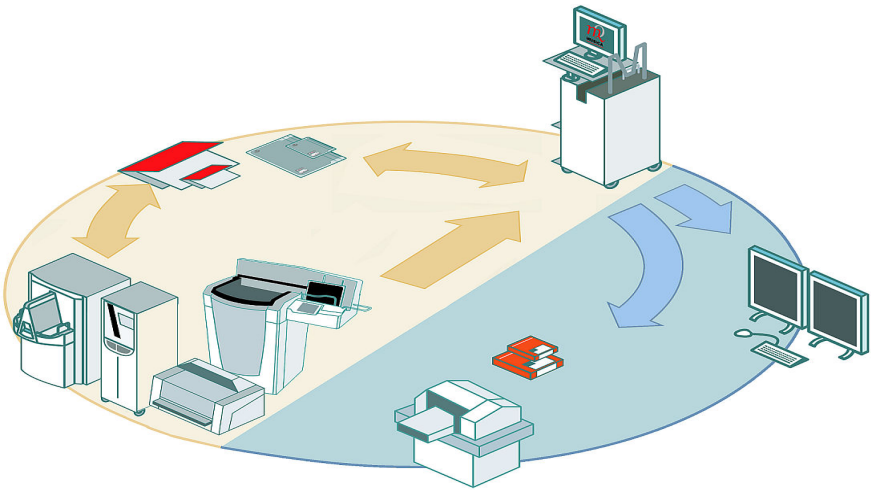
CR Mammography

User Manual



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Contents

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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 User manual describes the features of the CR Mammography System. It explains how the different products of the CR Mammography System work together. The manual covers the following Mammography Systems:

- Mammography Systems based on CR 35-X/CR 85-X Digitizers.
- Mammography Systems based on CR 25.0/CR 75.0 Digitizers.
- Mammography Systems based on the DX-M Digitizer.
- Mammography Systems based on CR 30-Xm Digitizer.

Warnings, Cautions, Instructions and Notes

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

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

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

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

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

Disclaimer

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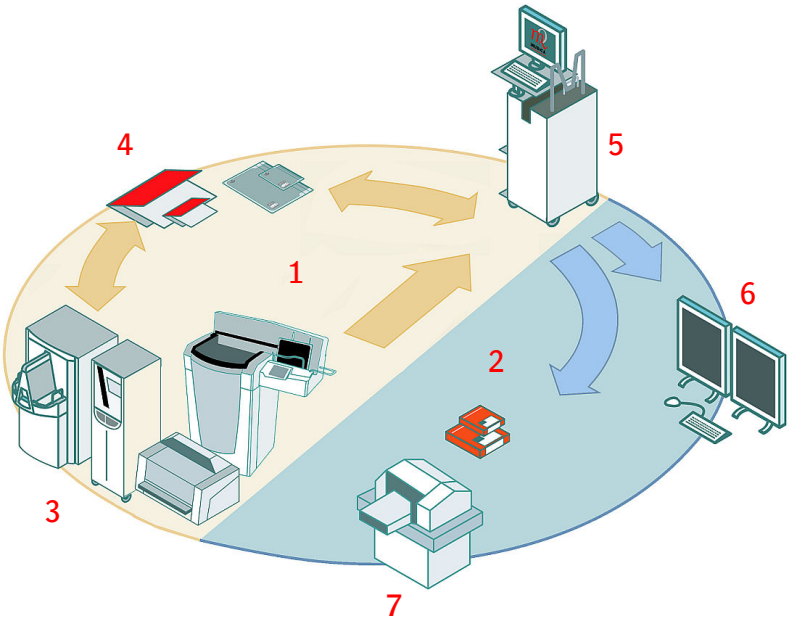
Introduction to the CR Mammography System

Topics:

Configuration

The Agfa CR Mammography System consists of a digitizer, detectors, plates and cassettes and a CR workstation. It supports hardcopy devices and softcopy reading stations as optional components:



1. System components
2. Optional components
3. CR Digitizer
4. CR Mammography Detectors, Plates and Cassettes
5. CR Workstation
6. Diagnostic Workstation
7. Mammography Printer and Film

Figure 1: CR Mammography System Configuration.

