

MAMMOMAT Inspiration

Tomosynthesis Option

SIEMENS

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The CE marking applies only to medical devices which have been put on the market according to the above mentioned EC Directive.

Unauthorized changes to this product invalidate this declaration.

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Tomosynthesis

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Tomosynthesis

System overview



Please be aware that this Operator Manual Tomosynthesis is just one option.

Only the complete manual is valid:

- *Operator Manual - MAMMOMAT Inspiration system*
- *Quality control manual*
- *syngo Operator Manual - syngo VE33A*
- *Tomosynthesis Option*

Indication for Use

The MAMMOMAT Inspiration with Tomosynthesis Option is indicated for acquisition of 2D as well as 3D digital mammography images to be used in screening and diagnosis of breast cancer.

Each screening examination must consist of CC and MLO views in:

- 2D image set or
- 2D and 3D image set.

Note: The screening examination may consist of 2D FFDM images set with or without the 3D image set.

Caution: Federal law restricts this device to sale or on order of a physician.

System description

MAMMOMAT Inspiration and MAMMOMAT Inspiration PRIME Edition are supporting the Tomosynthesis Option. All described features of this user manual are available on both versions.

With tomosynthesis, three-dimensional information can be obtained by taking exposures from different angles. This significantly reduces the tissue overlap problem which limits diagnosis in conventional mammography. Tomosynthesis is displayed and controlled at the workstation.

In tomosynthesis, the X-ray tube rotates in a defined angular range. During the acquisition, several X-rays are taken from different directions. Each of these single exposures is taken with a very low dose. Due to the different acquisition directions, the set of 2-dimensional X-ray images contains the 3D information of the object, allowing the volume of the breast to be reconstructed by appropriate software algorithms and visualized in the form of slice images.

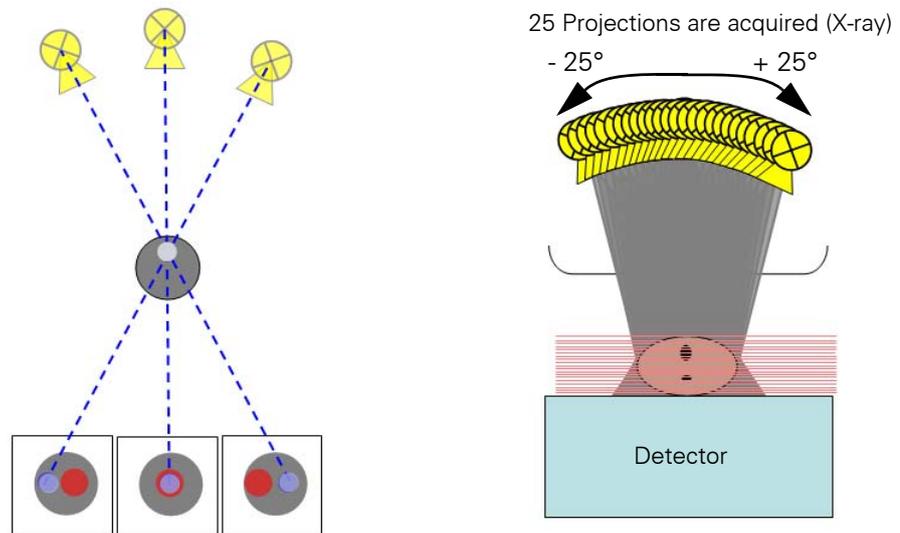
During tomosynthesis acquisition, the swivel arm of the MAMMOMAT Inspiration covers an angular range from $+25^\circ$ to -25° while 25 views are acquired.

Inform the patient in detail about the examination procedure, in particular about the time required and the automatic movement of the swivel arm.



- (1) Face shield
- (2) Compression plate

Acquisition area

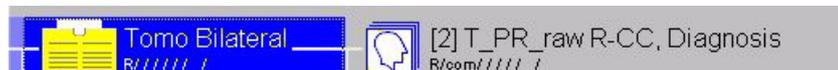


Tomo scan

Generated data set of a definite view, consisting of raw projections and/or processed projections and/or the slices or combinations of these.

Raw projections

Single image taken during the tomo scan. 25 projections are acquired during the sweep of 50°, every other degree one projection. The projections are saved as DICOM MG objects.



Processed projections

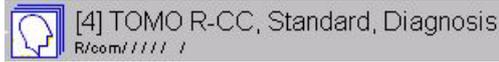
Projections acquired during a tomo acquisition, processed with OpView 2D image processing for better visualization. These images are saved as DICOM MG for presentation.

When using **2D+Tomo-Scan** the first image of the stored projections series is the 2D image.



First view First exposure during tomo scan which the swivel arm is at an angle of 0°. When using **2D+Tomo-Scan** the first image is the 2D image.

Slices Stack of images parallel to the detector surface reconstructed from projections with the purpose of display at the workstation monitor.



Bounding box Region of interest, describing the area that will be reconstructed. Using the handles you can adjust the bounding box to the breast tissue area to be reconstructed for slices.

Reconstruction The calculation of the stack of slices (3D volume) from the projections using a reconstruction algorithm.

Reprocessing Processing of the projections and 2D image with new parameter set (OpView).

Automatic movement of the swivel arm

25 views are acquired in an angular range from -25° to $+25^\circ$. The exposure release button on the control box or on the foot or hand switch must be pressed and held during all exposures.



- The swivel arm is in the 0° position.
The first view is acquired for automatic exposure control.
- Swivel arm moves to -25° , second exposure is taken.
- The swivel arm covers the entire angular range from -25° to $+25^\circ$ while an exposure is taken at every 2° .
- Swivel arm returns to the start position.



- Letting go of the exposure release button.



- The first view is displayed.
- The slices are automatically reconstructed and then displayed.
- The projections are processed and displayed.



Inform the patient in detail about the examination procedure, in particular about the time required and the automatic movement of the swivel arm.

Compression plate

The following compression plates can be used for a tomo examination:



(1) Compression plate 26 cm x 35 cm for tomo examination



(2) Compression plate 24 cm x 30 cm Low for tomo examination

The plastic paddles can be removed, see register: *System overview, page 12.*

Tomo face shield

A special face shield must be used during tomo examinations:



(1) Face shield



Warning

The patient's head can enter the beam path.

Unnecessary radiation exposure!

- ◆ Make sure that the special face shield is always used during a tomo examination if there is a risk that the patient's head can enter the beam path.

System setting

Before beginning with the tomo examination, the appropriate compression plate and the tomo face shield must be attached to the MAMMOMAT.

Performing detector calibration

Type of calibration

Your MAMMOMAT Inspiration offers a large number of different types of examinations. To ensure the optimal detector settings for each type in all cases, the following different types of calibrations are performed:

Type of calibration	Special features
CONTACT	none
MAGNIFICATION	without magnification table
TOMOSYNTHESIS	none

If the difference between the detector temperature and the calibration temperature reaches 7°C or more, allow the MAMMOMAT Inspiration to warm up for at least 30 minutes in order to ensure optimal results in the image quality test.

Calibration intervals

As a rule, the detector should be calibrated every 3 months.

The calibration should also be performed if the room temperature deviates by more than 7 °C from the temperature at the last calibration.



*Calibration is performed without a compression plate.
It is recommend that the tomosynthesis calibration be performed after contact calibration.*

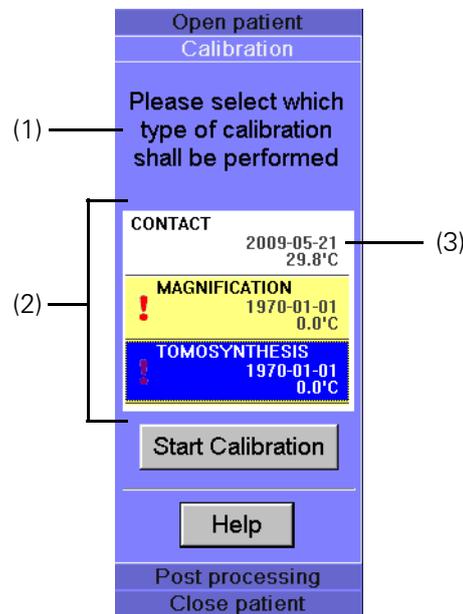
Preparing the swivel arm

Before you begin calibration, you have to set the swivel arm up for the calibration.

- ◆ Install the 40 mm Plexiglass plate on the swivel arm so that the entire image area is covered.
- ◆ Move the swivel arm to the 0° position.
- ◆ Remove the compression plate.

Starting the calibration

- ◆ Select **Patient > Detector Calibration** from the main menu of the **Examination** task card.
 - *Calibration* is automatically registered.
 - The **Calibration** subtask card is displayed.



- (1) Next required step
- (2) Area for selecting the type of calibration
- (3) Date of the last calibration for the respective type of calibration (if a "!" appears, the calibration is overdue)



- ◆ Click the **TOMOSYNTHESIS** type of calibration.



When the calibration subtask is selected, the exposure parameters are automatically correctly set and displayed in the generator control field for each anode/filter combination.

→ see register: *Examination*, section *Generator control field*



*Please note that for the **TOMOSYNTHESIS** calibration type, the calibration can only be repeated five times. After that the system has to be restarted.*

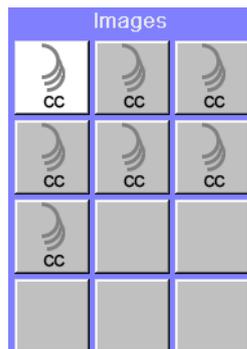
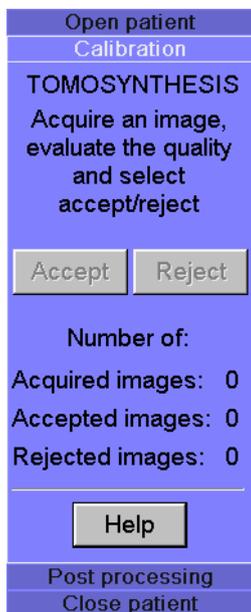


- ◆ Click **Start Calibration**.

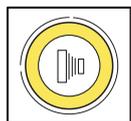
Calibration images

When calibration is started, the **Calibration** subtask card for the type of calibration selected changes. The projection view to be acquired is shown in the **Images** subtask card.

At least 7 displayed exposures must be taken.



- ◆ In the **Images** subtask card, double-click the first projection view, if it has not already been activated, to release the exposure.



- ◆ Press the exposure button on the control box until all 26 exposure pulses have been completed. The gantry will remain in 0° position.
 - Radiation is released and the first calibration image is taken.
 - After the exposure is complete, the finished image is displayed in the image area.

Accept

- ◆ Click **Accept** if the exposure is suitable for calibration.
 - Windowing may be required to check image quality.
 - The detector is re-calibrated on the basis of the calibration image.

Or

Reject

- ◆ Click **Reject** if the exposure is not suitable.
 - The calibration image is rejected and a new exposure is added.

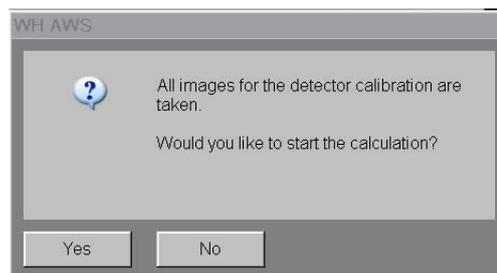
Number of:
Acquired images: 7
Accepted images: 7
Rejected images: 0

- ◆ Continue acquiring calibration images until you have produced 7 suitable exposures.
 - The number of accepted and rejected exposures is counted in the **Calibration** subtask card.

Ending detector calibration

The calibration process ends as soon as you have calibrated the detector using a sufficient number of suitable acquisitions (recommendation: at least 7 images).

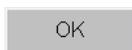
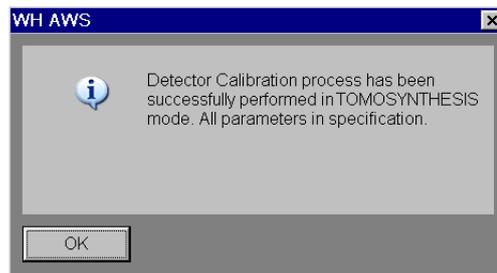
The following message window appears:



Confirm the message window by clicking **Yes** to start calibration calculation.

