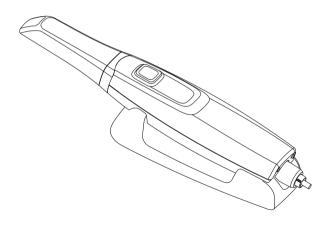


Intraoral Scanner

Operation Manual Technical Manual



Version Number: 2023-10-25





Product Model:	
Product Name:	
Serial Number:	
Date of Manufacture:	



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Introduction

Thank you for your trust in us. We hope this product will satify you completely. It is recommended that you read this manual before installation and use, which is ben ficial to eliminate and reduce the risk to you and your patie ts due to misoperaation. It is used for oral digital printing.

♦ Components

Scanner Handpiece, Base, Protection Tip, D ta Cable, USB Connector Box, Power Adapter(12V), U Disk with Soft are, Operaation Manual.

♦ Intended use

Using opti al scanning method to collect the 3D geometric data of the tooth in the patie t's mouth and provide the 3D digital model for CAD/CAM denture design and processing.

♦ Features

The excellent image quality is based on advanced CMOS technology. The more convenient three-country collection pocess is more compact and comfortable, durable sccanning tip • easy to use USB 2.0 interface.

♦ Power

Power Adaptor

Input: 100-240V~ | 50-60Hz | 0.5A

Output: 12V === 1.5A

Intraoral scanner: 12V == 1.5A

♦ Product life

8 vears

◆ Contraindication

No

◆ Classificaation

GB 9706.1-2007 first part of medical electrical equipment: safety general requirements GB 191-2008 packaging and shipping diagram mark this product safety classification belongs to type II BF medical device equipment.

This device does not belong to the operation mode of AP type or APG type device. Operation mode of the device: onntinous oparation. Anti-infectio el: IPX0.



◆ Specificaation

According to the oral cavity digital printer area different classificacation

Model	Scope of reconstruction	Pixel
IOS-11	14 x 14 x 15 mm	1024 X 768 pixels

◆ Components of scanner

No.	Components	
1	Scanner Handpiece (with protecti ve tip)	
2	Scanner tip	
3	Base	
4	Data cable	
5	USB cable connector	USB 2.0
6	Power adaptor(12V)	
7	Dongle	
8	U disk with soft are	
9	Operation Manual	

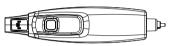
Please check the above table to see if the parts are complete before the installation of the Runyes 3DS Intraoral Scanner. If some components do not match, you cannot install them. Please contact the local distributor or agent for support if you can't install the system.

Scanner:

The scanner's 3D information is reconstructed from 2D images taken by the scanner. The scanner is mainly composed of opti al and imaging systems, and the top of the handpiece has protecti e glass prottection.



Made of medical non-pound steel and opti al prism, it is installed into the head of the scanner for scanning. The scanning head can be sterilized in accordance with the prescribed method.



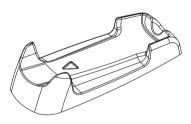


Base:

Hold the handpiece, after putting the handpiece on the base, the scanner will be at standby mode.



Connection bet een the handpiece and computer, mainly for the transition of the data signals.





Data cable:

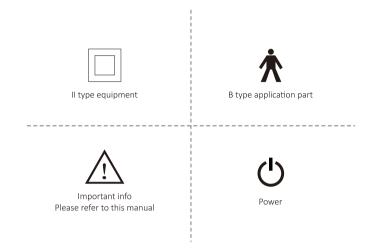
Used to transmit the output signal from the Scanner $\,$

USB cable: It is used to transmit output signals from the base to the computer, connecting the base and the omputer.

Power adapter: 12V= 1.25A medical certif acation er adapter.



Label





Represents useful information and how to use our sof are



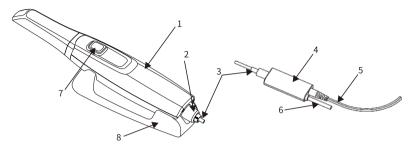
Express important instructions.

Failure or damage system or other property if not observed.



Represents warnings and safety instructions. Failure to comply may be a serious threat and injury to the patie t and operator.