The CR Mammography System supports different configurations specified in the columns of the following table:

CR Digitizer				
multi-plate	CR 85-X™	CR 75.0™	DX-M™	
single plate	CR 35-X™	CR 25.0™		CR 30-Xm™
CR Mammography Detectors, Plates and Cassettes				

available formats are 18x24cm and 24x30cm	CR MM3.0		CR MM3.0R	CR MM3.0T
		CR MM2.0	CR HM5.0	
CR Workstation				
	NX for Mammography™			

The CR MM2.0 Mammo plates and cassettes, CR MM3.0 Mammo plate and cassette, CR MM3.xR Mammo plate and cassette and CR HM5.x Mammo detector are generically referred to as 'plates and cassettes'.

Combination restrictions:

Digitizer support for detectors, plates and cassettes:

- CR 25.0 and CR 75.0 support both CR MM2.0 Mammo Plates and Cassettes and CR MM3.0 Mammo Plates and Cassettes.
- CR 35-X and CR 85-X supports CR MM3.0 Mammo Plates and Cassettes only.
- CR 30-Xm supports CR MM3.0T Plates and Cassettes only.
- DX-M supports CR HM5.0 or CR MM3.0R Plates and Cassettes.
- Mixed use of different mammo cassettes and plates is not allowed. In particular the mixed use of CR MM3.0R and CR HM5.0 on DX-M is not allowed.

Intended Use

Intended use for Mammography Systems based on CR 35-X/ CR 85-X; DX-M and CR 30-Xm Digitizers

- The CR Mammography System can be used for diagnostic mammography.
- The CR Mammography System can be used for screening mammography, in compliance to local regulations.

Intended use for Mammography Systems based on CR 25.0/ CR 75.0 Digitizers

- The CR Mammography System can be used for diagnostic mammography.
- The CR Mammography System is not intended for screening mammography.

Diagnostic mammography

Diagnostic mammography is a radiographic examination. It is performed to provide additional information about patients who have signs and/or symptoms of breast disease or radiographic findings of concern. It can also be performed in situations where direct supervision of the imaging is required by the interpreting physician.

A diagnostic mammogram is performed under the direct supervision of a qualified physician in mammography and may include mediolateral oblique (MLO), craniocaudal (CC) and/or additional views.

Note: Direct supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure.

Screening mammography

Screening mammography is a radiological examination to detect unsuspected breast cancer in asymptomatic women. This examination may be performed without a physician in attendance.

System Documentation

The user documentation consists of a set of manuals providing an overview of the complete CR Mammography System and manuals for the components of the system.

The following table lists the user documentation that contains the instructions required for safe and effective operation of the CR Mammography System.

CR Mammography System	
CR Mammography System User Documentation CD.	• CR Mammography System User Manual (this document). • Agfa Healthcare System Safety User Manual (3100).
CR Digitizer	
CR 35-X and CR 85-X User Documentation CD.	• CR 35-X User Manual (4454). • CR 85-X User Manual (4450).
CR 25.0 and CR 75.0 User Documentation CD.	• CR 25.0 User Manual (2312). • CR 75.0 User Manual (2242).
CR 30-X / CR 30-Xm User Manual (2386).	
DX-G / DX-M User Manual (2321).	
CR Mammography Plates and Cassettes	
CR Plates and Cassettes User Documentation CD.	CR Plates and Cassettes Instruction Manual (2199).
CR 30-X / CR 30-Xm Plates and Cassettes User Manual (2387)	
AGFA CR Detectors, Plates and Cassettes (CR HD5.x, CR MD4.xR, CR HM5.x, CR MM3.xR) User Manual (2322).	
CR Workstation	
NX User Documentation CD.	NX User Manual (4420).
NX Online Help.	

Training

Agfa provides training and support for installation, calibration and use of the CR Mammography System and components.

The Agfa training does not cover the interpretation of the diagnostic images.

At the outcome of the training, a Customer Acceptance Document will be endorsed accordingly.

A learning curve is needed to allow the Radiologist to get entirely familiar with the CR Mammography digital images, which have a different 'look and feel' or image rendering in comparison to conventional film/screen.

It is the responsibility of the Radiologist to determine the conditions needed to fulfill the learning curve process and to implement them.

Compliance

Agfa has performed a clinical study for diagnostic mammography.

