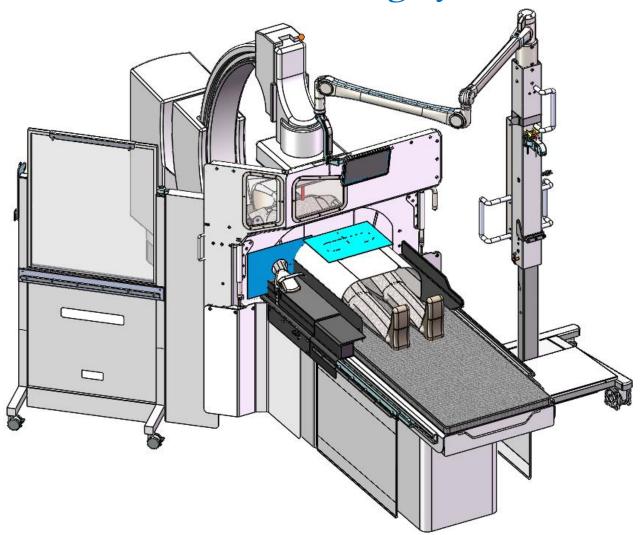


Protego Radiation Shielding System

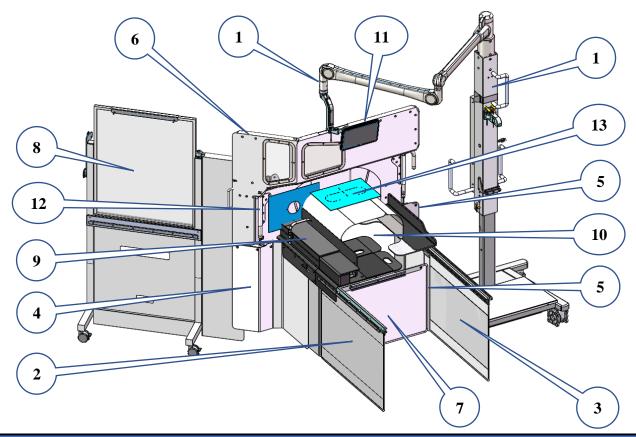


Installation Guide

The text of this manual was originally written, approved, and published by the manufacturer in English. The information and images in this document are proprietary to IDI and are only for use for and by IDI representatives or their Agents.

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1. Protego Product Picture - Main Assemblies Installation



2. Protego Product BOM, Main Assemblies A800-0002 (GE), A800-0004 (Siemens), A800-0006 (Philips), A800-0007 (Toshiba)

- 2.1. Item 1: Mobile Radiation Stand (MRS)
- 2.2. Item 2: Table Side Rail Shield, Right
- 2.3. Item 3: Table Side Rail Shield, Left
- 2.4. Item 4: Wing Mag Shield, Right
- 2.5. Item 5: Wing Mag Shield, Left
- 2.6. Item 6: Radiation Shield Barrier (RSB)
- 2.7. Item 7: Pedestal Shield, Table Base
- 2.8. Item 8: Mobile Barrier
- 2.9. Item 9: Patient Shield Kit (Contains: Radial Arm/Ext Board with all needed patient shielding panels.
- 2.10.Item 10: Arm Board, Left
- 2.11.Item 11: Monitor Camera System

3. Protego Accessories & Disposables

- 3.1. Item 12: X800-0147 Shield Pad, Radial Arm, Pb 0.25mm (12"x 16"), Box 15 pouches 2 Boxes provided.
- 3.2. Item 13: X800-0251 Shield Pad, Femoral, Pb 0.25mm (12" x 17"), Box 15 pouches 2 Boxes provided.
- 3.3. (Not Shown) A800-0310 Protego Pro Kit, Box 25 pouches 2 Boxes provided.
- 3.4. Other Accessories and Disposables may be added or changed for future use and improvements.

4. Other Protego features

- 4.1. All Protego shield panels rated for 0.50mm Pb EQ.
- 4.2. All Arm boards panels rated for 0.50mm Pb EQ.
- 4.3. All Patient shield panels from Patient Shield Kit are rated for 0.25mm 0.50mm Pb EQ.
- 4.4. Magnet 180 degree turn knob locks for right and left rail slides. Used to connect Item 6 (RSB) to table rails.
- 4.5. Lower Right- and Left-Wing Shields can slide 8" inches and lock in seven positions with a plunger lock for variable patient waist shield barrier alignments.
- 4.6. Park Assembly mounted on column on MRS to attach RSB when not in use with Velcro strap.
- 4.7. Articulating arm can be adjusted to counterbalance Item 5 (RSB) by using metric Allen wrench in vertical arm adjustment point. Arms have rotation tension brakes which can be adjusted with metric Allen wrench. Refer to Oasys Healthcare Operating Instructions Spring Arm Manual provided with each Protego System for adjusting Articulating arms.

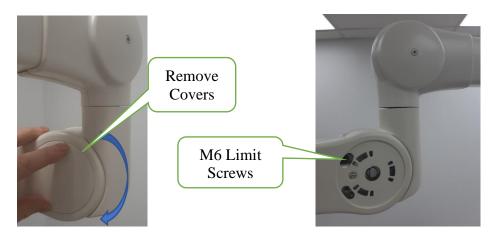
5. Site Installation Instructions

5.1. Crate Unpacking performed by crate shipping company staff.

5.1.1. The boxed crate(s) have been unloaded and the Protego System has been removed from crate and all components including boxes are at a designated location for Lab Room install.

5.2. **IDI Representative Lab Installation:**

- 5.2.1.IDI Rep. tools needed: Utility knife for boxes. Allen Wrench sets for English and Metric.
- 5.2.2.Remove any leftover packing materials from Mobile Stand.
- 5.2.3.Remove the Limit Screw (Black M6) from the Mobile Stand Arms.



5.2.4.Roll MRS forward and set the labeled directional cast and lock, this will allow easy turning and directional travel.



5.2.5.Mobile Barrier accessory positions for reference when unpacking patient Kit from Box or Bag. Remove Arm Boards and shields and place on Mobile Barrier door hangers to move to lab.



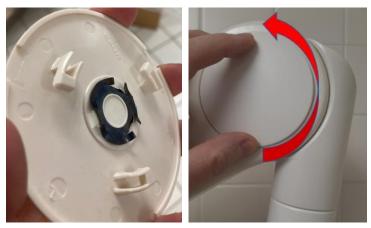
- 5.2.6.Move Mobile Stand, Mobile Barrier, remaining table shields and disposables to room for Protego Setup & Operator and staff Procedure review per following documents by IDI sales representative.
 - L800-0168 Q-Card, Protego, Mobile Attach to Mobile Stand handle
 - L800-0170 Protego User Manual
- 5.3. Additional positioning and adjustment details. Optional placement up to IDI Rep.
 - 5.3.1. Room placement for Item 1 (MRS) with Item 6 (RSB) attached.
 - 5.3.1.1. Roll and locate MRS with RSB attached facing left side of table as shown below. The center of the column should be about mid-line to the black knob lock on left table side rail assembly, Item 5. By releasing safety and lock knob, adjust MRS column up to top position on column, reset safety pin and tighten lock knob, Lock at least two castors. Future floor position markers will be needed.







- 5.4. Adjusting vertical arm limit/spring force and arm brake adjusts These settings were set at factory and should not be needed but if there is a need for additional adjustment during product use. Refer to OASYS Healthcare Instructions Spring Arms Manual document provided with product which contains tools needed for adjustments. A basic outline is provided below.
 - 5.4.1. **Removal of Spring Arm Covers for adjustments on A800-0185 RSB angle and loads.** References from OASYS Manual 4041013 are listed below. Removing the rotational covers on both ends of the spring arm. Covers are installed by pressing them into the designated slots and rotating clockwise.



Removing Covers

The following figure numbers listed below are from the OASYS Manual!

In order to access the spring arm to carry out load, parallel, and vertical adjustments, as well as access for cable routing, you must be able to remove the plastic covers surrounding the spring arm.

