DEXIS

Imprevo

Instructions for Use

Thank you for choosing the DEXIS™ Imprevo.

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If any serious incident occurs in relation to the device, the user must report it to Dental Imaging Technologies Corporation and to the competent authority of its Member State in the European Union.

This guide includes information on the usage, safety instructions, regulatory information, and the technical specifications of the devices. We recommend that you thoroughly familiarize yourself with this guide to make the most effective use of your system.

This document is originally written in English.

The DEXIS Imprevo is intended for professional use only.

US Federal law restricts this device to sale by or on the order of a dentist.

The manufacturer has no liability for consequential damage, personal injury, loss, damage or expense directly or indirectly caused by the use of the product. No agent, distributor or other party is authorized to give warranty or other liability on behalf of the manufacturer with respect to its products.

The DEXIS Imprevo complies with Medical Device Regulation (EU) 2017/745 and Medical Devices Regulations 2002 (SI618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).

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1 Introduction

1.1 Intended Use

The DEXIS™ Imprevo (referred to afterwards as the scanner) is a digital optical scanning device used to record the topographic characteristics of teeth or dental impressions in three dimensions. The resulting topographic impressions are intended for use in the computer-aided design and manufacturing of dental restorative prosthetic devices, dental implant prosthetic devices, and orthodontic models.

1.2 Clinical Benefits and Performance Characteristics

DEXIS intraoral scanners benefit a dental practice by enabling practitioners to acquire digital impressions with the quality and accuracy required for digital CAD/CAM dental applications. The actual performance of the device is dependent on the user's training and operating execution. The user is solely responsible for the accuracy, completeness, and adequacy of the acquired data.

1.3 Abbreviations

3D	Three Dimensional
CAD	Computer-aided design
CAM	Computer-aided manufacturing
LED	Light-emitting diode

1.4 Conventions Used in this Manual

The following special messages emphasize information or indicate potential risks to personnel or equipment.

 WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
 NOTICE	Highlights suggestions which will result in enhanced installation, reliability, or operation. Not used for safety related hazards

2 Safety Information

2.1 Warnings and Safety Instructions

	**DANGER OF ELECTRIC SHOCK** **This is an electrical unit. Do NOT expose it to water spray. Such action can cause an electric shock or a or a malfunction of the unit.**

	**All known residual risks, contraindications, or undesirable side effects are listed in this guide. If any serious incident occurs in relation to the device, you must report it to DEXIS and to the competent authority of your Member State in the European Union.**

2.1.1 Scanner

- You MUST read and understand this safety information before using the scanner.
- This scanner shall only be used inside hospitals, dental clinics, and other professional healthcare facilities and MUST NOT be used near high-frequency surgical equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Before using the scanner, check the outer surfaces of the unit and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- You are responsible for the operation and maintenance of the scanner. You MUST read this instruction before using the scanner.
- When the unit is not in use, ensure that the scanner is turned OFF.
- Do not use the scanner in conjunction with oxygen-rich environments.
- This unit is not intended for use with flammable anesthetics or flammable agents.
- Do not pull or twist the cable.
- Do not drop the scanner or the accessories.
- Do not heat sterilize the scanner handpiece.
- Do not expose the scanner to a water spray or submerge it in water or disinfectant.
- Do not directly expose the scanner to ultraviolet radiation.
- Do not stare at the LED and laser emission window.
- When the tip is removed, install the front protective cover to protect the scanner lens window.

- Do not remove the cover of any scanner components. The scanner contains no user-serviceable parts. For any repairs, contact a qualified DEXIS service technician.
- Do not replace the power adapter provided with the scanner with any other power adapter. Substitutes may not provide the required protection against electric shocks and other safety hazards.
- If the equipment is faulty, turn it OFF, display an “Out of Service” notice, and contact a qualified DEXIS service technician.
- Using components, accessories, cables, and spare parts other than those specified or provided by the manufacturer of this equipment may impair the safety protection of the scanner and may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.
- The maximum temperature of the applied part may reach to 43 °C (109.4 °F); to avoid overheating, do not use it for extended periods.
- Do not maintain or service this equipment while it is in use with the patient.
- Connection of the scanner to an IT NETWORK that includes other equipment could result in risks to patients, operators, or third parties. The responsible organization should identify, analyze, evaluate, and control these risks.