Regulatory requirements for digital mammography are still changing in many countries; therefore, Agfa cannot guarantee that the use of the CR Mammography System will be in compliance with evolving requirements.

The CR Mammography System is marked with the CE-label:

Note:

Manufacturer Declaration for the System and Declaration of Conformity for the different components are available.

The CE-label is conform the Medical Device Directive (MDD) 93/42/EEC for a class IIa system.

European Notified Body approval is obtained.

Connectivity

Refer to the CR Workstation User Documentation for information on connectivity aspects of RIS/PACS systems and mammography modalities. References to these documents can be found under *'System Documentation'*. For further information also refer to the respective documentation.

Related Links

System Documentation on page 12

Installation

The System components and the modality AEC (Automatic Exposure Control) have to be configured before mammography examinations will be performed.

Topics:

Installation of the CR Mammography System

The Agfa mammography application specialist configures all components of the CR Mammography System.

Following remarks/instructions should be taken into account when installing the CR Mammography System:

Caution**:** When deviating from the recommended settings, Agfa cannot guarantee optimal performance of the system.

Topics:

CR Digitizer

After proper installation of the CR Mammography System, the mammography scan mode on the Digitizer is activated automatically when a CR Mammo image Cassette, correctly initialized and identified, is introduced into the Digitizer.

CR Workstation

The CR Mammography Workstation software needs to be configured to ensure that the mandatory:

- Scanning parameters will be provided for the Digitizer.
- Dedicated MUSICA™ processing for mammography will be applied.
- The system allows adjustment to visualization preferences of local departments.
- Valid examination tree with dedicated image processing settings is used.

*Note***:** It is important that the correct exam is selected to allow application of the appropriate image processing.

The CR Workstation provides the possibility to achieve a consistent grayscale perception of the images, as described in the DICOM standards (known as Pvalues).

The configuration will also take care that images are displayed in the proper orientation and mammography specific hardcopy film layouts are used.

Print Layouts

For NX CR Workstation standard layouts are used.

These layouts optimize the hanging order of the films of the left and right breast on the light box, by minimizing the borders at the thorax side of both images.

Warning: For Diagnostic mammography use, true size printing is essential. In this case, use only the proper dedicated mammography printer layouts. If you use other printer layouts, diagnostic information can be lost.

CR Mammography Printer

Hardcopies with a maximum optical density of at least 3.6 are recommended to display the image details properly.

Diagnostic Workstation

The softcopy reading station shall be installed and configured in presence of the CR Mammography specialist. In case of deviation from these recommended settings, Agfa does not guarantee optimal performance of the system.

Softcopy reading stations of diagnostic quality require a dual head five mega-pixel mammo display system.

Calibration of the X-Ray Modality

AEC of the X-ray modality must be calibrated for the appropriate Mammo Cassette and Plate (MM2.0/MM3.0/MM3.0R/MM3.0T) or CR HM5.0 by the X-ray modality field engineer to ensure the correct diagnostic image quality.

The CR Mammography specialist will assist in or verify this process. To reach the optimal image quality the AEC must be in conformance with the following exposure settings:

Table 1: Recommended kV-Ranges

PMMA thickness (cm)	Equivalent breast thickness (cm)	Spectrum			
		Mo-Mo	Mo-Rh	Rh-Rh	W-Rh
20	21	24-27 kV			
30	32	25-28 kV			
40	45	26-29 kV	26-29 kV	26-29 kV	28-30 kV
45	53	26-30 kV	26-30 kV	26-30 kV	28-30 kV
50	60	26-30 kV	26-30 kV	26-30 kV	28-32 kV
60	75	27-32 kV	27-32 kV	27-32 kV	32-34 kV
70	90	28-32 kV	28-34 kV	28-34 kV	34-35 kV

Table 2: Target AGD Values as recommended by Agfa

PMMA thickness (cm)	Equivalent breast thickness (cm)	Target AGD for CR35-X/ CR85-X/ CR30-Xm/ DX-M with MM3.0R	Target AGD for DX-M with HM5.0 Standard	Target AGD for DX-M with HM5.0 Dose Optimized	Target AGD for DX-M with HM5.0 Image Quality Optimized
20	21	0.85	0.7	0.6	0.85
30	32	1.3	1.1	0.9	1.3
40	45	1.7	1.45	1.2	1.7
45	53	2.2	1.9	1.6	2.2
50	60	2.6	2.2	1.8	2.6

