AGFA CR Detectors, Plates and Cassettes (CR HD5.x, CR MD4.xR, CR HM5.x, CR MM3.xR)

User Manual

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Contents

Legal Notice

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

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Introduction to this Manual

Topics:

Scope of this Manual

This manual contains information for safe and effective operation of the AGFA CR Detectors, Plates and Cassettes: the CR HD5.x General/FLFS/AEC detector, the CR HM5.x Mammo detector, the CR MD4.xR General/FLFS plate and cassette and the CR MM3.xR Mammo plate and cassette.

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

Introduction to the AGFA CR Detectors, Plates and Cassettes

Topics:

Intended Use

The AGFA CR detectors, plates and cassettes are a part of a system, consisting of a digitizer and a workstation. The AGFA CR detectors or plates and cassettes are identified on the workstation. The exposed AGFA CR detectors or 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 HD5.x General detector and the CR MD4.xR plate and cassette are specifically designed for general radiography applications.

Topics:

Specific Application: Full Leg Full Spine

CR HD5.x FLFS detectors and CR MD4.xR FLFS cassettes are specifically designed for Full Leg Full Spine application, but can also be used for general radiography applications.

CR HD5.x FLFS detectors and CR MD4.xR FLFS cassettes are to be used as described in the CR Full Leg Full Spine User Manual, document 4408.

Specific Application: CR Mammography

CR HM5.x Mammo detectors or MM3.xR cassettes and plates are part of the Mammography System. Mixed use of both types in one system is not supported. The CR Mammography System can be used in a safe and effective way for diagnostic mammography and for screening mammography, in compliance with local regulations. For more information, refer to the CR Mammography System User Manual, document 2344.

CR HM5.x Mammo detectors can be delivered with an IP Gain Calibration CD. The contents of this CD (the IP gain calibration file) have to be uploaded to the NX workstation prior to use. The IP gain calibration file can only be used with the plate or detector it has been delivered with.

Specific Application: AEC - cassettes without backscatter protection

It is intended to use the CR HD5.x AEC Detectors for general radiography applications only in combination with X-ray modalities, with an AEC system (Automatic Exposure Control) positioned behind the cassette as this is the case for e.g. specific trauma- or pediatric X-ray modalities.

Intended User

This manual has been written for trained users of Agfa products and trained diagnostic X–ray clinical personnel who have received proper training.

Users are those persons who actually handle the equipment and those who have authority over the equipment.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

The different detector, plate and cassette types are :

- CR HD5.x General detector
- CR HD5.x FLFS detector
- CR HM5.x Mammo detector
- CR HD5.x AEC detector
- CR MD4.xR General plate and cassette
- CR MD4.xR FLFS cassette
- CR MM3.xR Mammo plate and cassette

System Documentation

The documentation consists of following items:

- DX-G/DX-M User Manual (2321).
- DX-G/DX-M Workflow Sheets (2323).
- AGFA CR Detectors, Plates and Cassettes (CR HD5.x, CR MD4.xR, CR HM5.x, CR MM3.xR) User Manual (2322, this document).
- CR Mammography System User Manual (2344).
- CR Full Leg Full Spine User Manual (4408).
- NX User Manual (4420).
- CR HM5.x User Documentation - IP Gain Calibration CD.

The documentation shall be kept with the system for easy reference. Technical documentation is available in the product service documentation which is available from your local support organization.

Product Complaints

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

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

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

The use of CR HM5.x Mammo detectors is restricted by compatibility criteria specified in the table below, depending on the availability of an IP gain calibration file.

There are two valid system configurations. If one component is upgraded or replaced, all other components must be upgraded or replaced to fit the new configuration.

Table 1: Compatibility of CR HM5.x Mammo detectors with the NX software

Configuration 1	
NX software	Version NX 2.0.8500/3.0.8500 or older
CR HM5.x Mammo detector	Without IP gain calibration file
Configuration 2	
NX software	Version NX 2.0.8500/3.0.8500 SU1 or newer. For plates or detectors that are delivered with an IP gain calibration file, the IP gain calibration files must be loaded on the NX workstation.
CR HM5.x Mammo detector	With or without IP gain calibration file

How to retrieve the version number of the NX software is described in the NX User Manual.

Installation

The CR HD5.x detectors and the CR MD4.xR plates and cassettes are factory predefined. No further configuration is required from customer side to use them with the digitizer.

The cassettes have to be erased before first use, as described later in this document.

Topics:

IP Gain Calibration

For CR HM5.x Mammo detectors that are delivered with an IP Gain Calibration CD, the IP gain calibration file has to be installed on the NX workstation prior to first use. The installation is performed by Agfa certified service personnel.

To replace a plate or detector or introduce a new plate or detector to the system without a certified Agfa service engineer being present, the IP gain calibration file has to be uploaded by the end-user.

Problem Solving

Table 2: Uploading the gain calibration file

Problem	A plate or detector is replaced or a new plate or detector is introduced to the system without a certified Agfa service engineer being present.
Solution	The IP gain calibration file has to be uploaded by the end-user.
Procedure	Follow the instructions on the IP Gain Calibration CD sleeve. The IP gain calibration file is automatically distributed to other NX workstations in the network.

Table 3: Checking whether a gain calibration file is required

Problem	It is not known if a plate or detector requires an IP gain calibration file.
Solution	If it is not clear if the plate or detector has been delivered with an IP gain calibration file, check on the NX workstation if the plate or detector requires an IP gain calibration file.

Procedure	**1.** On the NX workstation, click Read and Initialize Cassette in the Functionality Overview pane of the Main Menu window. **2.** Insert a cassette in the ID Tablet. **3.** Click Read. The Read and Initialize Cassette pane shows the details of the inserted cassette. On NX 2.0.8500/3.0.8500 or newer, the field “IP Gain Calibration” specifies if the plate or detector requires a gain calibration file. On NX 2.0.8400/3.0.8400 or older, an error is displayed in case the plate or detector requires a gain calibration file (“The cassette is not initialized (properly)”). The plate or detector can only be used after upgrade of the NX software.

Table 4: Finding the right gain calibration file

Problem	It is not clear which IP gain calibration CD belongs to which plate or detector.
Solution	Match the identification values.
Procedure	**1.** Read the RF tag on the plate or detector. The field “Identification” contains the plate identification. **2.** Check whether the “Identification” on the label of the CD corresponds with the plate identification.

Environmental Protection

For detectors, plates and cassettes combine the CR plate and CR Cassette recommendations.

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.

Safety Directions

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

When working with the automatic exposure control device, take into account the following two warnings and read the instructions:

- Overexposure (for the CR HD5.x General/FLFS detector, CR MD4.xR General/FLFS cassette)

WARNING:
The Automatic Exposure Control (AEC) device may cause overexposure if it is positioned underneath the cassette.

The backscatter protection (lead) contained in the front side of the cassette, retains a certain amount of X-rays. Therefore the dose measured by a cell of an AEC system positioned underneath the cassette will then be too low which will cause excessive dose actually given to the patient.

Make sure that the measurement cells of the AEC are placed between cassette and X-ray source.

For modalities with an AEC system positioned underneath the cassette, use the HD5.x AEC detector.

- Wrong response

WARNING:
The Automatic Exposure Control device may give wrong response.

The CR detector or CR plates and cassettes causes X-ray scattering during exposure, which is also detected by the measurement cells of the AEC.

Recalibrate the AEC for use with CR detectors and CR plates and cassettes to compensate for this effect.

When switching to a different type of CR detector or CR plates and cassettes the AEC has to be calibrated accordingly.

Note: For calibration instructions of mammography X-Ray modalities to be used in combination with a CR system, refer to the CR Mammography System User Manual (2344).

Quality Control

As is the case for all technical devices, the CR detectors, plates and cassettes must be operated, cared for an maintained correctly.

A regular quality control of the plates and cassettes inventory has to be applied in accordance with the local regulations. If no specific regulations are valid, a regular quality control of the complete plates and cassettes inventory applied at least quarterly with the Agfa Auto QC tools (Auto QC^2, Auto QC Mammo) or with an equivalent tool is required.

Description of the AGFA CR Detectors, Plates and Cassettes

The color of the cover of the cassettes depends on what image plate is inside: a red cover means it concerns a PIP (Powder Image Plate). The CR MD4.xR image plate is an example of a PIP.

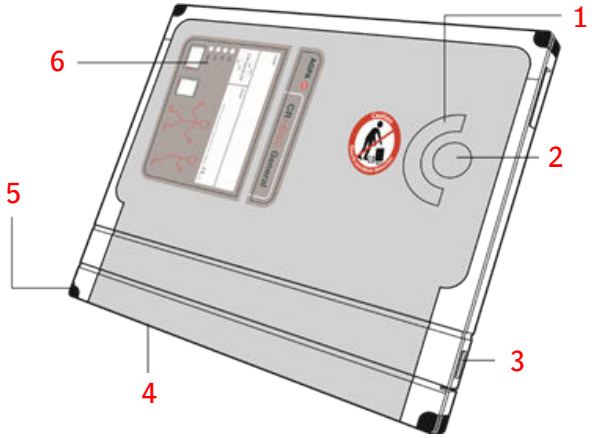
A cassette with a grey cover has a NIP (Needle Image Plate) inside. The CR HD5.x and CR HM5.x detectors are needle image plates.

Topics:

Description of the CR HD5.x General Detector and CR HD5.x FLFS Detector

The CR HD5.x General detector is used for general radiography and the CR HD5.x FLFS detector for full leg/full spine examinations. More details about the FLFS application can be found in *'Specific Application: Description of CR Full Leg Full Spine (FLFS) cassette'*.

The labeling and layout of the CR HD5.x detectors are illustrated below. The tube side is black.



1. Clip
2. Detector format
3. Lock to open the cassette
4. Shutter-opening mechanism
5. Rubber corner protections
6. Label

Figure 1: General view on CR HD5.x General Detector

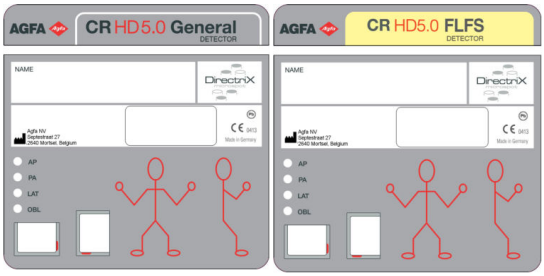
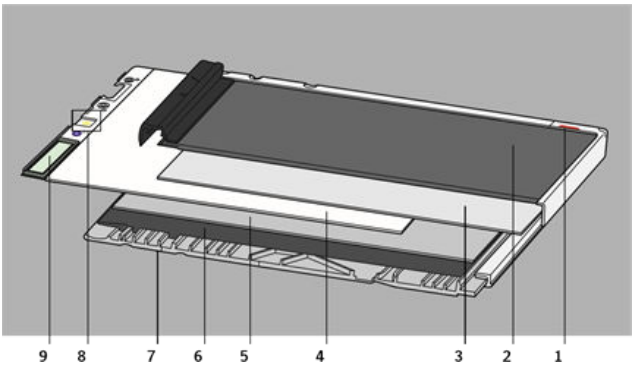


Figure 2: Detail view on CR HD5.x General/FLFS Detector label



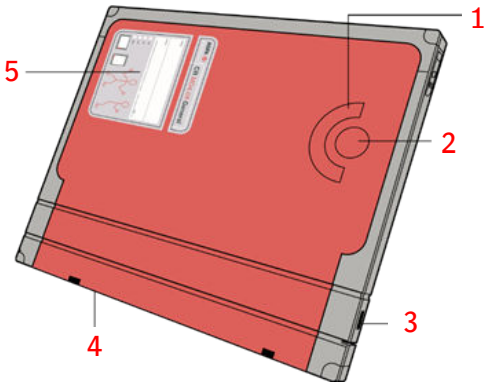
1. Cassette orientation marker
2. Black tube side
3. Fleece
4. Needle phosphor plate
5. Fleece
6. Lead foil
7. Cassette body (grey)
8. IP Label
9. RF-Tag

Figure 3: View on protruding image plate within CR HD5.x General Detector

Description of CR MD4.xR Plate and Cassette

The labeling and layout of the CR MD4.xR plates and cassettes are illustrated below.

There are two CR MD4.xR plates and cassettes available: one for general radiology and one for FLFS. More details about the FLFS application can be found in *'Specific Application: Description of CR Full Leg Full Spine (FLFS) cassette'*.



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

Figure 4: General view on the CR MD4.xR General Plate and Cassette

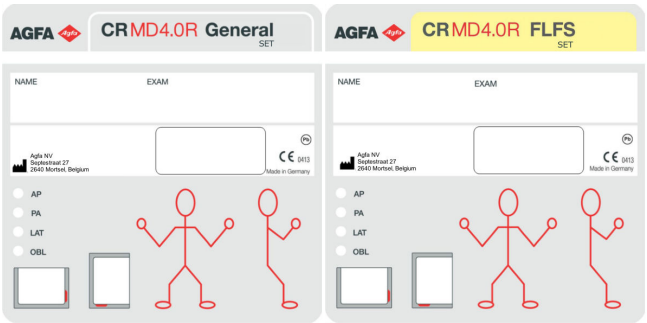
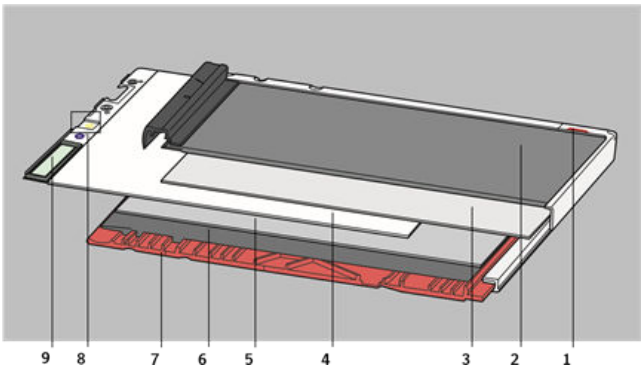


Figure 5: Detail view on CR MD4.xR General/FLFS Plate and Cassette label

Note: The label on the cassettes illustrated serves as an example. The name of the label “CR MD4.xR FLFS” is subject to change.Note:

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



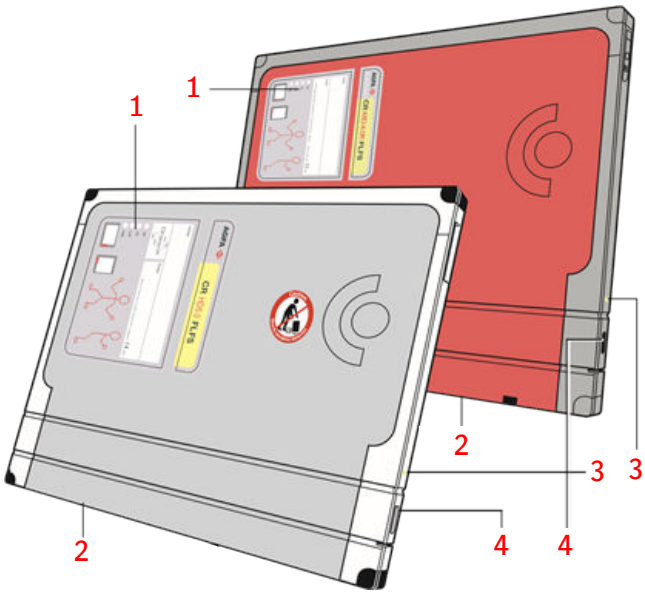
1. Cassette orientation marker
2. Black tube side
3. Fleece
4. Powder phosphor plate
5. Fleece
6. Lead foil
7. Cassette body (red)
8. IP Label
9. RF-Tag

Figure 6: Cross-section CR MD4.xR General Cassette

Specific Application: Description of CR Full Leg Full Spine (FLFS) cassette

The following paragraphs give a general description of the 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.



1. Label
2. Shutter-opening mechanism
3. Yellow dot
4. Lock to open and close the cassette

CR FLFS detectors/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.

The NX workstation is capable of stitching images made with detectors or cassettes of the same type and scan resolution only. E.g. it is not possible to stitch images made with HD5.x FLFS detectors and MD4.xR FLFS cassettes, or images made with MD4.xR FLFS and MD4.xR SR FLFS cassettes.

Limitations

CR FLFS detectors/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.

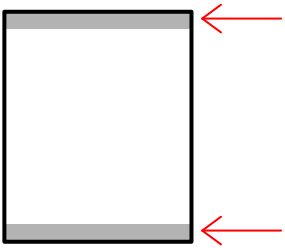


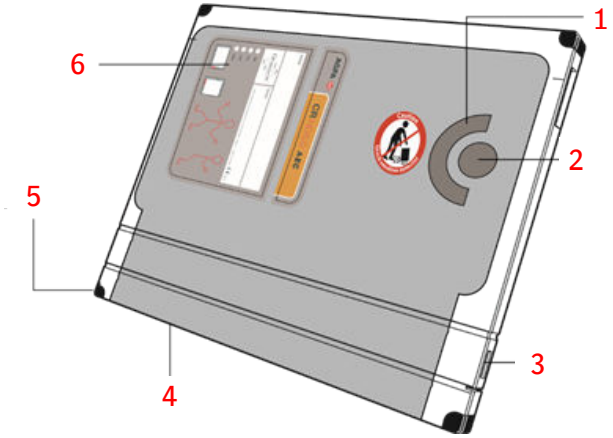
Figure 7: Risk of reduced image quality in border areas

Stitching area

The stitching area of FLFS images contains certain artifacts (such as: cassette border, stitching line) and as a consequence the image quality is not perfect.

