Bucky

5523/100 5523/110 5523/115
5523/120 5523/125 5523/200
5523/210 5523/215 5523/220
5523/225 5523/250 5523/260
5523/265 5523/270 5523/275
5523/300 5523/310 5523/320

User Manual

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AGFA

Contents

Legal Notice

CE

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

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Published by Agfa NV

B-2640 Mortsel - Belgium.

Introduction to this Manual

Topics:

Scope of this Manual

This User Manual describes the features of the listed bucky types, further referred to as the bucky. The bucky is part of a DR system.

- BT-Cassette-T-001
- BT-Cassette-T-GSS-001
- BT-Cassette-T-ACSS-001
- BT-Cassette-WS-L-001
- BT-Cassette-WS-GSS-L-001
- BT-Cassette-WS-ACSS-L-001
- BT-Cassette-WS-R-001
- BT-Cassette-WS-GSS-R-001
- BT-Cassette-WS-ACSS-R-001
- BT-Fixed-T-001
- BT-Fixed-WS-L-001
- BT-Fixed-WS-R-001
- CASS BUCKY TABLE W/O ACSS INCL DET CHARG
- CASS BUCKY WS LL W/O ACSS INCL DET CHARG
- CASS BUCKY WS RL W/O ACSS INCL DET CHARG
- CASS BUCKY TABLE ACSS INCL DET CHARG
- CASS BUCKY WS LL ACSS INCL DET CHARG
- CASS BUCKY WS RL ACSS INCL DET CHARG

This User Manual also describes the supported anti-scatter grids.

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 on order of a physician for prescription use only.*

Introduction

Topics:

Intended Use

The bucky is a component of a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to hold and position the X-ray cassette (CR), the DR detector and optionally to hold the AEC and grid.

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.

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.

Labels

Mark	Meaning
CE	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).
	Date of manufacture
	Manufacturer
MD	Medical device
SN	Serial number
UDI	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*

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

Labeling of the bucky

Figure 1: (Sample of subtype 5523/120)

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.

 **Figure 2: (Sample of subtype 5523/125)**	
	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 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.

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

To disinfect the device:

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

Approved disinfectants

Refer to the Agfa website for specifications on the disinfectants that have been found compatible with the cover material of the device and can be used on the outer surface of the device.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=41651138

Environmental protection

Figure 3: WEEE symbol

WEEE end user notice

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

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

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

Safety Directions

General Safety Directions

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.

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.

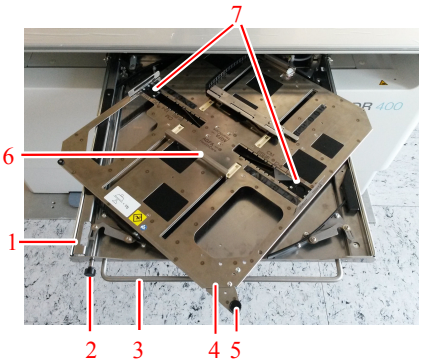
Bucky

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

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

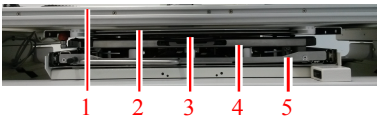
The bucky supports cassettes in standard formats as well as DR Detectors with cassette size format.

The bucky functionalities can be configured according the customer needs.



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

Figure 4: Bucky



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

Figure 5: 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.

Radiographic wall stand configuration

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

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

Rotating the bucky

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

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

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

Figure 6: Example: rotate clockwise to change from portrait to landscape position

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

Loading of the bucky in the Radiographic 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.

CAUTION:
Make sure your fingers are not between slider and detector. 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.

CAUTION:

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.

Loading of the bucky in the Radiographic Wall Stand

To load the bucky with a cassette or detector:

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

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

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

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

CAUTION:

When positioning the cassette or detector out of center:

- The alignment to the X-ray tube must be controlled manually.
- The AEC 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 Radiographic 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.

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

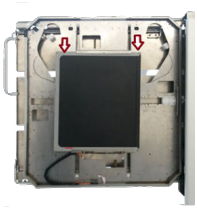
3. Lift the cassette or detector and remove it from the clamping. The openings in the carrier allow your fingers to grip the detector or cassette.
4. Load the bucky with another cassette or detector.

   - Alternatively, close the bucky drawer using the front handle and pushing the button to release the brake.

Unloading of the bucky in the Radiographic Wall Stand

To unload the bucky with a cassette or detector:

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



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

4. Remove the cassette or detector from the clamping. The openings in the carrier allow your fingers to grip the detector or cassette.
5. Load the bucky with another cassette or detector.

   - Alternatively, close the bucky drawer using the front handle and pushing the button to release the brake.

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. The ACCS functionality is not available when the collimator is in manual mode.

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.

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

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

The centering icon on the tube head display indicates the alignment of the X-ray field to the bucky.

Table 1: Centering status on the radiographic table

	X-ray tube is pointing towards table bucky. X-ray tube stand and bucky are mechanically coupled. X-ray tube arm is in center position of transversal axis.
	Any of the above conditions is not true.

Table 2: Centering status on the radiographic wall stand

	X-ray tube is pointing towards wall stand bucky. X-ray tube arm is in mid position of transversal and vertical axis.

	Any of the above conditions is not true.

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.

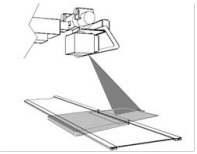


Figure 7: Center line and collimation area

Bucky types

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

Table 3: Modality positions

Radiographic table	5523/100 5523/110 5523/115 5523/120 5523/125 5523/300
Radiographic wall stand, left loading	5523/200 5523/210 5523/215 5523/220 5523/225 5523/310
Radiographic wall stand, right loading	5523/250 5523/260 5523/265 5523/270 5523/275 5523/320

Table 4: Bucky with tray for multiple cassette or detector formats

Clamping mechanism Rotation mechanism Cassette or detector detection CR double exposure protection Grid type and status detection AEC	All types

Automatic cassette size sensing (ACSS)	5523/120 5523/125 5523/220 5523/225 5523/270 5523/275
Integraded charger for DR 14s DR Detector	5523/115 5523/125 5523/215 5523/225 5523/265 5523/275

Table 5: Bucky for fixed DR detector

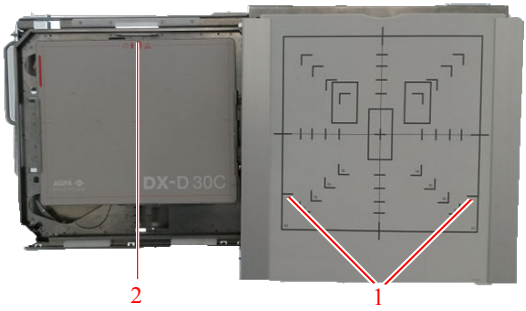
Radiographic table	5523/300
Radiographic wall stand, left loading	5523/310
Radiographic wall stand, right loading	5523/320
Grid type and status detection AEC	All types

ACSS requires the cassette to be positioned in the center of the bucky. Additionally for the radiographic 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

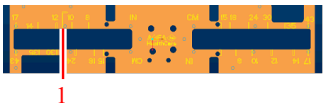
To adjust the side clamps to the format of the cassette or detector, indications are available in cm (and inch, depending on the bucky type). Corresponding indications are printed on the wall stand cover to align the collimation area.

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 8: 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 9: Indicators on bucky tray

Standard cassette formats

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

DR Detector formats and orientation

For information on how to use the DR Detector in the bucky, refer to following sections and to the user manual of the DR Detector.

Topics:

Orientation of DR 10s in the bucky

The clamps of the bucky may trigger the DR 10s power switch.

To avoid switching off the detector when inserting it in the bucky, apply the orientation as described below.

Topics:

Orientation in the radiographic table

To use the detector in portrait orientation, insert the detector in portrait orientation.

To use the detector in landscape orientation:

1. Insert the detector in portrait orientation.
2. Rotate the detector in the bucky.

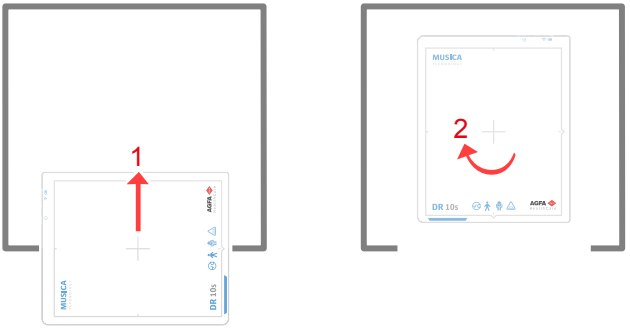


Figure 10: Landscape orientation in the radiographic table

Orientation in the radiographic wall stand left loading

- To use the detector in landscape orientation, insert the detector in landscape orientation.
- To use the detector in portrait orientation:

  1. Insert the detector in landscape orientation.
  2. Rotate the detector in the bucky.

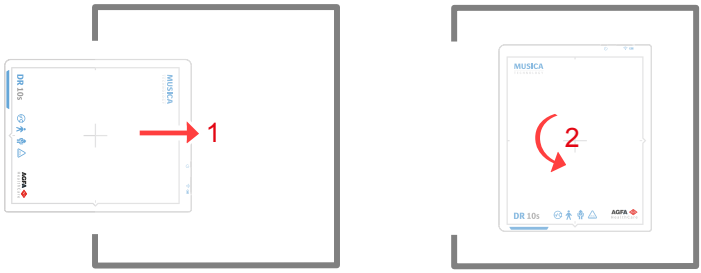


Figure 11: Portrait orientation in the radiographic wall stand left loading

Orientation in the radiographic wall stand right loading

- To use the detector landscape orientation, insert the detector in landscape orientation.
- To use the detector in portrait orientation:

  1. Insert the detector in landscape orientation.
  2. Rotate the detector in the bucky.

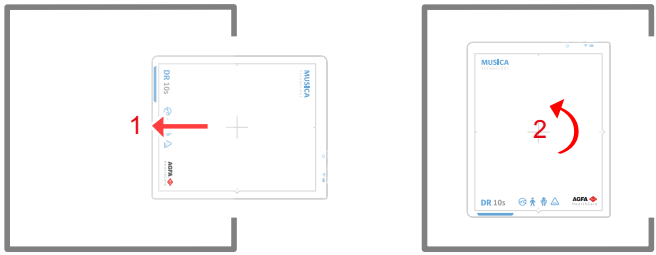


Figure 12: Portrait orientation in the radiographic wall stand right loading

Orientation of DR 14s in the bucky

If the bucky is equipped with an internal DR Detector connector, the battery will be charged while the detector is in the bucky.

Topics:

- *Orientation in the radiographic table*
- *Orientation in the radiographic wall stand left loading*
- *Orientation in the radiographic wall stand right loading*

Orientation in the radiographic table

To use the detector in portrait orientation, insert the detector in portrait orientation.

To use the detector in landscape orientation:

1. Insert the detector in portrait orientation.

2. Rotate the detector in the bucky.

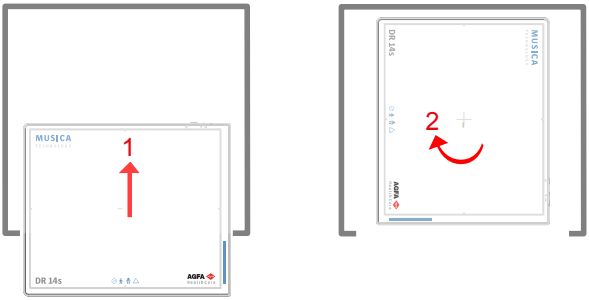


Figure 13: Landscape orientation in the radiographic table

Orientation in the radiographic wall stand left loading

- To use the detector in landscape orientation, insert the detector in landscape orientation.
- To use the detector in portrait orientation:

  1. Insert the detector in landscape orientation.
  2. Rotate the detector in the bucky.

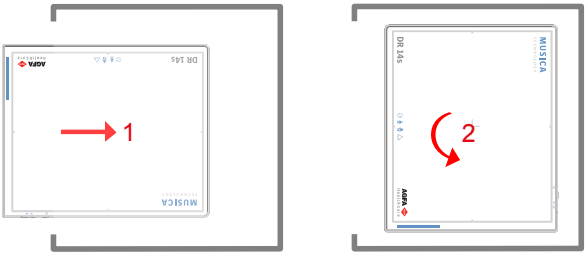


Figure 14: Portrait orientation in the radiographic wall stand left loading

Orientation in the radiographic wall stand right loading

- To use the detector landscape orientation, insert the detector in landscape orientation.
- To use the detector in portrait orientation:

  1. Insert the detector in landscape orientation.
  2. Rotate the detector in the bucky.

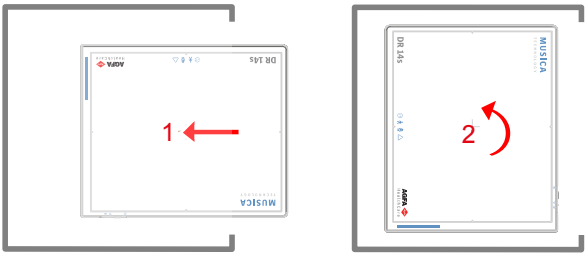


Figure 15: Portrait orientation in the radiographic wall stand right loading

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 radiographic table*
- *Orientation in the radiographic wall stand left loading*
- *Orientation in the radiographic wall stand right loading*

Orientation in the radiographic table

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

To use the detector in portrait orientation:

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

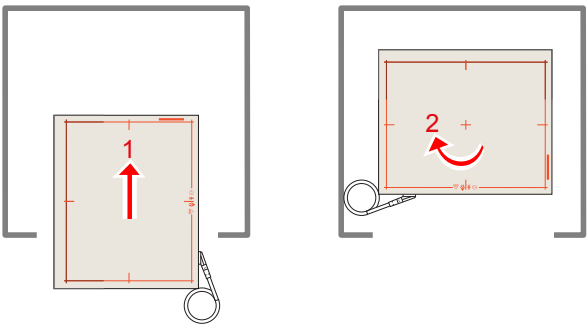


Figure 16: Portrait orientation in the radiographic table

Orientation in the radiographic 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.

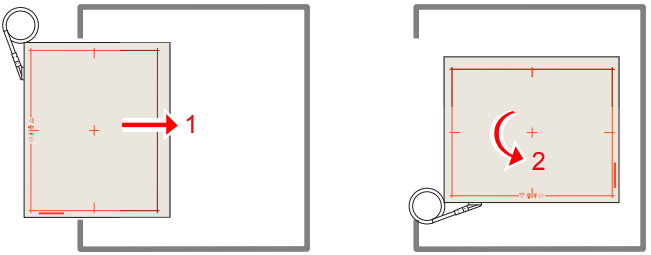


Figure 17: Landscape orientation in the radiographic wall stand left loading

Orientation in the radiographic wall stand right loading

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

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

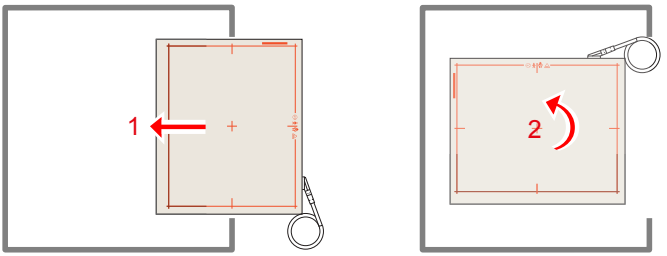


Figure 18: Landscape orientation in the radiographic wall stand right loading

Using DX-D 45C, DX-D 45G, XD 10, XD⁺10 only outside the bucky

Use the DX-D 45C, DX-D 45G, XD 10 and XD⁺10 detector only for free exposures. Do not put the detector inside the bucky of the radiographic table or the radiographic wall stand.

Grids

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

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

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

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

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

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

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.

Related Links

Bucky Unit Technical Data on page 51

Topics:

- *Anti-scatter grids*
- *Grid focal distance color indication*
- *Grid detection*

Anti-scatter grids

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

Refer to the Agfa website for specifications on the anti-scatter grids that have been found compatible with the system and the DR Detectors.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=54332498

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 of the grid and if the grid is correctly inserted in the bucky.

The grid status reflects if the inserted grid is suitable for the selected exposure and the current SID and is displayed on the tube head display and on the Software Console.

Product Information

Topics:

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

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.

Environmental Compliance

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

Equipment Classification

Per EN/IEC60601-1, Medical Electrical Equipment, General Requirements for Safety, this device is classified as following:

Table 6: Equipment classification

Class II equipment	Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.
Ingress	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 13

Product Complaints

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

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Training

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

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

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

Technical Data

Topics:

Bucky Unit Technical Data

Manufacturer	Agfa NV Septestraat 27 2640 Mortsel, Belgium
Type	
BT-Cassette-T-001	5523/100
BT-Cassette-T-GSS-001	5523/110
CASS BUCKY TABLE W/O ACSS INCL DET CHARG	5523/115
BT-Cassette-T-ACSS-001	5523/120
CASS BUCKY TABLE ACSS INCL DET CHARG	5523/125
BT-Cassette-WS-L-001	5523/200
BT-Cassette-WS-GSS-L-001	5523/210
CASS BUCKY WS LL W/O ACSS INCL DET CHARG	5523/215
BT-Cassette-WS-ACSS-L-001	5523/220
CASS BUCKY WS LL ACSS INCL DET CHARG	5523/225
BT-Cassette-WS-R-001	5523/250
BT-Cassette-WS-GSS-R-001	5523/260
CASS BUCKY WS RL W/O ACSS INCL DET CHARG	5523/265
BT-Cassette-WS-ACSS-R-001	5523/270
CASS BUCKY WS RL ACSS INCL DET CHARG	5523/275
BT-Fixed-T-001	5523/300

BT-Fixed-WS-L-001	5523/310
BT-Fixed-WS-R-001	5523/320

Dimensions	
Dimensions in radiographic table	65.5 cm x 60.0 cm x 8.0 cm (WxLxH)
Dimensions in radiographic 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 radiographic table	23.5 kg
Bucky for DR Detector or CR cassette in radiographic wall stand	26.0 kg
DX-D Fixed DR Detector bucky	13 kg
Electrical connection (type 5523/100, 5523/200, 5523/250)	
Operating voltage	24 VDC
Operating current	80 mA
Electrical connection (type 5523/110, 5523/120, 5523/210, 5523/220, 5523/260, 5523/270, 5523/300, 5523/310, 5523/320)	
Operating voltage	24 VDC
Operating current	375 mA
Electrical connection (type 5523/115, 5523/125, 5523/215, 5523/225, 5523/265, 5523/275)	
Operating voltage	24 VDC
Operating current	1.375 mA
Charging time of the DR Detector battery	maximum 4 hours
Supported sizes	

Supported sizes	15x30 to 43x35 in portrait and landscape orientation
Lifetime	
Expected lifetime for the bucky	10 years

Environmental conditions

Table 7: 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 CFR 47 Part 15 Class A.

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

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

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

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

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

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

RF Emission Measurements	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 might not offer adequate protection to radio-

Harmonic emission in accordance with IEC 61000-3-2	Class A	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	

DR 400 is used in a professional healthcare facility / 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*

- *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.

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.