FREQTY Panda Scanner

PANDA P4

Intraoral Digital Impression Instrument
Instruction for Use

MODEL:PANDA P4

CE

FREQTY

Panda Scanner

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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	PANDA P4
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
Protection against electric shock	Class II, internal power supply; The calibrator is connected to an independent power supply (computer) for power supply

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

Applied part	Type B
Defibrillation-proof applied part	No
Protection against harmful ingress of water or particulate matter	IPX0
Method of sterilization	By moist heat such as by autoclave (scanner head)
Suitability for use in an ox rich environment	No
Mode of operation	Continuous operation

3. Product Composition

The product is composed of the probe,the adapter, the calibrator, the base and the supporting software (release version: P4V1) . The probe includes the probe body and scanner head (include normal scanner head, D scanner head and M scanner head).
The scanner head is applied part.

The structure of PANDA P4 is showed as below Fig.1[2]

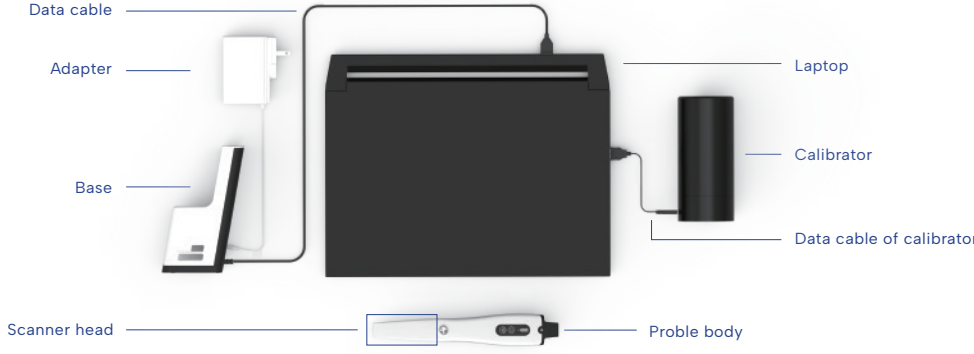

Fig.1 Connection diagram between PANDA P4 and the laptop

[2] The product do not include the laptop.

4. Main Dimension

Total size	238mm (L) *42mm (W) * 35mm (H)
Size of scanner head (length, width and height)	Normal scanner head: 83*19*14mm，window:18*16mm D scanner head: 82*20*16mm，window:18*20mm M scanner head: 88*20*16mm，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 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

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. If the patient's teeth have very severe black smoke stains that interfere with optical scanning, the smoke stain area can be sprayed with powder for optical enhancement..When optically enhanced powder spraying is required, patients suffering from diseases that cannot accept powder spraying are contraindications, mainly including but not limited to: allergy or multiple drug allergies, severe respiratory diseases and 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 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				
Storage Environment	Well-ventilated, non-corrosive gas chamber. Prevent moisture, corrosion, avoid direct sunlight.				

7. Working Power Requirements

The base is powered by a power adapter.

- Certified by IEC60601-1:2005+ A1:2012
- Model: UES36LCP2-120300SPA
- Input: 100-240V~ 50/60Hz, 1.0-0.5A
- Output: 12V⎓3A, 36W

The handheld part is powered by an internal lithium battery, which is charged in the base.

- Operating voltage: 3.6V
- Battery capacity: 3200mAh, continuous operation: 2.5 hours

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 instrument

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 of the instrument

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.

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.

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.

Internal batter

WARNING

Personnel not authorized by the manufacturer are not allowed to replace the internal battery. Incorrect replacement could result in HAZARDS (such as device damage, excessive temperatures, fire, or explosion).

CAUTION

Do not remove the battery, otherwise the device cannot be used.

8.5 Eye 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.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.

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.

8.6 Cautions

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.

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.

Fig.2 Probe in base

Installation step:

- Plug a power adapter into the base's power jack.
- The base connects to the USB3.0 port of the user's computer via USB3.0 of the data cable.
- Press the power button on the base to turn on the power, and a green indicator lights up. Long press will turn off the power, the indicator light off.
- Press and hold the power button on the body of the probe, and the white indicator light of the function button lights up. Long press the power button again to turn off the power. The white indicator light of the function button will turn off, and the power indicator light will turn off after a period of delay.
- Connection indicators on the probe and base are not on for not connected, blue for being connected, and green for successful connection. In general, the probe and base of a device have been pre-connected and paired, and no further connection is required.
- Run the scanning software and scan according to the requirements of the scanning operation. During normal scanning, light is projected from the scanning window.
- After scanning, place the probe on the base to prevent accidental fall damage. After the probe is placed on the base, it will charge the probe, and the probe will automatically turn off the power after a period of time.

