FireCR dental

User Manual.Rx Only

Dental Computed Radiography Reader

Intended Use: The ***FireCR Dental Imaging System*** is indicated for capture, digitization and processing of intra oral x-ray images stored on imaging plate recording media.

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3DISC

Contact

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The device complies with DHHS Radiation Safety Standards in effect as of the date of manufacture.

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 causes 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 system.

The following symbols will be used throughout this manual:

DANGER
General prohibition indication.
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.

DANGER
General mandatory action manual.
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 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 normal conditions only.

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

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 an authorized dealer.

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

Keep the device away 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.

WARNING
Pay particular attention to use, care, maintenance, and infection control of Imaging Plate, Chapter 4.3.

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Chapter 1. Introduction

Dear Customer

Thank you for choosing the ***3DISC Imaging FireCR Dental Reader*** as your new dental solution.

The advanced CR technology of the ***FireCR Dental Reader*** enables you to produce high-quality digital images for diagnosing the patients in your facility. The reader can be used as a central reader, which distributes images throughout your facility, or as an exam-room based solution. The reader is DICOM 3.0 compatible with existing systems and uses a full range of low-cost, reusable bitewings and intraoral imaging plates. The design features a built-in erase function and a color touch-screen LCD panel without physical push buttons for seamless device operation.

Please read and follow the instructions given in this 'User Manual' carefully prior to using the ***FireCR Dental Reader*** and keep this manual within reach for future reference.

The purpose of this manual is to direct you through the main functions and interfaces of the ***FireCR Dental Reader***. You will be guided through the procedures of 'Unpacking', 'Setting Up' and 'Operating' the ***FireCR Dental Reader***. You can also learn about 'Symbols', 'Warranty and Repair Service' and 'Technical Assistance'. It is important to observe all safety information to prevent potential personal injury or material damage.

Please complete and submit the 'Installation Report' (Appendix 1) when installing the device.

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.

- Common items

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.5E FTP Cable 2M(Cross type)
CR-FPA-03-00X	Power Cord
CR-FPM-11-001	***FireCR Dental*** User Manual
CR-PKM-11-004	IP Storage Box

- Medical application items

Part No.	Item
CR-FP-12-010	Imaging Plate Starter Kit – Dental Contains : 2 x IP size 0 and 4 x IP size2
CR-FPA-15-001	Size 0 IP Hygienic Bag Box of 100 pcs
CR-FPA-15-003	Size 2 IP Hygienic Bag Box of 100 pcs

- Veterinary application items

Part No.	Item
CR-FP-12-030	Imaging Plate Starter Kit – Veterinary Contains : 4 x IP size 2 and 1 x IP size 4c
CR-FPA-15-003	Size 2 IP Hygienic Bag Box of 100 pcs
CR-FPA-15-005	Size 4c IP Hygienic Bag(option) Box of 100 pcs

- Optional items

Part No.	Item
CR-FP-12-012	Size 0 Imaging Plate Kit Contains : 4 x IP size 0
CR-FP-12-013	Size 1 Imaging Plate Kit Contains : 4 x IP size 1
CR-FP-12-014	Size 2 Imaging Plate Kit Contains : 4 x IP size 2
CR-FP-12-015	Size 3 Imaging Plate Kit Contains : 4 x IP size 3
CR-FP-12-016	Size 4c Imaging Plate Kit Contains : 1 x IP size 4c
CR-FP-12-020	Hygienic Bags Size 0 Box of 100 pcs
CR-FP-12-021	Hygienic Bags Size 1 Box of 100 pcs
CR-FP-12-022	Hygienic Bags Size 2 Box of 100 pcs
CR-FP-12-023	Hygienic Bags Size 2 Box of 300 pcs
CR-FP-12-024	Hygienic Bags Size 3 Box of 100 pcs
CR-FP-12-025	Hygienic Bags Size 4c Box of 100 pcs
CR-FP-12-035	Protective Cover Size 0 Box of 100 pcs
CR-FP-12-036	Protective Cover Size 1 Box of 100 pcs
CR-FP-12-037	Protective Cover Size 2 Box of 100 pcs
CR-FP-12-038	Protective Cover Size 2 Box of 300 pcs
CR-FP-12-039	Protective Cover Size 3 Box of 100 pcs
CR-FP-12-040	Protective Cover Size 4c Box of 100 pcs
CR-FP-51-010	***FireID*** Kit (RFID Reader, mini USB cable)

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 a supply not located in the USA, make sure the power cord meets the requirements for 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 government agencies. Do not dispose of any part of this equipment without consulting a ***3D Imaging & Simulations Corp.*** 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 meets the requirements of IEC60601-1.

WARNING

Use only devices meeting the requirements of IEC60950-1 or IEC60601-1 when connecting to the ***FireCR Dental*** via the 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 inches) free space on both of the sides, 10 cm (4 inches) on rear side and 15 cm (6 inches) on front side for imaging plate insertion. Its space requirements are shown below.

Allow a minimum free space of 15 cm (6 inches) on the front side for imaging plate insertion and removal.

Allow a minimum free space of 10 cm (4 inches) on the backside 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 accidents, or deterioration in image quality.

WARNING
Sliding of 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 a rigid, flat and reinforced desk or tabletop.

DANGER
Do not place anything on top of the reader.

WARNING
This equipment may be interfered with or may interfere with electromagnetic or other interferences.

Assure a distance of minimum 1.0m between reader and 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 Connection Panel*

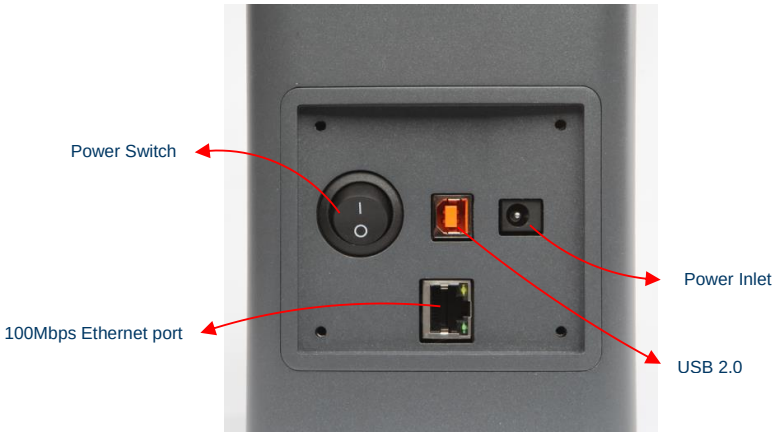


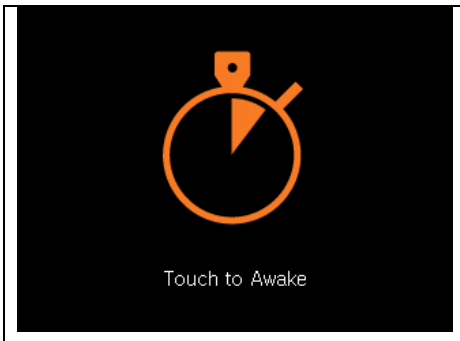
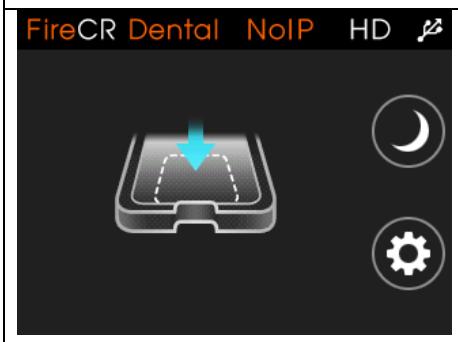
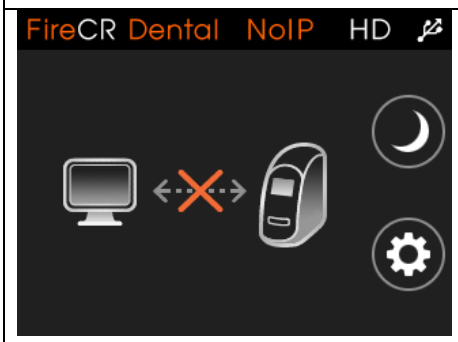
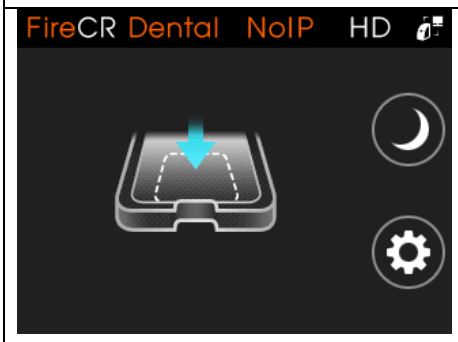
Figure 2. Reader Connection Panel

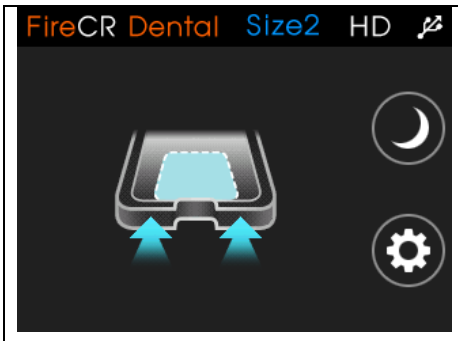
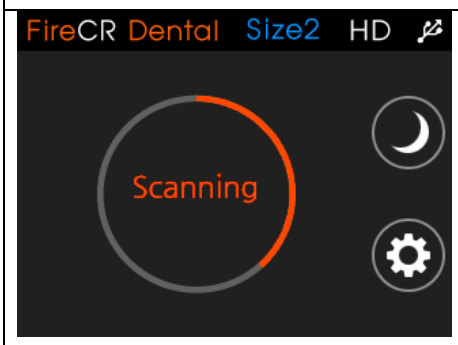
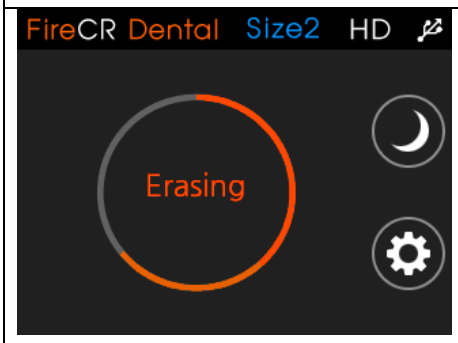
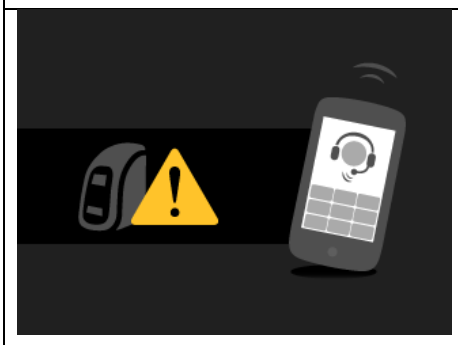
3.2.2. *Touch Display Panel*

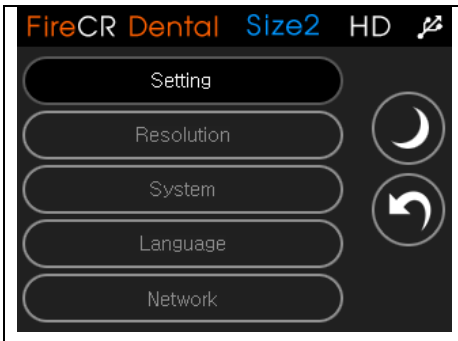
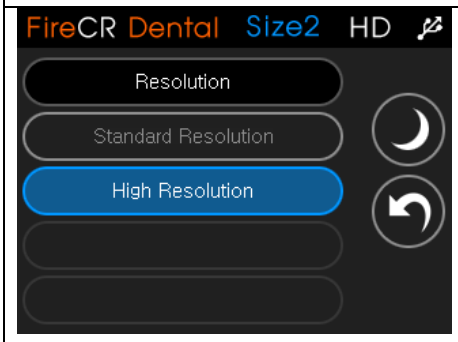
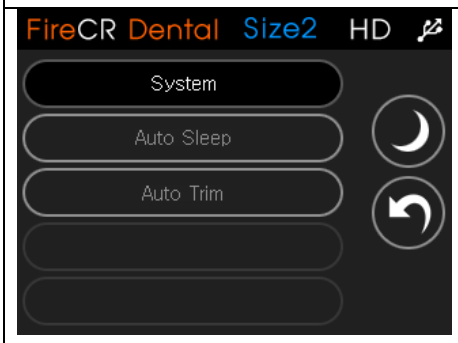
Screen displays the status of the reader and control of the reader can be done through touch display panel.

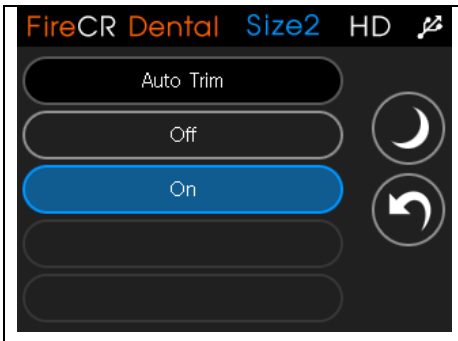
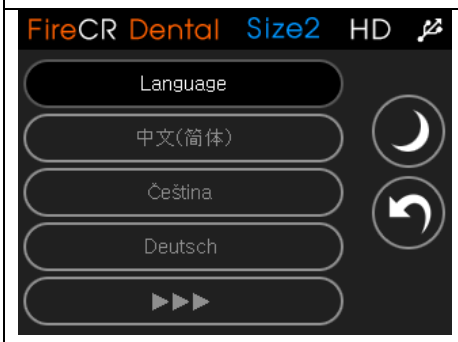
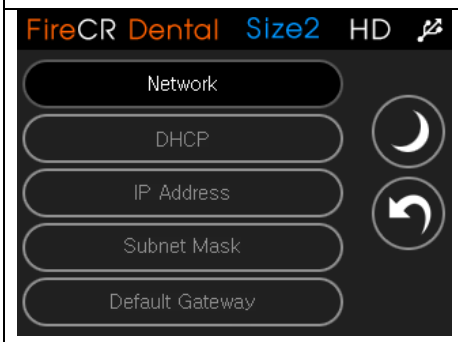
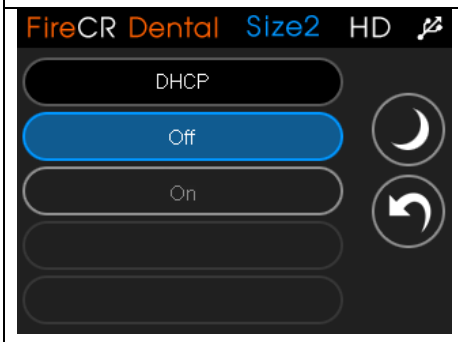
Figure 3. Touch Display Panel

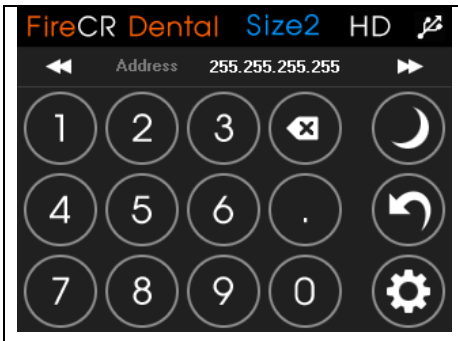
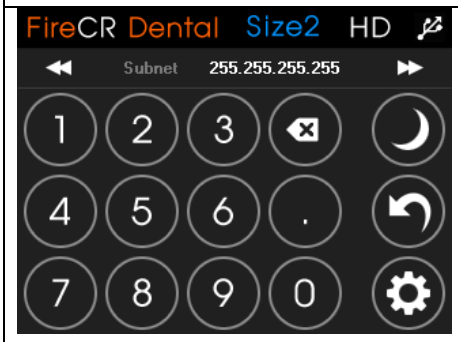
Display	Status	Remark
	Booting screen	When the reader is turned on, booting screen is displayed during system initialization.

	Sleeping	Auto Sleep mode – IP tray moves back into the reader and door will be closed.
	Description of icons at status bar	NoIP, Size0~Size4c: Size of imaging plate. HD SD: High resolution, standard resolution. Temporarily toggles when it is touched. : USB, Ethernet, no cable connection respectively.
	Disconnection	USB cable is connected but no application program is running on computer.
	Ready for scan, but no IP	Waiting for IP to be placed. Scan will not start with an empty tray.

	Ready for Scan	IP size is recognized and the reader is ready.
	Scanning	Scanning is in progress.
	Erasing	Erasing is in progress.
	System error	Unexpected system error. Contact technical support.

	Setting mode	When  button is selected from main screen, **Setting** mode is displayed.
	Scanning resolution setting	Choose HD or SD HD: High Definition SD: Standard Definition
	System setting	System setting for Auto Sleep and Auto Trim
	Auto Sleep setting	Choosing time duration until sleep mode.

