DR 400 (Radiographic wall stand)

5520/150

User Manual

3256D EN 20240802 1519

Contents

Legal Notice

CE 2862

UKCA 8532

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Introduction to this Manual

Scope of this Manual

This User Manual describes the features of the DR 400 wall stand, further referred to as the radiographic wall stand, that is a variant of the DR 800 system.

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

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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

Intended Use

- The DR 400 system is a General Radiography 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 or pediatric patients.
- Applications can be performed with the patient in the sitting or standing 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.

Radiographic wall stand

The radiographic wall stand is used for positioning of patients standing upright or sitting towards the bucky for exposure.

Figure 1: Radiographic wall stand with vertical bucky

Related information

Radiographic wall stand on page 32

Applied Parts

Applied Parts refer to parts of the medical electrical equipment that in normal use necessarily comes into physical contact with the patient for the equipment to perform its function. This system includes the following Applied Parts:

- Radiographic wall stand on page 11

Radiographic wall stand

- Front panel of the radiographic wall stand
- Lateral arm rest (optional)
- Patient hand grips (optional)

Installation

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

Radiation Protection

X-ray radiation can cause serious damage to the health, therefore observe great care and ensure that protection against X-ray exposure is always applied.

Some of the effects of X-ray radiation are cumulative and may extend over a period of time. Therefore the X-ray operator should avoid exposure by X-ray radiation at all times.

Objects in the path of the X-ray beam may produce scattered radiation. The intensity depends on the energy and intensity of the X-ray exposure, the material of the object and the distance to the object producing scattered radiation. Protective measures have to be taken to prevent exposure through scattered radiation.

Protective measures include:

- structural configuration of the X-ray room (e.g. lead shielded rooms)
- radiation protection for the operators (e.g. personal radiation dosimeters, lead aprons, radiation protection glasses, mobile lead screens, keep maximum distance from X-ray source and from the object producing scattered radiation, regular training, etc.)
- protection of patients against unnecessary radiation (e.g. limitation of X-ray field by collimation, lead shielding, lead aprons, etc.)

- Monitoring of Personnel on page 14
- Protected area and significant zones of occupancy on page 15

Monitoring of Personnel

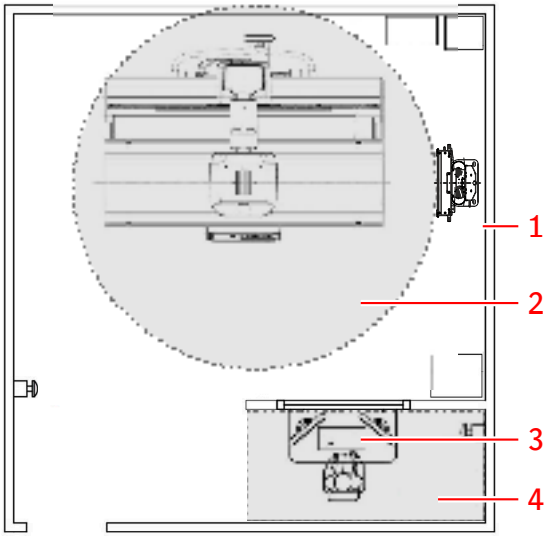
The monitoring checks the amount of X-ray radiation the personnel has been exposed to. It determines safety of the operators and it helps checking if safety measures of the X-ray environment are adequate. Inadequate or improper protection can lead to serious damage to the health.

To measure radiation, personal radiation dosimeters are typically used. They are worn on the body at all times during working in an environment where X-ray radiation is applied. They provide an indication for the amount of radiation the operator was exposed to.

Protected area and significant zones of occupancy

If the operator or staff does not need to be close to the patient during the exposure, the operator and staff use the protected area to control the following functions:

- selection of mode of operation
- selection of exposure settings (X-ray loading factors)
- actuation of the exposure button
- other necessary controls for the operator during exposure



1. X-ray room
2. Patient environment
3. Workstation
4. Operator room: protected area

Figure 2: Protected area and significant zones of occupancy

Warning: The patient must wear appropriate radiation protection garments.

If operator or staff needs to be close to the patient during normal use (e.g. some pediatric examinations or types of examinations for which the patient requires assistance), the significant zone of occupancy applies for operator and staff.

Keep maximum distance from the X-ray source and from the object producing scattered radiation. The intensity of scattered radiation depends on the energy and intensity of the X-ray exposure, the material of the object and the distance to the object.

