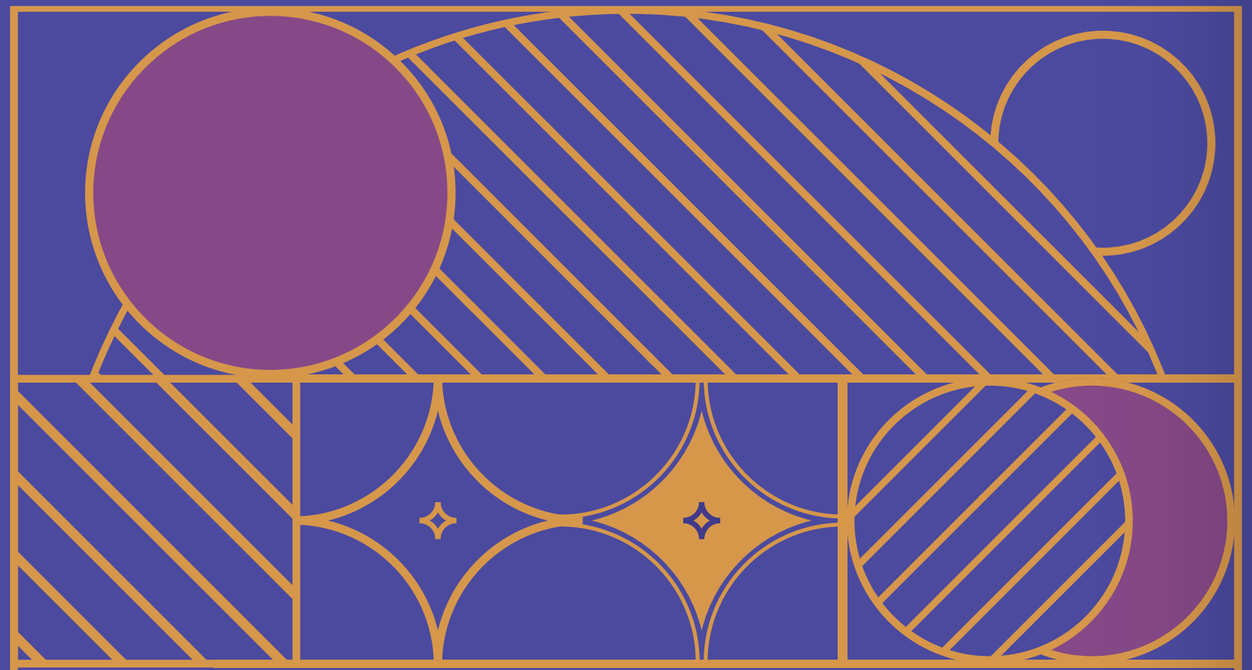

Panda Scanner

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PANDA SCANNER

PANDA P2

PRODUCT SPECIFICATION

CE 0598

Panda Scanner

Panda Scanner

Create
Maximum Value for
Every Use

Contents

Product Information

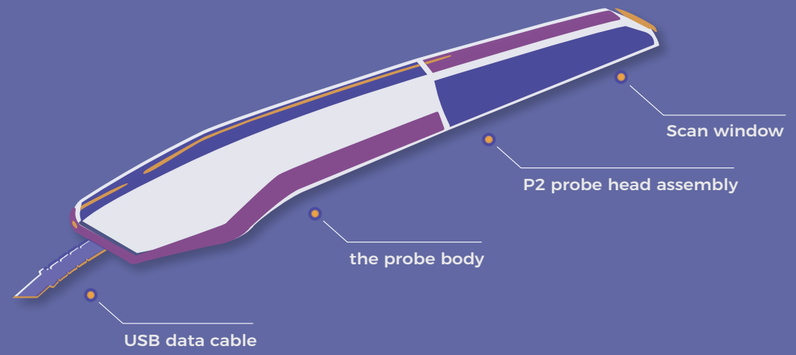
Panda Scanner

Product Name:	Intraoral Digital Impression Instrument
Model:	PANDA P2
Manufacturer Name:	Ziyang Freqty Medical Equipment Co.,Ltd
Manufacturer Address:	Zone A, B, C, 4 Floor, Building A, NO.3, Xiandai Road, Ziyang City, Sichuan Province, China
Production Address:	Zone A, B, C, 4 Floor, Building A, NO.3, Xiandai Road, Ziyang City, Sichuan Province, China
Manufacturer contact:	Tel:+86-21-64989018 E-mail:market@pingtum.com

Panda Scanner

Product Composition

The product is composed of the probe, the power adapter, the calibrator, the supporting software and the probe bracket. The probe includes the probe body and P2 probe head assembly.



