CR 30-X/CR 30-Xm Plates and Cassettes

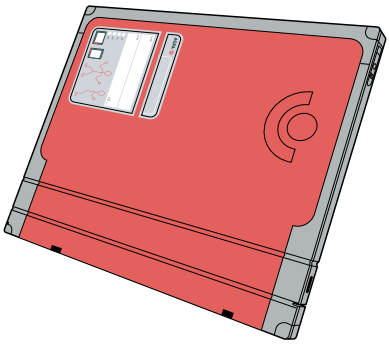
CR MD4.0T GENERAL SET

CR MD4.0T FLFS SET

CR MM3.0T MAMMO SET

CR MM3.0T EXTREMITIES SET

User Manual



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Contents

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Introduction to this Manual

Topics:

Scope

This manual contains information for safe and effective operation of the CR MD 4.xT and CR MM 3.xT Plates and Cassettes™.

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 Agfa CR Plates and Cassettes

Topics:

Intended Use

The AGFA CR plates and cassettes are part of a system, consisting of a digitizer and a workstation. The AGFA CR plates and cassettes are identified on the workstation. The exposed AGFA CR plates and cassettes will be scanned by the digitizer. The resulting digital image is further processed and routed by the workstation. It is intended that these devices are only operated in a radiological environment by qualified staff.

The CR MD4.xT General plate and cassette are specifically designed for general radiography applications.

CR MD4.xT FLFS cassettes are specifically designed for the Full Leg Full Spine application, but can also be used for general radiography applications.

CR MM3.xT Extremities plates and cassettes are specifically designed for extremities examinations.

CR MM3.xT Mammo cassettes and plates are part of the Mammography System, that can be used for diagnostic mammography and for screening mammography, in compliance with the local regulations. For more information refer to the CR Mammography System User Manual, document 2344.

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.

Product Complaints

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

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

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

System Documentation

The documentation shall be kept with the system for easy reference.

For information and safety notes on the CR 30-X/CR 30-Xm System, refer to the CR 30-X/CR 30-Xm User Manual, document 2386.

Environmental Protection

Topics:

CR Plate

Regulations about waste disposal may differ from one country to another. Please consult local regulations on the subject matter.

At the end of its life cycle, the CR Plate is considered as industrial waste in most countries.

Consequently it is not allowed to dispose of it as household waste. We recommend to have it hauled away by a licensed company.

When the CR Plate is disposed of through incineration, the nature of the combustion products is dependent on the physical characteristics of the burning process and on the degree of combustion, whereby different gases can be generated, such as e.g. water vapor, carbon dioxide, carbon monoxide and small concentrations of organic and inorganic degradation products.

Disposal

Waste codes applicable for European Union:

	Plates containing storage phosphor
Product	09 01 99 Waste not otherwise specified
Packaging	15 01 06 Mixed packaging

Information applicable for USA:

	Plates containing barium
Product	These plates, when discarded, are a hazardous waste (EPA waste code D005) under the Resource Conservation and Recovery Act (RCRA) due to the leachability of barium. Hazardous waste must be managed and transported in accordance with federal, state, and local regulations. Please contact your local authorities for more information.

CR Cassette

The cassette shall not be treated as household waste.

For more detailed information about take-back and proper recycling of this product, please contact your local sales representative.

This information applies to the cassette only, excluding the plate or screen.

Topics:

Labeling

	This label on the cassette indicates that the cassette contains lead.

Disposal

Waste codes applicable for European Union:

	Cassettes containing lead	Cassettes not containing lead
Product	16 02 13* Discarded equipment containing hazardous components other than those mentioned in 16 02 09 to 16 02 12	16 02 14 Discarded equipment other than those mentioned in 16 02 09 to 16 02 13
Packaging	15 01 06 Mixed packaging	15 01 06 Mixed packaging

Information applicable for USA:

	Cassettes containing lead
Product	These cassettes, when discarded, are a hazardous waste (EPA waste code D008) under the Resource Conservation and Recovery Act (RCRA) due to the leachability of lead. Hazardous waste must be managed and transported in accordance with federal, state, and local regulations. Please contact your local authorities for more information.

Installation

The tray and image plate have been factory predefined. No further action is required from customer side to use them with the CR 30-X/CR 30-Xm.

Safety Directions

Topics:

General Safety Instructions

CR plates and cassettes will not cause any special health or safety hazard, if they are used as intended.

