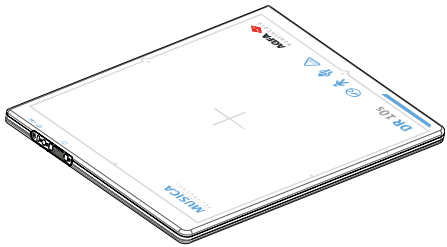
DR 10s

Pixium 2430 EZ

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 DR 10s DR Detector 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, service 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, service 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, service 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 on order of a physician for prescription use only.*

Introduction to the DR Detector

Topics:

Intended Use

The DR Detector is a wireless 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.

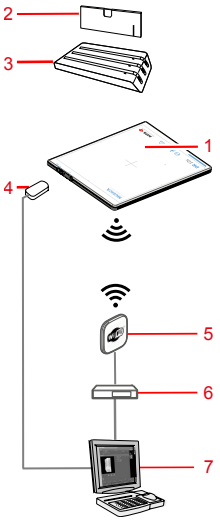
Intended User

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.

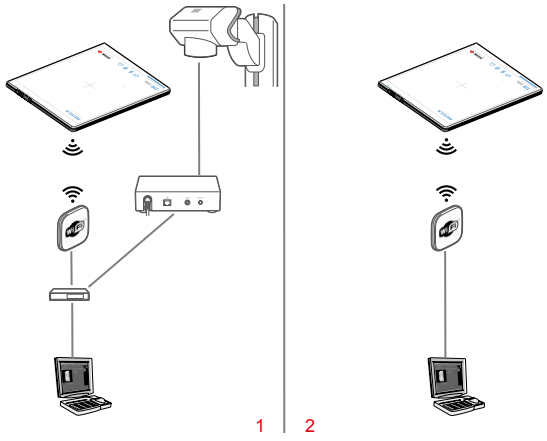
Configuration

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



1. DR Detector
2. DR Detector battery
3. DR Detector battery charger
4. IR data communication unit
5. Wireless access point
6. Network switch
7. Workstation

Figure 1: DR Detector configuration



1. X-ray generator synchronization through the DR Generator Sync Box
2. Automatic exposure detection

Figure 2: DR Detector configuration variants

Related Links

Automatic exposure detection on page 79

Equipment Classification

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

Class I equipment	Internally powered
Type B equipment	A Type B applied part is one that provides a particular degree of protection against electric shock particularly regarding allowable leakage current and reliability of the protective earth protection.
Applied Parts	The DR Detector tube side is an applied part.
Water ingress	Depending on the model of the DR detector, one of following ratings apply. The type label specifies which rating applies. • IP43. This device is protected against access to hazardous parts with solid objects greater than 1 mm in size. The device is protected against spraying water. • IP67. This device is protected against access to hazardous parts and dust tight. The device is protected against the effects of temporary submersion in 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.
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	Up to ten (10) years The minimal total dose that the panel shall absorb during its lifetime is 100 Gy at RQA5

Non-medical equipment

Following components are classified as non-medical equipment:

- DR Detector battery charger
- IR data communication unit

- Wireless access point
- Network switch
- Workstation
- DR Generator Sync Box

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

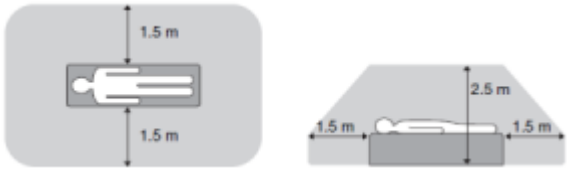


Figure 3: Patient's vicinity

Options and Accessories

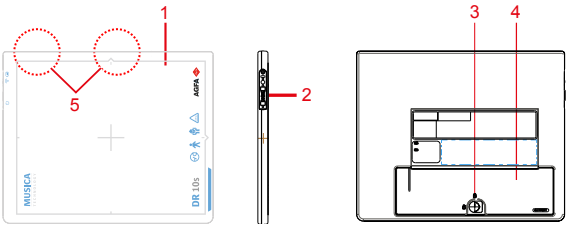
- DR Detector battery
- DR Detector battery charger

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

Operation Controls

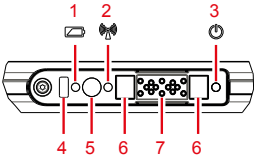
Topics:

DR 10s



1. Effective imaging area border and center position indication
2. Control panel
3. DR Detector battery lock lever
4. DR Detector battery
5. Antenna of the wireless network adapter

Figure 4: DR Detector operation controls



1. Battery indicator
2. Wifi indicator
3. Status indicator
4. IR data port: communication port for the detector link (registration/ connection).
5. On/off switch
6. Magnets for DR Detector connector
7. DR Detector cable connector

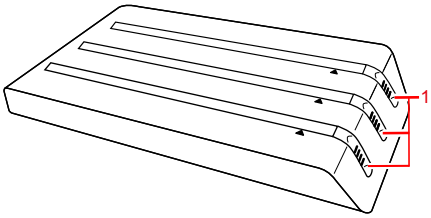
Figure 5: DR Detector control panel

Related Links

Detector Status Indicators on page 81

DR Detector Battery Charger

The battery charger has three slots to insert a battery.



