

FDXD-810

Flat-Panel Digital X-ray Detector Device

Technical Manual

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0	July 03, 2003	First edition
1	May 19, 2006	UL Certification
2		
3		
4		



DRTech Corporation

SUPPLY PART LIST

FDXD-810

No.	Item	Product Code
1	TFT Detector Plate (FDXD-810)	
2	Control Box	
3	Interface Cable (6m)	C10050101
4	Camera Link Cable (1m <input type="checkbox"/> 2m <input type="checkbox"/> 5m <input type="checkbox"/> 10m <input type="checkbox"/>)	C20050302
5	AC Power Supply Cable	
6	X-ray Hand Switch Box	B04000030
7	X-Ray Cable (7.6m)	C00050101
8	CD ROM <div> Technical Manual <input type="checkbox"/> Map Data <input type="checkbox"/> Test Image <input type="checkbox"/> Frame Grabber Driver <input type="checkbox"/> FDXD-810 View Program <input type="checkbox"/> </div>	-

Optional Product

No.	Item	Product Code
1	Frame Grabber (USB Type)	C00010402
2	Frame Grabber (PCI Type)	C00010403
3	DR Full Package Software	B05104002
4	EZView Software	B05104102
5	Calibration Software	B05104202
6	Post Processing Software	B05104300
7	X-ray Hand Switch	E00990001
8	Peltier Case	C10999999

Contents

Chapter 1. General Description	4
System Overview	5
Applications	5
System Integration	6
Basic Operation	7
Operation Sequence	7
X-ray Compatibility	9
Component Descriptions	10
System Specifications	12
Component Service	14
Chapter 2. Safety and Regulatory Compliance.....	15
Safety Information	16
Safety Symbols	19
Caution Regarding Small-Detail Object Imaging	21
Product Disposal	21
Chapter 3. Installation.....	22
Unpacking the Detector Panel and Control Box	23
Hardware Interconnections	24
Software Installation	27
Calibration Guideline of FDXD-810	30
Chapter 4. Servicing the FDXD-810 Device Components	31
Precautionary Maintenance.....	32
Diagnostics	32
Repair and Replacement of System Components	32
Chapter 5. Operating PC Requirements.....	33
Overview.....	34
Hardware Requirements	35
Functional Requirements	35
Chapter 6. CUSTOMER INFORMATION	36
Name Plate.....	37
Contact Information.....	38

Chapter

1

General Description

System Overview

Thank you for choosing our new FDXD-810 system.

The FDXD device is a flat-panel type digital X-ray detector that captures projection radiographic images in digital format within seconds, eliminating the need for an entire x-ray film or an image plate as an image capture medium. FDXD device differs from traditional X-ray systems in that, instead of exposing a film and chemically processing it to create a hard copy image, a device called a Detector Panel is used to capture the image in electronic form.

Once the FDXD system captures a radiographic image and subsequently displaying and storing an image, radiologists or physician can adjust the image electronically to optimize the view of the desired anatomy at a workstation.

The system enables a user to duplicate images without having to take additional exposures so that the user can easily transmit a duplicate to the second physician who needs the duplicate image through the network.

Hardcopy images can also be made from digital printers, optimizing for the user's preference.

The system can have DICOM-compliant output to ensure compatibility with existing imaging network infrastructure.

Applications

The **FDXD-810** is a portable type detector with a relatively small detective area around 8inch x 10inch, so that it will be suitable for objects that may not need a larger detective area and also suitable for on-site inspections due to its compact design and lightweight. For example, extremities (podiatry), orthopedics, cephalometry in orthodontics, pediatric ICU, and for on-site, ambulance, sports stadium, emergency rooms, military field hospitals, etc.

System Integration

FDXD device should be fully integrated with an operating PC and a X-ray source unit to capture radiographic images. A diagram of the system integration with **FDXD-810** is illustrated in Figure 1-1.

