



positioning
patients for life.®


PRODUCT GUIDE & USER MANUAL

RT-4551KV12 & RT-4551KV11

kVue™ EDGE™ Standard Insert &
kVue™ Calypso® Standard Insert





EC	REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta	 Made in the USA Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 610-268-0585 www.Qfix.com
----	-----	---	---

kVue and OneTouch are trademarks of Qfix.

Exact®, Calypso® and Beacon® are registered trademarks of Varian Medical Systems.

TrueBeam and EDGE are trademarks of Varian Medical Systems.

Cidex® is a registered trademark of Johnson & Johnson

Clorox® is a registered trademark of The Clorox Company.

! NOTE ! Throughout this IFU “kVue Couch Top” refers to all kVue Couch Tops, including the kVue Calypso®, the kVue EDGE™, and the kVue Couch Top.

! NOTE ! Throughout this IFU “kVue Insert” refers to all kVue Inserts, including the kVue Calypso® Standard Insert, the kVue EDGE™ Standard Insert, and all other kVue Inserts.

TABLE OF CONTENTS

GENERAL PRECAUTIONS.....	4
WARNING STATEMENTS	4
SERIOUS INCIDENTS.....	4
INFERIOR ISOCENTER LINE.....	4
LOAD RATING	4
WARNING LABELS & DESCRIPTIONS	5
INTENDED USE.....	6
OPERATING INSTRUCTIONS.....	7
INSTALLATION.....	7
SET-UP	8
REMOVAL.....	9
MAINTENANCE.....	10
CLEANING THE SYSTEM	10
DISINFECTING THE SYSTEM.....	10
SPECIFICATIONS.....	11
LENGTH.....	11
WEIGHT LIMIT	11
LOCATION OF INFERIOR ISOCENTER LINE	11
SETUP SHEET	12

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.

INFERIOR ISOCENTER LINE

The EDGE™ Insert and Calypso® Insert are marked with a blue line that represents the furthest proximal location for the isocenter when using the kVue Couch Top. Contact Varian Medical Systems or refer to Calypso® System User's Manual for more specific information about the importance of this line.

LOAD RATING

DO NOT exceed 200 kg (440 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less when using with the Varian Exact® or TrueBeam™ Couch Base.

DO NOT exceed 155 kg (341 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less when using with the Varian PRS.

! 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

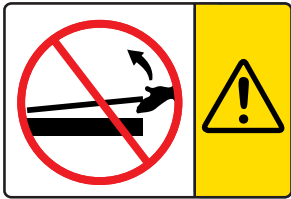
WARNING LABELS & DESCRIPTIONS

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



CALYPSO® SYSTEM COMPATIBLE

Indicates Calypso® compatible when used with the kVue Calypso® or kVue EDGE™.



KVUE CALYPSO INSERT INSTALLATION & REMOVAL

! WARNING ! NEVER LIFT THE END OF THE KVUE INSERT

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

↓ NO STEP ↓



“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 or lower torso; it is NOT designed to support the entire patient load.

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 COUCH TOP INSTALLATION

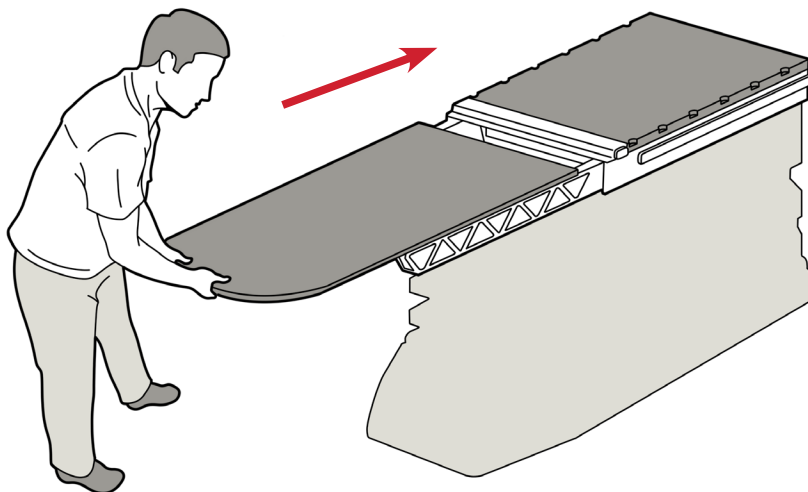
The kVue Couch Top is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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 kVue 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 kVue Insert directly into the receiving holes.

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



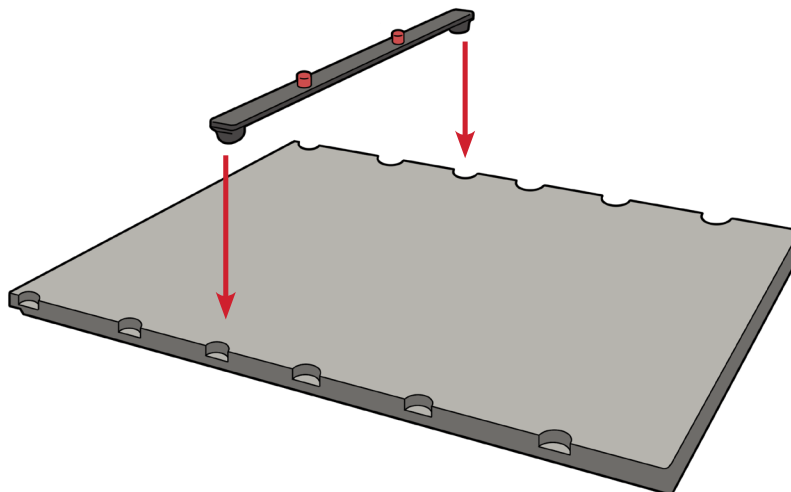
kVue with Standard Insert

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. When using the Calypso® System, use only Calypso compatible accessories.