1. Battery status indicator light

Figure 6: DR Detector Battery Charger

Related Links

Charging a battery on page 82
DR 10s, DR 14s Battery on page 100
DR 10s, DR 14s Battery Charger on page 101
Safety directions for the power supply on page 63
Non-medical equipment on page 14

DR Detector Switch

The **DR Detector Switch** is available in the title bar of the MUSICA Acquisition Workstation. The **DR Detector Switch** shows which DR detector is active and shows its status. The **DR Detector Switch** can be used to activate another DR detector.

Figure 7: DR Detector Switch

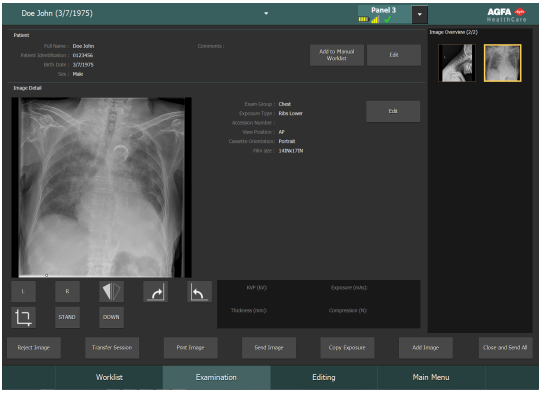


Figure 8: Title bar with DR Detector Switch

Battery status icon					(empty)
Meaning	Full	Medium	Low	Empty	Wired DR Detector Wireless DR detector is off or disconnected

Connection status icon (wifi/ wired)					(empty)
Meaning	Good	Low	Bad	Wired DR detector	DR detector is off or disconnected

DR Detector status icon				(empty)
		(blinking)		

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.

IR Data Communication Unit

This unit is used as an interface of the NX workstation for infrared communication with the DR Detector, which registers the DR Detector to the NX workstation.

Related Links

Non-medical equipment on page 14

Registering the DR Detector to an NX Workstation using automatic registration on page 89

Wireless Access Point

This antenna equipment relays captured images from the DR Detector to the NX workstation.

Related Links

Non-medical equipment on page 14

Using the Toggle Wifi button in the NX software to switch between the wireless DR Detector and the wireless hospital network

The NX Workstation can be configured to use a wireless DR Detector and to connect to a wireless hospital network.

In a configuration without a wireless access point that is connected to the workstation, the DR Detector communicates via the internal wireless adapter of the workstation and only one connection can be active at a time.The user must manually switch between the wireless connection to the hospital network and the wireless connection to the DR Detector.

To switch between wireless networks:

1. Press the **Toggle Wifi** button in the NX software.

   The name and location of the button depends on the configuration.

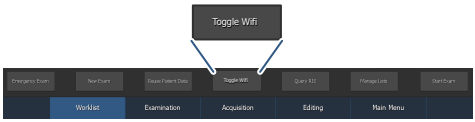


Figure 9: Action button to switch between wireless networks

   A dialog is displayed indicating which network is currently active.
2. Press the icon representing the other network to activate it.

Table 1: Status of the wireless network

	The NX Workstation is connected to the DR Detector to make exposures. No communication to the hospital network is possible, e.g. to RIS or PACS.
	The NX Workstation is connected to the hospital network to retrieve data from the RIS or to print or archive images. No communication to the DR Detector is possible, no exposures can be performed.

System Documentation

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

- MUSICA Acquisition Workstation user manual (document 4420).
- MUSICA Acquisition Workstation key user manual (document 4421).
- DR detector calibration key user manual (document 0134).
- DR 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*

Wireless access point

The wireless access point is delivered with its own user documentation.

Training

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

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

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

Product Complaints

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

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

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

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

Compliance

Topics:

General

- The 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 14971

Safety

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

Electromagnetic Compatibility

- IEC 60601-1-2

Radio Frequency

Declaration of conformity

Argentina	Marca: Trixell / Modelo: DNUR-S2 / CNC ID: C-13463
Australia and New Zealand	EMC standards
Brazil	ANATEL This product contains the board DNUR-S2, ANATEL ID: 1248-14-4386
Canada	IC RSS-210
Chile	Certificate no: 647/DFRS12357/F-50
China	SRRC Certificate no: CMIIT ID: 2013AJ7137
European Union (and EEA)	RED directive
India	WPC WING ETA certificate No.: NER-ETA/200 WPC WING ETA certificate No.: NER-ETA/199
Japan	R 207-643809 5Ghz product for indoor use only
Kuwait	Certificate no: MC/M/3/6-13714
Malaysia	SIRIM Approval no. RCCU/05A/S(14-0616)
Mexico	IFETEL Certificate no: IFT: RCPTRDN13-1686
Russia	Declaration of conformity No. D-RD-2801 of 01.04.2014, valid till 01.04.2020, registered in Federal Communication Agency on 07.04.2014
Saudi Arabi	Certificate no: 20131224058
Singapore	Complies with IDA Standards DA103787 registration number: N3210-13
South Korea	KCC Certificate no: KCC-RMM-TXL-Pixium3543EZ
Taiwan	NCC Certificate no: CCAI13LP1720T6
Thailand	Certificate no: JM 5401
The Philippines	NTC Type Accepted No.: ESD-1408587C
United Arab Emirates	TRA Registered No: ER0131569/14 Dealer no: DA0067151/11
U.S.A.	FCC Part 15 Class B

