X-Raying®

Dental Imaging System

Version: 1.0 Date: June 26th, 2023

User Note

Please check the model and serial number of the product. If there is an error, please contact your local dealer or manufacturer. If there is a failure during use, please inform your local dealer or the manufacturer of the model and series number.

Product Name

Model

Serial No.

Production Date

*Before operating this product, please carefully read all the safety and operating instructions in this manual. This manual will help you fully enjoy the various functions of
*Dental imaging System.

*During use, please strictly follow the operating regulations, maintain and protect it correctly.

*Please keep the manual properly for future reference.

*If there is a problem during the operation of this product, please contact your local dealer or the manufacturer for further quality service and help.

*Service Life: 4 years

*Contraindications: Considering this product needs to be used with X-Ray unit, pregnant women should be with caution; patients with epilepsy or mental illness should use it with caution.

Dental Imaging System

Contents

Production Description

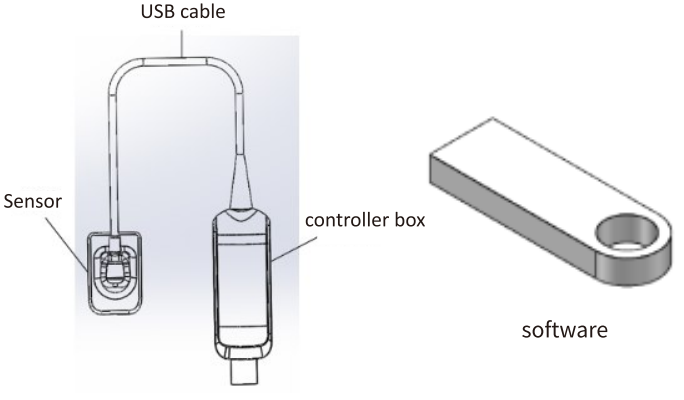
Dental imaging System sensor consists of sensors, controller box, USB cables, and software.

The product is connected to the controller box through a highly flexible cable. The controller box provides timing, image acquisition and transmission, and is connected to a PC or laptop through a USB interface. The power of the controller box and the sensor is provided by the USB interface, no battery or charging system is required. Need to be used in conjunction with supporting software.

⚠Remarks: The computer and peripheral equipment (such as monitor/printer etc.) connected to sensor, need to be arranged by the customer. Customers can follow the"Computer Requirement"mentioned in the 6th part while purchasing.

Overview

Schematic diagram of appearance and function



1.2 Physical image

DR530

DR550

1.3 Introduction

The signal receiving surface of Confident Eco Plus is the front (as shown in the figure below).

背面　　正面

2. Expected Usage

Dental imaging System is used for dental X-Ray digital imaging.

Safety Instruction

◆ Check and confirm the sensor and controller box

Please check the sensor and controller box before using,to see if there is any scratches on the surface. The surface of the sensor and controller box should be smooth,without cracks or damages.If there is any damages,please contact with our company.

◆ Prevent the potential electrostatic discharge damage

Similar to other electronic equipment, the sensor is easily to be affected by electrostatic discharge, especially when it is used in a mat or in the low humidity environment. When the wire is moved, if the sensor wire is bare, please ensure to pay attention to prevent the damages caused by electrostatic discharge. Touch the metal surface before moving the wire can reduce the risk of sensor damages caused by electrostatic discharge. Using anti-static mat or floor anti-static treatment can eliminate static electricity generated in the room.

◆ Please don't touch the bare connector of non-medical equipment and the patients simultaneously.

When the sensor and controller box is under using,please ensure to avoid touching the bare connector of non-medical equipment(such as computer etc.) and the patients simultaneously. Human body is a good conductor of electricity, it may cause a risk of electric shock to the patients, if the proper safety regulations are not been complied with.

◆ Ensure the correct installation and running of the system and computer servers.

The sensor and controller box comply with international safety standards and is considered to be suitable to be used in the patient area(the area within 1.5 meters from the patient).In order to keep consistency with the standards,please don't operate the non-medical equipment (such as computer servers) in the patient area.

Within the patient area, you must use the approved medical grade equipment and the computer equipment certified to meet the requirements of IEC 60601-1, IEC60601-1-2 standards. Out of the patient area, you must use the approved non-medical grade equipment and the computer equipment certified to meet the requirements of IEC60950 standards. The configuration of the medical electrical system should meet the medical system requirements of IEC60601-1-2; the personnel who is responsible for connecting the system and the computer servers should ensure the conformity of the entire system connection.

In order to ensure the best performance, please ensure all the software programs on the computer are non-virus; And it has been fully tested that the installation of the software programs will not affect the application of imaging.

◆ The safety characteristics of product

Safety type: BF
Power(through USB): DC5.0 V (≥4.25 V) 200mA Maximum
Power: 400mA
Water proof degree: IPX7(the sensor head part) IPX0(the controller box)
Non-AP type equipment Non-APG type equipment
Running mode: continuous running

◆ Electronics waste

After the product becomes void, please do the proper recycle by contacting with relevant local authorities or manufacturer, instead of random throw away.

▶ Symbol Introduction

Symbols	Introduction
	Attention!Please check the documents which with device
	BF type application part
SN	Manufacturer serial number
	Fragile.The product inside is fragile, please handle carefully.
	Up.Indicating the correct vertical position of the package.
	Anti-moisture.The package must avoid moisture.
	Anti-flip.
	Max and minimum temperature limits.

▶ Environment Requirement

◆ Using Environment

Environment Temperature: 10℃～40℃
Environment Relative Humidity: 30%～75%
Atmosphere Pressure:700hPa～1060hPa

◆ Transportation & Stock Environment

Environment Temperature: -20℃～+55℃
Environment Relative Humidity: 10%～93%
Atmosphere Pressure:860hPa～1060hPa

▶ Technical Specification

Model	DR530	DR550
Sensor	APS CMOS	APS CMOS
External Dimension(mm)	25.4 × 36.8 × 4.5	30.4 × 41.9 × 4.5
Sensor Active Area (mm)	20×30	26×36
Pixel	1000 × 1500	1300 × 1800
Grey Value	16Bit/0~65536	16Bit/0~65536
Power	5.0 V	5.0 V
Interface	USB2.0	USB2.0

Computer Requirement

Minimum computer configuration requirement

Items	Minimum Configuration
PC Processor	Intel 1.5GHz Or Above
RAM	4G above
Hard Disk	1GBfor software installation40GB available for software operation
Graphics Card	Based on graphics card of Nvidia/Ati,and RAM of 256MB
Display	Resolution 1024 x 768 and 32 bits color mode
USB Ports	At least 2 available USB2.0 ports(If used desktop computer, 2 available USB ports must be have at the back of compute)
Operating System	Windows 7/10(32 bits/64 bits)
Backup Media	Movable disk(Using mobile disk to avoid loss of patient data, some case like PC disk is corrupt/full, PC is attacked by virus, etc.)

