



positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4546, RT-4546MRI, RT-4546-01, & RT-4546-02

Access™ Supine Breast & Lung


Access™ Supine MR Breast & Lung

Access™ Supine Breast

Access™ Supine Breast & Lung, without Grid





EC	REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta		Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6053 www.Qfix.com
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Exact® is a registered trademark of Varian Medical Systems.

Access, MR Secure, kVue, VacQfix, and ArmShuttle Elite are trademarks of Qfix.

Cidex® is a registered trademark of Johnson & Johnson.

Clorox® is a registered trademark of The Clorox Company.

! NOTE ! Throughout this IFU “Access Supine” refers to all Access™ Supine Devices, including the Access™ Supine Breast & Lung, Access Supine MR Breast & Lung and Access™ Supine Breast unless otherwise noted.

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 484-720-6053 OR TECHSUPPORT@QFIX.COM.

! WARNING ! ENSURE ANGLE LADDERS ARE SECURED IN GROOVE ALONG THE HINGE PRIOR TO USING DEVICE. FAILING TO DO SO MAY DAMAGE THE DEVICE OR CAUSE INJURY.

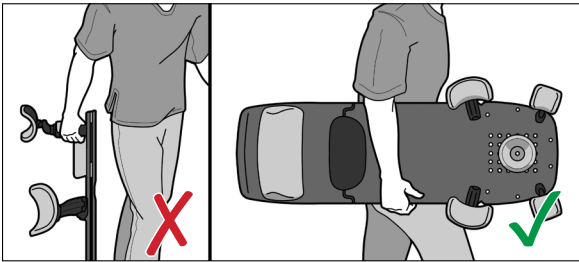
! WARNING ! NEVER RAISE OR LOWER LADDERS WHILE A PATIENT IS ON THE DEVICE.

! WARNING ! NEVER LIFT OR CARRY THE DEVICE BY HOLDING THE ARM OR WRIST SUPPORTS.

! WARNING ! DO NOT ALLOW PATIENT TO ADJUST POSITION USING THE ARMSHUTTLE HANDLES.

! WARNING ! DO NOT ALLOW PATIENT TO ADJUST POSITION USING THE ARM AND WRIST SUPPORTS.

! WARNING ! DO NOT USE THE ARMSHUTTLE TO ADJUST ANGLE OF THE PATIENT SURFACE.



SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

TRAPPING ZONES

- Trapping zones may occur when adjusting the Arm Support or Wrist Support height.
- Trapping zones may occur when adjusting the Arm Support or Wrist Support angle.
- Trapping zones may occur within the hinge between the Patient Surface and Base Plate.

TREATMENT BEAM ATTENUATION

The Access Supine is designed so that the patient can be positioned so that most posteroanterior (PA) treatment fields can be arranged with the beam passing through the device's lung cutouts. The structural regions of the Access Supine have a water equivalence of 5 mm at 6MV. Treatment through the treatment table will increase this attenuation. Actual attenuation based on setup should be verified with your particular equipment. Treatment through any device, even one constructed of composite material will lead to an increased skin dose.

GENERAL PRECAUTIONS

MRI SAFETY INFORMATION

 The **20 degree and 25 degree optional accessory ladders** are MR Safe.

Non-clinical testing has demonstrated the **20 degree and 25 degree optional accessory ladders** may be used in an MR system meeting the following conditions:

- The ladders must be used with the MR Safe version of the Access Supine (RT-4546MRI) clearly labeled with the following symbol prior to MR scanning:



 The **Arm & Wrist Supports** are MR Conditional.

Non-Clinical testing has demonstrated the **Arm and Wrist Supports** may be used in an MR system meeting the following conditions:

- The **Arm and Wrist Supports** may be placed in the bore of an MR system having a static Magnetic field of 1.5T or less.
- The **Arm and Wrist Supports** must be used with the MR Safe version of the Access Supine (RT-4546MRI) in accordance with its intended use prior to scanning.
- The MR Safe version of the Access Supine (RT-4546MRI) is clearly labeled with the following symbol:



 The **Bottom Stopper** is MR Conditional.

Non-Clinical testing has demonstrated the **Bottom Stopper** may be used in an MR system meeting the following conditions:

- The **Bottom Stopper** may be placed in the bore of an MR system having a static Magnetic field of 1.5T or less.
- The **Bottom Stopper** must be used with the MR Safe version of the Access Supine (RT-4546MRI) in accordance with its intended use prior to scanning.
- The MR Safe version of the Access Supine (RT-4546MRI) is clearly labeled with the following symbol:



GENERAL PRECAUTIONS

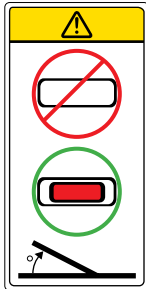
WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.



LOAD RATING

DO NOT exceed 249 kg (550 lb) uniformly distributed load or maximum safe working load of kVue Insert, or couch base, whichever is less.



LADDER WARNING

When using the Access Supine on an angle, be sure the ladder is securely locked into place and the red ends of the ladder are visible from the top of the device.

Using the Access Supine on an angle without properly securing the ladder into place may damage the device or cause injury.



MR SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

! NOTE ! FOR RT-4546MRI ONLY.

INTENDED USE

This device is intended to immobilize, position and reposition patients undergoing radiation therapy.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

PATIENT TARGET GROUPS

Patients undergoing radiation therapy or diagnostic imaging procedures.

INTENDED USERS

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

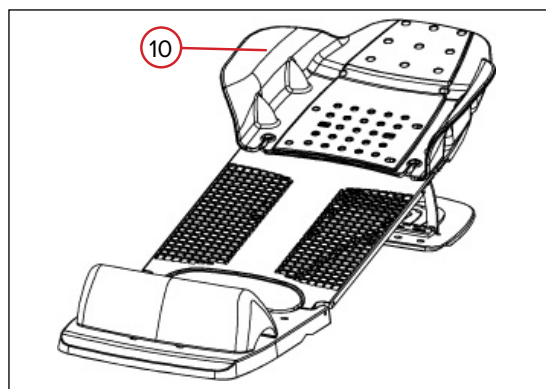
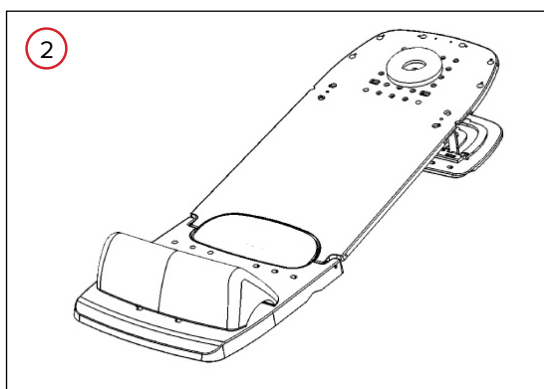
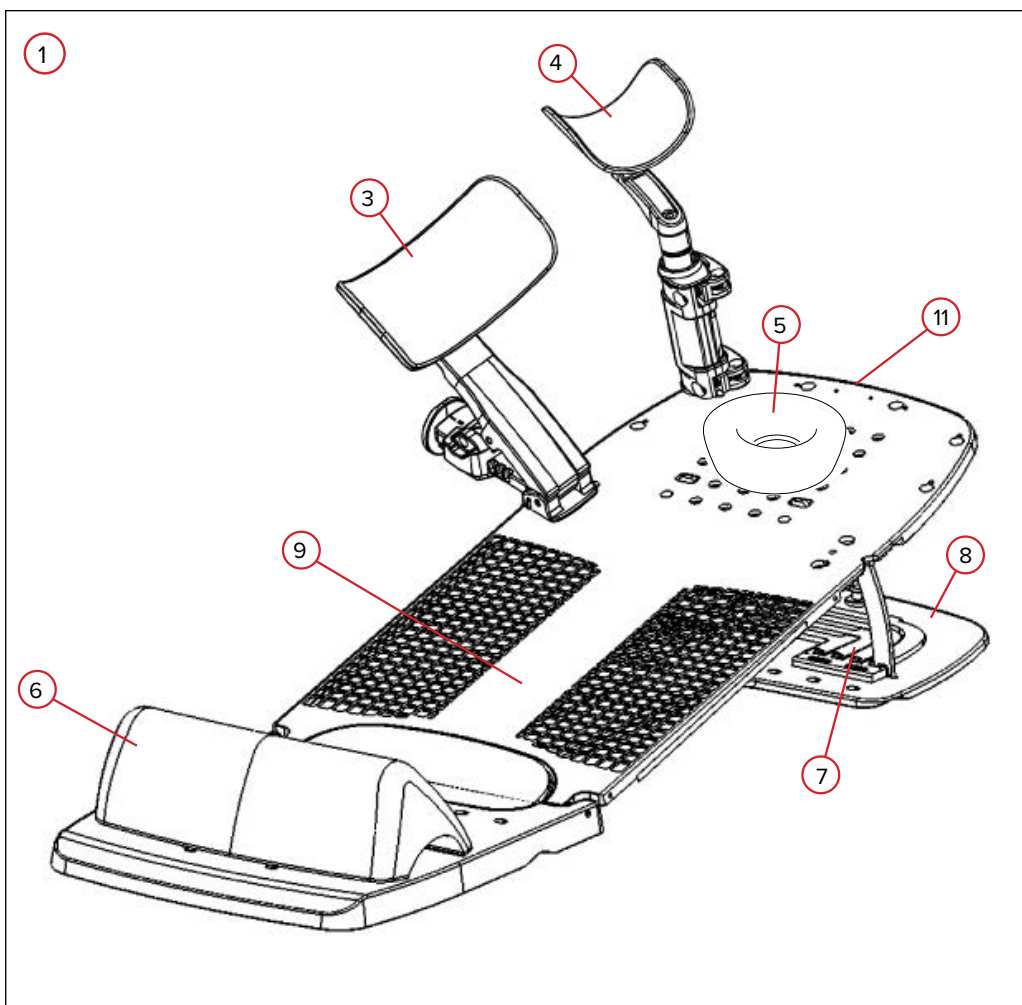
FEATURES

DESCRIPTION

The Access Supine should be used with 2, two-pin Locating Bars, such as RT-4551BAR, for secure attachment to the simulation or treatment couch top. These Locating Bars are not included with the Access Supine, and must be purchased separately from the couch manufacturer.

The Access Supine uses optional Arm Supports (RT-4546AA-01) and Wrist Supports (RT-4546AW-01) to hold the upper arms and wrists in a reproducible position. An optional ArmShuttle™ (RT-4546C) can be used in place of the Arm and Wrist Support.

COMPONENTS



FEATURES

COMPONENTS

1. ACCESS SUPINE BREAST & LUNG, ACCESS SUPINE BREAST, AND ACCESS SUPINE BREAST AND LUNG, WITHOUT GRID

The Access Supine is used to aid in the positioning and setup of patients undergoing radiotherapy of the breast and lungs.

2. ACCESS SUPINE MR BREAST & LUNG

The Access Supine MR (painted white) functions the same as the Access Supine, but may be used with MRI.

3. ARM SUPPORT

The Arm Supports have a full range of adjustment to accurately position the upper portion of the patient's arms during simulation and treatment.

4. WRIST SUPPORT

The Wrist Supports adjust to support the patient's wrists during simulation and treatment.

5. HEADREST

The included headrest can be positioned in various locations (labeled 1 to 28) on the Access Supine. Optional headrests are available, including large and small Gel Headrests and the TIMO B Headrest.

6. BOTTOM STOPPER

The included indexable Bottom Stopper maintains proper patient positioning by helping prevent the patient from sliding down the Access Supine.

7. ANGLE LADDERS

The Angle Ladders allow the patient's head and torso to be angled vertically at angles of 0, 5, 7.5, 10, 12.5, 15 degrees. Optional accessory ladders allow the patient's head and torso to be angled vertically at 20 or 25 degrees.

8. BASE PLATE

The Base Plate provides attachment points for the Angle Ladders and the Bottom Stopper and allows for secure attachment to the simulation or treatment couch.

9. PATIENT SURFACE

The Patient Surface is the portion of the device that adjusts between 0 to 15 degrees for treatment.

10. ARMSHUTTLE ELITE

The ArmShuttle Elite can be used in place of the Arm Supports to position the patients arm during simulation and treatment. This is normally used along with a VacQfix™ Cushion.

11. RELEASE LOCK

The release lock, secures the patient surface to the base plate.

OPERATING INSTRUCTIONS

INSTALLATION

ACCESS SUPINE INSTALLATION

1. Insert the ends of the Locating Bars into the appropriate Varian Exact®-compatible index notches on the couch top or device, spaced 700 mm (typically 5 notches) apart, and snap the Locating Bars into place. (Fig. 1)
2. Position the Access Supine over the Locating Bar so that the holes in the Base Plate align with the two pins in the Locating Bars. (Fig. 2)
3. Push the Access Supine down onto the Locating Bar to lock the Access Supine into place. (Fig. 3)

! NOTE ! The Access Supine can be offset to either side to position the tumor closer to isocenter as desired.

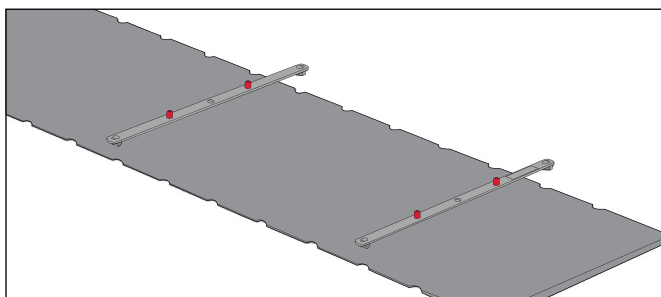


FIG. 1

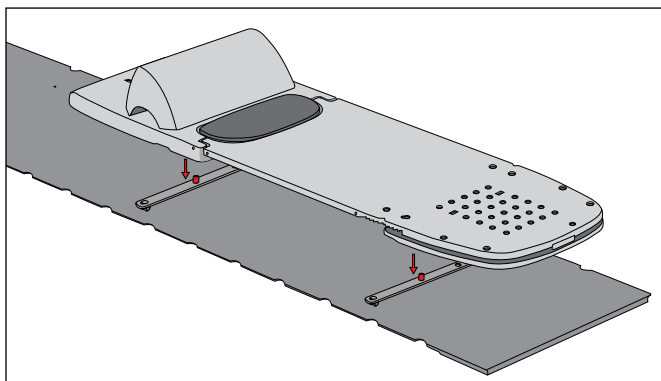


FIG. 2

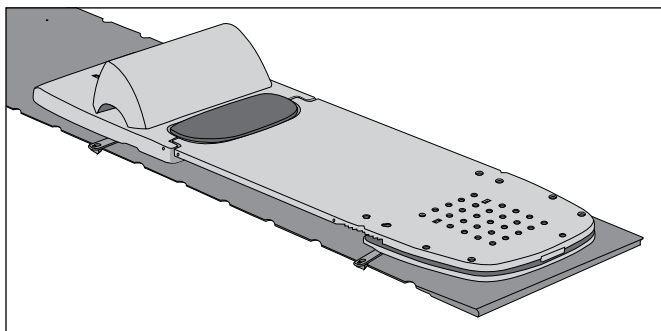


FIG. 3

OPERATING INSTRUCTIONS

SETUP

PATIENT ANGLE

! CAUTION ! WHEN USING THE ACCESS SUPINE AT AN ANGLE, ENSURE THAT THE ANGLE LADDERS ARE SECURED TO THE TOP PANEL, AND THE RED ENDS ARE VISIBLE FROM ABOVE THE DEVICE. IF THE ANGLE LADDERS ARE NOT PROPERLY SECURED, INJURY TO THE PATIENT AND/OR DAMAGE TO THE DEVICE MAY RESULT.

1. Press in on Release Lock to unlock. (Fig. 4)
2. Lift the Patient Surface, and raise the Angle Ladder into place. (Fig. 5 & 6)
3. Lower the Patient Surface until the Angle Ladder locks into the slots. Once locked, the red ends of the Angle Ladders will be visible from the Patient Surface. (Fig. 7)



FIG. 4



FIG. 5

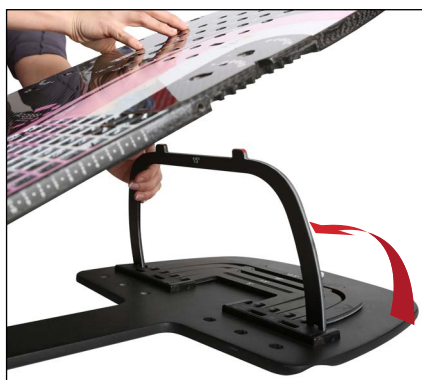


FIG. 6

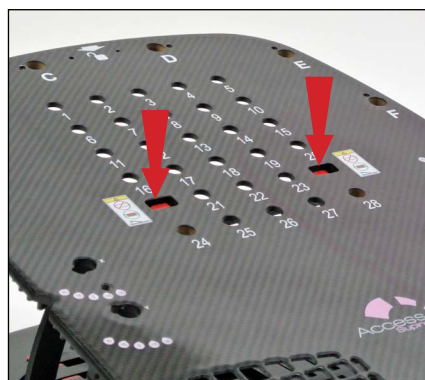


FIG. 7

! NOTE ! To install 20 or 25 degree OPTIONAL ACCESSORY ladders, insert either one into the open slots on the Angle Ladder Hinge. (Fig. 8)



FIG. 8

HEADREST

Install the Headrest in one of the available positions (1–28) at the superior end of the Patient Surface. (Fig. 9 & 10)

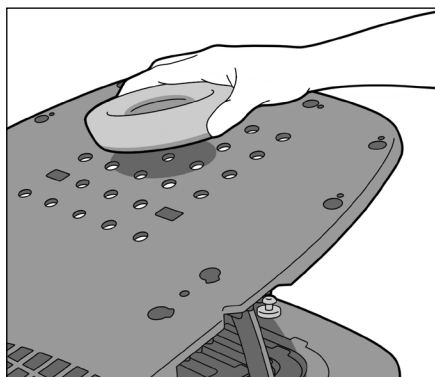


FIG. 9

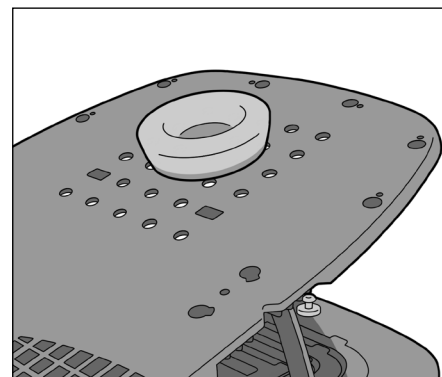


FIG. 10

OPERATING INSTRUCTIONS

SETUP

ARM SUPPORT

1. To attach the Arm Support loosen the knob and insert into one of the two locations (marked with “X” and “Y”). Tighten knob to lock Arm Support onto the Patient Surface. (Fig. 11)
 2. To adjust the rotation of the Arm Support, loosen knob and rotate the Arm Support to the desired location and tighten the knob. (Fig. 12)
- ! CAUTION ! DO NOT OVERTIGHTEN.**
3. To adjust the height, depress the button located on the height slider and slide along the arm, releasing the button once in the desired position. (Fig. 13)
 4. To adjust the length of the arm, depress the button located on the length slider and slide along the arm, releasing the button once in the desired position. (Fig. 14)