Main Performance

Main Dimension

Length into the mouth	85mm
Depth of field	15mm
Total sizet	216mm(L)*40mm(W)*36mm(H)

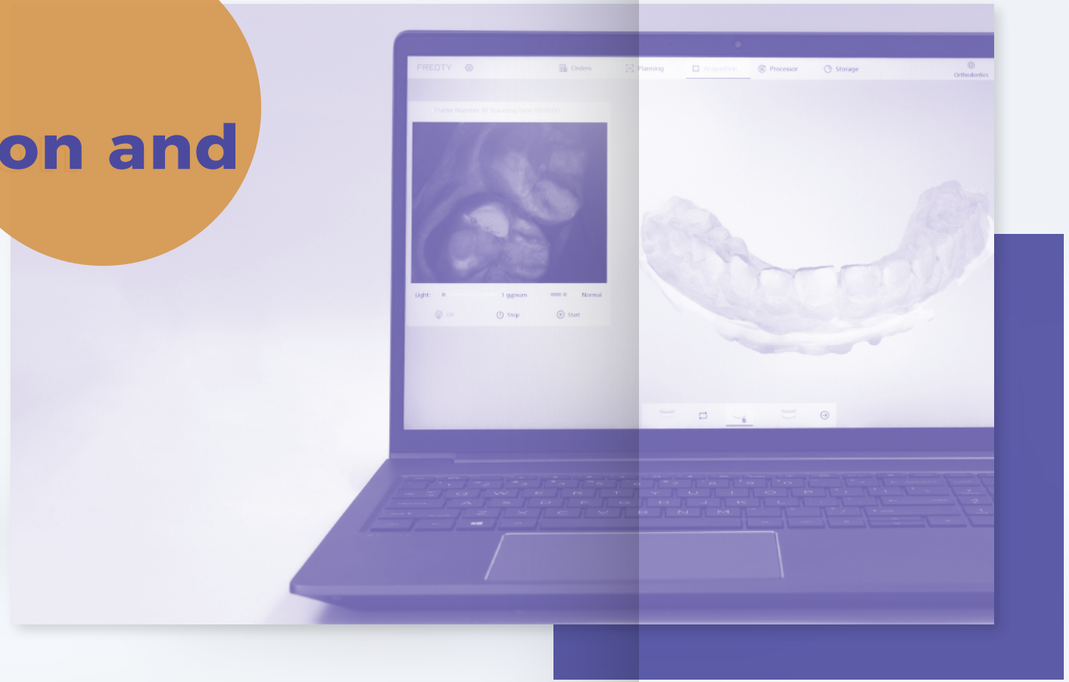
Specifications

Scanning depth	0~15mm
Scanning accuracy	≤15μm
Repeatability precision	≤10μm

Panda Scanner

Product Function and 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.



Environmental Requirements

Operating temperature	5℃ ~ 40℃
Storage temperature	-10℃ ~ 55℃
Operating humidity	≤80%
Storage humidity	≤93%
Atmospheric pressure	760hPa ~ 1060hPa
Operating Environment	Indoor operation and avoid direct to the scanned body

Working Power Requirements

Rate power	AC 100-240V, 50/60Hz
Input power	30VA

Caution

This product is a precision optical measuring instrument and must not be impacted during use. The calibrator in the product should be properly kept. Once the calibrator is defaced, 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 uses a visible laser light. In the process of use,please follow “Do not look into the visible laser beam” requirement, and prohibit the beam of the scan window (laser window) from directly hitting the operator and the patient’s eyes. The laser wavelength of the product is 450nm and 520nm, the beam divergence angle is 33˚, the pulse width is 25ms, the repetition frequency is 30Hz, and the maximum power is less than 0.4mW. The related warning label stickers are delivered to the user along with the product and are posted by the user on an external surface of product that can clearly see. After use, please place the probe on the probe bracket with the scanning window facing down. The patient should wear goggles before starting scanning.