2.1.2 Laser

- The scanner is a class 1 laser product according to IEC 60825-1:2014 / EN 60825-1: 2014+A11: 2021. This product doesn't have harmful laser radiation. Users will not be exposed to laser radiation if they operate this product correctly according to the Instructions.
- The scanner emits blue laser light (447nm Class 1) as well as white LED emissions. Avoid shining the scanner directly into anyone's eyes.
- Avoid activating the scanner outside the patient's mouth to prevent eye damage.

2.1.3 Computer / Other Equipment

- All devices meeting IEC60950 or IEC62368 must be kept outside the patient environment as defined in IEC60601-1, unless equipped with an additional protective earth or an extra isolating transformer.
- See the installation guide for your computer for information about the data processing system, computer, and screen. Leave a sufficient amount of clear space around the computer to ensure that it is properly ventilated.
- Position the screen to avoid light reflections from internal or external lighting for maximum image quality and visual comfort.

2.1.4 Scanner Battery

- Do not dismantle, open, or shred the batteries.
- Do not expose the batteries to heat or fire. Avoid storage in direct sunlight.
- Do not short-circuit the battery. Do not store the batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.

- Do not remove a cell or battery from its original packaging until required for use.
- Do not subject the batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Do not use any charger other than that specifically provided for use with the equipment. Refer to the manufacturer's instructions or equipment manual for proper charging instructions.
- Do not use any cell or battery which is not designed for use with the equipment.
- Always purchase the battery recommended by the device manufacturer for the equipment.
- Keep the batteries clean and dry.
- Wipe the battery terminals with a clean, dry cloth if they become dirty.
- The batteries need to be charged before use.
- Do not leave a battery on prolonged charge when not in use.
- After extended periods of storage, it may be necessary to charge and discharge the batteries several times to obtain maximum performance.
- Retain the original product literature for future reference.
- Use the battery only in the application for which it was intended.
- When possible, remove the battery from the equipment when not in use.
- Dispose of the batteries properly.

2.1.5 Disposal

This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper "end-of-life" disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the local jurisdiction.

Dispose of the scanner tips according to standard operating procedures or local regulations for the disposal of contaminated medical waste. For additional scanner tips, contact your dealer.

2.1.6 Cybersecurity

Cybersecurity controls and recommendations can be found in the Cybersecurity section of the DEXIS IS ScanFlow User Manual (TA2883), which can be downloaded from elabeling.dexis.com.

2.2 Cleaning, Disinfecting, Sterilizing

2.2.1 Cleaning and Disinfecting the Scanner

CAUTIONS

- The scanner must be thoroughly cleaned and disinfected after each patient.
- Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner for reuse.
- Wear gloves while cleaning and disinfecting the scanner.
- Never immerse the scanner into any cleaning or disinfectant solution.
- Clean and disinfect the scanner before attaching the protective covers. Do not allow patient contact with the protective covers.
- Excessive fluids may damage the scanner.

	WARNING: Make sure the contact points on the scanner handpiece, battery and charging station are dry and clean after cleaning and disinfecting, in order to avoid risk of short circuit.

Figure 1: Contact points on scanner handpiece

Figure 2: Contact points on battery

Figure 3: Contact points on battery charger

Figure 4: Scanner front and rear vents

	CAUTION: DO NOT allow liquid to enter through the gap or air inlet/outlet when cleaning and disinfecting the scanner.

2.2.1.1 Cleaning the Scanner

CAUTION: The scanner must be thoroughly cleaned prior to disinfecting.

To clean the scanner, follow these steps:

1 Dampen (**do not soak**) a lint-free cloth with lukewarm water.

2 Remove the blood and/or body fluids with the dampened lint-free cloth.

2.2.1.2 Disinfecting the Scanner

To adequately disinfect the scanner, follow the disinfectant manufacturer's instructions for the appropriate contact time.

To disinfect the scanner, follow these steps:

1 Remove the reusable tip.

2 Remove all visible soil (see "Cleaning the Scanner").

3 Use the approved wipes or disinfectants to thoroughly wipe all surfaces of the scanner. Follow the manufacturer's instructions for contact time.

Approved wiping disinfectants: CaviWipes, 75% Alcohol, 70% Isopropyl Alcohol (IPA).

CAUTION: Using a disinfectant that has not been approved may cause damage to the scanner.

4 Allow to air dry.

5 After the scanner has dried, use a clean, lint-free cloth dampened with water to remove residual disinfectant from the surface of the scanner.

2.2.2 Cleaning and Sterilizing the Scanner Tips

Scanner tips received from the manufacturer are NOT sterile. You must sterilize the tips before the first use.

The scanner tip must be cleaned and sterilized after each patient.

The scanner tips can be re-used up to 160 cycles following the instructions.

CAUTIONS

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

2.2.2.1 Manually Cleaning the Scanner Tips

CAUTION: Clean the tip as soon as practical after use before soiled materials become dried onto the tip.

To manually clean the scanner tips, follow these steps:

1 Rinse the tip with tap water to remove any visible soiled material.

2 Gently clean the inside and outside surfaces of the tip with a soft brush and enzyme cleaning detergent (for example, 3M 70503 Neutral multienzyme) for 3 minutes.

3 Rinse the tip thoroughly with distilled water for at least 3 minutes.

4 Visually inspect the tip for cleanliness. All visible surfaces, internal and external, should be visually inspected.

5 Carefully dry the tip, including the mirror, with a clean swabbing paper or lint-free cloth to check that there is no dust or fiber residue on the mirror surface.

2.2.2.2 Sterilizing the Scanner Tips

To sterilize the cleaned scanner tips, follow these steps:

1 Place the tip in a sealed FDA-cleared or CE-marked sterilization pouch. Use either a self-adhesive pouch or a heat-sealed pouch.

2 Place the tips in a Class B pre-vacuum autoclave with one of the two programs depending on your region.

- In the USA: Autoclave the tips at 132 °C (269.6 °F) with a cycle of 4 minutes exposure time and 20 minutes dry time.
- In the EU: Autoclave the tips at 134 °C (273.2 °F) with a cycle of 3 minutes exposure time and 20 minutes dry time.

2.3 Precautions Before Use

Perform the following activities on your product and accessories before use.

2.3.1 Cleaning, Disinfecting, and Sterilizing

To ensure maximum hygienic safety for the patient and to minimize the risk of cross-contamination, carefully perform the following maintenance activities on your scanner and accessories.

After each patient:

- Clean and disinfect the scanner. See “Cleaning and Disinfecting the Scanner” on page 6.
- Clean and sterilize the scanner tip. See “Cleaning and Sterilizing the Scanner Tips” on page 8.

2.3.2 Visually Inspecting the Scanner

Visually inspect the scanner for damage or signs of deterioration by doing the following:

- Inspect the scanner's lens window.
- Inspect around the scanner buttons and battery contact points

If damage is noted, do not use the scanner and contact your representative or the manufacturer.

If any substance is noted around contact points, remove it with a dry cloth before use.

2.3.3 Visually Inspecting the Scanner Tips

Visually inspect the scanner tips for signs of deterioration by doing the following:

- Verify that the tip is not damaged and its components are not detached.
- Verify that the tip mirror does not have any smudges or scratches on it.

If deterioration is noted, replace the tip.

CAUTIONS

- The lens window on the scanner is a delicate optical component. Mount the front protective cover to protect the lens window from damage and dirt when the scanner is not in use.
- The mirror in the tip is a delicate optical component. Its clean and undamaged surface is critical to scan quality.
- Make sure the contact points on the scanner handpiece, battery, and battery charger are clean and dry in order to avoid the risk of a short circuit.

In the event that you see poor scan quality or an unclear video preview in the software, clean the tip mirror and the scanner's lens window using a microfiber cleaning swab, applying ethanol that is free of impurities.

2.4 Marking and Labeling Symbols

	Type BF applied part
	Class II equipment
	Class I laser device
	In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE), do not dispose this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product.
	Manufacturer Name and Address
	Date of manufacture
	Importer
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation
	Maximum number of packages permitted to be stacked on the bottom package
	Keep dry
	Fragile, handle with care
	This side up
	Lithium-ion batteries contained in equipment or packed with equipment

	Consult instructions for use or consult electronic instructions for use
	Unique device identifier
	Prescription only (applicable for United States of America)
	General warning
	CAUTION: Consult accompanying documentation
	Caution, risk of electric shock
	Refer to instruction manual/booklet
	Catalogue number
	Serial number
	Alternating current
	Direct current
	Medical device
	CE marking applicable for European Union
	FCC mark indicating the compliance with Part 15 of FCC Rules
	MIC/Giteki mark indicating the compliance with the Japanese Radio Law
	Authorized representative in the European Community / European Union
	Authorized representative in Switzerland

UK CA	UK Conformity Assessed marking
SGS C US	Conforms to U.S and Canada national safety standards

3 Hardware Overview

The following offers hardware parts supplied with DEXIS Imprevo product.

Figure 5: DEXIS Imprevo Hardware Parts

No.	Part Name
1	Scanner handpiece
2	Standard tip
3	Battery
4	Battery charger
5	Holder
6	WiFi adapter
7	Power adapter
8	Dock for WiFi adapter
9	Charging station
10	Shade calibration unit
11	Wrist strap
12	Front protective cover
13	Rear protective cover

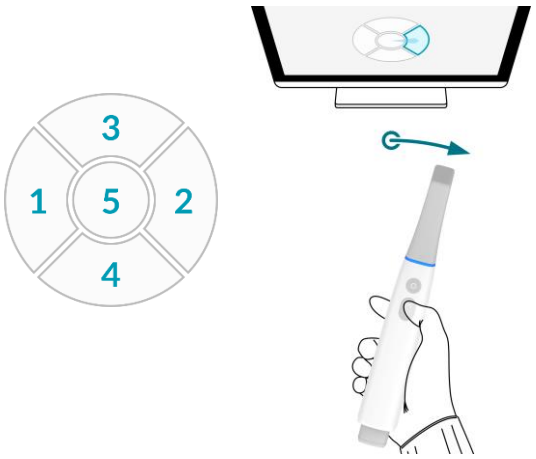
3.1 Scanner Overview

Here is an overview of the scanner components.

Figure 6: Scanner Components

1	Standard tip	The scanner tip, the only applied part. A lot number is located on the outer surface of each tip in the format "(10)YYYYMM".
2	Indicators	• BLUE: The scanner is active, and the battery capacity is plenty. • AMBER: The scanner is active, and the battery capacity is low. • CYAN: The scanner is in composite control mode. • GREEN: The scanning is in process. • YELLOW: The scanning software is unable to track the scanning. • DARK: Power is OFF.
3	Power button	• Press for three seconds to power ON. • Press for three seconds to power OFF.
4	Mode button	Press and hold the button to enter Composite Control mode. Release to select a menu option.

When you enter Composite Control mode, a menu plate appears on the screen and you can select menu options by gesturing with the scanner to execute the corresponding command in the workflow.



5	Battery	The rechargeable battery can be charged in the handpiece in the charging station, or the battery can be removed and charged in a battery charger.
6	WiFi Adapter	Plugs into the USB 3.0 port on the computer running the IS ScanFlow software to increase speed and signal strength.
7	Dock for WiFi Adapter	Use the dock as an extension cable when you cannot easily plug the WiFi adapter into the USB 3.0 port due to space limitations.

NOTE: The scanner goes into inactive mode when left idle for 20 seconds (if set down, for example). To use it again, pick it up, and press the power button for one second.

3.1.1 Protective Covers Overview

Figure 8: Scanner Front Protective Cover

NOTE: Use the front protective cover when the scanner is not in use.

Figure 9: Scanner Rear Protective Cover

NOTE: Use the rear protective cover when the battery is removed.

3.1.2 Charging Station Overview

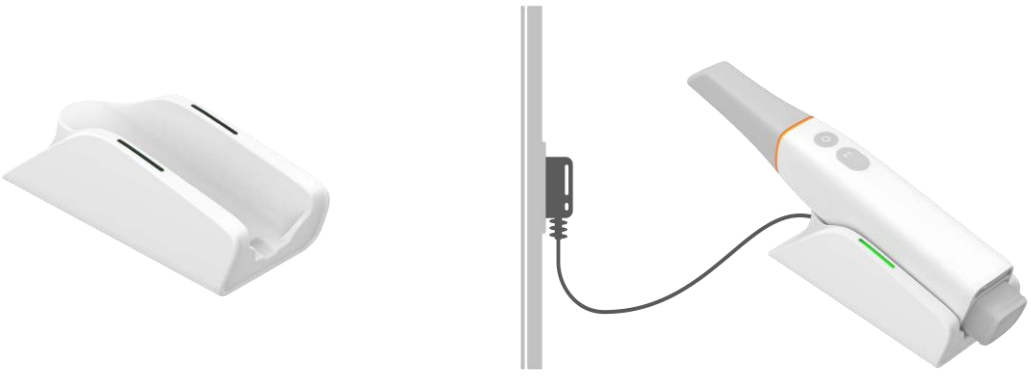
The scanner handpiece charging station is designed to hold the scanner safely and charge it at the same time. Place the scanner in the charging station when you are not using it.

