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# PRODUCT GUIDE & USER MANUAL


RT-4552 – Portrait™

RT-4552MRI – Portrait™ MR

RT-4552VI – Portrait™ with Virtual Indexing





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 +1 610-268-0585 <a href="http://www.Qfix.com">www.Qfix.com</a>
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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.**

## ADDITIONAL WARNINGS

- Always secure the Portrait to the treatment couch.
- Always assist the patient onto the Portrait by supporting their upper body and head region.
- Movement of the shoulders during treatment may cause the isocenter to shift.
- During assembly, do not modify the Portrait.
- Never put weight on the cantilevered portion of the device without a patient on the device.
- The cantilevered portion of the device is only designed to hold the weight of a patient's head. Do not allow a patient to lean on this portion of the device.

## 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) of 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 couch top load should NOT exceed the original couch base manufacturer's specifications. Please refer to the product literature provided by the original manufacturer

## MR SAFETY INFORMATION

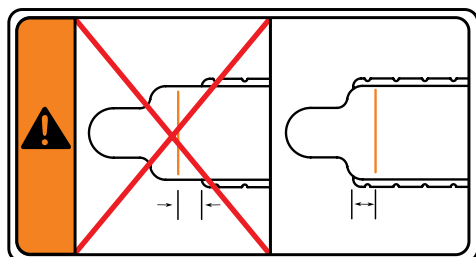
 Non-clinical testing has demonstrated that **RT-4552MRI Portrait™ MR** may be used in an MR environment.

The MR Safe version of the Portrait™ MR (RT-4552MRI) is clearly labeled with the following symbol: 

# GENERAL PRECAUTIONS

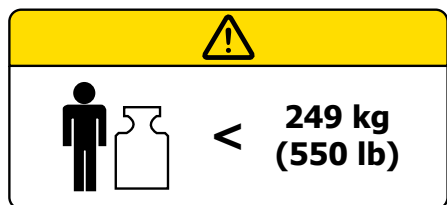
## WARNING LABELS & DESCRIPTIONS

Refer to [Qfix.com](http://Qfix.com) for a listing of symbols and their definitions.



### WARNING

DO NOT extend the Portrait off the end of the couch top beyond the warning line.



### LOAD RATING

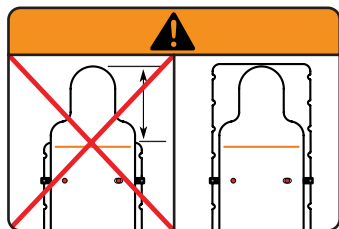
Do NOT exceed 249 kg (550 lb) uniformly distributed load or maximum safe working load of kVue Insert, or couch base, whichever is less.



### MRI SAFE

When present, item poses no known hazard in all MR environments. DO NOT use with any unapproved components or accessories. DO NOT use in conjunction with any ferromagnetic or conductive items.

**! NOTE !** For RT-4552MRI only



### WARNING

DO NOT extend the Portrait off the end of the couch top when using a locating bar for device indexing. Doing so may cause patient or personal injury.

If cantilevering the device, the proper Indexing Adapter must be used.

# 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

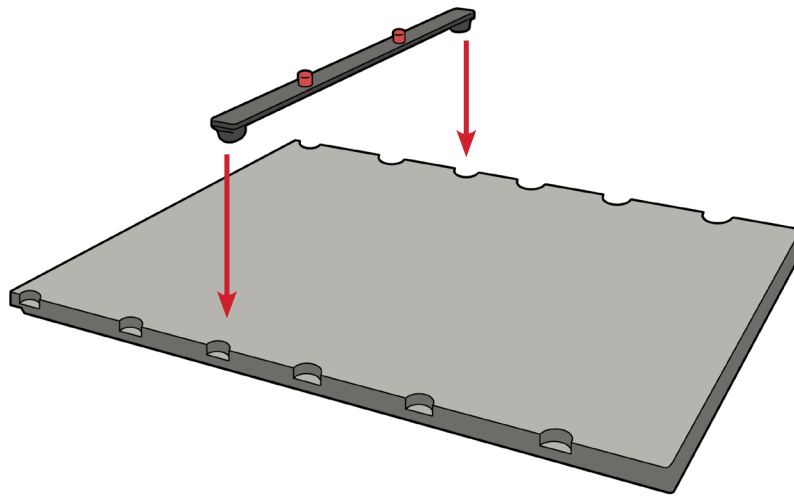
The Portrait is for the immobilization of the head/neck and shoulder regions. It is intended to provide optimum localization for the patient for radiation therapy. The Portrait is intended to be used with Aquaplast RT™/Fibreplast® Portrait S-Frames.

# OPERATING INSTRUCTIONS

## INSTALLATION

### 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.





# OPERATING INSTRUCTIONS

## INSTALLATION

### PORTRAIT INSTALLATION

**! NOTE !** When attaching to a couch top using an Indexing Adapter, refer to Indexing Adapter IFU for instructions on installation.

**! NOTE !** Check to ensure the adapter is properly fastened before use.

**! NOTE !** If using a removable tennis racket couch top insert, it may be necessary to reverse the insert to achieve a proper fit.

**! WARNING ! DO NOT EXTEND THE PORTRAIT OFF THE COUCH TOP BEYOND THE WARNING LINE.**

**! WARNING ! DO NOT EXTEND THE PORTRAIT OFF THE END OF THE COUCH TOP WHEN USING A LOCATING BAR FOR DEVICE INDEXING. DOING SO MAY CAUSE PATIENT OR PERSONAL INJURY.**

1. Align the red pins of the locating bar to the locating holes in the Portrait. (Fig. 4)
2. Place the Portrait onto the couch top and over the red pins. (Fig. 5)
3. Make sure the device is securely attached before moving the patient to the couch top.



Fig. 4



Fig. 5

# OPERATING INSTRUCTIONS

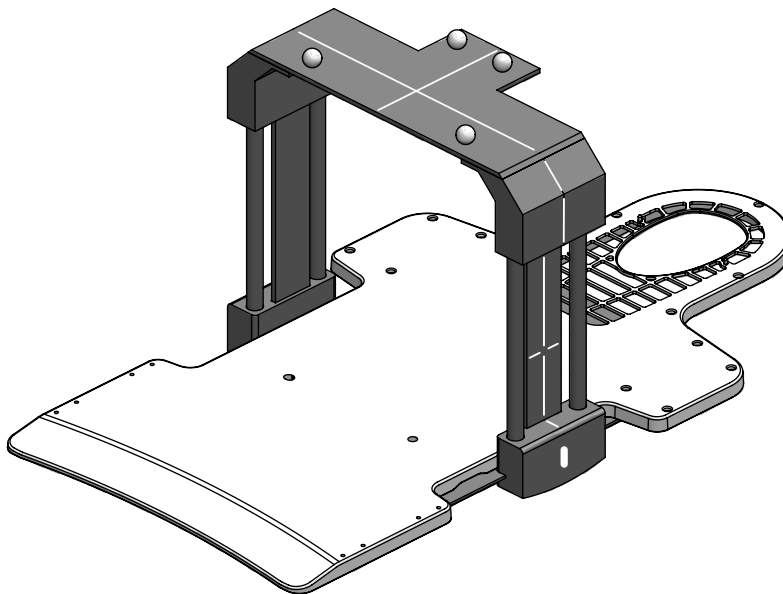
## INSTALLATION ACCESSORIES

### PORTRAIT™ MR AND THE ELEKTA HEXAPOD™

**! NOTE !** Refer to the Product Guide and User Manual for the Elekta HexaPOD for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Elekta HexaPOD.

The cutout features on the MR Portrait allow for the installation of the Elekta HexaPOD™ Reference Frame. Install Elekta HexaPOD Reference Frame on the Elekta iBEAM® evo Couch Top referring to manufacturer's instructions.

**! NOTE !** Ensure no interference between the Reference Frame and MR Portrait device.



# OPERATING INSTRUCTIONS

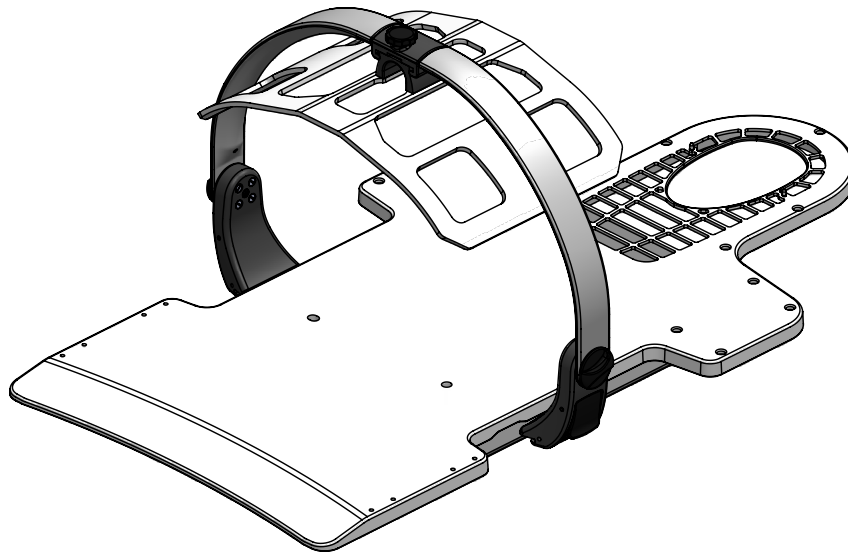
## INSTALLATION ACCESSORIES

### PORTRAIT™ MR AND THE INSIGHT™ MR BRIDGE

**! NOTE !** Refer to the Product Guide and User Manual for the Insight MR Bridge (P/N 2007254) for installation of the Insight MR Bridge onto the Overlay along with operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Insight MR Bridge.

The cutout features on the MR Portrait allows for the installation of the Insight MR Bridge with Body Coil Holders.

**! NOTE !** Ensure no interference between the Insight MR Bridge and MR Portrait device.



# OPERATING INSTRUCTIONS

## SET-UP

### PATIENT POSITIONING

1. Place appropriate Silverman head support onto the Portrait.
2. Sit the patient on the lower aspect of the Portrait.
3. Lift and rotate the patient's legs onto the treatment couch top, then lay the patient gently backwards until the patient's head is in the Silverman head support.
4. Form MOLDCARE® head cushion as desired (see MOLDCARE® Instructions for Use). (Fig. 6)
5. Place mask over patient, lining up Portrait S-Frame pins with attachment holes on the Portrait. (Fig. 7)
6. Insert pins into the Portrait S-Frame holes and press until each pin locks in place. (Fig. 8)

**! NOTE ! The four (4) Portrait mask holes on the inner part of the device are for pediatric masks.**

7. Mold the Aquaplast RT or Fibreplast Portrait S-Frame mask (see Aquaplast RT and Fibreplast Instructions for Use) applying gentle pressure around the nasion until the thermoplastic completely hardens. (Fig. 9)



Fig. 6

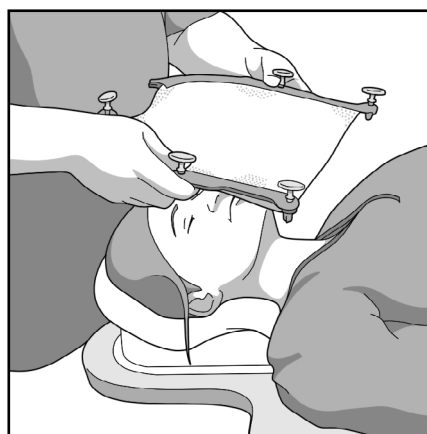


Fig. 7

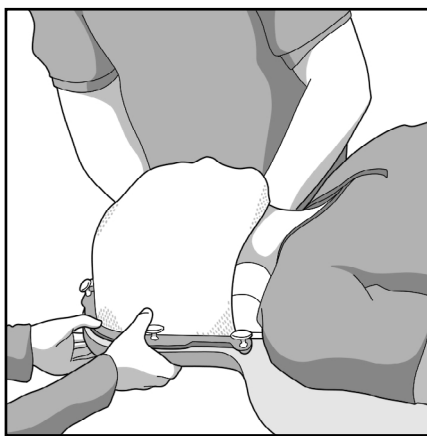


Fig. 8

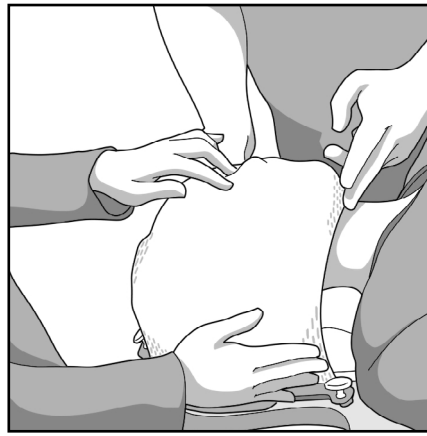


Fig. 9

# OPERATING INSTRUCTIONS

## REMOVAL

### PORTRAIT S-FRAME THERMOPLASTIC

1. To remove, pull up on each pin. (Fig. 10)
2. Lift the mask off of the patient.

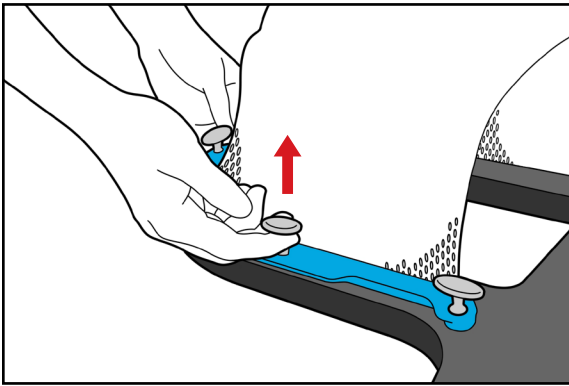


Fig. 10

### PORTRAIT

1. Remove the MOLDCARE® and Silverman from the Portrait.
2. Lift the Portrait off of the locating bar and couch top for storage.

### LOCATING BAR

Pull up on either end of the Locating Bar.

# 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 surface as they may flow into the mechanisms within device. 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 devices' surfaces. To disinfect the 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 device or allow to flow into the kVue Couch Top and/or Baseframe.

DO NOT place sharp objects on the device.

# SPECIFICATIONS

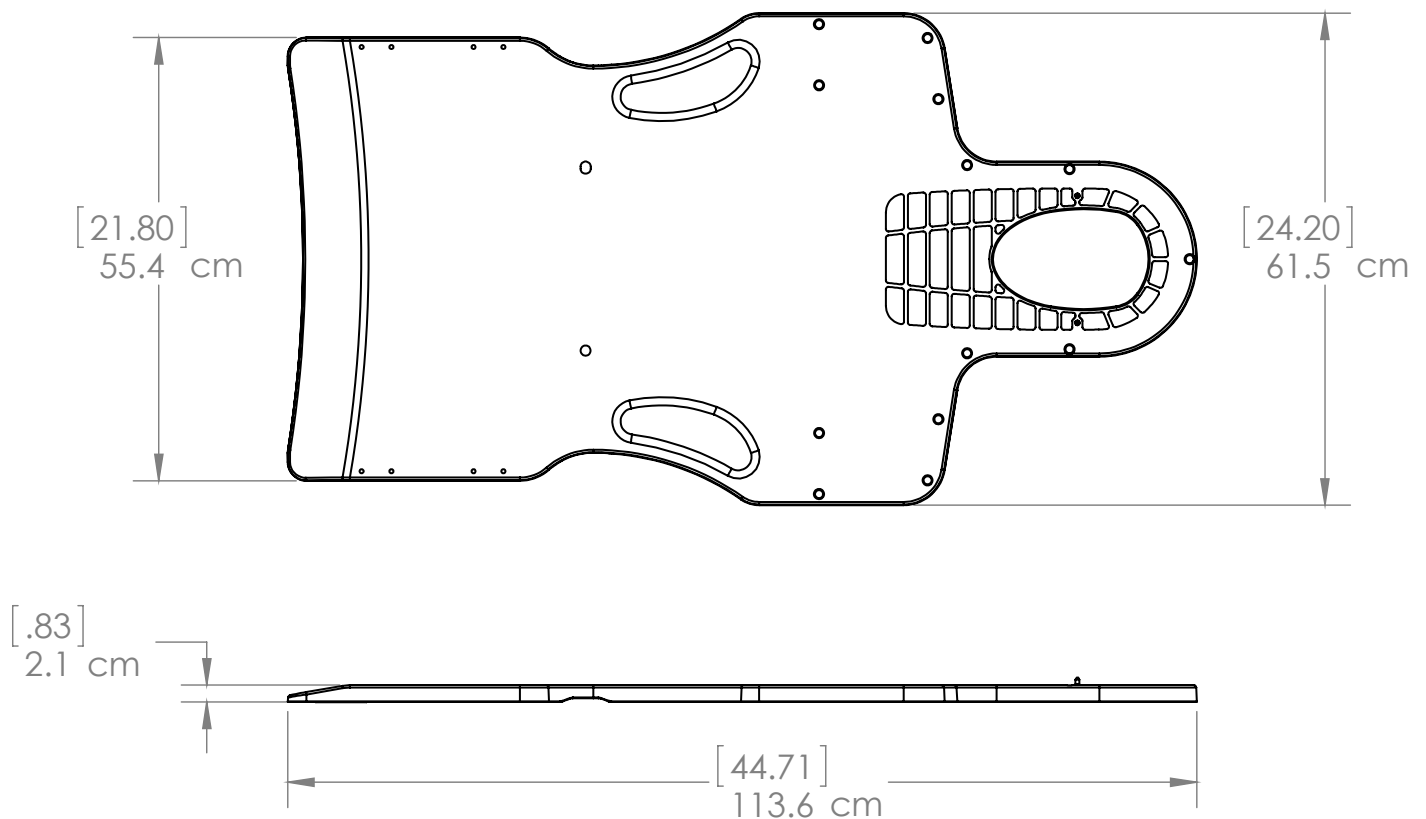
## RT-4552, RT-4552VI

**LENGTH:** 1136 mm

**ALUMINUM EQUIVALENCE:** ~0.4 mm @ 100 kVp

**WATER EQUIVALENCE:** 5 mm @ 6 MV

**WEIGHT LIMIT:** 249 kg (550 lb) of Uniformly Distributed Load



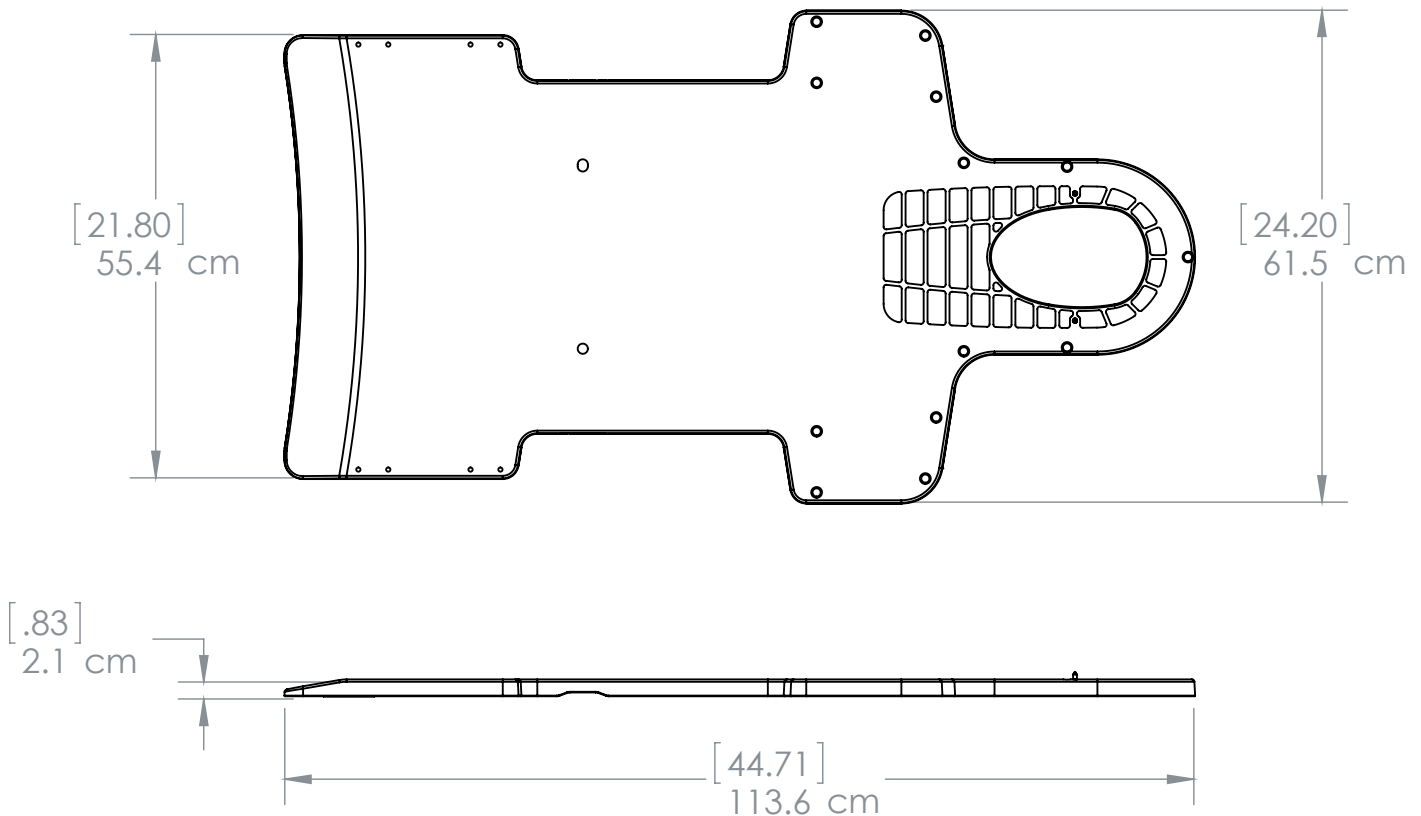
# SPECIFICATIONS

## RT-4552MRI

**LENGTH:** 1136 mm

**ALUMINUM EQUIVALENCE:** ~0.8 mm @ 100 kVp

**WEIGHT LIMIT:** 249 kg (550 lb) of Uniformly Distributed Load





# SETUP SHEET

## RT-4552, RT-4552MRI & RT-4552VI – PORTRAIT™

Patient Name:

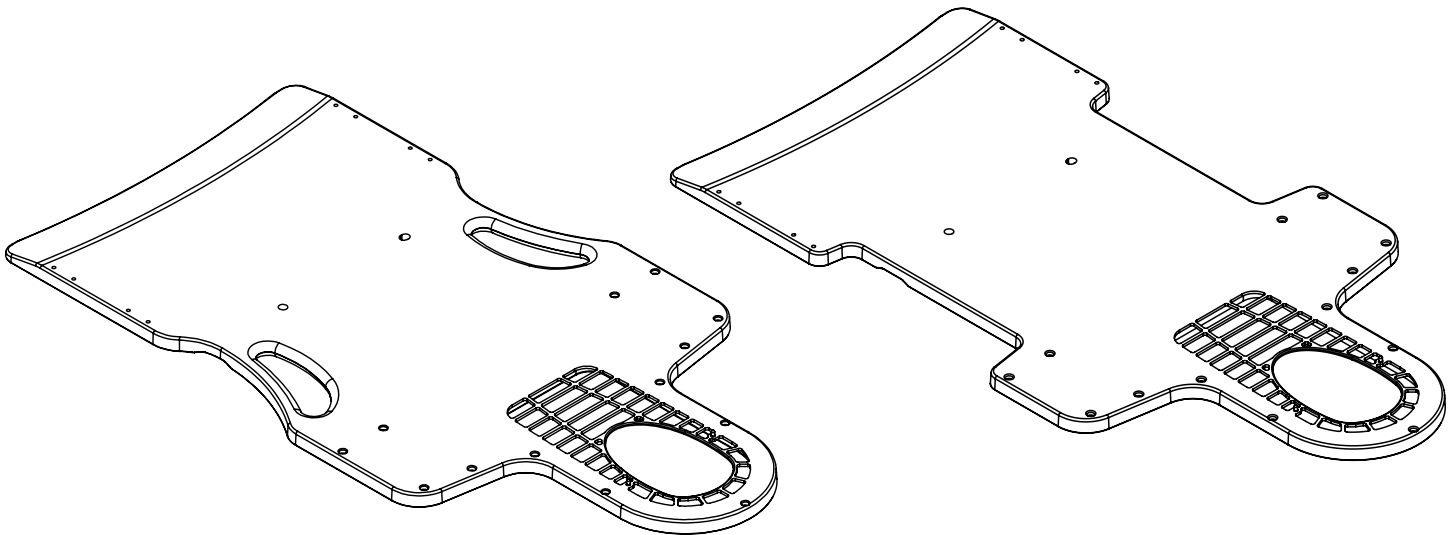
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Headrest Used:

Notes:







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