♦ Port and buton



1. Part 3, Type C cable is connected to handpiece, and tig tly screw the part; .

Note: Please plug in the cable connection t first, and then tig ten the screw. please pay agenention the snap direction(Figue 1);

- 2. The other port of the part 3 is connected to the part 4, connector box.
- 3. The USB port of the connector box is to connected to the computer;
- 4. The other port of the connector is connected to the power adaptor:
- 5. Afer all cconnection, the li t on handpiece is stable in blue, it means the scanner is ready;
- 6. Press the light buton on the handpiece, the light on handpiece becomes green, it means the scanner starts scanning;
- 7. Afer finishing scanning, please place the handpiece on the base, and the handpiece will be at standby mode and stop scanning automati ally.
- 8. Plug out the adaptor to disconnect the power supply if not using the scanner.

Note:

- 1.Before starting s anning, please kindly put on the scanner tip orrectly, Please parallelly insert or remove the scanner tip based on Figure 2, without tilting;
- 2.Indicating lig t:

Green light: The scanner was preparing/scanning; Blue light: Standby/ Ready to scan;

Blue light: Standby/ Ready to scan; Flashing blue light:: Connection ailed;

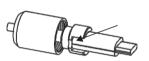


Figure 1

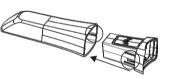


Figure 2

Operation Manual Operation Manual 5



Hardware Installation

♦ Components

You need to install the driver in the PC which to identify the 3DS s anner.

♦ Installation noes

- 1. When installing, please handle with care and minimize the distortion and pull of the wires. Do not thread or roll the wires.
- 2. Place the base in a suitable position o prevent falling.
- 3.Do not drop the handpiece and base on the ground so as not to cause irreparable
- 4.In order to avoid disturbing images, don't let the system approach the strong magnetic field and avoid the staatic emission soce.
- 5. Although the electromagnetic i terference of this product is low, it does not guarantee that the operation does not a ect the surrounding equipment.
- If there is interference, please keep the product away from the interference device.

♦ Specificaation



 $oldsymbol{\Lambda}$ We cannot guarantee the work of the Runyes 3DS scanner and the pirated Microsoft Windows. So please use the legitim te version of Microsoft Wind s 10.

PC Specificaation

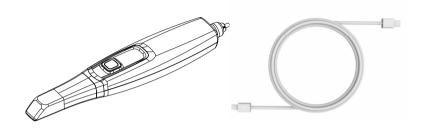
- ·OS: Microsoft Windo s 10 64 prro edition or ab e;
- •CPU: Intel i7-8700 or above(Laptop i7-8750H or above);
- ·Video card and video memory: NVIDIA GeForce 1660GT or above graphics card, more than 6G:
- ·Memory: 16G or higher;
- ·Hard disk: 256G solid state hard disk or 128G solid state hard disk + 1T mechanical hard disk:
- Display resolution: 1920x1080;
- Operating ystem: WINDOWS 10 professional/entterprise edition;
- USB port: USB 3.0



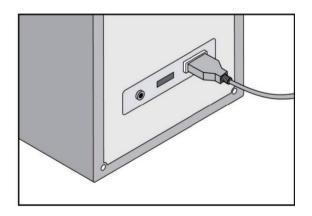
Before installing the soft are and the server, you must close the Windows system's firewall and the annti-virus so are with firewirewall functo make sure sure the are can be installed and run properly.

♦ Cable connection

1. Connect the handpiece to connector;



2.Plug USB cable to PC's USB port





3. Connect the power adaptor to the connector





Soft are Installaation

♦ Install soft are

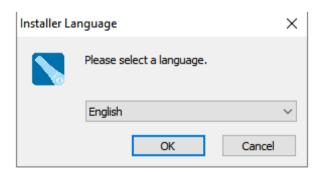
Step 1:

Insert U disc to the computer, manually operate installation

The file currently contained on the disc



Step 2: please select a language





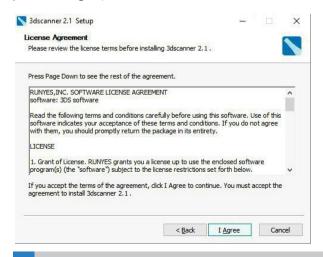
Step 3:

Enter the installation wiard, click"Next"

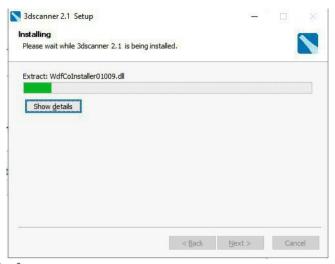


Step 4:

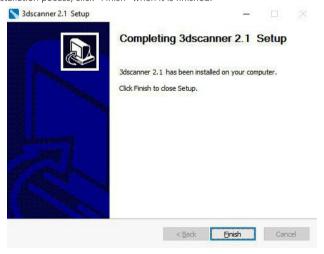
Read carefully the license terms before installation, if ou agree with the agreement, please click "I Agree", if not click "Cancel"



Step 5: When "Dental Viewer"'s installshield pops up, click"Next"



Step 6: Installation pocess, click" Finish" when it is finished.





