Intraoral Scanner
User Manual

Original User Manual

Model DW-IO-001

dental wings

CONTENTS

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.

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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.

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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 device is delivered in the following variants and configuration:

- 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. 34)*, in *Appendix A - Reprocessing of the handpiece (p.38)* and *Appendix B - Reprocessing of cart and accessories (p.44)*. 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 requires surface coating. 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 requied 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 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 maintenance, service 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 is required on the patient's teeth. 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.

Never put any load on the scanner.

Always lock the wheels when not moving the device.

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. 31)*.

The handpiece contains LEDs. They are rated exempt according to applicable standards *(see Technical data and label, p. 31)*.

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. 47)*.

> ⚠ **Caution**
>
> The use of accessories other than those specified in *Technical data and label (see Accessory parts, p. 34)* 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 repair and disposal. Unpack and pack your scanner following the instructions.

For instructions on how to pack the scanner, see *Packing the scanner (p.29)* .

3.1 Unpacking the scanner

Follow the steps below. Store the foam components in a safe place in case you need to transport or ship the scanner in future.
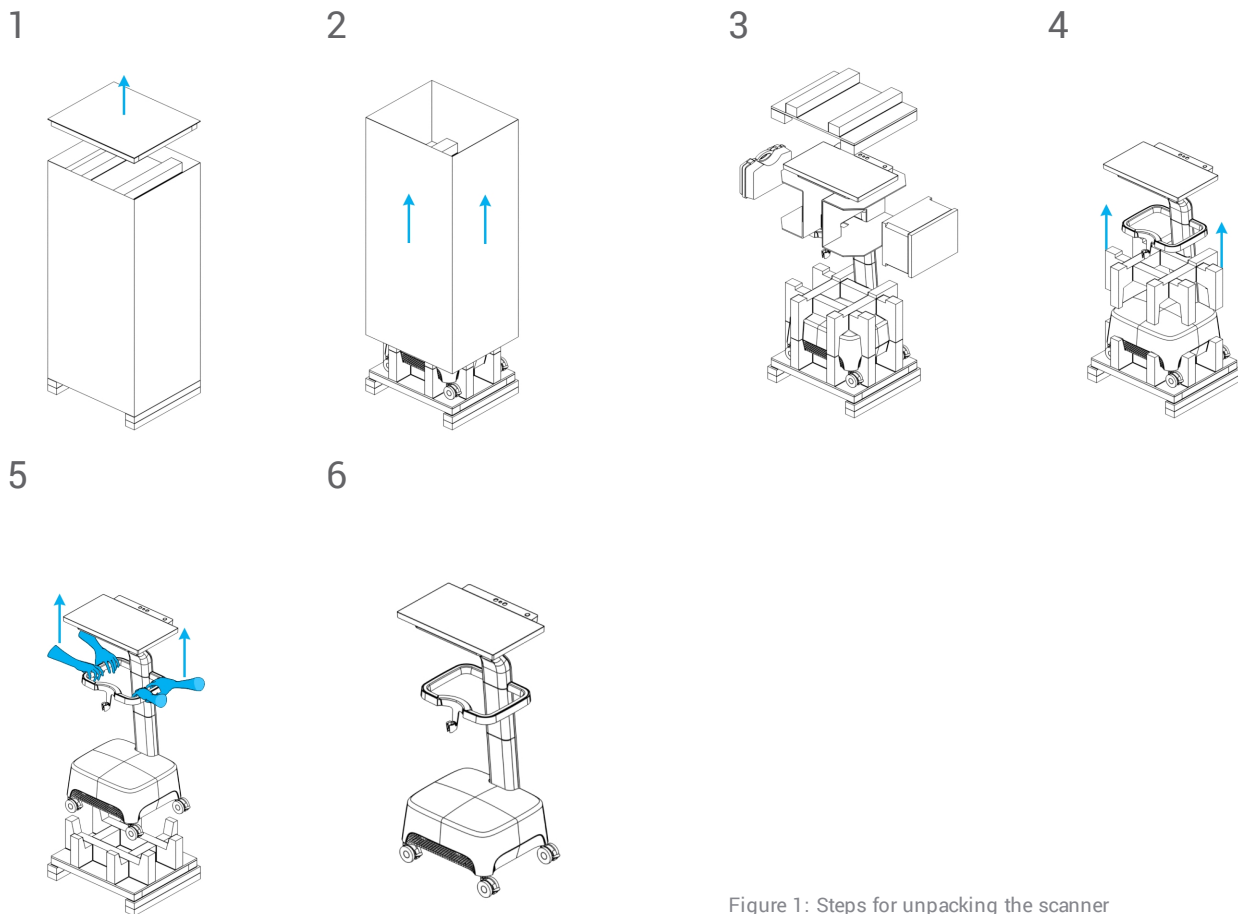
1   2   3   4

