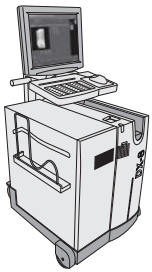
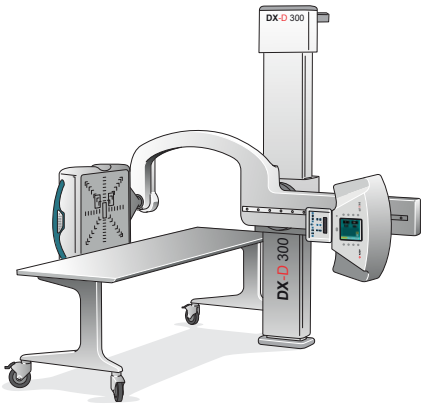
DX-D 300

8207/050

User Manual





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AGFA

Contents

Legal Notice

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Agfa NV, Septestraat 27, 2640 Mortsel - Belgium

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

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Introduction to this Manual

Topics:

Scope

This User Manual describes the features of the DX-D 300 System, an integrated Digital Radiography X-Ray System to be used as medical diagnostic aid in General Radiography and emergency departments. It explains how the different components of the DX-D 300 System work together.

About the safety notices in this document

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

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

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

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

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

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

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

Disclaimer

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

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

Note: *In the United States, Federal law restricts this device on order of a physician for prescription use only.*

Introduction

Topics:

Intended Use

The DX-D 300 system is an integrated X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients.

Applications can be performed with the patient in the sitting, standing or lying position.

This device is not intended for mammography applications.

Intended User

This manual has been written for trained users of Agfa products and trained diagnostic X–Ray clinical personnel who have received proper training.

Users are those persons who actually handle the equipment and those who have authority over the equipment.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

DX-D 300 is a DR X-ray system (Direct Radiography X-ray system) that can be combined with components from a CR X-ray system.

The complete DX-D 300 consists of the following components:

- Vertical column with U-arm
- X-Ray tube with automatic collimator with DAP (dose area product meter)
- Integrated 4343R DR Detector or DR Detector Bucky
- Portable DR Detector
- Mobile table
- X-Ray generator
- NX workstation

The DR Detector bucky has two variants. Depending on the configuration, the use of the DR Detector bucky is restricted to

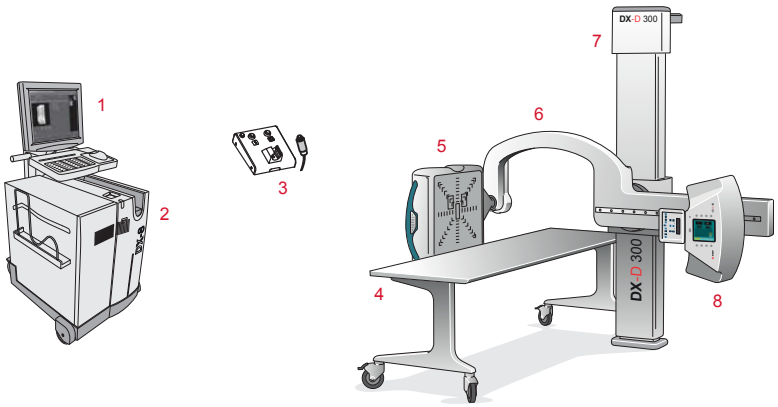
- DR Detectors with a size equivalent to 14x17 inch (43x35 cm) and 43x35 CR Cassettes
- DR Detectors with a size equivalent to 17x17 inch (43x43 cm)

The DX-D 300 configuration with integrated DR Detector automatically detects the grid status. The DX-D 300 configuration with DR Detector Bucky does not detect the grid status.

DX-D 300 can be used in combination with:

- CR digitizer

DX-D 300 supports the Full Leg Full Spine application using the integrated 4343R DR Detector or a portable DR Detector in the DR Detector bucky.

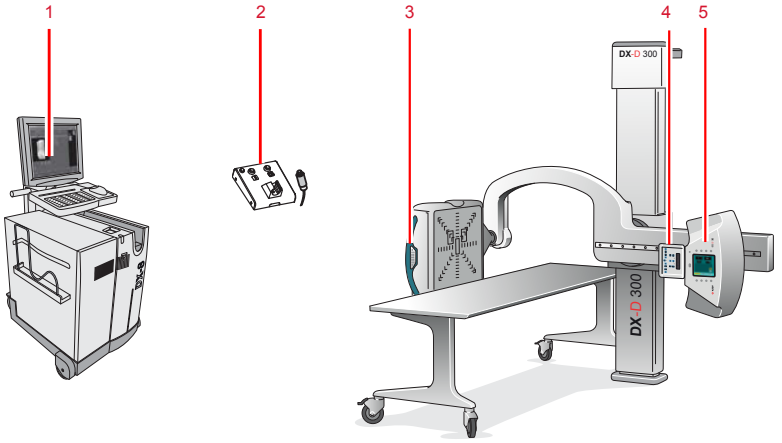


1. NX workstation
2. In-room CR Digitizer

3. X-Ray Generator Control
4. Mobile table
5. DR Detector
6. U-arm
7. Vertical column
8. X-Ray tube

Figure 1: DX-D 300 configuration with integrated DR Detector

Operation Controls



1. NX application and software console
2. X-Ray generator control box
3. DR Detector handle control buttons
4. Collimator control panel
5. U-arm control panel

