Digital Intraoral X-ray Imaging System Instruction Manual

Please carefully read this manual before operating

Guilin Woodpecker Medical Instrument Co., Ltd.

Catalogue

Preface

Thank you for purchasing the digital intraoral X-ray imaging system produced by Guilin Woodpecker Medical Instrument Co., Ltd. Woodpecker is a high-tech enterprise researching, developing, producing and selling dental products. It owns a sound quality control system. To ensure that you use the equipment correctly and safely, please read the full text of the instruction manual carefully before use.

1 Production introduction

1.1 Product introduction

The digital intraoral X-ray imaging system is applicable for oral two-dimensional image photographing, case diagnosis, and information management.

Features:

a) Ultra-high image resolution can provide doctors with clearer diagnostic images.

b) High-quality user interface makes photographing and reading easier.

c) User-friendly design makes the photographing process more comfortable.

1.2 Model

i-Sensor H1 / i-Sensor H2

1.3 Configuration

Equipment configuration is detailed in packing list.

1.4 Structure and Components

This equipment is composed of X-ray sensor, USB transmission cable, disposable protective sheath, sensor bracket, image management software system and other parts.

1.5 Scope of application

It is mainly applicable for oral two-dimensional image photographing, case diagnosis and information management.

1.6 Contraindications

Pregnant women and young children should be cautious to use the equipment.

1.7 Device safety classification

1.7.1 Type of operation mode: Intermittent operation

1.7.2 Type of protection against electric shock: Class Ⅱ equipment

1.7.3 Degree of protection against electric shock: BF type applied part

1.7.4 Degree of protection against harmful ingress of water: IP68

1.7.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8 Primary technical parameters

1.8.1 Power adapter input: 5V/USB interface

1.8.2 Effective area: 20*30mm(H1)/26*36mm(H2)

1.8.3 Pixel matrix size 1000*1500(H1)/1300*1800mm(H2)

1.8.4 Pixel size 20μm

1.8.5 Effective resolution ＞ 8lp/mm

1.8.6 Specifications: 38.5*25*4.5mm(H1)/40.0*31.0*4.5mm(H2)

1.8.7 Weight: 118g(H1)/158g(H2)

1.9 Operation environment

1.9.1 Environment temperature: 5℃～ 40℃

1.9.2 Relative humidity: 30% ～ 75%

1.9.3 Atmospheric pressure： 70kPa ～ 106kPa

2 Product installation and function description

2.1 Schematic diagram of the whole machine

Figure 1 X-ray sensor

2.2 Installation of accessories

2.2.1 configuration requirements

It is a must to first ensure that the computer and its peripheral devices do not cause any restrictions that may cause personal safety when using the digital intraoral X-ray imaging system. The computer system must also meet the following configuration requirements:

Windows®:	Configuration
Operating system	Windows® 7 or above
Processor	Intel® Core 2
Memory	2 GB or above
Hard disk	320 GB or above
USB port	4 high-speed USB 2.0 ports
Display board	Nvidia chip graphics card or ATI discrete graphics card
USB chip	Intel or NEC® / RENESAS®
Display resolution	1280 x 1024

X-ray generator compatibility

Digital intraoral X-ray imaging system is compatible with dental X-ray machines that comply with regulatory standards on the current market.

2.2.2 Software installation

a) Double-click to run the "Ai-Dental setup.exe" installation program.

Figure 2

b) After the installation program starts, click the "Browse" button to select the installation path. After the path is selected, click the "Next" button, as shown in Figure 3:

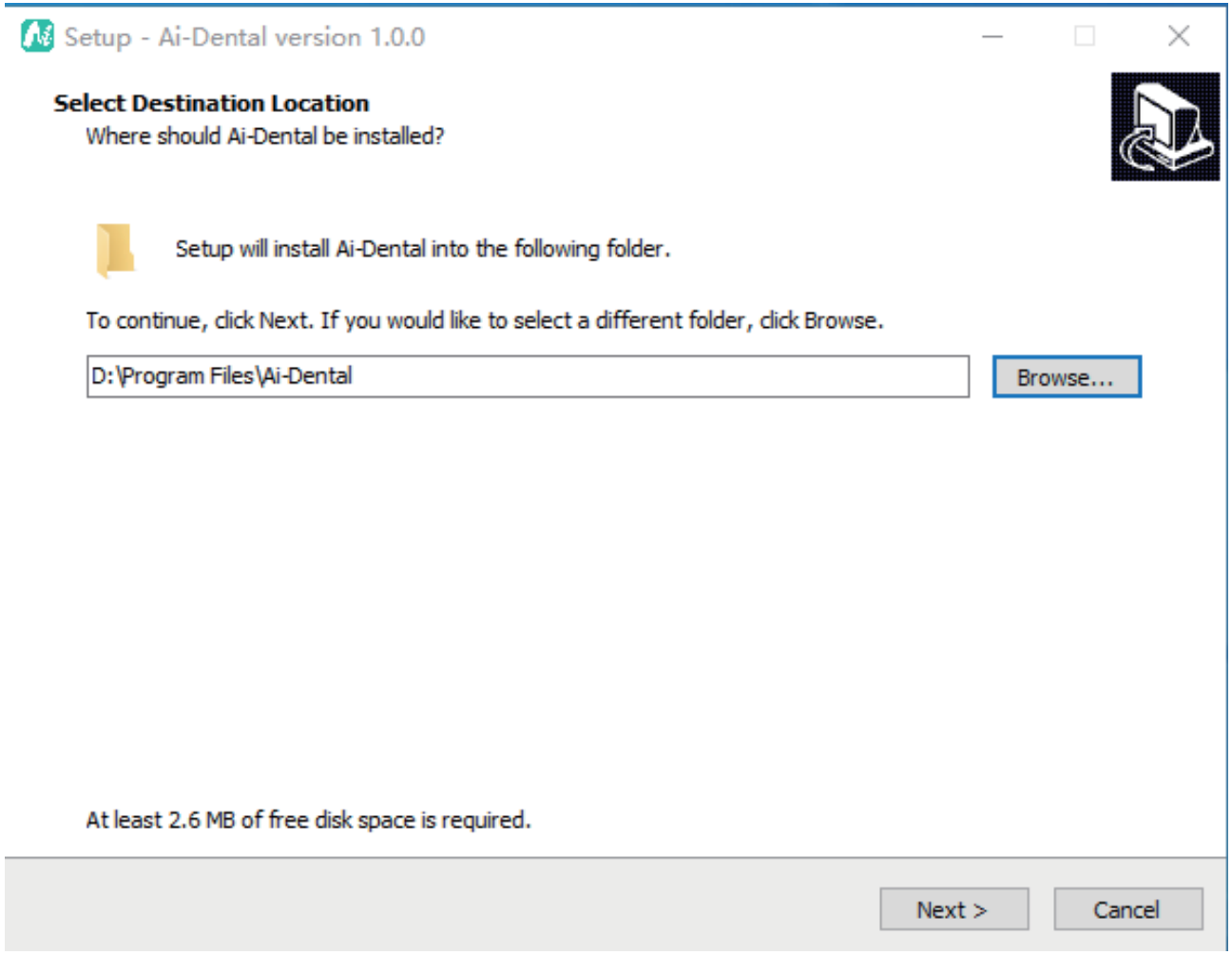


Figure 3

c) Select the component. The user selects the corresponding component as needed, and then click the "Next" button, as shown in Figure 4:

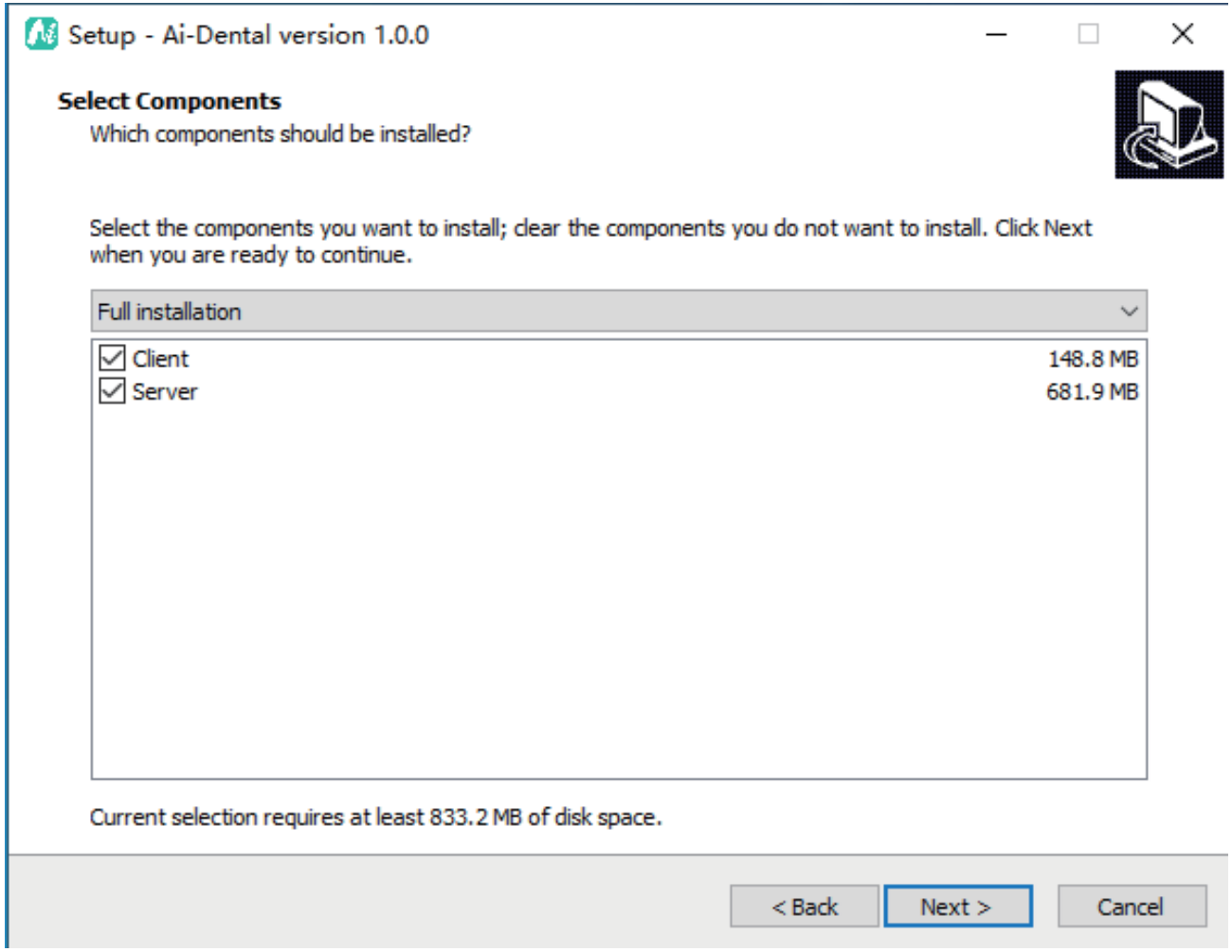


Figure 4

d) Choose whether to create a shortcut. The user selects the corresponding items as needed and clicks the "Next" button after completion, as shown in Figure 5:

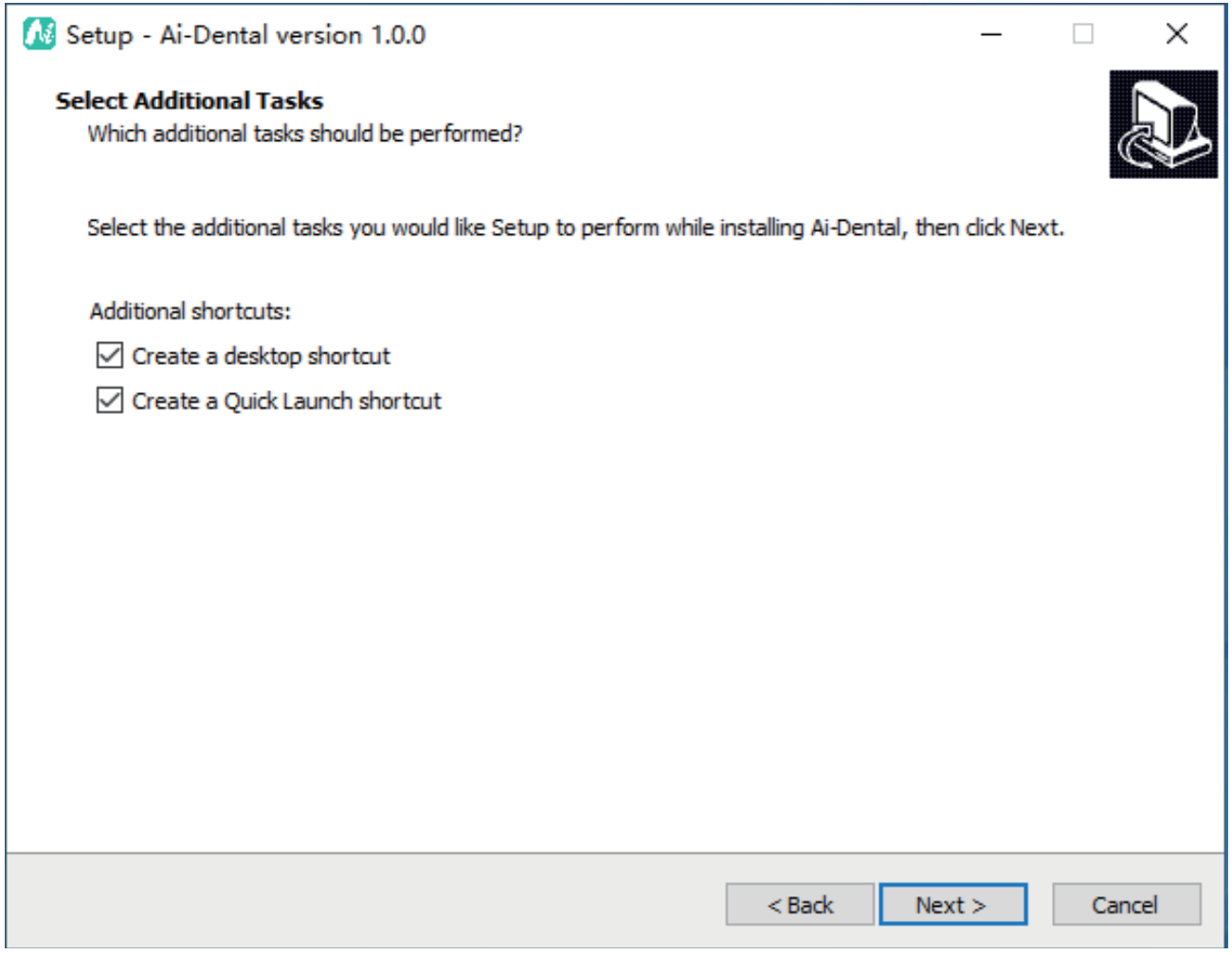


Figure 5

e) According to the user's choice, the installation program displays the component to be installed and the shortcut to be added. The user can click "Back" to modify or click "Next" to install, as shown in Figure 6:

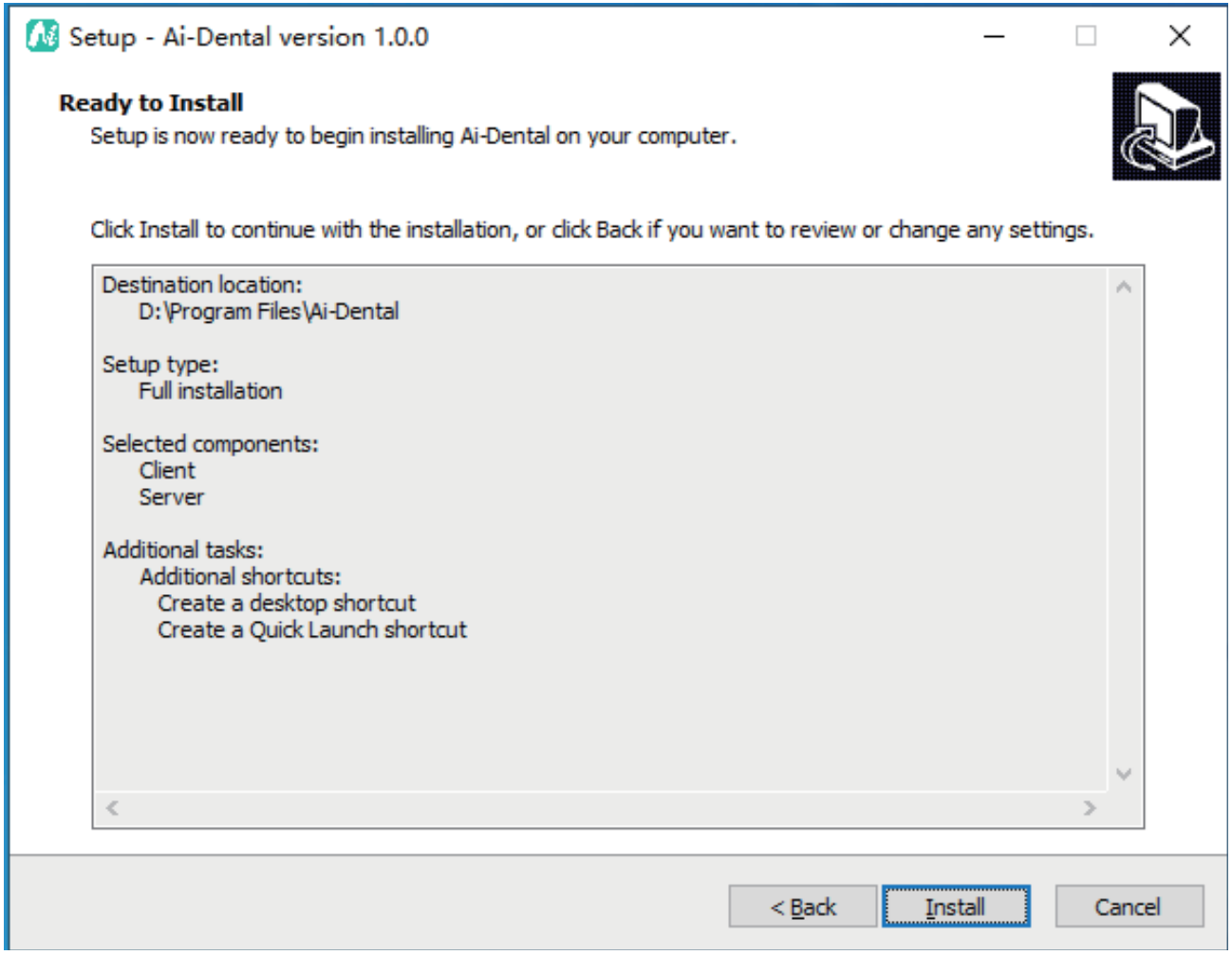


Figure 6

f) After clicking the "Install" button, the program starts to install. The user can wait for the installation to complete, as shown in Figure 7:

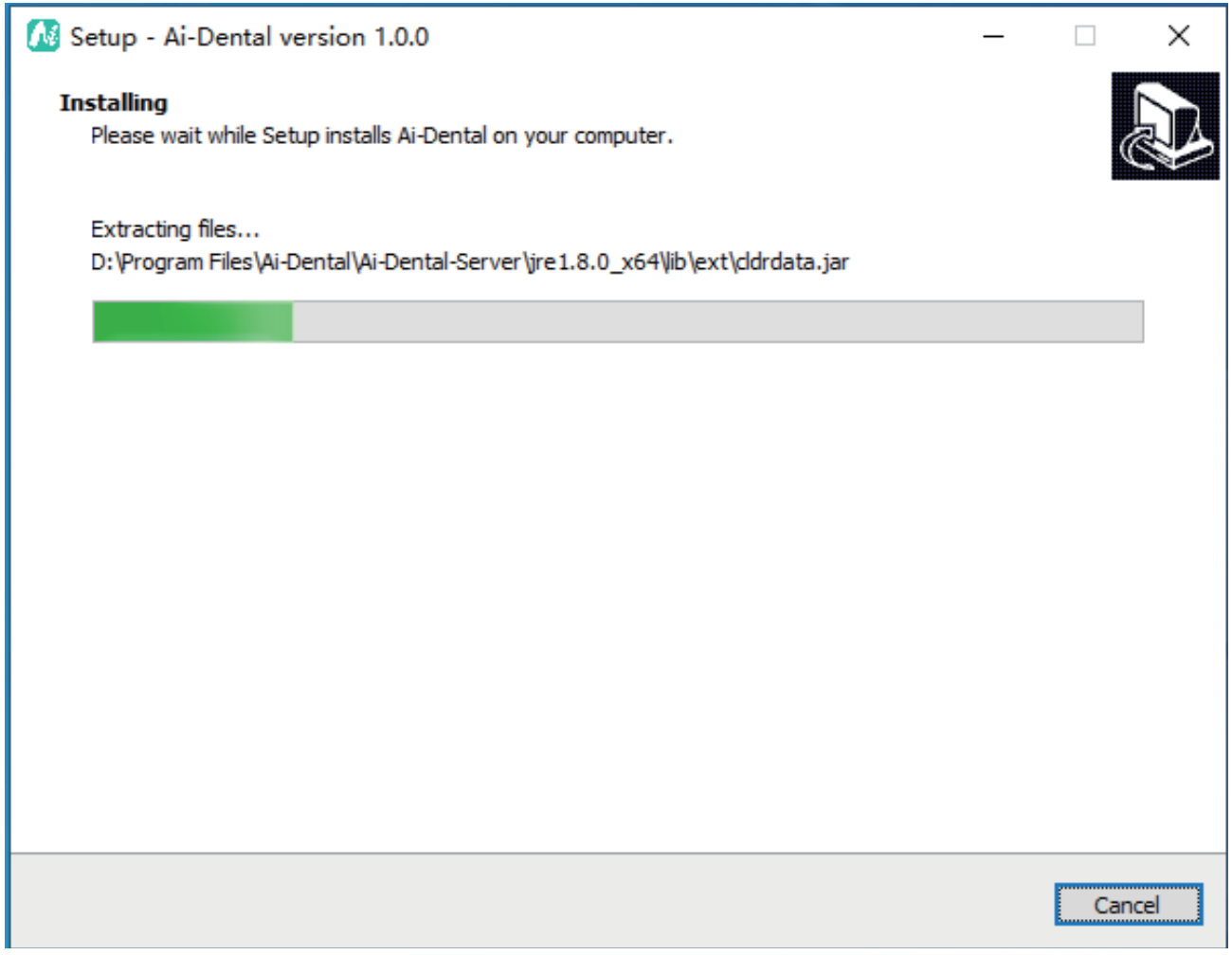


Figure 7

g) The Driver Installation Interface as shown in Figure 8 ,click “next step”, the Driver Installation is finished.

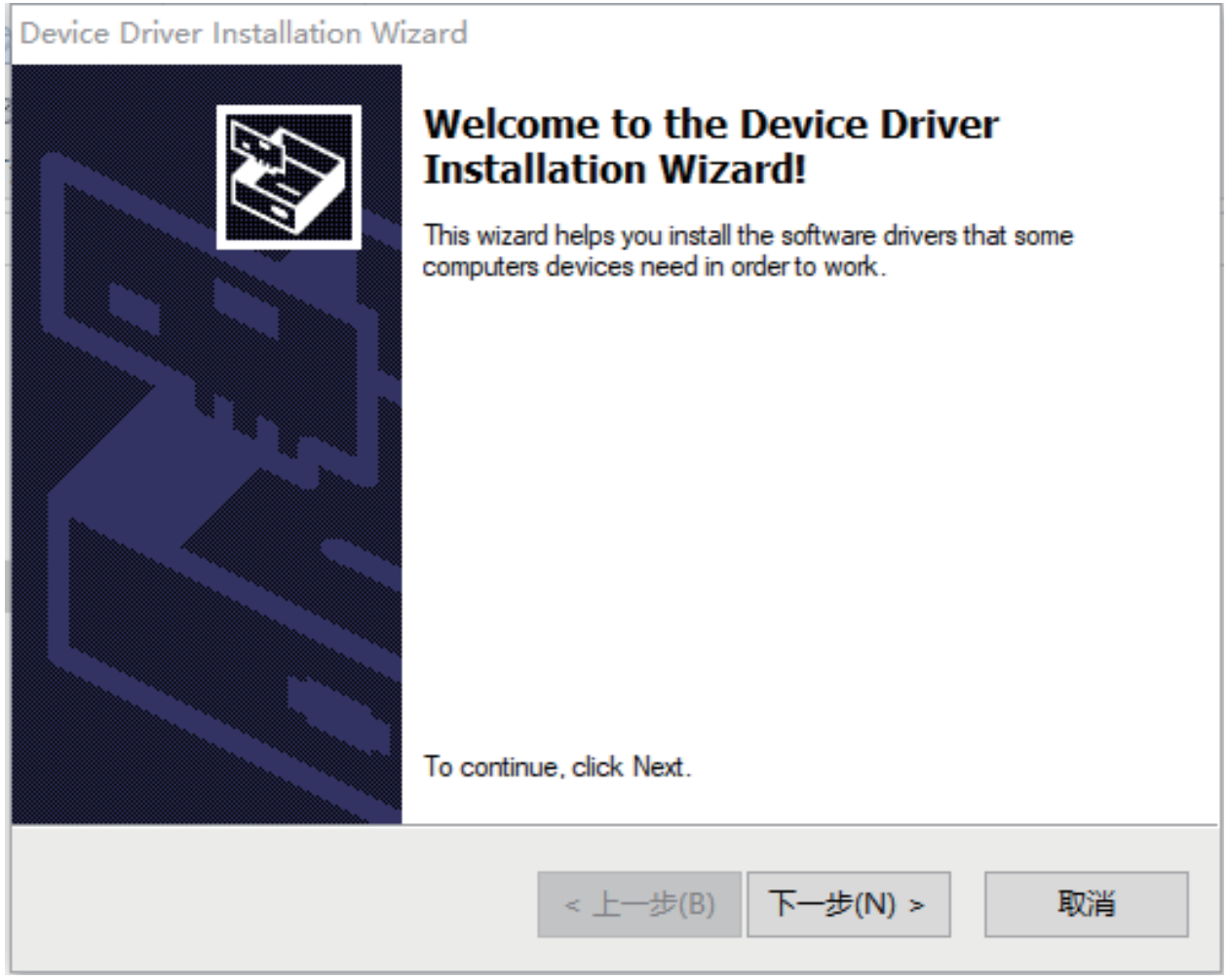

Device Driver Installation Wizard
Welcome to the Device Driver Installation Wizard!
This wizard helps you install the software drivers that some computers devices need in order to work.
To continue, click Next.
< 上一步(B)
下一步(N) >
取消

