



Intraoral Digital Impression Instrument Product Specification

MODEL:PANDA P3



RNA
SCANNER



FREQTY

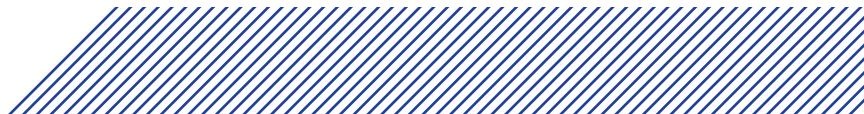
Danda 
Scanner

CONTENTS



1. General Information	1
2. Product Information	2
3. Product Composition	3
4. Main Dimension	4
5. Intended Use and Contraindication	5
5.1 Intended Use	5
5.2 Users	5
5.3 Contraindication	6
6. Environmental Requirements	7
7. Working Power Requirements	7
8. Safety Information	8
8.1 Prerequisites	8
8.2 Mechanical Hazards	10
8.3 Explosion Hazards	11
8.4 Electrical Safety	11
8.5 Laser Safety	13
8.6 Cautions	14

9. Product Hardware Installation Instructions	15
10. Product Software Description	17
10.1 Software Operation Configuration Requirements	17
10.2 Software Basic Information	18
10.3 Software Installation Method	19
10.4 Main Software Interface	19
11. Application Method	20
11.1 Operating Steps	20
11.2 Scan Technique	20
11.3 Calibration	22
12. Care and Maintenance Methods	23
13. Transport and Storage Life	26
14. Parts List	27
15. Revision History	28
16. Legend of Labels and Symbols	28
17. Other Contents	31
17.1 Liability of the Manufacturer	31
17.2 Warranty Description	31
18. About EMC Descriptions and Risk Warning	33



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 guide 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.

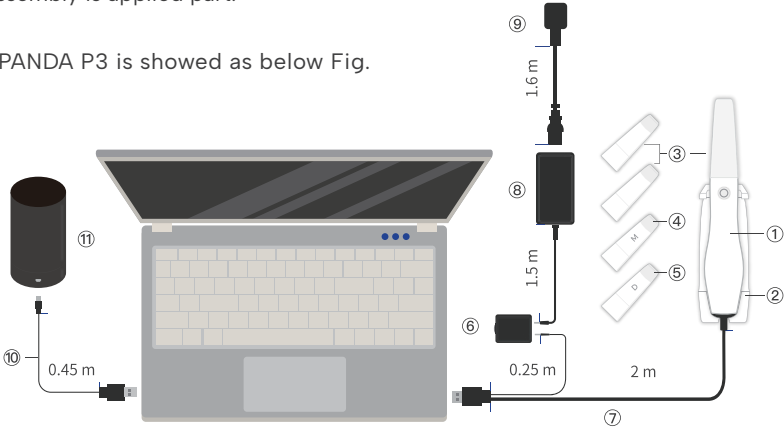
2. Product Information

Product Name	Intraoral Digital Impression Instrument
Model	PANDA P3
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: sales@freqty.com
Classification	The product is energized from an external electrical power source is classified as CLASS I. The APPLIED PARTS is classified as TYPE B.

3. Product Composition

The product is composed of the probe, the power adapter, the calibrator, electric switch box, the supporting software (release version: P3V1) and the probe bracket. The probe includes the probe body and probe head assembly (include Normal probe, D probe, M probe). The probe head assembly is applied part.

The structure of PANDA P3 is showed as below Fig.



- ① Probe Body
- ② Probe Bracket
- ③ Probe Head Assembly Normal*3
- ④ Probe Head Assembly M
- ⑤ Probe Head Assembly D
- ⑥ Power Switch
- ⑦ Data Cable (cannot be separated with the scanner)
- ⑧ Power Adapter Socket
- ⑨ AC Power Cable
- ⑩ Calibration Data Line
- ⑪ Calibrator

4. Main Dimension

Total size	216mm (L) *40mm (W) * 36mm
Size of probe head assembly(length, width and height)	
Normal Probe	83*19*14mm, window:18*16mm
D Probe	81*21*17mm, window:18*18mm
M Probe	88*21*17mm, window:18*18mm

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 output 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 User

The product may be operated only by trained dental professionals and qualified personnel.

