T-CO-DRXL Installation and User Guide

MAN-0015-D

RELEASED 07.22.2020

T-CO-DRXL Wall-Mounted Trans-Former

Installation and User Guide



Model: T-CO-DRXL

Revision: July 2020

Table of Contents

| i | | Intended Use | 3 | | |
|-----|-----|---|-------|--|--|
| ii | | Safety and Compliance | | | |
| iii | | Warranty | | | |
| 1 | | About This Manual | | | |
| | 1.1 | Disclaimer | | | |
| | 1.2 | Additional Information Concerning Risks | 5-6 | | |
| | 1.3 | Changes to This Manual | | | |
| 2 | | Product Description and Specifications | | | |
| | 2.1 | Product Description | | | |
| | 2.2 | Product Specifications | 6 | | |
| 3 | | Site Preparation and Equipment Placement | | | |
| | 3.1 | Site Preparation | | | |
| | 3.2 | Structural Reinforcement | 7 | | |
| | 3.3 | Device Placement Technical Safety Factors | 8-9 | | |
| 4 | | Required Tools and Equipment | | | |
| | 4.1 | Uncrating | 9 | | |
| | 4.2 | Assembly | 9 | | |
| | 4.3 | Mounting the Trans-Former Frame | 9 | | |
| 5 | | Uncrating the Device | 10 | | |
| | 5.1 | Uncrating – Two People to Remove from Box | 10 | | |
| | 5.2 | Removing Cardboard Container | 10 | | |
| | | Installation Precautions | 10 | | |
| 6 | | Installation of Wall-Mounted Trans-Former Frame | 11-12 | | |
| 7 | | Installing the Long-Length DR Panel and Grid | 12-14 | | |
| | 7.1 | Factory Set Position of Detector Mount | 12 | | |
| | 7.2 | Mounting the Long-Length DR Panel | 12-13 | | |
| | 7.3 | Mounting the Grid | 13 | | |
| | 7.4 | Securing the Long-Length DR Panel and Grid | 14 | | |
| | 7.5 | Removing the Red Safety Screw | 14 | | |
| 8 | | User Operations: Height Adjustment and Rotation | 15-16 | | |
| | 8.1 | Height Adjustment – Force Required | 15 | | |
| | 8.2 | Height Adjustment of Long-Length DR Panel | 16 | | |
| | 8.3 | Long-Length DR Panel Rotation | 16 | | |
| 9 | | Product Maintenance | 17 | | |
| | 8.1 | Maintenance | 17 | | |
| | 8.2 | Cleaning | 17 | | |
| 10 | | Changes to This Document | | | |

i. Intended Use

The T-CO-DRXL Wall-Mounted Trans-Former (Model# T-CO-DRXL) is designed to hold and position the Long-Length DR Panel and Anti-scatter Grid for use in general radiography. There are no contraindications for use of this device.

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 **T-CO-DRXL Wall-Mounted 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 T-CO-DRXL Wall-Mounted 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

Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com

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).

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

1. About This Manual

- 1.1. Disclaimer This manual was written to provide proper guidelines for using the T-CO-DRXL Wall-Mounted Trans-Former. Using the T-CO-DRXL Wall-Mounted 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 T-CO-DRXL Wall-Mounted Trans-Former. Use of the T-CO-DRXL Wall-Mounted 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

 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.

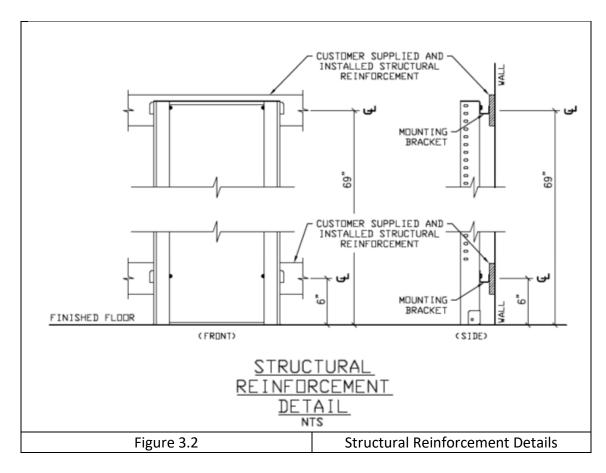
2. Product Description and Specifications

