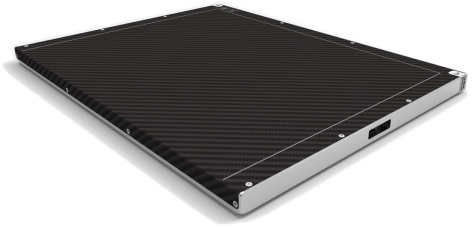
DR 18M, DR 24M

5400/527

5400/528

User Manual



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AGFA

Contents

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Agfa NV, Septestraat 27, B-2640 Mortsel - Belgium

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B-2640 Mortsel - Belgium.

Introduction to this Manual

Topics:

Scope

This manual contains information for the safe and effective operation of the DR 18M and DR 24M DR Detectors and peripheral equipment, further referred to as the DR detector.

About the safety notices in this document

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

DANGER:
A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING:
A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION:
A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

An instruction is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

A prohibition is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

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

Disclaimer

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

Introduction to the DR Detector

Topics:

Intended Use

The DR 18M and DR 24M are flat panel digital X-ray detectors designed for use in digital X-ray imaging of woman breast diagnosis (Mammography). They upgrade an analog or CR mammography unit into a digital unit to capture projection radiographic images in digital format within seconds, eliminating the need for an X-ray film or an image plate as an image capture medium.

The DR 18M and DR 24M is intended for mammography application only. The DR detectors are designed to be equivalent in size to a conventional film and CR image plate. The DR 18M is the appropriate size for a small bucky of any mammography unit and the DR 24M is the appropriate size for a large bucky of any mammography unit.

Indications for Use

The DX-D Retrofit Packages system is indicated for use in specific projection Mammography applications to capture of display diagnostic quality mammography images of human anatomy for adult examinations. The DX-D Retrofit Packages system converts the screen-film or CR Mammography system into a DR Mammography system. If the X-ray system contains preconfigured exposure settings, they will be updated for use with the DR detector and the system can no longer be used together with screen-film or CR systems.

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.

Only a physician or a legally certified operator should use this product.

Configuration

The DR Detector is a component that can be integrated in an X-ray system and that communicates to a workstation. A workstation can communicate to a single DR Detector. A DR Detector can communicate to a single workstation.

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.

Non-medical equipment

Following components are classified as non-medical equipment:

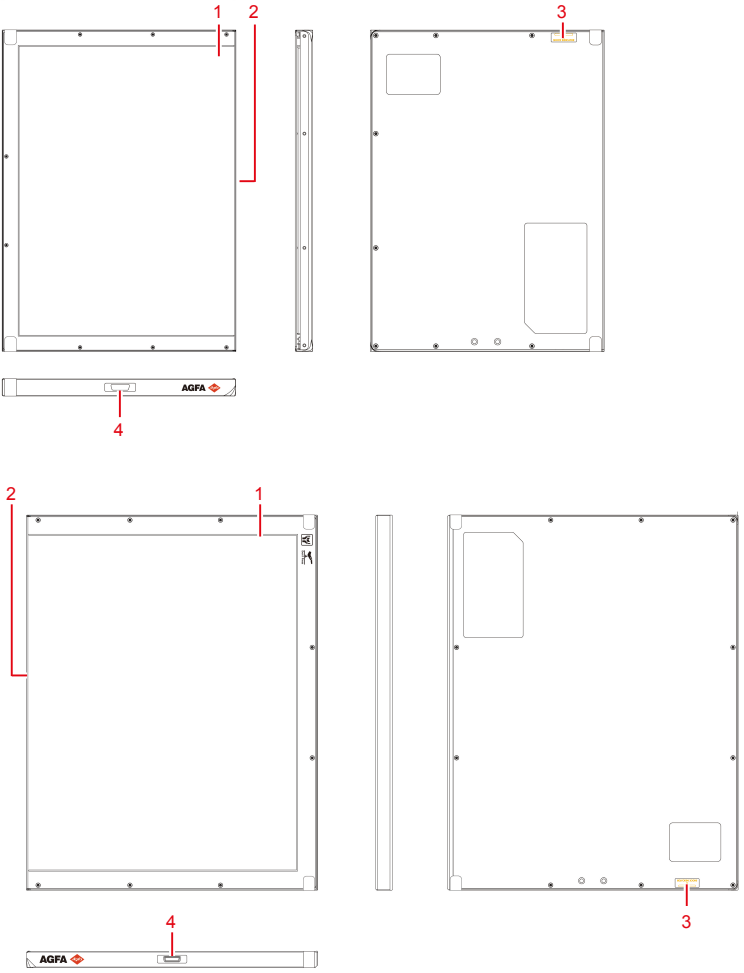
- Workstation
- DR detector control unit

WARNING:
Do not use non-medical equipment in the patient's vicinity.

