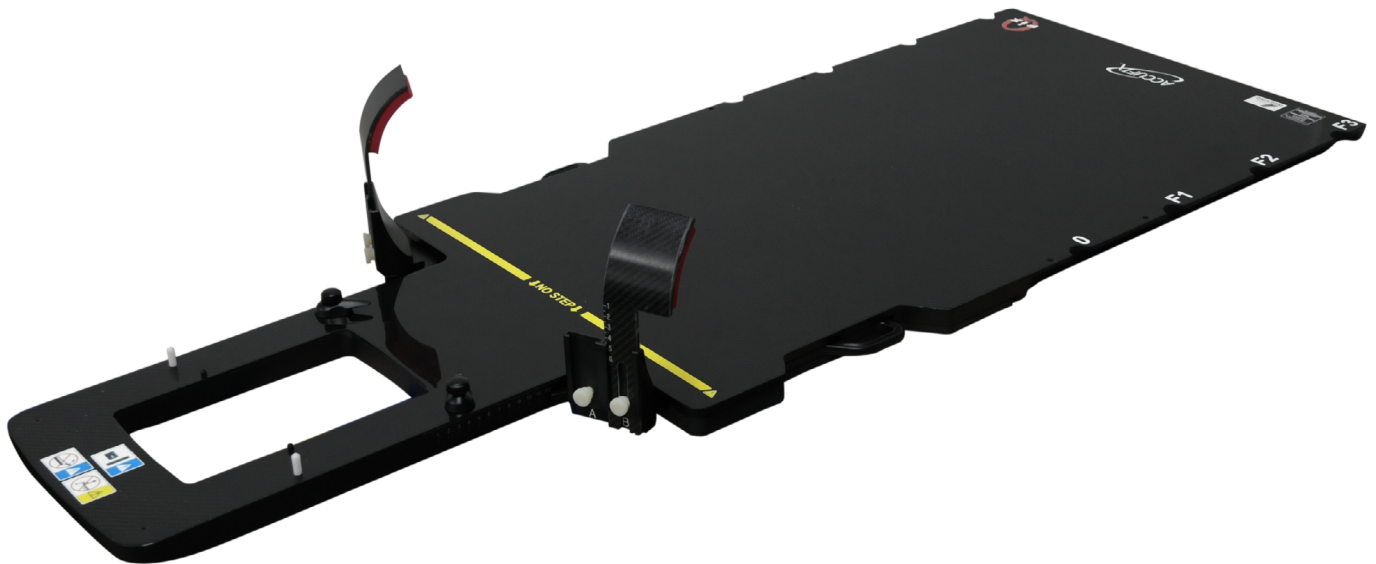



PRODUCT GUIDE & USER MANUAL

RT-4525KVL

kVue[™] AccuFix[™] Cantilever Board Insert
Featherline Edition for kVue[™] Couch Top





<div>EC</div> <div>REP</div>		<div>Advena Limited</div> <div>Tower Business Centre, 2nd Flr</div> <div>Tower Street, Swatar, BKR 4013</div> <div>Malta</div>	<div> Made in the USA by</div> <div>Qfix</div> <div>440 Church Rd, Avondale, Pennsylvania, USA</div> <div>+1 610-268-0585 www.Qfix.com</div>
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Aquaplast RT, AccuFix, kVue and OneTouch are trademarks of Qfix.

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Exact® is a registered trademark of Varian Medical Systems.

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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 ! THE ONETOUCH IS A PRECISION MECHANISM AND IS ONLY FOR USE WITH APPROVED QFIX KVUE DEVICES. UNAPPROVED NON-QFIX DEVICES THAT HAVE NOT BEEN VALIDATED BY QFIX MAY NOT BE SAFE FOR USE AND WILL VOID WARRANTY IF USED.

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

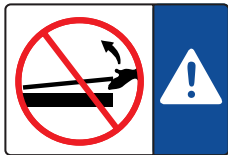
DO NOT exceed 249 kg (550 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! 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.

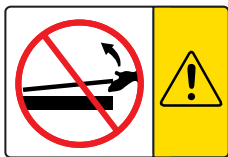
GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



OR



KVUE INSERT INSTALLATION AND REMOVAL

! WARNING ! NEVER LIFT THE END OF THE KVUE INSERT !

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

Refer to the kVue Couch Top Installation Manual for kVue installation and removal instructions.

↓ **NO STEP** ↓

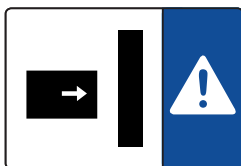
OR



“NO STEP” LINE

The yellow line on the kVue Insert represents the end of the support beams. The area beyond the line has been designed and tested to support the patient's upper torso or lower body not exceeding the load rating.

Standing or sitting on the kVue Insert beyond the “No Step” line may damage the kVue Insert or cause 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

Patient's 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.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE COUCH TOP INSTALLATION

The kVue Couch Top is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

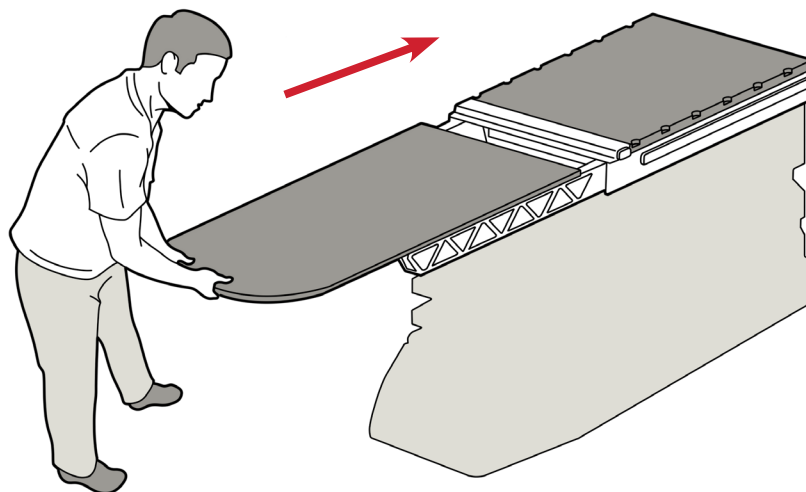
! NOTE ! As detailed in the kVue Couch Top Installation Manual, the final height of the kVue surface may be different from the original system. Refer to the original system instructions to reset the system zero (origin) prior to initial use.

KVUE INSERT INSTALLATION

1. Place the AccuFix™ Insert on top of the support beams and align the two mating pins with the receiving holes in the OneTouch Latch.
2. From the head end of the kVue, slide the AccuFix Insert directly into the receiving holes.

You will hear a click when the AccuFix Insert is locked into place. ONLY the green button surface will be visible when properly installed.

3. Verify insert is fully engaged by gently pulling it backwards, away from OneTouch Latch, to ensure it does not come out of receiving holes. Repeat this step during patient setup, even if insert has previously been installed.



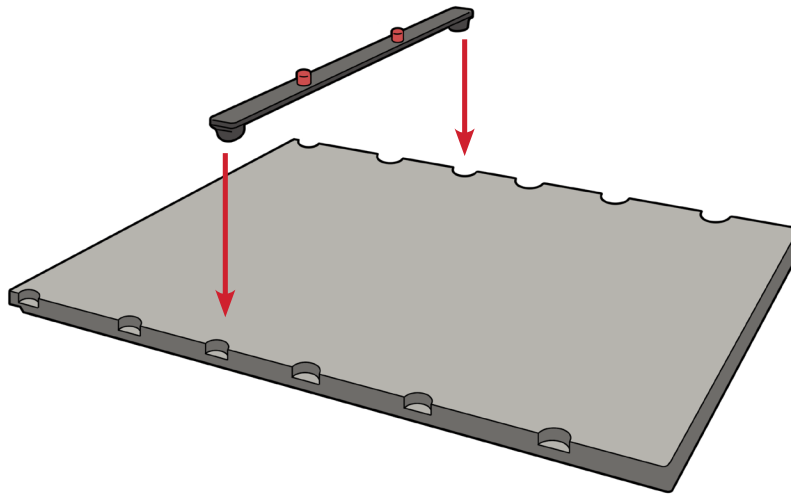
kVue with Standard Insert

OPERATING INSTRUCTIONS

SET-UP

LOCATING BAR INSTALLATION

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.



OPERATING INSTRUCTIONS

REMOVAL

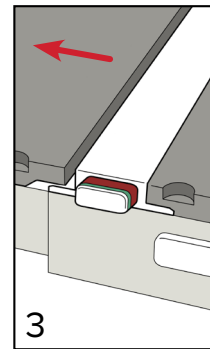
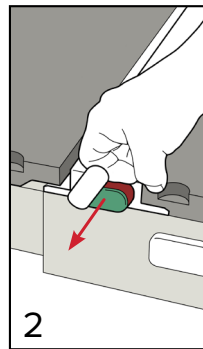
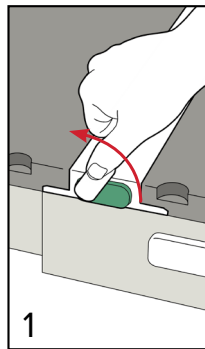
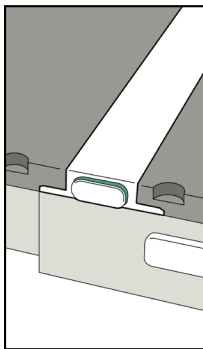
LOCATING BAR REMOVAL

Pull up on either end of the Locating Bar.

KVUE INSERT REMOVAL

! WARNING ! NEVER LIFT THE END OF THE KVUE INSERT ! ALTHOUGH THE MECHANISM IS VERY ROBUST, THE MATING PINS MAY BEND OR BREAK, RENDERING THE KVUE UNUSABLE.

1. Rotate Lever counter-clockwise.
2. Pull the rotated Lever from one side of the kVue until the kVue Insert is released.
3. Slide the kVue Insert away from the kVue.



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 kVue Couch Top surface as they may flow into the OneTouch Latch or mechanisms within the couch base. 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 kVue and AccuFix Insert surfaces. To disinfect the kVue 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 kVue or AccuFix Insert or allow to flow into the Baseframe.

DO NOT place sharp objects on the kVue or AccuFix Insert.

MAINTENANCE

SIDE SCALE REPLACEMENT

1. Completely remove the current side scale labels, including all adhesive residue.
2. Install both the left and right Shoulder-Loc by inserting them into the device to their furthest inserted position.
3. Then, pull on each Shoulder-Loc until it stops (Fig. 1).

! NOTE ! The Shoulder-Loc will only move slightly.

4. With a pencil, mark a small vertical line where the tip of the Shoulder-Loc lines up on the device (Fig. 2).

NOTE ! The line marked on the device will correspond with number 12 on the scale.

5. Remove Shoulder-Locs before applying the scales.
6. Place the labels on the device, with the line for number 12 corresponding with the line that was drawn on the device (Fig. 3).

! NOTE ! Fig. 4 shows the scale properly affixed to the patient right side of the device, and Fig. 5 shows it properly affixed to the patient left side.

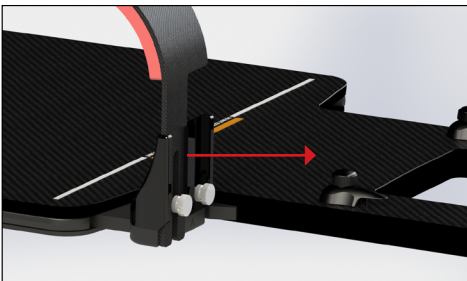


Fig. 1

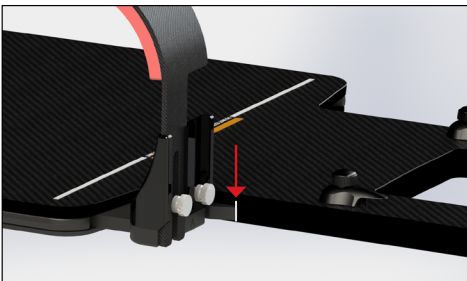


Fig. 2

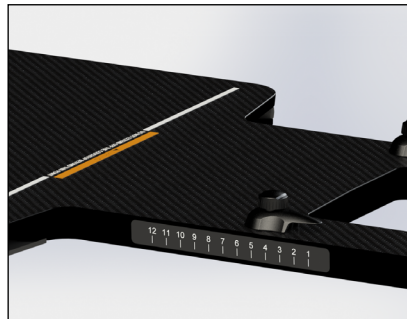


Fig. 3

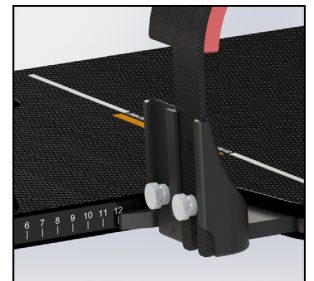


Fig. 4

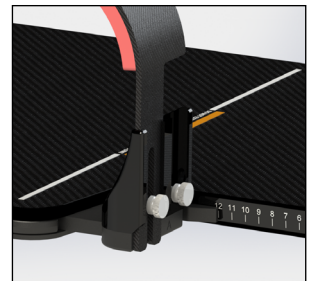


Fig. 5

SPECIFICATIONS

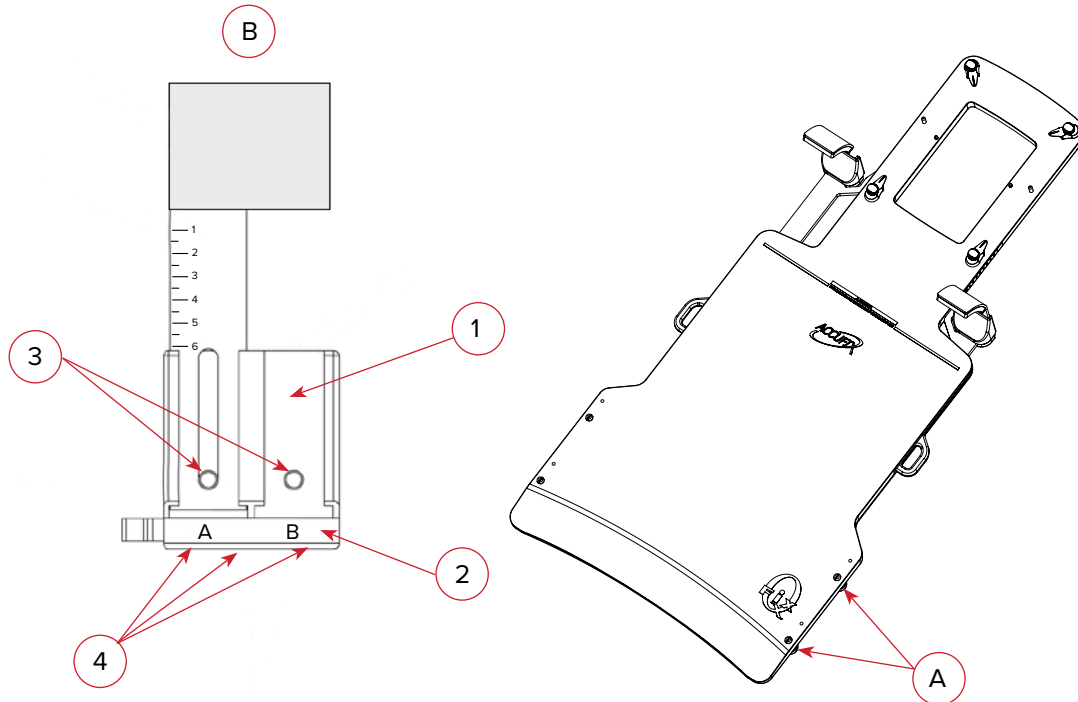
LENGTH: 1401 mm

ALUMINUM EQUIVALENCE: ~0.5 mm @ 100 kVp

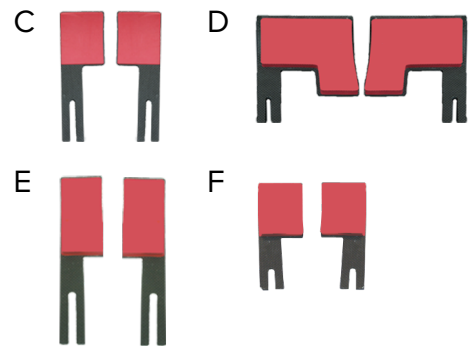
WATER EQUIVALENCE: 6 mm @ 6 MV

WEIGHT LIMIT: 249 kg (550 lb) Uniformly Distributed Load

PARTS LIST



- A. RT-4529M – AccuFix Medium Disk Set
- B. 8001887 – Shoulder-Loc Spare Parts Kit
 - 1. Canti 1.5 Upper Bearclaw Blocks
 - 2. Lower Shoulder-Loc Block (Left)
Lower Shoulder-Loc Block (Right)
 - 3. Thumb Screws
 - 4. Flat Head Screws
- C. RT-4524XX – AccuFix Standard Shoulder-Loc
- D. RT-4524PEDXX-S – AccuFix Pediatric Shoulder-Loc
- E. RT-4524LW – AccuFix Extra Tall Shoulder-Loc
- F. RT-4524XX-S – AccuFix Standard Shoulder-Loc, CT Compatible



