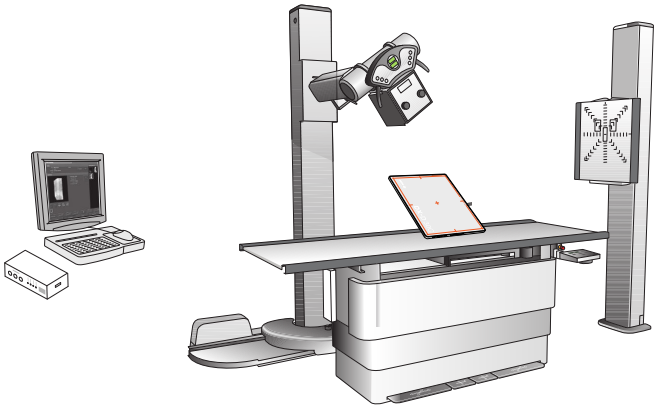
DX-D 400

5420/100

5420/101

User Manual



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Contents

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Introduction to this Manual

Topics:

Scope of this Manual

This User Manual describes the features of the DX-D 400 System, an integrated X-Ray imaging system. It explains how the different components of the DX-D 400 System work together.

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.

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

Introduction to DX-D 400

Topics:

Intended Use

- The DX-D 400 system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients.
- Applications can be performed with the patient in the sitting, standing or lying position.
- This device is not intended for mammography applications.

Intended User

This manual has been written for trained users of Agfa products and trained diagnostic X–Ray clinical personnel who have received proper training.

Users are those persons who actually handle the equipment and those who have 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

DX-D 400 is a configurable DR (Direct Radiography X-Ray system), CR (Computed Radiography) or film/screen X-ray system.

The complete DX-D 400 consists of the following components:

- Floor mounted tube stand
- RAD Table with integrated DX-D Fixed DR Detector or with DR Detector bucky or cassette bucky
- RAD Wall Stand with integrated DX-D Fixed DR Detector or with DR Detector bucky or cassette bucky
- Portable DR Detector
- DR Generator Sync Box
- X-ray generator
- X-ray generator control box
- X-ray tube with manual or automatic collimator
- NX workstation

The DR Detector bucky has two variants, supporting following formats:

- DR Detectors with a size equivalent to 14x17 inch (43x35 cm) and 43x35 CR Cassettes.
- DR Detectors with a size equivalent to 17x17 inch (43x43 cm)

DX-D 400 can be used in combination with:

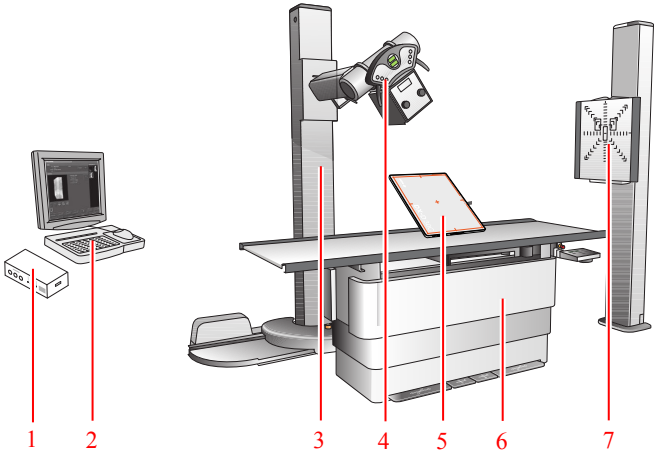
- CR Digitizer

DX-D 400 has three main configurations:

1. DR configuration with X-ray exposure parameter control on the NX workstation (5420/101).
    - X-ray parameters are controlled using the DX-D Software Console on the NX workstation.
2. CR configuration with X-ray exposure parameter control on the NX workstation (5420/100).
    - X-ray parameters are controlled using the DX-D Software Console on the NX workstation.
3. CR configuration with X-ray exposure parameter control on the X-ray console (5420/100).
    - X-ray exposure parameters are controlled on the DX-D 400 Touchscreen Console or on the DX-D 400 overlay console.
    - The NX workstation is optional.

The DR configuration contains a DR Generator Sync Box, to connect the DR Detector, the X-Ray generator and the NX workstation.

The DX-D Software Console is available on the NX workstation, to synchronize the X-ray exposure parameters between the NX application and the generator.



1. DR Generator Sync Box
2. NX workstation
3. Floor mounted tube stand
4. X-ray tube with collimator
5. DR Detector
6. RAD Table
7. RAD Wall Stand

Figure 1: DX-D 400 Configuration

Equipment Classification

Per EN/IEC60601-1, Medical Electrical Equipment, General Requirements for Safety 3rd Edition, this device is classified as following:

Table 1: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not relay 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	A Type B piece of equipment is one that provides a particular degree of protection against electric shock particularly regarding allowable leakage current and reliability of the protective earth protection.
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.

Related Links

Cleaning and Disinfecting on page 37

Options and Accessories

The system is delivered with 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.

For information on options and accessories, refer to these manuals:

- DX-D 400 X-Ray System User Manual, document 0232.
- User manuals for the supported DR Detectors.

Anti-scatter grids

Anti-scatter grids are used to reduce scattered radiation and improve image quality. Grids are available as an option.

Refer to the Agfa website for specifications on the anti-scatter grids that have been found compatible with the system and the DR Detectors.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=54332498

Operation Controls

Refer to the DX-D 400 X-Ray System User Manual (document 0232) for a description of the Touchscreen Console, the Overlay Console, the collimator controls, the RAD Table controls and the RAD Wall Stand controls.

The main operation controls of the DX-D 400:

Topics:

NX Application on the NX Workstation

The NX application is used to define patient information, select exposures and process images.

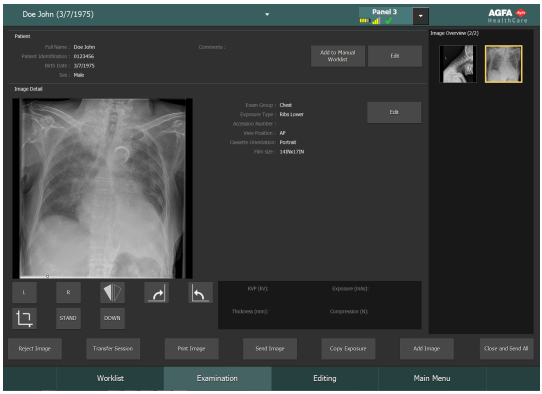


Figure 2: NX application

The operation of the NX application is described in the NX User Manual, document 4420..

DR Software Console

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

The DR Software Console contains the DR Detector Switch.

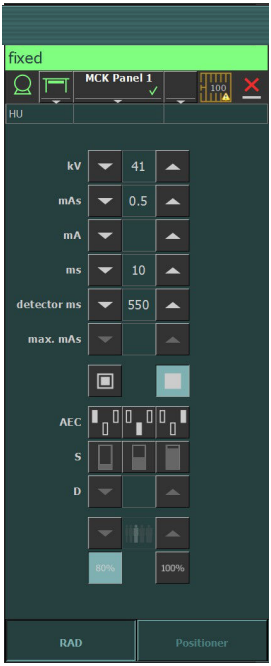


Figure 3: DR Software Console

DR Detector Switch

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. The DR Detector Switch can also be used to switch to CR for making an exposure on a cassette.

DR Detector Status

Battery status icon				
Meaning	Full	Medium	Low	Empty

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

DR detector status icon		 (blinking)			
Meaning	Ready	Initializing exposure	Error	Sleep	One DR detector must be selected

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.*

Portable DR Detector

When performing an exposure, keep in mind the following detector orientation aids:

1. Tube side
2. Patient orientation marker

For an overview of the operation controls of the DR Detector, refer to the user manual of the DR Detector.

The DR Detector may come in contact with the patient.

Note: DR Detectors that operate wireless contain an RF transmitter. For detailed information, refer to the DR Detector User Manual.

System Documentation

The documentation shall be kept with the system for easy reference.

The most extensive configuration is described within this manual, including the maximum number of options and accessories. Not every function, option or accessory described may have been purchased or licensed on a particular piece of equipment.

Technical documentation is available in the product service documentation which is available from your local support organization.

The DX-D 400 User Documentation

The DX-D 400 user documentation consists of

- DX-D 400 User Documentation CD (digital media)
- NX User Documentation CD (digital media)
- User documentation for the supported DR Detectors

The DX-D 400 User Documentation CD contains:

- DX-D 400 User Manual (this document), document 0230
- DX-D 400 X-ray System User Manual, document 0232
- DX-D Software Console User Manual, document 0289
- 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.

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer 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

The system is compliant with specific directives and standards.

Topics:

General

- The product has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and have been tested as part of the conformity assessment procedures required by 93/42/EEC Medical Device Directive (European Council Directive 93/42/EEC on Medical Devices).
- ISO 13485
- IEC 62366
- ISO 14971

Safety

- IEC 60601-1
- UL 60601-1
- CAN/CSA C 22.2 No.601.1-M90

X-Ray Safety

- IEC 60601-2-54

For USA

The system conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.

Electromagnetic Compatibility

- IEC 60601-1-2

Connectivity

On configurations with X-ray exposure parameter control on the NX workstation, the NX workstation is connected to the X-ray system to exchange X-ray exposure parameters.

Note: *The connections between the components of the 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

Mark	Meaning
	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	This mark indicates that this is a Type B Equipment
	Serial number
	Manufacturer
	Date of manufacture

Label	Meaning
	Dangerous voltage
	Ionizing radiation
	Pinch Points.
	Risk of stumbling.

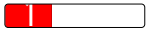
Further labels are listed and explained in the relevant modules of the System Documentation.

Topics:

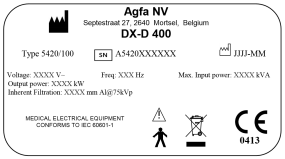
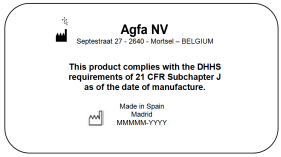
- *DR Detector identification label*
- *Type label*
- *Additional Labeling of the X-Ray Generator Control Box*

- *Labeling of the DR Generator Sync Box*

DR Detector identification label

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

Type label

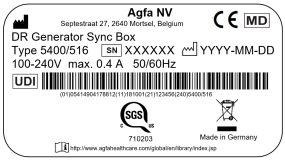
Mark	Meaning
 (Sample of subtype 5420/100)	Type label positioned on the column. The type label information for each combination of X-ray tube and X-ray generator is available in the technical data.
	The 21 CFR Subchapter J label is positioned close to the type label.

Additional Labeling of the X-Ray Generator Control Box

Following warning is printed on the X-ray generator control box in English:

Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

Labeling of the DR Generator Sync Box

 **Figure 4: Example of type label**	The type label is located on the DR Generator Sync Box
	Functional earth
	Medical equipotential

Cleaning and Disinfecting

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. The user is responsible for selecting a disinfection procedure.

Topics:

Cleaning

To clean the exterior of the equipment:

1. Stop the system

Warning: When the equipment is going to be cleaned, be sure to turn OFF the power of each device, and to unplug the power cord from the AC outlet. Never use anhydrous or high solvency alcohols, benzine, thinner or any other flammable cleaning agent. Otherwise, it may result in fire or electric shock.

2. Wipe the exterior of the system with a cloth slightly moistened with a neutral detergent.

Caution**:** Make sure no liquid gets in the device.

Caution**:** Clean the equipment with only a little moisture. Do not spray disinfectants or detergents directly on the equipment. Do not pour liquid directly on the equipment.

Caution**:**

Do not use solvents such as anhydrous or high solvency alcohols, thinner or benzine. Do not use any corrosive, dissolving or abrasive cleaning or polishing detergents.

Doing so may damage the surface of the equipment. Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. by using alcohol-containing agents).

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

3. Start up the system.

Disinfecting

WARNING:
To disinfect the device, use only disinfectants and disinfection methods that are approved by Agfa and that correspond to the national regulation and guidelines as well as explosion protection.

If you plan to use other disinfectants, approval of Agfa is needed before use, as most disinfectants can damage the device. UV disinfection is also not allowed.

Perform the procedure following the instructions for use, the disposal instructions and the safety instructions of the selected disinfectants and tools and of the hospital.

Items contaminated with blood or body fluids, which may contain blood-borne pathogens, should be cleaned and then receive intermediate level disinfection with a product having an EPA-registered claim for activity against hepatitis B.

Approved disinfectants

Refer to the Agfa website for specifications on the disinfectants that have been found compatible with the cover material of the device and can be used on the outer surface of the device.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=41651138

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 DR Detector Calibration Key User Manual (doc 0134).

Maintenance procedures

Maintenance procedures for the X-ray system are described in the DX-D 400 Owner's Manual.

Environmental protection

Figure 5: WEEE symbol

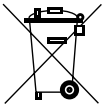


Figure 6: Battery symbol

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: Only qualified and authorized personnel shall operate this system. In this context 'qualified' means those persons legally permitted to operate this equipment in the jurisdiction in which the equipment is being used, and 'authorized' means those persons authorized by the authority controlling the use of the equipment. Full use must be made of all radiation protection features, devices, systems, procedures and accessories.

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: Improper changes, additions, maintenance or repair of the system can lead to personal injury, electrical shock 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. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

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 and make maximal use of the protected area.

Warning: The DR Detector is not intended to be used as a primary barrier to X-rays. The user 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 if the status of the DR Detector is ready for exposure.

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: As the cables of the equipment are long, be careful not to entangle the cables during use. Also, be careful not to trip over the cables. Falls could result in injury.

Warning: Unplugging the detector immediately after exposure may cause image loss.

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

Caution: When operating the DR detector, the calculated exposure time (ms) or manual overrides should never exceed the maximum exposure time (Max ms) specified as integration time of the DR detector.

Caution: Make sure the patient hand grips are properly mounted.

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.

Caution: Damaged grid. Reduced image quality. Please handle the grids with special care.

Caution: When inserting the scattered radiation grids, it is essential that the grid corresponds to the intended source-image-distance (SID) to which the grid is focussed. Because of the focussing of the grids, the tube unit must be centered onto the bucky.

Caution**:** To avoid images being lost due to a power failure, the workstation and the digitizer have to be connected to an uninterruptable power supply (UPS) or an institutional standby generator.

Caution**:** Install the NX workstation and CR digitizer at a minimum (safe) distance of 2 m from the X-Ray System components or provide a wall or window to separate both systems.

- For product safety directions, refer to the User Manuals.

Getting started

Topics:

Starting the System

Allow the DR Detector to warm up before the system is used for clinical purposes. The warming-up time starts as soon as the DR Detector has been powered on and the NX workstation is running. To check if a warming-up time is required, refer to the DR Detector technical data.

For using the fixed DR Detector, the temperature difference between calibration and usage must be within the recommended range of +/-6°C (for a DR Detector with CsI conversion screen) or +/-10°C (for a DR Detector with GOS conversion screen). Check the environmental conditions and observe the warming-up time of the DR Detector.

To start the system:

1. Switch on the electrical room switch.

   Check that neither the emergency shutdown power switch for the system nor any of the emergency stop buttons for the radiographic table is activated.
2. Press the Power ON button on the X-ray generator control box to switch on the system.
3. Start the NX workstation.

   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.
4. Switch on the DR Generator Sync (if applicable).
5. In a configuration with a wireless DR Detector, power on the DR Detector:
   a) attach a fully charged battery pack to the DR Detector.
   b) turn on the DR Detector.
   c) if needed, register the DR Detector to the NX workstation.

   For detailed information about starting up the DR Detector, refer to the DR Detector User Manual.
6. In a configuration with a wired DR detector, switch on the control unit for the DR Detector.

Performing an exposure using the DR Detector

Topics:

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 DR 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 DR 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

Related Links

DR Detector Status on page 19

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 if the status of the DR Detector is ready for exposure.

On a DR Detector that has a status indicator:

Check if the status of the DR Detector is ready for exposure. If the status is not ready for exposure, the DR Detector cannot be used for making an exposure.

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

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

Step 5: execute the exposure

In the operator room:

Press the exposure button to execute the exposure.

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:

- 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.

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).

Performing an exposure using a CR cassette

Note: Using an ID Tablet to identify cassettes before the exposure will break the communication of X-ray parameters between the NX workstation and the X-ray generator console. It is advised to identify cassettes after the exposure, as described in this workflow.

Topics:

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 at the NX workstation:

1. Select the thumbnail for the exposure in the Image Overview pane of the Examination window.

	RAD Table DR with cassette in the DR bucky
	RAD Wall Stand DR with cassette in the DR bucky
	Free exposure using a cassette

Note: For a bucky exposure, only cassette size 43x35 is supported.

On configurations 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 software console.

2. Select the subexposure if more than one image is required for the same cassette.
   If an image thumbnail is configured for multiple exposures on a single cassette, another set of thumbnails is shown in the image detail pane. Now you have to select one of these thumbnails to send the proper default X-Ray exposure parameters to the modality for each exposure.

Note: When working in a PACS environment, the preferred workflow is to have only one image per cassette. This is needed for optimal use of hanging protocols. However, in particular cases (e.g. printing sites) it is supported to make more than one exposure per cassette.

Step 3: prepare the exposure

In the examination room:

1. Position the cassette.

Note: For a free exposure, partial lead covering of the cassette may be required if multiple images are taken on one cassette.

Note: For a bucky exposure, always insert an unexposed cassette in the 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 cassette and the patient.
5. Set the correct distance between cassette 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 cassette.

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

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.

Step 5: execute the exposure

In the operator room:

Press the exposure button to execute the exposure.

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

- On configurations 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.
- The actual X-Ray exposure parameters and the Exposure Index (EI) value on the NX workstation can be used to monitor the performance of the Automatic Exposure Control of the X-Ray system.
- A green OK mark appears on all thumbnails for which the exposures are made and for which exposure settings are sent back to the NX workstation.

Step 6: repeat steps 2 to 5 for the next subexposures

Step 7: digitize the image

In the examination room:

Take the exposed cassette.

In the operator room:

1. Insert the cassette in the digitizer.
2. Click ID in the examination window of NX.

Note: You can also use an ID Tablet to identify the cassette and digitize it using any digitizer.

The image will appear in the image overview pane of the examination window.

Step 8: perform a quality control

In the operator room 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 the System

To stop the system:

1. Stop the NX workstation.

   NX can be stopped in two ways, either by logging out of Windows or without logging out of Windows.

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

   Note: *Stopping the NX workstation does not stop the DR Detector. If the power of the DR Detector remains on, no warming-up time will be needed after starting the NX workstation.*

2. Press the Power OFF button on the X-ray generator control box to switch off the generator.
3. In a configuration with a wireless DR Detector, power off the DR Detector:
   - turn off the DR Detector.
   - remove the battery pack.
4. Switch off the DR Generator Sync.

Note: *If the DR Detector is powered down, a warming-up may be required on the next start-up.*

Problem solving

Topics:

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	The exposure button was pushed to the first pressure point and released without making an exposure. Directly afterwards, the exposure button was pushed down fully. 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. Depending on the X-ray system, two situations can occur: • 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	To repeat the exposure workflow: **1.** On the NX workstation, click **Copy Exposure** to create a new thumbnail. **2.** Repeat the steps described in the Basic Workflow.

Related Links

Performing an exposure using the DR Detector on page 49

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 DR Software Console, the exposure button was pushed while the X-ray system was not ready for exposure.
Brief Solution	To repeat the exposure workflow: **1.** On the NX workstation, click **Copy Exposure** to create a new thumbnail. **2.** Repeat the steps described in the Basic Workflow.

Related Links

Performing an exposure using the DR Detector on page 49

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: **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.

Error E32 displayed on DX-D Software Console after preparing for exposure

Details	Error E32 displayed on DX-D Software Console after preparing for exposure.
Cause	The bucky of the X-ray system is not closed. The bucky of the X-ray system is empty. The CR cassette has not been replaced after the exposure.
Brief Solution	Check if the bucky of the X-ray system contains an unexposed CR cassette or a DR detector and if it is properly closed. Click the OK button on the DX-D Software Console or the Reset button on the DX-D 400 Touchscreen Console or on the DX-D 400 overlay console until the error indication disappears on the console. If the equipment remains inoperative, try restarting the generator or call service. In this case, the generator can still work in free exposure mode.

Error E38, E39 or E40 displayed on the console after preparing for exposure

Details	Error E38, E39 or E40 displayed on the console after preparing for exposure.
Cause	The X-ray tube orientation is incorrect for the selected workstation. Error E38 usually indicates that the RAD Table is selected. Error E39 usually indicates that the RAD Wall Stand is selected. Error E40 indicates that more than one workstation interlock is active at the same time.
Brief Solution	Adjust the orientation of the X-ray tube to match the selected workstation. Click the OK button on the DX-D Software Console or the Reset button on the DX-D 400 Touchscreen Console or on the DX-D 400 overlay console until the error indication disappears on the console. If the equipment remains inoperative, try restarting the generator or call service. In this case, the generator can still work in free exposure mode.

Technical Data

Topics:

DX-D 400 X-Ray System Technical Data

Refer to the DX-D 400 X-Ray System User Manual (document 0232) for technical data of the X-Ray system.

For overall system environmental conditions, the environmental conditions of the portable DR detector should be taken into account. Refer to the DR Detector User Manual for environmental conditions for the DR detector. When using the DR Detector inside the DR bucky, take into account that the temperature inside the DR bucky can be up to 5 degrees Celsius higher than the temperature in the X-ray room.

Fixed DR Detector Technical Data

Manufacturer	
Manufacturer DR Detector	Varex Imaging Corporation, 1678 So. Pioneer Rd, Salt Lake City, UT 84104, USA
Supported models	
4343R (part number 7965)	CsI conversion screen
4343R (part number 7964)	GOS conversion screen
Electrical Connection	
Operating voltage	90-240 V (AC)
Mains fuse protection	6A
Mains frequency	47-63 Hz
Power consumption	
Maximum power consumption	45 W
Warming-up time	
	1 hour
Throughput	
Maximum number of image acquisitions	150 acquisitions per hour
Pixel Matrix	
Pixel size	139 μm (H,V)
Pixel matrix	3072(H) x 3072(V)
Active pixel matrix	3056(H) x 3056(V)
Fill factor	100 %
Detector type	Amorphous Silicon
Active area size	42,7 cm (H) x 42,7 cm (V)

Reliability	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	100 000 RAD

Portable DR Detector Technical Data

Refer to the DR Detector User Manual.

DR Generator Sync Box Technical Data

Model name	DR Generator Sync Box
Type number	5400/516
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)
Estimated product life	7 years

NX Workstation Technical Data

Electrical connection	
Operating voltage	90 – 263VAC
Mains fuse protection	5.5A
Mains frequency	47 – 63 Hz
Power consumption	
Maximum power consumption	320W

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.

Table 2: Guidance and manufacturer's declaration on electromagnetic emissions (IEC 60601-1-2)

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions 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 CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Note: In accordance with Standard IEC 61601-1-2, the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A. If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment.

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.

Table 3: Guidance and manufacturer's declaration on electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV ± 8 kV	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.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV N/A	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	40% U_T (60% dip in U_T) for 5 cycles	60% for 5 periods	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 continuous-
	70% U_T (30% dip in U_T) for 25 cycles	30% for 25 periods	

	< 5% U_T (> 95% dip in U_T) for 250 cycles	> 95% for 250 periods	ly, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.
	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	> 95% for 0.5 periods	
	< 5% U_T (> 95% dip in U_T) for 1 cycle	> 95% for 1 period	
Power frequency (50 Hz) magnetic field 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.
• Note: U_T 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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	3 Vrms 150kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Radiographic Room, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

			Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency rangeb). Interference may occur in the vicinity of equipment marked with the following symbol: 

- 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.

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.

The field strength will be lower than 3 V/m above the frequency range from 150 kHz to 80 MHz.

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

TYPICAL RF DEVICES (Worst-Case scenario)	
Device: Power @ Frequency	Recommended distance(m)
GMRS device (Professional Walkie-Talkie): 5 W @ 462-467 MHz	2.7
GSM / UMTS cell phone: 2 W @ 850/1700/1900 MHz	3.3
FRS device (Amateur Walkie-Talkie): 500 mW @ 462-467 MHz	0.9
WiFi / Bluetooth devices: 100 mW @ 2400-2500 MHz	0.8
DECT devices (modern cordless phones): 100mW @ 1880-1900 MHz	0.8
RFID reader (3): 10 mW @ 125-150 KHz / 13.56 MHz	0.12
RFID reader (3): 10 mW @ 902-928 MHz / 2400-2500 MHz	0.23
Station transmitter ATSC TV broadcasting: 100 kW @ 54-800 MHz	380
Station transmitter ATSC TV broadcasting: 100 kW @ 800-890 MHz	730
Station transmitter FM radio broadcasting: 100 kW @ 87.5-108 MHz	380

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.

- REMARK 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
- 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.