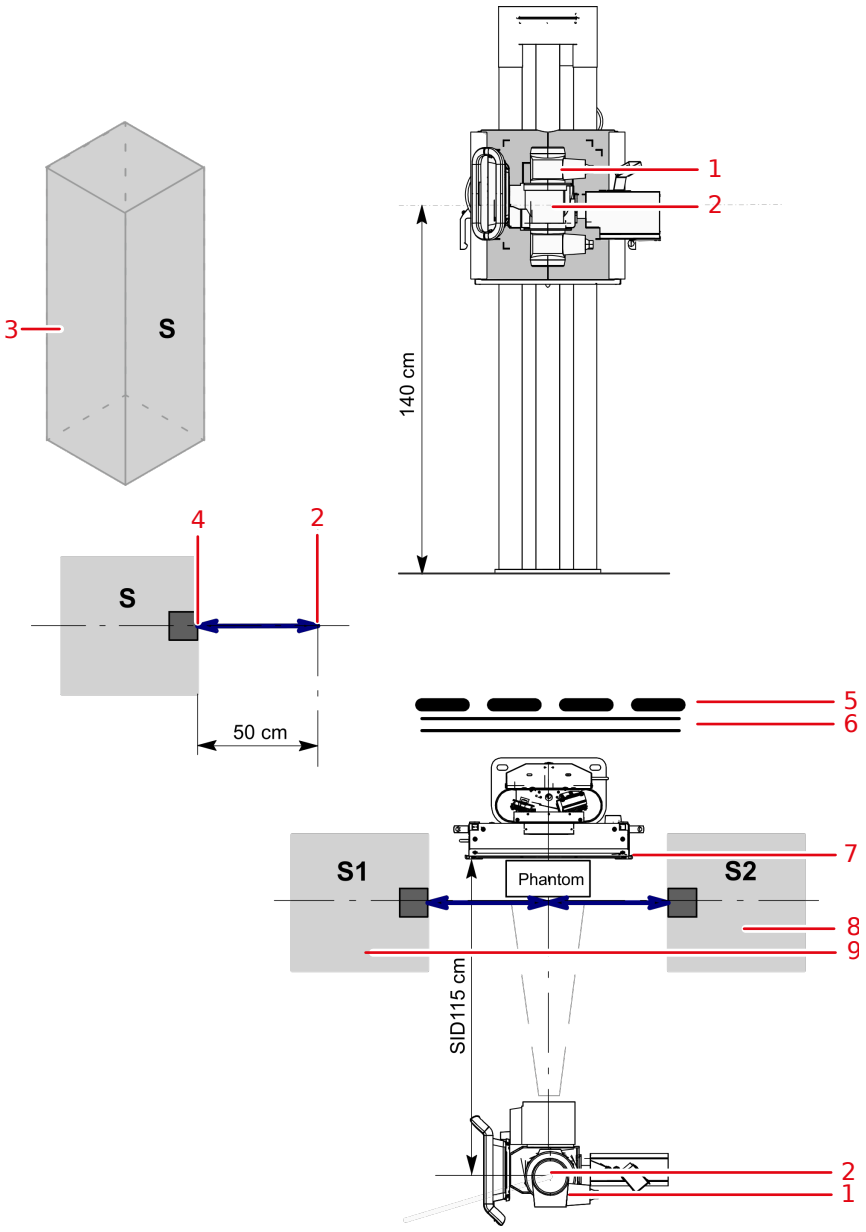
Warning: The patient and the operator must wear appropriate radiation protection garments.

Significant zones of occupancy at the radiographic wall stand

If operator or staff needs to be close to the patient during normal use (e.g. some pediatric examinations or types of examinations for which the patient requires assistance), the significant zone of occupancy applies for operator and staff.

Keep maximum distance from the X-ray source and from the object producing scattered radiation. The intensity of scattered radiation depends on the energy and intensity of the X-ray exposure, the material of the object and the distance to the object.

Warning: The patient and the operator must wear appropriate radiation protection garments.



1. X-ray tube
2. Focal spot label [—]
3. Significant zone of occupancy.

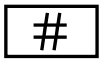
   Minimum area 60x60 cm.

   Minimum height above the floor 200 cm.
4. Dose meter
5. Protective device
6. Wall
7. DR Detector or cassette
8. S2: Significant zone of occupancy at the right side of the radiographic wall stand
9. S1: Significant zone of occupancy at the left side of the radiographic wall stand

Figure 3: Significant zones of occupancy at the radiographic wall stand

Caution: The radiation protection has to be applied for the patient and for the operator.

Labels

Mark	Meaning
	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).
	Type B applied part
	Date of manufacture
	Country of origin. The two character code on the actual label contains the country code defined in ISO 3166-1.
	Manufacturer
	Medical device
	Serial number
	Unique device identifier, in text format and in machine readable format
	Type and subtype number
	The most recent version of this document is available on http://www.agfahealthcare.com/global/en/library/index.jsp
	Read the instructions in the user manual.

Label	Meaning
	Dangerous voltage

Label	Meaning
	Ionizing radiation
	Pinch Points.
	Risk of stumbling.

Further labels are listed and explained in the relevant modules of the System Documentation.

- Warning labels on the radiographic wall stand on page 19
- Type label on page 20
- Additional Labeling of the radiographic wall stand on page 21
- Labeling of the bucky on page 22

