User Manual for Image Sensor

Sensor Y

Preface

Dear users:

Thank you for using iM3 Dental Ltd (Hereinafter referred to as ‘iM3’) image sensor and trust us on the product, we are deeply honored by your choice, and will provide our best to ensure your satisfaction with Sensor Y image sensor.

iM3 image sensor is performed in equipped Twain Software, which is designed to take full advantage of the sensor performance. To get the optimal image and higher processing quality, the use of iM3 image sensor with iM3 Vet Exam Pro software in combination is necessary.

To ensure your safety and efficient use of image sensor, please follow this user manual carefully. iM3 will not be held responsible for any failure or accidental damage caused by improper operation against the instructions in the manual.

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Modification and update of this manual, as well as the right of final explanation are belong to iM3 Dental Ltd

Contents

Chapter 1 Product Description

This product consists of sensor head, control box, connection cable and image management software.

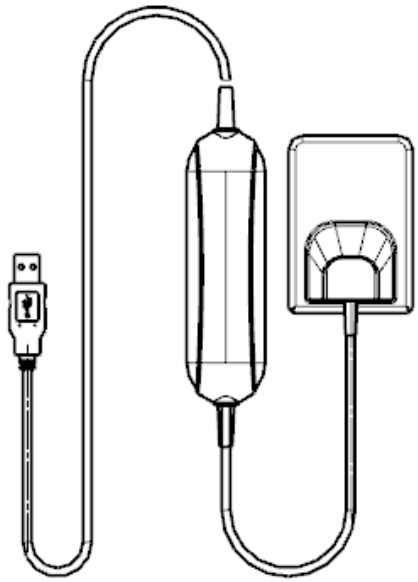
Additionally equipped with the sensor head holder and control box holder, for the user to place the product.

NOTE: Different product model is with different design and components, please refer to '1.1 Image Sensor Diagram'.

Image Sensor applies to collect x-ray photons for photoelectric conversion, digital data collection / conversion / transmission. Digital data is sent to computer via USB cable. The sensor is powered by the USB hub, instead of batteries or a charging system, but need to work with software.

The computer and other external devices (like monitor, printer, etc.) that work with this product are equipped by the user own self. For the suggested computer configuration, please refer to "3.2 Computer Configuration Requirements".

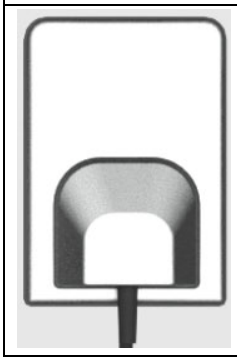
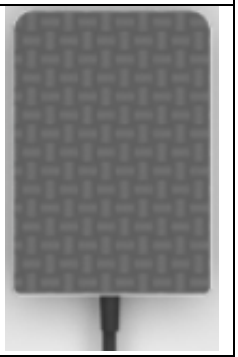
1.1 Image Sensor Appearance



Sensor Y

1.2 Image Sensor Description

Image Sensor is applied to collect x-ray photons for photoelectric conversion, digital data collection/conversion/transmission. (Image sensor head design is as below image)

Y5200	
	
nonsensitive side	sensitive side

1.3 Intended Use

This product is intended to convert x-ray photons emitted from X-ray generator into digital image, which is for viewing/saving/transferring.

Chapter 2 Safety Instruction

This chapter provides important safety information for image sensor use.

2.1 Safety Classification

Degree of Protection Against Electric Shock: BF
Mode of Operation: Continuous operation
Grade of Water Proof: IPX7(only applicable for the sensor head part)
Power Supply (through USB port): DC5V±0.5V
Input Power: 1W
Non AP equipment; Non APG equipment
No application for protection against defibrillation discharge effect
Non-permanent installation equipment

2.2 Symbols Description

Symbol	Description
	**Caution(refer to accompanying documentation）**
	**Refer to user manual**

	**Type BF applied part**
SN	**Manufacture's serial number**
	**Fragile** **Contents of the transport package are fragile** **Therefore it shall be handle with care**
	**THIS WAY UP** **Indicates correct upright position of the transport package**
	**KEEP AWAY FROM RAIN** **Transport package shall be kept away from rain**
	**Antiroll**
	**Max and Min temperature**
	**Manufacturer** **Name and address of the manufacturer**

2.3 Warning and Precaution

2.3.1 Precaution

- Check whether the image sensor surface is with visible physical damage before each usage, the surface should be smooth, without any crack or damage. Otherwise, please contact our after-sales team once any damage occurred.

