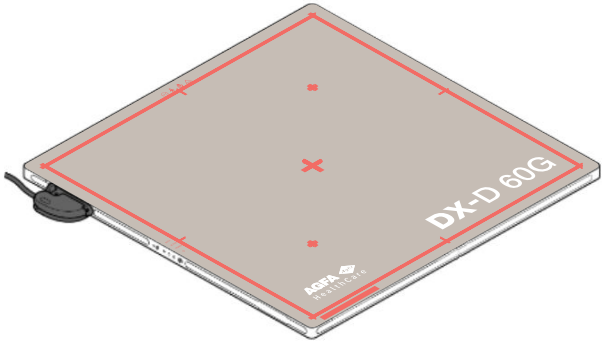
# DX-D 60C, DX-D 60G

6007/110

6007/111

## User Manual

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# Contents

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# Introduction to this Manual

**Topics:**

## Scope

This manual contains information for the safe and effective operation of the DX-D 60C and DX-D 60G 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

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

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

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

# Introduction to the DR Detector

**Topics:**

## Intended Use

The DR Detector is a wired radiographic digital X-ray imaging device commonly referred to as flat panel detector. It is designed for general radiography applications. The DR Detector will be used in a radiological environment by qualified staff to capture and route static X-ray images.

The DR Detector is not intended for mammography applications.

## Indications for 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. The DR Retrofit solution may be used wherever conventional screen-film systems may be used.

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

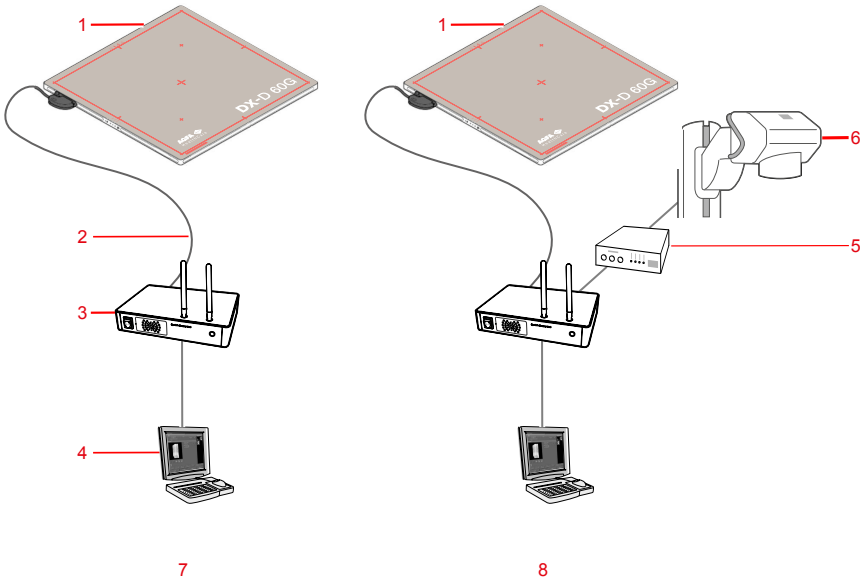
## Intended User

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

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. Two wired DR Detectors can communicate to a single workstation using the standard System Control Unit. The configuration can include wireless DR Detectors.




1. DR Detector
2. DR Detector connector cable
3. System Control Unit
4. Workstation
5. Generator Sync Box
6. X-ray generator
7. Automatic exposure detection
8. X-ray generator synchronization

**Figure 1: DR Detector configuration**

Depending on the configuration, the Generator Sync Box may not be part of the system.

**Related Links**

*Automatic exposure detection* on page 72

# Equipment Classification

Per EN/IEC60601-1, Medical Electrical Equipment, General Requirements for Safety 3rd Edition, the DR Detector is classified as following.

| | |
|---|---|
| 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 | IP53<br>This device is protected against spraying water. |
| 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. |
| Applied Parts | The DR Detector tube side is an applied part. |
| Expected service life | Up to seven (7) years<br>(if regularly serviced and maintained according to Agfa instructions) |

## Non-medical equipment

Following components are classified as non-medical equipment:

- System Control Unit
- Workstation

# 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.

## Anti-scatter grids

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

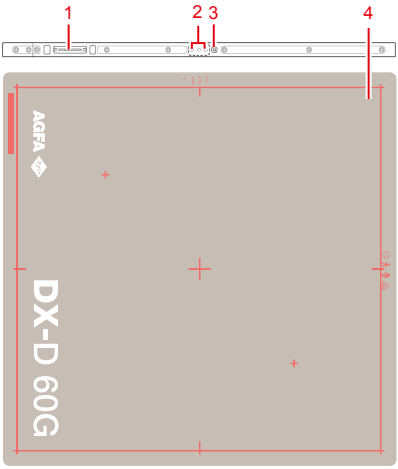
Refer to the Agfa website for specifications on the anti-scatter grids that have been found compatible with the system and the DR Detectors.

