

# 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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**Part No. : CR-FPM-11-001-EN**

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## Contact

The logo for DIGIRAY, featuring the word "DIGIRAY" in a bold, sans-serif font. The letter "Y" is stylized with an orange triangle pointing upwards and to the right, positioned above the top bar of the "Y".

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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 **Digiray Corp.** may only be made with prior written permission from **Digiray 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 **Digiray Corp.** becomes void.

**Digiray 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 **Digiray Corp.** becomes void.

**DigirayCorp.** 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.

***Digiray 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 ***Digiray 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 of 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 **Digiray 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  | <b>FireCR Dental Reader</b>          |
| 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 | <b>FireCR Dental</b> User Manual     |
| CR-PKM-11-004 | IP Storage Box                       |

- Medical application items

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

- Veterinary application items

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

● Optional items

| Part No.     | Item   |
|--------------|--|
| CR-FP-12-012 | Size 0 Imaging Plate Kit<br>Contains : 4 x IP size 0   |
| CR-FP-12-013 | Size 1 Imaging Plate Kit<br>Contains : 4 x IP size 1   |
| CR-FP-12-014 | Size 2 Imaging Plate Kit<br>Contains : 4 x IP size 2   |
| CR-FP-12-015 | Size 3 Imaging Plate Kit<br>Contains : 4 x IP size 3   |
| CR-FP-12-016 | Size 4c Imaging Plate Kit<br>Contains : 1 x IP size 4c |
| CR-FP-12-020 | Hygienic Bags Size 0<br>Box of 100 pcs                 |
| CR-FP-12-021 | Hygienic Bags Size 1<br>Box of 100 pcs                 |
| CR-FP-12-022 | Hygienic Bags Size 2<br>Box of 100 pcs                 |
| CR-FP-12-023 | Hygienic Bags Size 2<br>Box of 300 pcs                 |
| CR-FP-12-024 | Hygienic Bags Size 3<br>Box of 100 pcs                 |
| CR-FP-12-025 | Hygienic Bags Size 4c<br>Box of 100 pcs                |
| CR-FP-12-035 | Protective Cover Size 0<br>Box of 100 pcs              |
| CR-FP-12-036 | Protective Cover Size 1<br>Box of 100 pcs              |
| CR-FP-12-037 | Protective Cover Size 2<br>Box of 100 pcs              |
| CR-FP-12-038 | Protective Cover Size 2<br>Box of 300 pcs              |
| CR-FP-12-039 | Protective Cover Size 3<br>Box of 100 pcs              |
| CR-FP-12-040 | Protective Cover Size 4c<br>Box of 100 pcs             |
| CR-FP-51-010 | <b>FireID</b> 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 **Digiray Corp.**'s representative or related government agencies. Do not dispose of any part of this equipment without consulting a **Digiray Corp.** representative first.

**Digiray Corp.** does not assume any responsibility for damage resulting from disposal of this equipment without consulting **Digiray 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

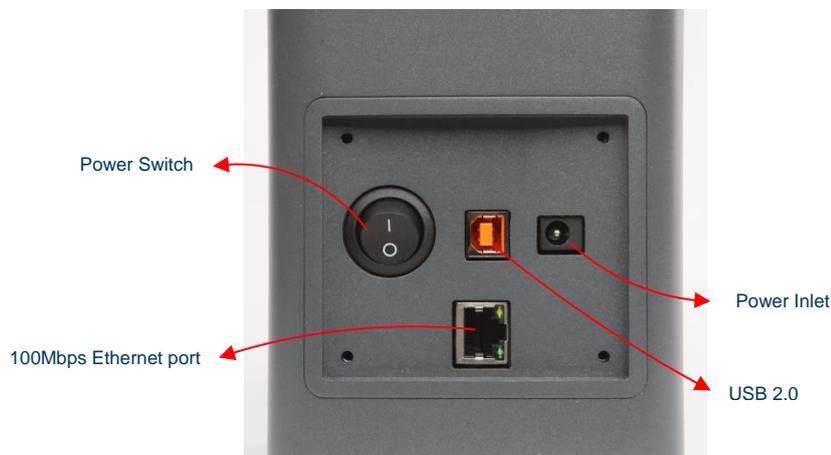


Figure 2. Reader Connection Panel

### 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.

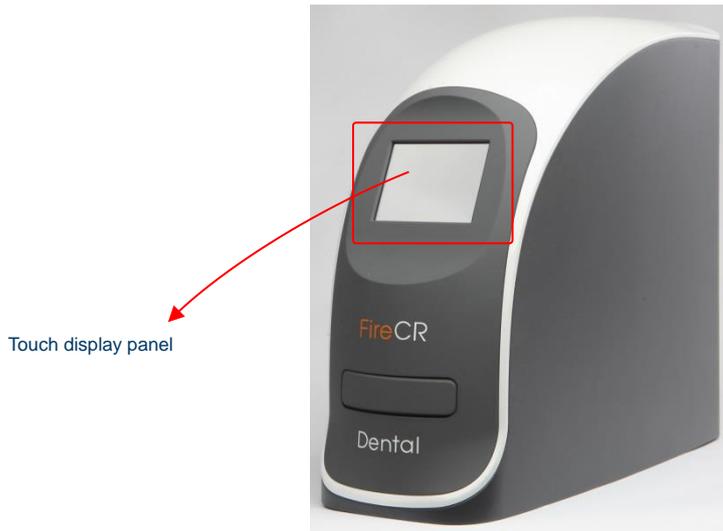
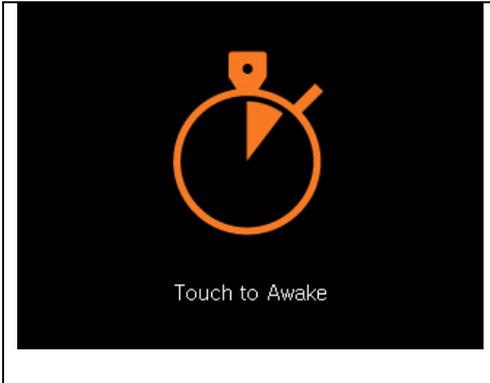
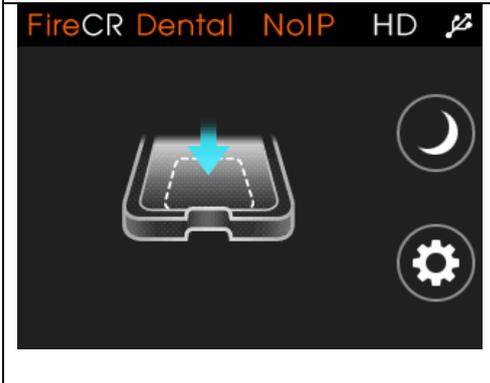
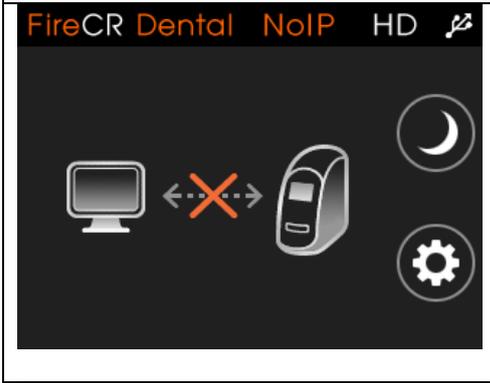
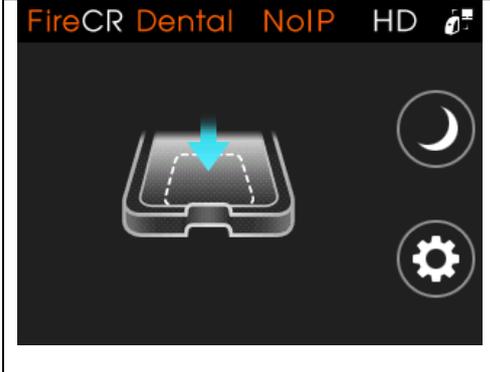
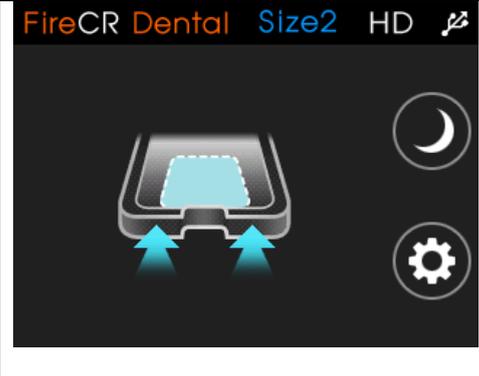
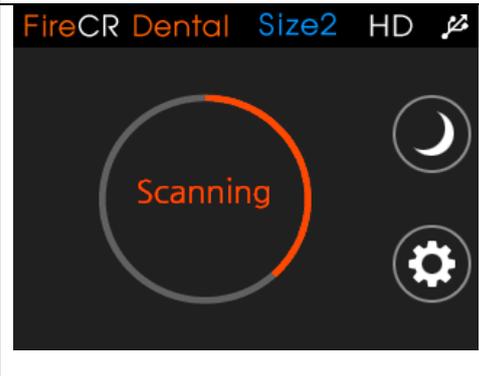
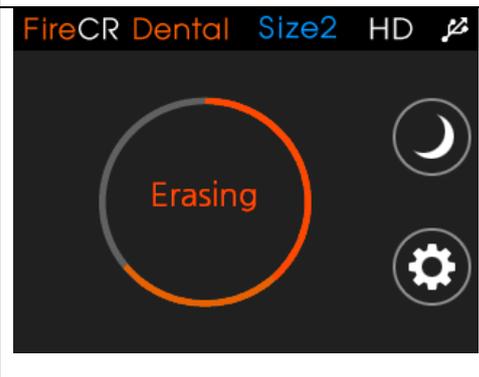
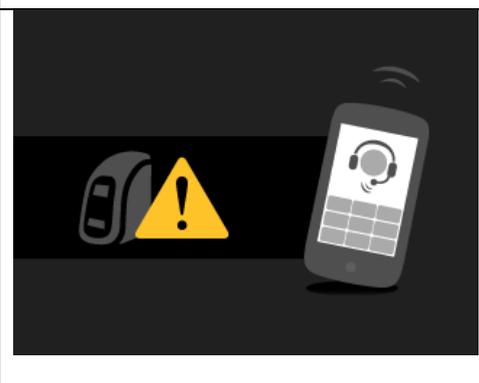
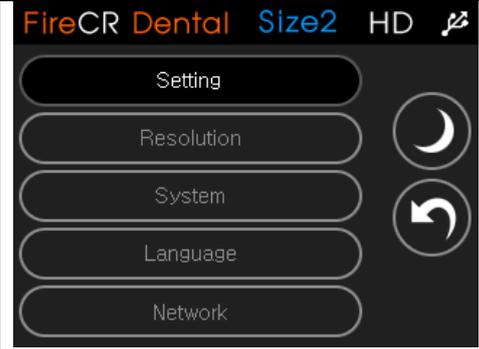
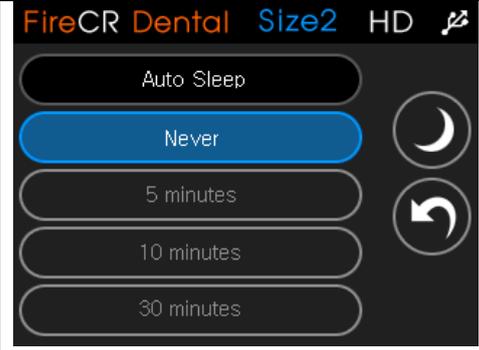


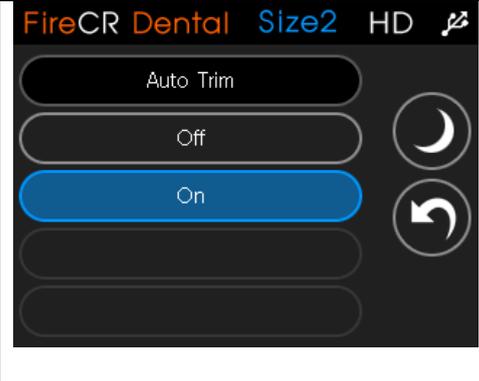
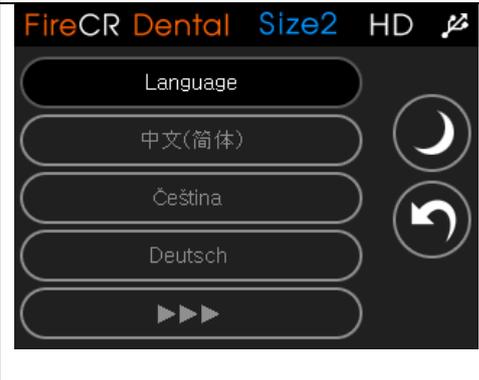
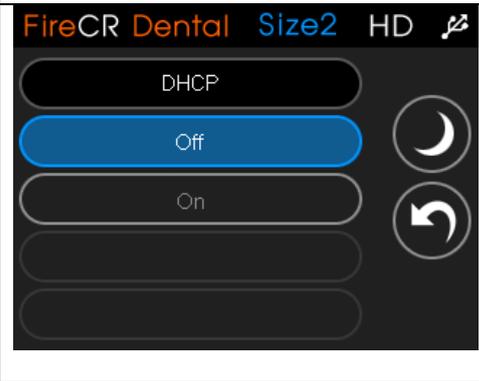
Figure 3. Touch Display Panel

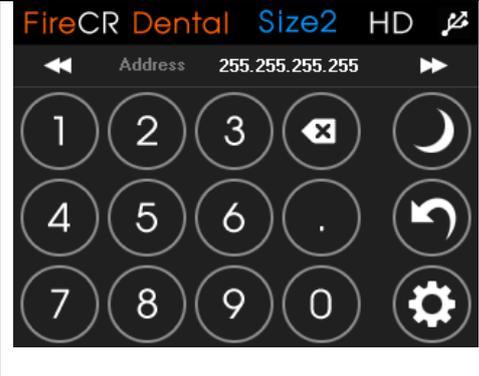
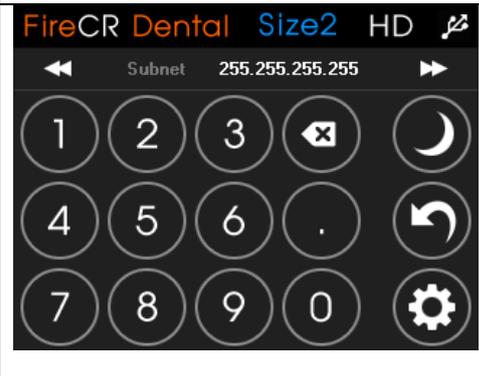
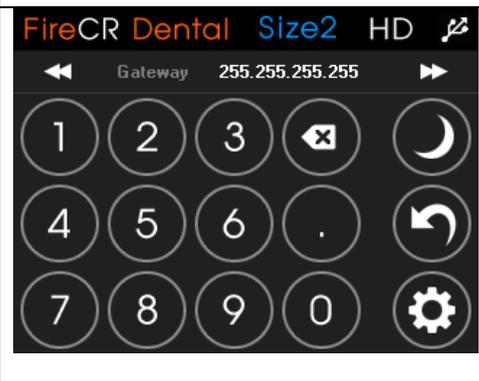
| Display   | Status         | Remark  |
|---|----------------|---|
|  | Booting screen | When the reader is turned on, booting screen is displayed during system initialization. |

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

|   |                       |   |
|---|-----------------------|---|
|    | <p>Ready for Scan</p> | <p>IP size is recognized and the reader is ready.</p>                       |
|   | <p>Scanning</p>       | <p>Scanning is in progress.</p>   |
|  | <p>Erasing</p>        | <p>Erasing is in progress.</p>  |
|  | <p>System error</p>   | <p>Unexpected system error.<br/>             Contact technical support.</p> |

|   |                                    |  |
|---|------------------------------------|--|
|    | <p>Setting mode</p>                | <p>When  button is selected from main screen, <b>Setting</b> mode is displayed.</p> |
|    | <p>Scanning resolution setting</p> | <p>Choose HD or SD<br/><br/>HD: High Definition<br/>SD: Standard Definition</p>  |
|  | <p>System setting</p>              | <p>System setting for Auto Sleep and Auto Trim</p>   |
|  | <p>Auto Sleep setting</p>          | <p>Choosing time duration until sleep mode.</p>  |

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

|   |  |  |
|---|--|--|
|    | <p>IP Address<br/>                 setting</p>                           | <p>Type in IP address manually.</p> <p>When this setting is changed, the system will restart automatically.</p>      |
|   | <p>Subnet mask<br/>                 setting</p>                          | <p>Type in Subnet mask manually.</p> <p>When this setting is changed, the system will restart automatically.</p>     |
|  | <p>Default<br/>                 Gateway<br/>                 Setting</p> | <p>Type in Gateway address manually.</p> <p>When this setting is changed, the system will restart automatically.</p> |

### 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 **Digiray & 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<br>10.4 (H) x 4.7 (W) x 12.5 (D) inch |             |
| Weight                      | 5.5 kg<br>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.<br>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.

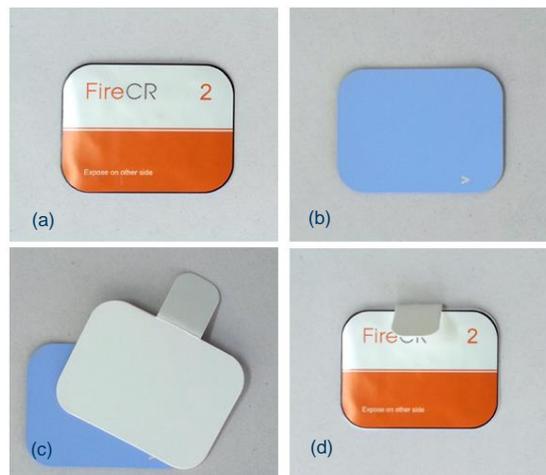


Figure 7. Protective Cover

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.

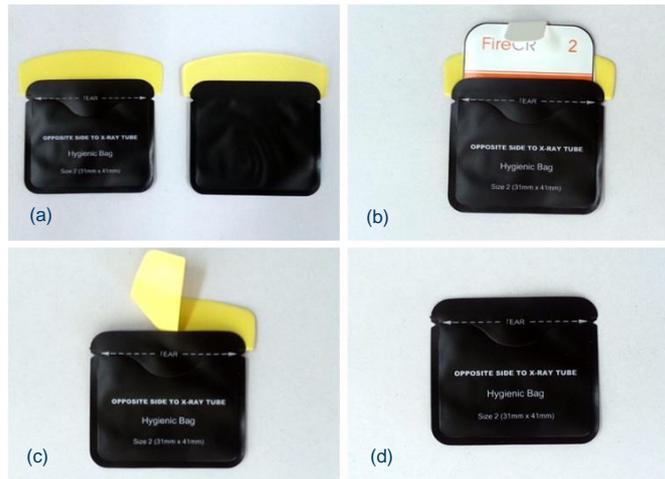


Figure 8. Hygienic Bag

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.

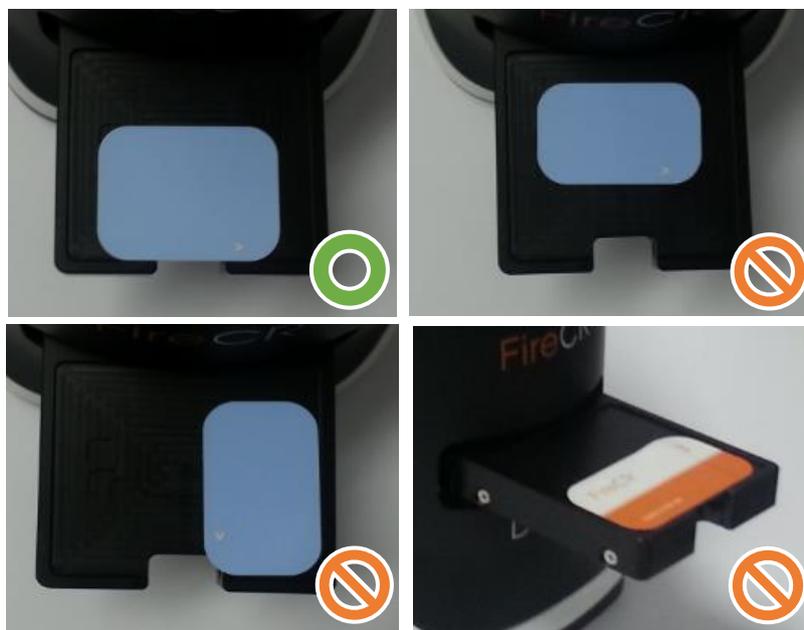


Figure 11. Correct positioning of imaging plate.

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

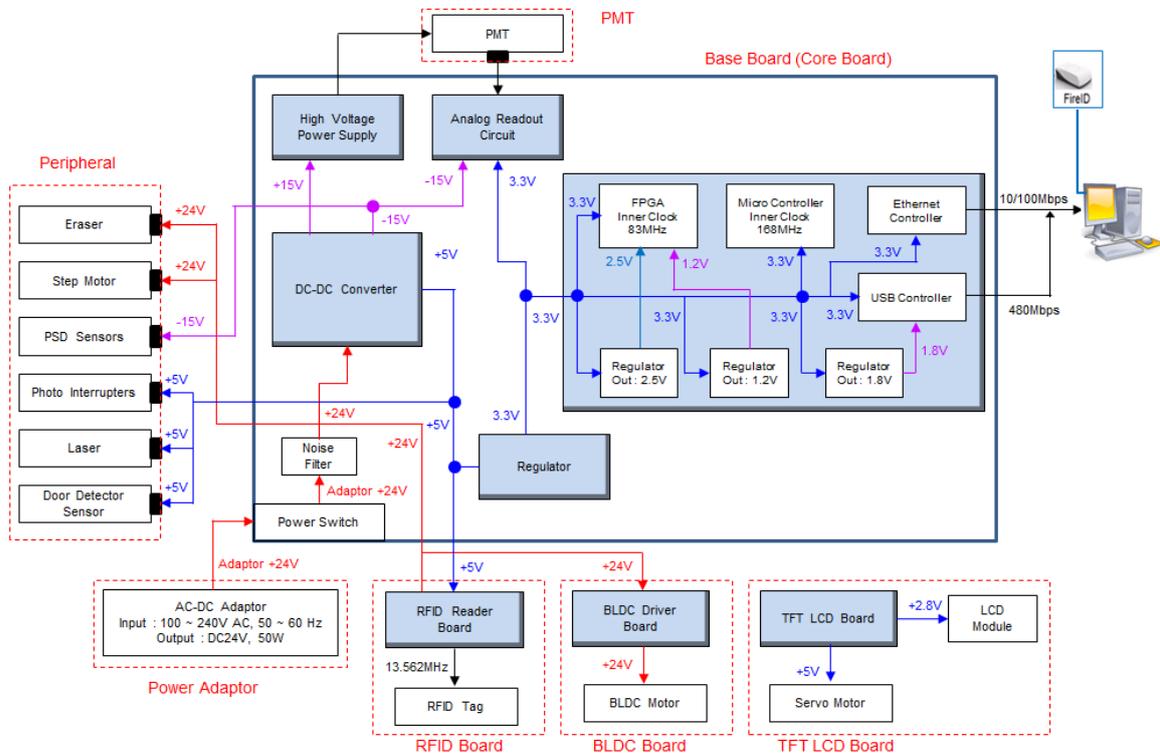
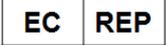


Figure 13. Circuit Diagram

- ✓ **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 |
|  | 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 :<br>X68CRSCANNER2   | FCC Mark   |
|   | Medical Equipment<br>WITH RESPECT TO ELECTRIC SHOCK<br>FIRE, AND MECHANICAL HAZARDS ONLY<br>IN ACCORDANCE WITH UL60601-1 / CAN / CSA CSS.2 No. 601.1<br>3SE3 |
|  | CE Mark  |

### 5.1. Manufacturer's Declaration- Electromagnetic Emission

| <i>The <b>FireCR Dental</b> system is intended for use in the electromagnetic environment specified below. The customer or the user of <b>FireCR Dental</b> system should assure that it is used in such an environment</i> |            |   |
|---|------------|---|
| Emission test   | Compliance | Electromagnetic environment - guidance  |
| RF emissions<br>CISPR 11  | Group 1    | The <b>FireCR Dental</b> 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<br>CISPR 11  | Class B    | The Model <b>FireCR Dental</b> 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<br>IEC 61000-3-2   | A          |   |
| Voltage fluctuation<br>IEC 61000-3-3  | Complies   |   |

## 5.2. Manufacturer's Declaration - Electromagnetic Immunity

| <i>The <b>FireCR Dental</b> system is intended for use in the electromagnetic environment specified below. The customer or the user of <b>FireCR Dental</b> system should assure that it is used in such an environment</i> |  |  |   |
|---|--|--|---|
| <b>Immunity test</b>  | <b>IEC 60601 Test level</b>  | <b>Compliance level</b>  | <b>Electromagnetic Environment -guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | 6 kV Contact<br>8 kV Air   | 6 kV Contact<br>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<br>IEC 61000-4-4  | 2kV for power supply lines<br>1kV for input/output lines   | 2kV for power supply lines<br>1kV for input/output lines   | Main power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | 1 kV differential mode<br>2 kV common mode   | 1 kV differential mode<br>2 kV common mode   | Main power quality should be that of a typical commercial or hospital environment.  |
| Power frequency (50/60Hz)<br>Magnetic field<br>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<br>IEC 61000-4-11  | <5% $U_T$ (>95% dip in $U_T$ ) for 0.5cycle<br><br>40% $U_T$ (60% dip in $U_T$ ) for 5 cycle<br><br>70% $U_T$ (30% dip in $U_T$ ) for 25 cycle<br><br><5% $U_T$ (<95% dip in $U_T$ ) for 5 s | <5% $U_T$ (>95% dip in $U_T$ ) for 0.5cycle<br><br>40% $U_T$ (60% dip in $U_T$ ) for 5 cycle<br><br>70% $U_T$ (30% dip in $U_T$ ) for 25 cycle<br><br><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 <b>FireCR Dental</b> system be powered from an uninterruptible power supply or a battery. |

|   |                                      |                                      |   |
|---|--------------------------------------|--------------------------------------|---|
| <p>Conducted RF<br/>IEC 61000-4-6</p>   | <p>3 Vrms<br/>150 kHz to 80 MHz</p>  | <p>3 Vrms<br/>150 kHz to 80 MHz</p>  | <p>Portable and mobile RF communications equipment should be used no closer to any part of the <b>FireCR Dental</b> system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$   |
| <p>Radiated RF<br/>IEC 61000-4-3</p>  | <p>3 V/m<br/>80.0 MHz to 2.5 GHz</p> | <p>3 V/m<br/>80.0 MHz to 2.5 GHz</p> | <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) Should be less than the compliance level in each frequency range (b).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p><b>Note 1)</b> <math>U_T</math> is the A.C. mains voltage prior to application of the test level.</p> <p><b>Note 2)</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p><b>Note 3)</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> |                                      |                                      |   |

**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 verify normal 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<br>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<br>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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80MHz  | 3 Vrms<br>150 kHz to 80 MHz | <b>FireCR Dental</b> 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<br>IEC 61000-4-3  | 3 V/m<br>80.0 MHz to 2.5GHz | 3 V/m<br>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.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |

**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*

**Digiray 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 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 **Digiray 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 mms (3 inches) 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, it is the 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 the user's claim for compensation. If the user does not have a means to adequately package it, additional shipping containers may be purchased from **Digiray Corp.**

## *Chapter 7. Technical Assistance*

If user has any questions about installing or using the device, contact your **Digiray Corp.** representative or your local dealer.

### ***Digiray Corp.***

#825, Unitech Venture Town, 142, Ilsan-ro,  
Ilsandong-gu, Goyang-si, Gyeonggi-do, 10442 Republic of Korea  
Tel : 82-31-932-8401      Fax : 82-31-927-9988  
[www.digiray.co.kr](http://www.digiray.co.kr)

## Appendix I

### Installation Report

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

- Fax : 82-31-927-9988
- E-mail : service1@digiray.co.kr

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      | <i>FireCR Dental Reader</i> |
| System S/N |                             |

Installer's Signature:

Date:

Customer's Signature:

Date: