



positioning
patients for life.®


PRODUCT GUIDE & USER MANUAL

RT-4547KV

kVue™ CURVE™ Insert
for kVue Couch Top





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 +1 610-268-0585 www.Qfix.com
----	-----	---	---	--

kVue, CURVE and OneTouch are trademarks of Qfix.

Exact® is a registered trademark of Varian Medical Systems.

Cidex® is a registered trademark of Johnson & Johnson.

Clorox® is a registered trademark of The Clorox Company.

TABLE OF CONTENTS

- GENERAL PRECAUTIONS..... 4
 - WARNING STATEMENTS 4
 - SERIOUS INCIDENTS..... 4
 - LOAD RATING 4
 - WARNING LABELS & DESCRIPTIONS 5
- INTENDED USE..... 6
- OPERATING INSTRUCTIONS.....7
 - INSTALLATION.....7
 - SET UP 9
 - REMOVAL.....10
- MAINTENANCE.....11
 - CLEANING THE SYSTEM11
 - DISINFECTING THE SYSTEM.....11
- SPECIFICATIONS.....12
- SETUP SHEET13
 - KVUE CURVE INSERT – RT-4547KV..... 13

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

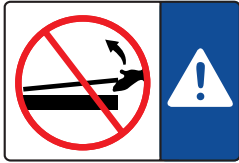
DO NOT exceed 249 kg (550 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! 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.

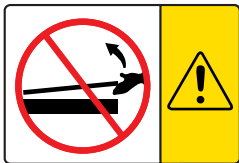
GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



OR



KVUE INSERT INSTALLATION AND REMOVAL

! NEVER LIFT THE END OF THE KVUE INSERT !

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

INTENDED USE

This device is intended to immobilize, position and reposition Patient's 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

SILVERMAN PIN INSTALLATION (RELOCATION)

The Silverman pins are located in the Qfix standard locations. The pins can be repositioned to make the CURVE Insert compatible with other manufacturers' treatment equipment.

1. Remove pins from current location by unscrewing counter clockwise (Fig. 1).
2. From the bottom of the CURVE Insert, screw pins clockwise into alternate location with a flat head screwdriver (Fig. 2).
3. Be sure that the pins are firmly tightened before use (Fig. 3).

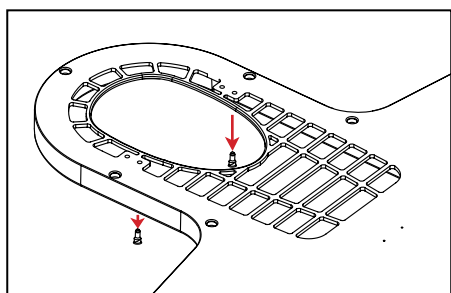
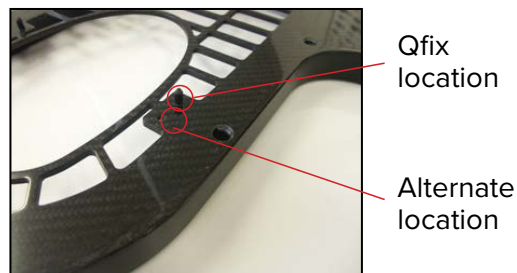