Related Links

Remarks for HF-emission and immunity on page 102

Topics:

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.

Restrictions on outdoor use

There are restrictions on the outdoor use of the U-NII Low (5150-5250 MHz) and U-NII Mid (5250-5350 MHz) bandwidths of the WLAN module incorporated in the device in the following Member States: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE) and United Kingdom (UK).

Connectivity

Wireless Communication

Wireless communication is established between the internal wireless module of the DR detector and the MUSICA Acquisition Workstation via the wireless access point. The DR detector is compliant with IEEE 802.11n (2.4 GHz/5 GHz). The available frequency band varies depending on local radio laws and system requirements. The frequency band (channel) of the DR detector is selected at installation.

Note: *Use of multiple pieces of equipment that use the same frequency band (channel) may interfere with each wireless communication and cause a decline in transmission speed.*

Note: *Before introducing other wireless equipment to the same environment where the DR detector is set up, consult the system engineer or qualified personnel at the medical site.*

Note: *Do not place obstacles in the way of the wireless access point or of the antenna of the internal wireless module of the DR detector. Otherwise, the properties of wireless communication, such as the throughput and operable distance, may decrease.*

Note: *Transmitting the image data to the MUSICA Acquisition Workstation takes a number of seconds. After making an exposure, stay with the detector in the direct neighbourhood of the wireless access point until the image is available on the MUSICA Acquisition Workstation.*

Installation

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

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

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

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.

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 MUSICA Acquisition 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.

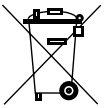
Related Links

Problem solving on page 92

Detector Status Indicators on page 81

Labels

Symbol	Explanation
	Tube side
	Direct current
	Alternating current
	Protective earth (ground)
	Type B applied part
	Protection against harmful ingress of water or particulate matter. IP Classification: Ordinary.
	Handle with care
	Maximum patient weight over the whole area of the detector surface
	Maximum patient weight on an area 80 mm in diameter
	Device contains a transmitter module that generates non-ionizing radiation.
	Manufacturer
	Date of manufacture
	Serial number

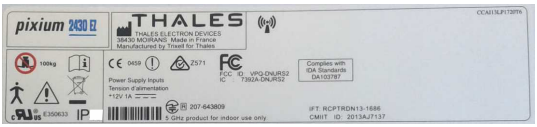
Symbol	Explanation
	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	CE non harmonized frequency marking
	FCC Declaration of Conformity label
	This mark shows compliance with both Canadian and U.S. safety requirements.
	Recognized Component Mark for Canada and the United States
	This mark shows the compliance with EMC standards. (For Australia and New Zealand)
	This mark shows the compliance with EMC standards. (For Australia and New Zealand)
	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.
	Recycling identification mark for lithium ion batteries in Japan
	This mark shows the compliance with China RoHS for 5 years.
	Recycling mark in Taiwan

Symbol	Explanation
	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.
	General Mandatory action.

Topics:

- *Additional Labeling of the DR Detector*
- *Additional Labeling of the DR Detector battery*
- *Additional Labeling of the DR Detector battery charger*

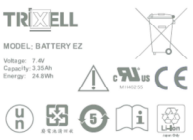
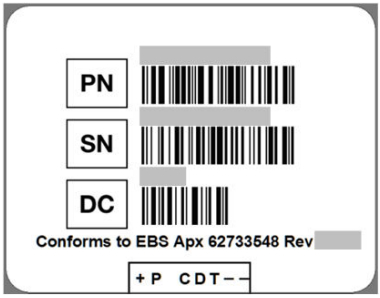
Additional Labeling of the DR Detector

 **Figure 10: Sample of type label**	Type label on the back side of the DR Detector.
	Secondary 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 DR Detector battery

 **Figure 11: Sample of type label**	Type label on the back side of the battery.
	Secondary label on the back side of the battery.

Additional Labeling of the DR Detector battery charger

 **Figure 12: Sample of type label**	Type label on the bottom side of the battery charger.

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 or the battery may cause malfunction and contamination. Take special care near the battery bay and 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 47

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

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

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

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

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

Approved disinfectants

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

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

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.

