

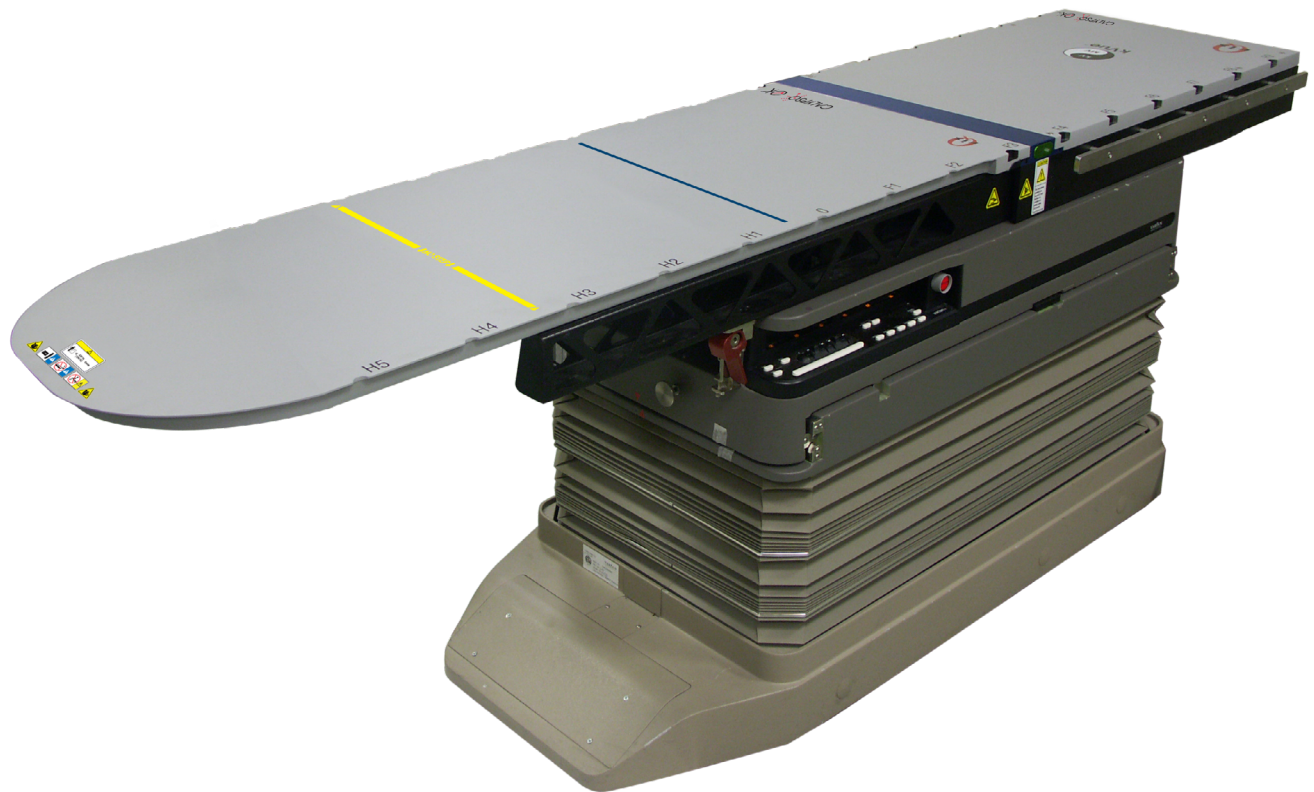


positioning
patients for life.®


PRODUCT GUIDE & USER MANUAL

RT-4551KVCL

kVue™ Calypso Couch Top
with Moving Rails Technology





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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

! 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.

COLLISION HAZARDS

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

GENERAL PRECAUTIONS

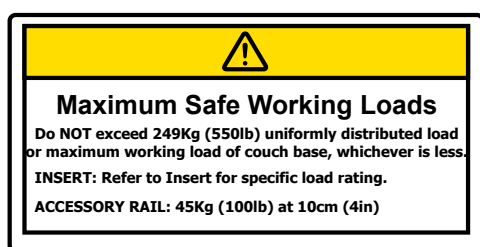
WARNING LABELS & DESCRIPTIONS

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 249 kg (550 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less.

The load rating for each kVue Calypso Insert is specified in the instructions for the kVue Calypso Insert.

The accessory rail load rating is 45 kg (100 lb) at 10 cm (4 in).



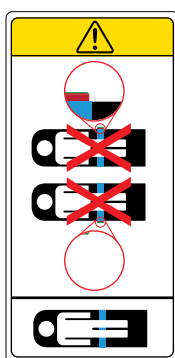
OR



“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.



