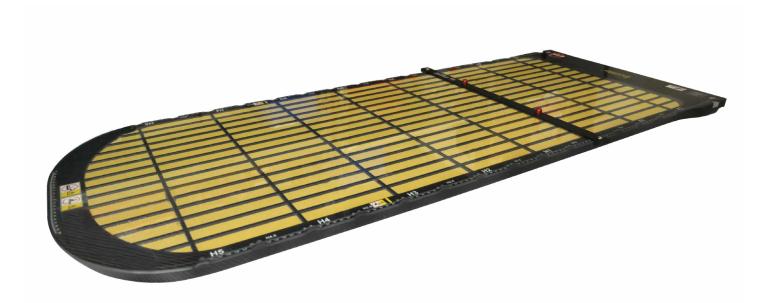


PRODUCT GUIDE & USER MANUAL

RT-4551KV5 & RT-4551KV18 kVue™ DoseMax™ Insert for kVue™ Couch Top





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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	
REMOVAL	9
MAINTENANCE	10
CLEANING THE SYSTEM	10
DISINFECTING THE SYSTEM	10
DOSEMAX MYLAR REPLACEMENT	10
SPECIFICATIONS	11
PARTS LIST	12
SETUP SHEET	13
RT-4551KV5 & RT-4551KV18 – KVUE DOSEMAX INSERT	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 +1 484-720-6053 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

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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.







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.



"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.

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

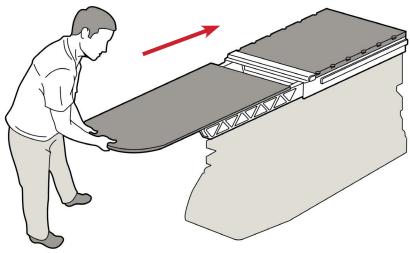
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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.



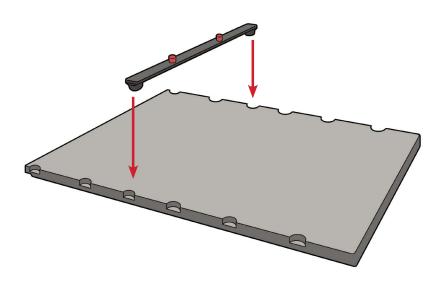
kVue with Standard Insert

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.



OPERATING INSTRUCTIONS

REMOVAL

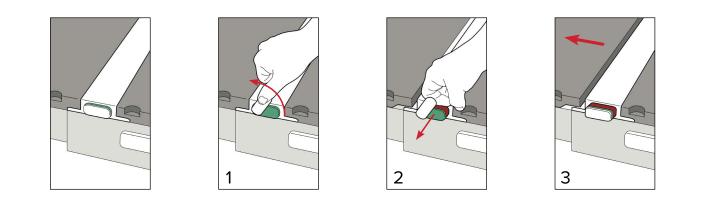
LOCATING BAR REMOVAL

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.

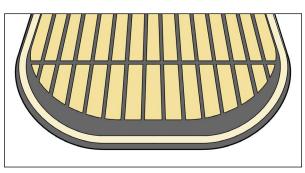
- 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex[®] 2.4% Activated Dialdehyde Solution

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

DO NOT spray directly onto the kVue or DoseMax insert or allow to flow into the BaseFrame.

DOSEMAX MYLAR REPLACEMENT

- 1. Peel the current film from an edge.
- 2. Prepare the surface by clearing all leftover adhesive with an adhesive remover.
- 3. Align the new film, making sure to cover the upper logo (Fig. 1). Each edge should be approximately 7.24 mm [.285"] from the outer edge of the device.
- 4. Place several pieces of tape along the edge to affix the film to the surface of the DoseMax (Fig. 2).
- 5. Remove masking tape from superior half of film. Pull up and peel adhesive backing from film. Firmly apply to the surface of the device.
- 6. Remove tape and the remaining adhesive backing from anterior half of film. Firmly apply to the surface of the device.
- 7. Peel the protective covering from the film.



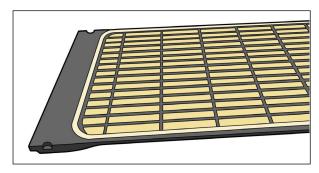




Fig. 1

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SPECIFICATIONS

LENGTH: 1325 mm WATER EQUIVALENCE: 2.0 mm @ 6 MV WEIGHT LIMIT: 249 kg (550 lb) Uniformly Distributed Load

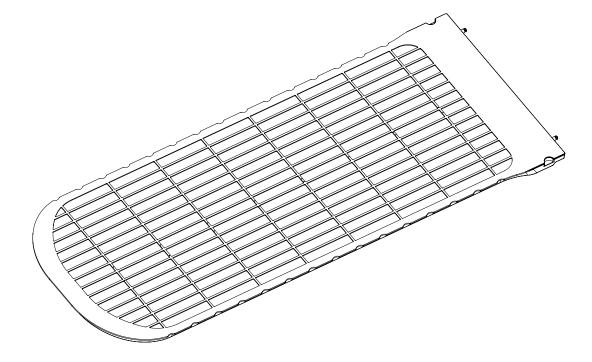
PARTS LIST

RT-4551KV5F – Replacement Film Skin for DoseMax (Pack of 3)

SETUP SHEET

RT-4551KV5 & RT-4551KV18 - KVUE DOSEMAX INSERT

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



Moving Rails Location: Notes:



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