FireCR Dental

User Manual

Dental Computed Radiography Reader

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The device complies with Part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. Modifications not expressly approved by the manufacturer could void the user's authority to operated the equipment under FCC rules.

Warnings and Used Symbols

To ensure the safety of patients, staff and other persons, any changes to software and hardware delivered by ***3D Imaging & Simulations Corp.*** may only be made with prior written permission from ***3D Imaging & Simulations Corp.***

Please read the respective manuals of the connected software, such as acquisition and diagnostic software, before starting to use the ***FireCR Dental*** system.

The following symbols will be used throughout this manual:

DANGER
This equipment is indoor use only and all the communication wirings are limited to inside of the building.

DANGER
The functionality of the system can be destroyed in the case of incorrect use.
If unauthorized changes have been made to delivered system and accessories, the warranty by ***3D Imaging & Simulations Corp.*** becomes void. ***3D Imaging & Simulations Corp.*** will not accept any responsibility or liability for the improper functioning of the product in such a case.

WARNING
The functionality of the system can be limited in the case of incorrect use. Hints that require special attention.

NOTE
Notes represent information that is important to know but which do not affect the functionality of the system.

General Safety Guidelines

All the safety and operating instructions should be read carefully before this device is operated.

This device has been designed and tested to meet strict safety requirements applicable to medical equipment, and has been supplied in a safe condition. To ensure personnel and patient safety, the device shall be operated and serviced in compliance with all procedures, warnings and precautions during all phases of operation and service of this device. Failure to comply to with safety guidelines may result in injury to service personnel, operator, or patient. ***3D Imaging & Simulations Corp.*** assumes no liability for failure to comply.

If this device is not used as specified, the protection provided by the device could be impaired. This device must be used in a normal condition only.

Installation, service and operation of this device should only be undertaken by qualified trained personnel. The operator should study instructions and precautions carefully before starting to use the device listed here and throughout the manual.

There are no user serviceable parts inside this device. The device should only be opened and serviced by qualified service personnel. Failure to heed this warning may result in injury to service personnel or damage to equipment, and void any and all warranties. If there is a service problem, please contact ***3D Imaging & Simulations Corp.*** or authorized dealer.

Do not spill liquids on the device, and never operate the device in a wet environment.

Keep the device from radiators and heat sources.

Use the device only with accessories supplied with this device.

This device is intended to be grounded. Plug power cord into properly grounded electrical outlets. This cord is equipped with three-prong plugs to help ensure proper grounding.

This device contains static sensitive components. Proper static handling procedures and equipment must be used when servicing this device.

Do not look inside of the device.

If any of the following conditions occur, unplug the device from the electrical outlet and contact authorized service personnel.

- The power cord or power adapter is damaged.
- An object has fallen into the device.
- The device has been exposed to water.
- The device has been dropped or damaged.
- The device does not operate correctly when the operating instructions are followed.

Federal law restricts this device to sale by or on the order or a physician

Intended Use

This device is a Dental Computed Radiography System and intended for use in producing digital X-Ray images for dental radiography purposes. It comprises of reader, reusable imaging plate and workstation software. It scans X-Ray exposed imaging plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing. This device is intended to be operated in a radiological environment by qualified staff.

Index of contents

Chapter 1. Introduction

FireCR Dental Reader

- Rapidly view high-quality digital images
- Easy-to-use system increases patient throughput
- Full-featured, affordable dental solution

Experience the Benefits of Digital Imaging

The full-featured ***Fire CR Dental Reader*** from ***3D Imaging & Simulations Corp.*** rapidly and affordably delivers high-quality digital images for busy dental practices.

Compact & Affordable

The ***FireCR Dental Reader*** is compact and affordable, helping to increase patient throughput and improve the overall productivity of your practice. With its small footprint, the reader fits seamlessly into even the most space-challenged dental offices and exam rooms.

Elegant Design & Streamlined Operation

The ***FireCR Dental Reader***'s elegant design belies a powerful yet easy-to-use system that gets the job done day in and day out.

The reader is DICOM 3.0 compatible with existing systems and uses a full range of low-cost, reusable bitewing and intraoral imaging plates that are easier and faster to position than intraoral digital sensors.

Unique Touch Screen Panel

The ***FireCR Dental Reader*** features a unique color touch-screen LCD panel for seamless device operation. With no physical push buttons on the unit and an intuitive user interface, entering operator instructions has never been easier.

Built-in Erase & UV Sterilization

A built-in erase function eliminates the need to purchase an additional device to erase imaging plates prior to reuse, improving efficiency and reducing costs. And, an integrated UV disinfection system sterilizes imaging plates that may be contaminated during handling, ensuring a hygienic workflow and protecting the safety of patients and staff.

Unmatched Flexibility to Help Your Practice Grow

In this increasingly competitive environment, show patients that your practice offers the latest in digital imaging technology for improved patient results. Whether you're looking for a central reader that can distribute images throughout your facility, or an affordable exam-room based solution, the next-generation ***FireCR Dental Reader*** is the natural choice for practices looking for a full-featured system that delivers high-quality digital images—along with the flexibility that helps them grow.

Chapter 2. Unpacking

2.1. Inspection for Damage

FireCR Dental Reader is shipped in a custom designed container to protect the reader from external shock. Before unpacking the reader, inspect the shipping container for damage. In case the container is damaged, notify the shipper immediately.

2.2. Identify the Components

Open the shipping container and identify each of these components.

Part No.	Item
CR-FP-11-001	***FireCR Dental Reader***
CR-FPA-01-002	Power Adapter
CR-FPA-02-001	USB 2.0 Interface Cable
CR-FPA-02-002	RJ45 CAT.6 UTP Cable 2M (direct type)
CR-FPA-03-00X	Power Cord
CR-FPM-11-001	***FireCR Dental*** User Manual
CR-PKM-11-004	IP Storage Case
CR-FP-12-001	Size 0 Imaging Plate (22mm x 31mm)
CR-FP-12-002	Size 1 Imaging Plate (24mm x 40mm)
CR-FP-12-003	Size 2 Imaging Plate (31mm x 41mm)
CR-FP-12-004	Size 3 Imaging Plate (27mm x 54mm)
CR-FP-12-005	Size 4c Imaging Plate (48mm x 54mm)
CR-FPA-15-001	Size 0 IP Hygienic Bag
CR-FPA-15-002	Size 1 IP Hygienic Bag
CR-FPA-15-003	Size 2 IP Hygienic Bag
CR-FPA-15-004	Size 3 IP Hygienic Bag
CR-FPA-15-005	Size 4c IP Hygienic Bag

WARNING

If the ***FireCR Dental*** needs to be returned to manufacturer or one of its representatives, the reader must be repacked in the original container with all accessories.

WARNING

Use of Power Cord;

Type SJT or SVT, min. 18AWG, 3-Conductor, VW-1 125V, min 10A (or 250V, 10A). Max 3.0m long; One end with Hospital Grade Type, NEMA 5-15P for 125V or NEMA 6-15P for 250V. Other end with appliance coupler. "CAUTION Grounding reliability can only be achieved when the equipment is connected to an equipment receptacle marked "Hospital Only" or "Hospital Grade".

For connection to supply not in USA, make sure the power cord is the correct type that is required in your area.

WARNING

Improper disposal of this product may result in environmental contamination. When disposing of this equipment, contact ***3D Imaging & Simulations Corp.***'s representative or related organs of government. Do not dispose of any part of this equipment without consulting a ***3D Imaging & Simulations Corp.***'s representative first.

3D Imaging & Simulations Corp. does not assume any responsibility for damage resulting from disposal of this equipment without consulting ***3D imaging & Simulations Corp***.

NOTE

AC/DC Adapter
Manufacturer : Bridge Power corp.
Model : BPM050X24XXX
This adapter is passed by IEC60601-1.

WARNING

Use the device passed IEC60950-1 or IEC60601-1 for the product connected via USB port.

Chapter 3. Setting Up

WARNING

Unsuitable Installation Sites

- Locations with excessive humidity or dust
- Locations subject to high temperature
- Locations subject to shaking or vibration
- Locations exposed to considerable electrical or magnetic noise, or other forms of electromagnetic energy
- Locations with poor heat radiation

3.1. Positioning

The reader must be placed on a rigid and flat desk or tabletop with at least 5 cm (2 inch) free space on both sides, 10 cm (4 inch) on rear side and 15 cm (6 inch) on front side for imaging plate insertion. Its space requirements are shown below.

