FireCRSpark

User Manual

Computed Radiography Reader

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Part No.: CR-FPM-31-001-EN

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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 B Digital Device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment dose cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: - Reorient or relocate the receiving antenna. - Increase the separation between the equipment and receiver - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. - Consult the dealer or an experienced radio/TV technician for help.

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 Spark* 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.

Intended Use

This device is a Computed Radiography System and intended for use in producing digital X-Ray images for general radiography purposes. It comprises of reader, cassette with reusable imaging plate and workstation software. It scans X-Ray exposed image 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.

FireCR Spark is not approved for the acquisition of mammographic image data.

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Chapter 1. Introduction

Thank you very much for deciding on FireCR Spark - Computed Radiography Reader.

The *FireCR Spark* System is ideal for a wide range of Computed Radiography examinations in specialty practices such as chiropractors, podiatrists and orthopedists.

The *FireCR Spark* can be configured for nearly every clinical application, and is designed for full DICOM connectivity, and allows user to setup the system to capture high quality X-ray images of any body parts with minimal steps including reading, processing, displaying and sending of the high quality image. All imaging parameters are optimized, resulting in digital images that can be enhanced, enlarged, duplicated, and sent to any location as a DICOM 3.0 file format in seconds with no loss of resolution.

Combine the system with reusable phosphor screen equipped *FireCR Spark* cassettes and portable X-ray equipment, it can be used for X-ray exams everywhere it is needed, e.g. nursing facilities, forensic institutions, employee screenings etc.

The *FireCR Spark* System is ideal for Computed Radiography examinations in busy clinics and specialty practices. Affordable, rugged, compact, lightweight, fast and effective *FireCR Spark* System enables all imaging functions to be performed with the advanced image management software, a solution that can be adapted most clinical applications.

The *FireCR Spark* Computed Radiography solution with enhanced workflow and improved productivity are the best solution for medium sized healthcare facilities and clinics. The *FireCR Spark* System complements centralized CR and DR environments such as clinics, ER and OR departments.

Main Features

State-of-the-Art Scanning Mechanism

FireCR Spark adopts state-of-the-art scanning mechanisms using high beam delivery efficiency optics module to construct its compact and rigid structure.

High Throughput

Its unique and patented dual direction scanning mechanism enables to improve the efficiency and high throughput.

Scanning Resolution

User selectable resolution of $100\mu m$ and $200\mu m$ allows user to make diagnosis on variable purposes.

Detector

High sensitive photomultiplier tube equipped in *FireCR Spark* delivers high gain, wide dynamic range and high speed response for radiographic imaging.

Powerful Acquisition and Diagnostic Software

Acquisition and Diagnostic Software designed for the *FireCR Spark*, and its accurate and rapid data processing make the reader more powerful.

Chapter 2. Unpacking

2.1. Inspection for Damage

FireCR Spark 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

Identify each of these components.

Part No.	Item	
CR-FP-31-001	FireCR Spark	
CR-FP-02-003	Universal Cassette 35cm x 43cm containing IP size 35cm x 43cm	
CR-FP-02-004	Universal Cassette 25cm x 30cm containing IP size 24cm x 30cm	
CR-FP-22-001	Universal Cassette 24cm x 30cm containing IP size 24cm x 30cm	
CR-FP-22-002	Universal Cassette 18cm x 24cm containing IP size 18cm x 24cm	
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-34-001	FireCR Spark User Manual	



WARNING

If the *FireCR Spark* needs to be returned to manufacturer or one of its representatives, the scanner 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**.



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. Tabletop Mount

The reader must be placed on a rigid and flat desk or tabletop with at least 10 cm (4 inch) free space on both sides, 20 cm (8 inch) on rear side and 50 cm (20 inch) on front side for cassette insertion. Its space requirements are shown below.

In case that desk or table is not flat, adjust feet under the reader for leveling. The reader weighs approximately 15 kg (33 lbs) and requires two persons to lift. Carefully place the reader into its final position.

DANGER



Never place the reader on the floor.

Sliding the reader may result in internal damage or misalignment of the optics.

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 scanner must be placed on rigid, flat and reinforced desk or tabletop.



WARNING

Do not place anything on top of the scanner.



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. Wall Mount (Option)

The *FireCR Spark* can be mounted on the wall to save space occupancy. When purchasing the wall mount kit, a detailed installation guide and all parts necessary for assembly are provided.



WARNING

Only authorized or trained personnel should set wall mount installation.



NOTE

Refer to Wall Mount Installation Guide provided with Wall Mount Installation Kit.



WARNING

Install the wall mount on a solid wall perpendicular to the floor. When attaching to other building materials, please contact your local dealer. If installed on a slanted wall, it may fall and result in severe injury.

<u>^</u>

WARNING

3D Imaging & Simulations Corp. is not liable for product damage or personal injury when the user fails to follow the product installation instruction.



WARNING

Pulling, pushing, or climbing on the system may cause the system fall

3.3. 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.

3.3.1. Reader Connecting Part

3.3.2. Reader Reset Button

In case that the reader is stuck during scanning, push reader reset button by sharp pin to initialize the reader.



WARNING

Do not push scanner reset button during scanning.

3.4. Computer Requirements

3.4.1. Recommended Requirement

Operation System	Microsoft Windows XP or 7	
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	

3.4.2. Minimum Requirement

Operation System	Microsoft Windows XP or 7
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 1024

3.5. Installation of Acquisition and Diagnostic Software

Refer to Acquisition and Diagnostic Software manual.

3.6. Connect the Cable and Power Cord

3.6.1. Connect Interface Cable

The reader interfaces with computer via USB2.0 cable or Ethernet cable. (RJ45 CAT.6 UTP)

- 1. Use the USB / Ethernet cable in the shipping container.
- 2. Connect the cable to the reader's USB2.0 / Ethernet port, located on the rear of the

reader.

3. Connect the other end of the cable to the USB2.0 / Ethernet port on the computer.



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 / Ethernet cable during scanning.

3.6.2. 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.



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 any power cord other than the 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.

3.6.3. 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

	Standard	200um	
Sampling Pixel Pitch	High	100um	
Divel Metrix (ID 25 em y 42 em)	Standard	1750 x 2150	
Pixel Matrix (IP 35cm x 43cm)	High	3500 x 4300	
Divol Matrix (ID 24am v 20am)	Standard	1200 x 1500	
Pixel Matrix (IP 24cm x 30cm)	High	2400 x 3000	
Pixel Matrix (IP 18cm x 24cm)	Standard	900 x 1200	
Pixel Matrix (IP Tocill x 24cm)	High	1800 x 2400	
Accepted Cassette Size	•	35cm x 43cm, 25cm x 30cm, 24cm x	
Accepted Cassette Size		30cm, 18cm x 24cm	
Gray Scale Resolution		16 bit	
Eraser	Embedded		
Computer Interface	USB 2.0 / Ethernet		
Dimensions	450 x 750x80mm		
Weight	15Kg		
Power Requirement	100 ~ 240V / 50 ~ 60Hz		
System Configuration	Tabletop or Wall Mount		
Image File Format	DICOM 3.0		

^{*} 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.	



DANGER

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 scanner.

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. Cassette Insert and Eject

Insert the cassette to the entrance of the reader and push gently until it reaches to the protection wall inside of the reader. Green indication LED is on when the cassette is inserted correctly. Insertion direction of the cassette must be parallel to the reader.

Cassette can be ejected when scanning and erasing are completed. Gently pull back the cassette and ejection direction of the cassette must be parallel to the reader.



WARNING

Do not insert the cassette in wrong direction or upside down when it is being inserted. Cassette insertion direction is marked on the cassette.

4.3.4. Getting a Scanned Image

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

4.3.5. Circuit Functions

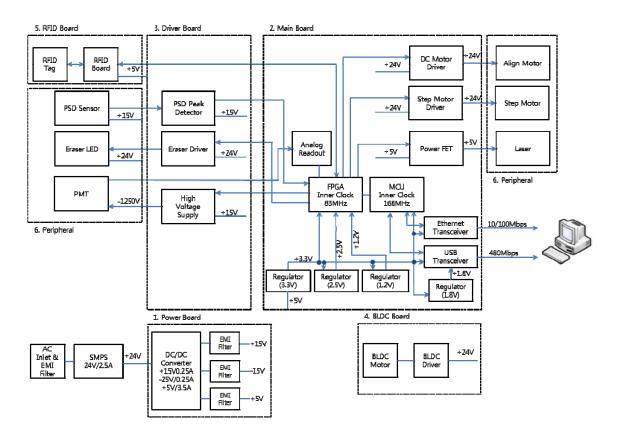


Figure 11. Circuit diagram

✓ Power Board :

Power board generated DC Power of +15V, -15V, +5V

✓ Main Board:

This parts controls peripherals for image acquisition. And it delivers amplified digitized signal to PC via USB and Ethernet.