**Calculation
successful**

The following message window appears when the calculation is successful:

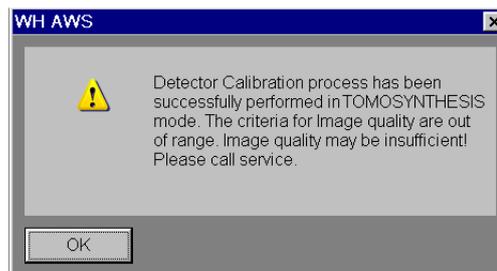


- ◆ Confirm the message window with **OK**.
 - The calibration closes automatically.
- ◆ Remove the 40 mm Plexiglass plate.

You can select and evaluate the calibration results. The results are available in the Service menu, see the *Check calibration results* section in the operator manual.

**Calculation
unsuccessful**

The following warning window appears when the calculation is unsuccessful:



This message means that several non-functioning pixels were found during the calibration. This requires a system check by a Siemens service technician. The results are available in the Service menu, see the *Check calibration results* section in the operator manual.

- ◆ Call a Siemens service technician or a technician trained by Siemens.



Until the analysis by the service technician, clinical operation may continue if:

- the daily checks run without errors
- there are no visible artifacts
- the quality authorities have no objections

Tomosynthesis

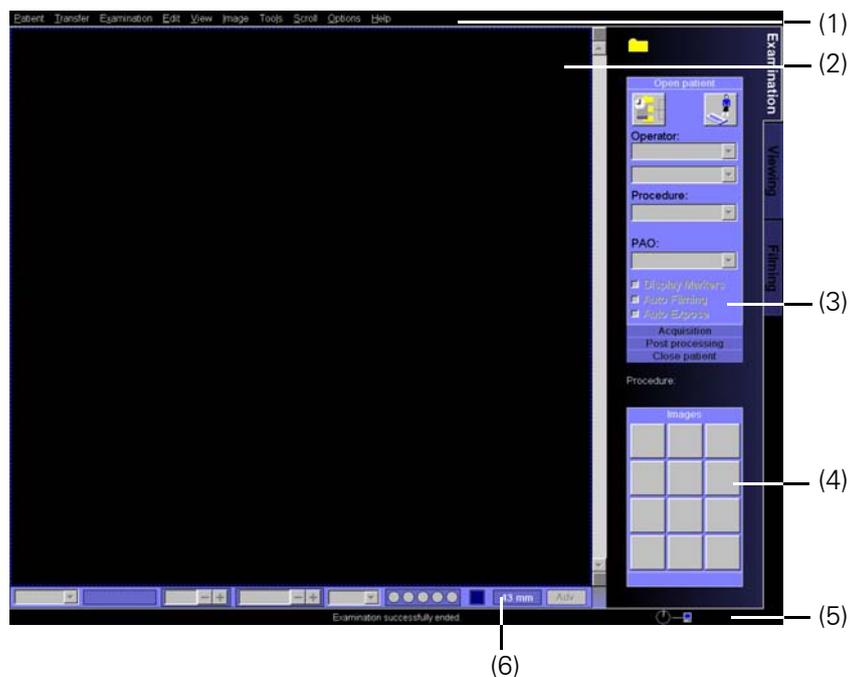
Tomosynthesis examination

This chapter describes a typical tomo examination. The examination is controlled at the workstation with preset examination parameters.

- For information about the control and display elements of the tomo examination see *Section System setting*, page 10.
- For further information on performing the examination at the workstation and changing examination settings, see the tab: *Examination task card*, page 3.

Layout of the Examination task card

The **Examination** task card is divided into different functional areas:



- (1) Menu bar
- (2) Image area
- (3) Stack of subtask cards
- (4) Control area
- (5) Status bar
- (6) Generator control field

Preparations

It is assumed that the MAMMOMAT has been correctly installed and started up.

- ◆ Prepare the MAMMOMAT for tomo mode.
- ◆ Inform the patient about the examination procedure.



*For the first examination of the day using tomosynthesis, automatic activation of the first acquisition is active (**Options > Auto Enable First PV**), after which the patient's breast can be compressed.*

If the breast is compressed first followed by activation of the first acquisition, an error message can occur. If an error message occurs, acknowledge it, wait 15 seconds, and continue the examination.

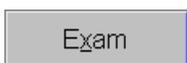
Registering the patient

At the beginning of an examination the patient must be registered:

- via the RIS/Scheduler or
- manually



- ◆ To open the Patient Registration window, click this button.
- ◆ Enter the required examination data in the **Patient Registration** window.



- ◆ Click the **Exam** button.
 - The **Examination** task card is opened.

Performing the examination settings

The settings for the tomo examination are performed in the subtask cards of the **Examination** task card.

Examination procedure



Open patient

Operator(s):

Procedure:

PAO:

- ◆ Select the required tomo procedure in the **Procedure** list.
 - The projection sequence preset for the procedure is displayed in the **PAO** list.
- ◆ If necessary, select the **Operator(s)**.
- ◆ Adjust the examination parameters, if necessary.

Examination parameters

- ◆ Click the **Acquisition** subtask card into the foreground.

Open patient
Acquisition
OP: IQ
Exp: IQ
RPG: TestRPG1
Max comp: 100 N
Left
Imp: None
IP: Unprocess
Right
Imp: None
IP: Unprocess
Tomo
Post processing
Close patient

- ◆ If an implant is present, then select the type of implant in the **Imp** list.
- ◆ Select the desired exposure technique in the **Exp** selection list.
 - If the patient has breast implants, an exposure technique with *Manual* exposure mode must be selected.
- ◆ In the **RPG** (**R**econstruction **P**arameter **G**roup) list, if necessary select a reconstruction parameter, e.g.
 - **Standard** - is used for all standard tomo examinations
 - **Calcification** - is used in cases where an additional tomo reconstruction is required with a particular focus on micro calcifications
 - **Phantom** - is used for quality control checks and/or technical measurements with phantoms only



The selectable reconstruction parameters are configured by the application specialist.



*Various OPDOSE settings for the tomo examination can be configured in the window **Configuration of the procedure** in the **OPDOSE program** tab card by local customer service.*

Positioning the patient

The tomo examination is intended for seated or standing patients.

Seated positioning

- ◆ Use a suitable fixable chair with a rigid back rest to fix the posture of the patient in relation to the swivel arm.
 - The breast should not be able to slip due to movement of the patient.



Caution

Swivel arm movements can cause parts of the body to be jammed or crushed.

Risk of injury!

- ◆ Ensure that the patient is positioned correctly.
 - ◆ Please note that the face shield also moves when the swivel arm moves.
 - ◆ The patient's head must not lean against the face shield while the swivel arm is moving.
-

Compressing the breast

All preparations for the examination must have been made before the compression.
The breast must remain compressed until all exposures have been taken.

Implants



Caution

If breast implants are not taken into consideration, this will lead to errors in treatment and incorrect settings during the examination.

Risk of injury during compression and tomo examination!

- ◆ Ask the patient about existing implants prior to the examination. Inform the patient about the risks of providing false information.
- ◆ Adjust the preparation and examination of the patient accordingly (e.g., performing compression, system parameter settings).

Performing compression

- ◆ Lower the compression plate with the control knob or foot switch and compress the breast with a force of at least 30 N to prevent the breast from moving.
- ◆ Patients with implants, or patients who recently have had breast surgery, must not be exposed to "optimized compression" OPCOMP.



Warning

Danger due to unintended decompression.

Risk of injury during decompression!

- ◆ Move the foot switches outside the reach of the patient and personnel as soon as the patient's breast is compressed.



Please note that a message box is displayed if the thickness of the compressed breast is between 80 and 100 mm:

- The image quality is limited.

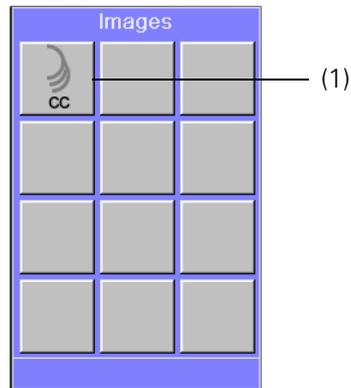
Please note that a message box is displayed if the thickness of the compressed breast is > 100 mm:

- Only slice images of up to 100 mm will be reconstructed.

- No slice images of more than 100 mm will be calculated.

Acquiring exposures

The exposure to be taken is shown in the **Images** subtask card of the **Examination** task card.

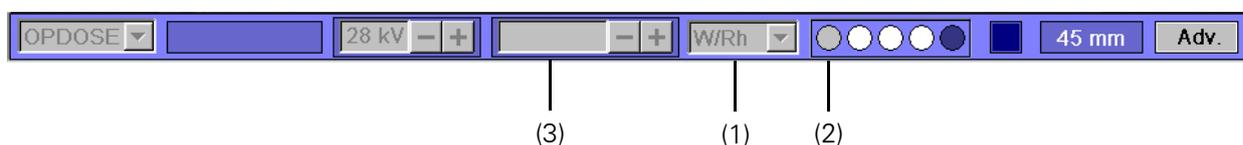
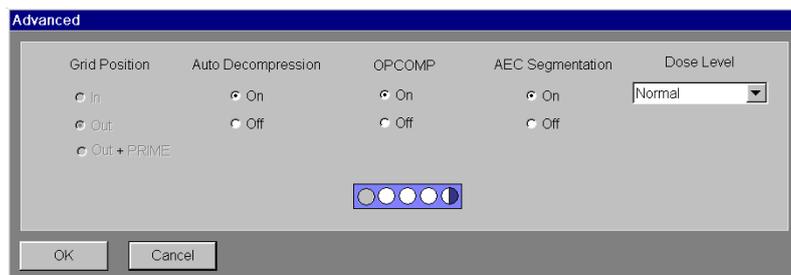


- (1) Tomo acquisition
During tomo acquisition, 25 exposures are released. The exposures are acquired successively.

Acquiring tomo images



- ◆ Double-click the button for tomo exposures.
 - The detector parameters are loaded.



The following settings for a tomo examination cannot be changed:

- (1) The anode/filter combination is always W/Rh.
- (2) The grid position is always defined to be outside the field of view.



Please note that the dose levels can be set individually for each breast thickness range.

For tomosynthesis acquisitions, please note in particular with thicker breasts that the two highest dose levels (medium high, high) have longer exposure times that can lead to blurring.



If the emergency STOP button is pressed during a tomosynthesis examination:
- the Entrance Dose will not be correctly displayed in the image.
- all other values (e.g. mAs-, kV values) will be correctly displayed in the image

- ◆ Check the exposure parameters and adapt them, if necessary.
 - Tomo images can be taken using the OPDOSE, AEC or MANUAL technique.



*The following message appears as soon as the mAs is too high or too low:
"Calculated mAs outside valid range.*

Please change to AEC mode.

*At low compression thickness < 20 mm, reduce the kV in 1 kV increments.
For larger compression thicknesses > 50 mm increase the kV in 1 kV increments."*

To switch to AEC mode, select the AEC acquisition mode on the generator control panel.

The AEC value set previously is retained and the kV can be increased in 1 kV increments.



- ◆ Press and hold the exposure button on the control box as long as the signal is audible.
 - The button will light up yellow during the exposure.
 - Radiation is released and tomo images are acquired.



Caution

Swivel arm stops during exposure.

Unnecessary radiation exposure!

- ◆ Let go of the exposure release button.
- ◆ Turn the control knob upward for manual decompression, or perform decompression using the control panel or foot pedal.

Tomosynthesis

Tomosynthesis examination

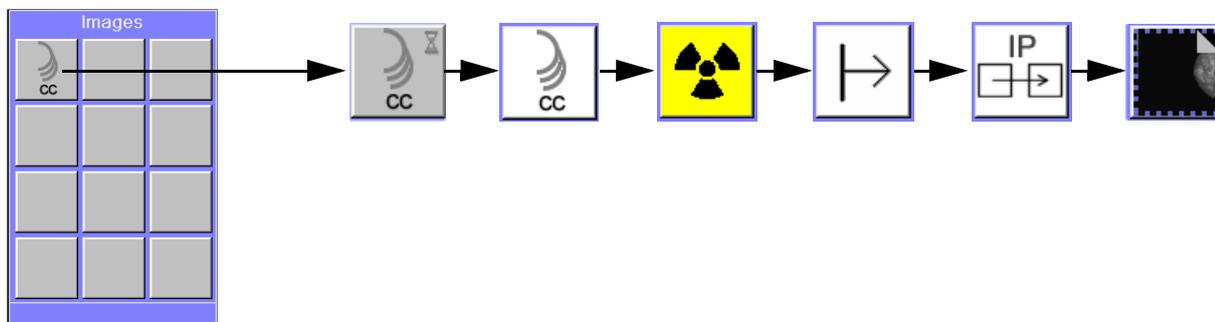
Exposure parameters for 3D implant exposures

Note that these figures are just suggested guideline values for the exposure. It may be necessary to adjust the exposures depending on the nature of the breast or implant concerned.