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

# Operation Controls

**Topics:**

## DX-D 60C, DX-D 60G




1. DR Detector connector
2. Status indicators
   - Blue indicator shows data communication status.
   - Orange indicator shows if the detector is ready.
   - Green indicator shows power on/off status of the detector.
3. On/off switch
4. Effective imaging area border and center position indication

**Figure 2: DR Detector operation controls**

### Related Links

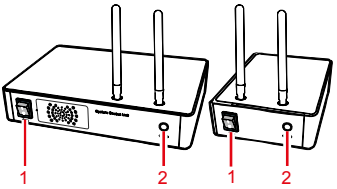
*Detector Status Indicators* on page 73

## System Control Unit

The System Control Unit is connected to the DR Detector via the DR Detector cable.

The System Control Unit is connected to the X-ray generator to synchronize the exposure, in a configuration with X-ray generator synchronization.

The System Control Unit is connected to the workstation via wired network.




1. Power switch
2. Status indicator

   - Blinking green: starting up
   - Green: ready
   - Blue: communicating to the detector

**Figure 3: System Control Unit (SCU) and Mini System Control Unit (Mini SCU)**

**WARNING:**
Do not use the System Control Unit within the patient's vicinity.

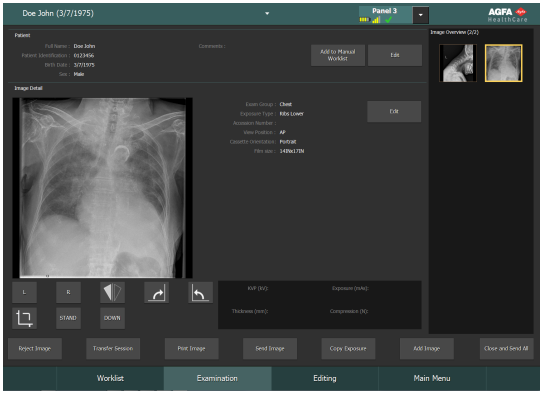
**Related Links**

*System Control Unit* on page 81
*Mini System Control Unit* on page 82
*Safety directions for the power supply* on page 55

## 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. The DR Detector Switch can be used to activate another DR Detector.


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




| **Battery status icon** |  |  |  |  | (empty) |
|---|---|---|---|---|---|
| **Meaning** | Full | Medium | Low | Empty | Wired DR Detector<br>Wireless DR Detector is off or disconnected |

| **Connection status icon (wi-fi/wired)** |  |  |  |  | (empty) |
|---|---|---|---|---|---|
| **Meaning** | Good | Low | Bad | Wired DR Detector | DR Detector is off or disconnected |

| **DR Detector status icon** |  |  <br>(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 exposure synchronization

| | | |
|---|---|---|
| **Automatic exposure detection icon** | **A** | (empty) |
| **Meaning** | The active DR Detector is using automatic exposure detection | The active DR Detector is using X-ray generator synchronization |

*Note*: Depending on the installed software version, the icon may not be displayed.

## System Documentation

The documentation consists of a User manual (this document) and related documentation:

- NX User Manual (4420).
- NX Key User Manual (4421).
- NX Getting Started Sheets (4424).
- NX Problem Solving Sheets (4425).
- DX-D DR Detector Calibration Key User Manual (0134).
- DX-D System User Documentation (if applicable).

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).
- ISO 13485
- ISO 14971

## Safety

- EN 60601-1
- IEC 60601-1
- UL 60601-1
- CAN.CSA-C22.2 No. 601.1

## Electromagnetic Compatibility

- IEC 60601-1-2

## Radio Frequency

Declaration of conformity

| | |
|---|---|
| U.S.A. | FCC Part 15.107(b) / Part 15.109(b)<br>FCC Part 15 Subpart E 15.407<br>FCC Part 15 Subpart C 15.247 |
| European Union (and EEA) | ETSI EN 301 489-1 V1.9.2:2011 (EMC)<br>ETSI EN 301 489-17 V2.2.1:2012 (EMC)<br>EN 300 328 V1.8.1<br>EN 301 893 V1.7.1 (RF) |
| South Korea | KN 301 489-1<br>KN 301 489-17 |

**Topics:**


- *Local regulations*
- *Specific absorption rate (SAR)*

## Local regulations

This product complies with local radio frequency regulations in the country or region where you purchased the product. Note that it cannot be used in any areas other than the country or region of its purchase.

The radio frequency channel (5 GHz) configured for indoor use may not be usable in outdoor areas, depending on local radio frequency regulations.

If you would like to add other equipment to the environment where this product is installed, or to use this product in other environments, please consult your sales representative or local dealer for details.

## Specific absorption rate (SAR)

**WARNING:**
The SAR limit set by FCC is 2W/kg (for EU and Japan) and 1.6W/kg (for USA and Korea). This equipment complies with FCC&CE SAR regulation. The front side of a detector should be used for image acquisition.