PMMA thickness (cm)	Equivalent breast thickness (cm)	Target AGD for CR35-X/ CR85-X/ CR30-Xm/ DX-M with MM3.0R	Target AGD for DX-M with HM5.0 Standard	Target AGD for DX-M with HM5.0 Dose Optimized	Target AGD for DX-M with HM5.0 Image Quality Optimized
60	75	3.9	3.3	2.7	3.9
70	90	5.5	4.7	4.5	5.5

These settings are based on the recommendations of the EUREF guidelines for digital mammography.

Alternatively, a PVI log-based dose setting or a less restrained EUREF dose setting is possible with the DX-M and CR 30-Xm system. With these settings the system is operated within a wider range of dose and hence image quality, still providing sufficient image quality and acceptable dose or close-to-EUREF adjustment respectively.

Note: Dose and image quality variation with the PVI log setting are not necessarily compliant with EUREF or similar guidelines.

The use of W/Rh is restricted to cases in which low dose is applied (Target AGD for DX-M with HM5.0 Dose Optimized). For a thickness less than 3 cm, W/Rh is not recommended as this exposure technique might lead to inadequate results. In order to avoid long exposure times, the use of considerably higher kV is necessary (28 kV or more for medium thickness, 32 kV or more for 6 cm, 34 kV or more for a thickness more than 6 cm). W/Rh is not recommended for magnification exposures.

Caution: When switching to a different type of plates and cassettes, the AEC has to be recalibrated.

For Mammography Systems based on CR MM2.0 (CR 25.0/CR 75.0 Digitizers)

Caution: We strongly recommend to use the same settings as for the CR35-X/CR 85-X digitizers, simply because they optimize the overall system performance.

For Mammography Systems based on CR MM3.0 (CR 35-X/CR 85-X Digitizers); CR MM3.0R (DX-M Digitizer) and CR MM3.0T (CR 30-Xm Digitizer)

Caution**:** These above mentioned alignments are mandatory because they were used for validation of the powder-based CR Mammography Systems. In addition the EUREF based alignments are in-line with the EUREF recommendations for digital mammography.

For Mammography Systems based on CR HM5.0 (DX-M Digitizers)

Caution**:** For the EUREF based alignment, higher doses up to the maximum AGD for DX-M may be used (target AGD for DX-M with HM5.0 Image Quality Optimized) if a further improvement of the image quality is desired.

Caution**:** If the CR HM5.0 is used besides the CR MM3.0R (or CR MM2.0 and MM3.0) on the same modality, two separate AEC channels of the X-ray device must be used and adjusted.

Caution**:** When using the CR HM5.0 instead of the CR MM3.0R (and vice versa) on one X-ray device channel, a new AEC calibration must be performed.

X-Ray Modality Operating Guidelines

Agfa advises to use X-ray modalities with AEC functionalities. The full automatic mode of the X-ray modality, aligned for CR Mammography, shall be used.

Caution**:** Do not use the film density adjustment of the X-ray modality.

In case semi-automatic or manual mode is needed for special examinations, the exposure kVp, filter and target combinations in relation to the type and compressed thickness of the breast have to be applied.

*Note***:** For needle biopsy specimen, Agfa recommends the lowest available kV setting (typical 22kV) and 15mAs.

Viewing conditions for hardcopy

Diagnostic quality of the system is validated and guaranteed under the clinical viewing conditions specified. This viewing condition is written in the text area on the hardcopy film:

- Luminance of the viewing box without film, in candela/m2.
- Luminance contribution due to ambient illuminance reflecting of the printout, in candela/m2.

Warning: Good viewing conditions are essential for the correct interpretation of the diagnostic mammography images.

Caution:

Viewing conditions must be conform to mammography diagnostic standards:

- A viewbox with a luminance of at least 3000 candela/m2.
- No light source directed to the viewbox.
- Ambient lighting must be less than 50 lux (lumen/m2).
- Glare must be minimized. Therefore masking of the viewbox (by shutters) up to the exposed area of the film is required.