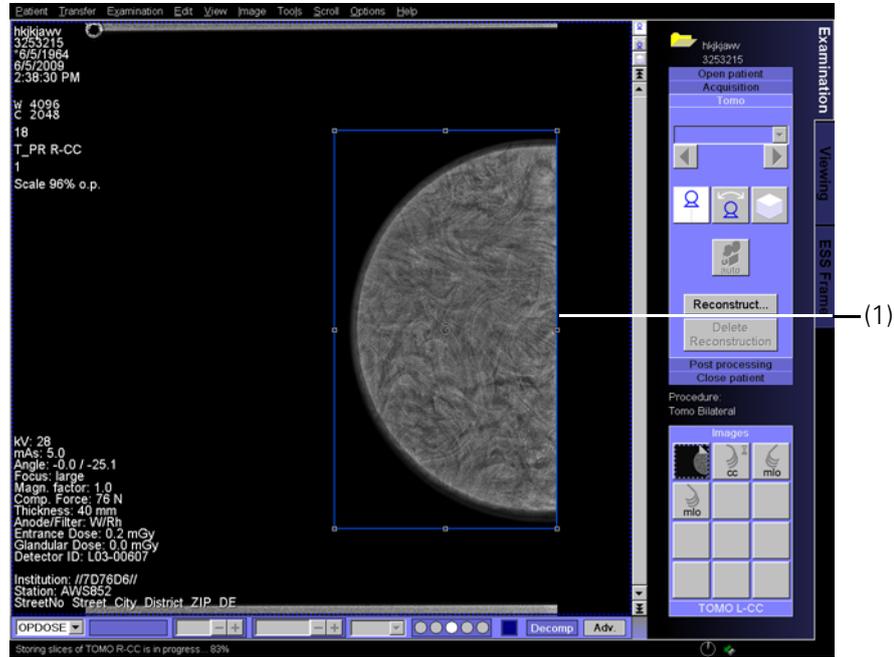
Thickness (mm)	Anode/filter combination	kV	mAs only with function 2D + Tomo-Scan	mAs Tomo
20	WRh	25	50	~100
30	WRh	26	70	~140
40	WRh	26	90	~180
50	WRh	27	110	~220
60	WRh	28	120	~240
70	WRh	29	130	~260
80	WRh	30	140	~280
90	WRh	30	160	~320
100	WRh	31	180	~360

Projection view status

In the **Images** subtask card, the individual projection views up to the reconstructed tomo data set are shown as follows:



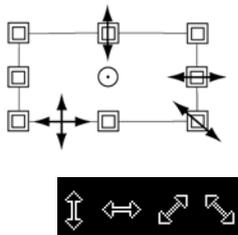
The first view is shown with the bounding box (1). It shows the reconstructed area.



Modifying the bounding box

The bounding box should enclose the entire breast. If the bounding box turns out to be too small or too large, you can modify it with the cursor.

If you click the mouse in the bounding box, the cursor changes its appearance and you can edit the graphic.



- ◆ Place the cursor on one of the handles.

- ◆ Increase or reduce the size of the region until it meets your requirements.

Or



- ◆ Move the region in the image. To do so, place the cursor on the contour line between the grab handles.

Reconstruct...

- ◆ Click the **Reconstruct...** button.
 - The tomo images will be reconstructed anew, see section *Reconstructing tomo images* page 32.



Please note that each parameter set from the **Reconstruction parameter group name** list has different reconstruction properties:
Standard is used for all standard tomo examinations.
Calcification is used in cases where an additional tomo reconstruction is required with a particular focus on micro calcifications.
Phantom is used for quality control checks and/or technical measurements with phantoms only.

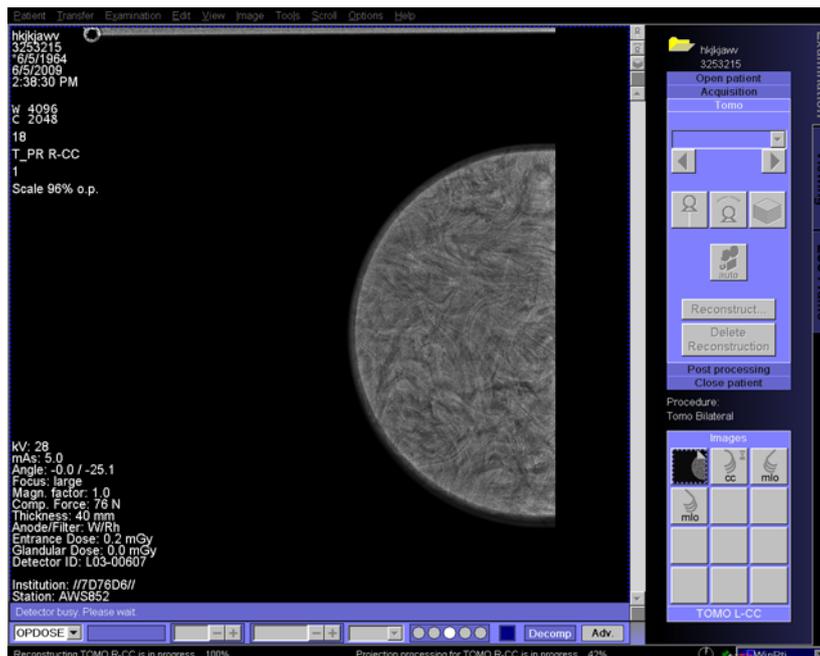
Status bar

The status bar shows the progress of the reconstruction of slices (1) and the projection processing (2) in percent.

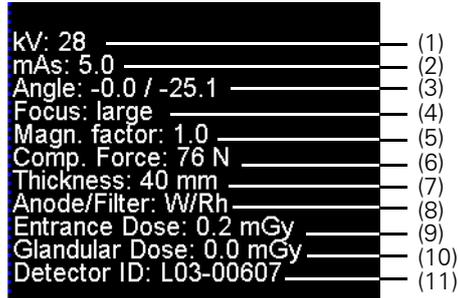


When calculating the projections, the initial acquisition is included so that 26 projections are processed.

When all 25 slices/projection views have been generated, the view changes to the **Tomo** subtask card.



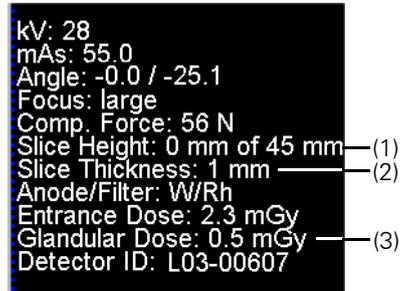
**Image text
projection images**



kV: 28 (1)
mAs: 5.0 (2)
Angle: -0.0 / -25.1 (3)
Focus: large (4)
Magn. factor: 1.0 (5)
Comp. Force: 76 N (6)
Thickness: 40 mm (7)
Anode/Filter: W/Rh (8)
Entrance Dose: 0.2 mGy (9)
Glandular Dose: 0.0 mGy (10)
Detector ID: L03-00607 (11)

- (1) kV value
- (2) mAs value
- (3) Angle of set projection view/projection angle during the exposure
- (4) Focus
- (5) Magnification factor
- (6) Compression force
- (7) Breast thickness
- (8) Anode/filter combination
- (9) Entrance dose
- (10) Glandular dose/projection
- (11) Detector ID

**Image text
slice images**

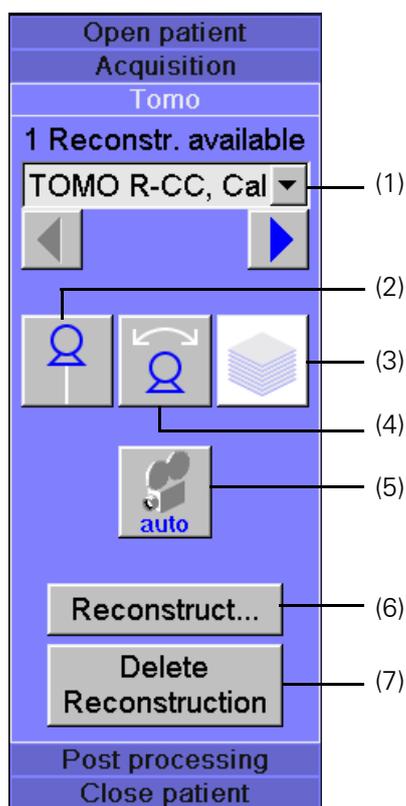


kV: 28
mAs: 55.0
Angle: -0.0 / -25.1
Focus: large
Comp. Force: 56 N
Slice Height: 0 mm of 45 mm (1)
Slice Thickness: 1 mm (2)
Anode/Filter: W/Rh
Entrance Dose: 2.3 mGy
Glandular Dose: 0.5 mGy (3)
Detector ID: L03-00607

- (1) Slice height, measured starting with the surface of the detector cover
- (2) Slice thickness
- (3) Glandular dose of complete scan

Displaying/processing tomo examination images

Tomo examination images can be processed in the **Tomo** subtask card in the **Examination** task card.



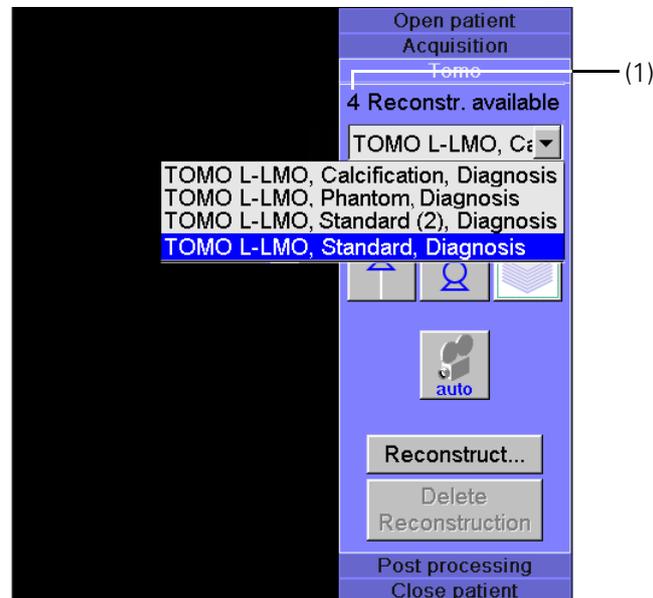
- (1) Information bar, projection and reconstruction parameter group (RPG)
- (2) Display first view (when using **2D+Tomo-Scan** display 2D image)
- (3) Display slice image
- (4) Display projection image
- (5) Play automatic movie
- (6) Reconstruct tomo images
- (7) Delete selected reconstructed tomo images



Subsequent acquisition must be deactivated in order to process tomo examination images.

Display of reconstructions

- ◆ If necessary, select a different reconstruction sequence in the list.
 - The selected reconstruction sequence is displayed on the monitor.



(1) The number indicates how many reconstructions there are of a tomo scan.



If there are several exposures, you can use the arrow buttons to skip to the next set of reconstructions.



Please note that the number of slices depends on the compression thickness, compression plate, and compression force. The compression plate can bend slightly during breast compression; as a result, there could be differences in the compression thickness shown on the digital stand display and the AWS monitor. The upper reconstructed slices do not contain real breast tissue.

Displaying tomo images

You can toggle between the different images.

First view

Exposure taken at an angle of 0°.

- ◆ Select **View > First view** in the menu bar.
 - The first view is displayed.

Or



- ◆ Click the **Single view** button in the **Tomo** subtask card or in the scroll bar.

Or

- ◆ Use the shortcut **Ctrl + F1**.

Projection images

25 views from different angles from which the slices are reconstructed.

Note that the acquisitions were taken with a low dose and restricted image quality.



Caution

The evaluation of distances in projected tomo images can be inaccurate.

Incorrect measurement results, incorrect diagnosis.

- ◆ Do not use projected tomo images to perform critical measurements.

