PIOS-EX5

Intraoral Digital Impression Instrument
Instruction for Use

MODEL:PIOS-EX5

CE

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1. General Information



CAUTION

Be sure to observe all warnings!
Please observe all safety information and warnings to prevent personal injury material damage or damage to your instrument.Safety information and warnings are highlighted in this IFU using the words WRNING, CAUTION.

The symbols used in this document imply the following:



WARNING

Warnings regarding situations where a risk of injury to person exists if the information is not observed.



CAUTION

Safety information where hazards such as:loss of data, invalidation of warranty or service contract, risk of property damage, damage to the instrument exist if the information is not observed.

2. Product Information

Product Name	Intraoral Digital Impression Instrument		
Model	PIOS-EX5		
Manufacturer Name	Ziyang Freqty Medical Equipment Co.,Ltd.		
Manufacturer Address	Floor 2-3, unit 7, building 3, No. 222, West Section 3, outer ring road, Yanjiang District, Ziyang City, 641300, Sichuan Province, P.R.China		
Manufacturer Contact	Tel: +86-028-26577388 | E-mail[1] : sales@freqty.com , support@freqty.com		
Method of Sterilization	By moist heat such as by autoclave (scanner head[2])		
Protection Against Electric Shock	Neither class I or class II equipment, DC 5V supplied by computer through USB.		
Applied Part	Type B		
Defibrillation-proof Applied Part	No	Mode of Operation	Continuous operation.
Protection Against Harmful Ingress of Water or Particulate Matter	IPX0	Suitability for Use in An Oxygen rich environment	No

[1]Product consultation: sales@freqty.com. After-sales service: support@freqty.com

[2]Commonly referred to as Tip.

3. Product Composition

The product is composed of the probe, the calibrator, scanner head, the probe bracket and the supporting software (release version: V1)
The scanner head is applied part.

The structure of PIOS-EX5 is showed as below Fig. 1

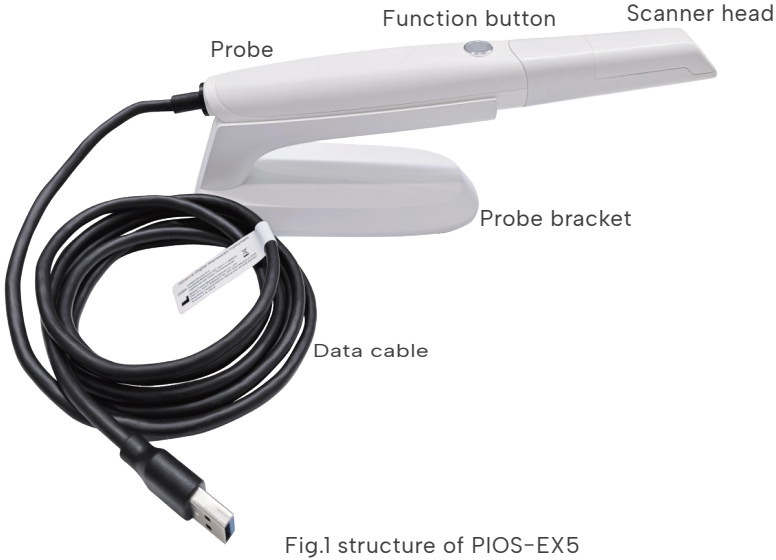


Fig.1 structure of PIOS-EX5

4. Main Dimension

Total size	222mm (L) *33mm (W) * 28mm (H)
Size of scanner head	87mm (L) *21 mm(W) *15mm (H) window:18*16mm

5. Intended Use and Contraindication

5.1 Intended Use

This product uses the optical scanning method to obtain the three-dimensional shape feature data of the surfaces of teeth, gums and other tissue. It outputs the three-dimensional digital impression data which can be used in the CAD / CAM denture design and processing.



WARNING

Unintended use of instrument can results in physical injury to patients, operators and damage to the product.

5.2 Users

Dental professionals such as trained physicians, physician assistants, technicians, etc.

5.3 Contraindication

No known contraindications.

6. Environmental Requirements

Operating conditions					
Temperature	5℃ ~ 30℃	Relative Humidity	≤80%	Atmospheric Pressure	700hPa ~ 1060hPa
Operating Environment	Home healthcare environment and professional healthcare facility environment. Indoor operation, prevent direct sunlight and strong lights, and keep away from electromagnetic sources, cold and heat sources, and vibration sources				

Transport conditions					
Temperature	-10℃~55℃	Relative Humidity	≤93%	Atmospheric Pressure	700hPa ~ 1060hPa

Storage conditions					
Temperature	-10℃~55℃	Relative Humidity	≤93%	Atmospheric Pressure	700hPa ~ 1060hPa
A clean indoor environment. Protect from moisture, corrosion, and direct sunlight.					