Ready to Start Scanning:

- 1. Make sure all the connections be eady
- 2. Enter the patie t information, ter the

scanning interface, and select the dental arch to be scanned.

3.Take the handpiece from the base, press the buton, when the light becomes green means it is ready to start scanning.

Scanner head:

Caution: The s canner tip should be cleaned and disiectcted er each use. Please follow the instructions of cleaning and disinfection avoid cross-infnfection b een pa pats.

There are four consecutie steps of images capturing:

- 1.Occlusal surface
- 2.Buccal side
- 3.Lingual Side
- 4. Mesial Side

Occlusal surface scanning

Importance: The distance between the scanning window of the scanner tip and the surface to be measured is required. The distance must be kept between 0 and 15mm (best distance: 5mm). The scanning tip should not be on the eeth or gums. If the distance is too long, data cannot be collected.





Buccal side scanning





The scanning tip is lo ated near the adjacent tooth of the prepared tooth.

- 1.Turn the scanning tip o the buccal side from 45 degrees to 90 degrees.(max degree)
- 2. Move the scanning tip o er the surface of the tooth, through the ennte buccal side.





Lingual side scanning

The scanning tip is lo ated near the adjacent tooth of the prepared tooth.

- 3.Rotate the scanner tip fom 90 degrees on the buccal to the side of the lingual 45 degrees to the maximum 90 degrees.
- 4. Move the scanning tip o er the surface of the teeth, through the ennte lingual side.

Mesial side scanning

Move the scanning tip owards the dirrection of Mesial side by tilting the e scanning tip,in order to take the good image of adjacent teeth.

Reminder:

Please remove the soft tissue.

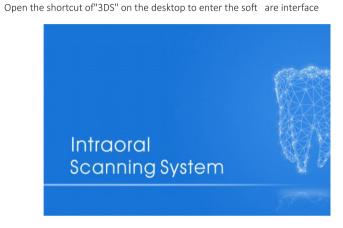
Remove the acti e gums so that the gums are 1 to 2 mm away from the teeth. The next buton is completed, and the calculationtagage is opti mized. After the op aimization calculation, the final enerated 3d image will be displayed. Please check the correct output. If part of the image is missing, click Scan and continue s anning.



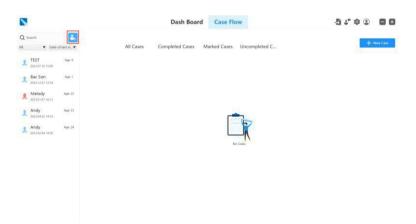
♦ Running 3DS scanner

Intraoral scanning soft are operaation ocess:

Step 1



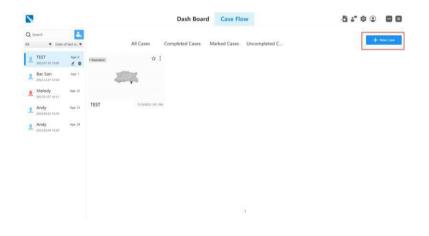
Step 2 Click the "New Patie t"icon in the red box



Step 3 Enter the "patie t name" and other relevant informaation, click Add



Step 4 Click the "New Case" icon in the red box

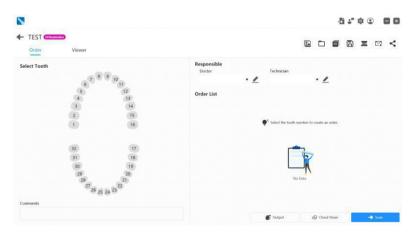




Step 5 Click the "Next step"



Step 6 Click "Scan"in the lower right corner



Step 7

The main function of the main i terface



- 1.System time and sof are version informamation
- 2.Process steps
- 3.Patie t name
- 4.Scan object switching
- 5.3D scan results show

6.Function ey area: including "True Color", "Lock the Scanning View", "Al Scan" "Metal Scan", "Eraser", "Cut", "Lock Scan Area", "Delete", "Preview", "Reset View"HD Camera" 7.Scanner Status/Video

Step 8

Switch the scan object to "upper jaw" and scan to obtain a 3D model of the patie t'supper jaw.





Step 9

Switch the scan object to "lower jaw" and scan to obtain a 3D model of the patie t'slower jaw.