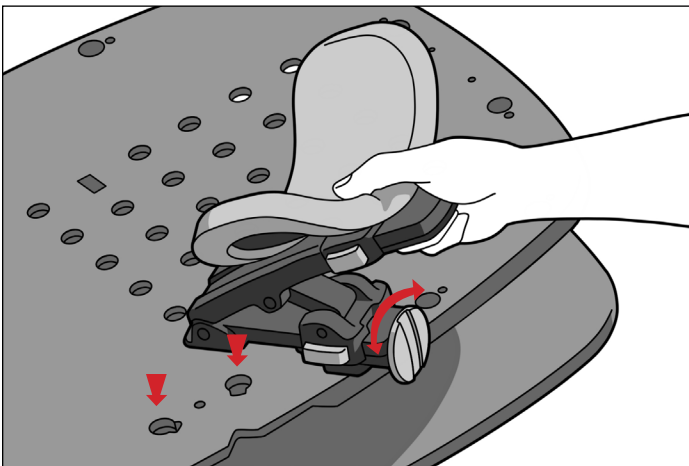


FIG. 11

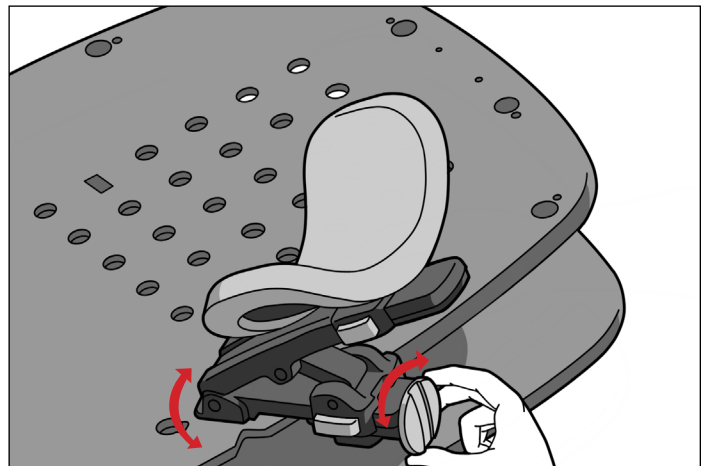


FIG. 12

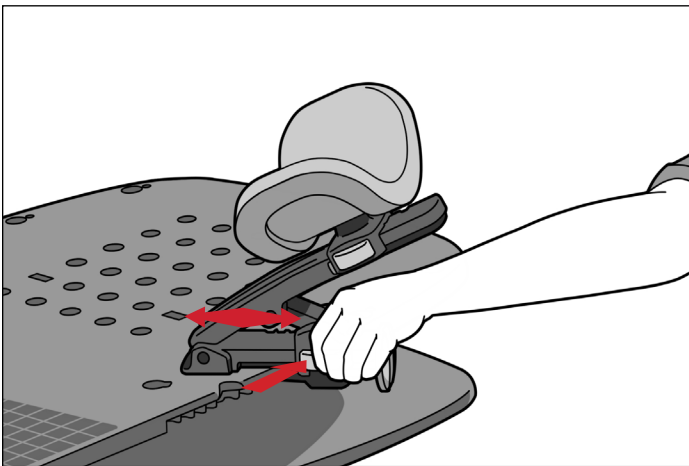


FIG. 13

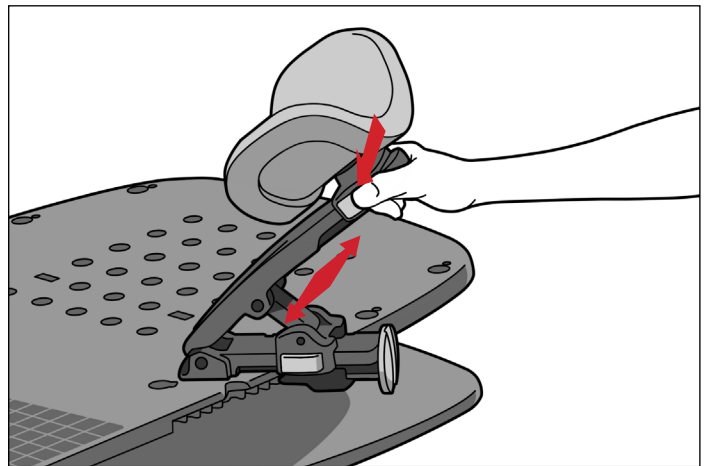


FIG. 14

OPERATING INSTRUCTIONS

SETUP

WRIST SUPPORT

1. To attach the Wrist Support, align both pegs on the bottom of the Wrist Support with the two corresponding holes in the Patient Surface. (Fig. 15)
2. Close lower lever to lock in place. (Fig. 16)
3. To raise or lower the cup of the Wrist Support, open the upper lever. Raise, lower, or rotate the cup into desired position and close the upper lever. (Fig. 17 and Fig. 18)