- 2.1. Product Description The T-CO-DRXL Wall-Mounted Trans-Former is designed to hold and position the Long-Length DR Panel and an Anti-Scatter Grid for use in general radiography. It is Wall-Mounted and features a lift-assist mechanism and a rotating detector mount.
- 2.2. Product Specifications (for 70" Trans-Former frame, also available in 60" and 50")

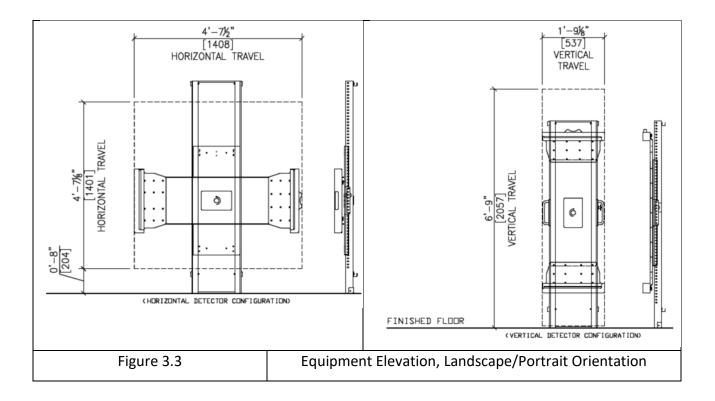
| Weight (without Long-Length DR Panel and Grid mounted) | 66lbs/30kg |
|--|--|
| Dimensions (lowest portrait position) | 70"H x 23.5"W x 7.5"D 178cm x 60cm x 19cm |
| Total Vertical Stroke | 20"/51cm |
| Max. Height Active Imaging Area – Portrait | 76"/193cm |
| Min. Height Active Imaging Area – Portrait | 2.5"/6.35cm |
| Max. Height Active Imaging Area - Landscape | 59.25"/150.5cm |
| Min. Height Active Imaging Area - Landscape | 12.75"/32.5cm |
| Environmental Operating Conditions | +4°C to 38°C (40°F to 100°F), |
| | Relative Humidity < 90%, Barometric |
| | Pressure 29.92 In Hg / 760 mm Hg to |
| | 11.12 In Hg / 282.4 mm Hg |

3. Site Preparation and Equipment Placement

- 3.1. Site Preparation The T-CO-DRXL Wall-Mounted Trans-Former must be secured in place prior to use. The T-CO-DRXL Wall-Mounted Trans-Former must be attached to the wall according to local code. Refer to the illustrations and notes below when determining the placement and mounting of the T-CO-DRXL Wall-Mounted Trans-Former.
- 3.2. Structural Reinforcement Customer supplied and installed structural reinforcement is required in or on the wall to which the T-CO-DRXL Wall-Mounted Trans-Former will be secured.
 - 3.2.1. The structural reinforcement must withstand a minimum pull force of 200 pounds per fastener.
 - 3.2.2. The placement of the structural reinforcement must fall within the location of the mounting points of the T-CO-DRXL Wall-Mounted Trans-Former.
 - 3.2.3. The structural reinforcement may be surface mounted or concealed within the wall and secured to existing structural support (e.g., studs) within the wall.
 - 3.2.3.1. If concealed within the wall, customer must ensure the location of the reinforcement is clearly marked and known to the installer of the device.
 - 3.2.4. Installers should not be required to penetrate lead (Pb) shielding within the walls in order to mount the T-CO-DRXL Wall-Mounted Trans-Former.
 - 3.2.5. The T-CO-DRXL Wall-Mounted Trans-Former rests on the floor but is attached to the wall behind it at four mounting points which are spaced horizontally 16 inches on center.
 - 3.2.6. Customer is responsible for providing fasteners that are compatible with the structural reinforcement. Fasteners must meet the minimum pull force required and conform to local code.



- 3.3. Device Placement Technical and Safety Factors When selecting the location for mounting the T-CO-DRXL Wall-Mounted Trans-Former, ensure the following:
 - 2.8 meters (110.24 inch) SID is achievable when the detector is mounted (2.8m SID is required to calibrate the detector).
 - The central ray of the x-ray source is perpendicular to the image plane.
 - The x-ray field height at 2.8 m SID is at least 52 inches to cover the full detector.
 - The device does not interfere with doorways or present other potential hazards in any working position.



4. Required Tools and Equipment

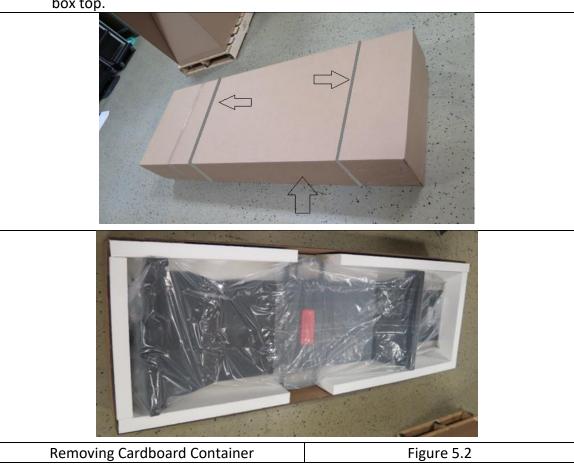
- 4.1. Uncrating Philips screwdriver, razor knife
- 4.2. Assembly No tools required
- 4.3. Wall Mounting Drill, wrench set, anchoring hardware



The device is heavy. Take care to move it with caution.

5. Uncrating the Device

- 5.1. The device comes fully assembled and can be lifted off the pallet by two people.
- 5.2. Cut the banding and packing tape connecting the lid and box and remove the box top.



Installation Precautions:

- The unit is pre-assembled but take care in uncrating, as the device is heavy.
- Device can be safely installed by two people.
- 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 device to the wall and mounting the Long-Length DR Panel.
- Do not remove red safety screw near release pin in the right-side handle until instructed to do so in Section 7.
- Failure to adhere to the Precautions listed above may result in injury to user!

Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com



The device's lift-assist mechanism employs a forceful coiled spring. Attempting to adjust the height of the Detector Mount before installing the Long-Length DR 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 7. Remove the red safety screw only after reading the complete instructions.

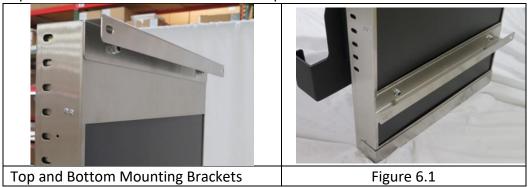




To install the Long-Length DR Panel and Grid, leave the red safety screw in place and do not attempt to adjust the height of the Detector Mount. The Long-Length DR Panel must be mounted with the Detector Mount in the factory-set position.

6. Installation of Wall-Mounted Trans-Former Frame

6.1. Top and bottom wall-mount brackets are pre-installed on the unit.



Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com

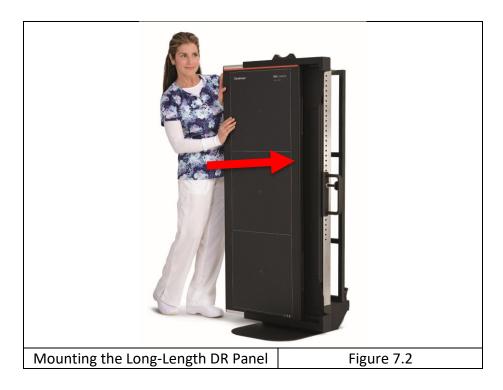
- 6.2. Place the Trans-Former frame on the floor in the desired mounting location, making sure the frame is plumb.
- 6.3. Mark the hole positions in the top and bottom brackets.
- 6.4. Move the Trans-Former frame out of the way and install mounting/anchoring hardware according to the local code.

7. Installation of Long-Length DR Panel and Grid onto the Detector Mount

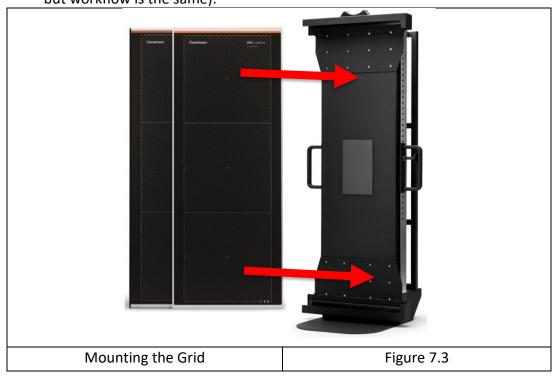
7.1. Leave the Detector Mount in the factory set position with the red safety screw in place.



7.2. Mounting the Long-Length DR Panel – Make sure the tensioner knobs on the rear of the Detector Mount are fully loosened by turning them *clockwise* until they stop (see Figure 7.4 for reference). Install the Long-Length DR Panel into the Detector Mount by sliding it between the support guides in the portrait orientation and carefully pushing it until it is fully seated against the stops (image is mobile version, but workflow is the same).

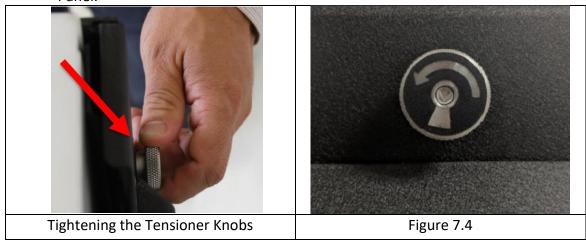


7.3. Mounting the Grid - Mount the Grid in either the storage position (behind the Long-Length DR Panel) or in the clinical use position (in front of the Long-Length DR Panel) by sliding it into the Detector Mount in the portrait orientation, taking care to keep it straight so it slides easily into position (mobile version shown, but workflow is the same).



Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com

7.4. Securing the Long-Length DR Panel and Grid - Tighten the four tensioner knobs on the rear of the Detector Mount by turning them anti-clockwise until tight. Take care to keep the clamping bars straight by tightening each knob only a few turns at a time. The Anti-scatter Grid can be mounted in front of the Long-Length DR 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 Long-Length DR Panel.



7.5. Remove the red safety screw after mounting and securing the Long-Length DR Panel and Grid.





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 Long-Length DR 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.

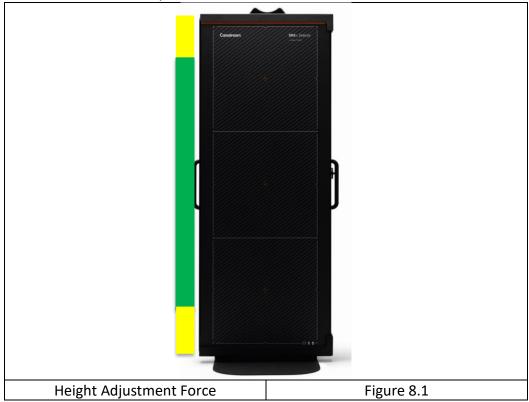


CAUTION!

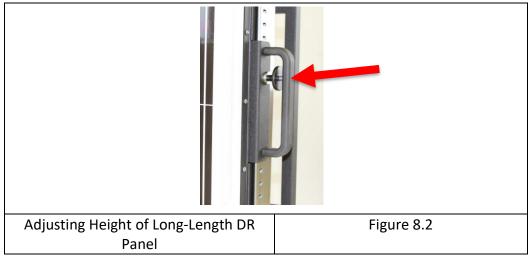
This is a mechanical device that relies upon coil springs and pulleys to control the height adjustment movements. The unit will move very easily near the center of its stroke. Extra effort is required to reach the uppermost and lowermost positions. To reach the uppermost position, use both handles to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

8. User Operations: Height Adjustment and Rotation

8.1. 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.



8.2. Long-Length DR Panel Height Adjustment - To actuate the Detector Mount's liftassist mechanism and raise or lower the height, pull the release pin in the rightside handle and raise or lower the Detector Mount.



8.3. Long-Length DR Panel Rotation - To turn the Long-Length DR Panel from portrait to landscape orientation, rotate the Detector Mount 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 anti-clockwise into the 0-degree detent.



Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com

9. Maintenance & Cleaning

- 9.1. 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.
- 9.2. Cleaning Surfaces can be cleaned using standard disinfection products. Do not submerge components. Do not autoclave components.

10. Changes to this document:

| Date | Revision | Description of Changes |
|------------|----------|--|
| 02.06.2020 | Α | Initial release |
| 04.27.2020 | В | Added environmental operating conditions |
| 06.30.2020 | С | Updated Model# to T-CO-DRXL |
| 07.22.20 | D | Updated Pictures |

ALL QUESTIONS AND CONCERNS SHOULD BE FORWARDED TO:

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

| Daine Investiga (107 W. Lee Arr. Co. 11 1 1 1 (2014 200 752 4042 |
|--|
| Reina Imaging 6107 W. Lou Ave., Crystal Lake, IL 60014 800-752-4918 www.reinaimaging.com |

T-CO-DRXL Installation and User Guide, July 2020