DEXIS™

IS 3800

Safety,Regulatory,and Technical Specifications User Guide

Notice

The Safety, Regulatory and Technical Specifications User Guide includes information on the 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.

The IS 3800 Family comprises:

- IS 3800W
- IS 3800

This document is originally written in English.

The IS 3800W and IS 3800 are intended for professional use only.

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

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.

Manual Name: *IS 3800 Family Safety, Regulatory, and Technical Specifications User Guide*
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The IS 3800W and IS 3800 comply 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).

CE UK CA

Contents

1 Safety Information

Indications for Use

The IS 3800 Family system 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.

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.

Conventions in This Guide

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

WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.

Caution: Alerts you to a condition that might cause serious damage.

Important: Alerts you to a condition that might cause problems.

Note: Emphasizes important information.

Tip: Provides extra information and hints.

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 malfunction of the unit.

IMPORTANT: 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.

WARNINGS

IS 3800 Family:

- **You MUST read and understand this safety information before using the scanner.**
- **This scanner shall only be used inside hospitals 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 have training to use the scanner.**
- **DO NOT place objects within the field of operation of the unit.**
- **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.**
- **DO NOT expose the scanner to water spray or submerge it in water or disinfectant.**
- **DO NOT expose the scanner to high vibrations.**
- **DO NOT expose the scanner to ultraviolet radiation directly. The scanner is not designed for ultraviolet disinfection.**
- **DO NOT stare at the LED emission window.**
- **When the tip is removed, install the rubber 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 cables provided with the scanner with other cables. Doing so may damage the scanner and adversely affect the safety protection and EMC performance of the scanner.**
- **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.**
- **Additional multiple outlet strips or extension cords should not be connected to the system.**
- **The maximum temperature of the applied part may reach to 43 °C; to avoid overheating, do not use it for extended periods.**
- **To power off the device, push the power button for 3 seconds. To isolate the device from mains supply on all poles, unplug the adapter from the mains power outlet.**
- **DO NOT maintain or service this equipment while it is in use with the patient.**
- **Always position the unit in such a way that it is easy to disconnect the adapter from the mains power outlet.**
- **Connection of the PEMS (Programmable Electrical Medical System) 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.

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.**

IS 3800W Battery:

- **Do not dismantle, open, or shred secondary cells or batteries.**
- **Do not expose cells or batteries to heat or fire. Avoid storage in direct sunlight.**
- **Do not short-circuit a cell or a battery. Do not store cells or 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 cells or 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 cells and batteries clean and dry.**

- **Wipe the cell or battery terminals with a clean, dry cloth if they become dirty.**
- **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 cells or batteries several times to obtain maximum performance.**
- **Retain the original product literature for future reference.**
- **Use only the cell or battery in the application for which it was intended.**
- **When possible, remove the battery from the equipment when not in use.**
- **Dispose of properly.**

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.

Cleaning, Disinfecting, Sterilizing

Cleaning and Disinfecting the Scanner

WARNINGS

- **Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner for reuse.**
- **You must wear gloves while cleaning and disinfecting the scanner.**
- **The scanner must be disinfected with an U.S. Environmental Protection Agency (EPA) registered or CE marked intermediate-level disinfectant solution with tuberculocidal activity between patients.**
- **DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the scanner.**
- **Never put the scanner in an autoclave device or immerse it in water or the disinfectant solution.**
- **Excessive fluids can damage the scanner. Do not use cotton, cloth, or tissues soaked with disinfectant to disinfect the scanner.**

IMPORTANT: Do NOT remove the detachable part (battery or cable) from the scanner when cleaning and disinfecting unless you see it necessary.

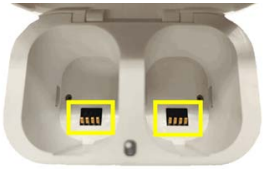
IMPORTANT: Make sure the contact points on the IS 3800W handpiece, battery and charging station are dry and clean after cleaning and disinfecting, in order to avoid risk of short circuit.