Operation Controls

Topics:

DR 18M, DR 24M



1. Effective imaging area border and center position indication
2. Chest wall
3. Shock indicator
4. DR Detector cable connector

Figure 1: DR Detector operation controls

DR Detector Switch on the NX Workstation

The DR Detector Switch is available in the title bar of the NX application. The DR Detector Switch shows which DR Detector is active and shows its status.

It is positioned in the title bar of the NX application.

Connection status icon		(empty)
Meaning	Wired DR Detector	DR Detector is off or disconnected

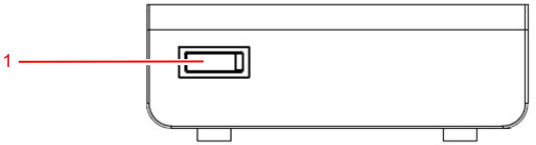
DR Detector status icon		(blinking)		(empty)
Meaning	DR Detector is ready for exposure	DR Detector is initializing for exposure	DR Detector is off or disconnected or in error	DR Detector is inactive (no thumbnail selected)

DR detector cable and control unit

The DR detector cable connects the DR detector to the DR Detector control unit.

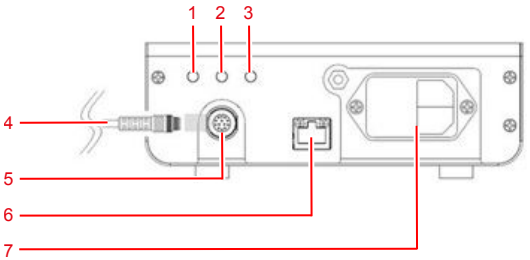
The DR detector control unit connects the DR detector to the mains power using a power supply and to the workstation.

Position all components appropriately to prevent that the DR detector cable or the power cable are unintendedly disconnected.



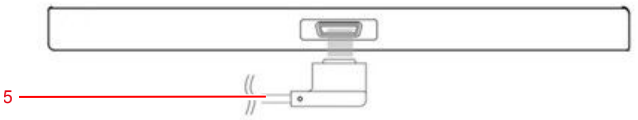
1. Power switch

Figure 2: Front view of the control unit



1. Indicator light is on when the DR detector is active
2. Indicator light is on when the DR detector is connected
3. Indicator light is on when the DR detector power supply is on
4. DR detector cable
5. Connector for the DR detector cable
6. Connector for the network cable to the workstation
7. Connector for the power cable

Figure 3: Rear view of the control unit



1. DR detector cable

Figure 4: Side view of the DR detector

Related Links

Non-medical equipment on page 14

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 most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*

Training

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

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

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

Product Complaints

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

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

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

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

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

Compliance

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) amended by European Directive 2007/47/CE.

Safety

- EN 60601-1:2006 + A1:2013
- IEC 60601-1:2015 + A1:2012

Electromagnetic Compatibility

- IEC 60601-1-2:2005, EN 60601-1-2:2007

X-ray devices

- EN 62220-1-2:2007

Connectivity

Wired communication

The use of accessories and cables other than those specified or sold by the manufacturer as replacement parts, may result in increased radiation emissions or decreased stability of the equipment.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards. All combinations of equipment must be in compliance with IEC 60601-1-1 system requirements.

Any person who connects additional equipment to the signal input or signal output ports, configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1.

Installation

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

The unit shall not be installed in wet environments like emergency operation rooms and operating theatre. The environment should be dust free and clean.

Environment of Use

The equipment is mainly for use in X-ray exposure rooms, hospital wards and mobile medical examination vehicles. To use it in other places, consult your sales representative or local Agfa dealer.