- As with other electronic equipment, image sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low humidity environments. During cable re-plugged, when image sensor contacts are exposed, it is

especially important to protect the device from potential ESD damage. Touching a metal surface prior to re-plugging the cable will reduce the risk of damaging image sensor components by accidental static discharge. The use of anti-static floor mats or floor treatments will also help eliminate static build-up in your office.

- When the image sensor is in use, do not touch exposed connectors on non-medical electrical equipment (like computer externals) and the object under test at the same time. If the object under test is capable of conducting electrical current and against the appropriate safety practices, that may cause a shock hazard to the object.

- The image sensor has been determined to be in accordance with international safety standards and is deemed suitable for use within 5ft (1.5m) away from the object under test. To comply with these standards, do not operate non-standard equipment within the test area. Within the test area, the presence of approved medical grade equipment and Listed/Approved/GB9706.1(IEC60601-1), YY0505(IEC60601-1-2) certified computer equipment is acceptable. Outside the test area, the presence of approved non-medical grade equipment and Listed/ Approved/GB4943(IEC60950) certified computer equipment is acceptable. The person in charge of connecting this product to the host computer shall ensure its compliance. To keep optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not impact imaging applications after installation.

- Portable and mobile radio frequency communication equipment probably impact on medical electrical equipment.

2.3.2 WARNING

- Non-following the user manual probably endanger the safety of object under test. Manufacture bear no compensation liability for any damage caused by improper operation.
- As a precision electronic product, avoid falling on the floor, pulling and long-time disinfectant soaking.
- The image sensor must be used by a trained personnel in accordance with the user manual carefully.
- Cover a disposable hygienic sheath before each usage to avoid cross infection and allergy (apply to animal clinical).
- Do not bite on sensor to avoid damage to the disposable hygienic sheath and the image sensor.
- Stop using once the product is malfunction, contact our company or authorized dealer immediately.
- Do not move or knock the device while in working state.
- This product is not used for treatment, all images are for users' reference only.
- Only professional vet/technician/trained staff are authorized to operate this product.
- Only the manufacturer is authorized to make repairs and maintain.
- Use with caution in epilepsy/psychosis animals.

● Do not work with or approach toward other equipment. If it must to work with or approach toward other equipment, please observe and verify that it can work normally under the existing configuration.

● The use of unspecified accessories/transducers/cables may result in an increase in the x-ray emission or a reduction in the disturbance immunity of this product.

2.4 Work Environment

2.4.1 Operating Conditions

Environment Temperature	10℃～40℃
Relative Humidity	0%～80%
Air Pressure	86kPa～106kPa

2.4.2 Transportation and Storage Environment

Environment Temperature	-25℃～60℃
Relative Humidity	10%～93%
Air pressure	80kPa～106kPa

Chapter 3 Specification

3.1 Image Sensor Specifications

Model	Sensor Y
Chip Type	APS CMOS
Pixel Size	18.5μm
Dimension (mm)	53.8 x 77.1 x 6.5
Active Area (mm)	46.7 x 67.3
Active Pixel Array (pixels)	2524 x 3640
Voltage (through USB connection)	5.0 V±0.5V
Electricity Current (though USB connection)	≤500mA
Power	≤1W
Digitization	12/14bit
Imaging Time	3～4 s
Spatial Resolution	CsI：≥20 lp/mm
Theoretical Resolution	27 lp/mm
Signal Output	USB 2.0

3.2 Computer Configuration Requirements

 **Note: Suggested minimum configuration for the computer, it's equipped by the user own self.**

Table of Minimum Computer Configuration Requirements

Items	Minimum Requirements
Processor	Intel 1.5GHz chip or above
Memory	Above 4G
Hard disk	Above 40G (1GB for software installation, 40GB for software operation)
Video card	32M or above
Display	Resolution 1024 × 768 (15") or above 32-bit color mode
Interface	At least 2 available USB2.0 / USB3.0 ports (if desktop computer used, 2 available USB ports must be had at the back of host)
Operating System	Windows XP/Win7/Win10（32bit&64bit）
Backup Medium	Removable device (the database should be copied frequently to avoid information lost by accident, some cases like PC Disk is corrupt/full/attacked by virus, etc.)

