



positioning  
patients for life.®

# PRODUCT GUIDE & USER MANUAL

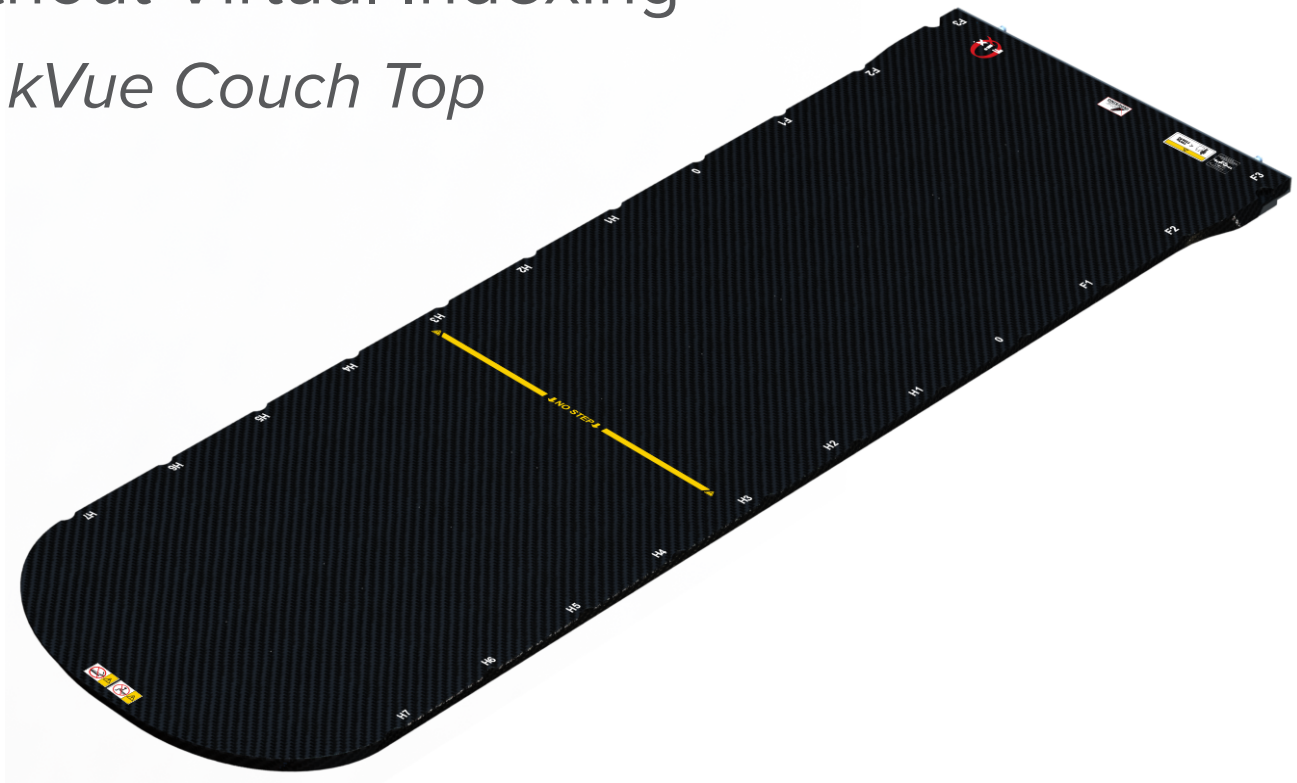
RT-4551KV13

kVue™ 161 cm Standard Insert

RT-4551KV16

kVue™ 161 cm Standard Insert  
without Virtual Indexing

*for kVue Couch Top*



 <div style="display: inline-block; border: 1px solid black; padding: 2px; margin: 5px 0;"><b>EC REP</b></div> Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta	<b>UK Responsible Person</b> QServe Group UK, Ltd. 49 Greek Street Soho, London W1D 4EG United Kingdom
 <i>Made in the USA by</i> Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6054 www.Qfix.com	<div style="display: inline-block; border: 1px solid black; padding: 2px; margin: 5px 0;"><b>CH REP</b></div> Raditec Medical AG Schlossberg 5a 5454 Bellikon Switzerland

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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.**

**! WARNING ! DOSE DEPTH, DEPOSITION, AND TRANSITION AREA EFFECTS MUST BE EVALUATED DURING PLANNING AND TREATMENT WITHIN A PROTON THERAPY ENVIRONMENT.**

## 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

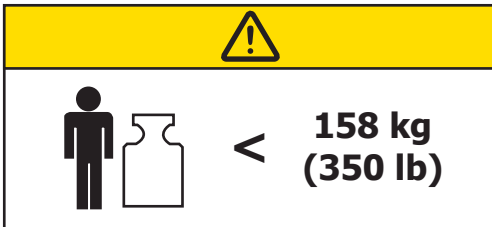
DO NOT exceed 158 kg (350 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

**! 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](http://Qfix.com) for a listing of symbols and their definitions.