	Auto Trim setting	Choose Off or On Auto Trim Off : Scan corresponding area of IP detected by the reader Auto trim on : Scan whole tray area and crop the image automatically
	Language	Choose language
	Network	Network setting menu
	DHCP setting	Choose DHCP mode for automatic network setting. When this setting is changed, the system will restart automatically.

	IP Address setting	Type in IP address manually. When this setting is changed, the system will restart automatically.
	Subnet mask setting	Type in Subnet mask manually. When this setting is changed, the system will restart automatically.
	Default Gateway Setting	Type in Gateway address manually. When this setting is changed, the system will restart automatically.

3.3. *Computer Requirements*

3.3.1. *Recommended Configuration*

Operation System	Microsoft Windows 7, 8, 10 (32 bit or 64 bit)
CPU	Core Duo / Core2 Processor
Memory	RAM 4GB or more
Hard Disk	300GB Free Hard Disk Space
Network	100Mbps Ethernet
USB	2.0 High speed
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	100Mbps Ethernet
USB	2.0 High Speed
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*

FireCR Dental supports **direct connection mode** for single reader with single computer and **network sharing mode** for multiple readers with multiple computers. This manual describes direct connection mode only. Network sharing mode requires additional ***FireID*** Kit (RFID reader) and detailed instruction for network sharing mode is provided with ***FireID*** Kit.

3.5.1. *Connecting the USB Interface Cable*

The reader interfaces with computer via USB2.0 cable.

1. Use the supplied USB cable.
2. Connect the cable to the reader's USB2.0 port, located on the connection panel.
3. Connect the other end of the cable to the USB2.0 port on the computer.

Figure 4. USB Connection

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

WARNING
Do not pull out the USB cable during scanning.

3.5.2. *Connecting the Ethernet Cable*

The reader interfaces with the computer via Ethernet cable (RJ45 CAT.5E FTP).

1. Connect the cable to the reader's Ethernet port, located on the connection panel.
2. Connect the other end of the cable to the Ethernet port of the Ethernet-hub.
3. To connect the PC directly, use the supplied crossed cable.

Figure 5. Ethernet Connection

DANGER

This equipment is for indoor use only and all the communication wiring is limited to inside of the building.

WARNING

Do not pull out the Ethernet cable during scanning.

3.5.3. *Connecting the Power Cord*

1. Connect the power cord to the reader, located on the connection panel.
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. For your safety, do not remove the ground from the grounding-type plug.

DANGER

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

DANGER

Only use the supplied power adapter and power cord included with the system. Not doing so may lead to fire, electrical shock, or electrocution.

WARNING

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

Do not place the device where access to appliance inlet is obstructed.

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.'s*** service department by fax or e-mail.

- Fax : +82-42-931-2299
- E-mail : support@3DISC.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
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		5.5 kg 12.1 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 an authorized dealer.

4.3. *Use, Care, Maintenance and Infection Control*

Use proper dental aseptic techniques. As with other radiographic procedures, the use of imaging plate requires the same high standards of infection control. Unfortunately, imaging plates create a greater challenge since they are not disposable. Another problem is that there is a higher potential for damaging them since they are reusable. Damage can result in the production of artifacts that may interfere with the diagnosis of disease. Hygienic bags have been found in most cases to be effective in protecting the imaging plate from becoming contaminated. The hygienic bags should be removed after use on each patient to prevent cross-contamination. The hygienic bags are for single patient use only. Never reuse a hygienic bag.

DANGER

Never reuse a hygienic bag. Hygienic bag is for single patient use only.

4.3.1. *Use Protective Cover*

Put protective cover on active side of imaging plate and fold tail of protective cover to backside of imaging plate.

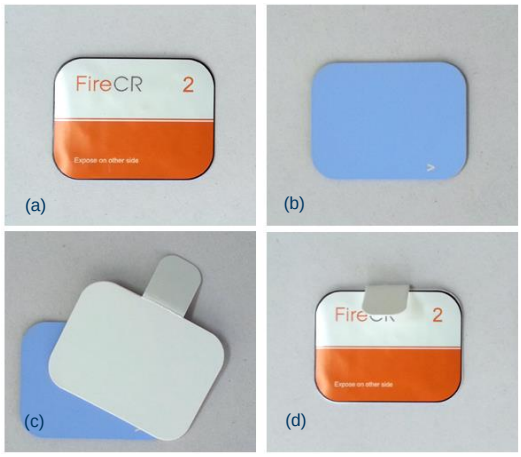


Figure 7.Protective Cover

Figure 7. Put protective cover on imaging plate: (a) Back side of imaging plate. (b) Front/active side of imaging plate. (c) Put protective cover on active side of imaging plate. (d) Fold the tail of protective cover to opposite side of imaging plate.

4.3.2. *Use Hygienic Bag*

Insert prepared imaging plate with protective cover into hygienic bag. Please beware of correct side of imaging plate as shown in Figure 8.

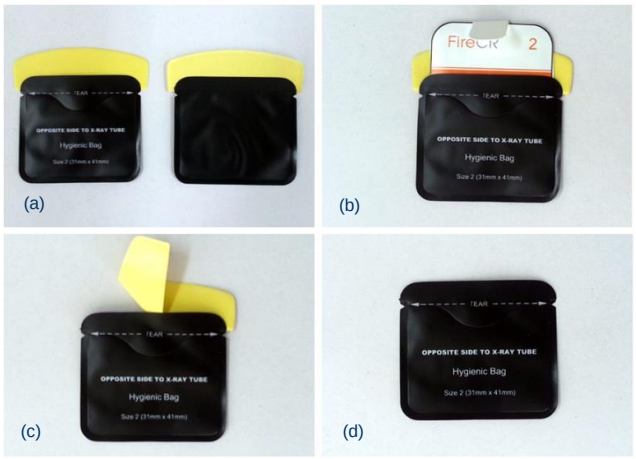


Figure 8. Hygienic Bag

Figure 8. Insertion of imaging plate into hygienic bag: (a) Blank side should face to X-ray source. (b) Insert imaging **plate with hygienic bag into hygienic bag correctly.** (c) Peel off the adhesive strip and seal the hygienic bag. (d) Prepare imaging plate for X-ray exposure.

WARNING
Active side of the imaging plate should face to blank side of the hygienic bag.

WARNING
Active side of the imaging plate and blank side of the hygienic bag should face to X-ray source.

4.3.3. *Cleaning of the Tray*

Clean the tray using soft lint-free cellulose cloth with Ethanol (99.7%)

Figure 9. Imaging Plate Tray

4.4. *Operating Instructions*

4.4.1. *Turn on the Reader*

Turn on the reader. Power switch is located on the connection panel.

DANGER

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

4.4.2. *Turn on the Computer*

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

4.4.3. *X-ray exposure on imaging plate*

Blank side of hygienic bag (active side of imaging plate) must face the tooth and X-ray source.

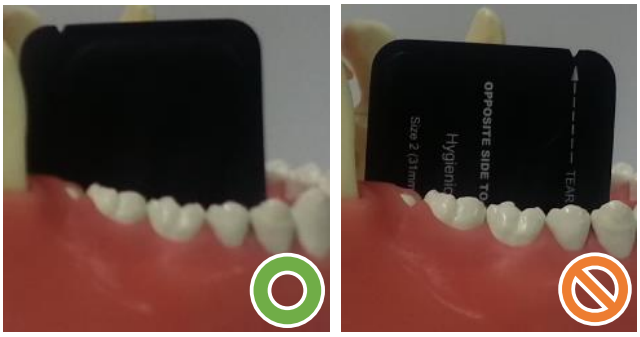


Figure 10. Direction of imaging plate for X-ray exposure.

4.4.4. *Imaging Plate Placement and Removal*

Take imaging plate out of the hygienic bag after tearing off the seal. Place the imaging plate towards the front and center of the tray, as shown in Figure 11, and remove the protective cover.

Figure 11. Correct positioning of imaging plate.

Push tray in to start scan. The imaging plate can be removed when scanning and erasing are completed **and the tray is outside again**. Gently pull up the imaging plate not to scratch the active side.

Figure 12. Push left side or right side of tray gently to start scan.

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.

4.4.5. *Getting a scanned image*

To acquire an image, refer to Acquisition and Diagnostic Software manual.