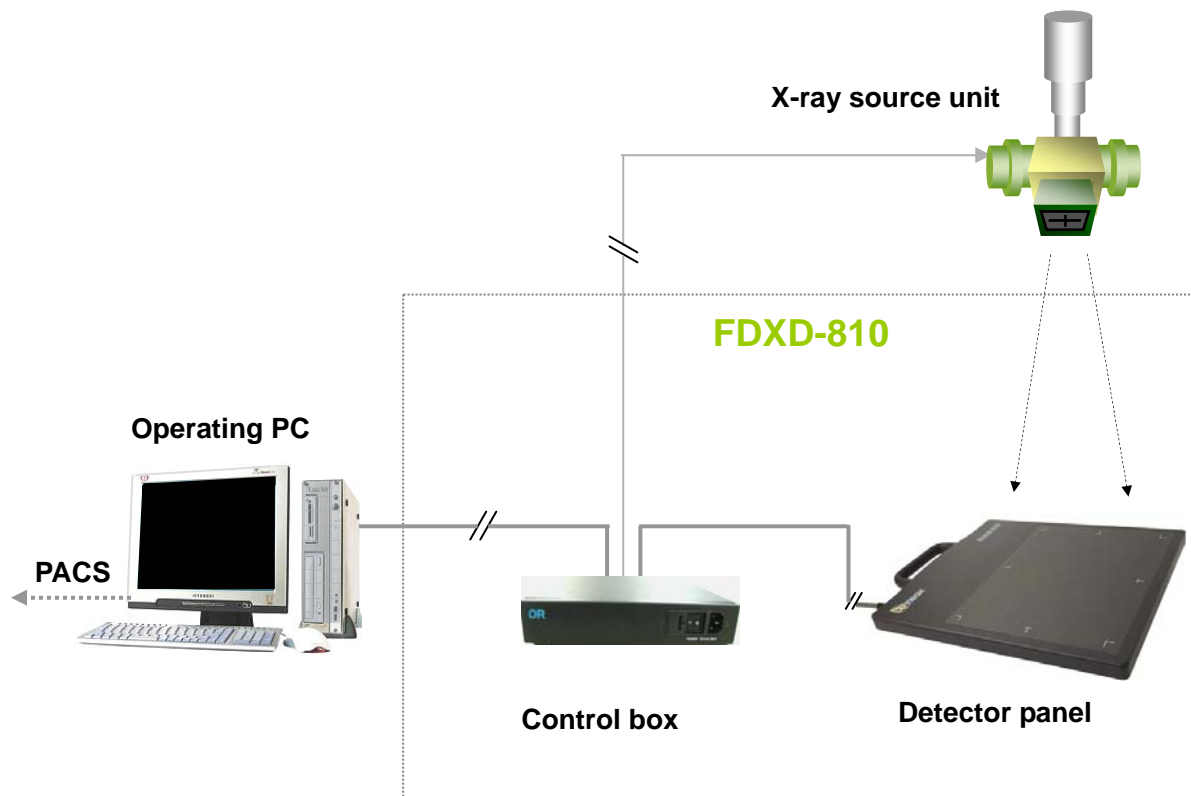


Figure 1-1. An example of system integration with FDXD-810

Basic Operation

The Detector Panel is positioned on the body part of a patient or an object which is prepared for the X-ray examination in the same manner as if the exam were to be performed with film. The X-ray generating equipment is also prepared using the normal method to set the exposure level.

The user enters patient information at the Operating PC (Personal Computer) and specify the output parameters and destinations for the image to be captured.

When the X-ray is ready to exposure, the user initiates the scanning process from the U/I (User Interface) at the Operating PC. The user can make the exposure when the Detector Panel is charged and ready. Once the exposure is made, the Detector Panel captures the image electrically, and then the 14-bit raw image data is transferred to the Operating PC through the Control box.

Then the Operating PC performs calculation to produce a corrected image with linear 14-bit from the raw data, and views the corrected image on the monitor.

If necessary, the Operating PC can apply the image processing software including exam-specific LUT (Look-Up Table) to suit the anatomical desire like extremities, skull, chest, abdomens, etc.

***NOTE:** the user interface, network interface and image processing portion of the system is implemented in the Operating PC, which may be provided directly by DRTech or custom-designed by other manufactures.*

Operation Sequence

The FDXD detector panel is in a Standby Mode repeating a dark scan when the panel does not work to capture image. Once the ready button of the x-ray switch is pushed at time T0, the idling is stopped and the initializing process begins. After T1, the panel is ready to shot and the yellow LED is turned ON with a beep sound. This is an Exposure Mode and then user can push the shot button to expose the X-ray beam within 7 seconds. When user does not expose within 7 seconds, there is another beep sound. In this case, user should release and push again the ready button for next exposure available. It takes approx. 10 seconds to reset the panel. Figure 1-2 shows a time line of the operation sequence for the image capture in FDXD-810 system.