Specific Application: Description of the CR HD5.x AEC Detector

The following paragraphs give a general description of the layout and limitations of the CR HD5.x AEC detector.



1. Clip
2. Detector format
3. Lock to open the cassette
4. Shutter-opening mechanism
5. Rubber corner protections
6. Label

Figure 8: General view on the CR HD5.x AEC Detector

It is intended to use the CR HD5.x AEC Detectors for general radiography applications only in combination with X-ray modalities, with an AEC system positioned behind the cassette as this is the case for e.g. specific trauma- or pediatric X-ray modalities.

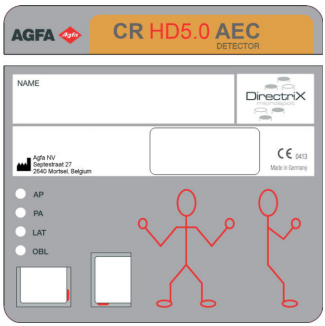
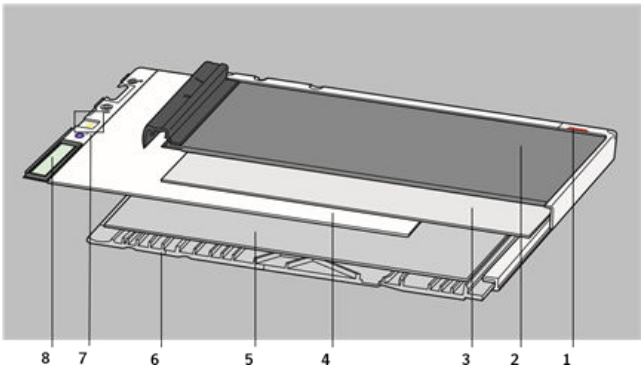


Figure 9: Detail view on CR HD5.x AEC Detector label

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

Note: The illustrated label on the cassettes serves as an example. The name of the label “CR HD5.x AEC” is subject to change.



1. Cassette orientation marker
2. Black tube side
3. Fleece
4. Needle phosphor plate
5. Fleece
6. Cassette body (grey)
7. IP Label
8. RF-Tag

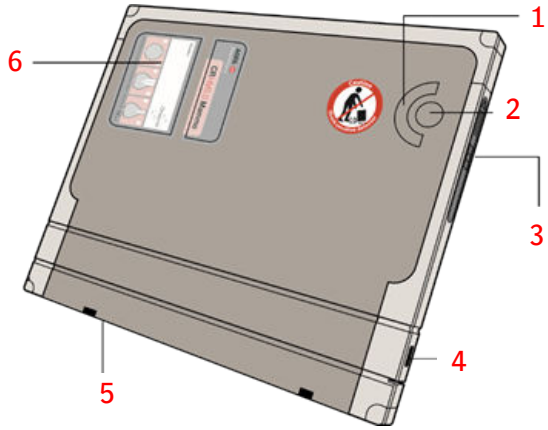
Figure 10: View on protruding image plate within CR HD5.x AEC Detector

CR HD5.x AEC detectors are not equipped with a lead foil backscatter protection which will cause a significant reduction of image quality if used in other applications than in the cassette support (or bucky-tray) of X-ray modalities specified for general radiography applications.

Description of CR HM5.x Mammo Detector

The labeling and layout of the CR HM5.x Mammo detector is illustrated below. The tube side is black.

More details about the mammo application can be found in *'Special Application: Description of CR Mammo Cassette'*.



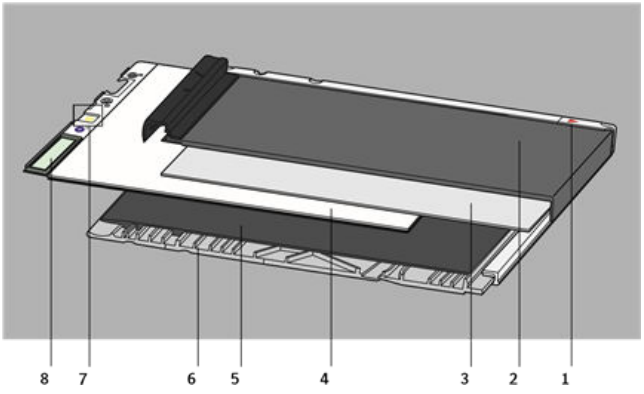
1. Clip
2. Detector format
3. Opening mechanism with status indicator
4. Lock to open and close the cassette
5. Shutter-opening mechanism
6. Label

Figure 11: General view on the CR HM5.x Mammo Detector

Figure 12: Detail view on CR HM5.x Mammo Detector label

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

Note: The illustrated label on the cassettes serves as an example. The name of the label “CR HM5.x Mammo” is subject to change.



1. Chest wall side marker
2. Black tube side
3. Fleece
4. Needle phosphor plate
5. Fleece
6. Cassette body (grey)
7. IP Label
8. RF-Tag

Figure 13: Cross-section CR HM5.x Mammo Detector

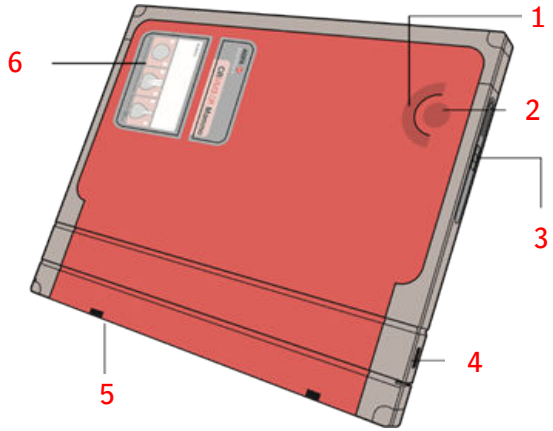
1. Red cassette orientation marker, pointing towards the chest wall side
2. Label indicating tube side of the cassette

Figure 14: Orientation markers on the CR HM5.x Mammo Detector

Description of CR MM3.xR Plate and Cassette

The labeling and layout of the CR MM3.xR Plate and Cassette is illustrated below. The tube side is black.