ONETOUCH™ LATCH

Place a patient on the kVue Calypso ONLY when the red collar of the latch button is not visible. The OneTouch Latch has a built-in indicator to verify proper engagement. If the red collar of the latch button is visible, the locking mechanism is not engaged.

GENERAL PRECAUTIONS

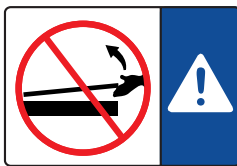
WARNING LABELS & DESCRIPTIONS



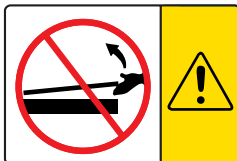
PINCH POINTS

Use caution when moving the kVue Calypso to avoid patient injury. Extreme care has been taken to minimize pinch points and other hazards associated with the kVue Calypso. Common pinch points include:

- Between the kVue Calypso Insert and the One-Touch Latch
- Between the kVue Calypso Insert and the support beams
- Between the kVue Calypso and other pieces of equipment in the treatment room, including the Linac treatment head.



OR

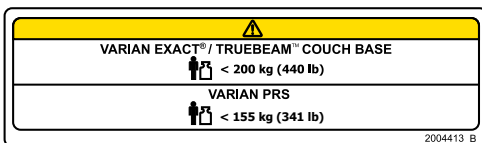


KVUE CALYPSO INSERT INSTALLATION AND REMOVAL

! NEVER LIFT THE END OF THE KVUE CALYPSO INSERT !

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

Refer to the RT-4551KV kVue Couch Top Installation Manual for kVue installation and removal instructions.



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.

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

The kVue Calypso is a state of the art radiotherapy couch top optimized for the most recent advances in technology and designed to be compatible with the Calypso® System. It is engineered to ensure precise and repeatable sub-millimeter patient positioning. The kVue Calypso is a version of the kVue product line. It is constructed from high strength advanced fiber composites that are completely metal free and non-conductive to enable its use with the Calypso System. The kVue Calypso adds significant versatility to your treatment room and allows the use of most standard indexed positioning devices.

The kVue Calypso is designed for superior performance when used with Kilovoltage imaging such as cone beam CT while simultaneously reducing skin dose for treatments that pass through the couch. This, combined with the ability to swap the kVue Calypso Inserts for a wide range of kVue Inserts, makes the kVue Calypso one of the most advanced solutions available for IMRT and IGRT patient positioning.

Versions of the kVue Calypso are available for Elekta Precise®, Varian TrueBeam™, Varian ETR®, Varian Exact®, Siemens ZXT™ and Siemens TxT™ couches.

REQUIRED ACCESSORIES

kVue Calypso Insert

FEATURES

CALYPSO SYSTEM COMPATIBLE COUCH TOP

The Calypso System uses electromagnetic signals to detect the position of implanted Beacon® electromagnetic transponders and localize the treatment target position during radiation therapy. System accuracy can be affected by conductive materials close to the Beacon transponders during localization. Extensive testing has been performed on the kVue Calypso as well as on all Calypso System Compatible accessories. When using the Calypso System, only Calypso System compatible accessories should be used. Contact Varian Medical Systems for a list of compatible accessories.

The kVue Calypso is the complete patient support system, excluding the original equipment couch base. It consists of the Baseframe (including support beams), the Interface Plate (if required), and the appropriate kVue Calypso Insert.

CALYPSO SYSTEM COMPATIBLE LOCATING BAR

The Calypso System Compatible Locating Bar is made from non-conductive materials and fits the kVue Calypso locating notches spaced every 140 mm on the patient surface. It has (2) locating pins designed to match Calypso System Compatible accessories as well as other Qfix accessories. When using the Calypso System, use only Calypso compatible accessories.



FEATURES

INDEX NOTCHES

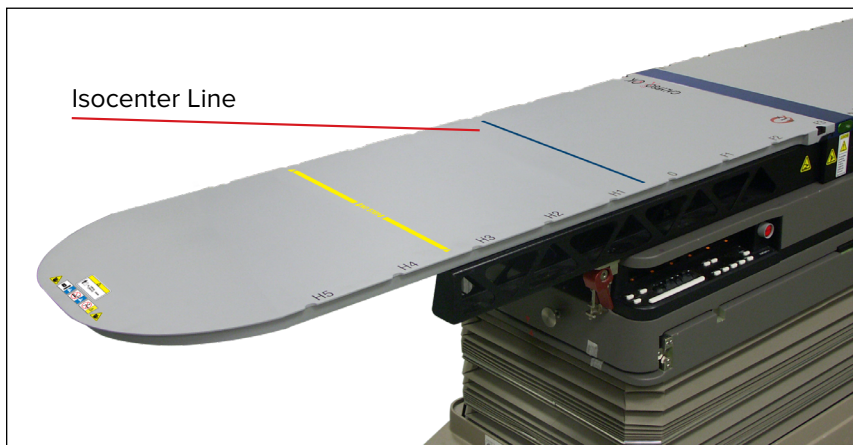
The kVue Calypso Insert and Base Section have kVue Calypso Index Notches spaced at the current industry standard of 140 mm. These notches are used to accurately position the Calypso System Compatible Non-conductive Locating Bar. The kVue Calypso Indexing Notches help ensure proper Calypso System functionality by preventing the inadvertent use of standard, metallic or conductive Locating Bars and positioning accessories during target localization with the Calypso System.



Indexing Notches

INFERIOR ISOCENTER LINE

The kVue Calypso Insert is marked with a blue line that represents the furthest proximal location for the isocenter when using the Calypso System. Contact your Varian Medical Systems Representative or refer to Calypso System User's Manual for more specific information about the importance of this line.



Isocenter Line

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

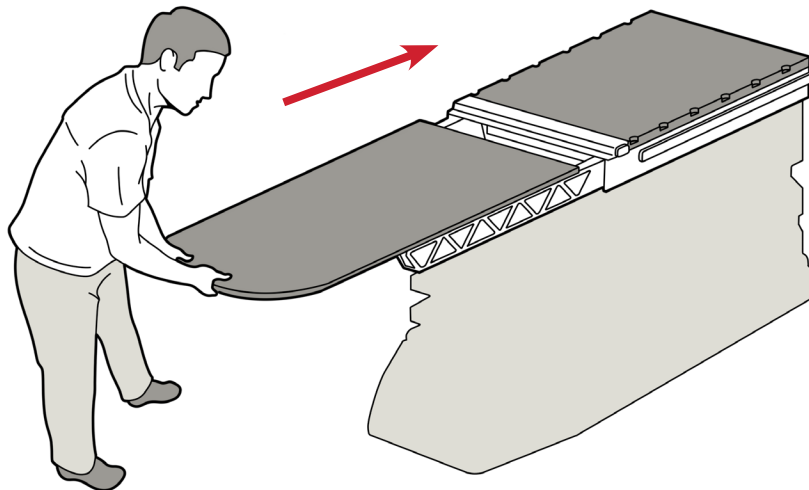
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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

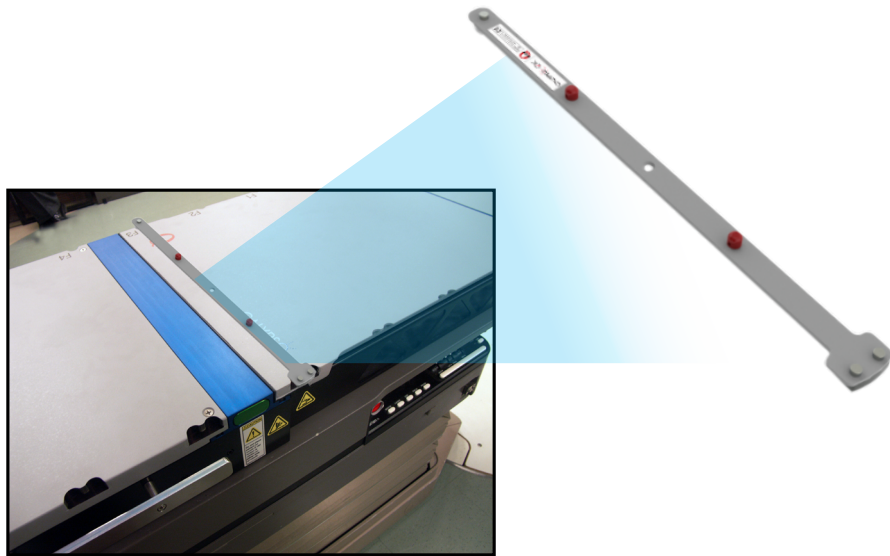
OPERATING INSTRUCTIONS

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

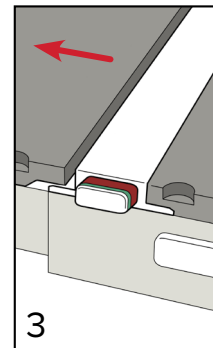
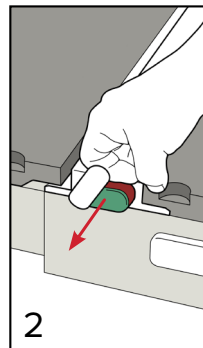
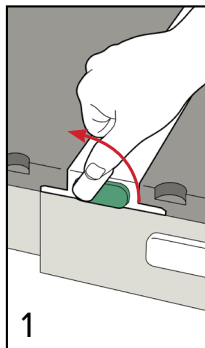
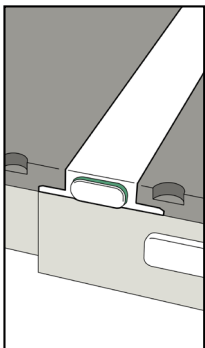
LOCATING BAR REMOVAL

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 Insert surfaces. To disinfect the kVue Calypso surface, refer to specific instructions from the cleaning agent manufacturer.

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

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

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

If body fluids enter the Baseframe, remove the six screws that connect the Back Panel and clean appropriately. Do not use any water-based cleaners on the linear bearing rail. After cleaning, lubricate the linear bearing rail with fluoropolymer (PTFE) dry film lubricant.

The OneTouch Latch requires periodic lubrication; refer to specific instructions on how to properly lubricate and clean the OneTouch Latch.

Disassembly of the OneTouch Latch will void the kVue Calypso warranty.

Periodically check all fasteners for tightness.

MAINTENANCE

CLEANING AND LUBRICATING PROCEDURE FOR ONETOUCH LATCH

We recommend performing this procedure monthly.

Materials List: fluoropolymer (PTFE) dry film lubricant, cotton swabs, and dry wipes or paper towels

! NOTE ! The images below show the procedure performed on a kVue, but the procedure is the same for kVue Calypso.

1. Remove kVue Calypso Insert. (Fig.1)
2. Wipe any lint or debris from the outside of latch. (Fig. 2)
3. Use dry cotton swab to clean out the inside of the receiving holes. (Fig. 3)
4. Spray lubricant into the receiving holes. (Fig. 4)
5. Use dry cotton swab to wipe out loose lint and debris. (Fig. 3)
6. Spray lubricant into the receiving holes again. (Fig. 4)
7. Spray lubricant into the gap between the top of the button and the latch housing to lubricate interior components. (Fig. 5)
8. Reinsert the kVue Calypso Insert and eject by pulling latch from opposite side. Repeat lubrication step 7.
9. Cycle kVue Calypso Insert installation and removal 3 to 4 times and repeat lubrication process if Calypso Insert does not eject freely.
10. Wipe off any excess lubricant from the exterior of the OneTouch Latch.

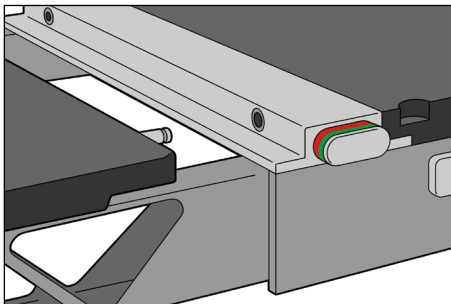


Fig. 1

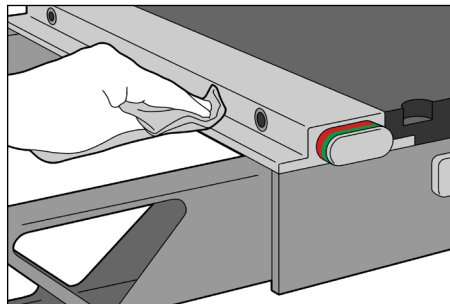


Fig. 2

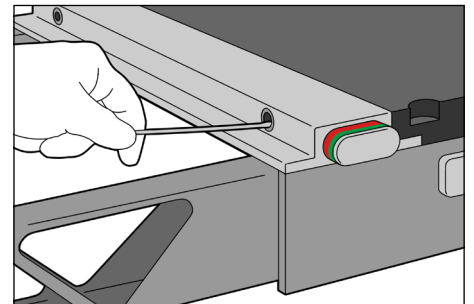


Fig. 3

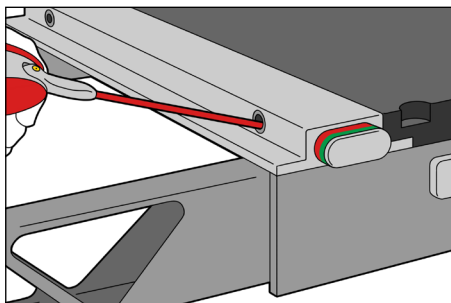


Fig. 4

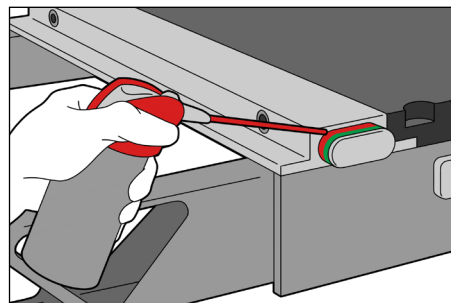
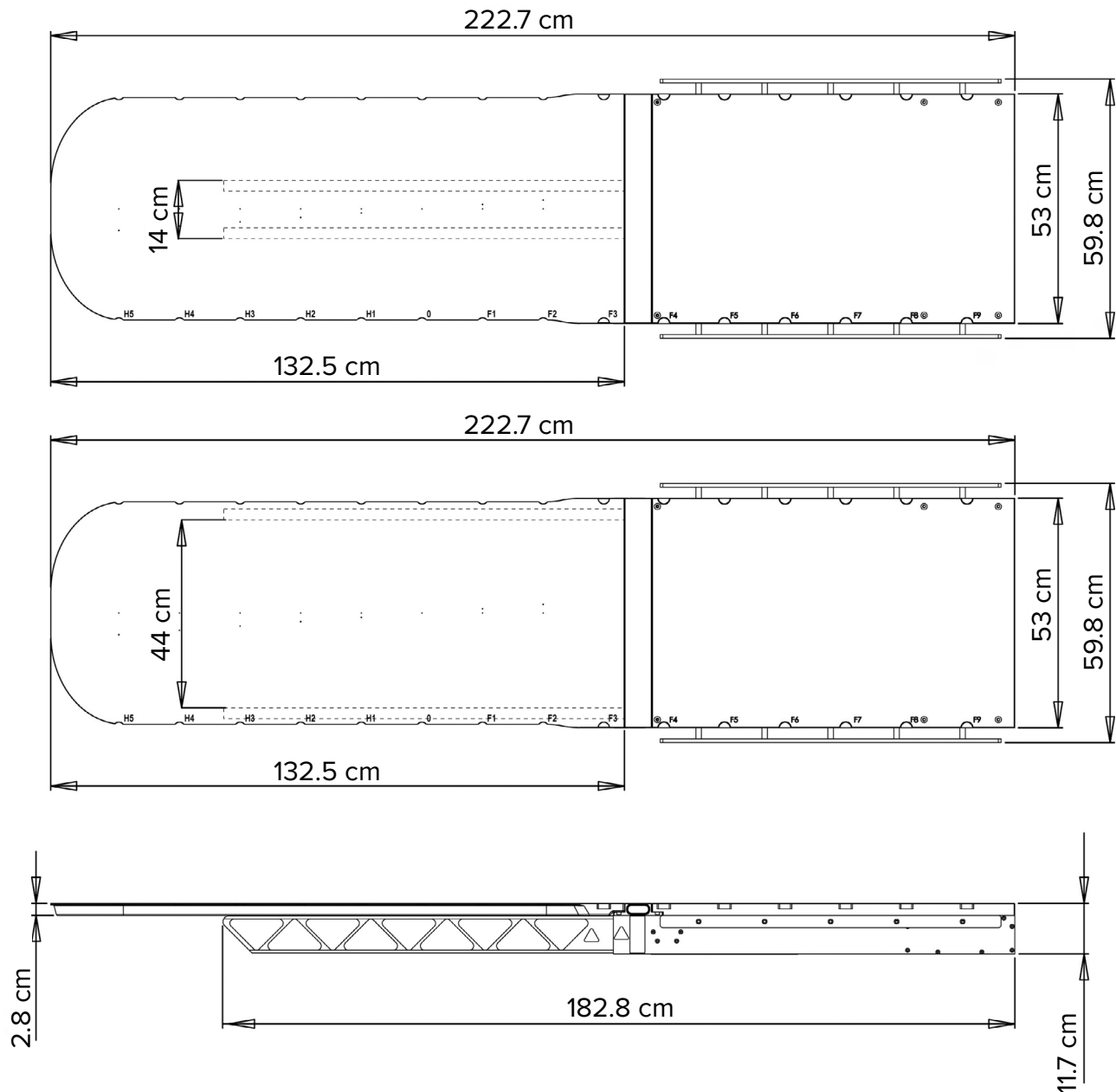


Fig. 5

SPECIFICATIONS

KVUE WITH STANDARD INSERT



! NOTE ! For specifications pertaining to individual kVue Calypso Inserts, refer to the particular kVue Calypso Insert IFU.



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