

TM-GL Mobile Trans-Former

Installation Guide and User Instructions



Model: TM-GL

Revision: December 2019

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i. Intended Use

The TM-GL Mobile Trans-Former (Model# TM-GL) is designed to hold and position the D-EVO GL Long-Length DR Panel 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-GL Mobile Trans-Former** 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-GL Mobile Trans-Former** 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-GL Mobile Trans-Former. Using the TM-GL 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-GL Mobile Trans-Former. Use of the TM-GL 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.

	The Caution Symbol
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- *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
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- **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
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- 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-GL Mobile Trans-Former is designed to hold and position the D-EVO GL Long-Length DR Panel and an Anti-Scatter Grid 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 (with D-EVO GL Panel and Grid mounted)	155 pounds
Dimensions (lowest portrait position)	55H x 24W x 22D inches
Total Vertical Stroke	22 inches
Max. Height Active Imaging Area - Portrait	73.5 inches
Min. Height Active Imaging Area - Portrait	2.5 inches
Max. Height Active Imaging Area - Landscape	58 inches
Min. Height Active Imaging Area - Landscape	9.75 inches

3. Required Tools and Equipment

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

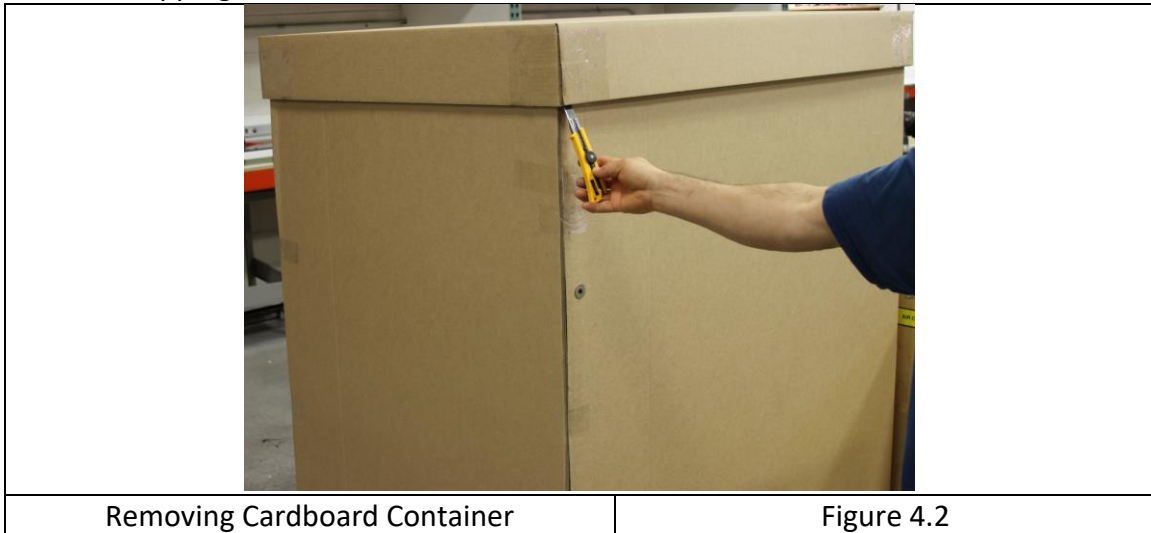


CAUTION!

The device is 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.



Installation Precautions:

- The unit is pre-assembled but take care in uncrating, as the device is 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 D-EVO GL Panel.
- 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 D-EVO GL Panel and the anti-scatter grid 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.



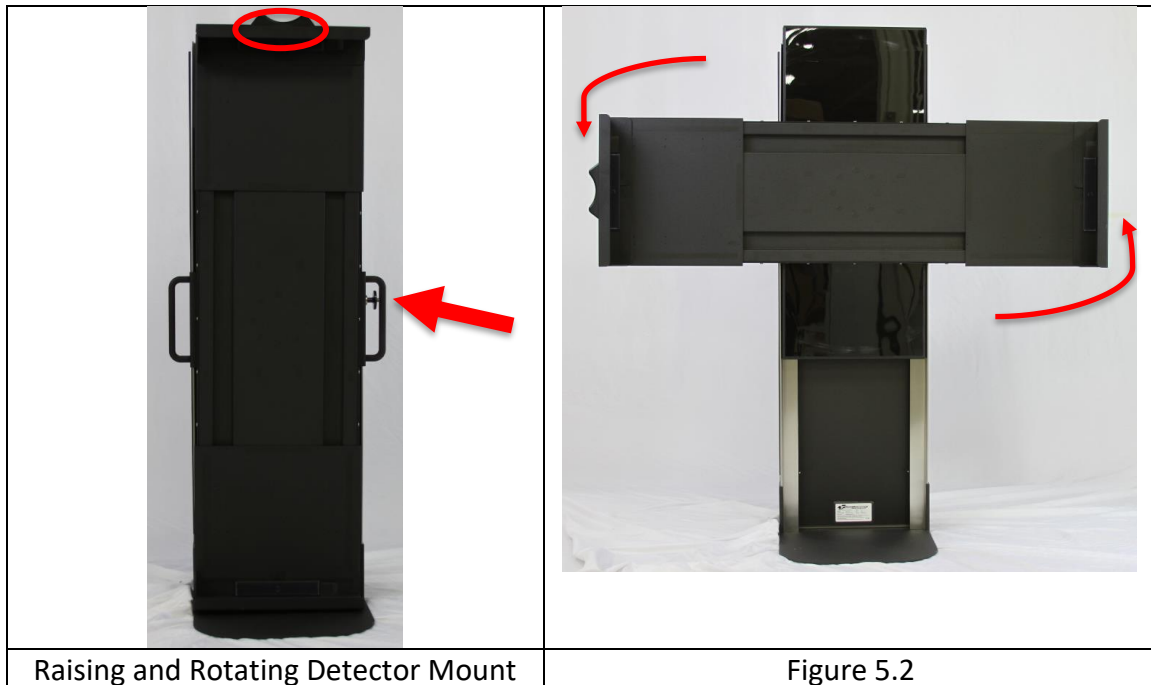
CAUTION!

Before rotating the Detector Mount to the landscape orientation to install the D-EVO GL Panel 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.

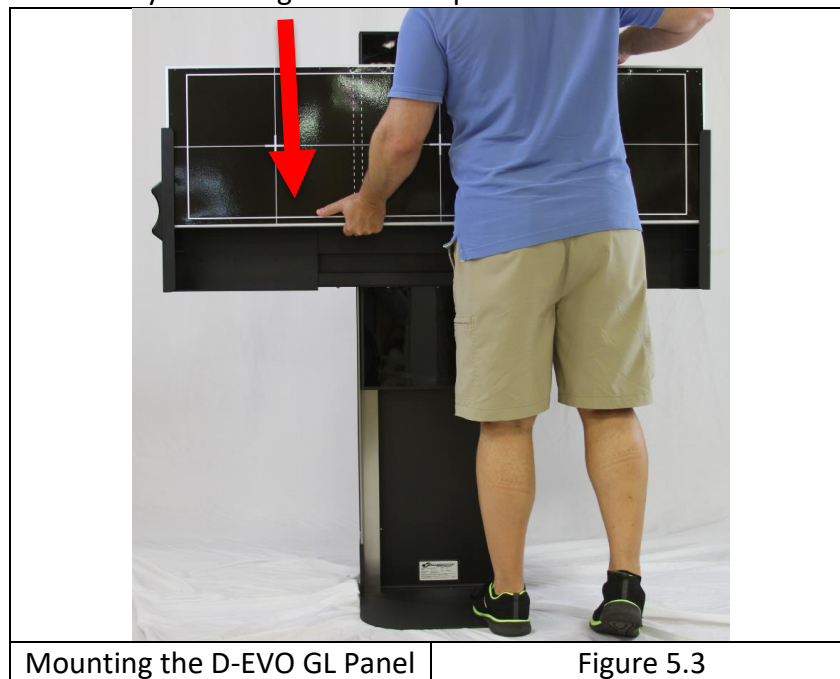
NOTE: Some images in this manual do not reflect the D-EVO GL Long-Length DR Panel product, however, the work instructions are the same.

5. Installation of D-EVO GL Panel and Grid onto the Detector Mount

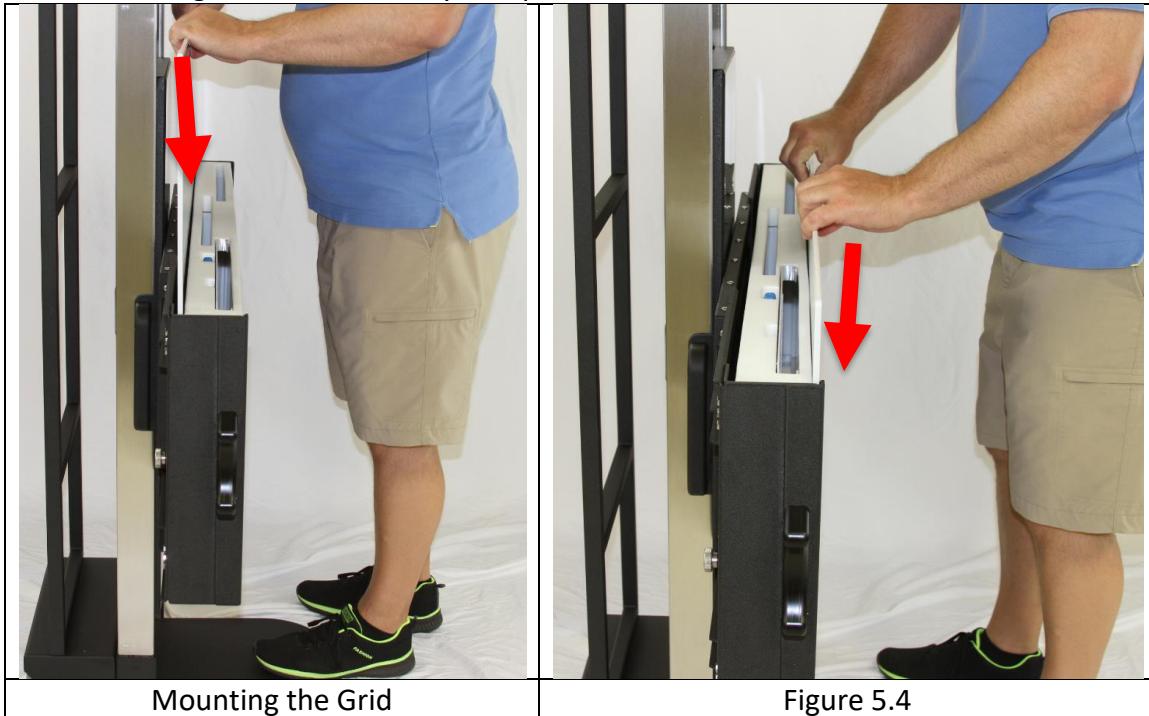
- 5.1. Remove Safety Screw and Raise Detector Mount – Remove the red safety screw from the right side support rail. Raise the Detector Mount about halfway by placing your left hand on the top center of the detector mount (red oval, Figure 5.2) and maintaining control of the lift-assist force by applying 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.



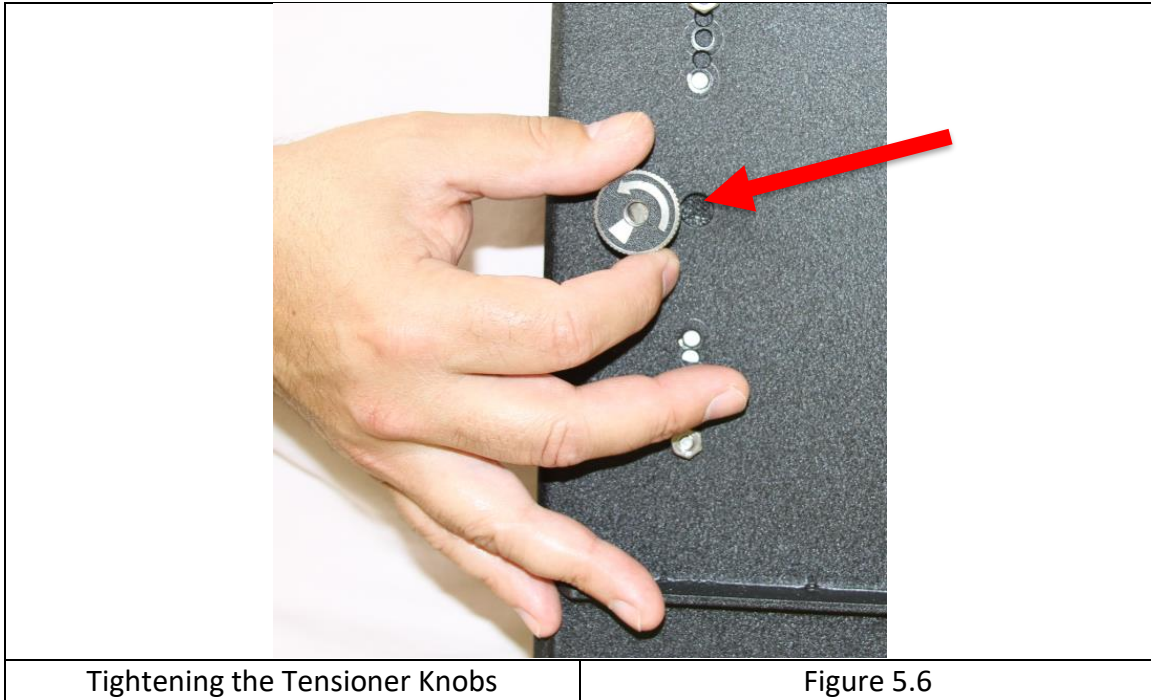
5.3. Installing the D-EVO GL Panel – Make sure the tensioner knobs are fully loosened by turning them *clockwise* until they stop (see Figure 5.6 for reference). Install the D-EVO GL Panel into the Detector Mount by sliding it between the support guides in the landscape orientation and carefully lowering it until it is fully seated against the stops.



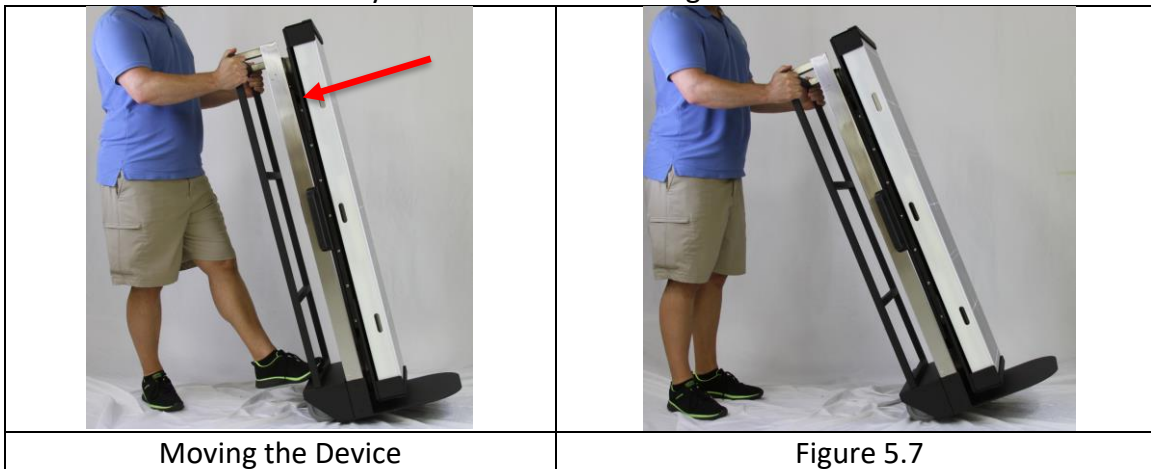
- 5.4. Installing the Grid - Install the Grid in either the storage position (behind the D-EVO GL Panel – left image) or in the clinical use position (in front of the D-EVO GL Panel – right image) by sliding it into the Detector Mount, taking care to keep it straight so it slides easily into position.



- 5.5. Mock-up Grid – If the TM-GL is ordered without an Anti-scatter Grid, it will ship with a mock-up grid that simulates the weight and dimensions of the Anti-scatter Grid. The TM-GL is a mechanical device that requires a constant load in the Detector Mount to maintain a “zero gravity” feel for the user. The mock-up grid must be installed into the Detector Mount behind the D-EVO GL Panel. If at any time the end user requires a Grid for clinical use, the mock-up grid may be discarded and replaced with a live anti-scatter Grid and proper counterbalance will be maintained.
- 5.6. Securing the D-EVO GL Panel 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 D-EVO GL Panel 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 the D-EVO GL Panel.



5.7. Moving the TM-GL – 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 D-EVO GL Panel 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!

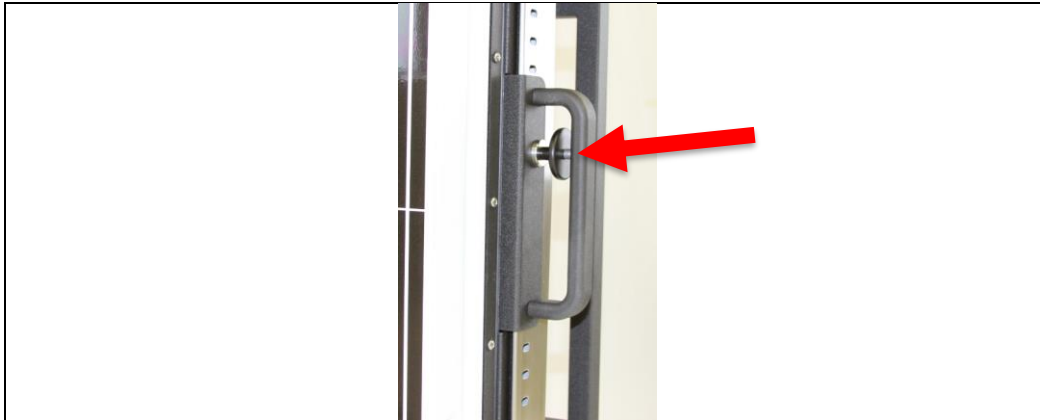
This is a mechanical device that relies upon coil springs and pulleys to control the height adjustment movements. The unit will move very easily near the center of its stroke. Extra effort is required to reach the uppermost and lowermost positions. To reach the uppermost position, use both handles to 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. D-EVO GL Panel 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.



Adjusting Height of D-EVO GL Panel

Figure 6.2

- 6.3. D-EVO GL Panel Rotation - To turn the D-EVO GL Panel 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.



Rotating the D-EVO GL Panel

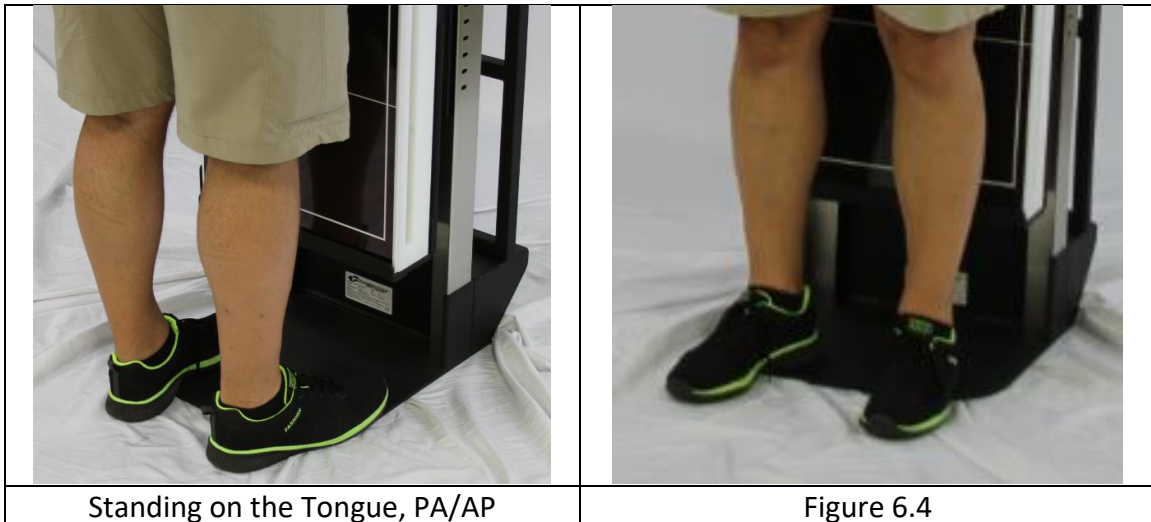
Figure 6.3



CAUTION!

Always make sure the patient is standing on the tongue of the TM-GL 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-GL 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:

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Changes to this document:

09.30.19	DRAFT	Released DRAFT version
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