### LOAD RATING

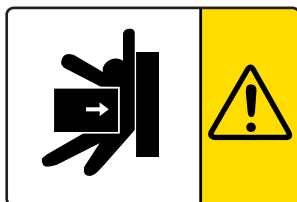
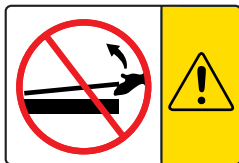
DO NOT exceed 158 kg (350 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

**↓ NO STEP ↓**

OR



OR



### “NO STEP” LINE (IF PRESENT)

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.

### KVUE INSERT INSTALLATION AND REMOVAL

**! WARNING ! 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.

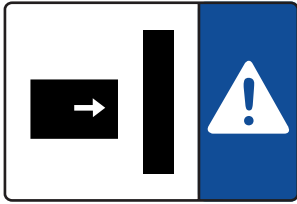
### POTENTIAL INJURY

There is potential for injury between the kVue Insert and other equipment in the treatment suite. Use caution when moving the kVue to avoid injury.

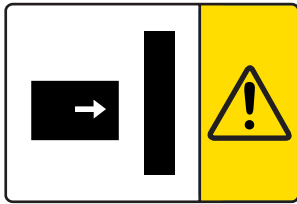
# GENERAL PRECAUTIONS

## WARNING LABELS & DESCRIPTIONS

Refer to [Qfix.com](http://Qfix.com) for a listing of symbols and their definitions.



OR



### GANTRY COLLISION

The wide variety of motions obtainable by couch bases and treatment heads may present situations where the kVue 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 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.

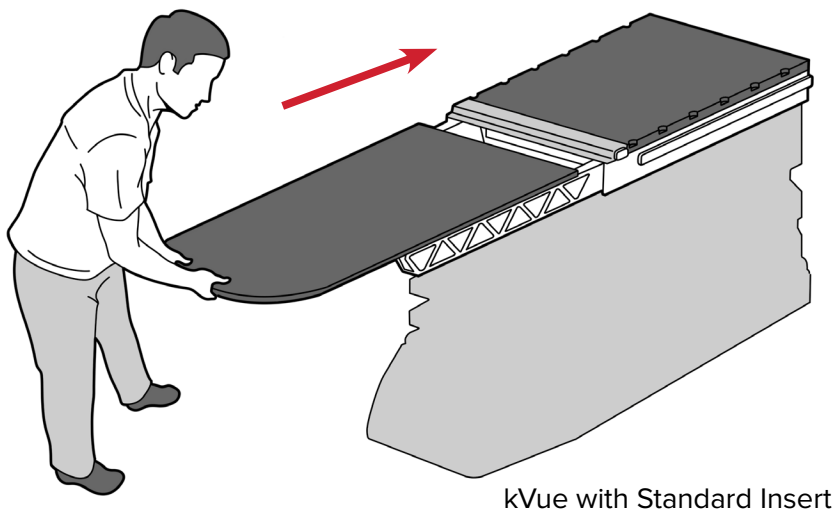
**! NOTE !** As detailed in the kVue Couch Top Installation Manual, the final height of the kVue surface may be different from the original system. Refer to the original system instructions to reset the system zero (origin) prior to initial use.

### KVUE INSERT INSTALLATION

1. Place the 161 cm 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 161 cm Insert directly into the receiving holes.

You will hear a click when the 161 cm 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.



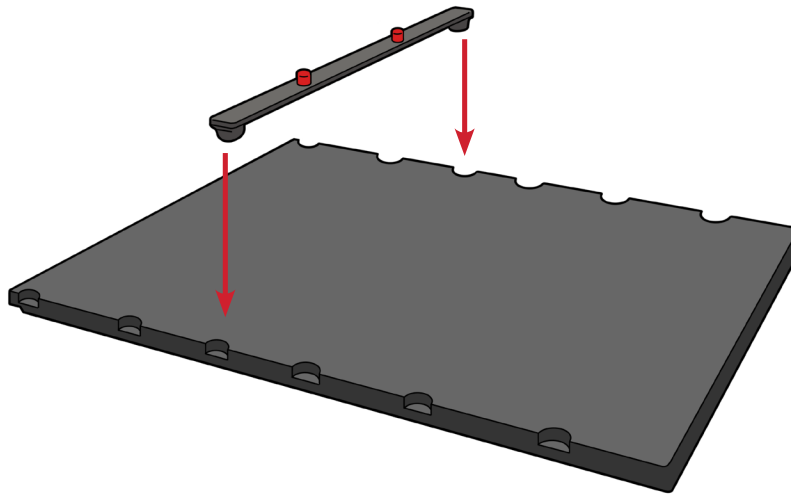


# OPERATING INSTRUCTIONS

## 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

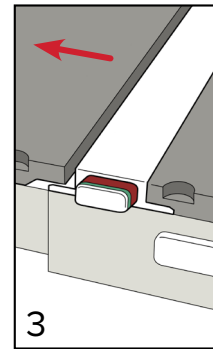
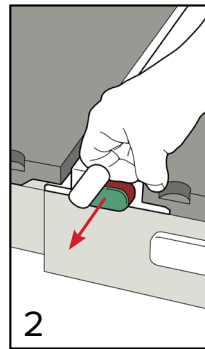
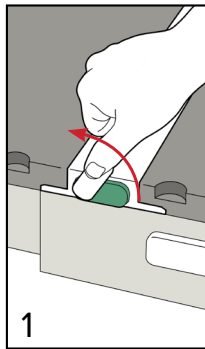
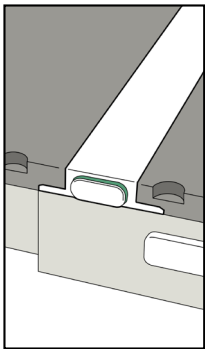
### LOCATING BAR REMOVAL

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. 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

DO NOT spray or pour liquids onto the kVue surface as they may flow into the OneTouch Latch or mechanisms within the couch base.

DO NOT spray directly onto the kVue or 161 cm Insert or allow to flow into the baseframe.

DO NOT place sharp objects on the kVue or 161 cm insert.

# SPECIFICATIONS

**LENGTH:** 1610 mm

**ALUMINUM EQUIVALENCE:** ~1 mm @ 100 kVp

**WATER EQUIVALENCE:** 6 mm @ 6 MV

**WEIGHT LIMIT:** 158 kg (350 lb) Uniformly Distributed Load

# SETUP SHEET

## KVUE 161 CM STANDARD INSERT—RT-4551KV13 & RT-4551KV16

Patient Name:

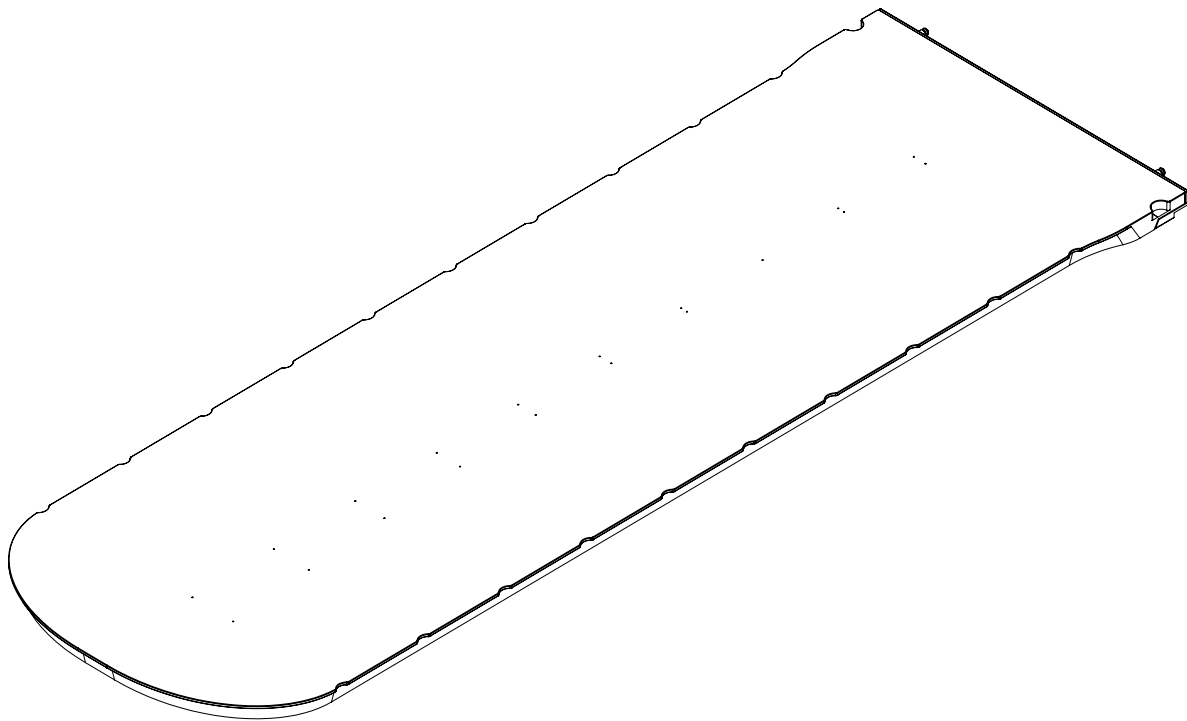
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Moving Rails Location:

Notes:







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