

User Manual Canis014D07 Portable X-ray System





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To Customers

Thanks you for purchasing the CANIS014D07 Portable X-Ray System (hereinafter referred to as CANIS014D07) from iRay Technology Taicang Ltd. (hereinafter referred to as iRay) as your X-ray solution.

This manual contains all the general information about the CANIS014D07, which is intended to provide users with instructions on installation, operation and maintenance.

All information in this manual, including illustrations, is based on the equipment prototype. If your equipment does not match with these contents, they will not apply to your equipment.

Information regarding the specifications, compositions, and appearance of this product is subject to change without prior notice.

Store this manual safely so that you can access it in the future.

Do not operate this equipment until you have fully read this manual.

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Trademarks



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Environmental Protection



This symbol indicates that this product cannot be disposed as domestic or commercial waste. Improper handling of this type of waste may result in a negative impact on health and environment.



Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Please contact your local authorities for information about practices established in your region. If collection systems are not available, call iRay Customer Service for assistance.

Disclaimer

- In no event shall iRay be reliable for any abnormality, equipment damage and personal injury caused due to
 your failure to follow the warnings and operating instructions in this manual.
- In no event shall iRay be reliable for any damage, loss, or injury incurred by purchaser or third parties as a result of fire, earthquake, any accident, misuse or abuse of this product.
- In no event shall iRay be reliable for any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to this product or failure to strictly comply with iRay's operating and maintenance instructions.
- In no event shall iRay be reliable for any damage or loss arising from the use of any options or consumable products other than those dedicated as original iRay products.
- During X-ray imaging, collecting, processing, reading and storing of image data, the user should comply with the law of the countries where the product is used.
- The user and operator are responsible for maintaining the privacy of image data acquired from this product.
- The clinician is responsible for providing medical service and erroneous treatment due to misdiagnosis.

Warning Symbols

The warning symbols that appear in this user manual are classfied as follows for better comprehension of their meanings. Make sure that you fully understand them and obey the instructions they contain.



This indicates a potentially hazardous situation which, if ignored, may result in severe personal injury, death, or substantial property damage.



This indicates a potentially hazardous situation which, if ignored, may result in minor personal injury or property damage.



This symbol is used to indicate a prohibited operation.



This emphasizes or supplements important information about the main text.



This symbol is used to indicate "Consult other sections of this manual for information".



Abbreviations

Abbreviations	Explanation
FCC	Federal Communications Commission
SSD	Source-to-Skin Distance
SN	Serial Number
UI	User Interface
WL	Window Level
WW	Window Width



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1 Safety Precautions

To avoid personal injury or product damage, be sure to read the user manual and all accompanying documents carefully and pay attention to all safety precautions before using the equipment. Operation and Maintenance must be in accordance with the instructions contained in this manual.

1.1 Radiation Safety

This equipment may be dangerous to the patient and operator unless safe exposure factors and operating instructions are observed.

• The owner and/or operator of this equipment to comply with all applicable rules and regulations concerning radiation safety and protection in their area.



- Excessive exposure to X-ray radiation is harmful.
 - Verify the exclusion zone is clear of all personnel. Failure to comply may result in personnel injury.
- All users should comply with the Radiation Protection Policies established by the government.



- All users and patients should wear protective garment, such as a lead apron which is covered until collar, for radiation protection.
- Do not enable this equipment until patient and operator are positioned and ready for the exposure, reducing the likelihood of interruption and preventing inadvertent exposure of anyone to x-rays.

1.2 Equipment and Power Source



- To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth when charging.
- Use only the supplied adapter provided by iRay.

The equipment may be damaged if you use another power adapter.

• Do not hit or drop the equipment.



The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired.

 Be sure to disconnect the power cable by holding the plug or connector, not by pulling the cable itself.

If you pull the cable too hard, the core wire may be damaged, resulting in fire or electric shock.



1.3 Battery

 Observe and follow all safety information in this manual and on the warning labels on the battery.

Ignoring this warning could result in personal injury or product damage.



- Do not charge the battery in the environment with patient.
- Do not use batteries not provided by iRay, do not charge damaged battery, or charge battery with damaged adapter. If the enclosure is broken or emits unusual odors, smoke, overheats, or leaks anything. Avoid contact with any material leaking from the battery pack.