⚠ Note:Computer and peripheral equipment(such as display,printer,etc.)must meet the requirement of IEC60950 standards.
Computer and peripheral equipment(such as display,printer,etc.)are all prepared by customers.
The above table is what our suggests about the computer minimum configuration requirements, if your computer performance can't reach the above required, it may affect the performance of this product.
Customers are strictly prohibited from using computers that do not comply with GB4943, such as assembly machines, which may pose safety hazards.

Precaution

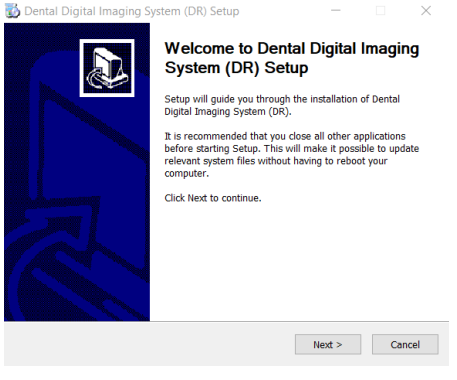
- As a precision devices,please avoid dropping, pulling and long-time soaking disinfection
- Must be covered with a single-use medical plastic film cover before use, to avoid cross-infection and allergies
- Please do not bite, so as not to bite the single-use plastic film and sensor
- Caution for epilepsy or psychiatric patients
- Please read the use manual and precautions carefully before use
- The user must be a professional dental or technician
- All parts of the system are suitable for use in the patient environment

Installation Instruction

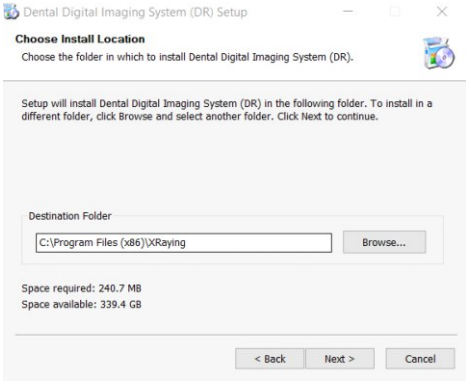
◆ Step1:Software Installation

Open the Driver folder on USB flash disk with sensor , and double click the driver installation file"X-Raying_Setup.exe"(The name of software will change with the update version, please refer the actual name), display the following information:

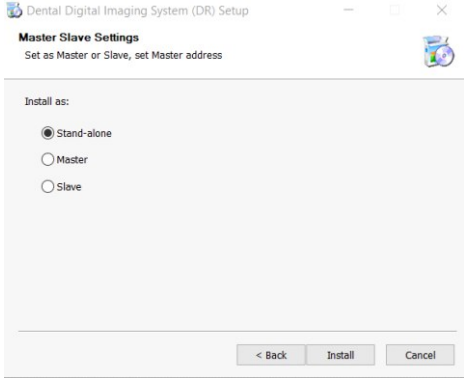
Click 'Next' to continue installing the software



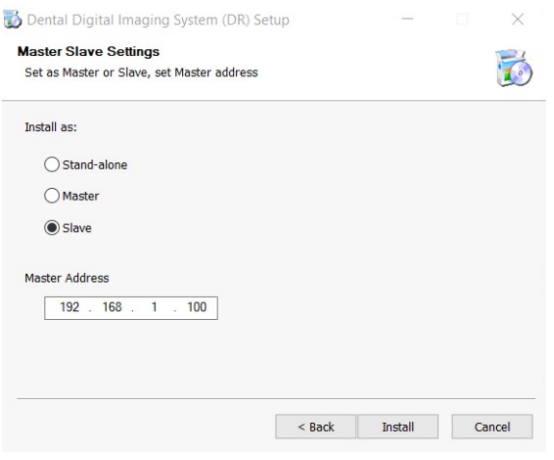
Step 2: Select the installation directory, you can click "Browse" to change the installation directory or directly click "Next" to continue the installation.



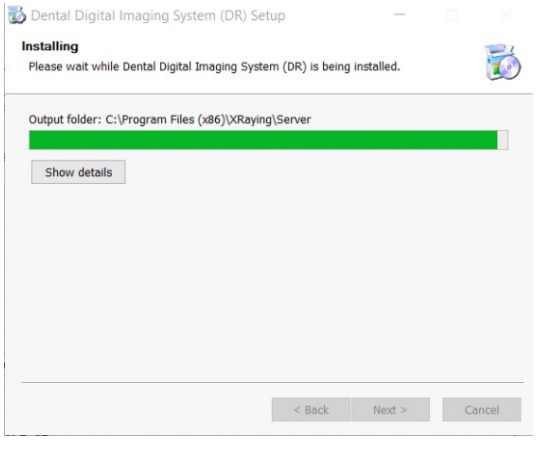
Step 3: Select the installation type
If there is only one computer or clinic, you can select "Stand-alone".
If you need to interconnect multiple computers or clinics, select "Master" for the computer connected to the sensor and other clinics select "Slave".
Select "Stand-alone" or "Master" and click "Install" directly.



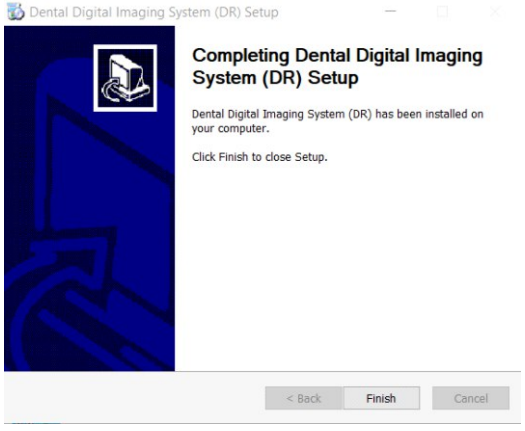
When choosing the "Slave" , you need to enter the IP address of the host computer, such as: 192.169.1.100,G, and then click "Install" .



Step 4: Waiting for the Install to complete



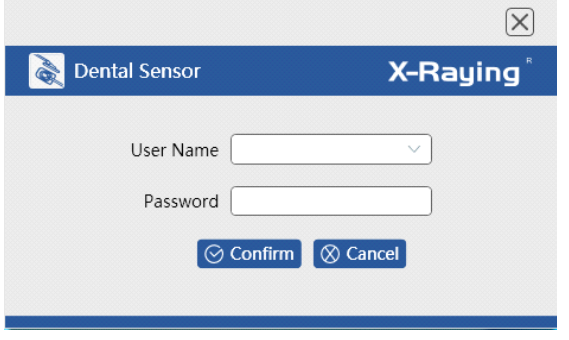
Step 5: The installation is finished, click "Finish"



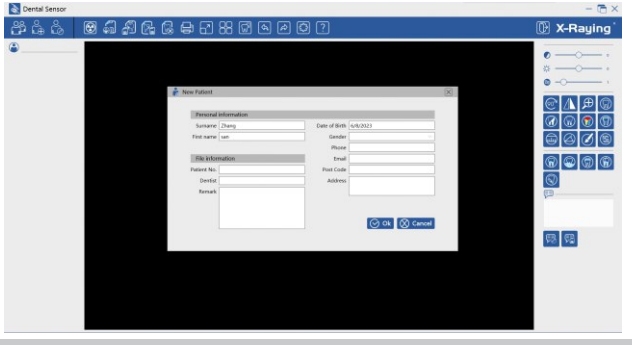
Step 6: Remove the sensor from the box and plug the sensor into the USB port of your computer to complete the installation.Take the dongle out of the box and plug it into the computer's USB port, otherwise you can only shoot 50 images.

Operation Instruction

Step 1:
Double-click the icon  to open the software, enter the user name and password and click "OK" to login the software.
The initial user name is: user, the password is: 123456.



Step 2: Create a new patient or select a patient
The first time to login the software, you need to create a new patient. After entering the basic information of the patient, click "OK" to enter the software.



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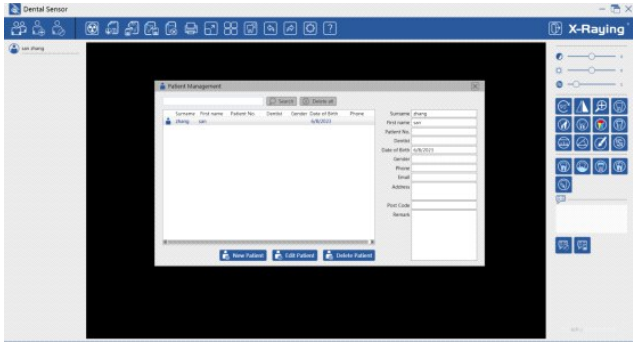
If patient is already there,after the software starts, there will show a list of existing patients. Select a patient and double-click to enter the software.

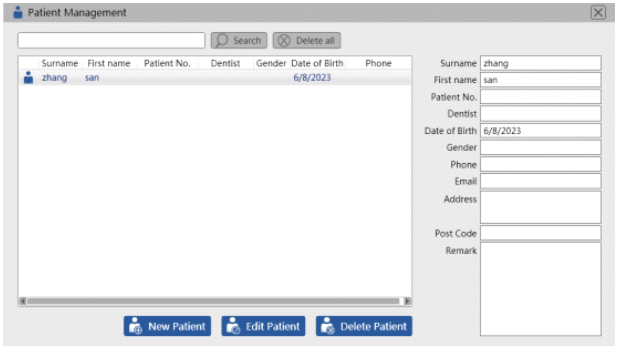


◆ Patient Management

Through the toolbar icons, you can manager patients, add patients, and edit patients.

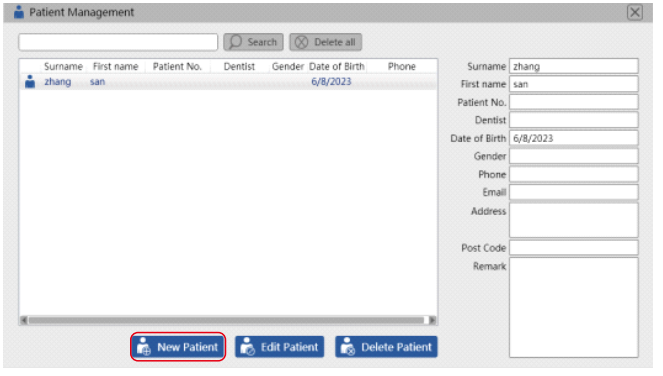
Patient Management

Click the patient management icon ,then will pop up the patient management interface

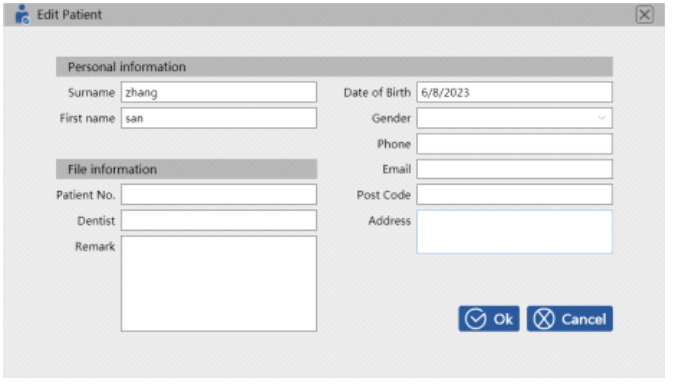


◆ Add a patient

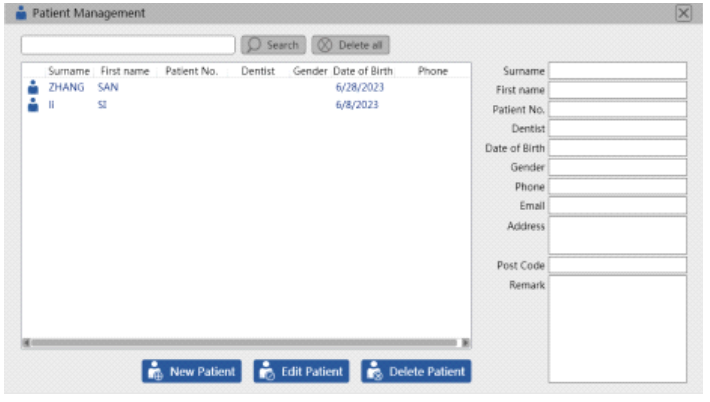
Click "New Patient" on the patient management interface