WARNING: Do not put anything other than Scanner handpiece in the charging station.

When the scanner is inserted in the charging station, the indicator light of the charging station:

- GREEN: Charging Station is powered on.
- GREEN (blinking): Station is charging the handpiece. This light stops blinking when the scanner is fully charged.
- YELLOW: There is an error with the Charging Station.

Figure 10: Charging Station



NOTE: The scanner powers off when left idle for 20 minutes when not charging and on battery power.

	NOTE: The scanner powers off if left idle for more than 5 minutes.
	NOTE: The only reliable means to disconnect the system from mains is to unplug the power cord of charging station. Do not position the system so that it is difficult to unplug the power cord.

3.1.3 Battery Charger Overview

The battery charger can charge up to two batteries at the same time.

The indicator on the battery charger:

- GREEN: Charging Station is powered on.
- BLUE (blinking): Charging and the battery capacity is plenty.
- AMBER (blinking): Charging and the battery capacity is low.
- BLUE: Fully charged.

Figure 11: Battery Charger

3.1.4 Shade Calibration Unit Overview

After 50 hours of scanning (approximately 13 days), use the shade calibration unit to recalibrate the scanner.

Figure 12: Shade Calibration Unit

Follow these recommendations:

- Keep the cap on the calibration unit until you are ready to use it.
- Always install a cleaned and sterilized tip on the scanner before attaching the shade calibration unit.
    - Attach the shade calibration unit to the tip using the opening.
    - Push the shade calibration unit to the end when attaching to the tip.
- Do not touch the gray card in the shade calibration unit or expose it to liquids.
- Store the calibration unit away from light, heat, and moisture.
- Order a new shade calibration unit if the gray card quality check fails when performing a calibration or if the expiration date on the shade calibration unit is approaching.

See the **IS ScanFlow User Guide** for more information.

4 Setting Up

4.1 Setting Up the Scanner

To set up the scanner, follow these steps:

1 Request the **IS ScanFlow** software from https://dexis.com/en-us/download-center.

2 Click the link in the email sent to you, and double-click the **InstallationWizard.iso** file to extract the files.

3 Double-click **autorun.exe**. A license agreement window is displayed.

4 Acknowledge the license agreement. The **System Check** window is displayed.

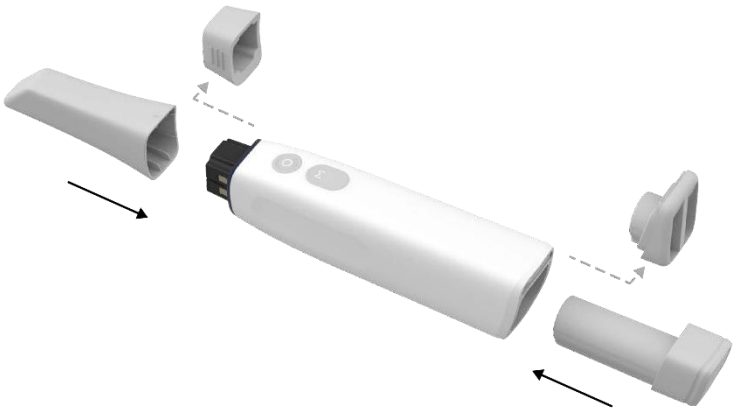
5 When the System Check finishes, click  . The **Prerequisites** window is displayed.

6 When the Prerequisites check finishes, click  . The **IS ScanFlow Maintenance Toolkit** window is displayed, and the installation begins.

7 When the installation has finished, the **Tutorials** window is displayed. Click on the video for the type of scanner you are using to view a setup video. When finished, click  . The **Finish** window is displayed.

