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

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 Degree of protection against electric shock: BF type applied part

1.7.3 Degree of protection against harmful ingress of water: IP68

1.7.4 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: 10℃～35℃

1.9.2 Relative humidity: 20% ～ 90%

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:

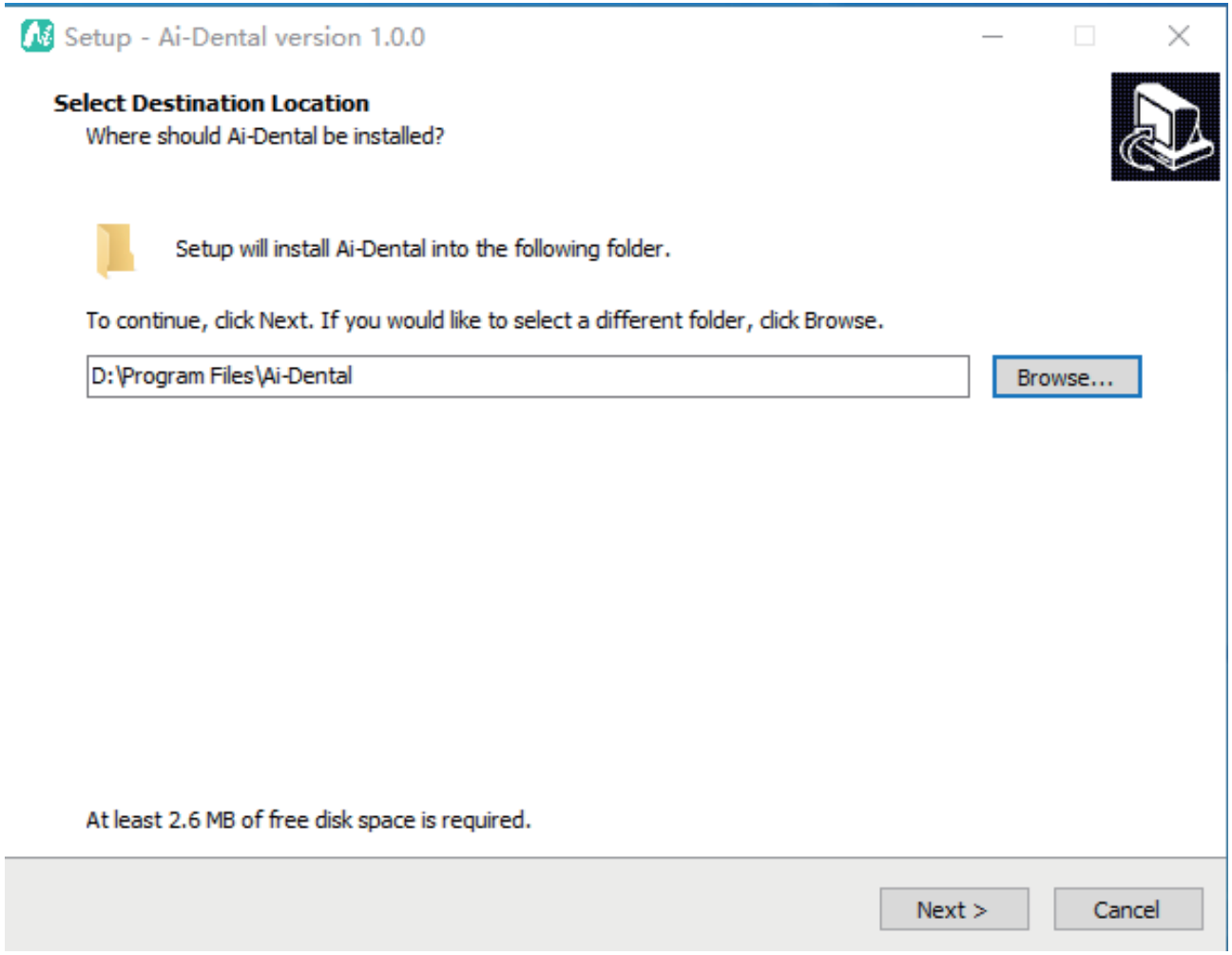


Figure 3

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

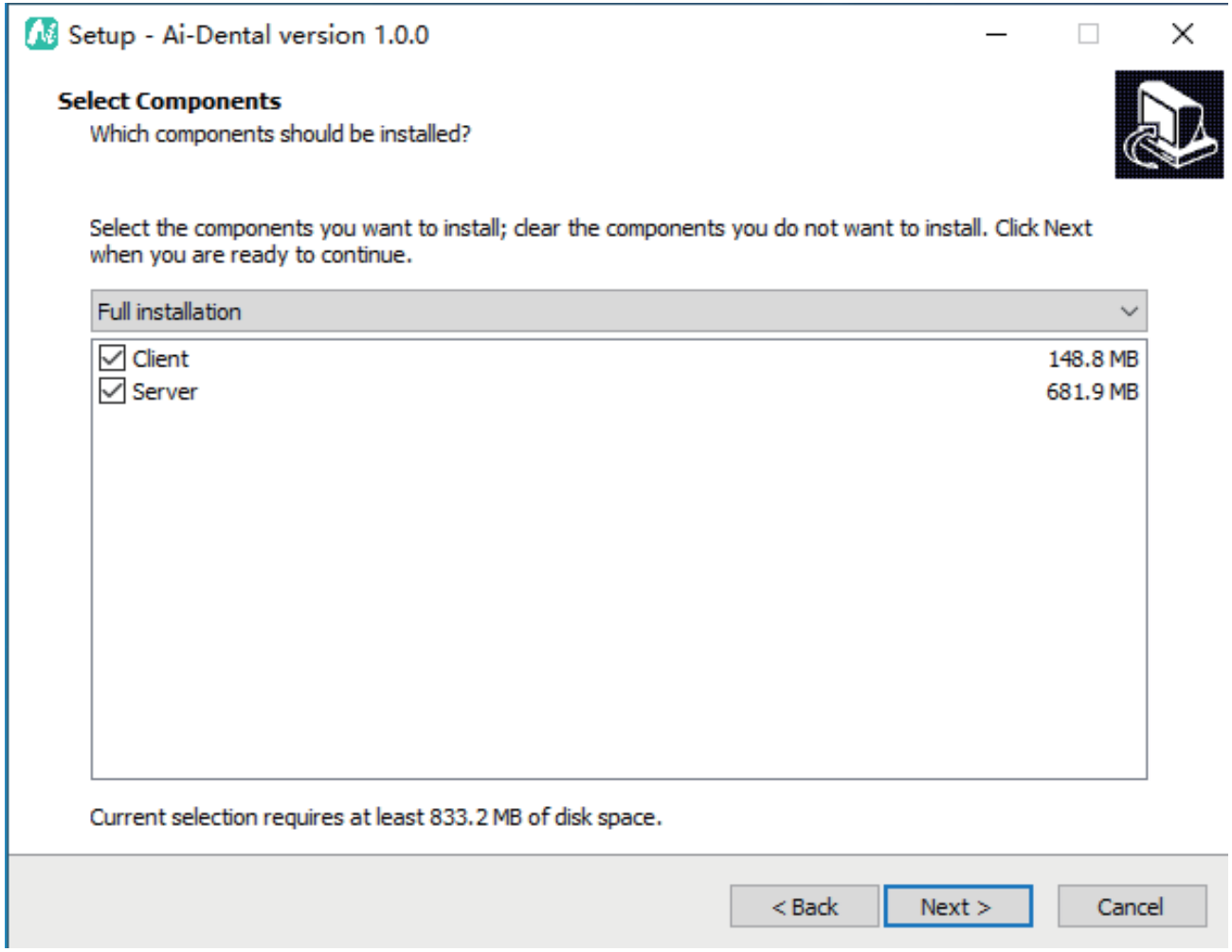


Figure 4

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:

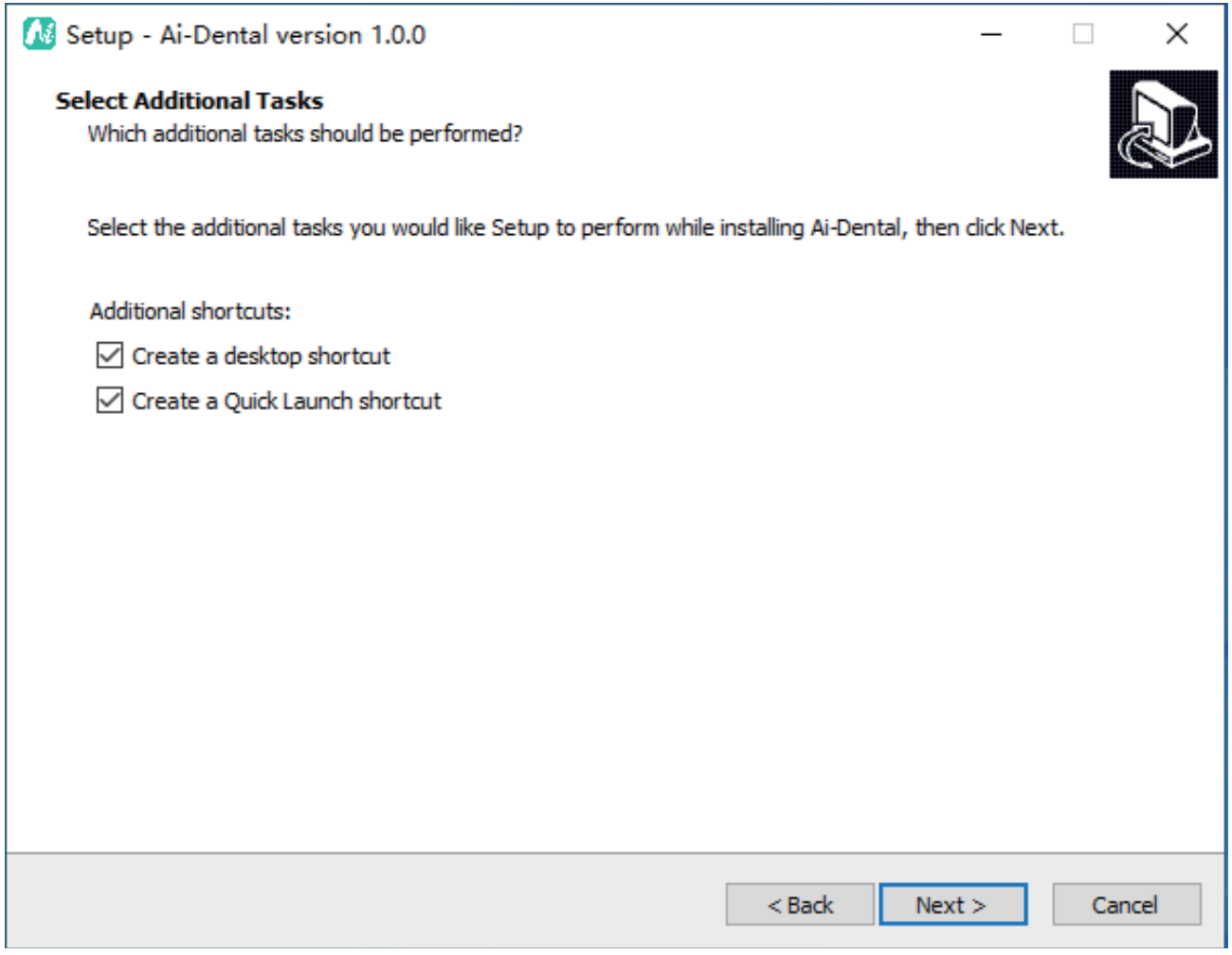


Figure 5

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:

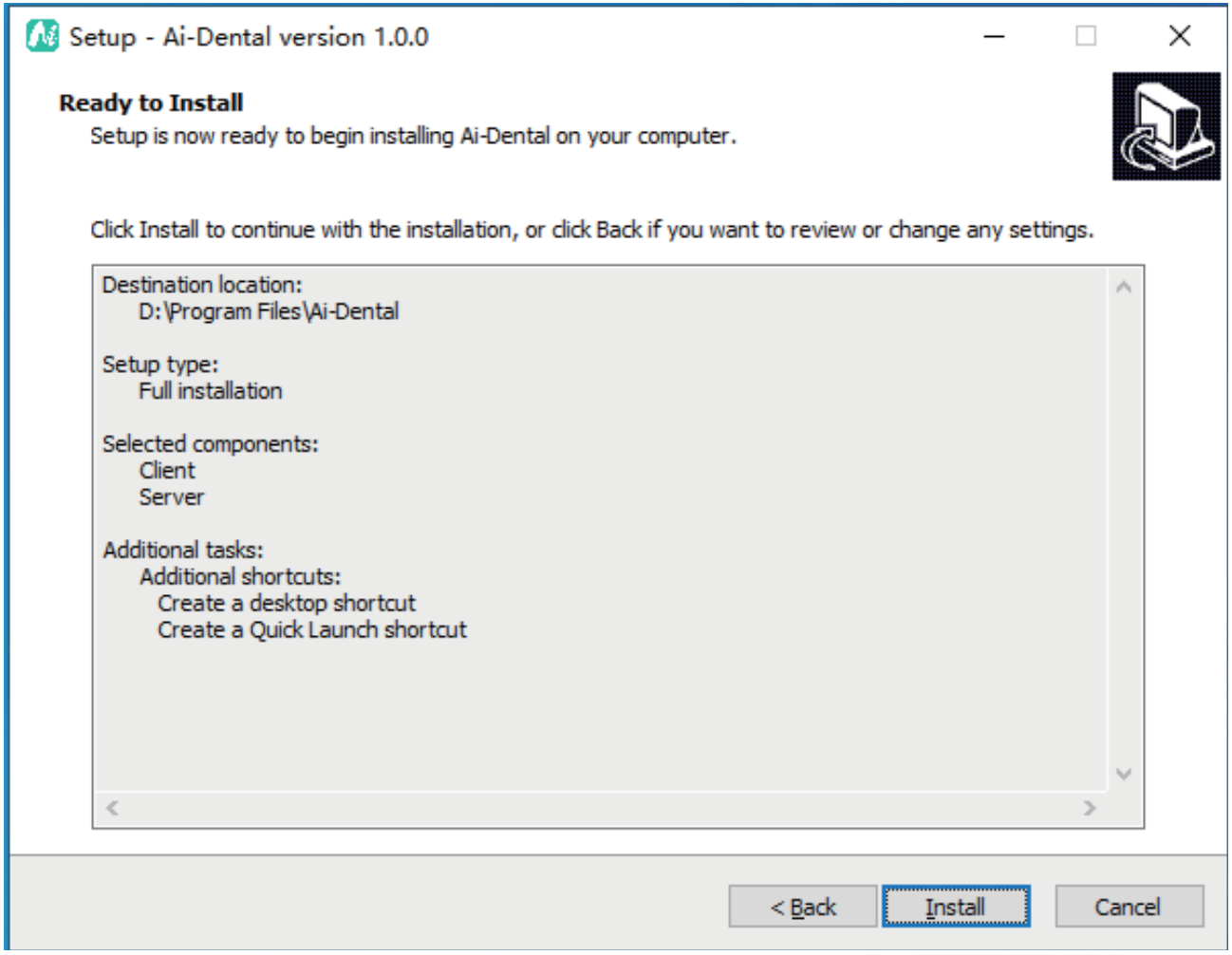


Figure 6

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:

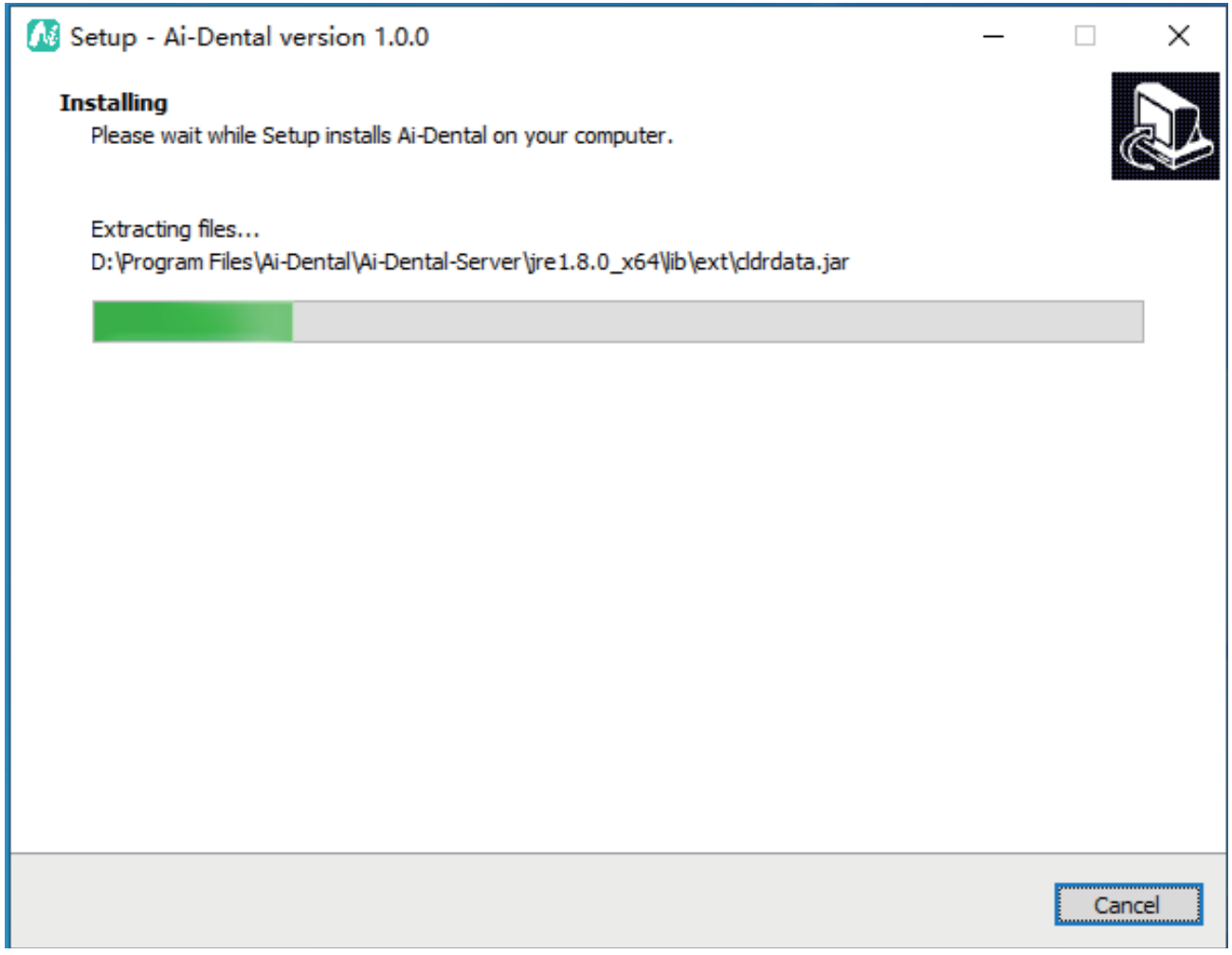


Figure 7

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

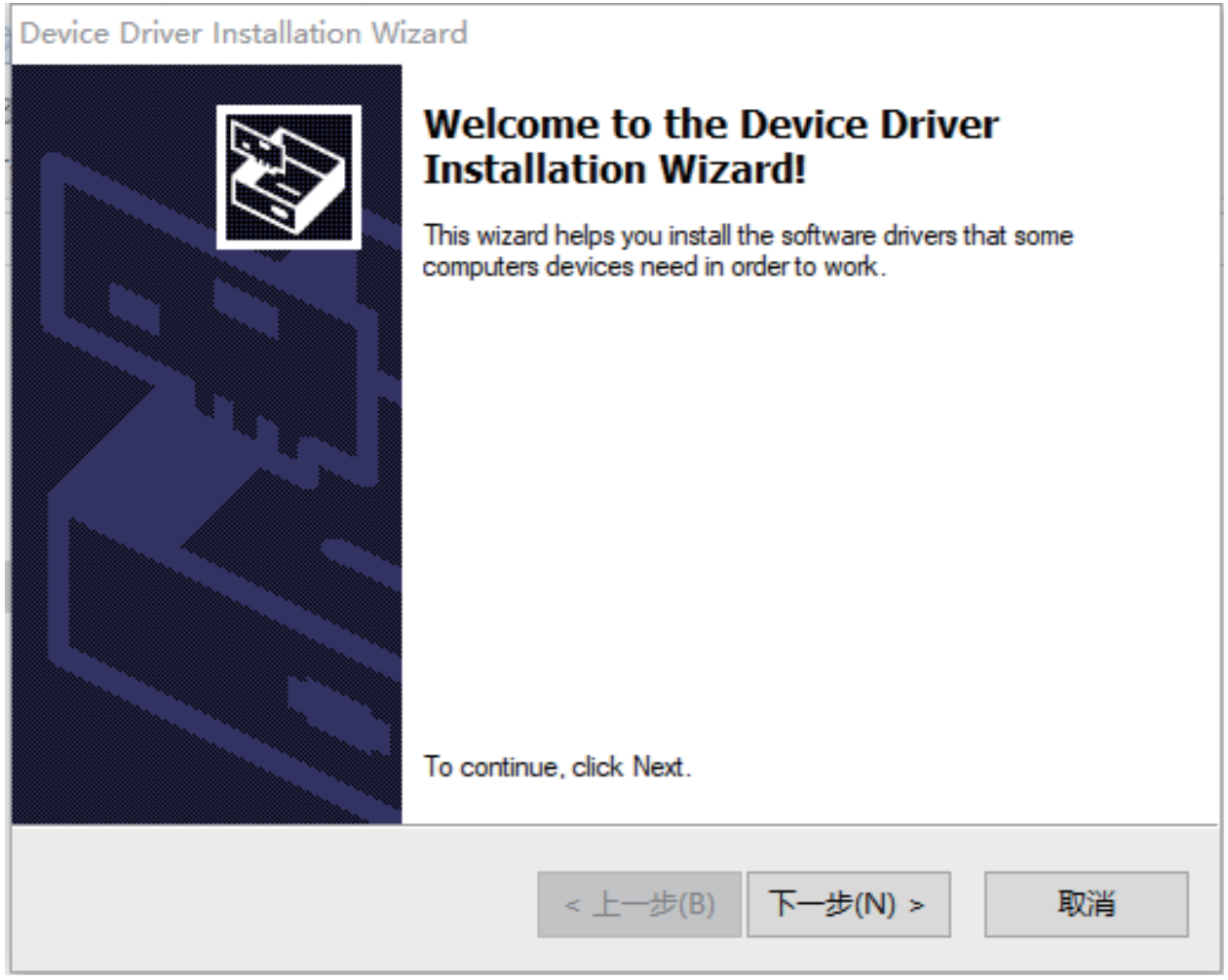

Device Driver Installation Wizard
Welcome to the Device Driver Installation Wizard!