Enter the patient information in the patient information window and click "Ok"

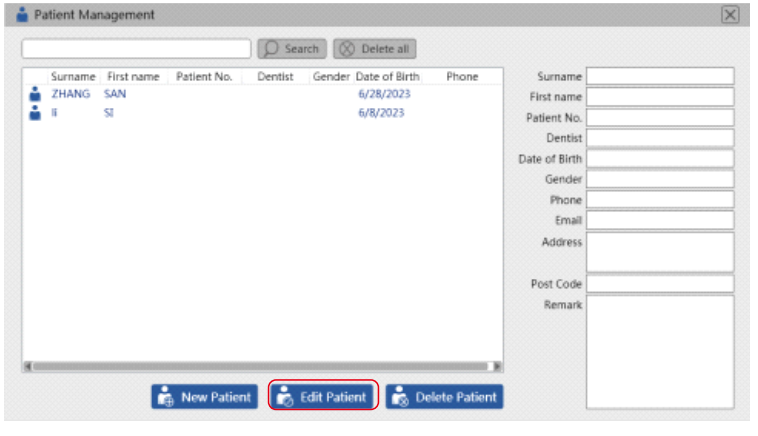


Successfully Added Patient

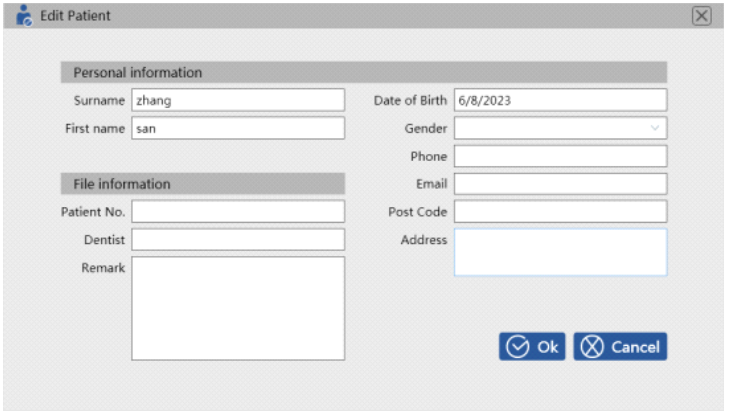


◆ Edit patient information

select a patient in the list and click "Edit Patient" to edit patient information.

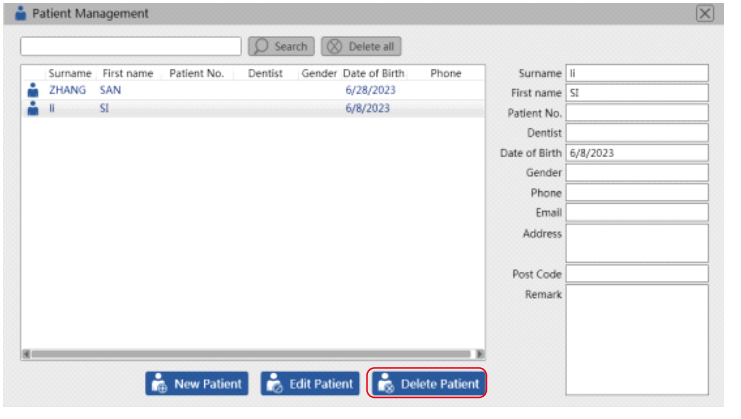


After editing the patient information in the pop-up patient window, click "ok", and the patient information has been modified successfully.



◆ Delete Patient

Select one patient in the list, and click “Delete Patient”to delete.



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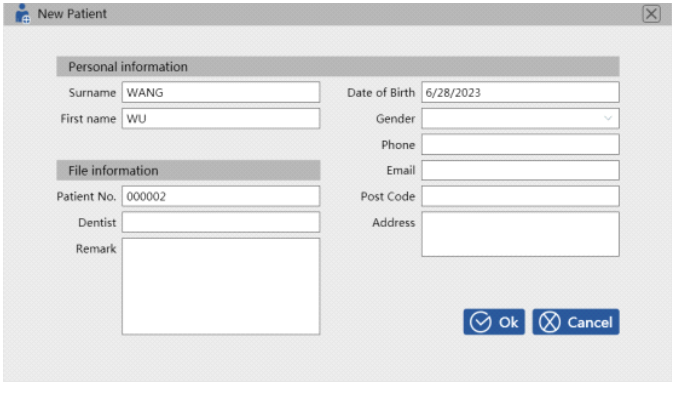
◆ Search Patient

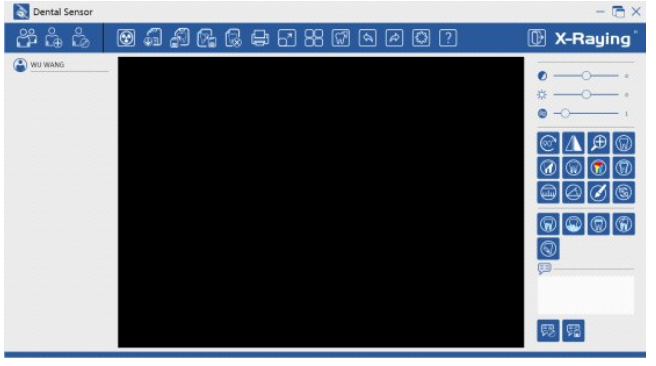
Enter the keyword of patient information in the search bar ,and click "find" to search out the patient with relevant information.

Create New Patient

Click “New patient” icon, the page will pop-up a blank information bar, enter the patient information and then click "OK".



After creating a new patient, it will enter patient image management interface directly, as below picture shows:

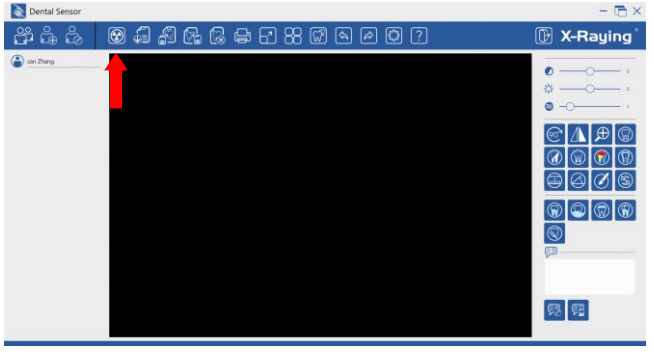


Edit patient

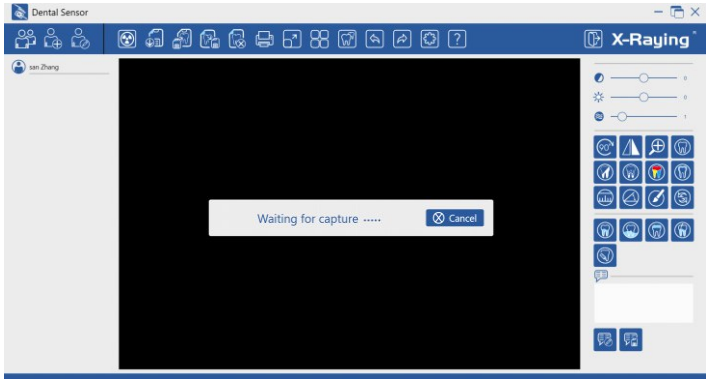
Click “Edit patient”icon to edit patient information.

◆ Shooting images

Step 1: Click on the shoot icon in the toolbar

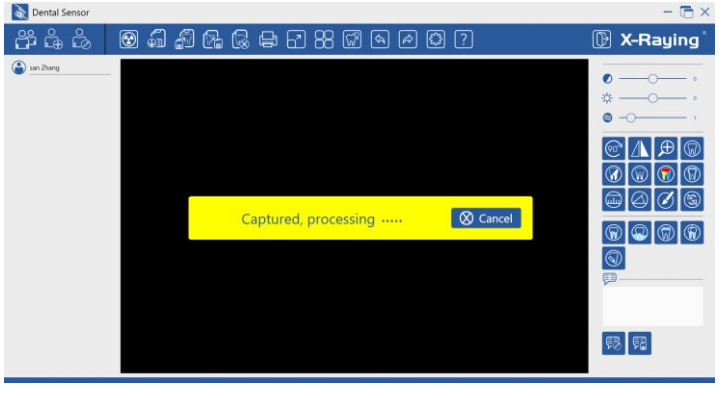


Step 2: Click the exposure and wait for capture



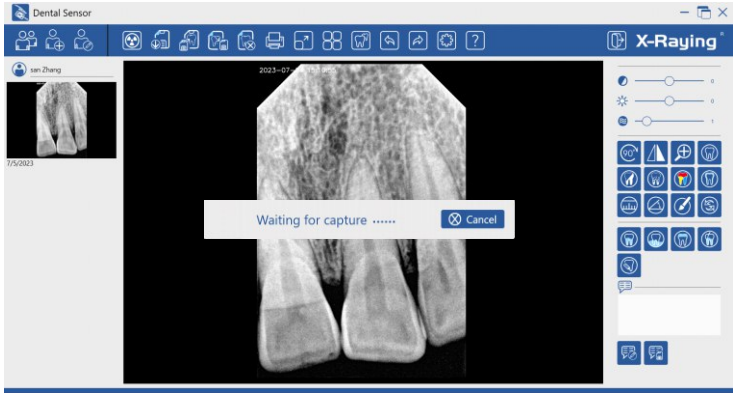
Step 3: Capture

1. Set the exposure specification of the X-Ray equipment.
2. Cover the sensor with a plastic film and place it in the proper position of the patient. Aim the tube of the X-Ray equipment at the location to be photographed. Please let the flat side of the sensor towards the tube when capuring.
3. After X-Ray equipment exposure and images capuring, the interface will prompt “Capured, processing”



Step 4: Turn off device

If you want to stop shooting after images captured, please click "Cancel" to close the device and end the shooting.



◆ Image Viewing

The toolbar on the right side of the software can realize the image contrast, distance, angle, draw, rotate and other functions, which is convenient for users to view more details of the image.

Note:

When the device is not in use, please pull out the USB cable from the USB port of the computer to prevent the LED light from overheating!

Before placing the sensor in the patient's mouth, make sure you have a single-use plastic film, which should be replaced by each person.

The single-use plastic film shall comply with GB/T16886 biological compatibility requirements: no cytotoxicity; No delayed type hypersensitivity reaction; No stimulation or endothelial reaction.

The used single-use plastic film shall be disposed of by the medical and health institutions in accordance with the requirements of the medical waste management regulations.

◆ Introduction To Software Functions

Tips: The function of any icon will be displayed when the mouse is placed over the icon

Toolbar

Patient management:

Click this icon and the patient management interface will pop up. You can create a new patient, delete a patient, edit a patient, search a patient, etc. Kindly see patient management for specific operations in section 9.1.

New Patient:

Click this icon to pop up the new patient interface. See Section 9.2 for detailed operation. Click this icon to create a new patient, and you will directly enter the new patient interface.

Edit Patient:

Click this icon to enter the patient information management interface, you can modify the current patient's personal information.

Exposure:

Click this icon on and open device for exposure, as detailed in part 9.3.

Save:

Save the currently edited image (add an image).

Image Import:

Import image, can be DCM, JPG, PNG format.

Export Image:

Export the currently displayed picture, can export DCM, JPG, PNG three formats.

Delete Image:

Delete the currently displayed image.

Print:

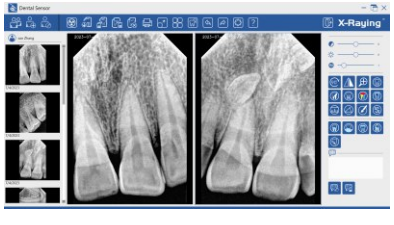
Prints a report of the current image.

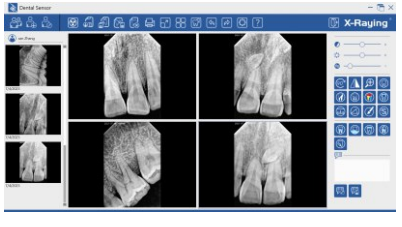
Full screen:

Full screen view of the current image. In full screen, hold down the right mouse button, move the mouse up and down to adjust the brightness, and move left and right to adjust the contrast of the image.