- ◆ In the main menu select **View > Tomo Projections**.
 - The projection views are displayed.

Or



- ◆ Click the **Tomo Projections** button in the **Tomo** subtask card or in the scroll bar.



Or

- ◆ Use the shortcut **Ctrl + F2**.



*Note that projection acquisitions cannot be sent to the **Filming** task card.*

Slice images

Reconstructed slices (3D volumes) from which projections of different reconstruction algorithms (RPG) are possible.

- ◆ In the main menu select **View > Slices**.
 - The slice views are displayed.

Or



- ◆ Click the **Slices** button in the **Tomo** subtask card or in the scroll bar.



Or

- ◆ Use the short cut **Ctrl + F3**.

Reconstructing tomo images

For better visualization of details, tomo images can be reconstructed with different reconstruction parameters, see page 18.

Reconstructing images



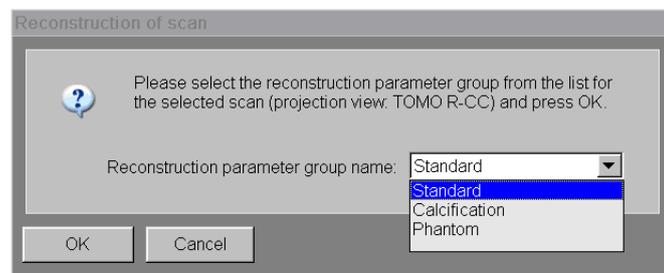
Reconstructed images are displayed in the **Tomo** subtask card and in the **Patient Browser**.

- ◆ Click the **Reconstruct...** button.

Or

- ◆ Click on the image with the right mouse button.
 - A selection window appears.

- ◆ Select **Reconstruct Tomo Scan...** in the popup menu displayed.
 - The **Reconstruction of scan** dialog box is displayed:



- ◆ Select a reconstruction parameter from the **Reconstruction parameter group name** list. e.g.
 - **Standard** - is used for all standard tomo examinations
 - **Calcification** - is used in cases where an additional tomo reconstruction is required with a particular focus on micro calcifications
 - **Phantom** - is used for quality control checks and/or technical measurements with phantoms only



Caution

The specific **Reconstruction parameter group name** for calcification is focusing on micro calcification.

Decreased perceptibility of low contrast information of the breast tissue!

- ◆ Use **Standard Reconstruction parameter group name** for all standard tomo examinations in addition to calcification parameter.

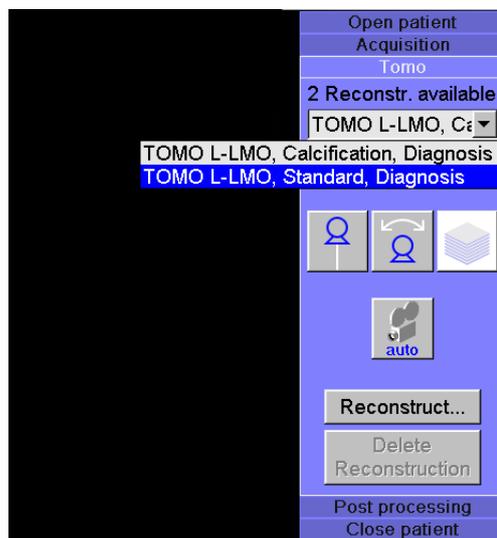


Please note that in some cases it might be necessary to adjust brightness/contrast (or window width and window level) manually each view.



- ◆ Click **OK**.
 - The tomo images will be reconstructed anew with the selected reconstruction parameter.

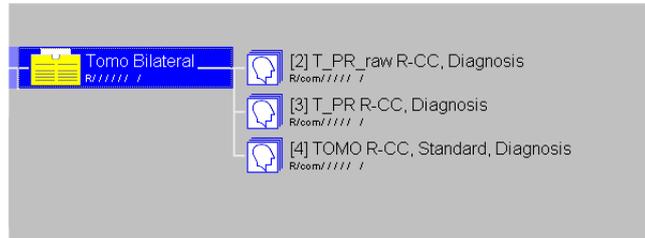
The list in the **Tomo** subtask card shows the new 3D volume from the reconstructed slices (e.g. TOMO L-LMO, Calcification, Diagnosis).



Tomosynthesis

Tomosynthesis examination

At the same time, a new series is saved and displayed with the selected reconstruction parameter in the **Patient Browser**.



With each additional reconstruction the data volume increases considerably. Therefore, you should save only those reconstructions that are really needed. Before closing the examination, reconstructions that are not required should be deleted.

- ◆ Click **Cancel**.
 - The **Reconstruction of scan** dialog box closes.
 - The tomo images remain unchanged.

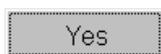
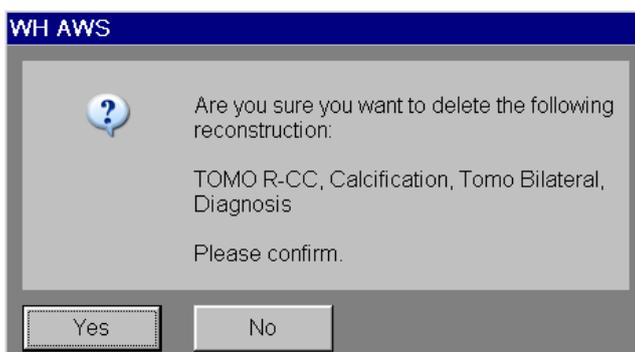
Deleting reconstructed images

You can delete reconstructed images using the pop-up menu or the **Delete Reconstruction** button.

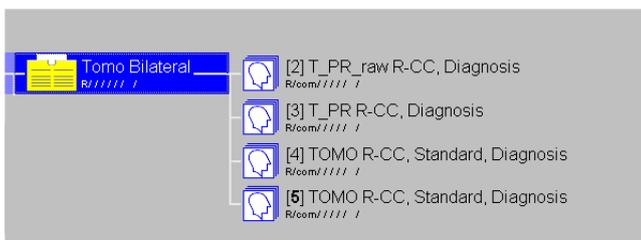
Pop-up menu:



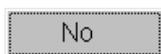
- ◆ Click the **Slices** button in the **Tomo** subtask card.
 - The slice views are displayed.
- ◆ Click on the image with the right mouse button.
 - A selection window appears.
- ◆ Select **Delete Reconstruction** in the popup menu displayed.
 - The following message window appears:



- ◆ Click **Yes** to make the changes.
 - The stored series with the selected reconstruction parameter in the **Patient Browser** are deleted.



Or

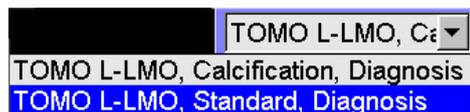


- ◆ Click **No** if you don't want to make the changes.

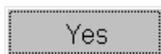
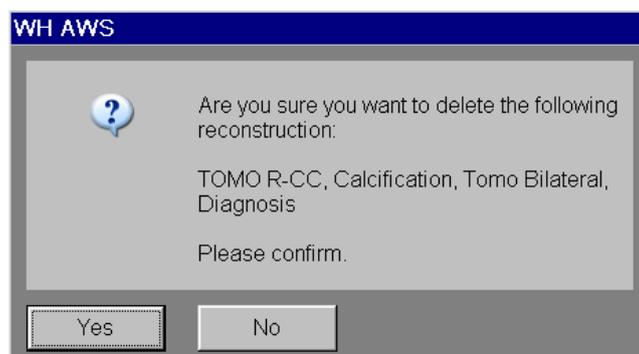
Button:



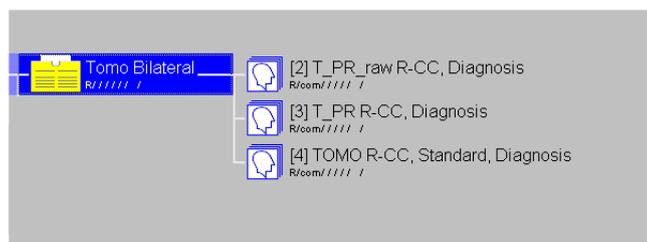
- ◆ Click the **Slices** button in the **Tomo** subtask card.
 - The slice views are displayed.
- ◆ Select a reconstruction e.g. *TOMO L-LMO, Standard, Diagnosis* from the list.



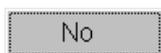
- ◆ Click the **Delete Reconstruction** button.
 - The following message window appears:



- ◆ Click **Yes** to make the changes.
 - The stored series with the selected reconstruction parameter in the **Patient Browser** are deleted.



Or



- ◆ Click **No** if you don't want to make the changes.

Playing back motion images (movie/cine)

Abnormalities in the images are generally easier to detect if you view the images in quick succession like a movie. The **Tomo** subtask card provides a function for fast, automatic scrolling through the images of a series.

During playback of the movie, data sets should not be corrected or rearranged.

Layout and display mode

- ◆ In the menu bar, select the stack display (**View > Slices**) to view a series as a movie.
- ◆ Select a large enough layout so that you can see all details.
Recommended layout:
 - **1 : 1**
The movie takes up the whole screen.

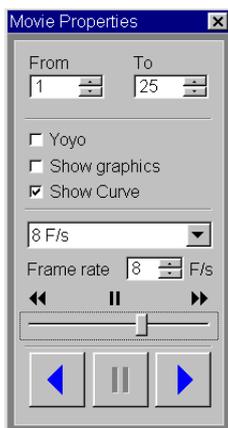
Automatically playing back a movie

If you want to ensure a constant playback speed, you can have the movie played back automatically. In this mode you can change a number of settings for movie playback.

Starting the movie



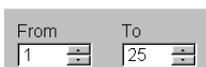
- ◆ Click the **Movie Properties** button.
 - The **Movie Properties** subtask card is displayed.



In the **Movie Properties** subtask card you can:

- Exclude irrelevant first/last images
- Pause and restart the movie
- Change the playback speed and direction

Excluding first/last images



- ◆ Use the spin boxes **From** and **To** to specify which images are to be included in the movie.
 - In this way, you can exclude irrelevant first and last images. This setting can not be changed while the movie is being played back.

Pausing the movie, scrolling forward and back in steps



- ◆ Click the Stop button to pause movie playback.
 - Scroll through the image stack step by step using the scroll bar or the dog ears.

Playback speed and direction



- ◆ Select a speed from the list.

Or



- ◆ Enter a playback speed using the spin box next to **Frame rate**.

Or



- ◆ Select a playback speed and direction with the slider:
 - All the way to the right – fast forward
 - Right center – slow forward
 - Center position – freeze frame
 - Left center – slow backward
 - All the way to the left – fast backward

Or



- ◆ Change the playback direction by clicking the Forward/Back button.



- ◆ Click the **Yoyo** option.
 - When the movie has reached the last frame in forward playback mode, it will wind back to the first frame and then advance again to the last frame, etc.

Or



- ◆ Deselect the **Yoyo** option to play the movie back in a loop.
 - Once it has reached the last frame, the movie will start at the first frame again (loop).



- ◆ Click the **Show graphics** option.
 - The graphics inserted will be shown as part of the movie.

Or



- ◆ Deselect the **Show graphics** option.
 - The graphics inserted will not be shown as part of the movie.



- ◆ Click the **Show Curve** option.
 - The curves inserted will be shown as part of the movie.

Or



- ◆ Deselect the **Show Curve** option.
 - The curves inserted will not be shown as part of the movie.

Additional notes on the tomo examination

With the projection and slice views you can query the exposure data of an image.

Correcting tomo image information

Correcting tomo image information, e.g. changing L-CC to R-CC, is not possible after closing an examination or using **Reenter examination**.

If, however, you do attempt to correct the image information using this function, please note the following:

If you reenter an examination and correct a tomo image, as described below, an error message appears:

- ◆ Click on the **Reenter examination** button.
- ◆ With the right mouse button, click on the subtask card **Images** for the relevant image.
- ◆ Select the **Correct** entry.
An error message appears.

Acknowledge the error message 26 times and continue working.

A system restart is not required.

The tomosynthesis image has not been corrected.

You must use PACS to retrospectively correct tomo images.

Correcting projection views

The exposures displayed in the image area must correspond to the planned projection views. If there is a discrepancy, a subsequent correction will be necessary.



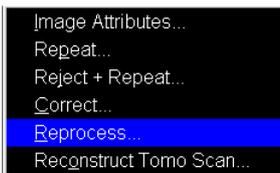
Caution

If the wrong breast side or an unintended view was acquired, the image will be saved under an incorrect projection view.