- OET Bulletin 65, Supplement C (edition 01-01)
- EN 62311:2008
- EN 62209-1:2006
- EN 62209-2:2010

# 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.

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

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

## 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.

**WARNING:**
Do not install or store the equipment in any of the locations listed below. Doing so may result in failure or malfunction, equipment falling, or fire or injury:

- **Close to facilities where water is used**
- **Where it will be exposed to direct sunlight**
- **Close to the air outlet of an air-conditioner or ventilation equipment**
- **Close to a heat source such as a heater**
- **In a dusty environment**
- **In a saline or sulfurous environment**
- **Where temperature or humidity is high**
- **Where there is freezing or condensation**
- **In areas prone to vibration**
- **On an incline or in an unstable area**

*Note*: *Do not use the detector near devices generating a strong magnetic field. Doing so may produce image noise or artifacts.*

*Note*: *Do not use this equipment in combination with peripherals such as defibrillators or large electric motors as these may cause power-supply noise or power supply voltage variations. Doing so may prevent normal operation of this equipment and peripherals.*

*Note*: *This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as these, which affect this product, brought near the product.*

**CAUTION:**
Sudden heating of the room in cold areas will cause condensation to form on the equipment. In this case, wait until the condensation evaporates before use. If the equipment is used while condensation is formed on it, problems may occur. When an air-conditioner is used, be sure to raise/lower the temperature gradually so that a difference in temperature in the room and in the equipment does not occur, to prevent condensation.

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

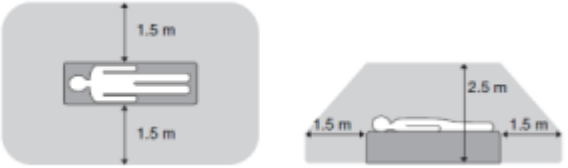



**Figure 4: Patient's vicinity**

**Related Links**

*DR Detector Switch on the NX Workstation* on page 17
*System Control Unit* on page 16

## Messages

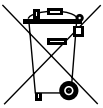
Under certain conditions the DR Detector shows a dialog box containing a message in the middle of the screen of the NX workstation. This message informs the user that either a problem has occurred or that a requested action cannot be performed. The user must read these messages carefully. They will provide 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.

**Related Links**

*Problem solving* on page 74
*Detector Status Indicators* on page 73

## Labels

| Symbol | Explanation |
|---|---|
|  | On (power: connection to the mains) |
|  | On (power: connection to the mains) for part of the equipment |
|  | Off (power: disconnection from the mains) |
|  | Off (power: disconnection from the mains) for part of the equipment |
|  | Tube side |
|  | Direct current |
|  | Alternating current |
|  | Protective earth (ground) |
|  | Equipotential connector:<br>Provides a connection between the equipment and the potential bus bar of the electrical system as found in medical environments.<br>It is recommended to use the equipotential connection as additional safety measure. |
|  | This mark indicates that this is a Type B Equipment |
|  | Handle with care |
|  | Maximum patient weight over the whole area of the detector surface |
|  | Device contains a transmitter module that generates non-ionizing radiation. |

| Symbol | Explanation |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|  | Serial number |
|  | This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union). |
|  | This mark shows compliance with both Canadian and U.S. safety requirements. With respect to electric shock, fire, and mechanical hazards only. |
|  | 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. |
|  | This wheeled bin symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste. |
|  | Medicine that can only be given by a prescription from a doctor or a doctor's recommendation to use a certain medicine.<br>(for U.S.A. only) |
|  | Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep manual for future reference. |
|  | Safety warning, indicating that the manuals should be consulted. |
|  | General warning, caution, risk of danger. |

| Symbol | Explanation |
|---|---|
|  | Dangerous voltage |
|  | General Mandatory action. |

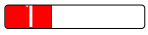
**Topics:**

- *Additional Labeling of the DR Detector*
- *Additional Labeling of the System Control Unit*
- *Additional Labeling of the Mini System Control Unit*
- *Consulting the About box*

## Additional Labeling of the DR Detector

| | |
|---|---|
|   | Type label on the back side of the DR Detector. |

## DR Detector identification label

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

## Additional Labeling of the System Control Unit


Type label on the bottom side of the System Control Unit.

## Additional Labeling of the Mini System Control Unit


Type label on the bottom side of the Mini System Control Unit.