View:

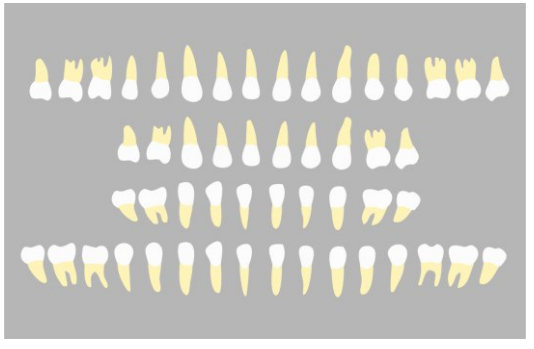
2 or 4 images can be selected to view or compare at the same time, as shown in the figure below:



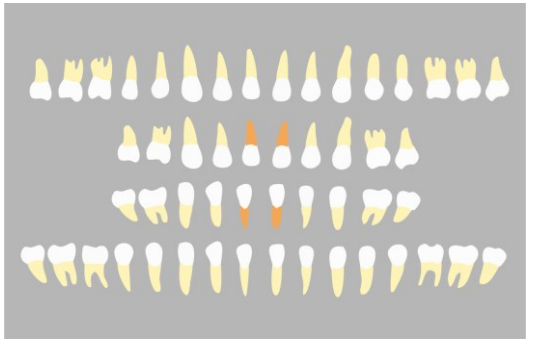


Tooth Number:

Click this icon to display the tooth number map, as shown in the figure below. The upper and lower two rows are adult tooth number, and the middle two rows are children's tooth number.



When clicking the corresponding tooth number with the mouse, the modified tooth number will change color. The tooth number map is used to indicate the tooth number captured by the current image



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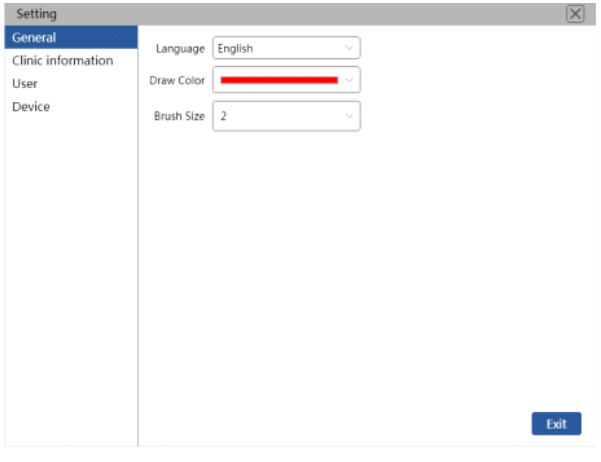
Undo/Redo:Go back to the previous operation

Setting:Setting clinic information,change password,language,etc.

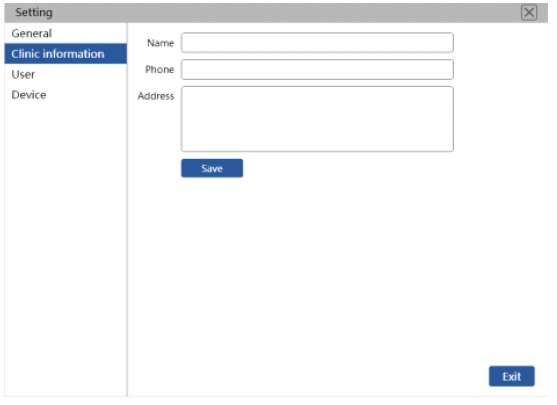
Setings-General:

● Language:Only English and Chinese now,will add more language in the further.Restart software after setting
●Draw Color:Set the color of draw which draws on the image.
●Brush Size:Set the draws size,the range is 1-10

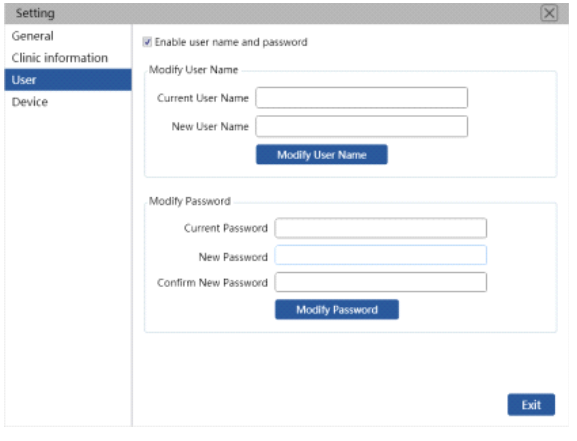


Setting:Clinic Information

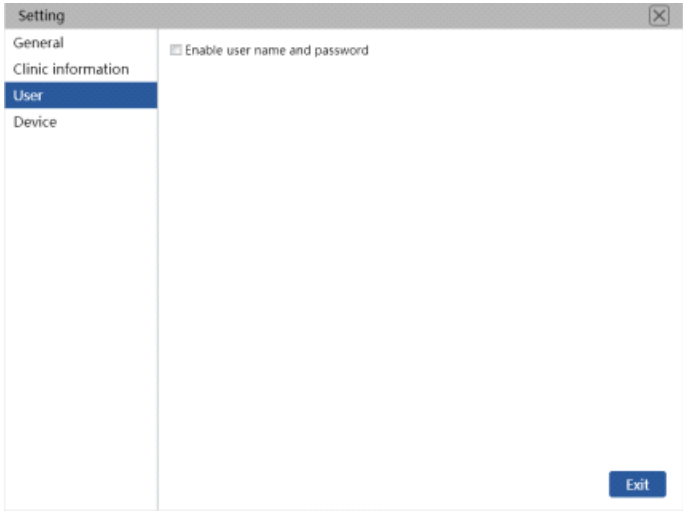
Add clinic name,phone,address.It will show in report



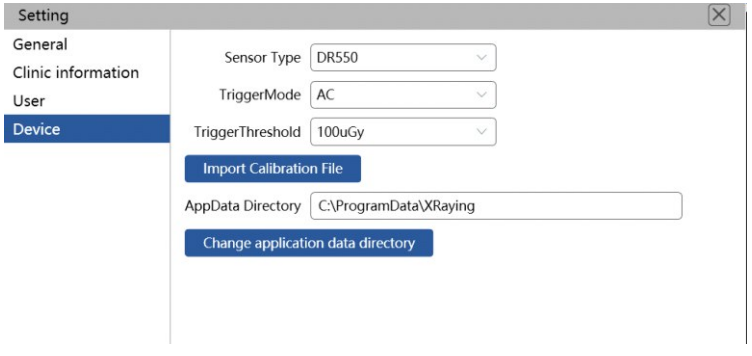
Setting:User
Set the User name and password.
● Change User Name.
● Change Password.



