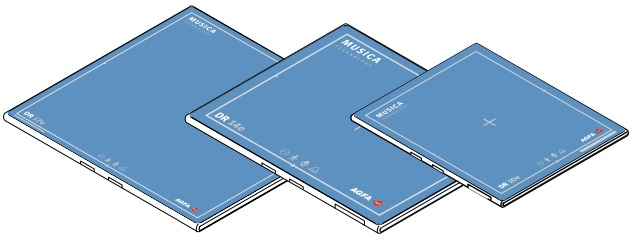
DR 10e, DR 14e, DR 17e

DR 10e C (6011/111)
DR 14e C (6011/101)
DR 14e G (6011/102)
DR 17e C (6011/103)
DR 17e G (6011/104)

User Manual



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AGFA

Contents

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Agfa NV, Septestraat 27, 2640 Mortsel - Belgium

For more information on Agfa products, please visit www.agfa.com.

Published by Agfa NV

2640 Mortsel - Belgium.

Introduction to this Manual

Topics:

Scope

This manual contains information for the safe and effective operation of the DR 10e, DR 14e and DR 17e wireless 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, 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 or 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 of the DR Retrofit solution

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.

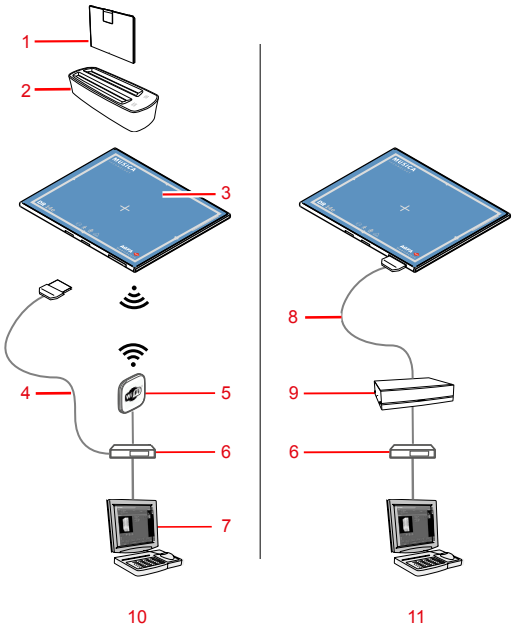
Intended User

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. Multiple DR Detectors can communicate to a single workstation.

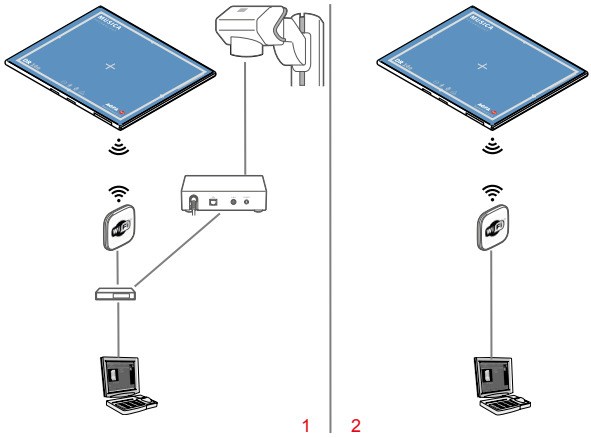


1. DR Detector battery
2. DR Detector battery charger
3. DR Detector
4. DR Detector registration cable (wireless configuration)

   This cable is only required to register the DR Detector on another NX Workstation.
5. Wireless access point
6. Network switch (optional)
7. Workstation
8. DR Detector connector cable (wired configuration)
9. Power box
10. Wireless configuration
11. Wired configuration

Figure 1: DR Detector configuration

The wired and wireless configurations can be combined.



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

Figure 2: DR Detector synchronization

Both synchronization methods are available on the wired configuration as well.

Related Links

Automatic exposure detection on page 97

Equipment Classification

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

Type of protection agains electrical shock	Internally powered (wireless configuration) Class I equipment (wired configuration)
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.
Water ingress	IPX0 (The DR detector conforms to IPX3)
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 (if regularly serviced and maintained according to Agfa instructions)

Non-medical equipment

Following components are classified as non-medical equipment:

- DR Detector battery
- DR Detector battery charger
- Wireless access point
- Network switch
- Workstation
- DR Generator Sync Box

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

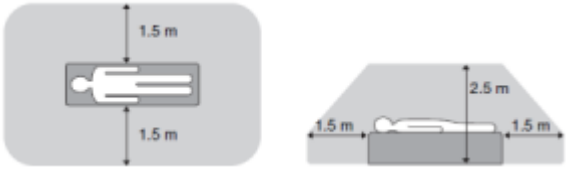


Figure 3: Patient's vicinity

Accessories

- DR Detector battery
- DR Detector battery charger
- Power box with DR Detector connector cable
- DR Detector registration cable
- Click-on grid
- Cover plates for the battery bay and for the connector for the cable

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.

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:

DR 10e, DR 14e, DR 17e

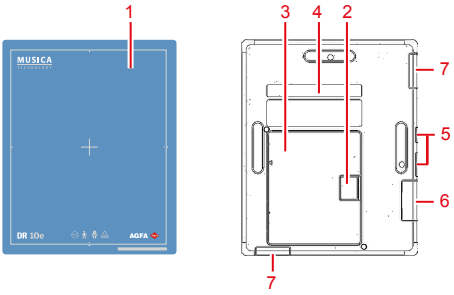


Figure 4: DR 10e operation controls

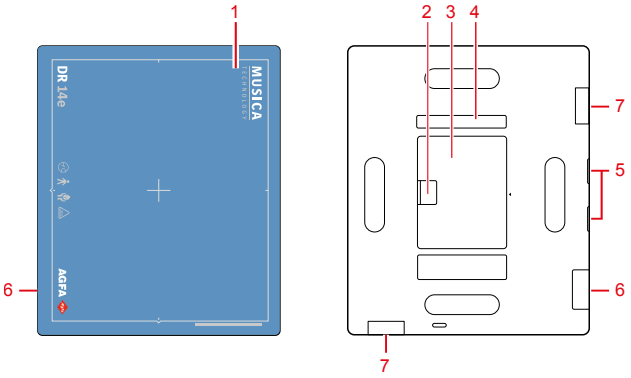
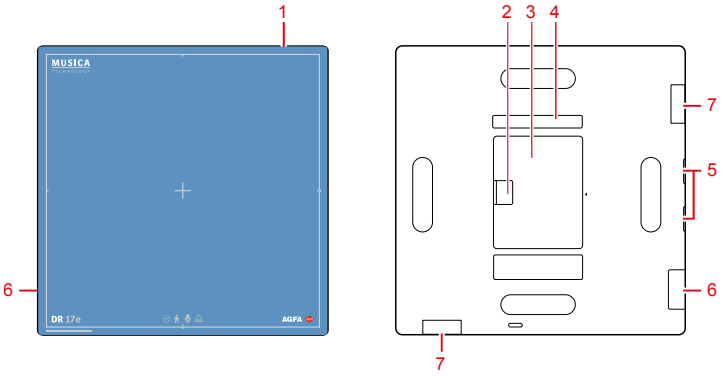


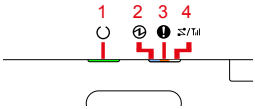
Figure 5: DR 14e operation controls



1. Effective imaging area border and center position indication
2. DR Detector battery lock lever
3. DR Detector battery
4. Battery status indicator

5. DR Detector status indicators
6. DR Detector cable connector
7. Antenna of the wireless network adapter

Figure 6: DR 17e operation controls



1. **Ready** indicator
2. **Power** indicator
3. **Error** indicator
4. **Link** indicator

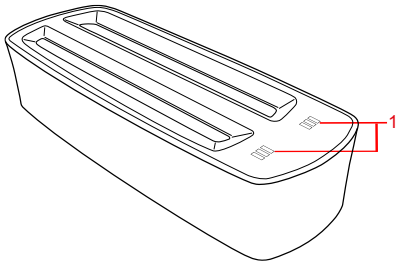
Figure 7: DR Detector status indicators

Related Links

Detector Status Indicators on page 101
Introduction to this Manual on page 6

DR Detector Battery Charger

The battery charger has two slots to insert a battery.