8 Click **Exit**.

9 Firmly slide one of the tips onto the end of the scanner. Ensure that the indentation on the base of the tip aligns with the raised notch on the top of the scanner.

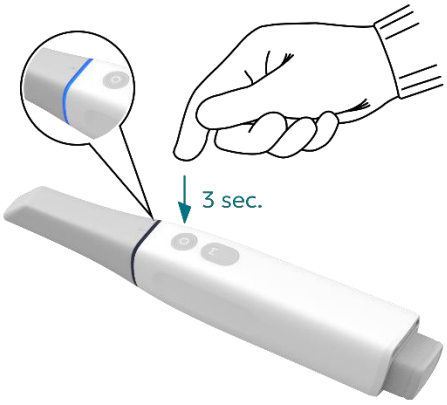


	**WARNING: Do not block the ventilation openings of the handpiece, the charging station, or the battery charger. If you do, the system will overheat.**

10 Insert the battery into the base of the scanner, and ensure that the contact points of the power connector are aligned with the battery. Gently push until the battery clicks into place. Insert the DC power supply into the socket on the charging station, and insert the power adapter into an outlet. Place the scanner in the charging station.

	NOTE: You must charge each battery before using it for the first time. The battery comes from the factory with approximately 30% of its full capacity.

11 Press the power button three seconds to power on the scanner. Ensure the power indicator turns blue (or amber if the battery is low).



4.1.1 Setting Up the WiFi Adapter

To set up the WiFi adapter, follow these steps:

1 Connect the WiFi adapter to the USB port directly or through the dock, depending on the space around the USB port. The installation wizard window is displayed.

2 Follow the on-screen instructions to connect the WiFi adapter to your network.

4.1.2 Charging the Batteries in the Battery Charger

The battery in the handpiece is charged each time you place it in the handpiece charging station. If you have the battery charger, you can charge additional batteries while you are using the handpiece.

To charge the batteries, follow these steps:

1 Insert the DC power supply into the jack on the battery charger, and insert the power adapter into an outlet.

2 Remove the battery from the handpiece by grasping the battery at the base, depressing the button at the bottom of the battery, and gently sliding the battery out of the handpiece.

3 Place a battery in one of the openings of the battery charger, making sure that the charging contact on the base of the battery is aligned with the contact on the bottom of the charging station. You can charge two batteries at once.

4.2 Preparing the Scanner

The reusable tip attaches to the scanner handpiece and provides a sanitary shield for the patient. Always disinfect the scanner handpiece, and clean and sterilize the tip after each use.

For information about processing the scanner, see “Cleaning, Disinfecting, Sterilizing” on page 6.

To prepare the scanner, follow these steps:

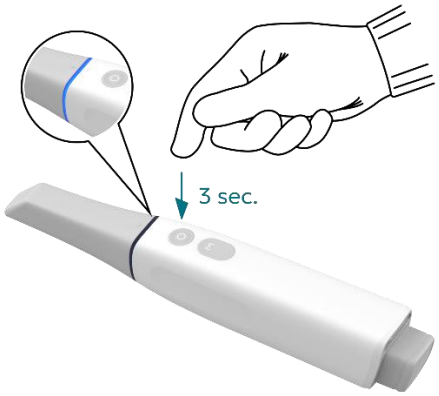
1 Make sure the lens window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue.

2 Slide the tip onto the scanner.

3 (Optional) Install the wrist strap at the bottom of the scanner.

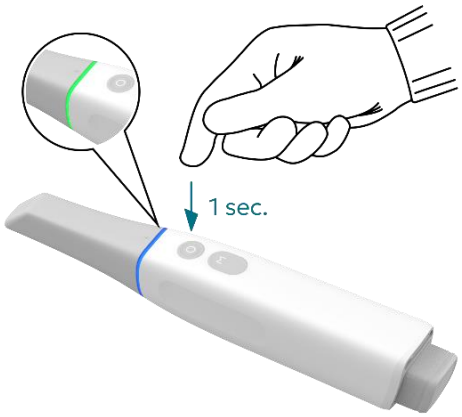
	**WARNING: Do not cover the ventilation openings of the handpiece or the handpiece charger. If you do, the system will overheat.**

4 Press the power button for three seconds to power on the scanner.



5 Verify that the WiFi Adapter is inserted on the PC and the scanner is connected to the IS ScanFlow interface.

6 Press the power button for 1 second to start scan



5 Maintenance

5.1 Cleaning, Disinfecting, and Sterilizing

You must clean and disinfect the scanner according to the section “Cleaning and Disinfecting the Scanner” on page 6.

You must clean and sterilize the scanner tips according to the section “Cleaning and Sterilizing the Scanner Tips” on page 8.

6 Troubleshooting

6.1 Scanner Troubleshooting Instructions

Problem Description	Action
Precision degradation is observed, or images are not well-stitched during acquisition.	Ensure that the lens window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue. Use a lens tissue or lint-free cloth to remove any dust or water stains from the mirror in the tip. Make sure the tip is firmly installed and there are no dark edges on the live video.
The tip is installed, but not detected. No live video is displayed, and the **Scanner Tip Loose** icon is displayed at the lower-right of the **IS ScanFlow** interface.	Ensure that you attach the tip to the scanner firmly and in the correct direction.
The **Overheating** icon is displayed at the lower-right of the **IS ScanFlow** interface.	Place the scanner in the charging station for 5 to 10 minutes. The scanner will become inactive and cool down.
Hardware error code ERR-00130AXX (where XX is a two-digit code) from the **IS ScanFlow** interface.	A component might be failing. Contact your local service provider for assistance.

7 Technical Specifications

7.1 Factory

Envista (Suzhou) Medical Device Co., Ltd.
1st floor 2nd floor
Building 18#, No.8 Jinfeng Road
Suzhou Jiangsu
215163 China

7.2 Manufacturer

Dental Imaging Technologies Corporation
450 Commerce Drive
Quakertown, PA USA 18951

7.3 Model

DEXIS Imprevo

7.4 Technical Specifications

7.4.1 Scanner Handpiece

Item	Technical Specification
Light source	Laser and LED
Field of view	16 x 14 mm
Depth of field	0 - 23 mm (distance from tip window plane)
Wireless	802.11ax (Wi-Fi 6)
Dimension (L x W x H)	257 x 45 x 36 mm
Weight	294 g (including battery and tip)
Power	Powered by DEXIS 1INR19/66 battery: 3.635 V, 3500 mAh, 12.7 Wh
Protection class	IP30

7.4.2 Charging Station

Item	Technical Specification
Dimension (L x W x H)	146 x 63 x 49 mm
Weight	190 g
Power	Input: 12 V DC/2.5 A Output: 15 W
Protection class	IP30

7.4.3 Battery Charger

Item	Technical Specification
Dimension (L x W x H)	85 x 83 x 42 mm
Weight	100 g
Power	Input: 12 V DC/2.5 A Output: 4.2 V DC/2.5 A x 2
Protection class	IP30

7.5 Length of Cables

Illustration of Part	Part Name	Length of Cable (m)
	Power Adapter	1.8 m

7.6 Scanner Environmental Requirements

Item	Environmental Requirements
Operating Temperature	+5 – +26 °C (41 – 78.8 °F)
Storage/Transport Temperature	-10 – +50 °C (14 – 122 °F)
Operating Relative Humidity	10 – 85% RH
Storage/Transport Relative Humidity	10 – 95% RH
Operating Atmospheric Pressure	700 – 1,060 hPa
Storage/Transport Atmospheric Pressure	600 – 1,060 hPa

7.7 Computer System Requirements

If necessary, you must update your computer system configuration.

Item	Recommended
CPU	Intel Core i7, 9th generation
RAM	32 GB RAM
Monitor	Screen resolution: 1920 X 1080
Operating system	Windows 10 Professional, version 1809 or higher
USB port	USB 3.0 for WiFi adapter
Video card	NVIDIA GeForce RTX 4080, 12GB memory or NVIDIA RTX 4000 Ada, 12GB
Video card driver	Support OpenGL 4.3 and OpenCL 1.1

The computer and its screen should be situated in or close to the operating area, in the visual field of the practitioner when using the scanner.

CAUTION: It is MANDATORY to check that your system configuration is compatible with the computer system requirements for the scanner software.

NOTE: Always use Microsoft Windows Update to ensure that the latest security patches are correctly installed.

