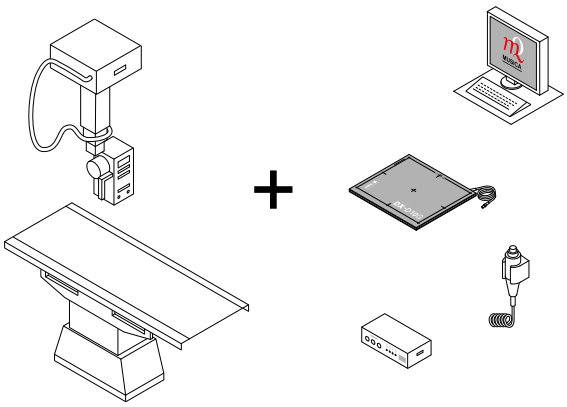
DR Generator Sync Box, DR Retrofit Solution

5400/516

5400/526

User Manual



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Contents

Legal Notice

DR Generator Sync Box:

DR Retrofit Solution:

0413

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Introduction to this Manual

Topics:

Scope of this Manual

This manual contains information for safe and effective operation of the DR Retrofit Solution, further referred to as the system and the DR Generator Sync Box, further referred to as the device.

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 on order of a physician for prescription use only.*

Introduction

Topics:

Intended Use

The DR Retrofit Solution 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 DR Retrofit Solution converts the screen-film or CR system into a DR system.

The DR Retrofit Solution is not indicated for use in mammography.

The DR Generator Sync Box is indicated for use as a component of the DR Retrofit Solution. The DR Generator Sync Box is making the connection between the DR detector, the NX workstation and the X-ray generator.

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 DR Retrofit Solution consists of the following components:

- DR Detector
- NX workstation
- DR Generator Sync Box

The DR Retrofit Solution supports two levels of integration with the X-ray system.

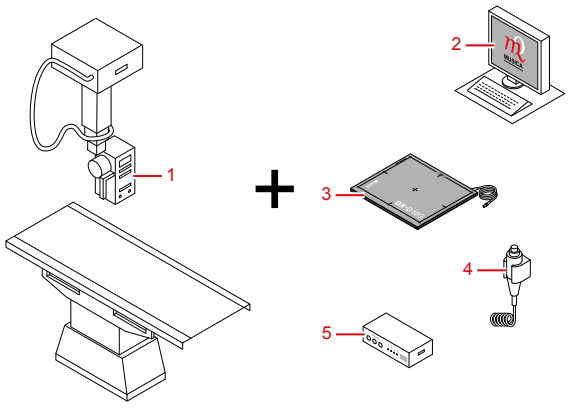
1. Integration of the exposure signal.
   - The exposure button of the X-ray system is removed or disabled and a new exposure button is connected to the DR Generator Sync Box.
2. Integration of X-ray exposure parameters.
   - The exposure button of the X-ray system is replaced by an exposure button connected to the DR Generator Sync Box.
   - X-ray parameters can be controlled using either the Software Console on the NX workstation or the X-ray generator console of the X-ray system, depending on the configuration.

The DR Generator Sync Box synchronizes the exposure signal between the DR detector, the NX workstation and the generator.

Maximum three exposure buttons can be connected to the DR Generator Sync 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 DR Software Console or DR Detector Switch
3. DR Detector
4. Replacement exposure button
5. DR Generator Sync 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 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	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.

Related Links

Cleaning and Disinfecting on page 32

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*
- *DR 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.

CAUTION:
Wear of X-ray tube due to prolonged preparing of the X-ray tube.

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.

CAUTION:
Releasing the exposure button ends the exposure immediately and the image can be underexposed.

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.

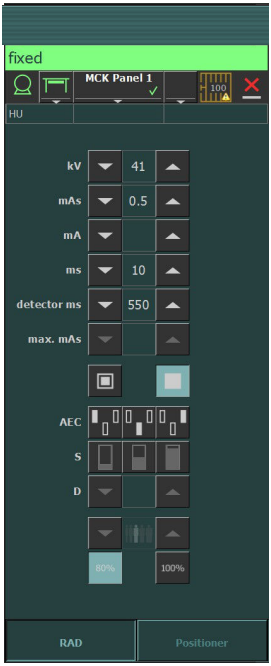


Figure 1: DR Software Console

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 DR 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

