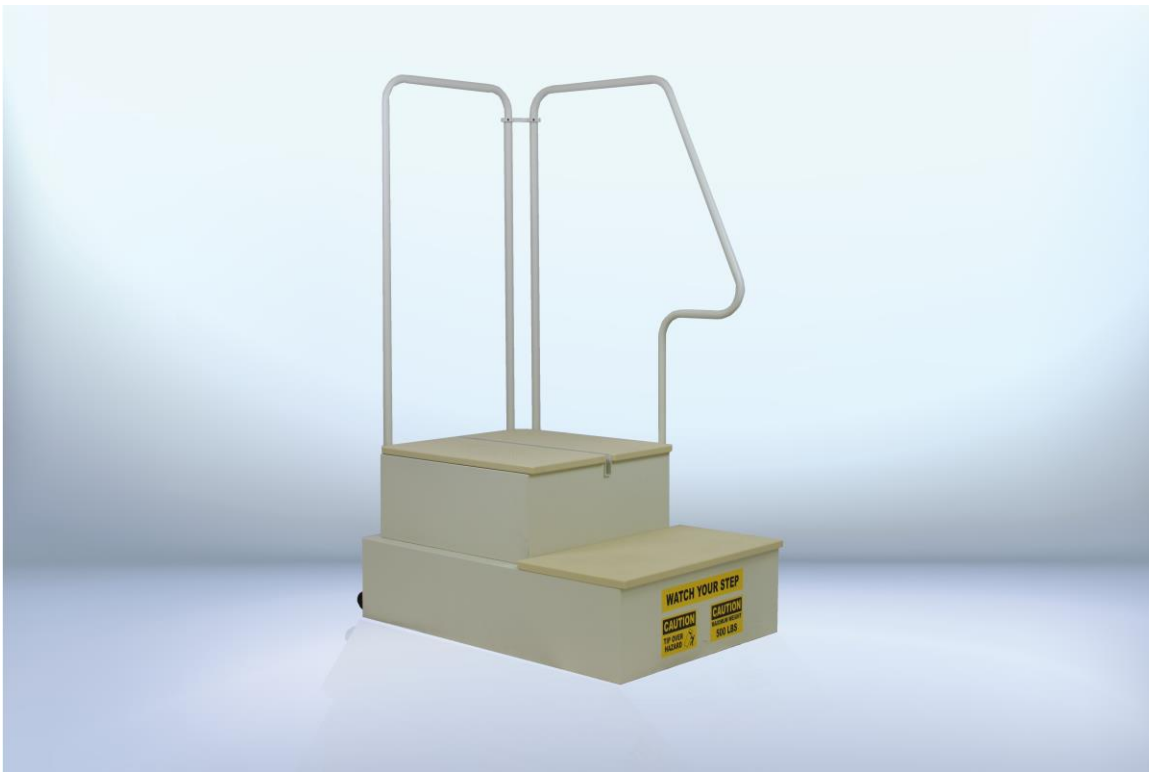


Two Step Footstool

Installation Guide and User Instructions



Model: FS2

Revision: May 2019

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i. Intended Use

The Two Step Footstool (Model# FS2) is 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 **Two Step Footstool** 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 **Two Step Footstool** 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 (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).

About This Manual

- 1.1. Disclaimer - This manual was written to provide proper guidelines for using the Two Step Footstool. Using the Two Step Footstool 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 Two Step Footstool. Use of the Two Step Footstool 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:

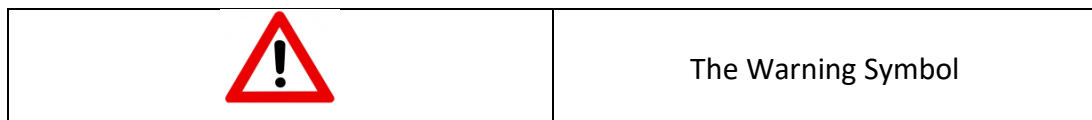
- *Caution* – Cautions in this manual contain information to help the user avoid minor risks such as product problems due to improper assembly or usage. Failure to heed this level of warning may result in product failure, minor product damage, unusable product, property damage and the like.