More details about the mammo application can be found in *'Special Application: Description of CR Mammo Cassette'*.



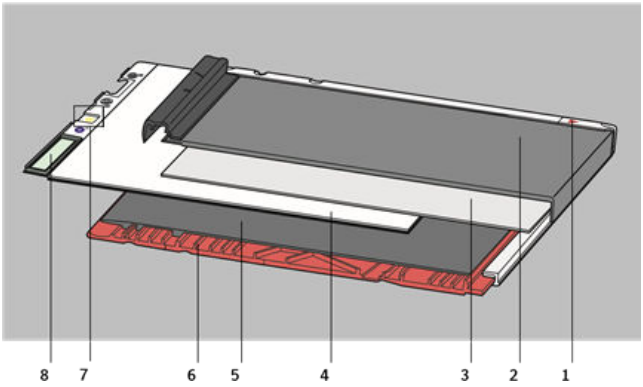
1. Clip
2. Detector format
3. Opening mechanism with status indicator
4. Lock to open and close the cassette
5. Shutter-opening mechanism
6. Label

Figure 15: General view on the CR MM3.xR Plate and Cassette

Figure 16: Detail view on CR MM3.xR Mammo plate and cassette label

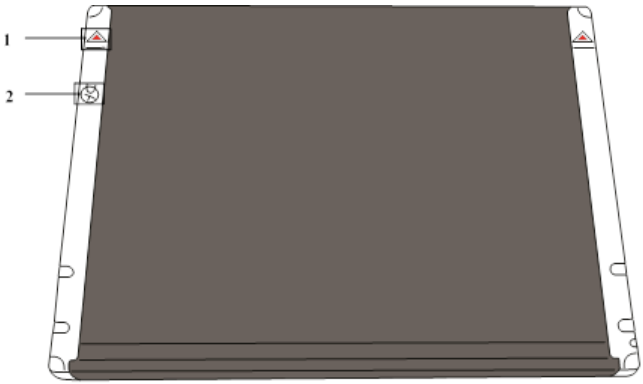
Note: You can use non-permanent markers to write on all labels of the cassettes.

Note: The illustrated label on the cassettes serves as an example. The name of the label “CR MM3.xR Mammo” is subject to change.



1. Chest wall side marker
2. Black tube side
3. Fleece
4. Needle phosphor plate
5. Fleece
6. Cassette body (red)
7. IP Label
8. RF-Tag

Figure 17: Cross-section CR MM3.xR Mammo plate and cassette



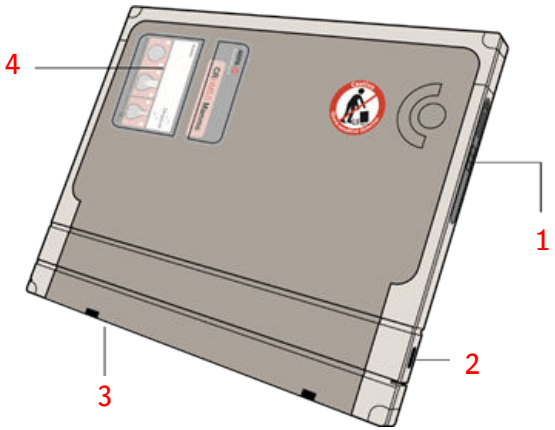
1. Red cassette orientation marker, pointing towards the chest wall side
2. Label indicating tube side of the cassette

Figure 18: Orientation markers on the CR MM3.xR Mammo plate and cassette

Special Application: Description of CR Mammo Cassette

The following paragraphs give a general description of the layout and limitations of the CR HM5.x Mammo detector and the CR MM3.xR cassette and plate.

For specific information and instructions on the mammography application consult the CR Mammography System User Manual.



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

Figure 19: General view on the CR Mammo cassette

CR Mammo cassettes are specifically designed for the mammography application and are easily distinguishable from CR General cassettes by their label.

CR HM5.x Mammo detectors and CR MM3.xR 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.

Handling the AGFA CR Detectors, Plates and Cassettes

Topics:

First Use and Normal Operation

When using new CR detectors or CR plates and cassettes, you need to manually erase them twice before use.

When CR HD5.x detectors and CR MD4.xR plates and cassettes have not been used for 48 hours, you equally need to erase them manually.

When CR HM5.x detectors and CR MM3.xR plates and cassettes have not been used for 24 hours, you equally need to erase them manually.

CR detectors and CR plates and cassettes should only be used with CR equipment.

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

Cassette and plate must not be dropped as this might damage the cassette and plate. It is good practice to check the integrity of the cassette and plate after a cassette drop.

	Observe great care when handling the detectors. The needle detector is shock sensitive and drops should be avoided. When the detector has been dropped, put it aside and contact your local service to check for functionality.

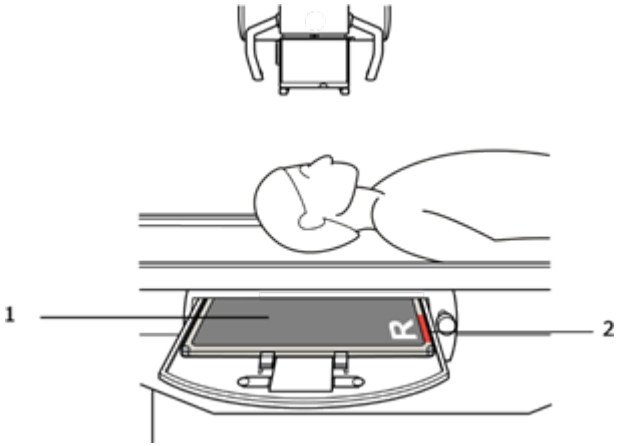
CAUTION:
Do not use the detector again, a corrupt detector can damage the digitizer!