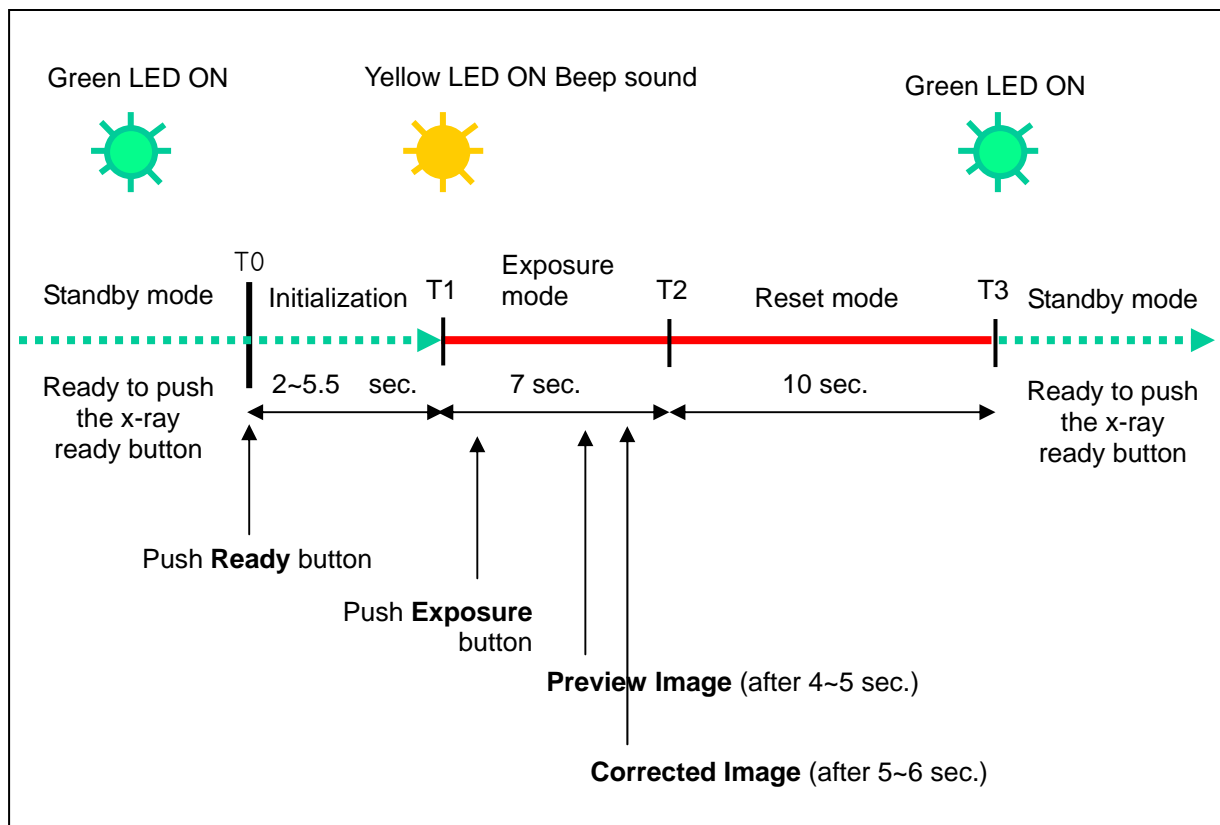


Figure 1-2. Time sequence of the FDXD-810 operation

Where,

T0 ~ T1: Initialize after X-ray ready switch push ON

(2 sec ~ max. 5.5 sec, it depends on process status from time to time.)

T1 ~ T2: Image data readout time after x-ray exposure

It takes about 4 ~ 5 sec.(it depends on the CPU performance of PC)

The LED lamp change to YELLOW light from Green one.

T2 ~ T3: Reset process (10 sec.)

T3 ~ : The LED turn Green light on and return to x-ray wait mode.

NOTE: User must push the exposure button within 5 second after the Ready beep sound (with Yellow light On). When user does not expose within 5 seconds, there is another beep sound of the abort exposure mode. In this case, user should release the ready button and push the ready button again to make next exposure available.

NOTE: When the detector main power is Turned On for the first time in a day, warming up time is surely needed at least 1(one) minute even after the green LED is ON.

X-ray Compatibility

The FDXD-810 device is designed to work with a wide variety of X-ray generating equipment of general radiography and portable type x-ray units. The OEM will integrate the FDXD-810 device with their X-ray generating equipment offering. Both physical integration with holder mechanisms and electronic integration with the exposure control system are expected.

When an existing X-ray unit is used, your OEM or ISO may conduct a feasibility of an upgrade to FDXD-810 device. The feasibility study will consider variables such as age, usage factors, equipment condition, and other factors at the discretion of

Component Descriptions

FDXD-810 device consists of the followings:

- Detector panel
- Control box
- PC Interface adaptor
- Operating Software
- Interconnect Cable

Detector Panel



The Detector Panel has a sensor array that captures radiographic images and peripheral electronics which converts the images to digital format. Like a conventional film cassette, it is usually used as a portable configuration but rarely can be installed in a table or wall bucky and exposed when an X-ray is taken. Its imaging area on the Detector Panel is 19.8mm x 26.4mm (around 8 x 10 inches).

Control Box



The Control Box triggers X-ray generator and transfers the image data which is captured from the Detector Panel to Operating PC. In addition, it converts the input AC power to DC voltage to supply the manipulated DC voltage to the Detector panel.

PC Interface adaptor



A Frame Grabber is inserted in the operating PC to receive the input from the Detector Panel via Control Box by LVDS interface, and also to transfer the operating commands to the Detector Panel via the Control Box by RS-232C interface. The interface adaptor is provided by DRTech.

NOTE: When a U/I is prepared by custom-designed and other manufacturers, DRTech provides technical support to interface the program.

Operating Software



The operating software is the user interface to the image capturing system which includes the Detector Panel with the Control Box. The user interface program (U/I) provides basic image viewer, interface to hardcopy, softcopy, and archive device.

Interconnect Cables

There are two interconnect cables for the FDXD-810 device system:

Data input: Interface cable between the Detector Panel and the Control Box



This cable transmits control information between the Control Box and the Detector Panel, DC power from the Control Box to the Detector Panel, and image data from the Detector Panel to the Control Box.

This is a custom cable with a length of 6m..

Data output: Camera Link cable between the Control Box and the Operating PC



This cable transmits the system commands from the Operating PC to the Control Box. It also transmits the captured image from the Control Box to the Operating PC. This is a camera link cable with a length of 2m. Extension cables up to 10m are available..

X-ray trigger cable : Modular cable between the Control Box and the X-Ray Generator



This cable transmits the sync commands from the Control Box to the X-Ray generator. This is a modular cable with a length of 7.6m.

System Specifications

Specifications are provided for the Detector Panel and the Control Box.

Dimension and Weight

Component	(W x L x H)	Weight
Detector Panel	327 x 377 x 22 mm	3.2kg
Control Box	234 x 249 x 64 mm	2.2kg

Power

The Control Box has the following requirements:

- 100-240 Va.c., 2.0 A
- 50/60 Hz
- Single phase

The main power fuse for the Control Box is a 2-A, 250VAC Type T fuse

Note: The power cord must be supplied by the OEM to meet applicable regulatory agency requirements.

Power Cord Information:

Caution: When operate the digital x-ray detector, the detachable power supply cord shall be provided complying with the following.

*Certified detachable power cord, Type SJT, min. No. 18 AWG, 3-conductor terminating in molded-on Listed "**Hospital Grade**" attachment plug of grounding type attachment plug with parallel blade, rated minimum 15 A, 125 V. Maximum 4.0 m long.*

Caution: Grounding reliability can only be achieved when the control box is connected to an equivalent receptacle marked "**Hospital Only**" or "Hospital Grade."

Environment

The Detector Panel and Control Box are designed to operate properly in normal living environments. The specific temperature, humidity, and altitude requirement for operation, storage, and transit of the components are:

Operating Environment

Temperature:	10 to 35 °C (50 to 95 °F)
Humidity:	5 to 95% RH (non-condensing)
Max. Rate of Change:	<10 °C (18 °F) per hour
Atmospheric pressure:	500 to 1060 hPa

Storage Environment

Temperature:	5 to 40 °C (50 to 104 °F)
Humidity:	5 to 95% RH (non-condensing)
Max. Rate of Change:	<15 °C (27 °F) per hour
Altitude	3 km (10,000 ft)
Atmospheric pressure:	500 to 1060 hPa

Transit Environment

Temperature:	
Control Box	-40 to 45 °C (-40 to 113 °F)
Detector Panel	5 to 40 °C (41 to 104 °F)
Humidity:	5 to 95% RH (non-condensing)
Max. Rate of Change:	<15 °C (27 °F) per hour
Altitude:	15.2 km (50,000 ft)
Atmospheric pressure:	500 to 1060 hPa

Maximum Allowable Forces

The Detector Panel Maximum front-cover load is 135kg static load applied to the center of the front surface over the entire area.

Laser Printer Requirements

The laser printer used with the FDXD-810 device must meet the following requirements:

Minimum optical density on output hardcopy: 2.4

Able accept 12-bit images

Minimum 2048 x 1536 image data matrix

Component Service



The Detector Panel and the Control Box are not field serviceable.

If the Detector Panel is defective, both the Detector Panel and the Control box must be returned to DRTech Corporation. If the Control Box is defective, return only the Control Box to DRTech Corporation.

Chapter

2

Safety and Regulatory Compliance

Safety Information

Applicable Standard

The FDXD 810 device and associated cables have all been tested for compliance with the safety standards in effect at the time of manufacture in the United States (UL60601-1), Canada(C22.2 No.601.1) and the European Union (EN60601-1).

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

1. Classification

- Class I equipment
- Ordinary equipment
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
- Continuous operation

2. Signal Input / Signal Output connection

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical services department or your local representative.

Safety information



The FDXD-810 device and associated cables must not be operated in the presence of moisture.



To avoid excessive product leakage currents and maintain product compliance to medical protective earthing and grounding requirements, the Control Box's power cord shall be connected directly to a hardwired AC Mains receptacle. Under no circumstances shall the Control Box's power cord be connected to a multiple receptacle extension device that also supplies power to the Control Box and/or other electrical hardware which is electrically connected to the Control Box.



The FDXD-810 device is not suitable for operation in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.



The Detector Panel must not be carried by its connecting cable.

NOTE : *The FDXD-810 device provides a digital image capture capability for conventional radiographic examinations (excluding fluoroscopy, angiography, and mammography application). The system has application wherever traditional X-ray screen-film cassette are currently used.*

Follow all safety labels on the equipment.

Sealed System

The Detector Panel is sealed so that biological fluids will not penetrate the outer casing during normal use. The exterior of the array can be cleaned with common hospital decontamination solutions, including 20% chlorine bleach solution (1 part bleach to 4 parts water). A 5% glutaraldehyde or 70% alcohol solution can also be used. To apply the cleaning solution, power down the system and disconnect from power source, moisten a cloth with the solution, and wipe the panel.

NOTE : *The user must follow hospital cleaning and decontamination policies and procedure*



CAUTION

Do not spray cleaning solution directly onto the panel. Instead, moisten a cloth with the solution with the solution and wipe the panel



CAUTION

Do not immerse the panel in liquid. Do not autoclave the panel.

Safety Symbols

The following safety related symbol is found in this manual. To avoid injury, learn to recognize it.



Attention---Read the CAUTION or WARNING statement that follows.

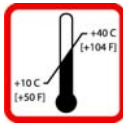
The following safety related symbols are found on the FDXD-810 device components. To avoid injury, learn to recognize them



Power on



Power off



Operating temperature range --- Exposure to temperatures outside of this range could damage equipment or affect performance



Fragile---Handle with care



Special cleaning instructions-Refer to document



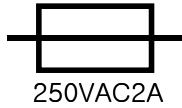
Do not immerse in liquids



No field serviceable component inside-Do not attempt to open the case



Explosive gas (flammable)



Control Box Main Poser Fuse: 250VAC, 2A, Type T



To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground electrode)



Dangerous voltage



Alternate Current



Medical Equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 NO.601.1



Medical Device Directive MDD 93/42/EEC, Applies to all medical equipment except for active implantable devices

Caution Regarding Small-Detail Object Imaging

As with all digital imaging devices, there is the potential that small-detail structures, high-contrast edge structures, and fine-line structures with a repeating pattern could appear differently in the digital image than in an image created with an analog device_ such as screen-film system-or with another digital device having smaller individual detector elements. For example, for a sharp-edged object, the edges of that object may appear to have “stair-step” when in fact the object edge does not have such structure. This is an effect of digital under-sampling.

For small-detail objects having a size on the same order of magnitude as an individual pixel or smaller, the apparent contrast of that object can vary based on the position relative to the individual detector element locations. For example, the contrast of a single spherical object the same size as a pixel would have a dramatically different appearance if the object were imaged directly overlying a detector element (highest contrast) or places at the intersection of four detector element (lowest contrast). Objects inherently smaller than individual pixel will have a radiation intensity signal over an area larger than the small object. In each case, a lower apparent signal-to-noise can result in reduced visibility of such objects.