Figure 8

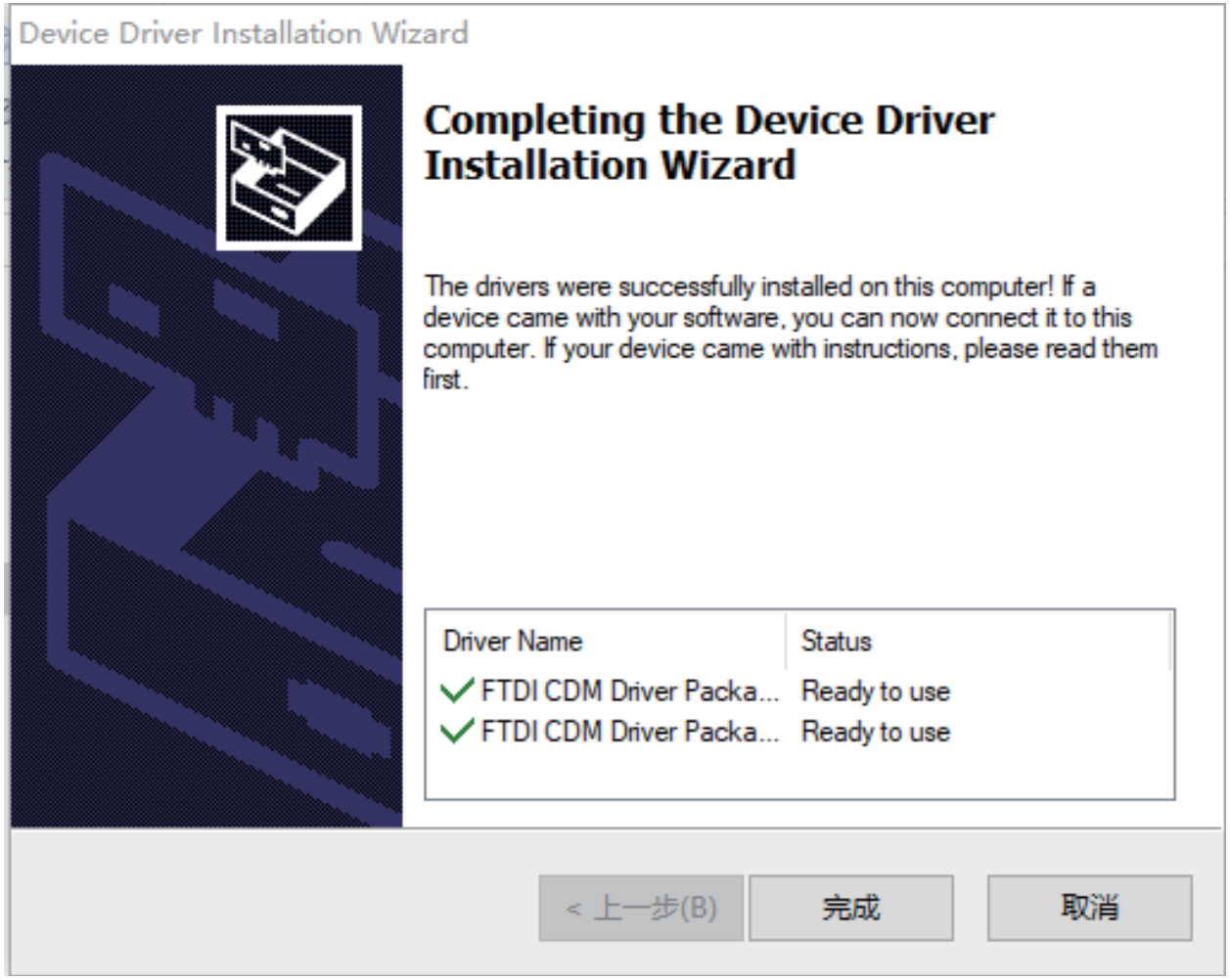


Figure 9

h) After the database is installed, the installation completion interface is displayed. Click "Finish" to exit the installation program, and the software is successfully installed.

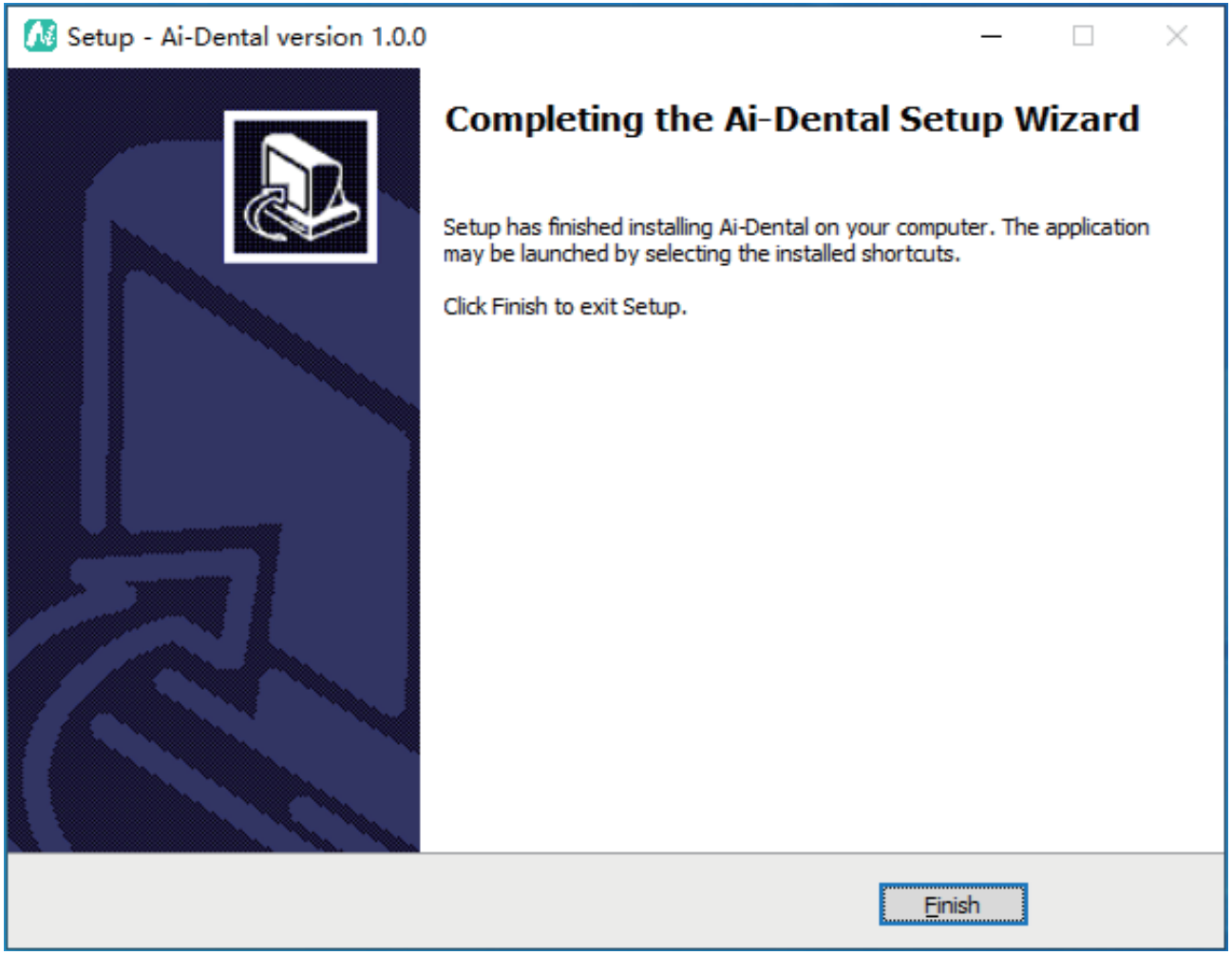


Figure 10

2.2.4 Installation of support frame

The sensor support frame is fixed on a flat wall by two screws. When the sensor is idle, secure it on the support frame, as shown in the following figure:

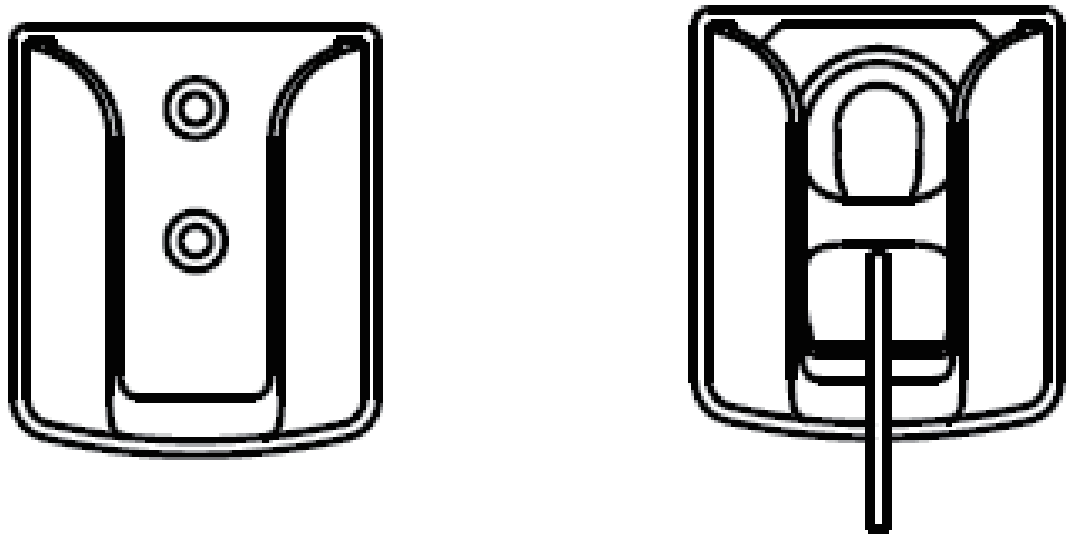


Figure 14

3 Operation instructions

3.1 Brief description of photographing steps

3.1.1 First, turn on the PC with the image software system installed and start the image processing software.

3.1.2 Start the matching X-ray generator and set photographing parameters.

3.1.3 Put the protective sheath on the sensor and place the sensor in the patient's mouth parallel to the long axis of the teeth, so that the effective surface of the sensor is close to the teeth.

3.1.4 Move the generator to the patient's head. Ensure that the generator cone is perpendicular to the position of the sensor. Press the generator switch.

3.1.5 After exposure, the imaging software downloads the X-ray image to the screen for display.

3.2 Use of sensor protective sheath

In order to ensure the maximum health and safety of the patient, the sensor must be used with a disposable sensor protective sheath. Pay attention to the following points during operation:

1. Wear gloves to place the sensor protective sheath.
2. Replace the sensor protective sheath every time finishing photographing.
3. Place the sensor protective sheath in a dry and clean place.
4. The used sensor protective sheath should be disposed of together with other organisms and potentially infectious waste.
5. It is better to use the sensor protective sheath specially designed for digital intraoral X-ray imaging system.
6. When the sensor protection device is damaged while the patient is Being examined or if the sensor is contaminated due to the removal of the protective sheath, the sensor and the front 40cm cable must be thoroughly disinfected.

4 Notes

4.1 Notes for sensor use

4.1.1 Be sure to place the sensor carefully.
4.1.2 Be sure to use a disinfectant wipe to clean the sensor.
4.1.3 Be sure to place the sensor on the holder.
4.1.4 Do not ask the patient to bite the sensor and connecting cable.
4.1.5 Do not put the sensor in water.
4.1.6 If a malfunction occurs, do not open the sensor.
4.1.7 Our company is a professional manufacturer of medical devices. The maintenance, repair and modification of the product must be carried out by our company or our authorized distributors. We are responsible for the safety of maintenance, repair and modification only when they are replaced by the original accessories of our company and operated according to the instruction manual.

5 Trouble shooting

Fault	Possible cause	Solution
The software interface shows the connection timeout	1. USB driver is not installed. 2. USB driver is incorrectly installed. 3. The USB port is not inserted correctly. 4. The USB cable is damaged.	1. Reinstall the USB driver 2. Reinstall the USB driver 3. Re-plug the USB port 4. Contact the local distributor

If the above methods can not eliminate the fault, please contact the distributor to return the device to the manufacturer for handling. Do not try to open the casing of this device and repair it yourself.

6 Cleaning, disinfection and sterilization

6.1 Cleaning and disinfection of x-ray sensor and USB cable

To further eliminate the latent danger of cross infection, in addition to using disposable protective sheath, the sensor and the front 40cm cable should be cleaned and disinfected before each patient is replaced for photographing. The recommended disinfectant for cleaning and decontamination is 70% is opropanol. It's recommended to use a cloth sprayed with aldehyde-free disinfectant to wipe and disinfect the surface.

6.2 Unavailable cleaning and disinfection methods

a) Do not use hard tools to clean for avoiding abrasion.

b) The following disinfectants are forbidden: trichloroethylene, dichloroethylene, ammonium hydrochloride, chlorinated hydrocarbons and aromatic hydrocarbons, dichloroethane, methylene chloride and methyl ketone.

c) Do not spray the disinfectant directly on the X-ray sensor.

7 Storage, maintenance and transportation

7.1 Storage

7.1.1 This device should be handled with care, away from the source of the earthquake, and should be installed or stored in a cool, dry and ventilated place.

7.1.2 Do not mix it with toxic, corrosive, flammable and explosive materials during storage.

7.1.3 The product should be stored in an environment with a relative humidity of 10%~93%, an atmospheric pressure of 70kPa~106kP, and a temperature of -20℃ ~ +55℃ .

7.2 Calibration

In some European countries-especially Germany-current laws require the quality of sensors to be checked through specially designed test cards (once a month). Even when used in other countries that do not require this type of calibration, it is recommended to perform this type of calibration regularly (once a month) to ensure that the product can still be used for diagnostic purposes. The calibration process is as follows:

Step 1: Connect the sensor and start the image management software.

Step 2: Place the test phantom in the field of view of the sensor.

Step 3: Set the matching X-ray generator parameters (60KV, 50mAs) and take exposure photographing.

Step 4: Confirm whether the resolution is not less than 8lp/mm.

7.3 Transportation

7.3.1 During transportation, excessive impact and vibration should be

prevented. Handle it with care and avoid inversion.

7.3.2 It should not be mixed with dangerous goods during transportation.

7.3.3 Avoid sunlight, rain or snow during transportation.

8 Environment protection

The product does not contain any harmful ingredients. It can be processed or destroyed in accordance with the relevant local regulations.

Part names	Toxic and harmful substances or elements					
	(Pb)	(Hg)	(Cd)	(Cr6+)	(PBB)	(PBDE)
X-ray sensor	○	○	○	○	○	○
USB cable	○	○	○	○	○	○

○: Indicates that the content of the toxic substance in all homogeneous materials of the component is below the limit requirement in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.
×: Indicates that the content of the toxic substance in at least a certain homogeneous material of the part exceeds the limit requirement of SJ/T-11363-2006.
(This product complies with EU RoHS environmental protection requirements. At present, there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys.)
According to the Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, the Regulations on the Management of Recycling and Disposal of Waste Electrical and Electronic Products and related standards, please observe the safety and use precautions of the products and recycle or discard the products in accordance with local laws and regulations after use.

9 After-sales service

Since the date of sale, if the device fails to work normally due to quality problems, our company will be responsible for the maintenance with the warranty

card. Please refer to the warranty card for the warranty period and scope. This product does not contain self-maintained parts, and the maintenance of this device should be carried out by designated professionals or special repair shops.

10 Electromagnetic compatibility

For this device, special precautions regarding electromagnetic compatibility (EMC) must be taken. The installation and use must be in accordance with the electromagnetic compatibility information specified in this manual. Portable and mobile radio frequency communication equipment may affect this device.

The following cables must be used to meet electromagnetic emission and anti-interference requirements:

Name	Cable length	Whether to block	Remark
USB cable	2.7m	No	EUT

The equipment or system should not be used close to or stacked with other equipment. If must be used in this way, it should be observed to verify that it can operate normally under the configuration used.

10.1 Guidance and manufacturer's declaration-electromagnetic emission

Guidance and manufacturer's declaration-electromagnetic emission

Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emission GB 4824	Group 1	Digital intraoral X-ray imaging system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emission GB 4824	Class 1	Digital intraoral X-ray imaging system is suitable for used 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 emission GB17625.1	Not conformable	Power is less than 75W

Voltage fluctuation/ Flicker emission GB17625.2	Conformable	

10.2 Guidance and manufacturer's declaration-electromagnetic immunity

Guidance and manufacturer's declaration-electromagnetic immunity			
Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge GB/T17626.	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	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 GB/T 17626.4	±2kV for power supply lines ±1kV for handpiece lines	±2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	±1kV line to line ±2kV line to earth	±1kV line to line Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

GB/T 17626.11 Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	<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 5s	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 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of digital intraoral X-ray imaging system requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an un interruptible power supply or a battery.

Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m (50Hz)	The power frequency magnetic field should have the level characteristics of that in a typical commercial or hospital environment.
[NOTE: UT is the AC mains voltage prior to application of the test level.]			

10.3 Guidance and manufacturer's declaration-electromagnetic immunity

Guidance and manufacturer's declaration-electromagnetic immunity			
Digital intraoral X-ray imaging system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment - guidance

Conducted RF GB/ T17626.6 Radiated RF GB/T17626.	3Vrms 150kHz~ 80MHz 3V/m 80MHz~ 2.5GHz	3Vrms 3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the digital intraoral X-ray imaging system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz to 2.5 GHz Here the “P” is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W). “d” is the recommended separation distance, in meters (m). The field strength of the fixed RF transmitter “b” is determined by surveying the electromagnetic field “a”, and “b” should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols. 

NOTE1: At 80 MHz end 800 MHz, the formula of higher frequency range is applied. NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission of buildings, objects and human bodies.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the digital intraoral X-ray imaging system is used exceeds the applicable RF compliance level above, the imaging system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the digital intraoral X-ray imaging system. b. In the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

10.4 Recommended separation distances between portable and mobile RF communication equipment and the digital intraoral X-ray imaging system

Recommended separation distances between portable and mobile RF communication equipment and the digital intraoral X-ray imaging system			
The digital intraoral X-ray imaging system is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the imaging system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the digital intraoral X-ray imaging system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter /W	Separation distance according to frequency of transmitter/m		
	150kHz~80MHz	80MHz~800MHz	800MHz~2.5GHz
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 the rated maximum output power of transmitters not listed in the above table, the recommended separation distance “d”, in meters (m), can be determined by the formula in the corresponding transmitter frequency column. Here “P” is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W).
NOTE1: At 80 MHz end 800 MHz, the formula of higher frequency range is applied.
NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission of buildings, objects and human bodies.

Notes:

Without the explicit consent of Guilin Woodpecker Medical Equipment Co., Ltd., unauthorized changes or modifications to the equipment may cause electromagnetic compatibility problems of this equipment or other equipment.

11 Symbol instruction


Manufacturer


Type BF applied part

SN
Serial number


Follow instructions for use

Date of manufacture

Handle with care

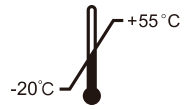
Recovery

Humidity limitation

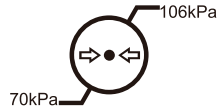
Class II equipment

Non-reusable

Keep dry



Temperature limitation



Atmospheric pressure for storage

Products comply with WEEE directive

12 Statement

All rights of modifying the equipment design, product technology or accessories, manual and packaging content at any time are reserved to the manufacturer without further notice.

(Please refer to the product packaging label for the production date, the service life: 5 years).

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