1. Battery status indicator light

Figure 8: DR Detector Battery Charger

Related Links

Safety directions for the power supply on page 71
Charging a battery on page 103
Battery charger indicator lights on page 105
DR 10e, DR 14e, DR 17e Battery Charger on page 120
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 9: DR Detector Switch

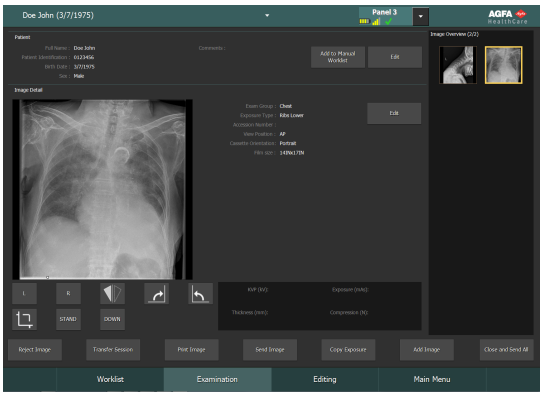


Figure 10: Title bar with DR Detector Switch

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		(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.

Wireless Access Point

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

Related Links

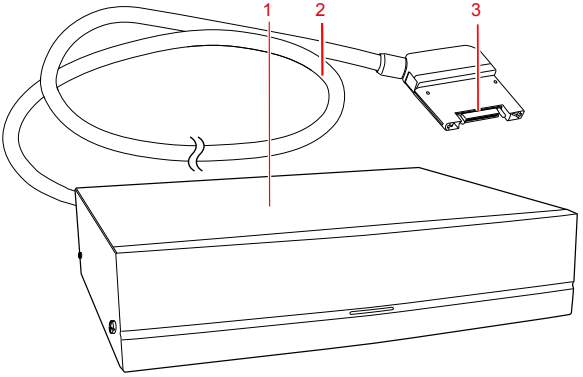
Non-medical equipment on page 14

DR Detector connector cable and power box

The DR Detector connector cable and power box are part of the wired configuration.

The DR Detector connector cable connects the DR Detector to the DR Detector power box.

The DR Detector power box connects the DR Detector to the mains power using a power supply and to the network switch for wired operation.



1. Power box
2. Cable
3. Connector for the DR Detector

Figure 11: DR Detector connector cable and power box

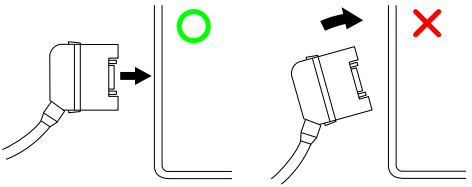
Warning: Only use the dedicated power supply provided with the product.

Topics:

- *Connecting the cable*
- *Disconnecting the cable*
- *Orientation of the cable*
- *Precautions for using the DR Detector connector cable*

Connecting the cable

Push the connector of the cable straight into the connector slot of the DR Detector.

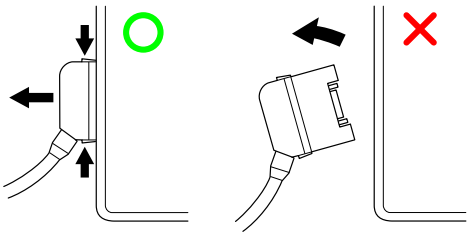


Hold the connector straight and not at an angle, to prevent damage.

Make sure that the latches on both sides of the connector are properly engaged when connecting the connector. If the connector is not inserted completely, the power may turn off.

Disconnecting the cable

1. Press and hold the latches on both sides of the connector.
2. Pull the connector of the cable straight out of the connector slot of the DR Detector.

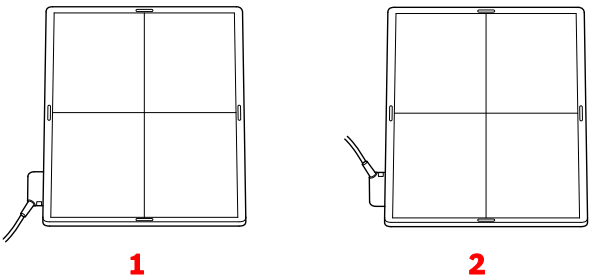


Hold the connector straight and not at an angle, to prevent damage.

Orientation of the cable

The orientation of the connector of the DR Detector connector cable can be changed, to fit the X-ray system in which the detector is used.

To change the orientation of the cable, contact your local service organization.

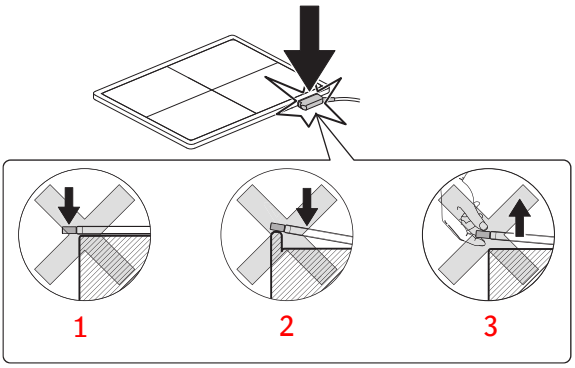


1. Default orientation
2. Alternative orientation

Figure 12: Orientation of the cable

Precautions for using the DR Detector connector cable

When the DR Detector connector cable is used to make an exposure on a bed, follow the precautions below. Otherwise a load may be applied locally to the connector, causing damage to the DR Detector.



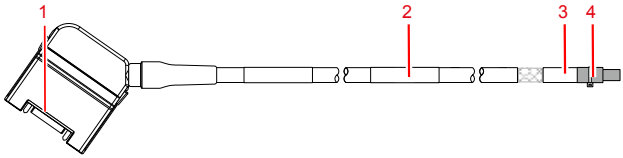
1. Make sure that the connector does not protrude from the edge of a bed.
2. Do not place the connector on a hard surface such as the edge of a bed.
3. Do not raise the DR Detector by holding only the connector.

Figure 13: Precautions for using the DR Detector connector cable

DR Detector registration cable

The DR Detector registration cable is part of the wireless configuration and required for initial setup and for sharing the DR Detector between NX workstations.

The DR Detector registration cable connects the DR Detector to the network.



1. Connector for the DR Detector
2. Cable
3. Part identification label
4. Connector for the network switch

Figure 14: DR Detector registration cable

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).

Safety

- IEC 60601-1

Electromagnetic Compatibility

- IEC 60601-1-2
- The product has been designed in accordance with 2014/53/EU Radio Equipment Directive (RED)

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.