1. Check the cables
   a) Ensure that cables are not damaged and cable jackets are not torn.
   b) Ensure that the power cord plugs are securely connected to both the equipment AC inlet and the AC outlet.
2. Check the detector
   a) Ensure that there are no loose screws or breaks.
   b) Ensure that there is no dust or foreign matter on the battery bay connector.
   c) Ensure that there are no breaks or short-circuits in the battery bay connector.
3. Start the NX workstation and perform a test exposure.

Yearly inspection

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

Perform calibration 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 13: 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.

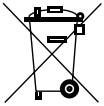


Figure 14: Battery Notice

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 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 any objects 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. If liquid or water flows into an electrical component, turn off the power, mark it as "Out of Order" and contact service.

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

WARNING:
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.

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.

WARNING:
System unavailability due to hardware or software failure. If the product is used in critical clinical workflows, a backup system has to be foreseen.

WARNING:
Patients or operators wearing a pacemaker must keep a safe distance between the DR Detector and the pacemaker. If 2.4 GHz wireless connection is used, keep minimum 30 cm distance. If 5 GHz wireless connection is used, keep minimum 41 cm distance. If no wireless connection is used, keep minimum 5 cm distance between the pacemaker and any of the three magnets contained in the DR Detector: two in the cable connector and one in the battery locker. These values apply if the pacemaker is conformant to EN45502-2-1.

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.

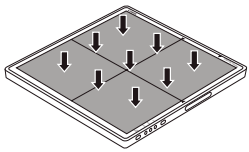
CAUTION:
Excessive ambient temperature may impact performance of DR Detectors and cause permanent damage to the equipment. If ambient temperature and humidity is outside the range of 15 - 35 °C and 20 - 80% RH, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

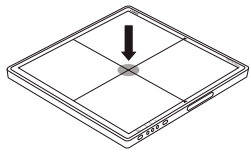
CAUTION:
Turn OFF the power to each piece of equipment for safety when not being used.

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 80 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. The DR Detector contains a shock sensor to detect if the detector is dropped from a height of more than 70 cm. 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.

CAUTION:
In order to avoid damage of the plastic detector cover it is recommended to protect with thin tape (like kapton) any sharp metallic parts in the bucky tray such as fixation clamps or insertion rails.

CAUTION:
The detector is delivered non sterile.

Topics:

- *DR Detector Battery*
- *Safety directions for the power supply*

DR Detector Battery

Safety directions for the DR detector battery

WARNING:

Do not use any means for charging the battery other than that specifically provided for use with the equipment.

The battery is used with the DR Detector. Do not use them in other combinations.

Use only a power adapter complying with IEC 60601-1, IEC 60950-1 or IEC 62368-1.

Make sure to turn off the detector before detaching a battery pack.

When replacing the battery, only use batteries that are designated for the Agfa DR detectors. If you use a battery other than the specified one, the battery may explode, or electrolyte may spill out, resulting in a fire or electrical shock.

When the detector is not to be used for some time, remove the battery pack. Otherwise, over discharge may occur resulting in the shortened battery life.

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

Stop charging the battery when the battery charger indicator lights keep indicating that the battery is charging, beyond the specified charging time. Not doing so may result in the battery overheating or smoking or in an explosion or fire.

Always check the remaining amount of the battery pack during use of the detector. If performance of the battery pack has some problems, consult your local Agfa representative.

The battery charger is designed for the dedicated battery pack. Do not use the battery charger other than the dedicated one. Otherwise, a battery explosion or a battery leak may occur, resulting in fire or electrical shock.

Do not operate the battery charger using any type of power supply other than the one indicated on the rating label.

Do not handle the product with wet hands.

Do not attempt to disassemble, alter, or apply heat to the product.

Avoid dropping or subjecting the product to severe impacts. To avoid the risk of injury, do not touch the internal parts of the battery if it has been cracked or otherwise damaged.

Stop using the battery pack immediately if it emits smoke, a strange smell, or otherwise behaves abnormally.

Do not let the battery pack and battery charger come into contact with water or other liquids and do not allow them to get wet.

Do not clean with substances containing organic solvents such as alcohol, benzene, thinner, or other chemicals. Otherwise, fire or electrical shock may result.

Do not allow dirt or metal objects (such as hair pins, clips, staples or keys) to contact the terminals. Otherwise, battery explosion or leakage of electrolyte may occur, resulting in fire, injury or pollution of surrounding area. If the battery leaks and the electrolytes come into contact with your eyes, mouth, skin or clothing, immediately wash it away with running water and seek medical attention.

Do not leave, store, or place the product in a location near heat sources, or in a place subject to direct sunlight, high temperature, high humidity, excessive dust, or mechanical shock. Otherwise, battery leakage, overheating or damage to the product may occur, resulting in electrical shock, burns, injury or fire.

If the battery pack becomes heated or swollen, immediately replace the battery with a new one before using it. Otherwise, overheat, smoke, explosion, or fire may occur.

The Lithium ion/polymer battery is recyclable.

Battery slowly discharges even if not in use. The battery pack may have expired if it discharges immediately after being fully charged. You can purchase an optional battery pack to replace an exhausted one. The battery pack is a consumable item. If a fully charged battery is consumed quickly, use a new and fully charged battery pack.

Be sure to charge the battery periodically (once a year) if it is not used for an extended period of time. The battery pack cannot be charged if it has been over discharged.

Before discarding the battery pack, cover the terminals with adhesive tape or other insulators. Contact with other metal materials may cause fire or explosion.

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:
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Make sure that all components of the system are connected to a common earth point.

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.

CAUTION:
Position the power supply so that it is possible to disconnect it from the mains power if required.

Getting started

Topics:

Starting the DR Detector

CAUTION:
Do not use the battery pack as a power source for equipment other than DR 10s or DR 14s detectors. Be sure to use only the dedicated battery pack for the DR 10s or DR 14s detector.

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

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

To start the DR Detector:

1. Fully charge the battery.

   Charge the battery on the day of examination or on the previous day.

   Note: *The battery slowly discharges even if not in use. The battery pack may have expired if it discharges immediately after being fully charged. You can purchase an optional battery pack to replace an exhausted one.*

2. Attach the battery.

   Note: *Make sure that the lock lever is placed to the (unlock) side.*

   Align the claw on the battery pack and the groove on the battery bay (1). Insert the battery pack fully (2). Push down the battery pack (3). Turn the latch clockwise (4) and lock it.

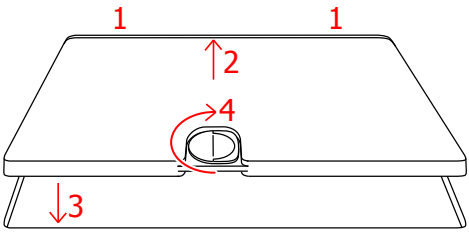


Figure 15: Attach the battery

Note: Make sure that the battery is securely attached.

The detector starts up.

3. If the detector was turned off without removing the battery, use the power button to turn on the detector.

   Press and hold the power button until the detector starts up (status indicator is lighting up).

   Do not use a sharp object or pen/roller ball to operate the power button of the detector!

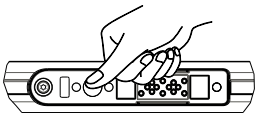


Figure 16: Power button

   During startup the status indicator is flashing orange. After startup the status indicator is lit green, indicating the power status.

4. Check the DR Detector status icon on the DR Detector Switch. If the displayed status is error and the detector is shared between NX workstations, it may still be connected to another NX workstation. Hold the detector with its IR data port close to the IR Data Communication Unit that is connected to the NX workstation.

All status indicators on the DR Detector are lit green. The DR Detector is ready.

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

Related Links

DR 10s on page 18
Charging a battery on page 82
Detector Status Indicators on page 81
Registering the DR Detector to an NX Workstation using automatic registration on page 89
Problem solving on page 92

Basic Workflow DR Detector

Topics:

Step 1: retrieve the patient info

At the MUSICA Acquisition Workstation:

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

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

Step 2: select the exposure

1. At the MUSICA Acquisition 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.

   - 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

DR Detector Switch on page 20
Automatic exposure detection on page 79

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 MUSICA Acquisition 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.

Positioning the DR Detector

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

- tube side
- patient orientation marker

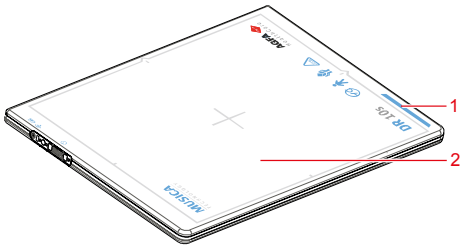


Figure 17: Detector orientation aids

1. Location blue patient orientation marker
2. Tube side of the detector

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.

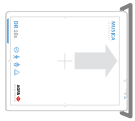
The user is responsible for the correct and clear marking on the left or right side of the image to eliminate possible errors.

Table 2: Table with bucky

Table with bucky, portrait	
Table with bucky, landscape	

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

Table 3: Wallstand bucky

Wallstand with left loading bucky, landscape	
Wallstand with right loading bucky, landscape	

Guidelines for Pediatric Applications

CAUTION:
Use special care when imaging patients outside the typical adult size range. Children are more radiosensitive than adults.

Reducing dose for radiographic procedures while maintaining acceptable clinical image quality will benefit patients.

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 and to limit the duration of fluoroscopy sequences and rapid sequences.

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, limiting the duration of dynamic imaging).
- 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 by removing the battery.

Turn the latch counterclockwise (unlock) (1) and lift the battery up (2), and then remove the battery.

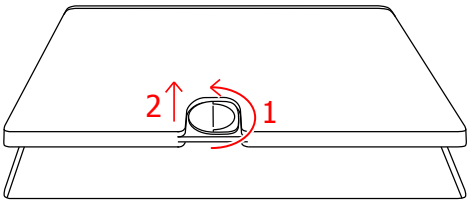


Figure 18: Remove the battery

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.*

Related Links

Charging a battery on page 82
Storing a battery on page 87

Topics:

- *Automatically turning the DR Detector to sleep*
- *Automatically turning off DR Detector*

Automatically turning the DR Detector to sleep

The DR Detector can be configured to switch to standby (sleep) automatically after not being used for a specific time.

New exposures can be made. After selecting an exposure on the NX workstation, there will be a short delay until the DR Detector becomes ready for exposure.

Automatically turning off DR Detector

The DR Detector can be configured to switch off automatically after not being used for a specific time.

For making new exposures, the DR Detector must be started again by removing the battery and inserting it again.

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:
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 5 ms.

WARNING:
Applying collimation to leave only a very small area exposed can cause failure to trigger the image acquisition.

WARNING:
Very low dose can cause failure to trigger the image acquisition. A dose of at least 5 nGy is required.

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.

Related Links

Positioning the DR Detector on page 73

Advanced Operating

Topics:

Detector Status Indicators

Table 4: DR Detector status

Indicator	Light		Status
 Status indicator	OFF		Power OFF
		Orange Blinking	During startup or shutdown or to indicate an error
		Green	Ready status
		Orange	Not ready for exposure or during image transmission
		Green Blinking	Sleep mode
 Battery indicator	OFF		During startup or when no battery is inserted
		Orange Blinking fast	Battery charge level below 5%
		Orange	Battery charge level between 5% and 10%
		Green	Battery charge level between 10% and 100%
 Wifi indicator	OFF		During startup
		Green	Connected to wireless access point
		Orange	Not connected to wireless access point

Related Links

Problem solving on page 92

Charging a battery

To charge a battery using the battery charger:

1. Connect the power supply to the mains power and to the power socket of the battery charger.
2. Insert the battery in an empty slot of the battery charger.

   The battery charger automatically detects the battery and starts charging the battery.

   The battery status can be read from the indicator lights.

   The charge level of the battery is monitored and it is kept at maximum level until the battery is removed from the battery charger.
3. Remove the charged battery from the battery charger.

Related Links

Safety directions for the DR detector battery on page 61

DR Detector Battery Charger on page 19

Topics:

Inserting the battery in the battery charger

Insert the battery aligning the position indicators.

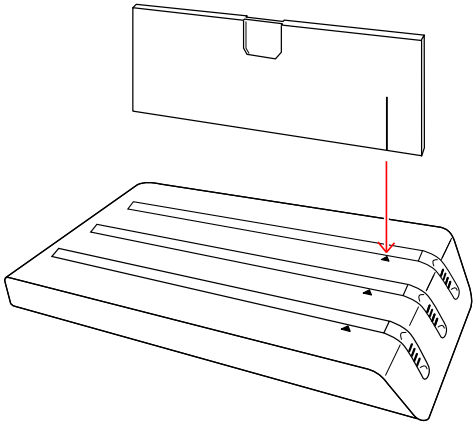


Figure 19: Inserting the battery in the battery charger

Battery charger indicator lights

The battery charger has three slots to insert a battery.

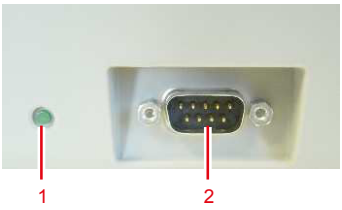
Each slot has a battery status display with indicator lights to inform the user about the status of the inserted battery.

Table 5: Battery status display

Label	Light	Status
	Green blinking	The battery is being charged. Battery charge level 0-25%.
		The battery is being charged. Battery charge level 25-50%.
		The battery is being charged. Battery charge level 50-75%.
		The battery is being charged. Battery charge level 75-100%.
	Green	Battery charging is completed. Charge is sufficient to perform examinations. In order to optimize battery lifetime, it is recommended not to leave the battery permanently powered by the charger.
	Orange	Error. Battery charging not possible.

WARNING:
The lifetime and full charge level of the battery can degrade if the battery is removed before the battery charging is completed and if the charge is performed at low temperature (less than 20 °C).

The green indicator light at the back of the battery charger indicates that the battery charger is connected to the power supply.



1. Green indicator light
2. Connector

Figure 20: Back of the battery charger

First use of a new battery

A new battery may need activation before using it in the DR Detector.

1. Insert the battery in the battery charger.
   The battery charger indicator lights light up.
2. Remove the battery from the battery charger.

The battery is activated and can be used in the DR Detector.

Storing a battery

Prolonged storage of a fully discharged or fully charged battery can damage the battery. Storage of a battery at elevated temperature can damage the battery. Batteries should be stored in a partially charged state, at storage temperature.

A new battery contains sufficient charge and requires no maintenance if used within one year of manufacture.

Following use in the device, if a used battery must be stored for more than one month, follow this procedure to store the battery on the appropriate charge level:

To store a battery:

1. Put the battery in normal use until the battery charge level is below the storage charge level.

   New batteries already have a battery charge level lower than the storage charge level.
2. Start charging the battery.
3. Monitor the battery status and stop charging the battery when the charge level has reached the storage charge level.
4. Store the battery at storage temperature in an environment with low humidity and free from corrosive gas.
5. Repeat previous steps if storage is more than 6 months.

After an extended period of storage, it may be necessary to charge and discharge the battery several times to obtain the maximum performance.

Storage conditions

Storage charge level	50%
Storage temperature	at or below room temperature (+20°C)

Sharing the DR Detector between NX Workstations

To share a DR Detector between NX Workstations, the DR Detector must be configured on each of the workstations. An IR Data Communication Unit is connected to each of the workstations.

Note: *The IR Data Communication Unit is configured to be connected to a specific USB port. Do not connect it to another USB port.*

The DR Detector is set up to communicate to a specific NX workstation. The procedure of registering the DR Detector to another NX workstation switches the availability of the DR Detector between NX workstations.

There are two workflows for registering the DR Detector. Which workflow is used, is configured on the NX workstation during installation.

- Using automatic registration.

  The registration is initiated by holding the detector with its IR data port close to the IR Data Communication Unit that is connected to the NX workstation.
- Using the **DR 10s DR 14s Registration Tool**

  The registration is initiated by running the tool on the NX workstation.

Topics:

Registering the DR Detector to an NX Workstation using automatic registration

1. Start the NX workstation.
2. Turn on the detector.

   During startup the status indicator is flashing orange. After startup the status indicator is lit green, indicating the power status.
3. Hold the detector with its IR data port close to the IR Data Communication Unit that is connected to the NX workstation.

   A dialog is displayed on the NX workstation indicating that the network settings of the DR Detector are being updated.

   Note: *Do not cover the IR data port of the DR Detector with your hands. Otherwise, the properties of wireless communication, such as the throughput and operable distance, may decrease.*

   Note: Other detectors in the direct vicinity may interfere with the communication to the NX workstation. Make sure they are out of reach of the IR Data Communication Unit.

   After a short time another dialog is displayed indicating that sharing the DR Detector has been successful. It may take up to 30 seconds for the dialog to pop up.

   The DR Detector is restarting.
4. Remove the detector from the IR Data Communication Unit and click **OK**.

The DR Detector is set up to make connection to the selected NX workstation. The DR Detector connection status icon in the DR Detector Switch is displayed.

Related Links

Stopping the DR Detector on page 77
Starting the DR Detector on page 66

Registering the DR Detector to an NX Workstation using the DR 10s DR 14s Registration Tool

1. Start the NX workstation.
2. Turn on the detector.

   During startup the status indicator is flashing orange. After startup the status indicator is lit green, indicating the power status.
3. On the NX workstation, go to the **Main Menu**
4. Click the **Show Desktop** action button.

   The Windows desktop is shown.
5. Click the **DR 10s DR 14s Registration Tool** icon on the desktop.

   A dialog is displayed instructing to remove all DR Detectors away from the IR Data Communication Unit.

   Note: Other detectors in the direct vicinity may interfere with the communication to the NX workstation. Make sure they are out of reach of the IR Data Communication Unit.
6. Click **OK**.
   A dialog is displayed instructing to hold the detector with its IR data port close to the IR Data Communication Unit.
7. Hold the detector with its IR data port close to the IR Data Communication Unit that is connected to the NX workstation.

   A dialog is displayed on the NX workstation indicating that the network settings of the DR Detector are being updated.

   Note: *Do not cover the IR data port of the DR Detector with your hands. Otherwise, the properties of wireless communication, such as the throughput and operable distance, may decrease.*

   After a short time another dialog is displayed indicating that sharing the DR Detector has been successful. It may take up to 30 seconds for the dialog to pop up.

   The DR Detector is restarting.
8. Remove the detector from the IR Data Communication Unit and click **OK**.
9. Go back to NX by clicking **NX** in the Windows task bar.

The DR Detector is set up to make connection to the selected NX workstation. The DR Detector connection status icon in the DR Detector Switch is displayed.

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. For details, refer to the DR Detector Calibration Key User Manual (document 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 battery is not attached.	Attach the battery.
	The battery pack is not charged.	Fully charge the battery pack.
	The battery pack is broken.	Replace the battery pack.
A fully charged battery is consumed quickly.	The battery capacity decreases.	The DR Detector battery can deteriorate because of its characteristics and structure. For purchase of consumables, contact your sales representative or local dealer.
	The battery was charged or used in low temperatures.	In low temperatures the battery capacity decreases. Use a battery charged in normal temperatures.
The battery bay is unusually hot.	The battery is malfunctioning.	Stop using the battery and consult your sales representative or local dealer.
Sharing the DR Detector between NX Workstations fails	The DR Detector is not configured on the NX workstation.	Contact your local service representative.

Symptom	Cause	Remedy
	The IR Data Communication Unit is connected to the wrong USB port.	Reconnect the IR Data Communication Unit to the USB port where it was connected during setup.

Battery thermal protection

The battery pack has a thermal protection that shuts down the battery power in case of very high temperature.

Two situations can occur:

- Software protection: the battery pack will be usable as soon as the temperature drops below a specified limit.
- Hardware protection: the battery pack must be exchanged.

Technical Data

Topics:

DR 10s

Commercial name	DR 10s
Manufacturer	
Manufacturer DR Detector	THALES AVS FRANCE SAS 460 rue du Pommarin 38430 MOIRANS FRANCE
Distributor DR Detector	Agfa NV Septestraat 27, B-2640 Mortsel - Belgium
Original manufacturer model name	
DR 10s	Pixium 2430 EZ-C
Electrical connection DR Detector	
Rated power supply (powered by battery pack)	+12V 1A DC
Wireless connection	IEEE 802.11a/b/g/n (2.4 GHz/5 GHz)
Wireless signal range (in an open space)	maximum 6 m
Environmental conditions (during normal operation)	
Room temperature	between +15 °C and +35 °C
Humidity (non condensing)	between 20% and 80% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1100 hPa
Environmental conditions (during storage)	
Temperature (ambient)	between -10 °C and +55 °C
Humidity (non condensing)	between 5% and 95% (non-condensing)
Atmospheric pressure	between 500 and 1100 hPa
Warming-up time	

30 minutes	
Dimensions	
Dimensions width x length x height	approx. 268.5 x 328.5 x 16.0 mm
Weight (incl. battery)	1.6 kg
Maximum total load	135 kg over the whole detector surface 150 kg over the whole detector surface (image quality of the exposure may not be optimal)
Maximum load	80 kg on an area of 80 mm in diameter 100 kg on an area of 80 mm in diameter (image quality of the exposure may not be optimal)
Vibration tolerance	2 g
Shock tolerance	10 g
SAR value	0.276 W/kg
Throughput (images per hour)	240

Conversion screen	CsI
Pixel size	148 μm
Active pixel matrix	1560 x 1920
Effective pixel matrix	1500 x 1920
Detector type	amorphous silicium
Active area size	230.9 mm x 284.2 mm
Effective area size	222.0 mm x 284.2 mm

X-ray performance

Performance	Typical	Minimum
MTF horizontal 1 lp/mm	61	55
MTF vertical	61	55

Performance	Typical	Minimum
1 lp/mm		
MTF horizontal 2 lp/mm	31	25
MTF vertical 2 lp/mm	30	25
MTF horizontal 3 lp/mm	15	10
MTF vertical 3 lp/mm	14	10
MTF horizontal Nyquist frequency	12	7
MTF vertical Nyquist frequency	10	7
DQE 0.05 lp/mm, 2µGy	66	56
DQE 1 lp/mm, 2µGy	50	42
DQE 2 lp/mm, 2µGy	40	33
DQE 3 lp/mm, 2µGy	24	19
DQE Nyquist frequency, 2µGy	17	12

DR 10s, DR 14s Battery

Type of product	Rechargeable lithium ion battery pack
Model	BATTERY EZ
Dimensions	
Dimensions (length x width x height)	250 mm x 75 mm x 6 mm
Weight	228 g
Battery output	
Output voltage	DC +7.4 V
Capacity	3.68 Ah
Lifecycle	
Preventive maintenance frequency.	No preventive maintenance required.
Estimated product life	Estimated product life: 1 year

DR 10s, DR 14s Battery Charger

Type of product	Lithium ion battery pack charger
Model	CHARGER 2EZ
Charging time	4 hours
Simultaneous charging	3 batteries
Dimensions	
Dimensions (width x height x depth)	320 mm x 50 mm x 170 mm
Weight	1065 g
Electrical connection	
Rated Power Supply	12 Vdc, 5 A Max
Lifecycle	
Preventive maintenance frequency.	No preventive maintenance required.

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.

Precautions on EMC

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the manual.

Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING:
The DR Detector should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the DR Detector should be observed to verify normal operation in the configuration in which it will be used.

WARNING:
Avoid to place the DR Detector too close to life supporting devices. Keep a minimal distance of 26 cm between the DR Detector and life supporting devices.

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

Electromagnetic emissions

This DR Detector has been tested for a normal hospital 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 for data transmission. Therefore, its RF emissions can cause interferences in nearby electronic equipment.
RF emissions in accordance with CISPR 11	Class B	The DR Detector is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions in accordance with IEC 61000-3-2	Complies Class B	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	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 not applicable	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 5 s	not applicable	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	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.
GSM modulation ENV 50204	3 V/m 900 MHz modulated @ 200 Hz (square signal)	3 V/m 900 MHz modulated @ 200 Hz (square signal)	Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 80 MHz to 1 GHz	3 V/m 80 MHz to 2.5 GHz 80 MHz to 1 GHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
	*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.

Recommended separation distance

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

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device			
Rated Power of the Transmitter W	Protective Distance in accordance with Transmission Frequency m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. REMARK 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. REMARK 2: These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.			

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 B 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.