5   6

Figure 1: Steps for unpacking the scanner

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. 31)*.
>
> 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
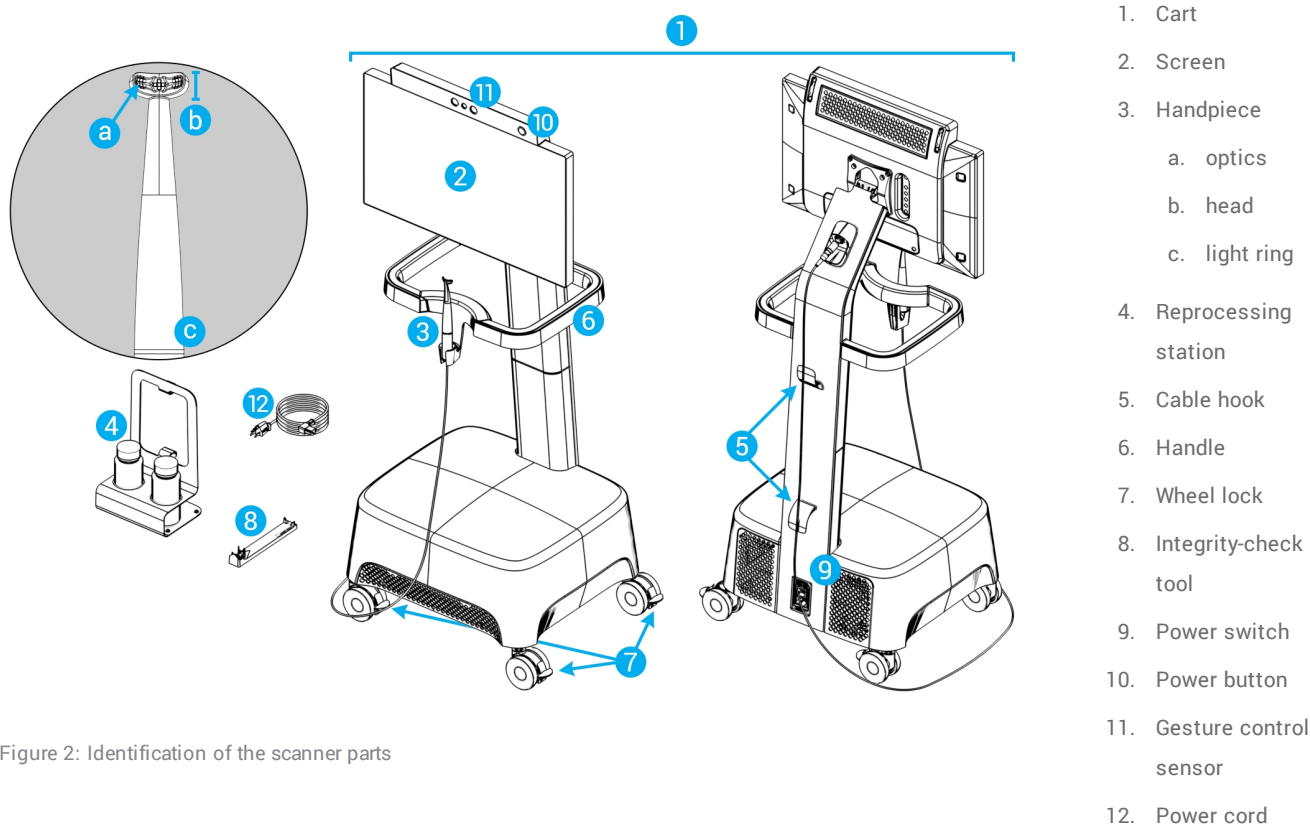
Figure 2: Identification of the scanner parts