Warning labels on the radiographic wall stand

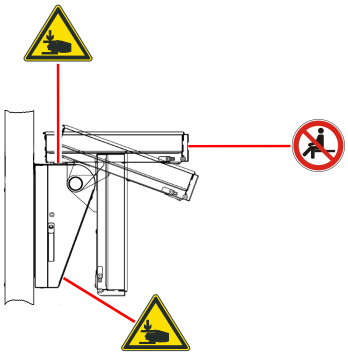
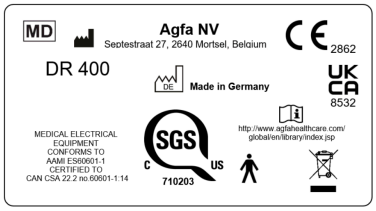
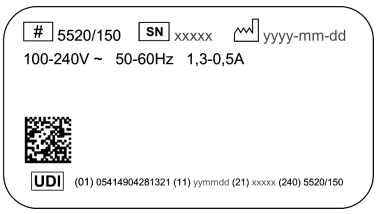
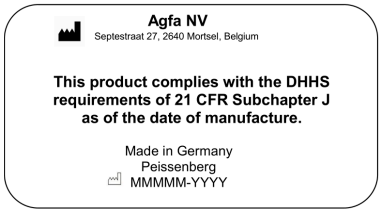
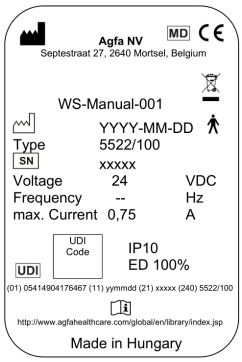
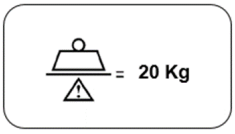


Figure 4: Warning labels on the radiographic wall stand

Type label

Mark	Meaning
  (Sample of subtype 5520/150) **Note** The CE sign and safety signs are only valid at time of product release.	Type label positioned on the lower right hand side of the radiographic wall stand.
	Type B applied part
	The 21 CFR Subchapter J label is positioned close to the type label.

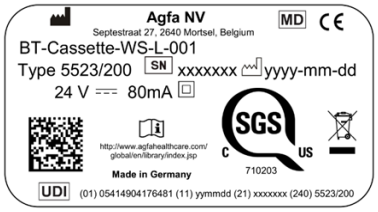
Additional Labeling of the radiographic wall stand

 (Sample of subtype 5522/100)	Type label on the lower right hand side of the radiographic wall stand.
	Type B applied part
	Earth (ground)
	Do not sit. The bucky can be tilted to horizontal position. Do not use the bucky as a seat.
	The maximum load for the bucky movement in vertical direction is 20 kg.
	A pinch point label is located on top of the tilting extension.

Related information

Radiographic Wall Stand Technical Data on page 61

Labeling of the bucky

 **Figure 5: (Sample of subtype 5523/200)**	The type label is located on the rear cover of the bucky or on the bucky drawer below the rotating platform. The type label information for each bucky model is available in the technical data.
	Class II equipment.
	Pinch Points. The label is positioned on the lateral cover of the bucky or on the rotating platform.
	Maximum load capacity is 10 kg on the bucky drawer when it is pulled out. Do not lean or sit on the bucky. The label is positioned on the lateral cover of the bucky or on the rotating platform.
	Read the instructions in the user manual. The label is positioned on the lateral cover of the bucky or on the rotating platform.
	Compliance with China RoHS SJ/T11364-2006. Indication of the Environment Friendly Use Period (EFUP) as the period (years) during which the hazardous substances do not leak or mutate under normal use. The label is located on the rear cover of the bucky or on the bucky drawer below the rotating platform.

Related information

Bucky Unit Technical Data on page 63

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.

- Cleaning on page 24
- Disinfecting on page 25
- Disinfecting safety directions on page 26
- Approved disinfectants on page 27

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 main power of the system. 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.

   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:

   Do not use solvents such as anhydrous or high solvency alcohols, thinner or benzine. Do not use any corrosive, dissolving or abrasive cleaning or polishing detergents.

   Doing so may damage the surface of the equipment. Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. by using alcohol-containing agents).

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

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.

Disinfecting safety directions

Warning: Using a disinfectant that can form an explosive or flammable gas mixtures is hazard to life and health because of explosion risk. Switch the equipment off before disinfecting. Allow the gas mixture to evaporate before switching the x-ray system back on.

Caution: Using unsuitable disinfectants can cause discoloration and damage of the surface of the equipment. If a functional degradation or malfunctioning of the product is noticed due to disinfection, contact the medical device manufacturer.

To disinfect the device:

- Do not use any corrosive, soluble or gaseous disinfectants.
- Consult the manufacturer's Material Safety Data Sheets (MSDS) and recommendations on the product label for additional information prior to use.
- Use of spray disinfection can cause malfunctions due to ingress of the disinfectant into the equipment. Disinfect all parts of the unit, including the accessories and connection cables by just wiping them. Switch off the system and cover the cooled system carefully before performing a room disinfection using nebuliser.

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

Maintenance

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

- Maintenance of the radiographic wall stand on page 28

Maintenance of the radiographic wall stand

The radiographic wall stand requires regular maintenance to ensure the equipment is safe and reliable for operation.

Warning: Operation in unsafe condition includes the risk of radiological exposure and injury of the patient and/or the operator. The customer is responsible to ensure the fault-free condition of the equipment.

Warning: Wear of equipment due to excessively long intervals between service may lead to personal injury and property damage due to worn and unsafe parts.

Warning: Incorrect or defective spare parts may adversely affect the safety of the system and lead to damages, malfunctions or total failure. Use only original spare parts provided by the manufacturer.

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.