If any liquid comes into contact with your skin or eyes, wash the affected area with clean running water and seek immediate medical attention.

 If the equipment is not used for an extended time period, charge the battery once every 3 months.



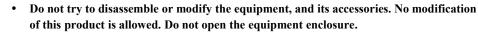
After full charge, at least 1 exposure has to be made to keep the battery in best function.

The battery is a consumable part. After several months, the battery capacity may slowly
decrease.

For reliable function and safety, battery pack should be replaced when its capacity is noticeably decreased.

1.4 Operation

Operation should be performed only by qualified and trained dentists, radiologists, dental hygienists, or maintenance service technicians who are experienced in installing and servicing dental X-ray systems.





• Have the patient take a fixed posture and do not leave the device within the reach of a patient.

Ignoring this warning may cause electrical shock and/or unknown hazards, which may result in severe personal injury, death, or substantial product damage.

Pregnant women should not be exposed to X-rays unless it is strictly necessary.



• Try not to move the equipment or incur vibration during X-ray exposure.

The image will not be clear if the equipment moves or there is a vibration during X-ray exposure.

Do not handle the equipment with wet hands.

Otherwise, it may result in electric shock that could result in death or serious injury.



1.5 Failure Handling



 Turn off the equipment and contact your sales representative or local iRay distributor if any of the following occurs:

When there is smoke, an odd smell or abnormal sound

When liquid has been spilled into the equipment

When the equipment has been dropped and is damaged

1.6 Environment

The equipment should be stored and operated in a specified dental clinic environment and maintained by professional maintenance personnel under safe and operable conditions.



Static electricity may affect this device at any time. Please use this device within the permissible range of humidity defined by the specifications. Please refrain from wearing a garment that may generate such static electricity.

Do not store the equipment or its parts in places listed below:

Water sources

Heat sources that produce heat

In an area prone to vibration

Chemicals or gases are generated

Where flammable materials are placed

Oxygen-rich environment

Other than the specified storage environment

• The equipment can be used at an altitude of less than 3,000 meters.



2 Regulatory Information

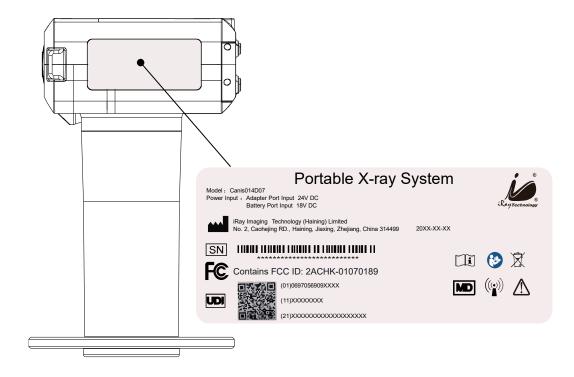
2.1 Labels and Symbols

The detector and other components have labels and symbols on them. Their contents and locations are indicated below.

The labels in this document are only examples, please refer to the actual labels.

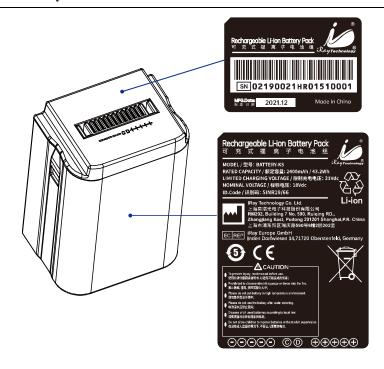
■ Product Label

A sample label is shown in the figure below. The label information includes model, SN, manufacturer information and other information.





■ Labels on the Battery



Symbol	Explanation	Location
SN	This symbol is used to identify the manufacture series number which is made of 19 digits as shown below: A ₁ A ₂ A ₃ A ₄ B ₁ B ₂ C ₁ C ₂ L M ₁ M ₂ D ₁ D ₂ Y ₁ Y ₂ X ₁ X ₂ X ₃ X ₄ Production Series No. Production Site Production Version No. Derivative Type Production Type	Product label
~	This symbol indicates the name and address of manufacturer. The date of manufacture is combined in this symbol.	Product label
<u> </u>	Caution: please refer to the instructions in the user manual.	Product label
Ţį.	This symbol represents reference to the user manual for general information.	Product label
	This symbol indicates that the product must be sent to the appropriate facility for recycling when the end user intends to discard the product.	Product label Battery label
③	This symbol represents a safety symbol that indicates "reference to user manual".	Product label



MD	This symbol is used to indicate that the product is a medical device.	Product label
$((\bullet))$	This symbol is used to represent nonionizing electromagnetic radiation.	Product label
UDI	This symbol indicates a carrier that contains unique device identifier information.	Product label
F©	This symbol is used to indicate Federal Communications Commission certificate.	Product label

2.2 Safety Standards for Medical Equipment

2.2.1 Medical Equipment Classification

Item	Classification
Type of protection against electrical shock	Class I ME equipment, using the medical approved adaptor; Internally powered ME equipment, using the internal battery
Degree of protection against electrical shock	Without applied part
Degree of protection against ingress of water	IPx0
Mode of operation	Continous operation
Flammable anesthetics	CAN NOT be suitability for use in an OXYGEN RICH ENVIRONMENT

2.2.2 Product Safety Standards

Standard	Description
IEC 60601-1:2005 + A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety
/EN 60601-1:2006 + A1:2013	and essential performance
ANSI/AAMI ES60601-1:2005 + A1:2012 + Amendment 2:2010	Medical Electrical Equipment – Part 1: General requirements for safety and essential performance
CSA CAN/CSA-C22.2 NO. 60601-1:14-2014	Medical Electrical Equipment – Part 1: General requirements for safety and essential performance
IEC 60601-1-2:2014 /EN60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3:2008 + A1:2013 /EN 60601-1-3:2008 + A1:2013	Collateral standard: General requirements for radiation protection in diagnostic equipment.
IEC 60601-1-6:2010 + A1:2013/EN 60601-1-6:2010 + A1:2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability



Standard	Description
IEC 60601-2-65:2013 + A1:2017/EN 60601-2-65:2013 + A1:2017	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC62366-1:2015/EN62366- 1:2015	Medical devices - Part 1:Application of usability engineering to medical devices
IEC62133-2:2017/ EN62133- 2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes-safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications-part 2:lithium systems
UL62133-2:2020	Secondary cells and batteries containing alkaline or other non-acid electrolytes-safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications-part 2:lithium systems
CSA C22.2 NO. 62133-2-20	Secondary cells and batteries containing alkaline or other non-acid electrolytes-safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications-part 2:lithium systems
EN ISO 15223-1:2016	Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied—Part 1: General requirements

2.3 FCC

Contains FCC ID: 2ACHK-01070189

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.



Radio Frequency (RF) Energy

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the United States.

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit recommended by the general public is 1.6W/kg Averaged over one gram of tissue by IEEE Std 1528.

The FCC has granted an Equipment Authorization for this product with all reported SAR Levels evaluated as in compliance with the FCC RF exposure guidelines. While there may be differences between the SAR levels of various product and at various positions, they all meet the government requirements. SAR compliance for body-worn operation is based on a separation distance of 0 mm between the unit and the human body. Carry this device at least 0 mm away from your body to ensure RF exposure level compliant or lower to the reported level.



3 Product Introduction

3.1 Overview

3.2 Intended Use

The Canis014D07 is a portable dental X-ray system for dental diagnosis in adult and pediatric patients and is available only to trained and qualified dentist or dental technician.

Essential Performance

According to the IEC 60601-2-65, the clause 201.4.3.101, there are 2 potential essential performance:

- a. Accuracy of loading factors;
- b. Reproducibility of the radiation output

3.3 Key Features

- Portable portable smart X-ray source
- Intraoral X-Ray imaging
- 7" touch LCD display with high resolution (1024×600)
- Rechargeable battery allows mobility, easy to operate and move
- 2 USB interfaces equipped
- High capacity battery, up to 400 exposures on one full charge
- Low radiation dose, safe and reliable
- High specifications (70kV DC, 0.4mm focal spot) ensures high-quality images
- Applicable to multiple application scenarios
- All-in-one system, friendly user interface

3.4 Contraindication

Patients (children and pregnant women particularly) must wear lead aprons during their X-ray imaging.

