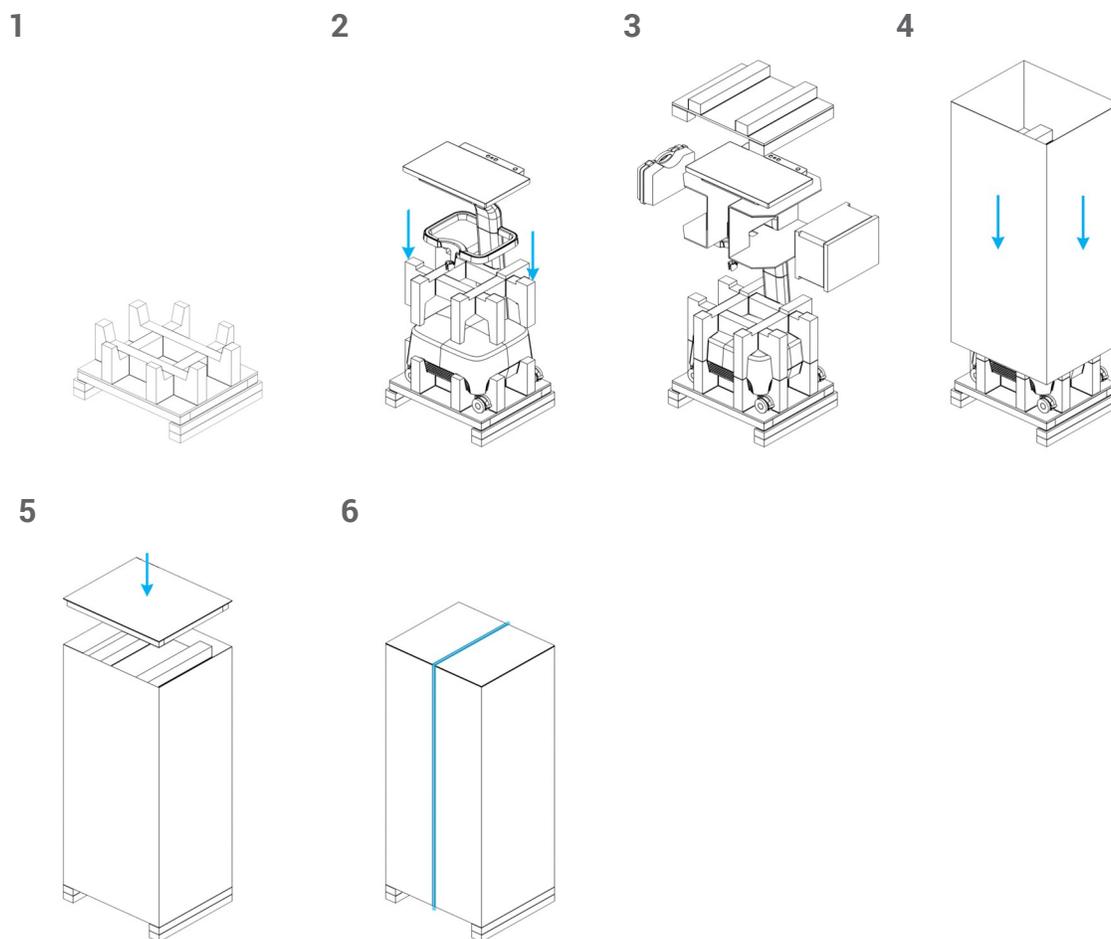


Figure 10: Steps for packing the scanner – Cart model

Portable Model

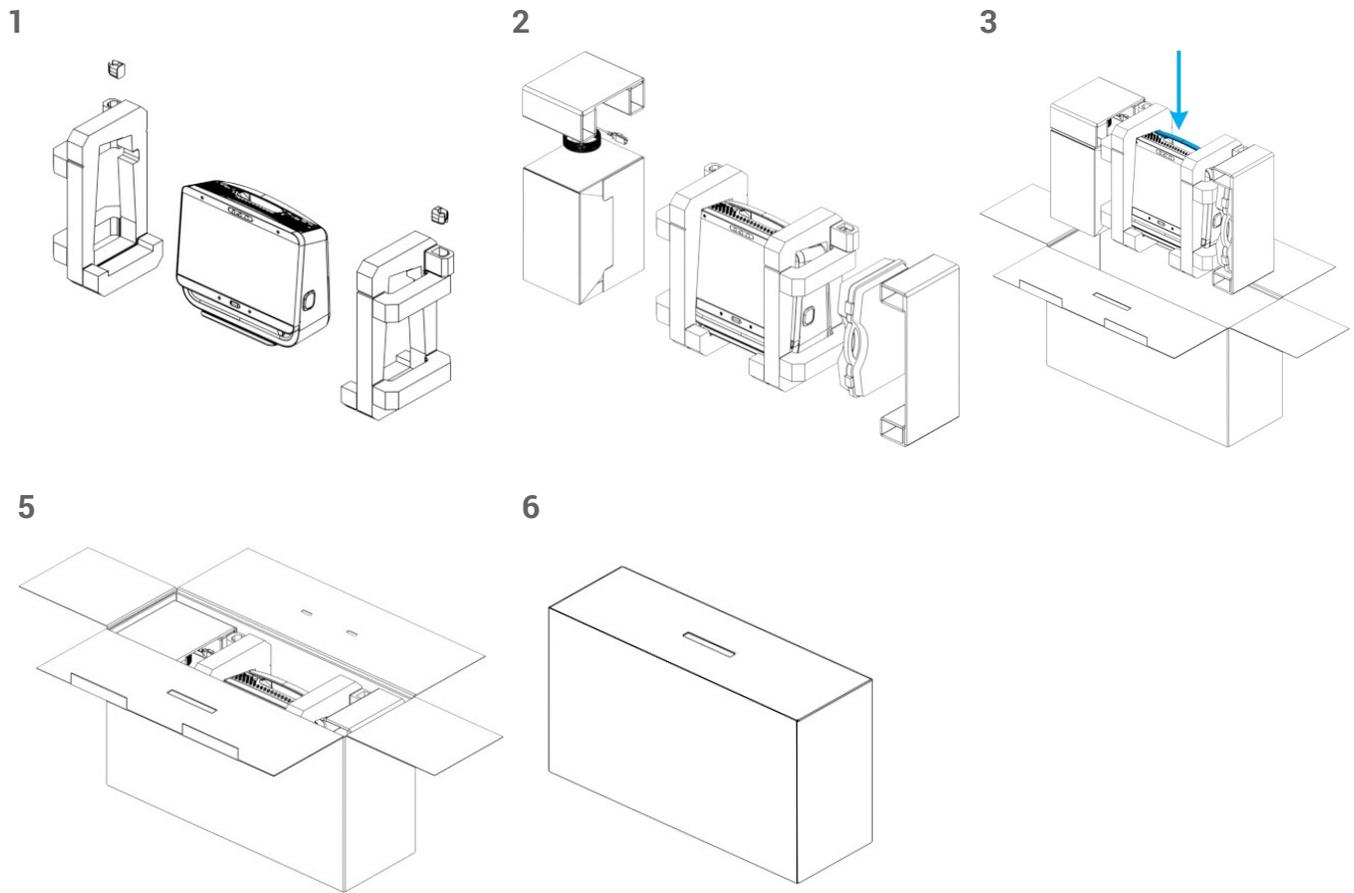


Figure 11: Steps for packing the scanner – Portable model

9. Distributors and service

Refer servicing to authorized service personnel. Contact your local distributor if your scanner needs to be repaired or if you need technical support for the scanner software.

10. Technical data and label

| Technical data | | |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Scanner input | 100 - 240 V ~, 50 Hz - 60 Hz, 540 VA | |
| Fuse | 5 mm x 20 mm, medium speed, 6 A, ceramic (high breaking capacity), 250 V ~ (2 x M6AH250V) | |
| WiFi | Frequency | 2.4 GHz or 5 GHz |
| | Standards | IEEE 802.11g/n/ac |
| | Security | Protected Access (WPA2) Protected Setup (PIN & PBC) |
| | Power Input | 5 V DC +/- 10%; 220 mA |
| | Effective Radiated Power Output | 0,085 W for IEEE 802.11 n/ac (dual band) 5 GHz 0,353 W for IEEE 802.11 g/n (single band) 2,4 GHz |
| Handpiece | Temperature limits | 40°C - 48°C (104°F - 118°F) |
| | Weight | 105 g (without cable) / 250 g (with cable) |
| | Dimensions | Length: 198 mm (7.8") Arc thickness: 5 mm (0.2") |
| | Applied part type BF (acc. IEC 60601-1) | |
| LED risk group (acc. IEC 62471) | Exempt | |
| Laser class (acc. IEC 60825) | Class 1 | |
| Protection class (acc: IEC 60529) | IPX5 (semicritical area - protection against low pressure jets of water from all directions); IPX0 (noncritical area - no protection) | |
| Protection class (electrical) | Class 1 Equipment; Basic insulation, relies on an earth for protection. The earth connection is achieved with a 3-conductor mains cable ending in a 3-prong AC connector which shall be plugged into a corresponding AC outlet. | |
| Pollution Degree | 2; Normally only non-conductive pollution occurs. Temporary conductivity caused by condensation is to be expected. | |