Precautions for installation:

- There must be no dripping water in the area.
- The environment must be free of harmful elements such as humid or acidic air, air with a saline or sulfur content, poor ventilation, or unusual air pressure or temperature.
- The equipment must not be placed at an angle or subjected to vibration or shock (including when it is transported).
- The equipment must not be kept where chemical products are stored or where gasses are generated.
- The site's power supply must be of the correct voltage and frequency for the equipment.
- The site must be connected to a fully grounded cable with sufficient ground resistance to meet standard values.

Related Links

Non-medical equipment on page 14

Messages

Under certain conditions the DR Detector shows a dialog box containing a message in the middle of the screen of the NX workstation. 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. They 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 local service organization. Details on the contents of messages can be found in the service documentation which is available to local service personnel.

Labels

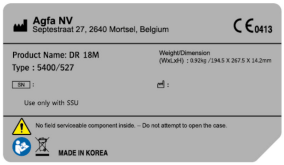
Symbol	Explanation
	Operating temperature range: Exposure to temperatures outside the recommended range may damage the equipment or affect performance.
	Fragile. Handle with care.
	Special cleaning instructions
	Do not immerse in liquids
	No serviceable component inside. Do not attempt to open the case.
	Explosive gas (flammable)
	Control unit mains power fuse: 250VAC, 2A, Type T
	Alternating current
	Dangerous voltage
	Protective earth (ground)
I	On (power: connection to the mains)
O	Off (power: disconnection from the mains)
	Manufacturer

Symbol	Explanation
	Date of manufacture
	Serial number
	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	This 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.
	Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep manual for future reference.

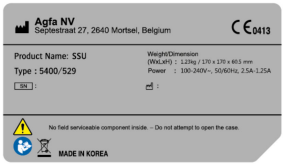
Topics:

- *Additional Labeling of the DR detector*
- *Additional Labeling of the DR detector control unit*

Additional Labeling of the DR detector

 **Figure 5: Example of type label**	Type label on the back side of the DR detector.
	Warranty sealing label
	Do not to press the detector surface or carry the panel gripping the surface.
	Location of the internal shock sensor.

Additional Labeling of the DR detector control unit

 **Figure 6: Example of type label**	Type label on the bottom side of the control unit.

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.

It is advisable to keep the detector in the mammography X-ray modality bucky at all time and not to remove it without any reason. It is advisable to disinfect or clean the detector only when needed and following the local regulations. When disinfection or cleaning of the detector is necessary, be sure to put the detector on a flat and rigid surface so it will not bend.

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. 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. Some approved disinfectants can be used for cleaning as well.

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:
Liquids ingressing the DR Detector may cause malfunction and contamination. Take special care near the cable connector on the side of the DR Detector.

CAUTION:
Do not use abrasive brush and scraper to clean the product.

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

3. Start up the system.

Related Links

Approved disinfectants on page 37

Disinfecting

To disinfect the device, use only disinfectants approved by Agfa. 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.

Use of protective plastic envelope

WARNING:
Liquids ingressing the DR Detector may cause malfunction and contamination.

If there is a chance that the detector comes in contact with liquids (bodily fluids, water, parenteral nutrition,...) or in direct contact with patient or patient tissue, the DR Detector must be wrapped in a protective plastic envelope while performing the examination.

It is considered good clinical practice to use a single-use protective envelope in all cases where contact of the device or contaminants is expected, to avoid contamination of others.

Make sure that the plastic envelope is not wrinkled to avoid the creases showing in the image.

Approved disinfectants

Disinfectants based upon quaternary ammonium salt (<1 weight percent) and/or alcohol (<75 weight percent) have been found compatible and can be used on the outer surface of the DR 18M and DR 24M DR detector.

WARNING:
Use only disinfectants that comply with the allowed disinfection practices in your country.

WARNING:
Do not use disinfectants based upon gluteraldehyde, formaldehyde, bleach or peroxide, as the exterior of the detector may be affected and/or difficult to remove deposit may occur on the surface of the detector.

Safety directions for disinfection

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. Otherwise, it may result in fire or electric shock.

WARNING:
Before disinfecting the equipment, assure that the equipment is clean.