When the “Enable username and password” is unchecked,it isn’t need to enter user name and password when start software and login directly.



Setting - Device

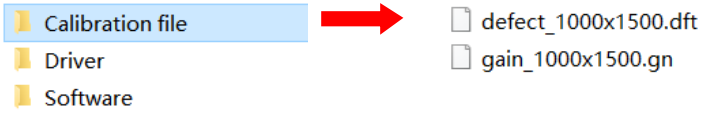


Sensor model - DR530 or DR550
Trigger mode-
AC mode: timing trigger mode, suitable for AC X-ray.
DC mode: pulse trigger mode, suitable for DC X-ray.
The trigger dose is 50uGy/100uGy/200uGy optional, which is selected according to the dose of the X-
ray unit actually used. The smaller the trigger dose, the more sensitive it is. Generally, t he default value is sufficient.

◆ Import calibration files

Each sensor has a set of calibration files stored in the attached USB flash disk, and the calibration files need to be imported during use.

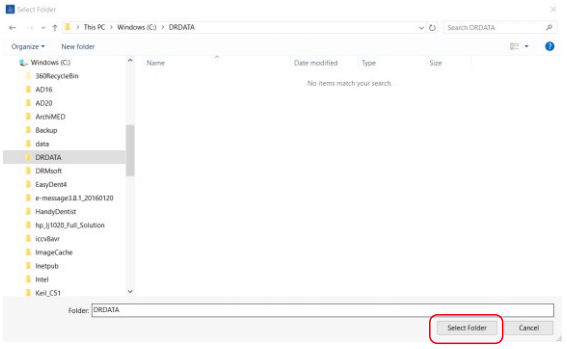
Operation Methods
Step 1: Connect USB flash disk with computer and connect the sensor.
Step 2: Open Settings ->Device, click "Import Calibration File" -
>Open USB flash drive, select all the calibration files in the "Calibration File" folder to i mport.



◆ Modify the database directory

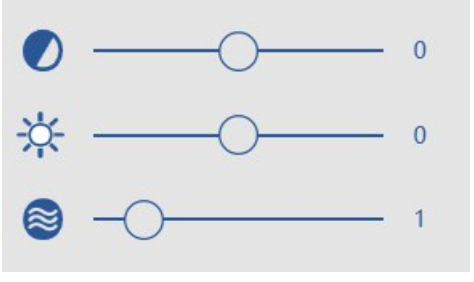
The default database directory of the software is C disk. Due to the limited space of C disk, it is recommended to change the database directory to another disk after the software is installed.

Operation Method
Step 1: Create a new folder on another disk. Such as named with DRDATA
Step 2: Click "Modify Data Directory", select the ‘DRDATA’ folder, and click "Select Folder".



Exit: Exit The Software

◆ Image Editing Toolbar



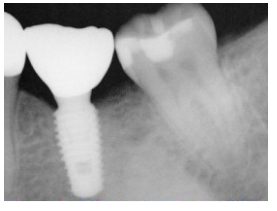
Brightness/Contrast/Gamma Adjustment: slide the button to the left or right as needed to adjust the brightness/contrast/gamma value. Press and hold the right button of the mouse and move the mouse up and down on the image to adjust the brightness, and move left and right to adjust the contrast of the image.

Rotated 90°clockwise

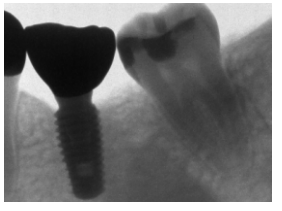
Flip left and right

Zoom in: After clicking icon, move the mouse on the image to realize partial zoom in.

Negative: Make the image show the effect of the negative.



Original

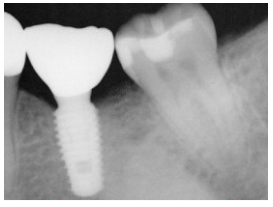


Negative effect

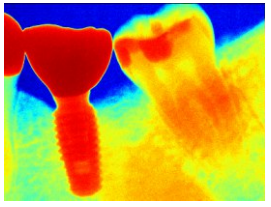
Sharpen: Highlight the edge information of the image.

Denoise: Remove spots on the image

Pseudocolor: Different parts will show different colors. Because some differences can be better distinguished in color, coloring provides an important way to identify potential problems.



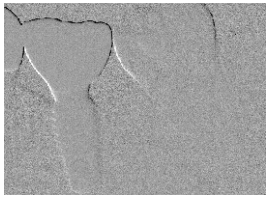
Original



着色效果

Embossment: Make image more three-dimensional

原图片

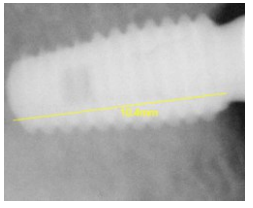


浮雕效果

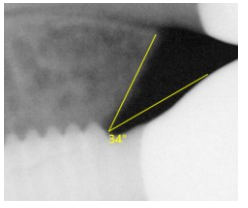
Distance: After clicking this icon, you can measure the length between any two points on the image.

Angle: Click this icon and use the mouse to select three points on the image , and can measure the angle between the three points.

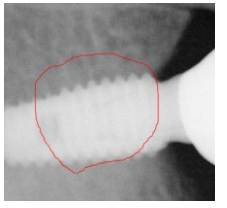
Draw: After clicking this icon, press the left mouse button on the image and move it arbitrarily to draw any line on the image



Distance



Angle



Draw

Initialize: Click this icon and the currently image will return to the initial state of the image if it is adjusted

Saprodontia : More clearly to check the decayed teeth

Periodontal: More clearly to observe the periodontal

Crown: More clearly to observe the crown

Root canal: More clearly to observe the root

Smart Contrast: Auto-enhance image contrast, make image details clearer

Image Information Bar

Make notes at this area

Edit : Click this icon to enter information in the information bar

Save: Click this icon to save information for the information bar

▶ Disassembly Instruction

Note: Before do any of the following operations, please make sure that the USB is removed from the computer's USB port, and ensure that this is done away from the patient's area.
Loosen the fixing screw of the controller box with a screwdriver
Warning: Equipment shall not be modified.
Warning: Equipment shall not be modified without the authorization of the manufacturer
Warning: If equipment is modified, appropriate inspections and tests must be carried out to ensure that the equipment can continue to be used safely

▶Cleaning and Disinfection

The product can not be soaked in the liquid for a long time, try to avoid using liquid disinfection.The product shall be used with medical single-use plastic film to disinfectant (We don't provide medical single-use plastic film, please use medical single-use plastic film which are compliant with GB/T 16886 biocompatibility requirements)
It is recommended that users use a damp, lint-free cloth dipped in isopropyl alcohol (70%), and then use this gauze to wipe the surface of the part to be disinfected twice for 3 minutes. Air dry naturally or wipe off residual disinfectant with a clean, dry soft cloth.
Note that cleaning should be done before disinfection.
Alcohols are flammable, and open flames should not be present during use.
Those who are allergic to alcohol should use this disinfectant with caution.
After disinfection, the residual disinfectant should be removed in time to avoid direct contact with patients. Other cleaners can damage the CMOS sensor or control box. The use of other cleaning agents is considered to be contrary to the guidelines for use in the intended use. The manufacturer is not liable for damage caused by unauthorized disassembly and incorrect use. All risks are borne by the user.

- Do not place sensor in autoclave
- Do not put the sensor in an ultrasonic cleaner
- Avoid spray contact with any connectors of the CMOS sensor
- Before disinfection, remove dirt and wipe with a soft, non-fiber cloth.

▶ Maintenance

Visual Inspection

Like all electrical equipment, the product requires not only correct use, but also visual inspection prior to operation, and routine checks at regular intervals. These precautions will help ensure that the product operates accurately, safety and effectively.
Before operating the system, users shall check it for any signs of physical damage or defect. If detected, contact your local distributor of this product for further instructions.

Periodic Maintenance

Periodic maintenance should be performed as required, but at least once a month. These maintenance include the following checks, which should be carried out by the user or a qualified technician.
Check that the label is complete, readable and firmly adhered.
Check all of the cables are undamaged.
Check that there is no external damage to the product which could compromise its ability to operate safely.
After the installation, then do the step 1.2 of operation and check that the indicator lights and indicator area in software are in normal.

Damaged or Non-Functioning sensor

If the sensor is physically damaged or does not work properly, you should immediately stop using it and contact your local dealer. Do not disassemble the shell for maintenance. If you need more technical information can contact the manufacturer for consultation.

▶ Exposure Time

As with conventional radiological devices, the exposure time depends on the type of generator, the shape of the patient, and the tooth being irradiated. The exposure times given below are recommended. Using experience in your practice to set specific configurations will become clearer over time

Tooth Number	Recommended Exposure Time (s)
Upper Incisor/Canine	0.18
Upper Premolar	0.24
Upper Molar	0.40
Lower Incisor/Canine	0.12
Lower Premolar	0.18
Lower Molar	0.24

▶ Troubleshooting

Fault	Solution
Computer can not recognize the sensor	Re-install the driver program and try another USB port
Data control box stop working (The light is off)	Check the connect interface between controller box and computer
No response after x -ray emission	Re-install the driver program and try another USB port
No response when double-click the icon	Close all anti-virus program and re-install software and driver
Warning “ lack of calibration file”	Please import the calibration file from USB Drive
Image too dark or too white	Try to reduce or increase x rayose and exposure time(refere to recommend exposure time)
Tip: "No dongle detected, can only take 50 images”	Please insert the dongle in the package
Vertical white line on image	Check the calibration file

⚠ Note: If the failure occurs, you can try the above solutions; If the failure continues or more serious situation occurs, please contact the local distributor.

▶ Guarantee Certificate

We guarantee that the product functions correctly and that there are no faults in the material or workmanship for duration of 12 months starting from the release date.
1. From the date of purchase, if it cannot work normally due to quality problems within one year, our company will be responsible for free maintenance.
2. Under any of the following circumstances, only fee-based repairs will be made:
• Damage caused by the user's failure to operate, maintain, and store according to the instructions, or the user's carelessness;
• Damage caused by disassembly by the user;
• Damage caused by force majeure;
• Beyond the free maintenance period.
Following reasonable complaints about failure or delivery, we will provide replacement or repair, and our factory reserves the right to perform the repair. Including other natural or special damage requirements. In order to prevent default, malfeasance or intentionality, the latter are only provided if they do not violate mandatory legal provisions.
If the product breaks down, please contact the local office and our company will be responsible for repairing it. Do not disassemble it without authorization. We are not responsible for problems directly caused by unauthorized repairs by customers or third parties.
If the oral digital X-ray imaging system is operated under normal conditions, the expected service life of the product is 4 years. The calculation method is expressed as follows:

Shooting times	Lifetime (The calculation is based on the average 10,000 times shooting per year)
40000	4years

▶ Product Configuration

Packing list

1.Dental Imaging System	1set
2.USB disk flash	1pcs
3.dongle	1pcs
4.User Manual	1pcs

Dental Imaging System

Appendix A. EMC

This device complies with the relevant requirements of IEC60601-1-2: 2014 standard for electromagnetic compatibility which shown as below:

Emission and Immunity test		Basic Standard	Compliant Level/Note
Electromagnetic compatible emission	Radiated Emission	CISPR 11	Group 1, Class B
	Conducted Emission	CISPR 11	N/A
Electromagnetic compatible immunity	Electrostatic Discharge	IEC 61000-4-2	Contact: ±6KV Air: ±2KV ±4KV ±8KV ±15KV
	Radiated RF Electromagnetic Fields	IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 1KHz 80%AM
	Electrical Fast Transients and Bursts	IEC 61000-4-4	±2kV 100kHz to power cord
	Conducted Disturbance, Induced by RF Fields	IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band
	Power Frequency Magnetic Field	IEC 61000-4-8	30A/m

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Test Frequency	Band (MHZ)	Modulation	LMMUNITY TEST LEVEL
(Mhz)			(V/m)
385	380-390	Pulse Modulation 18Hz	27
450	430-470	FM ±5kHz deviation 1kHz sine	28
710	704-787	Pulse Modulation 217Hz	9
745			
780			
810	800-960	Pulse Modulation 18Hz	28
870			
930			
1720	1700-1990	Pulse Modulation 217Hz	28
1845			
1970			
2450	2400-2570	Pulse Modulation 217Hz	28
5240	5100-5800	Pulse Modulation 217Hz	9
5500			
5785			