OPERATING INSTRUCTIONS

REMOVAL

LOCATING BAR REMOVAL

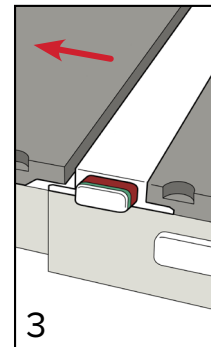
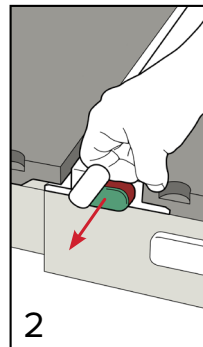
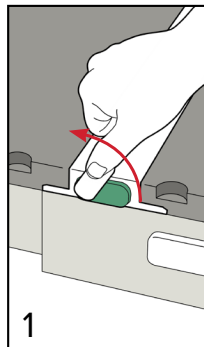
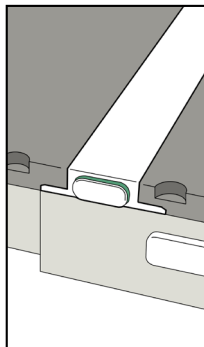
Pull up on either end of the Locating Bar.

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.

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.

! NOTE ! The images shown below are of a standard kVue Couch Top. kVue Insert removal is the same for all versions of 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 Couch Top and kVue Insert surfaces. To disinfect the kVue Couch Top 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

DO NOT spray directly onto the kVue Couch Top or kVue Insert allow to flow into the Baseframe.

DO NOT place sharp objects on the kVue Couch Top or kVue Insert.

SPECIFICATIONS

LENGTH

1325 mm

WEIGHT LIMIT

200 kg (440 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less when using with the Varian Exact® or TrueBeam™ Couch Base.

151 kg (332 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less when using with the Varian PRS.

LOCATION OF INFERIOR ISOCENTER LINE

420 mm from Inferior End of Insert

SETUP SHEET

KVUE EDGE™ STANDARD INSERT – RT-4551KV12

KVUE CALYPSO® STANDARD INSERT – RT-4551KV11

Patient Name:

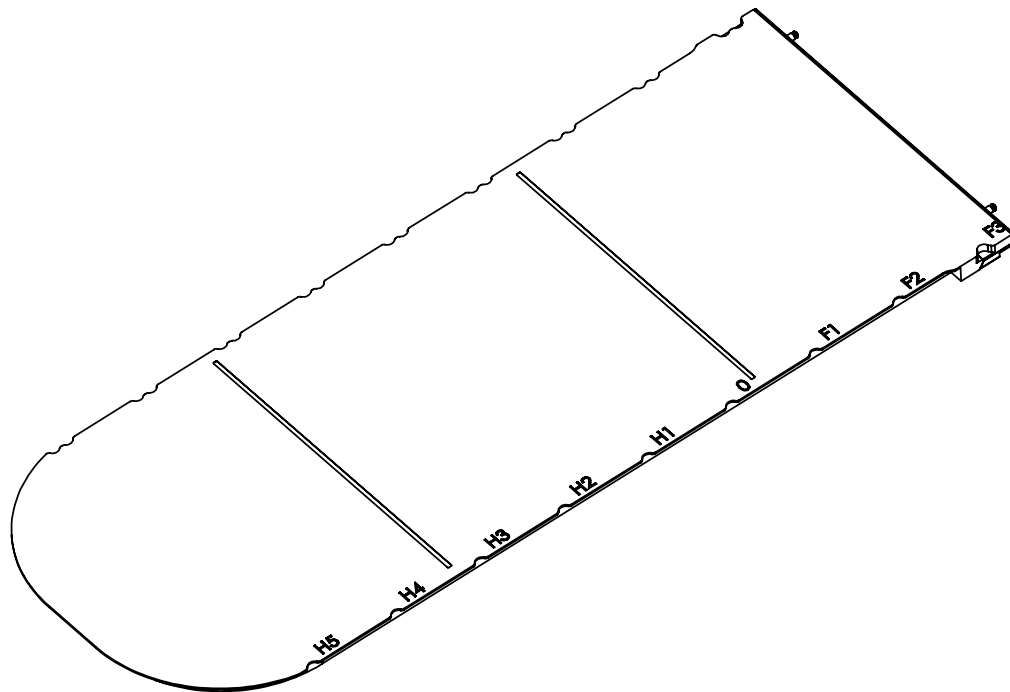
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Moving Rails Location:

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