Step 10

Switch the scan object to "occlusion", and ask the patie t to bite up and down in anormal state. Scan the teeth and move the scanner tip up and down o sccan part of the upper and lower teeth, and then the soft are will automaatally occlude the upper and lower teeth.



Step 11

Click "Check" to check whether there is any problem in the final 3D model andwhether it meets the design requirements, etc.



Step 12

Click "Export", select the required file type, then click "Ok", you can find the fileunder the corresponding path.





Maintenance

Visual Inspection

Like all electrical equipment, not only does the scanner need to be used correctly, it also needs to be inspected regularly. These measures will help ensure that the system operates accurately, safely and efficiently.

Before use, the operator should check for damage to the body or any system problems. If it is detected that it is different from the usual use, please further explain the problem of the product to the local dealer.

♦ Cleaning, Sterilization & Disinfection

1. Scanner Tip

Cleaning: Separate the scanning tip and the sanner handpiece, first clean the scscanning tip and the lens with clean water (running water) and alcohol (75% concentration of medi al alcohol), pay atenntion oremove the dirt, oil stains, spots and other traces on the lens. And dry the scanning tip and lens with a soft cloth (non oven fabric) and a clean c c on swab, and handle well with drving.

High Temperature & Pressure Sterilization:

Put the scanner tip in a special terilizaation bag and seal it, and aange the high-pressure steam sterilization in the ollowing two ways:

- a. Select sterilization under 134°C or more than 3.5 minutes:
- b. Select sterilization under 121°C or more than 15 minutes:

Afer sterilizaation, it needso be stored according to the infnfectioontrol requirements. Before use, it is necessary to check whether the scanning head and the lens are in good condition. Those tips t t need to be used immediatately er sterilizaization should aken out and allowed to stand for more than 30 minutes and cooled to room temperature before installation and operation.

Note: The scanning head is a consumable item and can be sterilized about 100 times in a high temperature sterilization e vironment. If the scanning head shell is broken, the contact reed falls off, the lens has cracks, serious spots and dirt that cannot be cleaned, etc., the scanner tips need o be disposed of.

Immersion Disinfection:

Immerse the scanner head in CIDEXOPA solution (0.55% o-p thalaldehyde) for more than 5 minutes. Afer ccompletion, dry the scan head and the lens with a soft cloth (no oven fabric) and a dust-free coton swab, and use it immediately to avoid seccondary pollution of the scanner tip. It is equired to check whether the scanner head and the lens are in good condition b fore sttarting use.

Note: During immersion disinfection, the sanner head needs to be placed yvertally in the disinfectant solution, and it must be dried aer being taken out.

Note: The scanner head needs to be sterilized or disinfected when it is used for the firsst time, and it also needs to be sterilized or disinfected when it is used on different paati ts.

2. Scanner Handpiece

2.1, Scanner Handpiece Disinfection & Cleaning

Wipe the product cover with a normal coton cloth dipped in a small amount of soapy water. Soapy water should be removed afer cleaning, do not allow soapy water to remain on the surface, and dry the cover with a clean, dry coton cloth.

Use a soft cloth (non-oven fabric) dipped in a small amount of 75% concentraation of medal alcohol to wipe the surface of the scanner handpiece. Afer a certtain period of time, air dry it naturally or use another clean and dry soft cloth (non-oven fabric) to dry the residual alcohol. It is recommended to clean and disinfect once a day.

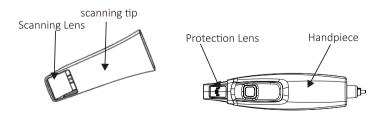
Note: Do not wipe with cleaning materials that will damage the surface of the covers, and do not allow liquids to enter the inside of the device and cause mechanical damage, and please pay special atenntion the parts as shown in the figure.





2.2. Cleaning and disinfection of the font prottection window of the anner body

Use a dust-free coton swab dipped in a small amount of 75% concentraation of medal alcohol to gently wipe the surface of the protecti e window to remove dirt, oil stains, spots and other traces on the lens. Use another clean, dry lint-free swab to dry the protecti e window surface. CAUTION: The protecti e window is a delicatte optal component and must be cleaned and disinfected with extreme care, and care must be taken not to allow excess liquid to flow into other locations when wiping.







A. Afer pressing the powwer buon, the device cannot be turned on.

- 1.Check the adapter connection.
- 2. If the power indicator is on check whether the computer can identify the sanner driver.
- 3.Check the cable connection bet een the base & computer.
- 4.Check the cable connection bet een scanner handle & the base.

B.The computer has identified the device, but the anning soft are can not start scanning.

- 1.Restart the soft are and reconnect with the device.
- 2. Turn offthe device power and restart the device.

C.During the use of the device, scanning stops and can not continue orking.

1. The device has the thermal protection function.

Solution is: turn off the device, and eep offfor 5 to 10 minutes according to different environment temperature, and then turn on again to see.

2. There is foggy issue on the scanning window.

Solution is: omove the fog directly or put back the handpiece to the base support for external heating o remove the fog,then you can start scanning again.

3.The device water proof level is IPXO, so please don't directly spray water onto the device, or get the device immersed in various liquids.

D.During the use of the device, the scanning image slows down or suspends.

- 1. Check the USB cable connection see if it is good.
- 2.Check Whether the device is used for a long time leads o higher internal temperature.
- 3.If the above issues occur frequently, it may be that the usb internal data cable is broken. Please contact the local afer-sales service staff.

E.During the use of the device, has large noise or the image color is distorted.

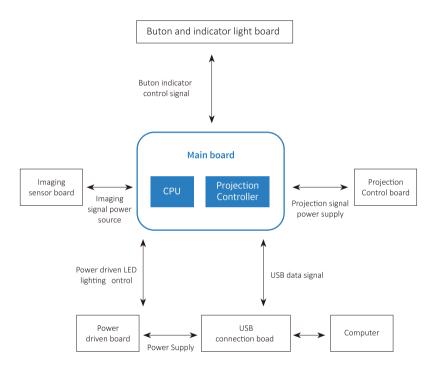
- 1. This device belongs to the precision instrument, should be handpieced gently. Heavier shocks may cause unpredictable damage to internal hardware.
- 2.Do Internal soft are calibration of the device.

◆ Product application peccautions

- 1. The product is a precision opti al device, which requires careful operaation and maintenance; accidental collision or drop may cause damage or deviation of the opt al components, and ultim tely affect the scanning results. If the above situauation ocs, please contact customer service staff in time.
- 2.When using and maintaining the Intraoral Scanner, it is necessary to protect the exposed opti al components, such as the mirror of sccanner tip mior, prototection glass on the end of the scanning head, etc.to avoid corrosive liquid erosion or sharp objects scratching the lens surface. If any of the above occurs, please contact customer service staff in time.
- 3.When scanning tip terilization, it is necessaryo avoid the infiltratration of liquiom the back end of the scanning head. If there is infiltration and antaminanation of the inner surface of the lens, it is necessary to clean and blow dry with pure (99.9%) alcohol.
- 4.Please pay atenution the c connections when using thetraoral Scanner. The extra force is easy to make the connection untable or even disconnected. Please also be careful not to bend the wire excessively to avoid damage.
- 5.When the scanner is not used, please remove the scanning head and cover the protecti e sleeve and turn o ffthe base power. When not in use f for a long time, pull out the power adapter.



Circuit connection chart



◆ Technical specificaation

·Cmos: 13 x 13mm

·Pixel Size: 1024 X 768 pixels

·Scope of reconstruction: 14 x 14 x 15 mm ·Intensity of light radiation: ≤ 100mWcm2

·Size of scanner (scanning tip xcluded): 200 x 58 x 36mm

Data cable of scanner (connection bet een base and handpiece): 1.9m

·Usb data cable (base and computer connection): 1.2m

·Usb Connection: USB2.0

PC Specificaation S gesestions:

·Os: Microsoft Windo s 10

·Microsoft Windo s 1064 Pro or above;

•Cpu: Intel i7-8700 quad-core or above (Laptop requires i7-8750H or above);

·Graphics Card & Video Memory: NVIDA GeForce 1660 GT or above, more than 6G;

·Memory: 16G or above; ·Disk: 1 TB SSD or above.

Equipment operating e vironment:

·Environment temperature: 10 °C-40°C

·Relati e humidity: ≤ 85%;

·Atmospheric pressure: 86KPa~106KPa;

Equipment storage, transportation e vironment:

·Environment temperature:-20°C-55°C

·Relati e humidity: 10%~93%;

·Atmospheric pressure: 86KPa~106KPa;

Power Adaptor

'Input: 100-240V~ 50-60Hz 0.7A

·Output: 12V == 1.5A

·Intraoral scanner: 12V == 1.5A



♦ Waste disposal

In order to reduce the burden on the environment, recyclable parts should be sent to the recycling center afer removing the hazardous materials. Disposing of obsolete products is the responsibility of the recycler.