SETUP SHEET

kVue™ AccuFix™ Cantilever Board Insert – Featherline Edition RT-4525KVL

Patient Name:

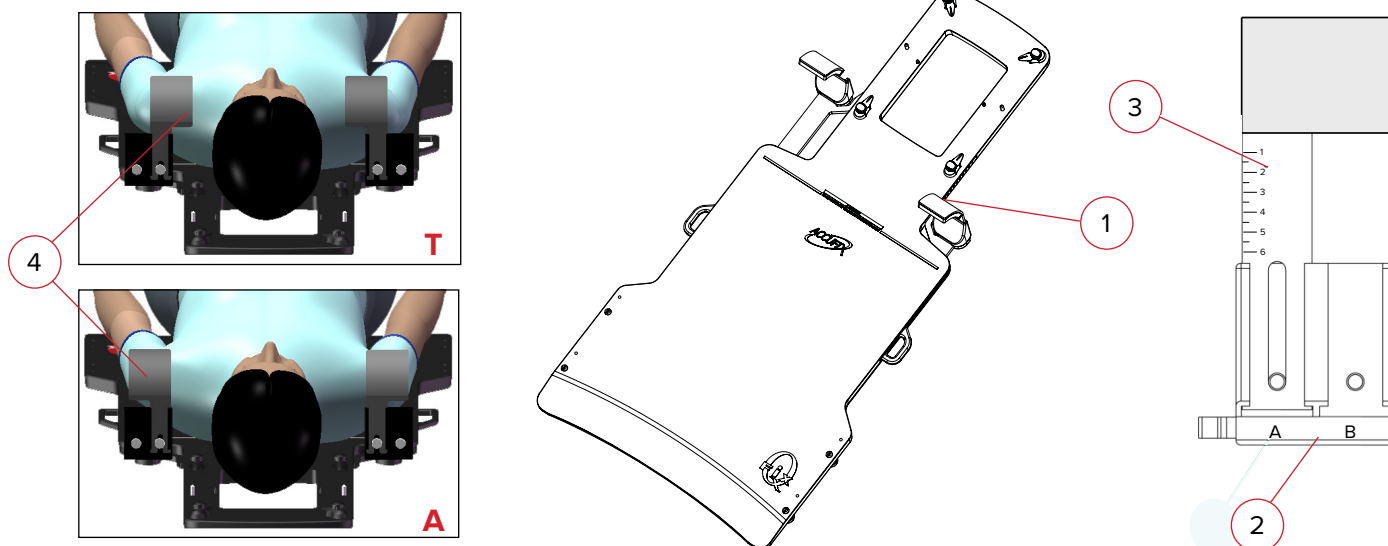
Patient ID #:

Setup by:

Physician:

Date:

Comments:



1. Shoulder-Loc setting (whole number from 1 to 12): Patient's Left Patient's Right
2. Width setting of Shoulder-Loc (A or B): Patient's Left Patient's Right
3. Height of Shoulder-Loc (number from 1 to 6): Patient's Left Patient's Right
4. Orientation of Shoulder-Loc flange (toward or away from patients neck—select one)
Patient's Left: **T** **A** Patient's Right: **T** **A**
5. Type of Shoulder-Loc used (select one): **RT-4524XX (Standard)** **RT-4524PEDXX-S (Pediatric)**
RT-4524LW (Extra-Tall) **RT-4524XX-S (CT Version)**
6. Head support used: **Silverman Model Number:**
 MOLDCARE Model Number:
7. Aquaplast RT™ or Fibreplast® mask used:



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