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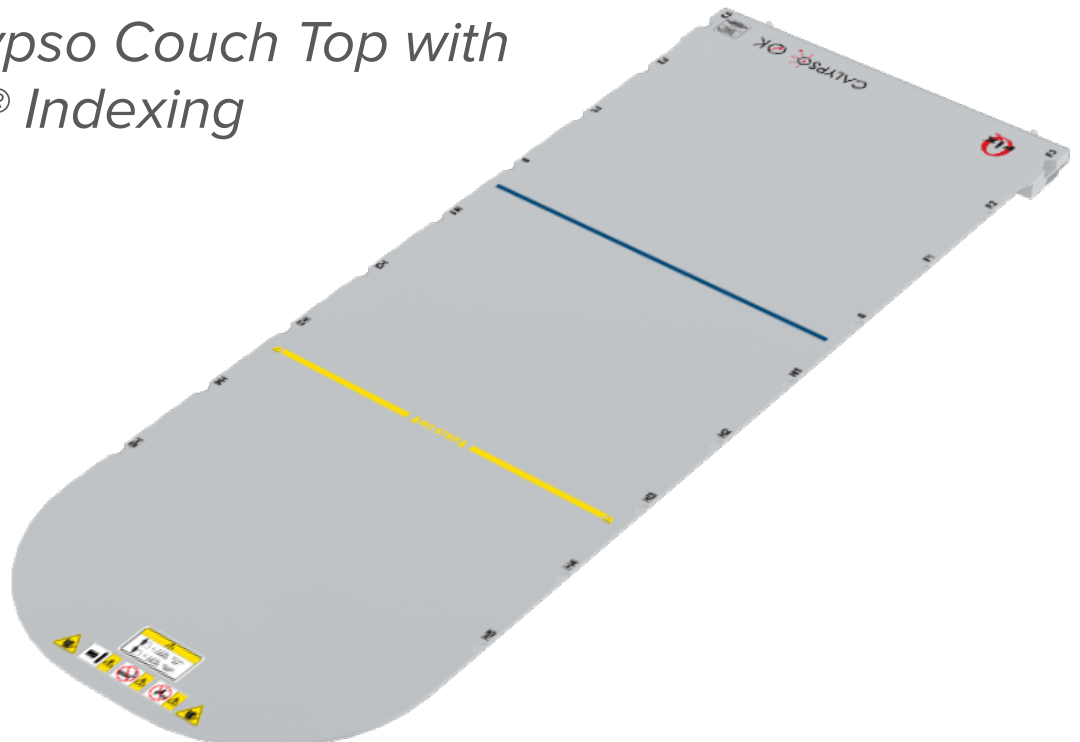
PRODUCT GUIDE & USER MANUAL

RT-4551KV7CLS


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

RT-4551KV14

kVue™ Calypso® Siemens® Insert
*for kVue Calypso Couch Top with
Varian Exact® Indexing*





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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.s

INFERIOR ISOCENTER LINE

The kVue Calypso Siemens Insert is marked with a blue line that represents the furthest proximal location for the isocenter when using the Calypso System. 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 212 kg (469 lbs) uniformly distributed load when used with Siemens TxT™ couch base or maximum working load of couch base, whichever is less.

DO NOT exceed 116 kg (256 lbs) uniformly distributed load when used with Siemens ZXT™ couch base 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

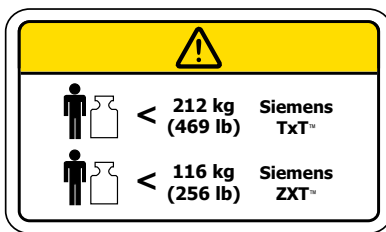
WARNING LABELS & DESCRIPTIONS

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



CALYPSO® SYSTEM COMPATIBLE

Indicates Calypso compatible when used with the kVue Calypso.

