



positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL


RT-4544-01 & RT-4544

Access™ Prone G2 and

Access™ Prone Breast Devices





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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 +1 484-720-6054 OR TECHSUPPORT@QFIX.COM.

! WARNING ! SCALES ON THE ACCESS PRONE AND ACCESS PRONE G2 BREAST DEVICES ARE FOR REFERENCE ONLY.

ADDITIONAL WARNINGS

- The Dual Hand Grips and Ipsilateral Grips are not designed to support the patient's weight
 - DO NOT use handles to position the patient
 - DO NOT use handles to get on or off of the device
- Patients may need assistance getting on and off of the device
- Due to the length of the device it is recommended to have two people handle the device during installation and removal
- DO NOT use more than 3 stacked CT Shims at one time. Doing so may cause device to be unstable
- DO NOT cantilever device
- There is potential for injury between the couch top insert and other equipment in the treatment suite. Use caution when moving the couch top to avoid injury.

TREATMENT BEAM ATTENUATION

The structural regions of the kVue Access™ Prone Couch Top Device will attenuate a photon beam. 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.

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.

LOAD RATING

DO NOT exceed 225 kg (500 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! NOTE ! When combined with the OEM couch base, the load rating is the lower of the two safe working loads. The kVue Couch Top load should NOT exceed the original couch base manufacturer's specifications. Please refer to the product literature provided by the original manufacturer.

GENERAL PRECAUTIONS

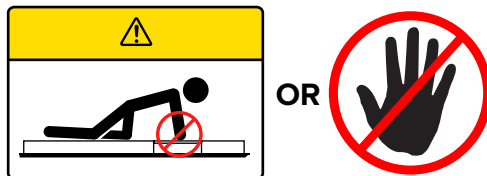
WARNING LABELS & DESCRIPTIONS

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



LOAD RATING

DO NOT exceed 225 kg (500 lb) uniformly distributed load or maximum safe working load of Couch Top Insert, or couch base, whichever is less.



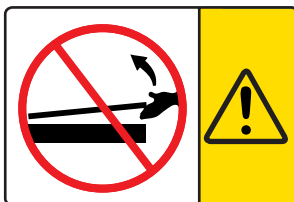
LOAD INSERT

DO NOT allow patient to use Insert for support when getting on or off the device. Doing so may cause injury to patient.



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.



DO NOT LIFT

! NEVER LIFT THE END OF THE COUCH TOP INSERT !

The mating pins may bend or break, rendering the Couch Top unusable.

GENERAL PRECAUTIONS

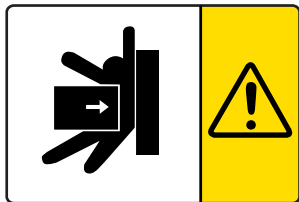
WARNING LABELS & DESCRIPTIONS



DO NOT SIT

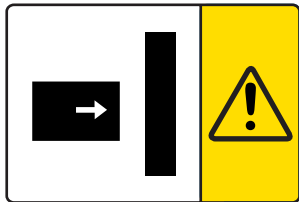
The area beyond the breast cut out has been designed and tested to support the patient's upper torso; it is NOT designed to support the entire patient load.

Standing or sitting on the Access Prone G2 or Access Prone beyond the breast cut out may damage the device or cause injury.



POTENTIAL INJURY

There is potential for injury between the Access Prone G2 or Access Prone and other equipment in the treatment suite. Use caution when moving the Access Prone to avoid injury.



GANTRY COLLISION

The wide variety of motions obtainable by couch bases and treatment heads may present situations where the Couch Top Insert can collide with other items, including the gantry. Use caution when moving the couch or gantry to avoid equipment damage or patient injury.

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

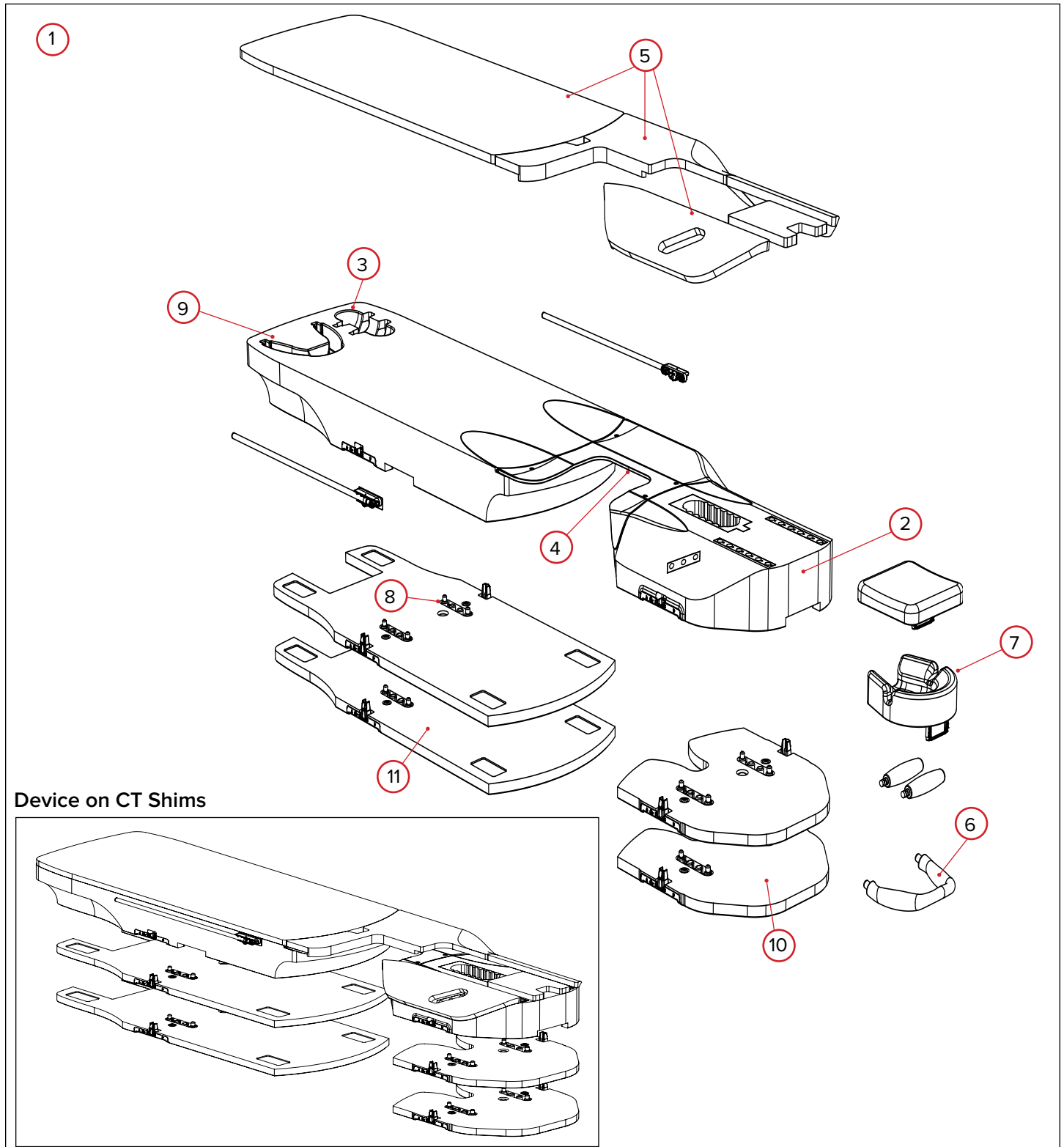
Access Prone G2 and Access Prone are designed to allow breast cancer treatment for both left and right breast. Placing the patient in prone position helps increase separation of the breast from critical organs at risk.

The Access Prone G2 (RT-4544-01) can be used as a CT/MR simulation device for the Access™ 360 G2 (RT-4544KV-10).

! CAUTION ! THE ACCESS PRONE (RT-4544) CANNOT BE USED AS A SIMULATION DEVICE FOR ANY PRODUCT, OTHER THAN ITSELF OR OTHER ACCESS PRONE (RT-4544) DEVICES.