Removal: (Refer to Figure 11 - Figure 13)

- Remove the plug covers [1] first by rotating each one counter clockwise until you hear a *click* and removing them from the spring arm main covers [2].
- 2. Remove the screws [3] from one main cover using a **2.5mm Allen Key** and pry the first cover off.
- Remove the screws from the second main cover and remove the final cover. Be sure not to damage the sliding flap covers [4] when removing the main covers.
- 4. In order to remove the nose cone [5] and the safety plug [6], use a **2mm Allen Key** to remove the screw [7] of the locking key door cover [8].
- 5. Rotate the nose cone 180° so that the slot in the nose cone [9] lines up with the slot in the stem [10]. The locking key should be exposed (refer to Figure 12).
- 6. Using a small flat head screwdriver, remove the locking key [11] from the groove in the device end stem.

Locking Key: The locking key is a safety mechanism that supports the weight of the end device inside the spring arm. The locking key is necessary in order to fasten any end device to an OASYS spring arm.

Once the locking key has been removed, slide the safety plug out from the device end.

Installation:

- In order to install the plastic covers, carry out the preceding Steps 1-6 in reverse.
- Do not attempt to install the main covers with the sliding cover flaps installed.
- Leave the flap covers extended (as seen in Figure 13), raise the spring arm to its highest and lowest positions and slide each flap into its groove when all other plastic covers have been assembled.

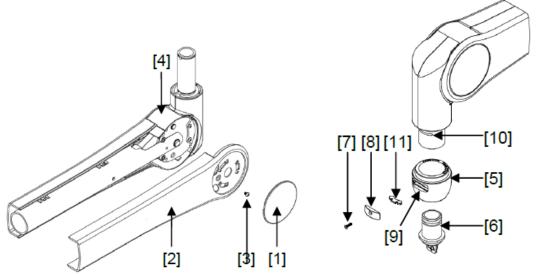
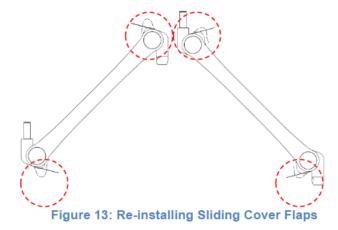


Figure 11: Removing Spring Arm Main Cover

Figure 12: Removing the Nose Cone and Safety Plug



5.4.2.**Load Adjustment.** Refer to Figure 26 from OASYS Manual 4041013 listed below.

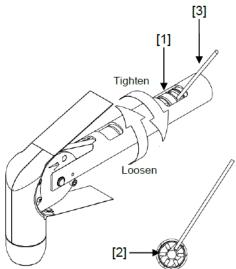


Figure 26: Spring Arm Load Adjustment

In order to carry out load adjustments, observe the following instructions (refer to Figure 26):

 Ensure that the main covers of the spring arm have been removed and the end device has been installed to the spring arm (refer to Installation/Removal of Covers in Section 4.4 for instructions for removing covers of different spring arm types).

While performing a load adjustment, it is recommended that you compensate for the removal of the covers by adding an equivalent to a 1lbs. weight (equal to one side cover being hung, see Figure 27) at the end of the spring arm.

- Locate the load adjustment window [1] in the spring arm body and the load adjustment nut [2]. (Depending on its initial calibration, the spring arm may have to be moved upward or downward to bring the nut into view.)
- 3. Insert the adjustment tool [3] into one of the holes on the nut.
- If the spring arm has a tendency to drift downwards, the spring tension is too low. Tighten the nut until the drift is eliminated and the spring arm supports the load evenly.
- If the spring arm has a tendency to drift upwards, the spring tension is too high. Loosen the nut until the drift is eliminated and the spring arm supports the load evenly.
- 5.4.3. Parallel Adjustment. Refer to Figure 29 & 30 from OASYS Manual 4041013

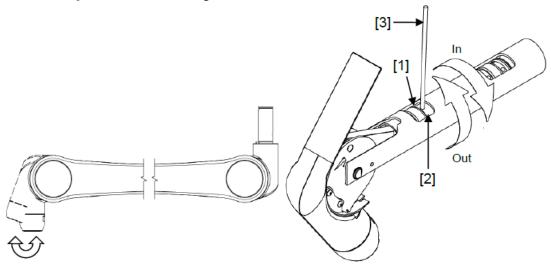


Figure 29: Spring Arm Parallel Adjustment

Figure 30: Spring Arm Parallel Adjustment

5.4.4.**Brake Adjustment.** Refer to Figure 32 from OASYS Manual 4041013 listed.