WARNING:
Do not pour liquid directly on the equipment. Always use a clean, low-linting cloth dampened (not dripping) with the solution.

WARNING:
Use in well-ventilated areas.

WARNING:
Do not reuse wipes.

WARNING:
Perform the procedure following the instructions for use as provided wit the cleaning or disinfection product.

CAUTION:
Be sure that all surfaces are thoroughly dry before returning the equipment to use.

CAUTION:
Make sure that the equipment is properly decontaminated and disinfected before shipment or servicing.

CAUTION:
Be sure that all surfaces are thoroughly dry before returning the equipment to use. Disinfecting solution may cause skin irritation to the patient.

CAUTION:
Disinfecting solution or wipes may cause eye and skin irritation. Wear gloves and wash hands with soap and water following use.

WARNING:
Consult the manufacturer's Material Safety Data Sheets (MSDS) and recommendations on the product label for additional information prior to use.

Disclaimer. The selection and description of the appropriate disinfection procedure and policy is the responsibility of the user.

Maintenance

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

In order to ensure that the equipment is used safely and normally, be sure to inspect the equipment before use. If any problem is found during the inspection and cannot be corrected, please contact your sales representative or local dealer.

Topics:

Daily inspection

As requested by the local procedures for mammography and Organisation for Quality Control for mammography, check the equipment on a regular basis to be sure that workflow and image quality can be guaranteed.

WARNING:
For safety reasons, be sure to turn OFF the power to each piece of equipment before performing the following. Otherwise, an electric shock may result.

1. Check the environment

   Check to make sure temperature and humidity are within normal operational range.
2. Check the cables
   a) Ensure that cables are not damaged and cable jackets are not torn.
   b) Check that the plugs, locks and connectors are fully inserted.
   c) Check that the covers of all components are not damaged and tightly fixed.
3. Check the detector
   a) Ensure that there are no loose screws or breaks.
4. Start the NX workstation.
5. Start the DR detector.

   The detector will automatically run a series of self-tests. The orange and green led lights next to the network connector are lit to indicate that the control unit is connected to the NX workstation. The three led lights are lit to indicate that the self-tests have been passed.
6. Perform a test exposure.

   Local procedures for mammography or the local Organisation for Quality Control for mammography can advise to expose a certain QC phantom. Follow their instructions and select the dedicated technical exam type on the NX workstation ("System Diagnosis Mammo").

   Alternatively a typical flat field exposure is made after selecting the dedicated technical exam type on the NX workstation ("System Diagnosis Mammo"). Compress the standard PMMA block and expose with the automatic settings. The alternative manual exposure settings can be 28kV - between 60 to 70 mAs - MoMo.
7. Check the displayed image for image distortion or indications of data loss or image defects.

If there is any problem found during the inspection, contact your local service representative.

Related Links

Technical Data on page 66

Half-yearly inspection

To indicate when the half-yearly calibration is due, a message is displayed on the NX workstation.

Perform calibration half-yearly or when exposure conditions have changed significantly. For details, refer to the DX-D DR Detector Calibration Key User Manual (0134).

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.

Environmental protection

Figure 7: WEEE 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.

Safety Directions

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:
Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzine, etc. If chemicals are spilled or evaporate, it may result in fire or electric shock through contact with electric parts inside the equipment. Also, some disinfectants are flammable. Take care when using them.

WARNING:
The DR detector is not suitable for operation in the presence of a flammable anesthetic mixture containing air, oxygen, or nitrous oxide.

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

WARNING:
The DR detector and associated cables must not be operated in the presence of moisture or any liquids.

WARNING:
Do not connect additional extensions cords or multiple power socket outlets to the system.

WARNING:
Do not connect the equipment with anything other than specified. Doing so may result in fire or electric shock.

WARNING:
The user must not touch part of the X-ray system or electrical input, and patient simultaneously.

WARNING:
Never disassemble or modify the equipment. Doing so may result in fire or electric shock. Also, since the equipment incorporates parts that may cause electric shock as well as other hazardous parts, touching them may cause death or serious injury.

WARNING:
Never remove or modify files on the workstation that are associated to the equipment software. Only use the tools provided with the product.