5.3 Contraindication

Patients with the following contraindications are not suitable for intraoral digital impressions. These contraindications include but are not limited to:

1. Patients have oral mucosal disease; patients have mental illness; patients have Parkinson's disease; patients have ADHD (Attention Deficit and Hyperactivity Disorder); patients have epilepsy.
2. Spray optical shading powder on smoked areas when patients have very severe black smoke stains that are not conducive to optical scanning. If the special shading powder need to be sprayed, these diseases need to avoid dust are contraindications, mainly including Not limited to: allergic or multi-drug allergic; severe respiratory diseases, asthma patients, etc.
3. It should not be used on patients who have or have had photobiological reactions (including those with excessive sun exposure or porphyria) or who have been treated with photosensitive drugs (including methoxsalen or chlortetracycline).

6. Environmental Requirements

Operating Temperature	5°C ~ 30°C	Operating Humidity	≤80%
Storage Temperature	-10°C ~ 55°C	Storage Humidity	≤93%
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.		

7. Working Power Requirements

Powered by a power adapter:

- Certified by IEC60601-1:2005+ A1:2012
- Model: UES48-120333SPA3
- Input: 100-240V~ 50/60Hz, 1.1A
- Output: 12V-3.33A

8. Safety Information

8.1 Prerequisites



CAUTION

Read all instructions carefully including all warnings and cautions. You must comply with the warnings in the manual to prevent injury to persons and damage to equipment. Proper functionality and safety can only be guaranteed if the safety precautions in this safety guide and on the instrument are observed.

Preventive inspection before use of the system.



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.

Modification



WARNING

No modification of this equipment is allowed.

Approved software only



CAUTION

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

In case of equipment 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 scanner 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.

8.2 Mechanical Hazards

Dropped or damaged equipment



CAUTION

If you drop a probe head assembly on the floor, you **MUST** dispose of it immediately and **NOT** use the same assembly again for scanning.

There is high risk that the mirror in the probe head assembly 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 this guide instructions on Calibrating the probe.

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

Ensure a grounded/ earth connection



WARNING

To avoid the risk of electric shock, the product must only be connected to a supply mains with protective earth.

Electrical shock



WARNING

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

Stress on cables



CAUTION

All externally connected cables such as power cable, data cable must never be subjected to pulling stress.

Spilled Liquids



WARNING

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

Disconnected from mains



WARNING

The power ON/OFF switch is on the electric switch box. Do not position the product so that it is difficult to operate the electric switch box.

8.5 Laser Safety

This product uses a visible laser light.



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. Both beam divergence angles (Parallel) are 9°, beam divergence angle (Perpendicular) are 44° and 49°. The pulse width is 60μs. The repetition frequency is 15Hz, and the maximum power is less than 0.5mW. 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.

8.6 Cautions

This product is a precision optical measuring instrument and must not be impacted during use. 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 interface of UL/CSA 60950-1 (or GB4943.1) certified computer equipment.

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.

The product label has two parts, including the label on the body of the product and the label on the electric switch box, the serial number on the product label (e.g. IS027E50820ZY) and the number on the electric switch box label (e.g. IS027E50820ZY-1) is actually the same, but in order to distinguish the two labels, -1 is added after the number of the electric control switch box as the distinction mark, -1 is only used for the distinction between the two and has no other meaning.

9. Product Hardware Installation Instructions



This product is a precision optical equipment. 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 probe is not scanned, it should be placed on the probe bracket and on the horizontal operating table as a whole to avoid falling damage caused by improper placement.

Installation step:

- ① Connect the power supply cord to the adapter.
- ② Insert the adapter into the power adapter socket on the electric switch box.
- ③ Insert the probe power supply line into the probe power socket on the electric switch box.
- ④ Connect the USB 3.0 of the probe data cable to the USB 3.0 port of the user's computer.
- ⑤ Plug the power cord into the SUPPLY MAINS.
- ⑥ Turn on the power switch on the electric switch box, and the green indicator light will turn on.
- ⑦ Run the scanning software and scan according to the requirements of the scanning operation. During normal scanning, light is projected from the scanning window.
- ⑧ After scanning, power should be turned off.

10. Product Software Description

10.1 Software Operation Configuration Requirements

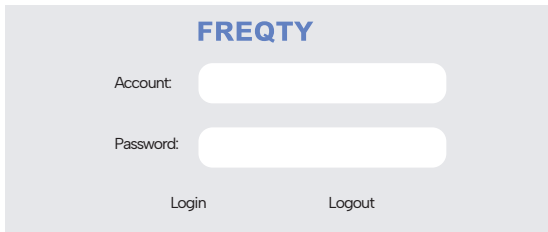
This product can only be used by installing software on the computer. The requirement for the recommended configuration of computer hardware is no less than the following configuration:

CPU	Intel i7-12700H/Intel i7-11800H or above
RAM	16G/32G
Hard disk	SSD 512G or above
GPU	RTX2060/RTX3060 or above
Operating system	Windows10/11 64bit