Free space of 15 cm (6 inch) on front side, at least, for imaging plate insertion and removal.

Free space of 10 cm (4 inch) on backside, at least, to allow the power switch, power cord and interface cable to be reached by hand at all times.

Front Side

Backside

Figure 1. Space Requirements (Top View)

DANGER

Never place the reader on the floor.

Install in a location that is level and stable. Installation in an unsuitable location can cause accident, or deterioration in image quality.

WARNING
Sliding the reader may result in internal damage or misalignment of the optics.
External vibration or shock during scanning may affect image quality. The reader must be placed on rigid, flat and reinforced desk or tabletop.

WARNING
Do not place anything on top of the reader.

WARNING
This equipment may be interfered or interfere by electromagnetic or other interference.

Assure a distance of minimum 1.0 m with neighboring equipment.

3.2. Identify Important Features

Look over the reader and features shown in this section. User will need to know where these features are when user operates the reader in later chapters.

3.2.1. Reader Connecting Part

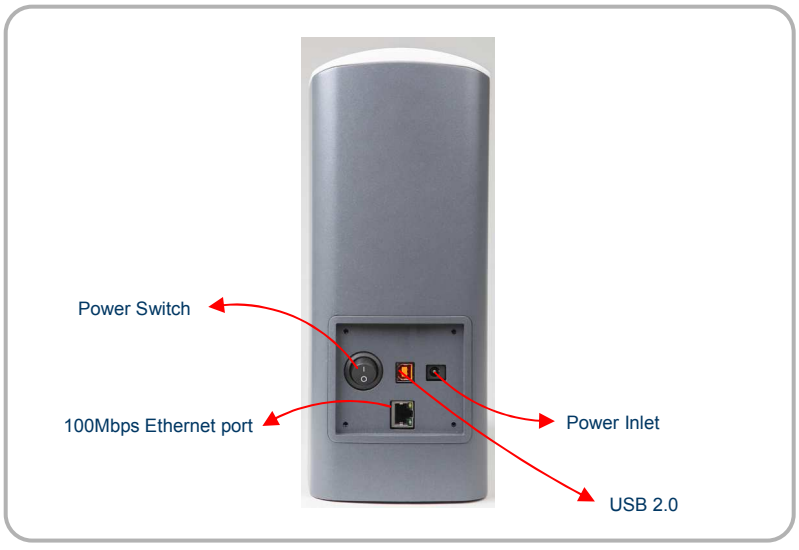


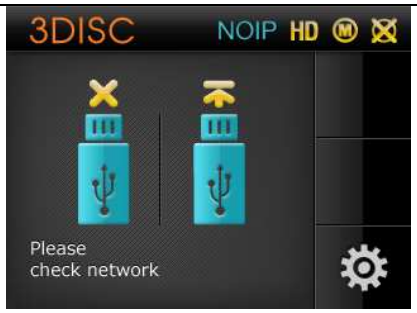
Figure 2. Reader Connecting Part

3.2.2. Touch Display Panel

Screen displays reader's status and control of the reader can be done by touch screen.

Figure 3. Touch Display Panel

display	Status	Remark
	Booting screen	When the reader is turned on, booting screen is displayed during system initialization.
	Sleeping	Power saving mode – IP tray moves back into the reader and door will be closed.

	Disconnection	USB / Ethernet is disconnected.
	No software	Software is not running on PC.
	Updating Firmware	Firmware is being updated.
	Ready for scan, but no IP	The reader is ready for scan, but IP is not placed on the tray.
	Ready for Scan	IP size is recognized and the reader is ready.

	Scanning	Scanning is in progress.
	Manual Erasing	Erasing image from IP manually.
	Preview	Preview of scanned image.
	Setting mode	Shows information and settings of the reader.
	Scanning resolution setting	Choosing scanning resolution.

	Auto sleep setting	Choosing time duration until sleep mode.
	Network setting	Manual input for network related settings.
	DHCP setting	Choosing DHCP mode for automatic network settings.
	IP Address setting	Type in IP address manually.
	Subnet mask setting	Type in subnet mask manually.

	Default gateway Setting	Type in gateway address manually.

3.3. Computer Requirements

3.3.1. Recommended Requirement

Operation System	Microsoft Windows 7 (32 bit or 64 bit)
CPU	Core Duo / Core2 Processor
Memory	RAM 4GB or more
Hard Disk	300GB Free Hard Disk Space
Network	1Gbps Ethernet
Video	32 bit Color Display
Video Resolution	1280 x 1024

3.3.2. Minimum Requirement

Operation System	Microsoft Windows 7 (32 bit or 64 bit)
CPU	Core Duo / Core2 Processor
Memory	RAM 2GB or more
Hard Disk	80GB Free Hard Disk Space
Network	1Gbps Ethernet
Video	32 bit Color Display
Video Resolution	1280 x 900

3.4. Installation of Acquisition and Diagnostic Software

Refer to Acquisition and Diagnostic Software manual.

3.5. Connect the Cable and Power Cord

3.5.1. Connect USB Interface Cable

The reader interfaces with computer via USB2.0 cable.

1. Use the USB cable inside the shipping container.
2. Connect the cable to the reader's USB2.0 port, located on the rear of the reader.
3. Connect the other end of the cable to the USB2.0 port on the computer.

Figure 4. USB Connection

DANGER
This equipment is indoor use only and all the communication wirings are limited to inside of the building.

WARNING
Do not pull out the USB cable during scanning.

3.5.2. Connect Ethernet Cable

The reader interfaces with computer via Ethernet cable (RJ45 CAT.6 UTP).

1. Connect the cable to the reader's Ethernet port, located on the rear of the reader.
2. Connect the other end of the cable to the Ethernet port of the Ethernet-hub.
3. If you want to connect to PC directly, use crossed type cable instead of normal Ethernet cable.

Figure 5. Ethernet Connection

DANGER
This equipment is indoor use only and all the communication wirings are limited to inside of the building.

WARNING
Do not pull out the Ethernet cable during scanning.

3.5.3. Connect the Power Cord

1. Connect the power cord to the reader, located on the rear side.
2. Connect the other end of the cord to a grounded power outlet.

Figure 6. Power Connection

DANGER

This equipment must only be connected to supply mains with protective earth. Use only a three-wire cord that has grounding. This is a safety feature**.** If you are unable to insert the plug into the outlet, contact your electrician to replace your obsolete outlet. Do not defeat the safety purpose of the grounding-type plug.

DANGER

Do not use with any electrical power supply that does not meet the ratings displayed on the power adapter. Use with any other power adapter may lead to fire or electrocution.

DANGER

Do not use any power adapter and power cord other than the power adapter and power cord included with the system. Doing so may lead to fire, electrical shock, or electrocution.

WARNING

Socket-outlet shall be installed near the device and shall be easily accessible.

Do not place the device where difficult to access to appliance inlet.

Do not unplug the power cord or turn the power switch off during scanning.

3.5.4. Installation Report

After installation of the reader, fill in Installation Report from (Appendix I) and send to ***3D Imaging & Simulations Corp.*** service department by fax or e-mail.

- Fax : +82-42-931-2299
- E-mail : support@3DISCimaging.com

Chapter 4. Operating

4.1. System Specifications

Sampling Pixel Pitch	SD	64um
	HD	35um
Pixel Matrix (Size 0)	SD	343 x 484
	HD	628 x 885
Pixel Matrix (Size 1)	SD	375 x 625
	HD	685 x 1143
Pixel Matrix (Size 2)	SD	484 x 640
	HD	886 x 1171
Pixel Matrix (Size 3)	SD	421 x 843
	HD	771 x 1542
Pixel Matrix (Size 4c)	SD	750 x 843
	HD	1370 x 1542
Accepted Imaging Plate Size		0, 1, 2, 3, 4c
Gray Scale Resolution		16 bit
Eraser		Embedded
UV Sterilizer		Embedded
Computer Interface		USB 2.0 / 100Mbps Ethernet
Dimensions		265 (H) x 120 (W) x 318 (D) mm 10.4 (H) x 4.7 (W) x 12.5 (D) inch
Weight		4.7 kg 10.4 lbs
Power Requirement		100 ~ 240V / 50 ~ 60Hz
Image File Format		DICOM 3.0, TIFF, BMP, JPEG

* Specifications subject to change without notice.
** Specific results may vary since operating conditions fluctuate.

4.2. Operation Conditions

Indoor use only	
Operating Temperature	15°C ~ 30°C (59°F ~ 86°F)
Temperature Gradient	0.5°C / Min
Relative Humidity	15% ~ 95% (non-condensing)
Storage Temperature	- 10°C ~ 50°C (14°F ~ 122°F)
Storage Humidity	15% ~ 95% (non-condensing)
Storage Atmospheric Pressure	500 ~ 1,060 hPa
Transportation Temperature	- 10°C ~ 50°C (14°F ~ 122°F)
Transportation Humidity	15% ~ 95% (non-condensing)
Transportation Atmospheric Pressure	500 ~ 1,060 hPa
Installation Category	II
Pollution Degree	2
Ingress of Liquids	IPX0
Altitude	Up to 2,000m
Protective Class	Class 1
Equipment Maintenance	No user maintenance is required and no user service is allowed. Please contact technical support if there is a problem.
Cleaning	Do not try to clean inside of the reader. Wipe outside of the reader for dust removing with soft and dry cloth.

WARNING

There are no user serviceable parts inside the reader. The reader should only be opened and serviced by qualified service personnel. Failure to heed this warning may result in injury to service personnel or damage to equipment, and void any and all warranties. If there is a service problem, please contact ***3D Imaging & Simulations Corp.*** or authorized dealer.

4.3. Operating Instructions

4.3.1. Turn on the Reader

Turn on the reader. Power switch is on the rear side of the reader.

DANGER

This device uses laser. Avoid looking inside of the reader.

4.3.2. Turn on the Computer

Turn on the computer. Acquisition and Diagnostic Software must be installed before operate the reader.

4.3.3. Imaging Plate Placement and Removal

Place the imaging plate on the tray to start scan. The imaging plate can be removed when scanning and erasing are completed. Gently pull up the imaging plate.

Figure 7. Imaging Plate Placement and Removal

WARNING

Do not place the imaging plate in wrong direction or upside down when it is being placed on the tray.

In order to scan or erase the IP, locate the IP on the tray correctly and push the tray into the reader fully until interlock holds the tray.

WARNING
Locate the IP in correct position.

WARNING
Do not reuse hygienic bag.

4.3.4. Getting a Scanned Image

To getting a scanned image, refer to Acquisition and Diagnostic Software manual.

4.3.5. Circuit Functions

Chapter 5. Symbols

Symbol	Description
	.Manufacturer
	Date of Manufacture
	Equipment Power ON
	Equipment Power OFF
	Warning, Consult Accompany Documents
	General mandatory action manual
	General prohibition indication
	User Manual Reference
	Directive on Waste Electrical and Electronic Equipment
	Authorised Representative in the European Community
	Keep Dry

	Fragile
	Handle with care
	This side up
	Non-ionizing electromagnetic radiation
FCC ID : X68CRSCANNER2	FCC Mark
	Medical Equipment WITH RESPECT TO ELECTRIC SHOCK FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1 / CAN / CSA CSS.2 No. 601.1 3SE3
	CE Mark

5.1. Manufacturer's Declaration- Electromagnetic Emission

*The **FireCR Dental** system is intended for use in the electromagnetic environment specified below. The customer or the user of **FireCR Dental** system should assure that it is used in such an environment*		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **FireCR *Dental*** system 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 CISPR 11	Class B	The Model ***FireCR Dental*** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

5.2. Manufacturer's Declaration - Electromagnetic Immunity

*The **FireCR Dental** system is intended for use in the electromagnetic environment specified below. The customer or the user of **FireCR Dental** system should assure that it is used in such an environment*			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic Environment -guidance**
Electrostatic discharge (ESD) IEC 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 IEC 61000-4-4	2kV for power supply lines 1kV for input/output lines	2kV for power supply lines 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BSVD-1000 system requires continued operation during power mains interruptions, it is recommended that the ***FireCR Dental*** system be powered from an uninterruptible power supply or a battery

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ***FireCR Dental*** system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	**Recommended separation distance** $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 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 deter-mined 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: 

Note 1) U_T is the A.C. mains voltage prior to application of the test level.

Note 2) At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3) 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 the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verifynormal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ***FireCR Dental*** system.

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

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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.

Immunity and Compliance Level			
Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz

5.3. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

*The **FireCR Dental** system is intended for use in the electromagnetic environment specified below. The customer or the user of **FireCR Dental** system should assure that it is used in such an environment*

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	***FireCR Dental*** system must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5GHz	3 V/m 80.0 MHz to 2.5GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.**a** Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

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 outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

5.4. Laser Safety Statement

The Computed Radiography Reader is Certified in the U.S. to Conform to the Requirements of DHHS 21 CFR, chapter 1 Subchapter J for Class I(1) Laser Products, and Elsewhere is Certified as a Class I(1) Laser Product Conforming to the Requirements of IEC 60825-1 : 2007. Class I(1) Laser Products are not Considered to be Hazardous. The Laser System and Computed Radiography Reader are Designed so there is never any Human Access to Laser Radiation above a Class I(1) level during normal Operation, user Maintenance or Prescribed Service Condition.

• Wavelength : 658 nm (Typ.)
• Beam Divergence
- Paraller : 9.5 degrees (-2.5/+2.5)
- Perpendicular : 17 degrees (-3/+3)
• Maximum Power of Energy Output : 80 mW (CW)

WARNING

Never operate or service the product with the protective cover removed from Laser/Reader assembly.
The reflected beam, although invisible, can damage your eyes.
When using this product, these basic safety precautions should always be followed to reduce risk of fire, electric shock and personal injury

CAUTION

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

Chapter 6. Warranty and Repair Service

6.1. Standard Warranty

3D Imaging & Simulations Corp. warrants its non-consumable hardware products to be free from defects in materials and workmanship. The warranty covers the cost of parts and labor to repair the product. Please keep the shipping container for future use. Products returned to the factory for repair should be properly packaged. To obtain warranty service, follow the procedure described in the Repair Service section. Failure to do so will cause long delays and additional expense to the customer.

The warranty is valid when the product is used for its intended purpose and does not cover products which have been modified without written permission from ***3D Imaging & Simulations Corp.***, or which have been damaged by abuse, accident or connection to incompatible equipment.

This warranty is in lieu of all other warranties, expressed or implied.

6.2. Repair Service

The company reserves the right to cease providing repair maintenance, parts and technical support for its non-consumable hardware products five years after a product is discontinued. Technical support for old versions of software products will cease 12 months after they are upgraded or discontinued.

6.3. Out of Warranty Repair Service

Out of warranty repair service is available in selected geographical locations. Contact the supplier for current terms and rates.

6.4. Shipping

The ***FireCR Dental Reader*** is a solidly built system designed to survive shipping around the world. However, in order to avoid damage during shipping, the ***FireCR Dental Reader*** must be properly packaged.

In general, the best way to package the ***FireCR Dental Reader*** is in the original factory container. If this is no longer available, we recommend that user carefully wraps the ***FireCR Dental Reader*** in at least 75 mm (3 inch) of foam or bubble pack sheeting. The wrapped device should then be placed in a sturdy cardboard carton. Mark the outside of the box with word ***FRAGILE*** and an arrow showing which way is up.

We do not recommend using loose foam pellets to protect the ***FireCR Dental Reader***. If the carton is dropped by the shipper, there is a good chance that the device will shift within the loose pellet packing and be damaged.

If user needs to ship the ***FireCR Dental Reader*** to another location, or back to the factory, and user does not have a means to adequately package it, user can order additional shipping container. This may seem an expense user would like to avoid, but it is inexpensive compared to the cost of repairing an instrument that has sustained shipping damage.

It is user's responsibility to package the system properly before shipping. If the packaging is inadequate, and the system is damaged during shipping, the shipper will not honor user's claim for compensation.

Chapter 7. Technical Assistance

If user has any questions about installing or using the device, contact your ***3D Imaging & Simulations Corp*** representative or your local dealer.

3D Imaging & Simulations Corp.

815, Tamnip-Dong, Yuseong-Gu, Daejeon, Korea
Tel : 82-42-931-2100 Fax : 82-42-931-2299
www.3DISCimaging.com

Appendix I

Installation Report

Please complete this report at the time of installation and submit the completed form signed by customer to:

- **Fax : +82-42-931-2299**
- **E-mail : support@3DISCimaging.com**

Date of Installation :

Customer Information

Hospital / Institute	
Name	
Address	
Tel	
Fax	
E-mail	

Installer Information

Company	
Name	
Address	
Tel	
Fax	
E-mail	

System Information

Model	***FireCR Dental Reader***
System S/N	

Installer's Signature: **Date:**

Customer's Signature: **Date:**