Incorrect diagnosis or incorrect treatment possible!

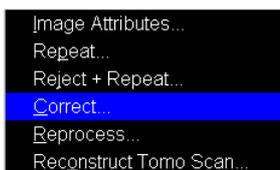
- ◆ Check that the correct projection view is assigned to the image and correct it, if necessary.

Reprocessing

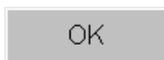
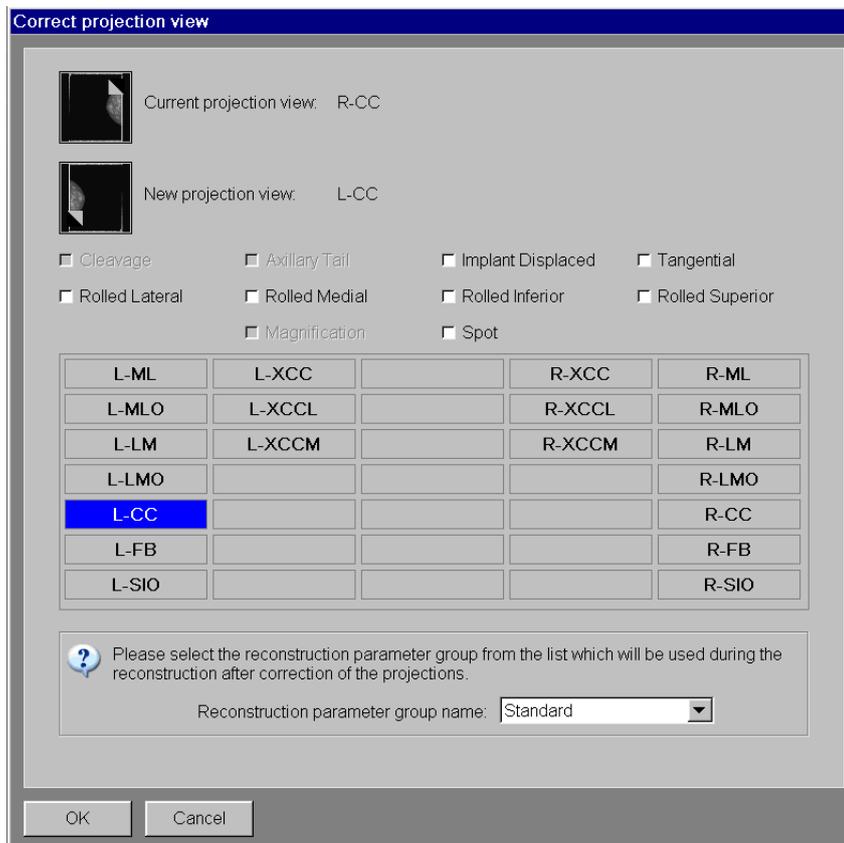


- ◆ Right-click the relevant image in the **Images** subtask card.
 - A popup menu is displayed.
- ◆ Select **Reprocess....**
 - The projection images (or 2D image of the **2D+Tomo-Scan**) will be reprocessed with the changed to 2D parameters.

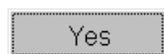
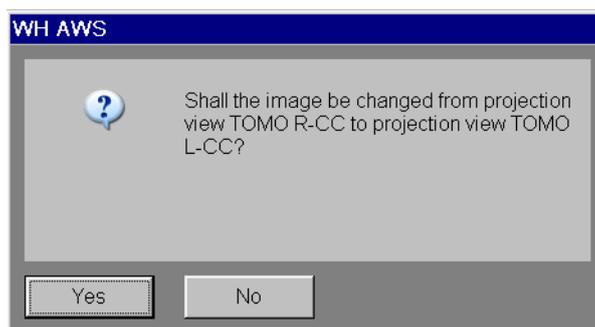
Correction



- ◆ Right-click the relevant image in the **Images** subtask card.
 - A popup menu is displayed.
- ◆ Select **Correct....**
 - The **Correct projection view** dialog box is displayed.



- ◆ Select the correct projection view in the **New projection view** window.
- ◆ Select a reconstruction parameter from the **Reconstruction parameter group name** list.
- ◆ Click **OK**.



- ◆ Click **Yes** to make the changes.
 - All available exposures are reconstructed and displayed in the changed view.

Adding projection views

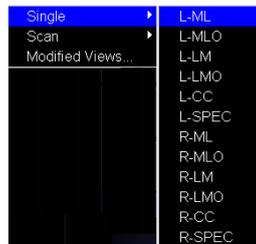
In the protocol control (**Images** subtask card) you can modify the projection views preset in the selected procedure as well as their number and sequence for the current examination.

Depending on the selected projection view (scout exposure/first stereo exposure/specimen exposure), the projection views can be modified, added, inserted or deleted, e.g.:

Adding a projection view



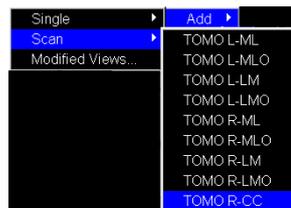
- ◆ In the **Images** subtask card, right-click on a projection view or on an empty view in order to insert a single image or scan.
 - A selection window appears.
- ◆ Select **Add > Single** in the popup menu displayed.
 - The following selection window appears.



- ◆ Select a single projection view from the list.

Or

- ◆ Select **Add > Scan** in the popup menu displayed.
 - The following selection window appears.



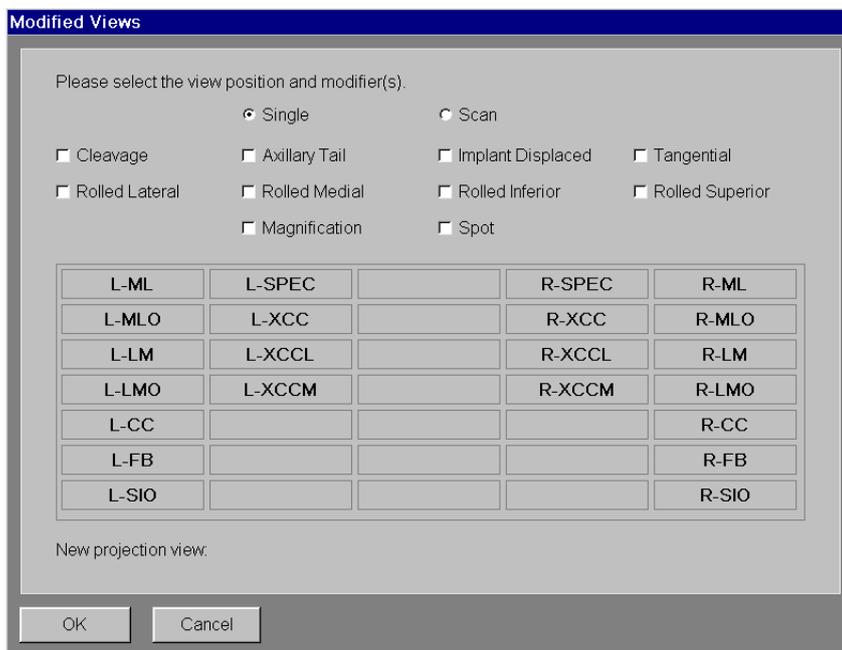
- ◆ Select a projection view from the list box.



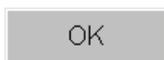
*The selection list can be configured in the **Projection Name** tab card, see tab: Configuration.*

Or

- ◆ Select **Add > Modified Views** for special projection views.
 - The **Modified Views** window opens.



- ◆ If necessary, define special settings for the desired projection view in the upper window area.
 - The list of projection views (lower box area) is restricted to the views that fulfill the selected criteria.



- ◆ Select the desired projection view and confirm by clicking **OK**.

The new projection view is added to the **Images** subtask card.

Creating a 2D + 3D exposure

The function **2D + Tomo-Scan** produces a conventional 2D exposure and a complete tomo scan during an exposure.



- ◆ Before the start of the examination, in the main menu select **Options > 2D + Tomo-Scan**.



- ◆ Double-click the button 2D + 3D Exposures.
 - The detector parameters are loaded.
 - The following exposures are created:
 - 2D exposure (single image)
 - Projections
 - Reconstructed layers



The 2D image is stored in the projection series.

During one examination only 2D + 3D exposures can be performed in a scan, or 2D and 3D in various exposures.



*In the function **2D + Tomo-Scan** the indicated glandular dose corresponds to*

- the dose applied during the 2D exposure, in the case of a 2D exposure
- the dose applied during the entire scan, in the case of tomo slices
- the dose applied during the single projection, in the case of projection views
- in the case of manual 2D + 3D mode:
 - the set mAs value corresponds to the mAs value during the 2D exposure
 - the mAs value for 3D is twice as high



When using the **2D + Tomo-Scan** the 2D exposure is always done with the Grid Position In, even if the user has selected the option Grid Position Out in Advanced dialog box.

Avoid interrupting the radiation release during a tomosynthesis examination when using the **2D + Tomo-Scan** function between the 2D exposure and the 3D scan.



If, during a tomosynthesis examination using the function **2D + Tomo-Scan**, an error message appears for the following setting:

- kV value: 32 kV
- mAs value: > 280 mAs

Reduce the mAs value (< 280 mAs) in order to continue the examination.

Please note the following settings in order to avoid error messages:

- 23 - 28 kV < 300 mAs
- 29 - 32 kV < 280 mAs
- 33 - 35 kV < 250 mAs



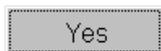
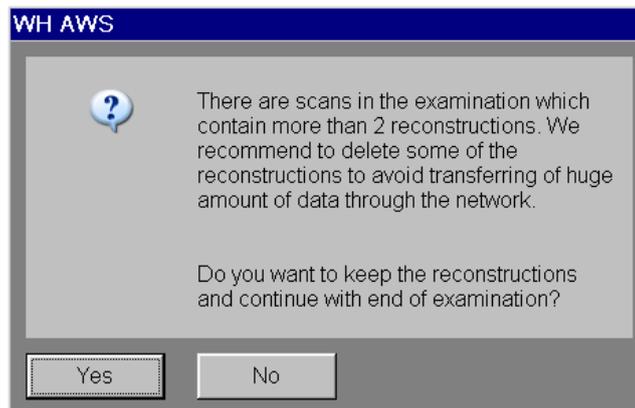
Please note that customer uses **2D+Tomo-Scan** as default for tomo procedures. The function **2D + Tomo-Scan** will be disabled automatically, when a tomo calibration will be performed.

Ending the examination



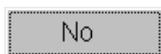
- ◆ To end the examination, click this button in the **Close Patient** subtask card.

As soon as you have generated more than 3 series with the reconstruction parameters, the following message window will appear before you can close the examination:

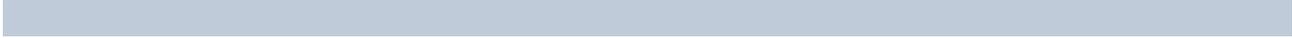


- ◆ Click **Yes**.
 - All series will be saved.

Or



- ◆ Click **No**.
 - Switch to the **Tomo** subtask card, see section *Deleting reconstructed images*, to delete series.