 **Caution:**

- The computer and other external devices (like monitor, printer, etc.) should comply with the requirements of GB4943（or IEC60950), and be certified by 3C (or CE) as well.
- The computer and other external devices (like monitor, printer, etc.) are equipped by the user own self.
- The requirement form above is the suggested minimum configuration for the computer, and the product performance might be affected if those above are not reached.
- Prohibit the use of computer non-comply with GB4943(or IEC60950), like some kind of unauthorized assembly computer may incur potential safety hazards.
- Prohibit the use of computer unapproved with 3C (or CE).

3.3 Exposure Requirement of X-ray Generator

 **Note: X-ray generator is equipped by the user own self.**

As with conventional radiological equipment, exposure time depends on the performance of generator, the shape and property of the object under test.

The recommended exposure time of x-ray generator for reference under the value of 70kV/7mA showed in below table, and reset a special value according to your practical experience to make the radiograph more clear.

Recommended exposure times (take medium dog dental as an example):

Tooth Position	Recommended exposure values（Unit: s）
Upper incisor/canine	0.18
Upper premolar	0.24
Upper molar	0.35~0.45
Lower incisor/canine	0.12
Lower premolar	0.18
Lower molar	0.25

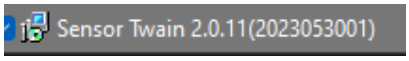
Caution:

- The X-ray generator tube voltage range should be 60~70kV.
- The X-ray generator is with DC power supply, if it with AC power supply, please increase the exposure time by 10~30%.

Chapter 4 Software Installation Instruction

4.1 Driver Installation

We provide a USB flash disk or a CD together with the sensor in package. Please open the driver installation folder, double click the driver icon 

to complete the installation by following install-shield wizard. (The Driver name might change with update version, please refer to the actual using name), then install 

again the version may change please check the name.

4.2 Software Installation

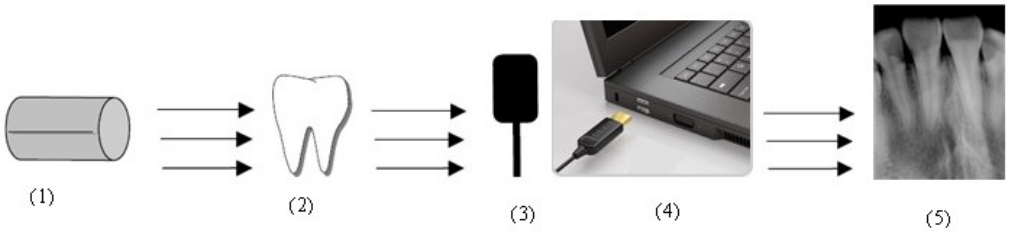
There is no software that comes with the Sensor, to install the sensor using the Twain driver, please refer to the user manual of your software

4.4 Calibration File Installation

Within the programdata folder in C Drive on the installion PC paste the calbration files into the folder Sensor Twain.

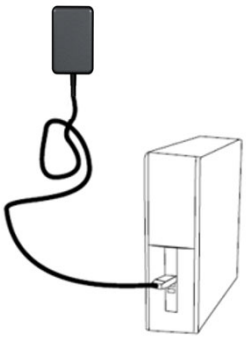
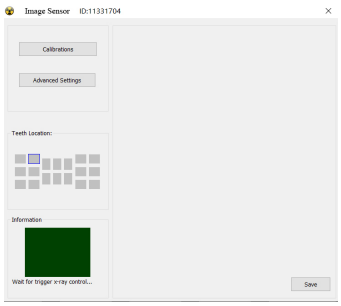
Chapter 6 Image Sensor Operation Guidelines

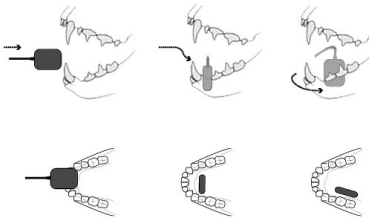
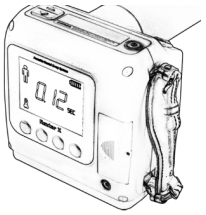
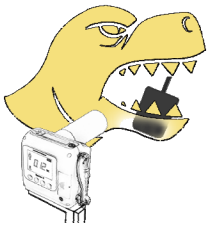
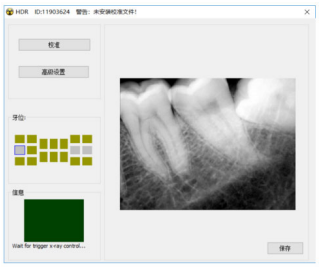
6.1 Working Sketch Map