The product is not expected to have long and frequent oral contact with patients. It is recommended to sterilize the P2 probe head assembly by means of moist heat steam sterilization (121˚C, 15min or 134˚C, 6min) ; in order to ensure the normal performance of the product, it is recommended that the number of repeated sterilization of the P2 probe head component is not more than 30 times; the P2 probe head should be replaced when the appearance of it assembly is damaged or the number of sterilizations is 30 times. The P2 probe head can be purchased by the user by contacting the seller or manufacturer.

Recommended sterilization method

Panda Scanner

1

Clean the P2 probe head with soapy water and a soft brush, then place it under running water for rinsing.

2

Wipe the water stain on the surface of the P2 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.

3

Place the P2 probe 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 P2 probe head into sterilizing instrument tray.

4

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.

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.

Panda Scanner

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.
- When the probe is not scanned, it should be placed on the probe bracket and on the horizontal oper-ating table as a whole to avoid falling damage caused by improper placement.
- The probe is connected to the USB 3.0 port of the user's computer through a cable.
- Insert the adapter into the power socket on the product cable, turn on the power switch, and light the music indicator. Run the scanning software (need to plug the USB Key into the computer) and scan according to the requirements of the scanning operation. During normal scanning, light is projected from the scanning window.
- After scanning, power should be turned off.

Panda Scanner

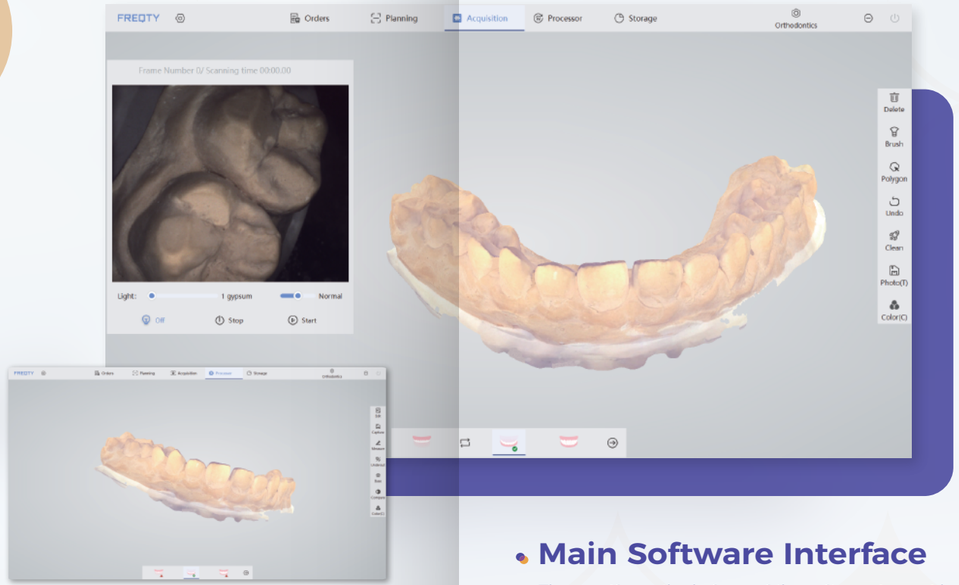
Product SOFTWARE DESCRIPTION

Software Operation Configuration Requirements

CUP	Intel i7-10870H / Intel i7-10875H Intel i7-11800H
RAM	16G/32G
Hard disk	SSD 512G/more than 512G
Graphics card	GTX1660TI/RTX2060/RTX3060
Computer operating system	Windows10*64 bit

The recommended graphics card is **NVIDIA**, and the graphics card memory requires **more than 6G**.
Common unqualified graphics cards are: **GTX1650/ GTX1650 Ti/ RTX 3050/ RTX3050Ti**

Recommended CPU is **Intel**, AMD is not supported.



Main Software Interface

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

Software Basic Information

Software name	Intraoral Digital Impression Instrument Scan Software
Applicable equipment	PANPA P2
Software security level	A

Software Installation Method

See Intraoral Digital Impression Instrument (PANDA P2) Software Operation Manual.