CAUTION:
Image quality may suffer if a cassette and plate is not scanned soon after exposure. The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is better than 50% up to 24 hours after irradiation. However, in order to preserve image quality, a cassette and plate should be scanned no later than 2 hours after exposure.

When working with the automatic exposure control device, take into account the following two safety notices:

- Overexposure (for the MD 4.xT General/FLFS and CR MM 3.xT Extremities cassettes)

  CAUTION:
  Automatic Exposure Control device may cause overexposure if they are positioned underneath the cassette. Make sure that the automatic exposure control device is placed above the cassette.

  The backscatter protection (lead) contained in the grey side of the cassette, retains a certain amount of X-rays. The dose measured by the cell will then be much lower than the dose actually given to the patient.
- Wrong response

  CAUTION:
  The image plate causes a specific X-ray scattering. This influences the response of the exposure control device. Automatic Exposure Control device may give wrong response. Recalibrate the X-ray device for use with MD 4.xT and MM3.xT cassettes to compensate for this effect

Fire Hazard and Extinguishing Media

The screen base is made of polyethylene terephthalate and meets the "Safety Film" specifications as described in ISO 18906-2000. Safety film passes the ignition time test when the ignition time is longer than or equals 10 minutes. It passes the burning time test when the burning time is longer than 45 seconds for a film thickness larger than or equal to 0.08 mm or when the burning time is longer than 30 seconds for a film thickness smaller than 0.08 mm. The nature of the combustion products depends on the physical characteristics of the burning process and on the degree of combustion, whereby different gases can be generated, such as e.g. water vapor, carbon dioxide, carbon monoxide and small concentrations of organic and inorganic degradation products.

Fire extinguishing media:

- water spray,
- carbon dioxide,
- extinguishing powder,
- foam.

CR 30-X/CR 30-Xm Plates and Cassettes Description

Topics:

Description

Topics:

Description of the MD 4.xT Cassettes

The labeling and layout of the CR MD 4.xT cassettes are illustrated below. The tube side is black.

Note: *You can use non-permanent markers to write on all labels of the cassettes.*

Topics:

CR General cassette

Note: *The label on the cassettes illustrated below serves as an example. The name of the label "CR MD4.0T General" is subject to change.*

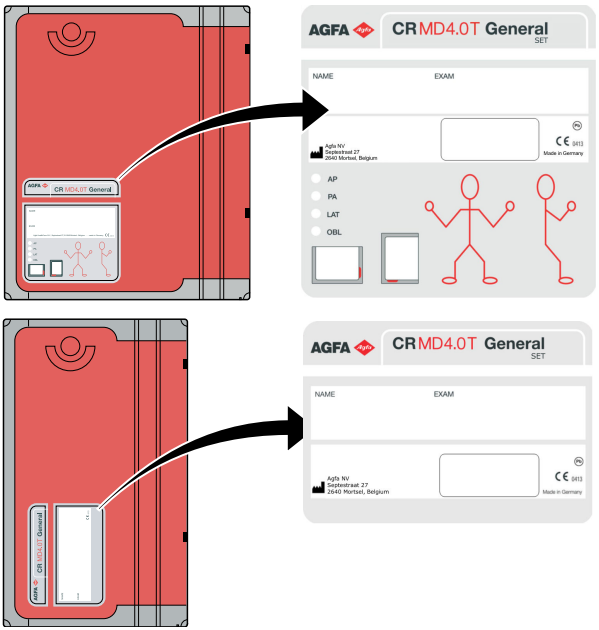
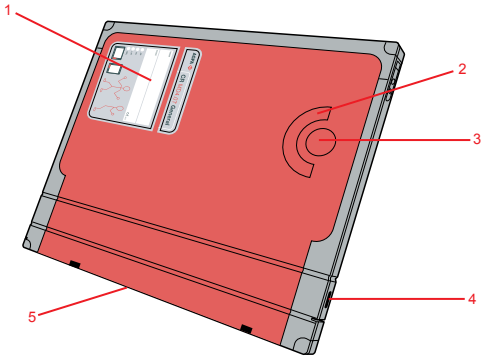


Figure 1: Label



1. Label
2. Clip
3. Cassette format
4. Lock to open and close the cassette
5. Shutter-opening mechanism

Figure 2: Layout

Specific applications: CR Full Leg Full Spine (FLFS) cassette

The following paragraphs only give a general description of the labeling, layout and limitations of the CR FLFS cassette.

For more specific information and instructions on the FLFS application consult the CR Full Leg Full Spine User Manual.

Note: The label on the cassettes illustrated below serves as an example. The name of the label "CR MD4.0T FLFS" is subject to change.