For notes

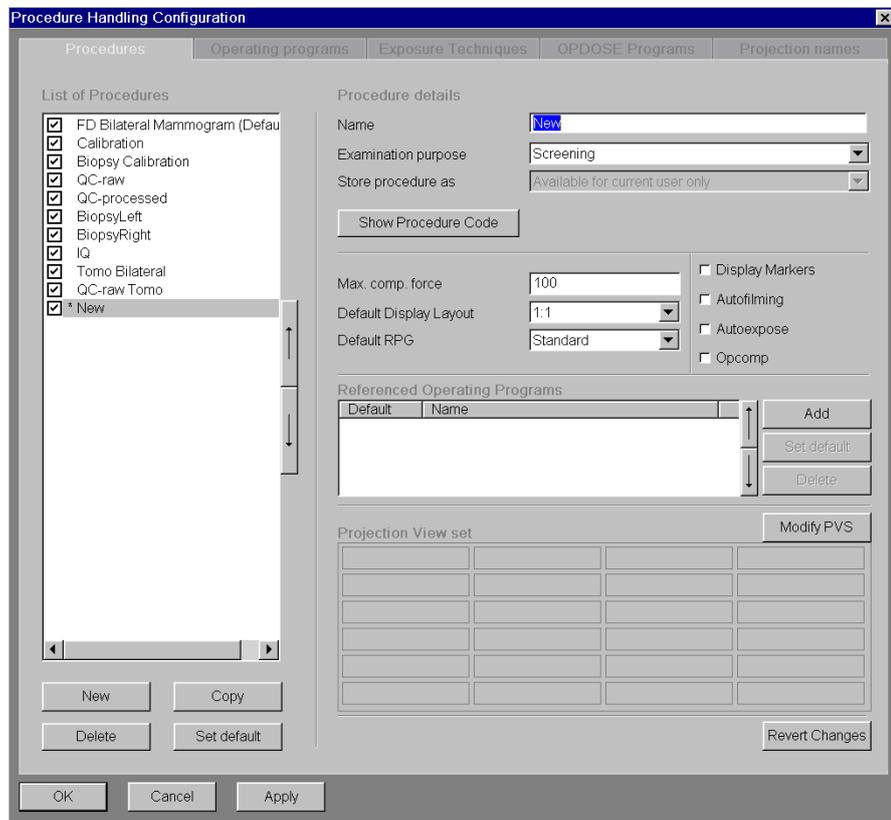
Tomosynthesis Configuration

Configuring a tomo examination

Only the changes regarding the tomo examination are described here. For the configuration of the **Examination** task card see register *Configuration*, chapter *Configuring examination*.

Configuring procedures

You can create additional examination procedures and revise or delete existing procedures with the **Procedures** tab card.



Reconstruction parameters

You can select the reconstruction parameters configured by the system engineer.

Default RPG

- ◆ In the list of examination purposes, select **Default RPG**, e.g.
 - Standard
 - Calcification
 - Phantom

Procedures provided as factory defaults

The following procedures are provided as factory defaults. You can use these procedures immediately for your examinations or use them as a template for additional new procedures you create.

Tomo:

Examination purpose:	Diagnosis (as default)
Referenced Operating Programs:	AEC Tomo (as default)
Projection View set:	TOMO R-CC, TOMO L-CC, TOMO R-MLO, TOMO L-MLO

QC-raw Tomo:

Examination purpose:	Phantom (for quality assurance)
Referenced Operating Programs:	Calibration-raw tomo (as default)
Projection View set:	TOMO R-CC, TOMO R-CC, TOMO R-CC

Details of the projection views

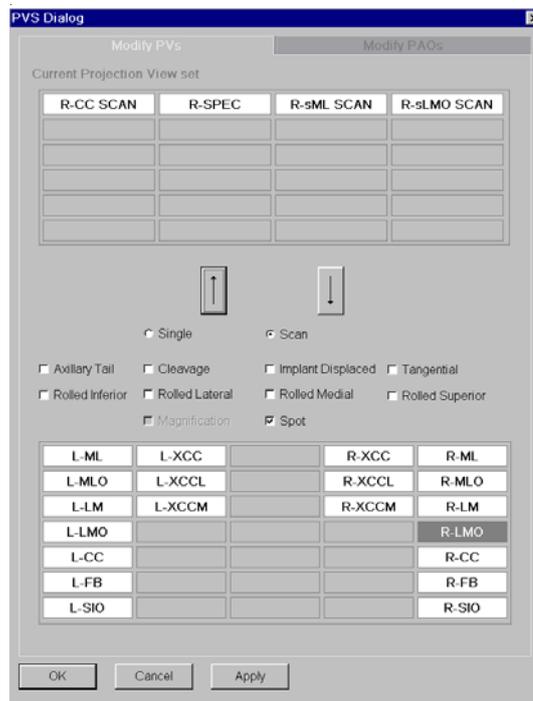
In the course of an examination procedure different projection views are acquired in a defined sequence. You can determine the composition and sequence of the projection views in the **PVS Dialog**.

Modify PVS

- ◆ Click **Modify PVS**.
 - The **PVS Dialog** dialog box opens.

Modifying projection views

- ◆ Click the **Modify PVs** tab into the foreground.



Single

- ◆ Click the **Single** option.
 - Only a single exposure (2D exposures) is selected.

Scan

- ◆ Click the **Scan** option.
 - When a projection view is selected, the corresponding tomo exposures (3D exposures) are entered automatically (e.g. Tomo R-CC).



*The projection views are defined in the **Projection names** subtask card. A list of available projection views is shown in the **Modify PVs** and **Modify PAOs** dialog.*

Configuring OPDOSE programs

In the **OPDOSE Programs** tab card, you can specify the parameters for the exposure technique that uses the OPDOSE mode.

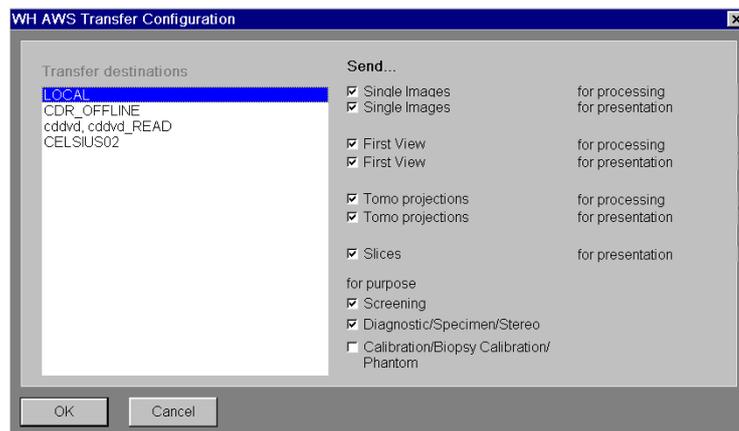
Examination type

Examination type	Normal
	Normal
	Stereo
	Tomo
	Magnification

- ◆ Select an examination type from the list.
 - The individual values in the **List of OPDOSE Programs** are adjusted to the selected examination type.

Image selection for autotransfer destinations

In the **WH AWS Transfer Configuration** configuration dialog you define which image material from the examination should be transmitted automatically to the individual destination addresses. You differentiate in this case according to image type and examination purpose of the images.



- Image type**
- ◆ Select the image type that is to be sent to the selected destination address.
 - **Single Images for processing**
only individual raw data (suitable for image processing/CAD server); correspond to 2D images
 - **Single Images for presentation**
only single processed images (suitable for reporting station, for example); correspond to 2D images
 - **First View for processing**
only raw data of the first exposure or 2D exposure (suitable for the special **2D + Tomo-Scan** mode)
 - **First View for presentation**
only finished image of the first exposure or 2D exposure (suitable for the special **2D + Tomo-Scan** mode)
 - **Tomo projections for processing**
raw data set of the 25 projections
 - **Tomo projections for presentation**
processed data set of the 25 projections
 - **Slices for presentation**
reconstructed slices (suitable for reporting station, for example)

For notes

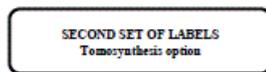
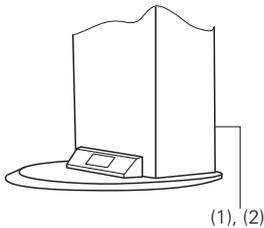
Tomosynthesis

Technical Description

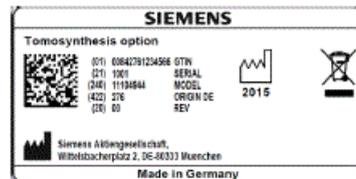
Identification Labels

The labels shown below are attached permanently to the corresponding locations of the following components of the X-ray stand.

Overall system

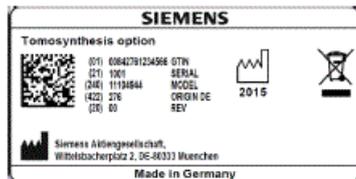
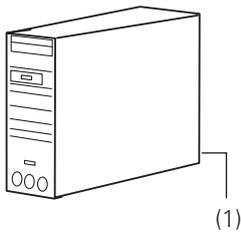


(1) Supplementary label

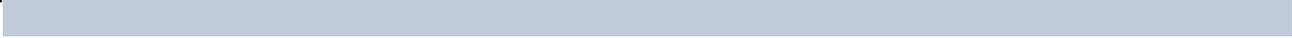


(2) UDI label Tomosynthesis Option

Workstation



(1) UDI label Tomosynthesis Option



For notes

MAMMOMAT Inspiration

**Physician Labeling
Tomosynthesis Option - Addendum
VB30 or higher**

SIEMENS

www.siemens.com/healthcare



0123

This device bears a CE mark in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993

concerning medical devices and the Council Directive 2011/65/EU of June 08, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking applies only to medical devices which have been put on the market according to the above mentioned EC Directive.

Original language: English

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Addendum to MAMMOMAT Inspiration Tomosynthesis Option

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Addendum to MAMMOMAT Inspiration Tomosynthesis Option

Physician Labeling

This section provides a brief summary of the physical laboratory testing results, including graphs and tables as appropriate.

Manufacturer Contact Information

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Prescription Use Statement

Federal law restricts this device to sale by or on order of a physician.

Indication for Use Statement

The MAMMOMAT Inspiration with Tomosynthesis Option is indicated for acquisition of 2D as well as 3D digital mammography images to be used in screening and diagnosis of breast cancer.

Each screening examination may consist of CC and MLO views in:

- a 2D image set or
- a 2D and 3D image set.

Note:

The screening examination may consist of 2D FFDM images set with or without the 3D image set.

Warnings / Cautions / Contraindications



Warning

The patient's head can enter the beam path.

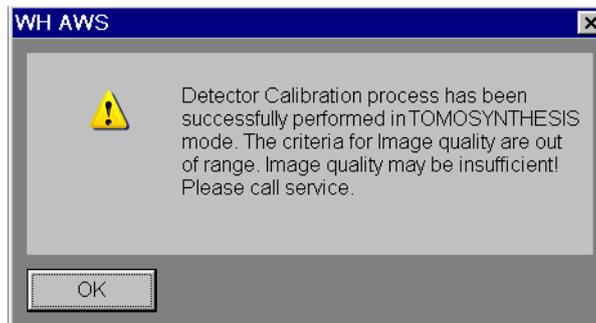
Unnecessary radiation exposure!

- ◆ Make sure that the special face shield is always used during a tomosynthesis examination if there is a risk that the patient's head can enter the beam path.
-

Detector Calibration

Calibration unsuccessful

The following warning window appears when the calibration is unsuccessful:



This message means that several non-functioning pixels were found during the calibration. This requires a system check by a Siemens service technician. The results are available in the Service menu, see the Check calibration results section in the operator manual.

- ◆ Call a Siemens service technician or a technician trained by Siemens.

Cautions



Caution

Danger due to unintended release of pressure.

Risk of injury during release of pressure!

- ◆ Move the foot switches outside the reach of the patient and personnel as soon as the patient's breast is compressed.
-



Caution

If breast implants are not taken into consideration, this will lead to errors in treatment and incorrect settings during the examination.

Risk of injury during compression and tomosynthesis examination!

- ◆ Ask the patient about existing implants prior to the examination. Inform the patient about the risks of providing false information.
 - ◆ Adjust the preparation and examination of the patient accordingly (e.g., performing compression, system parameter settings).
-



Caution

Swivel arm stops during exposure.

Unnecessary radiation exposure!

- ◆ Release the exposure on button.
 - ◆ Turn the control knob upward for manual release of compression, or perform release of compression using the control panel or foot pedal.
-



Caution

If the wrong breast side or an unintended view was acquired, the image will be saved under an incorrect projection view.

Incorrect diagnosis or incorrect treatment possible!

- ◆ Check that the correct projection view is assigned to the image and correct it if necessary.
-



Caution

Swivel arm movements can cause parts of the body to be touched or crushed.

Risk of injury!

- ◆ Ensure that the patient is positioned correctly.
 - ◆ Please note that the face shield also moves when the swivel arm moves. The patient's head must not lean against the face shield while the swivel arm is moving.
-

Contraindications

There are no known contraindications

Device Description of Siemens Breast Tomosynthesis

The MAMMOMAT Inspiration is a Full Field Digital Mammography (FFDM) system. The Mammography system stand provides a height-adjustable swivel arm with tube housing assembly and collimator on the upper end and an object table with FFDM detector on the lower end. The swivel arm can be angulated to the left and right for angulated image projections. This angulation feature is also used for the Tomosynthesis procedure. The X-ray generator and tube hardware are unchanged compared to the 2D system. The compression system is unchanged but is provided with compression plates specific for the tomosynthesis application. The detector technology for the tomosynthesis mode (3D) remains the same as for 2D mammography which is an amorphous selenium-based direct conversion DR detector. The solid-state sensor is designed to have the required image quality and resolution characteristics making it suitable for mammography imaging. The sensor, control electronics, and power supply are integrated in the detector enclosure. This enclosure is designed to be mechanically integrated in a mammography support device. It includes a high quality thin carbon cover window to protect the sensor active area. Temperature control of the detector is done by integrated fan cooling in the detector enclosure.