## Consulting the About box

1. Click **About the solution** in the Tools section of the Main Menu window on the NX workstation.

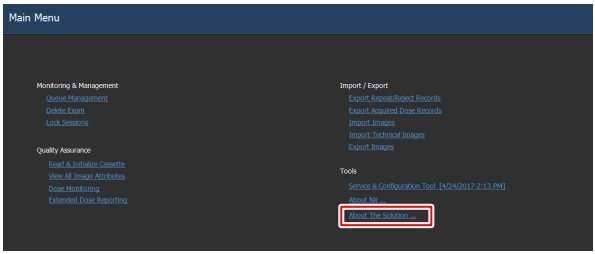



**Figure 5: Main Menu window.**

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


**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

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

**Topics:**

## Cleaning

To clean the exterior of the equipment:

1. Stop the system

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

2. Wipe the exterior of the system with a cloth slightly moistened with a neutral detergent. 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 41

## Use of protective plastic bag

**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, disinfectants,...), the DR Detector must be wrapped in a protective plastic bag while performing the examination.

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

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

## Disinfecting

To disinfect the device, use only disinfectants and disinfection methods that are approved by Agfa and that correspond to the national regulation and guidelines as well as explosion protection. If you plan to use other disinfectants, approval of Agfa is needed before use, as most disinfectants can damage the device. UV disinfection is also not allowed.

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

## Approved disinfectants

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

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

## 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:**
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 follow the instructions of use as provided with the cleaning or disinfection product.

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

**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:**
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.

# 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

**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.

Cable

1. Ensure that cables are not damaged and cable jackets are not torn.
2. Ensure that the power cord plugs are securely connected to both the equipment AC inlet and the AC outlet.

Detector

1. Ensure that there are no loose screws or breaks.
2. Ensure that there is no dust or foreign matter on the DR Detector cable connector.

After turning on the power

Start the NX workstation before performing a test exposure.

## 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).

## Regular Inspection and Maintenance

In order to ensure the safety of patients, operating personnel and third parties, and to maintain the performance and reliability of the equipment, be sure to perform regular inspection at least once a year. Clean up the equipment, make adjustments, or replace consumables. There may be cases where overhaul is recommended depending on the conditions. Contact your sales representative or local dealer for regular inspections or maintenance.

**CAUTION:**
Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug, its periphery and AC outlet with a dry cloth. If the cord is kept plugged in for a long time in a dusty, humid or sooty place, dust around the plug will attract moisture. This could cause insulation failure resulting in a fire.

**CAUTION:**
Do not perform maintenance and inspection while the equipment is used for a patient.

## Replacement Parts Support

Parts required to maintain the functioning of the product will be stocked for seven years after discontinuance of production, to allow for repair.

## Repair

The product can only be repaired in the factory.

## 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

Disposal of this product in an unlawful manner may have a negative impact on health and on the environment. Therefore, when disposing of this product, be absolutely sure to follow the procedure which is in conformity with the laws and regulations applicable in your area.

**Figure 7: WEEE end user information**

The directive on Waste Electrical and Electronic Equipment (WEEE Directive 2012/19/EU) 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.

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

For more detailed information about take-back and recycling of this product please contact your local Agfa service organization and/or Agfa 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.

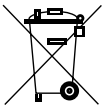


**Figure 8: Battery Notice**

This wheeled bin symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste.

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

**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 modify the cables. Doing so may damage them and result in fire or electric shock.

**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 place anything on top of the equipment. The object may fall and cause an injury. Also, if metal objects such as needles,

staples or clips fall into the equipment, or if liquid is spilled, it may result in fire or electric shock.

**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:**
If an X-ray image is taken while the patient is moving, the quality of the image may be affected. Make sure that the patient maintains a fixed posture as much as possible.

**WARNING:**
To avoid electric shocks and burns caused by use of the wrong type of fire extinguisher, make sure that the fire extinguisher at the site has been approved for use on electrical fires.

**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:**
This device is not intended to supply heat to a patient. However, during normal use, surfaces will become heated due to power dissipation. Patient contact surfaces will not exceed 48 °C under normal useconditions. The operator should monitor and evaluate how much of the patient's body area is in contact with these surfaces and for how long.

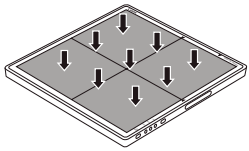
**CAUTION:**
Excessive ambient temperature may impact performance of DR Detectors and cause permanent damage to the equipment. If ambient temperature and humidity is outside the range of 10 - 35 °C and 30 - 85% RH, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

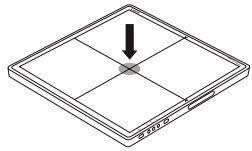
**CAUTION:**
Turn OFF the power to each piece of equipment for safety when not being used.

**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:**

**Do not place excessive weight on the detector. Avoid the whole weight of the patient body to rest on the detector. Otherwise, the internal image sensor may be damaged. Load limit - Uniform load: 150 kg over the whole area of the detector surface. Load limit - Local load: 100 kg on an area 40 mm in diameter.**





**CAUTION:**
Be sure to use the detector on a flat and rigid surface so it will not bend. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright positions. Otherwise, the detector may fall over, resulting in injury to the user or patient, or may flip over, resulting in damage to the inner device.