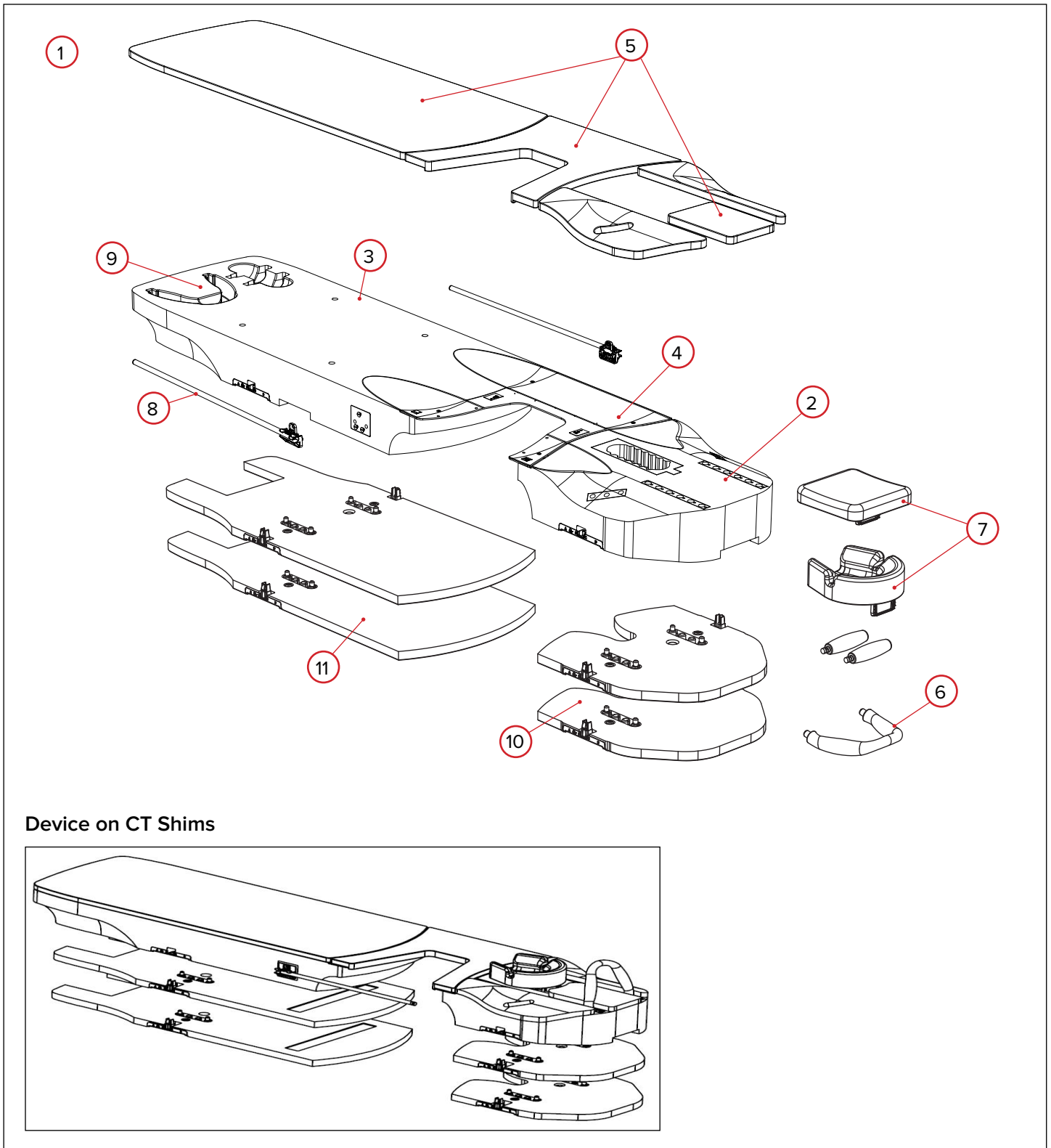
FEATURES

COMPONENTS OF ACCESS PRONE G2 (RT-4544-01)



FEATURES

COMPONENTS OF ACCESS PRONE (RT-4544)



FEATURES

COMPONENTS

1. ACCESS PRONE G2 AND ACCESS PRONE BREAST DEVICES

The Access Prone G2 and Access Prone are used to aid in the positioning and setup of patients undergoing radiotherapy of the breast and clavicle region in the prone position.

2. ARM & HEAD COMPONENT

3. LEG COMPONENT

4. INSERT

Reversible mid-section insert allows the device to be quickly configured for left or right breast treatment.

5. PADS

The pads are for patient comfort, however they can be removed and vacuum cushions may be used. These pads also provide additional patient positioning graphics.

6. DUAL HAND GRIP

The Dual Hand Grip is ergonomically designed to reduce strain on the patient's wrist, unlike the standard post that is used with other devices.

7. HEADRESTS

The system comes with a Prone and Contour Headrest. Either can be used depending on the preference of set-up. They can be indexed to the Access Prone in multiple locations depending on the patients height.

8. IPSILATERAL SCALE

The Ipsilateral Scale swings and snaps in place superiorly for set-up and swings back inferiorly for treatment and storage. The scale may be used as an alignment aid. It's accuracy is ± 1 mm. There is a scale on both sides of the device for left or right breast treatment.

9. STORAGE

Internal hand grip accessory compartments for convenient storage.

10. ARM & HEAD COMPONENT CT SHIM

The CT Shim indexes to a Locating Bar and raises the Arm & Head Component in increments of 2.5 mm. This shim can snap to another Arm & Head Component CT Shim.

11. LEG COMPONENT CT SHIM

The CT Shim indexes to a Locating Bar and raises the Leg Component in increments of 2.5 mm. This shim can snap to another Leg Component CT Shim.

OPERATING INSTRUCTIONS

INSTALLATION

LOCATING BAR

1. The Locating Bar has two locating pins that match most standard positioning accessories. To attach, place either end of the Locating Bar in the appropriate Varian Exact® compatible index notches and snap in place. To remove or reposition, pull up on either end of the bar.

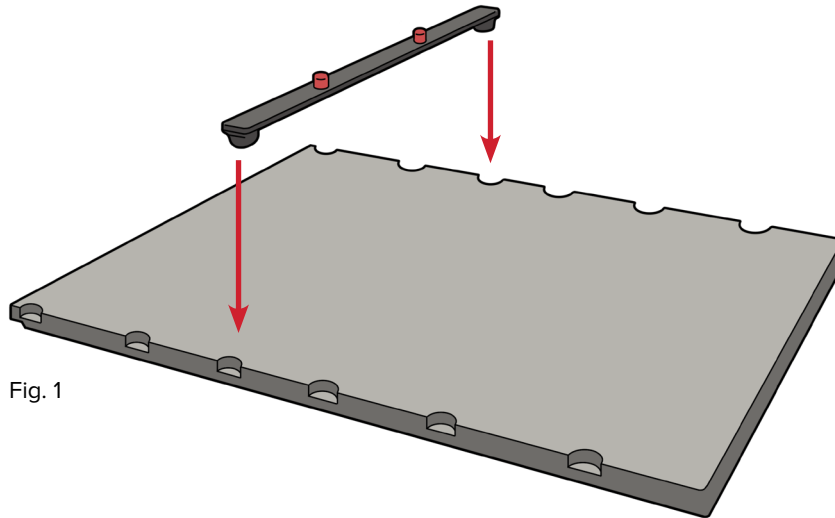


Fig. 1

OPERATING INSTRUCTIONS

INSTALLATION

LOCATING BAR

2. Insert the ends of 2 Locating Bars into the Varian Exact®-compatible index notches on the CT Overlay 1260 mm (typically 9 index notches) apart, and snap the Locating Bars into place. (Fig. 2 & 3)

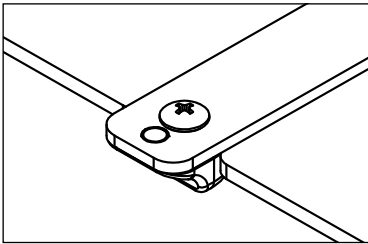


Fig. 2

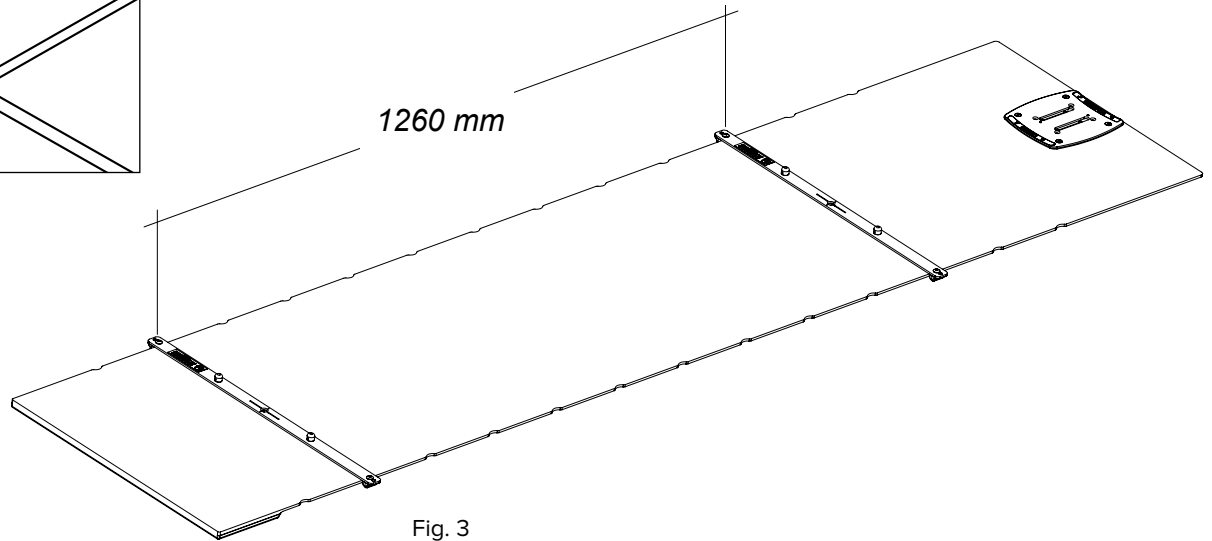


Fig. 3

OPERATING INSTRUCTIONS

SET-UP

ATTACHING THE ARM & HEAD AND LEG COMPONENT TO THE OVERLAY

Place the Access Prone G2 and Access Prone Arm & Head and Foot Components onto the CT Overlay, indexing to the Locating Bars. Be sure to index the Access Prone G2 and Access Prone Components using the same locations on both the Head and Foot Components. (Fig. 4, 5 & 6)

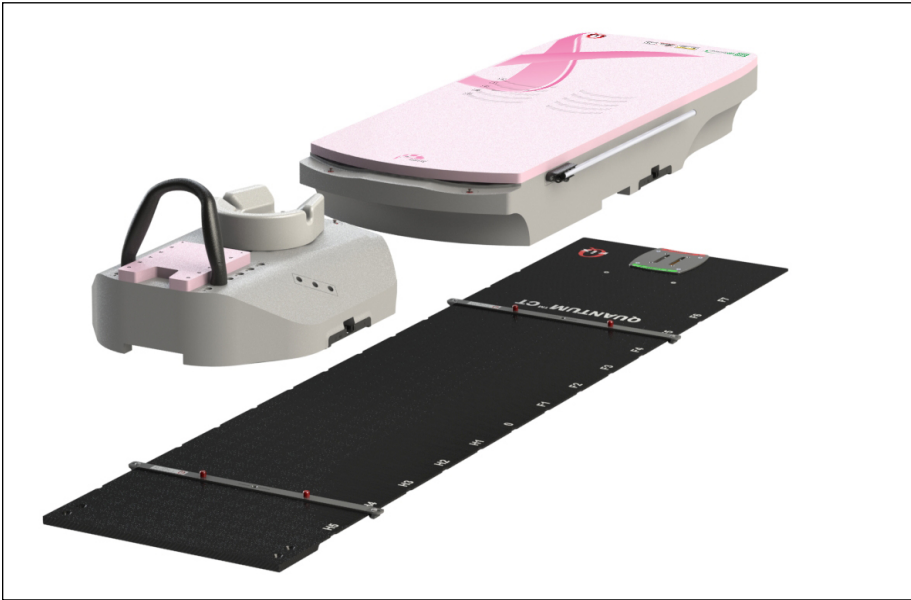


Fig. 4

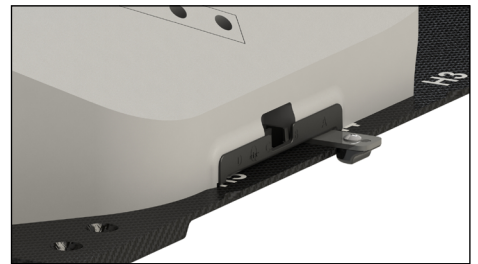


Fig. 5

ATTACHING THE INSERT TO THE ARM & HEAD AND LEG COMPONENT

Attach the insert to the Arm & Head and Leg components using the locating pins on the underside of the insert. (Fig. 6) This insert can be rotated to treat either side.



Fig. 6

OPERATING INSTRUCTIONS

SET-UP

VISUAL ALIGNMENT CHECK

Visually check that the Access™ Prone Components are centered properly on the overlay. (Fig. 7)

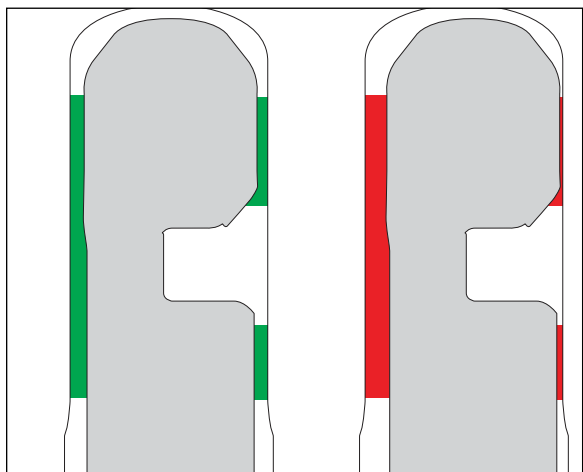


Fig. 7

CT SHIMS

1. To install CT Shims, first remove Access Prone.
2. Place CT Shims in the same indexing spot as Foot and Head Components. CT Shims may be stacked on each other to increase the height by 2.5 cm increments. (Fig. 8)

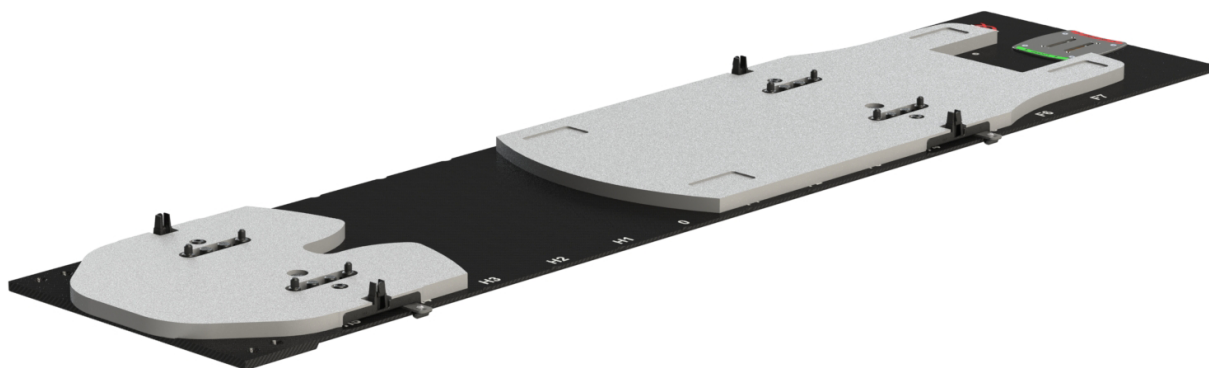


Fig. 8

! CAUTION ! DO NOT USE MORE THAN 3 STACKED CT SHIMS AT ONE TIME. DOING SO MAY CAUSE DEVICE TO BE UNSTABLE.

OPERATING INSTRUCTIONS

SET-UP

CT SHIMS, continued

3. Place Access Prone G2 or Access Prone onto CT Shims. (Fig. 9)

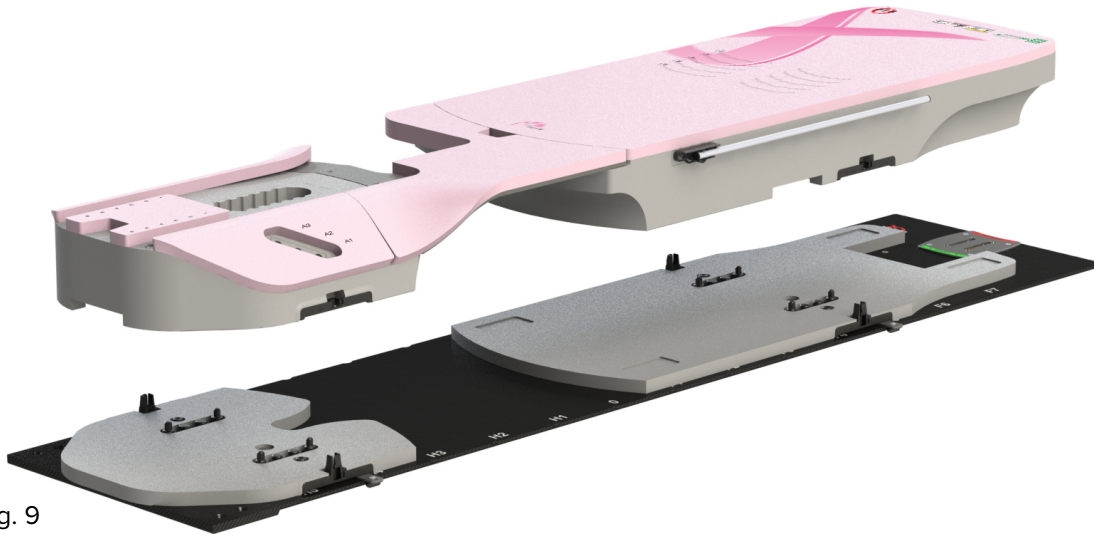


Fig. 9

4. To decrease the height of the device, remove the Access Prone G2 or Access Prone Breast Device. Press in release button on each side of indexing plate. (Fig. 10)