Panda Scanner

Care & Maintenance Methods

It is suggested to calibrate the product regularly with the calibrator.

Keep the outside of the product clean.

When the scan window's reflective glass is soiled, it can be wiped clean with a degreasing cotton with a small amount of anhydrous alcohol.

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 recov–ered, contact the manufacturer or the seller.

The maintenance personnel must take laser protective measures during the inspection process, such as wearing goggles. During the inspection, ensure that there is no person in the direction of laser irradia–tion.

Note: Replacement equipment parts must be obtained from the manufacturer or manufacturer approved dealer, otherwise it 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.

Transport and Storage Life

Transport conditions:

Temperature –10℃~55℃, relative humidity ≤93% and an atmospheric pressure 760hPa~1060hPa, note rain, drop.

Storage:

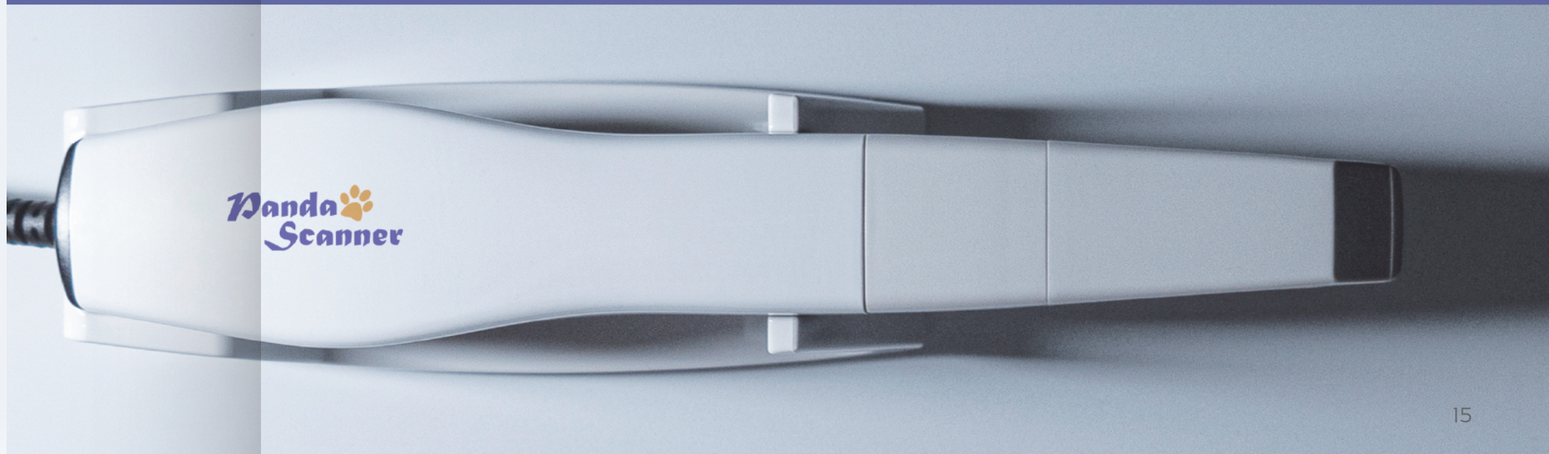
Should be stored at ambient temperature of –10℃~55℃, relative humidity not exceed 93% and an atmospheric pressure 760hPa~1060hPa, well–ventilated, non–corrosive gas chamber. Prevent moisture, corrosion, avoid direct sunlight.

Lifespan:

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

PRATS LIST

Part Name	Quantity
Probe body	1
Probe head assembly	3
Probe head protector	1
Power adapter	1
Power cable	1
Calibrator	1
USB Key	1
Probe bracket	1
Specification	1
Warranty card	1
Certificate	1



Graphic Explanation

	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 0598	CE marking in conformity with EC directive 93/42/EEC
	Indicates a medical device that needs to be protected from moisture.

LASER 2	Laser Categories and Warnings.
IEC/EN 60825-1:2014 VISIBLE LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT	Laser parameters and standards.
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Manufacturer information
	Date of manufacture

Other Content

Liability of the Manufacturer

The installation, adjustment, modification, and repair of this product are performed by persons or organizations should be approved by the manufacturer or distributor. And the manufacturer must 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.

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 six years;
(2) Product failure caused by subjective destruction of users.