| Technical data | | |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Mode of operation | Continuous | |
| Type / Model number | DW-IO-001 (cart) | DW-IO-010 (portable) |
| Computer / OS | Integrated high-performance computer storage for 8000 cases Dedicated high-end graphic card Windows 10 operating system Integrated gesture control and voice commands | |
| | 21" multi-touch screen | 17" multi-touch screen |
| Dimensions uncrated (W x D x H) | 520 mm x 460 mm x 1270 mm (20.5" x 18.1" x 50.0") | 513 mm x 178 mm x 375 mm (20.2" x 7.0" x 14.8") |
| Dimensions crated (client) (L x W x H) | 600 mm x 510 mm x 1370 mm (23.6" x 20.1" x 53.9") | 850 mm x 270 mm x 500 mm (33.5" x 10.5" x 19.5") |
| Dimensions crated (demo unit) (L x W x H) | 605 mm x 515 mm x 1345 mm (23.8" x 20.3" x 53.0") | Plastic case 625 mm x 500 mm x 366 mm (24.6" x 19.7" x 14.4") |
| | | Reprocessing station 370 mm x 265 mm x 225 mm (14.6" x 10.5" x 8.9") |
| Weight uncrated | 38.0 kg (84 lb) | 12 kg (27 lb) |
| Weight crated (client) | 54 kg (119 lb) | 17 kg (35 lb) |
| Weight crated (demo unit) | 70 kg (154 lb) | Plastic case 23 kg (50 lb) |
| | | Reprocessing station 1.4 kg (2.2 lb) |

| Ambient conditions | |
|----------------------------|---------------------------------------------------------------------|
| Operating temperature | 15 °C - 40 °C (59°F - 104°F) |
| Storage conditions | 10 °C - 40 °C (50°F - 104°F), controlled moisture (no condensation) |
| Transportation temperature | -62°C - 71°C (-80°F - 160°F) |
| Relative humidity | 20% - 80% |
| Atmospheric pressure | 60 kPa - 106 kPa |

| Software applications | Included | Optional |
|----------------------------------------|----------|----------|
| Intraoral Scanner software application | x | |

| Scanning parameters | |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patient characteristics | No restrictions apply |
| Optical technology | LED light High-speed measuring cameras Video cameras |
| Scannable material | No restrictions Some situations may require the use of surface coating according to the reflectivity and opacity of the surface (<i>see Accessories and products used in combination, p. 7</i>). |
| Scanning volume | Up to 3 teeth |
| Scanning accuracy | According to Dental Wings testing standard : 20 µm (single unit); 50 µm (quadrant without surface coating); 50 µm (full arch with surface coating) |
| Scanning time | 45 s (full arch with surface coating) |
| Output format | Open STL or cloud sharing through DWOS Connect |

Scanner label

This is an example of the label on your device:

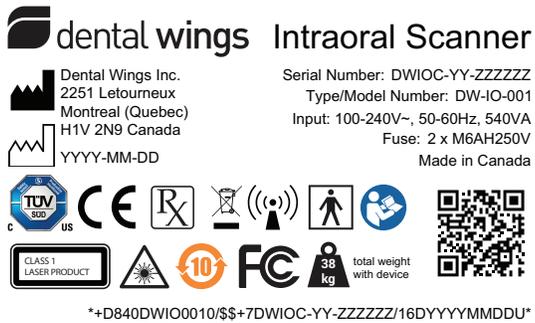


Figure 12: Device label – Model 001

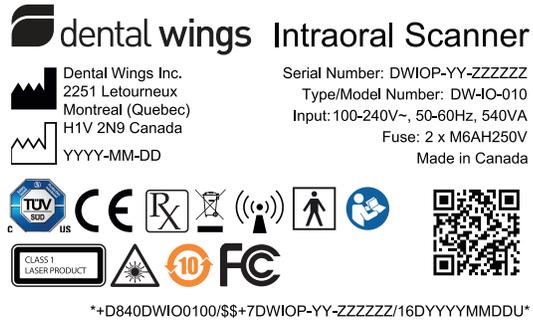
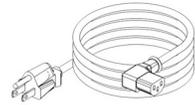
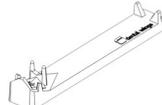
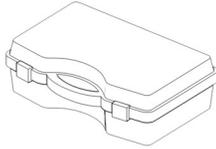
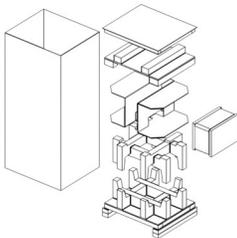
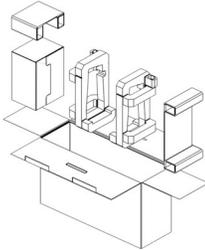
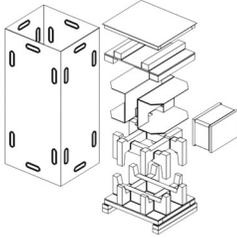


Figure 13: Device label – Model 010

The label on the device shows its legal manufacturer. The country of origin of the legal manufacturer defines which certifications and Declaration of Conformity apply to your device.

| Certifications | |
|--------------------------|------------------------|
| Dental Wings inc. Canada | CE, OHSA, Canada (SCC) |

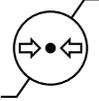
| Accessory parts | Standard | Standard | Optional | Part No. | Image | Intended use |
|----------------------|-----------|-----------|----------|--------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| | Model 001 | Model 010 | | | | |
| Handpiece | | | ● | 6100-1 |  | Replacement or additional handpiece for the Intraoral Scanner. |
| Power Cord | ● | | | 22-0156 (US) 22-0159 (EU) 22-0165 (UK) 22-0167 (BR) |  | The country-specific power cord connects the Intraoral Scanner to power outlet. |
| Power Cord | | ● | | 22-0163 (US) 22-0162 (EU) 22-0164 (UK) 22-0166 (BR) |  | The country-specific power cord connects the Intraoral Scanner to power outlet. |
| Integrity-check Tool | ● | ● | | 30-0126 |  | The integrity-check tool is used to confirm accuracy of the handpiece. |
| Reprocessing Station | ● | ● | | 40-0131 |  | Holding device for standard laboratory bottle and handpiece during reprocessing. |
| Reprocessing Bottle | ● | ● | | e.g. 312105-0008, from ThermoScientific Nalgene (19-0046) |  | Standard laboratory bottle to be filled with enzymatic detergent or (high-level) disinfectant. |

| Accessory parts | Standard | Standard | Optional | Part No. | Image | Intended use |
|--------------------------------------|-----------|-----------|----------|----------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| | Model 001 | Model 010 | | | | |
| Handpiece Storage Case | ● | ● | | 70-0045 |  | Protects the handpiece during shipment and stores integrity-check tool. |
| Client Shipping Crate | ● | | | 70-0040 |  | This box serves as (replacement) box for return shipment. |
| Client Shipping Box | | ● | | 6250-1 |  | This box serves as (replacement) box for return shipment. |
| Demo Unit Shipping Crate (Model 001) | | | ● | 70-0046 |  | Demonstration unit shipping box for Dental Wings and distributors. |
| Demo Unit Travel Case (Model 010) | | | ● | 6255-1 |  | Demonstration unit shipping box for Dental Wings and distributors. |

| Accessory parts | Standard | Standard | Optional | Part No. | Image | Intended use |
|-----------------------------------------------------------|-----------|-----------|----------|--------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Model 001 | Model 010 | | | | |
| Surface Coating | | | ● | e.g. 400.200 from Dentaco |  | Surface coating material used for intra- or extra-oral application in digital dentistry for matting surfaces and enhancing contrast on objects to be scanned. |
| Applicator Tips | | | ● | e.g. 400.204 from Dentaco |  | Replacement applicator tips for surface coating material. |
| Standard see-through Sterilization Pouch (90 mm x 200 mm) | | | ● | e.g. Tyvek® 90 mm x 200 mm, single use |  | Standard see-through sterilization pouch to protect the semicritical area of the handpiece. |
| Standard Plastic Bag (250 mm x 400 mm) | | | ● | e.g. Tyvek® 300 mm x 450 mm, single use |  | Standard plastic bag to store the complete handpiece. |

11. Explanation of symbols

| | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
|  | Indicates the legal manufacturer |
|  | Indicates the date when the device was manufactured |
|  | Caution, consult the User Manual for important cautionary information |
|  | Laser radiation |
|  | Class 1 laser product acc. to IEC 60825-1 |
|  | Direct current |
|  | Alternative current |
|  | Device fulfills the requirements of the european directives given on the EC Declaration of Conformity |
|  | Compliance with U.S. Occupational Safety and Health standards as well as SCC requirements (Canada) |
|  | Device complies with part 15 of the FCC rules |
|  | Environment friendly use period acc. to China RoHS |
|  | Caution: US Federal law restricts this device to sale by or on the order of a licensed health-care practitioner |

| | |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
|  | Contents of the transport package are fragile. Handle with care. |
|  | Indicates the correct upright position of the transport package |
|  | Do not dispose of this device as unsorted municipal waste. Collect separately. |
|  | Follow instructions of the User Manual |
|  | Device includes a radio frequency transmitter; interference may occur in the vicinity of equipment marked with this symbol |
|  | Type BF Applied Part |
|  | Device weight is as indicated in the label, no working load permitted. |
|  | Temperature limit for transport |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |

Appendix A - Reprocessing of the handpiece

Manufacturer: Dental Wings inc.

Method: Combination of high- and low-level disinfection

Device: Intraoral Scanner handpiece

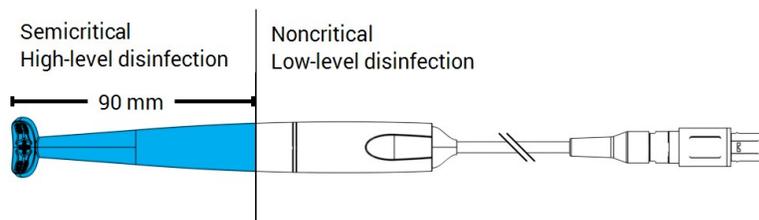


Figure 14: Handpiece - Reprocessing characteristics

Precautions

- Do not autoclave.
- Never immerse the handpiece completely in liquids. Never immerse deeper than indicated in the User Manual.
- Be very careful when rinsing the handpiece. Make sure that the rinsing covers the entire area immersed in chemicals.
- While rinsing, pay particular attention to the cable strain relief. Liquids would easily enter there and damage the handpiece.
- Do not use abrasive cleaners.
- Scratches on the optics cause damage to the handpiece. Be very careful in applying the soft, nylon-bristled toothbrush. Do not rub cloth against optics. Use a blotting motion.
- Brushing can only be conducted outside the bottle. Protect personnel and surroundings from contamination.
- Do not use corrosive cleaning agents or disinfectants with acids, bases, oxidizing agents, and solvents (with exception of simple alcohol).
- Ensure that the packaging for storage is large enough to contain the handpiece without excessively bending the cable.
- Make sure the handpiece is completely dry before storage or assembly to the scanner unit.

Limitations on reprocessing

Repeated reprocessing has minimal effect on the handpiece. End of life is normally determined by damage and wear due to use. Reprocessing validation has been done for 250 cycles. We strongly recommend that the user regularly inspect the handpiece. User is solely responsible for issues arising from the use of a damaged or worn handpiece.

Equipment and material

- Enzymatic detergent¹ intended for cleaning of medical devices made of metal, glass and plastics
- High-level disinfectant¹ (for outside US: disinfectant with at least mycobactericidal effectiveness); intended for disinfection of medical devices made of metal, glass and plastics; proven efficiency (e.g. FDA clearance, VAH/DGHM listing, CE marking)
- Low-level disinfectant¹ (for outside US: alcohol-based disinfectant) intended for surface disinfection of medical devices made of metal, glass and plastics; proven efficiency (e.g. FDA clearance, VAH/DGHM listing, CE marking)
- Potable tap water (unless national regulation requires differently)
- Soft, lint-free, non-abrasive, disposable cloth
- Soft, nylon-bristled toothbrush
- Reprocessing station with bottles

Instructions

Point of use

- Immediately remove excess soil within semicritical area using a soft, lint-free, non-abrasive, disposable cloth.
- Reprocess within two hours maximum.

¹ Use only the validated cleaning products that are detailed at the end of this Appendix (p. 48).

Instructions

Preparation for decontamination

1. Disconnect handpiece from scanner (see User Manual).
2. Transport handpiece to designated reprocessing area (there are no particular requirements on containment and transportation).
3. Select specific enzymatic detergent, high-level and low-level disinfectant¹ so that they comply with the equipment description of this procedure. Follow their instruction for use in terms of storage, concentration, application, temperature and post-rinsing.
4. Prepare reprocessing station (Figure A). It has cutouts to hold two standard laboratory bottles (see *Accessories and products used in combination*, p. 7). One bottle shall contain enzymatic detergent¹, the other high-level disinfectant¹.
5. Prepare enzymatic detergent and high-level disinfectant¹ as described in their instructions for use.
6. Fill each bottle up to 225 ml (Figure B) - left bottle with enzymatic detergent¹, right bottle with high-level disinfectant¹. Label each bottle to avoid mistakes.

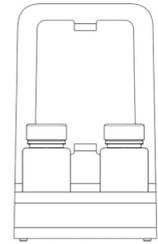


Figure A

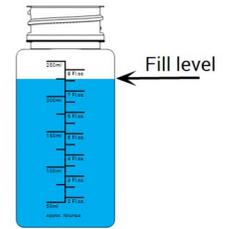


Figure B

Cleaning: Automated

Automated cleaning must not be applied to handpiece.

¹ Use only the validated cleaning products that are detailed at the end of this Appendix (p. 48)

Instructions

Cleaning: Manual

1. Clean noncritical area of handpiece with a soft, lint-free, non-abrasive, disposable cloth, moistened with potable tap water.
2. Secure the cable on the backside of the reprocessing station (Figure C).
3. Immerse semicritical area of handpiece in the bottle with enzymatic detergent¹ and soak as described in its instructions for use.
4. Unless no residues are visible, thoroughly brush semicritical area of handpiece completely with a soft, nylon-bristled toothbrush.
5. Thoroughly but very carefully rinse semicritical area of handpiece completely under potable tap water (Figure D). Conduct rinsing three (3) times, each for a minimum of one (1) minute in duration. Turn handpiece repeatedly while rinsing.
6. Dry using a fresh, soft, lint-free, non-abrasive, disposable cloth, beginning at the semicritical area of the handpiece. Use a blotting motion for the optics.

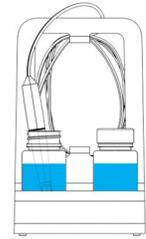


Figure C

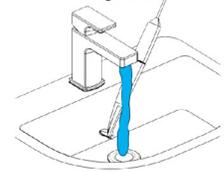


Figure D

Disinfection: Automated

Automated disinfection must not be applied to the handpiece.

Disinfection: Manual

1. Apply low-level disinfectant¹ to noncritical area of handpiece as described in its instructions for use.
2. Secure the cable on the backside of the reprocessing station (Figure E).
3. Immerse semicritical area of handpiece in the bottle with high-level disinfectant¹ and soak as described in its instructions for use.
4. Thoroughly but very carefully rinse semicritical area of handpiece completely under potable tap water (Figure D). Conduct rinsing five (5) times, each for a minimum of one (1) minute in duration. Turn handpiece repeatedly while rinsing.
5. Dry using a fresh, soft, lint-free, non-abrasive, disposable cloth, beginning at the semicritical area of the handpiece. Use a blotting motion for the optics.

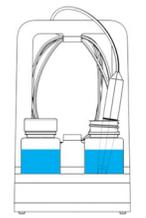


Figure E

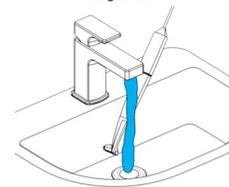


Figure D

¹ Use only the validated cleaning products that are detailed at the end of this Appendix (p. 48)

Instructions

Drying

Rest handpiece on a clean place at room temperature until it is completely dry.

Maintenance

Maintenance is not applicable.

Inspection and Testing

- Visually inspect for damage and wear (e.g. for scratches, discoloration, corrosion).
- Check in particular that there is neither clouding nor scratches on the optics.
- In case of doubt, conduct an integrity check (see User Manual).
- Replace handpiece in case of damage and wear (e.g. deep scratches, corrosion, failed integrity check).

Sterilization

Sterilization must not be applied to handpiece and is not required (handpiece is classified semicritical/noncritical).

Packaging/Storage

- Cover semicritical parts of the handpiece with an open see-through sterilization pouch. A size of 9 cm x 20 cm is required.
- In addition, a standard plastic bag may be used to store the handpiece. A minimum size of 25 cm x 40 cm is required.

Additional Information

The User Manual contains more detailed descriptions and figures on disconnecting from and connecting to scanner, integrity check, transportation, handling (including storage), disposal, technical data, ambient temperature etc.

Manufacturer Contact

See the User Manual back cover.

Fundamental suitability of the handpiece (initial state and after 250 cycles) and the instructions provided above for effective high-level disinfection has been validated by an independent government accredited and recognized test laboratory using Cole-Parmer Graduated bottle PP (write on, wide mouth, 250 ml, Item # WE-06041-14) as part of the reprocessing station, CIDEZYME® / Enzol® and Cidex® OPA Solution (both ASP Johnson & Johnson).

Non-detraction of functionality was demonstrated in 250 cycles using Cole-Parmer Graduated bottle PP (write on, wide mouth, 250 ml, Item # WE-06041-14) as part of the reprocessing station, CIDEZYME®/ Enzol®, Cidex® OPA Solution (both ASP Johnson & Johnson), and Bacillo® 30 Foam (Bode Chemie). In addition, it has been validated by Dental Wings using the aforementioned equipment and material , and Isopropanol 70% (Jedmon Products Ltd.).

The instructions given have been validated by Dental Wings as being capable of preparing the Intraoral Scanner for re-use. It remains the responsibility of the user to ensure that the reprocessing as actually performed using equipment, material and personnel in the dental or reprocessing facility achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the instructions provided is performed under sole responsibility of the user and should be properly evaluated for effectiveness and potential adverse consequences.

Date issued: January, 2016

Appendix B - Reprocessing of scanner unit and accessories

Manufacturer : Dental Wings inc.

Method : Low-level disinfection

Device : Intraoral Scanner unit and accessories

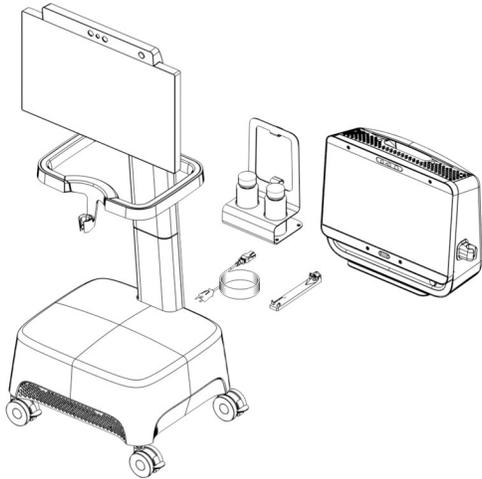


Figure 15: Scanner units and accessories - reprocessing characteristics

Precautions

- Do not use abrasive cleaners.
- Do not use corrosive cleaning agents or disinfectants with acids, bases, oxidizing agents, and solvents (with exception of simple alcohol).
- Do not rinse the scanner unit.
- Make sure the scanner is completely dry before plugged into power outlet.

Limitations on reprocessing

Repeated reprocessing has minimal effect on the scanner and accessories. End of life is normally determined by damage and wear due to use. Reprocessing validation has been done for 250 cycles. We strongly recommend that the user regularly inspect the scanner and the accessories. User is solely responsible for issues arising from the use of damaged or worn scanner and accessories.

Equipment and material

- Low-level disinfectant¹ (for outside US: alcohol-based disinfectant) intended for surface disinfection of medical devices made of metal, glass and plastics; proven efficiency (e.g. FDA clearance, VAH/DGHM listing, CE marking)
- Soft, lint-free, non-abrasive, disposable cloth

Instructions

Point of use

Reprocess within two hours maximum.

Preparation for decontamination

- Select specific low-level disinfectant¹ according to its instructions for use. Follow it in terms of storage, concentration, application and temperature.
- Unplug scanner (see User Manual).

Cleaning: Automated

Automated cleaning must not be applied for scanner and accessories.

Cleaning: Manual

Clean noncritical area as described in the low-level disinfectant's instructions for use. Use a soft, lint-free, non-abrasive, disposable cloth for wiping.

Disinfection: Automated

Automated disinfection must not be applied for scanner and accessories.

Disinfection: Manual

Conducted in one step with cleaning step.

Drying

Dry at room temperature until it is completely dry.

Maintenance

Maintenance is not applicable.

¹ Use only the validated cleaning products that are detailed at the end of this Appendix (p. 52)

Instructions

Inspection and Testing

- Visually inspect for damage and wear (e.g. for scratches, discoloration, corrosion).
- In case of doubt, conduct an integrity check (see User Manual).
- Replace components and accessories with signs of damage and wear (e.g. with deep cracks).

Sterilization

Sterilization must not be applied for scanner and accessories and is not required (scanner unit and accessories are classified noncritical).

Packaging/Storage

No requirement in particular.

Additional Information

Consult the User Manual for more details.

Manufacturer Contact

See the User Manual back cover.

Non-detraction of functionality was demonstrated in 250 cycles using Isopropanol 70% (Jedmon Products Ltd.).

The instructions given have been validated by Dental Wings as being capable of preparing the Intraoral Scanner for re-use. It remains the responsibility of the user to ensure that the reprocessing as actually performed using equipment, material and personnel in the dental or reprocessing facility achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the instructions provided is performed under sole responsibility of the user and should be properly evaluated for effectiveness and potential adverse consequences.

Date issued: January, 2016

Appendix C - Electromagnetic Compatibility Guideline

Guidance and manufacturer's declaration - electromagnetic emissions

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

| Emission test | Compliance | Electromagnetic environment – guidance |
|-------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions CISPR 11 | Group 1 | The Intraoral Scanner uses radio frequency (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 emissions 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 emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Table 1

Guidance and manufacturer's declaration – electromagnetic immunity

The Intraoral Scanner is intended for use in the electromagnetic environment specified below. 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 |
|--------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 2/4/8/15 kV air | ± 8 kV contact ± 2/4/8/15 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 IEC 61000-4-4 | ± 2 kV 100 kHz repetition frequency | ± 2 kV 100 kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 0.5/1 kV line to line ± 0.5/1/2 kV line to ground | ± 0.5/1 kV line to line ± 0.5/1/2 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. |

| | | | |
|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Voltage dips and interruptions IEC 61000-4-11 | 0% U _T ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° | 0% U _T ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° | 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 interruptions, it is recommended that the Intraoral Scanner be powered from an uninterruptible power supply or a battery. |
| | 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0° 0% U _T ; 250/300 cycles | 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0° 0% U _T ; 250/300 cycles | |
| Rated power frequency magnetic field IEC 61000-4-8 | 30 A/m 60 Hz | 30 A/m 60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE U _T is the a.c. mains voltage prior to application of the test level. | | | |

Table 2

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------------------------------|----------------------------------------|
| The Intraoral Scanner is intended for use in the electromagnetic environment specified below. 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 |
| Portable and mobile RF communications equipment should be used no closer to any part of the Intraoral Scanner, including cables, than the recommended distance calculated from the equation applicable to the frequency of the transmitter. | | | |
| | | | Equation for distance calculation |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V | 3 V | $d = 1,2 \sqrt{P}$ |
| | 0,15 MHz - 80 MHz | 0,15 MHz - 80 MHz | |
| | 6 V in ISM bands between 0,15 MHz – 80 MHz | 6V in ISM bands between 0,15 MHz – 80 MHz | |
| | 80% AM at 1 kHz | 80% AM at 1 kHz | |

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------|-------------------------------------------------------------------------------------|
| Radiated RF EM fields IEC 61000-4-3 | 3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz | 3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz | $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,7 GHz |
| Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3 (IEC61000-4-39) | IEC 60601-1-2:2014; Table 9 | IEC 60601-1-2:2014; Table 9 | $d = 6/E \sqrt{P}$ 380 MHz to 5,8 GHz |
| <p>P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and E is the Immunity Test Level (V/m), and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p>  | | | |
| <p>NOTE 1: At 80 MHz and 800 MHz, 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> | | | |
| <p>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Intraoral Scanner is used exceeds the applicable RF compliance level above, the Intraoral Scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Intraoral Scanner.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

Table 3

| IEC 60601-1-2:2014, Table 9 | | | | |
|-----------------------------|---------|------------------------|----------------------|-----------------------------------|
| Band (MHz) | Service | P Max. power (W) | d Distance (m) | E Immunity test level (V/m) |

| | | | | |
|-----------|--------------------------------------------------------|-----|-----|----|
| 380-390 | TETRA 400 | 1.8 | 0.3 | 27 |
| 430-470 | GMRS 460; FRS 460 | 2 | 0.3 | 28 |
| 704-787 | LTE Band 13, 17 | 0.2 | 0.3 | 9 |
| 800-960 | GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5 | 2 | 0.3 | 28 |
| 2400-2570 | Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7 | 2 | 0.3 | 28 |
| 5100-5800 | WLAN 802.11 a/n | 0.2 | 0.3 | 9 |

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Intraoral Scanner

The Intraoral Scanner is intended to be use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Intraoral Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Intraoral Scanner 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) | | |
|-----------------------------------------------|---------------------------------------------------------------|------------------------------------------|------------------------------------------|
| | 150 kHz to 800 MHz $d = 1,2 \sqrt{P}$ | 800 MHz to 2,7 GHz $d = 2,3 \sqrt{P}$ | 380 MHz to 5,8 GHz $d = 6/E \sqrt{P}$ |
| 0,01 | 0,12 | 0,23 | N.A. |
| 0,085 ¹ | N.A. | N.A. | 0,19 |
| 0,1 | 0,38 | 0,73 | N.A. |
| 0,352 ¹ | N.A. | N.A. | 0,13 |
| 1 | 1,2 | 2,3 | N.A. |
| 10 | 3,8 | 7,3 | N.A. |
| 100 | 12 | 23 | N.A. |

For transmitters rated at 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.

- 1) Maximum output power of the RF transmitter included in the Intraoral Scanner used in IEEE 802.11ac and 802.11n dual band (5 GHz).
- 2) Maximum output power of the RF transmitter included in the Intraoral Scanner used in IEEE 802.11g and 802.11n single band (2,4 GHz).

Table 5



EU Declaration of Conformity

Manufacturer

**Dental Wings Inc.
2251 Letourneux
Montreal, Quebec
Canada, H1V 2N9**

declares under sole responsibility that the dental 3D scanner

**Type DW-IO
Model 001, Model 010**

meets the relevant provisions of the applicable directives, whereas the following directives require CE marking:

**Directive 2014/35/EU relating to electrical equipment
Directive 2014/30/EU relating to electromagnetic compatibility
Directive 2014/53/EU relating to radio equipment
Directive 2011/65/EU on the restriction of the use of certain hazardous substances
(RoHS) in electrical and electronic equipment**

A Technical File has been compiled in accordance with the requirements set out in the applicable directives. The Technical File is available with our authorized representative: Dental Wings GmbH, Düsseldorf Platz 1, 09111 Chemnitz, Germany.

The following information is part of the product:

**Quick Start Guides
User Manual**

To verify the requirements of the directives, the following harmonized standards were applied:

**IEC 60601-1:2012 / EN 60601-1:2010
IEC 60601-1-2:2014 / EN 60601-1-2:2010
IEC 60601-1-6:2013 / IEC / EN 62366:2014
IEC 62471:2006 / EN 62471:2008
IEC / EN 60529:2013
IEC / EN 60825-1:2007
ISO 10993-1:2009 / EN ISO 10993-1:2010
ISO /EN ISO 17664:2004**

The appropriate conformity assessment procedures were carried out in accordance with the applicable directives.

Valid for:

**DWIOC-04-000073 and higher
DWIOP-01-000001 and higher**

Montreal, July 28th 2017

Location, date


Dental Wings Inc.
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Distributor stamp