Figure 2: DX-D 300 operation controls

Topics:

- *MUSICA Acquisition Workstation (NX)*
- *Software Console on the NX Workstation*
- *DR Detector Switch*
- *X-Ray generator control in the operator room*
- *U-arm control panel*
- *Control panel of the collimator*
- *DR Detector handle control buttons*
- *U-arm remote control*
- *Portable DR detector*
- *Emergency stop button*
- *Emergency shutdown power switch*

MUSICA Acquisition Workstation (NX)

The MUSICA Acquisition workstation is used to define patient information, select exposures and process images.

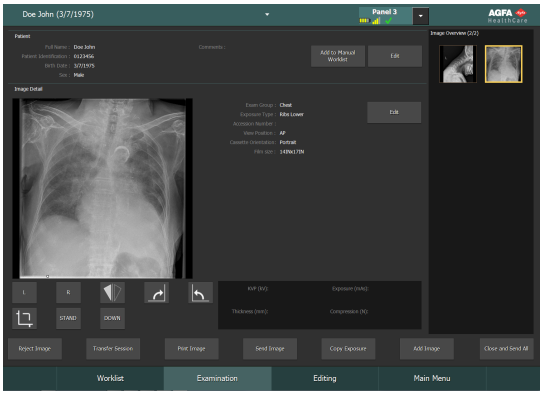


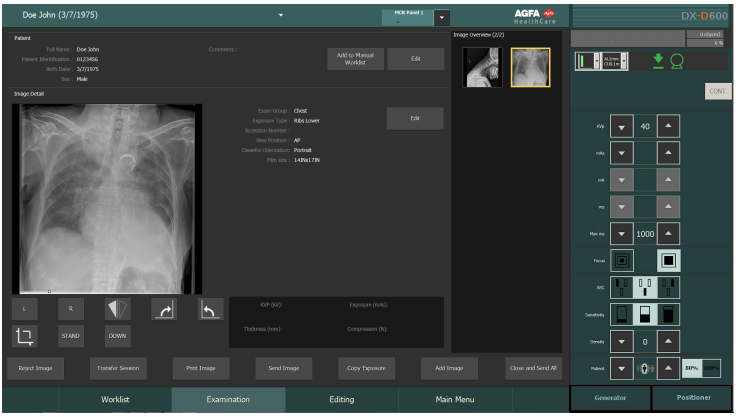
Figure 3: MUSICA Acquisition workstation software

The operation of the workstation application is described in the MUSICA Acquisition Workstation User Manual, document 4420.

The software is further referred to as "NX" and the pc on which it runs the "NX workstation".

Software Console on the NX Workstation

The Software Console is used to control X-Ray generator settings and X-Ray system position.



The software console has two screens:

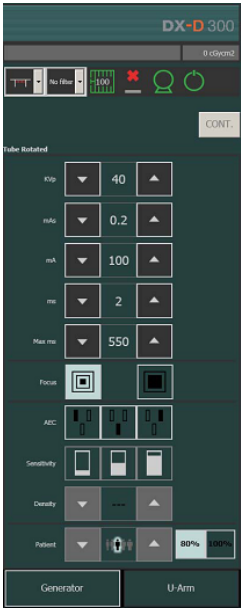


Figure 4: X-Ray generator controls

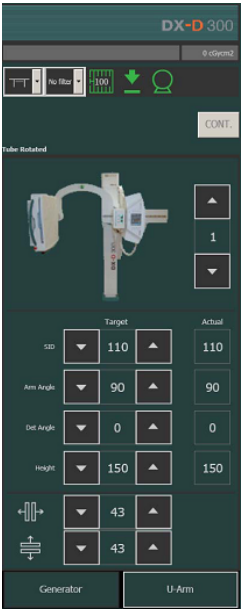


Figure 5: X-Ray system automatic positioning controls

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 6: DR Detector Switch

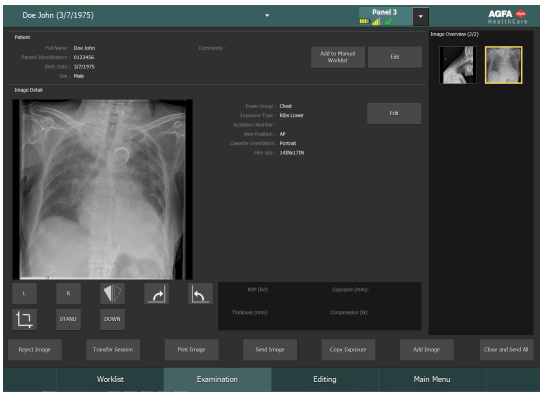


Figure 7: Title bar with DR Detector Switch

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

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

DR Detector status icon				(empty)
		(blinking)		

Meaning	DR detector is ready for exposure	DR detector is initializing for exposure	DR detector is off or disconnected or in error	DR detector is inactive (no thumbnail selected)

X-Ray generator control in the operator room

The X-Ray generator control box contains buttons to switch on and off the X-Ray generator and a handswitch to make exposures.

