

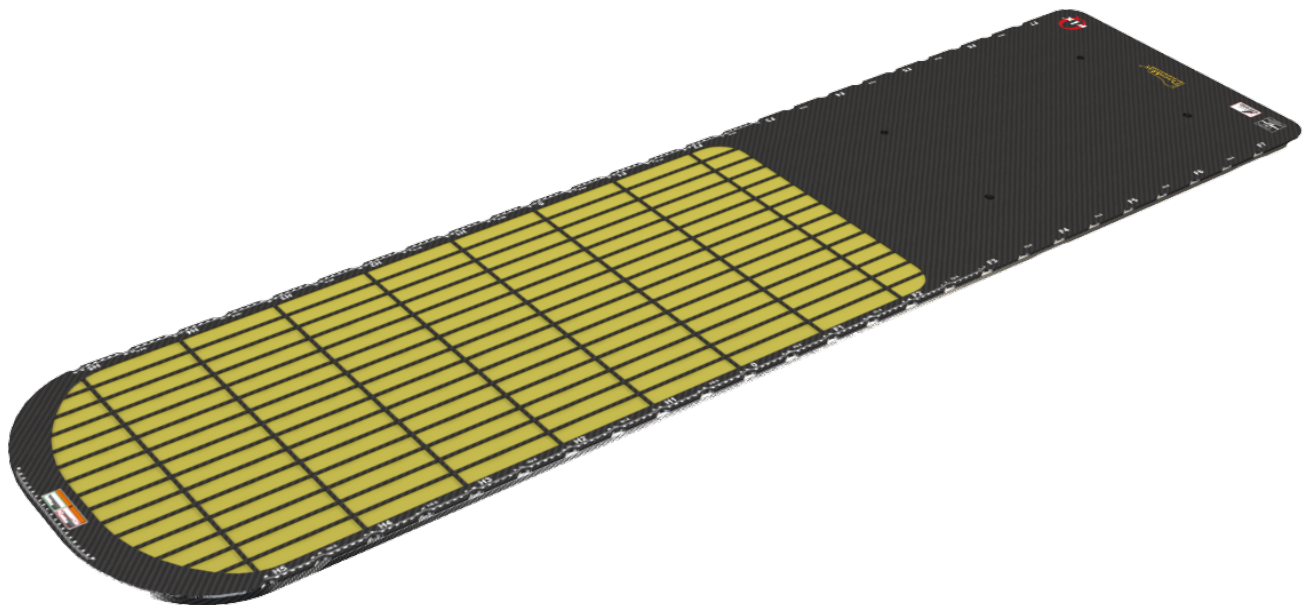


positioning
patients for life.®


PRODUCT GUIDE & USER MANUAL

RT-4588-01

DoseMax™ Standalone Device





EC	REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta		Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6053 www.Qfix.com
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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 +1 484-720-6053 OR TECHSUPPORT@QFIX.COM.

! WARNING ! THE DOSEMAX WILL ATTENUATE A RADIOTHERAPY BEAM AND INCREASE SKIN DOSE. ATTENUATION AND INCREASED SKIN DOSE SHOULD BE TAKEN INTO ACCOUNT DURING PLANNING AND TREATMENT.

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

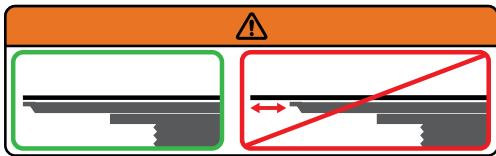
DO NOT exceed 249 kg (550 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! 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.



DO NOT CANTILEVER

DO NOT cantilever the device off the end of the couch base.

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

Patient's 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

INSTALLING DOSEMAX TO CT OVERLAY

Install two Locating Bars (8002595) on the DoseMax Standalone with the provided 10-32 x 1/2" (3001046) screws and a #2 screwdriver (Fig. 1).

Place the DoseMax onto the CT Overlay, lining up the Locating Bars with the index notches (Fig. 2).

! NOTE ! Be sure DoseMax is secure prior to having patient get on the device.

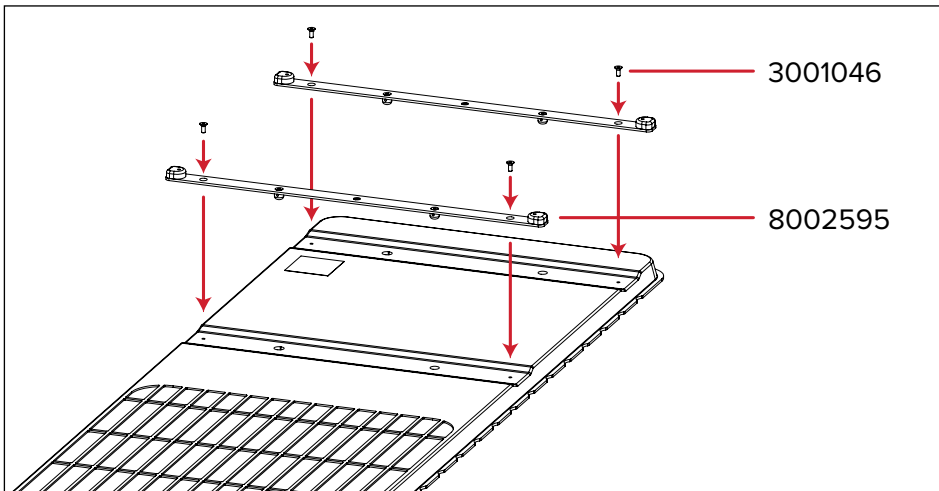


Fig. 1

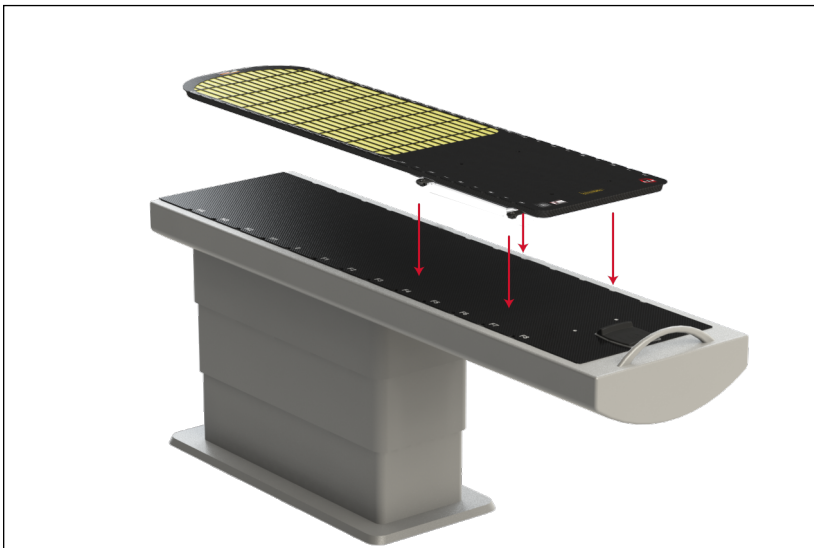


Fig. 2

OPERATING INSTRUCTIONS

SET UP

kVue SBRT Bridges may be attached to the lip of the DoseMax. For more information on using the kVue SBRT Bridges with the DoseMax refer to the kVue SBRT Bridge IFU (P/N 2005053).

! NOTE ! The scale on the DoseMax is in the same location as on the DoseMax Insert. When using the DoseMax Insert as the treatment device, accessories should not be setup inferior of the scale.

REMOVAL

To remove the DoseMax, lift vertically until it clears the locating pins, then the device may be safely removed from the CT Overlay.

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

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

DO NOT spray directly onto the DoseMax or allow to flow into the couch base.

DO NOT place sharp objects on the DoseMax.

MAINTENANCE

DOSEMAX MYLAR REPLACEMENT

Peel the current film from an edge.

Prepare the surface by clearing all leftover adhesive with an adhesive remover.

Align the new film, making sure to cover the superior label (Fig. 3). Each edge should be approximately 7.24 mm [0.285"] from the outer edge of the device.

Place several pieces of tape along the edge to affix the film to the surface of the DoseMax (Fig. 4).

Remove masking tape from superior half of film. Pull up and peel adhesive backing from film. Firmly apply to the surface of the device.

Remove tape and the remaining adhesive backing from anterior half of film. Firmly apply to the surface of the device.

Peel the protective covering from the film.

! NOTE ! Images shown below are that of the kVue DoseMax Insert, however the replacement of the mylar remains the same for both.

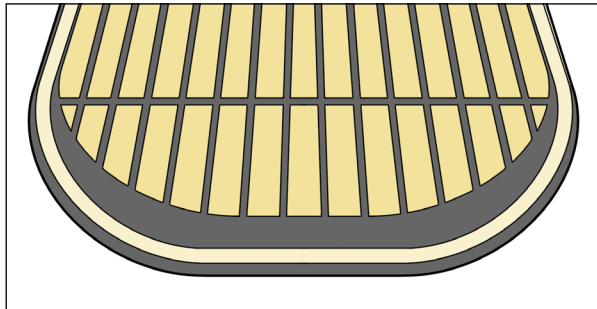


Fig. 3

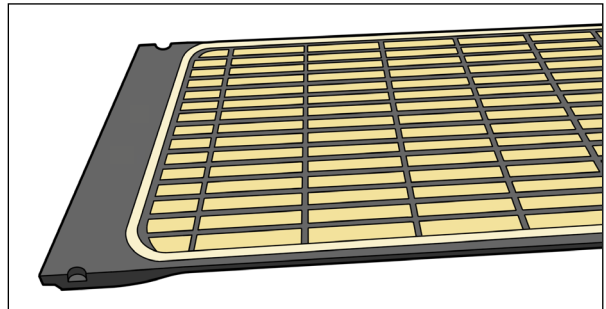


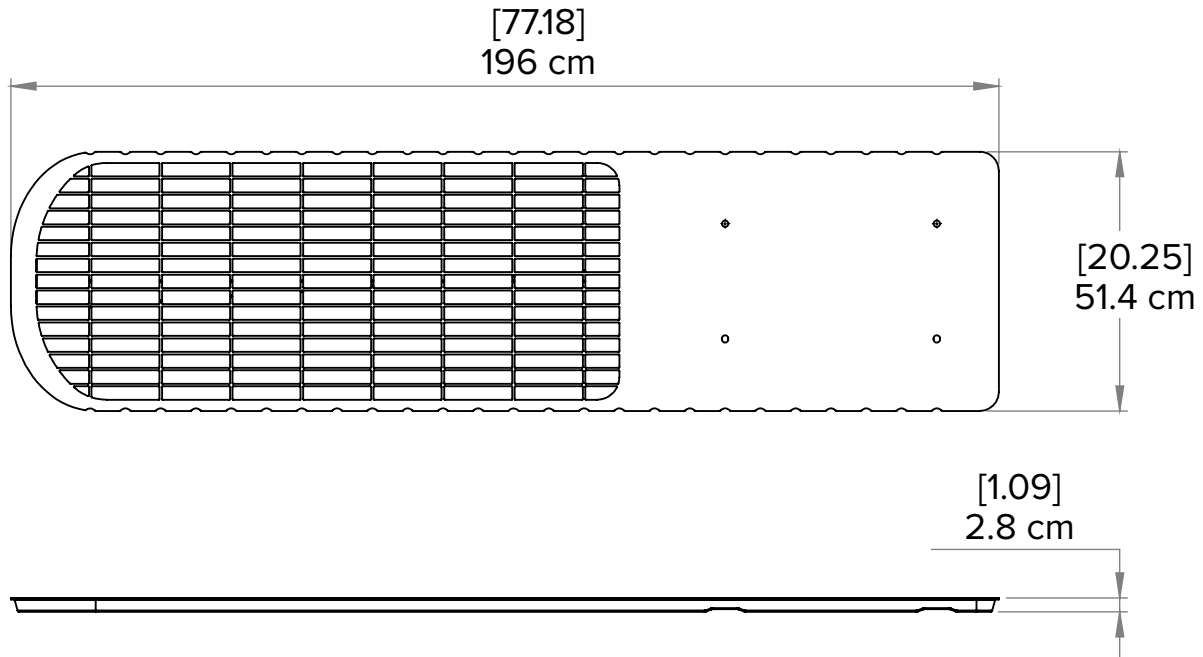
Fig. 4

SPECIFICATIONS

LENGTH: 1960 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-4558-01 DOSEMAX STANDALONE DEVICE

Patient Name:

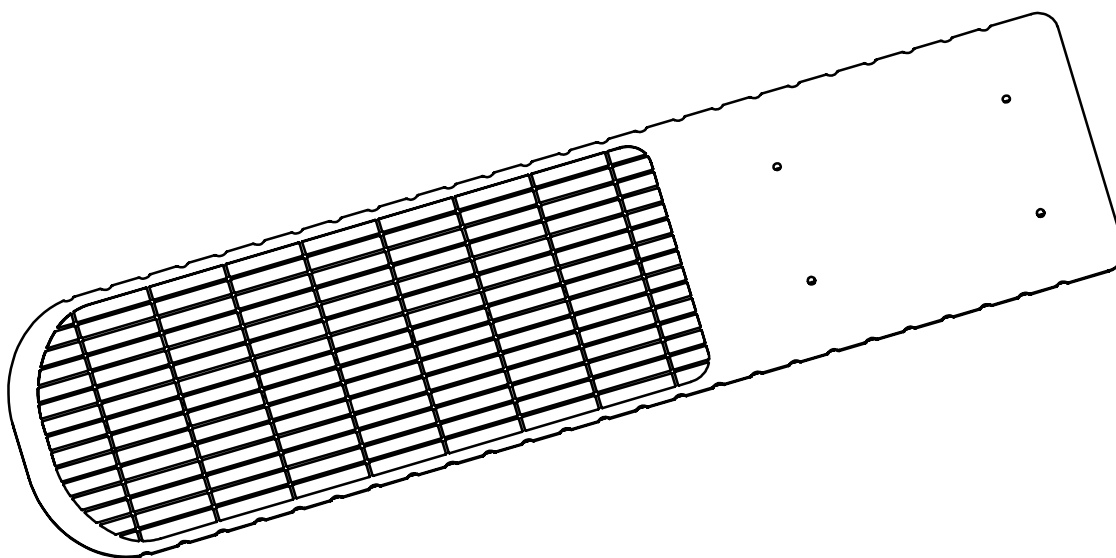
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Notes:



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