This wizard helps you install the software drivers that some computers devices need in order to work.
To continue, click Next.
< 上一步(B)
下一步(N) >
取消

Figure 8

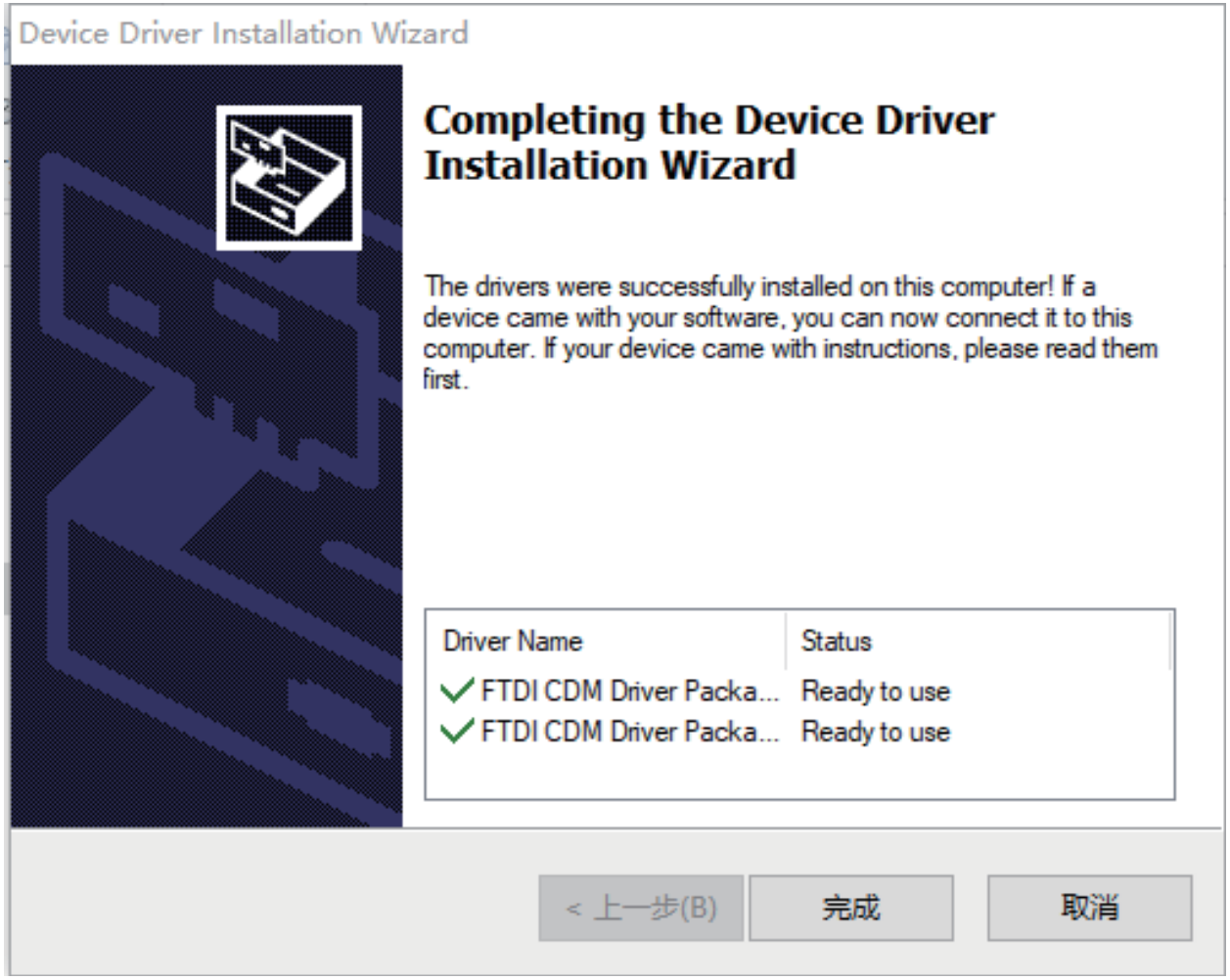


Figure 9

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.

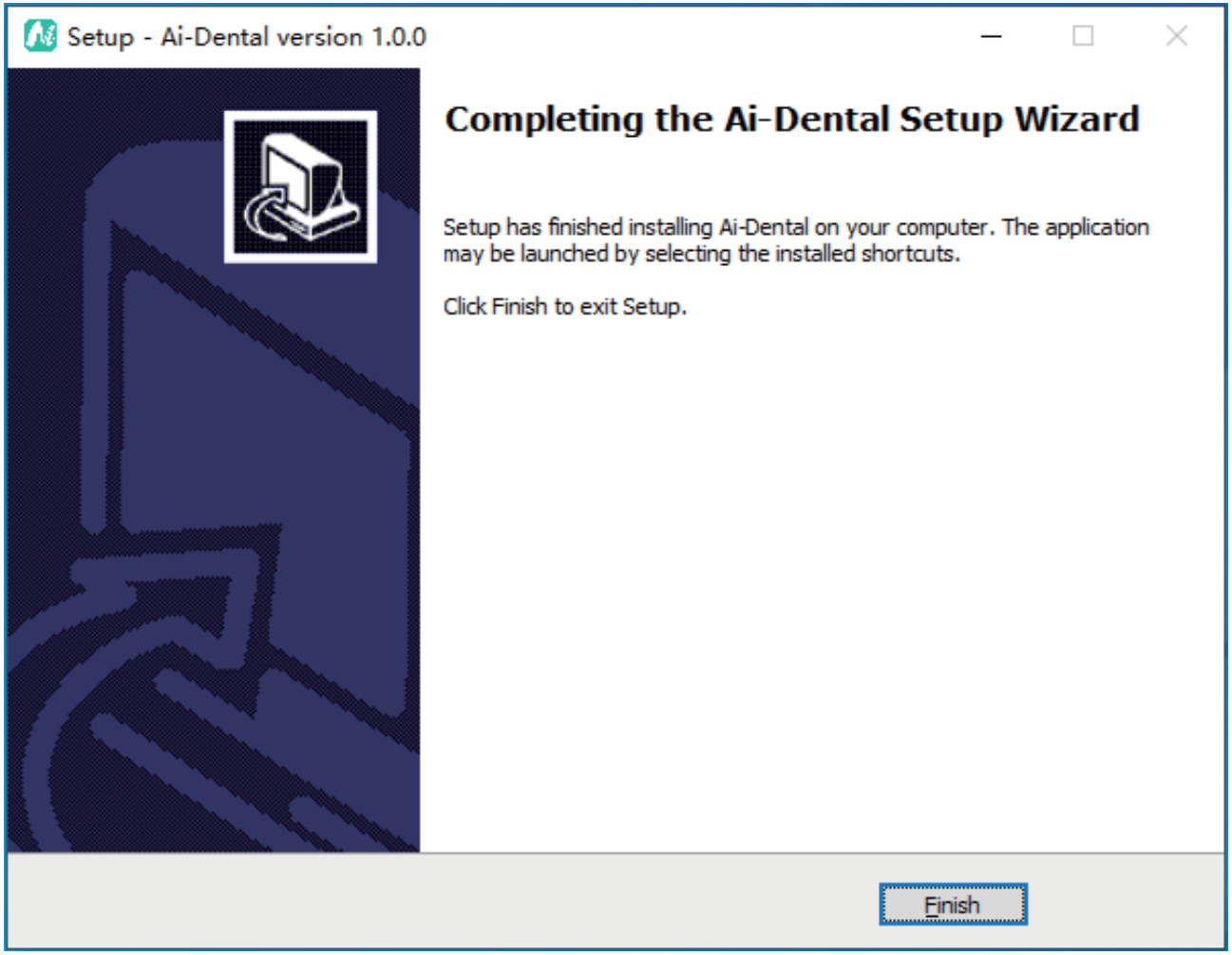


Figure 10

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:

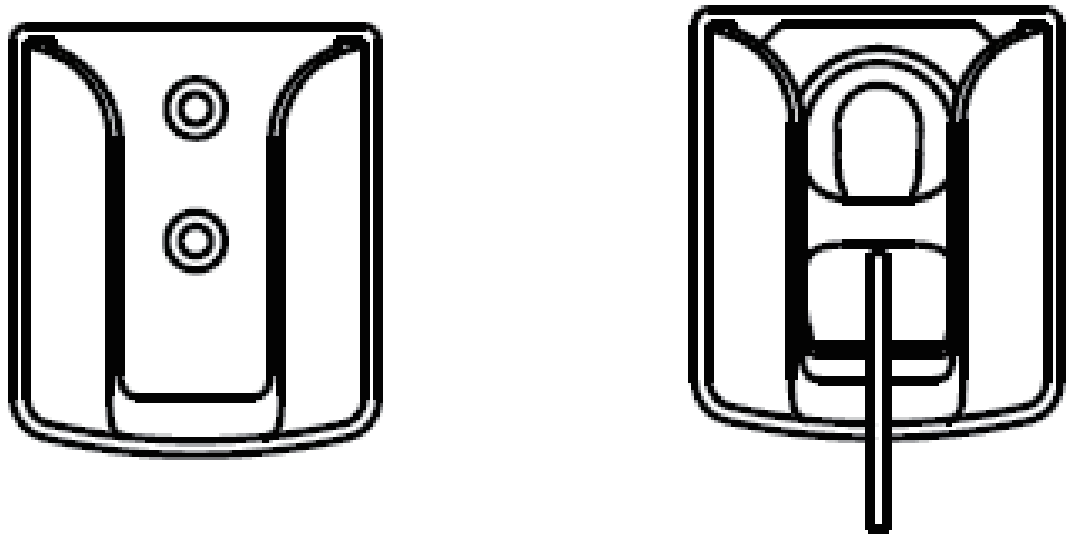


Figure 14

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.

4.1.8 Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g.less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements which approximately correspond to that of an average 12 year old.The following ranges of pediatric subpopulations are to be used as a guide for manufacturers in developing medical devices:

Pediatric Subgroup	Approximate Age Range
Newborn (Neonate)	From birth to 1 month of age

Infant	Greater than 1 month to 2 years of age
Child	Greater than 2 to 12 years of age
Adolescent	Greater than 12 through 21 years of age

Exposure to ionizing radiation is of particular concern in pediatric patients because:

1) for certain organs and tumor types, younger patients are more radiosensitive than adults (the cancer risk per unit dose of ionizing radiation is higher for younger patients);

2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients;

3) younger patients have a longer expected lifetime putting them at higher risk of cancer from the effects of radiation exposure.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

Additional guidance and recommendation are provided by the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Alliance) https://www.imagegently.org/

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%~95%, an atmospheric pressure of 70kPa~106kP, and a temperature of -10℃ ~ +55℃ .

7.2 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

10.1 EMI Compliance Table

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, ClassB	Professional healthcare facility environment

10.2 EMS Compliance Table

10.2.1 Enclosure USB Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air

Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Near fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Near fields from RF wireless communications equipment”
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

10.2.2 Near fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz 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		

Recommended separation distances between portable or mobile RF communication device and detector:

Portable RF communications equipment, including antennas, can effect medical electrical equipment. The warning should include a use distance such as

“be used no closer than 30 cm (12 inches) to any part of the i-Sensor H1 / i-Sensor H2, including cables by the manufacturer”.

10.2.3 Cable provided for EMC

Cable	Recommended length	Shield/ Unshielded	Number	Cable classification
Cable	2.8m	shielded	1 piece	DC power and SIP/SOP

10.2.4 Electromagnetic Compatibility (EMC)

The i-Sensor H1 / i-Sensor H2 digital intraoral X-ray imaging system need special precautions regarding EMC, and should be installed by authorized personnel and follow EMC guidance in the user manual. The product when in use may interfere with portable and mobile RF communication devices such as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and a potentially dangerous situation.

The i-Sensor H1 / i-Sensor H2 digital intraoral X-ray imaging system should not be stacked with or adjacent to other devices. If inevitable, verify the product.

The i-Sensor H1 / i-Sensor H2 digital intraoral X-ray imaging systemconforms to the IEC60601-1-2:2014 and EN60601-1-2:2015 standard on both immunity and emissions.

Accessories, transmitters and cables other than those by the user manual

or sold together with product may result in increased emissions or decreased immunity of the product.

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


Date of manufacture


Handle with care


Recovery

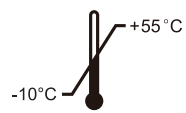
Humidity limitation

Serial number


Follow instructions for use


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.