The workflow for the Breast Tomosynthesis (DBT) procedure is similar to that of a Digital Mammography (DM). The breast is compressed on the mammography support device.

In tomosynthesis mode the Siemens MAMMOMAT Inspiration acquires 25 images with short X-ray pulses over an angular range of 50°. A filtered back projection algorithm is applied to the projections to produce an initial reconstruction. Specific algorithms are used to reduce artifacts and image blurring. The result is an image data set of the entire breast volume.

The DBT processing is done in the acquisition workstation provided with the Mammography stand. The acquisition workstation features a preview image display to check the completeness of the examination. This image display is not for image diagnosis. The processed DBT image data can be sent to mammography viewing station capable for 3D image display such as the *syngo* MammoReport (K042868) or *syngo*.BreastCare (K123420) or any other PACS workstation cleared for breast tomosynthesis (PACS = Picture Archiving and Communication System).

Differences between the Device used in the clinical trial and the Marketed Device

Siemens conducted the MRMC study with an investigational MAMMOMAT Inspiration with tomosynthesis option. The differences between the investigational device and the marketed device are.

- ❑ The X-ray detector has been updated since the investigation. Comparative studies did confirm that performance and image quality are equivalent.
- ❑ The acquisition workstation comprises a newer computer generation as compared to the investigational device. There is no impact on the safety and effectiveness of the MAMMOMAT Inspiration.
- ❑ For the MRMC reader study, the raw image data were processed with new reconstruction algorithms.

Non-Clinical Testing

Summary of Image Quality Testing

Siemens conducted testing to demonstrate the imaging performance of the MAMMOMAT Inspiration system. The following 3D performance tests are summarized in this section:

1. Sensitometric Response
2. Modulation Transfer Function
3. Noise Power Spectrum
4. Detective Quantum Efficiency
5. Lag Test
6. Slice Sensitivity profiles
7. ACR phantom image quality
8. Uniformity in reconstructed slices
9. Geometric Accuracy
10. Visual In-Plane Resolution
11. Average Glandular Dose

1. Sensitometric response of imaging detector in tomosynthesis mode

The purpose of this test is to demonstrate how the imaging detector responds to radiation exposure. The detector was exposed to radiation ranging between 2 µGy and 90 µGy. The detector output responded linear (0.999990) to this radiation exposure range.

2. Modulation transfer function (MTF)

The purpose of this test is to describe the spatial resolution of the detector. An edge phantom was placed on the mammography table in two orthogonal directions to evaluate the spatial resolution in two directions (horizontal and vertical). The results are listed in the following table and show that the detector can record details smaller than 0.1 mm. It was also observed that there is a difference in the spatial resolution power.

Spatial frequency Line pairs	Spatial resolution power	
	Horizontal	vertical
1 / mm	0.95	0.93
2 / mm	0.88	0.84
3 / mm	0.79	0.69
4 / mm	0.68	0.56
5 / mm	0.60	0.43
5.88 / mm	0.53	0.32

Table 1: MTF

3. Noise power spectrum (NPS)

The purpose of this test is to evaluate the noise response of the imaging detector versus the spatial resolution and radiation exposure. The results show the pixel noise variance responses in linear manner to the incoming air kerma. The conclusion is that neither electronic noise nor fixed pattern noise plays a significant role in the imaging detector.

4. Detective quantum efficiency (DQE)

The purpose of this test is to describe the efficiency of signal-to-noise transfer of the image system. The measure is obtained by calculating the detective quantum efficiency as a function of the spatial frequency for several levels of radiation exposure. The DQE values recorded show almost no dependence on the input air kerma in the range between 8 µGy and 90 µGy. For oblique irradiation (25° for tomo) the DQE values are about 10% lower than compared to the orthogonal irradiation used for 2D imaging.

5. Lag test

The purpose of this test is to assess the appearance of residual image intensity from irradiations in the past on the time scale of a tomosynthesis image acquisition.

Image acquisition and analysis was performed by applying a single exposure and analyzing the image intensity thereafter in equal time steps 1 to 12.

It was found that the residual image intensity after the first time step was about 2% for step 2 to 12 less than 1%. The conclusion is that temporal effects have a very small impact on the clinical image.

6. Slice sensitivity profiles

The purpose of this test is to obtain quantitative data on the spatial resolution power perpendicular to the slices inside the reconstructed Tomosynthesis volume.

An ACR phantom was placed upon PMMA plates in order to achieve height positions of either 10 mm, 30 mm or 50 mm. The visibility of structures in the ACR (American College of Radiology) phantom was evaluated in the 3 different height positions. There was no noticeable deviation between variable object height positions.

7. ACR phantom image quality

The purpose of this test is to evaluate images from the ACR phantom. All tomosynthesis scans were generated under automatic compression and automatic exposure control using a primary X-ray spectrum from the W anode with a tube voltage of 28 kV and 0.05 mm Rh inherent filtering. The thickness of the reconstructed slices was 1 mm in all cases.

Reconstructed images from the ACR phantom are recorded and assessed afterwards by a group of experienced human observers.

The following table summarizes the results achieved.

<i>recording conditions / score values</i>	<i>masses</i>	<i>speck groups</i>	<i>fibers</i>
<i>Average</i>	4.02	3.50	5.38

8. Uniformity in reconstructed slices

From reconstructed Tomosynthesis volumes of a spatially homogeneous PMMA block the achieved grayscale uniformity inside individual slices is assessed by comparing slice by slice the mean pixel values in several regions-of-interest. The detected non-uniformities fall in the range 5 % and lower.

9. Geometric accuracy

The purpose of this test is to assess the fidelity in the mapping of geometrical length inside individual slices. The test phantom insert measured 79.9 mm in horizontal and 79.7 mm in vertical direction.

The results did not show significant variation of the detected object sizes with varying height position inside the reconstructed volume. The measured phantom sizes fit together on a length scale well below 0.1 mm.

10. Visual limiting resolution in tomosynthesis plane

The purpose of this test is to assess the visual spatial resolution in the reconstructed image of a bar pattern phantom in variable height positions. The phantom was put upon PMMA plates in order to achieve height positions of either 10 mm, 30 mm, or 50 mm.

The main result was that there is only a small dependence of the achieved results with the phantom height position in the sense that greater distance to the detector reduces recognizability.

11. Average glandular dose

The purpose of this test is to provide a quantitative estimate of the Average Glandular Dose delivered during a full tomosynthesis scan of piles of PMMA plates of variable height. Several tube voltage settings in the typical range are applied. The following table provides a summary of the achieved results.

<i>measured object thickness / mm</i>	<i>tube voltage / kV</i>	<i>tube load / mAs</i>	<i>average glandular dose / mSv</i>
19	26	69,75	1,108
37	26	190,00	2,095
56	26	523,24	4,207
19	28	55,00	1,065
37	28	139,00	1,913
56	28	363,29	3,705
19	30	55,01	1,275
37	30	106,25	1,750
56	30	268,75	3,333

Table 2: AGD

The Clinical Study Summary will provide more evidence about the dose used in the study.

Clinical Study Summary

An image collection study was conducted to support various MRMC reader studies, the first of which was to test the superiority of the Inspiration DBT system as an adjunct to FFDM vs. FFDM alone.

The primary purpose of the collection study was to collect FFDM and DBT images in order to conduct a reader study in support of the Inspiration DBT system. The reader study was a Multi-Reader, Multi-Case (MRMC) Receiver Operating Characteristic (ROC) study with a primary objective to demonstrate safety and effectiveness of the system by showing its superiority with respect to the readers' ability to detect and diagnose malignant lesions when used as an adjunct to FFDM in comparison to FFDM alone.

Image Collection Study

This was a prospective, multi-center; non-randomized image collection study conducted at seven (7) clinical sites in the US under an IRB approved protocol through a written consent process. FFDM images were acquired on any commercially available FFDM system and the DBT images were acquired on the investigational Inspiration DBT system. Subjects were enrolled prior to screening, or prior to diagnostic work-up or biopsy procedures. All subjects consented to a 4-view DBT examination on the Inspiration DBT system in addition to a 4-view FFDM examination obtained as part of standard care.

1. Inclusion/Exclusion Criteria for the study

Inclusion Criteria

Subjects must have met the following overall criteria:

- Female over 40, or 30 or older presenting for a biopsy
- A mammogram read as BI-RADS 0, 1,2,3,4 or 5 with applicable reports

Exclusion Criteria

Subjects meeting any of the following criteria were not enrolled in the study:

- Pregnant women or women who believe they may be pregnant or are trying to become pregnant
- Mastectomy patients
- Subjects who have had lumpectomy (cancer) \leq 5 years prior to the study entry
- Inmates (in accordance with 45 CFR 46.306) or mentally disabled individuals
- BI-RADS Category 6
- BI-RADS[®] Category 4 or 5 without confirming pathology reports will be considered incomplete
- Subjects with mammograms that lack the required views
- Subjects being accrued from the screening population who know that they will not be in the United States or available for follow up mammograms in one year.

2. Follow-up schedule

Individual participation in the study was limited to FFDM screening, or screening and diagnostic mammography examinations and any associated biopsy procedures, if applicable. In addition at study entry a DBT scan was performed during any of the above listed visits, or on a scheduled day. Depending on the results of the overall examination at study entry, the study required a follow-up examination in either six (6) or twelve (12) months from all study subjects except subjects diagnosed with malignancy. The follow-up confirmed the subject non-cancer status in 6 or 12 months based on FFDM examination only. Therefore individual subject participation in the study lasted a minimum of 6 to 12 months for non-cancer subjects, and from enrollment to malignancy diagnosis for subjects with cancerous lesion(s).

Average Glandular Dose distribution of subjects enrolled

The patient dose applied for the 300 subjects used for the tomo reader study have been collected and evaluated. The following figure provides a graphical representation of the AGD for different breast thickness ranges.

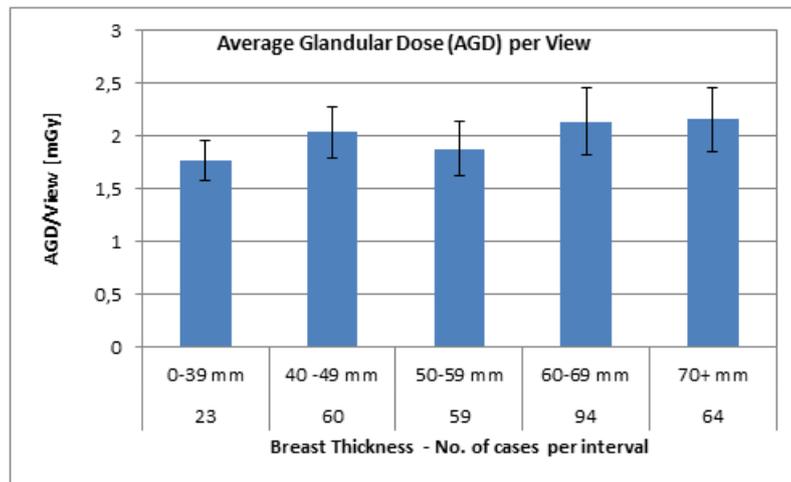


Figure 1: AGD versus breast thickness

3. Adverse Events

One Adverse Event and one Serious Adverse Event were recorded in the study and are described below.

3.a Serious Adverse Event

One subject was enrolled in the study in May 2011. While the Study Coordinator was reviewing a list of subjects whose yearly follow up had passed or was approaching, she was notified that the subject had passed away from pneumonia in July 2012. The subject did not complete her follow-up and was classified as "lost to follow up". The SAE was not device related.

3.b Adverse Event

One subject was enrolled and the day after undergoing DBT the subject called the site complaining about lightheadedness. It was determined that the AE was not related to the device.