7. Working Power Requirements

- Powered by USB3.0 port of computer: 5V ⎓, 0.9A

8. Safety Information

8.1 Prerequisites



CAUTION

Read all instructions carefully including all warnings and cautions. You must comply with the warnings in the IFU to prevent injury to persons and damage to Intraoral Digital Impression Instrument(hereinafter referred to as instrument). Proper functionality and safety can only be guaranteed if the safety precautions in this IFU and on the instrument are observed.

Preventive inspection before use of the instrumen



CAUTION

Please examine the instrument for any mechanical damage on:

- All enclosures
- All cables

Safety can only be guaranteed if NO DAMAGE on the instrument is observed.



WARNING

The instrument is powder-free scanning. That is, there is no need to spray optical enhancement powder. If it is clinically necessary to spray teeth with the powder, please strictly follow the instructions for the use of optical enhancement powder and ask the patient's medical history.

Modification



WARNING

No modification of this instrument is allowed.

Approved software only



CAUTION

Install only approved software to prevent interference with the runtime reliability of the instrument and programs within it.

Proper training



CAUTION

Before you attempt to use the device with patients.

- You should be trained to use the device or have read and understood all sections of this specification describing correct operation.
- You should also be thoroughly familiar with the safe operation of the device as described in this documentation.

In case of instrument failure



WARNING

If at any time the instrument malfunctions, or if you suspect in any way that the instrument is not working correctly:

- Remove the instrument from contact with the patient.
- Unplug the probe and make sure it cannot be used before it is checked.
- Contact your reseller.
- DO NOT attempt to open any covers on the instrument.

Patient condition



CAUTION

Before using the instrument, it should be confirmed whether the patient is suitable for intraoral scanning, including but not limited to:

- Check the patient's oral condition, such as oral mucosal disease, and consider not performing oral scans or avoiding the infected part based on the patient's condition;
- Ask the patient's medical history, such as mental illness, Parkinson's disease, ADHD, epilepsy, etc., to determine if the patient is currently able to cooperate with intraoral scanning.

8.2 Mechanical Hazards

Dropped or damaged instrument



WARNING

If you drop a scanner head on the floor, you MUST dispose of it immediately and NOT use the same scanner head again for scanning.
There is high risk that the mirror in the scanner head has become dislodged and can fall out.



CAUTION

If the probe body is dropped or bumped it should immediately be calibrated before further use. If calibration fails, please contact your technical service provider. See instructions on Calibrating the instrument.

8.3 Explosion Hazards

Environment



WARNING

The product is not designed to be used in environments that are potentially explosive such as in close proximity to flammable liquids or gases or in oxygen-enriched atmospheres.

Distance to the patient



WARNING

There is a potential explosion hazard if the product is operated in the presence of flammable anesthetic.

8.4 Electrical Safety

The power interface



CAUTION

Only be connected to the USB interface of UL/CSA 60950-1 certified computer equipment.
Please contact the manufacturer when the data cable used for power supply needs to be replaced. Do not replace it by yourself.

Electrical shock



WARNING

There is a risk of electrical if you attempt to access the inside of any part of the instrument. Only authorized and qualified service personnel may access the inside of any part of the instrument.

Stress on cables



CAUTION

All externally connected cables must never be subjected to pulling stress.

Spilled Liquids



WARNING

Do not bring liquids such as beverages near the instrument.
Do not spill liquids on the instrument.

Disconnected from mains



WARNING

There is no power ON/OFF switch on the instrument therefore the only reliable means to disconnect the device from mains is unplug the data cable used for power supply. Do not position the instrument so that it is difficult to unplug the data cable.

8.5 Light Safety

Visible laser.



WARNING

Do not look into the visible laser beam in the process of use, and prohibit the beam of the scan window (laser window) from directly hitting the operator and the patient's eyes.

The laser wavelengths used by the product are 450nm and 520nm. The repetition frequency is 15Hz. The pulse duration is 60μs. According to IEC 60825-1, the maximum power is less than 390μW, and it is a class 1 laser product. According to 21 CFR 1040.10, the maximum power is less than 39μW, and it is a class I laser product.

