

TM-7103 Mobile Trans-Former Prototype

Installation Guide and User Instructions



Model: TM-7103 Prototype

Revision: August 2019

Table of Contents

i		Intended Use	3
ii		Safety and Compliance	3
iii		Warranty	4
1		About This Manual	5
	1.1	Disclaimer	5
	1.2	Additional Information Concerning Risks	5-6
	1.3	Changes to This Manual	6
2		Product Description and Specifications	6
	2.1	Product Description	6
	2.2	Product Specifications	6
3		Required Tools and Equipment	6
	3.1	Uncrating	6
	3.2	Assembly	6
4		Uncrating the Device	7
	4.1	Uncrating – Two People to Remove from Pallet	7
	4.2	Removing Cardboard Container	7
5		Installing the Exposure Unit, Grid and DR Panels	8
	5.1	Safety Screw Removal	8
	5.2	Landscape Position	8
	5.3	Mounting the Exposure Unit	8-9
	5.4	Mounting the Grid	9
	5.5	Securing the Exposure Unit and Grid	10
	5.6	Mounting the Bottom Two DR Panels	10-11
	5.7	Mounting the Top DR Panel	11
	5.8	Dismounting the DR Panels	12-13
	5.9	Moving the Device	13
6		User Operations: Height Adjustment and Rotation	14
	6.1	Height Adjustment – Force Required	14-15
	6.2	Height Adjustment of Exposure Unit	15
	6.3	Exposure Unit Rotation	16
	6.4	Patient Position	16-17
7		Product Maintenance	17
	7.1	Maintenance	17
	7.2	Cleaning	17
8		Changes to This Document	18

i. Intended Use

The TM-7103 Mobile Trans-Former (Model# TM-7103 Prototype) is designed to hold and position three Canon 710 DR Panels for use in general radiography.

ii. Safety and Compliance

Precautions!

- The unit is pre-assembled but take care in uncrating, as the device is very heavy.
- Follow any warning labels on the unit and these instructions.
- Do not attempt to adjust the Detector Mount height prior to reading the instructions.
- Failure to adhere to the Precautions listed herein may result in injury to user or patient!

Compliance

The **TM-7103 Prototype Compact Mobile Support** is a Class 1 Medical Device (510k exempt) in the USA and is registered to:

Reina Imaging

6107 W. Lou Avenue
Crystal Lake, IL 60014 USA
Phone: 800-752-4918



The **TM-7103 Prototype Compact Mobile Support** has been labeled and declared:



This model has been classified as a Class 1, Annex VII device.

European Authorized Representative:

Pinchet Rx SRL

Contact: Paolo Pinchet

Via Don Gnocchi 24 20148 Milano Italy

Phone: 02 / 48707603

iii. Warranty

Reina Imaging warrants to the Original Purchaser that this product will be free from defects in its workmanship and materials, under normal use and service conditions, as described herein. "Defects" as used in this warranty, is defined as any imperfections which impair the use of the product. The company will repair or replace, at its option, without charge to the original purchaser only, the defective products or parts for a period of 1 year from the date of purchase and while owned by the Original Purchaser. Should any component fail under normal use during this period, it is the buyer's responsibility to contact customer service at 800-752-4918.

Not Covered Under this Warranty

Damage caused by user abuse, misuse, negligence, accidental misuse and normal wear will not be covered under this warranty. Users are responsible for reading all instructions prior to using the product(s).

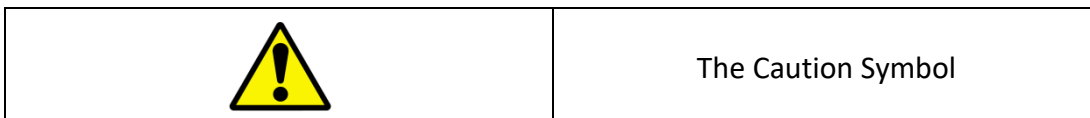
1. About This Manual

- 1.1. Disclaimer - This manual was written to provide proper guidelines for using the TM-7103 Mobile Trans-Former. Using the TM-7103 Mobile Trans-Former in a manner other than detailed in this manual can be dangerous and can cause serious property damage and injury. The user accepts all risks and Reina Imaging shall not be responsible for any liability caused by improper use. Reina Imaging assumes no responsibility to assess the user's technical ability or clearance to operate the TM-7103 Mobile Trans-Former. Use of the TM-7103 Mobile Trans-Former constitutes the user's acceptance of all responsibility for liability caused by its use.
- 1.2. Additional Information Concerning Risks - Throughout this manual additional information is presented to the user to aid in understanding of risks during certain operations. This additional information is not comprehensive of all risks assumed by the user and this product should only be operated by trained persons possessing the technical expertise required for safe operation.

There are three types of additional risk-related information presented to the user:

- *Caution* – Cautions in this manual contain information to help the user avoid minor risks such as product problems due to improper assembly or usage. Failure to heed this level of warning may result in product failure, minor product damage, unusable product, property damage and the like.

The user or patient may also experience minor injuries.



- *Warning* – Warnings in this manual contain information to help the user understand substantial risks. Failure to heed this level of warning could result in serious product damage and serious property damage.

The user or patient may also experience serious injuries that would likely require medical attention.



- *Dangers* – Dangers defined in this manual contain information to help the user understand extreme risks. Failure to heed this level of warning

could result in total product destruction and catastrophic property damage.

The user or patient may also experience grievous personal injury resulting in hospitalization or death.

	The Danger Symbol
---	-------------------

- 1.3. Changes to This Manual - User manuals are updated from time to time to offer information about product improvements, to reflect engineering changes, general workflow and the like. As these updates are released they will be made available for download by users. It is the user’s responsibility to consult our website or call our support line for the latest materials regarding this system prior to use. Users should check back periodically for updates and checking before installation of the product(s) is recommended.

2. Product Description and Specifications

2.1. Product Description - The TM-7103 Mobile Trans-Former is designed to hold and position three Canon 710 DR Panels for use in general radiography. It is mobile with a wheeled base and features a lift-assist mechanism and a rotating detector mount.

2.2. Product Specifications

Weight	TBD
Dimensions	TBD
Total Vertical Stroke	TBD
Max. Height Active Imaging Area - Portrait	TBD
Min. Height Active Imaging Area - Portrait	TBD
Max. Height Active Imaging Area - Landscape	TBD
Min. Height Active Imaging Area - Landscape	TBD

3. Required Tools and Equipment

- 3.1. Uncrating – Philips screwdriver, razor knife
- 3.2. Assembly – No tools required

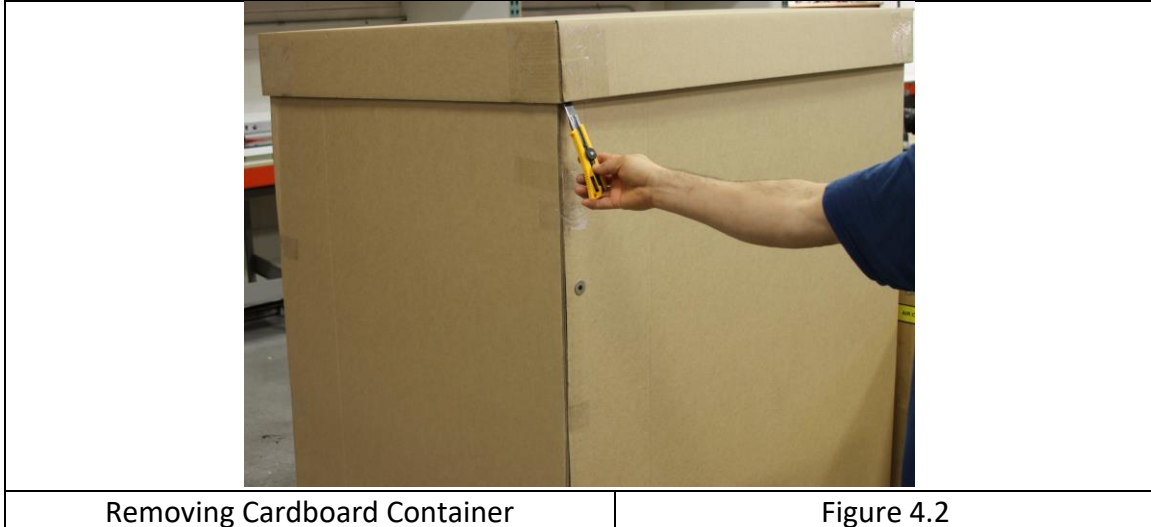


CAUTION!

The device is very heavy. Take care to move it with caution. Separate uncrating instructions are attached to the crate.

4. Uncrating the Device

- 4.1. The device comes fully assembled and can be lifted off the pallet by two people
- 4.2. Cut the packing tape connecting the lid and box and remove the box top.
Remove the remainder of the box from the pallet. Remove all bracing and strapping.



Removing Cardboard Container

Figure 4.2

Installation Precautions:

- The unit is pre-assembled but take care in uncrating, as the device is very heavy.
- Follow all warning labels on the unit and these instructions.
- Do not attempt to adjust height prior to reading the Warnings and instructions for mounting the Exposure Unit.
- Do not remove red safety screw near release pin in the right-side handle until instructed to do so in Section 5.
- Failure to adhere to the Precautions listed above may result in injury to user!



WARNING!

The device's lift-assist mechanism employs a forceful coiled spring. Attempting to adjust the height of the Detector Mount before installing the Exposure Unit and three Canon 710 DR Panels could cause the top of the Detector Mount to be driven upward with high force and velocity, possibly causing injury to the torso, arms, neck, face or head of the user. Do not actuate the release pin prior to reading the instructions in Section 5. Remove the red safety screw only after reading the complete instructions.



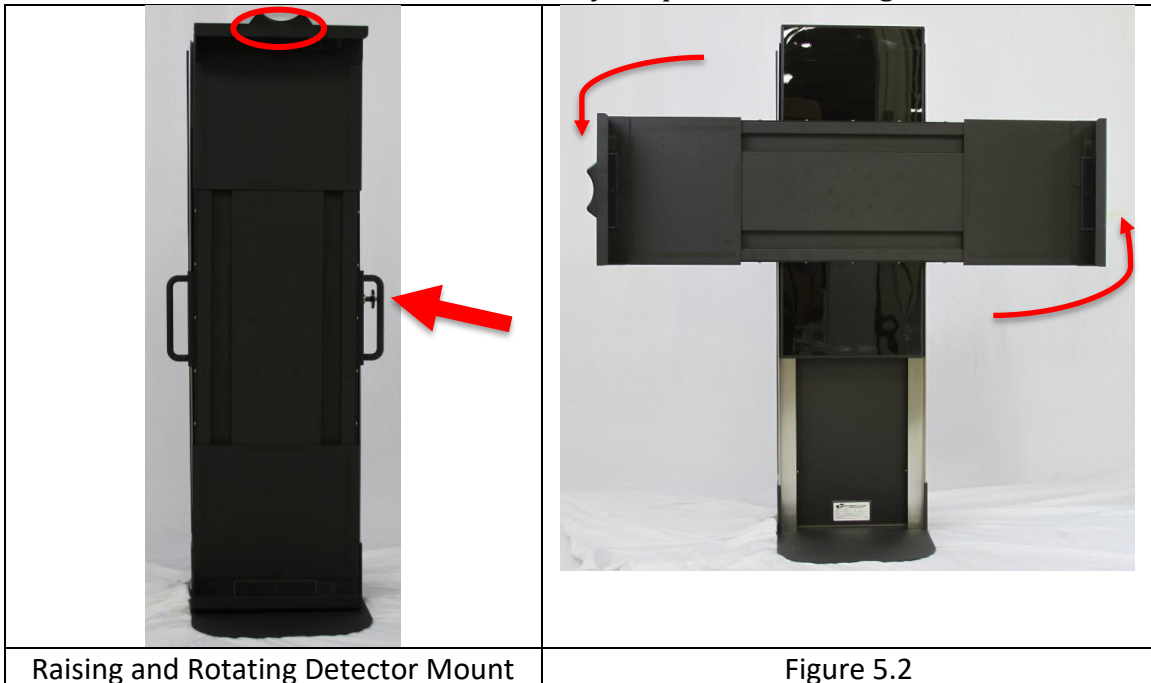
CAUTION!

Before rotating the Detector Mount to the landscape orientation to install the Exposure Unit and Grid, remove the red safety screw and raise the Detector Mount about halfway or the Detector Mount can hit the floor when rotated. See Section 6 for full explanation of controls before performing these operations.

5. Installation of Exposure Unit and Grid onto the Detector Mount and Installation/Removal of the three Canon 710 DR Panels

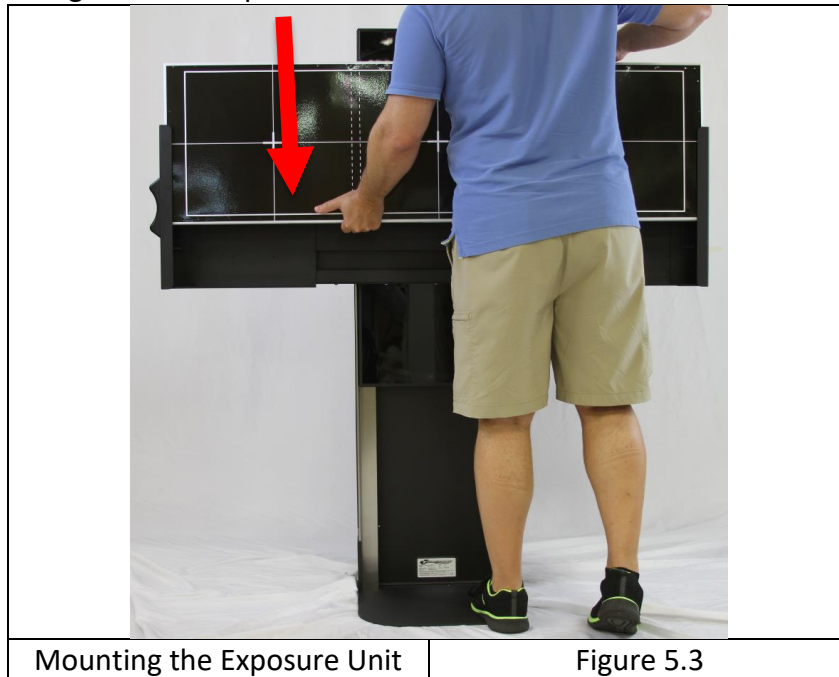
5.1. Remove Safety Screw and Raise Detector Mount – Remove the red safety screw from the right side support rail. Raise the Detector Mount about halfway by placing your left hand on the top center of the detector mount (red oval) and maintaining control of the lift-assist force by applying firm downward pressure before pulling the release pin located inside the right side handle opening (red arrow). Allow the Detector Mount to rise about halfway then let go of the release pin to allow it to lock. Keep your head away from the top of the Detector Mount.

5.2. Landscape Position - Rotate the Detector Mount anti-clockwise into the landscape position by holding the top and bottom and applying pressure until the unit rotates. It will automatically snap into the 90-degree detent.

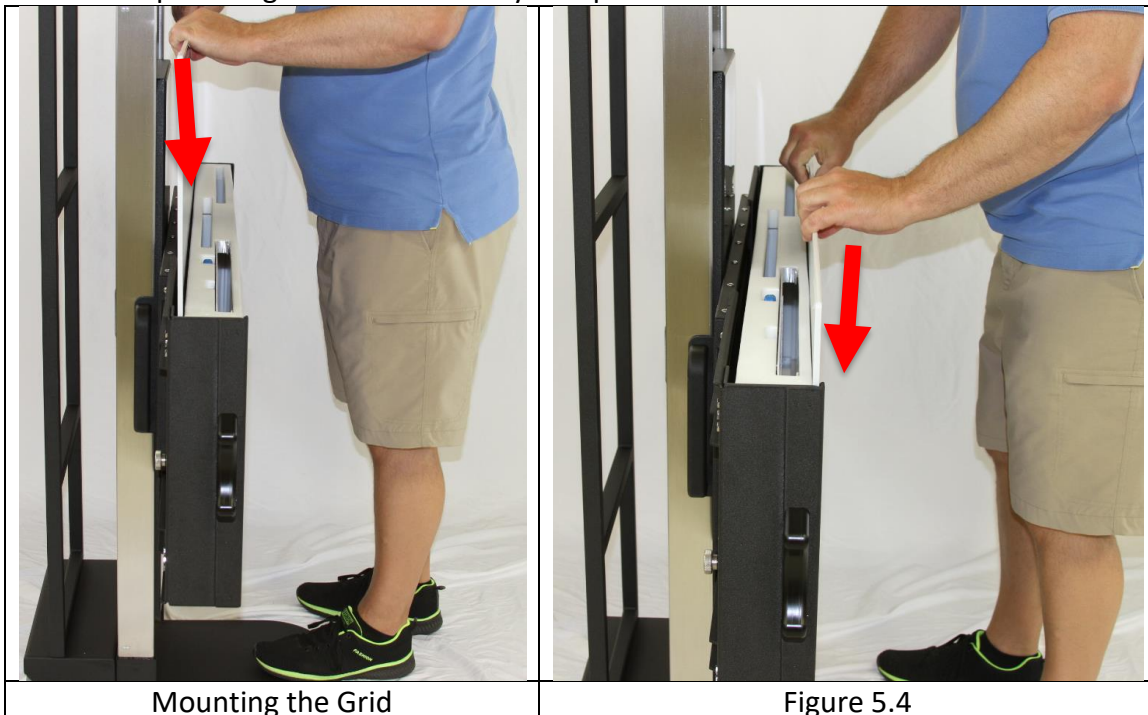


5.3. Installing the Exposure Unit – Make sure the tensioner knobs are fully loosened by turning them *clockwise* until they stop (see Figure 5.5 for reference). Install

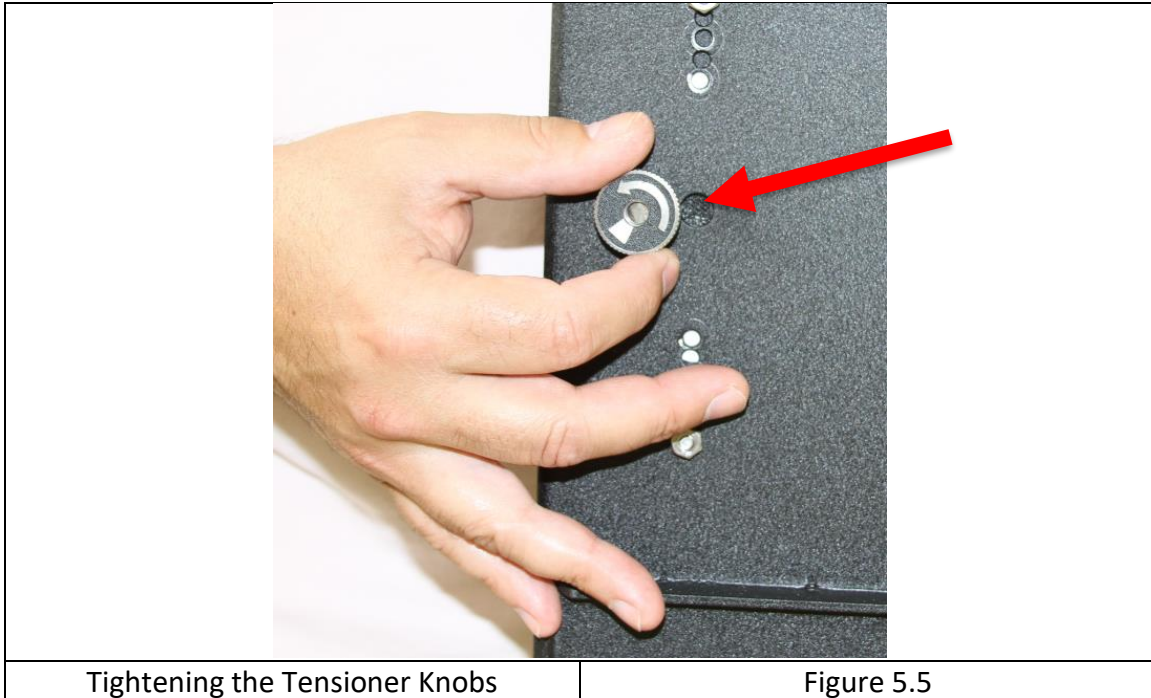
the Exposure Unit into the Detector Mount by sliding it between the support guides in the landscape orientation and carefully lowering it until it is fully seated against the stops.



5.4. Installing the Grid - Install the Grid in either the storage position (behind the Exposure Unit – left image) or in the clinical use position (in front of the Exposure Unit – right image) by sliding it into the Detector Mount, taking care to keep it straight so it slides easily into position.



- 5.5. Securing the Exposure Unit and Grid - Tighten the two tensioner knobs on the rear of the Detector Mount by turning them *anti-clockwise* until tight. The Anti-scatter Grid can be mounted in front of the Exposure Unit for clinical use or stored behind it when not in use. To maintain proper performance tuning, the Anti-scatter Grid must always be mounted in the Detector Mount either in front or behind.



CAUTION!

The DR Panels must be mounted/dismounted only in the portrait (vertical) position. Mounting/dismounting the DR Panels in any position other than the portrait position could damage the DR Panels. If the Detector Mount is not in the portrait position, the top detector slot slides will not function normally.

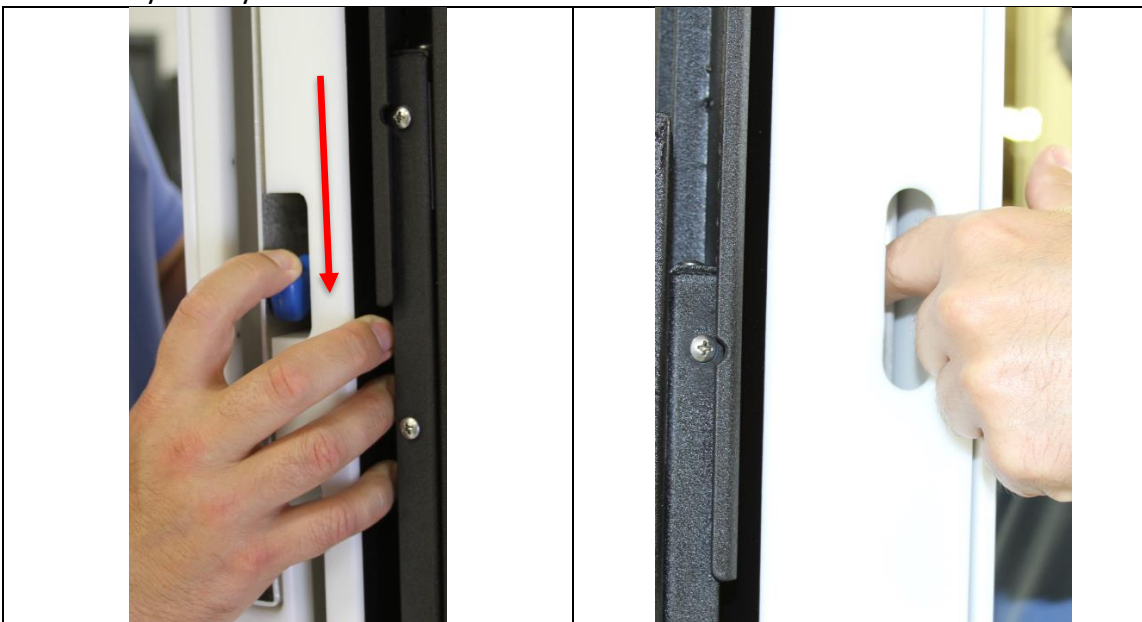
- 5.6. Mounting the DR Panels (two bottom slots) - Mount a Canon 710 DR Panel into the bottom two Detector Slots by pushing the DR Panels in all the way to the stop.



Mounting the DR Panels into the Bottom Detector Slots

Figure 5.6

5.7. Mounting the DR Panel (top slot) - To load the top Detector Slot, push down on the blue lever and use your fingers to push out the tray from the side opposite the Detector Slot. Grab the tray and draw it out fully until it locks. Carefully place the DR Panel into the tray so the bottom tabs of the tray are fully supporting the DR Panel. Push down on the blue lever to unlock it and slide the tray in fully until it locks.



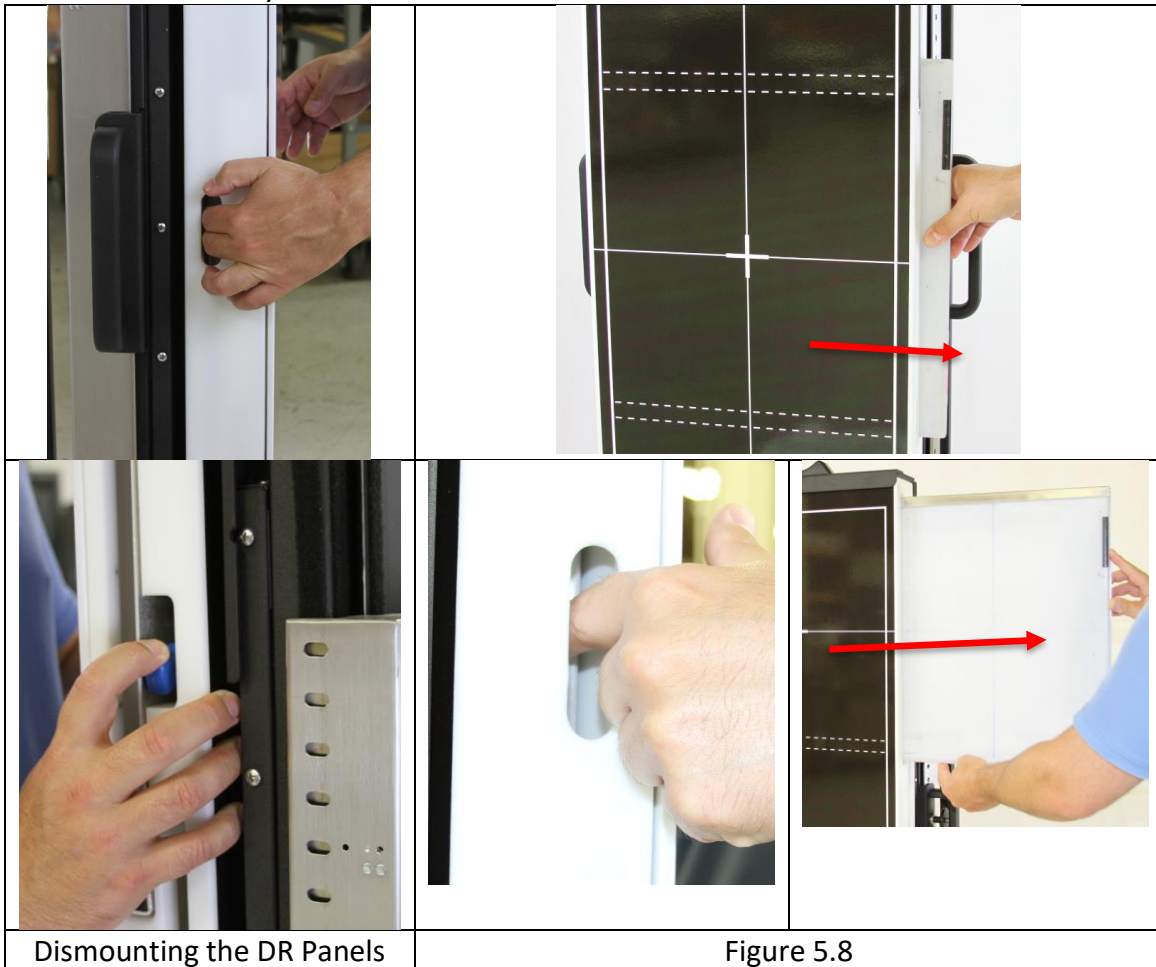


Mounting the DR Panel into the Top Detector Slot

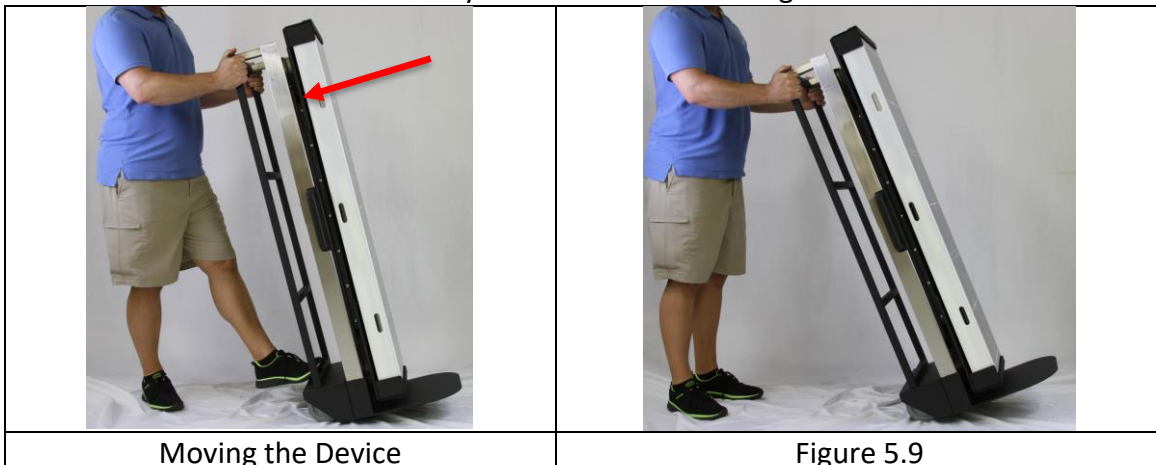
Figure 5.7

5.8. Dismounting the DR Panels - Dismount the bottom two Canon 710 DR Panels by sliding your fingers into the openings opposite the Detector Slots and pushing the DR Panels out slightly. The DR Panels will be partially ejected from the Detector Slots. Grab the center of the leading edge of the DR Panel and carefully draw straight out of the Detector Slot. To dismount the top DR Panel,

press down on the blue lever and use your fingers in the opening opposite the Detector Slot to push out the tray slightly. Draw the tray out fully until it locks and carefully dismount the DR Panel.



5.9. Moving the TM-7103 – Lower the Detector Mount to its lowermost position. Hold the frame from the rear near the top, place foot on bottom of frame and tilt the device back toward you. It will then be riding on the wheels.





CAUTION!

This device is designed to have articulating movement with a wide range of motion. There are no sensors, limit switches or physical stops to avoid collisions with walls, floors, objects in the room or people. The device itself or the Canon 710 DR Panels may be damaged by collisions. User or patient injury could occur if proper care is not taken while moving and positioning the device. Avoid pinching, squeezing, crushing or collision by moving the device slowly and carefully during operation.

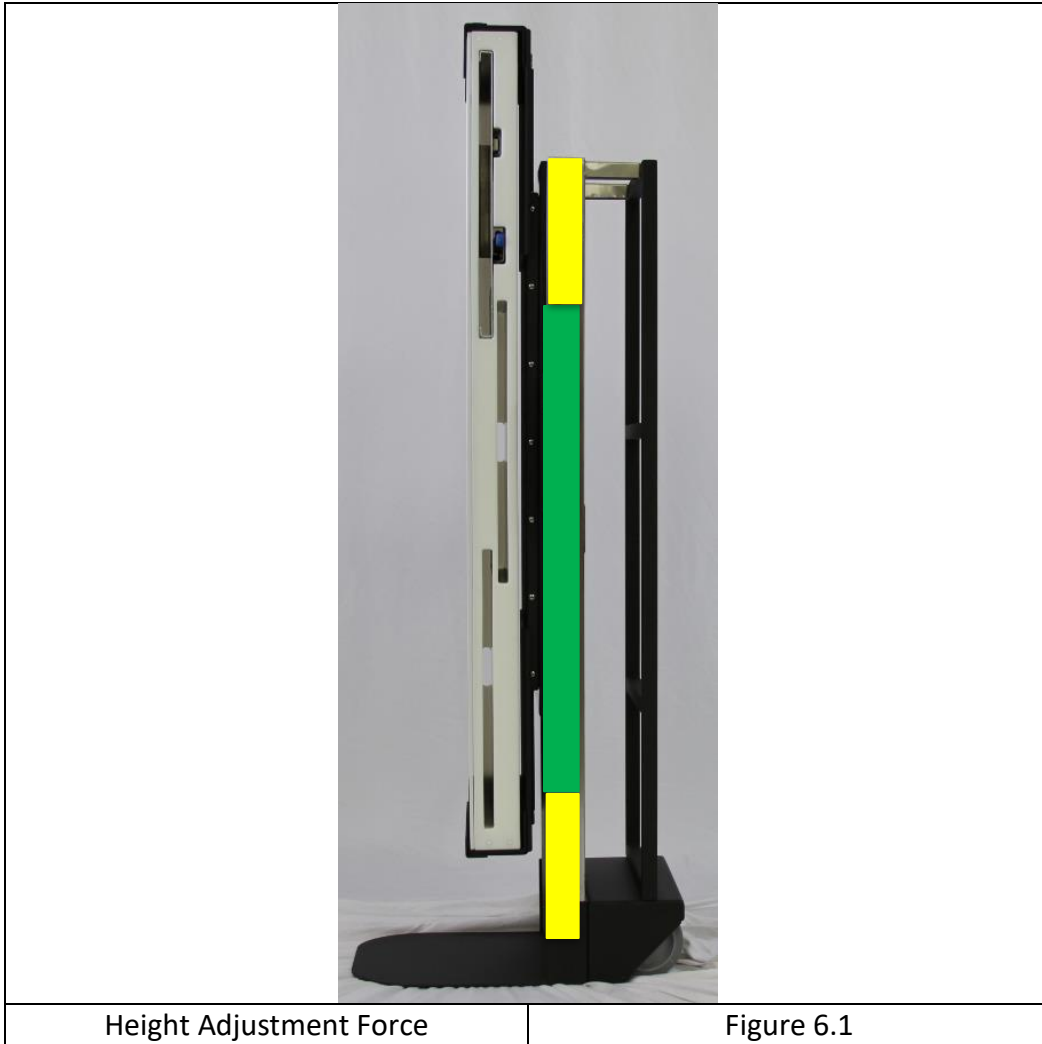


CAUTION!

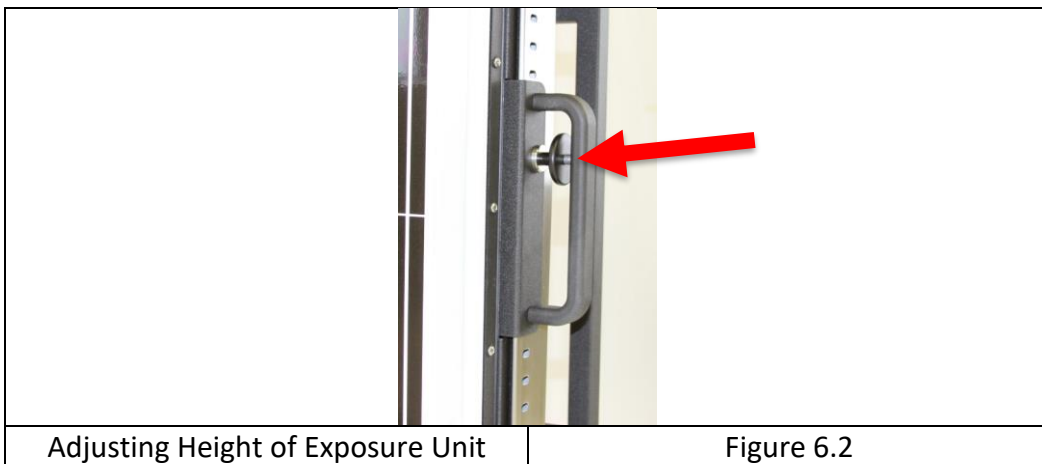
This is a mechanical device that relies upon coil springs and pulleys to control the height adjustment movements. The unit will move very easily near the center of its stroke. Extra effort is required to reach the uppermost and lowermost positions. To reach the uppermost position, use both handles to pull upward. To reach the lowermost position place your left hand on top of the Detector Mount and apply downward pressure.

6. User Operations: Height Adjustment and Rotation

- 6.1. Height Adjustment Force – The area marked in green has nearly zero-gravity balance. The areas marked in yellow require additional force to be applied by the user to achieve positions near the limits of vertical travel.



6.2. Exposure Unit Height Adjustment - To actuate the Detector Mount's lift-assist mechanism and raise or lower the height, pull the release pin in the right-side handle and raise or lower the Detector Mount.



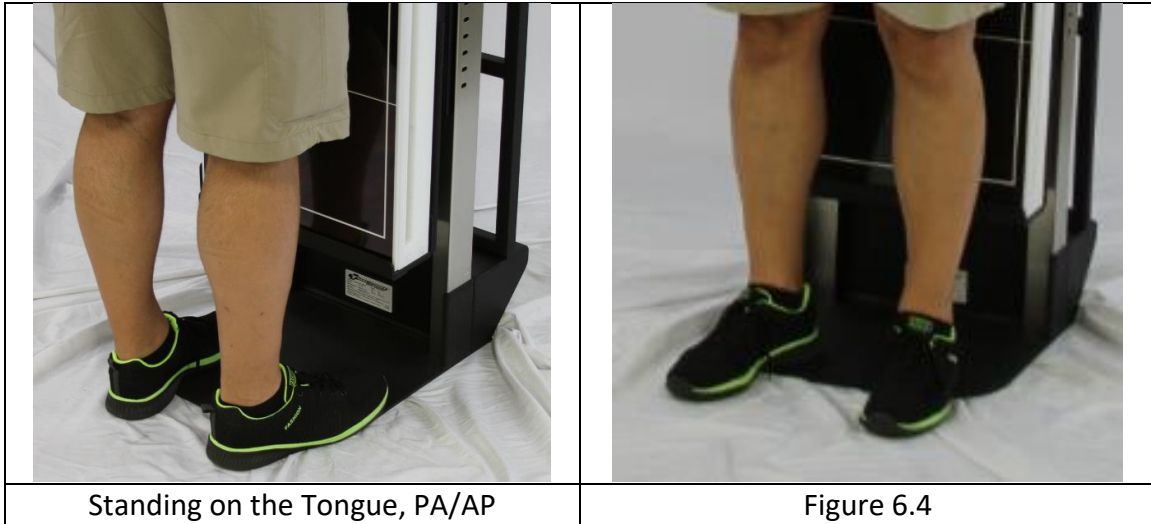
6.3. Exposure Unit Rotation - To turn the Exposure Unit from portrait to landscape orientation, rotate the Detector Mount anti-clockwise into the 90-degree detent taking care not to hit the floor or other objects. To turn back to portrait orientation, rotate the Detector Mount clockwise into the 0-degree detent.



CAUTION!

Always make sure the patient is standing on the tongue of the TM-7103 before performing a radiographic examination. If the patient is not standing on the tongue, the main body could move during the examination, potentially causing a patient to lose balance or fall, or create motion-induced blurring in the resultant image.

6.4. Patient Position – The patient should stand on the tongue of the TM-7103 to stabilize the device.



7. Maintenance & Cleaning

- 7.1. Maintenance - The unit does not require maintenance under normal operating conditions, although tightness of all fasteners should be routinely inspected and should be retightened if they become loose. If the unit is not performing as expected, contact Reina Imaging for assistance.
- 7.2. Cleaning - Surfaces can be cleaned using standard disinfection products. Do not submerge components. Do not autoclave components.

ALL QUESTIONS AND CONCERNS SHOULD BE FORWARDED TO:

REINA IMAGING
6107 W. LOU AVE., CRYSTAL LAKE, IL 60014
800-752-4918
www.reinaimaging.com

Changes to this document:

08.14.19	DRAFT	Released DRAFT version for Prototype
----------	-------	--------------------------------------