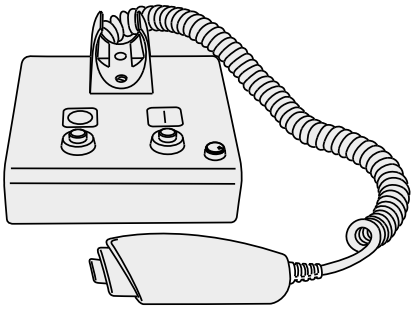


Figure 8: the X-Ray generator control box

Following warning is printed on the X-ray generator control box in English:

WARNING:
This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

U-arm control panel

On the U-arm.the control panel with touch screen console and control buttons to control X-Ray generator settings and U-arm position.

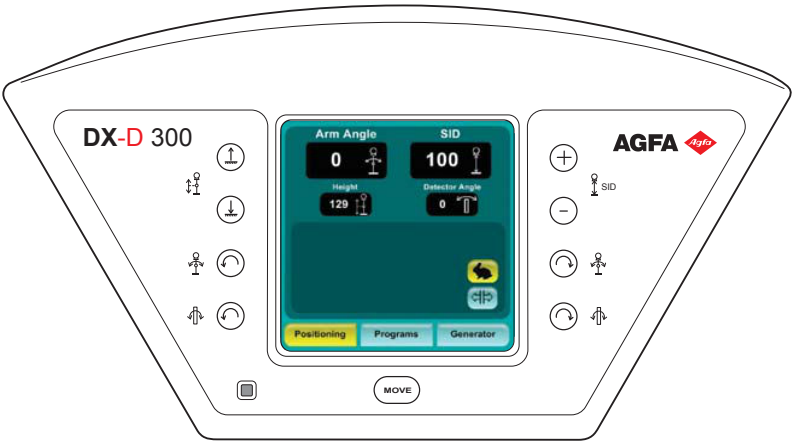


Figure 9: U-arm control panel

Control panel of the collimator

The control panel of the automatic collimator:

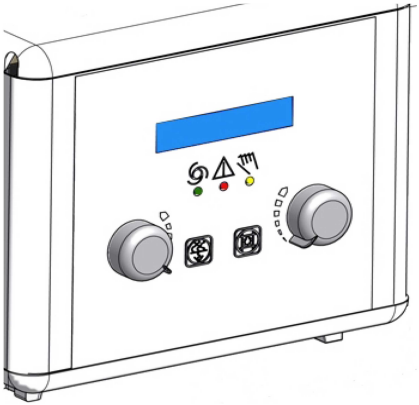


Figure 10: the control panel of the automatic collimator

The display shows the dimensions of the collimated area and of the source image distance (SID) in centimeters or in inches. Values in centimeter have no decimal point. Values in inches have one digit after the decimal point.

DR Detector handle control buttons

The DR Detector handle control buttons to control the U-arm position

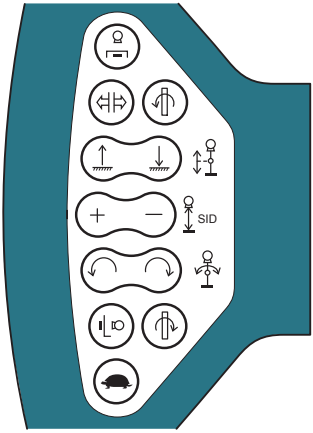


Figure 11: DR Detector handle control buttons

U-arm remote control

The remote control to control U-arm position

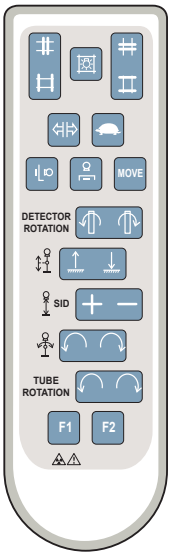


Figure 12: U-arm remote control

Portable DR detector

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

Table 1: Orientation aids

	Tube side icon, indicating the side that faces the X-ray tube
	Patient orientation marker, red rectange printed at the corner of the detector, for consistent orientation relative to the patient

For an overview of the operation controls of the DR detector, refer to the user manual of the DR detector.

The DR detector may come in contact with the patient.

Note: DR detectors that operate wireless contain an RF transmitter. For detailed information, refer to the DR detector user manual.

Emergency stop button

Figure 13: Emergency stop button

If a system malfunction causes an emergency situation involving the patient, operating personnel or any system component, activate the emergency stop. All motor driven system movements will be stopped.

For detailed information about the emergency button/switch, refer to the DX-D 300 U-arm User Manual (document 0171).

Emergency shutdown power switch

Use the emergency shutdown power switch, if a dangerous situation cannot be eliminated by pressing the emergency stop button.

WARNING:
Use the emergency shutdown power switch in case of danger to patients, operators, third parties, or one of the units. The entire system will be shut down and the power supply will be disconnected.