✓ Driver Board :

This parts controls peripherals for PSD peak detect, Eraser control, high voltage generation

✓ BLDC Board:

This parts controls BLDC Motor and square mirror spin

✓ RFID Board :

This part communicates with the RFID tag. RFID tag is contain IP Cassette information

✓ Peripheral :

This is peripherals for image acquisition. It consists of "Eraser" which erases residual images in imaging plate, "Step Motor and Photo Interrupters" which moves stage, "Laser, Mirror and DC Motor" which are required to radiate laser onto imaging plate, "DC Motor" which assures proper insertion of the cassette.

Chapter 5. Symbols

Symbol	Description	
	Manufacturer	
₩	Date of Manufacture	
•	Equipment Power ON	
<u> </u>	Warning, Consult Accompany Documents	
•	General mandatory action manual	
	General prohibition indication	
	User Manual Reference	
	Directive on Waste Electrical and Electronic Equipment	
EC REP	Authorised Representative in the European Community	
"	Keep Dry	
	Fragile	

	Handle with care
11	This side up
((<u></u>))	Non-ionizing electromagnetic radiation
FCC ID : X68CRSCANNER3	FCC Mark
c UL Us	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
C € ₀₁₂₀	CE Mark

5.1. Manufacturer's Declaration - Electromagnetic Emission

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

5.2. Manufacturer's Declaration - Electromagnetic Immunity

The **FireCR Spark** system is intended for use in the electromagnetic environment specified below. The customer or the user of **FireCR Spark** 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% Ut (>95% dip in Ut) for 0.5cycle 40% Ut (60% dip in Ut) for 5 cycle 70% Ut (30% dip in Ut) for 25 cycle <5% Ut (<95% dip in Ut) for 5 s	<5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>FireCR Spark</i> system requires continued operation during power mains interruptions, it is recommended that the <i>FireCR Spark</i> 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 <i>FireCR Spark</i> 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
			$d = [\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2.5 GHz
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:
			((<u>~</u>))

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 Spark* system.

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

Rated maximum output	Separation distance (m) according to frequency of transmitter			
power (W) 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	3 Vrms, 150 kHz to 80	3 Vrms, 150 kHz to 80	3 Vrms, 150 kHz to 80	
IEC 61000-4-6	MHz	MHz	MHz	
Radiated RF	3 V/m, 80 MHz to 2.5	3 V/m, 80 MHz to 2.5	3 V/m, 80 MHz to 2.5	
IEC 61000-4-3	GHz	GHz	GHz	

5.3. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF	3 Vrms	3 Vrms	FireCR Spark system must be used
IEC 61000-4-6	150 kHz to 80MHz	150 kHz to 80 MHz	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.

Radiated RF	3 V/m	3 V/m	Field strengths outside the shielded
IEC 61000-4-3	80.0 MHz to 2.5GHz	80.0 MHz to 2.5GHz	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 Spark* is a solidly built system designed to survive shipping around the world. However, in order to avoid damage during shipping, the *FireCR Spark* must be properly packaged.

In general, the best way to package the *FireCR Spark* is in the original factory container. If this is no longer available, we recommend that user carefully wraps the *FireCR Spark* 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 Spark*. 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 Spark* 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

■ Fax: +82-42-931-2299

■ E-mail: support@3DISCimaging.com

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Date of	111314	1141		

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Custo	mer	intori	nation

Hospital / Institute	
Name	
Address	
Tel	
Fax	
E-mail	

Installer Information

Company	
Name	
Address	
Tel	
Fax	
E-mail	

System Information

Model	FireCR Spark CR Reader
System S/N	

Installer's Sig	nature:	Date:
ilistaliel 5 Siu	Halule.	Dale.

Customer's Signature: Date: