

# Clear One and Two Step Footstool

## Installation Guide and User Instructions



**Models: CS1, CS2**

**Revision: May 2021**

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## i. Intended Use

The Clear One and Two Step Footstools (Model# CS1, CS2) are designed to position the patient for various x-ray examinations of lower extremities.

## ii. Safety and Compliance



### General Cautions

- Follow any warning labels on the unit during assembly and these instructions.
- The device is heavy, and care should be taken when uncrating and moving it.
- Ensure that the device is used on a smooth, level surface for stability.
- Do not exceed 500lbs load on the platform.
- Always ensure the patient is stable and able to stand on the platform without assistance.
- Failure to adhere to the Precautions listed above may result in injury to user or patient!

## Compliance

The **Clear One and Two Step Footstools** are Class 1 Medical Devices (510k exempt) in the USA and are registered to:

### Reina Imaging

6107 W. Lou Avenue  
Crystal Lake, ILLINOIS – 60014, USA  
Phone: +1 800-752-4918



The **Clear One and Two Step Footstools** have been labeled and declared:



These models have been classified as Class 1 devices per Annex VIII of MDR 2017/745.

European Authorized Representative:



Meddevices Lifesciences B.V.  
Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands  
Email: [info@meddevices.net](mailto:info@meddevices.net)  
Tel: +31-20225455

### **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 (one) 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, failure to assemble properly and normal wear will not be covered under this warranty. Users are responsible for reading all instructions prior to using the product(s).

***Note: Pictures in this manual reflect the CS2 product, but workflow for the CS1 product is identical.***

**About This Manual**

- 1.1. Disclaimer - This manual was written to provide proper guidelines for using the Compact Mobile GL Positioning Partner. Using the Compact Mobile GL 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 GL Positioning Partner. Use of the Compact Mobile GL Positioning Partner constitutes the user’s acceptance of all responsibility for liability caused by its use.
- 1.2. Symbols Used in This Manual – There are various symbols included in this manual with which the user should be familiar. Table 1.2 identifies these symbols and explains their meanings.

| Symbol  | Symbol Name                              | Symbol Meaning  |
|---|--|---|
|   | Manufacturer                             | Signifies the manufacturer of the product, accompanied by plain text details of factory name and location |
|  | Date of Manufacture                      | Signifies the date the product was manufactured, accompanied by plain text date in YYYY MM DD format      |
|  | Operator’s Manual/Operating Instructions | Signifies that the Operator’s Manual/Operating Instructions contain pertinent information for the user    |
|  | Unique Device Identification             | Provides a globally harmonized identifier of medical devices  |

|   |                                   |  |
|---|-----------------------------------|--|
|    | Device Serial Number              | Provides a means to identify a particular device of a series   |
|    | Device Model Number               | Provides a means to identify device type   |
|    | Medical Device                    | Identifies a device as a medical device  |
|    | European Conformity Mark          | Signifies a device meets the essential requirements of all relevant European Medical Device Directives     |
|  | European Community Representative | Provides a point of contact between a non-EU device manufacturer and competent authorities/notified bodies |
|  | Caution                           | See Section 1.3 for complete details   |
|  | Warning                           | See Section 1.3 for complete details   |
|  | Danger                            | See Section 1.3 for complete details   |

|   |                    |  |
|---|--------------------|--|
|  | <p>Do Not Lean</p> | <p>The user nor the patient should lean on the CS1/CS2, as it is a mobile device and could shift or move</p> |
| <p>Symbols Used in This Manual</p>  |                    | <p>Table 1.2</p>   |

1.3. 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.

|   |                           |
|---|---------------------------|
|  | <p>The Caution Symbol</p> |
|---|---------------------------|

- *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.

|   |                           |
|---|---------------------------|
|  | <p>The Warning Symbol</p> |
|---|---------------------------|

- *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 |
|---|-------------------|

- 1.4. 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 for the latest materials regarding this system prior to use. Users should check back periodically for updates and check before installation of the product(s) is recommended.

## 2. Product Description and Specifications

- 2.1. Product Description –The Clear One/Two Step Footstool (Model# CS1/CS2) is designed to position the patient for various x-ray examinations of lower extremities. It is mobile with tip-back casters, features a large patient platform, support handles and a detector slot to position the receptor in the correct orientation for imaging.
- 2.2. BASIC UDI: 00860001700121
- 2.3. Product Specifications, CS2

|            |                |
|------------|----------------|
| Weight     | 62lbs/28.2kg   |
| Dimensions | See Figure 2.2 |

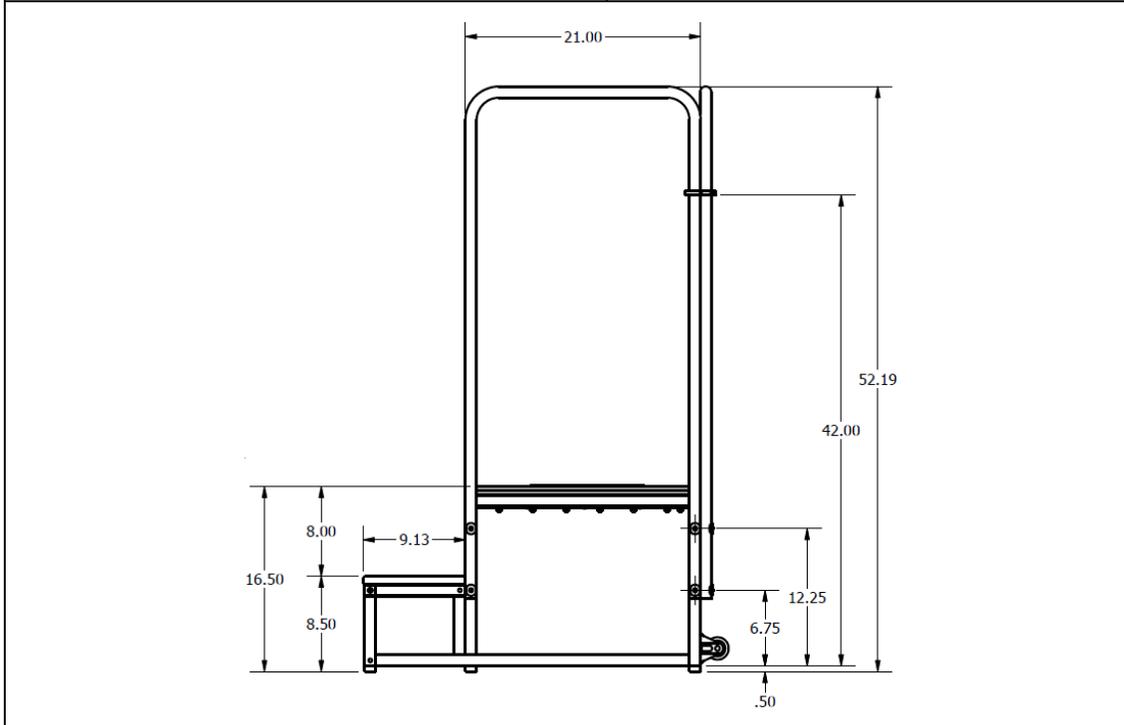
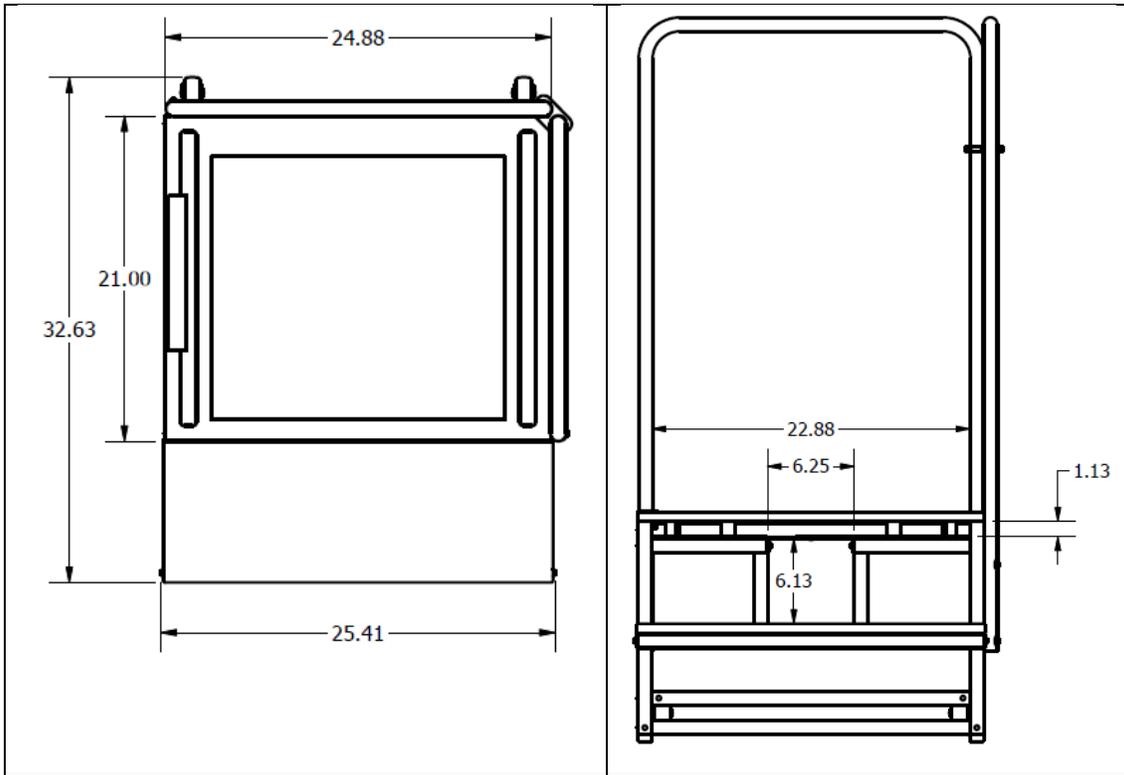


Figure 2.2

CS2 Dimensions

2.4. Product Specifications, CS1

|            |                |
|------------|----------------|
| Weight     | 45lbs/20.5kg   |
| Dimensions | See Figure 2.3 |

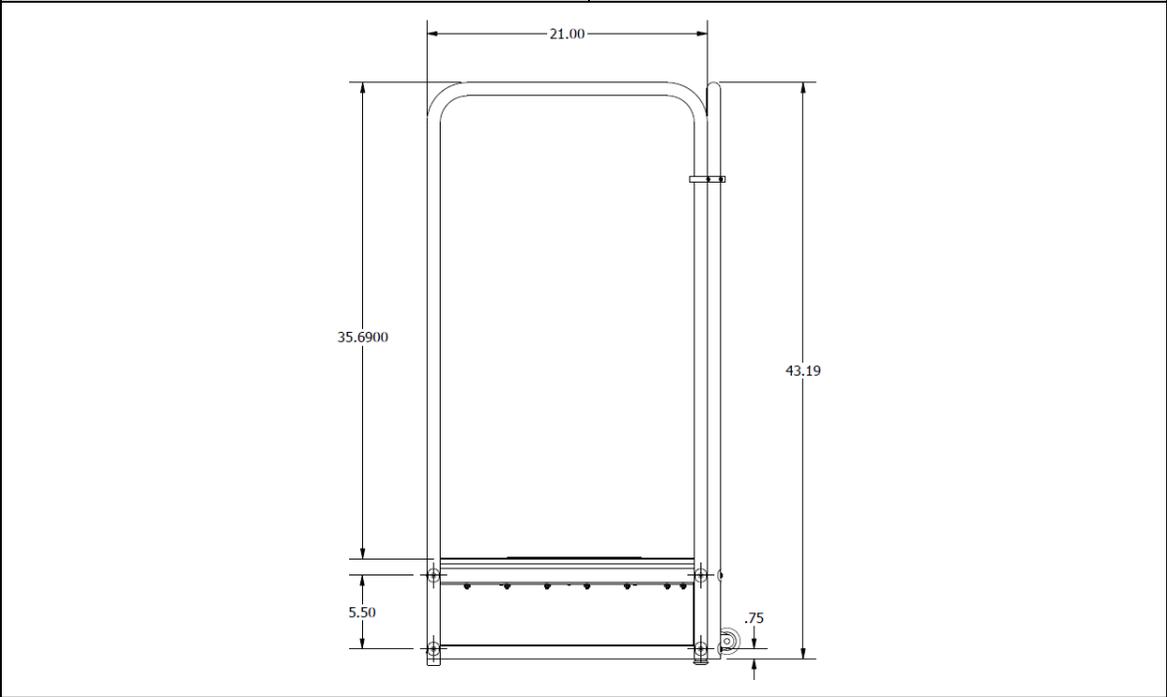
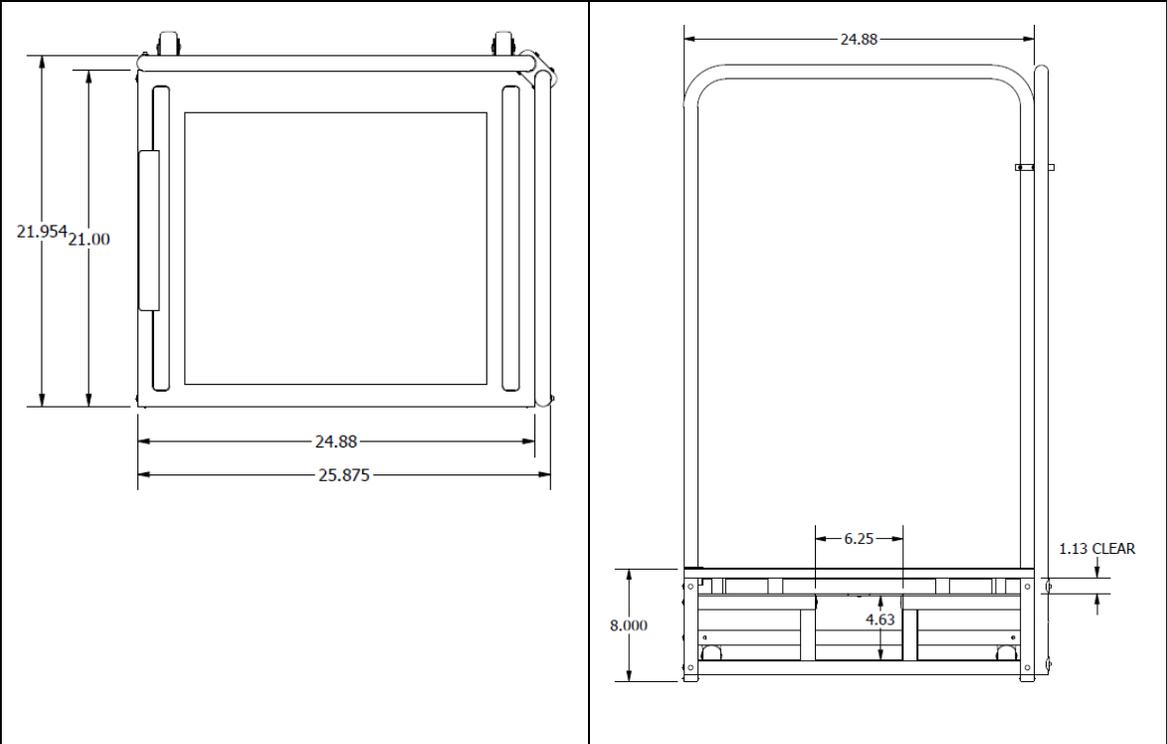


Figure 2.3

CS1 Dimensions

### 3. Required Tools and Equipment

- 3.1. Uncrating – Razor knife or scissors
- 3.2. Assembly- 1/8" hex head wrench, 5/32" hex head wrench



**CAUTION!**

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

### 4. Uncrating Device and User Assembly on Site

- 4.1. Remove Base Unit from box and retain packaging



**CAUTION!**

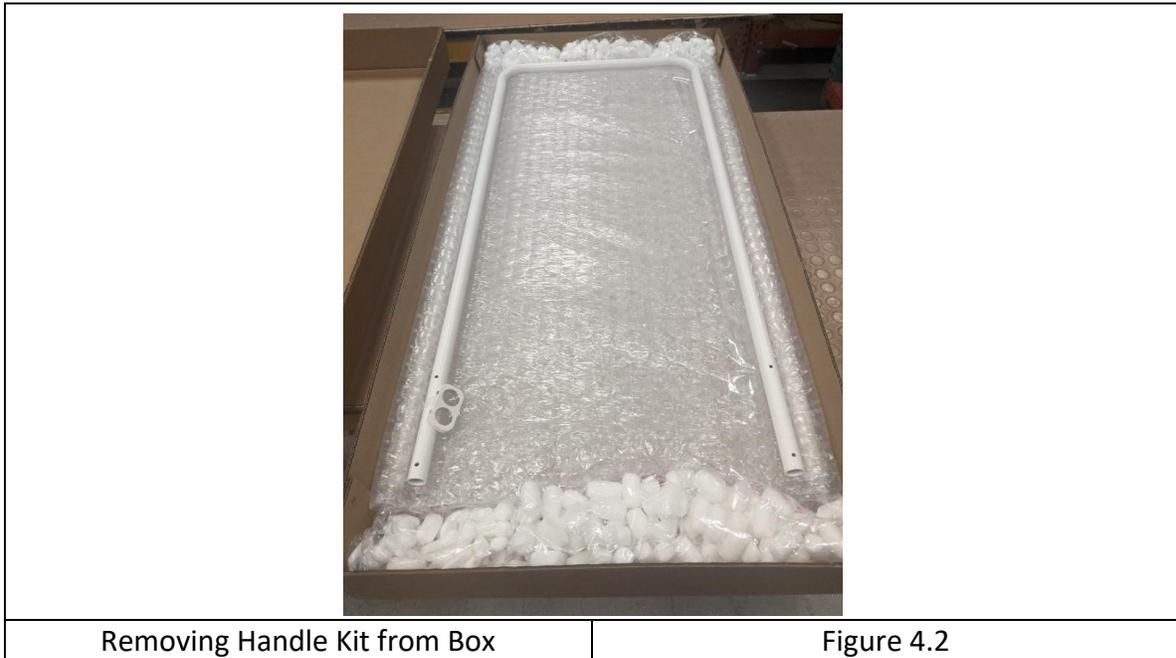
*Two people are required to lift the CS1/CS2 from the box.*



Removing Base Unit from Box

Figure 4.1

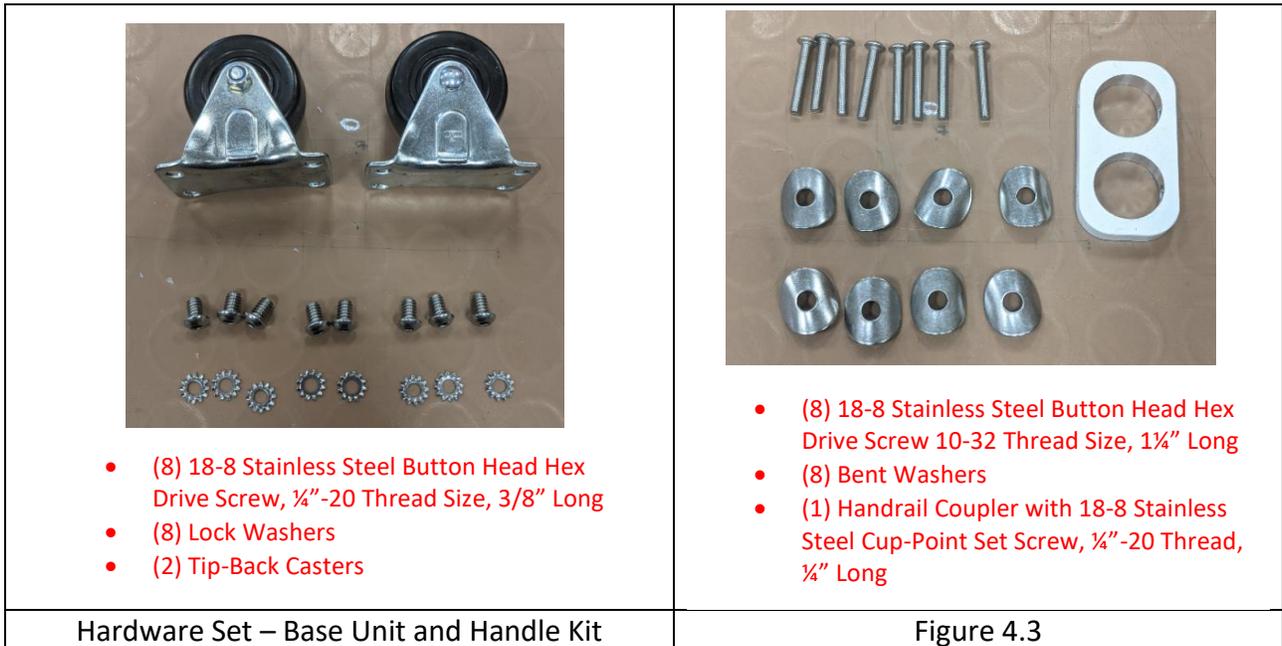
4.2. Remove Handle Kit from box and retain packaging



Removing Handle Kit from Box

Figure 4.2

4.3. Set aside the bag of hardware that comes in each box. Base Unit has two Tip-Back Casters, eight 5/32" hex button cap screws and eight lock washers. Handle Kit has eight 1/8" hex button cap screws, eight bent washers and one Handrail Coupler with 1/8" hex set screws.



- (8) 18-8 Stainless Steel Button Head Hex Drive Screw, 1/8" -20 Thread Size, 3/8" Long
- (8) Lock Washers
- (2) Tip-Back Casters

- (8) 18-8 Stainless Steel Button Head Hex Drive Screw 10-32 Thread Size, 1/4" Long
- (8) Bent Washers
- (1) Handrail Coupler with 18-8 Stainless Steel Cup-Point Set Screw, 1/8" -20 Thread, 1/4" Long

Hardware Set – Base Unit and Handle Kit

Figure 4.3

- 4.4. Set the Base Unit upright on the work surface taking care not to scratch any components. Attach the Tip-Back Casters as shown in Figure 4.4. Start each screw into the t-nut provided in the frame and then tighten all screws once all are started into the t-nuts. Tighten firmly.



- 4.5. Set Base Unit on its side and place the empty Base Unit box on top of the empty Handrail Kit box as shown. Place the smaller-width Handrail onto the boxes and over frame of the Base Unit using packaging material to shim the handrail so it aligns with the t-nuts in the rails. Slide the Handrail Coupler onto the rear-side end of the Handrail above the Base Unit roof plate and leave it loose.



Setting Base Unit and Boxes to Align Handrail and Coupler

Figure 4.5

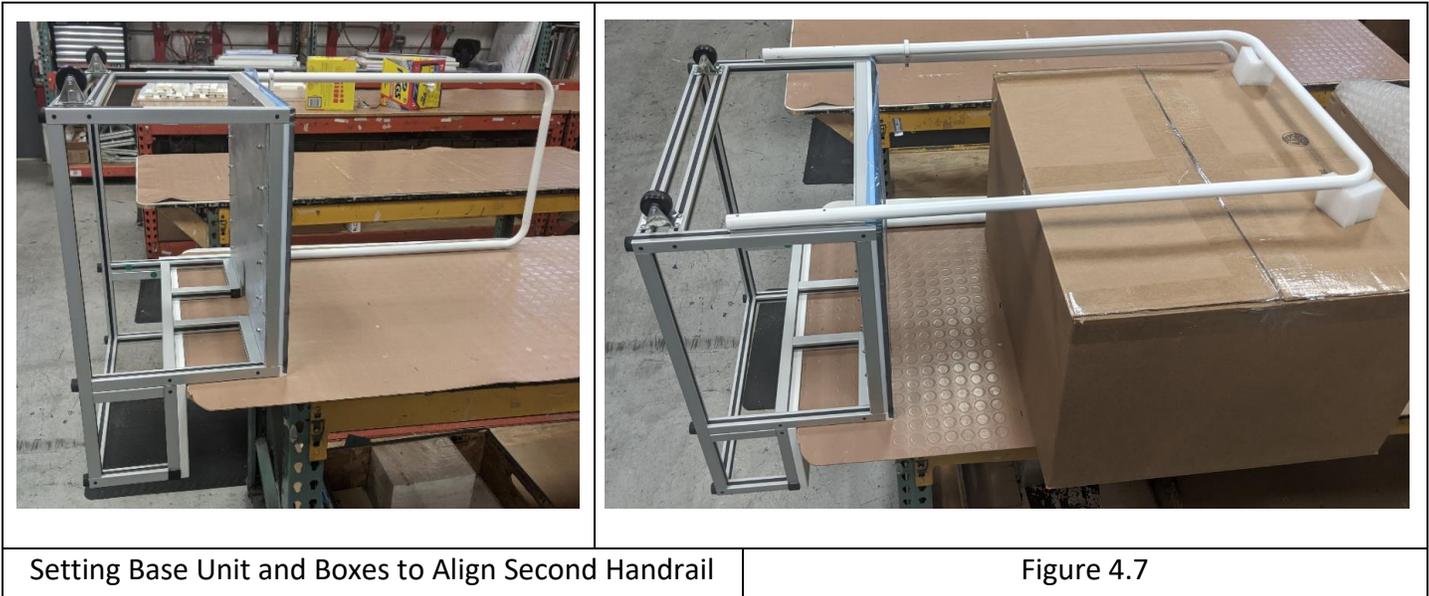
4.6. Place bent washers onto Handrail screws and insert screws through the Handrail and into the t-nuts in the Base Unit frame. Loosely tighten the two screws on the rear side of the Handrail (Handrail Coupler side) and tighten the two screws on the front side of the Handrail. Do not overtighten, as the tubing will crush.



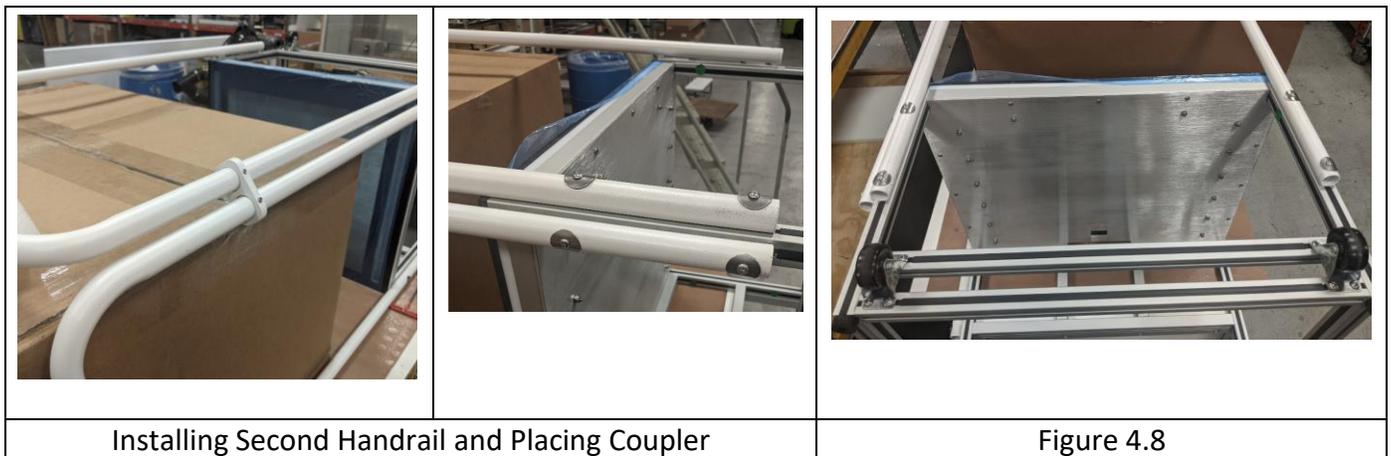
Setting the Handrail Screws, Full Set and Loose

Figure 4.6

- 4.7. Set the Base Unit on its side and set the Base Unit box on the work surface as shown in Figure 4.7. Place the larger-width Handrail on top of the box and over the Base Unit frame, carefully sliding it through the Handrail Coupler, taking care not to scratch the paint. Shim with packaging material to align with the t-nuts in the Base Unit frame.

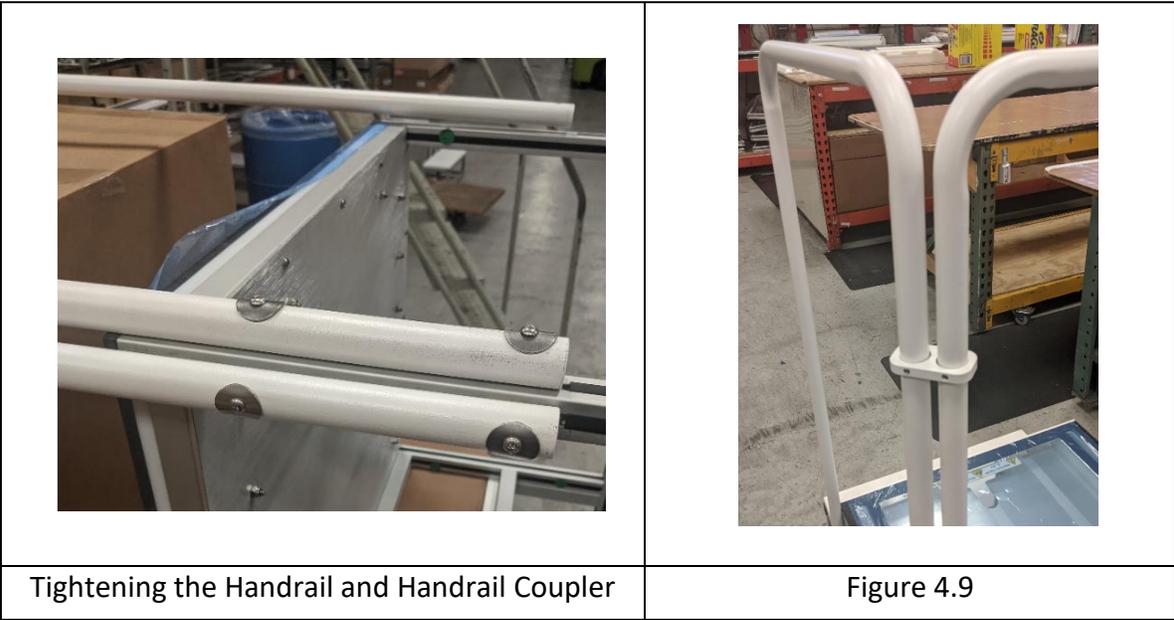


- 4.8. Carefully slide the Handrail Coupler up both Handrails taking care not to scratch the paint. Handrail Coupler should be about 9" from the top of the Handrails. Place the bent washers onto the Handrail screws and loosely tighten the side with the Handrail Coupler on it. Fully set the other side. Do not overtighten, as the tubing will crush.