Fig. 1

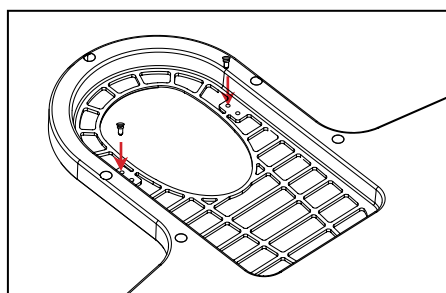


Fig. 2

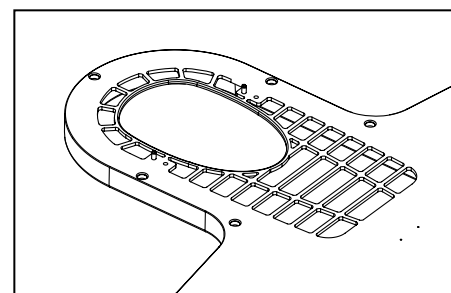


Fig. 3

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

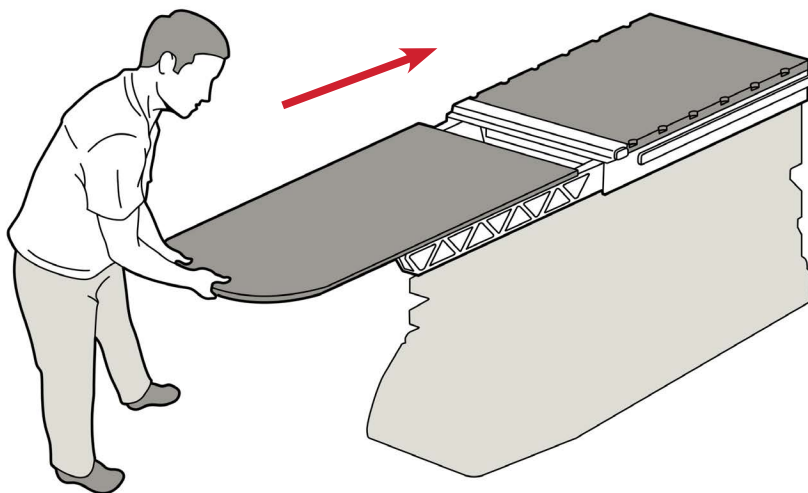
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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 Standard 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 Standard Insert directly into the receiving holes.

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



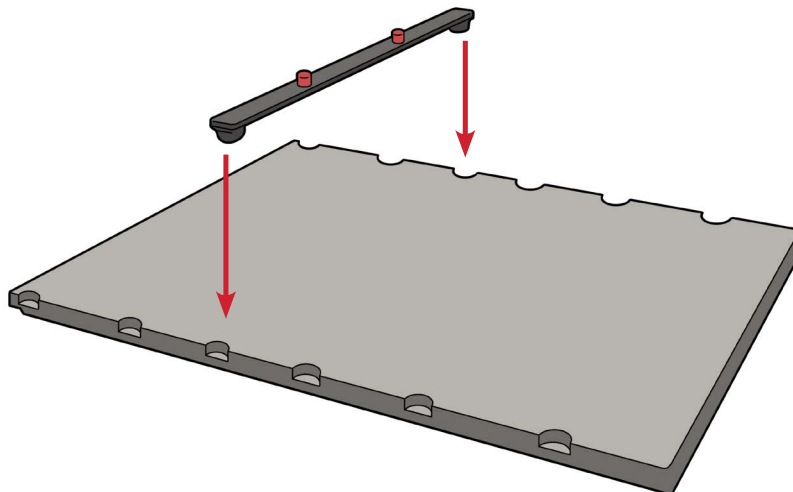
kVue with Standard Insert

OPERATING INSTRUCTIONS

SET UP

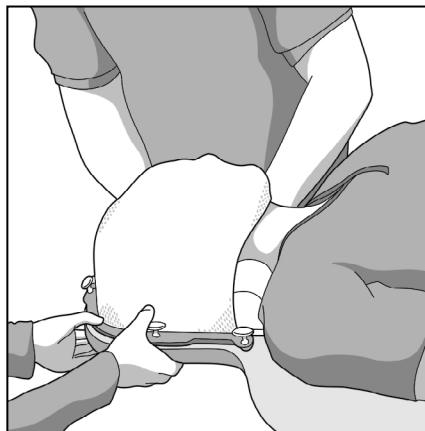
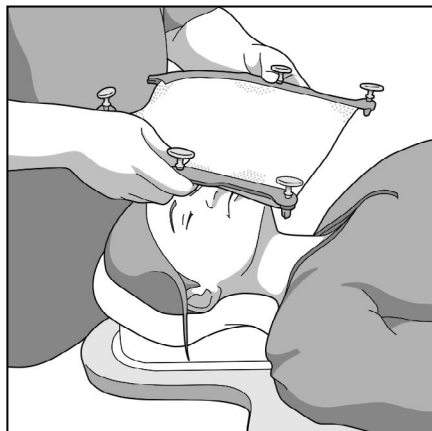
LOCATING BAR INSTALLATION

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.



INSTALLATION OF S-FRAME THERMOPLASTIC

1. Place mask over patient, lining up S-Frame pins with attachment holes on the Insert.
2. Insert pins into the CURVE Insert holes and press until each pin locks in place.