1. Cart
2. Screen
3. Handpiece
   a. optics
   b. head
   c. light ring
4. Reprocessing station
5. Cable hook
6. Handle
7. Wheel lock
8. Integrity-check tool
9. Power switch
10. Power button
11. Gesture control sensor
12. Power cord

Connecting the handpiece to the cart

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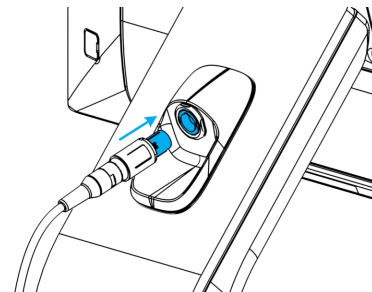2. Insert the handpiece connector into the dedicated socket on the back of the cart.

Figure 3: Connecting the handpiece

Disconnecting the handpiece from the cart

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 from the cart, press both sides of the mobile cylinder and pull it towards you.
4. Then the cord can be released from the socket.

Plugging the cart

> ⚠ **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 cart's base.
2. Plug the power cord into the power outlet.
3. Flip the power switch in the *power on position (see Scanner controls, p. 15)*.
4. Press the power button *(see Scanner controls, p. 15)*.

Refer to instructions for using the device *(see Basic principles and user interface, p. 15)*.

Unplugging the cart

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

1. Turn off the device *(see Shutting down the device, p. 16)*.
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 hooks.

Integrity check

> ⚠ **Caution**
>
> Make sure the integrity-check tool is reprocessed as required before and after it's use *(see Appendix B - Reprocessing of cart and accessories, p. 44)*.

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 4).
4. Select the *Start test* button and wait for the confirmation and further instructions to display on the screen.
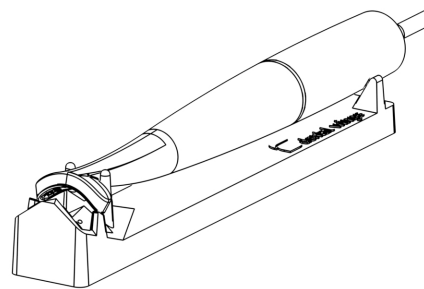
Figure 4: Using the integrity-check tool

📖 **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.
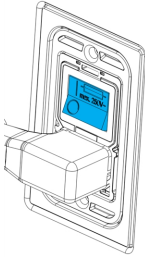
System language

The system language is preset. If this is not the case, contact your local distributor.
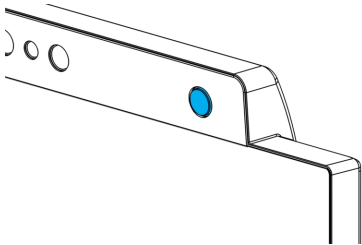
4. Basic principles and user interface

Scanner controls
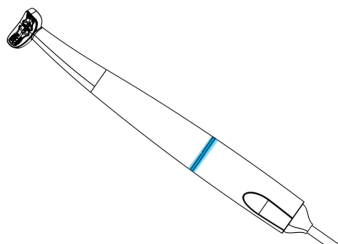
Power switch : used to power on the scanner

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

Power button: used to start up the scanner

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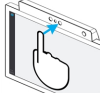> Use protected WiFi setup and access. Keep a distance to other communication devices of 13 cm when you are using 2,4 GHz and 19 cm when you are using 5 GHz.