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.



- *Danger* – 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.



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 Reina Imaging for the latest materials regarding this device prior to use. Users should check back periodically for updates and checking before installation of the product(s) is recommended.

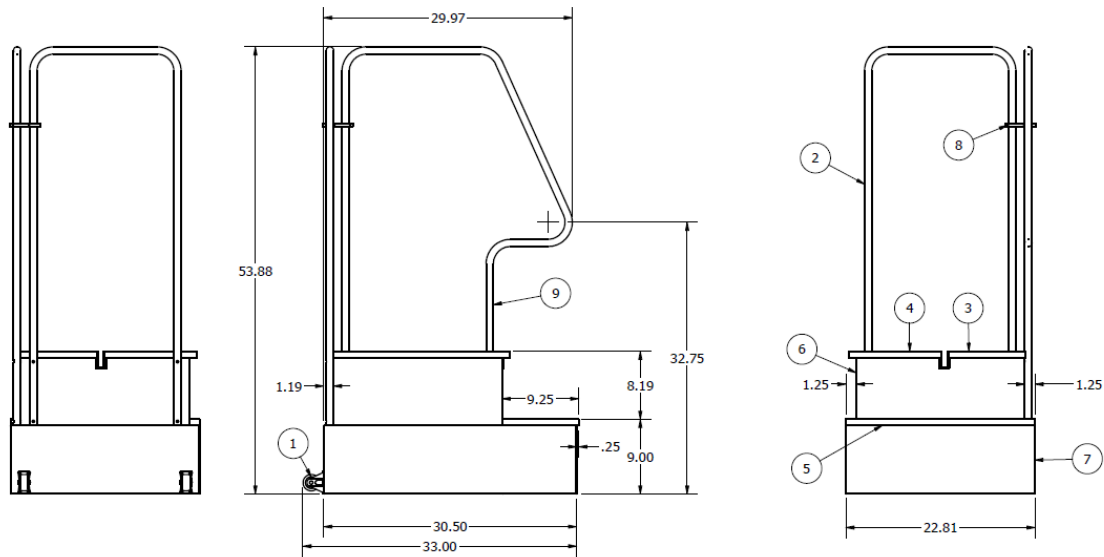
2. Product Description and Specifications

2.1. Product Description – The Two Step Footstool (Model# FS2) 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 position for imaging.

2.2. Product Specifications

Weight	78lbs/35.4kg
Dimensions	See Figure 2.2

Figure 2.2



3. Required Tools and Equipment

- 3.1. Uncrating – Razor knife or scissors
- 3.2. Assembly (if using self-assembly option) – Philips head screwdriver, 1/8" hex head wrench, 5/32" hex head wrench



CAUTION!

The device is heavy. Take care to move it with caution. Removing the fully assembled device from the pallet requires two people.

4. Uncrating the Fully-Assembled Device and User Assembly on Site

4.1. Fully Assembled from Factory

- 4.1.1. If device is purchased fully assembled, remove the cardboard container upwardly, cut the plastic band (red arrow) as shown in figure 4.1, then lift the device off the pallet and place on floor.