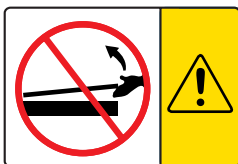


LOAD RATING

DO NOT exceed 212 kg (469 lbs) uniformly distributed load when used with Siemens TxT™ couch base. DO NOT exceed 116 kg (256 lbs) uniformly distributed load when used with Siemens ZXT™ couch base. For use with Siemens 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.

↓ NO STEP ↓

OR



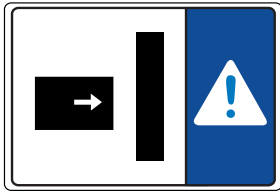
“NO STEP” LINE

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 Siemens TxT™ and ZXT™ couch base.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

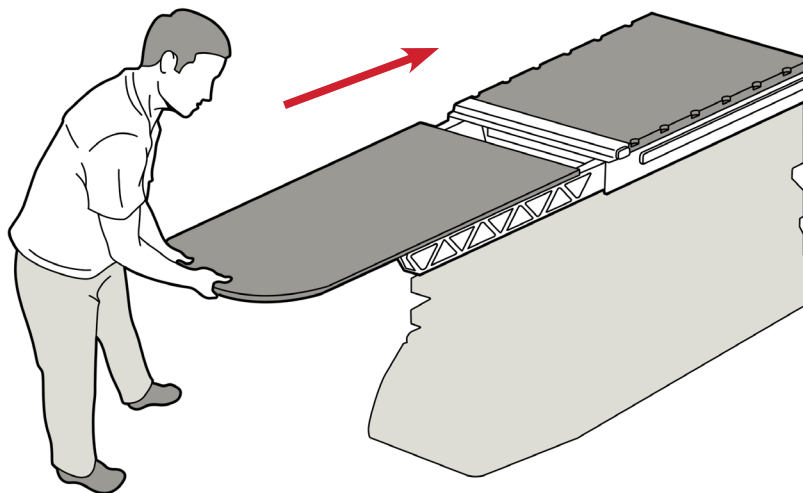
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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.



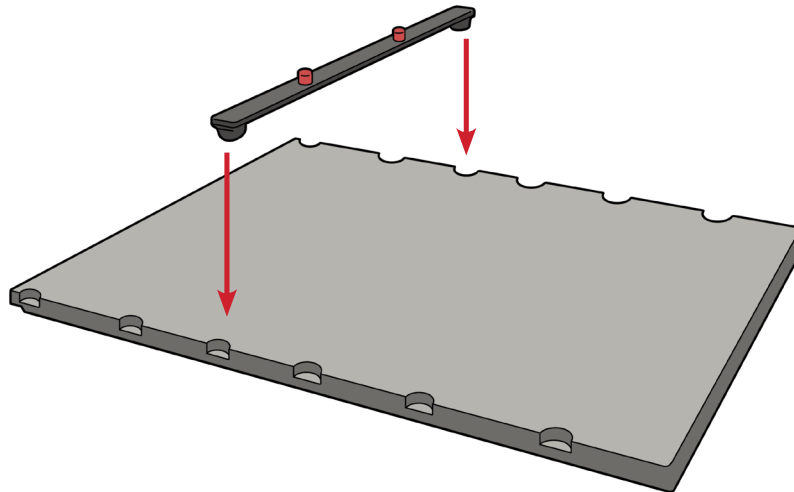
kVue with Standard Insert

OPERATING INSTRUCTIONS

SET UP

LOCATING BAR INSTALLATION

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 notches and snap in place.



OPERATING INSTRUCTIONS

REMOVAL

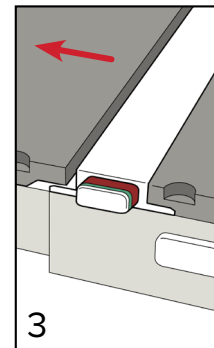
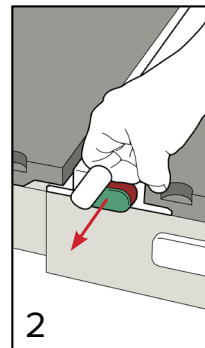
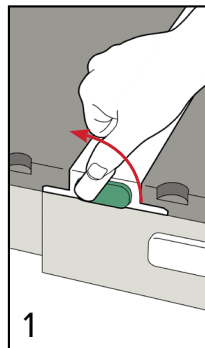
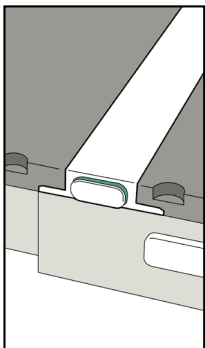
LOCATING BAR REMOVAL

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 Siemens 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 Siemens Insert or allow to flow into the Baseframe.

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

SPECIFICATIONS

LENGTH: 1460 mm

ALUMINUM EQUIVALENCE: ~0.75 mm @ 100 kVp

WATER EQUIVALENCE: 7 mm @ 6 MV

WEIGHT LIMIT:

- DO NOT exceed 212 kg (469 lbs) uniformly distributed load when used with Siemens TxT™ couch base.
- DO NOT exceed 116 kg (256 lbs) uniformly distributed load when used with Siemens ZXT™ couch base.

LOCATION OF INFERIOR ISOCENTER LINE: 520 mm from Inferior End of Insert

SETUP SHEET

KVUE CALYPSO SIEMENS INSERT – RT-4551KV7CLS & RT-4551KV14

Patient Name:

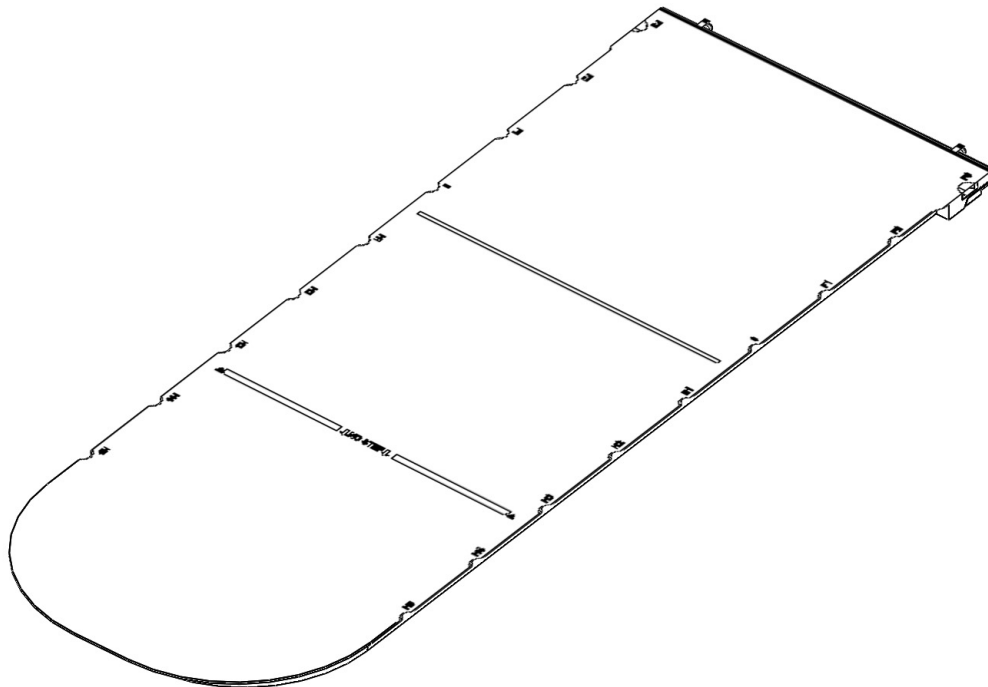
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Beam Location:

Notes:



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