Product Disposal

The Detector Panel and its Control box must be returned to DRTech Corporation for proper disposal of the selenium and electronic component

Chapter

3

Installation

The installation consists of three steps of unpacking, the hardware interconnections, and the software installation.

Unpacking the Detector Panel and Control Box

This section explains how to unpack the Detector Panel and Control Box from the shipping container.

Equipment Handling and Safety Precautions

The external dimensions and weight of the insulated shipping container are:

Width	800 mm (31.50 in.)
Length	510 mm (20.08 in.)
Height	310 mm (12.20 in.)

The shipping box must be kept in the upright position during transit, as indicated by the symbols printed on the outside of the box.

The Detector Panel is temperature sensitive and may not be subjected to temperatures below 10°C (50°F) or above 40°C (104°F). Each insulated shipping carton contains a temperature/humidity recorder (TempTale). Upon receipt of the equipment, this recorder must be returned to DRTech Corp., Ltd. to maintain the warranty agreement.

To complete the unpacking procedure, you will need cutting tools for the box packing tape.

Hardware Interconnections

This section explains how to accomplish the cable connections between the Detector Panel, the Control Box, the X-ray source and the operating PC. The full integration is illustrated in the Figure 1-1 in Chapter 1.

Specific connections at each of the components are described in the subsections that follow. When cabling the components, refer to the appropriate illustrations to determine where to attach each cable.

Connect the Detector Panel with the Control Box

The data cable of the Detector Panel is connected to the data cable connector in front of the Control Box as illustrated in the Figure 4-1.



Figure 4-1. Detector Panel and Control Box interconnection

The standard cable length is 7 meters (23ft) and the extension of the cable length is available up to 20 meters (65 ft). DRTech Corporation provides the extension.

Connect the operating PC with the Control Box

To interconnect the operating PC, the PC Interface adaptor board, Matrox board, should be installed inside the operating PC first. Please follow the PC Interface adaptor installation manual provided.

Figure 4-2 shows the backside for the Control Box and interconnections with operating PC. One end of the data output cable is connected to the 'data output terminal' of the Control Box and the other is to the PC interface adaptor installed in the operating PC.

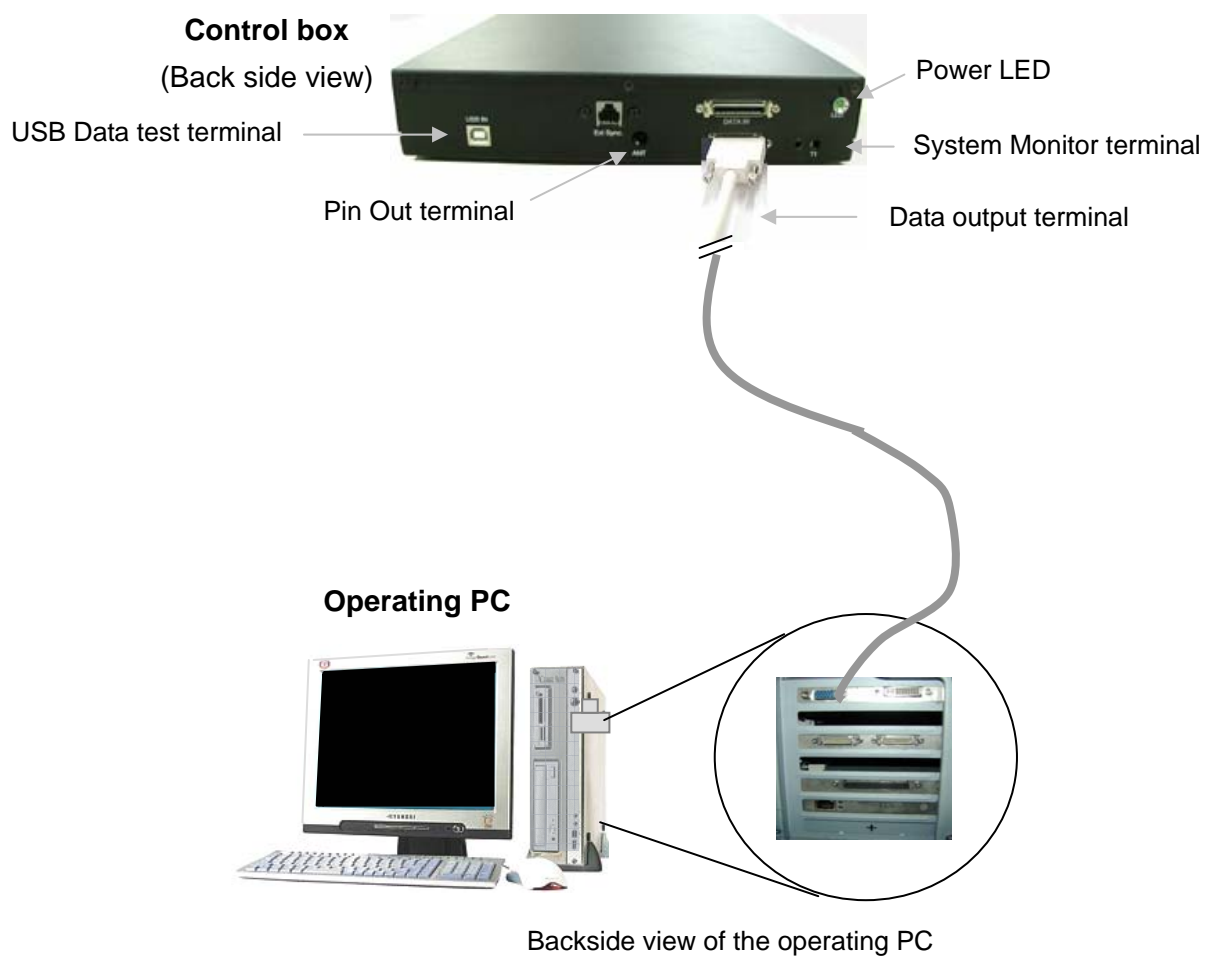


Figure 4-2. Operating PC interconnection with the Control Box

Warning : The used PC and any other non-medical equipment (such as printer) are not allowed to be sued within the patient vicinity (1.83m/6 ft).

Connect the X-ray unit with the Control Box

The readout sequences of the detector panel should be synchronized to the X-ray exposure. This section explains how to interconnect the X-ray unit with the Control box.

In general, there are many kinds of X-ray units for general radiography and the portable units, which usually have different signal output and different shaped connectors. But the hand switches are almost common having three signal lines, for COMMON, READY, and EXPOSURE.

The provided X-ray Interface Module makes it easy to connect the x-ray unit to the FDXD-810 detector system. The interconnection can be done easily as illustrated in the figure 4-3.

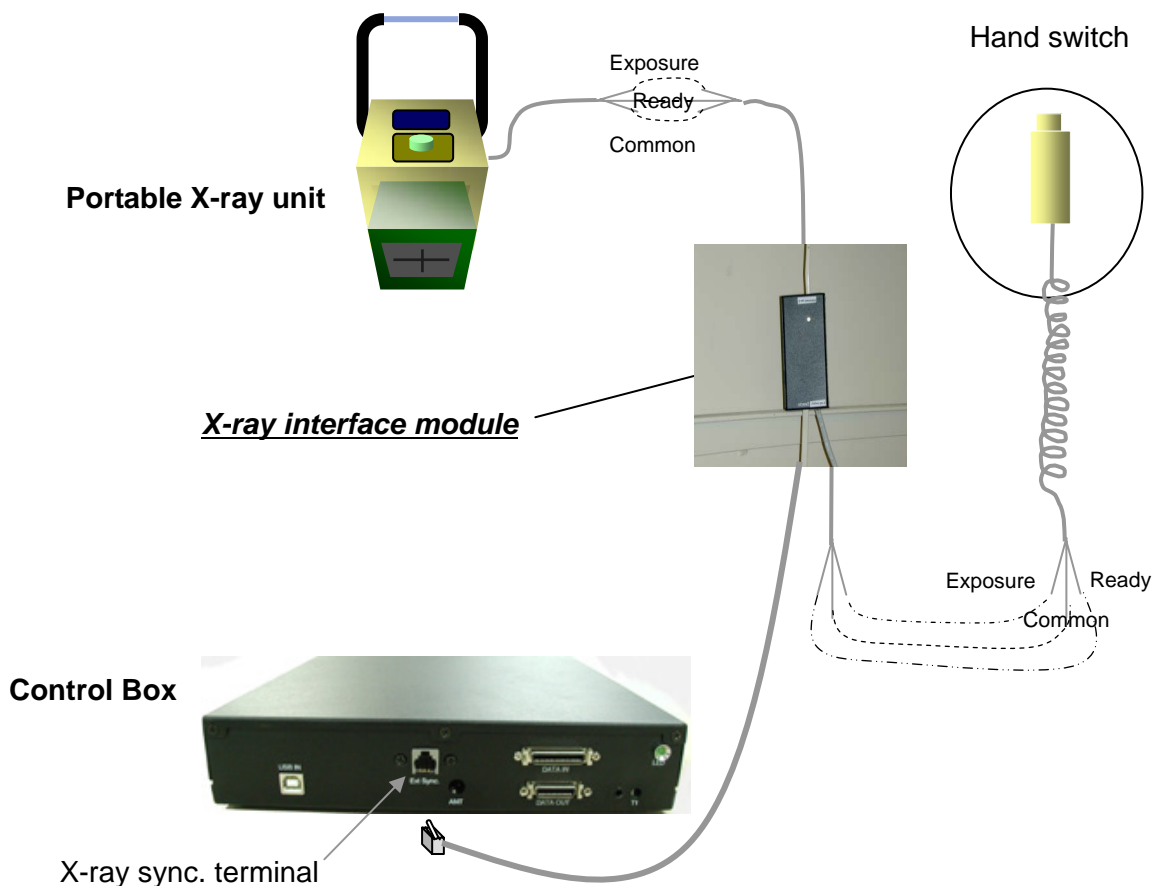


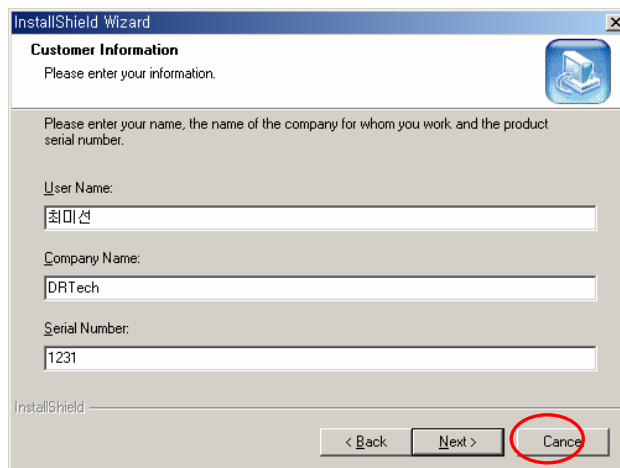
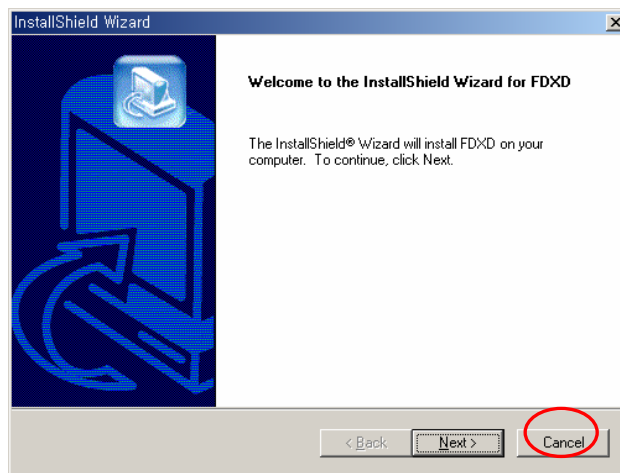
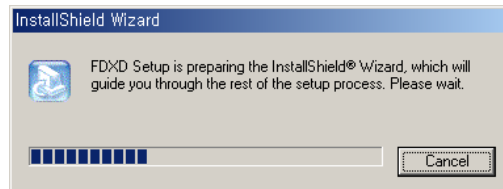
Figure 4-3. Interconnection of X-ray unit with the Control Box

NOTE: Please contact DRTech Corp. if the interconnection to X-ray unit is not performed correctly or there are errors.

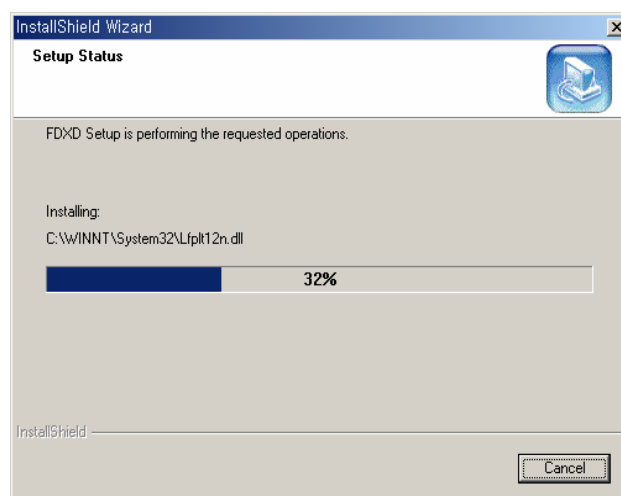
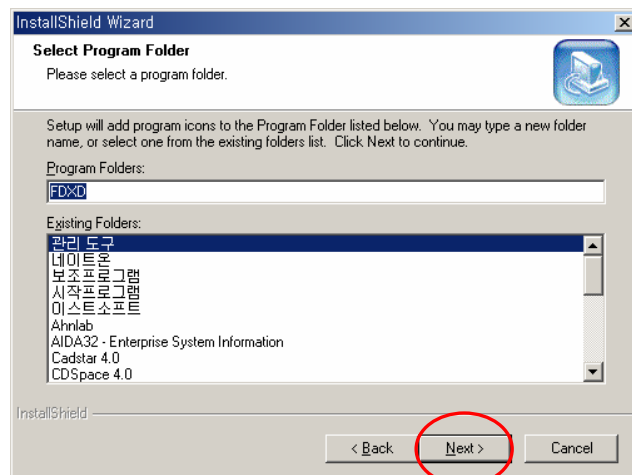
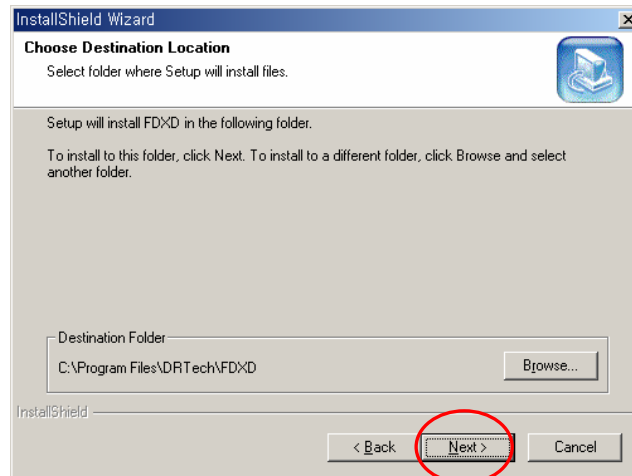
Software Installation

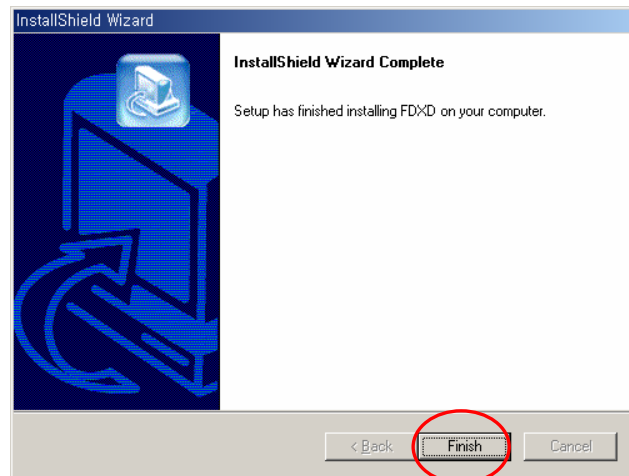
This section explains how to install the operating software.

Insert the operating software CD in the CD-ROM drive of the operating PC, and then double click the setup.exe program.



(Serial number: type any number)





NOTE: *If warning window appears during the installation, select “ignore” button.*

You will see the “FDXD810” icon in your desktop.



By double click of this icon, the operating program is getting started. See “USER GUIDE” of FDXD-810 to refer how to operate the FDXD-810 system to capture radiographic images properly.

Calibration Guideline of FDXD-810

The Detector Panel is shipped after the calibration process is done., and user doesn't need to do any calibration process at installation. However, it may need to calibrate at regular intervals thereafter. DRTech Corporation will provide the calibration instructions if it is needed.

Warming Up

To obtain the best quality radiographic images, warming up time is needed at least 10 minutes after main power switch of the FDXD-810 is turned ON which is on the rear side of the Control box.

Chapter

4

Servicing the FDXD-810 Device Components

Precautionary Maintenance

Precautionary maintenance will be handled by the OEM service provider.

Diagnostics

The Operating PC will initiate service diagnostics via the Camera Link interface. Service diagnostics will involve initiating power-on tests and component self-tests.

Repair and Replacement of System Components

If the Detector Panel is defective, both the Detector Panel and the Control Box must be sent back to DRTech Cor.. If the Control Box is faulty, return only the Control Box to DRTech Corp. Neither component is field serviceable.

Special packaging and transport must be arranged for the return of material. Contact DRTech Corp. for return authorization and instructions.

The manufacturer of the Operating PC decides which parts are field replaceable and provided the necessary repair and replacement instructions.

Chapter

5

Operating PC Requirements

Overview

This chapter describes the hardware compatibility and functional requirements for the Operating PC, which provides the user interface to the image capture components of the FDXD-810 device (the Detector Panel and the Control Box) and to output devices such as printing, display, or archiving devices.

The user enters patient information, initiates the exposure process at the Operating PC. In addition the user typically uses the Operating PC to view, recall, and manage images stored in the Operating PC database. However, the specific functions of the Operating PC are determined by the Operating PC manufacturer.

The Operating PC contains two elements:

- A Windows 2000-compatible computer with an optional SXGA video output for viewing images, with normal storage devices and keyboards and a pointing device.(SXGA: 1,280x1,024)
- A frame grabber using Camera Link interface to capture the pre and expose image.

The Operating PC performs the following functions:

- Provides a control and data transfer channel to and from the Control Box over a camera link data interface
- Controls and monitors the Detector Panel via communication with the PACS.
- Captures reference and exposure data from the Detector Panel and subtracts reference data from exposure data to produce 14-bit linear image data
- Corrects the image data for dead pixels, gain and offset variations, and device-induced artifacts
- Rotates, crops, and mirrors image data based on operator input
- This chapter specifies minimum hardware and functional requirements that the Operating PC must meet, whether the Operating PC is manufactured by DRTech Corp., or by another, approved manufacturer.

Hardware Requirements

The Operating PC must have

- PCI slot: at least one PCI slot to insert PC Interface adaptor,
- Display monitor: 1280 x 1024 pixel resolution (larger display area is better)
Gray levels at least 256 levels or more.
- Hard disk: 1GByte or more (approx. 8.5 MByte per image)
- CPU: Pentium III or higher
- O/S: Windows 2000, Window XP

Functional Requirements

The Operating PC must provide control and monitoring the Detector Panel through a user interface.

The control functions that must be available from the Operating PC include:

- Initiation of image capture
- Routing of images to output device(s)
- Calibration of the Detector Panel
- Setting system date and time
- Monitoring of system performance and error logging and display












Chapter

6












Customer Information

Name Plate

Detector Panel

DRTECH		DRTECH Corp.	
http://www.drtech.co.kr		333-1 Sangdeawon 1-dong, Jungwon-Ku, Seongnam-Shi, Gyeonggi-Do, Republic Korea Tel : 82-31-730-6800 Fax : 82-31-730-6899	
Product Name	: Flat Panel Digital X-ray Dectetor		
Model	: FDXD-810		
Weight/Dimension	: 3.1kg/ 331 x 377 x 22 mm		 UL60601-1 CAN/CSA C22.2 NO 601-1
Power:	Use only with Control Box Model FCB-810		
Serial Number	:		
ITS Idexx			
  Turmstrasse 22, D-78467 Konstanz, Germany			
     No Field serviceable component inside - Do not attempt to open the case			
Made in Korea			

Control Box

DRTECH		DRTECH Corp.	
http://www.drtech.co.kr		333-1 Sangdeawon 1-dong, Jungwon-Ku, Seongnam-Shi, Gyeonggi-Do, Republic Korea Tel : 82-31-730-6800 Fax : 82-31-730-6899	
Product Name	: Control Box		
Model	: FCB-810		
Weight/Dimension	: 1.8kg/ 249 x 234 x 46 mm		 UL60601-1 CAN/CSA C22.2 NO 601-1
Input	: 100 - 240Va.c., 50/60 Hz, 2A		
Serial Number	:		
ITS Idexx			
  Turmstrasse 22, D-78467 Konstanz, Germany			
     No Field serviceable component inside - Do not attempt to open the case			
Made in Korea			

Contact Information

Our trained service department staff is readily available to assist you with all of your service needs. We will recommend the best way to resolve the problems as quickly as possible.

If you need repair of your system or accessories, Or if you have questions or need more information, please feel free to contact us as follows;

KOREA :

DRTECH Corp.

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