The warning label related laser product has been affixed to the external surface of the product which can be clearly seen. After use, please place the probe on the probe bracket with the scanning window facing down.



WARNING

The patient should wear goggles before starting scanning.

The requirements for goggles are as follows: protection wavelength 200-540nm, OD4+ (transmittance of 0.01%), visible light transmittance of 60%. Goggles should be kept properly after use, for example, put them in a glasses case.



CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.



CAUTION

The use of optical instruments with this product will increase eye hazard.



WARNING

The instrument emits white light from the scanner head during operation. The instrument complies with EN(IEC)62471(Photobiological safety of lamp and lamp systems). However, we recommend caution when handling the instrument.

A brief glimpse of the light into eye is not dangerous, but do not gaze at the beam or view directly at it with optical instruments, and do not aim the beam towards other people's eyes.



WARNING

For patients who have had or have experienced photobiological reactions (including excessive exposure to sunlight or cyanosis) or patients who have received treatment with photosensitive drugs (including methoxysarin or chlorotetracycline), strict adherence to medication usage precautions should be followed, and appropriate protection should be provided to patients during the scanning process.

8.6 Others

This product is an optical scanning instrument, during the use of the product must not be vigorously collision.

Please take good care of the calibrator in the product. Once the calibrator is stained, the performance of the product will be degraded

This product meets the requirements for electromagnetic compatibility of medical devices in use, but it is not recommended to use it in environments with strong magnetic fields, strong switches and strong light sources, otherwise it may affect the performance of the product.

This product can only be connected to the USB port of a computer device that is UL/CSA 60950-1 certified.

After the product is used at the end of its life, the product should be disposed of in accordance with the requirements of local laws and regulations, or contacted by the manufacturer for recycling and centralized disposal in accordance with local laws and regulations.

9. Product Hardware Installation Instructions

This product is a precision optical instrument. Manufacturers and distributors shall not be liable for the loss of product safety and reliability and performance if the operator do not operate in accordance with the instructions, or if they do not use the product in a collision and fall due to improper use. After falling, please check the product function and calibrate the product with a calibrator. If the calibration fails, please contact the manufacturer for repair.

When the device is stopped, the probe should be placed on the probe bracket located on a horizontal table to avoid falling and causing damage due to improper placement.

Installation step:

1. Connect the data cable to the computer USB port, and the function button is lit up.
2. Run the scanning software and scan according to the requirements of the scanning operation. During normal scanning, light is projected from the scanning window.
3. After scanning, the data cable should be unplugged to disconnect the device.

Note: When the instrument is working, the power of the heating element on the scanner head is 0.35w

10. Product Software Description

10.1 Recommended Configuration

This product can only be used by installing software on the computer.

CPU	Intel i7-12700H，Intel i7-13700H，Intel i7-14650HX
GPU	Nvidia RTX 3060，Nvidia RTX 4060
Memory	16G, 32G
Hard disk	512G, 1T
Display	Resolution 1920×1080
OS	Windows 11

10.2 Software Basic Information

Software Name	EX5-Scan
Release Version	V1
Full Version	V1.X.X.XXXX
Software Security Level	A

User access control can choose optionally to use user name and password for identity authentication. The user type is ordinary user. Ordinary users can use the instrument normally and view data results. The login interface is shown in the Fig.2 below:

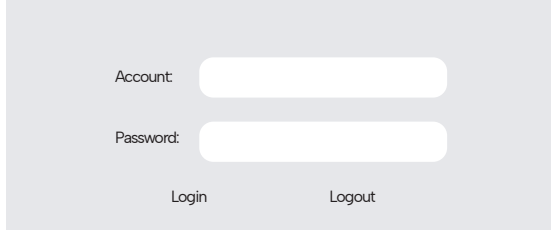


Fig.2 Login interface

Data saving format: standard STL, PLY format and PTY format defined by our company.

10.3 Software Installation Method

The File name format of installation file in the USB Flash Drive Accompanying is EX5-Scan-X.X.X.XXXX-StandardGlobalXXXXXX.iso. The installation steps are as follows:

1. Double-click to open the installation file;
2. Carefully read the license agreement and choose to agree;
3. Click next according to the prompts;
4. The uninstallation is completed, select "Yes" to continue the installation[3];
5. Finished.

The installation steps can be found in the Instrument Software Operation Manual.