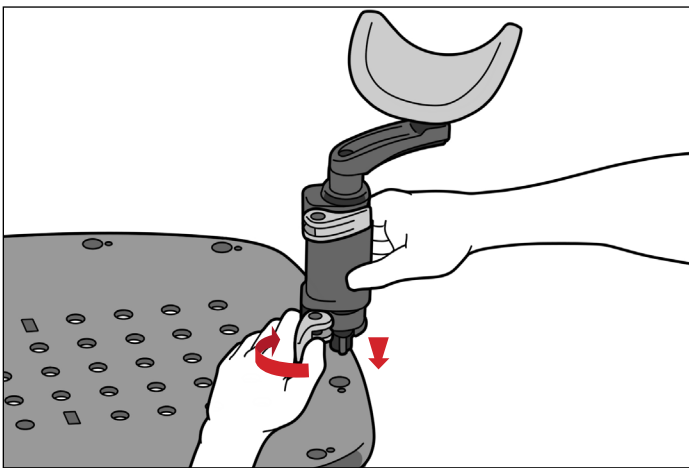


FIG. 15

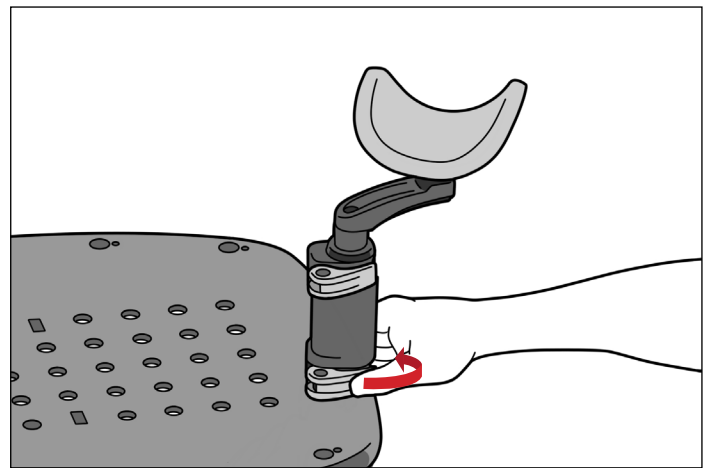


FIG. 16

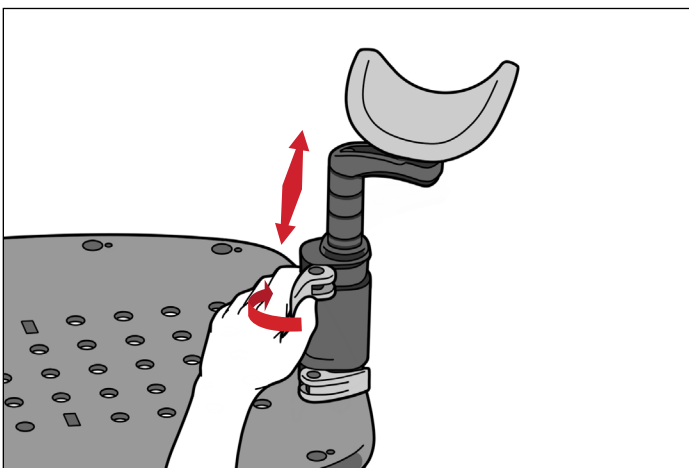


FIG. 17

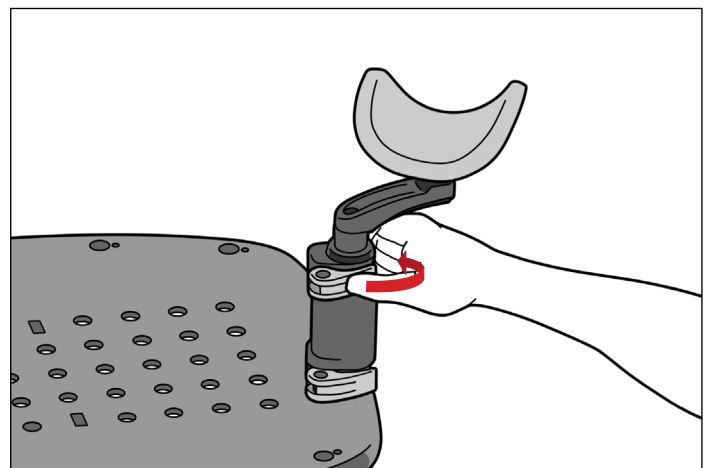


FIG. 18

OPERATING INSTRUCTIONS

SETUP

BOTTOM STOPPER

1. Position the Bottom Stopper so that the curved side faces the Patient Surface, and insert into the opening at the bottom of the slots. (Fig. 19)
2. Once attached to the Base Plate, the Bottom Stopper can be positioned by pushing it superiorly (the Bottom Stopper will ratchet in this direction). (Fig. 20)
3. To move the Bottom Stopper inferiorly, lift up slightly, and slide back to the desired location. (Fig. 21)

! NOTE ! Figure 22 shows the indexing locations for the Bottom Stopper and Locating Bar.



FIG. 19



FIG. 20



FIG. 21



FIG. 22

OPERATING INSTRUCTIONS

SETUP

ARMSHUTTLE ELITE

! NOTE ! The ArmShuttle is an alternative to the Arm and Wrist Supports. Refer to the Product Guide and User Manual for the Armshuttle (P/N 2004227) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Armshuttle.

1. Remove Arm Support(s) by loosening the knob, rotate the Arm Support so that it lines up with the notch at the side of the Patient Surface and pull the Arm Support out of the holes in the Patient Surface. (Fig. 23)
2. Remove Wrist Support(s) by opening the lower lever and pull the Wrist Support out of the holes in the Patient Surface. (Fig. 24)
3. Place the ArmShuttle on top of the Access Supine, aligning the attachment knob holes with the threaded holes located between the Arm Support locations on the Access Supine. (Fig. 25)
4. Secure the ArmShuttle with the attachment knobs, by turning them clockwise until they are tightened. (Fig. 25)

! NOTE ! Figure 26 shows the completed setup.

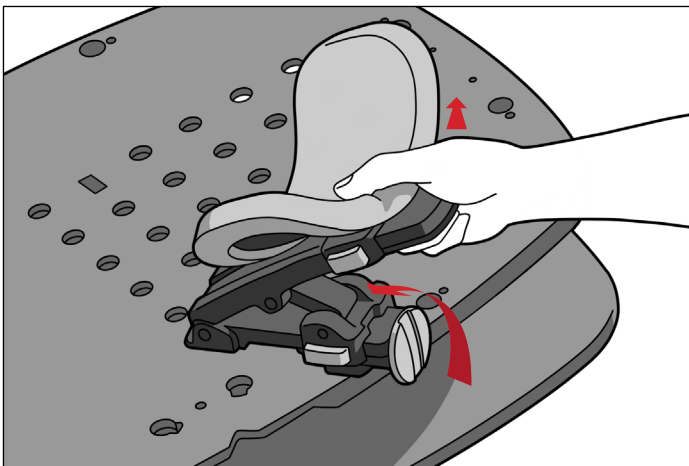


FIG. 23

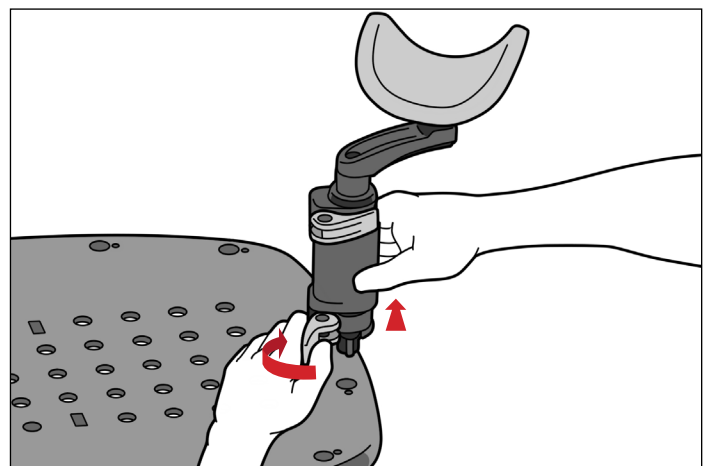


FIG. 24

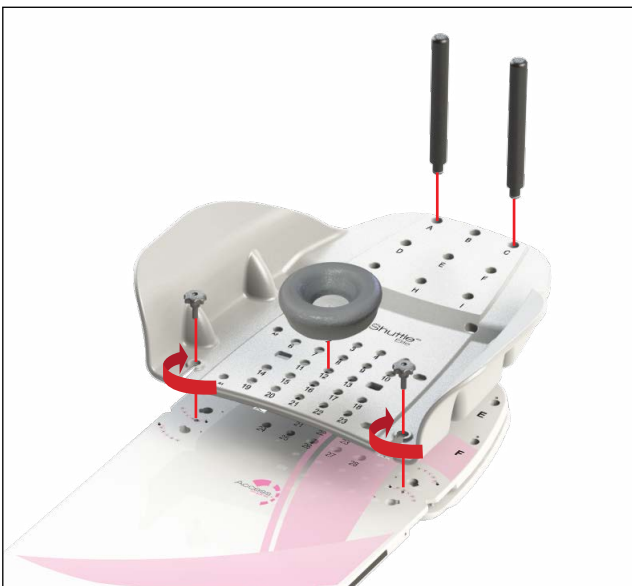


FIG. 25



FIG. 26

OPERATING INSTRUCTIONS

REMOVAL

ARMSHUTTLE ELITE

1. Remove knobs that secure ArmShuttle by turning counter-clockwise.
2. Repeat step 1 for opposing side.
3. Lift the ArmShuttle from Patient Surface.

BOTTOM STOPPER

1. Move the Bottom Stopper inferiorly by lifting up slightly, and sliding back to the removal location.
2. Lift the Bottom Stopper up out of the Base Plate.

ARM SUPPORT

Loosen the knob, rotate the Arm Support so that it lines up with the notch at the side of the Patient Surface and pull the Arm Support out of the holes in the Patient Surface.

WRIST SUPPORT

Open the lower lever and pull the Wrist Support out of the holes in the Patient Surface.

HEADREST

Lift up on the headrest until it is removed from the locating hole.

ACCESS SUPINE

1. Lift the Patient Surface, and lower the Angle Ladder until it is flat on the Base Plate.
2. Lower the Patient Surface until you hear it snap and lock into the Base Plate.
3. Lift the Access Supine off the Locating Bars.
4. Lift up on each end of the Locating Bars to remove from the couch top.

MAINTENANCE

CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe the surface. Visually inspect the device, if it is not clean, repeat the previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe the device to remove any cleaning agent residue. To dry, wipe the device with a clean, dry cloth. The following cleaning material has been tested and found to be appropriate for cleaning the device.

- Water
- Soap and Water

DISINFECTING THE SYSTEM

To disinfect the device surface, refer to specific instructions from the cleaning agent manufacturer.

- 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution

Periodically check all fasteners for tightness.

MAINTENANCE

SIDE MARKING REPLACEMENT

1. Completely remove the current side markings label, including all adhesive residue.
2. Peel paper backing off the new label.
3. Line up the alignment mark in the middle of the side scale to the registration mark on the patient surface, and the bottom edge of label just above the bottom edge of the Patient Surface. Zero should be positioned at the head end of the device. (Fig. 27 & 28)
4. Firmly press the entire label onto the side of the device.
5. Repeat with the other side, if needed.

! NOTE ! DO NOT apply label to the radius of the Patient Surface, doing so may allow for the label to peel off.

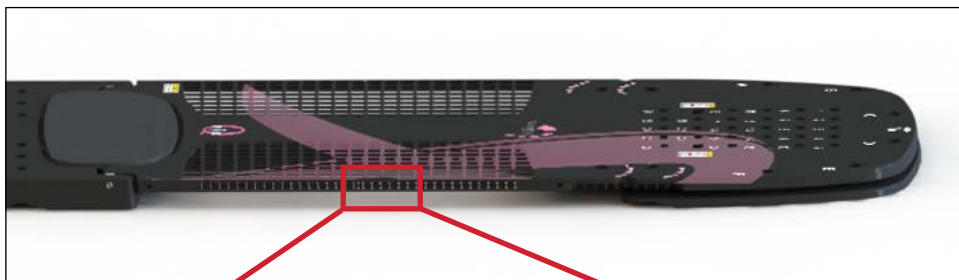


FIG. 27

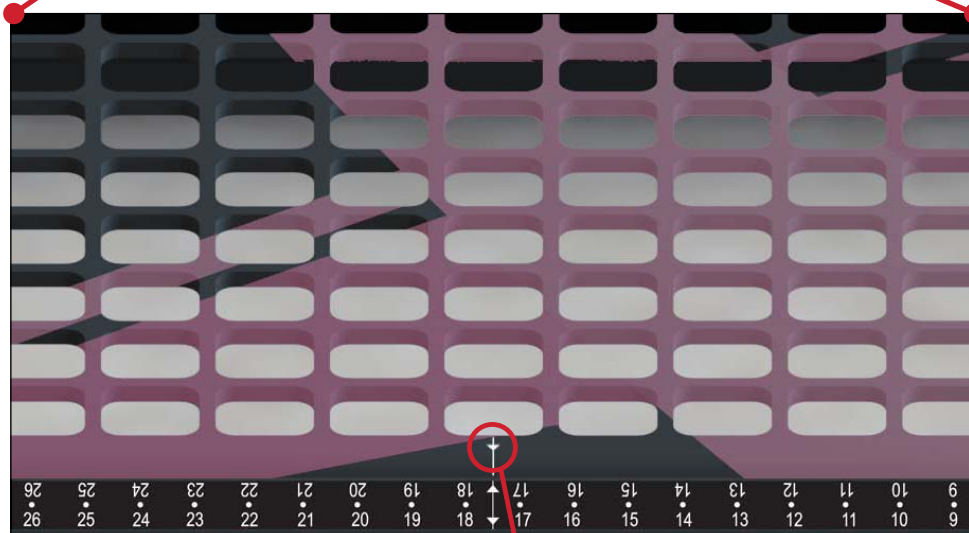


FIG. 28

registration mark

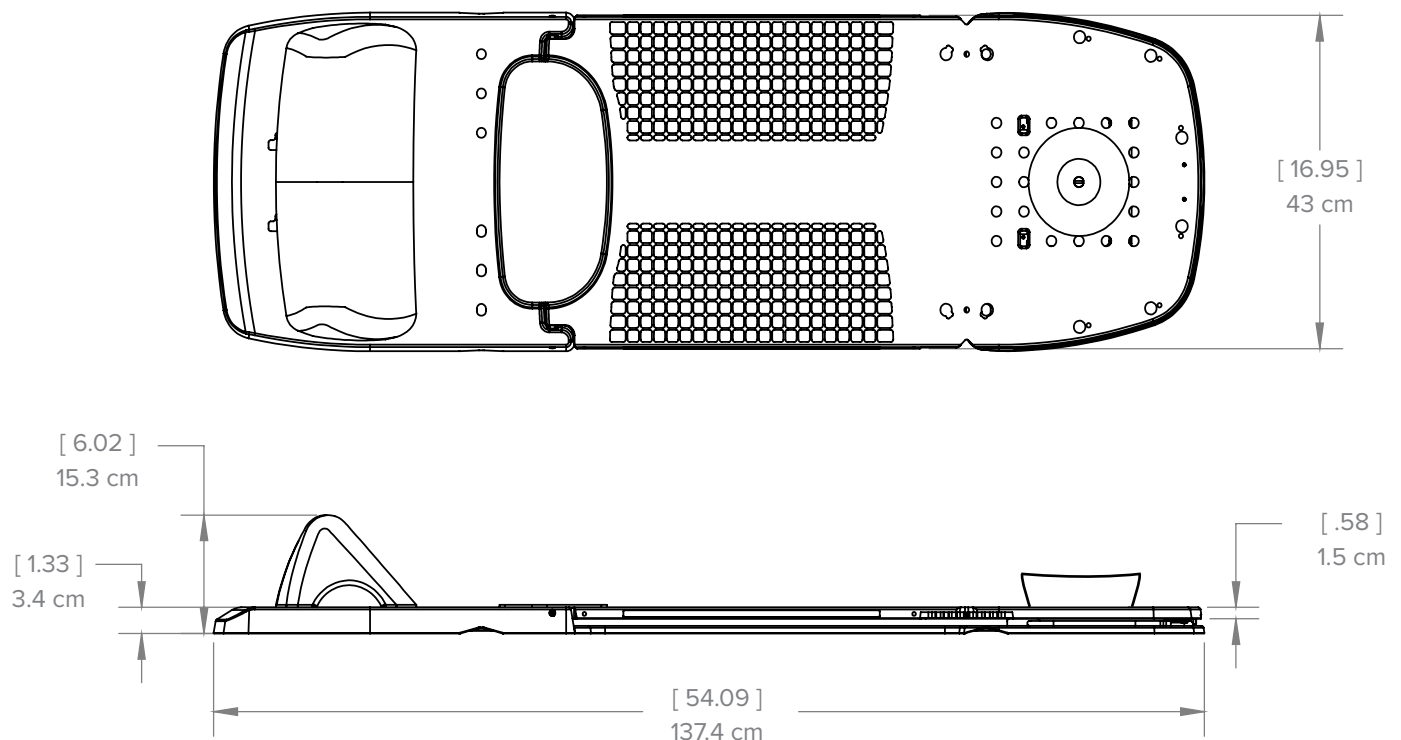
SPECIFICATIONS

DIMENSIONS

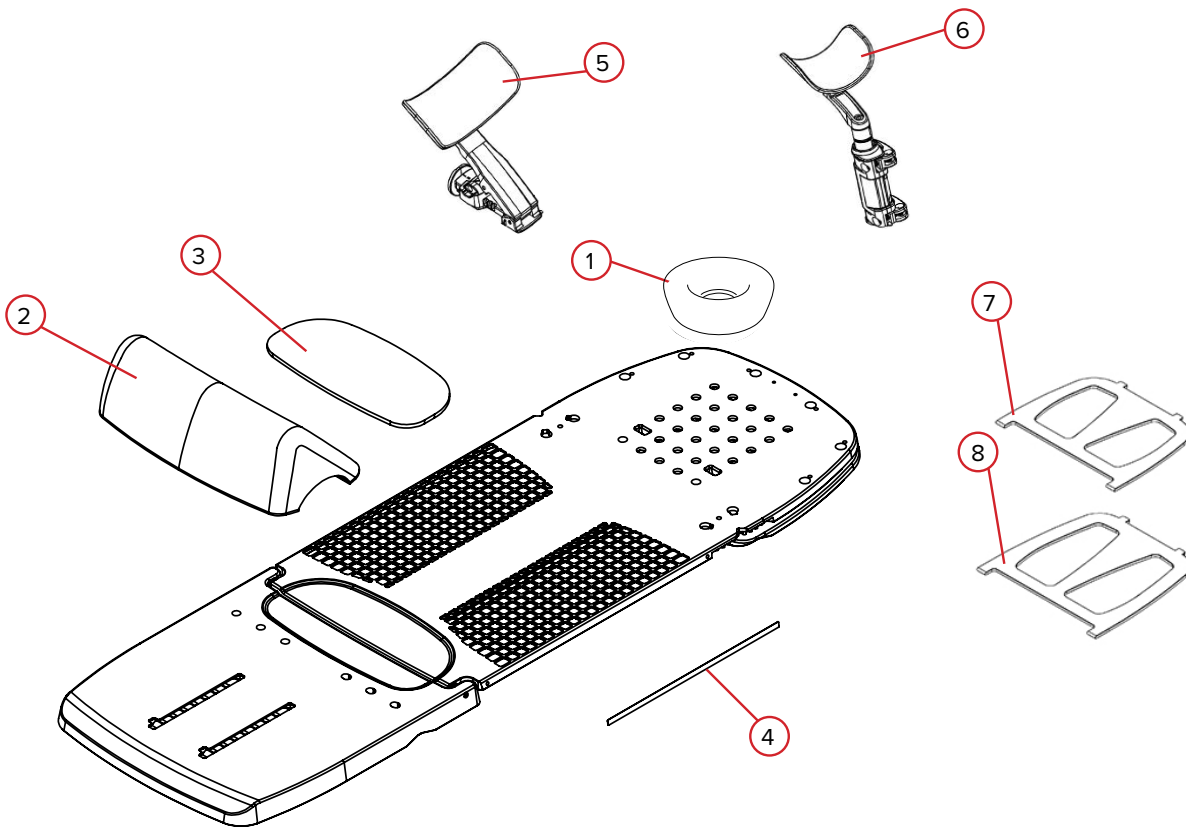
Length (L): 1374 mm

Weight Limit: 249 kg (550 lb) Uniformly Distributed Load

Water Equivalence: *Note: Only applicable for RT-4546 – Access™ Supine Breast and Lung:*
~ 3 mm @ 6 MV in the treatment regions



PARTS LIST



RT-4546, RT-4545MRI, RT-4546-01, & RT-4546-02

- 1. RT-4546H – Foam Headrest
- 2. 2004034 – Foam Bottom Stopper Assembly
- 3. 2004047 – Tailbone Pad
- 4. 2004392 – Side Marking Label (1 each)

RT-4546AA-01

- 5. 2005353 – Foam Arm Cup Pad, wrap-around

RT-4546AW-01

- 6. 2005386 – Foam Wrist Cup Pad, wrap-around

RT-4546L

- 7. 2004121 – Accessory Ladder, 20 degree
- 8. 2004122 – Accessory Ladder, 25 degree

SETUP SHEET

RT-4546: Access Supine Breast & Lung, RT-4546MRI: Access Supine MR Breast & Lung,
RT-4546-01: Access Supine Breast or RT-4546-02: Access Supine Breast & Lung without Grid

Patient Name:

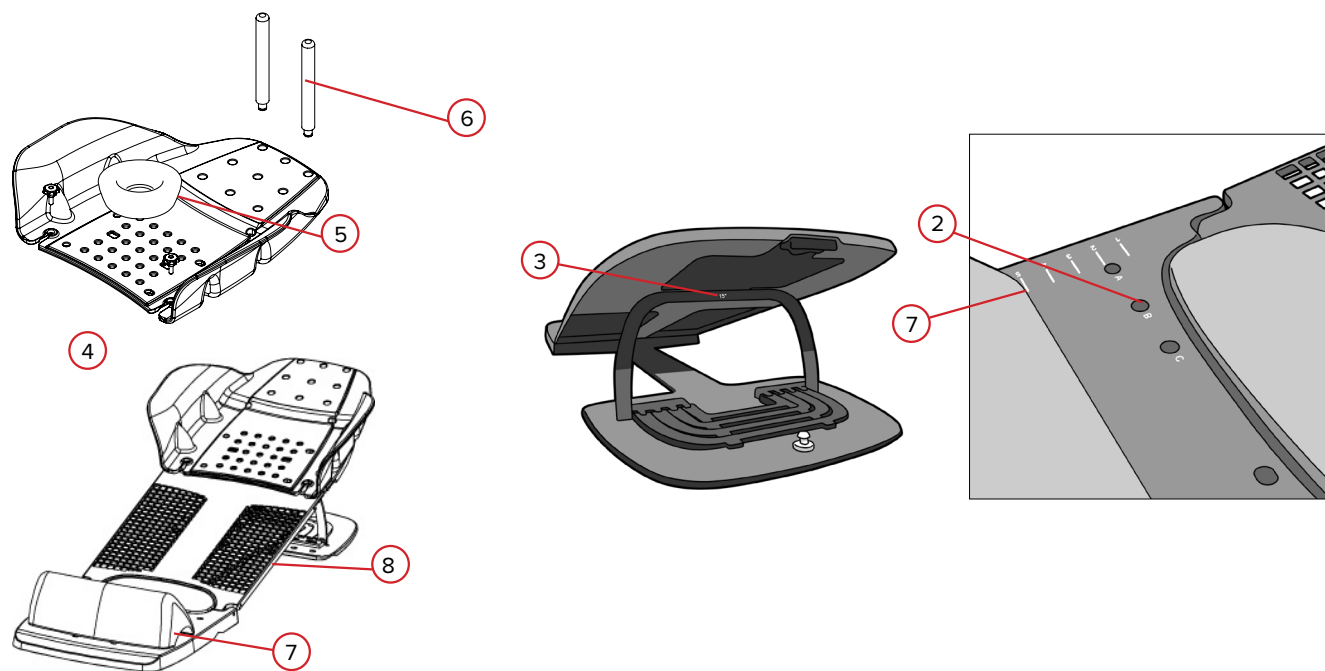
Patient ID #:

Setup by:

Physician:

Date:

Comments:



1. Indexed to simulation or treatment table? **Yes** **No** If yes, Index notch setting
2. Locating bar pin location (select one): **A** **B** **C**
3. Angle of Patient Surface (select one): **0°** **5°** **7.5°** **10°** **12.5°** **15°** **20°** **25°**
4. Used with the ArmShuttle: **Yes** **No**
5. Location of head rest (number 1–28):
6. Location of Hand Post(s) (select ones used)
A **B** **C** **D** **E** **F** **G** **H** **I** **NONE USED**
7. Is a Bottom Stopper used? **Yes** **No** If yes, what setting? (number 1–8)
8. Side marking laser location:

SETUP SHEET

RT-4546: Access Supine Breast & Lung, RT-4546MRI: Access Supine MR Breast & Lung,
RT-4546-01: Access Supine Breast or RT-4546-02: Access Supine Breast & Lung without Grid

Patient Name:

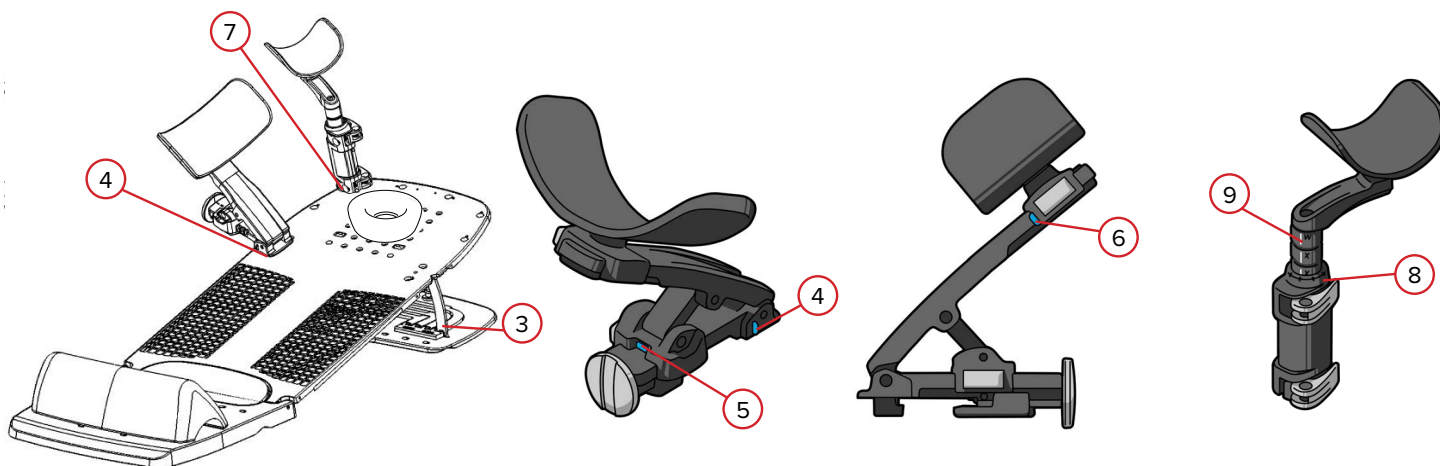
Patient ID #:

Setup by:

Physician:

Date:

Comments:



1. Indexed to simulation or treatment table? **Yes** **No** If yes, Index notch setting
2. Locating bar pin location (select one): **A** **B** **C**
3. Angle of Patient Surface (select one): **0°** **5°** **7.5°** **10°** **12.5°** **15°** **20°** **25°**
4. Location and angle of Arm Supports (select one)—
 Patient's Left: **X** **Y** **-30°** **-15°** **0°** **15°** **30°**
 Patient's Right: **X** **Y** **-30°** **-15°** **0°** **15°** **30°**
5. Height of Arm Supports (number 1–8): Patient's Left Patient's Right
6. Length of Arm Supports (select one): Patient's Left: **A** **B** **C** Patient's Right: **A** **B** **C**
7. Location of Wrist Supports (letter from A to H): Patient's Left Patient's Right
8. Angle of Wrist Supports:
 Patient's Left: **0°** **45°** **90°** **135°** **180°** **225°** **270°** **315°**
 Patient's Right: **0°** **45°** **90°** **135°** **180°** **225°** **270°** **315°**
9. Height of Wrist Supports (letters W–Z): Patient's Left Patient's Right



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