4. Accountability of the subject population

At the time of the MRMC Adjunct reader study being conducted, approximately 700 subjects were enrolled into the image collection study. The collection study remained open and actively recruited potential subjects. Therefore only 338 subjects out of the 700 enrolled were eligible to be selected for the MRMC Adjunct reader study. All subjects with 4 standard screening FFDM views and DBT images available to the sponsor were considered for selection. This group was further reduced by: 1) subjects with negative mammograms at baseline, but without 1 year follow-up completed; 2) subjects whose follow-up was not negative; 3) subjects whose images were not yet retrieved from the clinical sites, 4) subjects whose images were not yet quality checked and reprocessed; 5) subjects recently enrolled; 6) screen failures.

MRMC Reader Study Summary

1 Objective

The primary objective of this MRMC reader study was to test superiority of the DBT as an adjunct to FFDM with regards to readers' diagnostic accuracy in detecting and characterizing breast lesions.

2 Study Endpoint

The primary endpoint was a comparison of the breast-level ROC areas, based on all subjects and all 22 readers, to evaluate the superiority of DBT as an adjunct to FFDM vs. FFDM alone.

3. Methods

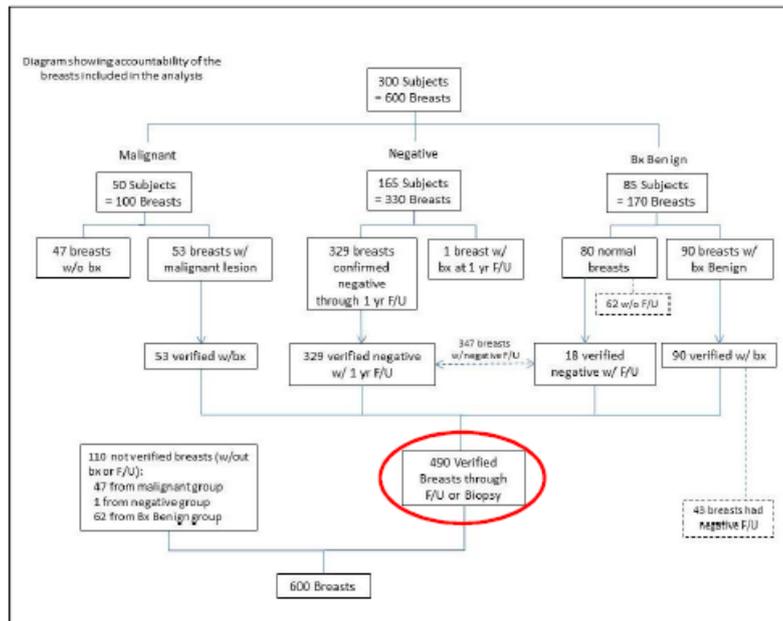
300 FFDM and DBT images (50 cancers, 85 biopsy benign, 165 negative cases) from the eligible subjects were used in the MRMC reader study. The images were interpreted by twenty two (22) board certified radiologists, who had varying degrees of mammography experience and were blinded to any history data of the subjects. Readers were informed that the study is enriched with cancer cases.

Prior to the read all readers were trained on the basics of breast tomosynthesis and DBT image interpretation.

The images were randomized and read sequentially: FFDM followed by FFDM plus DBT MLO views, and FFDM plus 4-view DBT. The data entry order by the reader was 1) the assignment of a BI-RADS score at the breast level and if an actionable finding was identified, 2) type of finding, 3) a forced BI-RADS score and 4) a Probability of Malignancy (POM) confidence score for each finding. The readers recorded only the BI-RADS score for FFDM images read as negative and were not able to describe a finding if they assigned BI-RADS score of 1 or 2 to a breast. Any findings identified on FFDM were transferred to the FFDM DBT MLO and FFDM plus 4-view DBT reads to allow readers make adjustments in the BI-RADS and POM scores if needed based on the DBT read.

Readers' Probability of Malignancy (POM) confidence scores assigned to the cancerous lesions were used to estimate sensitivity. If a patient had multiple cancerous lesions, then the highest (POM) confidence score was used. If a reader did not correctly locate any of the cancerous lesions, then a POM confidence score of zero was assigned. For estimating specificity, the highest POM confidence score assigned to any false positive finding was used; if there were no false positive findings, then a POM confidence score of zero was assigned. Analyses were performed at both the breast- and patient-level.

The statistical analyses were based on 490 breasts out of the 600 breasts included in the MRMC reader study. Per the MRMC Protocol all breasts included in the analyses required verification: either one year follow-up or biopsy. A detailed diagram showing breast accountability of the 300 cases used in the MRMC reader study is presented below.



4. MRMC Results

4.1 Primary analysis

The primary AUC endpoint of the study was met with statistically significant results showing superiority of DBT as an adjunct to FFDM. The ROC analysis showed that all readers while reading DBT in addition to FFDM improved their diagnostic accuracy in diagnosing and detecting cancer. For a breast-level ROC analysis, the readers' mean ROC area with FFDM plus 4-view DBT was 0.853 (Standard Error=0.027), which was significantly greater than the readers' mean ROC area with FFDM only of 0.752 (SE=0.028).

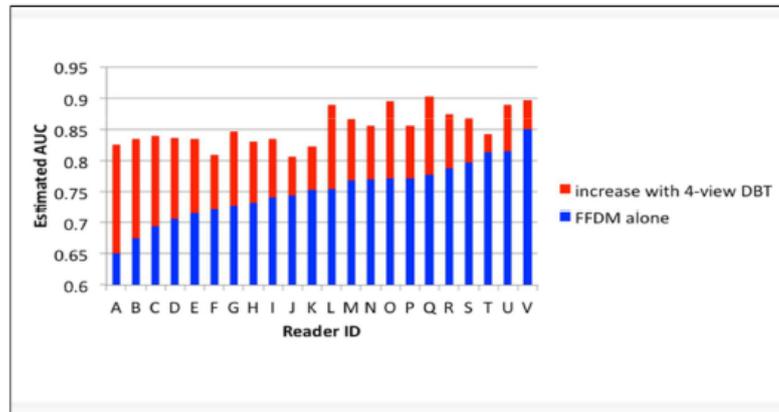


Figure 2: Readers' estimated breast-level AUC with FFDM alone (blue) and their improvement with 4-view DBT (red). Readers were sorted from lowest AUC on FFDM alone to highest.

4.2 Secondary analyses

Seven secondary analyses were performed and the results of these are presented below. The readers' parametric and nonparametric estimates of the patient-level ROC curve areas comparing FFDM alone with FFDM plus 4-view DBT also showed significant improvement with DBT. The readers' mean ROC area with FFDM only was 0.687 (SE=0.040), which improved significantly to 0.829 (SE=0.039) with FFDM plus 4-view DBT for the parametric measures and the readers' mean ROC area with FFDM was 0.709 (SE=0.033) and with FFDM plus 4-view DBT was 0.831 (SE=0.032) for the non-parametric measures. We observed an increase in diagnostic accuracy for patients with dense breasts, fatty breasts, microcalcifications, and masses in our MRMC study; however the statistical significance of these findings was not assessed.

For 18 of the 22 readers, their non-cancer recall rate was lower for DBT as an adjunct to FFDM than for FFDM alone. For 12 of the 18 readers, the decrease in recall rate was statistically significant. Overall, the readers' mean recall rate with FFDM alone was 0.438 (SE=0.030) and with FFDM plus 4-view DBT was 0.355 (SE=0.022), which is a statistically significant reduction.

The readers' mean sensitivities and specificities are summarized in Table 3. In the MRMC study we observed that readers' mean sensitivity with 4-view DBT was superior to readers' mean sensitivity with FFDM only; however the statistical significance of these findings was not assessed.

	FFDM alone	FFDM + 4view DBT
SENSITIVITY at BI-RADS 4 or 5 as a positive test result		
All subjects (n=50)	0.595 (0.041)	0.786 (0.036)
All breasts (n=53)	0.586 (0.049)	0.771 (0.044)
Dense breasts (n=27)	0.557 (0.059)	0.768 (0.053)
Fatty breasts (n=25)	0.638 (0.071)	0.798 (0.069)
Breasts w/ calcs (n=15)	0.591 (0.090)	0.676 (0.087)
Breasts w/ masses (n=38)	0.630 (0.054)	0.829 (0.050)
SPECIFICITY at BI-RADS 4 or 5 as a positive test result		
All subjects (n=250)	0.732 (0.036)	0.730 (0.029)
All breasts (n=437)	0.829 (0.028)	0.830 (0.022)
Dense breasts (n=239)	0.839 (0.028)	0.839 (0.023)
Fatty breasts (n=197)	0.817 (0.033)	0.820 (0.026)
SENSITIVITY at BI-RADS 3, 4 or 5 as a positive test result		
All subjects (n=50)	0.672 (0.037)	0.822 (0.035)
All breasts (n=53)	0.664 (0.044)	0.809 (0.042)
SPECIFICITY at BI-RADS 3, 4 or 5 as a positive test result		
All subjects (n=250)	0.562 (0.030)	0.593 (0.024)
All breasts (n=437)	0.718 (0.025)	0.741 (0.020)

Table 3: Estimates of Sensitivity and Specificity

We observed in our study through the ROC analysis that the average diagnostic accuracy of radiologists is superior with FFDM plus DBT MLO than with FFDM alone. The statistical significance of this finding was not assessed.

The summary ROC curves, derived from the parametric estimates, are shown in Figure 3. The readers' mean ROC area with FFDM only was 0.687 (SE=0.040), which improved significantly to 0.829 (SE=0.039) with FFDM plus 4-view DBT.

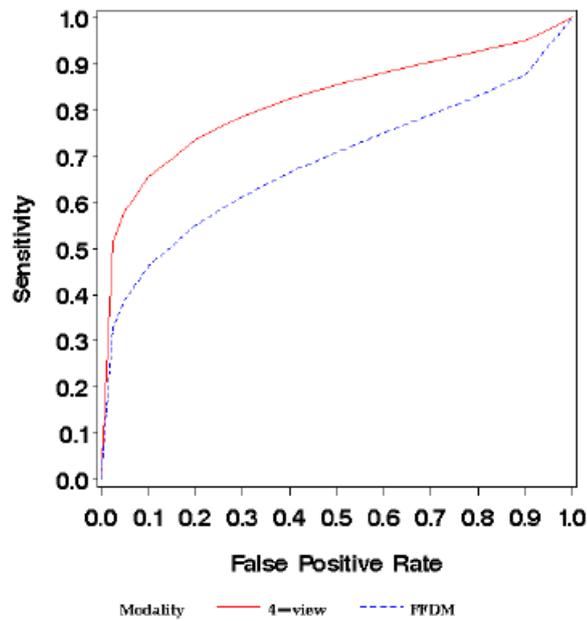


Figure 3: Summary ROC curves for FFDM (blue dashed) and FFDM plus 4-view DBT (red solid).

Conclusions Drawn from the Studies

- ❑ Siemens conducted an MRMC study with 22 readers having a broad range of experience. All readers improved their accuracy in detecting and diagnosing cancers when reading DBT as an adjunct to FFDM.

In that study, when readers used Siemens Tomosynthesis as an adjunct to FFDM, on average

- diagnostic accuracy (measured by the AUC ROC) in screening mammography increased,
 - cancer detection rate increased,
 - identification of lesions that were ultimately proven to be malignant increased,
 - non-cancer recall rate was reduced,
 - patient recall rate was reduced,
 - sensitivity in the detection of cancer in the patients with dense and fatty breasts increased.
- ❑ Siemens DBT as an adjunct to FFDM has been shown to reduce the non-cancer recall rate compared with FFDM alone.
 - ❑ Siemens Tomosynthesis solution in adjunct to FFDM has been shown to improve diagnostic accuracy in screening mammography compared with FFDM alone.
 - ❑ In the pivotal study, reader sensitivity on average was greater for readings based on 4-view DBT as an adjunct to FFDM than for readings based on FFDM alone.
 - ❑ In the pivotal study, reader's patient-level AUC on average was greater for readings based on 4-view DBT (MLO+CC) as an adjunct to FFDM than for readings based on FFDM alone (AUC difference 0.1408, standard error 0.0386).
 - ❑ In the pivotal study, reader's patient-level AUC on average was greater for readings based on 2-view DBT (MLO) as an adjunct to FFDM than for readings based on FFDM alone (AUC difference 0.095, standard error 0.033).
 - ❑ The benefit of additional 4-view DBT exam outweighs the increased risk from the additional radiation dose as shown in the Siemens MRMC study.