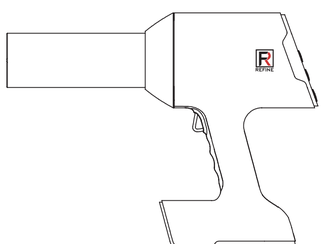
Portable Dental X-ray User Manual



Guilin Refine Medical Instrument Co., Ltd.

RF-UGT-M001 Version: 1.1 20240703

Introduction

Dear customer,
Thank you for selecting our product!
In order to use the product correctly，please read the users, manual carefully before using the equipment.
The equipment is only for qualified professional technicians and trained or qualified professionals (such as a dentist) in the hospital or clinic to use.
The equipment belongs to the radioactive equipment, the operator should operate the equipment according to the users, manual, the equipment shall not be used for other purposes except for medical radiography.

The following identifiers are used on the equipment, their meanings are as follows:

Symbol	Description	Symbol	Description
~	AC	⎓	DC
⚠	Caution	⚠	Dangerous warning for ionizing radiation
	Follow the operating instruction		Do not discard the electronic equipment casually, according to the regulations, the equipment should be disposed according to the local legal requirements, after the useful life.
	Type B application section		X-ray emit or imminent emit
	Standby		Dangerous Voltage
	Manufacturer	EC REP	Authorized representative in the European Community
	Class II equipment	MD	Medical device
	Date of manufacture		Protective ground

Chapter 1 Overview

Product Basic Information

Product Name：Portable Dental X-ray
Working principle: The high voltage generator provides high voltage to both ends of the X-ray tube filament and metal target in the internal X-ray source assembly, a large number of electrons are generated on the cathode filament of the X-ray tube and move at a high speed in the vacuum tube, impacting the metal target to generate the X-ray. The X-ray penetrate the different tissue densities of the body, such as teeth and muscles after passing through the X-ray window and beam tube, the X-ray which carry image information through body tissue, are passed through image receiving devices such as phosphor sheets, film or digital image receivers, to show different densities of human tissue images.
Application Range: used on the teeth to take an X-ray radiograph, with an intraoral image receiver, images are obtained for the clinical diagnosis.
Intended users: Dentists
Intended patient population: Adults and children
Structural composition: the product consists of the host (including the X-ray tube, controller and rechargeable battery), beam limiting tube, power adapter, stand and exposure switch.
Product model：GT-1

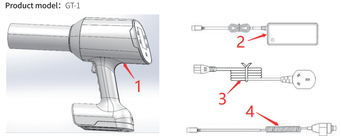


Figure 1-1 GT-1 Main Components

1—Host，2—Adaptor，3—Power Cable，4—Exposure Switch（optional）
Contraindication: Do not use it on people with cardiac pacemakers or pregnant women. Use it carefully on children.
Main features: the product is a high frequency dental X-ray equipment, rated tube voltage is 65kV DC, rate tube current is 2.5 mA, the inverter X-ray control method is adopted, for chemical film and digital sensor diagnostics to obtain high quality dental images, the power supply of GT-1 is 14.4V DC, powered by a rechargeable battery pack.

Chapter 2 Product Description

2.1 Technical specification

2.1.1 Product technical specification

Serial number	Name		Parameter value
1	Power Adapter	Input Voltage	Uniphase AC 220V，±10%
		Supply Frequency	50/60Hz，±1Hz
		Input Power	330W
2	Output Power		37.8W
3	Charge voltage		DC 25.2V
4	Charge current		1.5A
5	Nominal value of the focal point		0.4mm
6	Anode angle		15°
7	Available maximum tube voltage at 2.5mA		65kV
8	Maximum output electric power		162.5W
9	Maximum loading factor combination		65kV，2.5mA，2s
10	Repeatability of radiation output		No more than 0.5
11	Tube voltage (The deviation is within the range of ±10%)		65kV
12	Tube current (The deviation is within the range of ±20%)		2.5mA
13	Running mode		Discontinuous operation, maximum excitation (open) time：minimum excitation (close) time＝1：30
14	Total filtration of X-ray tube assembly		＞2.5mm Al
15	Intrinsic filtration of X-ray tube assembly		0.75mm Al
16	Additional filtration		1.5mm Al
17	Half-value layer		≥ 1.5mm Al（65kV）
18	Leakage radiation		≤ 0.25mGy/h（65kV，2.5mA，2s）
19	Adjustment range of the loading time		0.02 ～ 2.00s, adjustable by R10 coefficient
20	Distance of the Focal point to skin (The deviation is within 0~5%)		214mm±3mm
21	X-ray field size at the end of beam limiting tube		round，Φ54mm ± 3mm
22	Nominal electric power		0.16kW（65kV，2.5mA，0.1s）
23	Available maximum tube current at 65kV		2.5mA
24	Inverter frequency of the high voltage generator		80kHz

2.1.2 Product basic safety features
Safety category：Class Ⅰ or internal power supply class，do not use when charging.
（a）Classified by electric shock protection type：Type B application section.
（b）Classified by the degree of protection against fluid intake：Common equipment.
（c）Classified by the manufacturer’s recommended disinfection and sterilization methods：As required by the manufacturer to carry out.
（d）Classified by the degree of safety for use with flammable anesthetic gases mixed with air or with oxygen or nitrous oxide：Non AP/APG type.
（e）Classified by operation mode：Discontinuous operation，Maximum excitation (open) time：Minimum excitation (close) time＝1：30.
（f）The product has no application part with protection against defibrillation discharge effect.
（g）Whether the equipment has a signal output or input part：No.
（h）The product is a common equipment.
（i）Permanent or non-permanent installation equipment：Non-permanent installation equipment.
（j）Radiation type：Ionizing radiation.
（k）Radiation property：X-ray.
（l）Radiation distribution：The X-ray radiates from the positive direction of 6cm circle in the window of the limited beam barrel when used.

2.1.3 X-ray tube technical specification

Serial number	Name	Parameter value
1	The X-ray tube model	XD10DF-0.2/70
2	Nominal value of the focal point	0.4mm
3	Target material	Tungsten
4	Maximum working tube voltage	70kVP
5	Anode angle of the X-ray tube	15°
6	Intrinsic filtration	0.75 mm Al
7	Filament current	2.0 A
8	Filament voltage	2.35~3.35 V

The emission characteristics of X-ray tubes are shown in Figure 2-1.

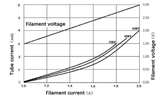


Figure 2-1 Filament emission characteristics of X-ray tube

The X-ray tube load characteristics are shown in Figure 2-2

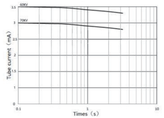


Figure 2-2 Load characteristics curve

Heating and cooling characteristics of the anode are shown in Figure 2-3

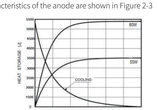


Figure 2-3 Heating and cooling characteristics of the anode

The X-ray tube dimension is shown in Figure 2-4.

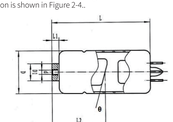


Figure 2-4 Dimension

L	L1	L2	D	D1	d
68±2mm	4.5±1mm	37±0.5mm	Φ30±0.1	Φ12±0.1	M4

2.1.4 Product software
Software name：The control software of the dental X-ray system
Release version：V1.0.0

2.2 Warnings and cautions

2.2.1 Warnings
⚠ **Warning:** To avoid the risk of electric shock，the product must be connected to the power supply network with protective grounding when charging.
⚠ **Warning:** The users, manual instructs product operators to operate the product safely. The product should only be used by persons with the necessary radiological knowledge and training，the manufacturer is not responsible for any improper operation, negligence or improper use.
⚠ **Warning:** The power supply of the host must be turned off when the exposure is over.
⚠ **Warning:** When taken an X-ray radiograph for tooth，the medical staff should always monitor during exposure.
⚠ **Warning:** Ionizing radiation.
⚠ **Warning:** Do not place the equipment on the position that is difficult to operate the disconnecting device. The equipment uses a flexible wire with a mesh power plug as a breaking device.
⚠ **Warning:** Modification of the product is not permitted.

2.2.2 Cautions
（a）In order to use the product correctly, please read the users, manual carefully before using the equipment.
（b）The equipment is only for qualified professional technicians and trained or qualified professionals (such as a dentist) in the hospital or clinic to use.
（c）The equipment belongs to the radioactive equipment, the operator should operate the equipment according to the users, manual, the equipment shall not be used for other purposes except for medical radiography.
（d）The equipment should not be used when there is any electrical or mechanical fault.
（e）The protective circuit and protective facilities of the equipment shall not be removed when it’s powered on.
（f）The equipment must not be used in a humid, flammable, or explosive environment.
（g）Any modification to the equipment shall be approved by our company or its authorized maintenance personnel.
（h）Ensure that there is no risk to the patient or the operator when replace the components of the equipment, if necessary, contact our maintenance personnel.
Any improper operation of the equipment will cause damage to the equipment, regular inspection and maintenance is also necessary. Our company assumes full responsibility for any loss of life or property caused by the quality of this product., except for those who do not follow the user’s requirements and change the system manually or without authorization.

2.2.3 Electric safety
（a）Ensure the voltage and current meet the power requirements of the product.
（b）Ensure there is no flammable or explosive gas leakage in the room where the equipment is located.
（c）Ensure the battery charger is unplugged before cleaning. Cleaning should be carried out when the equipment is powered off, only use non-alcohol sanitizer wipes or cloths dampened with liquid or spray.
（d）GT-1 and the included battery charger is not suitable for any type of disinfection.
（e）Turn off after use.

2.2.4 X-ray protective safety
Ensure that precautions are taken against X-ray before each exposure, keep the following in mind:
Wear protective barriers during the X-ray examination.

Irradiation dose should be as low as possible when x-ray examination permits.
（a）Human skin should be as far away from X-ray sources as possible, as long as diagnostic requirements are met.
（b）The radiation exposure and absorbed radiation dose are inversely proportional to the square of the distance from the radiation source, the farther away you are from the source, the lower the dose you receive. The operator should be 3 meters away from the X-ray tube head.
（c）The X-ray Generated by the equipment has certain harm to human body. Besides operating GT-1 properly to ensure normal operation, it is more important to pay special attention to the protection of human body against X-ray, so as to minimize the harm of X-ray operators and patients. For example, the equipment room should have protective equipment and measures (such as lead plates), and the operator must use protective equipment (such as lead glasses) and wear protective clothing (such as lead caps, lead aprons, and lead gloves). The operator must operate in an occupied area when approaching patients for radiological examination.

Chapter 3 Product operation instruction

3.1 Product overall layout

3.1.1 The host view

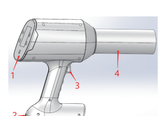


Figure 3-1 The host view

Figure 3-1 functional descriptions：

Serial number	Position	Name	Functional descriptions
1	“1”	Operation panel	See the details below at 3.2.
2	“2”	Adapter or exposure switch connection port	Open the cover and plug the adapter charging cable into the port to charge, internal battery.Plug put the exposure switch cable into the port to connect the, exposure switch.
3	“3”	Exposure switch	Press the exposure button to activate the X-ray exposure.
4	“4”	Beam tube	The pathway for the X-ray beam to travel from the X-ray source to the patient’s mouth.

3.1.2 The battery cover of the host base view

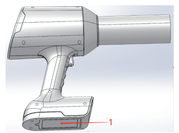


Figure 3-2 The battery cover of the host base view

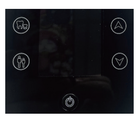
Figure 3-2 functional descriptions：

Serial number	Position	Name	Functional descriptions
1	“1”	Battery cover	Open the battery cover to replace the battery.

3.2 Operation panel description

3.2.1 Operation panel

Press key



Touch key

Figure 3-3 Operation panel

Figure 3-3 functional descriptions：

Serial number	Keypad	Name	Functional descriptions
1		Power On/Off button	Turn on or turn off the equipment power supply
2	or	Patient body type selection button	Select body type large/small
3	or	Up button	Increase loading time
4	or	Down button	Decrease loading time
5	or	Teeth type selection button	Select teeth type

3.2.2 Product operating description
（a）Product power ON/OFF
Power ON：press the power On/Off button，GT-1 powers on，the buzzer beeps，the screen lights up, ensure that at least one bar of power is available before starting the equipment.
Power OFF：press the power On/Off button，the buzzer beeps，GT-1 powers off.
Enter the main interface：

Figure 3-4 Main interface

Figure 3-4 functional descriptions：

Serial number	Symbol/Value	Name	functional descriptions
1		Tooth	Display the selected tooth type
2		Standby/Pre-exposure/Exposure	Indicate Standby/Pre-exposure/Exposure state
3		Battery level	Display the battery level
4		Patient	Display the selected patient type
5	65kV	Exposure tube voltage	Display the fixed exposure tube voltage
6	2.5mA	Exposure tube current	Display the fixed exposure tube current
7	2.000	Exposure time	Display the set exposure time
8		Charge reminder	The battery needs charging
9		Receptor	Display the receptor that receive X-ray
10	24°	Angle	Display the photograph angle
11		Child lock	Lock or unlock
12		Await symbol	End await (gray)/Await state (blue)

（b）Body type large/small selection button
Select the type of patient，please press the patient body type selection button （or ）.
The corresponding symbol will be displayed in blue on the screen.
（c）Teeth type selection button
To select the tooth type，please press the teeth type selection button （or ），the corresponding tooth type symbol will be displayed on the screen, as shown in Table 1-1

Table 1-1

Teeth type							
Description	Upper canine tooth	Lower molar tooth	Upper molar tooth	Wing bite teeth	Lower front tooth	Upper front tooth	Lower canine tooth

（d）Standard exposure time
Preset standard exposure time as shown in Table 1-2.

Table 1-2

Patient type	Receptor type							
Child	Sensor	0.1	0.125	0.2	0.32	0.08	0.08	0.1
Adult	Sensor	0.25	0.2	0.32	0.4	0.16	0.16	0.25
Child	Photophor	0.125	0.16	0.25	0.4	0.1	0.1	0.125
Adult	Photophor	0.32	0.25	0.4	0.5	0.2	0.2	0.32
Child	Film	0.2	0.25	0.4	0.63	0.16	0.16	0.2
Adult	Film	0.5	0.4	0.63	0.8	0.32	0.32	0.5

（e）Radiograph angle
The patient keeps a correct seated position, sitting on a chair upright. Adjust the photograph angle of the X-ray machine, the reference values of the photograph angle are as shown in Table 1-3.

Table1-3

Tooth	X-ray direction	Recommend angle
	Down-tilted	+45°
	Up-tilted	-5°

	Down-tilted	+30°
	Down-tilted	+5° ~ +8°
	Up-tilted	-25°
	Down-tilted	+45°
	Up-tilted	-20°

(f) Exposure time

Change the exposure time, please press the Up button (or) to increase the exposure time, or press the Down button (or) to decrease the exposure time.

(g) Exposure operating steps

- Firstly set the exposure conditions you want for radiograph.
- Fix the sensor to the opposite side to be exposed, then connect the device in the exposure section.
- Press the exposure button .
- When the Exposure starts, the pre-exposure symbol " " will be displayed on the screen, then the exposure symbol " " will be displayed on the screen. Meanwhile, the buzzer beeps.
- After radiographs are taken, the screen will display standby symbol " ", the next exposure can be made.
- 400 radiographs can be taken if battery is fully charged. (exposure condition : 0.5s exposure time at an 120s-interval)
- Please charge before exposure if the battery level has only 3 bars or less.

(h) Battery charge and exchange

- Charge

The battery level displays at the top right corner on the screen. It will influence image quality if the battery level is low. Therefore, you must always check the battery state. If the battery level is low, The charge reminder on the screen next to the battery symbol indicates charging is needed.It takes about two hour to fully charge, the indicator light on the adaptor is red when charging and turns green when it's fully charged; Turn off the equipment when charging.

The white charge reminder on the screen next to the battery symbol indicates the adapter has plugged in and it's charging. It'll remain on the screen until the adapter has been pulled off..

(i) Mode Setting

Press the button combination (+ or +), enter the setting interface to set modes, see figure 3-5.

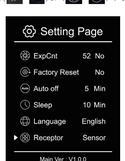


Figure 3-5 Setting interface

- ExpCnt (Exposure count)

In the mode setting interface, press the Up button (or) or Down button (or) to select the ExpCnt, then press the patient body type selection button (or), the exposure number following ExpCnt turns blue, press the Up button (or) or the Down button (or) again, set the No to Yes, press the patient body type selection button (or) to clear the exposure number, press the button combination (+ or +) to exit the setting interface and return to the main interface.

- Factory Reset

Restore factory defaults.

In the mode setting interface, press the Up button (or) or Down button (or) to select the Factory Reset, then press the patient body type selection button (or), the No following Factory Reset turns blue, press the Up button (or) or the Down button (or) again, set the No to Yes, press the patient body type selection button (or) to restore factory defaults, return to the main interface automatically after the factory defaults is restored.

- Auto OFF

If the equipment is not working within the Auto OFF time, the equipment turns off automatically to prevent unnecessary power consumption.

In the mode setting interface, press the Up button (or) or Down button (or) to select the Auto OFF, then press the patient body type selection button (or), the time following Auto OFF turns blue, press the Up button (or) or the Down button (or) again, to set the Auto OFF time, press the patient body type selection button (or) again, the time following Auto OFF turns white, save the Auto OFF time, press the button combination (+ or +) to exit the setting interface and return to the main interface.

- Sleep time

If the equipment is not working within the sleep time, it will go into sleep mode automatically.

If you want to change the sleep time, please press the button combination(+ or +) to enter the setting interface, then set the sleep time.

In the mode setting interface, press the Up button (or) or Down button (or) select the Sleep time, then press the patient body type selection button (or), the time following Sleep time turns blue, press the Up button (or) or the Down button (or) again, to set the Sleep time, press the patient body type selection button (or) again, the time following Sleep time turns white, save the Sleep time, press the button combination (+ or +) or (+) to exit the setting interface and return to the main interface.

- Language

The user can choose the language between English and Chinese.

In the mode setting interface, press the Up button (or) or Down button (or) to select the Language, then press the patient body type selection button (or), the English following Language turns blue, press the Up button (or) or the Down button (or) again, set English to Chinese, or set Chinese to English, press the patient body type selection button (or) again, the English or Chinese turns white, save the language, press the button combination (+ or +) or (+) to exit the setting interface and return to the main interface.

- Receptor

The user can choose a receptor between the sensor , the photophor and the film to receive the X-ray.

In the mode setting interface, press the Up button (or) or Down button (or) to select the Receptor, then press the patient body type selection button (or), the sensor or the photophor or the film following the Receptor turns blue, press the Up button (or) or the Down button (or) again, set the appropriate receptor, press the patient body type selection button (or) again, the appropriate receptor turns white, save the appropriate receptor, press the button combination (+ or +) or (+), to exit the setting interface and return to the main interface.

- Main Ver

Main Ver：Software version.

- Child lock

Press the button combination (+ or +) to lock or unlock the screen. The unlock symbol is displayed on the screen when the screen is unlocked. The lock symbol is displayed on the screen when the screen is locked.

When the screen is locked, the following operations are prohibited: exposure operation, adjusting the exposure time, selecting the body type, selecting the tooth position, entering the setting screen and angle refreshing the display.

3.3 Matters to be noted during use

3.3.1 The X-ray image receptor will affect the image quality，the digital sensor that obtains the filing certificate of Class II medical device is needed.

3.3.2 During exposure, the host should be held in a steady position to avoid the image degradation due to dithering.

3.3.3 The equipment should be placed in a clean and dry room with air circulating to avoid humidity, high temperature and heavy sunshine.

3.3.4 Each button shouldn't be applied to much force on to prevent dislocation poor contact, even damage.

3.3.5 Turn off the equipment after use.

3.3.6 Avoid impacts.

Chapter 4 Installation、Maintenance and Maintain

4.1 Product Installation

4.1.1 Zone of significant occupancy

The zone of significant occupancy is shown in figure 4-1.

The zone of significant occupancy shall be provided when the operator is required to be present, the area is no less than 200cm * 60cm, the height is no less than 200cm.

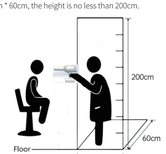


Figure 4-1 Zone of significant occupancy

4.1.2 Power Adapter Connection

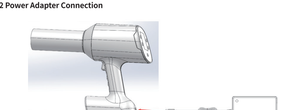


Figure 4-2 Power adapter connection

The power adapter connection is shown in Figure 4-2，put the adapter Type-C plug into the adapter connection port of the host, the adapter AC plug connect with the user AC220V to charge.

4.1.3 Exposure Switch Installation

Figure 4-3 Exposure switch

The exposure switch installation is shown in figure 4-3, plug the exposure switch into the exposure switch connection port.

4.2 Equipment Maintenance

4.2.1 General Principle

The equipment needs regular maintenance:

(a) Keep the room clean, dry, well ventilated.

(b) The equipment should be taken charge by special personnel with management files.

(c) In order to ensure the safety of user and patient, the equipment shall not be reformed at will. If necessary, please contact manufacturer.

(d) The professional must be recognized by the manufacturer to inspect and repair the equipment if any any malfunction occurs.

(e) The operator should be well trained and able to complete the routine inspection.

(f) If the X-ray tube has not been used for a long time (such as more than 1 month), it must be loaded gradually before use, that is, the exposure time should be loaded twice successively from 0.02s → 0.1s → 1.0s to avoid the X-ray tube damage caused by excessive instantaneous power.

4.2.2 Clean

A soft brush or cleaning cloth should be used to clean the visible pollutant of the equipment surface, dampen the gauze with alcohol (alcoholicity 70-80 vol%) to wipe the surface.

⚠ **Warning:** When performing the above cleaning work, the power supply of the unit must be turned off！Cleaning liquid shall not go into the unit to avoid circuit leakage and short circuit, and a variety of failures that might even result in personal injury accidents.

4.3 Product Maintenance

4.3.1 Daily Maintenance

(a) The equipment surface should be kept clean and dry, use a soft cloth dipped in a little anhydrous alcohol to scrub the surface of various residues.

(b) Flammable liquids and gases should not approach the equipment to prevent explosion.

4.3.2 Cleaning and maintenance that can be performed by authorized technicians

Dental X-ray system is a precise and valuable medical diagnostic equipment, the user should understand the technical performance, structural principle and operating procedures of the equipment, perform the routine maintenance and maintain, to give full play to the efficiency of the equipment, extend the service life, ensure the normal operation of the equipment, ensure the safety of operators and inspected personnel.

4.3.3 Maintain and Maintenance Cycle

Time Interval	Maintenance and inspection contents
Daily Check	Check signal, display and indicator light. Check the buzzer. Check if there is any abnormal sound when the high voltage generator is exposed. Check if any button is loose or stuck.
Monthly Check	Check the continuous endurance of the used battery .
Annual Check	Safety checks must be carried out on the equipment to ensure the equipment runs properly.

4.4 Normal working and transportation storage conditions

4.4.1 Normal working condition

(a) Environment temperature：10℃～ 40℃

(b) Relative humidity：30% ～ 75%

(c) Atmospheric pressure：700hPa ～ 1060hPa

(d) Altitude：⩽ 2000m

4.4.2 Transportation and storage conditions

(a) Environment temperature：-20 ～ 55° C

(b) Relative humidity：10% ～ 93%

(c) Atmospheric pressure：70kPa ～ 106kPa

4.4.3 Waste disposal

Concerning waste disposal shall be complied with the local laws and regulations when the equipment is scrapped. The X-ray source assembly and electronic circuit (such as PCB, etc.) related parts shall be regarded as non-environmentally friendly waste products.

Chapter 5 Common troubleshooting and others

5.1 Fault diagnosis and resolution

5.1.1 Fault codes and troubleshooting method

During normal and abnormal operation, the status will be displayed on the screen. We provide common fault symptoms and suggested measures for troubleshooting. Users can refer to the solutions provided to troubleshoot the fault. If you cannot identify the cause of the fault, or if you have tried the following methods but still cannot resolve the fault, please contact us.

The error code is displayed on the screen, when any of the following faults occur. The error code content and troubleshooting methods are described in table 5-1.

Table 5-1

Error Code	Description	Recommended measure
ERR0	Connection fail	Turn off and restart
ERR1	Overcurrent protection or disconnection of tank line or mA, kV is to high.	Contact the technical support
ERR2	kV too low	Contact the technical support
ERR3	mA too low	Contact the technical support
ERR4	Filament driving voltage is low	Contact the technical support

If the equipment can't turn on, or can't expose normally, or is charging abnormally, the battery could be faulty. Please contact our engineers to replace the battery, unauthorized personnel should not open the product shell.

If the exposure button is pressed for a shorter time than the set exposure time, the " " displayed on the screen, press the patient body type selection button ,or Up button or Down button to remove the " " to make an exposure.

5.1.2 Circuit diagram of the product

Any operation relating to maintenance involving access to the interior of the equipment must be performed by our Company's engineers. If Circuit diagram, drawing notes, calibration rules and other relevant data related to the maintenance of this product are required, our company will provide the data that can be provided.

5.2 Quality Guarantee

5.2.1 Manufacturer's Responsibility

The manufacturer shall be responsible for the safety, reliability and performance of the equipment in the following cases:

(a) Assembly, debugging, modification and maintenance are carried out by our company or authorized personnels by our Company.

(b) The electrical facilities used in the equipment meet the requirements specified in the user manual.

(c) The operators are skilled technicians who have received training and use the equipment in strict accordance with the requirements of the user manual.

5.2.2 Guarantee content

(a) The quality of the product is guaranteed for one year from the date of purchase.

(b) The equipment is damaged because the user fails to comply with the above terms and conditions, or more than one year since the date of delivery of the equipment, our company will repair or replace parts for the user, but will charge the cost of maintenance.

(c) If it is difficult to identify the warranty period, the warranty shall apply after three months of manufacture.

(d) For defects of the product or improper process, we'll provide free maintenance or replacement according to the state of the product.

(e) If the damage is caused by the user's fault, the repair won't be free even within the warranty period.

(f) If additional grades of seals have been removed or have such instructions, they shall not be free repair.

(g) Repairs performed in places other than our company or without our company's authorization are not covered by the warranty.

(h) The service life of the product which are free or have been repaired for free shall not be extended.

5.3 Product life and manufacturing date

The product operating life is 5 years, the manufacture date see the nameplate of the equipment

5.4 Packing List

The host, the base, the exposure switch (optional), the adaptor, the power cable, the protection plate (optional) contained in the product, one piece each.

Chapter 6 Electromagnetic Compatibility

The ME EQUIPMENT or ME SYSTEM is suitable for use in in hospitals or dental clinics.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

List of all cables:

Name	Length (m)	Whether shield
Power cable	1.0	NO
Adapter cable	1.0	NO
Exposure switch connection cable	3.0	NO

Performance of the me equipment

1. Accuracy of loading factors.
2. Repeatability of radiation output.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° . 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° . 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° . 0 % UT; 1 cycle and 70 % UT; 25cycles; Single phase: at 0° . 0 % UT; 250 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 ~ 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 ~ 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710 745 780	704 ~ 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	810 870 930	800 ~ 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	1720 1845 1970	1700 ~1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2400 ~2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	5100 ~5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2,1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5

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