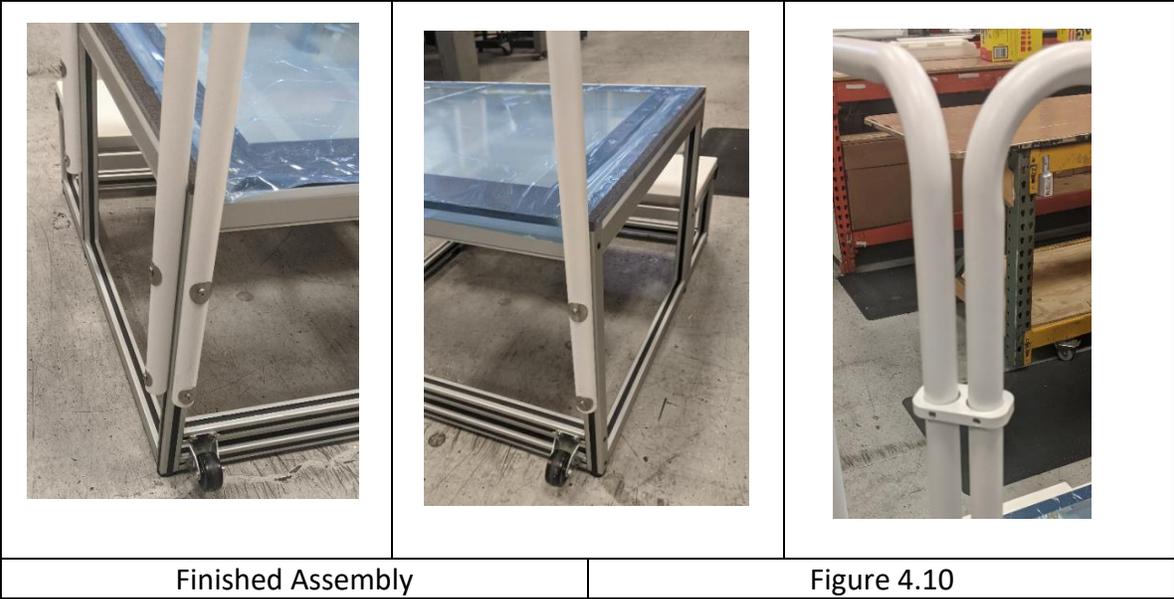


- 4.9. Fully set the four Handrail screws on the Handrail Coupler side. Do not overtighten, as the tubing will crush. Tighten the four set screws on the  
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[www.reinaimaging.com](http://www.reinaimaging.com)

Handrail Coupler with 1/8" hex wrench a little bit at a time until evenly tight. Do not overtighten or the tubing will crush.



4.10. Finished assembly, Tip-Back Casters, Handrails, Handrail Coupler. Installation is now complete.



**5. User Operations: Moving the Device and Positioning the Detector**

5.1. Moving the Device- To move the CS1/CS2, hold handles from rear side, place foot on frame on rear of Base Unit and tip the CS1/CS2 backwards toward you

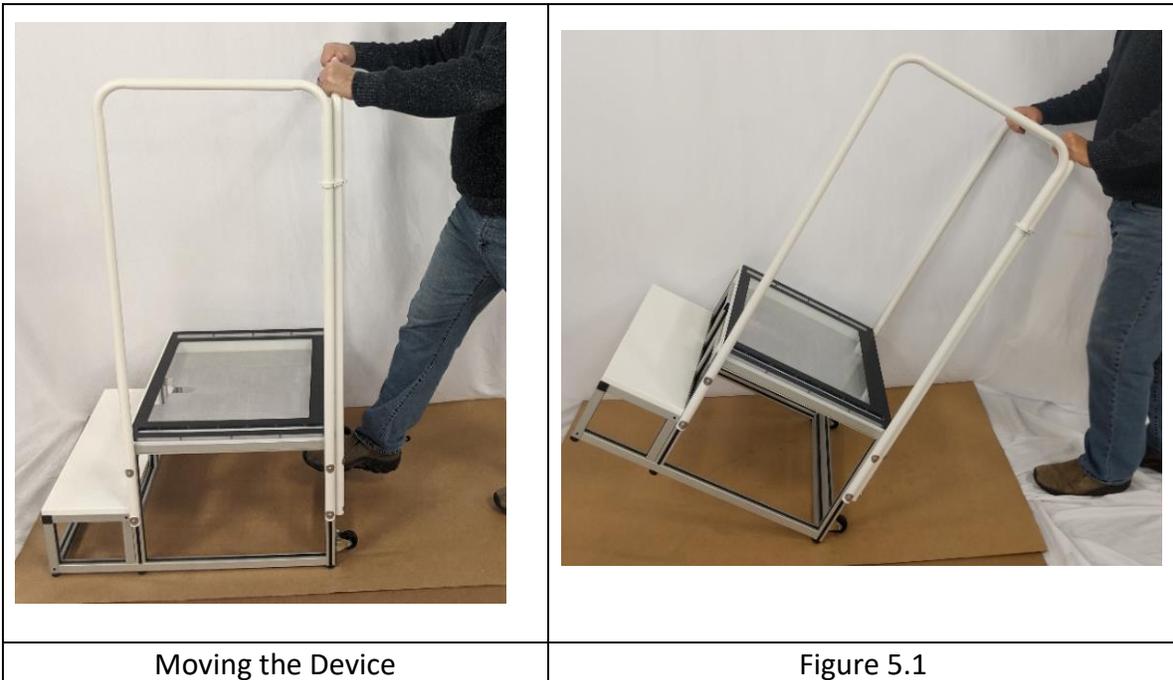
until it is riding on the Tip-back Casters. Maneuver into the desired position and set down flat on floor by placing foot back on frame and slowly lowering the device until it rests on its rubber feet.



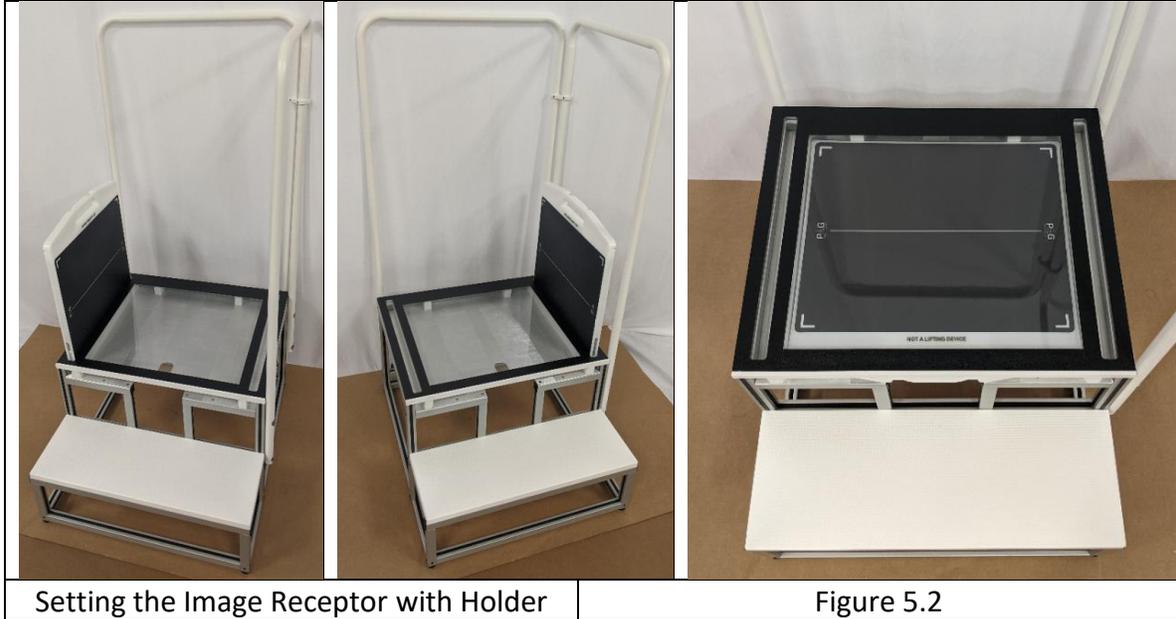
**Warning!**

***Take care not to damage the x-ray equipment by colliding with the CS1/CS2. The CS1/CS2 has no limit switches or sensors to avoid collisions. The operator is solely responsible for positioning the x-ray equipment.***

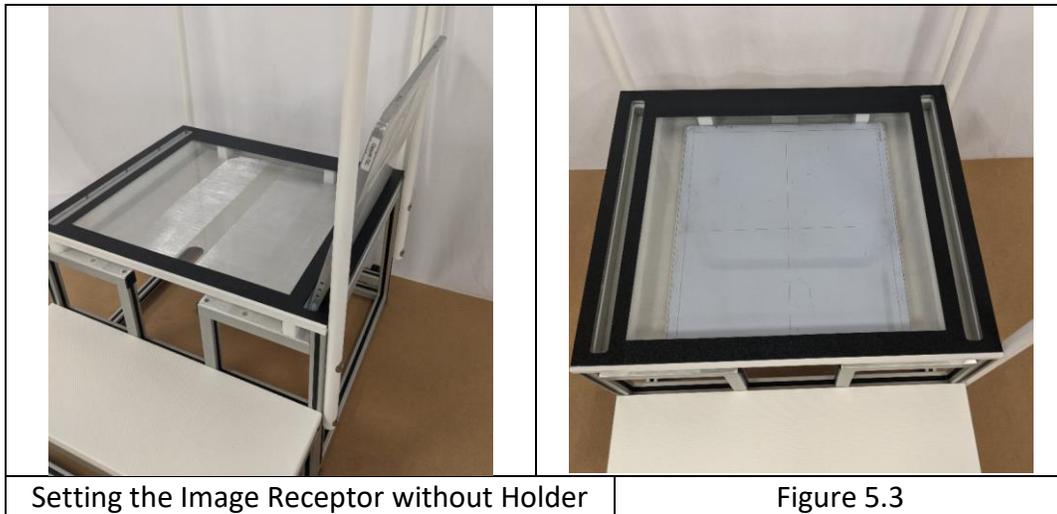
***Do not move the CS1/CS2 with the receptor mounted, as it could fall and be damaged. Always dismount the receptor before moving the CS1/CS2.***



5.2. Setting the Image Receptor with Holder–Left Slot, Right Slot and Tray. Set the image receptor (x-ray cassette or DR panel) into the slot with the tube side of the receptor facing the x-ray source. Set the image receptor into the tray with the tube side facing up.



5.3. Setting the Image Receptor without Holder – Slots and Tray. Set the image receptor into the either slot. The image receptor is smaller than the slot and will lean when placed in the slot (See Figure 5.4 below for instruction to set the shim). Set the image receptor into the Tray, center it to the region of clinical interest.



5.4. Shim Placement and Thickness Adjustment – The included Shim Kit is configured for an ANSI-sized image receptor 16mm thick. If the image receptor fits loosely with the shim, add the included friction tape to the inside of the shim. Set the image receptor in the slot first, then add the shim.



## 6. Checks and Adjustments – Fasteners

6.1. Check Screw Tightness– Before putting the CS1/CS2 into clinical service, check the tightness of all fasteners to be sure everything is snug. Do not overtighten any screws.

## 7. Maintenance & Cleaning

7.1. Maintenance - Every 12 months or whenever any screws appear to be loose, tighten the screws according to the instructions in the assembly process. Also check the screws holding the Tip-back Casters. The Stair Tread and Top Platform should not require any maintenance but should be inspected periodically along with the rest of the CS1/CS2.

7.2. Cleaning - Surfaces can be cleaned using standard disinfection products. Do not submerge components.

**ALL QUESTIONS AND CONCERNS SHOULD BE FORWARDED TO:**

**REINA IMAGING**

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## **8. Changes to This Manual**

| Date       | Revision | Description of Changes |
|------------|----------|------------------------|
| 12.01.2020 | A        | Released               |
| 04.26.2021 | B        | Added CS1 product      |