4.4.6. *Circuit Functions*

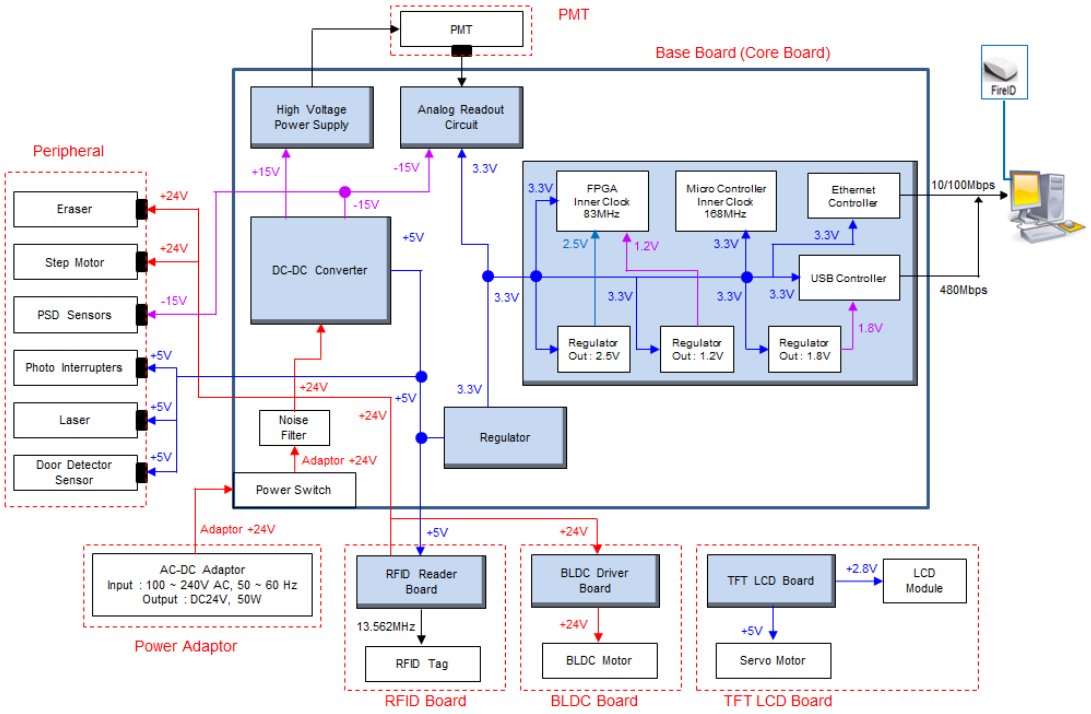


Figure 13. Circuit Diagram

✓ Base Board:
Base board is a controller of peripherals. It controls peripherals upon command of core board.

✓ Peripheral:
These are peripherals for image acquisition. They consist of “Eraser” which erases residual images in imaging plate, “Step Motor” which moves the stage, “PSD (Edge) Sensor” which detects the laser beam rotating speed, “Door detect sensor” which detects status of the door (open or closed), “Photo Interrupters” which detects the position of the stage and “Laser” which is required to radiate laser onto imaging plate.

✓ Base Board Image Data Controller (Core Board):
This part controls peripherals for image acquisition, and delivers amplified digitized signal to PC via USB or Ethernet.

✓ Touch Display Panel
Screen displays reader’s status and control of the reader can be done using the touch display panel.

- ✓ Image Sensor (PMT):
  This Photomultiplier Tube receives the signal through scanning of the imaging plate, and then sends the signal to the analog readout circuit.

- ✓ Power Adapter:
  Supplies power to all modules of the system which are required for operation.

Chapter 5. Symbols

Symbol	Description
	Manufacturer
	Date of Manufacture
	Equipment Power ON
	Warning, Consult Accompanying Documents
	General mandatory action manual
	General prohibition indication
	User Manual Reference
	Directive on Waste Electrical and Electronic Equipment
EC REP	Authorized Representative in the European Community
	Keep Dry
	Fragile

	Handle with care
	This side up
	Non-ionizing electromagnetic radiation
	IEC60825 Warning; Laser beam
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	Main 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	Main 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	Main 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 main 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 the minimum RF shielding effectiveness and, each cable should have the minimum RF shielding effectiveness.
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. 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.

Bldg.1, 48, Yuseong-daero 1184 beon-gil, Yuseong-gu, Daejeon, 34109 Korea
Tel : 82-42-931-2100 Fax : 82-42-931-2299
www.3DISC.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@3DISC.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:**