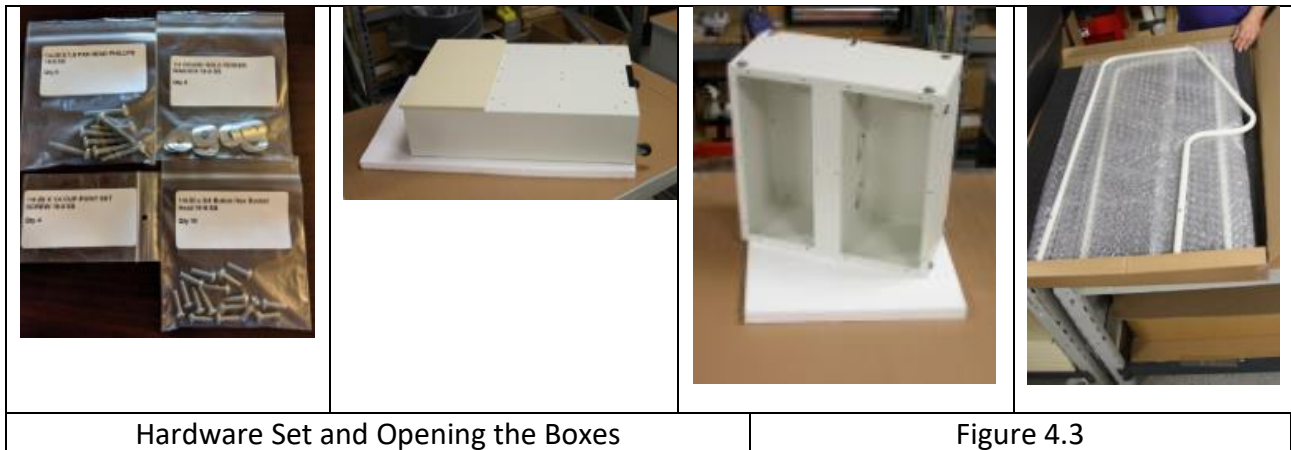
CAUTION! *Two people are required to lift the FS2 from the pallet.*



4.2. User Assembly on Site - The device comes in three boxes: Sub-base, Top and Rails.



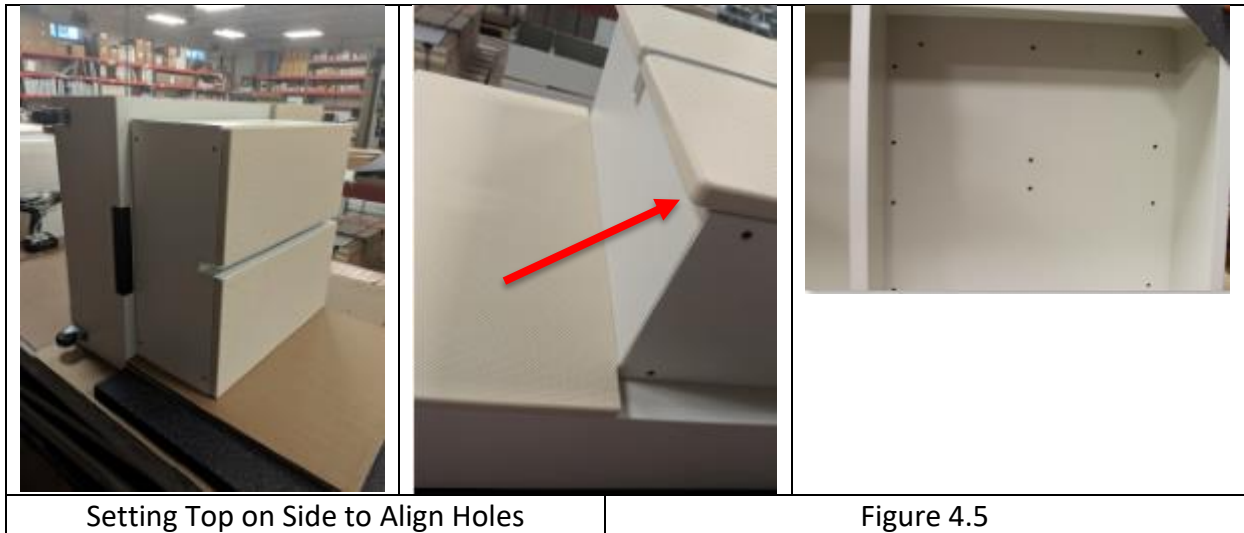
4.3. Open all three boxes and set aside the bag of hardware. Don't discard packaging until assembly is complete. Take care not to damage the surface of the assembly area by placing the components on top of packaging material.



- 4.4. Set the sub-base on its side on a single-layer piece of cardboard from the packaging material to protect the assembly surface from scratching or marring.

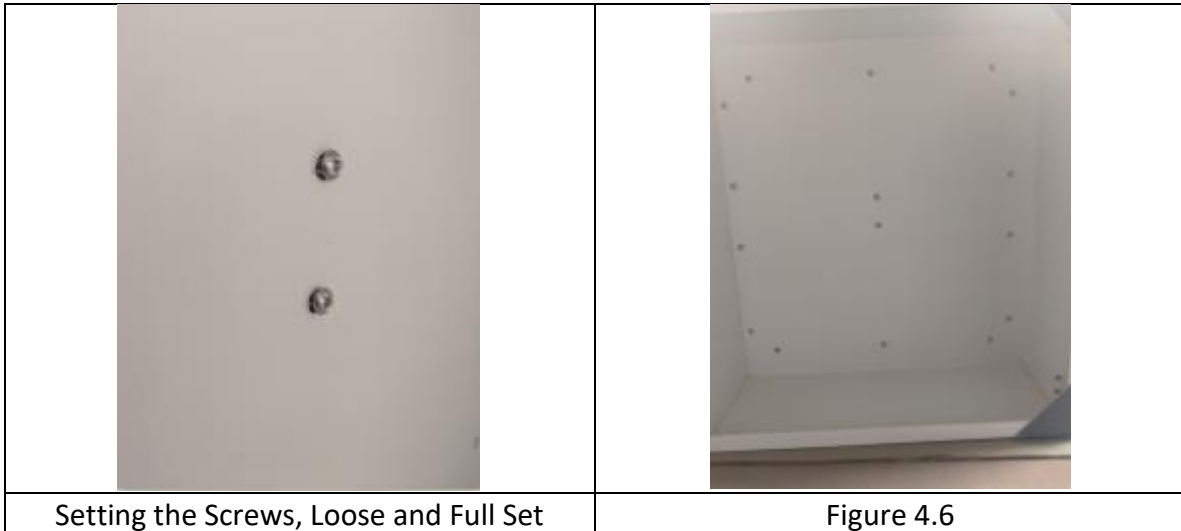


- 4.5. Set Top on its side on foam and cardboard from packaging materials such that the overhanging edge of the step in the Top (red arrow) is on the same side as the step of the Sub-base and holes in the Sub-base and Top align.