Table 1: Lifetime and maintenance

Lifetime	
Expected lifetime	10 years
Periodic maintenance	
The equipment shall have a technical maintenance to maintain fault-free operation and ensure safety for patient and operator.	Every 12 months or after 60.000 cycles, whatever comes first
All steel cables of the radiographic wall stand shall be checked	
All steel cables of the radiographic wall stand shall be exchanged to maintain fault-free operation and ensure safety for patient and operator	Every 36 months
Maintenance by the user	
Check constant smooth movements	Daily
Check ease of movements	Daily
Check secure release and locking of brakes	Daily
Check functioning of operating controls	Daily

Check markers and warning signs	Daily
Check all electric cables and connections for damage or broken cables.	Weekly

Caution: In case of functional defects or other deviations from normal operation behavior the unit has to be switched off immediately and the service to be informed. The equipment must only be put back into operation when the fault has been repaired.

Environmental protection

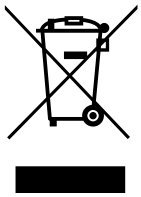


Figure 6: WEEE symbol

WEEE end user notice

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

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

Safety Directions

- General Safety Directions on page 31
- Safety directions for the radiographic wall stand on page 32

General Safety Directions

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

Warning: The product must only be installed using released components and in released configurations.

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

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 must take precautions to protect himself 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.

Warning: Operating the equipment when it is faulty includes the risk of radiological exposure and injury to the patient and to the operator. Operate the equipment only in safe and fault-free conditions.

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.

Safety directions for the radiographic wall stand

Warning: Unauthorized manipulation or opening of the equipment housing may lead to personal injuries and to property damage. Take all necessary precautions with respect to the applicable level of safety.

Warning: The system is operated with electric current and includes therefore a risk of electric shock.

Radiographic wall stand

The radiographic wall stand allows vertical X-ray exposures of patients standing or sitting in front of the radiographic wall stand.

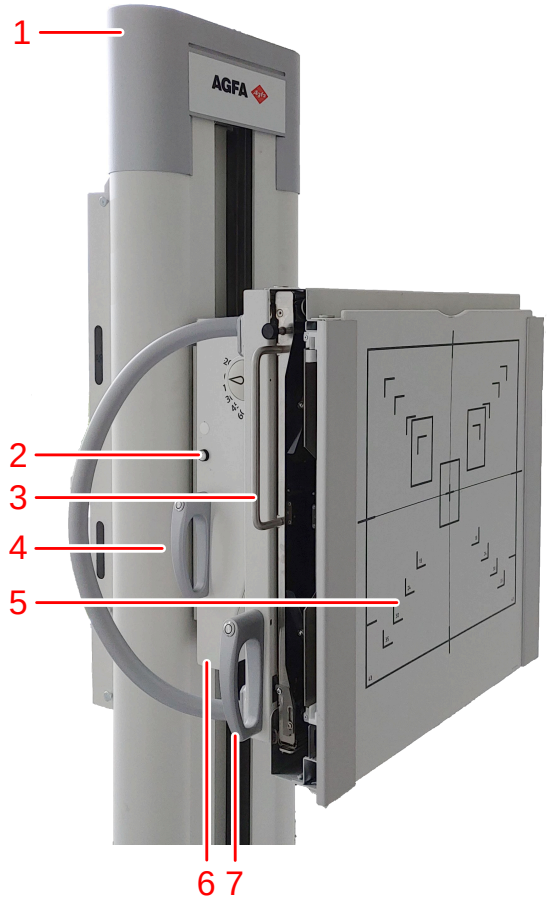
The wall stand has two variants:

- wall stand with vertical bucky, supporting vertical movement (up and down)
- wall stand with tilting bucky, supporting vertical movement (up and down) and tilting of the bucky

The bucky has two variants, depending on the orientation for loading a detector:

- Right hand side loading
- Left hand side loading

The wall stand bucky is height adjustable in a large range.



1. Wall Stand column
2. Bucky
3. Button to switch on the collimator light (this functionality is not available on DR 800)
4. Vertical movement handle (both sides)
5. Front panel
6. Tilting extension
7. Tilting handle

Figure 7: Radiographic wall stand, vertical version and vertical tilting version

Caution: The format indications on the front of the bucky unit show the format and position of the cassette or detector. Take into account that the actual area for imaging is smaller than indicated. The image of the exposed object is slightly magnified because there is a distance between the front of the bucky unit and the cassette or detector. The sensitive area of the cassette or detector may be slightly smaller than the indicated area. Check the technical data of the cassette or detector for exact values.

- Positioning the Radiographic Wall Stand on page 34
- Radiographic Wall Stand Accessories on page 36

Positioning the Radiographic Wall Stand

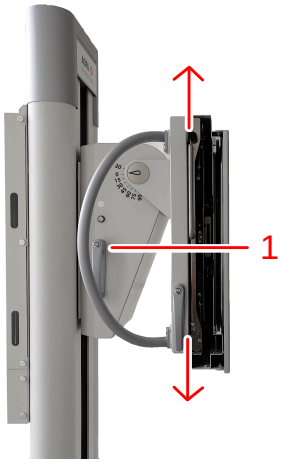
DANGER: Make sure that no persons or objects are within the movement area of the system where they can collide with moving parts of the system.

Warning: Maintain visual contact with the patient while moving the equipment close to the patient in order to detect hazardous situations (e.g. collisions) early and to avoid them.

Warning: Be careful not to squeeze your finger or hand. Keep your hands at the handles while positioning the system.

Warning: If the tilting bucky is out of vertical position, do not use auto collimation. In this case switch the collimator to manual mode. When using automatic collimation on a tilting bucky, make sure that the bucky is in vertical position.

