MAGNETOM Flow. Platform

Operator Manual – Breast BI 7
syngo MR XA70

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SIEMENS Healthineers

Legend

	Indicates a hint Provides information on how to avoid operating errors or information emphasizing important details
	Indicates the solution to a problem Provides troubleshooting information or answers to frequently asked questions
■	Indicates a list item
✓	Indicates a prerequisite A condition that has to be fulfilled before starting a particular operation
◆	Indicates a single-step operation
1 2 3	Indicates steps within operating sequences
Italic	Used for references and for table or figure titles
➔	Used to identify a link to related information as well as previous or next steps
Bold	Used to identify window titles, menu items, function names, buttons, and keys, for example, the Save button Used for on-screen output of the system including code-related elements or commands
Orange	Used to emphasize **particularly** important sections of the text
`Courier`	Identifies inputs you need to provide
Menu > Menu Item	Used for the navigation to a certain submenu entry
<variable>	Identifies variables or parameters, for example, within a string

CAUTION

CAUTION

Used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.

CAUTION consists of the following elements:

- Information about the nature of a hazardous situation
- Consequences of not avoiding a hazardous situation
- Methods of avoiding a hazardous situation

WARNING

WARNING

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

WARNING consists of the following elements:

- Information about the nature of a hazardous situation
- Consequences of not avoiding a hazardous situation
- Methods of avoiding a hazardous situation

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1 Introduction

This operator manual is an addendum to the operator manual MR system.

This manual may include descriptions covering standard as well as optional hardware and software. The description of an option does not infer a legal requirement to provide it.

The graphics, figures, and medical images used in this documentation are examples only. Their actual display and design may be different on your system. In particular, the screenshots may show the color design of an older user interface.

References to "Siemens Service" include service personnel authorized by Siemens.

All components of the complete operator manual may include safety information that must be adhered to. The intended use of the system is stated in the operator manual MR System.

1.1 Valid systems

This manual is valid for the following systems:

- MAGNETOM Flow.Ace
- MAGNETOM Flow.Ace S
- MAGNETOM Flow.Apex
- MAGNETOM Flow.Plus
- MAGNETOM Flow.Plus Z

Not all MR systems are released for all countries! Contact your Siemens Healthineers Sales Organization about the systems available in your country.

1.2 Manufacturer of your MR system

For the address of the manufacturer and additional legal information, refer to the **Addendum – Regulatory Information, Manufacturer information for your MR system**.

2 General safety information

All safety information in the valid operator manuals must be adhered to without fail. It is merely supplemented by the notes contained in this document.

The following caution applies to MR systems with a Select&GO display:

CAUTION

Accidental patient table movement!

Injury to the patient

- If you plan an intervention outside the magnet, activate the **Table Lock** function at the Select&GO display to avoid accidental patient table movement, or injury to the patient. After completing the intervention, the table can be unlocked.

The following caution applies to MR systems with a Dot display:

CAUTION

Accidental patient table movement!

Injury to the patient

- If you plan an intervention outside the magnet, activate the **Table Stop** button to avoid accidental patient table movement, or injury to the patient. After completing the intervention, the table can be unlocked.

CAUTION

Collision when moving into the magnet!

Injury to the patient

- Carefully pay attention to the patient while moving the patient manually into the magnet bore.
- Do not use the **Center Position** button.

2.1 Employee qualifications

Prior to working with the coil, the employees have to be trained in the correct use of the coil and the biopsy device.

WARNING

Improper handling of the coil and biopsy accessories!

Incorrect diagnosis, bodily injury

- Instruct your employees in the correct use of the biopsy accessories, in particular in the setting of the positioning unit based on the calculated offset data.

  Follow the instructions in this manual, which explicitly explain the procedures and possible hazards.
- Train personnel with phantoms before using the biopsy device on female patients.

2.2 Risks related to incorrect handling of the coil

CAUTION

Damaged biopsy device!

Risk of injury and contamination

- Prior to each use, check all components and individual parts of the biopsy device for damage.
- Use only undamaged components.

WARNING

Breast implants!

Risk of rupture

Risk of damage caused by puncture

- Use the greatest of care when performing biopsies on female patients with breast implants and avoid overcompression.

If a previously enhanced lesion is not visible during the examination using the breast biopsy device, perform a follow-up examination the next day without applying compression.

CAUTION

Anatomy changed through biopsy!

Incorrect image selection/incorrect diagnosis

- After completing the biopsy, do not reuse the old MR reference images for additional biopsies, create new MR images instead.

CAUTION

Lesions/reference markers outside the magnet isocenter! Biopsy software may fail to calculate biopsy data correctly due to geometric image distortion caused by magnetic field inhomogeneities.

Lesion is missed, incorrect diagnosis

- Ensure that both marker and lesion are located as close as possible to the magnet isocenter - possible axial expansions are limited. If necessary, reposition the patient.

CAUTION

Inaccurate detection of the marker tip through unfavorable selection of the slice location!

Incorrect diagnosis

- Post&Pillar method: to select the reference position, select only slices that run parallel to the marker (medial/lateral: transverse slices).
- Grid method: to select the reference position, select only slices that run parallel to the grid (medial/lateral: sagittal slices).
- Measure the slices without slice distance and a slice thickness < 2 mm.
- Check the diameter and length of the marker for plausibility and click the tip of the marker to determine the reference position.

CAUTION

Diameter of the needle guide or needle block is too large! Length of biopsy needle is too short!

Needle is incorrectly positioned

- Use a needle guide (Post&Pillar method) or a needle block (Grid method) that corresponds to the diameter of the needle thickness.
- Use a biopsy needle whose length corresponds to the calculated puncture depth.

CAUTION

The puncture depth of the breast biopsy needles is limited!

Lesion cannot be targeted because the puncture depth depends on the biopsy device used

- Before administering contrast agent to the patient, consider the length of the needle and assess whether the lesion can be reached with the biopsy device used.

CAUTION

Puncture depth is read incorrectly!

Needle is incorrectly positioned

- Take into account the length of the needle block.
- Please consult the documentation provided by your biopsy needle vendor regarding selecting the correct needle depth.

WARNING

Incorrect operation of the biopsy device! Carelessness while inserting the needle!

Injury to the patient

- When inserting the needle, take special care to avoid penetrating the breast completely.
- If you accidentally penetrate the breast completely and the needle touches the opposite grid, do not pull back the needle. This action might bend the distal needle end and could injure the patient. Shorten the distal needle end with an MR Safe or MR Conditional tool and remove the remaining introducer sheath/stylet.

WARNING

Releasing or repositioning of the breast while instruments are still positioned!

Injury to the patient

- Always remove all instruments (for example, needle and trocar) before you move or release the breast of the patient.

WARNING

Use of unapproved biopsy accessories with the breast biopsy coil!

Injury to patient and operating personnel

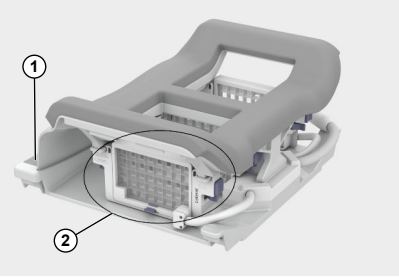
- Only use accessories that are approved for the coil and that are suitable for MR operation (MR Safe or MR Conditional).

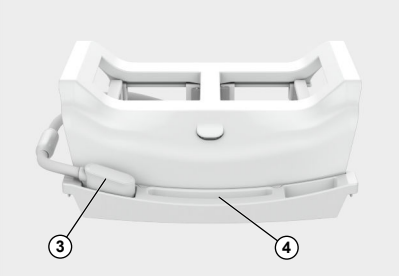
3 Breast BI 7

3.1 Description

You can use the Breast BI 7 for breast imaging and biopsies. The coil can only be used in the head first orientation.

The coil consists of a rigid frame carrier equipped with a rail system. You can position different grids, plates, and frames using the rails. This allows you to use the Breast BI 7 for breast imaging and to perform biopsies (depending on the accessories used).





(1) Coil frame/main coil housing
(2) Frame carrier with lateral coil frame
(3) Coil plug in park position
(4) Carrying handle





Coil frame/main coil housing without adapter frame (right) for use on a system with 60 cm tunnel bore diameter

In case the adapter frame is mounted, it must be removed before positioning the coil.

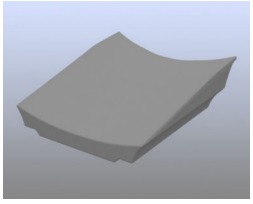
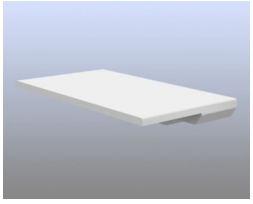
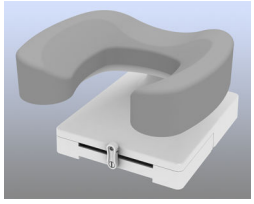
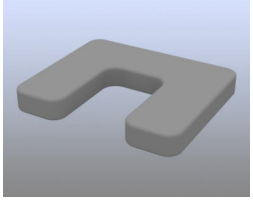
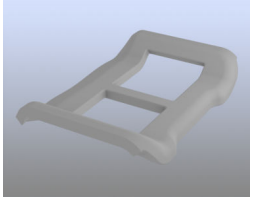
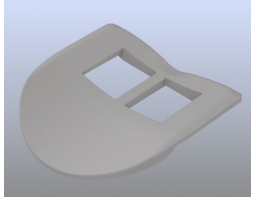
A description of the positioning aids is included in the chapter on accessories. (➔ Page 65 *Coil accessories*)

3.1.1 Coil and biopsy components

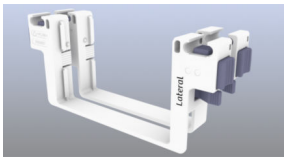
Please note that the scope of delivery from Siemens Healthineers provides biopsy accessories only for training purposes. Accessories for the examination (needles, needle guide, grid, etc.) must be ordered separately, for example, from NORAS MRI products GmbH.

3.1.1.1 Cushions and positioning aids

The following positioning aids are available:

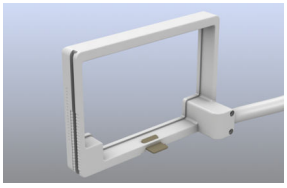
 Body pad 60 (wedge connector 60 Breast 18)	 Table cushion Breast 18	 Head rest Breast 18
 Armrest pad	 Support cushion	 Support cushion, comfort

3.1.1.2 Frame carrier



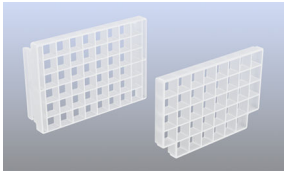
The lateral and medial frame carrier support the coil frame and the available biopsy plates. You can slide the frame carrier onto the rails of the main coil housing. When they are attached, you can adjust the height of the lateral coil frame and the biopsy components.

3.1.1.3 Lateral coil frame



The lateral coil frame is used to attach the lateral biopsy grid, the lateral slat plate, or the lateral fixation plate. The lateral coil frame contains a coil element and a cable. It is permanently connected to the main coil housing. You can attach the lateral coil frame to the lateral frame carrier.

3.1.1.4 Biopsy grids



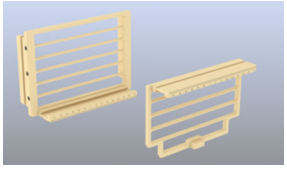
The following biopsy grids are used to stabilize the breast for the Grid method:

- Lateral biopsy grid (fits into the lateral coil frame)
- Medial biopsy grid (fits directly in the medial frame carrier)

The biopsy grids are available as sterile disposable grids for single use.

The needle or marker blocks can be inserted into the individual grid openings.

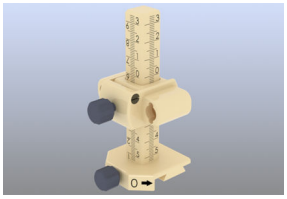
3.1.1.5 Horizontal slat plates (for Post&Pillar biopsy)



The following horizontal slat plates are used to stabilize the breast for the Post&Pillar method:

- Lateral slat plate (fits into the lateral coil frame)
- Medial slat plate (fits directly in the medial frame carrier)

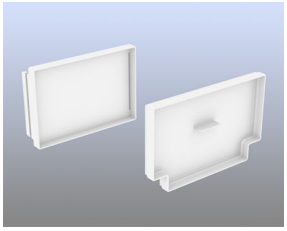
The horizontal scale for positioning the needle is part of the slat plate.



On the horizontal rails of both slat plates, you can attach the positioning unit with the pillar unit (vertical scale). On top of the pillar unit, you can attach the needle-guide unit. The needle guide holds the MR-visible marker as well as all the needles used during the intervention via insertable adapters with different inside diameters. The needles can be attached to both sides of the needle-guide unit.

You can move the needle guide unit vertically on the pillar unit. You can move the pillar unit horizontally on the slat plate. The positions are fixed by screws.

3.1.1.6 Fixation plates

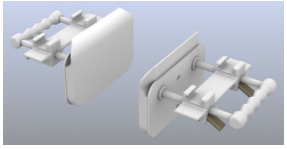


The fixation plates are used to immobilize the breast for breast imaging. They cannot be used for biopsy.