Figure 1 Contact points on IS 3800W handpiece

Figure 2 Contact points on battery

Figure 3 Contact points on IS 3800W handpiece charging station

Figure 4 Contact points on IS 3800W battery charging station



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

Figure 5 Gap between covers

Figure 6 Pin holes and air outlet

Figure 7 Air inlet - IS 3800W

Figure 8 Air Inlet - IS 3800

Cleaning the Scanner

If the scanner is visibly contaminated with blood and/or body fluids, you must clean it before disinfecting it.

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.

Disinfecting the Scanner

After each patient, the scanner must be thoroughly disinfected.

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

Important: If the scanner is visibly soiled, it must be thoroughly cleaned prior to disinfecting. See "Cleaning the Scanner."

To disinfect the scanner, follow these steps:

1 Remove the reusable tip.

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

3 Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time. Approved disinfectant wipes: Mikrozid AF Jumbo Wipes, CaviWipes, Oxivir Tb Wipes, Clorox Healthcare Bleach Germicidal Wipes, PDI Sani-Cloth Bleach Germicidal Wipes.

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

4 Thoroughly wipe all surfaces of the scanner.

WARNING: Do not rinse.

5 Allow to air dry.

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

Cleaning and Sterilizing the Scanner Tips

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

If you limit the exposure time at 134°C to not more than 4 minutes, you can autoclave the tip up to 110 cycles.

WARNINGS

- **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.**

Manually Cleaning the Scanner Tips

To manually clean the scanner tips, follow these steps:

1 Rinse excess soil from the tip.

2 Using a soft brush, apply an enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.

3 Rinse under clean, running water.

4 Inspect the tip. If the tip is not clean, repeat the steps.

5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Cleaning the Scanner Tips in an Automatic Washer or Disinfector

To clean the scanner tips in an automatic washer or disinfector, follow these steps:

1 Rinse excess soil from the tip.

2 Using a soft brush, apply an enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.

3 Load the tip into the washer/disinfector equipment.

4 Run the cycle per the equipment manufacturer's instructions.

5 If the machine does not have an automatic rinse cycle, rinse thoroughly to remove detergent residues by immersing in clean water.

6 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Sterilizing the Scanner Tips

Note: If you limit the exposure time at 134°C to not more than 4 minutes, you can autoclave the tip up to 110 cycles.

To sterilize the cleaned scanner tips, follow these steps:

1 Place the tip in an FDA-cleared or CE-marked sealed sterilization pouch. The pouch should be sealed air-tight. Use either a self-adhesive pouch or a heat-sealed pouch.

2 Place the tips in a steam autoclave for the following times:

Pre-Vacuum Autoclave (Class B)		
Exposure Time at 132°C	**Exposure Time at 134°C**	**Minimum Drying Time**
Minimum 4 Minutes	Minimum 3 Minutes	20-30 Minutes

Gravity Autoclave (Class N)		
Exposure Time at 132°C	**Exposure Time at 134°C**	**Minimum Drying Time**
Minimum 15 Minutes	Minimum 10 Minutes	15-30 Minutes

Important: **Do NOT exceed 134°C.**

Precautions Before Use

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

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 7.
- Clean and sterilize the scanner tip. See “Cleaning and Sterilizing the Scanner Tips” on page 10.

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 (IS 3800W only).

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.

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.

WARNINGS

- **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 IS 3800W handpiece, battery, and charging station 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.

Marking and Labeling Symbols

	Type BF applied part symbol classification in accordance with IEC 60601 standards.
	Class II equipment
	In the European Union, this symbol indicates: DO NOT discard 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’s address
	Manufactured date
	**CAUTION:** Consult accompanying documentation.
	Refer to instruction manual/booklet.
	Direct current

MD	Medical device
EC REP	Name of the European authorized representative and address of the registered place of business.
UK REP	Name of the Responsible Person in the United Kingdom and address of the registered place of business.

Label Locations

IS 3800W Labels

The following figures illustrate the label locations of the IS 3800W.

Figure 9 IS 3800W Box Label

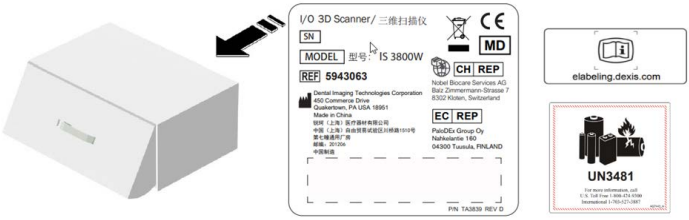


Figure 10 IS 3800W Scanner Label

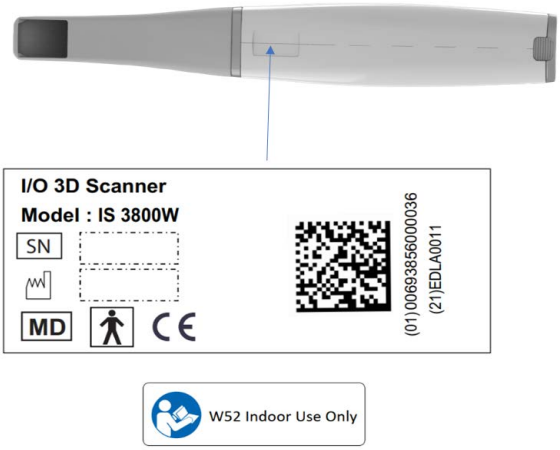


Figure 11 IS 3800W Charge Station Labels

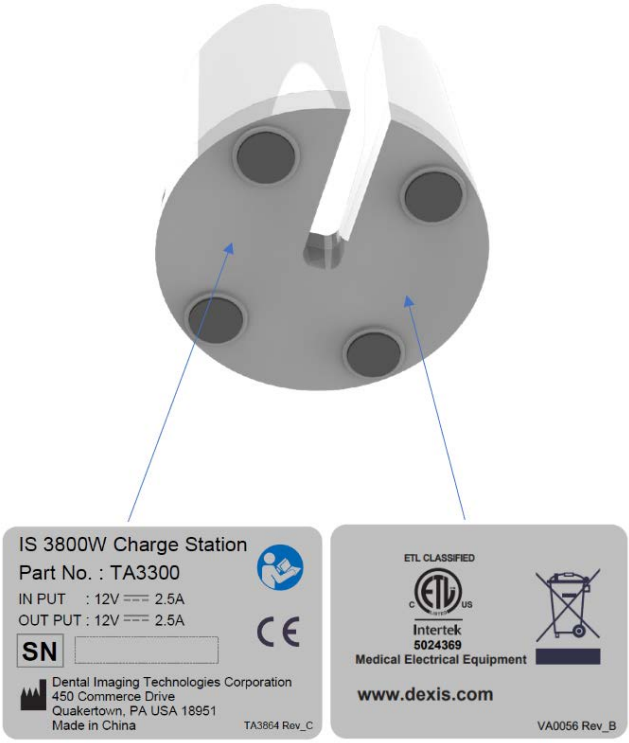


Figure 12 IS 3800W Battery Charge Station Label

Figure 13 IS 3800W Battery Label

IS 3800 Labels

The following figures illustrate the label locations of the IS 3800.

Figure 14 IS 3800 Box Label

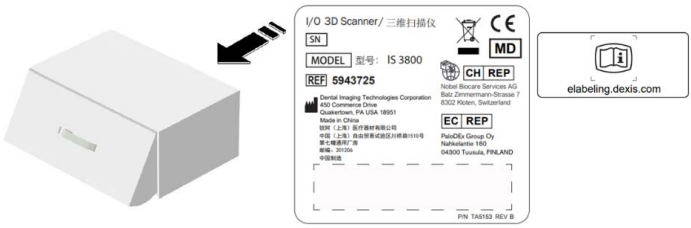
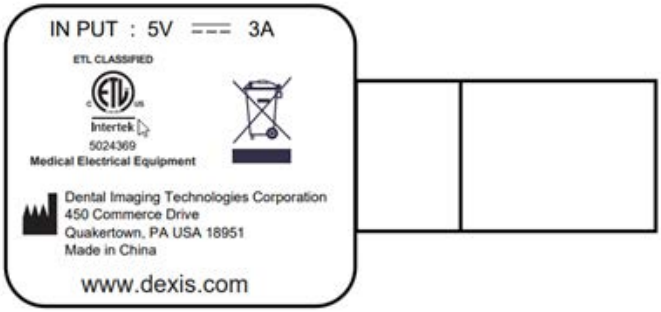


Figure 15 IS 3800 Scanner Label

Figure 16 IS 3800 Detachable Cable Label



2 Regulatory Information

General Regulatory Information

Compliance with European and International Standards	
EN 60601-1 / IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-18	Medical Electrical Equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 62471 / IEC 62471	Photobiological safety of lamps and lamp systems: Equipment classification, requirements, and User's Guide
EN ISO 17664	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
EN 60601-1-6 / IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN/IEC 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices
EN 62304 / IEC 62304	Medical device software - Software life cycle Processes

Compliance with European and International Standards	
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041	Information supplied by the manufacturer of medical devices
CAN/CSA-C22.2 No. 60601-1	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
EN 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
EN 50566	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body.

Compliance with European and International Standards	
EN 301 489-1	Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 893	5GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Classification in Accordance with EN/IEC 60601-1	
Type of protection against electric shock	Class II equipment
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: 2014 EMC requirements and t ests, Medical Electrical Equipment including CISPR 11:2009+A1:2010 Group 1, Class B.

Electromagnetic Compatibility Precautions

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 IS 3800 Family, 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 CS 3800 Family of intraoral scanners, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WiFi

This equipment complies with radio frequency exposure limits set forth by the RED, the FCC, and Innovation, Science and Economic Development Canada for an uncontrolled environment.
This device complies with part 15 of the FCC Rules and 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.

NOTE: 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.

SAR Value for IS 3800W Handpiece:
5150-5250MHz 0.803W/kg 1g-SAR
5250-5350MHz 0.147W/kg 1g-SAR
5470-5725MHz 0.329W/kg 1g-SAR
5725-5850MHz 0.629W/kg 1g-SAR

Caution: 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.

Limited by local law regulations, the version for North America does not have a region selection option.

The device is for indoor use only and operates in the 5150-5250 MHz band to reduce the potential for harmful interference to co-channel mobile satellite systems.

Guidance and Manufacturer's Declarations

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

The IS 3800 Family is intended for use in the electromagnetic environment specified below. The customer or user of the IS 3800 Family should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The IS 3800 Family 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 IS 3800 Family 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 IS 3800 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the IS 3800 Family 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.
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 IS 3800 Family requires continued operation during power mains interruptions, it is recommended that the IS 3800 Family 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 IS 3800 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the IS 3800 Family 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 IS 3800 Family 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 IS 3800 Family is used exceeds the applicable RF compliance level above, the IS 3800 Family should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IS 3800 Family.

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 IS 3800 Family is compliant with the test levels specified below, according to IEC60601-1-2 standard. The customer or user of the IS 3800 Family 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		

Compliance with International Regulations

- Medical Device Regulation (EU) 2017/745
- FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.3661 (USA)
- Medical Devices Regulations (Canada)
- Directive 2011/65/EU on the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS), as amended by Directive (EU) 2015/863
- Radio Equipment Directive 2014/53/EU (IS 3800W only)
- Medical Devices Regulations 2002 (SI618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).