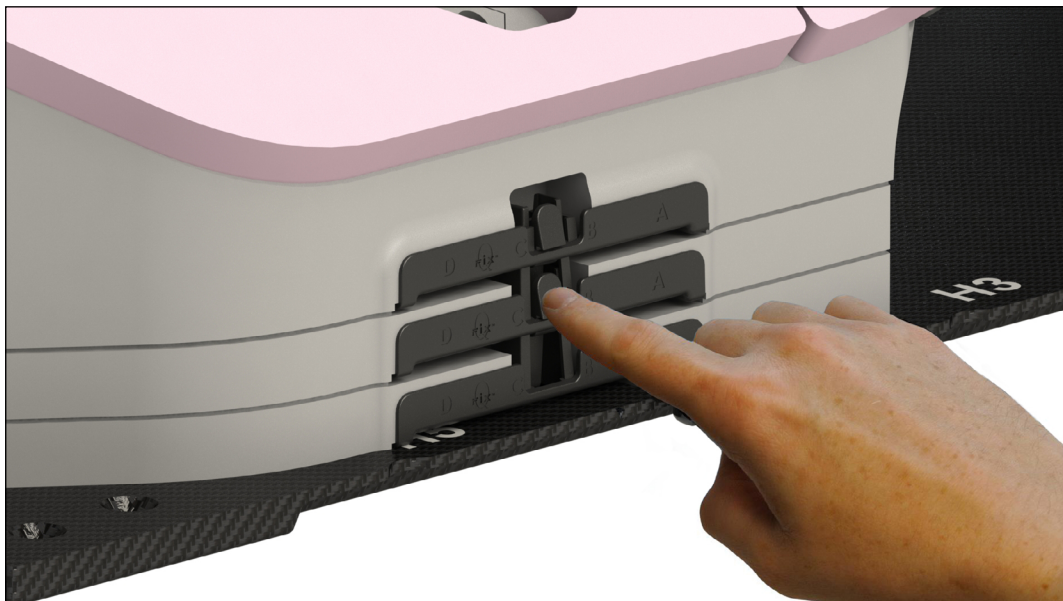


Fig. 10

OPERATING INSTRUCTIONS

SET-UP

HEADREST

1. Choose either the Prone Headrest or Contour Headrest to use for patient.
2. Insert the plastic alignment piece into the appropriate slot at the superior end of the device. (Fig. 11)

! NOTE ! Headrests may be installed prior to patient getting onto the device, but may need repositioning once patient is in place.

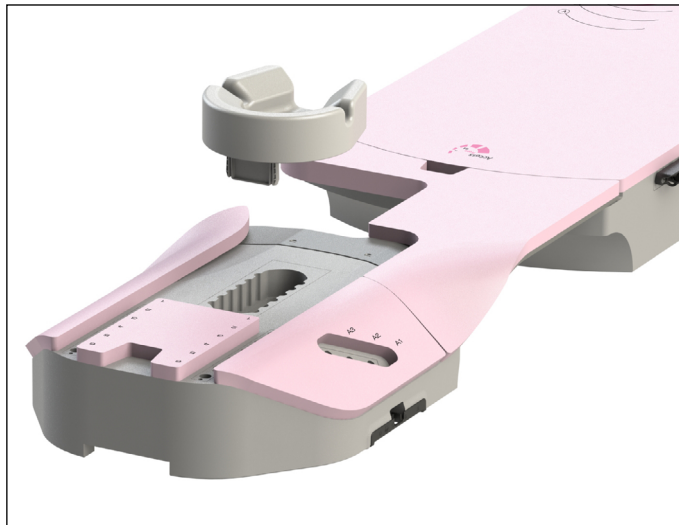


Fig. 11

OPERATING INSTRUCTIONS

SET-UP

PATIENT POSITIONING

! NOTE ! Patients may need assistance getting on and off of the device. The instructions below are our suggested technique, but may vary for each clinic.

HOW TO GET ON AND OFF THE ACCESS PRONE G2 OR ACCESS PRONE

1. Lower the Couch or use a step stool to assist the patient in getting onto the Insert.
2. Once the patient is on the Insert, line up their knees with the proper markings on the foam. (Fig. 12)
3. Have the patient use their hands or elbows to move their upper body into position. (Fig. 13)
4. Have the patient slowly lower into position.
5. Once in position, place the patients head into the head rest and have them grab the appropriate hand grips. (Fig. 14)

! CAUTION ! THE DUAL HANDLE AND IPSILATERAL HAND GRIP ARE NOT DESIGNED TO SUPPORT A PATIENTS WEIGHT:

- **DO NOT** use handles to position the patient.
- **DO NOT** use handles to get on or off of the device.

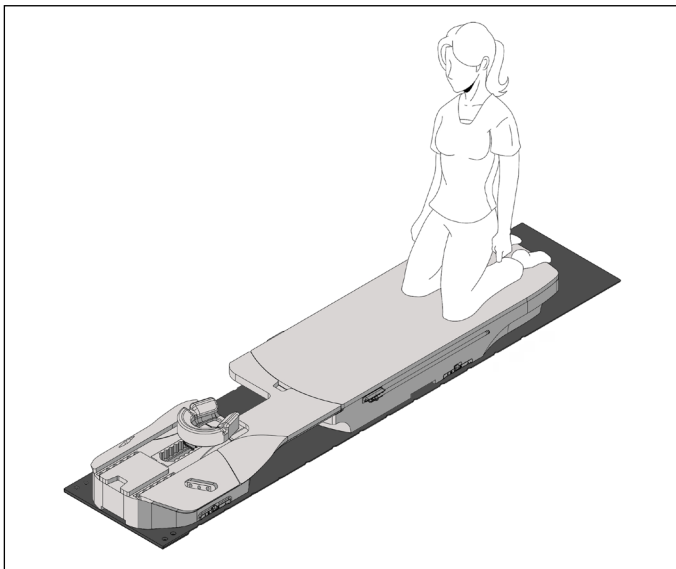


Fig. 12

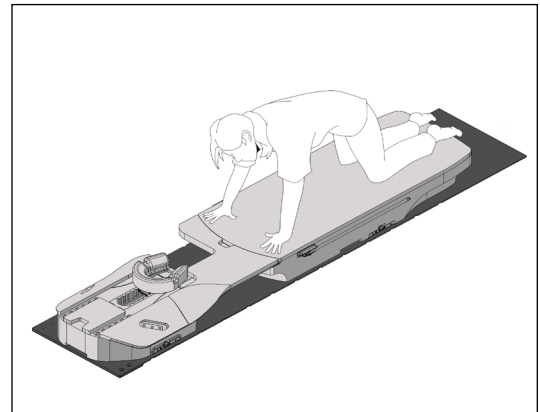


Fig. 13

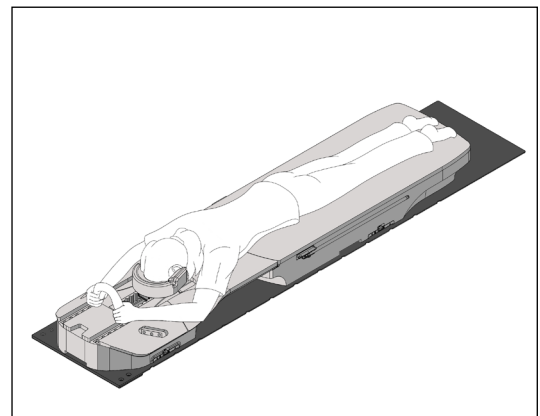


Fig. 14

OPERATING INSTRUCTIONS

SET-UP

DUAL HAND GRIP

! CAUTION ! THE DUAL HAND GRIP AND IPSILATERAL HAND GRIP ARE NOT DESIGNED TO SUPPORT A PATIENTS WEIGHT:

- **DO NOT** use handles to position the patient.
- **DO NOT** use handles to get on or off of the device.

1. Align ends of the Hand Grip with corresponding holes at the superior end of the Insert.
2. Push down on the Hand Grip until it snaps into the holes. (Fig. 15)

! NOTE ! The Hand Grip should be arched back towards the patient as shown in the image below. (Fig. 16)

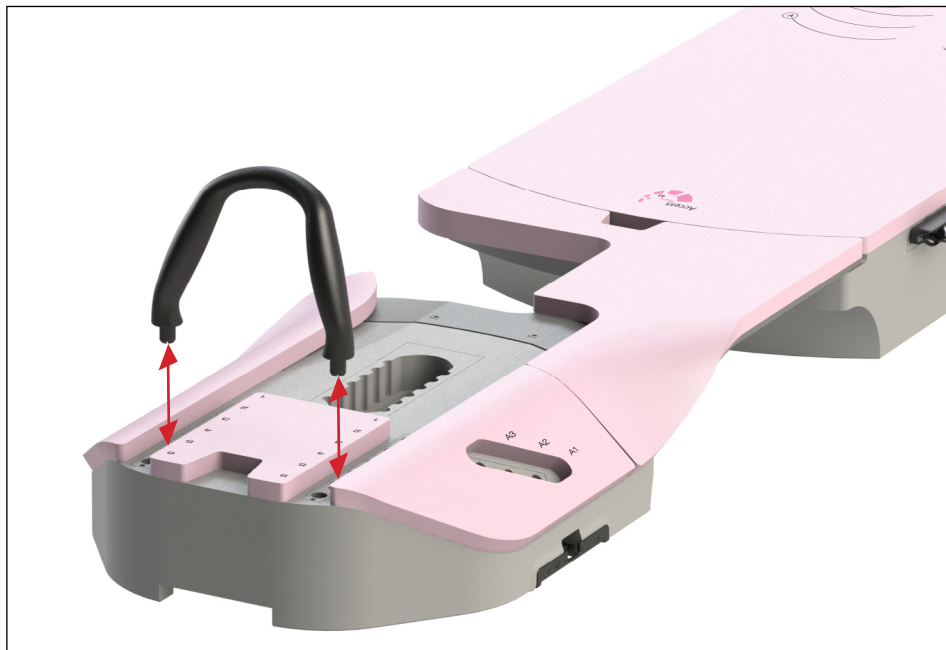


Fig. 15

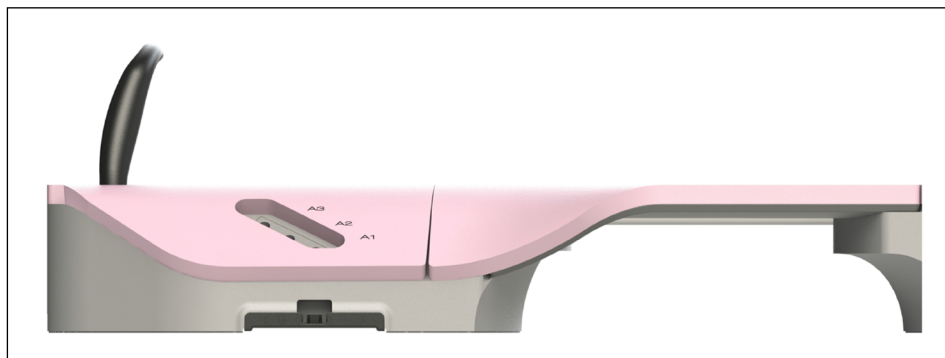


Fig. 16

OPERATING INSTRUCTIONS

SET-UP

IPSILATERAL HAND GRIP

1. Insert the Hand Grip into the appropriate hole at the superior end of the Insert. (Fig. 17)
2. Turn the Hand Grip either direction until handle tightens in the hole and locks into place. (Fig. 17)



Fig. 17

STORAGE

The Dual Hand Grip and Ipsilateral Hand Grips can be stored in the storage area located in the foot end of the leg component. (Fig. 18)



Fig. 18

OPERATING INSTRUCTIONS

SET-UP

IPSILATERAL SCALE

! CAUTION ! THE IPSILATERAL SCALE IS NOT DESIGNED TO SUPPORT A PATIENTS WEIGHT.

! CAUTION ! DO NOT USE HANDLES TO GET ON OR OFF OF THE DEVICE.

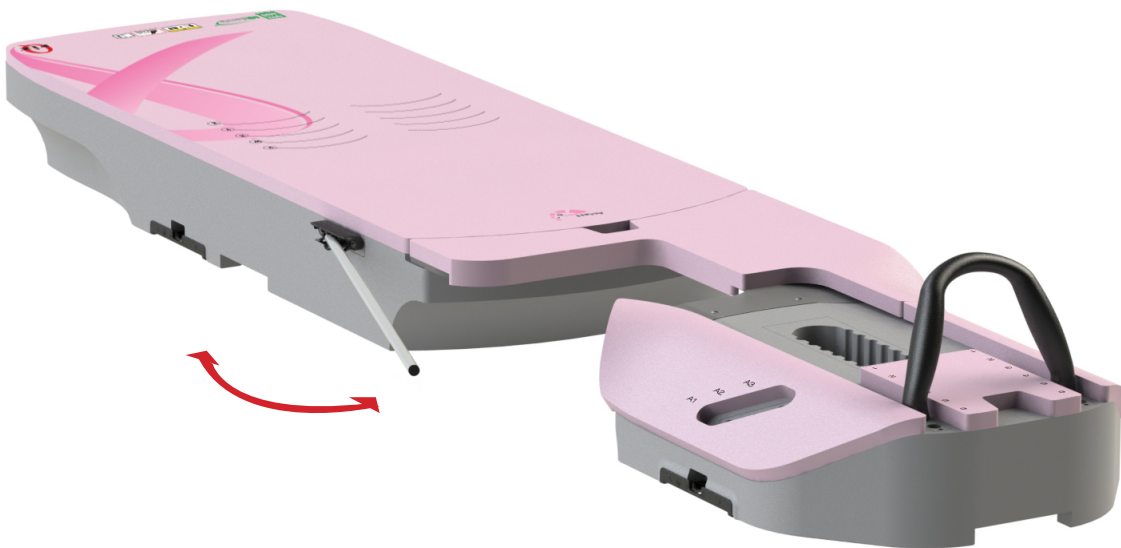
1. Align the patient.
2. Once patient is in place, swing Ipsilateral Scale superiorly until it locks into place. (Fig. 19)

! NOTE! The scales are present as an alignment aid; it is the user's responsibility to confirm the position of the patient.

! NOTE! The scales accuracy are tested to ± 1 mm

3. Swing the Ipsilateral Scale inferiorly, into it's storage position, prior to treatment and/or storage. (Fig. 19)

Fig. 19



OPERATING INSTRUCTIONS

REMOVAL

IPSILATERAL HAND GRIP

Turn the opposite direction of installation until the handle loosens, then pull straight out. The Ipsilateral Hand Grip can be stored in the base of the Foot Component under the Cushion.

DUAL HAND GRIP

Pull upward until it snaps out of the holes. The Dual Hand Grip can be stored in the base of the Foot Component under the Cushion.

PATIENT

Follow the positioning instructions in reverse.

! NOTE ! Patients may need assistance getting on and off of the device.

BREAST INSERT

Pull the Breast Insert upward away from the Head and Foot Components.

HEADREST

Pull the headrest upward away from the Insert.

ARM & HEAD AND FOOT COMPONENT

Lift the Arm & Head and Foot Components upward away from the Overlay. If required, the Shims may be disassembled from the Arm & Head and Foot Components by pushing in on the release buttons on each side of the blue indexing plates.

LOCATING BAR REMOVAL

Pull up on either end of the Locating Bar.

MAINTENANCE

CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. Do not spray or pour liquids onto the surface as they may flow into the OneTouch™ Latch or mechanisms within the device. To clean, apply solution to clean cloth and wipe the surface.

DISINFECTING THE SYSTEM

The following cleaning materials have been tested and found to be appropriate for cleaning the Access Prone G2, Access Prone and Couch Top Insert surfaces. To disinfect the couch top surface, refer to specific instructions from the cleaning agent manufacturer.

- Water
- A 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution
- Soap and Water

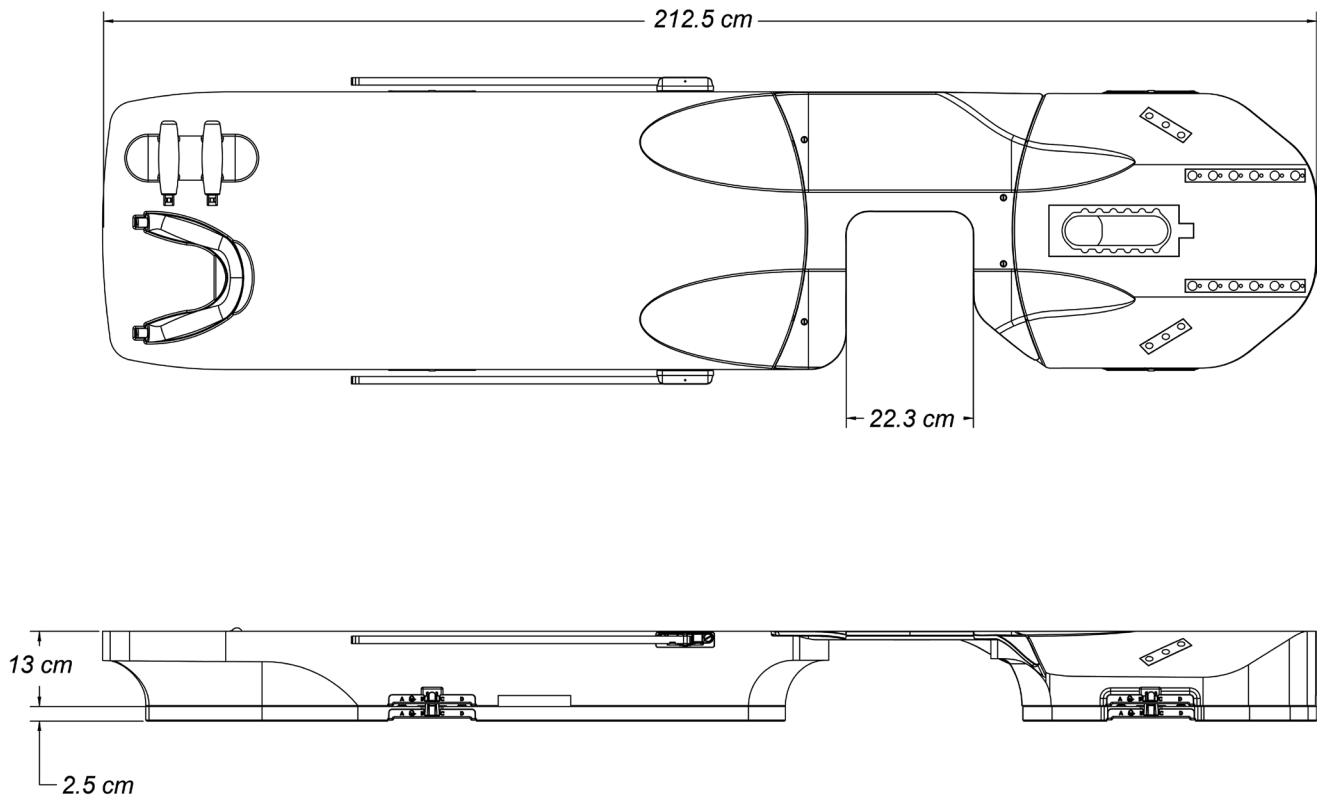
DO NOT spray directly onto the Access Prone G2, Access Prone or Couch Top Insert or allow to flow into the Baseframe.

DO NOT place sharp objects on the Access Prone G2, Access Prone or Couch Top Insert.

SPECIFICATIONS

ACCESS PRONE G2

Weight Limit: 225 kg (500 lb) Uniformly Distributed Load



PATIENT SETUP

ACCESS PRONE G2 (RT4544-01)—RIGHT AND LEFT BREAST

Patient Name:

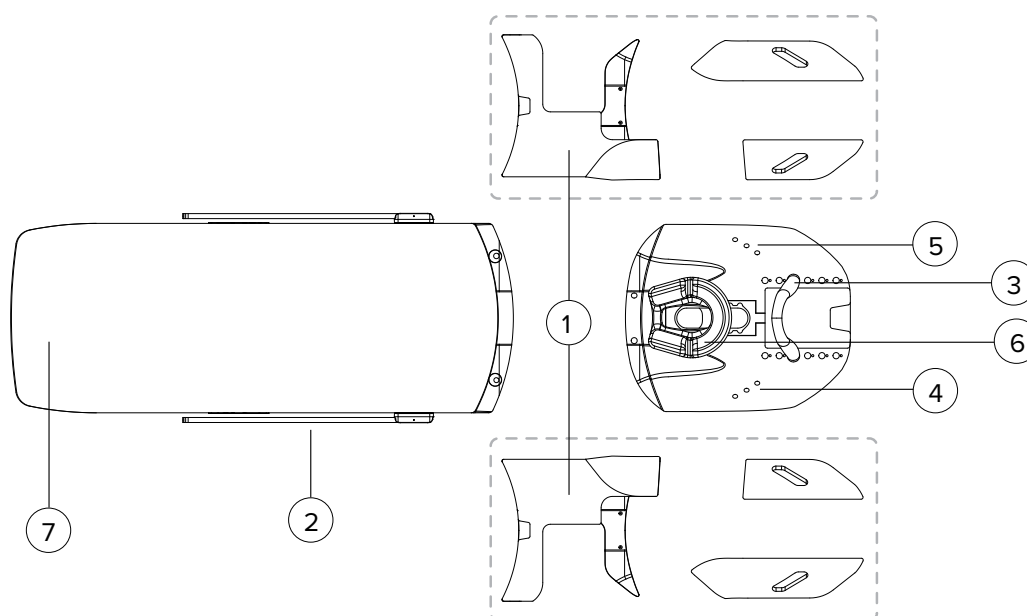
Patient ID #:

Setup by:

Physician:

Date:

Comments:



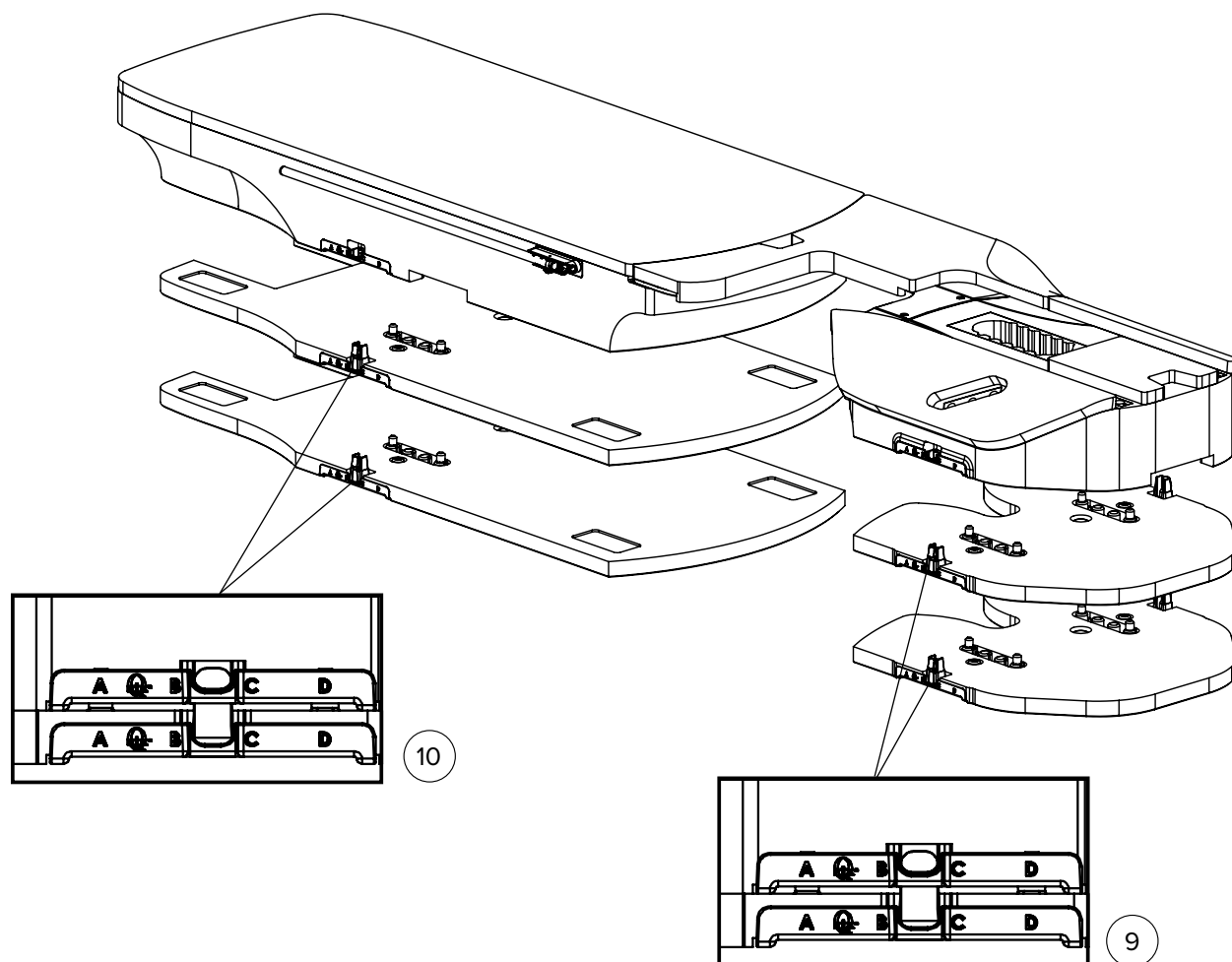
1. Insert: **Left** **Right**
2. Ipsilateral Scale:
3. Dual Hand Grip Location (select one): **1** **2** **3** **4** **5** **6** **N/A**
4. Hand Grip, *Patient Right* (select one): **A1** **A2** **A3** **N/A**
5. Hand Grip, *Patient Left* (select one): **A1** **A2** **A3** **N/A**
6. Headrest Used: **None** **Prone** **Contour**
Location (select one): **A** **B** **C** **D** **E** **F**
7. Knee Location (select one): **V** **W** **X** **Y** **Z**

Notes:

(Continued on back)

PATIENT SETUP

ACCESS PRONE G2 (RT4544-01) (CONTINUED)



CT Risers and Shims

8. How many sets of CT Riser Shims are being used (select one): **0** **1** **2**
9. Superior CT Riser—Location on Locating Bar **A** **B** **C** **D**
 - Locating Bar location on couch top:
10. Inferior CT Riser—Location on Locating Bar **A** **B** **C** **D**
 - Locating Bar location on couch top:

Notes:

PATIENT SETUP

ACCESS PRONE (RT-4544)—RIGHT AND LEFT BREAST

Patient Name:

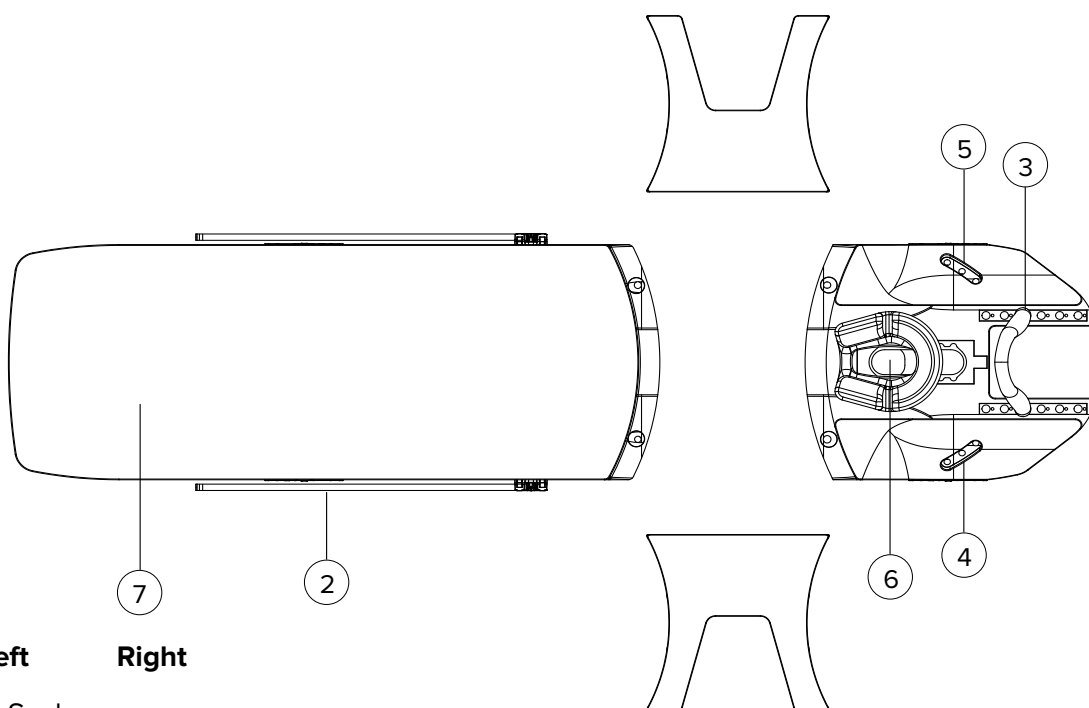
Patient ID #:

Setup by:

Physician:

Date:

Comments:



1. Insert: **Left** **Right**

2. Ipsilateral Scale:

3. Dual Hand Grip Location (select one): **1** **2** **3** **4** **5** **6** **N/A**

4. Hand Grip, *Patient Right* (select one): **A1** **A2** **A3** **N/A**

5. Hand Grip, *Patient Left* (select one): **A1** **A2** **A3** **N/A**

6. Headrest Used: **None** **Prone** **Contour**
Location (select one): **A** **B** **C** **D** **E** **F**

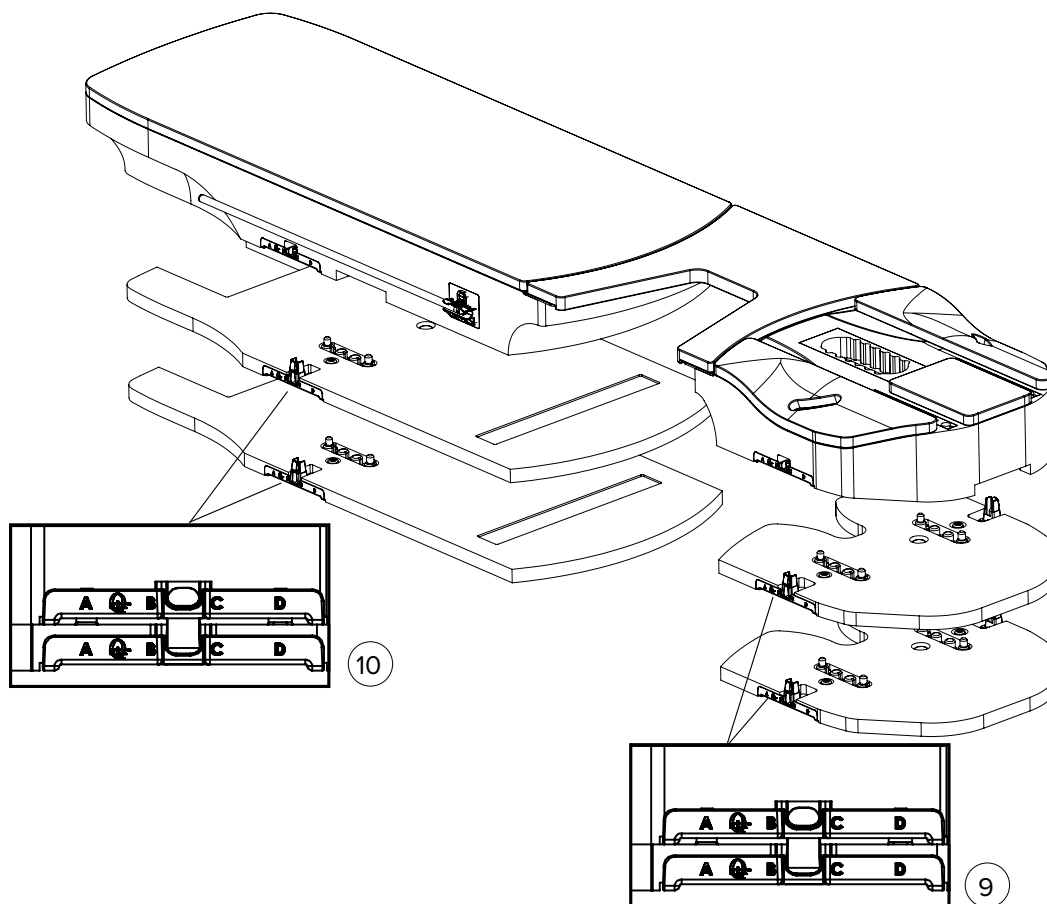
7. Knee Location (select one): **V** **W** **X** **Y** **Z**

Notes:

(Continued on back)

PATIENT SETUP

ACCESS PRONE (RT-4544) (CONTINUED)



CT Risers and Shims

8. How many sets of CT Riser Shims are being used (select one): **0** **1** **2**

9. Superior CT Riser—Location on Locating Bar **A** **B** **C** **D**

- Locating Bar location on couch top:

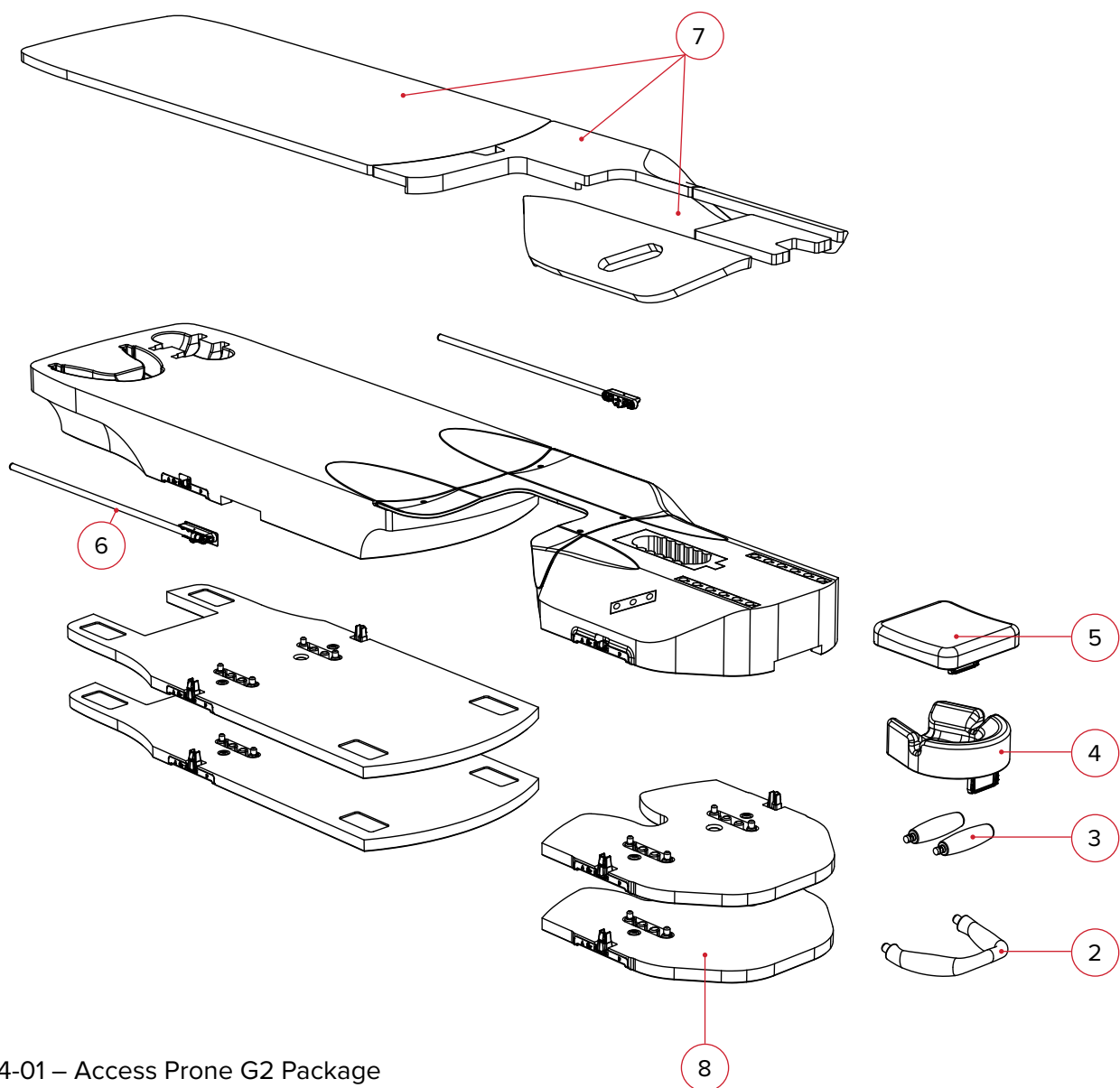
10. Inferior CT Riser—Location on Locating Bar **A** **B** **C** **D**

- Locating Bar location on couch top:

Notes:

PARTS LIST

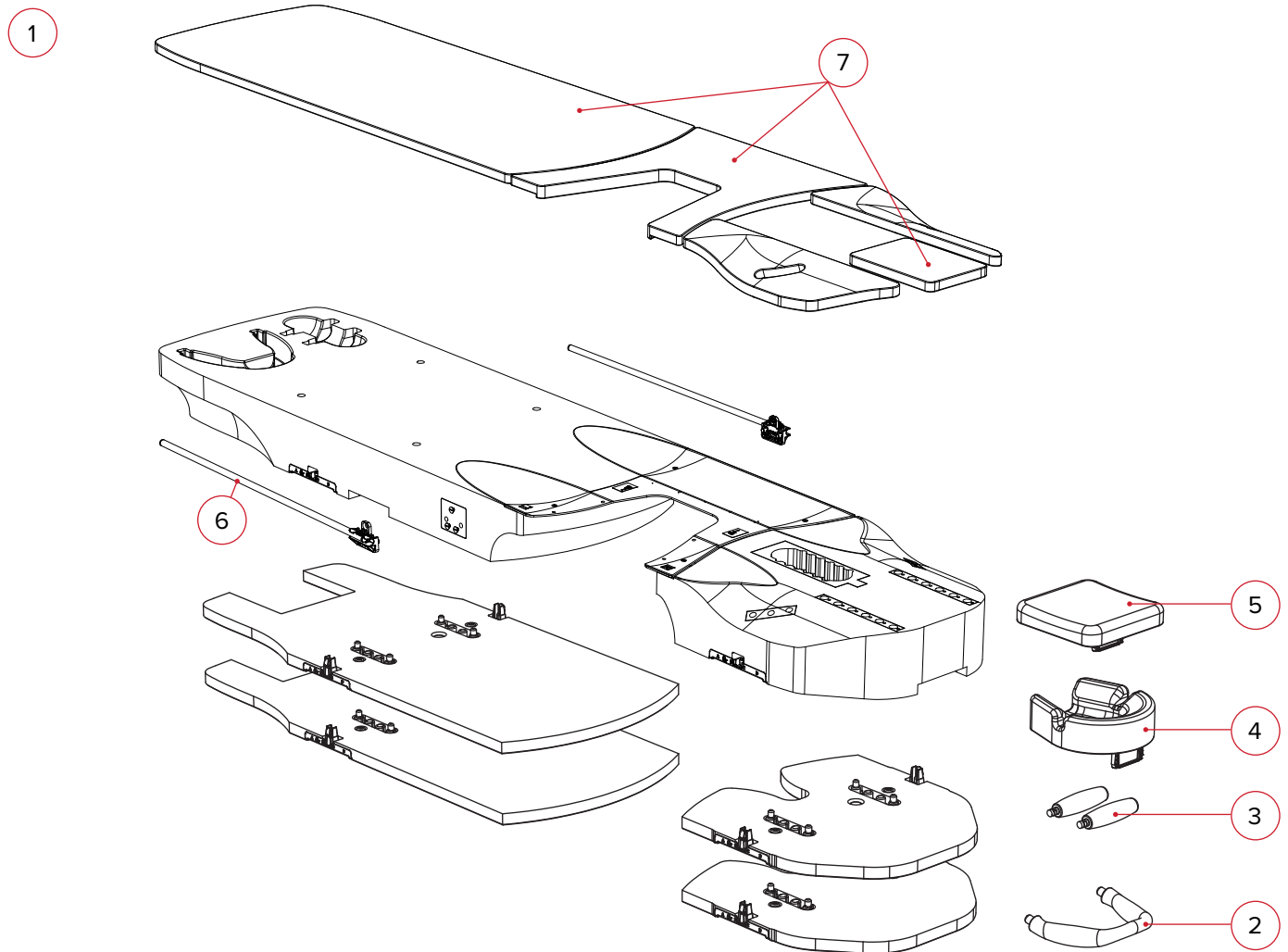
ACCESS PRONE G2 (RT-4544-01)



1. RT-4544-01 – Access Prone G2 Package
 - 2005408 Access Prone G2 Right Insert Assembly
 - 2005424 Access Prone G2 Left Insert Assembly
2. RT-4544KV-04 – Dual Grip Handle
3. RT-4544KV-05 – Hand Grip Post
4. RT-4544KV-06 – Prone Headrest
5. RT-4544KV-07 – Contour Headrest
6. Ipsilateral Scale, Low Profile
 - 8002601 – 40 cm (Replacement Scale)
 - 8002602 – 48 cm (Accessory Scale)
7. 2006813 – AP-2 Pad Set
8. 8002580 – AP-2 Shim Set

PARTS LIST

ACCESS PRONE (RT-4544)



1. RT-4544 – Access™ Prone Package
 - 2004257 Access Prone G1 Breast Insert Assembly
2. RT-4544KV-04 – Dual Grip Handle
3. RT-4544KV-05 – Hand Grip Post
4. RT-4544KV-06 – Prone Headrest
5. RT-4544KV-07 – Contour Headrest
6. 8001846 – Ipsilateral Scale
7. 8002215 – Access™ Prone Pad Set



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