The emergency shutdown power switch for the room is typically located on the wall and easy to access, often close to the power off switch of the X-ray system. It is installed and labeled by customer.

WARNING:
It must be ensured that the emergency switches are always freely accessible.

System Documentation

The user documentation consists of:

- DX-D 300 User Documentation CD (digital media).
- NX User Documentation CD (digital media).
- User documentation for the supported DR Detectors
- Digitizer User Documentation CD (digital media).
- DX-D 300 Owner's Manual (paper binder).
- Getting Started material.

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*

Topics:

The DX-D 300 User Documentation

- DX-D 300 User Manual (this document), document 0172.
- DX-D 300 U-arm User Manual, document 0171.
- DX-D Software Console User Manual, document 0189.
- DX-D Full Leg Full Spine User Manual, document 0179.
- DX-D DR Detector Calibration Key User Manual, document 0134.

The Getting Started material

- Getting Started with NX, document 4417.
- Getting started with DX-D 300, document 0170.

Options and Accessories

- DX Full Leg Full Spine Stand (for the DX-D Full Leg Full Spine application)
- CR FLFS Cassette Holder (for the CR Full Leg Full Spine application)

For options and accessories information, refer to the DX-D 300 U-arm User Manual, document 0171.

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

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

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

X-Ray Safety

- IEC 60601-1-3
- IEC 60601-2-54
- IEC 60601-2-7

For USA

The system conforms to DHHS radiation Standards of 21CFR subchapter J as of the date of manufacture.

Classification

Type of protection against electric shock	Class 1 Equipment
Degree of protection against electric shock	Type B Applied Part 
Degree of protection against ingress of liquids	IPX0 as defined in IEC60529. Ordinary equipment (enclosed equipment without protection against ingress of liquids).
Methods of disinfection recommended by the manufacturer	Disinfectable equipment (or elements)
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment for use in environments where no flammable gases or vapors are present
Mode of operation	Suitable for continuous operation
Labelling	• CE label: 93/42 EEC 'Medical Devices' (Europe), EN 60601-1 • CUL label: CSA 22.2 No 601.1 (Canada)
Remarks for HF-emission and immunity	This equipment generates, uses and can radiate radio frequency (RF) energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. In any circumstance; however, there is no guarantee that interference will not occur in a particular installation.

Connectivity

The NX workstation is connected to the X-ray system to exchange X-ray exposure parameters.

The NX workstation requires a 100 Mbit ethernet network to exchange information with a number of other devices.

The NX workstation communicates with other devices in the hospital network using one of the following protocols:

- DICOM
- IHE

The NX workstation can be connected to a RIS system (input scheduling), a PACS system (output image/data management) and to a hardcopy device (output image).

Note: *The connections between the components of the system are separate from the hospital network and should not be disconnected or modified.*

X-ray Exposure Parameters

The X-Ray Exposure Parameters and DAP value can be configured to be

- displayed in the NX Image Detail pane,
- printed in the film text box,
- transmitted to the Archive,
- transmitted to the RIS via MPPS (Modality Performed Procedure Step).

The NX Image Detail pane displays the X-Ray Exposure Parameters and DAP value for the individual sub-exposures.

Only the cumulative DAP value is transmitted to the Archive.

CAUTION:
Incomplete exposure parameters (kV, mAs) are transmitted to Archive for multiple sub-exposures on one cassette. Only the exposure parameters for one sub-exposure are transmitted. Don't use multiple sub-exposures when the exposure parameters are interpreted by the Archive.

Labels

Lable	Meaning
CE	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	This mark indicates that the equipment has a Type B applied part
SN	Serial number
	Manufacturer
	Date of manufacture
	Dangerous voltage
	Ionizing radiation
Segurança SGS Compulsório INMETRO	The INMETRO label is positioned close to the type label.

Type label

Mark	Meaning
Agfa NV DX-D 300 CE 0413 MEDICAL ELECTRICAL EQUIPMENT CONFORMS TO IEC 60601-1 (Sample of subtype 8207/050)	The type label is located near to the top of the vertical column. The type label information for each combination of X-ray tube and X-ray generator is available in the technical data.

Mark	Meaning
	The 21 CFR Subchapter J label is positioned close to the type label.

Messages

Messages are displayed on the NX workstation monitor, on the touch screen console in the operator room or on the control panel.

Special messages are displayed in a dialog box in the middle of the screen or in a fixed part of the screen. This message will tell 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 Agfa service organization.

Details on the contents of messages can be found in the service documentation which is available to Agfa service personnel.

Installation

The NX Workstation complies with the IEC 60950 and IEC 62368-1 standards for Information Technology. This means that, although it is absolutely safe, patients may not come into direct contact with the equipment. Therefore, the workstation must be placed outside a radius of 1.5 m (IEC/EN 60601-1) or 1.83 m (ANSI/AAMI ES60601-1) around the patient (according to the local valid regulation).

The other components of the DX-D 300 are suitable for use within the patient environment.

Labeling the DR Detectors

CAUTION:
Selecting the wrong DR detector can cause the need to retake the image.

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

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.

CAUTION:
Wet cleaning of the equipment while it is connected to the electric circuit includes the risk of electric shock and of short circuit.

2. Wipe the exterior of the device with a clean, soft, damp cloth. Use a mild soap or detergent if required. Do not use any corrosive, dissolving or abrasive cleaning or polishing agents. Make sure no liquid gets in the device.

CAUTION:
Clean the equipment with only a little moisture.

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

Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. alcohol-containing agents).

3. Start up the system.

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

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.

Maintenance

Maintenance procedures are described in the DX-D 300 Owner's Manual.

Environmental protection

Figure 14: WEEE symbol

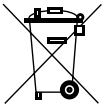


Figure 15: Battery symbol

WEEE end user notice

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. The recycling of materials will help to conserve natural resources.

CAUTION:
By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

Battery notice

The battery symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste. The battery symbol on batteries or its packaging may be used in combination with a chemical symbol. In cases where a chemical symbol is available it indicates the presence of respective chemical substances. If your equipment or replaced spare parts contain batteries or accumulators please dispose of them separately according to local regulations.

For battery replacements please contact your local sales organization.

Safety Directions

WARNING:
Only qualified and authorized personnel shall operate this system. In this context 'qualified' means those persons legally permitted to operate this equipment in the jurisdiction in which the equipment is being used, and 'authorized' means those persons authorized by the authority controlling the use of the equipment. Full use must be made of all radiation protection features, devices, systems, procedures and accessories.

WARNING:
Improper changes, additions, maintenance or repair of the equipment or the software 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 connect the equipment with anything other than specified. Doing so may result in fire or electric shock.

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

WARNING:
Safety is only guaranteed when an Agfa certified field service engineer has installed the product.

WARNING:
Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with.

WARNING:
The operator and end-user must take precautions to protect themselves against dangerous X-ray exposure when using the DR Detector in the X-ray beam path of an X-ray source.

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

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:
Avoid unnecessary dose by checking before exposure if the DR Detector Switch displays the name of the DR Detector that is being used and if the status of the DR Detector is ready for exposure.

WARNING:
There is a risk of collision or crushing for patients, operating staff, unit and objects, caused by unit movements which could be released by inadmissible actuation of operating elements by patients.

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:
Before moving the U-arm out of horizontal position, check that no objects are lying on the bucky that can fall off.

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

CAUTION:
When inserting the scattered radiation grids, it is essential that the grid corresponds to the intended source-image-distance (SID) to which the grid is focussed. Because of the focussing of the grids, the tube unit must be centered onto the bucky.

CAUTION:
Excessive ambient temperature may impact performance of DR Detectors and cause permanent damage to the equipment. Refer to the related user manual for environmental conditions for the DR detector. If ambient temperature and humidity is outside the

specified range, do not operate the system or use air conditioning. Frost due to low temperatures can damage internal circuits. Warranty will be void if it is obvious that operating conditions are not met.

CAUTION:
Power failure can cause an image being lost.

Connect the workstation and the digitizer to an uninterrupted power supply (UPS) or an institutional standby generator.

Operation

Topics:

Starting DX-D 300

Note: Allow the DR Detector to warm up before the DX-D 300 is used for clinical purposes. The warming-up time starts as soon as the DR Detector has been powered on and the NX workstation is running. To check if a warming-up time is required, refer to the DR Detector User Manual.

1. Switch on the X-Ray generator control in the operator room.

   The X-Ray generator and the wired DR Detector are powered on.
2. Switch on the U-arm unit using the button on the U-arm control box in the examination room.

   The U-arm unit and the touch screen console are powered on.
3. Start NX.

   The NX application and the software console are available on the NX workstation.

   For detailed information about starting up NX, refer to the NX User Manual, document 4420.
4. In a configuration with a wireless DR Detector, power on the DR Detector:

   - attach a fully charged battery pack to the DR Detector.
   - turn on the DR Detector.
   - if needed, register the DR Detector to the NX workstation.

   For detailed information about starting up the DR Detector, refer to the DR Detector User Manual.

Performing an exposure using the 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

In the operator room at the NX workstation:

Select the thumbnail for the exposure in the Image Overview pane of the Examination window.

	U-arm with integrated DR Detector
	Portable DR Detector in the DR bucky
	Free exposure using a portable DR Detector

The selected DR Detector is activated. The DR Detector Switch shows which DR Detector is active and shows its status.

The default X-Ray exposure parameters for the selected exposure are sent to the modality and displayed on the software console.

The default U-arm position for the selected exposure is sent to the modality and displayed on the software console, for automatic positioning of the U-arm.

Step 3: Prepare the exposure

1. In the examination room, position the U-arm:

   Press and hold the MOVE button on the U-arm control panel or remote control.

   The U-arm moves to the default position for the selected exposure.
2. When using a portable DR Detector, position the DR Detector for the exposure.

   The DR Detector Switch shows which DR Detector is active and shows its status.
3. Position the patient:
   a) Position the patient.
   b) Check if the X-Ray system position is suitable for the exposure.
   c) Make final adjustments to the position of the U-arm using the control buttons on the control panel or remote control.
   d) Switch on the light localizer on the collimator. Adapt collimation if required.
   e) Apply radiation protective measures for the patient if needed.

