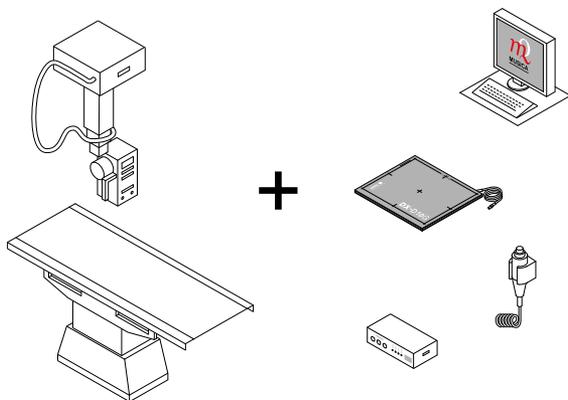


DX-D Retrofit Kit, DX-D Retrofit Box

5400/517

5400/500

User Manual



Contents

Legal Notice	4
Introduction	6
Introduction to this Manual	7
Scope of this Manual	8
Warnings, Cautions, Instructions and Notes	9
Disclaimer	10
Introduction to DX-D Retrofit Packages	10
Intended Use	11
Intended User	11
Configuration	12
Equipment Classification	14
Options and Accessories	15
Operation Controls	16
System Documentation	19
Training	20
Product Complaints	21
Compatibility	22
Compliance	23
Connectivity	25
Installation	26
Messages	27
Labels	28
Cleaning and Disinfecting	30
Patient data security	31
Maintenance	32
Environmental protection	33
Safety Directions	34
Getting started	36
Starting DX-D Retrofit Packages	37
Basic Workflow	37
Step 1: retrieve the patient info	38
Step 2: select the exposure	39
Step 3: prepare the exposure	40
Step 4: check the exposure settings	41
Step 5: execute the exposure	42
Step 6: perform a quality control	43
Stopping DX-D Retrofit Packages	43
Problem solving	44
NX receives black or underexposed DR image due to repeatedly pushing the exposure button	45
NX receives black DR image when X-ray system not ready for exposure	46
Wrong modality position selected	47
Panel status remains in error	48

Technical Data	50
DX-D Retrofit Packages Technical Data	51
DX-D Retrofit Box Technical Data	52
DX-D Fixed DR Detector Technical Data	53
Technical Documentation	56
Remarks for HF-emission and immunity	56

Legal Notice



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Introduction

Topics:

- *Introduction to this Manual*
- *Introduction to DX-D Retrofit Packages*

Introduction to this Manual

Topics:

- *Scope of this Manual*
- *Warnings, Cautions, Instructions and Notes*
- *Disclaimer*

Scope of this Manual

This manual contains information for safe and effective operation of the DX-D Retrofit Kit system and the DX-D Retrofit Box, further referred to as the device.

The DX-D Retrofit Kit is further referred to as DX-D Retrofit Packages or as the system.

Warnings, Cautions, Instructions and Notes

The following samples show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.



Warning: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.



Caution: Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.



Instruction: This sign is typically used in combination with the warning sign when providing a specific instruction. If it is followed exactly, it should avoid the subject of the warning.



Note: Notes provide advice and highlight unusual points. A note is not intended as an instruction.

Disclaimer

Agfa assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

Every care has been taken to ensure the accuracy of the information in this document. However, Agfa assumes no responsibility or liability for errors, inaccuracies or omissions that may appear in this document. To improve reliability, function or design Agfa reserves the right to change the product without further notice. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.



Caution: In the United States, Federal law restricts this device to sale by or on the order of a physician.

Introduction to DX-D Retrofit Packages

Topics:

- *Intended Use*
- *Intended User*
- *Configuration*
- *Equipment Classification*
- *Options and Accessories*
- *Operation Controls*
- *System Documentation*
- *Training*
- *Product Complaints*
- *Compatibility*
- *Compliance*
- *Connectivity*
- *Installation*
- *Messages*
- *Labels*
- *Cleaning and Disinfecting*
- *Patient data security*
- *Maintenance*
- *Environmental protection*
- *Safety Directions*

Intended Use

The DX-D Retrofit Packages system is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy for adult, pediatric and neonatal examinations. The DX-D Retrofit Packages system converts the screen-film or CR system into a DR system.

The DX-D Retrofit Packages system is not indicated for use in mammography.

Intended User

This manual is written for trained users of Agfa products. Users are considered as the persons who actually handle the equipment as well as the persons having authority over the equipment. Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

The DX-D Retrofit Packages system consists of the following components:

- DX-D DR Detector (with X-Ray Interface Unit)
- NX workstation
- DX-D Retrofit Box

The DX-D Retrofit Packages system supports following DR Detectors:

- DX-D 10C
- DX-D 10G
- DX-D 20C
- DX-D 20G
- DX-D 25C
- DX-D 30C
- DX-D 35C
- DX-D Fixed DR Detector

The DX-D Retrofit Packages system supports two levels of integration with the X-ray system.

1. Integration of the exposure signal.

- The exposure button of the X-ray system is removed or disabled and a new exposure button is connected to the DX-D Retrofit Box.

2. Integration of X-ray exposure parameters.

- The exposure button of the X-ray system is replaced by an exposure button connected to the DX-D Retrofit Box.
- The X-ray generator console of the X-ray system is removed or disabled. X-ray parameters are controlled using the Software Console on the NX workstation.

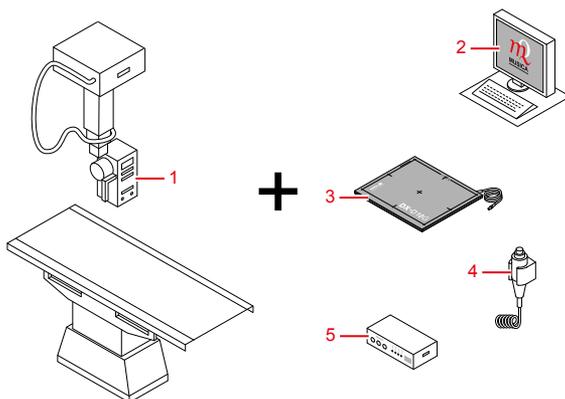
The DX-D Retrofit Box synchronizes the exposure signal between the DR detector, the NX workstation and the generator.

Maximum three exposure buttons can be connected to the DX-D Retrofit Box. An exposure button can be a hand switch or a foot switch.

The Software Console is available on the NX workstation and synchronizes the X-ray exposure parameters between the NX workstation and the generator.



Note: Integration of X-ray exposure parameters is only supported on specific types of X-ray systems. Contact your local service representative for more information about the supported X-ray systems.



1. X-ray system
2. NX workstation with NX application and DX-D Software Console or DR Detector Switch
3. DX-D DR Detector
4. Replacement exposure button
5. DX-D Retrofit Box

Equipment Classification

This device is classified as following:

Table 1: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not rely on basic insulation only, but includes a power supply cord with protective earth conductor. For earth reliability always plug the main power cord into an earthed mains power outlet.
Type B equipment	Not classified. The patient does not get in contact with any part of the equipment.
Water ingress	This device does not have protection against ingress of water.
Cleaning	See section on cleaning and disinfecting.
Disinfection	See section on cleaning and disinfecting.
Flammable anesthetics	This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
Operation	Continuous operation.

Options and Accessories

The delivery contains a set of labels. When using multiple DR Detectors, on the labels a nickname is written to identify the DR Detector. An identical label is attached to the bucky of the X-ray system to identify the dedicated workspace of each DR Detector.

Operation Controls

The main operation controls are:

- Power switch
- Exposure button
- DR Detector Switch on the NX workstation



Warning: The exposure button of the original system should be disabled.

Topics:

- *Exposure button*
- *DX-D Software Console*
- *DR Detector Switch*

Exposure button

Preparing for exposure

Press the exposure button down to the first pressure point and hold it for approximately 0.5 s to 2 s.



The X-ray tube is prepared for performing an exposure.

Starting the exposure

Before starting the exposure:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check the Ready for Exposure status.

Press the exposure button down fully and keep it pressed until the exposure has ended.



The radiation indicator on the control console lights up and a signal sounds to indicate the exposure.



Note: Letting the exposure button go ends the exposure immediately and the exposure can be underexposed.

DX-D Software Console

The DX-D Software Console is available to support X-ray exposure parameter control on the NX workstation. It is displayed on the NX workstation next to the NX application.

The DX-D Software Console is used to control the X-ray exposure settings.

The DX-D Software Console contains the DR Detector Switch.

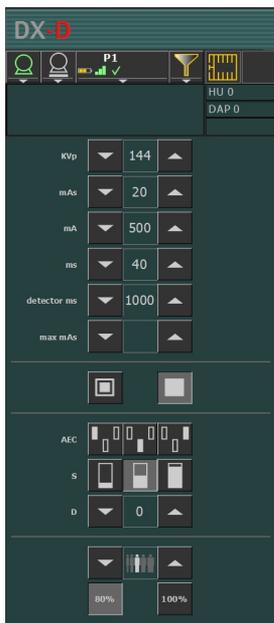


Figure 1: DX-D Software Console

DR Detector Switch

The DR Detector Switch is available in the title bar of the NX application or in the device status frame of the DX-D Software Console.

The DR Detector Switch shows which DR Detector is active and shows its status. The DR Detector Switch can be used to activate another DR Detector.



Figure 2: DR Detector Switch

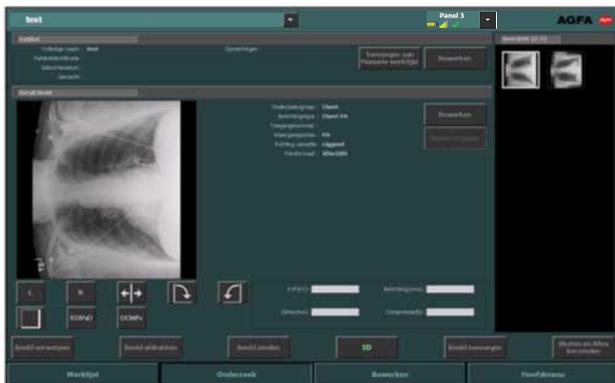


Figure 3: DR Detector Switch in the title bar of the NX application

DR Detector Status

Battery status icon				
Meaning	Full	Medium	Low	Empty

Connection status icon (wifi/wired)				
Meaning	Good	Low	Bad	Wired DR Detector

Panel status icon					
		(blinking)	(blinking)		
Meaning	Ready	Initializing exposure	Starting up	Error	Sleep

System Documentation

The DX-D Retrofit Packages user documentation consists of

- DX-D Retrofit Packages User Documentation CD (digital media)
- NX User Documentation CD (digital media)

The DX-D Retrofit Packages User Documentation CD contains:

- DX-D Retrofit Packages User Manual (this document), document 0312
- DX-D Software Console User Manual, document 0289
- DX-D 10G DX-D 10C DX-D 20G DX-D 20C User manual, document 0129
- DX-D 30C, DX-D 35C User Manual, document 0197
- DX-D 25C User Manual, document 0280
- DX-D DR Detector Calibration Key User manual, document 0134

Training

The user must have received adequate training on the safe and effective use of the system before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law. Your local Agfa or dealer representative can provide further information on training.

The user must note the following information in the system documentation:

- Intended Use.
- Intended User.
- Safety Directions.

Product Complaints

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Agfa.

If the device malfunctions and may have caused or contributed to a serious injury, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

Agfa Service Support - local support addresses and phone numbers are listed on www.agfa.com

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

The system must only be used in combination with other equipment or components if these are expressly recognized by Agfa as compatible. A list of such equipment and components is available from Agfa service on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by Agfa. Such changes must comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Compliance

This paragraph sums up the directives, standards and harmonization initiatives DX-D Retrofit Packages and DX-D Retrofit Box complies with.

Topics:

- *Directive*
- *Standards*
- *Harmonization*

Directive

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ No L 169/1 of 1993-07-12) and amendments.

ANNEX I: ESSENTIAL REQUIREMENTS - GENERAL REQUIREMENTS

The devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users.

ANNEX II: EC DECLARATION OF CONFORMITY

Full quality assurance system ISO 13485

ANNEX X: CLINICAL EVALUATION

The clinical evaluation follows a defined and methodologically sound procedure.

Standards

IEC 60601-1, Ed. 2: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

ISO 14971: 2000, Medical devices - Application of risk management to medical devices.

IEC 60601-1-2: It specifies the manufacturer of the medical equipment or medical system. It also provides information to the responsible organization that is essential in determining the suitability of the medical equipment or medical system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the medical equipment or medical system to maintain basic safety and provide its essential performance without disturbing other equipment.

UL 60601-1, Second Edition (North America)

CSA 22.2 No 601.1 (Canada)

Additional standards for documentation

IEC 62079 Ed. 1: Preparation of instructions - Structuring, content and presentation

ISO 62366-2008: Application of usability engineering to medical devices.

Harmonization

Global Harmonization Task Force (GHTF) www.ghtf.org

This document has been prepared to comply with Study Group 1 guidance document of the Global Harmonization Task Force (GHTF). To assist development of a consistent, harmonized definition for a medical device that could be used within a global regulatory model would offer significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities and support global convergence of regulatory systems.

IECEE CB SCHEME www.iecee.org

The IECEE CB Scheme is the world's first truly international system for acceptance of test reports dealing with the safety of electrical and electronic products. It is a multilateral agreement among participating countries and certification organizations. Agfa has produced a CB test report and claims national certification in all other member countries of the CB Scheme.

Connectivity

The DX-D Retrofit Box is connected to the NX workstation and the X-ray generator and replaces the interface to the original exposure button.

The DX-D Retrofit exposure button is connected to the DX-D Retrofit Box device.

On supported X-ray systems, the NX workstation is connected to the X-ray system to exchange X-ray exposure parameters.



Note: The connections between the components of the DX-D Retrofit Box and towards the NX workstation and the X-ray system should not be disconnected or modified.

The NX workstation requires a 100 Mbit ethernet network to exchange information with a number of other devices.

The NX workstation communicates with other devices in the hospital network using one of the following protocols:

- DICOM
- IHE

The NX workstation can be connected to a RIS system (input scheduling), a PACS system (output image/data management) and to a hardcopy device (output image).

Related Links

[Configuration](#) on page 12

Installation

Installation and configuration is performed by an Agfa trained and authorized service engineer. Contact your local support organization for more information.

On a configuration with multiple DR Detectors of the same type, it is required to apply labeling to the DR Detector containing a unique nickname for each DR Detector. The nicknames must be configured on the NX Workstation. The DR Detector Switch shows which DR Detector is active and shows its status, by means of the nickname of the DR Detector.

An identical label is attached to the bucky of the X-ray system to identify the dedicated workspace of each DR Detector.

Messages

Under certain conditions the system shows a dialog box in the middle of the screen containing a message, or a message is displayed in a fixed message area in the user interface. This message informs the user that either a problem has occurred or that a requested action cannot be performed. The user must read these messages carefully. It will provide information on what to do from then on. This will be either performing an action to resolve the problem or to contact the service organization. Details on the contents of messages can be found in the service documentation which is available to service personnel.

Labels

 <p>AGFA HEALTHCARE N.V. Septestraat 27 - 2040 - Molenbeek - BELGIUM DX-D Retrofit Box</p> <p>REF: 5400-500 SN: 5400-XXXXXX MID: JJJJ-MM</p> <p>Voltage: 100 - 240 V ac Freq: 50-60 Hz Input power: 60W</p> <p>MEDICAL ELECTRICAL EQUIPMENT CONFORME TO EN 60601-1</p> <p>UL 60601-1 CSA C22.2 No. 401.1 I113404</p> <p>MET CE 0113</p> <p>Made in Germany</p>	<p>The DX-D Retrofit Box type label is located on the DX-D Retrofit Box.</p>
 <p>AGFA HEALTHCARE N.V. Septestraat 27 - 2040 - Molenbeek - BELGIUM DX-D Retrofit Kit</p> <p>Type: 5400-517 SN: 5400-XXXXXX MID: JJJJ-MM</p> <p>MEDICAL ELECTRICAL EQUIPMENT CONFORME TO EN 60601-1</p> <p>UL 60601-1 CSA C22.2 No. 401.1 I113404</p> <p>MET CE 0113</p> <p>Made in Germany</p>	<p>The DX-D Retrofit Kit type label is located on the DX-D Retrofit Box.</p> <p>This label is absent if the DX-D Retrofit Box is not used as part of the DX-D Retrofit Kit.</p>
	<p>In order to reduce the risk of electric shock, do not remove any covers.</p>
	<p>Date of manufacture</p>
	<p>Manufacturer</p>
	<p>Serial number</p>
	<p>If the exposure button of the original system is visible, this label is attached.</p> <p>The user manual (this document) instructs not to use the exposure button of the original system.</p>
	<p>Functional earth</p>
	<p>Equipotential connector:</p> <p>Provides a connection between the equipment and the potential bus bar of the electrical system as found in medical environments.</p> <p>It is recommended to use the equipotential connection as additional safety measure.</p>

	Writable label to identify and dedicate a DR Detector to an X-ray system bucky.
--	---

Cleaning and Disinfecting

Cleaning and disinfecting procedures are described in the relevant modules of the device user documentation.