WARNING:
For mammography cassettes and plates or detectors (MM3.xR and HM5.x) that are delivered with an IP Gain Calibration CD, the IP gain calibration file has to be uploaded to the NX workstation prior to use.

Topics:

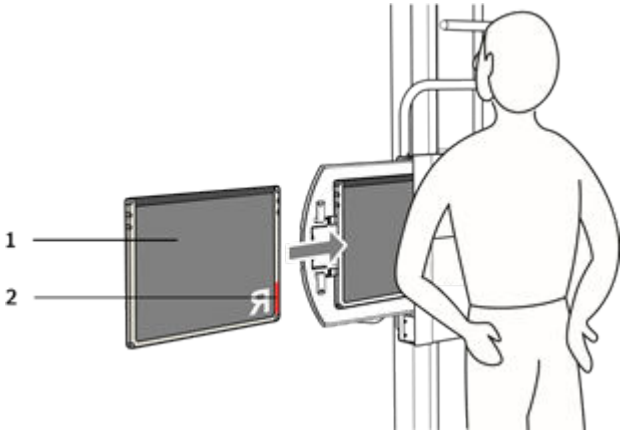
Orientation of CR Detectors and CR Plates and Cassettes

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



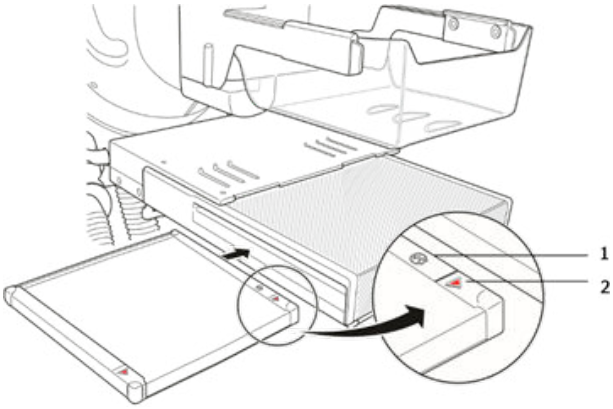
1. Black tube side of the cassette
2. Red cassette orientation marker

Figure 20: Skull AP Portrait



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

Figure 21: Chest PA Landscape



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

Figure 22: Mammography

Maximum Cassette Load

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

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

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

Storage and Transport

Protect the CR detectors and CR plates and cassettes from excessive climatic conditions during storage and transport:

Allowed temperature and humidity levels in packed condition:

Table 5: Allowed temperature and humidity levels in packed conditions

Temperature	-25°C to 55°C (-13°F to 131°F)
Relative humidity	15 to 80%

Take the precautions necessary to ensure that the CR detectors and CR plates and cassettes remain protected from impact.

The gain calibration CD and the CD sleeve are an integral part of the corresponding CR Mammography cassette and plate or detector. It is necessary to store the gain calibration CD accordingly.

In case of loss of the gain calibration CD, contact Agfa service personnel.

Operation Conditions

Temperature and humidity levels during operation:

Table 6: Allowed temperature and humidity levels during operation

Temperature	CR HD5.x detectors, CR MD4.xR and CR MM3.xR plates: 15°C - 30°C (59°F - 86°F) CR HM5.x detectors: 20°C - 30°C (68°F - 86°F)
Relative humidity	15 to 75% (recommended 30 to 60%), IEC 721-3-3: class 3K2

Do not place any excessive loads on the CR detectors and CR plates and cassettes.

Avoid UV-radiation or direct sunlight on the CR detectors and CR plates and cassettes.

The storage of CR detectors and CR plates and cassettes shall be protected against radiation in such a way, that the annual dose rate at the place of installation will not exceed 1m Sv/a.

Use plastic envelops to protect the CR detectors and CR cassettes against contact with body-fluids.

Cleaning

Topics:

Cleaning Image Plates of the CR Detectors, Plates and Cassettes

WARNING:
Be aware that the image plate of the CR HD5.x and CR HM5.x detectors is a very expensive part and therefore needs extra care!

WARNING:
Do not put the image plate with the phosphor side facing down!

WARNING:
To avoid any deformation always store the image plate horizontally on a flat surface.

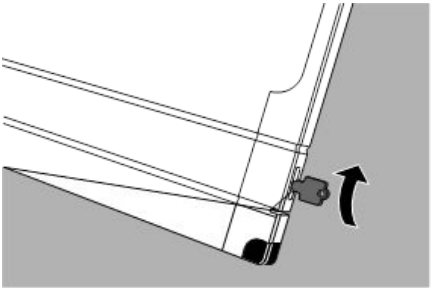
WARNING:
Do not use AGFA CR Phosphor Plate Cleaner or any alcohol containing liquid on the cassette surface, as this can cause damage to the cassette.

WARNING:
Do not use disinfectants or any other solution on the image plate.

The inner lining of the CR detectors 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 HD5.x detectors and CR MD 4.xR plates and cassettes quarterly using the following procedure.

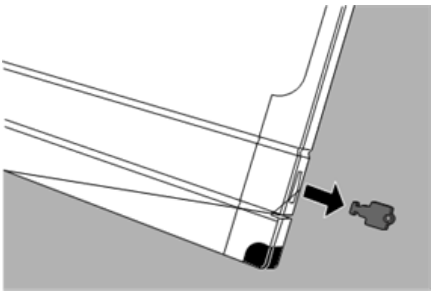
The CR MM3.xR image plate and the image plate of a CR HM5.x Mammo detector requires a more frequent cleaning: at least once a week or after every 200 cycles (whatever comes first).