Related Links

Remarks for HF-emission and immunity on page 122

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

Topics:

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.*

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 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

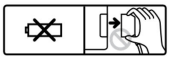
Messages

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 111
Detector Status Indicators on page 101

Labels

Symbol	Explanation
	Tube side
	Direct current
	Alternating current
	Protective earth (ground)
	This mark indicates that the equipment has a Type B applied part
	Handle with care
	Caution for local load. Do not drop the detector on the user or on the patient.
	Maximum patient weight over the whole area of the detector surface
	Maximum patient weight on an area 40 mm in diameter
	Device contains a transmitter module that generates non-ionizing radiation.
	This part is not a battery. Do not disconnect the DR Detector cable during use.
	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
	Indicates the autorized representative in the European Community
	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.
	Recycling identification mark for lithium ion batteries in Japan
	This mark shows the compliance with China RoHS for 10 years.
	Recycling mark in Taiwan
	Safety warning, indicating that the manuals should be consulted.
	Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep manual for future reference.

Topics:

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

- *Additional Labeling of the DR Detector power box*
- *Consulting the About box*

Additional Labeling of the DR Detector

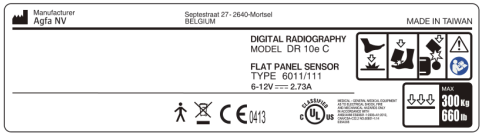


Figure 15: Example of type label

Type label on the back side of the DR Detector.

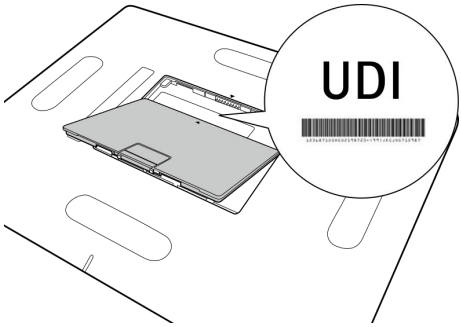


Figure 16: Unique device identification (UDI)

Access the label by removing the battery.

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 17: Example of type label

Type label on the back side of the battery.

Additional Labeling of the DR Detector battery charger

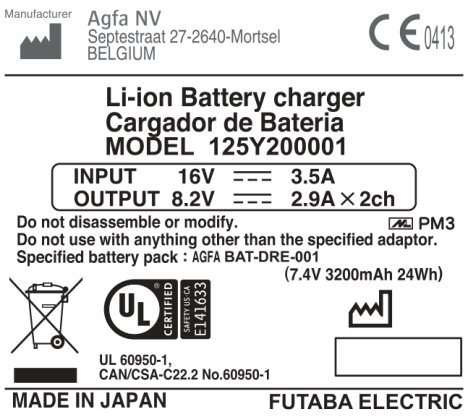


Figure 18: Example of type label

Type label on the bottom side of the battery charger.

Additional Labeling of the DR Detector power box

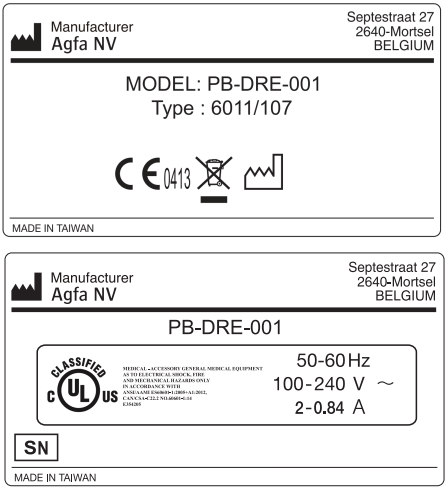


Figure 19: Example of type label

Type label on the back side of the power box.

Consulting the About box

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

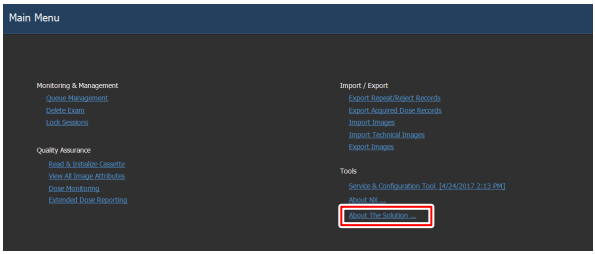


Figure 20: Main Menu window.

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

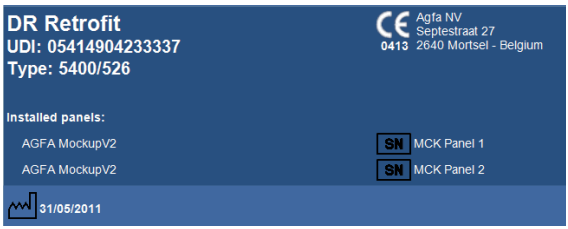


Figure 21: DR Retrofit About box (Displayed data may be different).

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 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 52

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:

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).

Calibration

DR 14e G and DR 17e G do not require calibration.

DR 10e C, DR 14e C and DR 17e C require yearly calibration.

A single set of calibration data is used for all NX Workstations on which the DR Detector is used. Perform the regular calibration each time on the same NX Workstation.

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 22: 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.

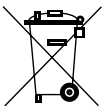


Figure 23: Battery Notice

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.

Disposal

Part of the components contains harmful substances which may pollute the ambient environment if disposed carelessly. In particular, lead is contained in

concentrations > 0.1 wt% in flat panel sensor. For details on product disposal, contact your local Agfa service organization and/or Agfa dealer.

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:
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.

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.

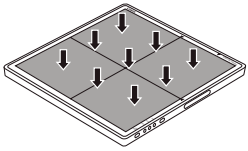
CAUTION:
Excessive ambient temperature may impact performance of DR Detectors and cause permanent damage to the equipment. If ambient temperature and humidity is outside the range of 15 - 35 °C and 15 - 80% RH, do not operate the system or use air conditioning. Warranty will be void if it is obvious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

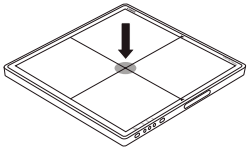
CAUTION:
Turn OFF the power to each piece of equipment for safety when not being used.

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: 300 kg over the whole area of the detector surface. Load limit - Local load: 120 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 and the waterproof function may be compromized. 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:
Be sure that exposures are only made with the tube side of the DR Detector facing towards the X-ray tube. If the rear side of the DR Detector is exposed, no clinical image can be obtained and electric parts inside the detector may be damaged.

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:
Although the DR Detector conforms to IPX3, no warranty is given as to the prevention of water intrusion in the DR Detector. If the DR Detector is splashed with water, wipe off moisture. Be

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

CAUTION:
If the seal that covers a screw peels from the side surface of the DR Detector, contact your local support organization. If the seal is not attached, artifacts caused by discharge of static electricity may appear.

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.

CAUTION:
Do not store magnetic media near the DR detector. Otherwise, magnetism generated by the equipment may cause the data to be lost.

CAUTION:
When not using the DR Detector for making an exposure, protect the DR Detector from X-ray exposure.

Topics:

Safety Directions for the DR Detector battery

CAUTION:

To recharge the battery, use the battery charger specifically designed for the purpose and observe the recharging conditions specified by Agfa. A recharging operation under nonconforming recharging conditions (higher temperature and larger voltage/current than specified, modified battery charger, etc.) can cause the battery to be overcharged, or charged with extremely high current, abnormal chemical reaction can occur in it, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

Do not recharge the battery near fire or in extremely hot weather. Otherwise, hot temperatures can trigger its built-in protective features, inhibiting recharging, or can damage the built-in protective features, causing it to be charged with an extremely high current and voltage and, as a result, abnormal chemical reactions can occur in it, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

If recharging operation fails to complete even when a specified recharging time has elapsed, immediately stop further recharging. Otherwise, electrolyte leakage, overheating, smoke emission, bursting and/or ignition can occur.

Do not use a faulty or broken battery charger or AC adapter.

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.

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.

Do not use the battery for a purpose other than those specified. Otherwise, its guaranteed performance will be lost and/or its service life will be shortened. Depending on the equipment in which the battery is used, excessively high current can flow through battery, possibly damaging it and leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

Use or store the battery only in the specified environmental conditions. If the battery is used or stored in a place where it is exposed to high temperature, the battery pack may emit smoke, ignite, explode or leak fluid.

Recharge the stored battery pack every six months or every year. Otherwise a decrease in battery capacity or other problems may result.

Do not use or subject the battery to intense sunlight or hot temperatures such as in a car in hot weather. Otherwise, electrolyte leakage, overheating and/or smoke emission can occur. Also, its guaranteed performance will be lost and/or its service life will be shortened.

Dispose of properly.

Do not disassemble or modify the battery. The battery is equipped with built-in safety/protection features. Should these features be disabled, the battery can leak electrolyte, overheat, emit smoke, burst and/or ignite.

Be careful not to drop the battery pack. The patient may be injured.

Do not touch the terminal of the battery pack directly. There is a risk of electric shock.

Do not connect the positive (+) and negative (-) terminals with a metal object such as wire. Do not transport or store the battery together with metal objects such as necklaces, hair pins, etc. Otherwise, short-circuiting will occur, over-current will flow, causing the battery to leak electrolyte, overheat, emit smoke, burst and/or ignite, or the metal object such as wire, necklace or hair pin can generate heat.

Do not discard the battery into fire or heat it. Otherwise, its insulation can melt down, its gas release vent or safety features will be damaged and/or its electrolyte can ignite, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition on it.

Do not use or leave the battery near a heat source such as a fire or a heater (+80°C or higher). If the resin separator should be damaged owing to overheating, internal short-circuiting may occur to the battery, possibly leading to electrolyte leakage, smoke emission, bursting and/or ignition of the battery.

Do not immerse the battery in water or seawater and do not allow it to get wet. Otherwise, the protective features in it can be damaged, it can be charged with extremely high current and voltage, abnormal chemical reactions may occur in it, possibly leading to electrolyte leakage, smoke emission, bursting and/or ignition.

Do not pierce the battery with a nail or other sharp objects, strike it with a hammer, or step on it. otherwise, the battery will become damaged and deformed, internal short-circuiting can occur, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

Do not strike or throw the battery. The impact might cause leakage, overheating, smoke emission, bursting and/or ignition. Also, if the protective feature in it becomes damaged, it could become charged with an extremely high current and voltage, abnormal chemical reactions can occur, which can lead to electrolyte leakage, overheating smoke emission, bursting and/or ignition.

Do not use an apparently damaged or deformed battery. Otherwise, electrolyte leakage, overheating, smoke emission, bursting and/or ignition of the battery may occur.

Do not directly solder the battery. Otherwise, heat can melt down its insulation, damage its gas release vent or safety features, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

The positive (+) and negative (-) terminals are arranged in a particular orientation. Do not force the connection if you cannot easily connect the battery terminals to the battery charger or other equipment. Confirm that the terminals are correctly oriented. Reversing the terminals will result in reverse-charging, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition of the battery.

Do not connect the battery to an electrical outlet, vehicle cigarette lighter, etc. When subjected to large voltage, over-current can flow on the battery pack, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

If the battery leaks and the electrolyte gets into the eyes, do not rub them. Instead, rinse the eyes with clean running water and immediately seek medical attention. Otherwise, eye injury may result.

Do not use the battery in combination with primary battery (such as dry-cell battery packs) or battery of different capacities or brands. Otherwise, the battery can be overdischarged during use or overcharged during recharging, abnormal chemical reactions may occur, possibly leading to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

Do not put the battery into a microwave oven or pressurised container. Rapid heating or disrupted sealing can lead to electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

If the battery leaks or gives off a bad odour, remove it from any exposed flame. Otherwise, the leaking electrolyte may catch fire and the battery may emit smoke, burst or ignite.

If the battery gives off an odour, generates heat, becomes discoloured or deformed, or in any way appears abnormal

during use, recharging or storage, immediately remove it from the equipment or battery charger and stop using it. Otherwise, the problematic battery can develop electrolyte leakage, overheating, smoke emission, bursting and/or ignition.

Do not use the battery exposed to a strong magnetic field of an MRI system, etc.

Do not use the battery immersed in liquid.

Do not cover the holes in the battery charger with foreign matter.

Avoid the accumulation of dust on the battery charger.

Insert the battery pack into the battery charger securely.

When inserting the battery pack, prevent foreign matter from getting into the battery charger.

When inserting the battery pack, make sure that orientation of the battery pack is correct. If the battery is forcibly inserted in the wrong orientation, both the batter pack and the battery charger may be damaged and emit smoke, ignite, leak fluid or cause electric shock.

While charging the battery, do not allow the battery pack or battery charger get wet or dusty.

Do not step on the AC adapter of the battery charger. Also, be careful not to trip over the power cable.

Do not place the battery charger within the reach of patients.

Safety Directions for the DR Detector power box

WARNING:

Do not touch the patient's body while touching the image processing unit. Otherwise, the patient may receive an electric shock.

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

CAUTION:

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

Follow the specified procedure when turning off the equipment. Otherwise, the flat panel sensor could be damaged by thermal shock.

Do not install the device in a high place. If the cable is pulled, the device may fall down, leading to damage to the device or personal injury.

Position the device so that it is possible to disconnect the mains power connection if required.

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 (wireless configuration)

CAUTION:
Do not use the battery pack as a power source for equipment other than DR 10e, DR 14e or DR 17e detectors. Be sure to use only the dedicated battery pack for the DR 10e, DR 14e or DR 17e detector.

CAUTION:
Monitor the battery status. If the charging level of the battery is low, the battery has to be charged or replaced by another battery.

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

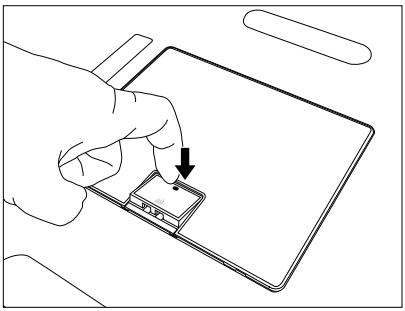
To start the DR Detector:

1. Fully charge the battery.

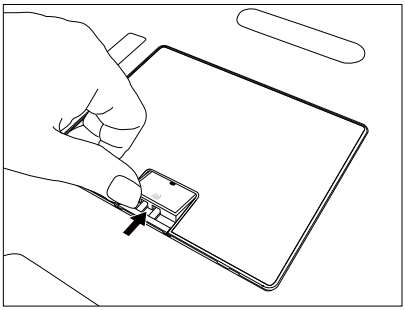
   Charge the battery on the day of examination or on the previous day.

   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. Remove the cover plate of the battery bay.
   a) Push the lock lever at the side with the dot.

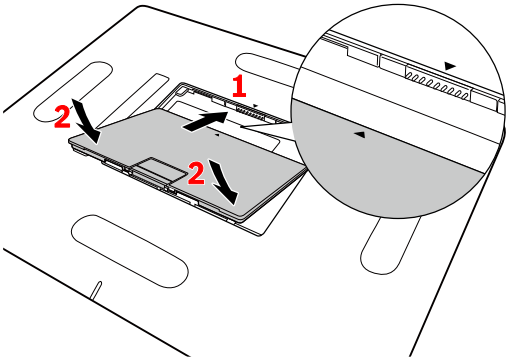
   

   b) Slide the lock lever in the direction of the arrow.



c) Grip the lock lever to pull out the cover plate.

3. Attach the battery.



1. Align the battery according to the guide marks. Insert the battery fully.
2. Push down the battery.

Figure 24: Attach the battery

The battery is locked in position automatically.

Note: *Make sure that the battery is securely attached.*

The detector starts up. The power indicator lights up green.

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. In that case, register the DR Detector to the NX workstation.

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

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

Related Links

Charging a battery on page 103

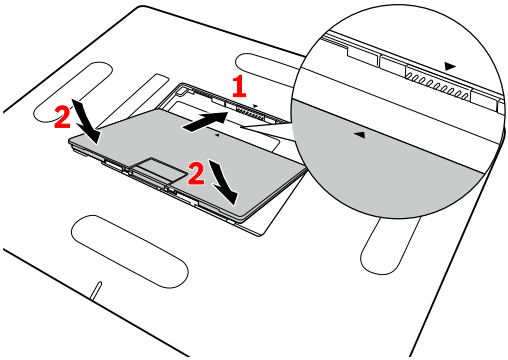
Detector Status Indicators on page 101
Registering the DR Detector on another NX Workstation on page 108
Problem solving on page 111

Starting the DR Detector (wired configuration)

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

To start the DR Detector:

1. Atach the cover plate of the battery bay if no battery is attached.



   1. Align the cover plate according to the guide marks. Insert the cover plate fully.
   2. Push down the cover plate.

   Figure 25: Attach the cover plate of the battery bay

   The cover plate is locked in position automatically.
2. Plug the power cable of the DR Detector power box into a mains power socket.
   The power status light on the front panel of the DR Detector power box lights up.
3. Connect the DR Detector cable.

   Push the connector of the cable straight into the connector slot of the DR Detector.

   The detector starts up. The power indicator lights up green.
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. In that case, register the DR Detector to the NX workstation.

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

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

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

Automatic exposure detection on page 97
DR Detector Switch on page 21

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 10e

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

- tube side
- patient orientation marker

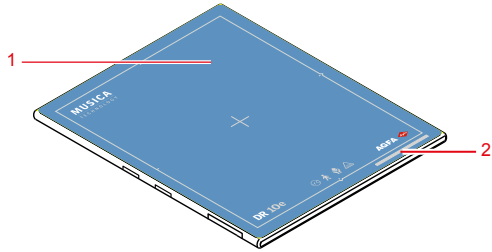


Figure 26: Detector orientation aids

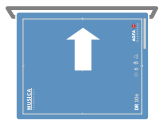
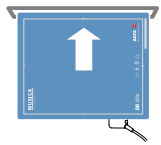
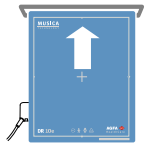
1. Tube side of the detector
2. Location of the patient orientation marker

   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, portrait		
Table with bucky, landscape		

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

Note: *Depending on the design of the bucky, the wired configuration may not support the use of the DR Detector in the bucky.*

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

Positioning the DR 14e

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

- tube side
- patient orientation marker

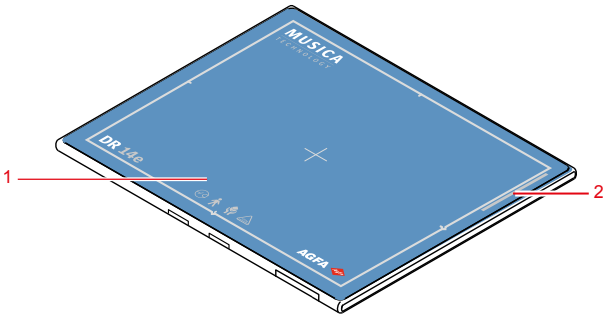


Figure 27: Detector orientation aids

1. Tube side of the detector
2. Location of the 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.

Below some examples to illustrate the importance of the detector orientation marker.

Table 2: Skull AP portrait

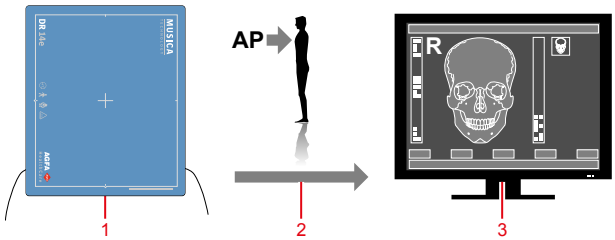


Figure 28: Skull AP portrait

1. Detector orientation (Portrait)
2. Patient orientation (AP)
3. Result on monitor

Table 3: Chest PA Landscape

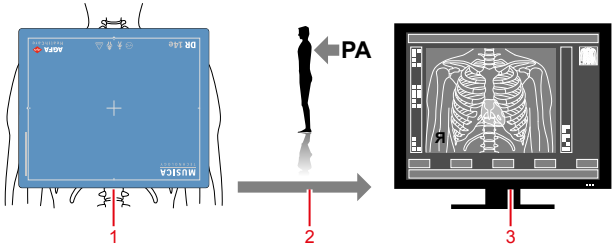
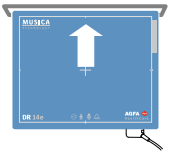
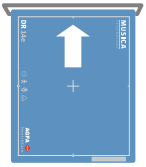
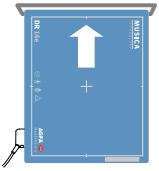


Figure 29: Chest PA landscape

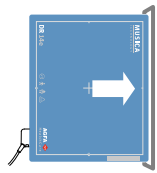
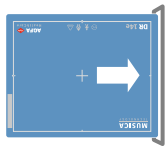
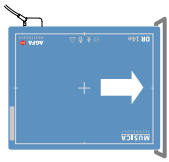
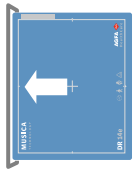
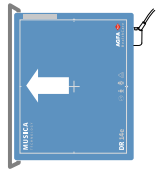
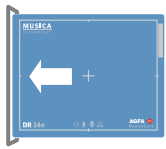
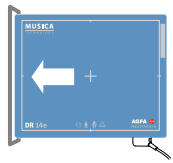
1. Detector orientation (Landscape)
2. Patient orientation (PA)
3. Result on monitor

Table 4: 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 5: Wallstand bucky

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

Note: *Depending on the design of the bucky, the wired configuration may not support the use of the DR Detector in the bucky.*

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

Positioning the DR 17e

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

- tube side
- patient orientation marker

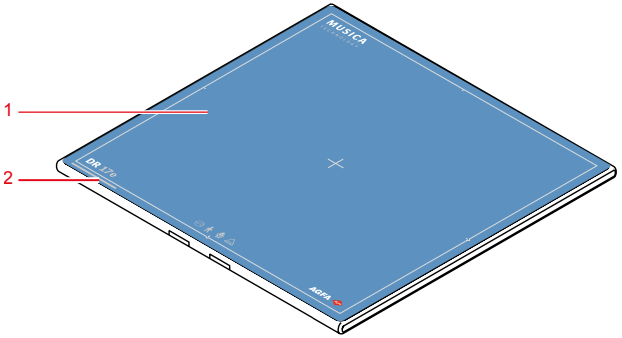


Figure 30: Detector orientation aids

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

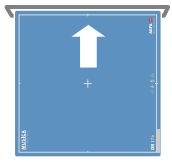
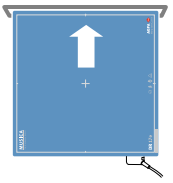
   The detector must be positioned with the patient orientation marker at the lower side of the region of interest.

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.

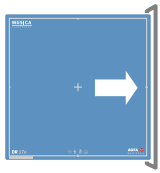
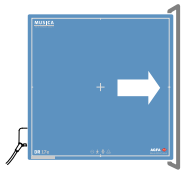
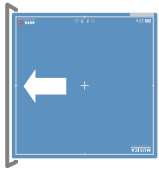
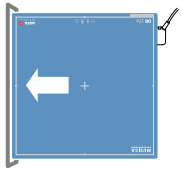
Below some examples to illustrate the importance of the detector orientation marker.

Table 6: Table with bucky

Table with bucky		

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

Table 7: Wallstand bucky

Wallstand with left loading bucky		
Wallstand with right loading bucky		

Note: *Depending on the design of the bucky, the wired configuration may not support the use of the DR Detector in the bucky.*

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

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.

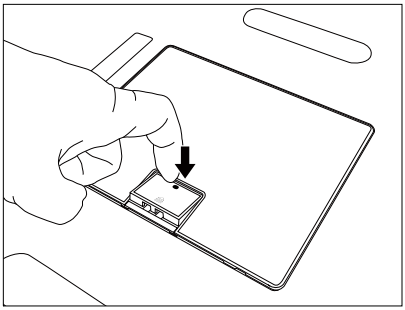
- Image only the indicated area.
- Use the lowest amount of radiation for adequate imaging based on size of the child (reducing tube output -- kVp and mAs, limiting the duration of dynamic imaging).
- Try to use always short exposure times, large SID values and immobilizing devices.
- Avoid multiple scans and use alternative diagnostic studies (such as ultrasound or MRI) when possible.

Stopping the DR Detector (wireless configuration)

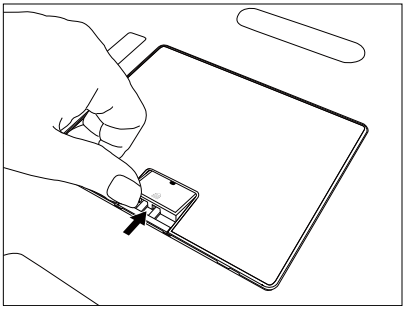
WARNING:
When the detector will not be used for some time, remove the battery. Otherwise, overdischarge may occur, leading to a shorter battery life.

To stop the DR Detector:

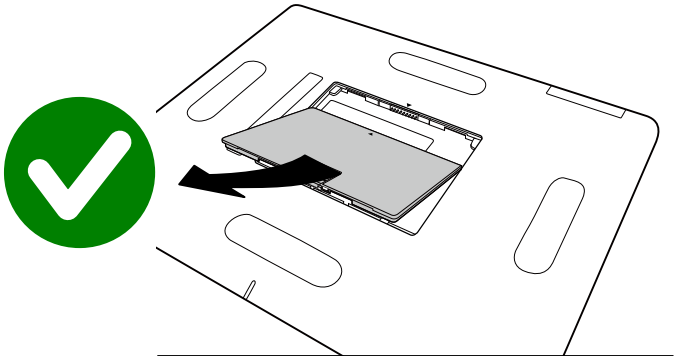
1. Remove the battery.
   a) Push the lock lever at the side with the dot.



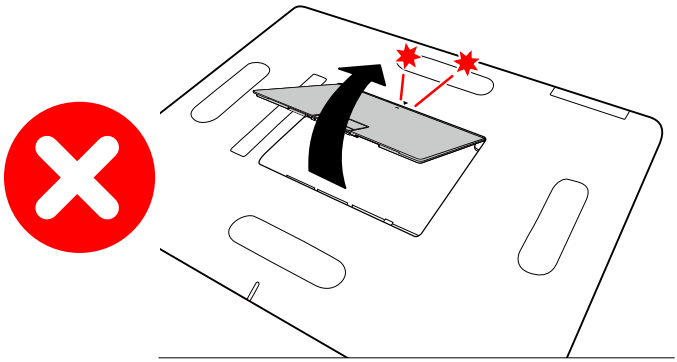
   b) Slide the lock lever in the direction of the arrow.



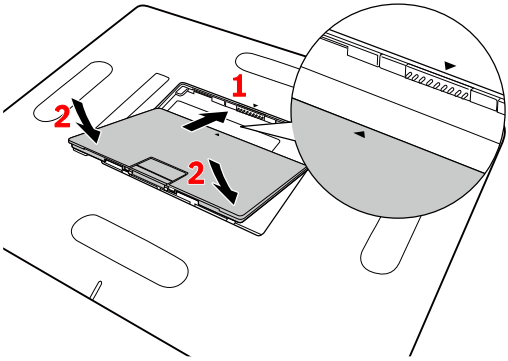
   The battery is unlocked.
   c) Grip the lock lever to pull out the battery as indicated on following drawing.



Do not try to remove the battery by flipping it over towards the side of the electrical connector. This will cause damage to the battery.



2. Attach the cover plate to protect the battery bay.



1. Align the cover plate according to the guide marks.
2. Push down the cover plate.

Figure 31: Attach the cover plate

The cover plate is locked in position automatically.

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 103
Storing a battery on page 107

Topics:

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.

The power indicator and the battery status indicator remain on.

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.

The power indicator remains on. The battery status indicator is off.

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

Stopping the DR Detector (wired configuration)

The DR Detector is connected to the DR Detector power box. No battery is attached to the DR Detector.

To stop the DR Detector:

1. Disconnect the DR Detector cable.

   Press and hold the latches on both sides of the connector.

   Pull the connector of the cable straight out of the connector slot of the DR Detector.
2. Unplug the power cable of the DR Detector power box.

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

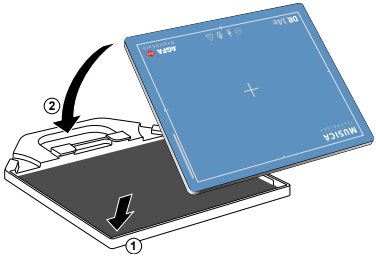
WARNING:
Very short exposure time can cause failure to trigger the image acquisition. Use an exposure time of at least 1 ms.

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.

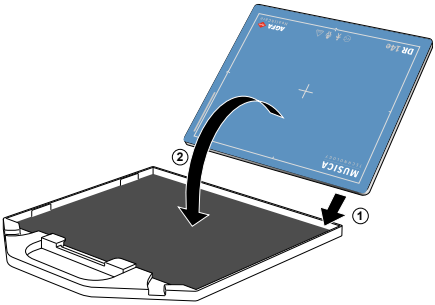
Attaching the handle unit without anti-scatter grid



To attach the handle unit for making exposures without using the grid

1. Lay down the handle unit on a flat surface.
2. Lay the DR detector in the handle unit, bottom edge first, with the tube side facing up (1).
3. Attach the handle unit to the DR detector (2).

Attaching the handle unit with anti-scatter grid



CAUTION:
To safely attach the handle unit for making exposures using the grid, follow these instructions.

1. Lay down the grid on a flat surface.
2. Lay the DR detector in the grid, bottom edge first, with the tube side facing down (1).
3. Attach the grid to the DR detector (2).

WARNING:
Use only the grid that is supplied as option to the DR detector.

Advanced Operating

Topics:

Detector Status Indicators

Table 8: DR Detector status

Indicator	Light	Status X-ray generator synchronization	Status Automatic exposure detection
Status indicator	OFF	Not ready for exposure	
	Green	-	Ready status
	Green Blinking	Ready status	During image transmission
Power indicator	OFF	Power off	
	Blue	Power on	
Error indicator	OFF	Normal	
	Orange Blinking	An error has occurred	
Connection indicator	OFF	No communication with the NX workstation	
	White	Connected to the NX workstation	

Related Links

Problem solving on page 111

Battery Status Indicator

Table 9: Battery status during wireless operation (battery is discharging)

Status indicator	Charging level of the battery
	Available time: 60 minutes or more
	Available time: 20 minutes or more but less than 60 minutes
	Available time: Less than 20 minutes
 The orange dot lights up.	Available time: 10 minutes or less

Table 10: Battery status while connected to the power box (battery is charging)

Status indicator	Charging level of the battery
	Available time: Less than 30 minutes
	Available time: 30 minutes or more but less than 60 minutes
	Available time: 60 minutes or more
	Fully charged

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 66
DR Detector Battery Charger on page 20

Topics:

Inserting the battery in the battery charger

Insert the battery in the battery charger.

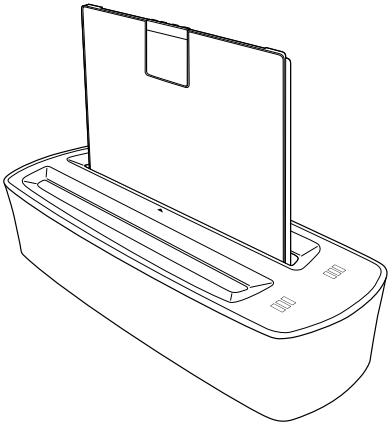


Figure 32: Inserting the battery in the battery charger

The battery charger produces a sound signal and the indicator lights light up.

Battery charger indicator lights

The battery charger has two 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 11: Battery status display

Label	Status
	The battery is being charged. Available time: Less than 30 minutes.
	The battery is being charged. Available time: 30 minutes or more but less than 60 minutes.
	The battery is being charged. Available time: 60 minutes or more.
	The battery is fully charged.
	Battery error. Battery charging not possible.
	Battery charger error. Contact your local service organization.
	Charging temperature is out of range.

CAUTION:
Charge the battery in the operating environment.

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 produces a sound signal and the indicator lights light up.
2. Remove the charged 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	-20°C – +50°C

Registering the DR Detector on another NX Workstation

The DR Detector can be used for examinations on different NX workstations. 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.

In a configuration with multiple NX workstations sharing a DR Detector, each NX workstation is equipped with a DR Detector connector cable (wired configuration) or a DR Detector registration cable (wireless configuration).

To register the DR Detector and make a connection to another X-ray room:

1. Make sure that no empty thumbnail is selected in the NX workstation, so no other DR Detector is active.
2. Connect the DR Detector to the NX workstation using the DR Detector Cable.

   Wait for the DR Detector Switch to display the wired connection icon.

   The DR Detector is set up to make connection to the selected NX workstation.
3. To operate wireless, disconnect the DR Detector registration cable.

In specific configurations, the DR Detector turns to error status directly after registration to another NX workstation, or after attempting a first exposure. In this case, the DR Detector must be started again by removing the battery and inserting it again.

Related Links

Starting the DR Detector (wireless configuration) on page 74
Stopping the DR Detector (wireless configuration) on page 92

Renewing the EPS license

The EPS variant of the DR detector requires an active EPS license (Easy Payment Scheme). The EPS license is stored on the licensing dongle that is plugged into the NX workstation. The EPS license must be renewed at regular intervals via an online web portal.

The EPS variant of the DR detector is identified by the word "EPS" printed next to the model name at the back side of the DR detector.

The DR detector must only be used for making exposure using the NX software. If an NX workstation is configured with an EPS variant of the DR detector, no other DR detectors can be additionally be configured on the NX workstation. If an EPS DR detector is shared between NX workstations, an EPS license must be stored on the dongle of each of the workstations and the procedure for renewing the EPS license must be performed for each dongle.

Five days before the renewal of the EPS license is due, messages start to appear on the NX workstation.

WARNING:
In case the renewal due date is not met, the license expires and the DR detector cannot be used for examinations until the license is renewed. If the product is used in critical clinical workflows, a backup system has to be foreseen.

1. Plug in the dongle on a PC with access to the internet.
   - If the NX workstation has access to the internet, the renewal procedure can be performed on the NX workstation.
   - If the NX workstation has no access to the internet, remove the dongle from the NX workstation and plug it in on a PC with access to the internet.

   Note: Do not leave the NX workstation running without the dongle for more than a day. If the dongle is not plugged in again after a day, the license grace period will eventually run down.
2. Open a browser and navigate to the online web portal for EPS.
   http://www.licensing.healthcare.agfa.net
3. Log in to the web portal and follow the instructions on the screen.

   After completing the procedure, the EPS license is renewed and stored on the dongle.
4. Reinsert the dongle into the NX workstation.
5. Stop the DR detector.

6. Start the DR detector again.

The DR detector is now using the new license.

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).

DR Detector status is not changing to ready for exposure

Details	Select the thumbnail for an exposure in the Image Overview pane of the Examination window. The DR Detector Switch shows the active DR Detector and shows its status. The DR Detector status is not changing to ready for exposure.
Cause	The DR Detector is performing an internal process.
Brief Solution	Wait at least 2 minutes and select the thumbnail again.

DR Detector is not switched to standby or switched off automatically

Details	The DR detector is configured to switch to standby (sleep) or to switch off after not being used for a specific time, but it stays active.
Cause	In following conditions, the DR detector will not be switched to standby or be switched off automatically: • On the NX workstation an empty thumbnail is selected for an exposure on the DR detector • The NX software is not running • The DR detector is out of range of the wireless network • The DR detector is being calibrated • The DR detector is in error
Brief Solution	Make sure none of the above conditions apply.

A program is preventing Windows from logging off

Details	Log out of Windows. Windows is waiting for a program that is preventing Windows from logging off.
Cause	A program that is part of the DR Detector software is running when logging out of Windows.
Brief Solution	Wait for the log off to continue or click **Force log off**.

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.