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 2 *(p. 12)*. 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 most basic commands are listed below with their associated action.

Voice command	Triggered action
Jarvis start	Launches the scan for the current element (upper, lower or occlusion).
Jarvis pause	Pauses the current scan (re-lauch with the start command).
Jarvis finish	Indicates that the current scan is done.
Jarvis next	Switches to the next step.
Jarvis reset	Erases the current data.
Jarvis abort	Stops the meshing computation.
Jarvis undo	Removes surface data in a chronological fashion.
Jarvis redo	Restores surface data in a chronological fashion.

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.31)*.

> ⚠ **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 and uneven application of surface coating

5.2 Step-by-step

Setup

> ⚠ **Caution**
>
> The scanner must be turned off before plugging or unplugging any device or cable.
>
> Make sure the scanner has been reprocessed as described in *Reprocessing (p.23)*.

- 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;

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[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 is required on the patient's teeth. Apply a uniform and very thin layer to ensure teeth characteristics are not modified by the material. Always comply with the instructions given by the surface coating manufacturer.
>
> The handpiece will heat up over normal body temperature *(see Temperature limits, p. 31)*, 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;
- Lift the handpiece from its cradle on the cart;
- 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 cradle.

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 cart according to the given ambient conditions *(see Ambient conditions, p. 32)*.

Use standard packaging material to protect the handpiece from contamination between uses *(see Accessories and products used in combination, p. 6)*.

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**
>
> 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.
>
> Never leave the handpiece elsewhere than in its dedicated cradle.
>
> Ensure that the packaging is large enough to contain the handpiece without excessively bending the cable.
>
> Always lock the wheels when not moving the device. Push down the red tab for locking the wheels.
>
> Do not install or uninstall software on the system.

Moving to another room

- Shut down according to instructions *(see Shutting down the device, p. 16)*
- Flip the power switch in the "power off" position.
- Unplug the cord from the power outlet.
- Loop the power cord around the hooks.
- Unlock the wheels by lifting up the red tab on each one of them.
- Move the cart while holding it by the handle.
- When arrived at destination lock each wheel by pushing down the red tab.

📖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. 14)*.

Transportation

Always use the original packaging to transport the scanner. Refer to instructions for *Packing the scanner (p.29)* and *Unpacking the scanner (p.11)*.

6.2 Reprocessing

> ⚠ Warning
>
> Reprocessing shall be done before the first use, then after each use, as well as prior to maintenance, service 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.

Noncritical: low-level disinfection   Semicritical: high-level disinfection
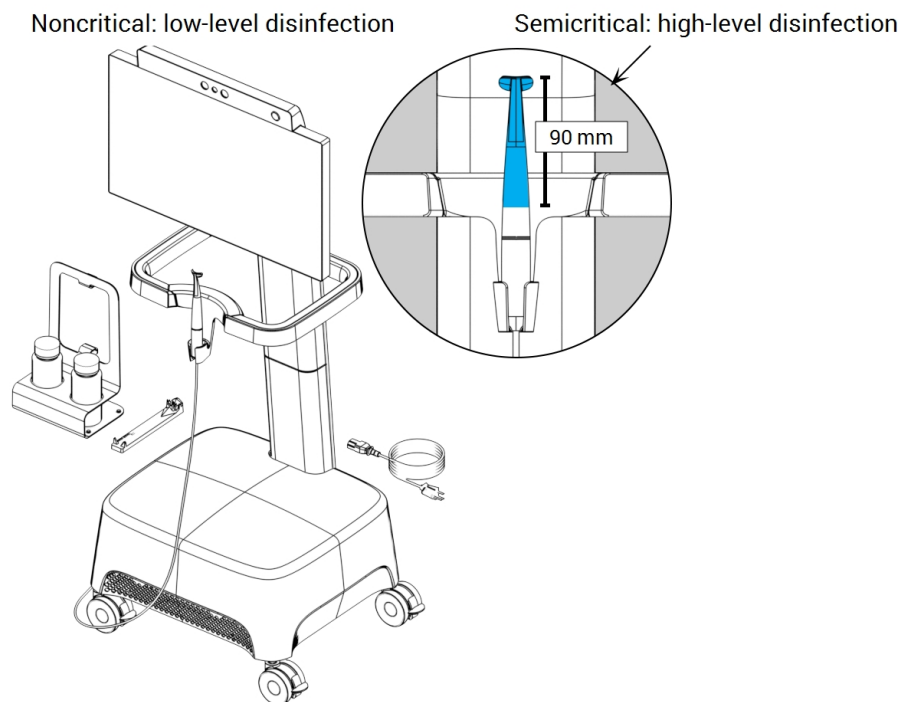
90 mm