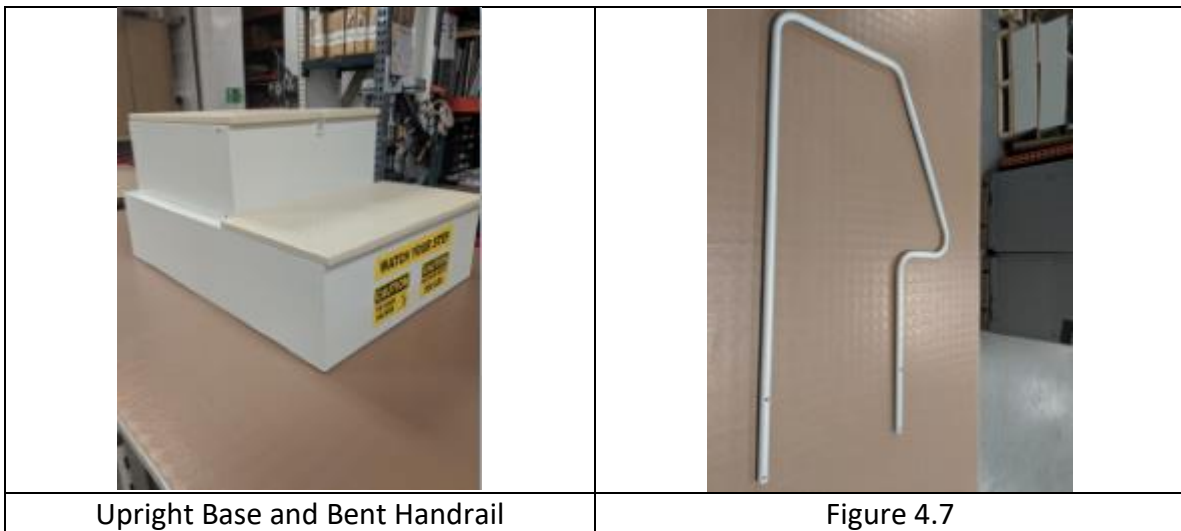


- 4.6. Set the sixteen (16) $\frac{1}{4}$ -20 x $\frac{3}{4}$ " button socket cap screws loosely in the holes beginning with the center two screws and working around to loosely set the rest using $\frac{5}{32}$ " hex head wrench. You may need to slightly adjust the positions of the Sub-base and Top as you go, taking care to set the screws straight and not

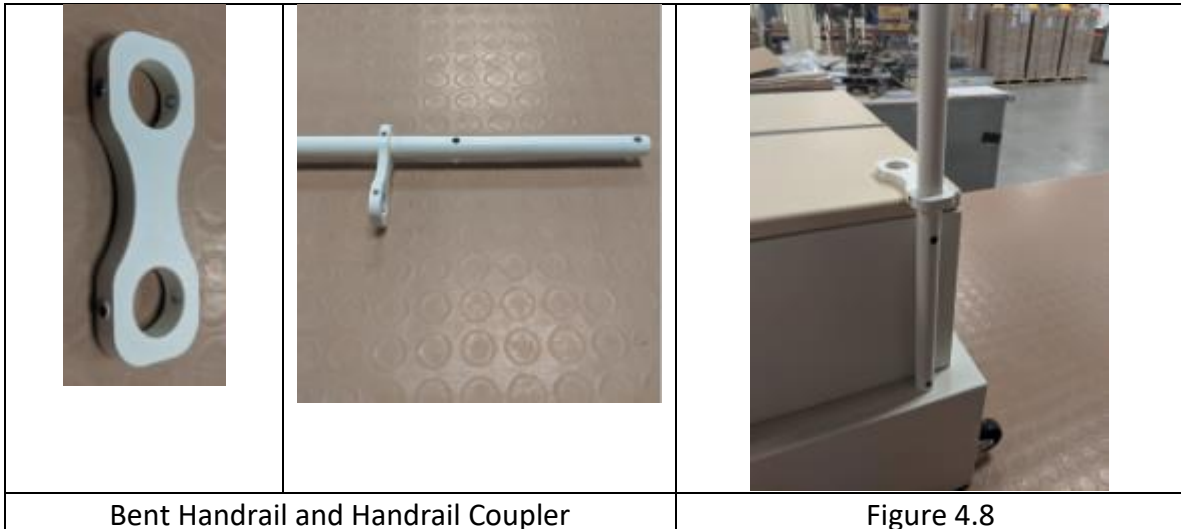
to strip them. Once all screws are loosely fit, tighten them down in random order, skipping around until all are firmly “hand tight”. Do not overtighten the screws.



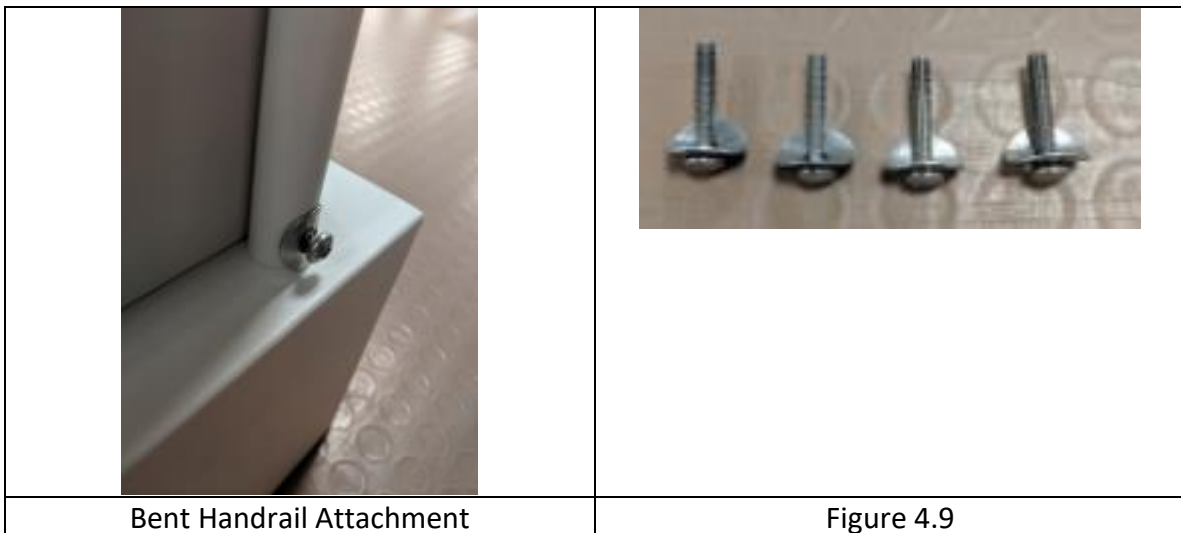
4.7. Set assembled Base upright taking care not to scratch the assembly area surface and take the bent Handrail from the box.



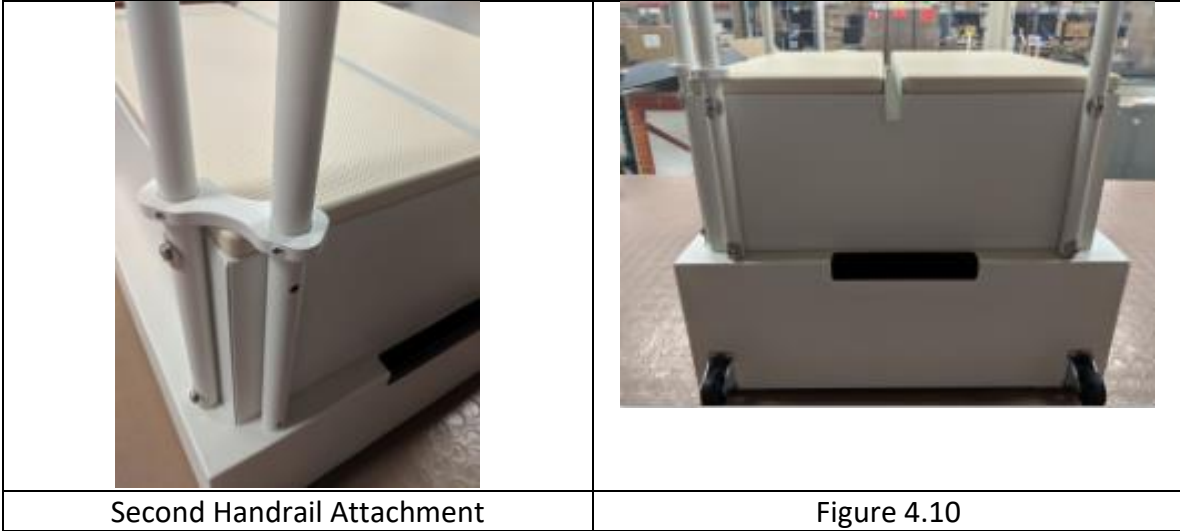
4.8. The Bent Handrail can be assembled on the left or right side. Slide Handrail Coupler up the straight leg of the Bent Handrail and set the Handrail and Handrail Coupler onto the Sub-base and Top as shown in figure 4.8.



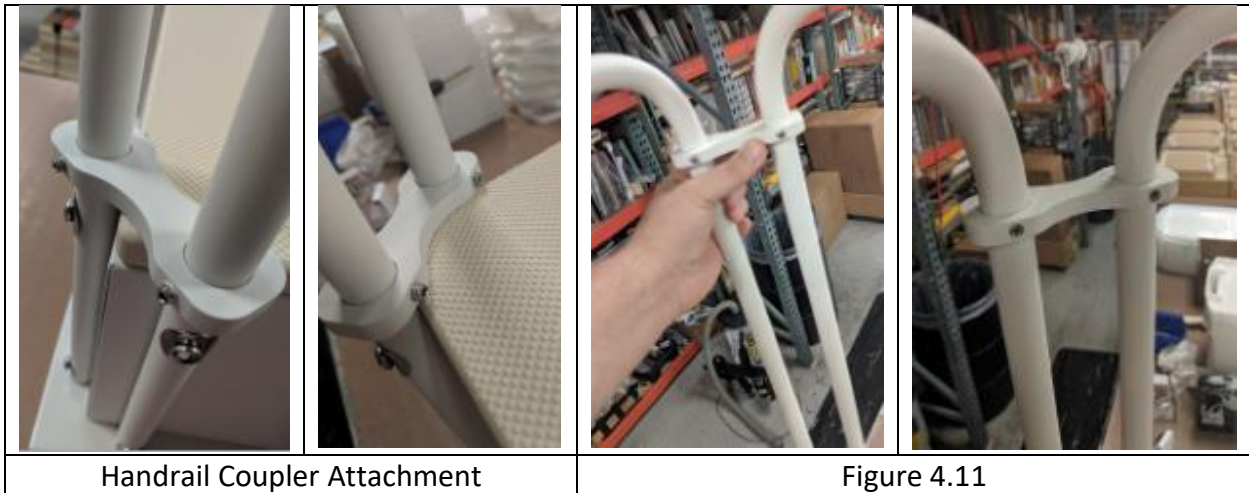
4.9. Attach the Bent Handrail with 4 (four) $\frac{1}{4}$ -20 x 1 $\frac{1}{2}$ " screws with bent washers using Philips head screwdriver. Start with the top holes, fit the screws loosely, then set the screws loosely in the bottom holes and tighten all four. Do not overtighten, as the tubing will crush.



4.10. Slide second Handrail through Handrail Coupler and set on top of Sub-base. Attach second Handrail as done with the Bent Handrail with 4 (four) ¼-20 x 1 ½” screws with bent washers using Philips head screwdriver. Start with the top holes, fit the screws loosely, then set the screws in the bottom holes and tighten all four. Do not overtighten, as the tubing will crush.



4.11. Loosely fit the 4 (four) ¼ -20 x ¼” Set Screws into the Handrail Coupler using a 1/8” hex head wrench. Do not set screws deeper than two turns, as the paint will be scratched when positioning the Handrail Coupler. Slide Handrail coupler up to within 5”-12” of the top of the Handrails (user’s preference) and tighten all four Set Screws taking care not to crush the tubing by overtightening.



Installation is now complete.

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

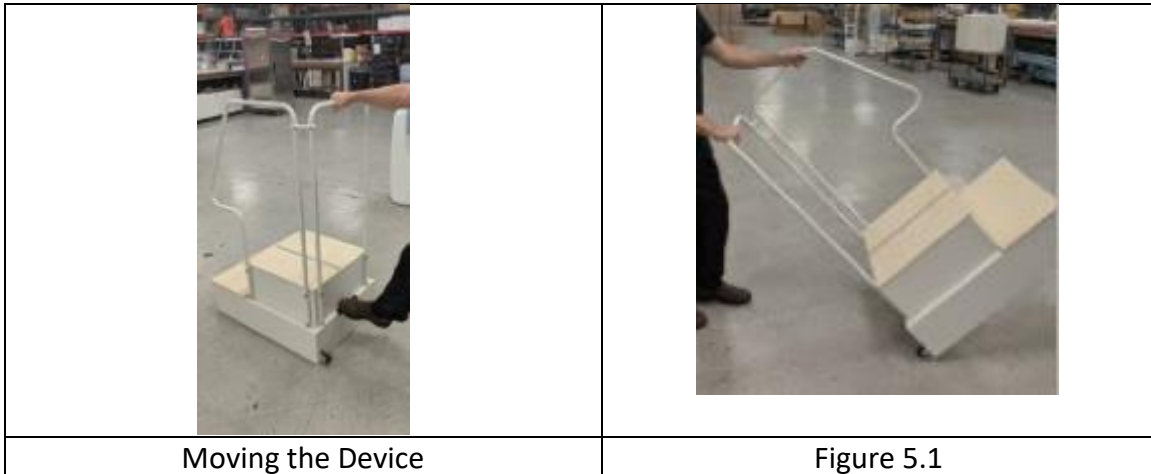
5.1. Moving the Device - To move the FS2, hold handles from rear side, place foot on friction tape on rear of Sub-base and tip the FS2 backwards toward you until it is riding on the Tip-back Casters. Maneuver into the desired position and set down flat on floor by placing foot back on friction tape and slowly lowering the device.



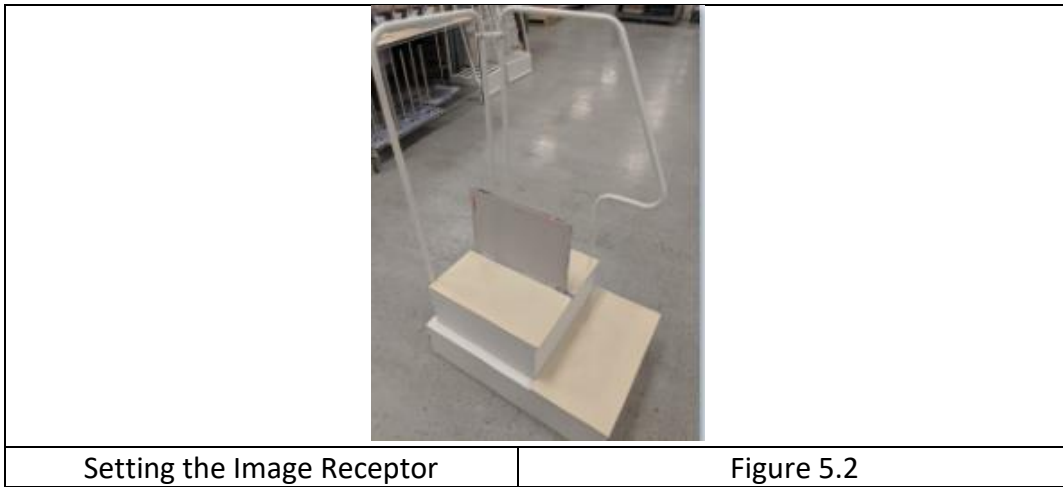
Warning!

Take care not to damage the x-ray equipment by colliding with the FS2. The FS2 has no limit switches or sensors to avoid collisions. The operator is solely responsible for positioning the x-ray equipment.

Don't move the FS2 with the receptor mounted, as it could fall and be damaged. Always dismount the receptor before moving the FS2.



- 5.2. Setting the Image Receptor – 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.



6. Checks and Adjustments – Fasteners

- 6.1. Check Screw Tightness – Before putting the FS2 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 FS2.
- 7.2. Cleaning - Surfaces can be cleaned using standard disinfection products. Do not submerge components.

ALL QUESTIONS AND CONCERNS SHOULD BE FORWARDED TO:

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