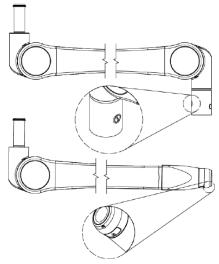
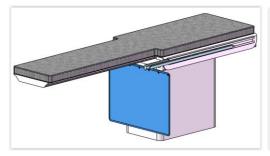
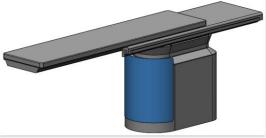


Figure 32: Locations of Brake Screws on Spring Arms

In order to carry out brake adjustments, observe the following instructions (refer to):

- 1. Ensure that the adaptor or end device has been installed.
- Locate the brake screw on the spring arm.
- On an OASYS LCH spring arm, the brake screw is located in the nose cone.
- On an OASYS 3001 spring arm, the brake screw is located on the device end stem.
- Using a flat head screwdriver or a 3mm Allen key, tighten the brake screw to stiffen the end device's movement or loosen the brake screw to loosen the end device's movement.
- 5.5. Using wrench, tighten brakes on horizontal arm before first adjusting vertical arm. Adjust set screws to bring brake tension on vertical arm rotation point by turning clockwise to tension. Move arm in different locations and look for arm movement/floating. Tighten each set screw equally to a point just beyond stopping arm movement as needed, this can be at IDI Rep discretion.
- 5.6. Attaching Item 7, Pedestal Shield Five Versions Rail or Velcro attachment
 - 5.6.1. For Siemens large width tables. Slide onto rail and center with table base. Lock with small knob.
 - 5.6.2. For **Philips, Toshiba, and GE** tables which use Velcro attachment. Hook Velcro strips need to be put on the table base inside cover at center from top edge.

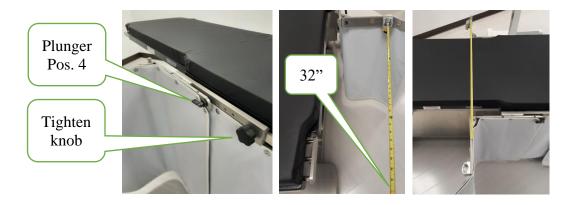






5.7. Attaching Items 4 & 5, Right & Left-Wing Shields to Table rails.

- 5.7.1.Using the existing table rail found on both fixed and mobile tables. Remove all existing accessories from table rails. These will be returned to the same positions on new rails for Items 2/3.
- 5.7.2.Remove Items 4 & 5, Right & Left Rail Slide Assemblies from MB (Item 8) or from box. and slide onto right and left side table rails. Unfold magnet extensions by pulling down corner plunger, both sides, swing out and lock to 90-degree extended angle. Set slide rail plunger at fourth hole for average patient waist center. The slide rail has 7 adjustment positions.
- 5.7.3. Tape measure from table head end position to magnet locks, the parallel table distance should be around 32 inches for starting position. Tighten lock knob to table rail both sides, magnet should be in line cross table. Further adjustments to this position may be needed later when patient waistline to magnet lock position is set.



5.8. Attaching Item 2/3, Table Side Rail Shields (Qty 2 for right & left table rails)

5.8.1.Remove assemblies from storage rail on MB (Item 8) or box. Slide Items 2/3 onto table rail and butt up to the previous Item 4 & 5 assemblies. For permanent installation there are five set screws, at least two must be locked into the existing table rail, see **WARNING**. If Protego is to be moved from room to room, then Allen wrench must be used to retract set screw(s).



WARNING: A least two set screw on Items 2 and 3 must be secure to rail for table use. Possible injury may occur if shield assembly slides off. There is a restriction that Trendelenburg motion cannot be used. Use of the table ability to move in the Trendelenburg angles by staff can be dangerous.



5.7. MRS, Item 1, Floor Position Setup

5.7.1.Remove strap for moving Item 1 (MRS) used to hold Item 6 (RSB). Rotate RSB to cross table position to attach to magnet rail locks. Secure RSB to magnet locks by turning locks 180 degrees to Green for locking. There is an adjustment slide on the left-Wing Shield on Item 5 for magnet alignment issues. Loosen slide knob, position so that leveling foot drops within magnet lock block and then tighten knob. This knob position will then be set for future procedures. Adjustment can be reset anytime.







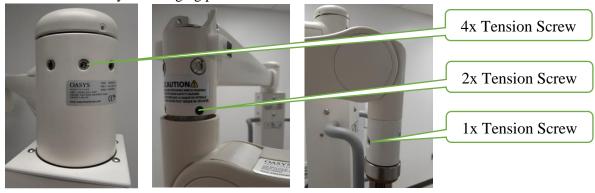
Left side magnet adjust / Magnet turn lock knob.

7.7.1.Table panning adjustment of Mobile Stand, Item 1, to floor position for Fixed and Mobile Tables. Because tables can pan/float in a rectangular area of space with table movement, the articulating arm must have full movement for the panning motion. The Mobile Stand may need to be repositioned for this to happen. After adjustment is made for full panning, lock casters and mark the floor with tape at Mobile Stand caster positions. This will enable future placement in the same position if the system is moved.



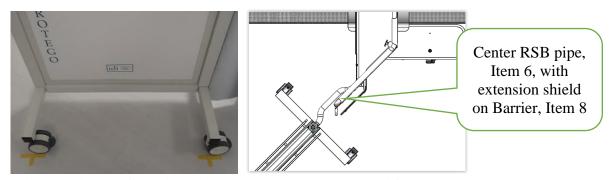


WARNING: Issue of table panning tension, pre-set at IDI. The shield radiation barrier which is attached to the magnet locks crossing patient table may add a higher-than-normal pull tension during table panning. To reduce this tension, adjust the 6mm screws for braking on the articulating arms in 3 location, 4 screws at top column, 2 screws at center arm to arm, and 1 screw at spring arm end. End covers would need to be removed for center arm to arm location for adjustment. Adjustments should not be made where barrier wanders at stationary free hanging position.

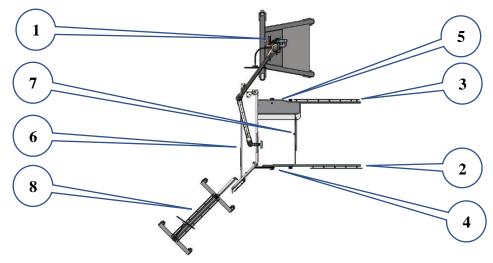


7.8. Mobile Barrier Usage, Item 8

7.8.1.The Mobile Barrier, Item 8, is used as an extension radiation barrier for enlarging the safe zone radiation protection area when rolled to right side of RSB, Item 6. No connection is needed, just roll to extension center at 45-degree angle to table when table panning is centered and lock the two casters at same angle as RSB (Item 6). Barriers are also used as an accessory cart for holding the table rail shield assemblies when not in use. Floor tape may also be used to show proper location during procedure before Mobile Barrier is moved for patient transfer or storage.



7.8.2. Final top view configuration with product components attached for procedure.



6. Instructions for Operation & Usage

6.1. For Protego instructions for proper usage with patient shielded drapes and disposable sterile products, please see L800-0170 Protego User Manual.



At least two Casters must be fully Locked while system is in use or in storage.



Do NOT move cart over cords or uneven, soft, or sloping surfaces. Failure to comply may result in cart instability leading to equipment damage or personal injury.



For Mobile Radiation Stand use: Use handles to move cart with the help of an assistant to avoid collision with other equipment and walls.

7. General Cleaning

7.1. For Protego instructions for proper cleaning, please see L800-0170 Protego User Manual.