WS-Manual-001, WS-Manual-T-001, WS-Manual-002, WS-Manual-T-002

5522/100
5522/200
5522/300
5522/400

User Manual

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AGFA

Contents

Legal Notice

CE

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

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Introduction to this Manual

Topics:

Scope of this Manual

This User Manual describes the features of the WS-Manual-L-001, WS-Manual-R-001, WS-Manual-T-L-001 and WS-Manual-T-R-001, further referred to as the radiographic wall stand, that is part of the DR 400 system.

About the safety notices in this document

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

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

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

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

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

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

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

Disclaimer

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

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

Introduction to DR 400

Topics:

Intended Use

The wall stand is a component of a general radiography X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to support examinations with patient standing upright or sitting.

The 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.

Applied Parts

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

Radiographic wall stand

- Front panel of the radiographic wall stand
- Overhead arm support (optional)
- Patient hand grips (optional)

Equipment Classification

Per EN/IEC 60601-1, EN/IEC 60601-2-54, 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 32

Operation Controls

Topics:

Radiographic wall stand

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

Figure 1: Radiographic wall stand with vertical bucky

Related Links

Radiographic wall stand on page 44

Emergency stop button

Figure 2: 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 radiographic table. All motor driven movements will be stopped.

Motor driven movements:

- Radiographic table
- Radiographic 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.

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.

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

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

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

Compliance

The system is compliant with specific directives and standards.

Topics:

General

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

Safety

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

Electromagnetic Compatibility

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

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
- IEC 60601-2-54
- IEC 60601-2-28

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

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.

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.

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

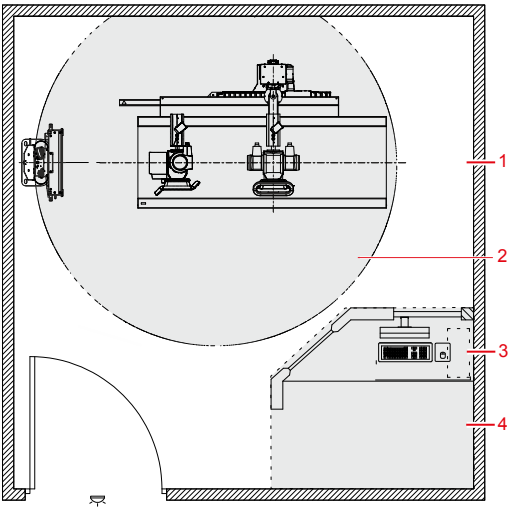
The monitoring checks the amount of X-ray radiation the personnel has been exposed to. It determines safety of the operators and it helps checking if safety measures of the X-ray environment are adequate. Inadequate or improper protection can lead to serious damage to the health.

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 3: Protected area and significant zones of occupancy

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

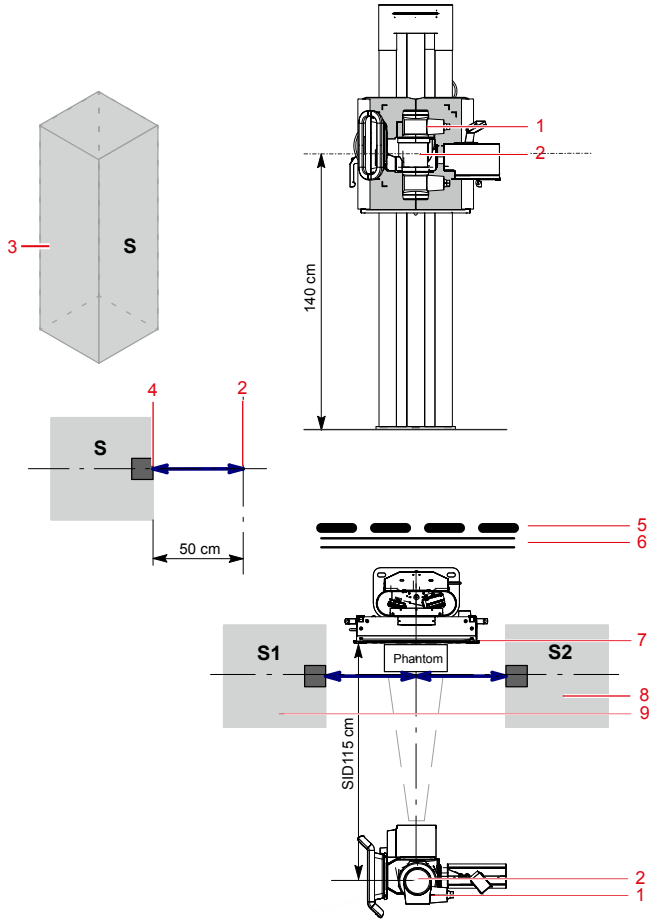
If operator or staff needs to be close to the patient during normal use (e.g. some pediatric examinations or types of examinations for which the patient requires assistance), the significant zone of occupancy applies for operator and staff.

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

Related Links

Radiation Protection on page 23

Significant zones of occupancy at the radiographic 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 radiographic wall stand
9. Significant zone of occupancy at the left side of the radiographic wall stand

Figure 4: Significant zones of occupancy at the radiographic wall stand

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

Related Links

Radiation Protection on page 23

Labels

Mark	Meaning
	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).
	This mark indicates that this is a Type B Equipment
	Date of manufacture
	Manufacturer
	Medical device
	Serial number
	Unique device identifier, in text format and in machine readable format
	The most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*

Label	Meaning
	Dangerous voltage
	Ionizing radiation
	Pinch Points.
	Risk of stumbling.

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

Topics:

Warning labels on the radiographic wall stand

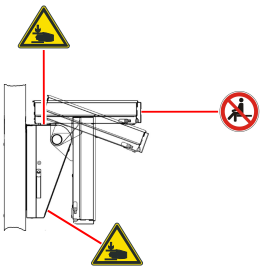
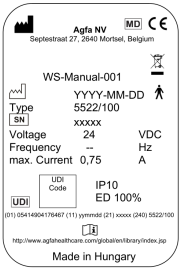
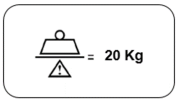


Figure 5: Warning labels on the radiographic wall stand

Additional Labeling of the radiographic wall stand

 (Sample of subtype 5522/100)	Type label on the lower right hand side of the radiographic wall stand.
	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.
	The maximum load for the bucky movement in vertical direction is 20 kg.
	A pinch point label is located on top of the tilting extension.

Related Links

Radiographic Wall Stand Technical Data on page 51

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 (e.g. by using alcohol-containing agents).

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

3. Start up the system.

Disinfecting

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

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

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

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

Disinfecting safety directions

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

To disinfect the device:

- Do not use any corrosive, soluble or gaseous disinfectants.
- Consult the manufacturer's Material Safety Data Sheets (MSDS) and recommendations on the product label for additional information prior to use.
- Use of spray disinfection can cause malfunctions due to ingress of the disinfectant into the equipment. Disinfect all parts of the unit, including the accessories and connection cables by just wiping them. Switch off the system and cover the cooled system carefully before performing a room disinfection using nebuliser.
- 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/library/overview.jsp?ID=41651138

Maintenance

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

Maintenance of the radiographic table, radiographic 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:
Wear of equipment due to excessively long intervals between service may lead to personal injury and property damage due to worn and unsafe parts.

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

WARNING:
Improper changes, additions, maintenance or repair of the equipment or the software can lead to personal injury, electrical shock and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

Table 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 or after 60.000 cycles, whatever comes first

All steel cables of X-ray tube stand and radiographic wall stand shall be checked	
All steel cables of X-ray tube stand and radiographic wall stand shall be exchanged to maintain fault-free operation and ensure safety for patient and operator	Every 36 months
Replacing the coin cell battery of the X-ray generator	
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.

Environmental protection

Figure 6: WEEE symbol

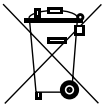


Figure 7: Battery symbol

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

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

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

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

WARNING:
The operator 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.

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

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

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

Safety directions for the radiographic wall stand

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

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

Operation

Topics:

Radiographic wall stand

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

The wall stand has two variants:

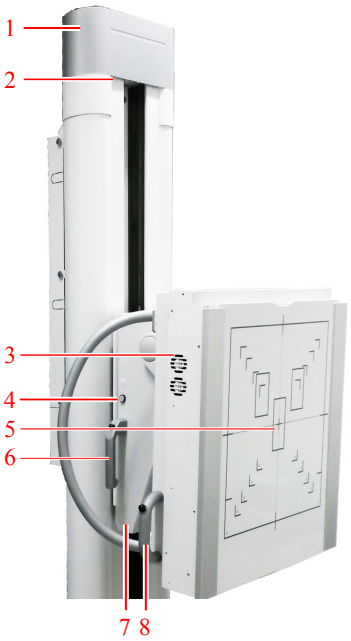
- wall stand with vertical bucky, supporting vertical movement (up and down)
- wall stand with tilting bucky, supporting vertical movement (up and down) and tilting of the bucky

The bucky has two variants, depending on the orientation for loading a detector 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 radiographic 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 8: Radiographic 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 Radiographic Wall Stand

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

Figure 9: Positioning controls

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

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

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

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

Vertical movement

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

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

CAUTION:
The maximum load for the 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.

Topics:

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 10: 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 48
Emergency stop button on page 14

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 10 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.

Radiographic Wall Stand Accessories

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

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.

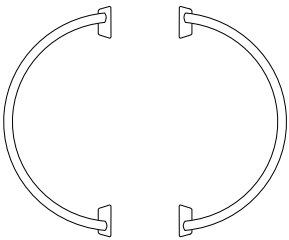


Figure 11: Patient hand grips

Mounting the overhead handle

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

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.

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

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.

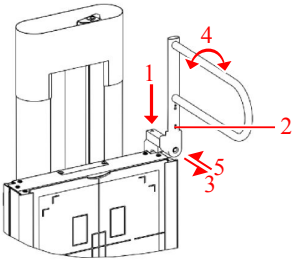


Figure 12: Overhead handle

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

Spacer

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

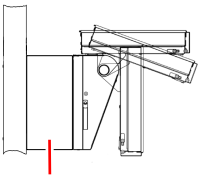


Figure 13: Spacer

Wall stand fixation kit

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

Technical Data

Topics:

Radiographic Wall Stand Technical Data

Manufacturer	Agfa NV Septestraat 27 2640 Mortsel, Belgium
Type	
WS-Manual-001	5522/100
WS-Manual-T-001	5522/200
WS-Manual-002	5522/300
WS-Manual-T-002	5522/400
Dimensions	
Height	2245 mm
Width	651 mm (only front panel) 715 mm (with tilting handles) 825 mm (with patient hand grips)
Depth	640 mm
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 radiographic wall stand	157 kg
Vertical and tilting radiographic 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

Environmental conditions

Table 3: Environmental conditions for the X-ray system

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

For overall system environmental conditions, the environmental conditions of the DR Detector or image plate should be taken into account. Refer to the

related User Manual for environmental conditions for the DR Detector or image plate. When using the DR Detector or image plate inside the bucky, take into account that the temperature inside the bucky can be up to 5°C higher than the temperature in the X-ray room.

Remarks for HF-emission and immunity

It is hereby certified that the device has interference suppression according to the EN 55011 Class A as well as the FCC Rules CR47 Part 15 Class A.

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

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

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

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

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

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

RF Emission Measurements	Agree-ment	Electromagnetic Environment Guidelines
High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclu-sively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment

Harmonic emission in accordance with IEC 61000-3-2	Class A	might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Fulfilled	

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

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

Resistance to Jamming Test	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment Guidelines**
Discharge of static electricity in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV mains ± 1 kV data lines	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV line-line voltage ± 2 kV line-ground voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakdown, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• 0% U_r for ½ period • 0% U_r for 1 period • 70% U_r (30% breakdown of U_r) for 25 periods at 0°	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommen-

	• 0% U_r for 250 periods	ded to use an energy supply free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
REMARK : U_r is the alternating current in the network before the application of the test level.		

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

Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	
RF communication	Refer to the section "Immunity to RF wireless communication equipment"	
		Disruptions are possible near devices that carry the following symbol: 

The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and FM radio transmitters, cannot be precisely predetermined theoretically. An

investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the test level given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.

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

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device			
Rated Power of the Transmitter W	Protective Distance in accordance with RF emission Frequency m		
	150 kHz to 80 MHz $d = 1.0 \sqrt{P}$	80 MHz to 800 MHz $d = 0.3 \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.3 \sqrt{P}$
0.01	0.1	0.05	0.05
0.1	0.32	0.1	0.1
1	1.0	0.3	0.3
10	3.2	1.0	1.0
The distance can be determined through the equation for each respective column. P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table. REMARK : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.			

Topics:

- *Immunity to RF wireless communication equipment*
- *Precautions on EMC*

- *Cables, transducers and accessories*
- *Maintenance on EMC relevant parts*

Immunity to RF wireless communication equipment

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

Precautions on EMC

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

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

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

Cables, transducers and accessories

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

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

from; **to**	**type;** **maximum length**	**remark**
Transfer point table; transfer point wall stand	10 x AWG21 (0.5 mm^2) ; 20 m	unshielded
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	shielded
control room (Com B); table input terminal	Standard RS-232 cable (9 pin sub D); 20 m	shielded
control room (ground); table input terminal	1 x AWG8 (10 mm^2) ; 15 m	mandatory

from; **to**	**type;** **maximum length**	**remark**
Table output terminal (x8 24V, light push button, double exposure protection); wall stand input terminal	10 x AWG21 (0.5 mm^2); 20 m	mandatory
table output terminal (230 V); wall stand input terminal	3 x AWG18 (1.0 mm^2); 20 m	mandatory
table output terminal (AEC); wall stand input terminal	CAT 5e (SF/UTP); 20 m	shielded mandatory
table output terminal (ground); wall stand input terminal	1 x AWG8 (10 mm^2); 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); 20 m	unshielded
control room (DR Generator Sync Box 2); table input terminal (Sync 02)	9 pin sub D (Pin 9 is not connected); 20 m	unshielded
control room (DR Generator Sync Box 1); wall stand input terminal (Sync 03)	9 pin sub D (Pin 9 is not connected); 20 m	unshielded
control room (DR Generator Sync Box 2); wall stand input terminal (Sync 04)	9 pin sub D (Pin 9 is not connected); 20 m	unshielded
DX-D Fixed DR Detector or DR Detector I/O box; NX workstation	CAT 6 SF/UTP; 40 m	shielded (no connectors allowed)
table output terminal Aux.; control room NX Workstation	Cat 5e; 15 m	shielded
table output terminal;	01090350F;	unshielded, optional

from; **to**	**type;** **maximum length**	**remark**
wired hand control	1.8 m	

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

Maintenance on EMC relevant parts

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