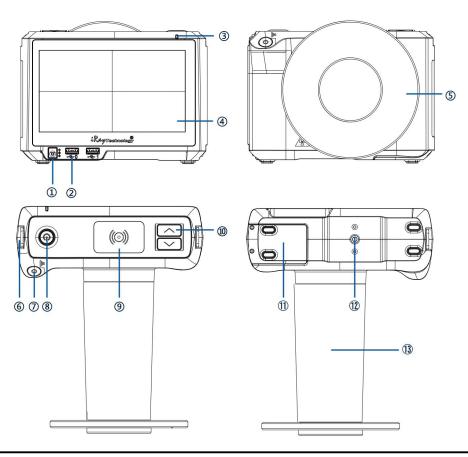


3.5 Product Components

Please check the following items carefully to ensure they are complete and confirmed by iRay engineers. If any items are lost or damaged, please contact your iRay dealer.

No.	Item	Qty.	Remarks
1	Canis Smart P	1 pc.	Default
2	Adapter	1 pc.	Default
3	Power cord	1 pc.	Default
4	Battery	1 pc.	Default
5	Wrist strap	1 pc.	Default
6	Collimator Cone (200mm)	1 pc.	Default

3.6 Product Description



1	DI-IN	8	Power button (ON/OFF)
2	USB port	9	Product label



3	Exposure indicator	10	Adjusting button
4	Control screen	111	Battery cover
(5)	Back scatter shield	12	Cradle head
6	Wrist buckle	13	Beam limiting device
7	Exposure button		

3.7 Component Installation

3.7.1 Battery Replacement

To be added...

3.7.2 Battery Removal

To be added...

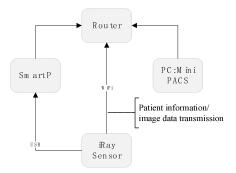
3.8 Application Scenarios

■ Smart P+iRay Sensor



Free from a computer, Smart P is an independent dental DR system and could finish the whole workflow: Patient registration, image acquisition, image diagnostics.

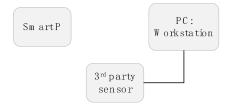
■ Smart P+PC+iRay Sensor



Smart P is an independent dental DR system, and need a PC for Mini PACS installation.



■ Smart P+Third Party Sensor



Smart P is just an X-Ray machine, which could adjust the exposure parameters easily, touch or button control.

3.9 Recommended Exposure Time

Tooth Position	Exposure Time of Digital Dental Film (s)
Maxillary incisor	0.08~0.10
Maxillary monocuspid	0.12~0.16
Maxillary bicuspids and first molar	0.12~0.16
Maxillary second and third molars	0.16~0.20
Mandibular incisor	0.06~0.08
Mandibular canine	0.10~0.16
Mandibular bicuspids and first molar	0.10~0.25
Mandibular second and third molars	0.10~0.25



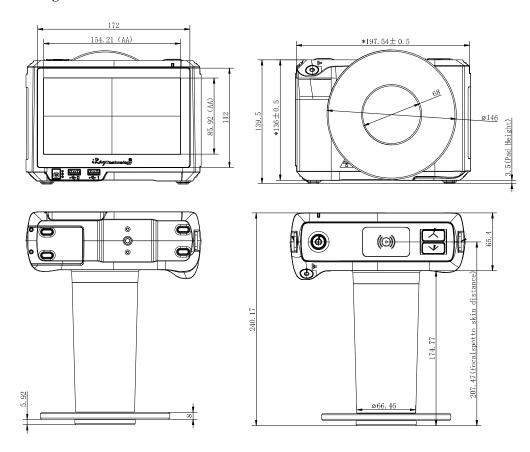
The exposure time set in each mode is recommended by the manufacturer, and each time can be adjusted.



4 Technical Specifications

4.1 Portable X-Ray System

■ Drawing



■ Specifications

Item	Specification
Model	Canis014D07
Application	Intraoral X-Ray imaging
Output kV	70KV±10%
Output mA	2mA±20%
X-ray tube anode angle	12°
X-ray tube focal spot	0.4mm
X-ray exposure time range	0.1~2sec
HVG frequency	30kHz



Item	Specification
Power Input(adapter)	100-240V AC, 50/60Hz
Focal length	≥200mm
Exit filed size	≤60mm (Circle)
Device power source	Battery: 2400mAh - 400 exposures (full charge,70KV,2mA, 0.5sec, cycle time 15sec) -Standby mode(full charge): 1 week (Power off) -3 hours empty to full charging -2 months shipping mode: full charge -battery could be replaced by end-user
Exposure control	Hand switch / Button control / Remote control
Sync with sensor	IEEE802.11/USB connection
Shooting angle	Automatic calculation and display
X-ray image transmission	USB & IEEE802.11 a/b/g/n/ac
Wireless Frequency Range	2412-2462MHz, 5180-5240MHz, 5745-5825MHz
Data Transmission Power	13dBm (Typ.) @802.11a 13.5dBm (Typ.) @802.11b 15dBm (Typ.) @802.11g 15dBm (Typ.) @802.11n HT20 14dBm (Typ.) @802.11n HT40 13dBm (Typ.) @802.11ac
Wireless Modulation	11b: DSSS (DBPSK, DQPSK and CCK) 11a/g/n: OFDM (BPSK, QPSK,16QAM, 64QAM)
Wireless Band	2.4GHz≤35MHz 5.GHz≤50MHz
Internal radiation shielding	≤0.1Gy/h @1 meter
Total filter	≥1.5mm Al
Display and control	7inch display (Resolution:1024×600) with touch panel
Full image time (image processing included)	10s
Weight	≤2.2kg (without shield)
Dimensions	195mm×136mm×65mm
Fixed model	Mountable/portable
OS	Android
Exposure record	Cumulative exposure time and times record

■ Environment Requirements

Please confirm that the environment meets the basic requirements of Canis014D07 to ensure that it can be stored or operated in a reliable environment.

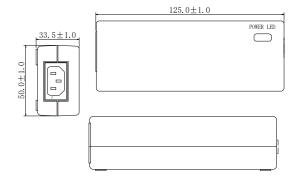
Item	Operation	Storage & Transport



Item	Operation	Storage & Transport
Temperature range	10~40°C	-10~45°C
Humidity range	30%RH~75%RH	30%RH~75%RH
Atmospheric pressure range (mbar)	700mbar~1060mbar	700mbar~1060mbar

4.2 Adapter

■ Drawing

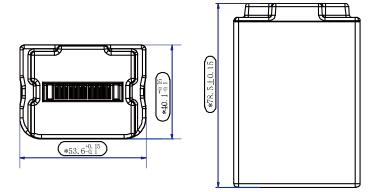


■ Specifications

Item	Specification
Model	LXCP61-024300
Input	100~240V AC input
Output	24V single output mode, 72W

4.3 Battery

■ Drawing





■ Specifications

Item	Specification
Model	BATTERY-KS
Rated capacity	Typ.2500mAh; Min.2400mAh
Nominal voltage	18V
Limited charging voltage	21V
Discharge cut-off voltage	12.5V
Charge method	CC-CV
	Charge: 0°C≤T≤20°C 0.2C (500mA); 20°C < T≤45°C 1.2C (3000mA)
Operating temperature	Discharge: 20°C < T≤45°C 7.2C (18000mA); 45°C < T≤60°C 4.0C (10000mA)
	Less than 1 month: -20°C ~ +50°C
Storage temperature	Less than 3 months: -20°C ~ +40°C
	Less than 1 year: -20°C ~ +20°C
Relative humidity	65±20%RH
Dimensions (L×W×H)	78.5×54×40mm³

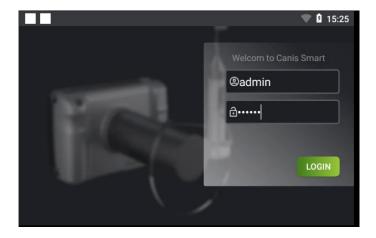


5 User Interface

The interface mainly includes login page, work list page, patient information page, image acquisition page, image browsing page and setting page. The main functions of each page are described as follows:

Tab	Description
Login page	Enter the user name and password to log in to the home page
Home page	Query patient information, jump to the patient information page, image acquisition page, image browsing page and setting page
Patient information page	Modify and manage patient information, including name, gender, tooth position, etc.
Image acquisition page	Set exposure parameters according to tooth position and age, and display the status related to exposure services
Image view page	View images and perform related operations on images
Setting page	Account settings, function settings, network settings, sensor settings, etc.

5.1 Login Page



On the login page, enter the account and password information correctly, you can jump to the home page. If one of the account passwords is incorrect, a prompt message will pop up and stay in this interface. The login interface is shown on the right.

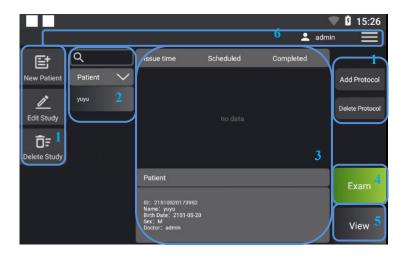


A touch user interface enables you to enter the user name and password information by a finger touch.

The default user name is "admin" and the password is "123456". Username and password can be changed in the setting page. The length of the user name must be no more than 60 characters, and the length of the password must be within $6\sim10$ characters.



5.2 Home page



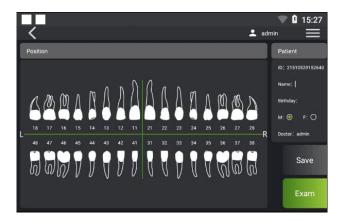


The home page is mainly divided into 6 areas, and the main functions of each area are as follows:

No.	Function	Button	Description
		New Patient	Add information of a new patient, including name, gender, birth date, and dental location
		<u>/*</u> Edit Study	Edit patient information, including name, gender, and birth date
1	Information management	Delete Study	Delete all medical information
		Add Protocol	Jump to the "new information" page, select the tooth position and add to the current patient's medical record
		Delete Protocol	Delete the selected medical record of the selected patient
2	Patient-based search	Q	Enter the keyword/pinyin and click to search to match the information in the database
3	Selected patient information	/	Used to display the patient information of selected patient, including all medical records, patient ID, name, gender, birth date, attending doctor, etc.
4	Image acquisition button	Exam	Click this button to jump to the image acquisition interface
5	Image browse button	View	Click this button to jump to the image browse interface
6	Status bar	admin	Current logged-in username
			Navigation button includes "Back to login", "Setting", "About" and "Correct".

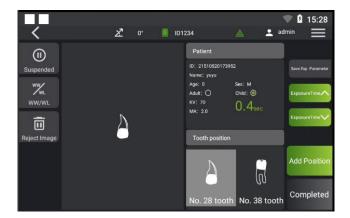


5.3 Patient Information Page



Button		Description
	Information modification	Modify patient information, touch the name, birth date, gender, and click [Save] to save the modified information
Save	Addition of tooth position	Touch the corresponding tooth position and click [Save] to add the tooth position to be examined
Exam		Jump to the image acquisition page to examine the selected patient
<		Back to Home page

5.4 Image Acquisition Page



The detailed functions of the buttons on this interface are described in the following table:

No.	Item	Description
Status bar	👱 admin	Current logged-in username



No.	Item	Description
	\equiv	Navigation button
	ID1234	Connected detector ID
	∠ 0°	The pitch angle refers to a certain angle between the head and the horizontal line during the shooting process
	A	Red symbol means that exposure is prohibited or an error is reported, yellow means that it is being exposed, and green means that it can be exposed
	Suspended	In the process of shooting, if there is any tooth position that has not been checked, you can suspend the examination next time
	WW/WL	Adjust the window width and window level of the acquired pictures to confirm whether they are qualified
	Reject Image	Delete and re-shoot the tooth position that do not meet the requirements
	Save Exp. Parameter	You can save the default parameters according to your needs, and the default parameters set by each user are independent of each other
Button	ExposureTime ExposureTime	There are default exposure times for patients of different genders and ages, and the exposure times are also adjustable
	Selection of tooth position	Select and shoot multiple tooth positions registered by the patient
	Add Position	During the shooting process, jump to the patient information page to add the tooth position to be shot
	Completed	Jump to the image view page and view the teeth images that have been shot
	<	A prompt box will pop up, "Closing the detector, please wait a moment", and then return to the home page



5.5 Image View Page



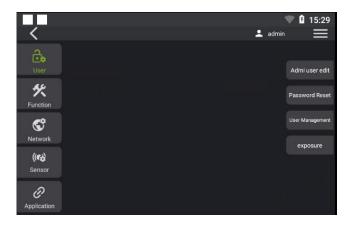
In this page, you can perform some related operations on the image, including post-processing and image translation and rotation operations. The detailed functions of the buttons on the interface are described in the following table:

Item		Description
Reset		Reset the operated image and undo the previous operation
Rotate		Click this button, and the image rotates 90° clockwise every time
Annotation		You can mark where the image needs to be marked
WW/WL WW/WL		Click to adjust the window width and window level of the selected image
Export		The acquired images can be exported to the PC via a data cable
Save		Save the image to the local, supporting .jpg, .raw, .dicom three formats
Patient information		Display patient ID number, name, gender, date of birth, image, etc.
	Enhance edge	Enhance the edge of the image, the range is $0\sim100$, the default value is 75
Advanced	Reduce noise	Perform noise reduction processing on the image, the range is $0\sim30$, the default value is 5
	Enhance contrast	Enhance the contrast of the image, the range is 0~5, the default value is 3
	Adjust light/dark	Adjust the overall brightness and darkness of the image, the range is $1{\sim}50$, the default value is 10
	High threshold	Adjust the high threshold of the image, the range is 0~5, the default value is 1



Item		Description
	Low threshold	Adjust the low threshold of the image, the range is $0\sim5$, the default value is 1
	OK	Click OK, and the processed image will be obtained if the set parameters do not exceed the range
	Exit	Click the button to return to the image browsing interface, and the image is the processed image

5.6 Setting Page



This page is mainly used to set account, function, network, sensor, and application connection mode.

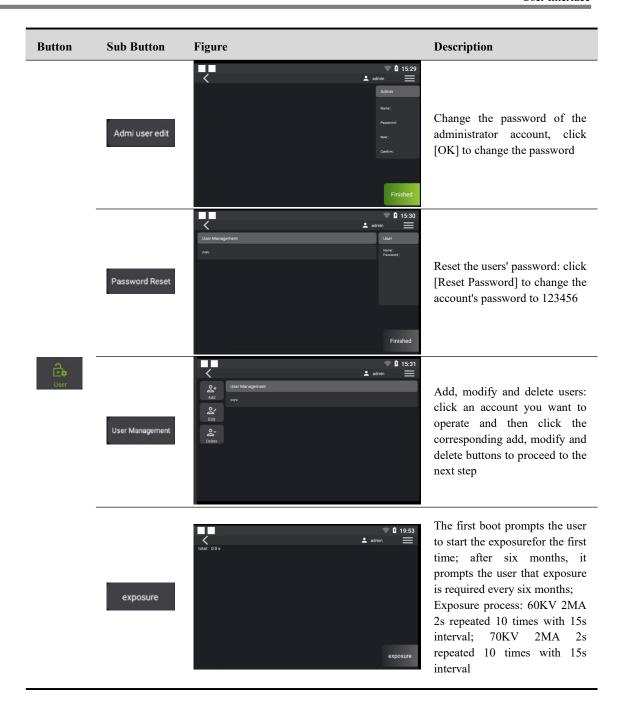
■ General User's Functions

Button	Description
* Function	Jump to the Android system for settings, such as brightness, wifi, etc.
© Network	This page is still under development
((Ca) Sensor	Set the country code, account number, password, detector IP of the connected sensor
⊘ Application	Select the applied connection mode, such as demo mode, independent mode, intelligent filming mode, etc.

■ Administrator's Functions

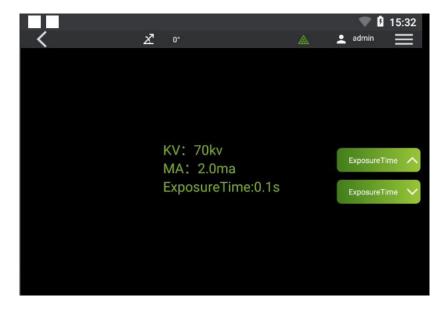
Rutton	Sub Rutton	Figuro	Description
Button	Sub Button	Figure	Description







■ Exposure Time Setting



You can enter the independent exposure mode by clicking the [application] button of the setting page and selecting the independent mode.

The exposure time can be controlled by clicking the ExposureTime increase or decrease on the screen, and the exposure time can also be adjusted through the physical buttons of the equipment head. exposure is performed by long pressing the 1S exposure button, and the exposure conditions are battery voltage, power level, tube temperature, and time interval. Only when certain conditions are met, a buzzer will be heard during exposure, and the end of the buzzer indicates the end of the exposure. If the exposure button is released during the buzzer sound, the exposure will end at any time.

Press and hold the exposure button on the equipment for 1 second to expose exposure. When certain conditions are met for battery voltage, power, tube temperature, time interval, and detector status, exposure can be performed. During exposure, you will hear a buzzer sound, and the end of the buzzer indicates the end of the exposure. If you release the exposure button during the buzzer sound, the exposure will end at any time.

You can change the exposure judgment adjustment by modifying the configuration file, such as the range of exposure temperature, the range of battery power, the range of battery voltage, the interval of exposure time, the voltage and current during exposure;

The path to the configuration file is in Explorer /iray/default.config. Open the file with an editor, edit and save it. The configured parameters are kv, ua, minTemp, maxTemp, minBattery, maxBattery, minVoltage, maxVoltage, isMarket. Among them, when isMartket is set to false, the time interval of two exposures is 30 times, and when it is set to true, the time interval of two exposures is 7 times. The relevant configuration file page is shown in the figure below





6 Service Information

6.1 Service Life

The estimated product lifetime is up to 7 years under appropriate regular inspection and maintenance.



- The product life is decided by that of the equipment.
- For other replaceable parts, their service life will not affect the life cycle of the whole product.
- Main parts (parts required to maintain the function of the product) of this product will be stocked for 5 years after discontinuance of production for repairing.

6.2 Periodic Inspection and Maintenance

To ensure image quality and the safety for the patient and operator, it is highly recommended that periodic inspection and maintenance be carried out by the qualified maintenance personnel.

Item	Operation	Frequency
Pre-startup check	Before operation, check if the equipment is clean and ready for use	Daily
Post-shutdown check	After each use, check if the equipment has been turned off	Daily
Sceen	Check if the screen can be displayed normally when starting.	Daily
Exposure button	Check if the exposure indicator light turns on when the exposure button is pressed.	Daily
Buzzer	Check if the buzzer sound works OK	Daily
Charging LED indicator	Check if the battery charging LED indicator comes on when charging the battery.	Daily
Labels	Check if all visible labels are intact and legible.	Monthly
Battery	Check the battery life and check whether the battery is swollen	Yearly
Enssential performance	The enssential performance of the equipment should be tested by the local third-party organization.	Yearly





For the maintenance and overhaul involving the disassembly of the equipment enclosure, contact qualified service engineers. Please contact iRay's Customer Service Department or your product distributors.

6.3 Disinfection and Cleaning

In order to ensure proper hygiene and cleaning of the equipment, the following steps must be followed:

- Wipe the surface of the equipment with a cloth/wipe moistened disinfectant to disinfect the patient's contact surface, 96% ethanol is recommended;
- Wipe off the disinfectant with a cloth/wipe dampened with water and dry the surface with a dry cloth/wipe;
- Store the equipment in specified environment when the surface turns dry.



- The equipment must be powered off before disinfection and cleaning the equipment.
- Disposable cloth or wipe should be used instead of reusable one.

6.4 Troubleshooting

If any fault occurs but cannot be solved, turn off the equipment and contact iRay's Customer Service Department (service@iraygroup.com) for professional technical support and provide the following information as per the product label:

Name and model of product

Product SN

3 Description of product failure as detailed as possible

6.5 Manufacturer Information

Company: iRay Imaging Technology (Haining) Limited

Residence: No. 2, Caohejing RD., Haining 314499, Jiaxing, Zhejiang, P.R.China

Tel: +86-21-50720560

CS dept.: Customer service of iRay Imaging Technology (Haining) Limited

CS dept. address: No. 2, Caohejing RD., Haining 314499, Jiaxing, Zhejiang, P.R.China

CS tel: +86-21-50720560

CS fax: +86-4008266163-60610



CS email: <u>service@iraygroup.com</u>

Website: <u>www.iraygroup.com</u>

6.6 Factory Site

Factory: iRay Imaging Technology (Haining) Limited

Address: 3rd floor, Building 1, No. 2, Caohejing RD., Haining 314499, Jiaxing, Zhejiang,

P.R.China

Tel: +86-512-53690872





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Website: www.iraygroup.com