1	X-ray generator
2	Animal tooth to be X-rayed/the object under test
3	X-ray collection and conversion (through image sensor)
4	Data transmission (through USB cable)
5	Image acquisition in software

6.2 Image Sensor Operation Guidelines

No	Description	Picture
1	Plug the image sensor into computer	
2	Create or search for a case to bring up the shooting window	

3	Cover a disposable sheath on the sensor head	
4	Position the image sensor in animal's mouth just like conventional film, or in/under the object under test, keep the sensitive side close to the target part.	
5	Set required x-ray parameters (exposure time, etc.)	
6	Position the X-ray generator appropriately, then take shooting	
7	Acquire and view the image, please refer to '5.4', '5.5'	

WARNING:

- Connect the sensor into back side of the computer case USB port (about the computer configuration please refer to 3.2 'Computer Configuration Requirements').
- Use a disposable sheath.
- Avoid biting the image sensor and its accessories.
- The recommended exposure conditions for X-ray generator, please refer to 3.3 'Exposure Requirement of X-ray Generator.

Chapter 7 Cleaning and Disinfection

Do not keep immersing this product in liquids for a long time, please try to avoid disinfecting with any liquids. Cover a disposable hygienic sheath prior to use to achieve the purpose of disinfection (Disposable sheath is not provided in this product package, please purchase with alone). Use soft cloth with a little bit ethanol to do regularly clean on sensor head and control box. Any other disinfectants may cause damage to CMOS sensor and control box, that is regarded as against the usage guideline in intended application. Manufacture bears no responsibility for any damage caused by unauthorized disassembled or improper operation.

 **WARNING:**

- Do not sterilize the image sensor by heating/autoclave.
- Do not put the image sensor in an ultrasonic bath for cleaning or disinfecting.
- Keep the sensor away from spray.
- Remove dirt before clean, wipe the sensor with a soft cloth gently.

Manufacture will not be held responsible for any damage caused by non-following the user manual to proceed with cleaning or disinfection, all risks should be born by the user.

Chapter 8 Maintenance

As with all kinds of electronic equipment, this product requires not only proper operation, but also visual inspection and routine check at regular intervals. These precautions can ensure the product with accurate, safe and high-efficient running.

Before each usage, the operator should check for whether there is any physical damage on sensor or malfunction. Contact our after-sales team for more guidance if happened.

8.1 Periodic Maintenance

Periodic maintenance is performed as needed, but at least once a month, include the below inspection items, which should be executed by the user or a qualified technician.

- The labels are with intact, readable, and adhere well on the surface.
- No damage on sensor cable.
- No damage on the product surface which could incur safely issue.
- The indicator lights and software both are in normal status after installed by following the user manual correctly.

8.2 Damaged or Nonfunctional Image Sensor

Stop using and contact your local distributor immediately once the image sensor occur visible

physical damage or abnormal working state.

Do not disassemble sensor housing to take repair without permission.

Please consult the manufacture for more technical information if needed.

Chapter 9 Troubleshooting

The following table shows some solutions for common troubles. If the problem persists, please contact your local distributor or our after-sales team.

9.1 Fault State Information

Fault	Causes and Solutions
Working box color is red instead of green blinking	·Correct image Source option 'Image Sensor/USB Series'; ·Check whether the sensor is well connected to the computer; ·Re-install the sensor Driver; ·Switch to the case back side USB port, make sure USB interface is 2.0 or above. If a laptop is used, please connect to power supply, avoid selecting energy saving mode which may result in USB port voltage unstable;
No images acquired after X-ray emission	·Make sure the shooting windows is launched, normal working state is with green blinking. ·Make sure the X-ray generator faces to the sensor sensitive side. ·Make sure the X-ray generator exposure values are correct. ·Re-install the sensor Driver and switch to the case back side USB port, make sure USB interface is 2.0 or above, and increase the exposure time appropriately.
Unable to opening shooing window	·Close anti-virus program and re-install X-CMOS software
Remind of calibration file absence	·Please refer to section 4.4 'Calibration File Installation'
Unable to use the software after 30 days trial, remind of registration	·Please refer to section 4.3 'Software Registration'

9.2 Faulty Images

Faulty Images	Causes and Solutions
White lines or ripples on the images	·Lack of calibration file: Please refer to section 4.4 'Calibration File Installation';
Images are too pale with grainy	·Refer to section 3.3 'Suggested Exposure Time' to reset x-ray exposure values; ·Under the chosen X-ray dose, generator is too far away from the object under test, please position closer; ·Check your monitor brightness/contrast setting, make sure there is no reflects light on the screen; ·Shot of exposure time, please increase exposure time; ·The X-ray generator voltage is too low, check your generator;
Images are too dark	·Excessive of exposure time, please decline exposure time; ·Inspect your generator, decline tube voltage or electric current;
Images are blurred	·The object under test moved at the moment of x-ray exposure; ·X-ray generator work state is unstable; ·Increase the Contrast Pro value under Advanced Setting in shooting window;
Images are too light	·Exposure values (Kv/mA/s) are too low; ·Make sure your X-ray generator is able to generate X-rays, consult with a certified technician to inspect this generator;

CAUTION：

- Try the above solutions if the same failure occurs.
- Please contact our after-sales team for support on the condition of failure persists or even more serious.

Chapter 10 Warranty

We guarantee that the product functions are correct and that there is no failure in raw

materials and workmanship within 24 months starting from the release date.

Please contact your local distributor in case of malfunction occurred, by according to the below condition:

We would responsible for free of the maintenance charge against the product's abnormal working state due to quality problem within 24 months start from the date of delivery.

If any of the following situation happened, maintenance charge would be attracted:

- Damage caused by improper operation/maintenance/storage against the instructions in the manual or by user's carelessness;
- Damage caused by unauthorized disassembly;
- Damage caused by irresistible factors;
- The warranty period has expired;

Regarding a reasonable complain about the product failure or delivery, we would provide replacement or maintenance. We reserve the right to take repair, include some kind of natural or special damage, which is only under the compliance with legal provisions to avoid default/ malfeasance / wilful misconduct.

Please contact your local distributor for the maintenance executed by our company in case of malfunction occurred. Please do not disassemble the product without permission, and we will not be held responsible for any damage due to unauthorized disassemble by customer or a third-party.

The expectant lifetime of the product is 4 years under normal operating conditions. Calculation method is as below:

The number of exposures	Lifetime (The calculation is based on the average of 10000 times shooting per year)
40000	4 years

Chapter 11 Product Components

1	Image Sensor		1 Pc
2	USB flash disk (Image management software and sensor Driver have been downloaded inside)		1 Pc
3	Holder	Sensor head holder	1 Pc
		Control box holder	1 Pc (if applicable)
4	Manual		1 Pc

Annex A. EMC table

The following tables provide this product compliance information of electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) standards. To ensure conformance, the user must operate this product in environments that are consistent with these standards.

Table 1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: This product is intended for use in the electromagnetic environment specified below.

Emissions Test	Compliance	Guidance
RF emissions CISPR11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	This product is suitable for use in all establishments, including domestic and those directly connected to the public low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions EN 61000-3-3	N/A	

Table 2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This product is intended for use in the electromagnetic environment specified below. The purchaser or user must ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 610004-4	±2 kV for power supply lines ±1 kV for input/out put lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Surge EN 61000-4-5	± 1 kV line(s) to line(s) ±2 kV Line(s) to ground	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% UT, 0.5 cycle, >95% voltage dips in UT; 40% UT, 5 cycles, 60% voltage dips in UT; 70% UT, 25 cycles, 30% voltages dips in UT; <5% UT; 0.5 s, >95% voltage dips in UT;	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic fields EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr>
<td>Conducted RF
EN 61000-4-6</td>
<td>3 Vrms

150 kHz ~ 80 MHz</td>
<td>3 V</td>
<td rowspan="2">Portable and mobile RF communication equipment should not be used close to any part of this product within the recommended separation distance, including its cables. This separation distance is calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$
80 MHz ~ 800 MHz
$d = 2.3\sqrt{P}$
800 MHz ~ 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol.
  </td>
</tr>
<tr>
<td>Radiated RF
EN 61000-4-3</td>
<td>3 V/m
80 MHz ~ 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</table>

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 3. Recommended Separation Distance between Portable and Mobile RF Communications Equipment and this product

PLEASE NOTE: this product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The purchaser or user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable, mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	150 kHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable 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.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people