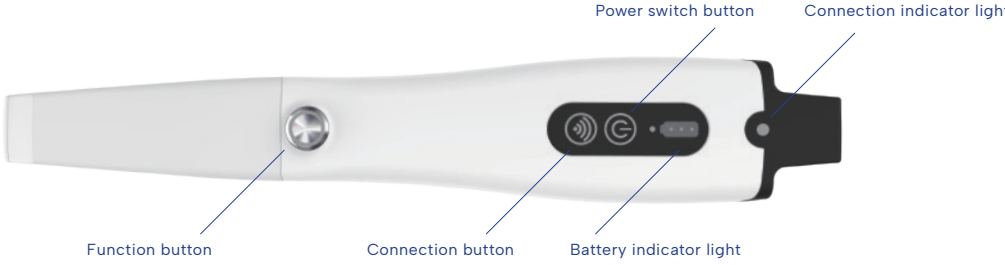

Fig.3 Plan view of probe

Please note:

- Keep the probe and the base within the range of 2m, and there is no obvious hindering object between the probe and the base, ensuring wireless stable connection and stable transmission.
- When the power indicator light on the probe is only one light, please charge in time.
- When the instrument is working, the power of the heating element on the scanning head is 0.35w.

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 i7-8700(3.2GHz)and above
GPU	NVIDIA GTX1060 (6G) and above
Memory	DDR2400 16G and above
Hard disk	Solid state drive SSD 120G and above
Display	Resolution 1920×1080 and above

10.2 Software Basic Information

Software Name	Intraoral Digital Impression Instrument Scan Software(PANDA SCANNER)
Release Version	P4V1
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。
Data saving format	standard STL, PLY format and PTY format defined by our company

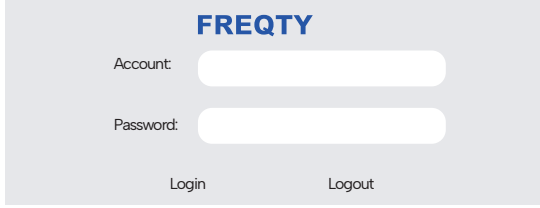

Fig.4 Login interface

10.3 Software Installation Method

The File name format of installation file in the USB Flash Drive Accompanying is PANDAP4V1 X.X.X XXX. Full. exe format. 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[If the user has not installed the company's software, this interface will not appear.] ;
5. Finished.

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

10.4 Main Software Interface

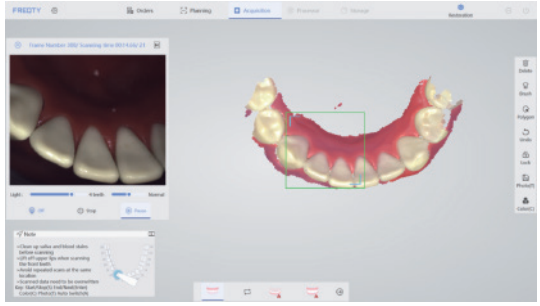

Fig.5 Main interface

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

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. During the scanning process, the function button can be used to control the start, pause and end of the scan.

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.

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.

Fig.6 mesial surfac and distal surface schematic diagram

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 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. 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 20.

The scanner head should be replaced when the appearance is damaged or the times of sterilizations is 20. 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: 5 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 body	1
Base	1
Calibrator	1
Adapter	1
Protective Casing	1
Calibrator cable	1
scanner head	5
IFU	1
Qualified label	1
Warranty card	1
USB Flash Disk	1

15. Revision History

Edition	Date
A.00	2023.03.01
A.01	2023.12.06
A.02	2024.03.07

16. Legend of Labels and Symbols

Caution

General Warning

Type B Application Part

Refer to instruction manual/ booklet

EC REP

EU Authorized Representative

SN

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.

Laser parameters and standards.

Humidity limitation

Atmospheric Pressure Limitation

Temperature Limit

Manufacturer Information

Date of Manufacture

MD

Medical Device

Function button

External markings for devices or components of devices that contain radiofrequency transmitters or use radiofrequency electro-magnetic energy for diagnosis or therapy.

Wireless connection button

CN

Country of manufacture

UDI

Unique device identification

Stand by

17. Other Contents

17.1Liability 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 provides maintenance in one of the following situations:

(1) The product has been used for more than 8 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 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 A equipment specified in IEC/CISPR 11, non-permanent installation equipment, non-living support equipment, and belongs to equipment that is not 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	DC power supply line	1.5	No	\
2	Data cable of base	1	Yes	\
3	Data cable of calibrator	0.5	Yes	\

WARNING

The use of accessories or cables outside of the regulations together with equip-ment 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.

WARNING

This product is intended for industrial and hospital use (CISPR 11 Class A). If used in a residential environment (CISPR 11 Class B), RF communications may not be adequately protected.

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	- 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.
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.

Issue	Solution
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.
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	Recalibration
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 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 A
Harmonic emission IEC 61000-3-2	Complies
voltage fluctuations / flicker emission IEC 61000-3-3	Complies

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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.	± 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 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	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

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Table 3

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The PANDA smart is intended for use in the electromagnetic environment specified below.
The customer or the user of the PANDA smart 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.

Manufacturer Information

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