**CAUTION:**

**If a malfunction occurs, do not use this device until qualified personnel correct the problem.**

Should any of the following occur, immediately turn OFF the power to each piece of equipment, unplug the power cord from the AC outlet, and contact your sales representative or local dealer:

- When there is smoke, an odd smell or abnormal sound
- When liquid has been spilled into the equipment or a metal object has entered through an opening
- When the equipment has been dropped and is damaged

**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.

If the DR Detector has been dropped:

1. *Visually check the DR Detector for deformations.*

2. *Perform a calibration of the DR Detector. For instructions, refer to the DX-D DR Detector Calibration Key User Manual (document 0134).*
3. *Perform a flat field exposure and check the image for visible artifacts. Typical flat field exposure settings are 75 kV, 10 µGy, large focus and using 1.5 mm Cu filter without grid.*

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

**Topics:**

## Safety directions for the power supply

**WARNING:**
Do not operate the equipment using any type of power supply other than the one indicated on the rating label. Otherwise, it may result in fire or electric shock.

**WARNING:**
Do not use any power cords other than the one provided with this equipment. Otherwise, it may result in fire or electric shock.

**WARNING:**
Do not handle the equipment with wet hands. You may experience an electric shock that could result in death or serious injury.

**WARNING:**
Do not place heavy objects such as medical equipment on cables and cords, or do not pull, bend, bundle or step on them to prevent their sheath from being damaged, and do not alter them neither. Doing so may result in fire or electric shock.

**WARNING:**
Do not supply power to more than one piece of equipment using the same AC outlet. Doing so may result in fire or electric shock.

**WARNING:**
Do not connect a multiple portable socket-outlet or extension cord to the system. Doing so may result in a fire or electric shock.

**WARNING:**
Securely plug the power cord into the AC outlet. If contact failure occurs, or if dust or metal objects come into contact with the exposed metal prongs of the plug, fire or electric shock may result.

**WARNING:**
Be sure to turn off the power to each piece of equipment before connecting or disconnecting the cords. Otherwise, you may get an electric shock that could result in death or serious injury.

**WARNING:**
Do not connect the AC or DC power cable to the product with the power applied. Failure to do so may result in damage to the product.

**WARNING:**
Be sure to hold the plug or connector to unplug the power cord. If you pull the power cord, the core wire may be damaged, resulting in fire or electric shock.

**WARNING:**
When using the power supply, care must be taken to ensure that there is either a mains plug or an all-cable disconnecting device in the internal installation fitted near the device and that it is easily accessible in case of emergency.

## Safety directions for the System Control Unit

**WARNING:**
Do not block the ventilation ports to prevent overheating. Overheating can cause system malfunction and damages.

**WARNING:**
Ensure continuous power supply to the system, with voltage and current according to the product specifications. If power failures are frequent, an uninterrupted power supply (UPS) should be installed to avoid loss of data.

**CAUTION:**
The System Control Unit and the X-ray generator must be grounded to a common protective earth. Always connect the three-core power cord plug to a grounded AC power outlet.

## Limitations for patient contact

This device is not intended to supply heat to a patient. However, during normal use, surfaces will become heated due to power dissipation.

Patient contact surfaces will not exceed 48 degrees C under normal use conditions. The operator should monitor and evaluate how much of the patient's body area is in contact with these surfaces and for how long.

If the temperature limit is exceeded, an error is displayed and further exposures are impossible to avoid further heating, until the temperature has dropped.

# Getting started

**Topics:**

## Starting the DR Detector

To start the DR Detector:

1. Check if the DR Detector cable is connected to the System Control Unit.
2. Check if the power cable of the System Control Unit is connected to the mains power.
3. Turn on the detector.

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

   Press and hold the power button for 1 second.

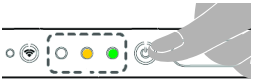
   

   **Figure 9: Power button**

   After startup the power indicator is green and the status indicator is orange.
4. Turn on the System Control Unit using the power switch.

   The status indicator is green.

   Depending on the configuration, the System Control Unit may not be part of the system.

The DR Detector is ready.

Before exposure make sure to check the equipment daily and confirm that it works properly.

**Related Links**

*Detector Status Indicators* on page 73

# 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 DR Detector.

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

   Apply radiation protective measures for the patient if needed.
3. Check if the X-Ray system position is suitable for the exposure.
4. Position the X-Ray tube with respect to the DR Detector and the patient.
5. Set the correct distance between DR Detector and X-Ray tube.
6. Switch on the light on the collimator. Adapt collimation if required.

   Take care that the collimated area is not larger than the detector.

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

## Step 4: check the exposure settings

On the DR Detector Switch:

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

On the X-ray system:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check if no error messages are displayed on the X-ray system.

### Exposure synchronization

Depending on the configuration, the DR Detector synchronizes to the exposure using one of these methods:

- X-ray generator synchronization
- Automatic exposure detection

**WARNING:**
In a configuration using automatic exposure detection, the X-ray system allows executing an exposure, even if the DR Detector is not ready. Avoid unnecessary dose by checking the status of the DR Detector before exposure. The DR Detector Switch displays the DR Detector status icon.

**Related Links**

*Automatic exposure detection* on page 72
*DR Detector Switch on the NX Workstation* on page 17

## 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.
- If collimation is applied, the image is automatically cropped at the collimation borders.

## Step 6: perform a quality control

At the NX workstation:

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

## Positioning the DR Detector

**WARNING:**
Because the equipment cable is long, take care that cables do not become tangled during use. Also, be careful not to get your feet caught in the cable. It may cause a malfunction of the equipment or injury to the user from tripping over the cable.

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

- tube side
- patient orientation marker

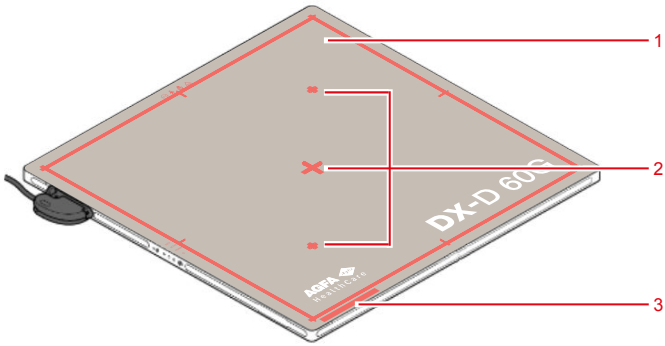



**Figure 10: Detector orientation aids**

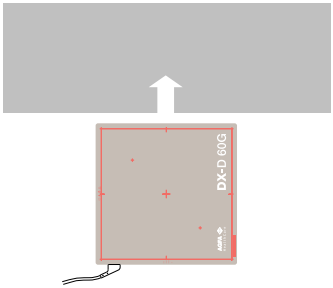
1. Tube side of the detector
2. Position of the sensor for automatic exposure detection
3. Location red patient orientation marker

   The detector must be positioned with the patient orientation marker at the lower side of the region of interest.

The detector orientation and the patient orientation are exposure settings on the NX workstation. The detector orientation is displayed on the NX workstation as cassette orientation.

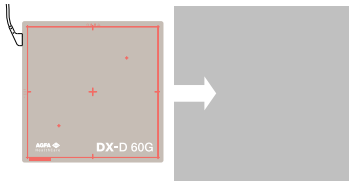
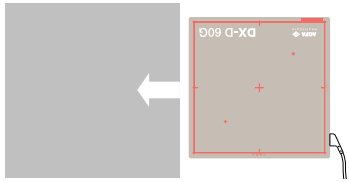
The user is responsible for the correct and clear marking on the left or right side of the image to eliminate possible errors.

**Table 1: Table with bucky**

| | |
|---|---|
| Table with bucky |  |

*Note: NX is configured for a specific patient orientation, either head left (default) or head right.*

**Table 2: Wallstand with bucky**

| | |
|---|---|
| Wallstand with left loading bucky |  |
| Wallstand with right loading bucky |  |

# Guidelines for Pediatric Applications

**CAUTION:**
Children are more radiosensitive than adults. Adopting the Image Gently campaign guidelines and reducing dose for radiographic procedures while maintaining acceptable clinical image quality will benefit patients.

Please review the following link and reduce pediatric technique factors accordingly: http://www.imagegently.org

As a general rule, next recommendations shall be observed in pediatrics:

- X-Ray Generator must have short exposures times.
- AEC must be used carefully, preferably use manual technique setting, applying lower doses.
- If possible, use high kVp techniques.

Positioning the pediatric patient: Pediatric patients are not as likely as adults to understand the need to remain still during the procedure. Therefore it makes sense to provide aids to maintaining stable positioning. It is strongly recommended the use of immobilizing devices such as bean bags and restraint systems (foam wedges, adhesive tapes, etc.) to avoid the need of repeating exposures due to the movement of the pediatric patients. Whenever possible use techniques based on the lowest exposure times.

Shielding: We recommend you provide extra shielding of radiosensitive organs or tissues such as eyes, gonads and thyroid glands. Applying a correct collimation will help to protect the patient against excessive radiation as well. Please review the following scientific literature regarding pediatric radiosensitivity: GROSSMAN, Herman. “Radiation Protection in Diagnostic Radiography of Children”. Pediatric Radiology, Vol. 51, (No. 1): 141--144, January, 1973:

http://pediatrics.aappublications.org/cgi/reprint/51/1/141.

Technique factors: You should take steps to reduce technique factors to the lowest possible levels consistent with good image acquisition.

For example if your adult abdomen settings are: 70--85 kVp, 200--400 mA, 15--80 mAs, consider starting at 65--75 kVp, 100--160 mA, 2.5--10 mAs for a pediatric patient. Whenever possible use high kVp techniques and large SID (Source Image Distance).

Summary:

- Image only when there is a clear medical benefit.
- Image only the indicated area.
- Use the lowest amount of radiation for adequate imaging based on size of the child (reducing tube output -- kVp and mAs).
- Try to use always short exposure times, large SID values and immobilizing devices.

- Avoid multiple scans and use alternative diagnostic studies (such as ultrasound or MRI) when possible.

## Stopping the DR Detector

To stop the DR Detector:

Turn off the detector.

Press and hold the power button (approx. 3 seconds).

All the status indicator lights are off.

*Note***:** *When not in use, keep the detector, handle unit with grid in a designated location or in a location where they are safe and cannot fall down.*

## Automatic exposure detection

The DR detector detects X-ray exposure to automatically perform the image acquisition.

Before performing the exposure, the DR detector must be ready. Check the status of the DR detector in the DR Detector Switch.

**WARNING:**
The sensor for automatic exposure detection must be in the exposed area. Positioning the sensor for automatic exposure detection outside the exposed area can cause failure to trigger the image acquisition.

**WARNING:**
Do not hit or drop the equipment. If it receives a strong jolt, image acquisition can be triggered without X-ray exposure.

**WARNING:**
Very short exposure time can cause failure to trigger the image acquisition. Use an exposure time of at least 3 ms.

**WARNING:**
Specific exposure conditions (use of grid, thickness of the exposed object) can cause failure to trigger the image acquisition or horizontal artifacts in the acquired image.

**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 10 - 35 °C and 30 - 85% RH, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

**Related Links**

*Positioning the DR Detector* on page 67

# Advanced Operating

## Detector Status Indicators

**Table 3: Detector status**

| Status | Power indicator | Status indicator | Data indicator |
|---|---|---|---|
| Power on but not ready yet |  | OFF | OFF |
| Power on |  |  | OFF |
| Detector ready |  |  |  |
| Data communication ongoing |  |  |  |
| Power off | OFF | OFF | OFF |

*Note*: When two or more status indicator lights are flashing, an error has occurred.

**Related Links**

*Problem solving* on page 74

# Problem solving

**Topics:**

## Artifact in DR Detector images

| | |
|---|---|
| Details | An artifact is visible in the images produced by a DR Detector. |
| Cause | Exposure conditions have changed significantly since latest calibration. |
| Brief Solution | Perform calibration of the DR Detector.<br>For details, refer to the DX-D DR Detector Calibration Key User Manual (0134). |

## Identifying problems

Please refer to the details of following symptoms or error messages. If the problem persists, turn off the detector and consult your sales representative or local dealer.

**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.

| Symptom | Cause | Remedy |
|---|---|---|
| The detector will not turn on. | The DR Detector cable is disconnected from the System Control Unit. | Connect the DR Detector cable to the DR Detector and to the System Control Unit. |
| | The System Control Unit is turned off. | Turn on the System Control Unit using the power switch. |
| The status indicator of the System Control Unit does not light up. | The power cord is unplugged from the AC outlet. | Connect the plug to the AC outlet firmly. If it still does not work, replace the System Control Unit. |
| The status indicator of the System Control Unit does not light up in green. | A hardware error has occurred. | Turn off the System Control Unit and turn it on again. If it still does not work, replace the System Control Unit. |
| The green status indicator lights up and the orange and blue status indicators are flashing. | An error has occurred during registration of the DR Detector. | Check the network connection on the System Control Unit.<br>Check the network configuration of the workstation. |
| | An error has occurred during data communication. | Check if the System Control Unit is turned on. |

| Symptom | Cause | Remedy |
|---|---|---|
| All status indicators are flashing. | A hardware error has occurred. | Turn off the DR Detector and turn it on again. |
| Two status indicators are flashing and the third is flashing slowly. | | |

# Technical Data

**Topics:**

# DX-D 60C, DX-D 60G

| | |
|---|---|
| Commercial name | DX-D 60C, DX-D 60G |
| **Electrical connection DR Detector** | |
| Rated power supply<br>(powered by System Control Unit) | DC +24 V, Max. 1.0 A |
| Power consumption | max. 24 W |
| **Environmental conditions (during normal operation)** | |
| Room temperature | between +10 °C and +35 °C |
| Humidity (non condensing) | between 30% and 85% RH<br>(non-condensing) |
| Atmospheric pressure | between 700 hPa and 1060 hPa |
| **Environmental conditions (during storage and transport)** | |
| Temperature (ambient) | between -15 °C and +55 °C |
| Humidity (non condensing) | between 10% and 90%<br>(non-condensing) |
| Atmospheric pressure | between 500 and 1060 hPa |
| **Warming-up time** | |
| 30 minutes | |
| **Dimensions** | |
| Dimensions<br>width x length x height | approx. 460 x 460 x 15.5 mm |
| Weight | 4.2 kg |
| Maximum load | 100 kg on an area of 40 mm in diameter |
| Maximum total load | 150 kg over the whole detector surface |
| Vibration tolerance | 2 G during normal operation<br>5G during storage and transport |
| Shock tolerance | 20 G during normal operation |

| | |
|---|---|
| | 30 G during storage and transport |
| Drop limit | 500 mm (once) |
| Image acquisition time | 1.5 s |

| | DX-D 60C | DX-D 60G |
|---|---|---|
| **Conversion screen** | CsI:TI | Gadox:Tb |
| Pixel size | 0.14 mm (140 $\mu$m) | |
| Active pixel matrix | 3072 x 3072 | |
| Effective pixel matrix | 3048 x 3048 | 3060 x 3060 |
| Detector type | amorphous silicium | |
| Active area size | 430.08 mm × 430.08 mm | |
| Effective area size | 426.72 mm x 426.72 mm | 428.4 mm × 428.4 mm |

## System Control Unit

| System Control Unit | |
|---|---|
| Type | 6007/300 |
| Rated power supply<br>(input) | AC100 to 240V, 50/60 Hz, Max. 2.0-0.8A |
| Rated power supply<br>(output) | DC +24V 3.25A, 78W |
| Wireless connection | IEEE 802.11n (2.4 GHz/5 GHz) |
| Dimensions (width x height x depth) | 300 mm x 236 mm x 58 mm<br>(140 mm antenna height) |
| Weight | 2.8 kg |

## Mini System Control Unit

| Mini System Control Unit | |
|---|---|
| Type | 6007/301 |
| Rated power supply<br>(input) | DC +24V 2A max |
| Wireless connection | IEEE 802.11n (2.4 GHz/5 GHz) |
| Dimensions (width x height x depth) | 210 mm x 170 mm x 45 mm<br>(140 mm antenna height) |
| Weight | 1.2 kg |

# Remarks for HF-emission and immunity

**Topics:**

# EMC (Electromagnetic Compatibility) Statements

**WARNING:**
This device has been tested for EMI/EMC compliance, but interference can still occur in an electromagnetically noisy location. Attempt to maintain a suitable distance between electrical devices to prevent malfunction.

**WARNING:**
Obtaining diagnostic images and transferring them to a PC (workstation) are the essential performance of the DR detector. If the required performance is degraded or lost due to electromagnetic interference, images that are not suitable for diagnosis may be obtained or the image may be lost.

## Electromagnetic emissions

This device has been tested for a normal hospital environment as described below.

The user of the device 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 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions in accordance with CISPR 11 | Class A | The device is directly connected to a low voltage power supply network, and can be used in all facilities except the ones that supply voltage to home facilities or buildings. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. |
| Harmonic emissions in accordance with IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3 | Complies (*) | |

(*) Applies to regions where the rated voltage is 220 V or higher. Not applicable to regions where the rated voltage is less than 220 V.

## 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 | ± 8 kV contact discharge<br>± 15 kV air discharge | ± 8 contact discharge<br>± 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 for network leads<br>± 1 kV for entry and outlet leads | ± 2 kV for network leads<br>± 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<br>± 2 kV common mode voltage | ± 1 kV push-pull voltage<br>± 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 | 100% reduction for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees<br>100% reduction for 1 cycle<br>30% reduction for 25/30 cycles at 0 degree<br>100% reduction for 250/300 cycles (5 sec.) | 100% reduction for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees<br>100% reduction for 1 cycle<br>30% reduction for 25/30 cycles at 0 degree<br>100% reduction for 250/300 cycles (5 sec.) | 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 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 | 30 A/m | Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment. |

| Tests of Resistance to Disruption | IEC 60601 Test Level | Level of Agreement | Electromagnetic Environment |
|---|---|---|---|
| Conducted high frequency disturbance variables in accordance with IEC 61000-4-6 | 3 $V_{eff}$ 150 kHz to 80 MHz<br>6 $V_{eff}$ in the ISM bands 150 KHz to 80 MHz | 3 $V_{eff}$ 150 kHz to 80 MHz<br>6 $V_{eff}$ in the ISM bands 150 KHz to 80 MHz | The electromagnetic field strength of a stationary RF transmitter determined by an electromagnetic test survey must be less than the compliance level of each frequency range. |
| Radiated high frequency disturbance variables in accordance with IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.7 GHz | 3 V/m<br>80 MHz to 2.7 GHz | |
| | | | Interference may occur in the vicinity of equipment marked with the symbol:<br>  |

*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.*

**WARNING:**
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.

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

**WARNING:**
Portable RF communications equipment (including peripherals such as antenna cables and external antenns) should be used no closer than 30cm (12 inches) to any part of the DR detector, including cables specified for use with the equipment. Otherwise, degradation of the performance of this equipment could result.

# For U.S.A.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

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 residential 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.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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 measure.

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from where the receiver is connected.
- Consult the distributor or an experienced radio/TV technician for help.

**FCC WARNING:**

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.