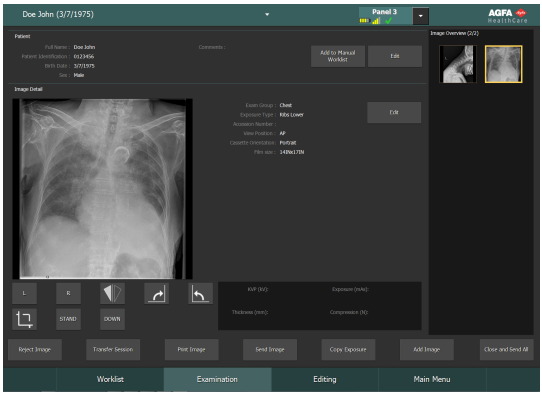


Figure 3: DR Detector Switch in the title bar of the NX application

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 DR Retrofit Solution user documentation consists of

- DR Generator Sync Box, DR Retrofit Solution User Documentation CD (digital media)
- NX User Documentation CD (digital media)
- User documentation for the supported DR Detectors

The DR Generator Sync Box, DR Retrofit Solution Documentation CD contains:

- DR Generator Sync Box, DR Retrofit Solution User Manual (this document), document 0319
- DR Software Console User Manual, document 0289
- 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, 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

Topics:

General

- The DR Retrofit Solution has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and has 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).
- The DR Generator Sync Box has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR).
- IEC 62366
- ISO 14971

Safety

- IEC 60601-1
- AAMI ES 60601-1
- CSA C 22.2 No.60601-1

Electromagnetic Compatibility

- IEC 60601-1-2

Environmental Compliance

- European Council Directive 1907/2006 (REACH)
- European Council Directive 2011/65/EU (RoHS 2)
- European Council Directive 2012/19/EU (WEEE)

Connectivity

The DR Generator Sync Box is connected to the NX workstation and the X-ray generator and replaces the interface to the original exposure button.

The DR Generator Sync exposure button is connected to the DR Generator Sync 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 DR Generator Sync 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

Connectivity requirements

Warning: Any kind of equipment connected to any interface must be certified according to the respective IEC standards (e.g. IEC 60950 / IEC 62368 for data processing equipment or IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the requirements for medical systems according to IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult your local service organization.

Installation

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

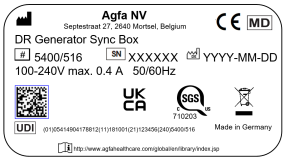
On a configuration with multiple DR detectors of the same type, it is required to apply labeling to the DR detector containing a unique nickname for each DR detector. The nicknames must be configured on the MUSICA Acquisition Workstation. The **DR Detector Switch** shows which DR detector is active and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

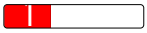
An identical label is attached to the bucky of the X-ray system to identify the dedicated workspace of each DR detector.

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

 **Figure 4: Example of the type label**	The type label is located on the DR Generator Sync Box.
	In order to reduce the risk of electric shock, do not remove any covers.
	Date of manufacture
	Country of origin. The two character code on the actual label contains the country code defined in ISO 3166-1.
	Manufacturer
	Medical device
	Serial number
	Unique device identifier, in text format and in machine readable format
	Type and subtype number
	The most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*
	If the exposure button of the original system is visible, this label is attached. The user manual (this document) instructs not to use the exposure button of the original system.

	Earth (ground)
	Equipotential connector: Provides a connection between the equipment and the potential bus bar of the electrical system as found in medical environments. It is recommended to use the equipotential connection as additional safety measure.
	Writable label to identify and dedicate a DR Detector to an X-ray system bucky.

Consulting the About box

1. Click **About the solution** in the Tools section of the **Main Menu** window on the MUSICA Acquisition Workstation.

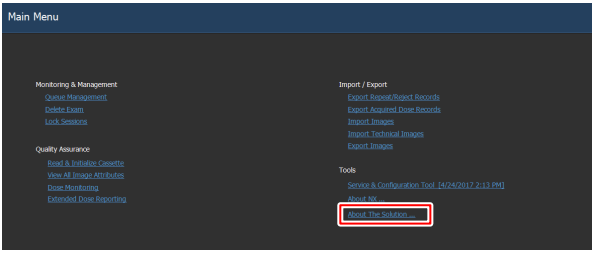


Figure 5: Main Menu window.

