DR 400

5520/100

5520/200

User Manual

3231A EN 20150710 1114

AGFA HealthCare

Contents

Legal Notice

CE

0413

Agfa HealthCare NV, Septestraat 27, B-2640 Mortsel - Belgium

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

Published by Agfa HealthCare N.V.

B-2640 Mortsel - Belgium.

Introduction

Topics:

Introduction to this Manual

Topics:

Scope of this Manual

This User Manual describes the features of the DR 400 System, an integrated X-Ray imaging system. It explains how the different components of the DR 400 System work together.

Warnings, Cautions, Instructions and Notes

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

Warning: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

Caution: Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

Instruction: This sign is typically used in combination with the warning sign when providing a specific instruction. If it is followed exactly, it should avoid the subject of the warning.

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.

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

Introduction to DR 400

Topics:

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, 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

DR 400 is a configurable DR (Direct Radiography X-ray system) or CR (Computed Radiography) X-ray system.

The complete DR 400 consists of the following components:

- RAD Table with an integrated DX-D Fixed DR Detector or with a bucky. In the bucky a DR Detector or a CR cassette can be inserted.
- RAD Wall Stand with an integrated DX-D Fixed DR Detector or with a bucky. In the bucky a DR Detector or a CR cassette can be inserted.
- X-ray tube stand mounted on the RAD Table
- X-ray generator integrated in the RAD Table
- X-ray generator console
- X-ray tube with manual or automatic collimator
- NX image processing software on the NX workstation
- DR Generator Sync Box (depending on the configuration)
- Automatic Exposure Control (AEC)
- Dose Area Product Meter (DAP, optional)

Depending on the configuration the following components are also available:

- Portable DR Detector

DR 400 can be used in combination with:

- DX-G
- DX-M
- CR 30-X (5175/2XX)
- CR 30-Xm
- CR 10-X
- CR 12-X
- CR 15-X

DR 400 has three main configurations:

1. DR configuration with X-ray exposure parameter control on the NX workstation.
2. CR configuration with X-ray exposure parameter control on the NX workstation.
3. Mixed DR and CR configuration with X-ray exposure parameter control on the NX workstation.

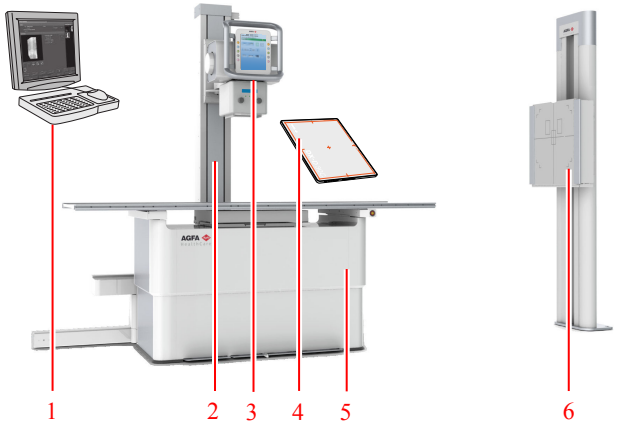
X-ray parameters are controlled using the Software Console on the NX workstation.

The Software Console is available on the NX workstation, to synchronize the X-ray exposure parameters between the NX application and the generator.

Other configurable features include:

- Tube head display with controls for X-ray exposure parameters

- Position tracking for keeping constand SID on table and wall stand
- Bucky with automatic cassette size sensing (ACSS) and automatic collimator



1. NX workstation
2. X-ray tube stand mounted on RAD Table
3. X-ray tube with collimator and tube head display
4. Portable DR Detector
5. RAD Table with integrated generator
6. RAD Wall Stand

Figure 1: DR 400 configuration for DR

Topics:

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:

Topics:

RAD Table

- Table top of the RAD Table
- Patient hand grips (optional)
- Lateral cassette holder (optional)

- Mattress (optional)
- Compression belt (optional)

RAD Wall Stand

- Front panel of the RAD Wall Stand
- Overhead arm support (optional)
- Patient hand grips (optional)

DR Detector

- DR Detector

Equipment Classification

Per EN/IEC 60601-1:2005, EN/IEC 60601-2-54:2009, this device is classified as following:

Table 1: 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 equipment	A Type B piece of equipment is one that provides a particular degree of protection against electric shock particularly regarding allowable leakage current and reliability of the protective earth protection.
Water ingress	IP10 This device does not have protection against ingress 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 Links

Cleaning and Disinfecting on page 46

Options and Accessories

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

For information on options and accessories of the DR Detector, refer to the user manual of the DR Detector.

Related Links

RAD Table Accessories on page 94
RAD Wall Stand Accessories on page 101

Operation Controls

Topics:

RAD Table

The RAD Table is used for positioning of the patient lying or sitting over the detector or the cassette in the bucky for exposure.

The RAD Table supports the patient and the detector or the cassette for free exposure.

Figure 2: RAD Table

Related Links

RAD Table and X-Ray Tube Stand

RAD Wall Stand

The RAD Wall Stand is used for positioning of patients standing upright or sitting towards the bucky for exposure.

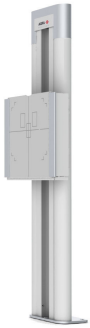


Figure 3: RAD Wall Stand with vertical bucky

Related Links

RAD Wall Stand on page 96

Control Panel of the X-Ray Tube Stand

Figure 4: Control Panel of the X-Ray Tube Stand with tube head display (controls for X-ray tube position and for X-ray exposure parameters)

Figure 5: Control Panel of the X-Ray Tube Stand with X-ray tube angle display

Related Links

RAD Table and X-Ray Tube Stand on page 86

Tube head display

The tube head display can be used to control X-ray exposure parameters. It displays the system status.

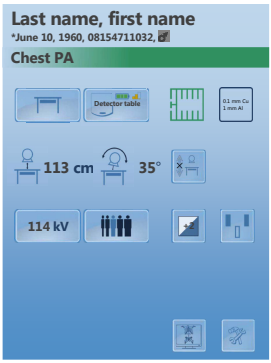


Figure 6: Example of the tube head display

Related Links

Tube head display on page 85

NX Application on the NX Workstation

The NX application is used to define patient information, select exposures and process images.

Figure 7: the NX application

Software Console

The Software Console is available to support X-ray exposure parameter control on the NX workstation. It is displayed on the NX workstation next to the NX application.

The Software Console is used to control the X-ray exposure settings.

The Software Console contains the DR Detector Switch.

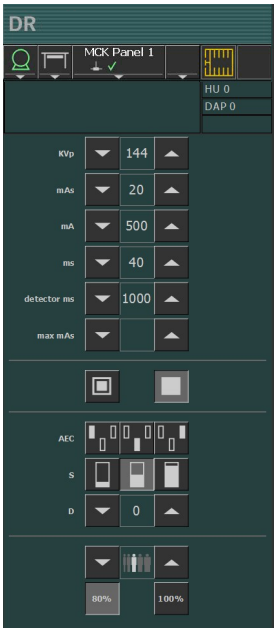


Figure 8: Software Console

DR Detector Switch

The DR Detector Switch is available in the device status frame of the Software Console.

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. The DR Detector Switch can be switched to CR, depending on the configuration.

Figure 9: DR Detector Switch

DR Detector Status

Battery status icon				
Meaning	Full	Medium	Low	Empty

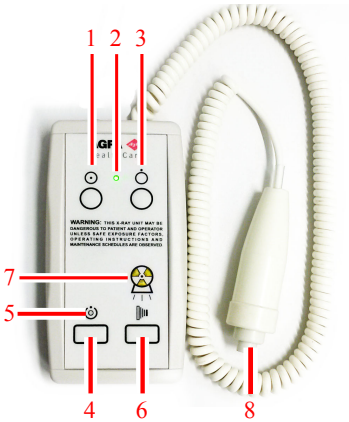
Connection status icon (wifi/ wired)				

Meaning	Good	Low	Bad	Wired DR Detector

DR detector status icon		 (blinking)			?
Meaning	Ready	Initializing exposure	Error	Sleep	One DR detector must be selected

X-ray generator mini console

The X-ray generator mini console is available in the operator room.



1. Power ON button
2. Power ON indicator
3. Power OFF button
4. Press and hold to prepare for exposure
5. Prepare ready indicator
6. Press and hold to start the exposure
7. Radiation indicator
8. Exposure button

Figure 10: X-ray generator mini console

Exposure button

Preparing for exposure

Press the exposure button down to the first pressure point and hold it for approximately 0.5 s to 2 s.

The X-ray tube is prepared for performing an exposure.

Starting the exposure

Before starting the exposure:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check the Ready for Exposure status.

Press the exposure button down fully and keep it pressed until the exposure has ended.

The radiation indicator on the control console lights up and a signal sounds to indicate the exposure.

Note: *Letting the exposure button go ends the exposure immediately and the exposure can be underexposed.*

Manual collimator

The collimator sets the exposure field and displays it by means of a light field.

The collimator provides X-ray filtering using the integrated filters or by inserting a filter in the rails.

A DAP meter (Dose Area Product Meter) can be mounted on the collimator by inserting it in the rails.

Figure 11: Collimator

Related Links

Ralco R221 Collimator Technical Data on page 167

Automatic collimator

The collimator sets the exposure field and displays it by means of a light field.

The collimator provides X-ray filtering using the integrated filters or by inserting a filter in the rails.

An integrated DAP meter (Dose Area Product Meter) in the collimator is available as an option.

Figure 12: Collimator

Related Links

Automatic Collimator on page 125

Automatic Cassette Size Sensing on page 114

Ralco R225 ACS Collimator Technical Data on page 168

DR Detector

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

1. Tube side
2. Patient orientation marker

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 on the RAD Table. All motor driven movements will be stopped.

Motor driven movements:

- RAD Table
- RAD Wall Stand
- X-ray tube stand

To allow motorized movements again, turn the cap of the emergency switch in clockwise direction (default position).

Warning: The emergency stop button does not switch off the voltage in the X-ray system.

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 DR 400 user documentation consists of

- DR 400 User Documentation CD (digital media)
- NX User Documentation CD (digital media)

The DR 400 User Documentation CD contains:

- DR 400 User Manual (this document)
- DX-D Software Console, DR Tube Head Display User Manual, document 0389
- User manuals for the supported DR Detectors
- DX-D DR Detector Calibration Key User manual, document 0134

Other documentation available on the DR 400 User Documentation CD:

- DAP Datasheet
- X-ray Tube Documentation
- Collimator Datasheet
- AEC Datasheet
- X-ray Generator User Manual
- Test Report for IEC60601-1-3
- Test Report for DIN6868-150

Training

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

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

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

Product Complaints

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

If the device malfunctions and may have caused or contributed to a serious injury, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

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

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

Compliance

The system is compliant with specific directives and standards.

Topics:

General

- The product has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and have been tested as part of the conformity assessment procedures required by 93/42/EEC Medical Device Directive (European Council Directive 93/42/EEC on Medical Devices).
- ISO 13485:2003 + Cor. 1:2009
- ISO 14971:2009

Safety

- IEC 60601-1: 2005
- IEC 60601-1-6:2006, EN 60601-1-6:2007
- CSA C22.2 60601-1:2008
- AAMI ES 60601-1:2005

Electromagnetic Compatibility

- IEC 60601-1-2:2007, EN 60601-1-2:2007

Topics:

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.

X-Ray Safety

- IEC 60601-1-3:2008
- IEC 60601-2-54:2009
- IEC 60601-2-28:2010

For USA

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

X-Ray Accuracy

The system fulfills the X-ray radiation accuracy according EN IEC 60601-2-54 with a variation of max. 0.05 (5%).

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 10993-1:2009

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.*

Installation

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

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

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

HF-emission and immunity

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

A specific installation environment may require special measures to put the system into operation according to the remarks for HF-emission and immunity.

Related Links

Cables, transducers and accessories

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 and the material of the object. 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, keep maximum distance from X-ray source, regular training, etc.)
- protection of patients against unnecessary radiation (e.g. limitation of X-ray field by collimation, lead shielding, lead aprons, etc.)

Topics:

- *Monitoring of Personnel*
- *Protected area and significant zones of occupancy*

Monitoring of Personnel

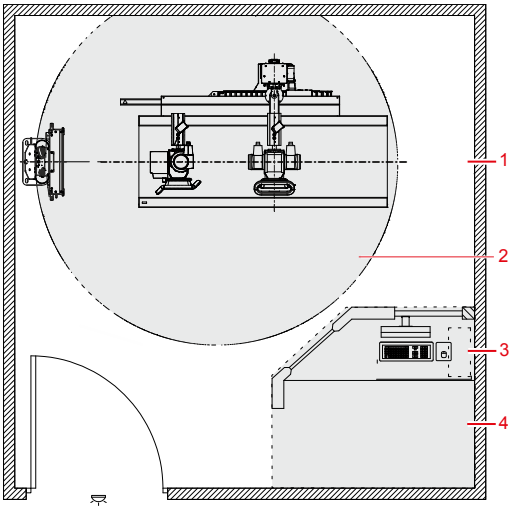
The monitoring checks the amount of X-ray radiation the personnel has been exposed to. It determines safety of the operators and it helps checking if safety measures of the X-ray environment are adequate. Inadequate or improper protection can lead to serious damage to the health.

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 14: Protected area and significant zones of occupancy

Warning: The radiation protection has to be applied to the patient.

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.

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

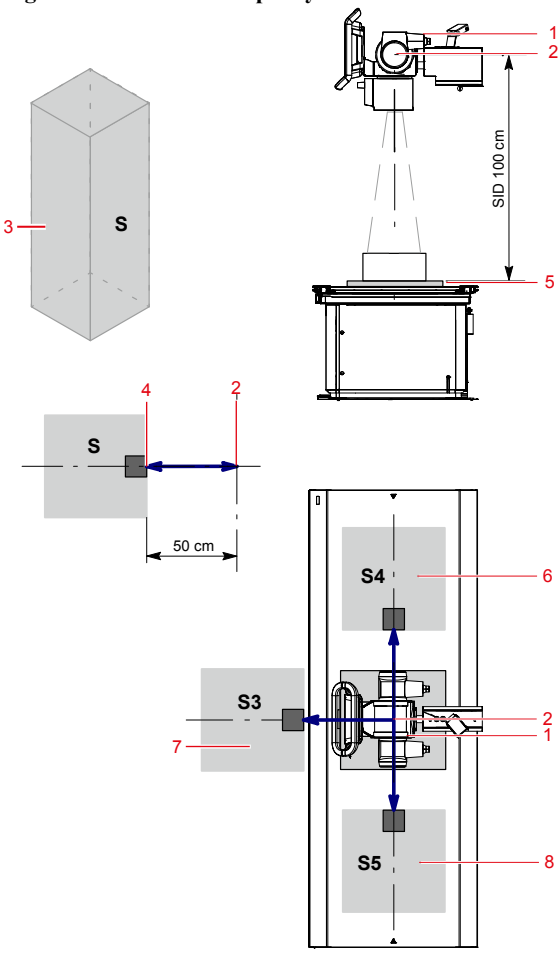
Related Links

Radiation Protection on page 35

Topics:

- *Significant zones of occupancy at the RAD Table*
- *Significant zones of occupancy at the RAD Wall Stand*

Significant zones of occupancy at the RAD Table



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

   Minimum area 60x60 cm.

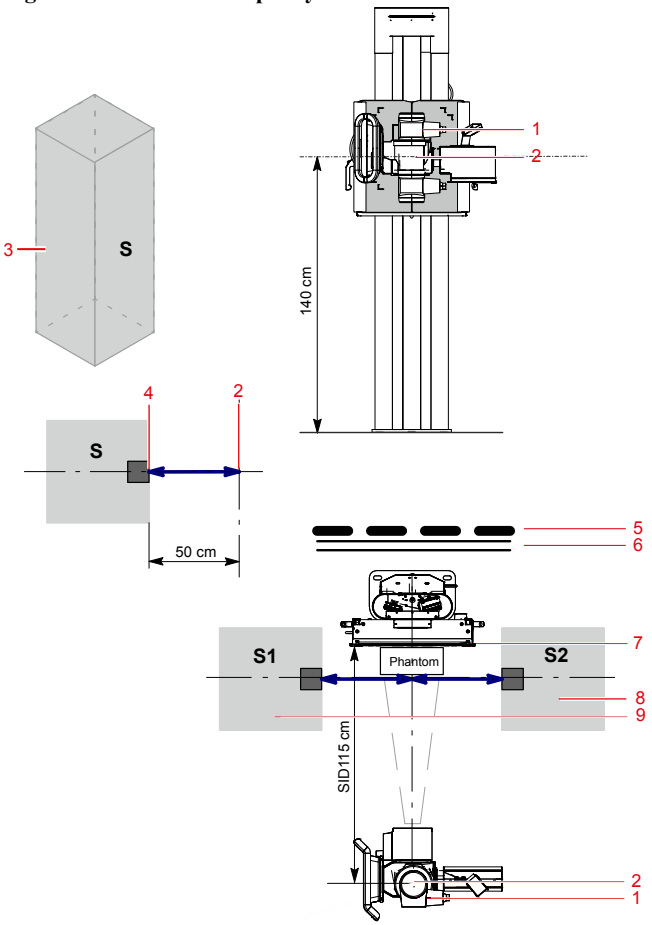
   Minimum height above the floor 200 cm.
4. Dose meter
5. DR Detector or cassette
6. Significant zone of occupancy at the left side of the RAD Table
7. Significant zone of occupancy in front of the RAD Table
8. Significant zone of occupancy at the right side of the RAD Table

Figure 15: Significant zones of occupancy at the RAD Table

Related Links

Radiation Protection on page 35
Stray Radiation on page 186

Significant zones of occupancy at the RAD Wall Stand



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. Significant zone of occupancy at the right side of the RAD Table

9. Significant zone of occupancy at the left side of the RAD Table

Figure 16: Significant zones of occupancy at the RAD Wall Stand

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

Related Links

Radiation Protection on page 35
Stray Radiation on page 186

Labels

Mark	Meaning
	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	This mark indicates that this is a Type B Equipment
	Serial number
	Manufacturer
	Date of manufacture

Label	Meaning
	Dangerous voltage
	Ionizing radiation
	Gaseous disinfectant. If a disinfectant is used that can form an explosive gaseous mixture, they must have evaporated and the system must be aerated before it is switched on again.
	Pinch Points.
	Risk of stumbling.

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

Topics:

- *Warning labels on the RAD Table*

Warning labels on the RAD Table

Figure 17: Warning labels on the RAD Table

Warning labels on the RAD Wall Stand

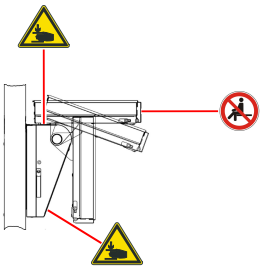
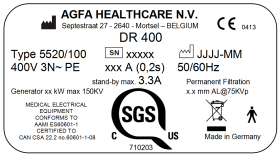
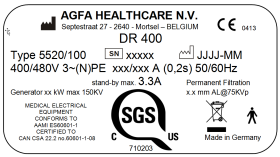
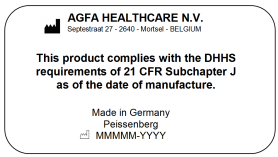


Figure 18: Warning labels on the RAD Wall Stand

Type label

Mark	Meaning
  (Sample of subtype 5520/100)  *Note*: The CE sign and safety signs are only valid at time of product release.	Type label positioned on the lower left hand side of the X-ray tube stand. The type label information for each combination of X-ray tube and X-ray generator is available in the technical data.
	This mark indicates that this is a Type B Equipment
	The 21 CFR Subchapter J label is positioned close to the type label.

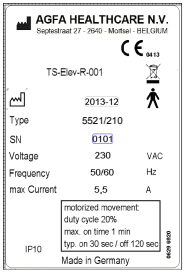
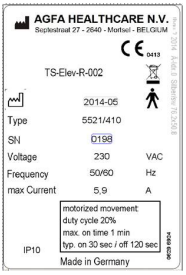
Related Links

DR 400 Technical Data on page 153

DR Detector identification label

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

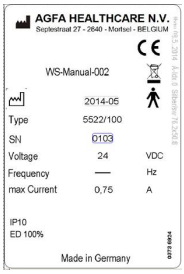
Additional Labeling of the RAD Table

 (sample of subtype 5521/210)  (sample of subtype 5521/410)	Type label on the lower left hand side of the X-ray tube stand. The type label information for each combination of X-ray tube and X-ray generator is available in the technical data.
	This mark indicates that this is a Type B Equipment
	The RAD table is designed for a maximum patient load of 320 kg.

Related Links

RAD Table and X-Ray Tube Stand Technical Data on page 157

Additional Labeling of the RAD Wall Stand

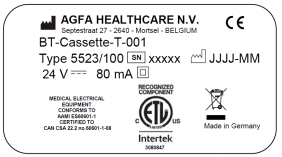
	Type label on the lower right hand side of the RAD Wall Stand stand The type label information for each combination of X-ray tube and X-ray generator is available in the technical data.

(Sample of subtype 5522/100)	
	This mark indicates that this is a Type B Equipment
	Functional earth
	The bucky can be tilted to horizontal position. Do not use the bucky as a seat.
	A pinch point label is located on top of the tilting extension.

Related Links

RAD Wall Stand Technical Data on page 160

Labeling of the bucky

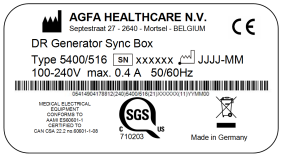
 (Sample of subtype 5523/100)	The type label is located on the rear cover of the bucky or on the bucky drawer below the rotating platform. The type label information for each bucky model is available in the technical data.
	Class II equipment.
	Pinch Points. The label is positioned on the lateral cover 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 Links

Bucky Unit Technical Data on page 164

Labeling of the DR Generator Sync Box

	The type label is located on the DR Generator Sync Box
	Functional earth
	Medical equipotential

Cleaning and Disinfecting

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

Topics:

Cleaning

To clean the exterior of the equipment:

1. Stop the system

Warning: **When the equipment is going to be cleaned, be sure to turn off the 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.

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

3. Start up the system.

Cleaning the tube head display during operation

To clean the tube head displayed during operation

1. Press the tools button

Figure 19: Tools button

2. Press the cleaning button

Figure 20: Cleaning button

A black screen hides the screen and shows a number counting down.

3. Clean the display.
   The operation is not affected.
4. The display can be used again after the countdown has finished.

Disinfecting

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

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

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.**

To disinfect the device:

- Do not use any corrosive, soluble or gaseous disinfectants.
- 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.

- Using unsuitable disinfectants can cause discoloration and damage of the surface of the equipment.

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/main/products_services/product-info/technology/disinfectants_dx_d_systems.jsp

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

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

Topics:

Maintenance

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

Maintenance of the DR Detector

The DR Detector requires regular calibration. Calibration instructions are described in the DX-D DR Detector Calibration Key User Manual (doc 0134).

Maintenance of the RAD Table, RAD Wall Stand and X-Ray Tube Stand

The X-ray unit and all components require 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: Improper, irregular or lack of maintenance of the equipment can lead to injuries to persons (e.g. by radiation hazard) and property damage as a result of malfunctions and defects 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 system can lead to personal injury 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.

Table 2: Lifetime and maintenance

Lifetime	
Expected lifetime for the X-ray unit	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
All steel cables of X-ray tube stand and RAD Wall Stand shall be checked	Every 12 months
All steel cables of X-ray tube stand and RAD 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
Warm-up of X-ray tube	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.

Caution**:** The use of spare parts from third party suppliers can affect the safety of the equipment. If components fail, use only original spare parts.

Warming-up of X-ray tube

The X-ray tube needs to be warmed-up before making X-ray exposures at the start of each day and when the X-ray tube has not been in use for more than an hour. This extends the X-ray tube lifetime.

To warm-up the X-ray tube

1. Close the collimator blades fully
2. Select 70 kV, 100 mAs, 200 mA and 500 ms exposure settings
3. Ensure that no one will be exposed
4. Make a total of three exposures, 15 seconds apart

This procedure is used for a typical X-ray tube. Consult the X-ray tube manufacturer instructions for the actual X-ray tube in use and comply with the instructions if there is conflict with this procedure.

Environmental protection

Figure 21: WEEE symbol

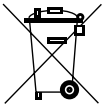


Figure 22: Battery symbol

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. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

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

Topics:

General Safety Directions

Warning: Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

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: All Agfa medical products must be used by trained and qualified personnel.

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.

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.

Safety Directions for the X-Ray System

Warning: 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: Avoid unnecessary dose by checking the workstation selection on the X-ray generator console before exposing. In a configuration with a DR Detector configured on a virtual port, the DR Detector will not be triggered if a free exposure is selected on the Generator console and yet the exposure will be allowed.

Warning: Repeated exposures to a patient with high doses can lead to deterministic effects. Therefore exposure settings shall be selected carefully and in accordance to the patient and the object to expose and balanced in such a way that patient dose is as low as possible while image quality is usable for diagnosis.

Warning: Even if the generator is switched off, parts on the inside of the generator cabinet and connected controls are still powered! Ensure that only trained service personnel open the generator cabinet and the housing of connected devices! Improper handling may cause a lethal hazard!

Caution: When operating the DR detector, the calculated exposure time (ms) or manual overrides should never exceed the maximum exposure time (Max ms) specified as integration time of the DR detector.

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. If ambient temperature and humidity is outside the range specified in the technical data, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

Caution**:** To avoid images being lost due to a power failure, the workstation and the digitizer have to be connected to an uninterruptable power supply (UPS) or an institutional standby generator.

Caution**:** Install the NX workstation and CR digitizer at a minimum (safe) distance of 2 m from the X-Ray System components or provide a wall or window to separate both systems.

Safety Directions for the RAD Table

Warning: The system is not intended for operation in explosion-prone areas. Such an operation is hazardous to life and health because of explosion risk. Please note the applicable regulations on formation of explosive gas mixtures when cleaning and using in combination with patients.

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 installed with components that emit radiation or can be triggered to emit radiation. Ionizing radiation can result in radiation damage or injury if not handled properly.

Warning: Portable and mobile HF communication devices may affect medical electrical equipment.

Caution**:** Using soft covers, sheets, mattresses, etc. may lead to visual image artifacts. If such shall be used, make sure that they are x-ray transparent and do not influence image quality.

Caution**:** Make sure that the patient hand grips are securely mounted.

Getting started

Topics:

Starting the System

To start the system:

Note: *Allow the DR Detector to warm up before the system 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 electrical room switch.

   Check that the emergency shutdown power switch for the system and the emergency stop button for the RAD Table is not activated.
2. Press the Power ON button on the X-ray generator control box to switch on the system.
3. Start the NX workstation.

   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. Switch on the DR Generator Sync (if applicable).
5. 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.
6. Switch on the control unit for the DR Detector.

Basic workflow using the DR Detector

Topics:

Step 1: retrieve the patient info

At the NX workstation:

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

Step 2: select the exposure

In the operator room:

At the NX workstation, select the thumbnail for the exposure in the Image Overview pane of the Examination window.

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

The selected DR Detector is activated.

The RAD Table or RAD Wall Stand lights up in blue, indicating the selected modality position.

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

- Red (flashing): starting up
- Green (constant): ready for exposure

Step 3: prepare the exposure

In the examination room:

1. Position the DR Detector.

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

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

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

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

Step 4: check the exposure settings

Related Links

DR Detector Switch on page 21

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 on the Software Console:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check the Ready for Exposure status.

Step 5: execute the exposure

In the operator room:

Press the exposure button to execute the exposure.

Instruction: *Make sure the generator is ready for exposure before you press the exposure button.*

Warning: During exposure ionizing radiation is emitted by the X-ray system. To indicate the presence of ionizing radiation, the radiation indicator on the control console lights up.

Warning: Do not select another thumbnail until the preview image is visible in the active thumbnail.

In the operator room at the NX workstation:

- While the acquisition is ongoing, the thumbnail status indicator is flashing green. 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 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).

Basic workflow 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 NX workstation:

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

Step 2: select the exposure

In the operator room at the NX workstation:

1. Select the thumbnail for the exposure in the Image Overview pane of the Examination window.
2. Select CR in the Detector Switch.
3. Select the Modality Position (RAD Table, RAD Wall Stand, Free exposure) in the Software Console.

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

   The RAD Table or RAD Wall Stand lights up in blue, indicating the selected modality position.
4. 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

In the examination room:

1. 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.

Note: For a bucky exposure, always insert an unexposed cassette in the bucky.

2. Position the patient.
   Apply radiation protective measures for the patient if needed.
3. Check if the X-Ray system position is suitable for the exposure.
4. Position the X-Ray tube with respect to the cassette and the patient.
5. Set the correct distance between cassette and X-Ray tube.
6. Switch on the light on the collimator. Adapt collimation if required.
   Take care that the collimated area is not larger than the cassette.

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

Step 4: check the exposure settings

In the operator room on the Software Console:

1. Check if the exposure settings displayed on the console are suitable for the exposure.
2. Check the Ready for Exposure status.

Step 5: execute the exposure

In the operator room:

Press the exposure button to execute the exposure.

Warning: During exposure ionizing radiation is emitted by the X-ray system. To indicate the presence of ionizing radiation, the radiation indicator on the control console lights up.

- The actual X-Ray exposure parameters are sent back from the generator 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).

X-Ray System Positioning

Topics:

RAD Table Exposures

1. Position the patient on the RAD table.
2. Position the X-ray tube stand with the X-ray tube over the patient.

   The bucky is automatically aligned to the X-ray tube by mechanical coupling.
3. Center the examined body part over the bucky using the floating table top.

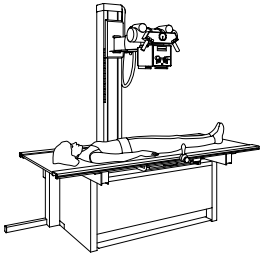


Figure 23: RAD Table Exposures

Oblique Exposures

1. Position the patient on the RAD Table.
2. Move the X-ray tube stand out of the coupling range of the bucky.
3. Position the bucky under the patient.
4. Set the required angle of the X-ray tube.
5. Adjust the position of the X-ray tube stand to align the X-ray exposure field to the center of the bucky using the collimator light and the bucky markers for orientation.

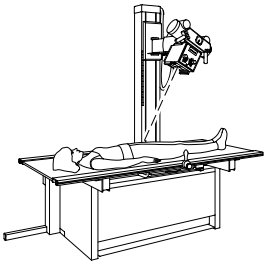


Figure 24: Oblique Exposures

Lateral Exposures

1. Unlock the X-ray tube arm and rotate 90° around.
2. Rotate the X-Ray tube 90° around.

   Check the angle on the angle display.
3. Mount the lateral cassette holder on the side rail of the tabletop. Fix it using the two lower screws. Take care to lift the holders slightly up when moving it, to protect the tabletop from scratching.
4. Insert a cassette or a DR detector. Fix it using the upper screw.
5. Position the patient on the table between the X-ray tube and the lateral cassette holder. Adjust the lateral cassette holder to position the cassette as close as possible to the patient. Fix the position using the middle screw.

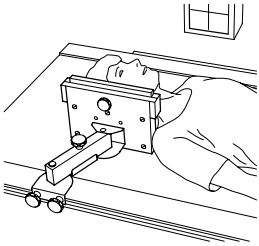


Figure 25: Lateral Exposures

RAD Wall Stand Exposures

1. Adjust the height of the bucky on the RAD Wall Stand.
2. Position the patient in front of the RAD Wall Stand.
3. Move the table top away from the RAD Wall Stand.
4. Rotate the X-ray tube 90° to face the RAD Wall Stand.

   Check the angle on the angle display.
5. Move the X-ray tube stand towards the RAD Wall Stand.
6. Adjust the height of the X-ray tube to center the X-ray exposure field on the bucky using the collimator light.

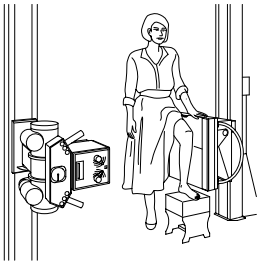


Figure 26: RAD Wall Stand Exposures

Guidelines for Pediatric Applications

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

Please review the following link and reduce pediatric technique factors accordingly: http://www.pedrad.org/associations/5364/ig/

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

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

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

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

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

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

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

Summary:

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

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

Stopping the 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.*

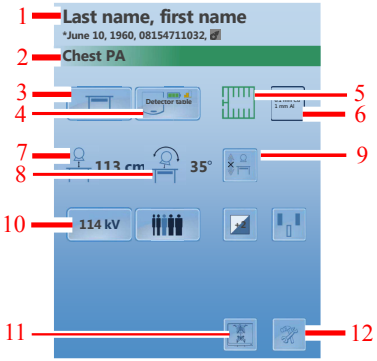
2. Press the Power OFF button on the X-ray generator control box to switch off the generator.
3. In a configuration with a wireless DR Detector, power off the DR Detector:
   - turn off the DR Detector.
   - remove the battery pack.
4. Switch off the DR Generator Sync.

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

Operation

Topics:

Tube head display



1. Patient information
2. Status bar with exam type
3. Modality position
4. DR Detector Switch
5. Grid status
6. Filter status
7. Source Image Distance (SID)
8. X-ray tube angle
9. Position tracking status
10. Radiographic parameters
11. Image preview
12. Tools

Figure 27: Example of the tube head display

For detailed information, refer to the DR Software Console and Tube Head Display User Manual (document 0389).

RAD Table and X-Ray Tube Stand

The RAD Table with integrated X-ray tube stand allows X-ray examinations from head to foot of lying or sitting patients.

The tube stand has two variants, depending on the side where the tube stand rail is protruding:

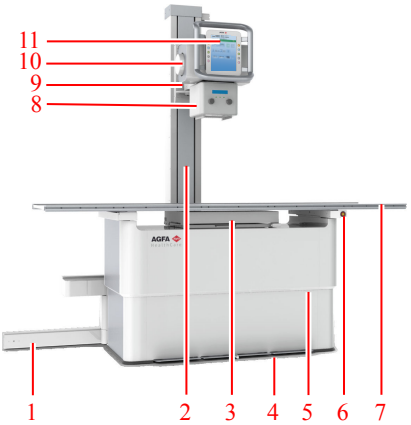
- Left hand version
- Right hand version

The table has two variants:

- table with fixed height
- elevating table with adjustable height

The table has a floating table top.

The table has blue LED in the table foot that is lit when the RAD Table is selected as active workstation.

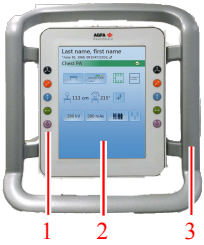


1. Rail system
2. X-ray tube stand with SID ruler
3. Bucky
4. Tabletop movement pedals,

   Blue LED indicator light for active workstation
5. Table covers with standard exposure height marker
6. Emergency stop button
7. Tabletop
8. Collimator
9. X-ray tube arm
10. X-ray tube

11. Control panel of the X-ray tube stand

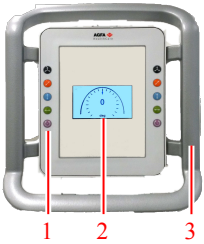
Figure 28: RAD Table with integrated X-ray tube stand, example of left hand version



1. Movement control buttons
2. Tube head display
3. Handle with integrated release button for omni direction movement.

Figure 29: Control panel of the X-ray tube stand

Depending on the configuration, an extra control button for omni direction movement is available on the lower side of the handle.



1. Movement control buttons
2. X-ray tube angle display
3. Handle

Figure 30: Control panel of the X-ray tube stand

Topics:

- *Positioning the X-Ray Tube Stand*
- *Positioning the RAD Table*
- *Positioning the Bucky*
- *RAD Table Accessories*

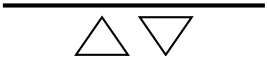
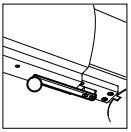
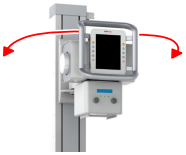
Positioning the X-Ray Tube Stand

The operation controls of the X-ray tube stand are located at the control panel. The X-ray tube stand must be positioned by the operator manually.

To release the brake for the selected movement direction or rotation, press and hold the button and move the X-ray tube stand.

To stop the movement and activate the brake, release the button.

Table 3: Movement controls

	Omni direction movement (longitudinal, vertical and alpha rotation)
	Transversal axis movement (back & front). A marker on the X-ray tube arm indicates the center position. 
	Vertical axis movement (up & down) A ruler on the X-ray tube stand indicates the SID when the RAD Table is positioned on the standard exposure height. The lower edge of the X-ray tube arm mounting is used for reference. 
	Longitudinal axis movement (right & left)
	Alpha axis rotation (Angle of the X-ray tube)
	Beta axis rotation (swivel of the X-ray tube arm around the tube stand axis) 

	Rotation of the collimator around the axis of the X-ray beam 

The standard position of the X-ray tube arm is indicated by markers. When the tube arm is in standard position it is centered in transversal direction on the bucky.

Note: To avoid shock and damage, move the column with normal speed and slow down when reaching the mechanical end stops.

Caution: If a grinding noise is heard during vertical movement of the X-ray tube arm or RAD Wall Stand, the steel cables inside the tube stand or wall stand could be broken. Do not operate the unit any further and try to avoid hard vibration or knocks of any kind. Please contact service.

Caution: Rotation may be limited by cables. Avoid strain on the cables during rotation.

Related Links

Movement ranges on page 158
Ralco R221 Collimator Technical Data on page 167
Ralco R225 ACS Collimator Technical Data on page 168
Positioning the Bucky on page 93

Topics:

Stop positions

The system includes stop positions.

- On the longitudinal axis movement, to position the X-ray tube in regularly used exposure distances to the RAD Wall Stand, e.g. 150 cm and 180 cm.
- On the vertical axis movement, to position the X-ray tube stand in regularly used exposure distances to the RAD Table, e.g. 115 cm.

The preferred positions of the stops are defined during installation.

The vertical stop on the tube stand is always active. The two transversal stops are active when the X-ray tube is rotated towards the wall stand (90°+/- 10°).

To enter a stop position, move the X-ray tube stand or the X-ray tube arm in longitudinal or vertical direction. The movement is stopped when the stop position is reached. Moving too fast may cause the X-ray tube stand to skip the stop position.

To leave a stop position, release and press again the according movement control button.

Collision indicator

Systems with motorized movement have a collision indicator. The collision indicator avoids collision of the X-ray tube head with the table.

The collision indicator will give a signal in following situations:

- The X-ray tube head is moved manually close than 30 cm to the table top when performing an examination using the table.
- The X-ray tube head is moved manually closer than 15 cm to the table top when performing an examination using the wall stand and the X-ray tube head is rotated toward the wall stand.

The brake is activated and a single beep indicates the collision warning.

To further adjust the position, release the brake button and press it again.

Related Links

X-ray tube stand tracks wall stand height on page 99

Positioning the RAD Table

There are two versions of the RAD table:

- Fixed height RAD Table with a height of 70 cm
- Elevating RAD Table with adjustable height from 55 cm to 90 cm

The movements of the RAD table are controlled by foot pedals mounted at front side of the table.

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: 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.

Positioning the floating tabletop

To release the brake for moving the floating tabletop, double click and hold the foot pedal. The tabletop can be moved in longitudinal and transversal direction manually.

To stop movement and activate the brake, release the foot pedal.

Table 4: Movement controls

	Foot pedal to release the brake for the floating table top.

Note: When the equipment is switched off, the tabletop can be moved freely. Pay extra attention when a patient needs to get off from the table.

The RAD table is designed for a maximum patient load of 320 kg.

Adjusting height

To adjust the height, double click and hold the foot pedal.

Table 5: Movement controls

	Foot pedal to lower table height (minimum 55 cm).

	Foot pedal to raise table height (maximum 90 cm).

When minimum or maximum position of the table is reached, the movement is stopped automatically.

When the standard exposure height (70 cm) is reached, the movement is stopped automatically. To continue the movement, release the foot pedal and double click it again.

Markers on both sides of the table covers indicate the standard exposure height position.

Figure 31: Standard exposure height

Related Links

Collision protection on page 94
Collision indicator on page 90
Emergency stop button on page 25

X-ray tube stand tracks table height

To keep constant SID while adjusting table height:

1. Set the required SID by adjusting the position of the X-ray tube stand.
   The distance between the X-ray tube head and the table top must not be less than 50 cm.
2. On the tube head display, press the position tracking button.

Figure 32: Table position tracking disabled and enabled

   The button is highlighted.
3. Adjust the table height.
   The X-ray tube stand is moving up or down accordingly.

Note: The movement of the X-ray tube stand has a small delay compared to the movement of the table. The movement of the X-ray tube is automatically stopped if the distance between the X-ray tube head and the table would become too small (SID lower than 45 cm).

Positioning the Bucky

The bucky center position is automatically aligned to the position of the X-ray tube stand. The mechanical coupling between the bucky and the X-ray tube stand is active within the travel range of the bucky.

The bucky can be positioned independently from the X-ray tube stand, e.g. for oblique X-ray exposures.

To position the bucky independently from the X-ray tube stand:

1. Move the X-ray tube stand on the longitudinal axis outside the travel range of the bucky.
   The mechanical coupling is released.
2. Press and hold the bucky lock switch.

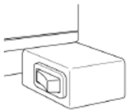


Figure 33: Bucky lock switch

   The lock for the bucky movement is released.
3. Move the bucky in longitudinal direction.
4. Release the bucky lock switch.
   The position is locked.

RAD Table Accessories

Caution**:** 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.

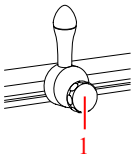
Topics:

Mounting the patient hand grips

The pair of patient hand grips are used to stabilize the patient and give a feeling of security. Using the hand grips will avoid the patient grasping the table edges which could cause a risk to pinch fingers.

To mount a hand grip:

1. Slide the hand grip in the rails of the tabletop.
2. Tighten the hand screw to lock the hand grip in position.



1. Hand screw

Figure 34: Hand grip

*Note***:** The hand grips are not intended to support the weight of the patient.

Collision protection

Collision protection is only available on the elevating RAD Table.

The collision protection accessories are mounted on the frame of the RAD Table. They protect the tabletop from damage when colliding with objects below.

When the collision protection stops downward movement of the RAD table, raise the table height and remove the object before lowering the table again.

Note: The collision protection is influenced by the patient weight. Take special care when moving the RAD Table with a patient lying on.

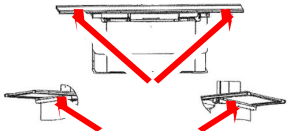


Figure 35: Location of the collision protection accessories

Other RAD Table accessories

On request further accessories for the RAD table are available:

- Mattress

  The mattress fits the tabletop (220 cm x 80 cm) and is X-ray translucent.
- Lateral cassette holder

  The lateral cassette holder supports a cassette or detector in lateral position and is attached to the tabletop.

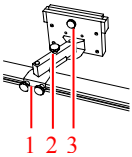


Figure 36: Lateral cassette holder

- Compression belt

  The compression belt provides additional fixation for the patient on the table. It can be adjusted to patient thickness.

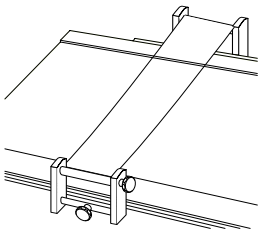


Figure 37: Compression belt

RAD Wall Stand

The RAD Wall Stand allows vertical X-ray exposures of patients standing or sitting in front of the RAD Wall Stand.

The wall stand has two variants:

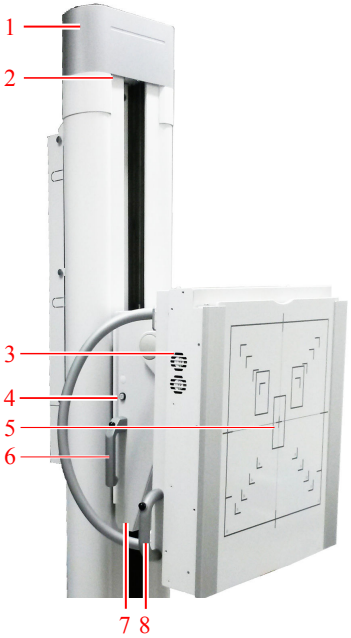
- wall stand with vertical bucky, supporting vertical movement (up and down)
- wall stand with tilting bucky, supporting vertical movement (up and down) and tilting of the bucky

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

- Right hand side loading
- Left hand side loading

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

The wall stand has blue LED in the top that is lit when the RAD Wall Stand is selected as active workstation.



1. Wall Stand column
2. Active workstation indicator
3. Bucky
4. Button to switch on the collimator light
5. Front panel

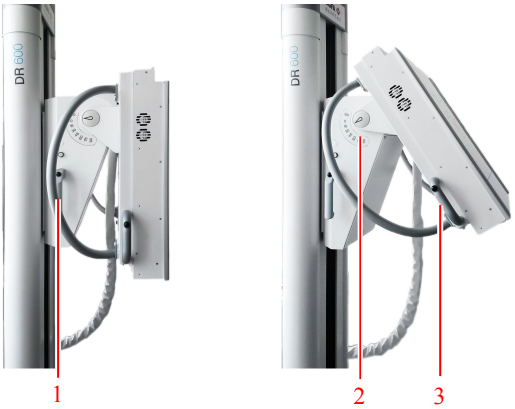
6. Vertical movement handle (both sides)
7. Tilting extension
8. Tilting handle

Figure 38: RAD Wall Stand, vertical version and vertical tilting version

Caution**:** The format indications on the front panel show the format 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 panel 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.

Topics:

Positioning the RAD Wall Stand



1. Vertical movement handle with brake switch
2. Tilting angle scale
3. Tilting handle

Figure 39: Positioning controls

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

Vertical movement

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 RAD 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 bucky movement in vertical direction is 20 kg. The bucky may slip downward when applying excessive load.

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

Tilting

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.

X-ray tube stand tracks wall stand height

To keep constant position of the tube head unit relative to wall stand bucky while adjusting wall stand height:

1. Set the required position of the X-ray tube stand.

   The distance between the X-ray tube head and the table top must not be less than 15 cm.

   Position the X-ray tube head and the table top such that they do not collide when the X-ray tube stand moves up or down.
2. On the tube head display, press the position tracking button.

   Warning: Do not use position tracking while the patient is lying on the table.

Figure 40: Wall stand position tracking disabled and enabled

   The button is highlighted.
3. Adjust the wall stand height.

The X-ray tube stand is moving up or down accordingly.

Note: The movement of the X-ray tube is automatically stopped if the distance between the X-ray tube head and the table top would become too small (less than 10 cm).

Related Links

Collision indicator on page 90
Emergency stop button on page 25

RAD Wall Stand Accessories

Caution**:** 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.

Topics:

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.

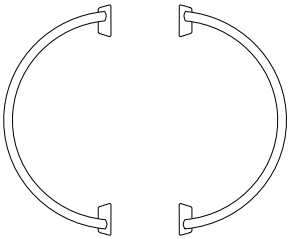


Figure 41: Patient hand grips

Mounting the overhead handle

Warning: The overhead handle can bear up to 20 kg. It is not intended to hold the whole weight of a patient.

Caution**:** Take care that the overhead handle does not collide with the ceiling when moving the bucky upward manually. For automatic movement, a sensor detects if the overhead handle is inserted and the movement is coordinated accordingly.

Caution**:** Do not insert the handle oriented parallel to the bucky. The handle may collide with the Wall Stand column.

Caution**:** Take care of the overhead handle position when tilting the bucky.

To mount and position the overhead handle:

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

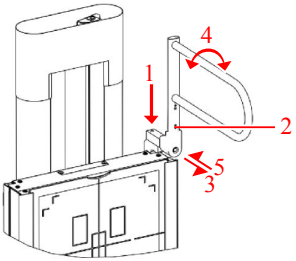


Figure 42: Overhead handle

Spacer

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

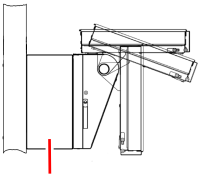


Figure 43: Spacer

Wall stand fixation kit (earthquake kit)

For additional stability of the RAD Wall Stand an additional fixation of the RAD Wall Stand is provided. The kit is installed at backside of the RAD Wall

Stand under the head cover and then fixed to a wall. It has to be installed by service.

Other RAD Wall Stand accessories

On request further accessories for the RAD Wall Stand is available:

- babix hull holder

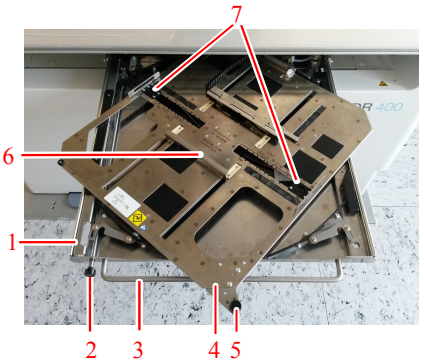
Bucky

The bucky is installed in RAD table and RAD 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 44: Bucky

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

Figure 45: Bucky front view

Topics:

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.