The following fixation plates are available:

- Lateral fixation plate (fits into the lateral coil frame)
- Medial fixation plate (fits directly in the medial frame carrier)

3.1.1.7 Cranio-caudal fixation unit

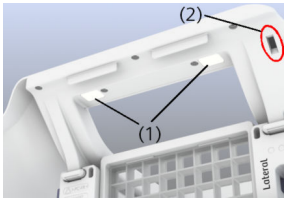


The cranio-caudal fixation unit consists of two identical elements that are positioned on the rails of the coil frame. You can push the plates toward the breast to immobilize the breast in the cranio-caudal direction.

The cranio-caudal fixation unit can be used in imaging to reduce the number of necessary slices.

3.1.1.8 LED Illumination

The coil is equipped with LEDs for illuminating the interventional area. Two LEDs are located on each lower side (left and right) of the main coil housing. The LEDs are controlled by a proximity sensor. As soon as the coil is connected to the system, you switch the LEDs on and off by touching the sensor or by swiping in front of the sensor (max. 1 cm distance).



(1) LEDs for illumination
(2) Sensor to switch the LEDs on and off

3.2 Breast imaging

3.2.1 Use

This coil is used only with the body pad 60 and without a spine coil.

CAUTION

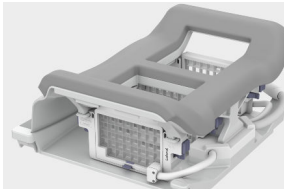
Improper handling of the coil!

Damage to the coil

- *Never* carry the coil by holding the coil cable or the lateral coil frame. To carry the coil, grasp the outer wings of the main coil housing or use the carrying handle.
- Do not tie knots in the coil cable.

3.2.1.1 Preparing the coil

1 Position the support cushion on the coil frame.

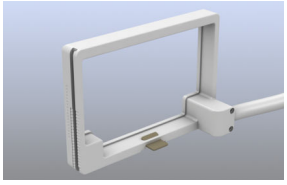


2 Slide the frame carriers onto the rails of the main coil housing.



To unlock the frame carrier and to shift the carrier to the required position, push the upper blue gray levers on the sides.

As soon as you release the blue gray levers, the frame carrier is automatically locked on the rails.



3 Attach the lateral coil frame to the frame carrier.



If necessary, use the lower levers on the sides of the frame carrier to unlock the lateral coil frame and to adjust the height of the lateral coil frame.

4 To immobilize the breast of the female patient, position the necessary accessories (biopsy grids, horizontal slat planes for Post&Pillar biopsy, or fixation plates) depending on your examination. (➔ Page 24 *Preparing the biopsy accessories*)

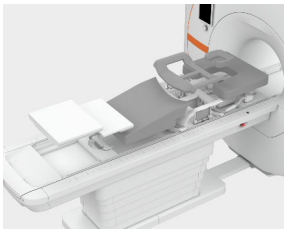
3.2.1.2 Positioning the coil

On systems with 60 cm tunnel bore diameter, you must use the breast coil without a spine coil, without the adapter frame, and only in the head first orientation. Due to the reduced tunnel bore diameter you must observe the increased risk of entrapment for the patient.

The bore diameter of your system is specified in the introduction.

✓ On systems with 60 cm tunnel bore diameter: The spine coil is removed from the table. The adapter frame is removed from the coil frame/main coil housing.

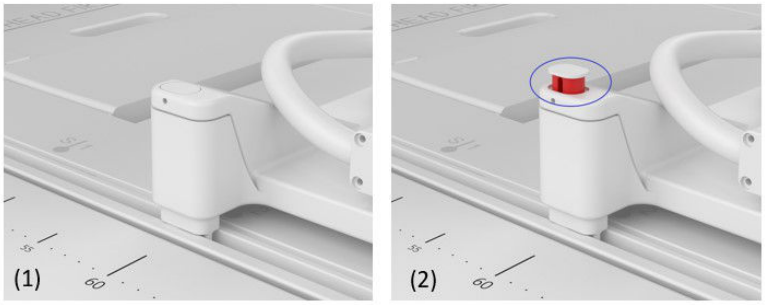
The following pictures show the use on a system with 60 cm tunnel bore diameter.



1 Position the coil frame on the patient table so that the detents at the bottom of the coil frame slot into the recesses of the T-shaped groove.

Make sure that the detents of the coil are positioned correctly in the T-shaped groove so that the coil and the female patient cannot fall off the table.

If the detents of coil are positioned in the T-shaped groove of the table, but not locked within the recess for the defined z-position, a pivot with a red marking protrudes on the left side of the coil.



(1) Detent locked into the recess of the T-shaped groove (pivot not visible)
(2) Detent in the T-shaped groove but not locked in the z-position recess (pivot with red marking visible)



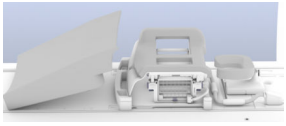
2 Ensure that the detent pin on the left side of the coil frame audibly engages in the corresponding z-position recess on the patient table. The pivot with the red marking must not be visible. If necessary, move the coil in z-direction (along the table) to find the correct position where the detent engages.

On systems with 60 cm tunnel bore diameter:

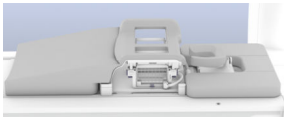
Do not position the detent pin on the left side of the coil frame in the corresponding z-position recess on the patient table. Instead, move the coil approx. 10 cm toward the head end of the patient table to provide enough space between the coil and the coil sockets for the spine coil to insert the body pad 60 and the table cushion Breast 18.

When positioning the Breast BI 7, make sure that the body pad 60 and the table cushion Breast 18 are used together. This fixes the Breast BI 7 in the z-position even without insertion of a detent pin in the corresponding recess.

3 Connect the plug of the coil frame to socket 1 or 2 (head first).



4 Place the head rest in front of the coil housing and the body pad 60 at the rear of the coil housing.



5 Place the armrest pad around the head rest.

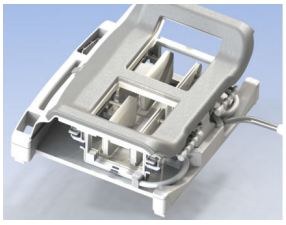
6 Use any further positioning aids and cushions best suited for the current situation.

Positioning the cranio-caudal fixation unit

You can use the cranio-caudal fixation unit in imaging to immobilize the breast in the cranio-caudal direction.

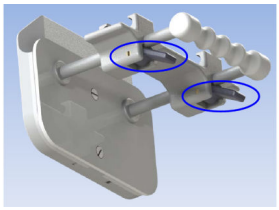
This immobilization may reduce motion artifacts and may optimize the shape of the breast for transverse MR images. It may also reduce the measurement time, as fewer transverse slices will be needed to scan both complete breasts.

1 Completely remove the medial frame carriers.



2 Slide both elements of the cranio-caudal fixation unit laterally onto the rails of the main coil housing. Ensure that the plate is located facing the breast.

3 On the side facing the breast, insert special cushions to accommodate different breast sizes, if necessary. You can also adjust their height.



4 Push the plates of the cranio-caudal fixation unit toward the breast and push down the gray levers to lock them into position in the cranio-caudal direction.

5 To lock the cranio-caudal fixation units in the lateral direction, slide the lateral frame carriers as far as possible onto the rails of the main coil housing. See: (➔ Page 24 *Preparing the biopsy accessories*)

3.2.1.3 Positioning the female patient



1 Position the female patient in the prone position with the breasts in the recesses.



2 When positioning the patient with the arms above the head: Position a suitable pad between the hands to avoid current loops.

3 Use suitable positioning aids.

3.2.1.4 Performing the measurement

1 Align the laser-light localizer with the center marking of the coil or use the system display to position the table.

2 Start the measurement.

3.2.2 Quality measurement

The quality measurement of the coil is performed in the head first orientation.

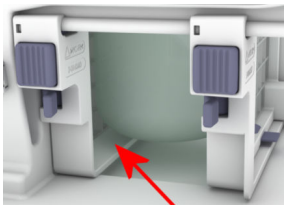
✓ On systems with 60 cm tunnel bore diameter: The spine coil is removed from the table. The adapter frame is removed from the coil frame/main coil housing.

1 Position the Breast BI 7 at the head end of the patient table and connect the coil plug to socket 1 or 2.

2 Attach the frame carriers with the lateral coil frames.



3 Position the biopsy grids, the horizontal slat planes, or fixation plates to stabilize the phantom bottles laterally. Position two 1900 ml plastic bottles, each between the medial and the lateral grid/slat plate.



4 Push the frame carriers with the lateral coil frames all the way in, until the bottles are in the most medial position. Position the bottles on the bottom struts of the (inner) medial frames, so that the bottles do not touch the bottom of the coil.

5 Align the laser-light localizer with the center marking of the coil.

6 Start the quality measurement. Please refer to the **Operator Manual MR System and Coils - Performing quality assurance (software).**

3.3 Biopsy examination

3.3.1 Biopsy - general

You can localize lesions using the Post&Pillar or the Grid method. The lesions can be accessed medially or laterally.

The following biopsy methods are used frequently:

- Wire localization (open biopsy)
- Vacuum biopsy (fully MR guided)
- Setting of clips
- Fine-needle aspiration biopsy

3.3.1.1 Procedure

Access to the lesion to be biopsied is based on diagnostic pre- and post-contrast images of the immobilized breast. Based on the images, the coordinates of the lesions and/or their position in the biopsy device (Grid or Post&Pillar) are determined, and access to the lesions is planned.

For *wire localization* a thin, core needle device (18G/20G) with inserted marking wire is introduced into the breast. After the control scan, the needle device is removed while the marking wire remains until an open biopsy is performed on the lesion. Correct positioning of the hook ensures free patient movement, eliminating the need for positioning shortly before the actual operation.

When performing a *vacuum biopsy*, a combination of introducer sheath and sharp-pointed stylet (trocar) is inserted into the breast. When the calculated lesion position has been reached, the stylet is replaced by a synthetic needle (obturator) followed by a control scan to check the biopsy channel. Subsequently, the obturator is removed and the biopsy is performed by inserting the biopsy needle in the introducer sheath.

Clips can be deployed through the introducer sheath (depending on the biopsy device marker) after the biopsy or similar to wire placements.

When performing a *fine-needle aspiration biopsy*, a thin (23-25 gauge) core needle is introduced into the breast. The tissue cells are withdrawn by aspiration with a syringe.

3.3.2 Preparation

All interventions for preparing and performing the biopsy are performed outside the magnet. The female patient remains on the patient table at all times.

The following items should be explained or known prior to a biopsy:

- The lesion has been pre-localized through previous measurements.
- The access path has been selected (lateral or medial).

Some of the biopsy accessories are only available as disposable items for single use (for example, the grid) while others are available as a reusable component (for example, the slat plates for Post&Pillar biopsy). Of course, all components must meet the hygiene requirements.

3.3.2.1 Preparing the biopsy accessories

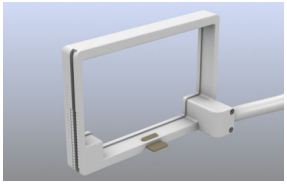
Prior to the examination, the biopsy accessories have to be assembled. The configuration depends on the method selected.

CAUTION

Frame carriers are seated incorrectly on the rails of the main coil housing!

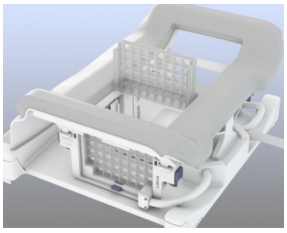
Risk of injury

- Slide the frame carriers onto the rails of the main coil housing so that the levers to operate the frame carriers point outward (not to the breast).



Cover the area of the clip and the grooves on the lateral coil frame with cloth or paper to prevent contamination with blood of this area during biopsy. If blood has seeped into the clip area cleaning is difficult and would potentially make it necessary to disassemble the clip.

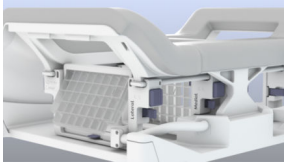
Preparing the grid



1 Slide the medial frame carrier onto the rails of the main coil housing (on the medial side) and insert the medial biopsy grid from above into the medial frame carrier.

– or –

Clip the medial biopsy grid directly in the medial frame carrier and slide the medial frame carrier onto the rails of the main coil housing (on the medial side).



2 Slide the lateral frame carrier onto the rails of the main coil housing (on the lateral side).

Insert the lateral biopsy grid in the lateral coil frame: Using a tilted position, first insert the top of the grid, then push the lower side into the coil frame.

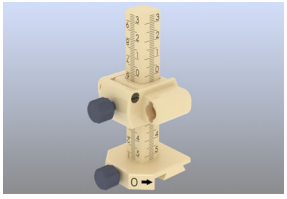


3 Adjust the positions of the frame carriers on the rails of the main coil housing: Push the upper blue gray levers on the sides and shift the carrier.

Position the medial frame carrier under the middle bar of the main coil housing and the lateral frame carrier in an outer position. Ensure that the space between the frame carriers is sufficient for the size of the breast to be examined.

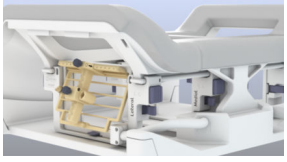
Preparing Post&Pillar biopsy

✓ The lateral slat plate and the medial slat plate are disinfected.



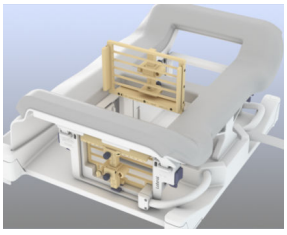
1 Attach the needle-guide unit to the pillar unit.

2 Slide the pillar unit with the needle-guide unit onto the lateral slat plate (for lateral access) or onto the medial slat plate (for medial access).



3 Slide the lateral frame carrier onto the rails of the main coil housing (on the lateral side).

Insert the lateral slat plate in the lateral coil frame: Using a tilted position, first insert the top of the slat plate, then push the lower side into the coil frame.



4 Slide the medial frame carrier onto the rails of the main coil housing (on the medial side) and insert the medial slat plate from above into the medial frame carrier.

– or –

Clip the medial slat plate directly in the medial frame carrier and slide the medial frame carrier onto the rails of the main coil housing (on the medial side).



5 Adjust the positions of the frame carriers on the rails of the main coil housing: Push the upper blue gray levers on the sides and shift the carrier.

Position the medial frame carrier under the middle bar of the main coil housing and the lateral frame carrier in an outer position. Ensure that the space between the frame carriers is sufficient for the size of the breast to be examined.

3.3.2.2 Positioning the female patient

✓ Intravenous drip in the arm is applied for contrast medium and/or sedative. Please note: The administration of sedatives is subject to the judgment of the physician.

✓ Coil, frame, and biopsy accessories are positioned.

✓ Skin of the female patient is disinfected.

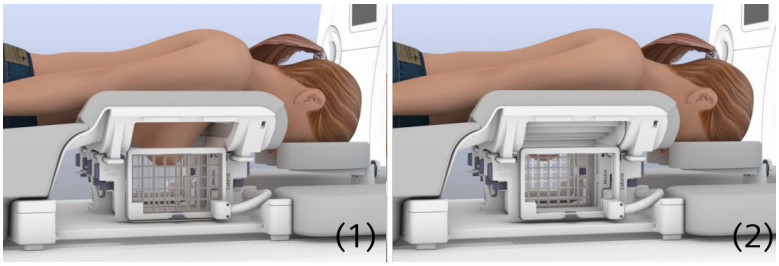
✓ Female patient received local anesthesia.

1 Ensure that the space between the frame carriers is sufficient for the size of the breast to be examined.

2 Place crepe paper to prevent soiling of the coil.

3 Position the female patient on the coil in the prone position.

4 Position the respective breast in the recess.



(1) Patient positioning for lateral access
(2) Patient positioning for medial access

5 Position the head of the female patient on the head rest.

6 Use positioning aids best suited for the current situation. Ensure that the patient lies as comfortable as possible.

Positioning the breast

The lesion should be centered inside the immobilization device to ensure optimal access.

1 When the lesion is located close to the mamilla, position only the mamilla so that the lesion is easily accessible.

2 For lateral access: If the lesion is located near the axillary tail, use straps at the elbow to elevate the arm on the puncture side.

3 For medial access: Insert the breast elevation plate into the main coil housing on the opposite site of the examined breast, so that the other breast does not restrict free access to the lesion.

4 If necessary, optimize the height of the grids or the slat plates.

Compressing the breast

CAUTION

Unsuitable breast compression!

Overcompression may lead to injury of the breast; with undercompression the breast remains movable and the biopsy target may be missed

Incorrect diagnosis due to insufficient contrast enhancement

- Apply just enough compression to immobilize the breast, but do not cause pain to the female patient and ensure that contrast enhancement is continued correctly.

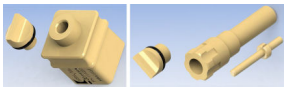
1 Carefully slide the frame carriers with the grids or slat plates together to compress the area of the breast to be examined.

2 Adjust compression to stabilize the breast during needle insertion, but avoid overcompression.

3.3.2.3 Attaching the marker

The marker must only be used to establish the reference position for needle insertion. The marker must be filled with diluted MRI contrast medium to make it visible in the MR image.

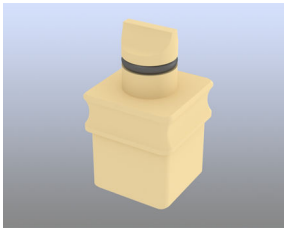
✓ Marker is disinfected.



1 Open the closing cap of the marker.

2 Slowly fill the marker using a syringe (for example, with 1:200 diluted 0.5 molar contrast medium). Rotate the syringe during filling to prevent the formation of bubbles. Ensure that the marker is filled completely.

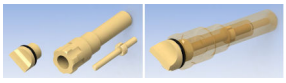
Positioning the marker block in the grid



1 Close the cap of the marker.

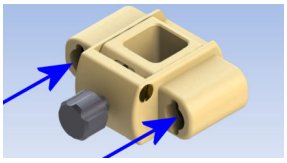
2 Position the marker block in a grid opening. A central position in the grid (C4) is recommended to identify the marker more easily.

Attaching the marker for Post&Pillar biopsy

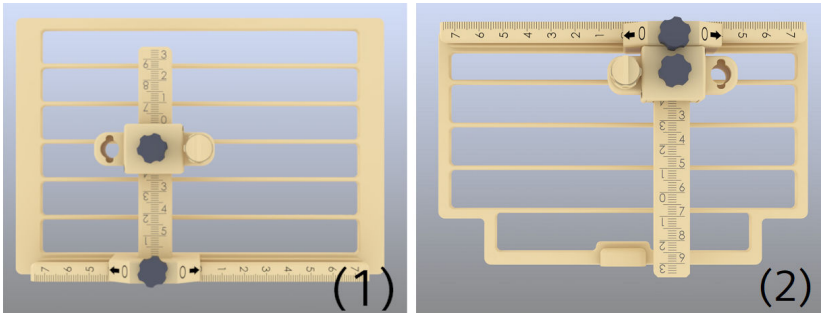


1 Slowly immerse the inset (small rod) into the previously filled and open marker as far as it will go. The end with the shorter bar is inserted first.

2 Close the cap of the marker.



3 Screw the filled marker into one of the holes of the needle guide (on the left or right side).



(1) Medial access: horizontal zero position
(2) Lateral access: horizontal zero position

4 Set the positioning unit with the needle guide to the zero position.

- Move the vertical pillar unit along the horizontal scale of the slat plate. Ensure that the zero point on the horizontal scale is on the same side of the vertical pillar as the marker. Tighten the screw of the vertical pillar unit to fix it in the horizontal position.
- Move the needle-guide unit on the vertical pillar unit and set the zero point on the vertical scale. Ensure that you use the scale with the legible numbers (not the scale with the upside down numbers). Tighten the screw of the needle-guide unit to fix it in the vertical position.
- Set the angle of the needle/marker holder to zero.

3.3.3 Post&Pillar method

With the Post&Pillar method, the lesion is sighted with the positioning unit. For this purpose, the pillar unit and the needle guide with the marker is initially set to zero. A scan is used to determine the target coordinates of the location of the lesion which are then set at the positioning unit. Then, either the introducer sheath/trocar combination (vacuum biopsy) or the core needle device (wire localization/clip) is inserted through a adapter at the positioning unit.

CAUTION

Setting error during the Post&Pillar method!

Incorrect diagnosis

- Ensure that the positioning unit is set to zero and fully inserted before determining the offset data.
- Fully attach the marker with screws.
- Later on position the needle on the same side as the marker was located on.

The following describes the examination sequence for a vacuum biopsy of the breast. The lesion is accessed in the lateral direction in the *head first* orientation.

✓ All necessary disinfections or sterilizations have been performed.

✓ Coil and biopsy accessories are positioned on the patient table.

✓ Bottom of the coil is covered with absorbent material.

✓ Female patient is positioned.

✓ Breast is immobilized.

✓ Marker is attached to the positioning unit of the pillar unit. Pillar unit with the needle guide is in the zero position.

3.3.3.1 Registering the female patient

✓ **Patient Browser (Scheduler)** is open.



1 On the toolbar of the **Patient Browser (Scheduler)**, click the **Add Patient** icon.

A new item in the **Patients** list is created and an empty **Patient Registration** tab opens.

2 Enter the required patient data in the **Patient Registration** tab.

Mandatory fields are marked by an asterisk *****.

Ensure that the correct *patient position* has been selected.

3 Select a measurement program in the **Program Selection** tab.

– or –

Select the **Breast Biopsy** program (e.g. Breast > Breast Assist > Biopsy).

The **Breast Biopsy** program includes a proposal of program steps, depending on the selected settings in the **Patient View** (for example, examination strategy).

4 To save the data and start the examination, click the **Exam** button.

For more information about patient registration, see: **Operator Manual - MR Examination and Review.**

3.3.3.2 Performing measurements

To plan the actual access to the lesion, the following measurements and evaluations are necessary:

- Localizer
- Pre and post-contrast imaging of the immobilized breast

◆ Prior to the measurement, ensure that the pillar unit with the needle guide is in the zero position.

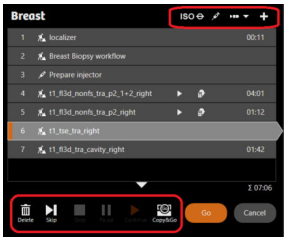
Measuring the localizer

1 Position the laser-light localizer on the center marking of the coil.



2 Move the table and the patient to the isocenter of the magnet with this icon.

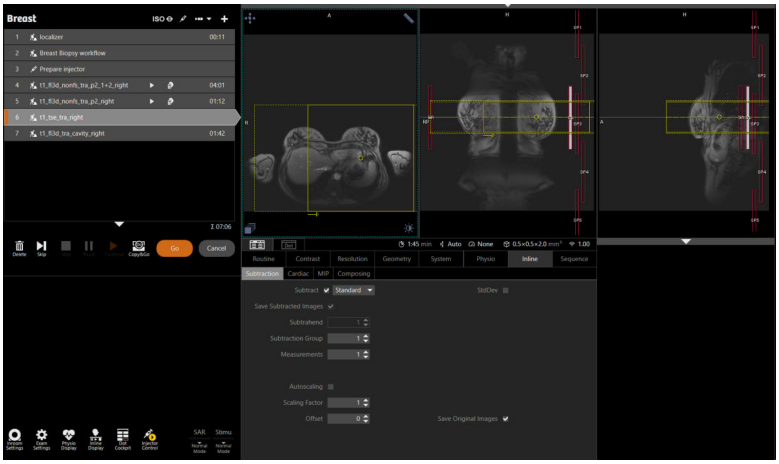
For systems with Select&GO display: You can also use the Select&GO display to position the table.



If **Load Program to Queue** or the **Breast Biopsy** program was selected during registration, the related program steps are already displayed in the queue and localizer scanning is started automatically. If necessary, you can modify the measurement program. The toolbar of the program control offers various functions for modifying the measurement programs in the queue.

For detailed information on managing protocols, see: **Operator Manual - MR Examination and Review.**

3 Start the localizer.



When the localizer has been completed, the resulting images are displayed in the GSP segments.

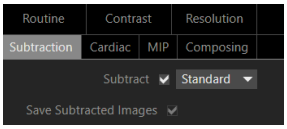
Breast biopsy protocols use 3D distortion correction for biopsy planning. This requires greater slice coverage to adequately cover the marker and anatomy.

Ensure that both marker and lesion are located as close as possible to the magnet isocenter. In the **Table Positioning Strategy** dialog, use **Iso Center** or adjust the **Local Range** accordingly.

Performing precontrast and postcontrast imaging

The next step is usually a short dynamic measurement comprising one precontrast scan and two postcontrast scans.

1 Select a suitable 3D protocol to perform a measurement with transverse slices.



2 Activate **Subtract** on the **Inline\Subtraction** parameter card of the protocol.

3 Position the 3D imaging volume in the localizer images.

Do NOT use oblique slices!

Biopsy coordinates can only be calculated manually with non-angled slices.

4 Start the pre-contrast measurement.

5 Administer the contrast medium.

6 Start the post-contrast measurement.

Subtraction images are automatically computed and facilitate locating the lesions.

3.3.3.3 Planning access to the lesion (using the MR Breast Biopsy application)

To plan access to the lesion you can use the advanced application **MR Breast Biopsy**.

- If you have used the **Breast Biopsy** program for the examination, the **MR Breast Biopsy** application opens automatically and the measured images are loaded as soon as the program step **Plan Biopsy** has been completed.
- If you have used an individual measurement program, you manually load the measured images from the **Patient Browser (Local Data)** and open the data with the **MR Breast Biopsy** application.

To ensure an adequate accuracy of the calculated target values, use the following values:

- Pixel size ≤ 1 mm
- Bandwith (3T) ≥ 300 Hz/px
- Bandwith (1.5T) ≥ 150 Hz/px

✓ **MR Breast Biopsy** application is open and images are loaded.

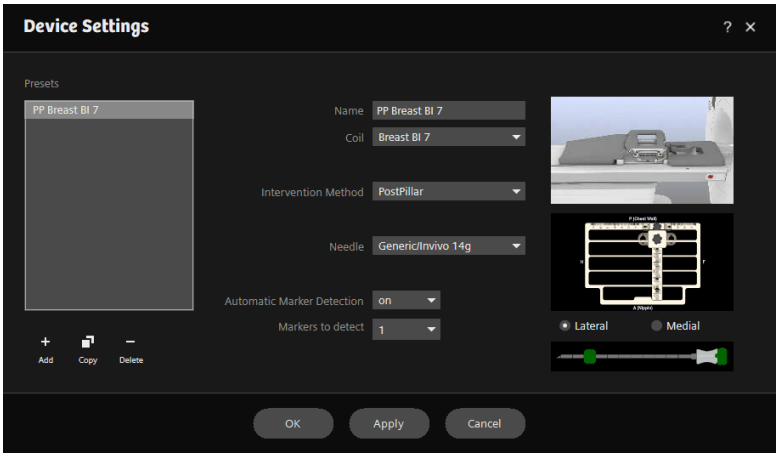
✓ **Calibration** step is open.

Configuring the device setting

If you are using the **MR Breast Biopsy** application for the first time, you will need to enter some data to define the biopsy device that you are using (for example, coil, biopsy method, and needle). Once defined, you can use the preset for all subsequent examinations that use the same biopsy device.

1 In the **MR Breast Biopsy** step, click this icon to open the **Device Settings** dialog box.

2 Click the **Add** icon to create a new preset.



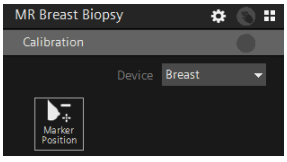
3 Enter the necessary data in the fields of the **Device Settings** dialog box:

- **Preset**: Enter a name for the preset.
- **Coil**: Select the Breast BI 7 coil.
- **Intervention Method**: Select **PostPillar**.
- **Needle**: Select the needle used for the biopsy.
- **Automatic Marker Detection**: If activated, you can also choose whether one or two markers should be detected.

4 Click the **OK** button to confirm the settings and save the preset.

Once the preset of a specific device setting has been defined, that preset is available for further examinations. You can directly select the preset in the **Device** list of the **Calibration** step.

Calibration step: Determining the marker position



By default, the preset of the last **Device** that was used is selected. If necessary, you can change the device settings accordingly.

The selected biopsy device and its components are shown in the lower-left segment. The slat plate, pillar unit, and the needle are shown as figures.

✓ **Calibration** step is open.

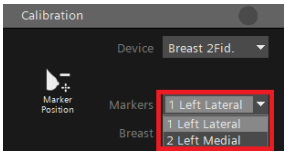
✓ Device settings are already configured.

✓ The **Device** preset for the Post&Pillar examination with the Breast BI 7 coil is selected.

✓ Layout for Post&Pillar device is selected.

If **Automatic Marker Detection** is activated in the selected **Device** preset, automatic detection starts when the **Calibration** step is opened. This is indicated by a progress bar.

As a result, the examination parameters and details about the detected marker are displayed in the **Calibration** step and the image segments are updated accordingly.

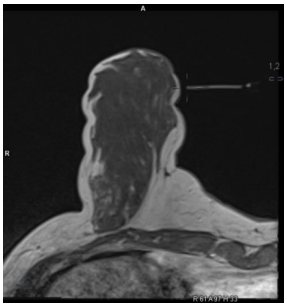


If a second marker is used and configured in the **Device** preset, a list with both markers is displayed. The image segments are updated depending on which marker is currently selected from the list.

1 For an automatically detected marker: Check that the position of the selected marker in the images is correct.

2 To change the position of an automatically detected marker or to manually define a marker position, click the **Marker Position** icon.

The icon name changes to **1. Select Marker** and the mouse pointer is displayed as crosshairs: 



3 The marker is visible as a straight line on the non-subtracted images.

In the segments, go through the image stack of the non-subtracted images and select the image that best shows the marker in full (including the marker tip).

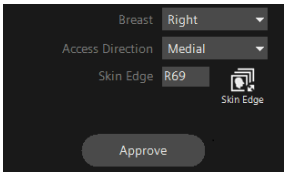
4 Move the mouse pointer across the image to the position of the marker tip and click to select the tip of the marker. To change the position, click again, or move the crosshairs to the correct position.

Once you have clicked in the image, the icon name again changes its name to **2. Approve Marker**.

5 Click the **2. Approve Marker** icon to confirm the position of the marker.

The shape of the mouse pointer changes to a yellow arrow and the edge of the skin is indicated by a pink line.

The examination parameters are shown in the step.



6 Check the examination parameters (**Breast**, **Access Direction**) and correct them, if necessary.

7 The **Skin Edge** parameter shows the gap between the marker tip and the skin of the patient.

To adjust the **Skin Edge**, click the **Skin Edge** icon and reposition the line in the images. Drag the line to the position of the skin surface and click the **Approve Skin Edge** icon to confirm the position.

8 Click the **Approve** button to complete the settings of the **Calibration** step.

The **Target Selection** step opens.

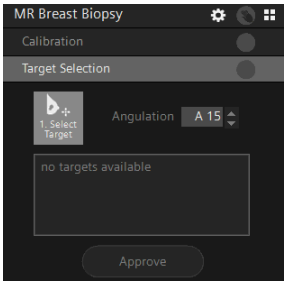
9 If required, you can select the **Calibration** step at any time and click the **Modify** button to change the calibration settings.

Target Selection step: Determining the lesion position

In this step, you plan the targets for the access direction that you previously defined in the **Calibration** step by selecting the marker position.

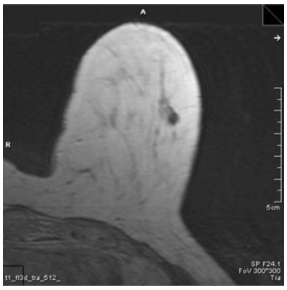
✓ **Calibration** step is approved.

✓ **Target Selection** step is open.



The icon **1. Select Target** is active and the mouse pointer is displayed as crosshairs: 

1 Go through the image stack and select the image that shows the lesion in full. If necessary, enlarge the segment by double-clicking the image. Double-click the image again to reduce it to the previous size.

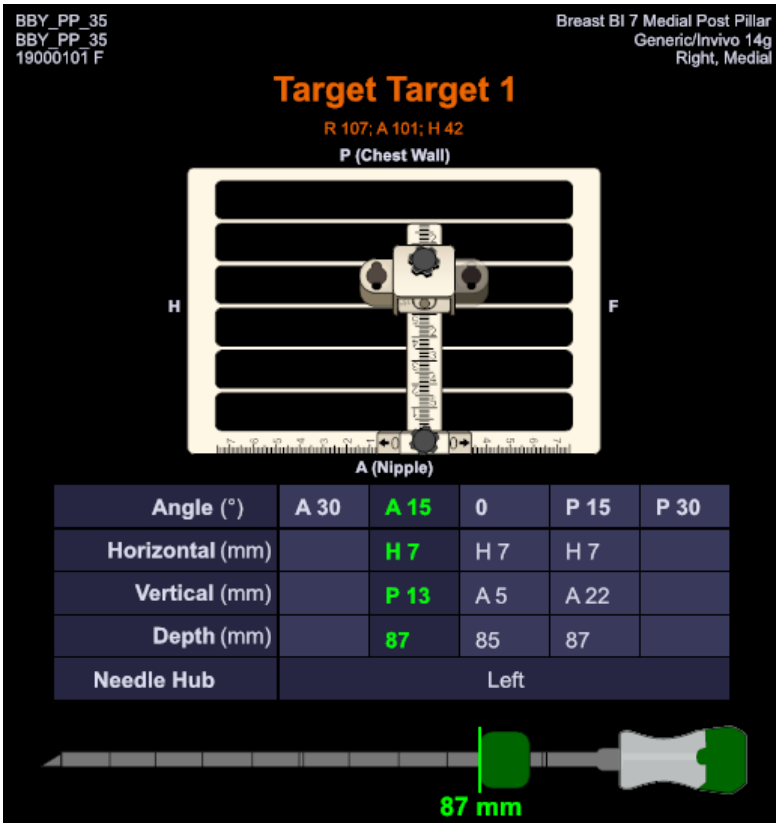


The lesion is visible on the subtracted images, in the second segment.

2 Move the mouse pointer across the image and click the position in the lesion that you want to target.

3 If necessary, select **Angulation** and enter an angle position for the needle-guide unit.

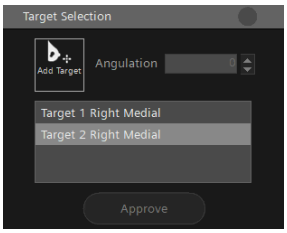
As soon as you click a position in an image, the target position values for the settings of the pillar unit are shown in the lower left segment.



Example: Target values for Post&Pillar settings using the Breast BI 7 coil

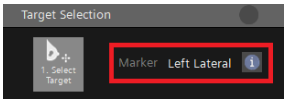
If the lesion is not accessible with the current device setting, the message **Target not reachable** is shown in the lower left segment. In this case, check your workflow and, if necessary, reposition the biopsy device or patient.

4 Click the **2. Approve Target** icon to determine the lesion position.



5 If required, you can click the **Add Target** button to create an additional lesion. Proceed as described above. The different targets are displayed as a list and can be sent individually to the display in the examination room.

To delete a target from the list, select the target in the list, right-click and choose **delete selected target**.



6 To plan a second access direction to the lesion, go back to the **Calibration** step and click the **Modify** button. Then select or create a second marker, check and approve the new **Calibration** settings (as already described above).

Afterward select the targets for this access direction. The currently selected approach is displayed in the **Target Selection** step and in the target name.

7 Click the **Approve & Send** button to complete the lesion detection.

A finding of the target position is created. The finding includes snapshot images of the segments.

Additionally, the result segment with the target values for the biopsy device settings is displayed on the system display in the examination room. The system display shows the last target confirmed with **Approve & Send** or the target explicitly sent from the list with **Send**. The target shown in the display is marked "(on display)" in the target list.

You can also document the target values in a worksheet. A master copy of the pillar unit to document the settings is available in the appendix of this manual.

Now you can perform the intervention. See chapter: *Performing the intervention*

3.3.3.4 Planning access to the lesion (manually)

As an alternative to planning with the advanced application **MR Breast Biopsy**, you can determine the target coordinates manually.

The following steps are required for planning access to the lesion manually:

- Determine the position of the marker tip
- Determine the position of the lesion
- Calculate and document the coordinates

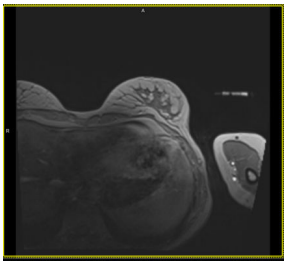
Determining the marker position

✓ Images with spatial information are loaded in the **MR View&GO** application.

1 Select the **Viewing** step.

2 Choose an appropriate layout (for example, 2x2 layout).

3 In the segments, choose a 2D display type from the bottom left corner menu.



4 Load the non-subtracted images, for example, into the first segment.

The marker is visible as a straight line on the non-subtracted images.

5 Go through the image stack and select the image that shows the marker in full (including the marker tip). If necessary, enlarge the segment by double-clicking the image. Double-click the image again to reduce it to the previous size.



6 On the marker image, choose **Pixel Lens** from the upper right corner menu.

The mouse pointer is displayed as crosshairs: 

7 Move the mouse pointer across the image to the position of the marker tip and click to select the tip of the marker.

The position values are shown next to the pixel lens marker.



The pixel lens only shows the pixel coordinates if the **Viewing** step is selected in the **MR View&GO** and if MR images with spatial information are loaded and a 2D view is selected.

Otherwise, the pixel lens shows only the grayscale value and you cannot determine the biopsy coordinates.

---

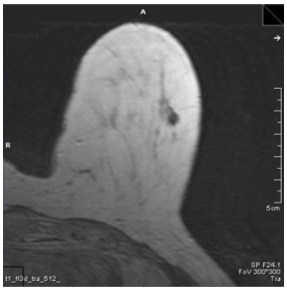
8 Note the coordinates of the marker tip (for example, L15 A10 F20). Document the coordinate values of the pixel lens measurement. You can also create snapshot images to document the coordinates.

A master copy of a worksheet to document the coordinates is available in the appendix of this manual.

Determining the lesion position

✓ Images with spatial information are loaded in the **MR View&GO** application.

1 Select the **Viewing** step.



2 Load the subtracted images, for example, into the second segment.

3 Go through the image stack and select the image that shows the lesion in full. If necessary, enlarge the segment by double-clicking the image. Double-click the image again to reduce it to the previous size.



4 On the lesion image, choose **Pixel Lens** from the upper right corner menu.

The mouse pointer is displayed as crosshairs: 

5 Move the mouse pointer across the image and click the position in the lesion that you want to target.

The position values are shown next to the pixel lens marker.

The pixel lens only shows the pixel coordinates if the **Viewing** step is selected in the **MR View&GO** and if MR images with spatial information are loaded and a 2D view is selected.

Otherwise, the pixel lens shows only the grayscale value and you cannot determine the biopsy coordinates.

---

6 Note the coordinates of the lesion (for example, L5 A20 H5). Document the coordinate values of the pixel lens measurement. You can also create snapshot images to document the coordinates.

A master copy of a worksheet to document the coordinates is available in the appendix of this manual.

Calculating coordinates

You need to determine the coordinates of the marker tip and the lesion in order to calculate the necessary settings of the positioning unit with the needle guide:

The distance between marker and lesion is calculated in three directions.

Horizontal offset H/F (head/feet)	Transverse direction Horizontal adjustment of the pillar unit (head or feet direction)
Vertical offset A/P (anterior/posterior)	Coronal direction Vertical adjustment of the needle-guide unit (to the breast wall or the mamilla)
Puncture depth L/R (left/right)	Sagittal direction Insertion depth of the core needle device (from the slat plate to the lesion)

1 Use the transverse H/F values of the pixel lens coordinates to calculate the **horizontal offset** between the marker tip and the lesion.

2 Use the coronal A/P values of the pixel lens coordinates to calculate the **vertical offset** between the marker tip and the lesion.

3 Use the sagittal L/R values of the pixel lens coordinates to calculate the **puncture depth** between the slat plate and the lesion.

The puncture depth corresponds to the distance between the slice positions.

4 Document the calculated offset data in a worksheet. A master copy of a worksheet to document the coordinates is available in the appendix of this manual. See: *Appendix: Master Copies*

Calculation examples

◆ Calculate the offsets by adding or deleting the coordinate values of the pixel lens:

- If the marker and lesion both extend in the same direction, subtract the values.
- If the marker and lesion extend in different directions, add the values.

The direction is determined by the lesion. Check the lesion position relative to the marker and choose the offset direction so that it is in the lesion direction.

Calculating the horizontal offset (transverse H/F values)

Example 1:	Marker tip: H20 Lesion: H8	20 - 8 = 12 Offset in the feet direction, as (relative to the marker) the lesion is in the feet direction.
Example 2:	Marker tip: F12 Lesion: F30	30 - 12 = 18 Offset in the feet direction, as (relative to the marker) the lesion is in the feet direction.
Example 3:	Marker tip: F6 Lesion: H13	13 + 6 = 19 Offset in the head direction, as (relative to the marker) the lesion is in the head direction.

Calculating the vertical offset (coronal A/P values)

Example 1:	Marker tip: A20 Lesion: A8	20 - 8 = 12 Offset in the posterior direction, as (relative to the marker) the lesion is in the posterior direction.
Example 2:	Marker tip: P12 Lesion: P30	30 - 12 = 18 Offset in the posterior direction, as (relative to the marker) the lesion is in the posterior direction.
Example 3:	Marker tip: P6 Lesion: A13	13 + 6 = 19 Offset in the anterior direction, as (relative to the marker) the lesion is in the anterior direction.

Calculating the puncture depth (sagittal L/R values)

Example 1:	Marker tip: L20 Lesion: L8	20 - 8 = 12
Example 2:	Marker tip: R12 Lesion: R30	30 - 12 = 18
Example 3:	Marker tip: L6 Lesion: R13	13 + 6 = 19

3.3.3.5 Performing the intervention

CAUTION

Wrong settings of the biopsy device (for example, needle stopper)!

Lesion is missed, incorrect diagnosis

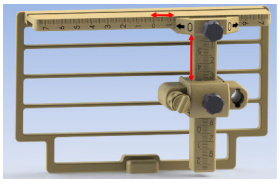
- Ensure that the settings of the biopsy device are the same as those displayed on the system display.
- If necessary, print out the result image with the target position values on paper to check the calculated values against the current settings of the biopsy device.

✓ Position of the lesion and corresponding target settings on the biopsy device have been determined.

Setting the offset data on the positioning unit

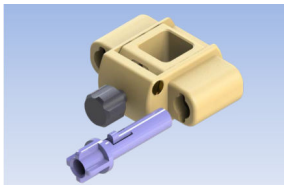
✓ The offset data has been determined and shown on the system display or documented in your worksheet.

1 Use the table movement buttons to move the table with the patient out of the magnet. Do NOT move the table to the Home position.



2 Set the horizontal and vertical offset data on the positioning unit as shown on the system display or as documented in your worksheet.

Always read the values of the horizontal scale from the side of the vertical scale. For this purpose, always use the values shown on the side of the marker or subsequently on the side of the needle holder.



3 Remove the marker from the needle guide on the positioning unit and replace the marker with a suitable adapter that corresponds to the thickness of the needle used. Insert the adapter and turn it clockwise to fasten it inside the hole.

4 Ensure that the adapter is firmly attached and is located on the same side of the vertical Post&Pillar unit as the marker previously was.

Inserting the introducer sheath/core needle

Once the needle block is positioned in the grid, you apply the sterile needle set. To perform a vacuum-assisted biopsy you use a needle set that usually consists of the following components:

- *Introducer sheath*/*Core needle*: The introducer sheath or core needle will be used as the biopsy channel to guide the biopsy needle.
- *Trocar*/*Stylet*: The sharp-pointed trocar or stylet is used to position the introducer sheath in the breast.
- *Obturator*: The obturator is used for the control scan to verify the correct position of the introducer sheath/core needle.

1 Position the trocar in the introducer sheath.

To insert the introducer sheath with the trocar into the lesion, you need to know the puncture depth. If you have used the MR Breast Biopsy application, the puncture depth is shown as the **Needle Stopper** position.

If you have *manually* determined the puncture depth, different values have to be added to the puncture depth for wire localizations to position the wire correctly. A typical value to add is 2 cm. Follow the needle manufacturer's instructions.

---

2 Insert the introducer sheath with the trocar into the adapter in the needle guide on the positioning unit and move both forward in the adapter by the puncture depth shown on the system display.

If you have *manually* determined the puncture depth, remember to include the length of the length of the needle guide (40 mm).

Checking the position of the introducer sheath/ core needle

After you have inserted the introducer sheath/core needle into the breast, you need to verify the correct position and puncture depth.

1 You first remove the trocar and replace it with a compatible (MR Safe or MR Conditional) obturator: Pull the trocar out of the introducer sheath and insert the obturator into the introducer sheath.

2 Move the table with the patient into the isocenter.

CAUTION

Setting error/needle guide does not point to the lesion!

Lesion is missed, incorrect diagnosis

- To check the location of the planned biopsy channel, perform a control scan before puncturing.

3 Perform a suitable measurement to check the puncture depth and that the position of the biopsy channel is correct.

In the MR Breast Biopsy application, the images of the control scan are loaded into the result segments.

4 In the result images of the control scan, check that the position of the introducer sheath and the biopsy channel are correct.

If necessary, reposition the introducer sheath.

Performing the biopsy/Positioning the marking wire

1 Use the table movement buttons to move the table with the patient out of the magnet.

2 Pull the obturator out of the introducer sheath/core needle.

Now the biopsy channel is prepared and you can perform the biopsy with the biopsy needle.

3 Insert the biopsy needle into the introducer sheath/core needle and perform the biopsy.

– or –

Position the wire anchor of the marking wire in the lesion and then remove the core needle from the breast.

After performing the biopsy or positioning the wire, you usually perform a further control scan to check the biopsied region or to verify that the wire position is correct.

CAUTION

Horizontal patient table movement after placement of the core needle device!

Injury to female patient: protruding parts can collide with the tunnel wall

- Prior to moving the patient table, carefully check that all parts of the core needle device are safely located.

4 When you have removed the biopsy needle, move the table with the patient into the isocenter.

Perform another measurement to check the biopsied region or to verify that the wire position is correct.

3.3.4 Grid method

When using the Grid method, the location of the lesion is determined using the grid. Sagittal slices are generated with medial/lateral access, which are used to determine the puncture depth. The impression of the grid plate is then shown on-screen after the measurement. This allows for determining the grid opening which corresponds to the location of the lesion. A needle block is positioned in the corresponding grid opening to enable access to the lesion.

The following describes the examination sequence for a vacuum biopsy of the breast. Access is in lateral direction in the *head first* orientation.

✓ All necessary disinfections or sterilizations have been performed.

✓ The coil and biopsy accessories are positioned on the patient table.

✓ Bottom of the coil is covered with absorbent material.

✓ Female patient is positioned.

✓ Breast is immobilized.

✓ Marker block is seated in the designated grid opening.

1 Register the female patient. (➔ Page 30 *Registering the female patient*)

2 Perform the localizer measurement. (➔ Page 31 *Measuring the localizer*)

3 Perform precontrast and postcontrast imaging as described for the Post&Pillar method, but use sagittal slices (instead of transverse slices for the Post&Pillar method) to achieve a better view of the grid. (➔ Page 32 *Performing precontrast and postcontrast imaging*)

3.3.4.1 Planning access to the lesion (using the MR Breast Biopsy application)

To plan access to the lesion you can use the advanced application **MR Breast Biopsy**.

- If you have used the **Breast Biopsy** program for the examination, the **MR Breast Biopsy** application opens automatically and the measured images are loaded as soon as the program step **Plan Biopsy** has been completed.
- If you have used an individual measurement program, you manually load the measured images from the **Patient Browser (Local Data)** and open the data with the **MR Breast Biopsy** application.

To ensure an adequate accuracy of the calculated target values, use the following values:

- Pixel size ≤ 1 mm
- Bandwith (3T) ≥ 300 Hz/px
- Bandwith (1.5T) ≥ 150 Hz/px

✓ **MR Breast Biopsy** application is open and images are loaded.

✓ **Calibration** step is open.

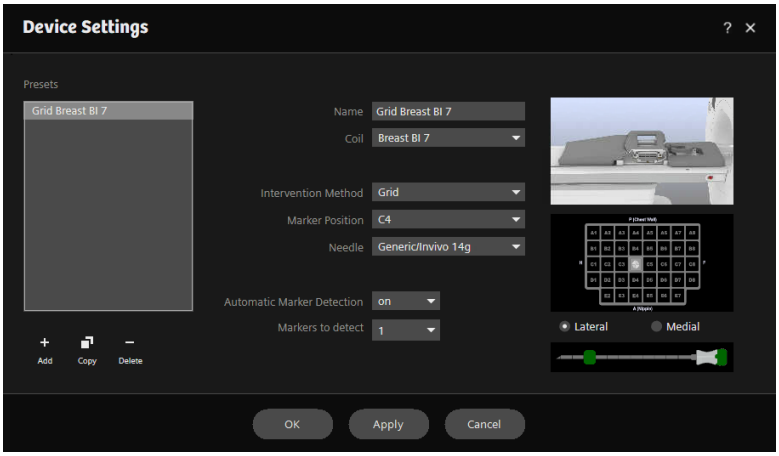
Configuring the device setting

If you are using the **MR Breast Biopsy** application for the first time, you will need to enter some data to define the biopsy device that you are using (for example, coil, biopsy method, and needle). Once defined, you can use the preset for all subsequent examinations that use the same biopsy device.



1 In the **MR Breast Biopsy** step, click this icon to open the **Device Settings** dialog box.

2 Click the **Add** icon to create a new preset.



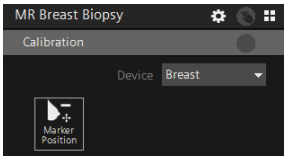
3 Enter the necessary data in the fields of the **Device Settings** dialog box:

- **Preset**: Enter a name for the preset.
- **Coil**: Select the Breast BI 7 coil.
- **Intervention Method**: Select **Grid**.
- **Marker Position**: Select the position of the marker block in the grid (for example, C4).
- **Needle**: Select the needle used for the biopsy.
- **Automatic Marker Detection**: If activated, you can also choose whether one or two markers should be detected.

4 Click the **OK** button to confirm the settings and save the preset.

Once the preset of a specific device setting has been defined, that preset is available for further examinations. You can directly select the preset in the **Device** list of the **Calibration** step.

Calibration step: Determining the marker position



By default, the preset of the last **Device** that was used is selected. If necessary, you can change the device settings accordingly.

The selected biopsy device and its components are shown in the lower-left segment. The grid, needle, and the needle block are shown as figures.

✓ **Calibration** step is open.

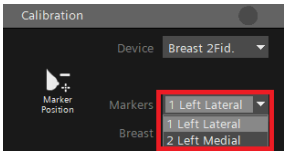
✓ Device settings are already configured.

✓ The **Device** preset for the Grid examination with the Breast BI 7 coil is selected.

✓ Layout for Grid device is selected.

If **Automatic Marker Detection** is activated in the selected **Device** preset, automatic detection starts when the **Calibration** step is opened. This is indicated by a progress bar.

As a result, the examination parameters and details about the detected marker are displayed in the **Calibration** step and the image segments are updated accordingly.

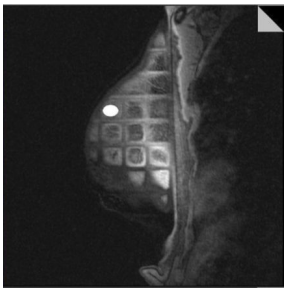


If a second marker is used and configured in the **Device** preset, a list with both markers is displayed. The image segments are updated depending on which marker is currently selected from the list.

1 For an automatically detected marker: Check that the position of the selected marker in the images is correct.

2 To change the position of an automatically detected marker or to manually define a marker position, click the **Marker Position** icon.

The icon name changes to **1. Select Marker** and the mouse pointer is displayed as crosshairs: 



3 The marker is visible on the non-subtracted images.

In the segments, go through the image stack of the non-subtracted images and search for the images that best show the grid with the marker. Select the image that shows the tip of the marker (slice position that is closest to the breast skin).

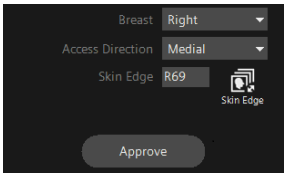
4 Move the mouse pointer across the image to the position of the marker tip and click to select the tip of the marker. To change the position, click again, or move the crosshairs to the correct position.

Once you have clicked in the image, the icon name again changes its name to **2. Approve Marker**.

5 Click the **2. Approve Marker** icon to confirm the position of the marker.

The shape of the mouse pointer changes to a yellow arrow and the edge of the skin is indicated by a pink line.

An image of the grid is displayed in the segments and the examination parameters are shown in the step.



6 Check the examination parameters (**Breast**, **Access Direction**) and correct them, if necessary.

7 The **Skin Edge** parameter shows the gap between the marker tip and the skin of the patient.

To adjust the **Skin Edge**, click the **Skin Edge** icon and scroll in the segment to the slice position that is closest to the skin and that shows the imprint of the grid. Click the **Approve Skin Edge** icon to confirm the position.

8 Click the **Approve** button to complete the settings of the **Calibration** step.

The **Target Selection** step opens.

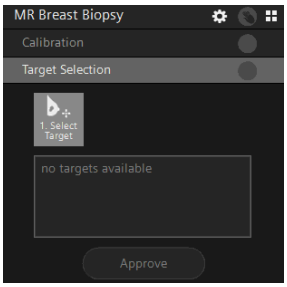
9 If required, you can select the **Calibration** step at any time and click the **Modify** button to change the calibration settings.

Target Selection step: Determining the lesion position

In this step, you plan the targets for the access direction that you previously defined in the **Calibration** step by selecting the marker position.

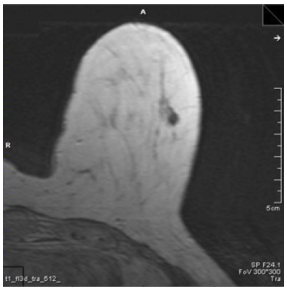
✓ **Calibration** step is approved.

✓ **Target Selection** step is open.



The icon **1. Select Target** is active and the mouse pointer is displayed as crosshairs:

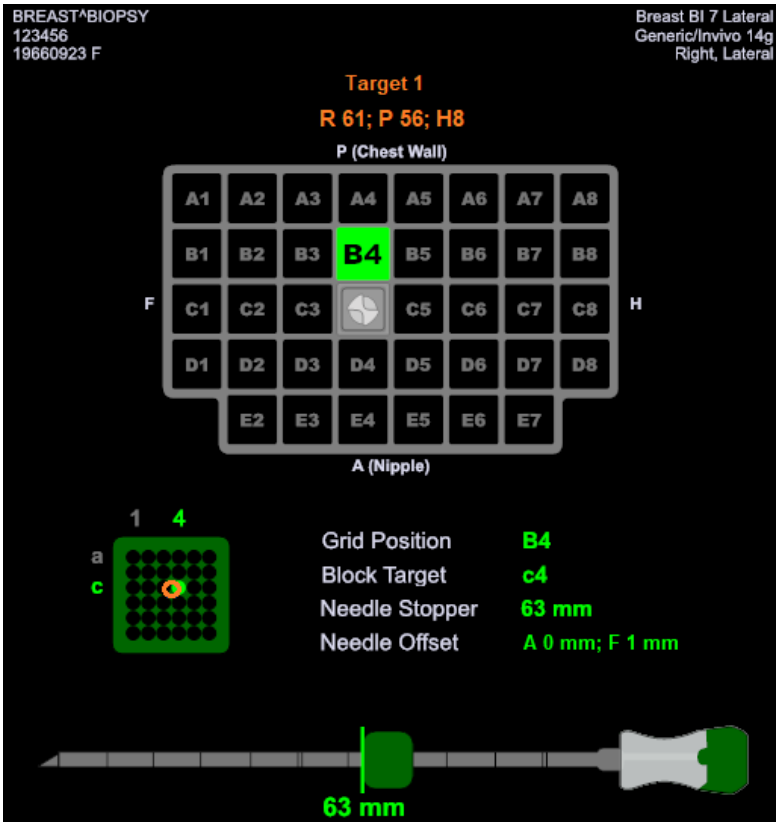
1 Go through the image stack and select the image that shows the lesion in full. If necessary, enlarge the segment by double-clicking the image. Double-click the image again to reduce it to the previous size.



The lesion is visible on the subtracted images, in the second segment.

2 Move the mouse pointer across the image and click the position in the lesion that you want to target.

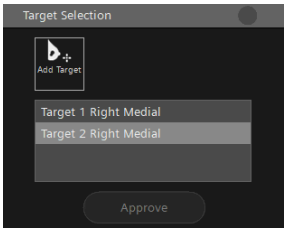
As soon as you click a position in an image, the target position values for the grid settings are shown in the lower left segment.



Example: Target values for grid settings using the Breast BI 7 coil

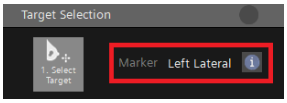
If the lesion is not accessible with the current device setting, the message **Target not reachable** is shown in the lower left segment. In this case, check your workflow and, if necessary, reposition the biopsy device or patient.

3 Click the **2. Approve Target** icon to determine the lesion position.



4 If required, you can click the **Add Target** button to create an additional lesion. Proceed as described above. The different targets are displayed as a list and can be sent individually to the display in the examination room.

To delete a target from the list, select the target in the list, right-click and choose **delete selected target**.



5 To plan a second access direction to the lesion, go back to the **Calibration** step and click the **Modify** button. Then select or create a second marker, check and approve the new **Calibration** settings (as already described above).

Afterward select the targets for this access direction. The currently selected approach is displayed in the **Target Selection** step and in the target name.

6 Click the **Approve & Send** button to complete the lesion detection.

A finding of the target position is created. The finding includes snapshot images of the segments.

Additionally, the result segment with the target values for the biopsy device settings is displayed on the system display in the examination room. The system display shows the last target confirmed with **Approve & Send** or the target explicitly sent from the list with **Send**. The target shown in the display is marked "(on display)" in the target list.

You can also document the target values in a worksheet. A master copy of the grid to document the grid opening is available in the appendix of this manual.

Now you can perform the intervention. See chapter: *Performing the intervention*

3.3.4.2 Planning access to the lesion (manually)

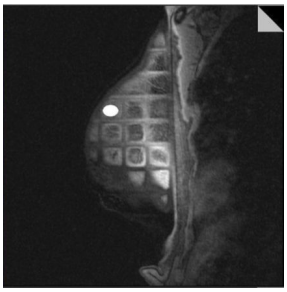
As an alternative to planning with the advanced application **MR Breast Biopsy**, you can determine the target coordinates manually.

✓ Images with spatial information are loaded in the **MR View&GO** application.

1 Select the **Viewing** step.

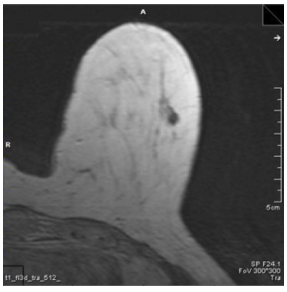
2 Choose an appropriate layout (for example, 2x2 layout).

3 In the segments, choose a 2D display type from the bottom left corner menu.



4 Load the non-subtracted images, for example, into the first segment.

5 Go through the image stack and select the image that best shows the grid.



6 Load the subtracted images, for example, into the second segment.

7 Go through the image stack and select the image that shows the lesion in full. If necessary, enlarge the segment by double-clicking the image. Double-click the image again to reduce it to the previous size.



8 On the lesion image, choose **Pixel Lens** from the upper right corner menu.

The mouse pointer is displayed as crosshairs: 

9 Move the mouse pointer across the image and click the position in the lesion that you want to target.

The position values are shown next to the pixel lens marker.

The pixel lens only shows the pixel coordinates if the **Viewing** step is selected in the **MR View&GO** and if MR images with spatial information are loaded and a 2D view is selected.

Otherwise, the pixel lens shows only the grayscale value and you cannot determine the biopsy coordinates.

---

10 Move the mouse pointer in the grid image (do not change the previously selected slice) to the same transverse (H/F) and coronal (A/P) coordinate values as for the lesion on the subtracted image. Click to position the pixel lens marker.

Now you have marked the lesion position on the grid image and you can determine the required grid opening, relative to the marker position, to puncture the lesion. You can also create snapshot images to document the coordinates.

A master copy of the grid to document the grid opening is available in the appendix of this manual.

The distance between the slice positions (SP values shown in the lower right corner) of the image with the grid and of the image with the lesion corresponds to the necessary puncture depth.

11 Calculate the puncture depth as the difference of the slice positions (sagittal coordinates L/R).

3.3.4.3 Performing the intervention

CAUTION

Wrong settings of the biopsy device (for example, needle stopper)!

Lesion is missed, incorrect diagnosis

- Ensure that the settings of the biopsy device are the same as those displayed on the system display.
- If necessary, print out the result image with the target position values on paper to check the calculated values against the current settings of the biopsy device.

✓ Position of the lesion and corresponding target settings on the biopsy device have been determined.

Inserting the needle block

1 Use the table movement buttons to move the table with the patient out of the magnet. Do NOT move the table to the Home position.

2 Position the needle block in the target grid position as shown on the system display or as documented in your worksheet.

Ensure that the diameter of the openings in the needle block corresponds to the thickness of the biopsy needle/core needle used.

Inserting the introducer sheath/core needle

Once the needle block is positioned in the grid, you apply the sterile needle set. To perform a vacuum-assisted biopsy you use a needle set that usually consists of the following components:

- *Introducer sheath*/*Core needle*: The introducer sheath or core needle will be used as the biopsy channel to guide the biopsy needle.
- *Trocar*/*Stylet*: The sharp-pointed trocar or stylet is used to position the introducer sheath in the breast.
- *Obturator*: The obturator is used for the control scan to verify the correct position of the introducer sheath/core needle.

1 Position the trocar in the introducer sheath.

To insert the introducer sheath with the trocar into the lesion, you need to know the puncture depth. If you have used the MR Breast Biopsy application, the puncture depth is shown as the **Needle Stopper** position.

If you have *manually* determined the puncture depth, different values have to be added to the puncture depth for wire localizations to position the wire correctly. A typical value to add is 2 cm. Follow the needle manufacturer's instructions.

To insert the introducer sheath with the trocar into the lesion, you need to know the puncture depth. If you have used the MR Breast Biopsy application, the puncture depth is shown as the **Needle Stopper** position.

2 Insert the introducer sheath with the trocar into the determined hole of the needle block as shown on the system display and move both forward in the needle block by the puncture depth.

Take the length of the needle block into account when considering the puncture depth.

Checking the position of the introducer sheath/ core needle

After you have inserted the introducer sheath/core needle into the breast, you need to verify the correct position and puncture depth.

1 You first remove the trocar and replace it with a compatible (MR Safe or MR Conditional) obturator: Pull the trocar out of the introducer sheath and insert the obturator into the introducer sheath.

2 Move the table with the patient into the isocenter.

CAUTION

Setting error/needle guide does not point to the lesion!

Lesion is missed, incorrect diagnosis

- To check the location of the planned biopsy channel, perform a control scan before puncturing.

3 Perform a suitable measurement to check the puncture depth and that the position of the biopsy channel is correct.

In the MR Breast Biopsy application, the images of the control scan are loaded into the result segments.

4 In the result images of the control scan, check that the position of the introducer sheath and the biopsy channel are correct.

If necessary, reposition the introducer sheath.

Performing the biopsy/Positioning the marking wire

1 Use the table movement buttons to move the table with the patient out of the magnet.

2 Pull the obturator out of the introducer sheath/core needle.

Now the biopsy channel is prepared and you can perform the biopsy with the biopsy needle.

3 Insert the biopsy needle into the introducer sheath/core needle and perform the biopsy.

– or –

Position the wire anchor of the marking wire in the lesion and then remove the core needle from the breast.

After performing the biopsy or positioning the wire, you usually perform a further control scan to check the biopsied region or to verify that the wire position is correct.

CAUTION

Horizontal patient table movement after placement of the core needle device!

Injury to female patient: protruding parts can collide with the tunnel wall

- Prior to moving the patient table, carefully check that all parts of the core needle device are safely located.

4 When you have removed the biopsy needle, move the table with the patient into the isocenter.

Perform another measurement to check the biopsied region or to verify that the wire position is correct.

3.4 Maintenance

All components have to be cleaned, disinfected, or sterilized immediately after each examination or biopsy. The type of preparation depends on the respective component.

The table shows which cleaning method you can use for the respective components.

Component	Manual and automated cleaning and disinfection Disinfectant washing	Wipe disinfection	Sterilization
Frame carriers	x		
Vertical Post&Pillar unit	x		
Needle guide for Post&Pillar unit	x		
Horizontal slat plates	x		

Component	Manual and automated cleaning and disinfection Disinfectant washing	Wipe disinfection	Sterilization
Post&Pillar marker	x		x
Grid marker block	x		x
Breast coil		x	
Cushions and pads (all variants)		x	
Head rest		x	
Elevation plate		x	

CAUTION

Incorrect cleaning, disinfecting, and sterilizing! Contamination!

Risk of infection

Damage to the coil, device defect

- Please adhere to the instructions for cleaning, disinfecting, and sterilizing the biopsy device and the coil.
- *Never* clean and disinfect the coil in immersion baths or under running water.
- *Never* sterilize the coil.

- Disassemble the components of the coil and process them individually.

Do *not* use any abrasive cleaners or organic solvents or solvent- based cleaners (such as petrol-based cleaners, alcohol or stain removers).

3.4.1 Manual cleaning

Recommended cleaning solution: 1.5% Dr. Weigert – MediClean forte

1 Clean contaminated components under cold running water for 2 min at < 25°C. Clean holes and cavities with a soft brush.

2 Soak the instruments in a fresh cleaning solution for 5 min at < 25°C. Manually clean the instruments in a fresh cleaning solution. Remove coarse soiling with a soft brush. Rinse cavities (5x) using an unused disposable syringe with a minimum volume of 20 ml.

3 Clean the components in an ultrasonic bath for 15 min at < 25°C.

4 Rinse the components under cold running water for 1 min at < 25°C. Rinse cavities (3x) using an unused disposable syringe with a minimum volume of 20 ml.

5 Check the components visually. Repeat the previous steps until there is no more visible soiling.

6 Rinse the components thoroughly with water again for 1 min at < 25°C.

7 Dry all components and completely remove all residual moisture.

3.4.2 Manual disinfection

Recommended disinfection solution: Paul Hartmann AG – 0.75% Korsolex med AF

1 Soak the manually cleaned components in the disinfection solution for 10 min at < 25°C. At the beginning and end of soaking, rinse cavities (2x) using an unused disposable syringe with a minimum volume of 20 ml.

2 Rinse the components under cold running water for 1 min at < 25°C. Rinse cavities (5x) using an unused disposable syringe with a minimum volume of 20 ml.

3.4.3 Wipe disinfection

Recommended disinfection solution: Paul Hartmann AG – Bacillol® 30 Sensitive Foam

1 Moisten contaminated components with the disinfection solution for 30 s at < 25°C.

2 Wipe the components with a cloth moistened with the disinfectant for 30 s at < 25°C until all visible soiling has been removed.

3 Dry the components by wiping with a lint-free cloth.

4 Repeat the previous steps until there is no more visible soiling.

3.4.4 Automated cleaning and disinfection

Recommended cleaning solution:

- 1.5% Dr. Weigert – MediClean forte (ultrasonic bath)
- 0.5% Dr. Weigert – MediClean forte (machine cleaning)
- 0.1% Dr. Weigert – Neodisher Z (neutralization)

1 Perform manual precleaning:

- Clean contaminated components under cold running water for 3 min at < 25°C until all visible soiling has been removed. Clean holes and cavities with a soft brush. Rinse cavities (5x) using an unused disposable syringe.
- Clean the components in an ultrasonic bath for 10 min at < 25°C.

2 Perform automated cleaning and disinfection:

- Precleaning for 2 min at < 25°C
- Cleaning for 10 min at 55°C
- Intermediate rinsing for 2 min at < 25°C
- Neutralization for 1 min at < 25°C
- Disinfection for 5 min at 93°C
- Drying for 10 min at < 90°C

3.4.5 Disinfecting washing procedure

Recommended cleaning solution: Heavy-duty detergent Persil Duo Caps

◆ Wash the components for 130 min at 95°C.

3.4.6 Sterilization

Refer to the table at the beginning of the chapter to find out which components can be sterilized.

✓ Components have been cleaned.

CAUTION

Unsterile components!

Risk of infection in case of broken skin

- Sterilize the components before each usage.
- Follow the instructions to properly and completely clean and sterilize each component.

1 Pack the components in sterilized/autoclave packing.

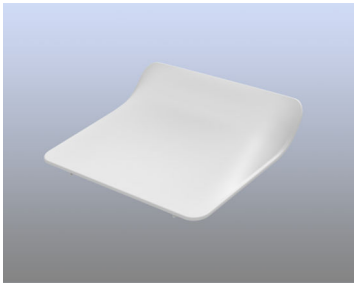
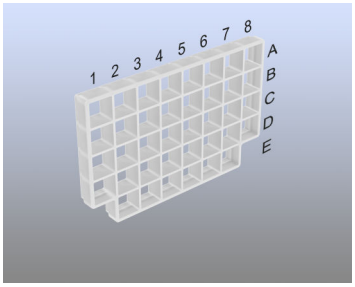
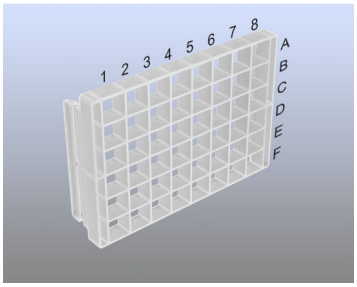
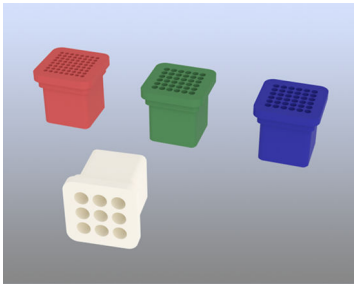
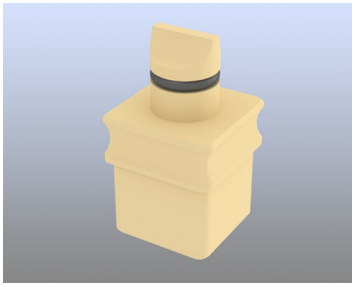
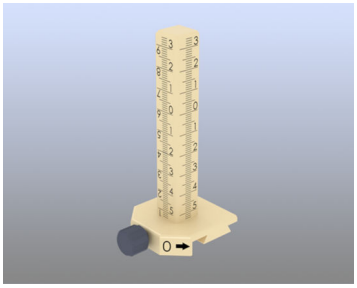
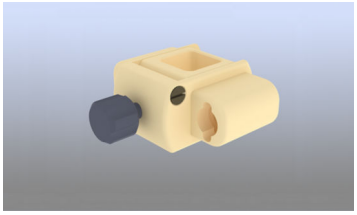
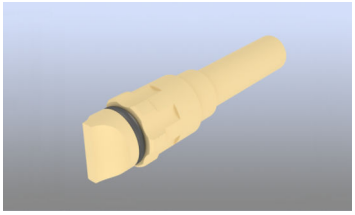
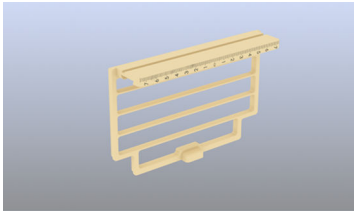
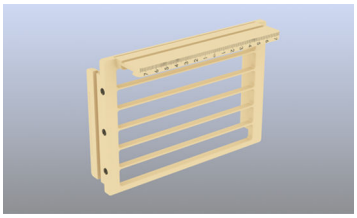
2 Use steam sterilization with fractional vacuum for 5 min at 134°C and 3.04 bar.

3 Dry the components for 20 min at < 134°C.

3.5 Accessories

3.5.1 Biopsy accessories

Please note that the scope of delivery from Siemens provides biopsy accessories only for training purposes. Accessories for the examination (needles, needle guide, grid, etc.) need to be ordered separately, for example, from NORAS MRI products GmbH.

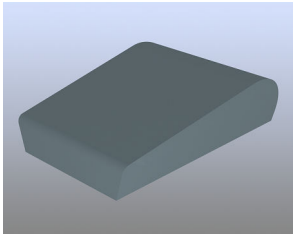
 Elevation plate (for medial access)	 Lateral grid (disposable)	 Medial grid (disposable)
 Disposable grid needle blocks (12G, 14G, 16G, and 18G)	 Grid marker block	 Vertical Post&Pillar unit
 Needle guide for Post&Pillar unit	 Post&Pillar marker	 Horizontal lateral slat plate
 Horizontal medial slat plate		

3.5.2 Coil accessories

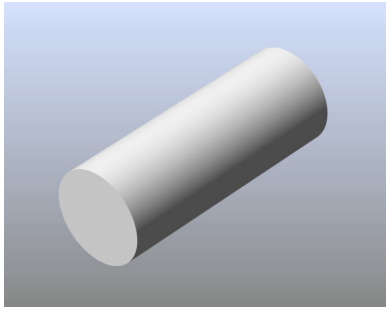
Specific positioning aids are available for the following coils and are included in their delivery volume.

3.5.2.1 General positioning aids

The following positioning aids are available to ensure safe and comfortable patient positioning:

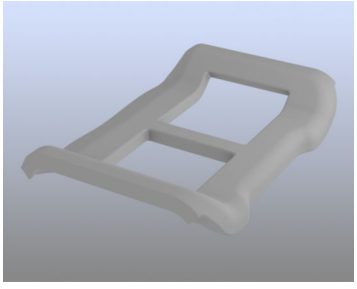


Knee wedge

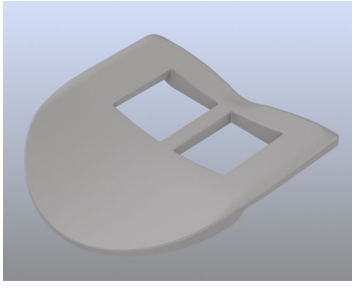


Foot support roll

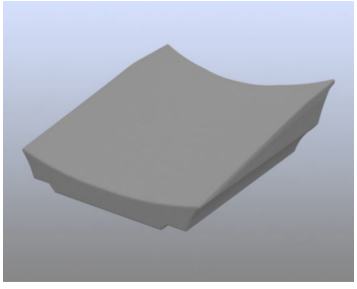
3.5.2.2 Breast BI 7



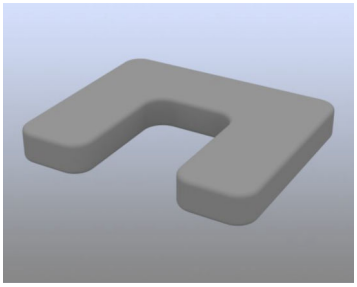
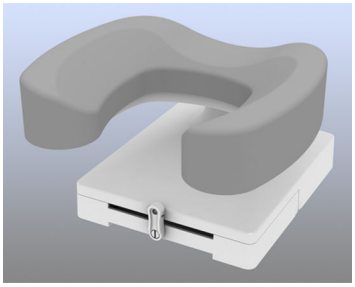
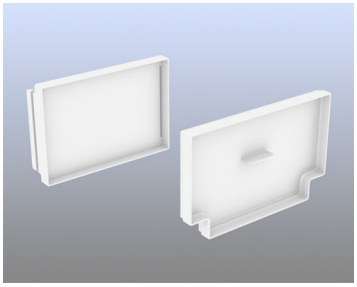
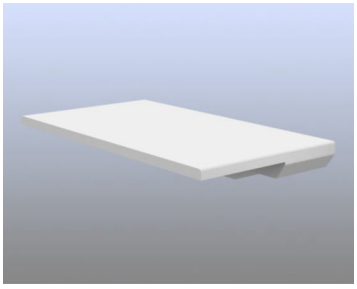
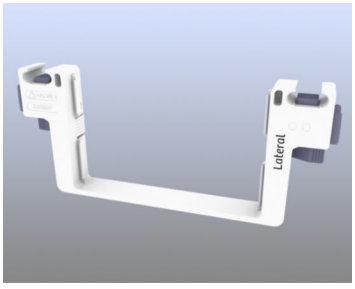
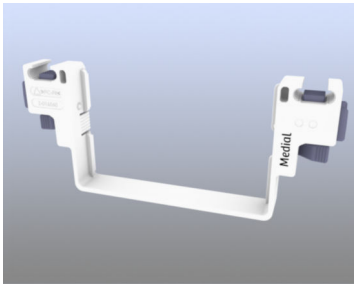
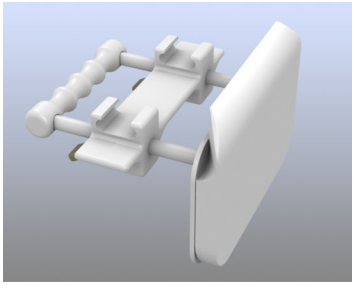
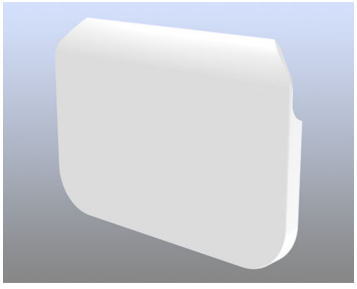
Support cushion



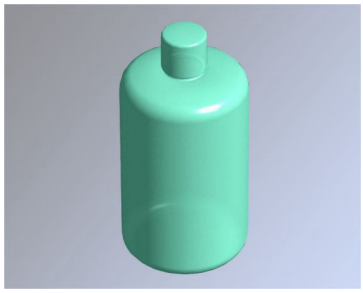
Support cushion, comfort



Body pad 60 (wedge connector 60 Breast 18)

		
Armrest pad	Head rest Breast 18	Fixation plates (lateral/medial)
		
Table cushion Breast 18	Frame carrier lateral	Frame carrier medial
		
	Cranio-caudal fixation unit (single element)	Pad for cranio-caudal fixation unit

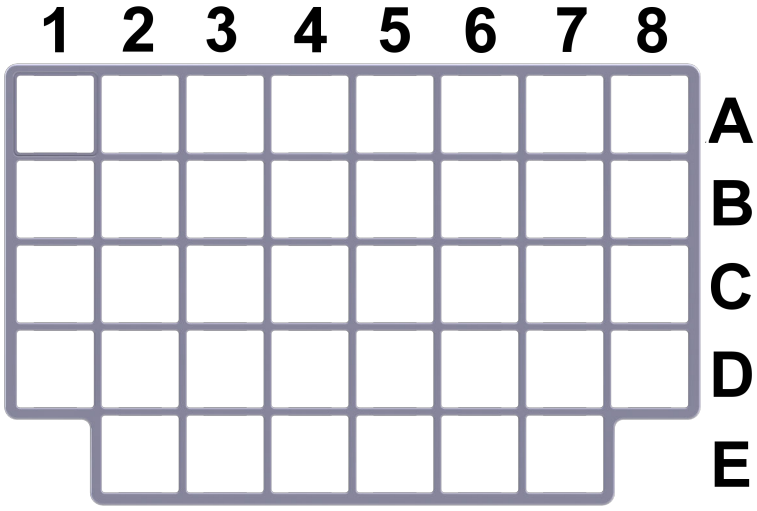
3.5.3 Accessories for quality assurance

	1900 ml plastic bottle

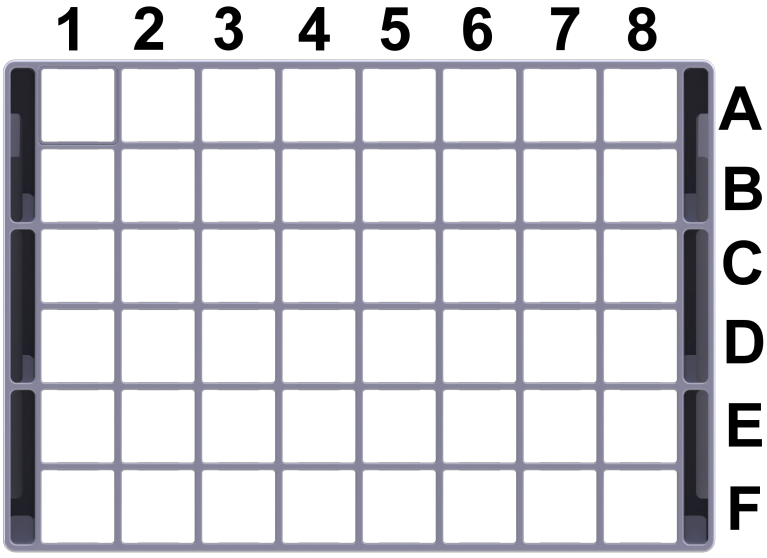
3.6 Master copies

The following pages show master copies which you can use for the biopsy examination:

- The graphic of the grids can be used for biopsy examinations with the grid method. If you have determined the coordinates of the lesion, you can mark the lesion position in the grid.
- The other worksheets can be used to document the determined coordinates of marker and lesion.



Lateral grid



Medial grid

Breast Biopsy Worksheet

Patient: _____ Performing Physician: _____

Date of birth: _____ Date: _____

Determine the coordinates in the images:

1. Coordinates of the marker tip

Marker tip position:
(for example: L20 A20 H20) _____

2. Coordinates of the lesion

Lesion position: _____
(for example: R10 P10 F10)

Calculate the settings to perform the biopsy:

3A. Puncture depth (offset of sagittal L/R values)

Marker tip _____ Distance/
Lesion _____ offset _____ mm

3B. Vertical offset (offset of coronal A/P values)

Marker tip _____ Distance/
Lesion _____ offset _____ mm

3C. Horizontal offset (offset of transversal H/F values)

Marker tip _____ Distance/
Lesion _____ offset _____ mm

Determine the coordinates in the images:

1. Coordinates of the marker tip

Marker tip position:
(for example: L20 A20 H20) _____

2. Coordinates of the lesion

Lesion position: _____
(for example: R10 P10 F10)

Calculate the settings to perform the biopsy:

3A. Puncture depth (offset of sagittal L/R values)

Marker tip _____ Distance/
Lesion _____ offset _____ mm

3B. Vertical offset (offset of coronal A/P values)

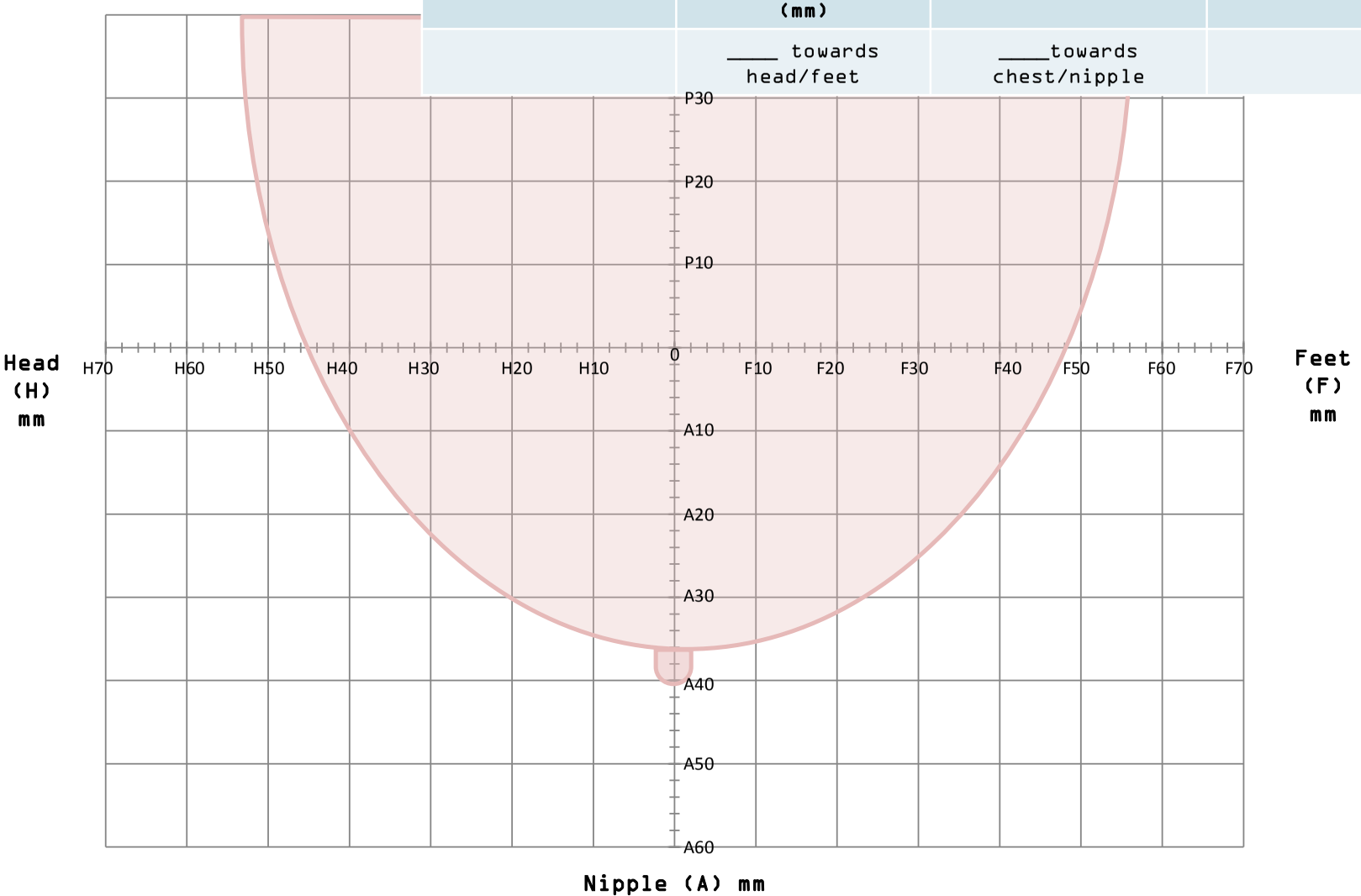
Marker tip _____ Distance/
Lesion _____ offset _____ mm

3C. Horizontal offset (offset of transversal H/F values)

Marker tip _____ Distance/
Lesion _____ offset _____ mm

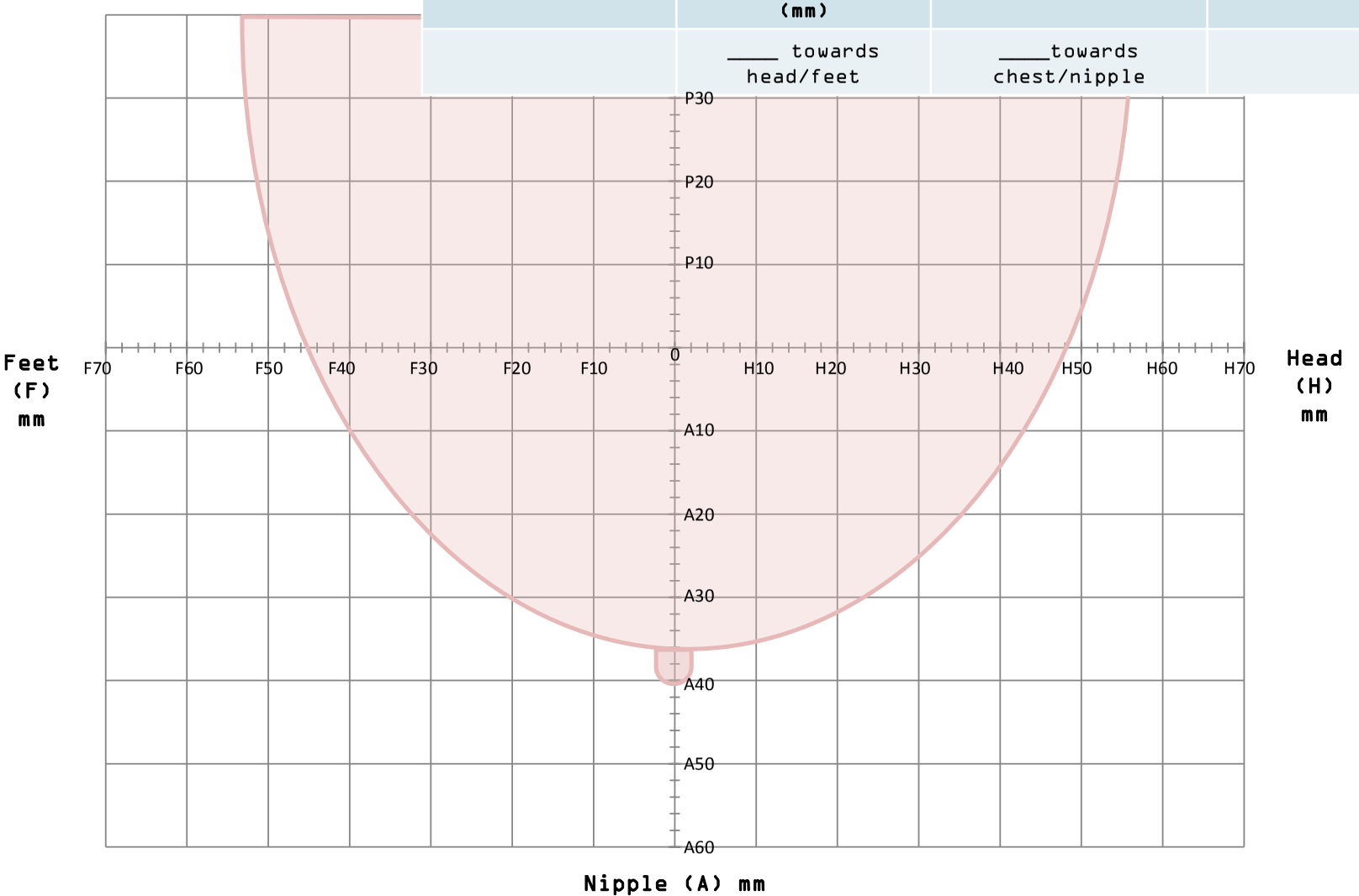
MRI Post&Pillar Worksheet:
Left Lateral Breast / Right Medial Breast

	Head/Feet (H/F)	Chest/Nipple (P/A)	Left/Right (L/R)
Marker co-ordinates			
Lesion co-ordinates			
	Horizontal Move (mm)	**Vertical Move (mm)**	**Depth (mm)**
	____ towards head/feet	____towards chest/nipple	



MRI Post&Pillar Worksheet:
Right Lateral Breast / Left Medial Breast

	Head/Feet (H/F)	Chest/Nipple (P/A)	Left/Right (L/R)
Marker co-ordinates			
Lesion co-ordinates			
	Horizontal Move (mm)	**Vertical Move (mm)**	**Depth (mm)**
	____ towards head/feet	____towards chest/nipple	



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Siemens Healthineers
Headquarters
Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim
Germany
Phone: +49 9191 18-0
siemens-healthineers.com

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