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.

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.

CAUTION:
Use the smallest X-ray field collimation. Make sure that the area of interest will be completely exposed and the X-ray field does not exceed the area of interest. The collimator automatically limits the collimated area to the size of the detector, unless it is unlocked to manual mode using the key on the back.

Step 4: Check the exposure settings

Related Links

DR Detector Switch on page 17

On the NX application:

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

On a DR Detector that has a status indicator:

Check if the status of the DR Detector is ready for exposure. If the status is not ready for exposure, the DR Detector cannot be used for making an exposure.

In the operator room at the X-ray generator console:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. If other exposure values are required than those defined in the NX exam, use the console to overwrite the default defined exposure settings.

Step 5: execute the exposure

In the operator room:

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.

In the operator room at the NX workstation:

- The image is acquired from the DR detector and displayed in the thumbnail.
- The actual X-Ray exposure parameters are sent back from the generator to the NX workstation and are shown in the Image Detail pane.
- If collimation is applied, the image is automatically cropped at the collimation borders.

Step 6: perform a quality control

At the MUSICA Acquisition Workstation:

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

Performing a Full Leg Full Spine examination

Refer to the DR Full Leg Full Spine User Manual (document 0179).

The availability of DR Full Leg Full Spine depends on the configuration of the system.

Refer to the CR Full Leg Full Spine User Manual (document 4408, part of the NX User Documentation).

Performing an exposure using a CR cassette

Note: Using an ID Tablet to identify cassettes before the exposure will break the communication of X-ray parameters between the NX workstation and the X-ray generator console. It is advised to identify cassettes after the exposure, as described in this workflow.

Topics:

Step 1: retrieve the patient info

At the MUSICA Acquisition Workstation:

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

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

Step 2: select the exposure

In the operator room at the NX workstation:

1. Select the thumbnail for the exposure in the Image Overview pane of the Examination window.

	Cassette in the DR bucky
	Free exposure using a cassette

Note: For a bucky exposure, only cassette size 43x35 is supported.

The default X-Ray exposure parameters for the selected exposure are sent to the modality and displayed on the software console.

The default U-arm position for the selected exposure is sent to the modality and displayed on the software console, for automatic positioning of the U-arm.

2. Select the subexposure if more than one image is required for the same cassette.
If an image thumbnail is configured for multiple exposures on a single cassette, another set of thumbnails is shown in the image detail pane. Now you have to select one of these thumbnails to send the proper default X-Ray exposure parameters to the modality for each exposure.

Note: When working in a PACS environment, the preferred workflow is to have only one image per cassette. This is needed for optimal use of hanging protocols. However, in particular cases (e.g. printing sites) it is supported to make more than one exposure per cassette.

Step 3: Prepare the exposure

1. In the examination room, position the U-arm:

   Press and hold the MOVE button on the U-arm control panel or remote control.

   The U-arm moves to the default position for the selected exposure.
2. Position the patient:
   a) Position the cassette.

Note: For a free exposure, partial lead covering of the cassette may be required if multiple images are taken on one cassette.

   b) Position the patient.
   c) Check if the X-Ray system position is suitable for the exposure.
   d) Make final adjustments to the position of the U-arm using the control buttons on the control panel or remote control.
   e) Set the correct distance between cassette and X-Ray tube.
   f) Switch on the light localizer on the collimator. Adapt collimation if required.
   g) Apply radiation protective measures for the patient if needed.

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.

CAUTION:
Use the smallest X-ray field collimation. Make sure that the area of interest will be completely exposed and the X-ray field does not exceed the area of interest. The collimator automatically limits the collimated area to the size of the detector, unless it is unlocked to manual mode using the key on the back.

Step 4: Check the exposure settings

In the operator room at the software console, or in the examination room at the touch screen console:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. If other exposure values are required than those defined in the NX exam, use the console to overwrite the default defined exposure settings.

Step 5: Execute the exposure

In the operator room:

Press the exposure button to execute the exposure.

WARNING:
The radiation indicator on the control console lights up during exposure release.

In the operator room at the NX workstation:

- The actual X-Ray exposure parameters are sent back from the console to the NX workstation and are shown in the Image Detail pane.
- The actual X-Ray exposure parameters and the Exposure Index (EI) value on the NX workstation can be used to monitor the performance of the Automatic Exposure Control of the X-Ray system.
- A green OK mark appears on all thumbnails for which the exposures are made and for which exposure settings are sent back to the NX workstation.

Step 6: repeat steps 2 to 5 for the next subexposures

Step 7: digitize the image

In the examination room:

Take the exposed cassette.

In the operator room:

1. Insert the cassette in the digitizer.
2. Click ID in the examination window of NX.

Note: You can also use an ID Tablet to identify the cassette and digitize it using any digitizer.

The image will appear in the image overview pane of the examination window.

Step 8: perform a quality control

In the operator room at the NX workstation:

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

Stopping the System

To stop the system:

1. Stop the NX workstation.

   NX can be stopped in two ways, either by logging out of Windows or without logging out of Windows.