This will open the About box showing the current release and version details of the DR Retrofit solution.

Figure 6: DR Retrofit About box (Displayed data may be different).

Note: *Always quote these details when you discuss any issues with Agfa service personnel.*

2. Click on the dialog to close it.

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.

Requirements on the operating environment

These operating environment requirements for information security and privacy (ISP), set in compliance with point 17(4) and 18(8) of Annex I of the EU Medical Device Regulation 2017/745, must be implemented and used in connection with the use of the Agfa medical device by the Customer (User). These are minimum requirements and designed to protect against unauthorised access that could hamper the device from functioning as intended.

Although Agfa has defined these ISP Operating Environment Requirements for implementation by the Customer, Agfa makes no warranties, expressed or implied regarding those ISP Operating Environment Requirements.

Agfa disclaims all liability if a security incident would occur despite the implementation of these ISP Operating Environment Requirements by the Customer.

Agfa reserves the right to revise these ISP Operating Environment Requirements and to make changes to them at any time. Possible revisions of the ISP Operating Environment Requirements will only be available in an electronic form, on request, via our website, by using the user documentation request form *http://www.agfahealthcare.com/global/en/library/index.jsp*.

The information presented herein is sensitive and is company confidential. Without written authority from Agfa, further distribution outside the company is not allowed.

- Perimeter firewalls shall be in place and appropriately configured in order to ensure that communications between medical devices and external resources are either denied or restricted to just the communications that are essential for the medical devices to properly function.
- Network Intrusion Detection/Prevention Systems (NIDS/NIPS) shall be in place at the perimeter and appropriately configured, in order to provide early warning of an attack attempt or successful compromise of a medical device as well as to attempt to prevent compromise of medical devices.
- A Network Time Protocol Server shall be configured in the medical devices in order to synchronize the time in the audit logs with the time on the NTP server.

- Medical devices shall be on an isolated network segment that restricts communication of the medical devices to the systems that are required for the device to function.
- Internal firewalls shall be put in place to improve upon network segmentation and to further restrict communications of medical devices to the systems (internal and external) that they need to interact with.
- Medical device configurations shall be backed up in a secure separate device.
- Security controls shall be put in place to ensure that physical access to medical devices is limited only to authorized individuals and that physical theft of the device is prohibited.
- An incident response plan detailing responsibilities and how to react and recover from incidents, shall be in place. Staff involved in the incident response plan shall be trained to respond appropriately and effectively.
- A formal user provisioning and de-provisioning process shall be implemented to enable the appropriate management of access rights to medical devices.
- Users shall be assigned unique accounts to medical devices.
- User access rights to medical devices shall be reviewed for appropriateness and corrected as needed, at regular intervals not exceeding once a year.

Maintenance

Complete maintenance schedules are available in the Agfa service documentation for consultation by an Agfa trained and authorized service engineer.

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).

Environmental protection

Figure 7: WEEE symbol

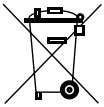


Figure 8: Battery symbol

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. The recycling of materials will help to conserve natural resources.

CAUTION:
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.

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 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: 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 DR Generator Sync Box from the mains power

To disconnect the DR Generator Sync Box from the mains power, switch off the power switch or remove the power plug from the socket.

Getting started

Topics:

Starting

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 DR Generator Sync 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

At the MUSICA Acquisition Workstation:

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

If the workstation is connected to a second monitor that is positioned outside the operator room, make sure that the patient data is not exposed to unauthorized persons.

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

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.

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:

- 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 the DAP in cGy.cm². X-ray systems may use other units to display the DAP.

The NX stores and transmitts the DAP DICOM compliant units: dGy.cm².

Step 6: perform a quality control

At the MUSICA Acquisition 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

1. Switch off the DR Generator Sync 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

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

Basic Workflow on page 41

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

Basic Workflow on page 41

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.

Exposure blocked after switching to CR

Details	The exposure is set to CR using the DR Detector Switch. Exposure is blocked.
Cause	The X-ray generator console is not automatically set to **free exposure**. This situation applies only to Siemens generators.
Brief Solution	On the X-ray generator console, select **free exposure**. Perform the CR exposure.

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:

DR Retrofit Solution Technical Data

Technical data is available in the relevant modules of the user documentation.

DR Generator Sync Technical Data

Labeling		
Type	5400/516	
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	

Fixed DR Detector Technical Data

Manufacturer	
Original manufacturer model name	4343R (part number 7965) 4343R (part number 7964)
Manufacturer DR Detector	Varex Imaging Corporation, 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 %
Atmospheric pressure	between 500 hPa and 1100 hPa
Environmental conditions (during normal operation)	
Room temperature	between +15 °C and +35 °C
Humidity (non condensing)	between 30 % and 75 %
Atmospheric pressure	between 700 hPa and 1100 hPa
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

Remarks for HF-emission and immunity

It is hereby certified that the DR Generator Sync Box has interference suppression according to the EN 55011 Class A as well as the FCC Rules CFR 47 Part 15 Class A.

This device was tested for a normal hospital environment as described above.

The user of the device should ensure that it is used in such an environment.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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.

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.

RF Emission Measurements	Agreement	Electromagnetic Environment Guidelines
High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclusively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class B	The DR Generator Sync Box is intended for use in all buildings, including living areas and areas directly connected to a public supply network that also supplies buildings that are used for domestic purposes.

Harmonic emission in accordance with IEC 61000-3-2	Class B
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Complies

The device is used in a professional healthcare / radiological environment. Environmental conditions are stated in the user manual.

This device was tested for a professional healthcare environment as described above. Nevertheless the HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

Resistance to Jamming Test	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment Guidelines**
Discharge of static electricity in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 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	± 2 kV mains ± 1 kV data lines	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	± 1 kV line-line voltage ± 2 kV line-ground voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakdown, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• 0% U_r for ½ period • 0% U_r for 1 period • 70% U_r (30% breakdown of U_r) for 25 periods at 0° • 0% U_r for 250 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 continuously, even when the energy supply is interrupted, it is recommended to use an energy supply

		free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
REMARK : U_r is the alternating current in the network before the application of the test level.		

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.

Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	
RF communication	Refer to the section "Immunity to RF wireless communication equipment"	
		Disruptions are possible near devices that carry the following symbol: 

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 test level 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.

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. See also the section with precautions on EMC.

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 RF emission Frequency m		
	150 kHz to 80 MHz $d = 1.0 \sqrt{P}$	80 MHz to 800 MHz $d = 0.3 \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.3 \sqrt{P}$
0.01	0.1	0.05	0.05
0.1	0.32	0.1	0.1
1	1.0	0.3	0.3
10	3.2	1.0	1.0
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 : 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.			

Topics:

- *Immunity to RF wireless communication equipment*
- *Precautions on EMC*
- *Cables, transducers and accessories*

- *Maintenance on EMC relevant parts*

Immunity to RF wireless communication equipment

ISM Band (MHz)	Service	Distance (m)	Immunity test level (V/m)
300-390	TETRA 400	0.3	27
430-470	GMRS 460; FRS 460	0.3	28
704-787	LTE Band 13, 17	0.3	9
800-960	GSM 800/900; TETRA 800, IDEN 820; COMA 850; LTE Band 5	0.3	28
1700-1990	GSM 1800; COMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	0.3	28
2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	0.3	28
5100-5800	WLAN 802.11 a/n	0.3	9

Precautions on EMC

WARNING:
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING:
The DR detectors might be interfered with by other equipment.

Cables, transducers and accessories

Cables, transducers and accessories which were tested and found to comply with the collateral standard IEC60601-1-2 (EMC):

CAUTION:
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

from	to	type	maximum length	remark
Wall outlet	DR Generator Sync box	3 x AWG18 unshielded	3 m	mains supply cable
Exposure button	DR Generator Sync box	AWG21 unshielded	1.5 m	
PC	DR Generator Sync box	CAT 5e shielded	5 m	ethernet
PC	DR Generator Sync box	USB shielded	5 m	
DR Detector	DR Generator Sync box	10*0.25 mm^2 (AWG23)	16 m	extension cable for DR Detector
X-ray generator control box	DR Generator Sync box	10*0.25 mm^2 (AWG23)	5 m	extension cable for the console
X-ray generator control box	X-ray generator	10*0.25 mm^2 (AWG23)	16 m	extension cable for the generator

The system needs to be installed and put into service according to the EMC information provided (shielded cables).

Maintenance on EMC relevant parts

Concerning the EMC safety of the DR Generator Sync Box, no relevant parts could be inspected by the operator or by a service engineer before the end of lifetime.