Figure 5: Disinfection levels of handpiece, cart 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 disinfection[1]. The noncritical area requires low-level disinfection[1].

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

The instructions given have been validated by Dental Wings[2] 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. 31)*. They are located at the back of the cart, inside the power switch assembly. If necessary, exchange them in the following way:

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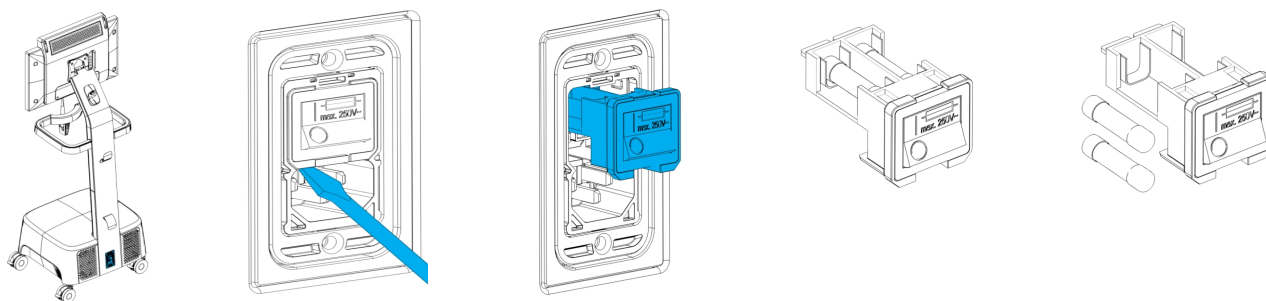2. Change the corresponding fine fuses.
3. Reassemble.

Figure 6: 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 (scanner top panel). 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.

Servicing 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.29)*.

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...	Restart the device and try again.
...credentials could not be verified.	
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...	Restart the device and try again.
An error has occurred.	
No configuration file found for the connected handpiece.	
The configuration file does not match the connected handpiece.	1. Check internet connection. 2. Click the *Settings* icon from the taskbar and select *Handpiece Management* 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.	
Database backup execution failed.	Try to export in a different folder and/or a different file name.
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.	
Wrong client version.	Run the updater again.
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.

On-screen message	Required action
No scan to save.	Complete the scan procedure and retry.
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 the cord around the hooks;
- Pack the scanner in its original box and packaging material as shown in the pictures below.
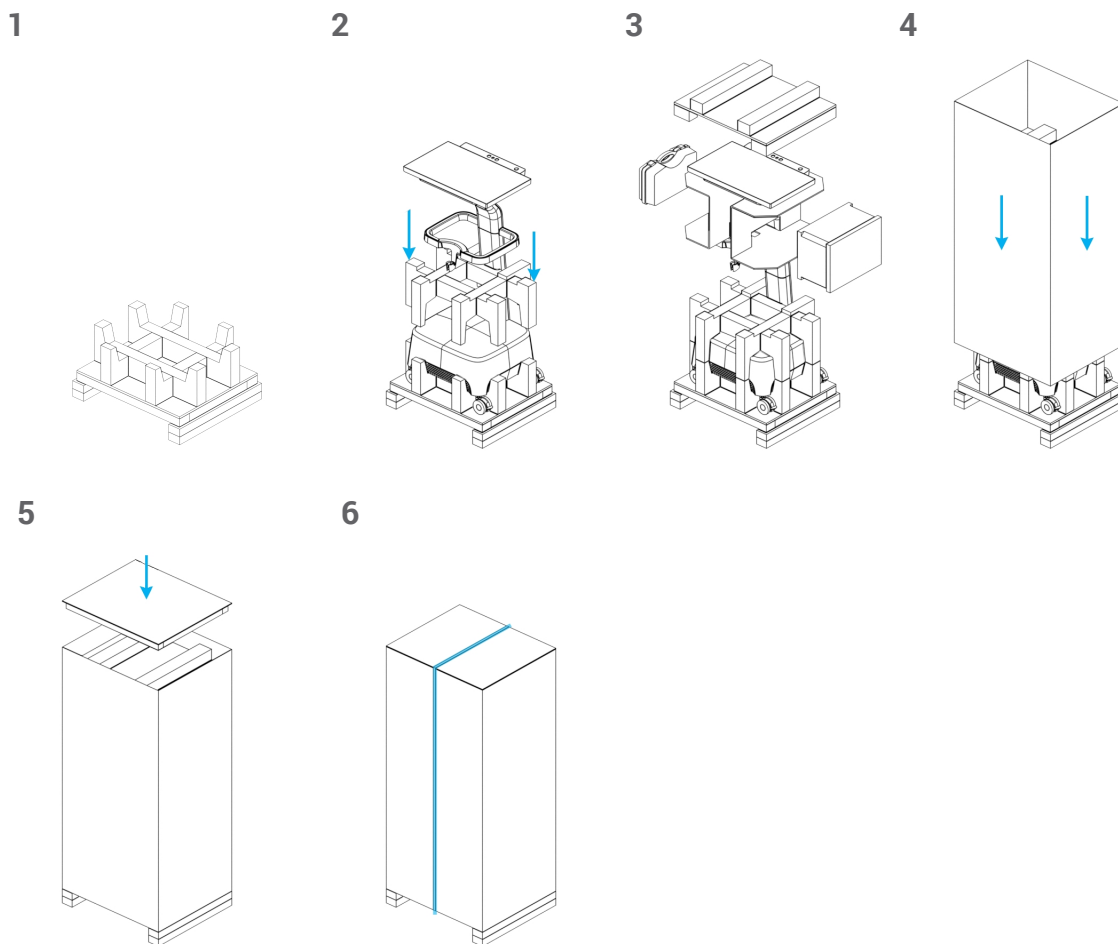

Figure 7: Steps for packing the scanner

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	
Type / Model number	DW-IO-001
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)
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); IPXO (noncritical area - no protection)
Pollution Degree	2; Normally only non-conductive pollution occurs. Temporary conductivity caused by condensation is to be expected.
Mode of operation	Continuous
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)
Computer / OS	Integrated computer, Core i7, 16 GB RAM 250 GB SSD 2 GB of dedicated RAM graphic card Windows 10, 64 bit 21" multi-touch screen with integrated gesture and voice control module

Technical data		
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
Dimensions crated (W x L x H)	51 cm x 60 cm x 137 cm (20" x 23.5" x 54")	
Dimensions uncrated (W x L x H)	46 cm x 52 cm x 127 cm (18" x 20.5" x 50")	
Weight crated	57 kg (126 lb)	
Weight uncrated	38 kg (84 lb)	
Certifications	CE, OHSA, Canada (SCC)	

Ambient conditions	
Operating temperature	15 ºC - 40 ºC (59°F - 104°F)
Storage conditions	10 ºC - 40 ºC (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
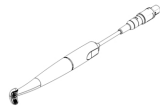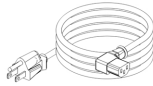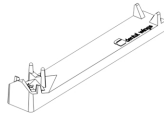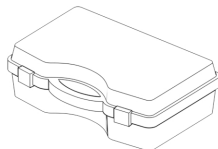
Scanning parameters	
Patient characteristics	No restrictions apply
Optical technology	LED light High-speed measuring cameras Video cameras
Scannable material	No restrictions apply, surface coating required *(see Accessories and products used in combination, p. 6)*
Scanning volume	Up to 3 teeth
Scanning accuracy	20 μm (single unit), 50 μm (full arch) according to Dental Wings testing standard
Scanning time	20 s (single unit), 2 min (full arch)
Output format	Open STL or cloud sharing through DWOS Connect
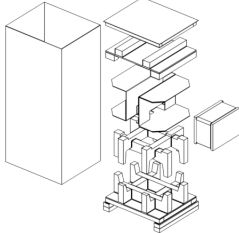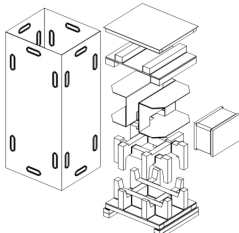
Scanner label

This is an example of the label on your device:

Software applications	Included	Optional
Intraoral Scanner sofware application	x	

Accessory parts	Standard	Optional	Part No.	Image	Intended use
Handpiece		●	6100-1		Replacement or additional handpiece for the Intraoral Scanner.
Country-specific Power Cord	●		22-0156 (US) 22-0159 (EU)		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.
Handpiece Storage Case	●		70-0045		Protects the handpiece during shipment and stores integrity-check tool.

Accessory parts	Standard	Optional	Part No.	Image	Intended use
Shipping Box	●		70-0040		This box serves as (replacement) box for return shipment.
Demonstrator Shipping Crate		●	70-0046		Demonstration unit shipping box for Dental Wings and distributors.
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

[manufacturer symbol]	Indicates the legal manufacturer and year of manufacturing
SN	Indicates the serial number of the device
REF	Indicates the article number of the device
[caution triangle symbol]	Caution, consult the User Manual for important cautionary information
[laser radiation symbol]	Laser radiation
CLASS 1 LASER PRODUCT	Class 1 laser product acc. to IEC 60825-1
[direct current symbol]	Direct current
~	Alternative current
CE	Device fulfills the requirements of Machinery Directive 2006/42/EC, Low Voltage Directive 2006/95/EC, Electromagnetic Compatibility Directive 2004/108/EC and RoHS 2011/65/EU
[TÜV SÜD symbol] C US	Compliance with U.S. Occupational Safety and Health standards as well as SCC requirements (Canada)
FC	Device complies with part 15 of the FCC rules
[10 China RoHS symbol]	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
total weight with cart **kg**	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
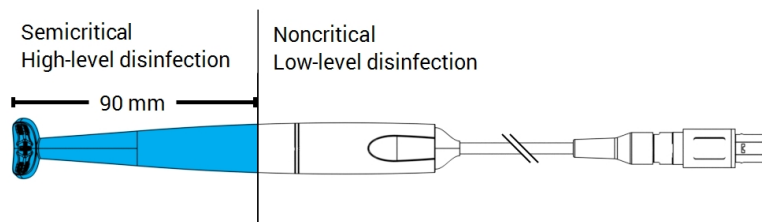
Figure 8: Handpiece - Reprocessing characteristics

Precautions
- 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 cart.

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 detergent[1] intended for cleaning of medical devices made of metal, glass and plastics
■ High-level disinfectant[1] (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 disinfectant[1] (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. 42)*.