10.4 Main Software Interface

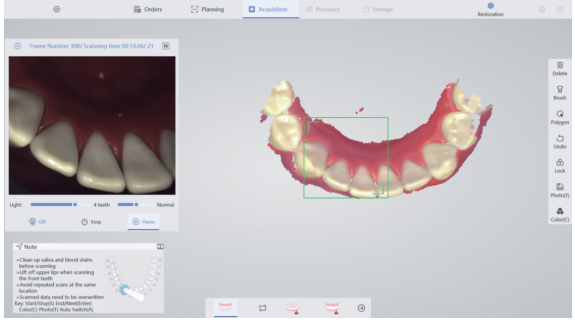


Fig.3 Main interface

The specific method of use of the software is provided by the company with training materials and operation manuals.

[3] If the user has not installed the company's software, this interface will not appear.

11. Application Method

11.1 Operating Steps

Follow the instructions for Product Hardware Installation in Chapter 9.

Open the software and scan after the startup is complete.

Click the button to start the machine after power-on; Click the button to start scanning after startup, click the button again to pause scanning, double-click the button to switch the color of the data model, and hold down the button for three seconds to end scanning.

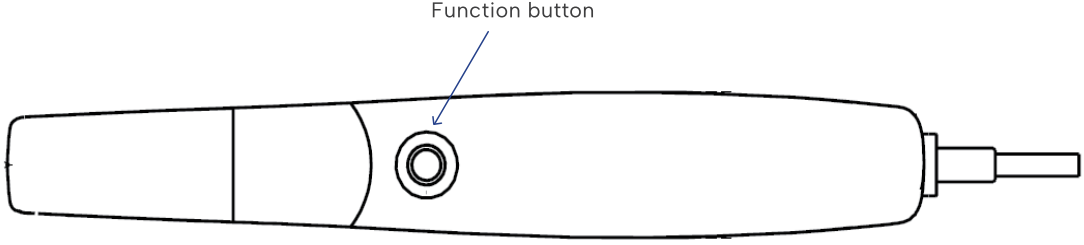


Fig.4 Probe planform

11.2 Scan Technique

Hold the probe body in the same way as a pen while scanning, Due to the limitation of the actual space in the mouth, it is necessary to ensure that the head window of the probe is as close to the tooth surface as possible (it is recommended to keep it within 2mm) for scanning, and the operation mode of suddenly far and suddenly near should be avoided.

Axial drag of the probe was the main scanning method, and radial drag of the probe was used in the scanning of the front teeth and occlusion points. Start scanning from the end teeth, first scan the oeclusal data, then scan part of the buccal and lingual data, and drag from oeclusal to mesial to scan the next tooth, and follow the same operation to complete the frame scan of the posterior tooth area. When entering the lingual surface of the anterior tooth area, drag the probe radial direction left and right to scan the lingual surface and incisal data, and then scan part of the labial surface data after the lingual surface is completed.

11.3 Calibration

According to the usage, it is recommended to use the calibrator to calibrate the product once a month . The product has not been used for three months, it is recommended to calibrate before use. When the device is impacted, or the product is moved or vibrated greatly, or in order to maintain the accuracy of the scanning accuracy, the scanner needs to be calibrated. Refer to "Operation Manual" for the calibration method.



CAUTION

The calibrator of the product should be properly kept. Once the calibrator is defaced, the performance of the product will be degraded.

12. Care and Maintenance Methods

The product is not expected to have long and frequent oral contact with patients. The scanner head must be cleaned and sterilized between patients to avoid cross contamination. It is recommended to sterilize the scanner head by means of moist heat steam sterilization (121 °C, 15 min or 134 °C, 6 min).



WARNING

In order to ensure the normal performance of the product, it is recommended that the times of repeated sterilization of the scanner head shall not more than 50.

The scanner head should be replaced when the appearance is damaged or sterilized for 50 times.

The scanner head can be purchased separately from the seller or manufacturer.

Recommended sterilization method:

- Clean the scanner head with soapy water and a soft brush, then place it under running water for rinsing.
- Wipe the water stain on the surface of the scanner head with medical gauze and wipe it thoroughly with absolute alcohol. Pay special attention to whether there are stains or water stains on the head mirror. If there is, use another medical gauze to draw the absolute alcohol and carefully wipe the head mirror. The sample was allowed to stand for two minutes after wiping.

