

PRODUCT GUIDE & USER MANUAL

RT-4551KV8 kVue™ Universal Tip Insert







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Made in the USA by

Qfix

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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 over Universal Tip Insert and Back Panel or maximum working load of couch base, which ever is less.

DO NOT exceed 38.5 kg (85 lbs) @ 25 cm extended from front edge.

! 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.



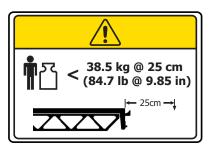


KVUE INSERT INSTALLATION AND REMOVAL

! 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.



TIP LOAD RATING

Tip Load 38.5 kg at 25 cm (84.7 lb at 9.85 in)

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.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

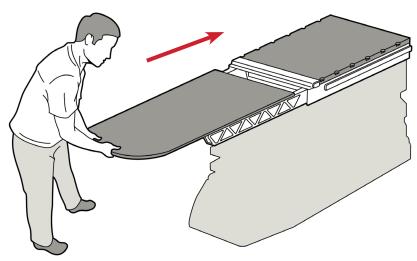
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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.



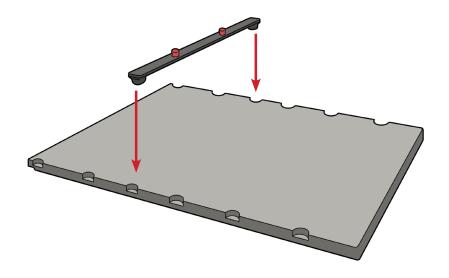
kVue with Standard Insert

OPERATING INSTRUCTIONS

SET-UP

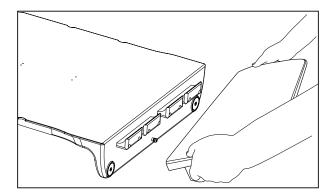
LOCATING BAR INSTALLATION

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.



ACCESSORIES INSTALLATION

- 1. Hold the accessory to be installed, and tilt it at a 30 degree angle to the support bracket.
- 2. Engage the accessory with the support bracket, and lower it until it rests securely on the bracket and the magnets engage.



OPERATING INSTRUCTIONS

REMOVAL

ACCESSORIES REMOVAL

Remove the end panel by tilting it until it can be lifted off the support brackets.

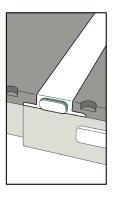
LOCATING BAR REMOVAL

Pull up on either end of the Locating Bar.

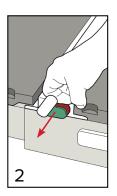
KVUE INSERT REMOVAL

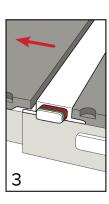
! NEVER LIFT THE END OF THE KVUE INSERT! ALTHOUGH THE MECHANISM IS VERY ROBUST, THE MATING PINS MAY BEND OR BREAK, RENDERING THE KVUE UNUSABLE.

- 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

The devices can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. Do not spray or pour liquids onto the devices 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.

The following cleaning materials have been tested and found to be appropriate for cleaning the devices' surfaces. To disinfect the surface, refer to specific instructions from the cleaning agent manufacturer.

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

SPECIFICATIONS

LENGTH: 950 mm

ALUMINUM EQUIVALENCE: ~0.5 mm @ 100 kVp

WATER EQUIVALENCE: 6 mm @ 6 MV

WEIGHT LIMIT: 38.5 kg (85 lb) @ 25 cm extended from front edge and 249 kg (550 lb) of Uniformly Distributed

Load over kVue Insert and Back Panel

SETUP SHEET

RT-4551KV8 - KVUE™ UNIVERSAL TIP INSERT

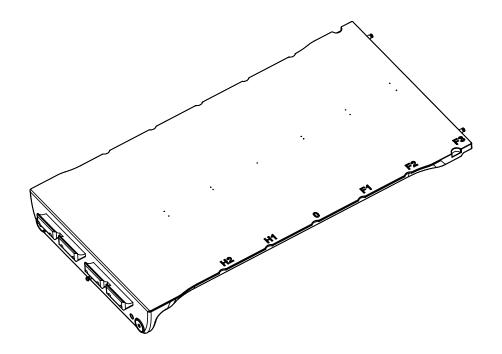
Patient Name:

Patient ID #:

Setup by:

Physician:

Comments:



Moving Rails Location:

Notes:



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