Instructions

Preparation for decontamination

1. Disconnect handpiece from cart (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 disinfectant[1] 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. 6)*. One bottle shall contain enzymatic detergent[1], the other high-level disinfectant[1].

Figure A

5. Prepare enzymatic detergent and high-level disinfectant[1] as described in their instructions for use.

6. Fill each bottle up to 225 ml (Figure B) - left bottle with enzymatic detergent[1], right bottle with high-level disinfectant[1]. Label each bottle to avoid mistakes.
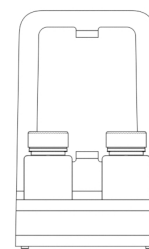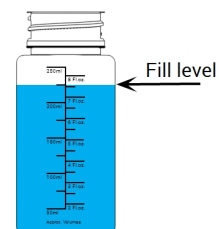

Fill level

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. 42)*

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 detergent[1] 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 disinfectant[1] 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 disinfectant[1] 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.
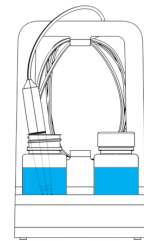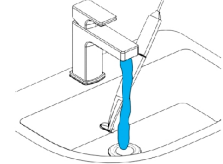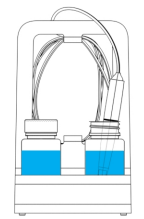
Figure E
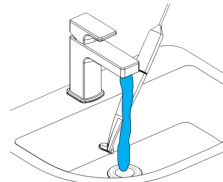
Figure D

Drying

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

[1] Use only the validated cleaning products that are detailed at the end of this Appendix *(p. 42)*

Instructions

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 cart, 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® 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®, Cidex® OPA Solution (both ASP Johnson & Johnson), and Bacillol® 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 cart and accessories

Manufacturer : Dental Wings inc.
Method : Low-level disinfection
Device : Intraoral Scanner cart and accessories
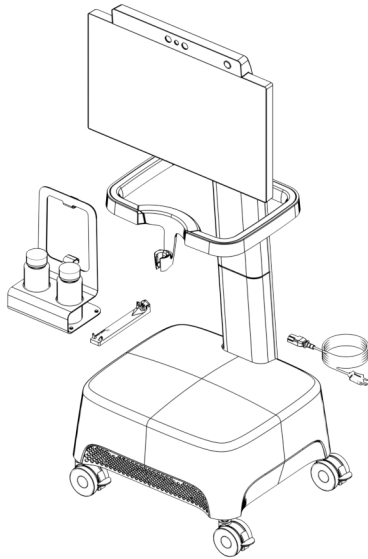
Figure 9: Cart and accessories - reprocessing characteristics

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 cart. ■ Make sure the cart is completely dry before plugged into power outlet.

Limitations on reprocessing
Repeated reprocessing has minimal effect on the cart 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 cart and the accessories. User is solely responsible for issues arising from the use of damaged or worn cart and accessories.

Equipment and material
- Low-level disinfectant[1] (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 disinfectant[1] according to its instructions for use. Follow it in terms of storage, concentration, application and temperature.   - Unplug cart (see User Manual).
Cleaning: Automated
Automated cleaning must not be applied for cart 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 cart 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. 46)*

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 cart and accessories and is not required (cart 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; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	0% U_T ; 0,5 cycle at 0°, 45°; 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	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.
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 inducted by RF fields IEC 61000-4-6	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz – 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz - 80 MHz 6V in ISM bands between 0,15 MHz – 80 MHz 80% AM at 1 kHz	d = 1,2 √ P
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 √ P 80 MHz to 800 MHz d = 2,3 √ 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 √ P 380 MHz to 5,8 GHz

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:

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

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

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.

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

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

$C\mathcal{E}$

EC 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**

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, Düsseldorfer 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-03-000006 and higher**

Montreal, January 29th 2016

Location, date

Dental Wings Inc.
Michael Rynerson, C.E.O.

www.dentalwings.com

Distributor stamp