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

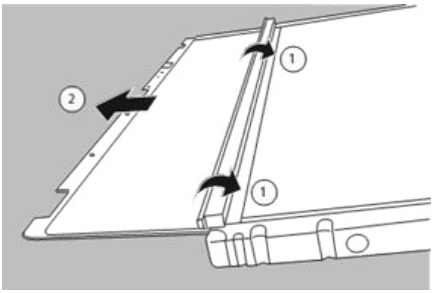


Note: You can also use a pen to open the shutter of the cassette.

2. Remove the key.

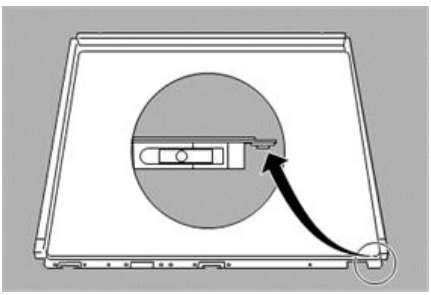


3. Turn the cassette around, so that the black tube side faces upwards.
4. Fix the shutter with both thumbs and let the image plate slide out carefully onto the table.



5. Put the image plate onto the black tube side of the empty cassette, as shown in the figure below.

   By putting the plate on the cassette so that the hooks are hanging over the border of the cassette, a bending of the image plate is avoided.

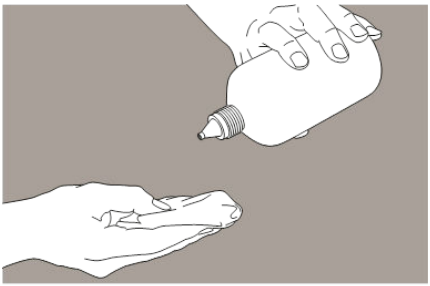


6. For CR MD4.xR and CR HD5.x, only use AGFA CR Phosphor Plate Cleaner and a soft lint-free cellulose cloth or Polynit wipes to clean the plate.

   For CR MM3.xR and CR HM5.x, only use AGFA CR Phosphor Plate Cleaner and Polynit wipes to clean the plate.

WARNING:
The use of Agfa CR Phosphor Plate Cleaner and Polynit wipes for CR MM3.xR is restricted to image plates that have a batch number starting with the letter “C” or higher. For CR MM3.xR image plates with a batch code starting with the letter “B”, use only the dedicated mammography PROSAT wipers purchased from Agfa or an Agfa certified dealer to clean the plate.

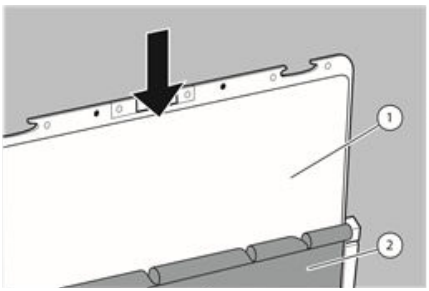
Note: In a mixed environment with old and new CR MM3.xR plates it is recommended to use only PROSAT wipers purchased from Agfa or an Agfa certified dealer to clean the plates.



WARNING:
If CR Phosphor Plate Cleaner is used, do not pour it directly onto the image plate.

7. Wait approximately 10 minutes until the surface is dry before putting the plate back in the cassette.
8. Put the image plate back into the cassette.

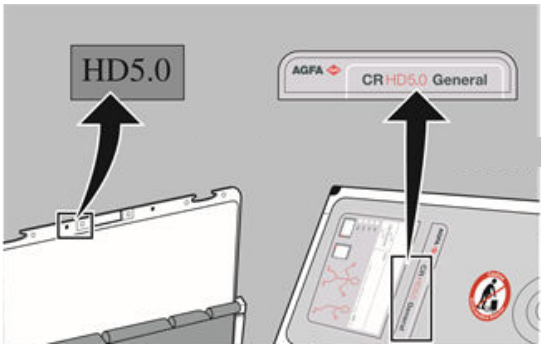
   Verify that the white phosphor side is oriented to the black tube side of the cassette and that the shutter does not scratch over the image plate.



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

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

Note: Make certain you put the correct image plate into the correct cassette. The label on the image plate must correspond to the label on the cassette.



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

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

10. Remove the key.

Note: After cleaning it is necessary to erase the detector before use.

Cleaning the Cassettes of the CR Detectors, Plates and Cassettes

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 cassette, with a lint-free cloth dampened (not dripping) with a solution of mild soap in water. Wipe dry with a soft, lint-free cloth.

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

CAUTION:
Never pour liquids directly on the surface of the cassette, as liquids could enter and damage the cassette.

CAUTION:
Be sure that all surfaces are thoroughly dry before returning the cassettes to use.

CAUTION:
Never use alcohol based cleaners or disinfectants (ethanol, isopropanol; n-propanol,…) as these chemicals will cause damage to the cassette and the digitizer.

CAUTION:
Do not use AGFA CR Phosphor Plate Cleaner, PROSAT wipes, AGFA CURIX screen cleaner or any other screen cleaners or alcohol containing liquid on the cassette surface, as this can cause damage to the cassette.

Note: If a cassette may get into contact with blood or other body fluids, protect the cassette with a clean protective bag.

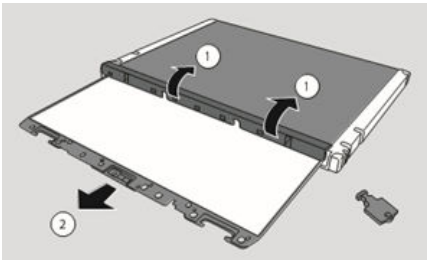
Cleaning the Interior of the Mammo Cassette

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

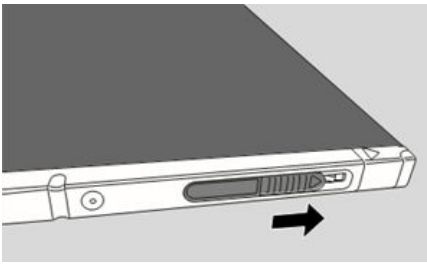
1. Unlock the shutter of the cassette with the dedicated key and open the shutter.

2. Remove the key from the cassette.

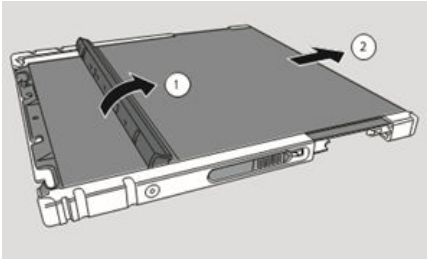
3. Turn the cassette around, so that the black tube side faces upwards.
4. Fix the shutter with both thumbs and let the image plate slide out carefully onto the table. Make sure that the surface of the plate is not scratched.



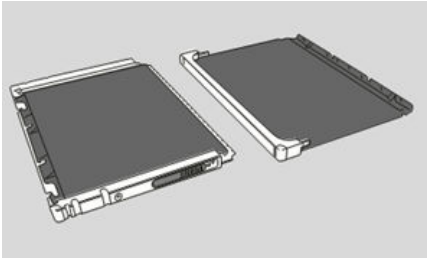
5. Open the locks on the right and left side of the cassette.



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

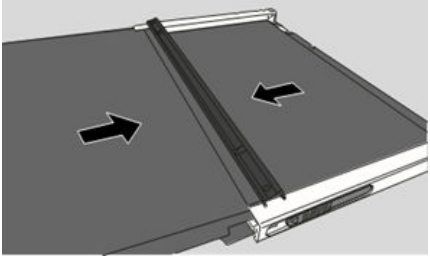


7. Clean the separate parts in the following way:



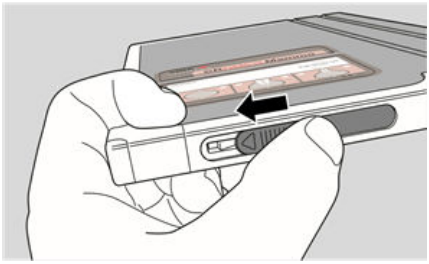
Tap each part with the fleece facing down a few times on a table with minimal force to beat out loose particles.

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

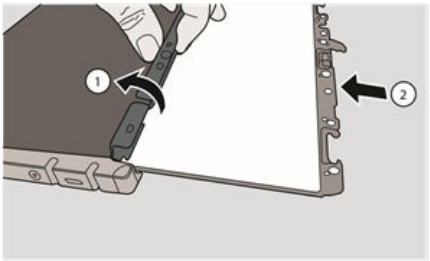


9. Slide the top part and the tube side part together.
10. Close the locks on the right and left side of the cassette.

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

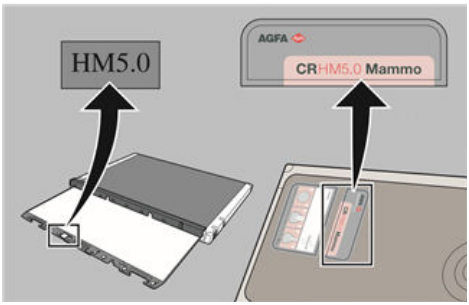


11. Put the image plate back into the cassette.



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

Note: Make certain you put the correct image plate into the correct cassette. The label on the image plate must correspond to the label on the cassette.



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

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

13. Remove the key.

Disinfecting the Cassettes

To disinfect the 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.

Technical Specifications

The table below lists the technical specifications of the CR detectors, plates and cassettes

Table 7: Specifications CR Detectors, Plates and Cassettes

	CR HD5.x General detector	**CR HD5.x AEC detector**	**CR HD5.x FLFS detector**
Available sizes (in cm)	35x43 24x30 18x24 15x30 *Note: Size 35x43 is available as HR [1] and SR [2]*	35x43 24x30 18x24 *Note: Size 35x43 is available as HR [1]*	35x43
Weight: cassette + image plate	35x43 cm: approximately 1900 g		
Cassette material Body:	ABS[3]		
Tube side:	Carbon fiber		
Corners:	Estane		
Shutter:	PP[4]		
Inner lining:	Fleece		
Backscatter protection:	150 μ lead	-	150 μ lead
Image plate material	CsBr:Eu		
Compatible AGFA digitizer	DX-S DX-G DX-M		
Gain calibration	-		

Table 8: Specifications CR Detectors, Plates and Cassettes

	CR MD4.xR General plate and cassette	CR MD4.xR FLFS cassette	CR HM5.x Mammo detector	CR MM3.xR Mammo Cassette and Plate
Available sizes (in cm)	35x43 35x35 24x30 18x24 15x30 *Note: Size* *35x43 and 35x35 are available as HR [1] and SR [2]*	35x43	18x24 24x30	18x24 24x30
Weight: cassette + image plate	35x43 cm: approximately 1900 g		18x24 cm: 580 g	18x24 cm: 540 g
Cassette material Body:	ABS		ABS	
Tube side:	ABS		ABS	
Corners:	Estane		Estane	
Shutter:	PP		PP	
Inner lining:	Fleece		Fleece	
Backscatter protection:	150 μ lead		-	
Image plate material	BaSrFBrl:Eu		CSBr:Eu	BaSrFBrI:Eu
Compatible AGFA digitizer	DX-G DX-M		DX-M	
Gain calibration	-		Can be required	

Scanned area and pixel matrix	Refer to the digitizer specifications
Environmental storage and transport conditions	Allowed temperature and humidity levels in packed condition:

	• Temperature: allowed -25 to +55 °C (-13°F to 113°F). • Relative humidity: allowed 10-80 %.
Environmental operation conditions	Refer to *'Operation Conditions'* on page *48*.
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.
Identification	Memory chip (RF-tag) embedded in the image plate
Compliance to ISO 40902001	Outer cassette dimensions are compliant with ISO 4090 - 2001

HR[1] High Resolution

SR[2] Standard Resolution

ABS[3] Acrylonitryl Butadiene Styrene

PP[4] Polypropylene