Vertical movement



1. Vertical movement handle with brake switch

Figure 8: Positioning controls

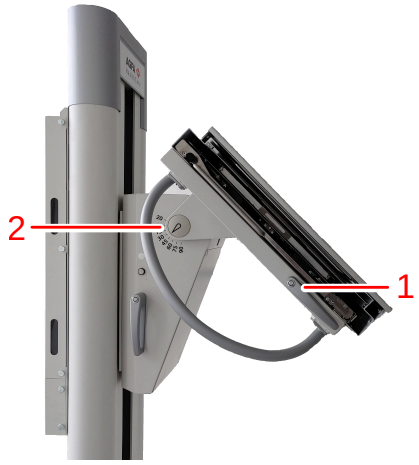
To release the brake for vertical movement, press the switch that is integrated at the upper side of the handle located at the left and right side of the radiographic wall stand. The bucky can be moved up and down.

To stop movement and lock the bucky into position, release the switch.

Caution: The maximum load for the wall stand movement in vertical direction is 20 kg. The bucky unit may slip downwards when applying excessive load.

Note Do not move the bucky with excessive force to the end stop positions.

Tilting



1. Tilting handle
2. Tilting angle scale

Figure 9: Positioning controls

To tilt the bucky, press and hold the button on the tilting handle and move the bucky. The scale for the angle is visible at the mounting point of the bucky.

To lock the bucky into position, release the button on the tilting handle.

Note The bucky can be tilted to horizontal position. Do not use the bucky as a seat.

Radiographic Wall Stand Accessories

Warning: Using wrong accessories that cannot be properly attached to the system can lead to hazardous situations and injury. Use only original accessories provided by the manufacturer.

Patient hand grips

The patient hand grips for wall stand are mounted fixed at the backside of the bucky. The patient uses these grips for stabilization and support of correct correct positioning, e.g. for chest exams.

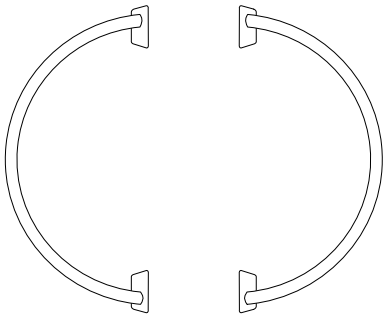


Figure 10: Patient hand grips

Mounting the lateral arm rest

Caution: The lateral arm rest can bear up to 20 kg. It is not intended to hold the whole weight of a patient.

Take care that the lateral arm rest does not collide with the ceiling when moving the bucky upward manually. For automatic movement, a sensor detects if the lateral arm rest is inserted and the movement is coordinated accordingly.

Do not insert the lateral arm rest oriented parallel to the bucky. The lateral arm rest may collide with the wall stand column.

To mount and position the lateral arm rest:

1. Insert the lateral arm rest on the left or on the right side of the bucky frame.
2. Grip the lower part of the lateral arm rest.
3. Pull the lateral arm rest forward
4. Adjust the angle.
5. Move the lateral arm rest back to fix the position.

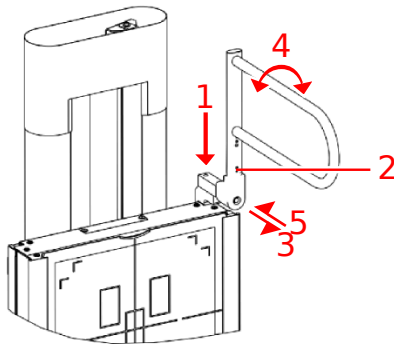


Figure 11: Lateral arm rest

Movement of the X-ray tube head is restricted in the neighbourhood of the lateral arm rest, to avoid collisions. To allow free movement of the tube head, the lateral arm rest must be unmounted from the wall stand. It is not sufficient to turn it 90 degrees out of the way.

Spacer

The spacer allows examination of sitting patients by offering additional space to position legs and feed under the bucky.

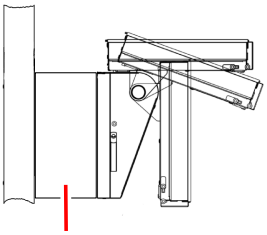


Figure 12: Spacer

Wall stand fixation kit

For additional stability of the radiographic wall stand an additional fixation of the radiographic wall stand is provided. The kit is installed at backside of the radiographic wall stand under the head cover and then fixed to a wall. It has to be installed by service.

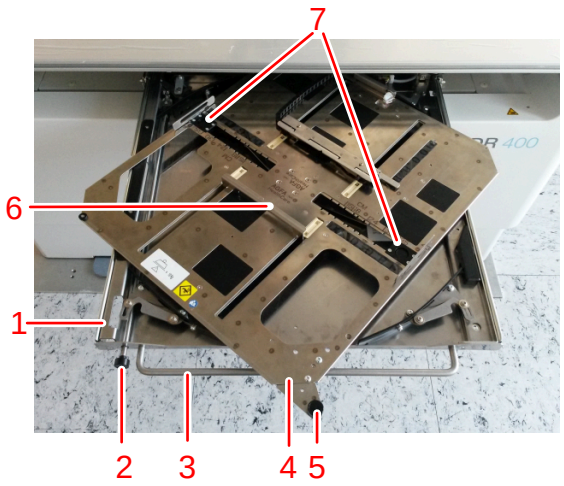
Bucky

The bucky is installed in the radiographic table and in the radiographic wall stand.