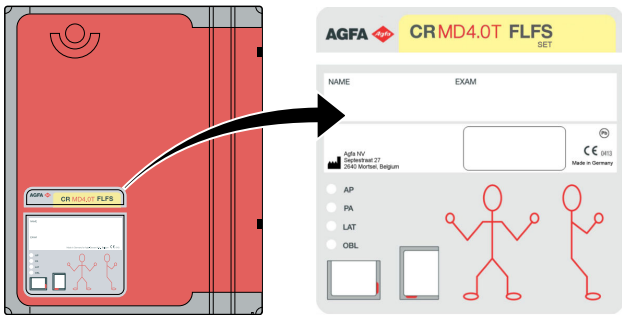
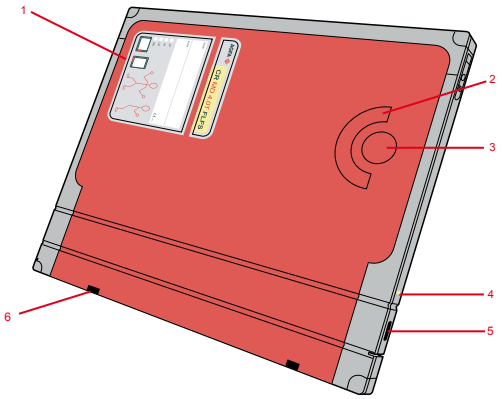


Figure 3: Label



1. Label
2. Clip
3. Cassette format
4. Yellow dot
5. Lock to open and close the cassette
6. Shutter-opening mechanism

Figure 4: Layout

CR FLFS cassettes are specifically designed for the Full Leg Full Spine application and are easily distinguishable from CR General cassettes by its yellow labeling and yellow dots.

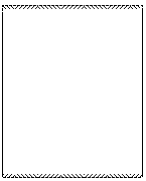
Note: In the CR 30-X you cannot use other than the above described cassettes.

Limitations

The use of CR General cassettes for Full Leg or Full Spine imaging will result in a white line in the stitching zone, in which there is no image information.

CR FLFS cassettes can be used for other than Full Leg or Full Spine imaging, however with a limitation in the border zone. Due to the presence of the reduced backscatter protection foil at the 35 cm borders of the cassette, there is a risk for reduced image quality in this border area (of maximum 1 cm) if this zone was exposed and in case there was an influence of backscattered radiation.

Risk of reduced image quality in border areas:



Description of the CR MM 3.xT Mammo Cassette

The labelling and layout of the CR MM3.xT cassettes is illustrated below. The tube side is black.

Note: *The label on the cassettes illustrated below serves as an example. The name of the label "CR MM3.0T Mammo" is subject to change.*

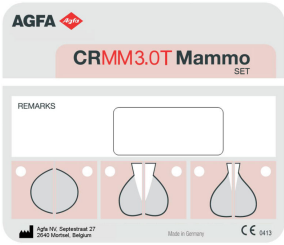
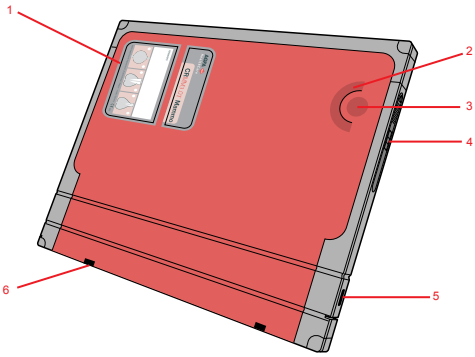
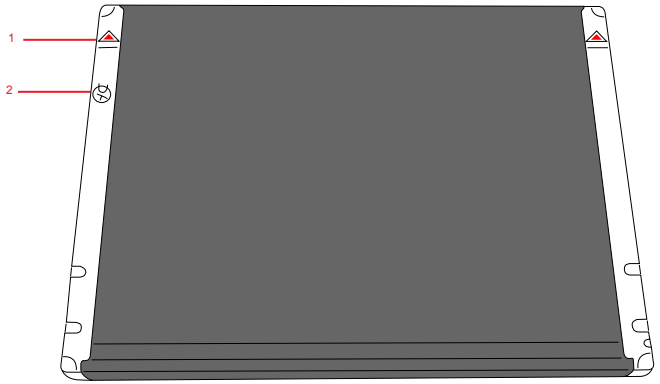


Figure 5: Label



1. Label
2. Clip
3. Cassette format
4. Opening mechanism with status indicator
5. Lock to open and close the cassette
6. Shutter-opening mechanism

Figure 6: Layout



1. Red cassette orientation marker, pointing towards the chest wall side
2. Label indicating tube side of the cassette

Figure 7: Tube side

Note: *The CR MM3.xT cassettes are not equipped with a lead foil back-scatter protection which will cause a significant reduction of image quality if used in other applications than mammography.*

Description of the CR MM 3.xT Extremities Cassette

The labelling and layout of the CR MM3.xT Extremities cassettes is illustrated below. The tube side is black.

Note: *The label on the cassettes illustrated below serves as an example. The name of the label "CR MM3.0T Extremities" is subject to change.*

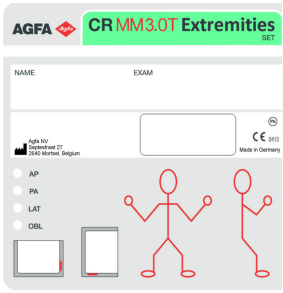
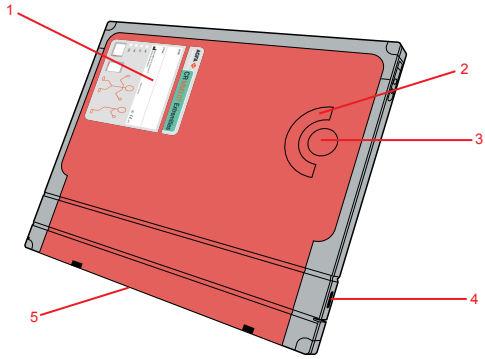


Figure 8: Label

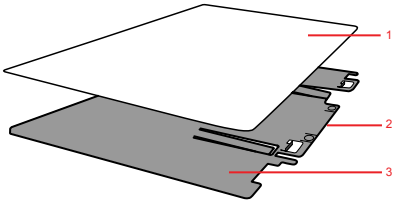


1. Label
2. Clip
3. Cassette format
4. Lock to open and close the cassette
5. Shutter-opening mechanism

Figure 9: Layout

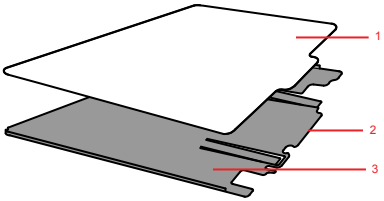
Description of the CR MD 4.xT and MM 3.xT Tray and Image Plate

The tray is part of the image plate. The tray supports the image plate and carries the RF tag.



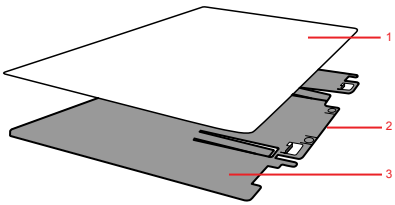
1. Image plate
2. RF-tag (backside)
3. Tray

Figure 10: Layout of the CR MD 4.xT tray and image plate



1. Image plate
2. RF-tag (backside)
3. Tray

Figure 11: Layout of the CR MM 3.xT Mammo tray and image plate

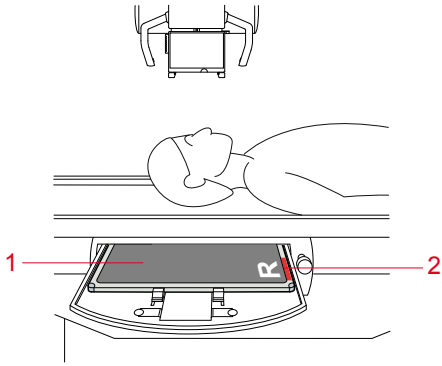


1. Image plate
2. RF-tag (backside)
3. Tray

Figure 12: Layout of the CR MM 3.xT Extremities tray and image plate

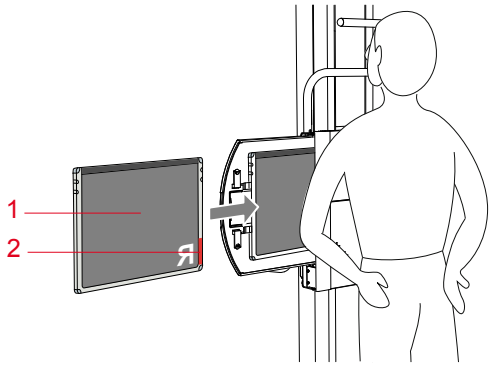
Orientation of CR Plates and Cassettes

Below some examples to illustrate the importance of the cassette orientation.



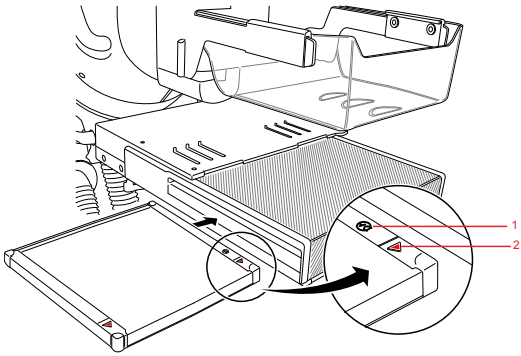
1. Black tube side of the cassette
2. Red cassette orientation marker

Figure 13: Skull AP Portrait



1. Black tube side of the cassette
2. Red cassette orientation marker

Figure 14: Chest PA Landscape



1. Label indicating tube side of the cassette
2. Red cassette orientation marker, pointing towards the chest wall side

Figure 15: Mammography

Initialization

Topics:

Initializing Cassette, Tray and Image Plate

For the MD4.xT and MM3.xT Plates and Cassettes, the image plate code has been factory embedded in the memory chip (RF-tag) of the tray. This means that the tray and the image plate should always be kept together. A tray and image plate set can be used in any cassette of the same type (MD4.xT General; MD4.xT FLFS; MM3.xT Mammo; MM3.xT Extremities). A mixture between the cassette types is not allowed. This feature makes initialization of the cassette redundant.

Replacement Image Plates

If you have received tray and image plate sets separately as replacement, always keep the image plate together with the supplied tray.

Precautionary Measures

Topics:

First Use and Normal Operation

- When using new CR plates, you need to manually erase them twice before use.
- CR plates and cassettes should only be used with CR equipment.

CAUTION:
When CR MD4.xT plates and cassettes have not been used for 48 hours, they must be erased manually. When CR MM3.xT plates and cassettes have not been used for 24 hours, they must be erased manually.

CAUTION:
Image quality may suffer if a cassette and plate is not scanned soon after exposure. The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is better than 50% up to 24 hours after irradiation. However, in order to preserve image quality, a cassette and plate should be scanned no later than 2 hours after exposure.

Maximum Cassette Load

CAUTION:
The maximum allowed weight load on the cassette is 150 kg over the whole area of the cassette surface.

The cassette must be laying on a flat and stable floor.

For foot exams the patient should always stand in the center of the cassette.

Transport

- Protect the plates from high temperatures during transport - max. 43°C (110°F).
- Take the precautions necessary to ensure that the plates remain protected from impact.

Storage

- Temperature and humidity levels:

  Packaged : -25°C to 55°C (-13°F to 131°F)

  Not packaged: Temperature : 15°C to 30°C (59°F to 86°F)

  Relative humidity : 15 to 80% (recommended 30 to 60%)
- To avoid any deformation, always store the image plates horizontally on a flat surface.
- Do not place any excessive loads on the image plate and/or cassette.
- Store a maximum of 5 image plates and/or cassettes, one on top of the other.
- Avoid UV-radiation or direct sunlight on the image plate and/or cassettes.

Handling the Tray and Image Plate

The necessary precautions must be taken when handling the tray and image plate to avoid scratches or damage. Any damage to the image plate, of whatever nature, will be visible in the image.

Cleaning

Topics:

Cleaning the Tray and Image Plate

WARNING:
Please make sure that the tray and image plate set always goes into the same cassette when cleaning. It is important that an image plate is not put together with a tray initialized for another image plate.

Topics:

When to clean the tray and image plate?

The inner lining of the cassette is made of fleece. This ensures a high degree of protection against electrostatic charging and dust collection on the image plates. Nonetheless it is recommended to clean the image plates of the CR MD4.xT at least once every month or whenever there is doubt about particles visible on the X-ray images. More frequent cleaning is required in case of excessive dust or under very dry conditions.

The CR MM3.xT image plate requires a more frequent cleaning: at least once a week or after every 200 cycles (whatever comes first).

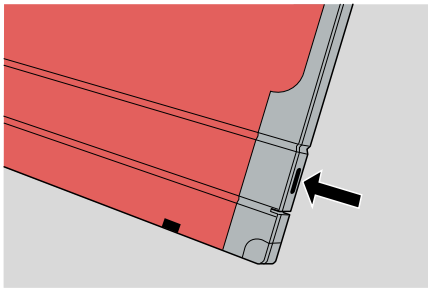
Permitted cleaning products?

- For CR MD4.xT General image plates only use AGFA CR Phosphor Plate cleaner and a soft lint-free cellulose cloth or Polynit wipes to clean the image plate.
- For CR MM3.0T Mammo and CR MM3.xT Extremities image plates only use AGFA CR Phosphor Plate cleaner and Polynit wipes to clean the image plate.
- Use only a dry cloth or blow away possible dust with compressed air to clean the tray.

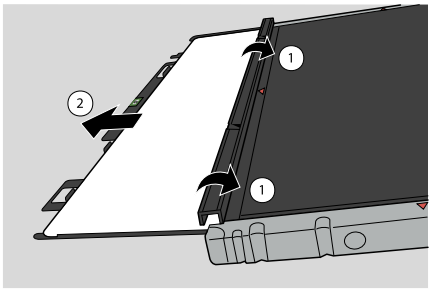
How to clean the tray and image plate?

To clean the tray and image plate:

1. Insert a key or a pen into the cassette lock to open the shutter.

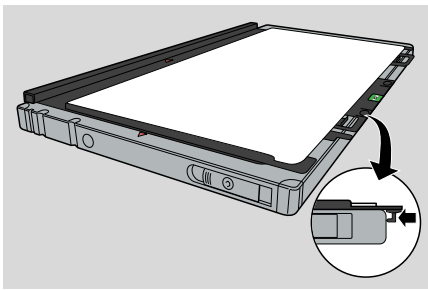


2. Remove the key or the pen.
3. Turn the cassette around, so that the black tube side is above.
4. Hold back the shutter with both thumbs and let the black tray and image plate slide out carefully onto the table.



5. Put the black tray with the image plate onto the cassette, as shown in the figure below.

   The tray has 2 little hooks. Put the tray onto the cassette in such a way that the hooks reach over the border of the cassette. This to avoid a bending of the tray and image plate.

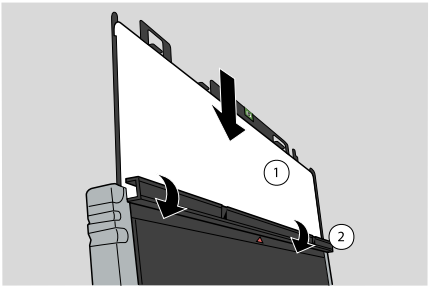


6. Clean the image plate and the tray as follows:

- Take an appropriate wipe or moisten the cloth with cleaner and wipe the **image plate surface** softly and evenly.
- Leave the **image plate surface** to dry for about 10 minutes to allow the solvents to evaporate.
- Use only a dry cloth or blow away possible dust with compressed air (canned air), to clean the **tray** thoroughly. (DO NOT USE A SCREEN CLEANER TO CLEAN THE TRAY.)
- Once the image plate surface is dry (after about 10 minutes), check once again for particles of material and other impurities before placing the tray and image plate set into the cassette.

7. Put the tray with the image plate back into the cassette.

WARNING:
Verify that the white phosphor side is oriented to the black tube side of the cassette and that the shutter does not scratch the image plate.

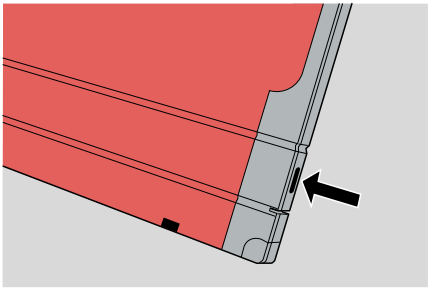


1. White phosphor side
2. Black tube side of the cassette

CAUTION:
Make sure to slide in the image plate carefully. Do not let the plate fall down vertically into the cassette! This causes damages of the phosphor.

8. When the black tray with the image plate is completely inside the cassette, close the shutter.

   To close the shutter easily, insert a key or a pen into the cassette lock while closing the shutter. Once closed, remove the key or the pen.



CAUTION:
After cleaning it is necessary to erase the image plate before use.

Cleaning the Cassette

When an increased number of dust particles is still visible in the image despite regular cleaning, you should clean the cassette.

Clean the inside of the cassette thoroughly. The recommended procedure is to tap the cassette to remove dust and dirt particles.

When necessary, you can clean the outside of the cassettes, preferably only with a damp cloth (water, soap).

Before doing a damp cleaning of the cassette, remove the image plate.

CAUTION:
If a cassette may get into contact with body fluids, protect the cassette with a plastic envelop.

Disinfecting the Cassettes of the CR Detectors, Plates and cassettes

To disinfect the Cassettes of the CR Detectors, Plates and Cassettes, use only disinfectants approved by Agfa (see list of Approved disinfectants). If you plan to use other disinfectants, approval of AGFA is needed before use, as most disinfectants can damage the cassette. UV disinfection is also not allowed.

For detailed information on how to apply disinfection, refer to the instructions for use that are delivered with the disinfectant.

Topics:

Approved disinfectants

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

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=37134794

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=45445721

Use of protective plastic envelope

If the cassette is used in an environment where disinfection is required or where it may get into contact with blood or other body fluids, use plastic envelopes to protect the cassette from direct patient contact. Make sure that the plastic envelope is not wrinkled to avoid the creases showing in the image.

Safety directions for disinfection

CAUTION:
All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment.

CAUTION:
Make sure that the equipment is properly decontaminated and disinfected before shipment or servicing.

CAUTION:
The selection and description of the appropriate disinfection procedure and policy is the responsibility of the user.

WARNING:
Do follow the instructions of use as provided with the cleaning or disinfection product.

CAUTION:
Before disinfecting the cassette, remove the image plate and assure that the cassette is clean.

CAUTION:
Be sure that all surfaces are thoroughly dry before returning the equipment to use. Disinfecting solution may cause skin irritation to the patient.

CAUTION:
Disinfecting solution or wipes may cause eye and skin irritation. Wear gloves and wash hands with soap and water following use. Consult the manufacturer's Material Safety Data Sheets (MSDS) and recommendations on the product label for additional information prior to use.

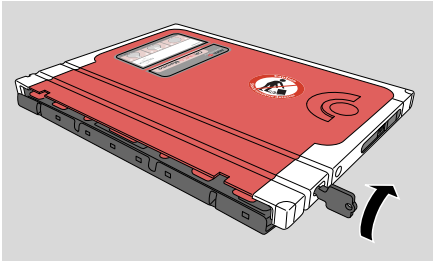
Do not pour liquid directly on the cassette. Always use a low-linting cloth dampened (not dripping) with the solution.

Cleaning the Interior of a Mammo Cassette

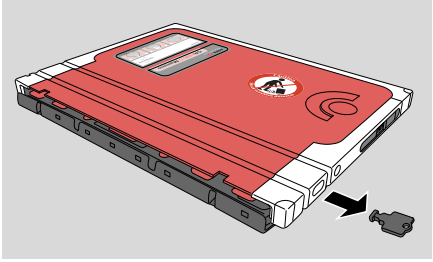
Cleaning the interior of a mammo cassette requires some special attention.

Procedure

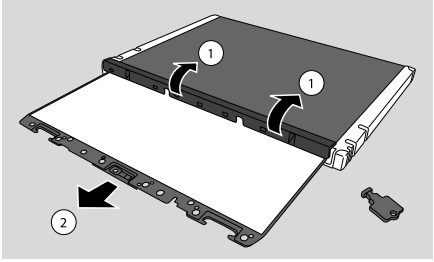
1. Open the shutter of the cassette with the dedicated key.



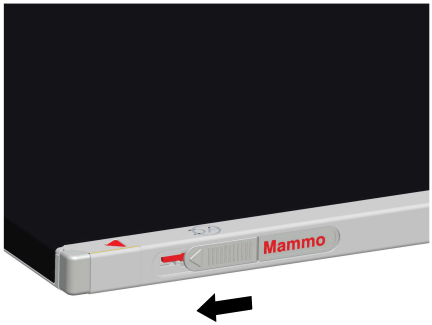
2. Remove the key from the cassette.



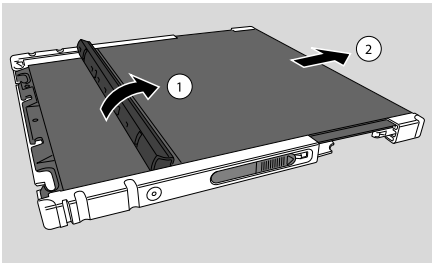
3. Turn the cassette around, so that the black tube side is above.
4. Fix the shutter with both thumbs and let the image plate slide out carefully onto the table. Make sure that the surface of the plate is not scratched.



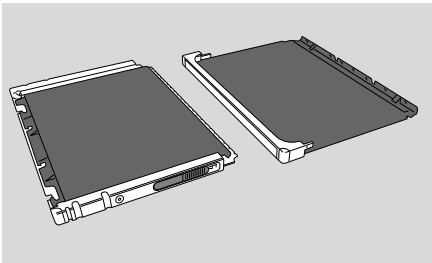
5. Open the locks on the right and left side of the cassette.



6. Push the top from the tube side part by slowly moving the shutter.

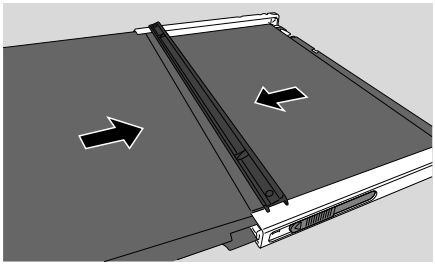


7. Clean the separate parts in the following way:



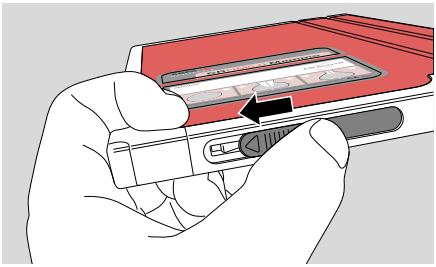
Tap each part with the fleece facing down a few times on a table with minimal force to beat out loose particles.

8. Put the top and the tube side part together. Make sure that the tube side part slides correctly in the top part.

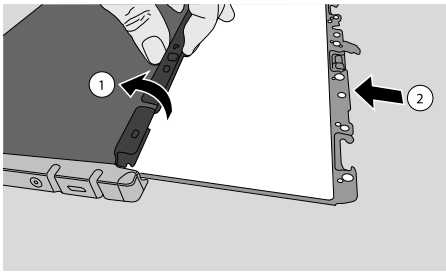


9. Slide the top part and the tube side part together.
10. Close the locks on the right and left side of the cassette.

    The red marker inside the lock indicates that the lock is open.



11. Put the image plate back into the cassette.



CAUTION:
Make sure to slide in the image plate carefully. Do not let the plate fall down vertically into the cassette! This causes damages of the phosphor.

12. When the image plate is completely inside, proceed as follows:

- First insert the key into the cassette.
- Then, close the shutter.

13. Remove the key.

Specifications

	CR MD4.xT General Cassette and Plate	CR MD4.xT FLFS Cassette	CR MM3.xT Mammo Cassette and Plate	CR MM3.xT Extremities Cassette and Plate
Available Sizes	35 x 43 35 x 35 24 x 30 18 x 24 15 x 30	35 x 43	24 x 30 18 x 24	24 x 30 18 x 24
Compliance	Outer cassette dimensions are compliant with ISO 4090 - 2001			
Weight (Cassette + Image Plate)	35x43 typical 1.6 kg 35x35 typical 1.3 kg 24x30 typical 0.8 kg 18x24 typical 0.5 kg 15x30 typical 0.6 kg	35x43 typical 1.6 kg	24x30 typical 0.8 kg 18x24 typical 0.5 kg	24x30 typical 0.8 kg 18x24 typical 0.5 kg
Cassette Material				
Body and Tray	Acrylonitryl Butadiene Styrene (ABS)			
Corners	Estane			
Shutter	Polypropylene (PP)			
Inner Lining	Fleece			
Backscatter protection	150 μ lead	150 μ lead		150 μ lead

	CR MD4.xT General Cassette and Plate	CR MD4.xT FLFS Cassette	CR MM3.xT Mammo Cassette and Plate	CR MM3.xT Extremities Cassette and Plate
Image plate material	BaSrFBrl:Eu	BaSrFBrl:Eu	BaSrFBrl:Eu	BaSrFBrl:Eu
Identification	Memory chip (RF-tag) embedded in the tray. The tray belongs to the image plate.			
Compatible AGFA Digitizer	CR 30-X CR 30-Xm	CR 30-X CR 30-Xm	CR 30-Xm	CR 30-Xm
Environmental storage and transport conditions	Allowed temperature and humidity levels in packed condition: Temperature: allowed -25 to 55°C (-13°F to 131°F) Relative Humidity: allowed: 15-80%			
Environmental operation conditions	Allowed temperature and humidity levels for operation: Temperature: recommended 20-25°C (68-77°F) / allowed: 15-30°C (59-86°F) Relative Humidity: recommended 30-60% / allowed: 15-80%			
Characteristics	The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is better than 50% up to 24 hours after irradiation.			