   For detailed information on stopping NX, refer to the NX User Manual, document 4420.

   Note: *Stopping the NX workstation does not stop the DR Detector. If the power of the DR Detector remains on, no warming-up time will be needed after starting the NX workstation.*

2. Press the Power OFF button on the X-ray generator control box to switch off the generator.
3. In a configuration with a wireless DR Detector, power off the DR Detector:
   - turn off the DR Detector.
   - remove the battery pack.
4. Switch off the DR Generator Sync.

Note: *If the DR Detector is powered down, a warming-up may be required on the next start-up.*

Problem solving

Topics:

DR Detector is Exceeding the Maximum Working Temperature

Details	A message is displayed on NX indicating that the DR Detector is exceeding the maximum working temperature.
Cause	Due to ambient temperature conditions and the number of acquired images, the DR Detector's internal temperature may become too high.
Brief Solution	**1.** Power off the DR Detector. **2.** Leave the DR Detector unpowered for at least one hour. **3.** Stop the NX workstation. **4.** Power on the DR Detector. **5.** Start the NX workstation.

DR Detector must be Recalibrated

Details	A message is displayed on NX indicating that the DR Detector must be recalibrated.
Cause	A DR Detector must be recalibrated at regular interval.
Brief Solution	Follow the instructions in the DR System Key User Manual to calibrate the DR Detector: • DX-D DR Detector Calibration Key User Manual, document 0134

DR Detector Problem

Details	An error message is displayed on NX indicating a problem related to the DR detector.
Cause	-
Brief Solution	**1.** Power off the DR detector. **2.** Stop the NX workstation. **3.** Power on the DR detector. **4.** Start the NX workstation.

Technical Data

Topics:

DX-D 300 technical data

The technical data are provided in this chapter or in the user manual of the component.

Table 2: Electrical connection

Rated power supply	230 / 240 V∿ Single Phase 50/60 Hz
Minimum input power required	2.5 kVA

Table 3: Environmental conditions for the U-arm

Environmental conditions (during storage and transport)	
Temperature (ambient)	between -20 and 70 degrees Celsius
Humidity (non condensing)	between 10 and 90 % relative humidity
Atmospheric pressure	between 50 and 106 kPa
Environmental conditions (during normal operation)	
Temperature (ambient)	between 10 and 35 degrees Celsius
Humidity (non condensing)	between 30 and 75 % relative humidity
Atmospheric pressure	between 70 and 106 kPa

For overall system environmental conditions, the environmental conditions of the DR detector or image plate should be taken into account. Refer to the related user manual for environmental conditions for the DR detector or image plate. When using the DR detector or image plate inside the bucky, take into account that the temperature inside the bucky can be up to 5°C higher than the temperature in the X-ray room.

Fixed DR detector technical data

Manufacturer	
Manufacturer DR detector	Vieworks Co., Ltd. (Gwanyang-dong), 41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Korea
Distributor DR detector	Agfa NV Septestraat 27, B-2640 Mortsel - Belgium
Original manufacturer model name	
XD 17	FXRD-4343VAW
XD⁺17	FXRD-4343VAW PLUS
Electrical connection	
Power adapter with USB Type-C cable	DC 18 V, max. 2.78 A
Power consumption	max. 24 W
Network connection	
Wireless connection	IEEE 802.11n/ac (2.4 GHz/5 GHz)
Environmental conditions (during normal operation)	
Room temperature	between 0 °C and +40 °C
Humidity (non condensing)	between 5% and 90% RH (non-condensing)
Atmospheric pressure	between 700 hPa and 1060 hPa
Environmental conditions (during storage and transport)	
Temperature (ambient)	between -15 °C and +55 °C
Humidity (non condensing)	between 5% and 90% (non-condensing)
Atmospheric pressure	between 500 and 1060 hPa
Image acquisition	
Image acquisition time (minimum cycle time)	4 s

Conversion screen	CsI
Pixel size	140 μm
Active pixel matrix	3072 x 3072
Effective pixel matrix	3048 x 3048
Detector type	amorphous silicium
Active area size	430 mm x 430 mm
Effective area size	426.7.0 mm x 426.7 mm

Fixed DR detector technical data

Manufacturer	
Manufacturer DR detector	Varex Imaging Corporation, 1678 So. Pioneer Rd, Salt Lake City, UT 84104, USA
Supported models	
4343R (part number 7965)	CsI conversion screen
4343R (part number 7964)	GOS conversion screen
Electrical connection	
Operating voltage	90-240 V (AC)
Mains fuse protection	6A
Mains frequency	47-63 Hz
Power consumption	
Maximum power consumption	45 W
Warming-up time	
	1 hour
Throughput	
Maximum number of image acquisitions	150 acquisitions per hour
Pixel matrix	
Pixel size	139 μm (H,V)
Pixel matrix	3072(H) x 3072(V)
Active pixel matrix	3056(H) x 3056(V)
Fill factor	100 %
Detector type	Amorphous Silicon
Active area size	42,7 cm (H) x 42,7 cm (V)

Reliability	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	100 000 RAD

Fixed DR detector technical data

Manufacturer	
Manufacturer DR detector	THALES AVS FRANCE SAS 460 Rue du Pommarin – BP122 38430 MOIRANS France
Supported models	
Pixium RAD 4343 C-E	CsI conversion screen
Pixium RAD 4343 G-E	GOS conversion screen
Electrical connection	
Operating voltage	+24V 3.5A DC
Warming-up time	
	5 minutes
Throughput	
Maximum number of image acquisitions	150 acquisitions per hour
Reliability	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	100 Gy

Pixel matrix	
Pixel size	148 μm (H,V)
Pixel matrix	2880(H) x 2880(V)
Active pixel matrix	2860(H) x 2874(V)
Fill factor	100 %
Detector type	Amorphous Silicon
Active area size	426.24 mm (H) x 426.24 mm (V)

Fixed DR detector environmental conditions

Pixium RAD 4343 C-E

Environmental conditions (during normal operation)	
Temperature (ambient)	between 15° and 35° Celsius
Humidity Atmospheric pressure Maximum altitude	Refer to environmental conditions of the X-ray system

	minimum	**maximum**
Distance to calibration temperature	-10 °C	+10 °C
Distance to calibration pressure	-100 mbar	+100 mbar

Pixium RAD 4343 G-E

Environmental conditions (during normal operation)	
Temperature (ambient)	between 15° and 40° Celsius
Humidity Atmospheric pressure Maximum altitude	Refer to environmental conditions of the X-ray system

	minimum	**maximum**
Distance to calibration temperature	-10 °C	+10 °C
Distance to calibration pressure	-100 mbar	+100 mbar

U-Arm technical data

Manufacturer	
Manufacturer U-Arm	Sedecal S.A. Polígono Ind. Rio de Janeiro 9-13 28110 Algete - Madrid Spain

Refer to the DX-D 300 U-arm User Manual (document 0171) for technical data of the U-arm.

Portable DR detector technical data

Refer to the DR Detector User Manual.

Remarks for HF-emission and immunity

This equipment generates, uses, and can radiate radio frequency energy.

CAUTION:
The equipment may cause radio frequency interference to other medical or non medical devices and to radio communications.

To provide reasonable protection against such interference, this equipment complies with emissions limits for a Group 1-Class A Medical Devices Directive as stated in IEC 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the operator (or qualified service personnel) should attempt to correct the problem by one or more of the following measures:

- reorient or relocate the affected device,
- increase the separation between the equipment and the affected device,
- power the equipment from a source different from that of the affected device,
- consult the service engineers for further suggestions.

To comply with the regulations applicable to an electromagnetic interference for a Group 1 - - Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Medical Device Directive and of Federal Communications Commission regulations.

CAUTION:
Before using this equipment make sure that all requirements about EMC included in this manual are accomplished.

CAUTION:
Should any interference (EMC) be detected with other equipment, please position other equipment away from this one.

CAUTION:
It is customer responsibility to assure that this equipment and vicinity equipment complies the value of radio frequency

interferences shown in General Regulation for safety according to IEC 60601-1-2 tables as described in this section.

CAUTION:
The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables, accessories and transducers or by unauthorized changes or modifications to this equipment.

The DX-D 300 system is intended for use in the electromagnetic environment specified below. The customer or the user of this DX-D 300 system should assure that it is used in such an environment.

Table 4: Guidance and manufacturer's declaration on electromagnetic emissions (IEC 60601-1-2)

Emission test	Compli-ance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
Note: In accordance with Standard IEC 61601-1-2, the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A. If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment.		

The DX-D 300 system is intended for use in the electromagnetic environment specified below. The customer or the user of this DX-D 300 system should assure that it is used in such an environment.

Table 5: Guidance and manufacturer's declaration on electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle at 0° 70% U_T for 25/30 cycles at 0° 0% 250/300 cycles	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle at 0° 70% U_T for 25/30 cycles at 0° 0% 250/300 cycles	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.

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

Table 6: Guidance and manufacturer's declaration on electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
Radiated RF EM fields IEC 61000-4-3	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	3 Vrms from 80 MHz to 2.7 GHz (80% AM at 1 kHz)	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the equipment, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to the section "Immunity to RF wireless communication equipment"	Refer to the section "Immunity to RF wireless communication equipment"	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz	3 Vrms from 150 kHz to 80 Mhz 6 Vrms in ISM bands from 150 kHz to 80 MHz	

	(80% AM at 1 kHz)	(80% AM at 1 kHz)	

Note: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; and 50.0 MHz to 54.0 MHz.

Immunity to RF wireless communication equipment

ISM Band (MHz)	Modulation	Distance (m)	Immunity test level (V/m)
300-390	Pulse modulation 18 Hz	0.3	27
430-470	FM ± 5 kHz deviation 1 kHz sine	0.3	28
704-787	Pulse modulation 217 Hz	0.3	9
800-960	Pulse modulation 18 Hz	0.3	28
1700-1990	Pulse modulation 217 Hz	0.3	28
2400-2570	Pulse modulation 217 Hz	0.3	28
5100-5800	Pulse modulation 217 Hz	0.3	9