The bucky provides a protection for double exposure by checking if the bucky is re-armed after each exposure.

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.

RAD 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.

Topics:

Bucky types

The type of bucky installed in the system defines which functionality is available.

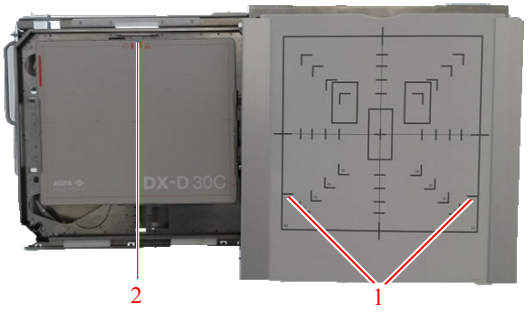
Function	Bucky with tray for multiple cassette or detector formats	Bucky with tray for multiple cassette or detector formats	Bucky for fixed DR detector
RAD Table	5523/100	5523/120	5523/300
RAD Wall Stand, left loading	5523/200	5523/220	5523/310
RAD Wall Stand, right loading	5523/250	5523/270	5523/320
Clamping mechanism	Yes	Yes	-
Rotation mechanism	Yes	Yes	-
Cassette or detector detection	Yes (by micro-switches)	Yes (by micro-switches)	-
CR double exposure protection	Yes	Yes	-
Automatic cassette size sensing (ACSS)	No	Yes	-
Grid type and status detection	No	Yes	Depending on configuration
AEC	Yes	Yes	Yes

ACSS requires the cassette to be positioned in the center of the bucky. Additionally for the RAD Wall Stand, ACSS is supported if a large format cassette or detector (43 cm x 35 cm or 17 inch x 14 inch) is aligned to the top of the bucky in landscape position.

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 large format cassette or detector (43 cm x 35 cm or 17 inch x 14 inch) 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 46: 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 47: 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

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 48: 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 RAD Table

To load the bucky with a cassette or detector:

1. Open the bucky drawer completely by pulling the front handle.
2. Push the cassette or detector towards the rear slider to open the clamping mechanism wide enough to contain the cassette or detector.
3. Let the cassette or detector slip into the clamping.

Warning: Make sure your fingers are not between slider and cassette. The clamping mechanism may hurt your fingers, therefore take special care.

4. Align the cassette or detector center indication to the center mark on the clamp.

Warning:

When positioning the cassette or detector out of center:

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

5. 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.

Related Links

Orientation of DX-D 10C, DX-D 10G in the bucky on page 116

Loading of the bucky in the RAD 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.

Warning: Make sure your fingers are not between slider and cassette. 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.

Warning:

When positioning the cassette or detector out of center:

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

To unload the bucky with a cassette or detector:

1. Open the bucky drawer completely by pulling the front handle.
2. Push firmly with both hands the cassette or detector towards the rear clamp to open the clamping mechanism.

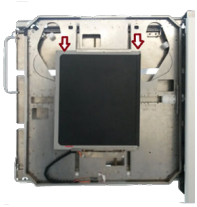
Warning: Make sure your fingers are not between slider and cassette. The clamping mechanism may hurt your fingers, therefore take special care.

3. Lift the cassette or detector and remove it from the clamping. The openings in the carrier allow your fingers to grip the detector or cassette.
4. 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.

Unloading of the bucky in the RAD 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.



Warning: **Make sure your fingers are not between slider and cassette. 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.

Centering and collimating

Depending on the format of the cassette or detector inside the bucky and the body part to expose, collimation and centering of the X-ray field have to be applied before exposure.

Centering

The bucky center position is automatically aligned to the position of the X-ray tube stand.

The bucky provides center marks to check for correct alignment:

- a notch within the hand grip to open/close the bucky drawer.
- a notch in the sliders in the bucky.

The collimator light field contains center lines to check the alignment of the X-ray field to the bucky.

To align the X-ray field, adjust the position of the X-ray tube.

Collimating

To set the X-ray collimation area, pull out the bucky drawer until the cassette or detector edge is visible. Align the X-ray collimation field to the size of the cassette or detector.

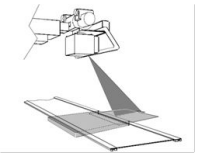


Figure 49: Center line and collimation area

Automatic Cassette Size Sensing

The ACSS functionality of the bucky detects the size and orientation of the CR cassette or the DR detector and allows the collimator to limit the collimated area accordingly. The collimation setting received from the NX workstation or the collimation area set by the user is automatically adjusted.

The cassette or detector must be positioned in the center of the bucky. If the cassette or detector is not in the center of the bucky, the collimated area is automatically expanded to expose the whole surface of the cassette or detector. Because automatic collimation is always symmetrical, on one side the exposure will extend beyond the surface of the cassette or detector and the collimation must be corrected manually to apply an asymmetrical collimation area.

The collimator must not be rotated.

The ACSS functionality of the bucky is only available in combination with the automatic collimator Ralco 225 ACS. The ACCS functionality is not available when the collimator is in manual mode.

Related Links

Automatic collimator on page 23

Orientation of DX-D 10C, DX-D 10G in the bucky

To avoid damage to the cable of the detector, there are restrictions on the orientation of the detector when loading the bucky.

Caution: Inserting DX-D 10C, DX-D 10G using other orientations than described will damage the cable when closing the bucky or when rotating the carrier.

Topics:

Orientation in the RAD Table

To use the detector in portrait orientation, insert the detector in portrait orientation with the cable at lower right hand side.

To use the detector in landscape orientation:

1. Insert the detector in portrait orientation with the cable at lower right hand side.
2. Rotate the detector in the bucky.

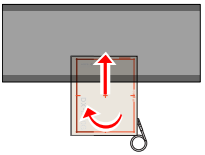


Figure 50: Landscape orientation in the RAD Table

Orientation in the RAD Wall Stand left loading

- To use the detector in portrait orientation, insert the detector in portrait mode with the cable at upper left hand side.
- To use the detector in landscape orientation:

  1. Insert the detector in portrait mode with the cable at upper left hand side.
  2. Rotate the detector in the bucky.

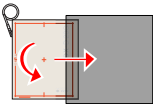


Figure 51: Landscape orientation in the RAD Wall Stand left loading

Orientation in the RAD Wall Stand right loading

- To use the detector landscape orientation, insert the detector in landscape mode with the cable at upper right hand side.
- To use the detector in portrait orientation:

  1. Insert the detector in landscape mode with the cable at upper right hand side.
  2. Rotate the detector in the bucky.

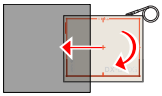


Figure 52: Portrait orientation in the RAD Wall Stand right loading

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 RAD Table or RAD 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.

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

Caution**:** Handle 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**:** If grid is not inserted completely, artifacts on the image can be visible, e.g. of the grid edges. Push the grid all the way up to the end.

Related Links

Bucky Unit Technical Data on page 164

Topics:

- *Grid focal distance color indication*
- *Grid detection*

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.

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

Grid detection

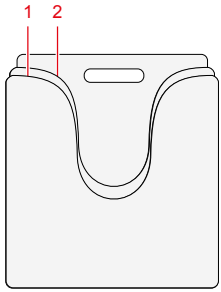
The grid detection functionality of the bucky detects the type and position of the inserted grid.

The grid status is shown on the tube head display and on the Software Console.

Storage box for DR Detector and grids

The storage box provides vertical storage space for a DR Detector and up to three grids. It can be mounted to the wall or stand on a stable surface.

Caution**:** insert the DR Detector and the grids in the storage box with care to avoid damage. Do not drop the items in the storage box.



1. Storage space for a DR Detector
2. Storage space for up to three grids

Figure 53: Storage box

Automatic Exposure Control (AEC)

The use of an AEC ensures optimal and reproducible image quality independent of the radiation, the object exposed or other factors.

The AEC has three sensor elements (ionization chambers)

The AEC is mounted in the bucky of RAD Table and RAD Wall Stand between the grid and the detector or cassette. It is fixed and not intended to be removed from the bucky by the customer. If an exposure shall be done without AEC, the free exposure workflow has to be used, where the detector or cassette is placed outside the bucky, or the AEC has to be switched off in the Software Console.

The AEC is calibrated during production with default values. The AEC can be recalibrated during installation, defining three custom cut-off doses for the AEC sensors, to suit user preferences or to balance out the three AEC sensors.

The shorted irradiation time when using AEC is 2 ms.

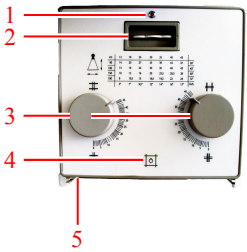
Note: The AEC sensor is located in the bucky above the cassette or detector and may be slightly visible on the image. This applies most to flat field exposures and less to diagnostic images.

Related Links

Automatic Exposure Control (AEC) Technical Data on page 166

Manual Collimator

The Collimator can rotate ± 90° on its vertical axis while the X-ray tube remains in the same position. This movement is performed by manually turning the collimator and has detents every 90°.



1. Filter indicator
2. Filter selection wheel
3. Knobs to adjust the internal blades

   The table on the front panel shows the number to set with the knobs for each combination of SID and image size.
4. Button to switch on the light field.

   After pressing the button, the lamp remains lit for a few seconds before automatically switching off.
5. Measurement tape to measure the distance between the focal spot of X-ray tube and the tabletop

Figure 54: Ralco 221 collimator controls

Another button to switch on the light field is available on the RAD Wall Stand.

Related Links

RAD Wall Stand on page 96

Dose Area Product Meter (DAP)

An optional radiation meter can be installed under the manual collimator and reads the radiation as Dose Area Product in [μGy x m^2].

The measured radiation value is transferred to the X-ray generator console and the Software Console automatically and displayed after each exposure.

The DAP meter can be removed from the rail system to be cleaned or serviced. To remove the radiation meter:

1. Disconnect the cable of the radiation meter.

1. cable connecting the radiation meter to the generator

2. Unscrew the screw on the left hand side of the rail system.
3. Pull out the radiation meter.

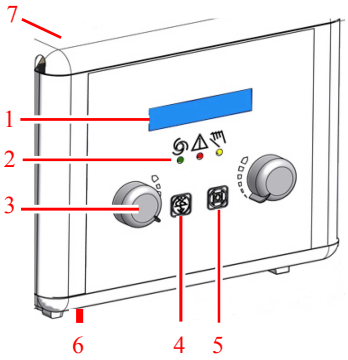
The DAP meter is calibrated during production to be used up to 2000 m altitude. Using the DAP meter on higher altitudes requires the application of a correction factor.

Related Links

Dose Area Product Meter (DAP) Technical Data on page 169

Automatic Collimator

The collimator can limit the collimated area to the size of the cassette or DR Detector inserted in the bucky.



1. Display
   - Size of the collimated area
   - Active filter
2. Operation mode indicators
   - Green: automatic mode
   - Red: error mode
   - Yellow: manual mode
3. Knobs to adjust the internal blades
4. Button to change the filter
5. Button to switch on or off the light field.

   After pressing the button, the lamp remains lit for a few seconds before automatically switching off.
6. Measurement tape to measure the distance between the focal spot of X-ray tube and the tabletop
7. Key to switch to manual mode

   The key is located on the backside of the collimator.

Figure 55: Ralco 225 ACS collimator controls

Another button to switch on the light field is available on both sides of the RAD Wall Stand.

The collimator operates in full automatic mode normally. Other operation modes are manual collimation mode and semi-automatic collimation mode.

Topics:

- *Dose Area Product Meter (DAP)*

Semi-automatic collimation mode

The semi-automatic collimation mode is activated if any of following conditions applies:

- the collimator is rotated by more than +/-3°
- the tube head unit is rotated by more than +/-3° from the center position
- the SID on the RAD Table is not within 90 cm to 130 cm
- the SID on the RAD Wall Stand is not within 90 cm to 205 cm
- the tube head unit is not centered to bucky

In semi-automatic collimation mode the registration of the cassette or detector format in the bucky is stopped, but the collimation is still adapted when the SID is changed. The user can adjust the collimation manually.

Figure 56: Indication on the tube head display for semi-automatic collimation mode

Manual collimation mode

The manual collimation mode is activated when the user turns the key at the backside of the collimator. The yellow indicator at front of collimator is lit and an open key lock is displayed in the lower left corner of the collimator display.

Manual mode is used to set the collimation area larger than the size of the cassette or detector, e.g. for detector calibration. The collimation field size is not limited to cassette or detector size nor kept constant with changing SID.

Figure 57: Indication on the tube head display for manual collimation mode

Dose Area Product Meter (DAP)

An integrated DAP meter (Dose Area Product Meter) in the collimator is availabe as an option.

The DAP meter reads the radiation as Dose Area Product in [μGy x m^2].

The measured radiation value is transferred to the Software Console automatically and displayed after each exposure.

The DAP meter cannot be removed from the collimator.

The DAP meter is calibrated during production to be used up to 2000 m altitude. Using the DAP meter on higher altitudes requires the application of a correction factor.

Effect of SID on patient dose

Changing the distance of the X-ray tube to the patient affects the dose applied to the patient.

For example doubling the distance reduces the dose by a factor of 4. The new dose can be calculated by a formula:

new mAs = known mAs × (new distance ^{2} / old distance ^{2})

X-Ray Generator Console

The X-ray generator console is limited in functionality to power on and power off the generator and to connect the DR Generator Sync with the exposure hand switch to trigger the exposure.

The X-ray exposure parameters are controlled on the **Software Console**. For detailed information about the Software Console, refer to the DX-D Software Console, DR Tube Head Display User Manual.

Related Links

System Documentation on page 27

Topics:

Starting and stopping the generator

The generator is switched on and off by the power buttons on the X-ray generator mini console.

⊙	Press the Power ON button on the X-ray generator control box to switch on the generator.
Ȯ	Press the Power OFF button on the X-ray generator control box to switch off the generator.

Following warning is printed on the X-ray generator mini console 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.

Related Links

X-ray generator mini console on page 22

X-ray tube start-up modes

The system can make exposures using two start-up modes, when pressing the exposure button in preparation stage:

- Low speed start-up that boosts the tube anode to ca. 3000 rpm.
- High speed start-up that boosts the tube anode to ca. 9000 rpm.

  No more than four high-speed start-ups are allowed per minute. An error is indicated if the number is exceeded.

High speed start-up is available during no more than 30 seconds. After that period the rotation speed will be reduced to low speed.

After the exposure and when the exposure button is released, the tube anode is braked automatically.

Caution**:** When the X-ray tube anode is rotating with high speed the generator must not be turned off. Please wait until the system is on low speed before switching the generator off. The bearings of the X-ray tube can be damaged if the generator is switched off before the anode is braked.

X-ray generator messages and warning signals

Acoustic signals

The generator indicates particular states with acoustic signals:

- Exposure is terminated: 500 ms tone
- Errors: rapid series of tones

Visual signals

The generator indicates particular states with visual signals:

- Preparation: flashing of prepare ready indicator (green LED)
- X-ray tube is prepared: prepare ready indicator is continuously lit (green LED)
- Exposure: radiation indicator is continuously lit (red LED)

Exposure termination

In normal operation the exposure is terminated by the generator when:

- mAs product is reached
- Exposure time is reached
- AEC switches off

If the exposure switch is released the exposure is terminated instantaneously and an error is indicated.

In case of failure the exposure is instantaneously terminated when:

- AEC faulty
- Initial dose too high or too low with AEC (if function is activated)
- Maximum exposure time of 3.2 sec reached in 1-point technique with AEC
- mAs product of 600 mAs is reached
- Maximum permissible exposure time of 6.3 sec is reached (safety switch off)
- Door contact is opened

Related Links

System messages on page 143
X-ray generator mini console on page 22

Topics:

X-ray generator errors

Follow the instructions for each specific error. Never open the machine.

The table contains an action for each error.

1	Notify service
2	Notify service on frequent occurrence
3	Can be eliminated by operator

Error numbers

Error number	Display	Explanation	Action
1	tube kV max	Tube voltage too high (>166 kV/132 kV)	2
2	control A max	Load current too high (> 250 A)	2
3	tube mA max	Tube current too high (> 900 A)	2
4	tube +-kV diff	Tube voltage difference between +URist and-URist>15kV	2
5	tube +-mA diff	Tube current difference between +IRist and -IRist >100mA	2
6	ROM test	ROM test checksum error	1
7	RAM test	RAM test error	1
8	unknown	unknown error	2
9	no Tube kV	Tube voltage < 10kV after 1ms or < 50% after 30ms	2
10	tube kV too high	Tube voltage > rated voltage + 25%	2
11	inverter overload	Converter overload (> 150000WS)	2
12	send timeout	Serial interface transmit timeout	2
13	E²Prom checksum	E2PROM checksum error	1
14	watchdog	Watchdog error	2

Error number	Display	Explanation	Action
15	receive timeout	Serial interface receipt timeout	2
16	E²Prom wait timeout	E2PROM access timeout	1
17	fillament system	Heater fault	2
18	DAP system	Area dose measuring system self test error	1
19	filament parameter	Deviating heating parameters in E2PROM	1
20	+-15V low	+-15V outside tolerance	2
21	+5V low	+5V outside tolerance	2
22	key is on	Key on control panel has been pressed during switch-on	2
23	XRAY key is on	Exposure or fluoroscopy key has been pressed during switch-on	2
24	mAs max	Current time product in mAs has reached its limit	3
25	exposure too short	Not used	2
26	generator not ready	Tube switchover error	2
27	service intervall	Service interval for maintenance	1
28	no Tube mA	Tube current < 50% after 30 ms	2
29	tube > 70°C	Hood temperature > 70°C	2/3
30	to save data push 'M'	-	-
31	'NOT' signal	'EMERGENCY' safety signal active	2
32	door open	Door contact open	3
33	exp. time > 6.3s	Exposure time > 6.3 sec	3
34	exp. time > 3.2s	Exposure time > 3.2 sec (automatic exposure control)	2/3
35	exp. time < 2ms	Exposure time < 2 msec (automatic exposure control)	2/3
36	AEC exposure break	Exposure aborted by operator (automatic exposure control)	3

Error number	Display	Explanation	Action
37	dose too low after 50ms	Dose too small after 50 ms (automatic exposure control)	3
38	pulse delay too long	Exposure pause between 2 pulses > 2 sec (automatic exposure control)	2
39	exp. prepare timeout	Exposure preparation timeout	3
40	device ready timeout	Device ready timeout	2
41	starter timeout	Normal speed starter timeout	2
42	grid is on	Grid active in idle state	2
43	RTC checksum, Batt. low	RTC (real time clock) error, RTC battery discharged	1
44	starter system	Normal speed starter fault current	2
45	no main current	Load current < 4A after 0.5 ms	2
46	exposure stopped by user	Exposure aborted by operator	3
47	controller - E²prom verify	Cpu-E2Prom alignment	1
48	Wrong tube position	Tube position sensor	2/3
49	Tube mA too high	Tube current outside tolerance	2
50	Device not ready (CAN)	Device or device interface not ready	2
51	No BUS-Signal from AEC	No stop signal from automatic exposure control	1
52	FLXIS not ready	No communication to TV chain	1
53	Anode heat content >100% !	Max Tube heat storage capacity, cool down the tube	2
61	Receiver overflow	Serial interface receive buffer overflow	2
62	Transmitter overflow	Serial interface transmit buffer overflow	2
63	Transfer system	Serial interface controller error	2

Error number	Display	Explanation	Action
64	CAN system	CAN bus transfer error	2
65	BUS system	CAN bus transfer is highly interfered or interrupted	1
67	SCB transfer timeout	Storz bus system timeout	2
68	SCB false version	Storz bus version error	1

Exposure parameters

Tube Voltage

The tube voltage can be selected in steps of 1 kV in the range of 40 to 150 kV.

mAs Product

Step	mAs	Step	mAs	Step	mAs	Step	mAs
0	0.5	10	5.0	20	50	30	500
1	0.63	11	6.3	21	63	31	600
2	0.8	12	8.0	22	80		
3	1.0	13	10	23	100		
4	1.3	14	13	24	125		
5	1.6	15	16	25	160		
6	2.0	16	20	26	200		
7	2.5	17	25	27	250		
8	3.2	18	32	28	320		
9	4.0	19	40	29	400		

Tube current [mA]

Step	mA	Step	mA
0	10	10	100
1	1 3	11	125
2	16	12	160
3	20	13	200
4	25	14	250
5	32	15	320
6	40	16	400
7	50	17	500
8	63	18	650

Step	mA	Step	mA
			(only for generator with 50 kW power or higher)
9	80	19	800 (only for generator with 65 kW power or higher)

Exposure time [ms]

Step	ms	Step	ms	Step	ms	Step	ms
0	1	10	13	20	130	30	1250
1	2	11	16	21	160	31	1600
2	3	12	20	22	200	32	2000
3	4	13	25	23	250	33	2500
4	5	14	32	24	320	34	3200
5	6	15	40	25	400	35	4000
6	7	16	50	26	500	36	5000
7	8	17	63	27	630	37	6300
8	10	18	80	28	800		
9	11	19	100	29	1000		

Note: Not all exposure parameters may be available, depending on the configuration of X-ray generator, X-ray tube and DR Detector.

Maximum tube current [mA] at 100 kVp and 0.1 s

	HFe 401 (40 kW)	HFe 501 (50 kW)	HFe 601 (65 kW)	HFe 801 (80 kW)
E7884X	LSS: 400 mA	LSS: 500 mA	-	-
E7252X	LSS: 400 mA HSS: 400 mA	LSS: 450 mA HSS: 500 mA	HSS: 650 mA	-
E7254FX	LSS: 400 mA	LSS: 500 mA	HSS: 650 mA	HSS: 800 mA

	HFe 401 (40 kW)	**HFe 501 (50 kW)**	**HFe 601 (65 kW)**	**HFe 801 (80 kW)**
	HSS: 400 mA	HSS: 500 mA		
E7869XX	-	-	HSS: 650 mA	HSS: 800 mA

- LSS: Low Speed Start option
- HSS: High Speed Start option

All Values are valid for 3-phase generator power line and large focal spot. Values for other exposure conditions can be determined using the technical data of the generator and the data sheets of the X-ray tubes.

In regular use these maximum exposure settings will not create doses that can cause deterministic effects. Effective patient doses for typical exposures are listed in Test Report for IEC 60601-1-3.

Switching between small focus and large focus may have a delay of a few seconds. The focus is controlled by a relais and it requires the filament to cool down before switching.

The settings of kV and mAs or of mA and ms are defined by an algorithm. The highest mA setting is used for which the kV can be reached by the system and the exposure time is not lower than 4 ms. When the kV setting is changed, the value of mA and ms are adjusted automatically to keep the mAs value constant, within the boundaries of generator or X-ray tube limitations.

Note: The accuracy for exposure parameter settings complies to EN IEC 60601-2-54 with absolute maximum of 10% for kV and an absolute maximum of 20% for mA.

Related Links

System Documentation on page 27

Problem solving

Topics:

System messages

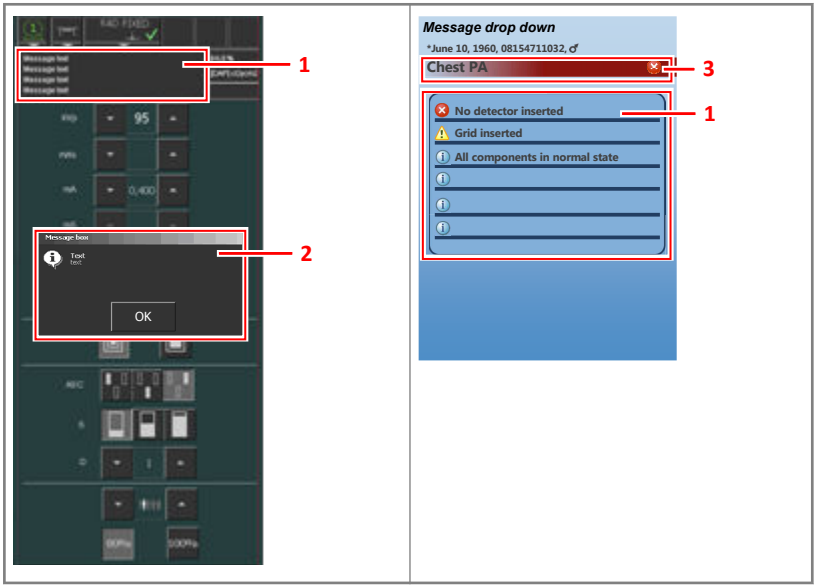
The system can display messages to the user on the screen.

- Software Console
  - Message frame

    Click the message frame to view older messages.
  - Dialog box

    The software console displays a dialog box in the middle of the screen. The dialog box can contain a title, a status description, an instruction for the user and a button.
- Tube head display
  - Message frame

    Click the right half of the device status frame to display the message frame. To hide the message frame, click anywhere in the display.



1. Message frame
2. Dialog box
3. Device status frame

Figure 58: Messages

Messages can appear on the software console, on the tube head display, or on both.

There are different types of messages.

Type of message	Icon	Display	User response
Information		Software Console message frame	Information messages help to understand the workflow status and do not affect safety or efficiency.
		Tube head display message frame	
Warning		Software Console dialog box	Read the message carefully. Click the button in the dialog box to continue operation.
		Software Console message frame	Read the message carefully.
		Tube head display message frame	
Error		Software Console dialog box	Read the message carefully. Click the button in the dialog box to continue operation.
		Tube head display message frame	Read the message carefully.
Blocking error		Software Console dialog box	Read the message carefully. It provides instructions to resolve the problem. Operation is blocked until the problem is resolved. The dialog box is closed automatically when the problem is resolved.

Messages that require no user response disappear automatically.

Warning or error messages may instruct to contact the Agfa service organization if the problem repeats, but by following the instructions in the message, the user can restore the operation of the system.

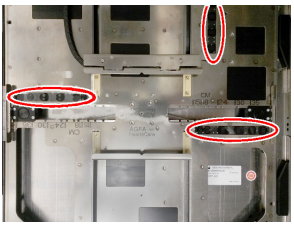
Related Links

X-ray generator messages and warning signals on page 134

Restoring connection between generator and NX after generator failure

Details	An error on the generator occurred. NX lost connection to the generator. An error message that no connection with the generator can be established is displayed on the Software Console.
Cause	After a shutdown of the generator, the communication between the X-ray generator and the NX workstation is broken.
Brief Solution	To set up the communication between the X-ray generator and the NX workstation: **1.** Switch off the X-ray generator at X-ray generator console. **2.** After some seconds, switch the X-ray generator back on. **3.** Select an empty thumbnail in the Image Overview pane of the Examination window. **4.** The error message disappears. This may take some time. If an error is indicated on the X-ray generator by a signal, repeat step 1 to 3. During startup of the NX application and the Software Console, the communication to the generator is set up and the self-test of the generator is triggered.

Automatic collimation always too wide or too narrow

Details	The collimated area is not adapted correctly to the size of the cassette or DR Detected inserted in the bucky.
Cause	The sensors in the bucky that detect the size of the cassette or DR Detector are dirty or have become weak.
Brief Solution	Wipe the sensors in the bucky with a lint-free cloth. If needed, moisten the cloth with a neutral detergent.  **Figure 59: Location of the sensors in the bucky** If the problem persists, contact your local service organization to exchange the sensors.

Empty Bucky Failure, Double Exposure Failure

Details	The exposure button was pressed but no exposure was performed. No radiation icon is displayed. The preparation icon is displayed. • CR: Error message 40 is displayed on the Software Console. • DR: No error message is displayed. An empty image is received in the NX.
Cause	Possible causes: • Functionality to avoid double exposure is activated and the cassette has not been removed after the last exposure. This applies to CR only. • No cassette or detector is inserted in the selected bucky.
Brief Solution	**1.** Enter an unexposed cassette or a detector in the bucky. **2.** Confirm the error message in the Software Console. This applies to CR only. **3.** On the NX workstation, click **Copy Exposure** to create a new thumbnail (DR) or click **Add Image** to add a new exposure. **4.** Repeat the steps described in the Basic Workflow.

NX does not connect to the generator due to ID tablet

Details	This occurs on a DR installation in combination with a digitizer using an ID Tablet. The NX application and the Software Console cannot connect to the generator. An error message that no connection with the generator can be established is displayed on the Software Console. Restarting the NX application does not help.
Cause	Conflicting communication sequence during startup of NX between the generator and the ID Tablet.
Brief Solution	**1.** Switch off the ID Tablet. **2.** Stop the NX workstation. **3.** Switch on the ID Tablet. **4.** Start the NX workstation.

No table movement

Details	The table is not moving up or down when pressing the foot pedals with double click. No error is shown.
Cause	One of the foot pedals was pressed longer than 90 seconds.
Brief Solution	**1.** Press the Power OFF button on the X-ray generator control box to switch off the generator. **2.** Switch off the electrical room switch. **3.** Wait for 30 seconds. **4.** Switch on the electrical room switch. **5.** Press the Power ON button on the X-ray generator control box to switch on the system.

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

Technical Data

Topics:

DR 400 Technical Data

Manufacturer	Agfa HealthCare N.V. Septestraat 27 2640 Mortsel, Belgium	
Type	5520/XXX	
Power line 400 V Y-source	400V 3N~ PE (Y) 50/60 Hz	
Power line 400/480 V Delta-source	400/480V 3~PE (delta without N) 50/60Hz The power setting is selected during installation and printed on the type label.	
Maximum current (0.2sec) / Power	**400V**	**480V**
40 kW generator	92 A / 62 kVA	79 A / 62 kVA
50 kW generator	113 A / 76 kVA	97 A / 76 kVA
65 kW generator	144 A / 96 kVA	124 A / 96 kVA
80 kW generator	180 A / 120 kVA	154 A / 120 kVA
Stand-by power	max. 3.3 A	
Table movement (full load of 320 kg)	max. 7.0 A	
Permanent filtration		
E7254FX X-ray tube	2.8 mm Al @75kVp (+ 0.2 mm Al with DAP meter integrated in the collimator)	
E7884X and E7252X X-ray tube	2.9 mm Al @ 75kVp (+ 0.2 mm Al with DAP meter integrated in the collimator)	
E7869X X-ray tube	3.1 mm Al @ 75kVp	

	(+ 0.2 mm Al with DAP meter integrated in the collimator)

Environmental conditions

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

Generator Technical Data

Manufacturer	Spellman High Voltage Electronics GmbH Josef-Baumann-Strasse 23 D-44805 Bochum, Germany			
Supported Models	EDITOR HFe 401	EDITOR HFe 501	EDITOR HFe 601	EDITOR HFe 801
Max. Power	40 kW	50 kW	65 kW	80 kW
Power Output (at 0.1s)	500mA: 80kVp 400mA: 100kVp 320mA: 125kVp 266mA: 150kVp	625mA: 80kVp 500mA: 100kVp 400mA: 125kVp 330mA: 150kVp	800mA: 80kVp 650mA: 100kVp 520mA: 125kVp 430mA: 150kVp	800mA: 80kVp 800mA: 100kVp 640mA: 125kVp 530mA: 150kVp
kV-Range	40-150 kV	40-150 kV	40-150 kV	40-150 kV
mAs-Range	0.5-600 mAs	0.5-600 mAs	0.5-600 mAs	0.5-600 mAs
mA-Range	10-500 mA	10-650 mA	10-800 mA	10-800 mA
ms-Range	1-6300 ms	1-6300 ms	1-6300 ms	1-6300 ms
Power line 400 V Y-source	400V 3N~ PE (Y) 50/60 Hz			
Power line 400/480 V Delta-source	400/480V 3~PE (delta without N) 50/60Hz The power setting is selected during installation and printed on the type label.			
Dimensions	89 cm x 43 cm x 29 cm (WxDxH)			
Weight	78 kg (400V) 90 kg (400/480V)			
Duty cycle	The Generator duty cycle is continuous, but limits should be set during installation depending on the capacity of the X-ray tube.			

The values for Power Output represent the maximum power output of the X-ray generator. These values do not represent the available exposure parameter settings on the Software Console.

Related Links

Exposure parameters on page 139

RAD Table and X-Ray Tube Stand Technical Data

Manufacturer	Agfa HealthCare N.V. Septestraat 27 2640 Mortsel, Belgium
Type	
TS-Fix-L-001	5521/100
TS-Fix-R-001	5521/110
TS-Elev-L-001	5521/200
TS-Elev-R-001	5521/210
TS-Fix-L-002	5521/300
TS-Fix-R-002	5521/310
TS-Elev-L-002	5521/400
TS-Elev-R-002	5521/410
Dimensions	
Fixed height RAD Table	140 cm x 77 cm x 70 cm (WxDxH)
Elevating RAD Table	140 cm x 77 cm x 55-90 cm (WxDxH)
Tabletop	220 cm x 81 cm x 4 cm (WxDxH)
Tabletop movement	Longitudinal 110 cm Transversal 24 cm
Maximum SID	110 cm (at 70 cm table height) 130 cm (at 55 cm table height, elevating RAD Table only)
Distance between tabletop and detector	< 60 mm
X-ray tube stand column height	228 cm
X-ray tube stand arm length	93 cm

Minimum room height	245 cm
Tabletop 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	
Fixed height RAD Table	290 kg
Elevating RAD Table	350 kg
X-ray tube stand column	120 kg
X-ray tube stand arm	25 kg
X-ray tube plus collimator (maximum weight)	40 kg
Maximum load on the RAD Table	320 kg

Movement ranges

Transversal axis or y-axis movement (back & front)	± 7 cm
Vertical axis or z-axis movement (up & down)	33.5 cm to 180 cm from the floor The movement range may vary depending on the type of X-ray tube.
Longitudinal axis (x-axis) movement (right & left)	131 cm
Alpha axis rotation (Angle of the X-ray tube)	±110° with mechanical detents at 0°, ±45°, ±90°
Beta axis rotation (swivel of the X-ray tube arm around the tube stand axis)	±90° with mechanical detents at 0°, ±45°, ±90°
Bucky horizontal movement in the table	50 cm

Rotation of the collimator around the axis of the X-ray beam	±90°  Caution**:** Rotation may be limited by cables. Avoid strain on the cables during rotation.

RAD Wall Stand Technical Data

Manufacturer	Agfa HealthCare N.V. Septestraat 27 2640 Mortsel, Belgium
Type	
WS-Manual-001	5522/100
WS-Manual-T-001	5522/200
WS-Manual-002	5522/300
WS-Manual-T-002	5522/400
Dimensions	
Vertical RAD Wall Stand	65.1 cm x 36.7 cm x 224.5 cm (WxDxH)
Vertical and tilting RAD Wall Stand	65.1 cm x 63.0 cm x 224.5 cm (WxDxH)
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	

Vertical RAD Wall Stand	157 kg
Vertical and tilting RAD Wall Stand	196 kg
Maximum load on the bucky	32 kg
Maximum load on the brakes for the vertical movement	250 N

(*) specific values do not apply as technical data of the system in China

X-Ray Tube Technical Data

Manufacturer	Toshiba Electron Tubes & Devices Co., Ltd. 1385 Shimoishigami Otawara-Shi, Tochigi-Ken 324-8550 Japan
E7884X	X-ray Tube 12° 150 kVp dual focal spots 0.6 and 1.2 mm 300 KHU LS 20/50 kW (50Hz) 22/54 kW (60Hz) $7{,}24x10^6$ mAh@150kVp maximum load
E7252X	X-ray Tube 12° 150 kVp dual focal spots 0.6 and 1.2 mm 300 KHU LS 14/41 kW (50Hz) 16/45 kW (60Hz) HS 27/75 kW (180Hz) $7{,}24x10^6$ mAh@150kVp maximum load
E7254FX	X-ray Tube 12° 150 kVp dual focal spots 0.6 and 1.2 mm 400 KHU LS 22/55 kW (50Hz) 23/60 kW (60Hz) HS 40/102 kW (180Hz) $9{,}66x10^6$ mAh@150kVp maximum load
E7869XX	X-ray Tube 12°

	150 kVp dual focal spots 0.6 and 1.2 mm 600 KHU LS 21/53 kW (50Hz) 23/58 kW (60Hz) HS 40/100 kW (180Hz) $14{,}49 \times 10^6$ mAh@150kVp maximum load

Bucky Unit Technical Data

Manufacturer	Agfa HealthCare N.V. Septestraat 27 2640 Mortsel, Belgium
Type	
BT-Cassette-T-001	5523/100
BT-Cassette-T-ACSS-001	5523/120
BT-Cassette-WS-L-001	5523/200
BT-Cassette-WS-ACSS-L-001	5523/220
BT-Cassette-WS-R-001	5523/250
BT-Cassette-WS-ACSS-R-001	5523/270
BT-Fixed-T-001	5523/300
BT-Fixed-WS-L-001	5523/310
BT-Fixed-WS-R-001	5523/320

Dimensions	
Dimensions in RAD Table	65.5 cm x 60.0 cm x 8.0 cm (WxLxH)
Dimensions in RAD Wall Stand	62.5 cm x 61.5 cm x 12.5 cm (WxLxH)
Weight (without detector)	
Bucky for DR Detector or CR cassette in RAD Table	23.5 kg
Bucky for DR Detector or CR cassette in RAD Wall Stand	26.0 kg
DX-D Fixed DR Detector bucky	13 kg
Electrical connection	

(type 5523/100, 5523/200, 5523/250, 5523/300, 5523/310, 5523/320)	
Operating voltage	24 VDC
Operating current	80 mA
Electrical connection (type 5523/120, 5523/220, 5523/270)	
Operating voltage	24 VDC
Operating current	375 mA
Supported sizes	
Supported sizes	15x30 to 43x35 in portrait and landscape orientation
Lifetime	
Expected lifetime for the bucky	10 years

Grid	
Manufacturer	JPI Healthcare Solutions Inc 52 Newtown Plaza Plainview NY 11803 USA
Type	
100 cm	5523/600
150 cm	5523/610
180 cm	5523/620
Parallell grid	5523/630
Dimensions	
Dimension	480 mm x 455 mm (W x L)
Orientation of grid lines	Parallel to 455 mm side
Weight	1.6 kg

Automatic Exposure Control (AEC) Technical Data

Manufacturer	VacuTec Messtechnik GmbH Dornblüthstrasse 13 D-01277 Dresden, Germany
Supported Type No.	145 00 44
Description	3-field chamber with electronics
Exposure dose range	1 to 100 uGy
Exposure time range	1 ms to 10 s
Attenuation equivalent mm Aluminum	< 0.75
Dimensions	45 cm x 45 cm x 0.75 cm (WxLxH)

Ralco R221 Collimator Technical Data

Manufacturer	Ralco Via dei Tigli 13/G 20853 Biassono (MB), Italy
Supported type	R 221
Maximum radiation leakage	150 kVp – 4 mA
Inherent filtration	2 mm Aluminum equivalent
Added filtration	0mm Al 2mm Al 1mm Al + 0.1mm Cu 1mm Al + 0.2mm Cu
Maximum field Size at SID of 100 cm	48 cm x 48 cm
Dimensions	18.3 cm x 24.1 cm x 16.8 cm (WxDxH)
Weight	7.7 kg

Ralco R225 ACS Collimator Technical Data

Manufacturer	Ralco Via dei Tigli 13/G 20853 Biassono (MB), Italy
Supported type	R 225 ACS
Maximum radiation leakage	150 kVp – 4 mA
Inherent filtration	2 mm Aluminum equivalent
Added filtration	0mm Al 2mm Al 1mm Al + 0.1mm Cu 1mm Al + 0.2mm Cu
Maximum field Size at SID of 100 cm	48 cm x 48 cm
Dimensions	28.5 cm x 24.4 cm x 20.2 cm (WxDxH)
Weight	11 kg

Dose Area Product Meter (DAP) Technical Data

Manufacturer	VacuTec Messtechnik GmbH Dornblüthstrasse 13 D-01277 Dresden, Germany
Supported Type	VacuDAP 2004
Dose area product range	(0.1 to $3x10^5$) μGy x cm^2/s
Attenuation	0.44 mm Al equivalent (70 kV)
Quality filtration	0.24 mm Al equivalent (70 kV)
Active area	14.7 cm x 14.7 cm
Dimensions	18.2 cm x 17.7 cm x 1.8 cm (WxDxH)
Weight	255 g

Correction factors for using the DAP meter on high altitude	
Environmental conditions	Correction factor
75 kPa (ca. 2500 m) 0° Celcius	1.26
75 kPa (ca. 2500 m) 20° Celcius	1.31
70 kPa (ca. 3000 m) 0° Celcius	1.35
70 kPa (ca. 3000 m) 20° Celcius	1.40

DX-D Fixed DR Detector Technical Data

Manufacturer	
Manufacturer DR Detector	Varian X-Ray Products, 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

Portable DR Detector Technical Data

Refer to the DR Detector User Manual.

NX Workstation Technical Data

Electrical connection	
Operating voltage	90 – 263VAC
Mains fuse protection	5.5A
Mains frequency	47 – 63 Hz
Power consumption	
Maximum power consumption	320W

DR Generator Sync Box Technical Data

Model name	DR Generator Sync Box
Type number	5400/516
Labeling	
Dimensions	
Depth	21.5 cm
Width	33.5 cm
Height	6.5 cm
Weight	3.2 kg
Electrical connection	100-240 V AC, 50/60 Hz
Power consumption	40 W (max. 0.4 A)
Estimated product life	7 years

Remarks for HF-emission and immunity

Topics:

Remarks for HF-emission and immunity

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.

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

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the DR 400 system (refer to the section Cables, transducers and accessories) as replacement parts for internal components, may result in increased HF-emission or decreased HF-immunity of the DR 400 system.

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

Warning: The DR 400 system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the DR 400 system should be observed to verify normal operation in the configuration in which it will be used.

Table 6: Guidance and manufacturer's declaration – electromagnetic emissions

The DR 400 system is intended for use in the electromagnetic environment specified below. The customer or the user of the DR 400 system should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment guidance**
RF emissions in accordance with CISPR 11	Group 1	The DR 400 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions in accordance with CISPR 11	Class A	The DR 400 system 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 in accordance with IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	Not applicable	

This DR 400 system is intended for operation in the electromagnetic environment given below. The user of the DR 400 system should ensure that it is used in such an environment.

Table 7: Guidance and manufacturer's declaration – electromagnetic immunity

The DR 400 system is intended for use in the electromagnetic environment specified below. The customer or the user of the DR 400 system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment guidance**
Discharge of static electricity in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV for network leads ± 1 kV for entry and outlet leads	± 2 kV for network leads ± 1 kV for entry and outlet leads	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.

Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage dips, short interruptions and voltage variations on power supply iput lines in accordance with IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle	not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DR 400 requires continued operation during power mains interruptions, it is recommended that the DR 400 be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	not applicable	
	70% U_T (30% dip in U_T) for 25 cycles	not applicable	
	< 5% U_T (>95% dip in U_T) for 5 s	< 5% U_T (>95% dip in U_T) for 5 s	
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
• REMARK : U_T is the alternating current in the network before the application of the test level.			

Table 8: Guidance and manufacturer's declaration – electromagnetic immunity

The DR 400 system is intended for use in the electromagnetic environment specified below. The customer or the user of the DR 400 system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment guidance**

			Use portable and mobile radio sets at a safe distance from the device (including the leads) not closer than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency. Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.2 \sqrt{P}$
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			With *P* as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the level of the agreement at all frequencies in accordance with an on-site investigation.

			Disruptions are possible near devices that carry the following symbol: 

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

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

- REMARK 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
- REMARK 2: These Guidelines may not apply to all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

Radio frequency communications equipment can effect medical electrical equipment.

Table 9: Recommended separation distances between portable and mobile RF communications equipment and the DR 400 system

The DR 400 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DR 400 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DR 400 system as recommended below, according to the maximum output power of the communications equipment.	
Rated maximum output	**Separation distance according to frequency of transmitter** m

power of transmitter W			
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Related Links

Cables, transducers and accessories on page 183

Essential performance

EUT-specific compliance criteria considering Essential Performance of Equipment under Test:

- No error messages on panel and on display of EUT
- No unintended move of table, wall stand and tube-head during mode X-Ray and Standby / no interruption during “Move” mode
- No unintended X-Ray triggering

Cables, transducers and accessories

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

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

from	to	type	maximum length	remark
wall outlet	table (cable mains input)	5 x AWG6	5 m	not delivered with the system
control room (light push button)	table input terminal	2 x AWG21 (0.5 mm^2)	15 m	not delivered with the system
control room (lamp red)	table input terminal	2 x AWG18 (1.0 mm^2)	15 m	not delivered with the system
control room (lamp yellow)	table input terminal	2 x AWG18 (1.0 mm^2)	15 m	not delivered with the system
control room (door contact)	table input terminal	2 x AWG18 (1.0 mm^2)	15 m	not delivered with the system
control room (Com A)	table input terminal	9 pin sub D	20 m	unshielded
control room (Com B)	table input terminal	Standard RS-232 cable (9 pin sub D)	15 m	unshielded
control room (ground)	table input terminal		15 m	
Table output terminal (x8	wall stand input terminal	10 x AWG21 (0.5 mm^2)	20 m	mandatory

from	to	type	maximum length	remark
24V, light push button, duple exposure protection)				
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	double shielded mandatory
table output terminal (ground)	wall stand input terminal		20 m	mandatory
Optional				
control room (DR Generator Sync Box 1)	table input terminal (Sync 01)	9 pin sub D (Pin 9 is not connected)	16 m	unshielded
control room (DR Generator Sync Box 2)	table input terminal (Sync 02)	9 pin sub D (Pin 9 is not connected)	16 m	unshielded
control room (DR Generator Sync Box 1)	wall stand input terminal (Sync 03)	9 pin sub D (Pin 9 is not connected)	16 m	unshielded
control room (DR Generator Sync Box 2)	wall stand input terminal (Sync 04)	9 pin sub D (Pin 9 is not connected)	16 m	unshielded
DX-D Fixed DR Detector or DR Detector I/O box	NX workstation	CAT 6 SF/UTP	40 m	double shielded (no connectors allowed)

Topics:

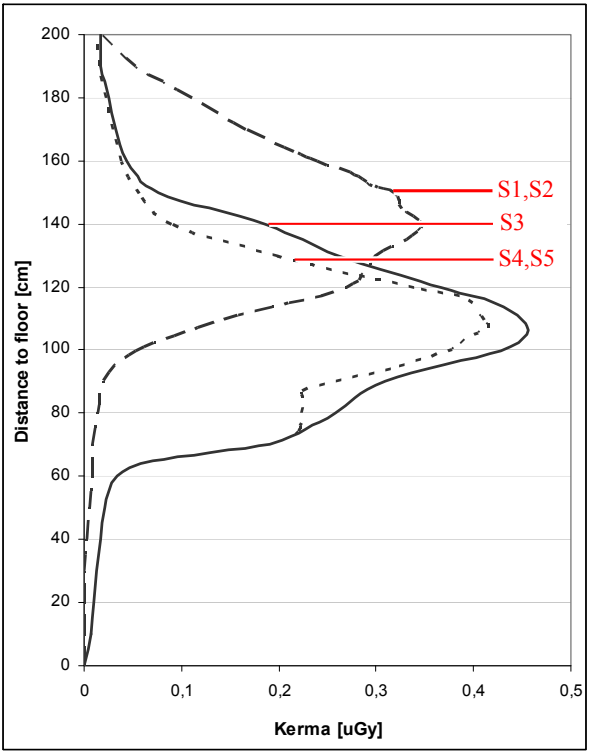
For type 5520/200 only

from	to	type	maximum length	remark
table output terminal	wall stand input terminal (CAN)	9 pin sub D	20 m	shielded

Optional

from	to	type	maximum length	remark
table output terminal Aux.	control room NX Workstation	Cat 5e	15 m	shielded
table output terminal	wired hand control	01090350F	1.8 m	unshielded, optional

Stray Radiation



- S1,S2: 100 kV; SID 110 cm; tube/detector centre height 140cm over floor
- S3: 100 kV; SID 100 cm; table height of 70 cm (standard working height)
- S4,S5: 100 kV; SID 100 cm; table height of 70 cm (standard working height)

Figure 60: Measurement of stray radiation in zones of occupancy (Sx)

For the diagram above a maximum throughput of 30 exposures/hour was used. This complies with a throughput of 15 patients/hour with typically 2 exposures done per patient.

Related Links

Significant zones of occupancy at the RAD Table on page 37
Significant zones of occupancy at the RAD Wall Stand on page 38