8 Regulatory Information

8.1 General Regulatory Information

Classification in Accordance with EN/IEC 60601-1	
Type of protection against electric shock	Class II equipment, internally powered
Degree of protection against electric shock	Type BF Applied Part
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide.

Conformity with EN/IEC 60601-1-2

IEC 60601-1-2: EMC requirements and tests, Medical Electrical Equipment including CISPR 11: Group 1, Class B.

Electromagnetic Compatibility

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this documentation.

Other equipment can interfere with communications with the scanner, even if the equipment complies with CISPR emissions requirements.

Warning: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the intraoral scanners, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8.1.1 Wireless

The wireless specifications and IT Network configuration are listed below:

Data Transmission

The scanner contains an IEEE 802.11ax module.

Item	Specification
Transmit power	Maximum 16.75 dBm
Frequency band	5150-5250 MHz, 5725-5850 MHz Supported channels: 42, 155 (The actual frequencies are dependent on local regulations and the configuration of the product)
Network configuration	Bi-directional traffic permitted between the scanner and PC Redirection of traffic must be disabled Port used: TCP ports (20, 21, 23, 1860, 1863)
Security	WPA2-PSK Authentication
SAR value	Maximum 1.32 W/kg, 10g for CE Maximum 1.32 W/kg, 10g for FCC

Inductive Charging

Item	Specification
Transmit Power	33.72 dBuA/m @3m
Operating frequency range	111-200 kHz

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

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

- L'appareil ne doit pas produire de brouillage;
- L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This product contains a wifi module, the module has been approved with
FCC ID: 2A7FYWNFB265AXIBT and IC: 28659-NFB265AXIBT

Ce produit contient un module wifi, le module a été approuvé avec l'
FCC ID: 2A7FYWNFB265AXIBT et IC : 28659-NFB265AXIBT

NOTES:

(1) Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

(2) This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.
les dispositifs fonctionnant dans la bande de 5 150 à 5 250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This EUT is compliant with SAR for general population/uncontrolled exposure limits in RSS-102 and had been tested in accordance with the measurement methods and procedures specified in IEEE 1528 and IEC 62209.
Cet adaptateur est conforme au SAR pour la population générale/limites d'exposition non contrôlées dans RSS-102 et a été testé conformément aux méthodes et procédures de mesure spécifiées dans IEEE 1528 et CEI 62209.

8.2 Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration - Electromagnetic Emission (IEC 60601-1-2)

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The 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	

Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-1-2: 2014

The scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 ±15 kV air	±8 kV contact ±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 for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-1-2: 2014			
Surge IEC 61000-4-5	±1 kV line to line	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines 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[a] cycles Single phase: at 0° 0% U_T; 250/300[a] 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[a] cycles Single phase: at 0° 0% U_T; 250/300[a] cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the scanner requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a) e.g., 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2)		
The scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the scanner should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz[a]	Environment of a professional healthcare facility.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the scanner including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
NOTE: 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 scanner is used exceeds the applicable RF compliance level above, the scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the scanner.		
a The ISM (industrial, scientific and medical) bands between 150 k Hz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
For the immunity to proximity fields from RF wireless communications equipment, the scanner is compliant with the test levels specified below, according to IEC60601-1-2 standard. The customer or user of the scanner should assure that it is used in such an environment.		
Test Frequency (MHz)	Band (MHz)	Immunity Test Levels
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5 kHz deviation, 1 kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

9 Contact Information

9.1 Manufacturer's Address

Dental Imaging Technologies Corporation
450 Commerce Drive
Quakertown, PA USA 18951

9.1.1 Authorized Representative in European Community

EC REP

PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, FINLAND

9.1.2 UK Responsible Person

Kerr UK Limited
c/o Orega Stockley Park
4 Longwalk Road
Stockley Park
Uxbridge UB11 1FE
United Kingdom

9.1.3 Authorized Representative in Ukraine

Representative office of Spofa Dental a.s.
26 Lesi Ukrainky Bulvar, office 717, 01133 Kyiv, Ukraine
Phone: +38 (044) 286 49 12
Fax: +38 (044) 286 10 03
Email: info.ua@kavokerr.com

9.2 List of Importers for European Union According to the MDR 2017/745

PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, FINLAND

Dental Imaging Technologies Corporation

450 Commerce Drive
Quakertown, PA USA 18951

For more information, visit: dexis.com

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