3 Technical Specifications

Factory

Rayco (Shanghai) Medical Products Company Limited
Building 7, No. 1510 Chuanqiao Road
China (Shanghai) Pilot Free Trade Zone
201206 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Manufacturer

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

Model

IS 3800W
IS 3800

IS 3800 Family Technical Specifications

IS 3800W

Components	Technical Specifications
Sensor technology	CMOS
Illumination	LED: Red, Blue, Green
Field of view	16 x 14 mm 13 x 7 mm (posterior tip)
Depth of field	-2 to +16 mm
Anti-fogging technology	By airflow
Digital connection	WiFi 5GHz, 802.11ac
Handpiece dimensions	226 x 38 x 50 mm (with normal/side tip)
Components	**Technical Specifications**
Weight	240 g (with battery)
Handpiece	Input: 5 V ⎓ 5A (with backup power cable) 4.2 V ⎓ 3A (with battery)
Handpiece Charger	Input: 12 V ⎓ 2.5A Output 1 (charging port): 4.2 V ⎓ 3A Output 2 (port for backup power cable): 12 V ⎓ 2.5A
Battery Charger	Input: 12V ⎓ 2.5A Output: 4.2V ⎓ 3A **Note**: When charging a single battery, the output is 3A. When charging two batteries at the same time, the output of each slot is limited to 2.4A, to prevent the power adapter from being overloaded.

Battery	**Model: 1INR18/65** 3.6 V/3500 mAh
Adapter	**Model: LXCP30A-120** Input: 100-240V ~ 50/60Hz, 0.8A Max Output: 12.0V ⎓ 2.5A
Backup Power Cable	Length: 2 m

IS 3800

Components	Technical Specifications
Sensor technology	CMOS
Illumination	LED: Red, Blue, Green
Field of view	16 x 14 mm 13 x 7 mm (posterior tip)
Depth of field	-2 to +16 mm
Anti-fogging technology	By airflow
Detachable cable	Interface: USB Type-C Length: 2 m
Digital connection	USB 3.1
Handpiece dimensions without cable	229 x 38 x 50 mm (with normal/side tip)
Components	**Technical Specifications**
Weight	190g (with normal/side tip, no cable)
Handpiece	Input: 5 V ⎓ 3A

Length of Cables Supplied with the Unit

Illustration of Part —IS 3800W	Part Name	Length of Cable (m)
	Backup Power Cable	2.0 m
	AC Adapter	1.8 m

Illustration of Part —IS 3800	Part Name	Length of Cable (m)
	Detachable Cable	2.0 m

IS 3800 Family Environmental Requirements

Components	Environmental Requirements
Operating Temperature	+5 ~ 30 °C
Transportation and Storage Temperature	-10 ~ 50 °C
Operating Relative Humidity	10 – 85% RH
Transportation and Storage Relative Humidity	10 – 95% RH
Operating Atmospheric Pressure	700 – 1060 hPa
Transportation and Storage Atmospheric Pressure	600 – 1060 hPa

Computer System Requirements

If necessary, you must update your computer system configuration.

Item	Recommended	Minimum
CPU	Intel Core i7, 9th generation	Laptop: Intel Core i7-7700HQ, Quad CPU, 2.8 GHz
RAM	32 GB RAM	16 GB RAM
Monitor	Screen resolution: 1920 X 1080	Screen resolution: 1920 X 1080
Operating system	Windows 10 Professional, version 1809 or higher	Windows 10 Professional, version 1809 or higher
USB port	USB 3.0 for WiFi adapter (IS 3800W) USB Type-C (IS 3800)	USB 3.0 for WiFi adapter (IS 3800W) USB Type-C (IS 3800)
Video card	NVIDIA GeForce RTX 2060, 6 GB memory	NVIDIA GeForce GTX 1050 Ti or Quadro P3000 or similar
Video card driver	Support OpenGL 4.3 and OpenCL 1.1	Support OpenGL 4.3 and OpenCL 1.1

Note: The All-In-One computer system requirement is an exception.

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 IS 3800 Family.

Important: It is MANDATORY to check that your system configuration is compatible with the computer system requirements for the IS 3800 Family software.

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

4 Contact Information

Manufacturer's Address

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

European Community

EC REP

PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, FINLAND

UK Responsible Person

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

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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