

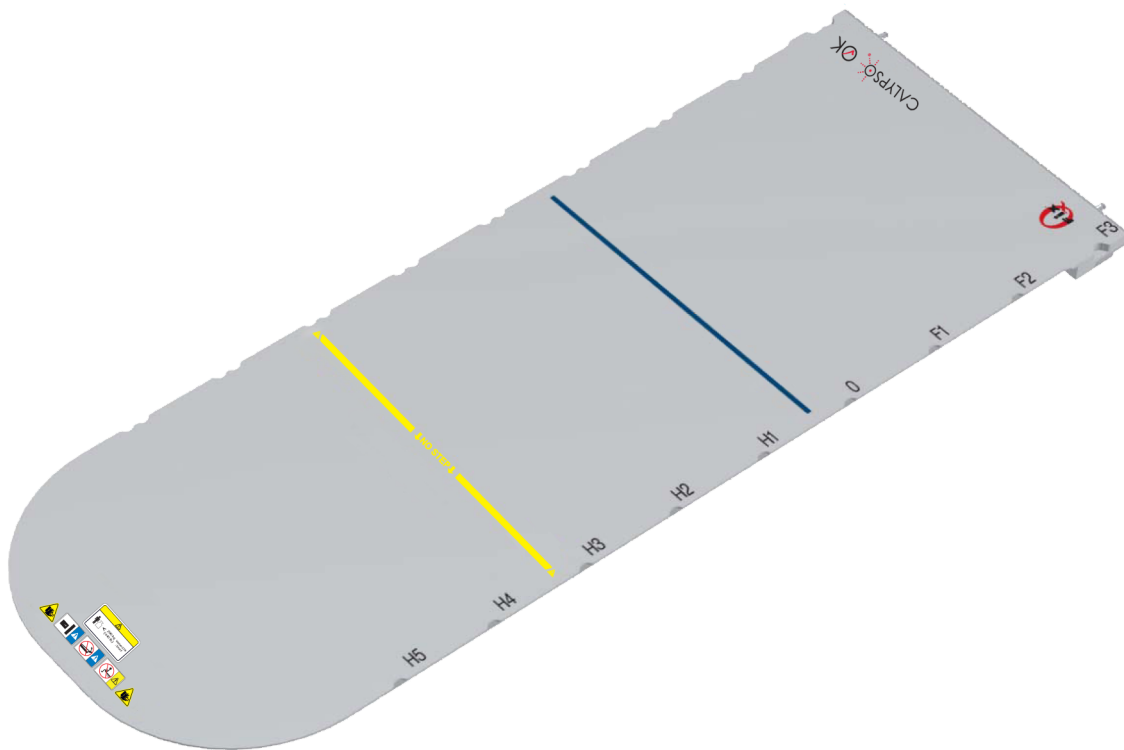


positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4551KV1CL

kVue™ Calypso® Varian Insert
for kVue™ Calypso Couch Top





EC	REP	<p>Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta</p>	<div data-bbox="1076 825 1161 905"></div> <p>Made in the USA Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 610-268-0585 www.Qfix.com</p>
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Calypso® is a registered trademark of Varian Medical Systems.

Exact® is a registered trademark of Varian Medical Systems.

TrueBeam is a trademark of Varian Medical Systems.

Cidex® is a registered trademark of Johnson & Johnson.

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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.

INFERIOR ISOCENTER LINE

The kVue Calypso Varian Insert is marked with a blue line that represents the furthest proximal location for the isocenter when using the kVue Calypso 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 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

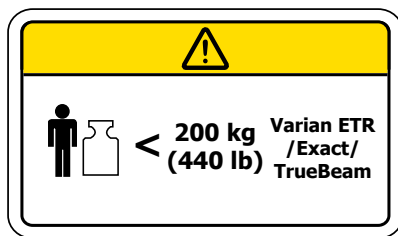
WARNING LABELS & DESCRIPTIONS

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



CALYPSO® SYSTEM COMPATIBLE

Indicates Calypso compatible when used with the kVue Calypso.

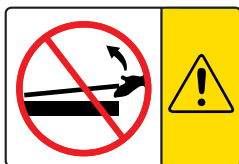


LOAD RATING

Do NOT exceed 200 kg (440 lbs) uniformly distributed load when used with Varian ETR, Exact and TrueBeam Couch base. For use with Varian ETR, Exact and TrueBeam base frame.



OR



KVUE CALYPSO INSERT INSTALLATION AND REMOVAL

! NEVER LIFT THE END OF THE KVUE CALYPSO INSERT !

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



OR



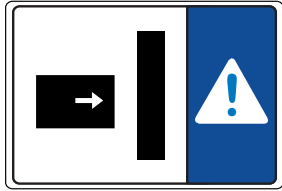
“NO STEP” LINE

The yellow line on the kVue Calypso 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 Calypso Insert beyond the “No Step” line may damage the kVue Calypso Insert or cause injury.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS



GANTRY COLLISION NOTICE

The wide variety of motions obtainable by couch bases and treatment heads may present situations where the kVue Calypso Insert can collide with other items. Use caution when moving the couch or gantry to avoid equipment damage or patient injury.



PINCH POINT CAUTION

Pinch points can occur between the kVue Calypso and other pieces of equipment in the treatment suite, including the treatment head. Use caution when moving the kVue Calypso to avoid 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.

FEATURES

DESCRIPTION

For use only with Varian ETR, Exact and TrueBeam couch base.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

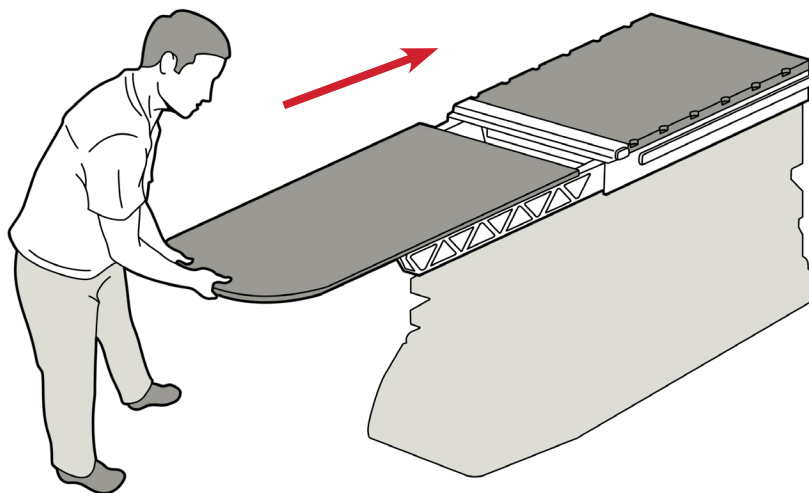
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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 kVue Calypso 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 Calypso Insert directly into the receiving holes.

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



kVue with Standard Insert

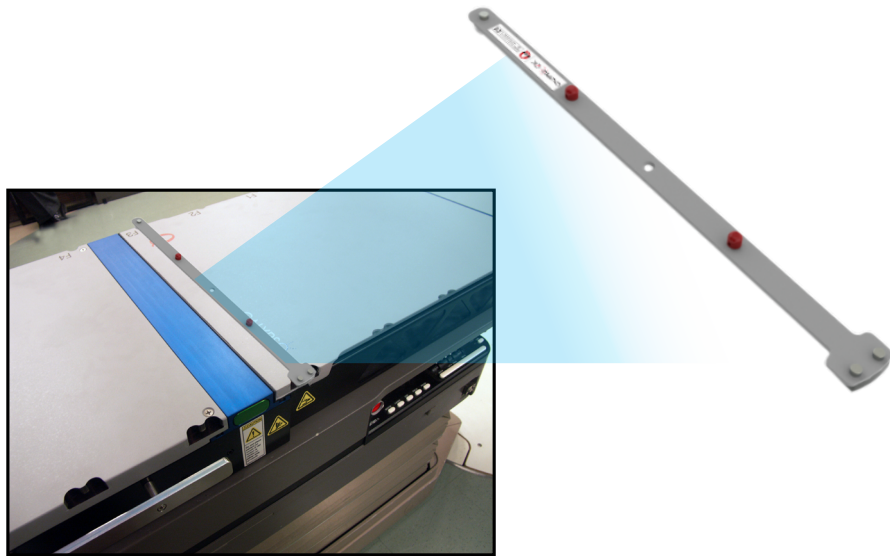
OPERATING INSTRUCTIONS

SET UP

LOCATING BAR INSTALLATION

This bar is approved for use with the Calypso System.

To install Locating Bars, place either end of the bar in the appropriate kVue Calypso notches and snap in place. The right side of the kVue Calypso has dual notches and the left side has single notches. This feature improves positioning accuracy and prevents use of unapproved Locating Bars.



OPERATING INSTRUCTIONS

REMOVAL

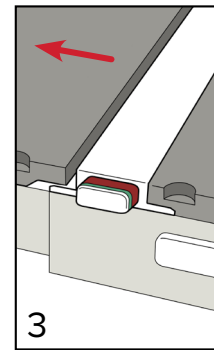
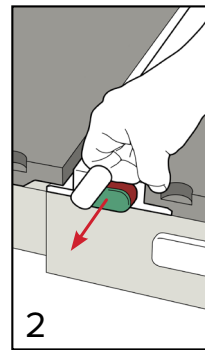
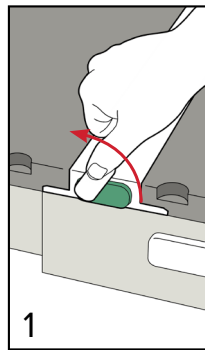
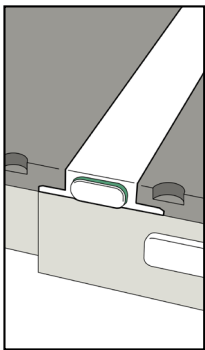
LOCATING BAR REMOVAL

Pull up on either end of the Locating Bar.

KVUE CALYPSO INSERT REMOVAL

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

1. Rotate Lever counter-clockwise.
2. Pull the rotated Lever from one side of the kVue Calypso until the kVue Calypso Insert is released.
3. Slide the kVue Calypso Insert away from the kVue Calypso.



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 Calypso 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 Calypso and kVue Calypso Varian Insert surfaces. To disinfect the kVue Calypso 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 Calypso or kVue Calypso Varian Insert or allow to flow into the Baseframe.

DO NOT place sharp objects on the kVue Calypso or kVue Calypso Varian Insert.

SPECIFICATIONS

LENGTH: 1359 mm

ALUMINUM EQUIVALENCE: ~0.75 mm @ 100 kVp

WATER EQUIVALENCE: 7 mm @ 6 MV

WEIGHT LIMIT: 200 kg (440 lb) Uniformly Distributed Load

LOCATION OF INFERIOR ISOCENTER LINE: 420 mm from Inferior End of Insert

SETUP SHEET

KVUE CALYPSO VARIAN INSERT – RT-4551KV1CL

Patient Name:

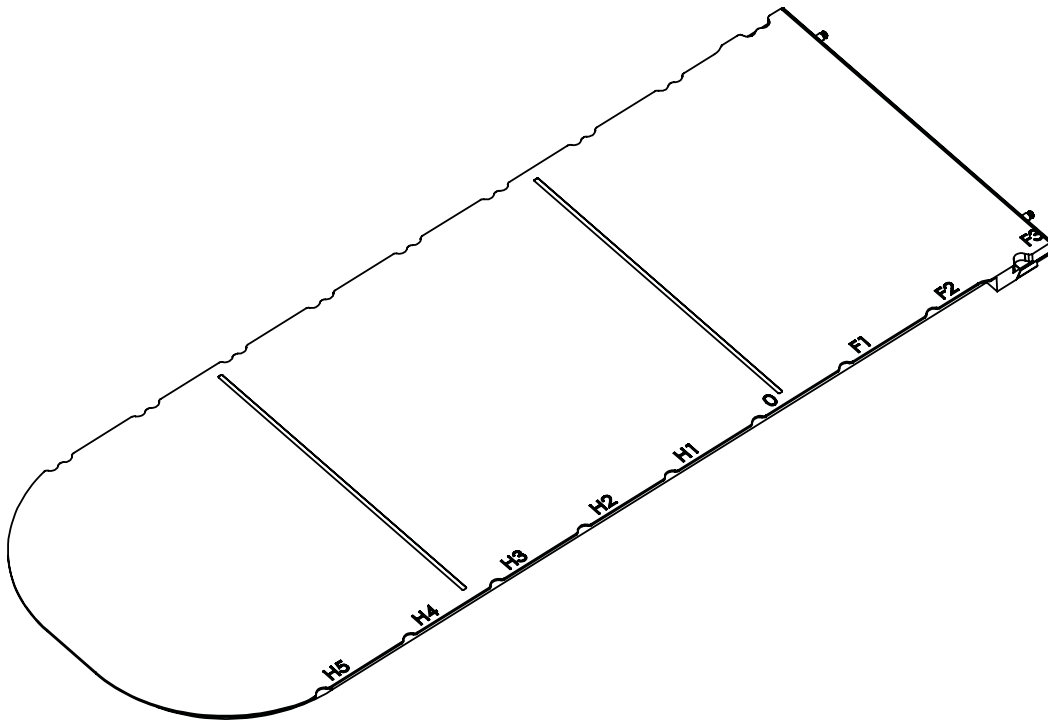
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Moving Rails Location:

Notes:



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