Caution: The viewing conditions must remain stable at all times. Therefore it is recommended to perform a regular check of all viewing conditions.

Viewing conditions for softcopy

The suggested settings for softcopy viewing are:

- An overview of the new study, presenting a proper hanging protocol.
- If you can consult prior studies, an overview of both new and prior studies.
- A one-on-one comparison view of images (e.g. right and left CC, left CC and left MLO,...).

Other settings should be discussed by the customer with the Agfa mammography application specialist.

Warning: Good viewing conditions are essential for the correct interpretation of the diagnostic mammography images

Caution:

Viewing conditions (ambient light) should not be changed after initial monitor calibration and alignment:

- Other light sources should not be directed towards the displays of the softcopy station.
- Ambient lighting must be as low as possible.
- Glare must be minimized.

Caution: The viewing conditions must remain stable at all times. Therefore it is recommended to perform a regular check of all viewing conditions.

Options and Accessories

Accessories are documented in the User Manuals of the components of the CR Mammography System.

The Mammography Printer and the Diagnostic Workstation are optional components of the CR Mammography System.

Micro Calcification Enhancement (MCE)

Note: MCE is not licensed for sale in Canada.

MCE provides supplemental automated image processing, integrated in the NX CR workstation. For mammography images identified for an exposure type requesting Musica Micro Calcification Enhancement (MCE), an extra copy of the image is sent to a dedicated archive destination. Two instances of the image will be available on the PACS workstation: the original image and the MCE enhanced image. The reader will be able to toggle between the two instances.

Musica MCE offers a further improved image processing which can help in drawing attention to potential microcalcifications in Diagnostic and Screening Mammography images. The Musica MCE image will assist in using the original image for diagnosis.

Cleaning and Disinfection

The following maintenance recommendations must be applied for optimal performance of the cassette:

- For the CR MM2.0/CR MM3.0/CR HM5.0 Mammo plate, use Agfa CR Phosphor Plate Cleaner and Polynit wipes or a lint-free cellulose cloth to clean the plate.

Warning: The use of Agfa CR Phosphor Plate Cleaner and Polynit wipes for CR MM3.0 is restricted to image plates with batch number starting with the letter C or higher. For CR MM3.0 image plates with batch code starting with letter B or a number, use only the dedicated mammography PROSAT wipers to clean the plate.

Note: In a mixed environment with old and new CR MM3.0 plates it is recommended to use only PROSAT wipers to clean the plates.

- CR Mammo plates require frequent cleaning: at least once a week or after every 200 cycles (whatever comes first).

For the detailed cleaning procedure, refer to the CR plates and cassettes Instruction manual.

Inadequate maintenance or improper cleaning can lead to dust on the image plate or in the fleece of the cassette, which can result in image artifacts. The fleece is a protective cloth in the cassette that makes sure the image plate is not damaged when the plate is inserted or removed from the cassette.

Safety Directions

For general safety directions, refer to the Agfa HealthCare System Safety User Manual, document 3100.

For product safety directions, refer to the User Manuals listed in *'System Documentation'*.

Warning: If Micro Calcification Enhancement (MCE) is applied, two instances of the image are available on the PACS workstation: the original image and the MCE enhanced image. Final diagnosis must be performed on the original image.

Warning: MCE can enhance the noise of underexposed images.

There are some good working practices that should be applied when operating the CR Mammography System:

Caution: If the cassette is dropped before the exposure, open the cassette and close it again to make sure for correct alignment to the thorax side before the new exposure. For more information, refer to the CR Plates and Cassettes User Manual (only applicable for CR MM2.0 and CR MM3.0 cassettes and plates).

Caution: When using annotation boxes, be aware that the diagnostic information can be possibly overlaid.

Caution: Lead markers for laterality (left or right) indication shall be used. Lead markers should be arranged towards the corners opposite of the chest wall and outside of the breast area.

Caution: It is important that the same image plate is always used with the same cassette.

Related Links

System Documentation on page 12

Getting started

Topics:

Basic workflow

The following procedure describes the workflow that will be followed when using the CR Mammography System.