10.2 Software Basic Information

Software Name	Intraoral Digital Impression Instrument Scan Software
Release Version	P3V1
Software Security Level	A

Network security: User access control can choose 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 figure below:



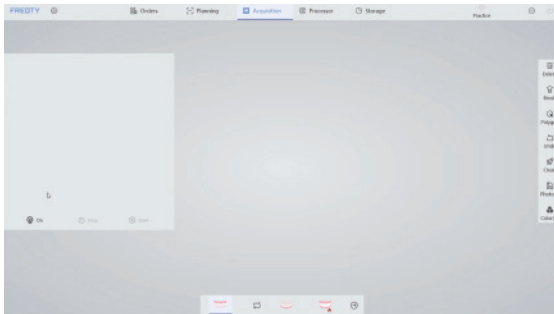
The image shows a login interface for 'FREQTY'. At the top center, the word 'FREQTY' is displayed in a bold, blue, sans-serif font. Below this, there are two input fields. The first is labeled 'Account:' and the second is labeled 'Password:'. Both labels are in a dark grey font. The input fields are white with rounded corners and a light grey border. At the bottom of the interface, there are two buttons: 'Login' on the left and 'Logout' on the right, both in a dark grey font.

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

10.3 Software Installation Method

See Intraoral Digital Impression Instrument Software Operation Manual.

10.4 Main Software Interface



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



II. Application Method

II.1 Operating Steps

Follow the instructions for Product Hardware Installation in Chapter 9.

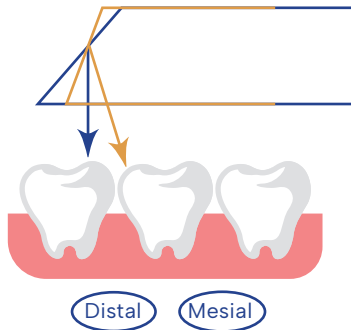
Open the software and scan after the startup is complete. During the scanning process, the function button can be used to control the start, pause and end of the scan.

II.2 Scan technique

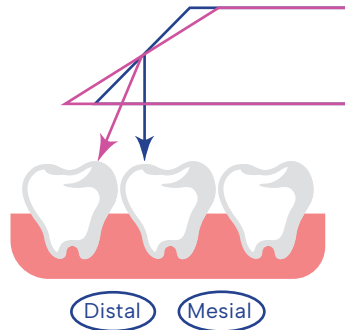
Hold the probe body in the same way as a pen while scanning, Due to the limitation of the actual space in the mouth, it is necessary to ensure that the head window of the probe is as close to the tooth surface as possible (it is recommended to keep it within 2mm) for scanning, and the operation mode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

In general, a normal probe is used for scanning, which can be used for partial or full scanning operations. For some special cases (such as insufficient mouth opening, or severe occlusion between teeth), D probe can be used to supplement the missing area of the distal surface, or the M probe can be used to supplement the missing area of the mesial surface.

Please refer to the following figure to select the probe.



complementary scan for Distal by D probe



complementary scan for Mesial by M probe

— Normal probe

— D probe

— M probe

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 occlusal data, then scan part of the buccal and lingual data, and drag from occlusal 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.

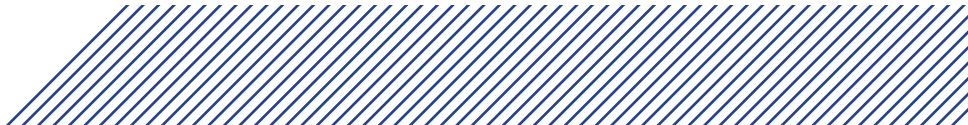
T.3 Calibration

According to the usage, it is recommended to use the calibrator to calibrate the product once a week. 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. It is recommended to sterilize the probe head assembly by means of moist heat steam sterilization (121°C, 15min or 134°C, 6min).



WARNING

In order to ensure the normal performance of the product, it is recommended that the times of repeated sterilization of the probe head assembly shall not more than 20.

The probe head should be replaced when the appearance is damaged or the times of sterilizations is 20. The probe head assembly can be purchased separately from the seller or manufacturer.

Recommended sterilization method:

- Clean the probe head assembly with soapy water and a soft brush, then place it under running water for rinsing.
- Wipe the water stain on the surface of the probe head assembly 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 probe head assembly 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 probe head assembly 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, 15min, or temperature 134° C, 6min.

Keep the outside of the product clean.

If the probe head reflective glass smudging, can dipping a small amount of anhydrous alcohol with skimmed cotton, from the center to gently wipe the rotation. If the glass is scratched, it needs to be replaced.