About EMC Descriptions & 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-electromagentic 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.

Description of portable and mobile RF communications equipment that may affect medical electrical equipment: Portable and mobile RF communications equipment may affect the normal operation of the high frequency surgical equipment that this product is expected to us. It should be ensured that the portable and mobile RF communication equipment and the high-frequency surgical equipment that this product is expected to use together meet a certain space distance.

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. Otherwise 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	Connection cable	1.9	Yes	\
2	DC power supply lines	1.5	No	\
3	Power supply line	1.5	No	\

Warning: The use of accessories or cables together with equipment and systems outside of the regulations 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.

Basic Performance: In the continuous scanning process, the communication should be normal and the image of the scanned object can be acquired 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.

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

TABLE 1

Guidance and 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**	**Electromagnetic environment – guidelines**
RF emission CISPR 11	Group 1	This product uses RF energy only for its internal functions. So its radio RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	This product is suitable for use in all facilities of domestic and direct public low-voltage power supply network for home use.
Harmonic emission IEC 61000-3-2	Complies	
voltage fluctuations /flicker emission IEC 61000-3-3	Complies	

TABLE 2

Guidance and 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	**IEC60601 test level guidenlines**	**Compliance level**	**Electromagnetic environment – guidelines**
electrostatic discharge IEC 61000-4-2	Contact: ±8kV. Air: ±15kV.	Contact: ±8kV. Air: ±15kV.	Floors should be wood,concrete or ceramic tile. If floors are covered with synthetic materials. The relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines. ±1kV for input/ output lines.	±2kV for power supply lines. ±1kV for input/ output lines.	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line (s) to line (s) ±2kV line (s) to earth	±1kV line (s) to line (s) ±2kV line (s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Power input line voltage dips, short interruptions and voltage variations IEC 61000-4-11	<5% UT, for 0.5 weeks (in UT, >95% of sag) 40% UT 5 weeks (on UT, 60% of sag) 70% UT, 25 weeks (on UT, 30% sag) <5% UT, sustained 5S (on UT, >95% of temporary drop).	<5% UT, for 0.5 cycle (>95% dip in UT) 40% UT, for 5 cycles (60% of dip in UT) 70% UT, for 25 cycles (30% dip in UT) <5% UT, for 5 s (>95% dip in UT).	Main power quality should be that of a typical commercial or hospital environment. If the user of this product needs continuous operation during a power interruption, it is recommended that the product be powered by an uninterruptible power supply or battery.
Power frequency magnetic field (50Hz) IEC 61000-4-8	3A/m.	3A/m.	Exception occurs if the work, it is necessary that the present product away frequency magnetic field or the magnetic shield is mounted at that location. Should be measured in the frequency field to meet the expected installation site below the level of compliancewith the requirements.
Note: UT is the ac mains voltage prior to application of the test level.			

TABLE 2

Guidance and 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	IEC60601 test level	Compliance level	Electromagnetic environment– guidelines
Conducted RF IEC 61000–4–6 Radiated RF IEC 61000–4–3	3v(RMS) 150kHz~80MHz 3V/m 80MHz~2.5GHz	3V(RMS) 3V/m	Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 800MHz~2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture. 'd' is the recommended separation distance in meter(m). Filed strengths from fixed RF transmitters, as determined by an electromagnetic site survey (notea), and each frequency range (note b) should be less than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.

Note a: Flied strengths from fixed transmitters, such as base stations for radio (celular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicte theoretically with transmitter. To assess the electromagnetic environment fixed RF transmitters, electromagnetic site survey should be considered. If the measured field strength of the product is higher than the above RF compliance level, the product should be observed to verify its normal operation.
Note b: Over the frequency range 150KHz~80MHz, field strengths should be less than 3V/m.

TABLE 4

Recommendation separation distances between the product and mobile RF communication equipment

This product is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The costumer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between the portable or mobile RF communications equipment (transmitters) and the product, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150KHz~80MHz $d=1.2\sqrt{p}$	80MHz~800MHz $d=1.2\sqrt{p}$	800MHz~2.5GHz $d=2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation application to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, V1 is the conducted RF compliance level and E1 is the RF radiated compliance level.

Note 1: At the 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, object and people.