All components and elements containing hazardous substances shall be disposed of in accordance with law and environmental provisions. When dealing with waste products, they must be protected from harm.

△Recyclable **▲**Unrecyclable

Part	Main material	Recyclable material	Disposal center	Separation of harmful substances
Cover	ABS	Δ		_
Metal	Aluminum	Δ		
Circuit board		A		
Wire	Copper	Δ		
Packing	Paper	Δ		
Other			Δ	

◆ Electromagnetic ompaatibility

For this equipment, special precautions shall be aken for electrromagneticompapatibility (EMC) and shall be installed and used in accordance with the EMC information specified in this manual. Portable and mobile radio frequency communications equipment t may have an impact on the equipment.

Except as internal components of the spare parts for sale cable (transducer), using the specified aaachment and cable (transducer) may lead to increase of equipment or system launch or immunity to reduce equipment or system should not be put to use with other devices or close to, if use must be close to or stacked, validation should be obseved in the use of a coffret under normal operaation.

The following cables must be used to meet the requirements of electromagnetic emission and anti-i terference:

Name of cable	Length
Power Cable	1. 9m
Cable (connection bet een base and scanner)	1. 9m
Cable (connection bet een scanner and computer)	1. 2m

The fundamental nature can be used for image acquisition.

Name	Description
Image acquisition	When you turn on the power, start the soft are and move the handle, the image display box on the soft are can display the image normally.



Guidance & Manufacturer's Declaration-Electromagnetic Immunit

The Intraoral Scanner is intended for use in the electromagnetic e vironment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic e vironment:

Immunity Test	IEC60601 Test Level	Compliance level	Electromagnetic Environment-Guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic m terial, the relati e humidity should be at least 30%.	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output 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 Differenntial mode ±2 kV common mode	±1 kV Differenntial mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (95% dip in UT) for 5 sec	<5 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intraoral Scanner requires continued operation during po er mans interruption, it is recommended that the Intraoral Scanner be powered from an uninterruptible po er supply or a batery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typi al location in a typi al commercial or hospital environment.	

Note: UT is the a.c. mains voltage prior to application of the est level.

Guidance & Manufacturer's Declaration-Electromagnetic Immunity

The Intraoral Scanner is intended for use in the electromagnetic e vironment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic e vironment:

Immunity test	IEC 60601 The test level	Compliance level	Electromagnetic environment- guide
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Intraoral Scanner, including cables, than the recommended separation ditance calculated from the equation appli able to the frequency of the transmiter. Recommended separation ditance d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 23√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmiter in waatts(W) aording to the transmiter manufacturer and d is the recommended separation ditance in meters(m). Field strengths from fixed RF trransmiers, as determined by an electromagnetic sie 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 opagagation isected by absorption and eeflectionom structures, objects and people.



Field strengths from fixed trransmiers, such as base statationor radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoreti ally with accuracy. To assess the electrromagnetic vironment due to fixed RF tr trans er transmiters, an electrromagnetic se survey should be considered. If the measured field strength in the location in which the I traoral Scanner is used exceeds the applicable RF compliance level above, the Intraoral Scanner should be observed to verify normal operation. If abnormal perormance observed, additional measues may be necessary, such as reoriennting orelocacating thetraoral Scanner.

Recommended separation ditances between portable and mobile RF communicaations equipm t and the Intraoral Scanner

The Intraoral Scanner is intended for use in an electromagnetic e vironment in which radiated RF disturbances are controlled. The customer or the user of the Intraoral Scanner can help prevent electromagnetic i terference by maintaining a minimum distance between portable and mobile RF communications equipme t (trransmiers) and the Intraoral Scanner as recommended below, according to the maximum output power of the communications equipme t.

Rated maximum output power of	Separation ditance according to frequency of trransmier /m			
transmiter /W	150 kHz ~ 80 MHz d = 1.2√P	80 MHz ~ 800 MHz d=1.2√P	800 MHz ~ 2.5 GHz d = 2.3√P	
0.01	0. 12	0. 12	0.23	
0.1	0. 38	0. 38	0. 73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmiters rated at a maximum output power not listed above, the recommended separaation distance d meters(m) can be estim ted using the equaation applable to the frequency of the transmiter, where P is the maximum output power raating of the transmer in wa watts(W)ording to the transmiter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation ditance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic opagagation isected by absorption and eeflectionom structures, objects and people.