Technical Data

Topics:

DR 10e, DR 14e, DR 17e

Electrical connection DR Detector	
Rated power supply (powered by battery pack)	6–12V 2.73A DC
Rated power supply (powered by power box)	100–240V 2–0.84A 50–60Hz AC
Wireless connection	IEEE 802.11n (2.4 GHz/5 GHz)
Environmental conditions (during normal operation)	
Room temperature	between +15 °C and +35 °C
Humidity (non condensing)	between 15% and 80% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa
Environmental conditions (during storage)	
Temperature (ambient)	between -30 °C and +50 °C
Humidity (non condensing)	between 10% and 90% (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa
Warming-up time	
30 minutes	
Dimensions	
Dimensions width x length x height	DR 10e: 268 x 328 x 15 mm DR 14e: 384 x 460 x 15 mm DR 17e: 460 x 460 x 15 mm
Weight (incl. battery)	DR 10e: 1.47 kg DR 14e: 2.95 kg DR 17e: 3.65 kg
Maximum total load	300 kg over the whole detector surface

Maximum load	120 kg on an area of 40 mm in diameter
Vibration tolerance	0.03 mm p-p (10 - 57.5 Hz) 0.2 G (57.5 - 150 Hz)
Shock tolerance	7 m/s^2
Drop limit	1200 mm (once)
Throughput (images per hour)	240 images per hour
Radio frequency band and maximum power	2400-2483.5 MHz: 100 mW (EIRP) 5150-5350 MHz and 5470-5725 MHz: 200 mW (EIRP)
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 years

Conversion screen	DR 10e C (6011/111): CsI DR 14e C (6011/101): CsI DR 14e G (6011/102): Gadox DR 17e C (6011/103): CsI DR 17e G (6011/104): Gadox
Pixel size	150 μm
Pixel matrix	DR 10e: 1536 x 1920 DR 14e: 2336 x 2836 DR 17e: 2832 x 2836
Detector type	amorphous silicium
Effective area size	DR 10e: 230.4 mm x 288.0 mm DR 14e: 350.4 mm x 425.4 mm DR 17e: 424.8 mm x 425.4 mm

DR 10e, DR 14e, DR 17e Battery

Type of product	Rechargeable lithium ion battery pack
Model	125N120009 2ICP/34/50-4
Dimensions	
Dimensions (length x width x height)	172.2 mm x 143.1 mm x 7.2 mm
Weight	230 g
Battery output	
Output voltage	DC +7.4 V
Capacity	3200 mAh
Lifecycle	
Preventive maintenance frequency.	No preventive maintenance required.
Estimated product life	after 400 charge cycles the remaining capacity will be at least 75%.

DR 10e, DR 14e, DR 17e Battery Charger

Type of product	Lithium ion battery pack charger
Model	6011/105
Charging time	3 hours
Simultaneous charging	2 batteries
Water ingress	IPX0 This device does not have protection against ingress of water.
Dimensions	
Dimensions (width x height x depth)	92.5 mm x 56.0 mm x 259.0 mm
Weight	0.6 kg
Electrical connection	
Rated Power Supply of the battery charger	16V 3.5A DC
Rated Power Supply of the AC adapter	100-240 V AC/1.5 A 50-60 Hz
Environmental conditions (during normal operation)	
Room temperature	between 0 °C and 35 °C
Humidity (non condensing)	between 10% and 85% RH (non-condensing)
Environmental conditions (power can be supplied, no normal operation)	
Room temperature	between -20 °C and +60 °C
Humidity (non condensing)	between 10% and 95% RH (non-condensing)
Lifecycle	
Preventive maintenance frequency.	No preventive maintenance required.

DR 10e, DR 14e, DR 17e Power Box

Model	6011/107
Original model number	PB-DRE-001
Dimensions	
Dimensions (width x height x depth)	259 mm x 70 mm x 205 mm
Weight	3.2 kg
Electrical connection	
Rated Power Supply	100-240 V AC, 2-0.84 A, 50-60 Hz
Environmental conditions (during normal operation)	
Room temperature	between 15 °C and 35 °C
Humidity (non condensing)	between 15% and 80% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa
Environmental conditions (power can be supplied, no normal operation)	
Room temperature	between 5 °C and 35 °C
Humidity (non condensing)	between 10% and 80% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa
Environmental conditions (storage)	
Room temperature	between -30 °C and 50 °C
Humidity (non condensing)	between 10% and 90% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa

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.

WARNING:
Do not place devices generating electromagnetic wave near this equipment.

WARNING:
If devices other than those specified are connected, predetermined EMC performance cannot be guaranteed.

WARNING:
Do not use mobile RF communications equipment within 30 cm (11.8 inch) of this equipment.

WARNING:
The DR detectors might be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

WARNING:
Do not use this equipment near devices that generate strong electromagnetic waves, such as thermotherapy devices or HF surgical equipment.

WARNING:
If this equipment is used near commercially available electronic devices, such as mobile phones, laptop computers or home appliances, which generate electromagnetic waves, this

equipment may malfunction due to electromagnetic interference.

WARNING:
The emissions characteristics of this equipment make it suitable for use in industrial areas and residential environments and hospitals (CISPR 11 class B). If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

WARNING:
Do not use this equipment near X-ray units other than the designated mobile X-ray units or near large medical devices, such as MRI scanners or X-ray CT scanners.

WARNING:
If this equipment complies with IEC 60601-1-2, the personal computer, hub and access point are provided with an isolation adapter. Do not remove the cover during use. If removed, the special EMC performance cannot be guaranteed.

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.

Cables, transducers and accessories

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

Electromagnetic emissions

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

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

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

Emissions test	Compliance	Electromagnetic Environment Guidelines
RF emissions in accordance with CISPR 11	Group 1	This DR Detector uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions in accordance with CISPR 11	Class 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	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	Complies	

Note: IEC 61000-3-2 and IEC 61000-3-3 are applicable only to the devices with a rated voltage of 220 V AC or higher.

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.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 5 s	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Magnetic field at the supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
• Note: U_T is the alternating current in the network before the application of the test level.			

Tests of Resistance to Disruption	**IEC 60601-1-2:2014 Test Level**	**Level of Agreement**	**Electromagnetic Environment**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz ISM frequency band Amateur radio band	3 V See next table	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended protective distance: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where 'P' is the maximum output power rating of
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity fields from RF	10 V/m See next table	

			the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 – At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.

b) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Table 12: Test compliance levels between portable and mobile RF communications equipment and the DR detector

ISM (Industrial, Scientific and Medical) frequency band compliance level			
Frequency MHz	**Test level** V	**Frequency** MHz	**Test level** V
6.765	6	13.553	6
26.957	6	40.66	6
Amateur radio band compliance level			
Frequency MHz	**Test Level** V	**Frequency** MHz	**Test level** V
1.8	6	3.5	6
5.3	6	7	6
10.1	6	14	6
18.07	6	21	6
24.89	6	28	6
50	6		
Proximity fields from RF compliance level			
Frequency MHz	**Test level** V/m	**Frequency** MHz	**Test level** V/m
385	27	450	28
710	9	745	9
780	9	810	28
870	28	930	28
1462	10	1720	28
1845	28	1970	28
2450	28	3540	10
5240	9	5500	9
5785	9		

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. and Canada

This device complies with Part 15 of FCC Rules and Industry Canada's licence-exempt RSSs.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC WARNING:

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

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.

The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power Wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research.

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 and meets the FCC radio frequency (RF) Exposure Guidelines. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment.

This equipment has been tested and found to comply with IC radiation exposure limits and meets the RSS-102 of the IC radio frequency (RF) Exposure rules.

Compliance with FCC requirement 15.407(c) and IC requirment RSS-210 A9.4.4 Data transmission is always initiated by software, which is then passed

down through the MAC, through the digital and analog baseband, and finally to the RF chip. Several special packets are initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which it then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted. In other words, this device automatically discontinue transmission in case of either absence of information to transmit or operational failure.

Radio waves in the 5.2 GHz and 5.3 GHz frequency bands can be used indoors only.

High-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Frequency Tolerance : ±20 ppm

(This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.)