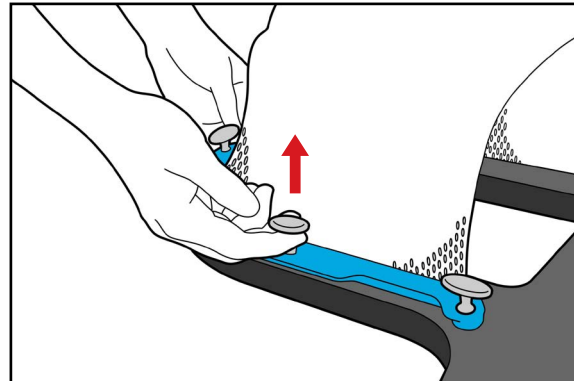


OPERATING INSTRUCTIONS

REMOVAL

REMOVAL OF S-FRAME THERMOPLASTIC

1. To remove, pull up on each pin.
2. Lift the mask off of the patient.



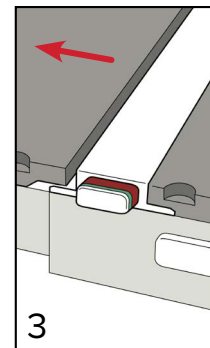
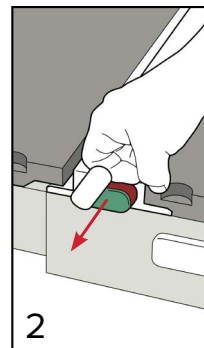
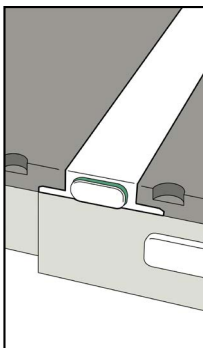
LOCATING BAR

Pull up on either end of the Locating Bar.

KVUE INSERT REMOVAL

! 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 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 CURVE 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 CURVE Insert or allow to flow into the Baseframe.

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

SPECIFICATIONS

LENGTH: 1328 mm

ALUMINUM EQUIVALENCE: ~0.5 mm @ 100 kVp

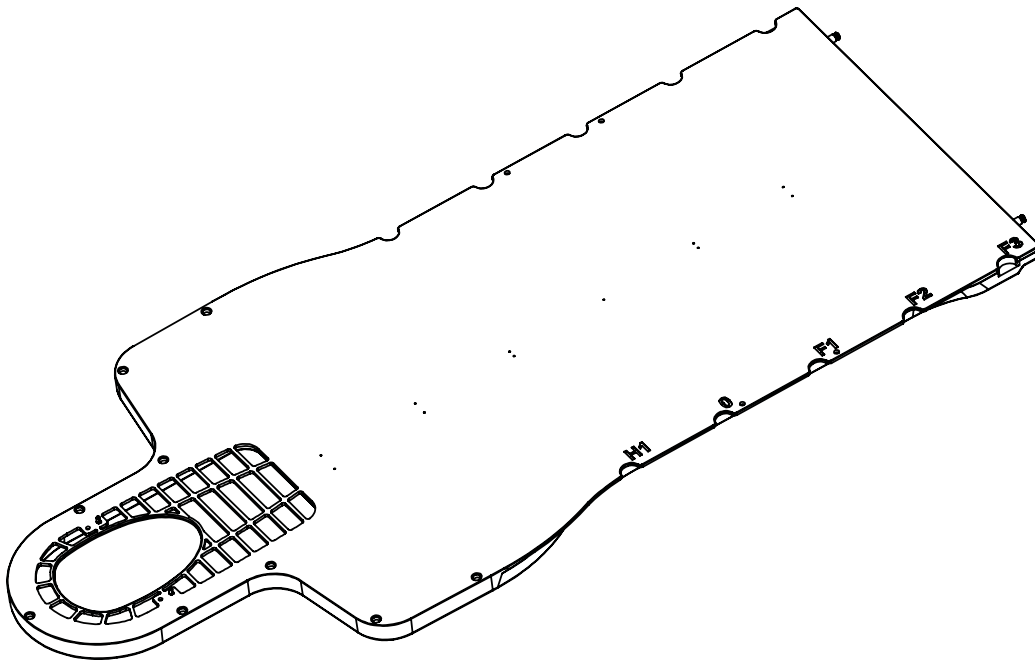
WATER EQUIVALENCE: 6 mm @ 6 MV

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

SETUP SHEET

KVUE CURVE INSERT – RT-4547KV

Patient Name:	
Patient ID #:	Setup by:
Physician:	Date:
Comments:	




Moving Rails Location:


Headrest Used:

Notes:



440 Church Road
Avondale, PA 19311 USA
www.Qfix.com

 +1 610.268.0585 / 800.526.5247

 +1 610.268.0588 / 800.831.8174

 sales@Qfix.com