The bucky clamps the cassette or detector during exposure and centers them relative to the Automatic Exposure Control (AEC) and the grid.

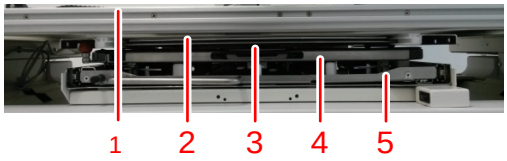
The bucky supports cassettes in standard formats as well as DR Detectors with cassette size format.

The bucky functionalities can be configured according the customer needs.



1. Bucky drawer
2. Button to release the brake
3. Bucky drawer handle
4. Carrier for the cassette or detector
5. Knob for rotating the cassette or detector
6. Clamps
7. Side clamps

Figure 13: Bucky



1. Tabletop
2. Removable grid
3. Automatic exposure control (AEC)
4. Carrier for cassette or detector
5. Bucky drawer with rotation mechanism

Figure 14: Bucky front view

Bucky configuration

Cassette only configuration

The workflow with cassettes requires removing the cassette from the bucky after each exposure. The cassette has to be scanned using a digitizer to get the final image.

The correct orientation of the cassette is applied by the way it is inserted in the bucky and there is no need to use the rotation mechanism.

In this configuration the rotation mechanism can be blocked during installation by the service engineer.

Fixed DR Detector configuration

The bucky for the fixed DR detector has no clamping or rotation mechanism. The detector is permanently fixed in the bucky and can not be removed. The detector has a square format and requires no rotation.

Radiographic wall stand configuration

The cassette or detector can be positioned centered or aligned with the upper edge of the bucky, to allow chest exams with patient chin resting at the wall stand front panel.

The bucky is available for left and right side loading of the wall stand.

Rotating the bucky

The cassette or detector in the bucky can be rotated without removing it from the clamping.

To change the orientation of the cassette or detector in the bucky:

1. Open the bucky drawer halfway by pulling the front handle.
2. Rotate the bucky carrier with the clamped cassette or detector using the rotation knob.
   - Rotate clockwise to change from portrait to landscape position
   - Rotate counterclockwise to change from landscape to portrait position

Figure 15: Example: rotate clockwise to change from portrait to landscape position

   Make sure the rotation is complete before closing the bucky drawer.
3. Close the bucky drawer using the front handle and pushing the button to release the brake. Make sure the bucky drawer is pushed up to the end to close completely.

Loading of the bucky in the Radiographic Wall Stand

To load the bucky with a cassette or detector:

1. Open the bucky drawer completely by pulling the front handle.
2. Rotate the drawer to portrait orientation.
3. Adjust the side clamps to the cassette or detector format by pushing the lock button and moving the clamp.

4. Push the cassette or detector towards the lower slider to open the clamping mechanism wide enough to contain the cassette or detector.
5. Let the cassette or detector slip into the clamping.

Caution: Make sure your fingers are not between the clamping mechanism and the detector. The clamping mechanism may hurt your fingers, therefore take special care.

6. Rotate the cassette or detector if needed to get the correct position for next exposure.
7. Align the cassette or detector. The alignment can be centered or out of center.

Caution:

When positioning the cassette or detector out of center:

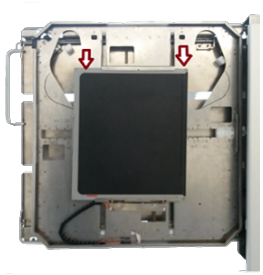
- The alignment to the X-ray tube must be controlled manually.
- The AEC cells might not be covered or not covered completely, causing wrong exposure dose. Make sure that AEC cells are covered.

8. Close the bucky drawer using the front handle and pushing the button to release the brake. Make sure the bucky drawer is pushed up to the end to close completely.

Unloading of the bucky in the Radiographic Wall Stand

To unload the bucky with a cassette or detector:

1. Open the bucky drawer completely by pulling the handle.
2. Rotate the carrier back to portrait position.
3. Push firmly with both hands the cassette or detector towards the lower clamp to open the clamping mechanism.



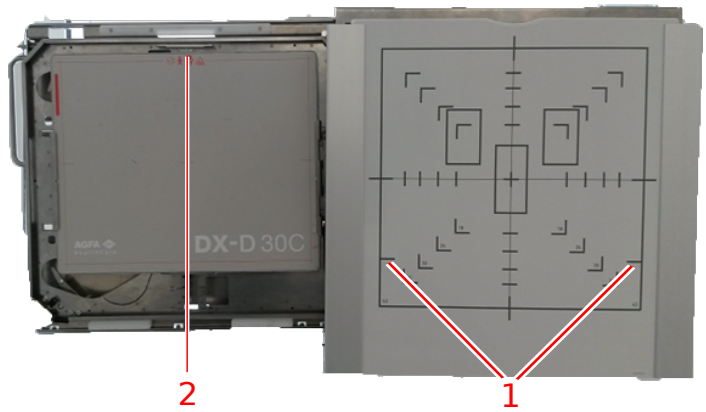
Caution: Make sure your fingers are not between the clamping mechanism and the detector. The clamping mechanism may hurt your fingers, therefore take special care.

4. Remove the cassette or detector from the clamping. The openings in the carrier allow your fingers to grip the detector or cassette.
5. Load the bucky with another cassette or detector.
   - Alternatively, close the bucky drawer using the front handle and pushing the button to release the brake.

Cassette and detector formats

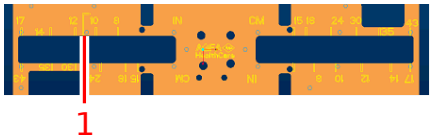
To adjust the side clamps to the format of the cassette or detector, indications are available in cm (and inch, depending on the bucky type). Corresponding indications are printed on the wall stand cover to align the collimation area.

The 43 cm x 35 cm (17 inch x 14 inch) cassette or detector can be positioned either centered or aligned to the top of the bucky in landscape position.



1. Indicators for large format cassette or detector position to the top of the bucky
2. Large format detector positioned to the top of the bucky

Figure 16: Wall stand bucky with large format detector positioned to the top of the bucky



1. Indicators for large format cassette or detector position to the top of the bucky

Figure 17: Indicators on bucky tray

Standard cassette formats

35 cm x 43 cm
35 cm x 35 cm
24 cm x 30 cm
18 cm x 24 cm
15 cm x 30 cm

DR Detector formats and orientation

Refer to the user manual of the DR detector for instructions on the correct orientation of the detector when using it in the bucky.

The following sections contain instructions for specific situations where the instructions in the user manual of the detector do not apply.

Anti-scatter grids

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

For DR detectors focused grids are used. Focused grids require centering of the X-ray source to the detector and a specific distance range between X-ray source and detector. The color of the handle of the grid indicates which distance the grid is used for.

To change the grid in the radiographic table or the radiographic wall stand:

1. Pull out the grid using the handle.
2. Store the grid in a safe place to avoid damage.
3. Insert the grid with labels facing up in the appropriate slit of the bucky. Make sure the grid is pushed up to the end.

Warning: Handle anti-scatter grids with care and store them in a safe place when not in use. Dropping the grid can cause damage and create visible image artifacts or reduce image quality.

Caution: Using a focused anti-scatter grid with the X-ray source not centered or on a wrong distance may cause reduced image quality.

Caution: Injury of the patient or damage to the equipment can be caused by the anti-scatter grid if it is not properly inserted in the bucky.

- Anti-scatter grids on page 50
- Anti-scatter grid focal distance color indication on page 51

Related information

Bucky Unit Technical Data on page 63

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

Anti-scatter grid focal distance color indication

The handle of the grid is visible when the grid is inserted and its color indicates the focal distance of the grid.

Table 2: Grid focal distance color indication

Focal Distance	Color	
100 cm	red	
150 cm	green	
180 cm	blue	
Parallell grid	gray	

Product Information

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

The system is compliant with specific directives and standards.

General

- The product has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR)
- ISO 13485
- ISO 14971

Safety

- IEC 60601-1
- IEC 60601-1-6, EN 60601-1-6
- CSA C22.2 60601-1
- AAMI ES 60601-1

Electromagnetic Compatibility

- IEC 60601-1-2, EN 60601-1-2

For USA

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the installation manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. If required, contact your local service organization.

For Canada

This class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Environmental Compliance

- European Council Directive 1907/2006 (REACH)
- European Council Directive 2011/65/EU (RoHS 2)
- European Council Directive 2012/19/EU (WEEE)

Biocompatibility

- EN ISO 10993-1

Equipment Classification

Per EN/IEC 60601-1, EN/IEC 60601-2-54, this device is classified as following:

Table 3: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not rely on basic insulation only, but includes a fixed connection to mains power with protective earth conductor.
Type B applied part	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.
Protection against ingress of solid foreign objects and water	IP10 This device is protected against solid objects with a size (diameter) of 50 mm or larger. This device is not protected against droplets of water.
Cleaning	See section on cleaning and disinfecting.
Disinfection	See section on cleaning and disinfecting.
Flammable anesthetics	This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
Operation	Continuous operation.

Related information

Cleaning and Disinfecting on page 23

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.

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on Medical Devices); 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.

Contact 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

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.

Technical Data

DR 400 Technical Data

Manufacturer	Agfa NV Septestraat 27 2640 Mortsel, Belgium
Type	5520/150
Electrical connection for system with fixed DR detector	100-240 V, 50-60 Hz, 1.3-0.5 A

Environmental conditions

Table 4: Environmental conditions for the X-ray system

Environmental Conditions (during storage and transport)	
Temperature (ambient)	between -15° and 50° Celsius
Humidity (non condensing)	between 15 and 90 % relative humidity
Atmospheric pressure	between 70 and 106 kPa
Environmental Conditions (during normal operation)	
Temperature (ambient)	between 10° and 35° Celsius
Humidity (non condensing)	between 30 and 75 % relative humidity
Atmospheric pressure	between 70 and 106 kPa
Maximum altitude	3000 m

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.

Radiographic Wall Stand Technical Data

Manufacturer	Agfa NV Septestraat 27 2640 Mortsel, Belgium
Type	
WS-Manual-001	5522/100
WS-Manual-T-001	5522/200
Dimensions	
Height	2245 mm
Width	610 mm (only front panel) 715 mm (with tilting handles) 825 mm (with patient hand grips)
Depth	380 mm (vertical wall stand) 640 mm (tilting wall stand) 730 mm (vertical wall stand with spacer) 990 mm (tilting wall stand with spacer)
Height of detector center	33.5 to 185 cm
Angle of the detector	-20° to +90°
Typical SID range	100 cm to 280 cm (decided during installation)
Distance between front panel and detector	48 mm
Front panel attenuation equivalent mm Aluminum	≤ 0.7 According to DIN EN 60601-1-3 with 100kV and HVL 3.6 mm Al FDA 21 CFR § 1020.30 (n) with 100kV and HVL 3.6 mm Al
Weight	
Weight	157 kg (vertical wall stand) 196 kg (tilting wall stand) 166 kg (vertical wall stand with spacer) 205 kg (tilting wall stand with spacer)
Maximum load on the bucky	32 kg
Maximum load on the brakes for the vertical movement	250 N
Electrical connection	

Operating voltage	24 VDC
Operating current	0.75 A

Bucky Unit Technical Data

Manufacturer	Agfa NV Septestraat 27 2640 Mortsel, Belgium
Type	
BT-Cassette-WS-L-001 (bucky for radiographic wall stand, left loading)	5523/200
BT-Cassette-WS-R-001 (bucky for radiographic wall stand, right loading)	5523/250
BT-Fixed-WS-L-001 (bucky for fixed DR detector, left loading)	5523/310
BT-Fixed-WS-R-001 (bucky for fixed DR detector, right loading)	5523/320

Dimensions	
Dimensions in radiographic wall stand	62.5 cm x 61.5 cm x 12.5 cm (WxLxH)
Weight (without detector)	
Bucky for DR Detector in radiographic wall stand	26.0 kg
Fixed DR Detector bucky	13 kg
Electrical connection (type 5523/200, 5523/250)	
Operating voltage	24 VDC
Operating current	80 mA
Electrical connection (type 5523/310, 5523/320)	
Operating voltage	24 VDC
Operating current	375 mA
Supported sizes	
Supported sizes	15x30 to 43x35 in portrait and landscape orientation 43x43
Lifetime	
Expected lifetime for the bucky	10 years

Portable DR detector technical data (mounted fixed in the bucky)

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

Remarks for HF-emission and immunity

It is hereby certified that the device has interference suppression according to the EN 55011 Class A as well as the FCC Rules CFR 47 Part 15 Class A.

This device was tested for a normal hospital environment as described above.

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

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning: This device is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

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

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

RF Emission Measurements	Agreement	Electromagnetic Environment Guidelines
High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclusively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emission in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Fulfilled	

The device is used in a professional healthcare / radiological environment. Environmental conditions are stated in the user manual.

This device was tested for a professional healthcare environment as described above. Nevertheless the HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

Resistance to Jamming Test	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment Guidelines**
Discharge of static electricity in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV mains ± 1 kV data lines	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV line-line voltage ± 2 kV line-ground voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakdown, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• 0% U_r for ½ period • 0% U_r for 1 period • 70% U_r (30% breakdown of U_r) for 25 periods at 0° • 0% U_r for 250 periods	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) in accordance with IEC 61000-4-8	30 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
REMARK : U_r is the alternating current in the network before the application of the test level.		

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

Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	

RF communication	Refer to the section "Immunity to RF wireless communication equipment"	
		Disruptions are possible near devices that carry the following symbol: 

The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and FM radio transmitters, cannot be precisely predetermined theoretically. An investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the test level given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.

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. See also the section with precautions on EMC.

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 RF emission Frequency m		
	150 kHz to 80 MHz $d = 1.0 \sqrt{P}$	80 MHz to 800 MHz $d = 0.3 \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.3 \sqrt{P}$
0.01	0.1	0.05	0.05
0.1	0.32	0.1	0.1
1	1.0	0.3	0.3
10	3.2	1.0	1.0

The distance can be determined through the equation for each respective column.

P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table.

REMARK : 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.

Immunity to RF wireless communication equipment

ISM Band (MHz)	**Service**	**Distance (m)**	**Immunity test level (V/m)**
300-390	TETRA 400	0.3	27
430-470	GMRS 460; FRS 460	0.3	28
704-787	LTE Band 13, 17	0.3	9
800-960	GSM 800/900; TETRA 800, IDEN 820; CO-MA 850; LTE Band 5	0.3	28
1700-1990	GSM 1800; COMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	0.3	28
2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	0.3	28
5100-5800	WLAN 802.11 a/n	0.3	9

Precautions on EMC

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: The DR detectors might be interfered with by other equipment.

Cables, transducers and accessories

Cables, transducers and accessories which were tested and found to comply with the collateral standard IEC60601-1-2 (EMC):

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.

from; **to**	**type;** **maximum length**	**remark**
Table output terminal; wall stand input terminal	10 x AWG21 (0.5 mm^2); 20 m	mandatory
table output terminal (230 V); wall stand input terminal	3 x AWG18 (1.0 mm^2); 20 m	mandatory
table output terminal (AEC); wall stand input terminal	CAT 5e (SF/UTP); 20 m	shielded mandatory

Maintenance on EMC relevant parts

Concerning the EMC safety of the DR 400 device, no relevant parts could be inspected by the operator. EMC relevant parts will be inspected from AFGA service engineer within the regular service interval until the end of lifetime. The needed verifications are described in the service manual.