- Place the scanner head which had been cleaned into 90* 260mm Self-sealing sterilization pouch (materials: Medical high-temperature dialysis paper and medical CPP/PET complex film) and seal the sterilization pouch. Then place the packaged scanner head into sterilizing instrument tray.
- Place the sterilizing instrument tray into a small pressure steam sterilizer and set the sterilization parameters according to the instructions of the small steam sterilizer: temperature 121 ° C, 15 min, or temperature 134 ° C, 6 min.

Keep the outside of the product clean.

If the reflector of the scanner head is stained, users can dip the degreasing cotton into a small amount of anhydrous alcohol (99.9%), and then gently wipe the reflective surface, rotating from the center to the periphery. If the reflector is scratched, it needs to be replaced.

In the course of instrument, software errors and warnings can be self-healed by the software. Serious problems may require shutting down the software and restarting. General hardware errors can be restored by turning off the power and then turning the power back on. If something cannot be recovered, contact the manufacturer or the seller.

The maintenance personnel must take laser protective measures during the inspection process, such as wearing goggles.



WARNING

During the inspection, ensure that there is no person in the direction of laser irradiation.

Replacement instrument parts must be obtained from the manufacturer or manufacturer approved dealer.



CAUTION

The parts that not supplied by the manufacturer may reduce the accuracy and safety of the instrument.

Disclaimer: We can provide the necessary information for maintenance instrument to the users with corresponding maintenance qualifications.



CAUTION

The instrument shall not to be services or maintained in use with a patient.

13. Service Life

Expected service life: 8 years.



CAUTION

Over period of use, the degradation of the product's main electronic and optical components may reduce product performance.

14. Parts List

Parts Name	Quantity
Probe	1
Probe bracket	1
Calibrator	1
Calibrator cable	1
Scanner head	6
IFU	1
Qualified label	1
Warranty card	1
Protective Casing	1
USB flash disk	1

15. Revision History

Edition	Date
A.00	2025.03
A.01	2025.06

16. Legend of Labels and Symbols



Caution



General Warning



Type B Application Part



Refer to instruction manual/ booklet



EU Authorized Representative



Serial Number



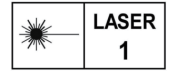
The device should be sent to the special agencies according to local regulations for separate collection after its useful life.



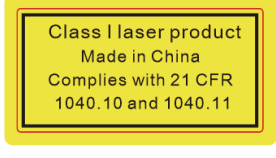
CE marking in conformity with Regulation (EU) 2017/745



Indicates a medical device that needs to be protected from moisture.



Laser Categories and Warnings (comply with IEC 60825-1)



Laser classification and certification label (comply with 21CFR 1040.10)



Country of manufacture



Unique device identification



Humidity Limitation



Atmospheric Pressure Limitation



Temperature Limit



Manufacturer Information



Date of Manufacture



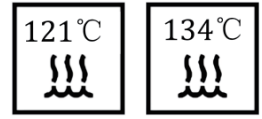
Medical Device



Function button



Recommended number of times for repeated sterilization



Recommended number of times for repeated sterilization

17. Liability of the Manufacturer

The installation, adjustment, modification, and repair of this product are performed by persons or organizations approved by the manufacturer or distributor. And the manufacturer must be able to ensure the safety of the product in accordance with the electrical, environmental, storage, maintenance, and operation requirements of the manual. Responsibility for reliability and performance.

Ziyang Freqty Medical Equipment Co., Ltd.
Floor 2-3, unit 7, building 3, No. 222, West Section 3, outer ring road, Yanjiang District, Ziyang City, 641300, Sichuan Province, P.R. China
Tel: +86-028-26577388 Email: support@freqty.com Website: http://www.freqty.com/

18. About EMC Descriptions and Risk Warning

This product has passed the electromagnetic compatibility test and meets the requirements of EN 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances — Requirements and tests.

The following application requirements shall be strictly observed during use, otherwise it may cause electromagnetic interference to other devices or reduce the anti-electromagnetic interference capability of the therapeutic device, or even lose the basic performance.

This product belongs to the Group 1 Class B equipment specified in IEC/CISPR 11, non-permanent installation equipment, non-living support equipment, and belongs to equipment that is expected to be directly connected to the public power grid.



WARNING

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

The cable information of this product is as shown in the following table. If there is a fault in the connection cable, please contact our company for maintenance or replacement. Other-wise it may cause excessive electromagnetic interference. If there is something wrong with this product, please contact our company promptly. Do not repair or replace the components yourself, or it may cause excessive electromagnetic interference.

No.	Name	Cable length (m)	Whether the cable is shielded	Remarks
1	Data cable	1.85	Yes	\
1	Data cable of calibrator	0.5	Yes	\



WARNING

The use of accessories or cables outside of the regulations together with equipment and systems may result in increased emissions or reduced immunity of the equipment or system.



WARNING

This product should not be used near or stacked with other devices. If it must be used close to or stacked, it should be observed and verified to work properly under its configuration.

Pass and Fail Criteria

During and after the immunity tests, each function worked as intended, such as parameter, as per IFU.

Work mode

scanning mode and calibrating mode.

Trouble Shooting

Issue	Solution
No image display in 2D image area	- Make sure the device's USB interface is properly connected to the computer's USB 3.0 interface. - Restart the software and scanning device to check if the image can be displayed normally.
2D image flicker	- Check if the modulator is connected properly. - Replace the USB port of the device with the computer. - Connect your computer to the Internet.

Issue	Solution
Scans are easily interrupted and not smooth	- Inappropriate scan brightness. For plaster model scanning, choose 1/2, for resin model scanning, choose 3, for the intraoral scanning, choose 4, 5 is suitable for patients with darker teeth in the mouth. - During scanning, confirm that A above the image area is blue. If it is black, use the keyboard A key to switch. - Standardize scanning methods. Ensure coverage of scanned data with existing data.
Out-sync of data between 2D and 3D	- Confirm whether the computer configuration meets the requirements (higher than or equal to our recommended configuration). - Delays caused by too many scans (single jaw scans should be completed within 3 minutes). - Uninstall antivirus software or add scanning software to the whitelist of antivirus software. - Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software.

Issue	Solution
Difficulty for scan relocation	- Ensure that the scanning direction is consistent with the previous scanning when repositioning - Avoid long scans.
No 3D data when scanning	- Calibrate again.
Abnormal interrupt during scanning	- Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software. - Check whether the remaining storage space of drive C is sufficient. - Turn off or uninstall anti-virus software.

This product declarations to meet
Table 1, Table 2, Table 3 and Table 4 of Contents.

Table 1

Manufacturer's Declaration – Electromagnetic Emissions	
The product intended for use in the electromagnetic environment specified below. The customers or users should ensure that it is used in such an environment.	
Emission measurement	**Conformity**
RF emission CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emission IEC 61000-3-2	Not applicable
voltage fluctuations / flicker emission IEC 61000-3-3	Not applicable

Table 2

Manufacturer's Declaration – Electromagnetic Immunity		
The product intended for use in the electromagnetic environment specified below. The customers or users should ensure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level Guidelines**	**Compliance Level**
electrostatic discharge IEC 61000-4-2	Contact:± 8 kV. Air:± 2kV, ±4kV, ±8kV, ± 15 kV	Contact:± 8 kV. Air:± 2kV, ±4kV, ±8kV, ± 15 kV.
Radiated RF EM fields IEC 61000-4-3	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
Electrical fast transientburst IEC 61000-4-4	± 2 kV for power supply lines.	N/A
Surge IEC 61000-4-5	± 1 kV line(s) to line(s). ± 2 kV line(s) to earth.	N/A
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	N/A
Power frequency magnetic field (50Hz and 60Hz)IEC 61000-4-8	30A/m.	30A/m.
Power input line voltage dips, short interruptions and voltage variations IEC 61000-4-11	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T, 1 cycle and 70%U_T,25/30 cycles Single phase:at 0° 0% U_T, 250/300 cycles	N/A

Table 3

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The PIOS-EX5 is intended for use in the electromagnetic environment specified below.
The customer or the user of the PIOS-EX5 should assure that it is used in such an environment.

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430-470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	2	0,3	28	28
870							
930							

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m) (For professional healthcare)
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
5500							
5785							

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 4

Manufacturer's declaration–electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The product intended for use in the electromagnetic environment specified below. The customers or users should ensure that it is used in such an environment.

Test Frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
1 34,2 kHz	Pulse modulation [b] 2,1 kHz	65[c]
1 3,56 MHz	Pulse modulation [b] 50 kHz	7,5[c]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT .

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

19. Customer Support

Email: support@freqty.com
Toll Free Number (USA): 888-855-2562
WhatsApp (Global): +86 18108286761

European Authorized Representative

EU REP

Company: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
Contact: Yan Zhang (Ms.) Tel /Fax: +31(0)10 3034500; +31(0)2021 11106 E-mail: ec.rep@sungogroup.com; yan.zhang@sungoglobal.com

Notes: