

Canon One Shot Mobile Positioning Partner Prototype

Installation Guide and User Instructions



Model: POSP7103-C 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	Included Ramp	7
	4.2	Removing Cardboard Container	8
	4.3	Lowering the Ramp	7
	4.4	Removing the Crossbar	9
	4.5	Removing the Plywood Brace	10
	4.6	Wheeling the POSP7103-C Prototype Down the Ramp	10-11
5		Installing the Exposure Unit	12
	5.1	Raising/Lowering the Horizontal Arm and Turning Detector Mount	12
	5.2	Mounting the Exposure Unit	12
	5.3	Mounting the Grid	13
	5.4	Securing the Exposure Unit and Grid	13
	5.5	Undertable Position and Horizontal Arm Extension	13-14
	5.6	Unlocking the Detector Slots	14
	5.7	Mounting the DR Panels and Locking the Detector Slots	14-15
	5.8	Dismounting the DR Panels	15
6		User Operations: Height Adjustment, Rotation, Extension and Tilt	15
	6.1	Height Adjustment of Nested Column	15-16
	6.2	Height Adjustment of Horizontal Arm	16
	6.3	Extending and Retracting the Horizontal Arm	16-17
	6.4	Exposure Unit Rotation	17
	6.5	Exposure Unit Tilting	17
	6.6	Patient Handle Operation	18
	6.7	Locking and Unlocking the Wheels	18-19
7		Product Maintenance	19
	7.1	Maintenance	19
	7.2	Cleaning	19
8		Changes to This Document	20

i. Intended Use

The Compact Mobile Canon One Shot Positioning Partner (Model# POSP7103-C 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 nested column height prior to installation of the exposure unit onto the detector mount.
- Failure to adhere to the Precautions listed herein may result in injury to user or patient!

Compliance

The **POSP7103-C 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 **POSP7103-C 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 Compact Mobile Canon One Shot Positioning Partner. Using the Compact Mobile Canon One Shot Positioning Partner 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 Compact Mobile Canon One Shot Positioning Partner. Use of the Compact Mobile Canon One Shot Positioning Partner 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.

	The Caution Symbol
---	--------------------


- *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.

	The Warning Symbol
---	--------------------

- **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 Compact Mobile Canon One Shot Positioning Partner 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 two-tiered nested column with lift-assist, a telescopic horizontal support arm and a rotating/tilting detector mount.

2.2. Product Specifications

Weight	170lbs/77kg
Dimensions	30"x23.25"x40" / (76.2cmx59cmx101.6cm)
Total Vertical Stroke	44" / 111.75cm
Pneumatic Piston Vertical Stroke	19" / 48.25cm
Horizontal Arm Vertical Stroke	25" / 63.5cm
Horizontal Stroke (Telescoping Arm)	6" / 15.25cm
Max. Height Active Imaging Area - Portrait	83" / 210.75cm
Min. Height Active Imaging Area - Portrait	3" / 7.5cm
Max. Height Active Imaging Area - Landscape	67" / 170cm
Min. Height Active Imaging Area - Landscape	6.25" / 16cm
Min. Height Active Imaging Area - Undertable	22" / 55.8cm

3. Required Tools and Equipment

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



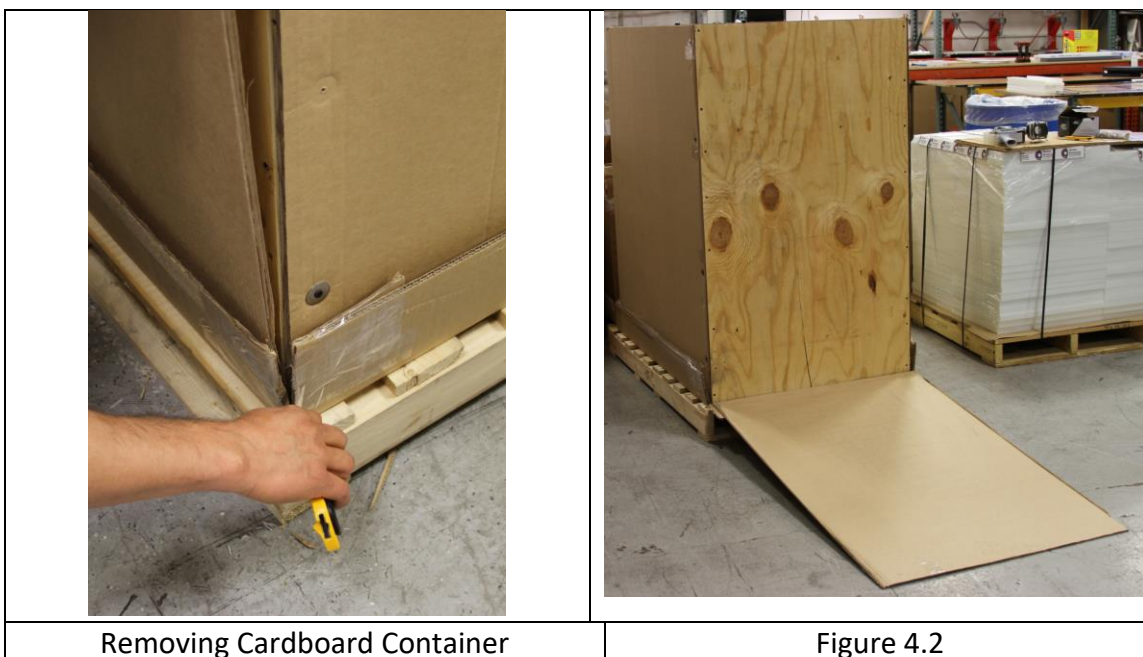
CAUTION!

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

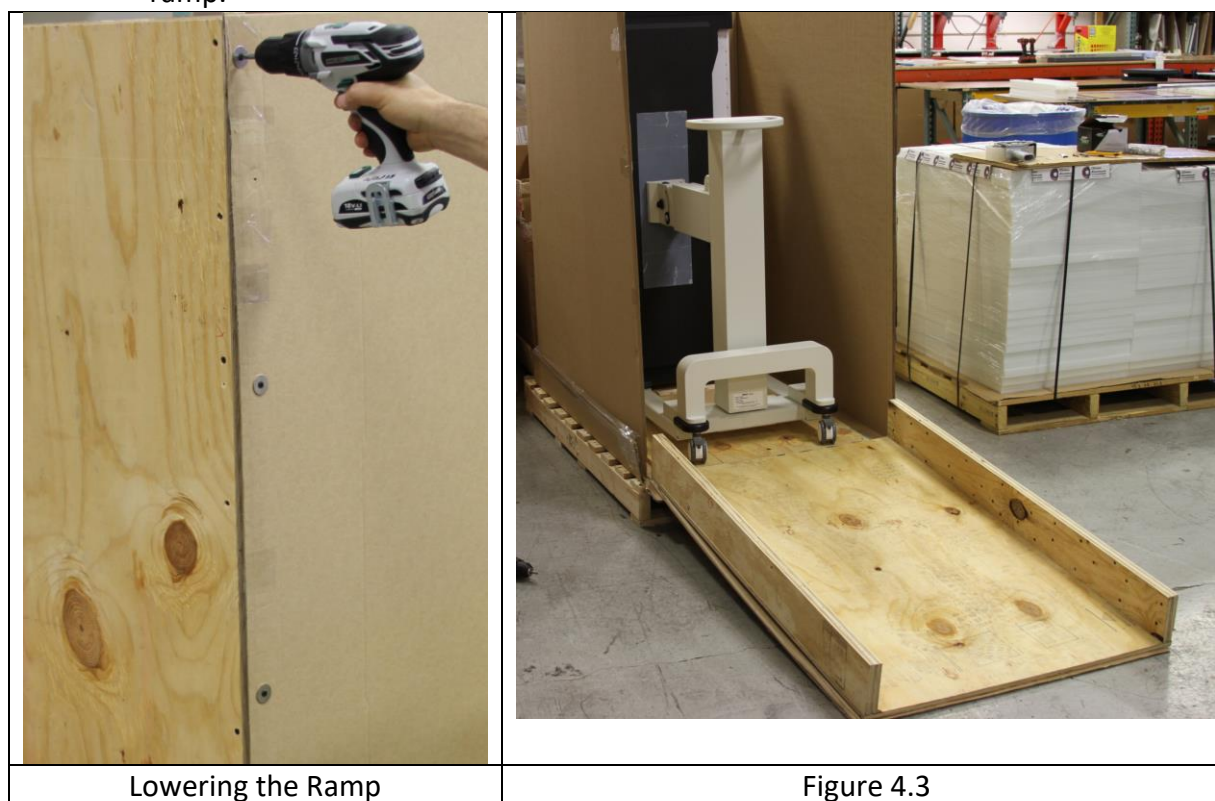
4. Uncrating the Device

- 4.1. The device comes fully assembled and can be wheeled off the pallet by means of the included ramp.
- 4.2. Cut the packing tape connecting the lid and box as well as the two edges where the screws are located and remove the box top. Allow the now cut side of the box to lower to the floor.





4.3. Remove the four screws from each side of the container and carefully lower the ramp.



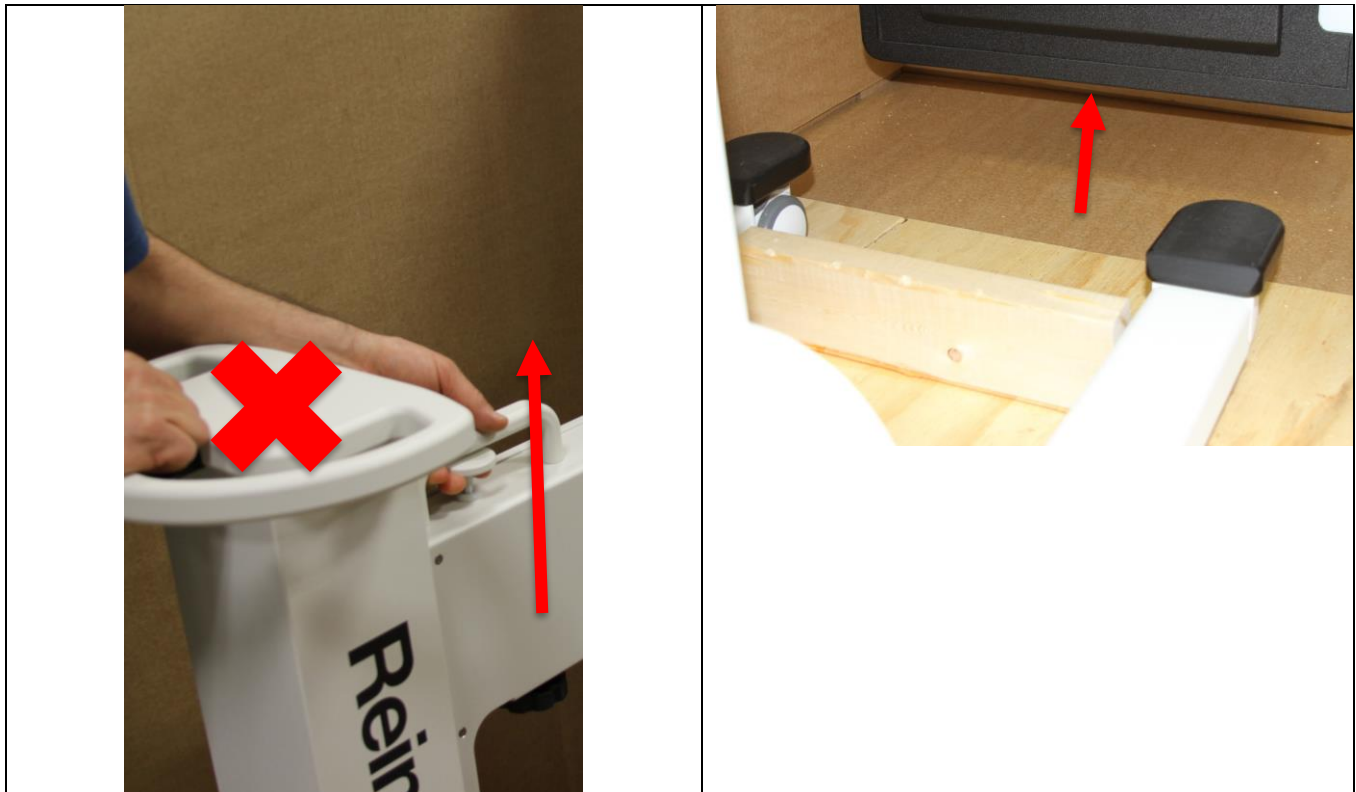
- 4.4. Remove the crossbar from the top of the Horizontal Arm by removing the two retaining screws from each side of the container.



4.5. Remove the plywood brace from the top of the Wheeled Base.



4.6. Raise the Horizontal Arm and Detector Mount high enough to clear the bottom bracing (see figure 6.1 and 6.2 and Warning before Section 5), unlock the wheels and carefully wheel the POSP7103-C Prototype off the pallet and down the ramp taking care to control momentum by holding the top handle. *Do not actuate the Two-Tiered Nested Column release!*





Wheel the POSP7103-C Prototype Down the Ramp

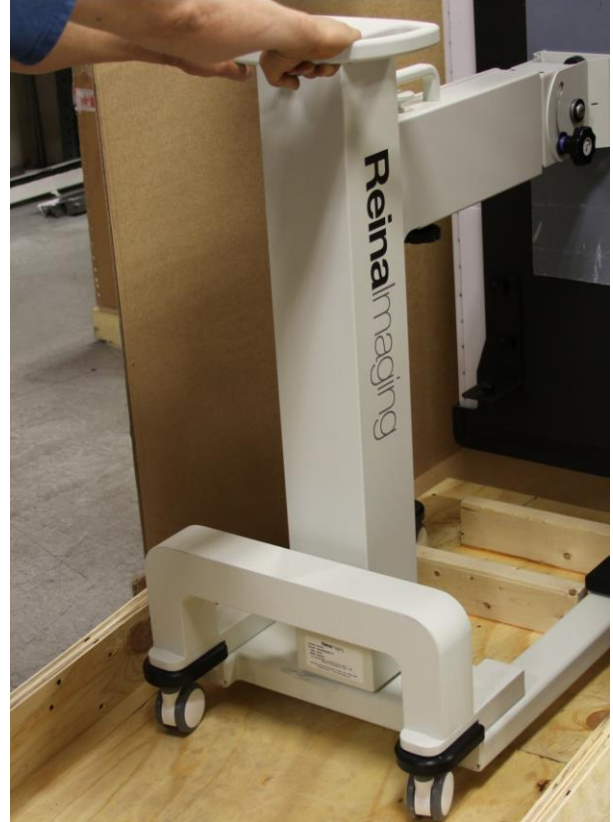


Figure 4.6

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 installation of the Exposure Unit and three DR Panels.
- Failure to adhere to the Precautions listed above may result in injury to user!



WARNING!

The two-tiered nested column's lift-assist mechanism employs a forceful pneumatic piston. Attempting to adjust the height of the nested column before installing the Exposure Unit and three Canon 710 DR Panels could cause the top of the nested column 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 pneumatic piston without the Exposure Unit and three Canon 710 DR Panels. Keep head and torso away from the unit during adjustment for uncrating.

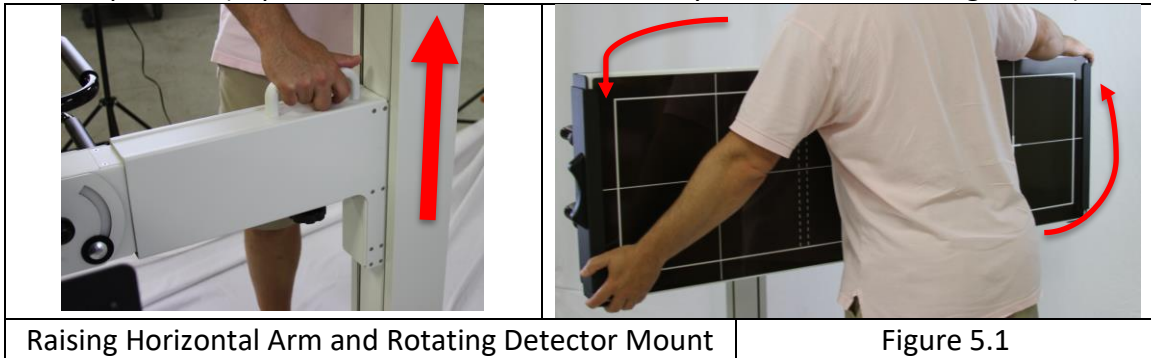


CAUTION!

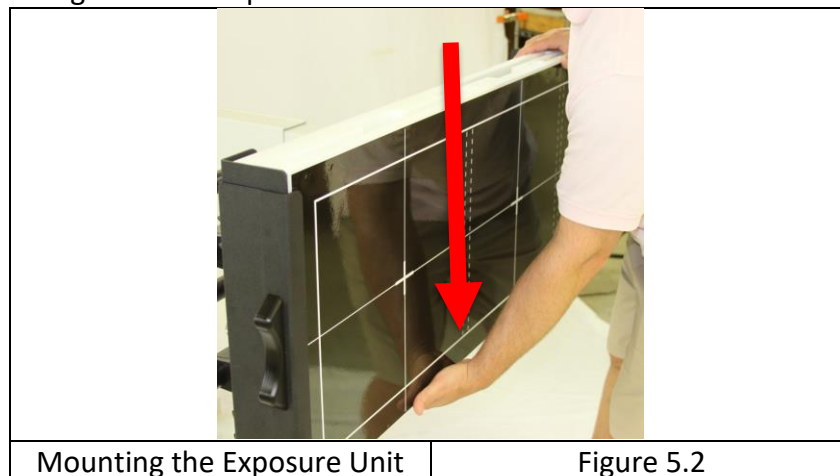
Before rotating the Detector Mount to the landscape orientation to install the Exposure Unit and Grid, raise the Horizontal Support Arm to its uppermost position or the Detector Mount can hit the floor when rotated. See Section 6 for full explanation of controls before performing these operations.

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

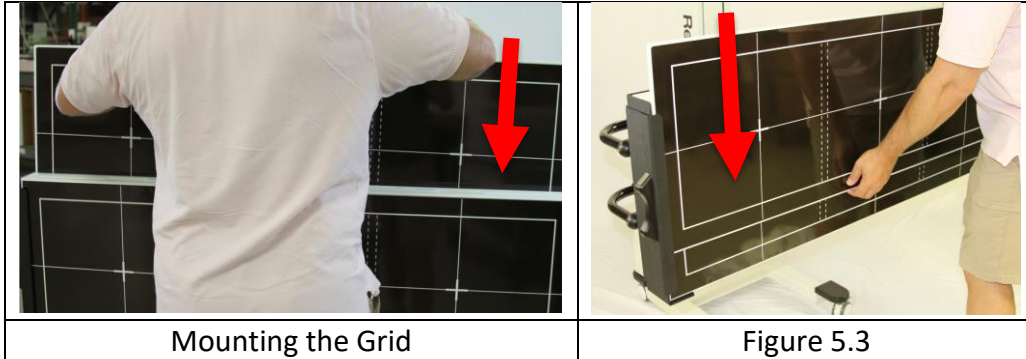
- 5.1. Landscape Position - Lock the wheels and raise the Horizontal Arm to its uppermost position by pulling up on the lever and pulling upward on the handlebar. Rotate the Detector Mount anti-clockwise into the landscape position (Exposure Unit will not be mounted yet but is shown in Figure 5.1).



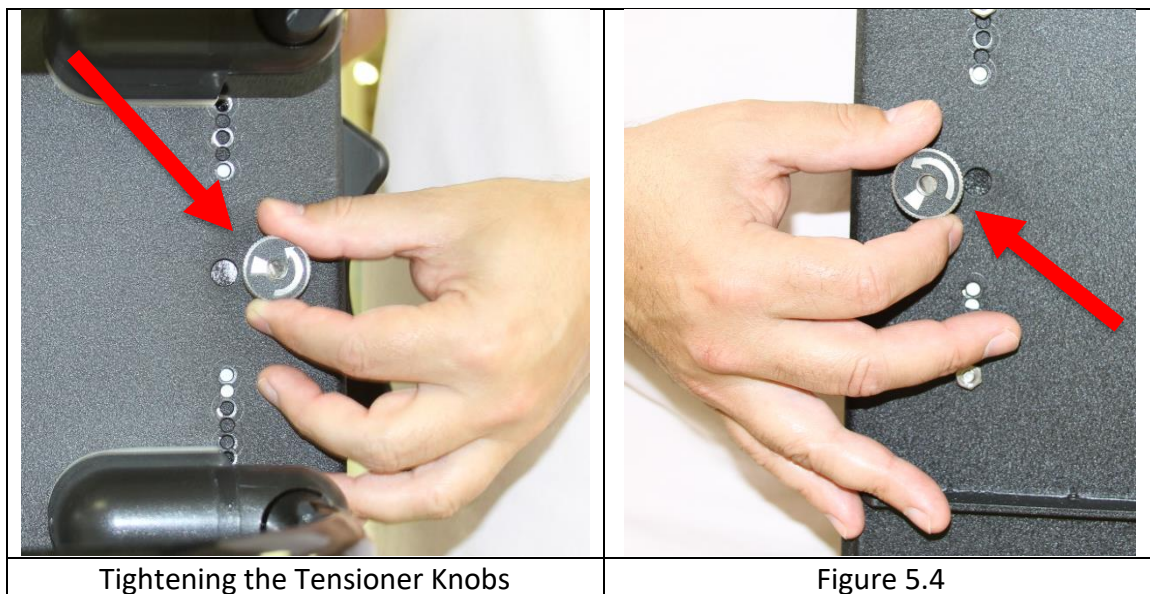
- 5.2. Installing the Exposure Unit – Make sure the tensioner knobs are fully loosened by turning them *clockwise* until they stop (see Figure 5.4 for reference). Install the Exposure Unit into the Detector Mount by sliding it between the support guides in the landscape orientation and carefully lowering it until it is fully seated against the stops.



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

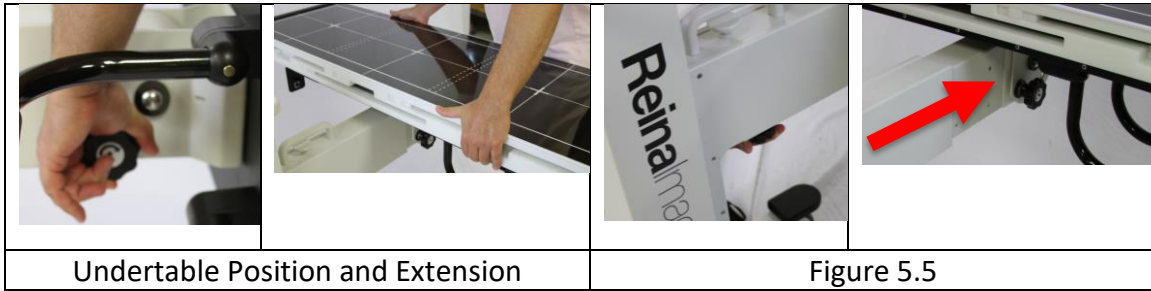


- 5.4. Securing the Exposure Unit and Grid - Tighten the two tensioner knobs on the rear of the detector mount by turning them *anti-clockwise* until tight. The Anti-scatter Grid can be mounted in front of the Exposure Unit for clinical use or stored behind it when not in use. To maintain proper performance tuning, all units delivered without an Anti-scatter Grid will have a mock-up grid. **Do not discard the mock-up grid until a live Anti-scatter Grid is installed. It must be mounted behind the detector to maintain balance (Serial# 180821000068635 and later – See Engineering Change Notice ECN-2018-0003).**

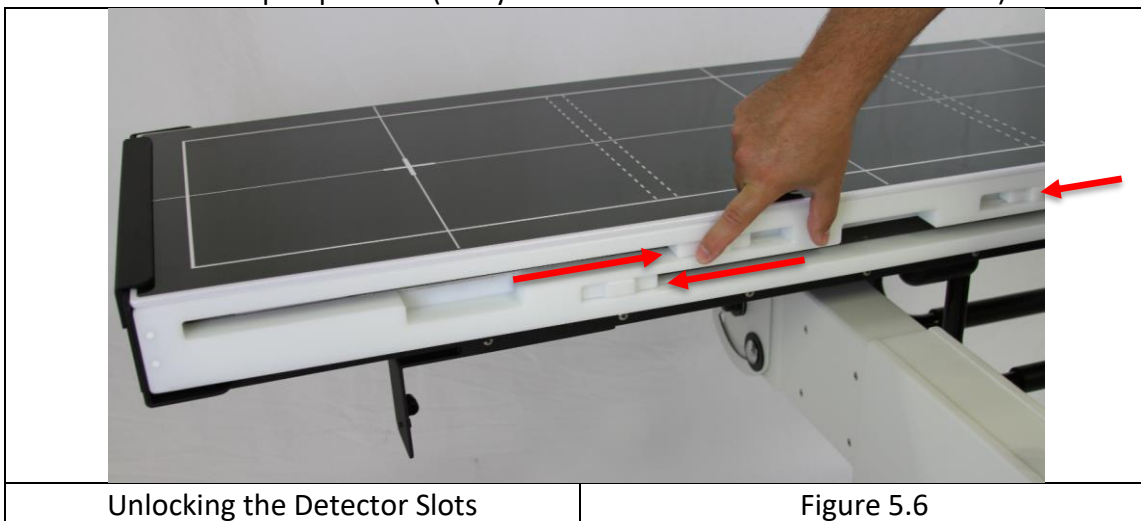


- 5.5. Undertable Position and Extension - To install the three Canon 710 DR Panels, place the Exposure Unit into the undertable position by loosening the locking nut at the end of the Horizontal Arm and tilting the Exposure Unit back until it

rests on the rubber stop. Tighten the locking nut. Loosen the locking nut under the Horizontal Arm and extend the arm fully. Tighten the locking nut.



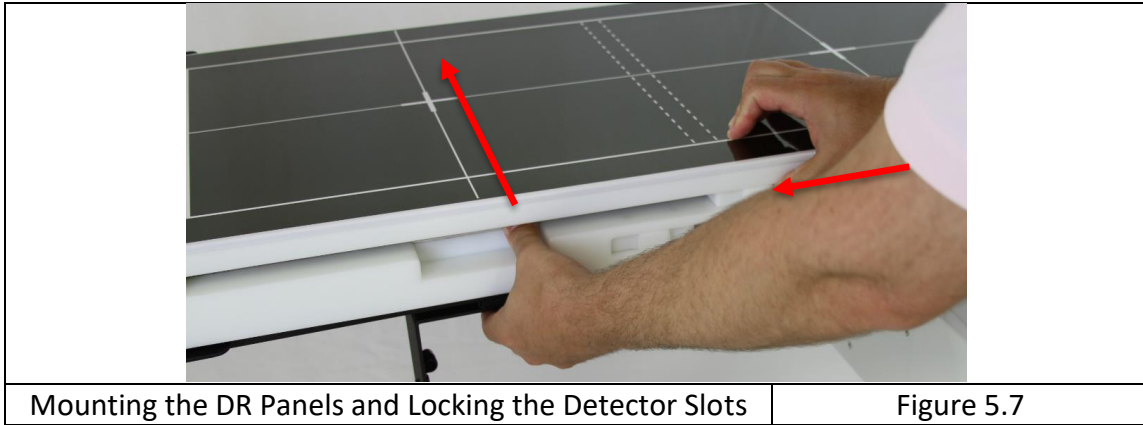
5.6. Unlocking the Detector Slots - Unlock each Detector Slot by sliding the locking tab to the open position (away from the center of the Detector Slots).



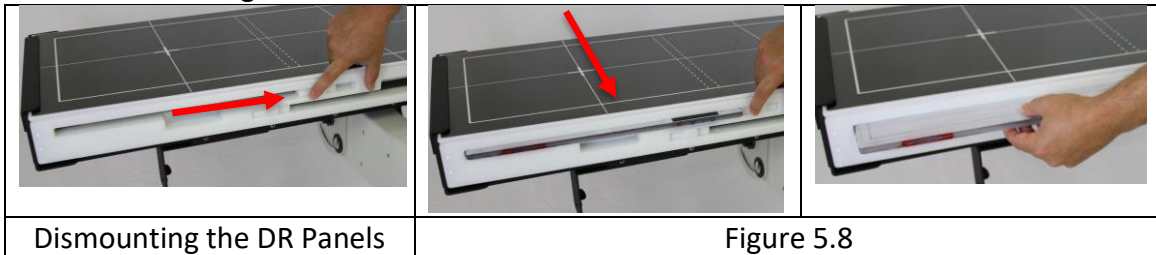
CAUTION!

The DR Panels must be mounted/dismounted only in the undertable position or they could get lodged into the Detector Slots at an angle and be difficult to remove. Mounting/dismounting the DR Panels in any position other than the undertable position with the Horizontal Arm extended could damage the DR Panels. If the Horizontal Arm is not extended, the main body hardware will interfere with center DR Panel's movement.

5.7. Mounting the DR Panels and Locking the Detector Slots - Mount a Canon 710 DR Panel into each Detector Slot by pushing the DR Panel in against the spring ejector. Make sure the DR Panel goes in straight by pushing against the middle of the panel edge and then slide the locking tab into the locked position (toward the center of the Detector Slot) when the DR Panel is fully seated.



5.8. Dismounting the DR Panels - Dismount the Canon 710 DR Panels by sliding the locking tab to the open position. The DR Panel will be partially ejected from the Detector Slot. Grab the center of the leading edge of the DR Panel and carefully draw straight out of the Detector Slot.

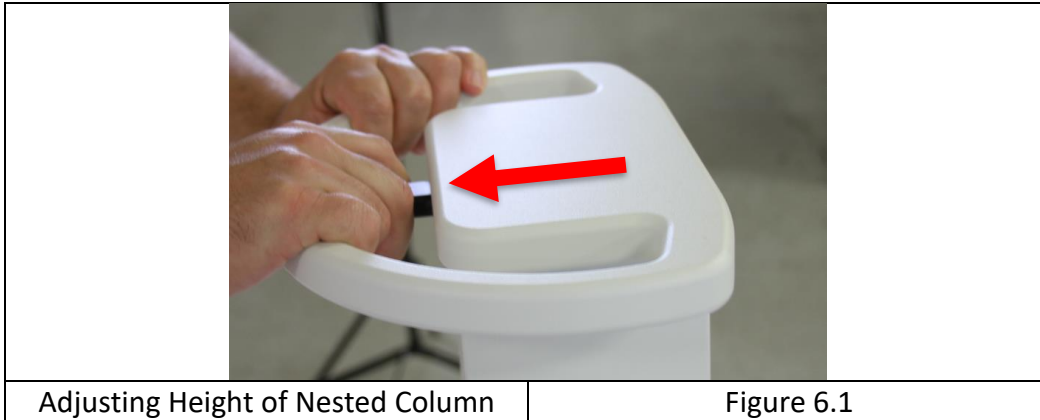


CAUTION!

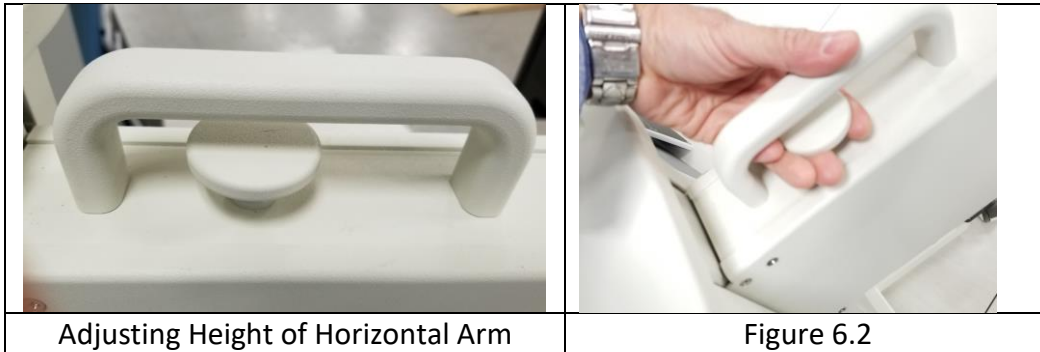
This device is designed to have articulating movement with a wide range of motion. There are no sensors, limit switches or physical stops to avoid collisions with walls, floors, objects in the room or people. The device itself or the Canon 710 DR Panels may be damaged by collisions. User or patient injury 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.

6. User Operations: Height Adjustment, Rotation, Extension and Tilt

6.1. Height Adjustment of Nested Column - To actuate the nested column's lift-assist mechanism and raise or lower the column height, pull the lever at the top of the rear side of the nested column.



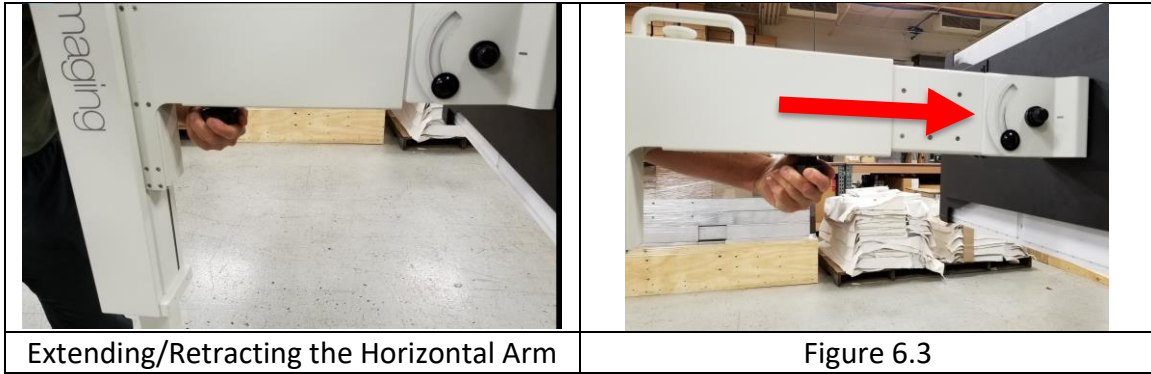
6.2. Height Adjustment of Horizontal Arm - To raise or lower the telescopic support arm, pull the lever on top of the telescoping support arm.



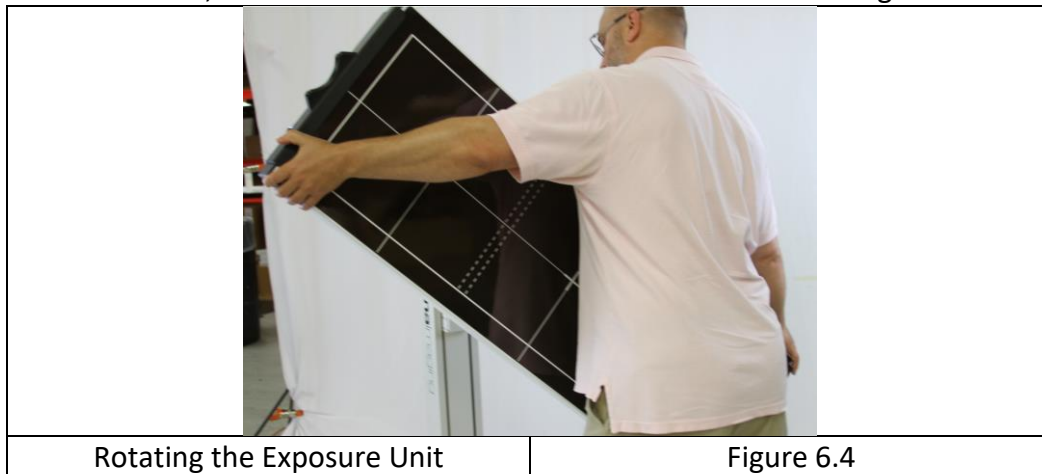
CAUTION!

During an upright radiographic examination, the Horizontal Arm should be fully retracted to keep the main body's center of gravity as far to the rear of the device as possible. Using the POSP7103-C with the Horizontal Arm extended during an upright radiographic examination could cause the device to become unstable if a patient pulls downward on the Patient Handles.

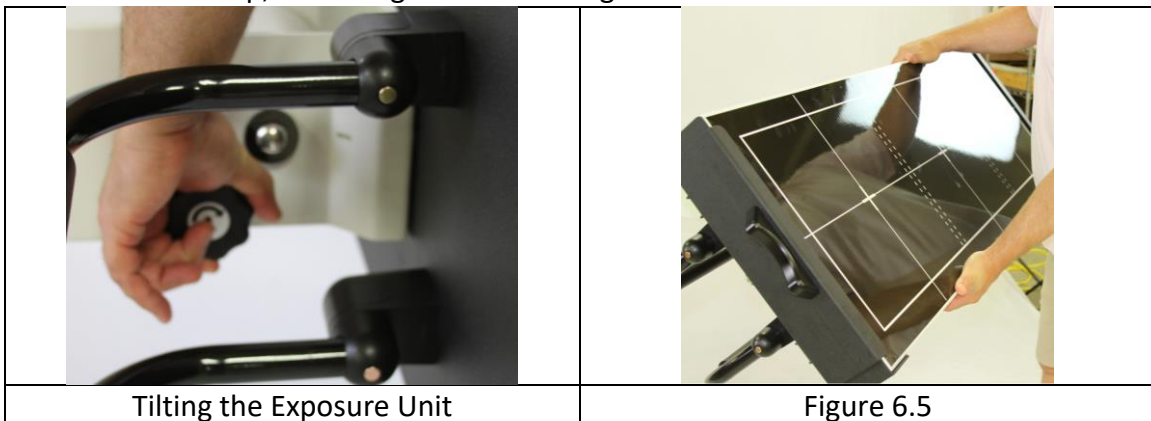
6.3. Extend and Retract the Horizontal Arm – To extend/retract the telescopic Horizontal Arm, loosen the locking nut and draw out/push in the extensible Horizontal Arm and retighten the locking nut.



6.4. 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.



6.5. Exposure Unit Tilting - To move the Exposure Unit into the undertable position, loosen the locking nut at the end of the Horizontal Arm and tilt the Detector Mount backwards toward the column until it rests on the rubber stop, taking care to support the Exposure Unit with two hands and not to let it fall onto the rubber stop, then retighten the locking nut.

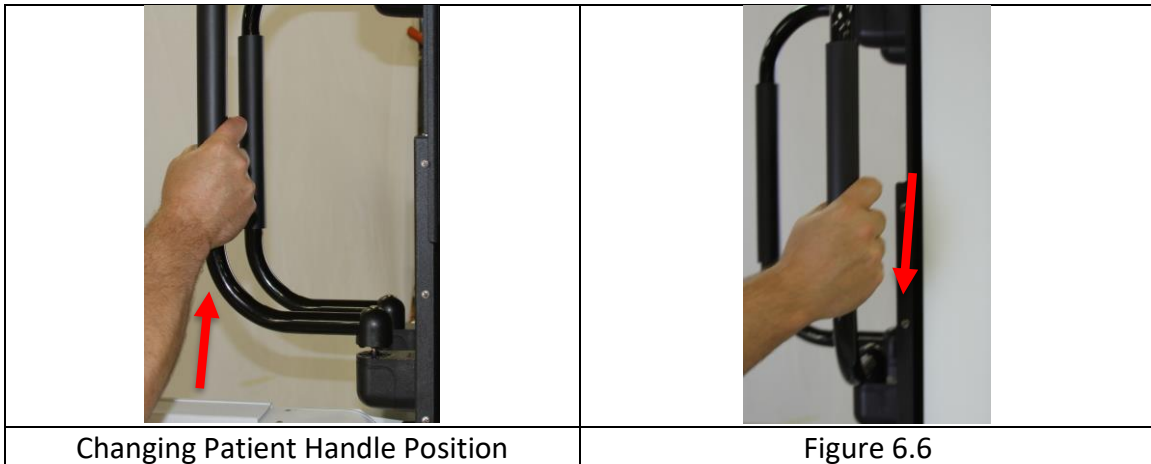




WARNING!

The Patient Handles are intended only as a positioning aid and to help steady the patient for a short hold time during the exposure. The Patient Handles should never be used as a weight-bearing support for a patient. Any patient not capable of standing freely for an exam should not be imaged upright on the POSP7103-C (for these cases a radiolucent table should be used with the POSP7103-C under it). Using the Patient Handles as weight-bearing support bars could topple the device onto the patient causing equipment damage and injury!

6.6. Patient Handle Operation – To bring the Patient Handles forward, lift upward to unlock, rotate into position and let down to lock in place. Patient Handles may be used in either position depending on the examination type and patient comfort.



CAUTION!

Always lock the wheels on the POSP7103-C before performing a radiographic examination. If the wheels are not locked, 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.

6.7. Locking and Unlocking the Wheels – Lock the wheels by pushing down on the locking mechanism. Unlock the wheels by pulling up on the locking mechanism.



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
----------	-------	--------------------------------------