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and device. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. Details about cleaning can be found in the following pages.

To clean the exterior of the equipment:

1. Switch off the device.
2. Remove the power plug of the socket.
3. Wipe the exterior of the device with a clean, soft, damp cloth. Use a mild soap or detergent if required but never use ammonia-based cleaner.



Caution: Make sure no liquid gets in the device.



Note: Do not open the equipment for cleaning. No components inside the device require cleaning by the user.

4. Plug the power plug into the socket.

Patient data security

The user must ensure that the patients' legal requirements are met and that the security of the patient data is guarded.

The user must define who can access patient data in which situations.

The user must have a strategy available on what to do with patient data in case of a disaster.

Maintenance

Always consult the Agfa Service documentation and an Agfa trained and authorized Service engineer for complete maintenance schedules.

Maintenance of the DR Detector

The DR Detector requires regular calibration. Calibration instructions are described in the DX-D DR Detector Calibration Key User Manual (doc 0134).

Environmental protection



Figure 4: WEEE symbol



Figure 5: Battery symbol

WEEE end user notice

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

Battery notice

The battery symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste. The battery symbol on batteries or its packaging may be used in combination with a chemical symbol. In cases where a chemical symbol is available it indicates the presence of respective chemical substances. If your equipment or replaced spare parts contain batteries or accumulators please dispose of them separately according to local regulations.

For battery replacements please contact your local sales organization.

Safety Directions



Warning: Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.



Warning: Safety is only guaranteed when an Agfa certified field service engineer has installed the product.



Warning: All Agfa medical products must be used by trained and qualified personnel.



Warning: Improper changes, additions, maintenance or repair of the system can lead to personal injury and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer.



Warning: If the equipment is modified, appropriate inspection and testing is required to ensure continued safe use of the equipment.



Warning: To avoid risk of electric shock, do not remove any covers. Changes, additions, maintenance or repairs must be carried out by an Agfa certified field service engineer.



Warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



Warning: Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with.



Warning: The operator and end-user must take precautions to protect themselves against dangerous X-ray exposure when using the DR Detector or CR cassette in the X-ray beam path of an X-ray source.



Warning: The DR Detector or CR cassette are not intended to be used as a primary barrier to X-rays. The user is responsible for ensuring the safety of the operator, bystanders, and the subjects being radiographed.



Warning: Avoid unnecessary dose by checking before exposure if the DR Detector Switch displays the name of the DR Detector that is being used and when using DX-D 30C or DX-D 35C if the green READY status indicator is on.



Warning: Avoid unnecessary dose by checking the workstation selection on the X-ray generator console before exposing. In a configuration with a DR Detector configured on a virtual port, the DR Detector will not be triggered if a free exposure is selected on the Generator console and yet the exposure will be allowed.



Warning: To prevent unintended exposure, the position of the exposure footswitch should be such that it cannot be accidentally stepped on.



Caution: Excessive ambient temperature may impact performance of DR Detectors and cause permanent damage to the equipment. If ambient temperature and humidity is outside the range specified in the technical data, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

Disconnecting the DX-D Retrofit Box from the mains power

To disconnect the DX-D Retrofit Box from the mains power, switch off the power switch or remove the power plug from the socket.

Getting started

Topics:

- [*Starting DX-D Retrofit Packages*](#)
- [*Basic Workflow*](#)
- [*Stopping DX-D Retrofit Packages*](#)

Starting DX-D Retrofit Packages

1. Power on the DR Detector.

For detailed information about powering on the DR Detector, refer to the DR Detector user manual.

2. Start NX.

For detailed information about starting up NX, refer to the NX User Manual, document 4420.

The NX application and the software console are available on the NX workstation.

3. Power on the DX-D Retrofit Box.

Basic Workflow

This section describes the workflow which will be followed when using the system for acquiring radiographic images.

Topics:

- *Step 1: retrieve the patient info*
- *Step 2: select the exposure*
- *Step 3: prepare the exposure*
- *Step 4: check the exposure settings*
- *Step 5: execute the exposure*
- *Step 6: perform a quality control*

Step 1: retrieve the patient info

At the NX workstation:

1. When a new patient comes in, define the patient info for the exam.
2. Start the exam.

Step 2: select the exposure

In the operator room:

1. At the NX workstation, select the thumbnail for the exposure in the Image Overview pane of the Examination window.

The selected DR Detector is activated.

The DR Detector Switch shows which DR Detector is active and shows its status.

- Red (flashing): starting up
- Green (constant): ready for exposure

2. At the X-ray generator console or on the DX-D Software Console, select the exposure settings suitable for the exposure.

On systems with integration of X-ray exposure parameters, the default X-Ray exposure parameters for the selected exposure are sent to the modality and displayed on the DX-D Software Console.

Step 3: prepare the exposure

In the examination room:

1. Position the DR Detector.

When using the bucky, check that the identification labels on the DR Detector and on the bucky match. Do not use a DR Detector that is dedicated to another bucky.

2. Position the patient.

Apply radiation protective measures for the patient if needed.

3. Check if the X-Ray system position is suitable for the exposure.
 4. Position the X-Ray tube with respect to the DR Detector and the patient.
 5. Set the correct distance between DR Detector and X-Ray tube.
 6. Switch on the light on the collimator. Adapt collimation if required.
- Take care that the collimated area is not larger than the detector.



Warning: Monitor the patient position (hands, feet, fingers, etc.) with special care to avoid injury to the patient caused by unit movements. Patient hands must be kept away from mobile components of the unit. Intravenous tubing, catheters and other patient connected lines should be routed away from moving equipment.

Step 4: check the exposure settings

On the DR Detector Switch:

1. Check if the DR Detector Switch displays the name of the DR Detector that's being used
2. If a wrong DR Detector is displayed, select the right DR Detector by clicking the drop down arrow on the DR Detector Switch.
3. Check the Panel Status icon.

In the operator room at the X-ray generator console or on the DX-D Software Console:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check the Ready for Exposure status.

On the DX-D 30C or DX-D 35C DR Detector:

Check if the green READY status indicator is on. If the status indicator is off or flashing, the DR Detector cannot be used for making an exposure.

Step 5: execute the exposure

In the operator room:

Press the exposure button to execute the exposure.



Warning: Use the replacement exposure button. The exposure button of the original system should be disabled.



Instruction: Make sure the generator is ready for exposure before you press the exposure button.



Warning: The radiation indicator on the control console lights up during exposure release.



Warning: Do not select another thumbnail until the preview image is visible in the active thumbnail.

In the operator room at the NX workstation:

- While the acquisition is ongoing, the thumbnail status indicator is flashing green. The image is acquired from the DR detector and displayed in the thumbnail.
- On systems with integration of X-ray exposure parameters, the actual X-Ray exposure parameters are sent back from the console to the NX workstation and are shown in the Image Detail pane.
- If collimation is applied, the image is automatically cropped at the collimation borders.

DAP values

The NX displays and transmits DAP in DICOM compliant units: $\text{dGy}\cdot\text{cm}^2$.

X-ray systems may use other units, e.g. if the X-ray generator console displays DAP in $\mu\text{Gy}\cdot\text{m}^2$, the displayed value on NX is 10 times smaller than on the X-ray generator console.

Step 6: perform a quality control

At the NX workstation:

1. Select the image on which quality control is to be performed.
2. Prepare the image for diagnosis by using e.g. L/R markers or annotations.
3. If the image is OK, send the image to a hardcopy printer and/or PACS (Picture Archiving and Communication System).

Stopping DX-D Retrofit Packages

1. Switch off the DX-D Retrofit Box.
2. Stop NX.

For detailed information about stopping NX, refer to the NX User Manual, document 4420.

3. Switch off the DR Detector.

For detailed information about switching off the DR Detector, refer to the DR Detector user manual.

Problem solving

Topics:

- *NX receives black or underexposed DR image due to repeatedly pushing the exposure button*
- *NX receives black DR image when X-ray system not ready for exposure*
- *Wrong modality position selected*
- *Panel status remains in error*

NX receives black or underexposed DR image due to repeatedly pushing the exposure button

Details	A black or underexposed image is arriving on the NX workstation.
Cause	<p>The exposure button was pushed to the first pressure point and released without making an exposure.</p> <p>Directly afterwards, the exposure button was pushed down fully.</p> <p>The X-ray system may need a longer preparation time directly after an interrupted preparation cycle. This prevents the DR Detector to synchronize with the X-ray system.</p> <p>Depending on the X-ray system, two situations can occur:</p> <ul style="list-style-type: none"> • The X-ray system will not make the exposure and the DR Detector acquires an image without exposure. • The X-ray system will start the exposure with a delay and the DR Detector cannot acquire the complete dose.
Brief Solution	<p>To repeat the exposure workflow:</p> <ol style="list-style-type: none"> 1. On the NX workstation, click Copy Exposure to create a new thumbnail. 2. Repeat the steps described in the Basic Workflow.

Related Links

[Basic Workflow](#) on page 37

NX receives black DR image when X-ray system not ready for exposure

Details	A black image is arriving on the NX workstation.
Cause	On a system without DX-D Software Console, the exposure button was pushed while the X-ray system was not ready for exposure.
Brief Solution	To repeat the exposure workflow: <ol style="list-style-type: none">1. On the NX workstation, click Copy Exposure to create a new thumbnail.2. Repeat the steps described in the Basic Workflow.

Related Links

[Basic Workflow](#) on page 37

Wrong modality position selected

Details	The active modality position on the X-ray system does not match the selected modality position on the NX Workstation.
Cause	The modality position has been modified on the generator console. This situation applies only to Siemens generators.
Brief Solution	To use another modality position for a scheduled exposure: <ol style="list-style-type: none">1. On the NX workstation, click Edit in the Image Detail Pane and select an exposure type for the correct modality position.2. Continue the exposure workflow.

Panel status remains in error

Details	The panel status remains in error.
Cause	The generator is in error state. This situation applies only to Siemens generators.
Brief Solution	Restart the generator.

Technical Data

Topics:

- [*DX-D Retrofit Packages Technical Data*](#)
- [*DX-D Retrofit Box Technical Data*](#)
- [*DX-D Fixed DR Detector Technical Data*](#)

DX-D Retrofit Packages Technical Data

Technical data is available in the relevant modules of the DX-D Retrofit Packages user documentation.

DX-D Retrofit Box Technical Data

Labeling		
Dimensions		
Depth	21.5 cm	
Width	33.5 cm	
Height	6.5 cm	
Weight	3.2 kg	
Electrical connection	100-240 V AC, 50/60 Hz	
Power consumption	40 W (max. 0.4 A)	
Environmental conditions (operational)	min	max
Temperature	5 °C	35 °C
Relative air-humidity	20%	80%
Altitude	0 m (102 kPa)	3000 m (70 kPa)
Environmental conditions (storage and transport)	min	max
Temperature	-15 °C	50 °C
Relative air-humidity	20%	80%
Altitude	0 m (102 kPa)	3000 m (70 kPa)
Estimated product life	7 years	

DX-D Fixed DR Detector Technical Data

Manufacturer	
Original manufacturer model name	4343R (part number 7965) 4343R (part number 7964)
Manufacturer DR Detector	Varian X-Ray Products, 1678 So. Pioneer Rd, Salt Lake City, UT 84104, USA
Electrical connection	
Operating voltage	90-240 V (AC)
Mains fuse protection	6A
Mains frequency	47-63 Hz
Power consumption	
Maximum power consumption	65 W
Environmental conditions (during storage and transport)	
Temperature (ambient)	between -20 °C and +70 °C
Humidity (non condensing)	between 10 % and 90 %
Environmental conditions (during normal operation)	
Room temperature	between +15 °C and +35 °C
Humidity (non condensing)	between 30 % and 75 %
Warming-up time	
30 minutes	
Throughput	
Maximum number of image acquisitions	150 acquisitions per hour
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	100000 RAD

Pixel Matrix	
Pixel size	139 μm (H,V)
Pixel matrix	3072 (H) x 3072 (V)
Active pixel matrix	3052 (H) x 3052 (V)
Fill factor	100 %
Detector type	Amorphous Silicon
Active area size	42,7 cm (H) x 42,7 cm (V)

	Partnumber 7965	Partnumber 7964
Maximum Linear Dose using RQA5	50 μGy	75 μGy
Minimum Modulation Transfer Function (MTF) using RQA5		
1 lp/mm	0.45	0.45
2 lp/mm	0.15	0.15
3 lp/mm	0.05	0.05
Typical Detective Quantum Efficiency (DQE) using RQA5		
	(at 2.1 μGy dose level)	(at 4.0 μGy dose level)
0 lp/mm	0.59	0.25
1 lp/mm	0.41	0.20
2 lp/mm	0.23	0.10
3 lp/mm	0.11	0.03
3.6 lp/mm	0.06	0.01
Minimum Signal Noise Ratio for 1mR		
SNR	115:1	115:1
Conversion screen	CsI	GOS

Technical Documentation

This appendix contains technical information. It is only available in English.

Remarks for HF-emission and immunity



Warning: This device is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.



Warning: The HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

Transmission Measurements	Agreement	Electromagnetic Environment Guidelines
RF emissions in accordance with CISPR 11	Group 1	The device 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 in accordance with CISPR 11	Class A	The device is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	Complies	

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Resistance to Jamming Test	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment Guidelines
Discharge of static electricity in accordance with IEC 61000-4-2	<ul style="list-style-type: none"> ± 6 kV contact discharge ± 8 kV air discharge 	<ul style="list-style-type: none"> ± 6 kV contact discharge ± 8 kV air discharge 	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	<ul style="list-style-type: none"> ± 2 kV for network leads ± 1 kV for entry and outlet leads 	<ul style="list-style-type: none"> ± 2 kV for network leads ± 1 kV for entry and outlet leads 	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	<ul style="list-style-type: none"> ± 1 kV push-pull voltage ± 2 kV common mode voltage 	<ul style="list-style-type: none"> ± 1 kV push-pull voltage ± 2 kV common mode voltage 	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakthroughs, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	<ul style="list-style-type: none"> • < 5% U_r (> 95% breakthrough of U_p) for ½ period • 40% U_r (> 60% breakthrough of U_p) for 5 periods • 70% U_r (30% breakthrough of U_p) for 25 periods • < 5% U_r (95% breakthrough 	<ul style="list-style-type: none"> • < 5% U_r (> 95% breakthrough of U_p) for ½ period • 40% U_r (> 60% breakthrough of U_p) for 5 periods • 70% U_r (30% breakthrough of U_p) for 25 periods • < 5% U_r (95% breakthrough 	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.

	h of U_r) for 5 s	h of U_r) for 5 s	
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
<ul style="list-style-type: none"> REMARK : U_r is the alternating current in the network before the application of the test level. 			

Tests of Resistance to Disruption	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment
			Use portable and mobile radio sets at a safe distance from the device (including the leads) not closer than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency. Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.2 \sqrt{P}$
Radiated high frequency disturbance variables in accordance	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz

with IEC 61000-4-3			
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			<p>With P as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m).</p> <p>The field strength of stationary radio transmitters is lower than the level of the agreement at all frequencies in accordance with an on-site investigation.</p> <p>Disruptions are possible near devices that carry the following symbol:</p> 
<p>The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and FM radio transmitters, cannot be precisely predetermined theoretically. An investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the level of agreement given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.</p> <p>The field strength will be lower than 3 V/m above the frequency range from 150 kHz to 80 MHz.</p> <ul style="list-style-type: none"> • REMARK 1: The higher value will apply at 80 MHz and 800 MHz. • REMARK 2: These Guidelines may not apply to all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people. 			

Radio frequency communications equipment can effect medical electrical equipment.

This device is intended for operation in an electromagnetic environment in which the radiated high frequency disturbance variables are monitored. The user of the device can help to prevent electromagnetic disruptions by maintaining the minimum distances between portable and mobile high frequency communication equipment (transmitters) and the device as recommended below, in accordance with the maximum output power of the communications equipment.

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device			
Rated Power of the Transmitter W	Protective Distance in accordance with Transmission Frequency m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The distance can be determined through the equation for each respective column. P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table.

- REMARK 1 : An additional factor of 10/3 has been used to calculate the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, to reduce the probability that mobile portable communication equipment unintentionally brought into the area of the patients will lead to a disruption.
- REMARK 2 : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