1. At the Mammography modality:

   Expose the cassette at the X-ray modality. The operator is responsible for manual labelling of the cassettes.
2. At the CR workstation:
   a) Enter patient demographics manually or import this data from a database (HIS/RIS) via DICOM protocol.
   b) Identify the cassette with the mammography examination data and patient demographic data. In case of CR 30-Xm, identification is always done after exposure via the Direct ID functionality. All other digitizers support identification via ID Tablet; steps 1 and 2 can be swapped there.

Note: It is important that the correct exam is selected to allow application of the appropriate image processing.

3. At the CR digitizer:

   The digitizer converts the image on the exposed cassette to a digital image, stores it as a file (or data set) and transfers it to the CR workstation via the network.
4. The file is transferred to the workstation via the network.
5. At the CR workstation:

   Automatic image processing is applied.
6. Transmission of the modified image, from the CR workstation:

   - To the hardcopy printer.
   - To the softcopy reading station.
7. The printer produces the hardcopy.

   The softcopy station displays the softcopy. To improve the workflow, it is advisory to use an extension keypad (optional), configured for CR Mammography use only.

Note: When using connectivity to the X-ray modality to retrieve the exposure data, each cassette must be identified before the next exposure is taken. Otherwise the exposure data can be lost or linked to the wrong image.

Micro Calcification Enhancement (MCE) and softcopy reading stations

On the CR workstation, two archive destinations can be configured:

- a destination intended for softcopy reading and archiving, receiving two instances of the image. Both are available on the PACS workstation: the original image and the MCE enhanced image. The MCE image is distinguished from the original image by an “MCE”-marker in the image and a note in the image comments.
- a destination intended for a second reader, receiving only the original image.

Micro Calcification Enhancement (MCE) and exporting images to CD or DVD

MCE enhanced images cannot be exported to CD or DVD.

Limitations

Limitations for image appearance

- Absolute measurements are not supported (even on true size prints). There is a deviation caused by the X-ray projection. This phenomenon is identical to conventional film/screen situations. This is also the case on the softcopy reading station.
- Under typical mammo exposures digitized with CR 25.0, CR 75.0, CR 35-X or CR 85-X (not applicable for CR 30-Xm or DX-M), the image shows a grey line along the image edge only. This is due to the edge protection of the image plate. However, there is no impact on the diagnostic output.
- To make sure that no diagnostic data is lost, the digitizer scans over the edge of the image plate. This may cause a black or white border at the thorax side in exceptional cases, for example with large implants. However, there is no impact on the diagnostic output.

Limitations for CR MM2.0 and CR MM3.0 Mammo cassettes

- The suction cup in the older generation cassette can leave a round shaped artefact that can be interfering with the diagnostic area. This artefact is typically positioned at the upper part of the image and close to the chest wall. However, there is no impact on the diagnostic output.
- It has been reported that in exceptional cases the automatic window/level processing fails. This results in completely black or white images. Adjusting the window/level manually will solve this problem. There is no need for retaking the images.

Limitations on workstation features

- Please note that because of the high resolution image size, some interactive functions may take longer.
- Importing/Exporting or sending General Radiography images to a dedicated mammography CR workstation is not supported.
- The CR display is not intended or suited for performing mammography diagnosis; only for verification of mammography positioning.
- Following functions are disabled in the mammography application: automatic image collimation, automatic image division detection, the interactive image post-processing function (MUSICA button); except for window/level processing, changing the study type related processing. Background darkening is disabled for the mammo specialty exams.
- The LgM value or EI (Exposure Index) (this is the exposure consistency indicator, used for General Radiography applications) is not relevant for mammography images. This should not cause a problem for mammography: the dose is controlled by the AEC.
- The automatic alignment of the chest wall will not be guaranteed if you drag an image manually onto a layout on the NX CR workstation. This can be corrected by clicking the true size button or manually roaming the image.

- Micro Calcification Enhancement (MCE) is only supported on systems based on CR 35-X/CR 85-X/DX-M/CR 30-Xm digitizers.
- Micro Calcification Enhancement (MCE) is not supported on speciality examinations (e.g. magnification-spot, biopsy, stereotaxy).

Technical data

The digitizers scan standard general radiology images as well as high resolution mammography images. The CR Mammo plate is scanned under special conditions:

- 50μm pixel size for high resolution scanning,
- asymmetric scanning towards the thorax side.

For more information, contact your sales representative.