WARNING:
Do not hit or drop the equipment. The equipment may be damaged if it receives a strong jolt, which may result in fire or electric shock if the equipment is used without being repaired.

WARNING:
Have the patient take a fixed posture and do not let the patient touch parts unnecessarily. If the patient touches connectors or switches, it may result in electric shock or malfunction of the equipment.

CAUTION:
Placing any objects on top of the detector or pressing down on the detector with pressure is prohibited. Such actions may cause the device not to operate or unexpected images may appear or there may be physical damage caused to the device. Agfa shall not be held liable for any problem caused by user negligence and is not responsible for refunding the user in such a case.

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

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

CAUTION:
The DR detector must not be carried by its connecting cable.

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 of 5 - 35 °C and 20 - 75% RH, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

CAUTION:
Turn OFF the power to each piece of equipment for safety when not being used.

CAUTION:
Handle the equipment carefully. Do not submerge the equipment in water. The internal image sensor may be damaged if something hits against it, or if it is dropped, or receives a strong jolt.

CAUTION:
Observe great care when handling the DR Detector. The detector is shock sensitive and drops should be avoided. Warranty will be void if it is obvious that operating conditions are not met.

Getting started

Topics:

Handling the DR detector

CAUTION:
Observe great care when handling the DR Detector. The detector is shock sensitive and drops should be avoided. Warranty will be void if it is obvious that operating conditions are not met.

A physical shock sensor is mounted in the panel and registers any heavy shock. In this case warranty can not be guaranteed.

In case a (minor) shock is noticed make sure to inspect the detector before any patient examination shall take place:

- Visually check the detector, connector and cable.
- Check for software indication of errors and connectivity problems.
- Perform a flat field exposure (see regular quality control inspection) and check the image for visible artifacts. Check for malfunction or workflow issues.
- Perform a calibration of the DR detector if there is any indication that image quality is suboptimal.

It is advisable to keep the detector in the mammography X-ray modality bucky at all time and not to remove it without any reason.

Make sure the fail-safe mechanism of the X-ray modality that detects cassette exchange between every exposure is switched off (contact the X-ray modality engineer for advise).

It is advisable not to use lead markers that are at a fixed position, as they cause a burn-in effect on the sensitive layer of the detector. Markers can be applied to the image on the NX workstation.

When the detector is stored or shipped, use the original packaging in the correct way to move it with care.

Do not bring the detector in direct contact with a patient, with a phantom or any weight that might bend the detector.

Do not bend or press locally the detector surface.

It is normal that the certain area's of the detector and bucky becomes sensibly warmer.

Starting the DR detector

Note: *Before operating the detector, start up the NX workstation.*

To start the DR Detector:

1. Check if the DR detector cable is connected to the control unit.
2. Check if the power cable of the DR detector control unit is connected to the mains power.
3. Power on the DR detector using the power switch at the front of the control unit.
4. Check the DR Detector status icon on the DR Detector Switch.

The connection indicator is lit. The DR Detector is ready.

Before exposure make sure to check the equipment daily and confirm that it works properly. Allow the DR detector to warm up for about 10 minutes before the system is used for clinical purposes. The DR Detector status icon on the DR Detector switch will show when the DR Detector is ready.

Basic Workflow 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

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 the active DR Detector and shows its status.

   - Red (flashing): starting up
   - Green (constant): ready for exposure
2. At the X-ray generator console, select the exposure settings suitable for the exposure.

Step 3: prepare the exposure

In the examination room:

1. Position the patient.

   Apply radiation protective measures for the patient if needed.
2. Check if the X-Ray system position is suitable for the exposure.

Step 4: check the exposure settings

1. On the DR Detector switch, check the DR Detector status icon.

   Do not execute the expose while the status icon indacates that the DR Detector is not ready. The exposure will be not detected by the DR Detector.
2. On the X-ray system, check if the exposure settings displayed on the console are suitable for the exposure.
3. Check if no error messages are displayed on the X-ray system.

Related Links

DR Detector Switch on the NX Workstation on page 17
Manual exposure table for examinations without AEC on page 55

Step 5: execute the exposure

Press the exposure button to execute the exposure.

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.

At the NX workstation:

- The image is acquired from the DR detector and displayed in the thumbnail.

Positioning the DR detector

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

- tube side
- chest wall side

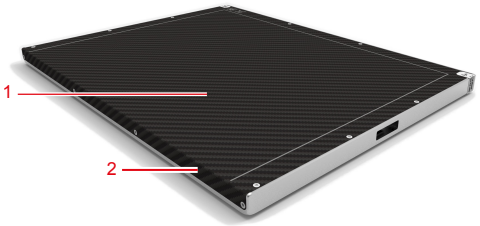


Figure 8: Detector orientation aids

1. Tube side of the detector
2. Chest wall side of the detector

CAUTION:
Take care not to bend or wind the cable too tightly. Otherwise, the cable may be damaged, causing fire, electric shock or a bad connection.

Manual exposure table for examinations without AEC

A manual exposure table containing the exposure settings in function of compressed thickness and breast density can be provided to the user during installation.

Breast Thickness (mm)	target/filter	kVp	mAs for fatty breast	mAs for standard breast	mAs for dense breast	PVIlog value
21	Mo/Mo	26 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
32	Mo/Mo	27 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
45	Mo/Mo	28 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
53	Mo/Rh	29 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
60	Mo/Rh	30 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
75	Mo/Rh	32 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured
90	Mo/Rh	34 KVp	target mAs - 25 %	target mAs	target mAs + 25 %	Pixel Value measured

Figure 9: Template of the manual exposure table, fo fill in the exposure settings in function of compressed thickness and breast density

For X-ray systems that do not have a read-out of the compressed breast thickness, a variant of the manual exposure table is available, that is attached to the X-ray system and acts as a ruler. By positioning the compression paddle, a row is indicated in the table with the applicable exposure settings. If the compression paddle is positioned inbetween two rows, the lower settings should be used.

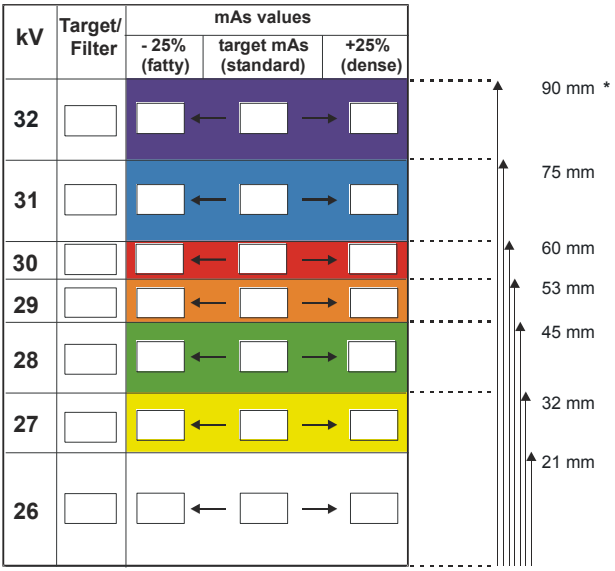


Figure 10: Template of the manual exposure table that can be attached to the X-ray system

Verifying if an image is exposed correctly

On the NX workstation (type 21.00 or higher) an area of the DR mammography image can be selected to measure the pixel value index (PVI). As a result two values are displayed: the **PVI Log** value and the **PVIc Log** value. The **PVIc Log** is the "offset corrected logarithmic pixel value index".

A reference value for the **PVIc Log** is provided to the user during installation.

1. Measure the **PVIc Log** of the image at the location of the AEC cells.
2. Compare the result to the reference value that is defined during installation.
3. Estimate the amount of overexposure or underexposure on the acquired image.

Table 2: Using the pixel value index (PVI) to estimate the exposure level

Measured PVIc Log value compared to a reference value	Estimated exposure level compared to a reference exposure
12000 points higher	400%
6000 points higher	200%
2000 points higher	125%
2000 points lower	75%
6000 points lower	50%
12000 points lower	25%

Special mammography views

Special mammography exams are the magnification views or focal/spot compression views (to make a small area of breast tissue easier to evaluate) that make use of a dedicated bucky.

It might be that the DR detector does not fit in this magnification bucky because only one size of detector is available at your mammography centre. In this case we advise an alternative workflow:

1. Use the spot compression paddle on the regular bucky instead of the magnification bucky of the modality.
2. Use the software tools of the NX workstation or the diagnostic review station to enlarge the local area of interest on the standard MLO and CC exams.

Automatic exposure detection

The DR detector detects X-ray exposure to automatically perform the image acquisition. The X-ray system has to generate a minimum exposure dose to trigger the DR detector's automatic exposure detection.

Related Links

No image available after exposure on page 63

Automatic Exposure Control with DR 18M

WARNING:
Incorrect dose or interrupted exposure in case of complete or partly blockage of the AEC cells. AEC cells control the X-ray exposures. Please be aware that some of the AEC cells may be covered by electronics.

The DR 18M detector is not fully compliant with the specifications in ISO 4090 with regard to positioning of the automatic exposure control (AEC) dose-measuring cells in the X-ray modality. Internal electronic parts of the detector may cover part of the AEC cells.

During installation a test is performed to determine which AEC cells can be activated when using the DR 18M detector.

The user is responsible to select the proper AEC cells when performing an examination.

Stopping the DR Detector

To stop the DR Detector:

Power off the DR Detector using the power switch at the front of the control unit.

Problem solving

Topics:

No image available after exposure

Details	An exposure is performed and no image becomes available on the NX workstation.
Cause	**1.** Due to the automatic exposure control, the dose may become too low to trigger the DR detector. **2.** The sensor(s) to trigger the automatic exposure detection of the DR detector are blocked.
Solution	Check both of following conditions: **1.** Check the output of the automatic exposure on the X-ray console. If the mAs value is low to your experience, make sure to manually raise the mAs (keep other settings) instead of repeating in automatic mode. **2.** Check if no objects with a high attenuation are blocking part of the image area.

DR image is not displayed

Details	An image is acquired using a DR detector, but not displayed in the examination.
Cause	The DR Detector could not send the image directly after the exposure to the NX workstation. The image recovery process is able to recover such an image in most cases. Demographic data might be lost however and default data are used.
Brief Solution	Refer to the NX user manual for more information about image recovery.  *Note*: If the DR detector cable is disconnected, the synchronization between the control unit and the NX workstation will be interrupted. If the cable is reconnected within 30 seconds, the recovery image will be transferred to the NX Workstation. If the connection stays interrupted for more than 30 seconds, the recovery image will be lost.

Image shows artifacts

Details	An exposure is performed and the image on the NX workstation shows lines and banding artifacts.
Cause	The exposure time exceeded the integration time of the DR detector (configured during installation).
Brief Solution	Depending on the frequency of the problem, take following measures: **1.** If this situation is exceptional and can be justified by the high compression thickness or by the type of examination, try to reduce the exposure time on the X-ray system. **2.** Perform a typical flat field exposure to check the general image quality. **3.** Contact your local service representative, who can extend the integration time of the DR detector.

Related Links

Daily inspection on page 41

Technical Data

Topics:

DR 18M, DR 24M

Electrical connection DR Detector	
Rated power supply (power over ethernet)	12V DC
Power consumption	30 W
Environmental conditions (during normal operation)	
Room temperature	between +5 °C and +35 °C
Maximum temperature change rate	max. 10 °C/hour
Humidity (non condensing)	between 20% and 75% RH (non-condensing)
Atmospheric pressure	between 500 hPa and 1060 hPa
Environmental conditions (during storage)	
Temperature (ambient)	between -10 °C and +40 °C
Maximum temperature change rate	max. 15 °C/hour
Humidity (non condensing)	between 5% and 95% (non-condensing)
Atmospheric pressure	between 500 hPa and 1060 hPa
Warming-up time	
5 minutes minimum 10 minutes recommended 30 minutes before calibration	
Dimensions	
Dimensions width x length x height	DR 18M: 267.5 x 194.5 x 14.2 mm DR 24M: 327.5 x 253.7 x 14.2 mm
Weight	DR 18M: 0.92 kg DR 24M: 1.20 kg
Chest wall distance	less than 2.0 mm

Lateral wall distance	DR 18M: less than 17.1 mm DR 24M: less than 17.7 mm
Shock sensitivity	
Shock tolerance	40 G
Vibration tolerance	1 G, 10~150 Hz
Drop tolerance (with shipment packaging)	50 cm
Drop tolerance (without shipment packaging)	less than 50 cm (not guaranteed)
Throughput (images per hour)	120 images per hour
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 years

Conversion screen	CsI
Pixel size	76 μm
Pixel matrix	DR 18M: 3054 x 2295 DR 24M: 3063 x 3822
Fill factor	80%
Effective area size	DR 18M: 232.0 mm x 174.4 mm DR 24M: 290.4 mm x 232.8 mm
Typical Detective Quantum Efficiency (DQE)	
0.5 lp/mm	≥ 50%
1 lp/mm	≥ 45%
2 lp/mm	≥ 40%
3 lp/mm	≥ 35%
4 lp/mm	≥ 25%
5 lp/mm	≥ 15%
6 lp/mm	≥ 10%

Minimum Modulation Transfer Function (MTF)	
1 lp/mm	≥ 65%
2 lp/mm	≥ 55%
3 lp/mm	≥ 35%
4 lp/mm	≥ 25%
5 lp/mm	≥ 20%
6 lp/mm	≥ 10%

DR 18M, DR 24M control unit

Model	SSU (System Synchronization Unit)
Type	5400/529
Water ingress	IPX0 This device does not have protection against ingress of water.
Dimensions	
Dimensions (width x height x depth)	170.0 mm x 60.5 mm x 170.0 mm
Weight	1.23 kg
Electrical connection	
Rated Power Supply	100-240 V AC, 50/60 Hz, 2.5-1.25 A
Maximum power system prospective short-circuit current	35-16 A

Remarks for HF-emission and immunity

Topics:

EMC (Electromagnetic Compatibility) Statements

The DR Detector is designed and tested to comply with IEC 60601-1-2(EN60601-1-2) which is applicable to regulations regarding EMC for medical devices and needs to be installed and put into service according to the EMC information stated as follows.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving device.
- increase the separation between the devices.
- connect the equipment into an outlet on a circuit different from that to which the other devices are connected.

If the problem cannot be solved with the above measures, stop using the equipment and consult your sales representative or local Agfa dealer.

Cables, transducers and accessories

CAUTION:
Using cables and accessories not mentioned in this manual or spare parts not ordered from Agfa, may cause a higher emission of electromagnetic phenomena and/or may rise the susceptibility against it.

Electromagnetic emissions

This DR Detector has been tested for the electromagnetic environment as described below.

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

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

Emissions test	Compliance	Electromagnetic Environment Guidelines
RF emissions in accordance with CISPR 11	Group 1	This DR Detector uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions in accordance with CISPR 11	Class A	The DR Detector is suitable not only in non-household facilities but can also be used by directly connecting it to the common low-power network in a building.
Harmonic emissions in accordance with CISPR 11	Complies Class A	
Voltage fluctuations / flicker emissions in accordance with CISPR 11	Complies	

Electromagnetic immunity

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

Resistance to Jamming Test	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment Guidelines
Discharge of static electricity in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 contact discharge ± 8 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV for network leads ± 1 kV for entry and outlet leads	± 2 kV for network leads ± 1 kV for entry and outlet leads	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakthroughs, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	< 5% Ur (> 95% breakthrough of Ur) for ½ period 40% Ur (> 60% breakthrough of Ur) for 5 periods 70% Ur (30% breakthrough of Ur) for 25 periods	< 5% Ur (> 95% breakthrough of Ur) for ½ period 40% Ur (> 60% breakthrough of Ur) for 5 periods 70% Ur (30% breakthrough of Ur) for 25 periods	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the DR Detector to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply

	< 5% Ur (95% breakthrough of Ur) for 5 s	< 5% Ur (95% breakthrough of Ur) for 5 s	free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.

Note: *Ur is the alternating voltage.*

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

			d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz
			With P as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the level of the agreement at all frequencies in accordance with an on-site investigation. Disruptions are possible near devices that carry the following symbol: 

Note: *The higher value will apply at 80 MHz and 800 MHz.*

Note: *These Guidelines may not apply to all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.*

Note: 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.

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