In the course of equipment, 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 equipment 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 equipment.

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



13. Transport and Storage Life

Transport Conditions:

Temperature $-10^{\circ}\text{C}\sim 55^{\circ}\text{C}$, relative humidity $\leq 93\%$, and an atmospheric pressure $700\text{hPa}\sim 1060\text{hPa}$, not rain drop.

Storage:

Should be stored at ambient temperature of $-10^{\circ}\text{C}\sim 55^{\circ}\text{C}$, relative humidity not exceed 93% and an atmospheric pressure $700\text{hPa}\sim 1060\text{hPa}$, well-ventilated, non-corrosive gas chamber. Prevent moisture, corrosion, avoid direct sunlight.

Expected service life:

Five years. 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 body	1
Probe bracket	1
Calibrator	1
Power adapter	1
Electric switch box	1
Power supply cord	1
Calibrator cable	1
Probe head assembly	5
Specification	1
Qualified label	1
Warranty card	1

15. Revision History

Revision	Revision Content	Date
A.00	First Release	2022.03.01

16. Legend of Labels and Symbols



General Warning



Caution



Type B Application Part



Refer to instruction
manual/ booklet



EU Authorized
Representative



Serial Number



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



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



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



Laser Categories and Warnings.



Laser Parameters and Standards



Humidity Limitation



Atmospheric Pressure
Limitation



Temperature Limit



Manufacturer
Information



Date of Manufacture



Medical Device

17. Other Contents



17.1 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.

17.2 Warranty Description

The warranty period for this product is one year, calculated from the date of sale (according to the date of sales invoice).

One of the following cases the company provides free maintenance:

- (1) Non-user subjective destruction within the warranty period, product failure caused only by product quality;
- (2) Product failure caused by force majeure (such as earthquake, flood, typhoon, etc.) during the warranty period.

One of the following cases the company provides paid maintenance:

- (1) Failure of the product due to non-subjective damage by the user during the warranty period;
- (2) Failure of the product after the warranty period but within the service period.

We no longer provide maintenance in one of the following situations:

- (1) The product has been used for more than six years;
- (2) Product failure caused by subjective destruction of users.

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 disturbance -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 I 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 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)	If the shield	Remarks
1	Power Supply Cord	1.6	No	\
2	DC Power Supply Line	1.5	No	With a magnetic loop
3	Data Cable	2.0	Yes	\
4	Probe Power Supply Line	0.3	No	\



WARNING

The use of accessories or cables outside of the regulation 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

Free from distortion in an image or error of a displayed. In the test, the communication was normal during the continuous scanning process, and the image of the tooth model could be obtained normally.

Test Method

The device is powered on, connected to the test software, set to continuous scan mode, a dental plaster model is placed on the front end of the probe for continuous scanning.

Work Mode

Continuous scan mode. After the device is connected to the power test software, for continuous scanning.

Trouble Shooting

Issue	Solution
No image display in 2D image area	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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
<p>Difficulty for scan relocation</p>	<ul style="list-style-type: none"> - Ensure that the scanning direction is consistent with the previous scanning when repositioning - Avoid long scans.
<p>No 3D data when scanning</p>	<ul style="list-style-type: none"> - Recalibration
<p>Abnormal interrupt during scanning</p>	<ul style="list-style-type: none"> - 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 declaration meets
Table 1, Table 2, Table 3 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	Complies
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies

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.
Conducted disturbances included by RF 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 transient/burst IEC 61000-4-4	±2 kV for power supply lines.	±2 kV for power supply lines.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s). ± 2 kV line(s) to earth.	± 1 kV line(s) to line(s). ± 2 kV line(s) to earth.
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	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
Power frequency magnetic field (50Hz) IEC 61000-4-8	30A/m.	30A/m.
Power input line voltage dips, short interruptions and voltage variations 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 cycles	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 cycles

Table 3

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The PANDA P3 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the PANDA P3 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) (For professional healthcare)
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	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)} 18 Hz	2	0,3	28	28
870							
930							
1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,	Pulse modulation ^{b)} 217 Hz	2	0,3	28	28
1845							
1970							

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)
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,	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.

Manufacturer Information



Manufacture: Ziyang Freqty Medical Equipment Co., Ltd.

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

Tel: +86-028-26577388

Email: sales@freqty.com

Website: <http://www.freqty.com/>

European Authorized Representative



Company: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam

Contact: SUNGO Secretary

Tel /Fax: +31 (0) 2021 11106

E-mail: ec.rep@sungogroup.com

