



Protego® Ceiling Mounted Radiation Protection System – User Manual



INTELLIGENT DESIGN
► *TANGIBLE OUTCOMES*



This document should be retained with, or in proximity to, the Protego Radiation Protection System and readily accessible to the medical team operating the system.

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Patents

The Protego Radiation Protection System is protected in the United States under U.S. Patent No. 10950359 B2; U.S. patent number 8807138; U.S. patent number 8716687; U.S. Patent No. 7057194 B2; owned by ECLS Inc. Image Diagnostics, Inc. has been granted licensed manufacturing rights by ECLS. Additional pending patents.

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Important Notices



PROTEGO SYSTEM SHIELDING IS DESIGNED FOR USE IN ENVIRONMENTS WHERE DANGEROUS RADIATION IS PRESENT. READ, UNDERSTAND, AND FOLLOW ALL INSTRUCTIONS AND WARNINGS PROVIDED IN THIS OPERATOR'S MANUAL AND ON PRODUCT LABELS. FAILURE TO READ AND FOLLOW ALL WARNINGS AND INSTRUCTIONS CAN RESULT IN SERIOUS INJURY OR DEATH.



RADIATION EXPOSURE IS DANGEROUS AND CUMULATIVE. THE PROTECTION AFFORDED BY THE PROTEGO RADIATION PROTECTION SYSTEM CANNOT REDUCE THE AMOUNT OF RADIATION TO WHICH AN INDIVIDUAL HAS ALREADY BEEN EXPOSED OR UNDO ANY DAMAGE AN INDIVIDUAL HAS ALREADY SUSTAINED FROM PREVIOUS EXPOSURE.



DO NOT USE THE PROTEGO RADIATION PROTECTION SYSTEM WITHOUT A REAL-TIME DOSIMETRY DEVICE TO MONITOR RADIATION EXPOSURE LEVELS AND PROTECTION. FAILURE TO MONITOR RADIATION EXPOSURE LEVELS WITHOUT THE REAL-TIME DOSIMETRY METER IS A MISUSE OF PROTEGO RADIATION PROTECTION SYSTEM AND CAN RESULT IN SERIOUS INJURY OR DEATH.

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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 Image Diagnostics, Inc. (IDI) and is only for use for and by IDI representatives or their Agents.

OVERVIEW

This manual pertains to the specified devices only and does not intend to replace or substitute for certified training in the application of this equipment. The device is intended for qualified medical personnel who have been trained in the use of medical equipment and have been thoroughly advised by the facility physicist and Radiation Safety Officer (RSO). The use of the Protego during an intervention in absence of lead aprons is the responsibility of the facility and RSO. The safety processes must be defined by the facility.

Functional capabilities and operation of the equipment described herein can be employed in a variety of diagnostic, therapeutic, and surgical applications.

OWNER RESPONSIBILITIES

The owner of this device is responsible to ensure system compatibility and the qualifications of the operator and maintenance personnel. The operator must be properly trained and have obtained credentials from the appropriate authorities.

The owner of this device is responsible for verifying continued compliance with all applicable state, federal and/or international agencies regulations and standards regarding radiation safety and should define and train the interventional staff when using this equipment to go Apron Free.

IDI certifies only the equipment. After-sale operating practices and safety are the responsibility of the owner and operator. IDI assumes no liability or responsibility for after-sale operating or safety practices; nor can it be responsible for personal injury or damage resulting from misuse.

Never make modifications or adjustments to the equipment unless directed by a qualified representative of IDI. This equipment, when properly assembled, meets US federal regulations and standards. Unauthorized modifications to the equipment may impact adherence to these standards and make the equipment unsafe to operate.



WARNING: Failure to use Protego Radiation Protection System as intended may cause permanent injuries as the result of radiation exposure. Consequences of radiation exposure may include tumors, cataracts, thyroid disease, cardiovascular effects, and other health problems, possibly leading to debilitation and death.



WARNING: Elimination of personal protection devices and apparel in a radiation exposure environment should **ONLY** be allowed with proper protection, real-time dose monitoring, and the approval of the facility Radiation Safety Officer (RSO). Removal of personal protection devices and apparel in a radiation exposure environment **MUST** be done **ONLY** in accordance with hospital radiation safety policy and protocols and as permitted under applicable state, federal and/or international agencies radiation safety regulations.



WARNING: The use of the Protego Radiation Protection System is predicated on the use of a real-time dosimetry system. IDI will not allow the deployment of the Protego Radiation Protection System in the absence of real-time dosimetry. If the healthcare facility does not already own a real-time dosimetry system, one can be purchased through IDI or another source.



WARNING: Any radiation exposure accumulated by healthcare personnel throughout their careers and lives is not impacted by the Protego Radiation Protection System. Previous radiation exposure remains a risk to the healthcare provider. When used properly, Protego Radiation Protection System can significantly reduce radiation exposure for the Interventionalist and staff. However, this product does not and cannot reset existing or historical exposure conditions or prevent the potential health risks associated with that exposure. Annual and lifetime radiation dose guidelines only reduce the risks associated with radiation exposure. There is no “safe level of exposure.” There are only varying degrees of risk.

CUSTOMER SUPPORT

IDI will make available, on request, radiation testing results, component part lists, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

For technical assistance, call IDI at (978) 829-0009. Be prepared to give the complete model and serial number found on the data plate on the Drop Tube above Ceiling Arms.

This Personnel Protective Shield component is manufactured by IDI complies with applicable FDA performance standards contained in 21CFR Sec. 892.6500 at date of manufacture.



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APRON-FREE™ IMAGING

The Protego Radiation Protection System by IDI provides radiation protection for approximately half the Cath lab space. Testing has determined that the Protego System provides enough radiation protection that it may be used in lieu of lead aprons and other protective devices provided that state, federal and/or international agencies regulations have been met. The following recommendations can be used to develop a successful radiation safety program to go Apron-Free with the Protego Radiation Protection System.

- Product Training:** Staff trained by Image Diagnostics personnel, or authorized representative, for safe use of the Protego Radiation Protection System will be required to sign an in-service training sheet. The RSO should contact the States Governing Regulatory Body for the safe operation of fluoroscopic devices in an interventional suite without wearing lead aprons. Data and specifications may have to be submitted to obtain approval of Apron Free Interventional use.
- Apron-Free Safety Protocol:** The Radiation Safety Officer (RSO) must establish, implement and oversee a process for Apron-Free Interventions including defining the safety coverage zone and identifying the staff positions that can safely work in an apron-free environment.
- Set Benchmark Exposure Reading:** Set by the Radiation Safety Officer (RSO), this is the maximum exposure level at which staff are required to put their lead back on.
- Monitoring and Recording:** It is suggested that Dosimetry badge readings for the first 40 cases be recorded on the data sheet provided by IDI and reviewed by the RSO.
- Map the Room:** It is recommended that the facility's Radiation Safety Officer or other responsible party within a facility "map" the room during clinical procedures and at various common angles in cine and fluoro mode to identify safe and unsafe zones of operation. Once established, these zones should be clearly and permanently marked on the floor to guide personnel. IDI can provide a mapping protocol for reference.
- Update Radiation Safety Protocols:** Protocols shall include but are not limited to management of real-time dosimetry badges (placement, monitoring, data review, and documentation); designation of authorized apron-free personnel; establishment of defined radiation safety zones; verification of badge use; and procedures for emergent release and radiation overexposure, all in compliance with institutional and regulatory standards.
- Safety Inspections:** The Protego Radiation Protection System shall be incorporated into all existing radiation protection equipment safety inspections conducted on a regular basis. Additional inspection protocols may be established and implemented at the discretion of the facility Radiation Safety Officer, Physicist or other designated staff.
- Legal Considerations:** The path to Apron-Free™ imaging shall include compliance with all applicable governing bodies at the state, federal and/or international agencies, as these regulations may ultimately impact decisions regarding the performance of procedures without personal radiation protection devices.



Real-Time Dosimetry Badges show real-time radiation exposure levels in severts or mRems. Micro dose levels above the point of stimulation are displayed numerically and visually. When there is a high reading, adjustments in shielding should be made immediately to reduce the exposure to meet facility guidelines. Do not continue with intervention until the radiation exposure is reduced to at least meet facility guidelines. Real-Time Dosimetry Badges are used *in conjunction with* lifetime radiation exposure badges.



CAUTION: A 0.0 mrem reading from a real-time dosimetry system does not necessarily mean that no radiation is present. Such a reading indicates that the radiation level is below the threshold ($<30\mu\text{Sv/h}$ detection limit) for the real-time dosimetry equipment to detect the presence of radiation.



Real-Time Dosimetry Badges are directional in nature and the face of the badge should be facing the source of radiation.

SYMBOL IDENTIFICATION



Attention! Consult accompanying documents. Failure to follow these instructions could cause serious personal injury or damage to equipment.



WARNING: Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which if not avoided, could result in death or serious injury.



CAUTION: Information or instructions shown near this symbol must be adhered to in order to prevent a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or equipment damage.



There is the potential of exposure to harmful x-rays. Be sure to read and comply with all warnings.



Recyclable material



Not made with natural rubber latex



Waste Electrical and Electronic Equipment compliance



Device serial number



Device model number



Unique device identifier



Location where device was manufactured



Medical device



Device date of manufacture



Read the manual



Use proper electrical power source



Maximum vertical arm support system lift load



Critical instructions for administering CPR

ETL CLASSIFIED



Intertek
60563

ETL CLASSIFIED



Intertek
60563

Testing Agency Approval Logos

INTENDED USE

The Protego Radiation Protection System is a series of shields that significantly mitigates radiation exposure from the personnel working in Interventional Hybrid or EP suites, thereby improving safety. Protego is a whole-body protection radiation protective barrier shielding Interventionalists and Staff in defined areas from exposure to primary, secondary, and scatter radiation.

Subject to validation from the hospital physicist or Radiation Safety Officer (RSO), and in accordance with state, federal and/or international agencies regulations. The Protego can create an environment that obviates the need to wear aprons. The Protego shielding construct utilizes overlapping shield panels ranging from 0.25 up to 0.5mm which when combined can provide up to 1.25mm lead equivalent (LE) in the high exposure areas. When properly installed and positioned, shielding construct can reduce exposure levels to the point where apron use is unnecessary.

It has been well documented that prolonged use of lead aprons contributes to workplace orthopedic injuries. Therefore, it is critically important that staff understand the defined safe coverage zones and follow established procedures when operating in unsafe zones. This includes protocols for emergent situations that ensure continued protection and compliance.

This manual should be accessible to all personnel who install, operate, or service this equipment. All personnel operating this equipment shall be required to fully understand its operating instructions, be familiar with established emergency procedures, and remain aware of all potential safety hazards. The use of the Protego requires the use of a real time dosimetry system that provides instant feedback on cumulative radiation exposure.

Notice to Users: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State/Country in which the user and/or patient is established. Please include the revision of this user manual and the serial number of the device located on the Drop Tube above the Ceiling Arms.



CAUTION: Only a qualified technician can install or service this equipment.



CAUTION: Failure to follow safety precautions may result in serious injury to user, patient or damage to equipment.



CAUTION: The Protego Radiation Protection System must be inspected regularly per the institution's radiation safety policy to ensure essential performance functions that would pose a risk due to failure or degradation of the unit or any of its components.



WARNING: Prior to installation and servicing the Protego Electrical Enclosure located in the ceiling, the 120V circuit breaker at the system's site supplying power to the Electrical Enclosure must be switched to the OFF position.

It is imperative that all personnel operating the Protego Radiation Protection System be familiar with the equipment operation, transport, and all documentation supplied by Image Diagnostics, Inc (IDI).

The Protego Radiation Protection System is intended to be used in a healthcare facility setting in accordance with national and international standards.



Comments and questions regarding safety should be addressed to:

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ELECTROMAGNETIC COMPATIBILITY (EMC) STATEMENT

Class B device.

Mobile RF Communications Equipment will not affect the Protego Radiation Protection System, which is a non-electrical system. No special precautions are needed regarding EMC when Protego Radiation Protection System is installed, operated, and maintained.

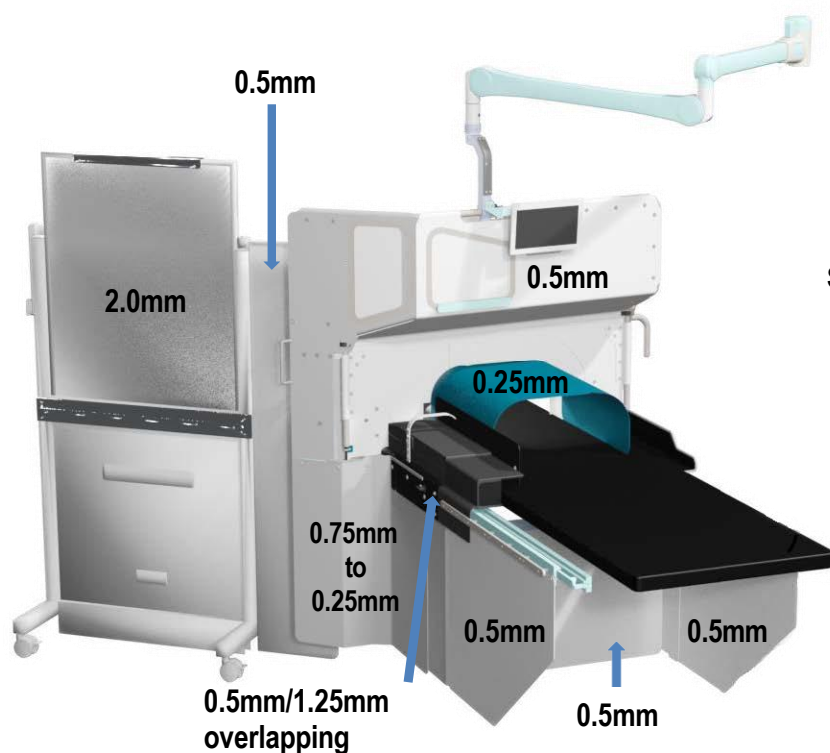
PRODUCT DESCRIPTION

The Protego Radiation Protection System is a comprehensive solution to mitigate radiation exposure to interventional healthcare providers and enhance safety for all team members in the cardiac catheterization labs. The System mounts directly to the imaging table and pans with table, allowing for unhindered femoral and radial access. Protego transfers the debilitating effects of wearing heavy lead aprons that provide incomplete whole-body coverage at a higher lead equivalence (LE). The Protego system provides a platform for the entire interventional team to operate Apron- Free™*.

**Procedure parameters for Apron-Free™ imaging at your facility must be defined by your Radiation Safety Officer or facility physicist as well as comply with hospital, state, federal and/or international agencies regulations.*



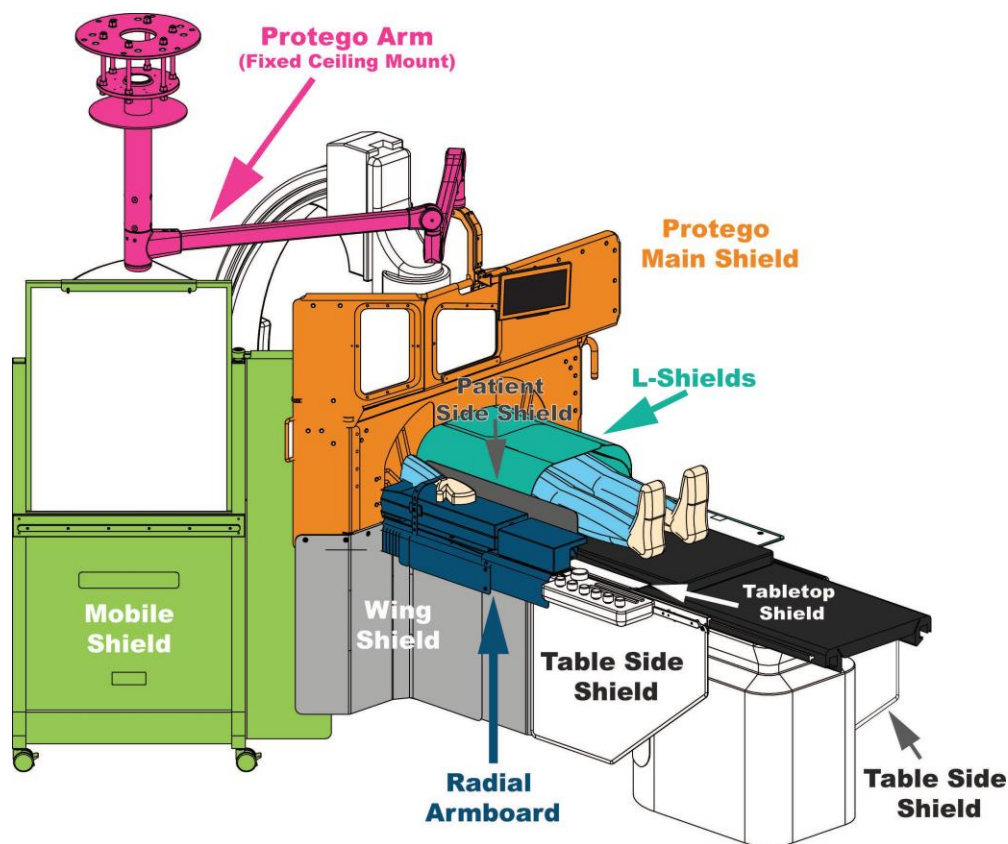
HOW THE PROTEGO STANDS OUT:



Shielding pieces' lead equivalencies range from **0.25mm to 0.5mm**

IDI's unique overlapping design equals **a total of OVER 1.25mm LE** in high exposure areas

GENERAL DESCRIPTIONS FOR SYSTEM COMPONENTS



Protego Main Shield

The Protego Main Shield is the heart of the system. Blocking scatter radiation coming from the patient, the shield has an aperture designed to accommodate a wide range of patient sizes and shapes. The Main shield pans and elevates with the table due to the unique magnetic connecting system reducing workflow disruptions and protecting the access point. The unique shape of the shield and its built-in flexibility, with pivoting feet and a jointed connection to the swing arm, allow for unhindered C-arm movement without shield manipulation during the procedure. Lead acrylic windows and built-in HD camera system allow for patient and C-arm position visualization. A patented shape and aperture maintains an overlapping construct for optimizing steeper angles without disruption. Lead equivalence is 0.5mm.



Side Shields

The Side Shields are bilateral and extend protection to the end of the table. They offer 0.5 mm lead equivalence and overlap the Wing Shields to increase the effective lead equivalence and to help ensure reliable shielding during cases. These shields slide onto the table's rails and are equipped with rails for equipment and accessories. They are secured by tightening the set screws located along the shields block under the rail with the smaller, yellow-handled tool included with your Protego.



Wing Shields

The Wing Shield overlaps the side shield and accommodates steep angles when the tube projects outside the table footprint. The wings have a security magnet nest that is used to passively connect the Main Shield to the table to enable panning. The Wing Shield has a “slide” feature which allows for up to 8” in movement that can relocate the shield on the patient to increase access or accommodate steeper angles.

Right Wing Shield provide a staggered LE design that reduces added table weight. In areas with higher levels of scatter and direct radiation, the shield delivers 0.75 mm lead equivalence, tapering to 0.25 mm in lower-exposure regions and is one part of the overlapping system. Left Wing Shield is 0.5mm lead equivalence.

In some cases, the left side may be released to increase the possible angulation range as well as accommodate the C-arm drive system.



Pedestal Shield

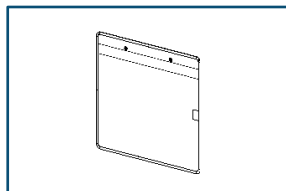
Pedestal Shield is included with each System and install first. This shield remains on the table between cases. The Shield is used to block scatter radiation from traveling down the length of the table. Styles include: Velcroed for rounded pedestals, adjustable hanger or a shield added to existing pedestal rails. Lead equivalence is 0.5mm.



Siemens



Philips



Toshiba

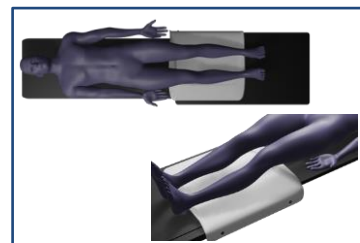


GE

Tabletop Shielding

TABLETOP SHIELD

The Tabletop Shield rests on the tabletop, under the tabletop pad. It is positioned under the patient's thighs to protect from tube scatter as it travels through the patient and under the table. Place this shield on top of the table before placing the tabletop pad and then placing the patient. When possible, cascade this shield over the PT right side for better radiation protection. It should be offset toward the clinical side. Lead equivalence is 0.5mm and dimensions are 26" x 32".



L-SHIELDS

The L-Shields are the primary patient scatter shields. L-Shields overlap each other and transcend down to the patient's knees. For radial approaches, L-Shields are overlapped to form a square. For femoral/groin approaches, rotate the L-Shield to create a “U” shape. These shields overlap the Tabletop Shield, Armboards and the primary aperture. Lead equivalence for each L-Shield is 0.25mm and the dimensions are 24" x 24".



Radial Armboard

The Radial Armboard is divided into two sections for improved handling and storage. The left side section is padded and provides a surgical interventional platform. A staggered overlapping concept on Radial Armboard provides lead equivalence from 0.5mm up to 1.25mm. An integral palm restraint keeps the patient's palm stabilized. There is a removable shield section that provides visualization of the right heart via a brachial approach. Each piece overlaps the side and wing shield. (See page 18 for brachial access details for the patient's arm).



Patient Side Shield

Patient Side Shield adds secondary layer of personnel protection in the patient primary scatter area. Place this shield upright along patient's right side overlapping Armboard vertical shield panel with the end in patient's armpit. Lead equivalence is 0.5mm and the dimensions are 7.5" x 32".



Left Armboard

Left Armboard is used under the patient's shoulder for support and added table shielding. Align the top of the Armboard to fully support the patient's upper elbow. Ensure the Armboard is placed far enough toward patient's feet to avoid imaging artifacts while using steep angles. Lead equivalence is 0.5mm and the dimensions are 11"W x 32"L x 4"



Flexi-Shield

The Flexi-Shield is made with an insert panel that is malleable enough to be bent into the shape you need and rigid enough to maintain that form. One is included with original system and are also sold separately. Lead Equivalence is 0.5mm and dimensions are 14" x 24"



Shown flat and bent.

Mobile Shield

Shields the back table for potential scatter and expands the coverage area on the clinical side of the room and for steep LAO angulations. Mobile Shield has a patient viewing window for patient visualization. Mobile Shield also act like a trolley storage cart for products that come off the table between cases (Arm Boards, Shield Panels) as well as for transporting the system to another lab. The Mobile Shield is rated at 2.0mm lead equivalence, and the attached extension shield is 0.5mm lead equivalence.



Dosimetry Reading System – Optional but highly recommended

The Real-Time Dosimetry System monitors and records exposure levels in real-time, communicating the levels visually, audibly, or otherwise. Product can be viewed on cell phone, a monitor or centralized collection point. The Badges are directional and must be placed on each person situated to face the radiation source. Refer to the dosimetry system manufacturer's instructions for use (IFU) and ensure all team members adhere to them.

RaySafe™ i3 is an example of an effective real-time dosimetry device available for purchase through Image Diagnostics Inc.

The RaySafe™ i3 is an active dosimetry system that provides immediate insights about radiation exposure, helping medical staff and physicians to evaluate and to actively take measures in the effective reduction of radiation. The RaySafe Real-time Dosimeter measures and records radiation every second. Data is transferred wirelessly to the RaySafe Real-time Display or Hub. RaySafe Real-time View visualizes radiation exposure in real time using easy-to-read, color-coded bar graphs displayed on either the dedicated RaySafe™ Real-time Display or your main X-ray monitor. Green, yellow and red bars indicate the dose rate for up to eight individuals. Instant feedback empowers users to learn, adapt, and take immediate actions to minimize unnecessary radiation exposure. Each badge records the total exposure for the given time frame.



Supplemental Disposable Drapes

PROKIT

One ProKit contains the three sterile drapes needed for one procedure: one Main Shield drape and two L-Shield drapes.



MONITOR DRAPE

Use Monitor power button to turn on when system is powered. The power button is on the bottom, right side. Expect 45 to 60 seconds to boot. Tap screen to toggle through left, right and split screen views.



DISPOSABLE FEMORAL SHIELD

Proprietary design, single-use radiation protection for femoral access. Lead equivalence is 0.25mm.



DISPOSABLE RADIAL SHIELD

Proprietary design, single-use radiation protection for radial access. Lead equivalence is 0.25mm.



DISPOSABLE FEMORAL SHIELD

Single use sterile drapes for L-Shields. Draping the L-Shields requires two people.

(See page 20)



Drapes Opened



Drapes Unopened



SYSTEM INSTALLATION SETUP OVERVIEW

1. Install Pedestal Shield. ([See page 11](#))
2. Place the Tabletop Shield under the tabletop pad so it is aligned under the patient's thighs. ([See page 11](#))
3. Install the Table Side Shields, leaving at least 5" of exposed rail and secure with the Allen wrench. ([See page 11](#))
4. Install the Wing Shield and align to the patient umbilicus. ([See page 11](#)). Remove or slide the Wing Shield on the egress side on the outside rail.
5. Place the Left Armboard. ([See page 12](#))
6. Locate the Radial Armboard such that the wing strut bisects the first smaller width black leaflet. Note the location and remove and store prior to patient loading and positioning. ([See page 11](#))
7. Note the placement of the equipment. Remove and store it so the patient can be loaded.

DETAILED INFORMATION FOR SYSTEM COMPONENTS

PEDESTAL SHIELD

When setting up the Protego System, the first piece to be installed is the Pedestal Shield. With most systems, the shield mounts to the pedestal rail. For systems without pedestal rails, VELCRO® is used to attach the Pedestal Shield or Hanger used between table supports. This shield remains on the table between cases.



TABLE SIDE SHIELDS

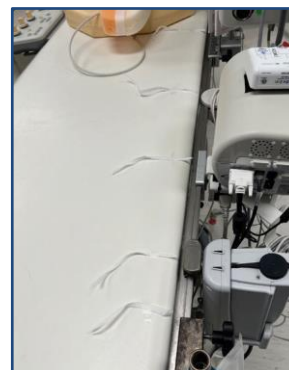
The Table Side Shields (left and right sides) help create a wall of protection. They remain on the table between cases.



INSTALLING TABLE SIDE SHIELDS

1. Take a picture or make note of the placement of the equipment mounted to the patient-left rail of the imaging table. Alternatively, use temporary markings.
2. Remove equipment mounted to the patient-left rail of the imaging table.
3. Slide the Side Shields onto the foot-end of the table rails, leaving 5" of table rail open at head-end for mounting the Wing Shields.
4. To secure Table Side Shields to the rail, use the 1/8" Allen wrench included with your Protego to tighten (or loosen when changing position on the rail or removing) the 5 set screws are found behind the Side Shield rail.

NOTE: Leaving the Side Shields a little loose on the rail will make it easier to reconfigure the shields when necessary, during setup. Be sure to lock them in place once you find your positioning. Not tightening these screws could result in equipment sliding off during procedure.



Take a picture of the equipment on the table rail before removing or use temporary markings to aid in returning items to their proper place.



Leave at least 5" of space on the rail when placing table side shields, to make room for Wing Shield.



Secure Table Side Shields to rail by at least 2 of the shield's 5 set screws found behind the Side Shield rail (see picture to the right). Possible injury to personnel or the patient may occur if either side shield slides off the rail.



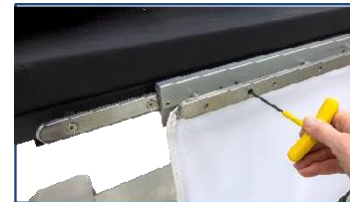
Use the 1/8" Allen wrench included with your Protego to engage or retract the shield's set screws to secure or release from the table rail.



The Protego Radiation Protection System reduces the ability to use steep Trendelenburg.



Leave at least 5" of rail exposed when adding Side Shield



Use tool to tighten (or Loosen) set screws behind rail to secure to table rail

WING SHIELDS

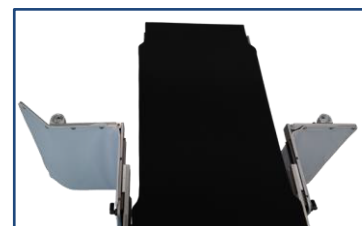
The Wing Shields are critical pieces of the system which connect the Protego Main Shield to the table, allowing for easy panning. They can be slid on the outside rail for patient egress or stored on the mobile shield rail.



For right-side patient transfer, the patient-right Wing Shield is stored on the Mobile Shield's rail

MOUNTING WING SHIELD TO TABLE

1. Remove Wing Shield from the storage location and slide onto table rail.
2. Secure/lock using the rail knob, Ensure the black lever faces PT feet.
3. Pull down the corner release knob and swing the wing out until it locks into place at 90° angle.
4. Set the shield's slide feature to halfway point to allow adjustment movements in either direction and set the Wing Shield magnet lock to green (locked).
5. Repeat the same actions for the other Wing Shield.



Wing Shields mounted on table extend protection for LAO and ROA angulation



Remove Wing Shield from Mobile Shield



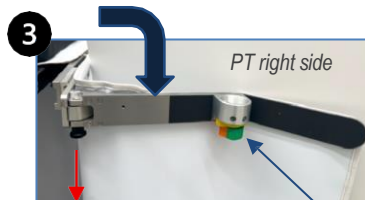
Slide Wing Shield onto table rail



Tighten knob to secure wing to rail



Ensure lever faces PT feet (Unlocked) to allow for slide adjustment



The corner plunger pulls down to swing out 90°

The Magnet Lock connects the Protego Main Shield to the Wing Shield



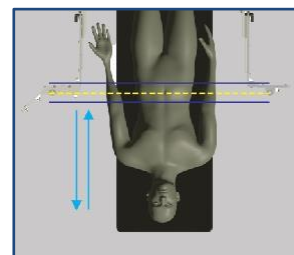
Locked

PATIENT UMBILICUS AND WING SHIELD ALIGNMENT

Wing Shield placement on the table must accommodate lining up with the patient umbilicus, and at transfer the patient's umbilicus must align with the Wing Shields. The Protego Main Shield attaches to the Wing Shields in this plane, making proper positioning of the patient critical for ensuring adequate surgical access, radiation protection, and patient comfort.



Align to umbilicus



WING SHIELD SLIDE FEATURE

The Wing Shield slides 8" down the length of the table.

Turn black Slide Release Knob 90° to PT feet to unlock. Gently pull/push the wing shield to your desired location.

NOTE: Always have the Slide Release Knob **unlocked** (toward the patient feet). This will allow Wing Shield adjustment based on your patient positioning.



Wing shield provides 8" of additional lateral shielding.



Unlocked (preferred position)



Center black lever facing PT feet to easily slide in both directions.



Locked

WING SHIELD CONNECTION ADJUSTMENTS



Before sliding the Protego Main Shield toward PT foot end of the table via the Wing Shield.



To start the case, always have the Lock Knob facing the green side of the sliding Protego Main Shield toward foot end to table via the Wing

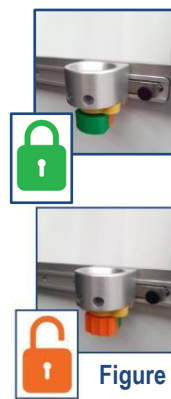


Figure 1



To Lock the Protego Main Shield to the Wing Shields, (**B - outlined in blue**) turn the knob 180° to show **Green** facing out. Place the connection foot (**A - outlined in light Green**) into the recess of the Magnet Lock (**B - outlined in Blue**). The magnet locks secure the Protego Shield to the Wing Shields. Remove the Main Shield by rotating knob 180° to Unlock position which will show in **Orange** facing outward (**Figure 1**) or lift upwards with about 5 lbs. of force.

Magnet locks are **Green when engaged (Locked)**. Rotate to **Orange to disengage (Unlocked)**.

NOTE: When magnets are engaged, the Protego Main Shield can be removed from the magnet locks with a strong, quick tug on the shield handles in emergent situations.

For very steep C-arm angles, the Protego Main Shield may need to be offset. There are two options. 1) Release the patient-left side Magnet Lock and allow that side of shield to float, or 2) unlock the Wing Shield from its 90° angle (**D - outlined knob**) and allow the wing to move.

NOTE: The Protego Main Shield connection feet allow for shield movement while it remains securely attached to accommodate C-arm positioning and table panning.



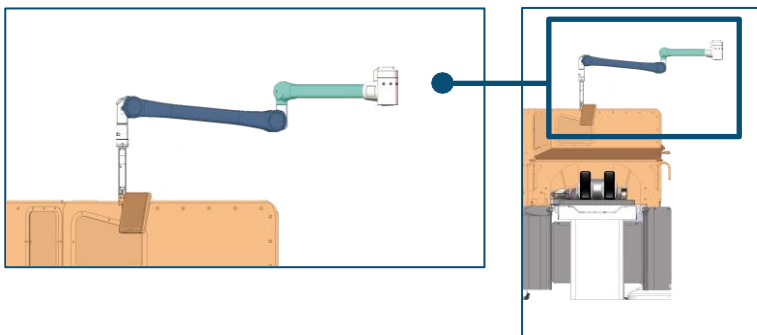
- A - Connection foot of the Protego Main Shield
- B - Magnet Lock of Wing Shield
- C - Locking knob for Magnet Lock positioning
- D - Release knob to unlock wing at 90°



WARNING: At least one side of the Protego Shield should be attached to the Wing Shields in order to create the proper radiation protection as well as table panning.

SPRING ARM POSITIONING

The Spring Arm is flexible to allow the Protego Shield to move in any direction, including up and down, with the imaging table.



POSITIONING THE SPRING AND FIXED ARMS

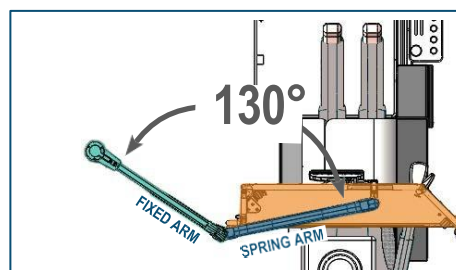
To ensure the Protego Main Shield pans properly with the table, the angle between the Fixed Arm and the Spring Arm will be 130° plus or minus 10 degrees. The arm can bend toward either direction (toward patient head or feet), depending on what works best with other equipment in the room.



WARNING: Start procedure with an approximate angle of $130^\circ \pm 10^\circ$ between the spring and fixed arms of the Protego Shield support system to ensure proper panning throughout procedure.



WARNING: Overextending the support arm center joint may prevent proper table panning.



BRACHIAL APPROACH

The Right Armboard provides a removeable section for visualization of the upper arm and elbow while performing right heart via a brachial access. Store the removeable Armboard section on the Mobile Shield hanger at window top.

When this patch is removed, use a Disposable Radial Arm Pad to prevent radiation leaks. Replace the section at end of procedure in Right Armboard.



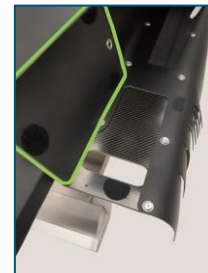
Removeable
Brachial Shield



Locate the removeable led section
under the Armboard pad indicated by
green circle.



Lift left-side Armboard
pad to find the
removeable led section (outlined in
Green in the image to
make it easy to see).



Removing led section
creates an opening
through which to X-ray the
brachial access area. Lift
section and store on the
Mobile Shield to replace
after the procedure.

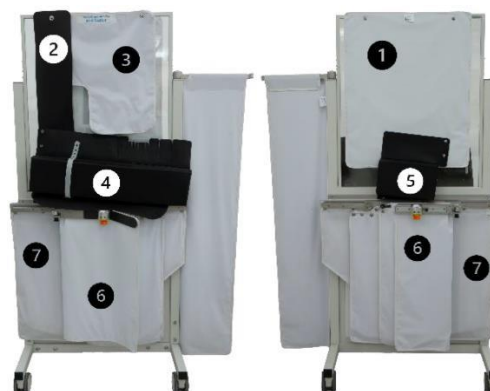


WARNING: ALWAYS use the Radial Arm Pad when the lead shield panel section of the Radial Armboard is removed.

MOBILE SHIELD FOR STORAGE

The Mobile Shield is equipped to store the pieces of the Protego Radiation Protection System both between cases and for transport into another room. Acts as a storage point for many Protego items between cases and when moving the system into another room.

1. **Table Shield** – peripheral cases and for transport
2. **Patient Side Shield** - between cases and for transport
3. **L-Shields** - between cases and for transport
4. **Radial Armboard** - between cases and for transport
5. **Radial Armboard Extension** - between cases and for transport
6. **Wing Shields** - patient-right side between cases, both shields for transport
7. **Side Shields** - both shields for transport



POST-PROCEDURE STORAGE OF PROTEGO SHIELD

When the patient procedure has been completed, it may be necessary to lower the table before removing the Protego Main Shield. The Protego Main Shield is connected to Wing Shields with magnet locks. Rotate lock knobs to **Orange to disengage**. The Protego Radiation Barrier can now be lifted straight up and then moved to the side out of the way of the interventional team. The sterile drape on the Protego Main Shield can be removed now or later and then disposed of in a proper manner.

After removing the Protego Shield, rotate the lock knob to **Green to engage** for next case procedure.



SYSTEM SETUP

1. Note the location of equipment mounted to the table rails. Remove this equipment for Protego System installation. Replace the devices in the exact location after the side shield has been installed.
2. Install Pedestal Shield.
3. Install the Table Side Shields onto the table rails leaving about 5" exposed table rail at patient's head end to mount the wing shields. Lock rail set screws using the tool included with the Protego after the Wing Shields have been mounted. The middle range slide function should be approximately 34" from the end of the table.
4. Ensure that there are nominal conflicts when placing and removing the Protego Main Shield.
5. Locate the patient's Left Armboard.
6. Locate the Radial Armboard such that the wing strut bisects the first smaller width black leaflets off Armboard overhanging shield. Note the location and remove and store prior to patient positioning.
7. Place the Tabletop Shield under the table pad so that it intersects the lower section of the L-Shields.
8. Remove the right-side Wing Shield and store on Mobile Shield until the patient is transferred to the table.
9. Drop the L-Shields into sterile bags and place them on the back sterile table. Drop the appropriate IDI radiation protection pad on the back table.
10. Store the Mobile Shield where conveniently available for case set up.
11. Place the egress side Wing Shield, Radial Armboard, Armboard Extension and Patient Side Shield after patient loading.
12. Place the patient's primary surgical drape over the patient and lower table.
13. Place the Protego Drape on the patient and open like a bed sheet being careful to open the drape per the arrows.
14. Raise the Protego Main Shield over the Protego drape being careful not to touch the patient drape, placing the shields aperture over the plastic seam of the Protego drape.
15. Position the front side elastic corner of Protego drape over the Protego Main Shield, move to the rear, look for the elastic bands and place around the side handles then place the last band around the "T" hooks provided. Close the Drape by using the 2 tapes.
16. Keep the system floating above the table if a femoral or brachial access is planned. If a radial access is planned lock the system into the magnet nest.
17. Place the patient's left side L Shield with the long end facing towards the foot of the table. The shorter end should be overlapping the aperture or up on the face of the Protego Main Shield about 4 inches.

PROCEDURE PREPARATION

BEFORE THE PATIENT IS IN THE ROOM

SUPPLY SCRUB/BACK TABLE.

Obtain two sets of ProKits, Radial Arm Pads, and Femoral Pads. One set is for use, and the other is for backup.

DRAPE THE L-SHIELDS

Requires both a sterile and a non-sterile team member.

1. The sterile person creates a cuff around the bag opening with the clear side facing away from self.
2. The non-sterile person holds L-Shield with LEFT HAND by the grommet side, making sure the manufacturer tag is facing them.
3. Non-Sterile staff folds the long end towards itself
4. Non-Sterile staff drops the shield into the drape.
5. Non-Sterile staff unfolds the L-Shield halfway through as it enters the sterile drape, sterile person grabs it as it is placed in, to prevent it folding on itself.
6. Sterile person places draped L-Shield on sterile flat surface, make sure the shield is fully at the end of the drape and old L-Shield is unfolded. Remove the tape covers and close the drape as tight as possible around the shield.



REAL- TIME DOSIMETRY SET UP

Real-time dosimetry devices are important for monitoring staff's radiation dosage. The real-time dosimetry devices also help staff monitor where a radiation leak may be present. Staff can refer to their badges and adjust the shielding to stop potential radiation leaks.

Consult the System manufactures Operating Manual for Proper use.

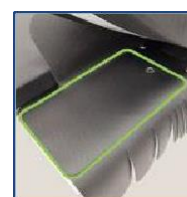
General Operational Suggestions

The designated team member responsible for badge oversight ensures:

1. Supply and position badges to staff. Reset real-time dosimetry meters to zero.
2. Each staff member should wear a real-time dosimetry badge. As the badges are directional, they must be positioned to face the radiation source. The operator positioned closest to the radiation source should wear two badges on the side nearest the C-arm—one at the thyroid level and one at the waist level.
3. Badges should be set to zero before the procedure starts.
4. Radiation levels should be continuously monitored during the procedure to alert the team of any detected leaks, allowing for immediate identification and resolution.

Status of deployed badges should be part of the Time-Out Process. If a badge exceeds the RSO's radiation limit, the dosed individual should break scrub and put on lead aprons.

CONFIRM RADIAL ARMBORARD RIGHT-HEART SHIELD IS POSITIONED CORRECTLY



POWER PATIENT VISUALIZATION SYSTEM (If not already on)

- The Monitor power button needs to be pressed to power up and loads in 45 seconds. The power switch is located on the bottom back, right side of monitor. Tap the screen to toggle through views options to find the split-screen view.
- After daily Monitor use is finished for the day, press the power button to turn of Monitor.



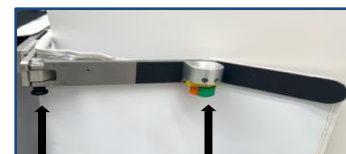
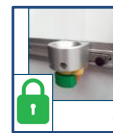
LOAD & DRAPE PATIENT

AFTER TRANSFERRING PATIENT TO TABLE - STEPS

1. MOUNT THE LOADING-SIDE WING SHIELD, EXTEND BOTH WING SHIELDS
2. POSITION THE RIGHT RADIAL ARMBOARD, SNAP SHIELDING TOGETHER, SECURE PATIENT PALM WITH RESTRAINT IF RADIAL ACCESS, AND PLACE PATIENT SIDE SHIELD.
3. ENSURE PROPER ALIGNMENT OF PATIENT AND SHIELDING.
4. PREP AND DRAPE PATIENT.
5. DRAPE THE PROTEGO MAIN SHIELD, THEN LOCK INTO WING SHIELDS.
6. PLACE THE L-SHIELDS & RADIATION RADIAL or FEMORAL PADS (IF REQUIRED).

1. MOUNT WING SHIELD TO TABLE RAIL, EXTEND WINGS

1. Confirm that the locking knob is in the **Green** position and the slide lever is facing the foot.
2. Mount the Wing Shield to the rail and lock.
3. Locate the wing release knob at the joint of the shield as shown. Pull down to swing the wing out until it locks into place at a 90° angle to the side of the table.
4. The magnet lock should be approximate to the patient's umbilicus. Note the patient's access location relative to the magnetics. The access point (radial or groin) should be below (caudal side) the magnet lock.
5. Rotate the locking knob so that **Green** (and smooth side) is facing outward in the locked position.



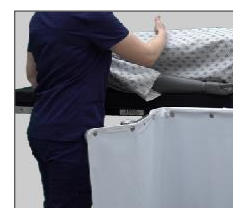
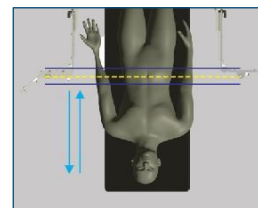
The corner plunger pulls down to release, rotate Wing out 90°

The Magnet Lock connects the Main Shield to the Wing



CHECK: PATIENT UMBILICUS AND WING SHIELDS

Wing Shield placement on table must accommodate lining up with the patient's umbilicus. The Protego Main Shield attaches to the Wing Shield in this plane, making proper positioning of the patient is critical for ensuring adequate surgical access, radiation protection, and patient comfort. Slide patient to correct position.



2. POSITION RIGHT RADIAL ARMBOARD & PATIENT SIDE SHIELD

1. Align Wing to PT umbilicus. See above. This will provide adequate distance for radial and femoral access.
2. Position the main Radial Armboard ensuring the large flap is to the right of the Wing Shield (See Fig. A).
3. Slide the Radial Armboard Ext. to the right of the Main Armboard under the table pad flush to the side of the table pad. Snap Armboard flaps together. (See Fig. B)
4. Strap palm in place and add patient side shield in armpit. (See Fig C)



Wing and Radial Armboard reference point (Fig. A)

(Fig. B)



(Fig. C)



WARNING: ALWAYS use the right-side Radial Armboard as it provides necessary radiation shielding.

3. PREP ACCESS SITES & PLACE THE PATIENT SURGICAL DRAPE

(The surgical drape is not a product associated with the Protego Radiation Protection System).

4. UNFOLD PROTEGO SHIELD DRAPE

1. Place the Protego drape with the head label toward the patient's head to the left and the foot label toward the patient's feet to the right.
2. IMPORTANT - unfold in the direction of the arrows, being careful to keep the right side above the top of the table.
3. Spread out the drape left to right over the Patient's drape, once fully exposed locate the Protego shield over the drape.



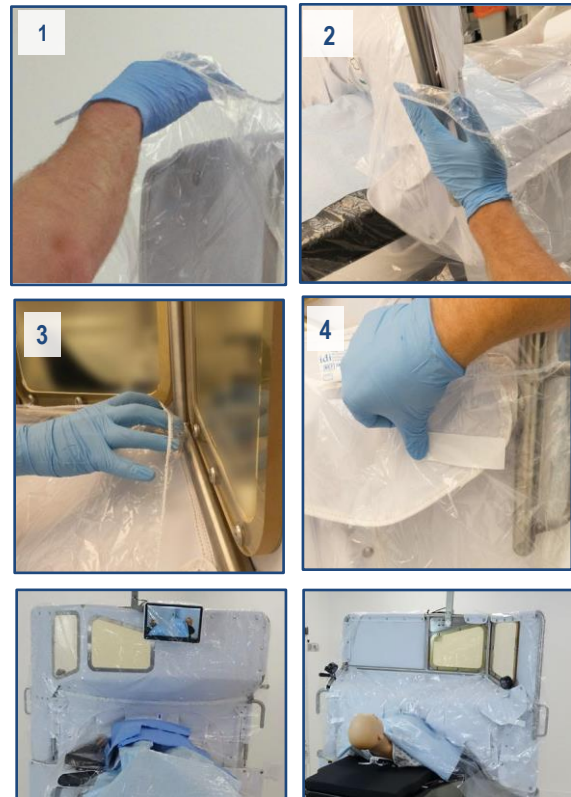
WARNING: Drape sterility will be compromised if the drape falls below the tabletop.



4. DRAPE PROTEGO MAIN SHIELD

Locate Protego Main Shield over the groin area of the patient. The shield should be over the drape's seam, and the **Blue dots** should be at or near the Wing Shield magnet locks.

1. The Protego Main Shield's aperture flaps should be centered over the drape seam and the drape's **Blue dots** near the magnet locks.
2. On the patient foot side, insert a sterile hand on to the drapes backside elastic corner and place up and over the right-side corner (as shown). Simultaneously repeat on the left-side.
3. On the C-arm side, there are two elasticized areas. Wrap the closest elastic area over the shield's side handle. Locate the second elastic area and place over the rear hook.
4. Using tape tabs provided, carefully enclose each side of the Protego Main Shield.
5. If using a Radial approach, move the Protego Main Shield feet into the Wing Shield magnet lock or Hoover the shield over the magnet lock, obtain access and then lock. If using groin access, leave Protego Main Shield floating for now. (See *Access Point Imaging Options* section on next page.)
6. Check the access site and confirm you have room to access. If you need more angulation or access, slide the Wing Shield & Protego shield together either toward the patient's head or feet.
7. Check to see that the drape is not over the rear cameras or front monitor and look for obvious distortions of the aperture flaps, they should lay flat on the patient. Correct as necessary.
8. Drape the front monitor if needed. (Optional)



5. DRAPE THE PATIENT VISUALIZATION MONITOR (OPTIONAL)

The drape for the patient visualization monitor is a sleeve. Roll the elastic over hand. Slide drape over monitor, limiting creases over the screen.

NOTE: Monitor touchscreen is operational after drape is applied.



6. ACCESS POINT IMAGING OPTIONS

Right Radial Access - If the access is right radial, continue with directions at Step 7 (below).

Brachial Right Radial Access- If the access is a right-heart pressure, remove the removeable Brachial Shield under the left side of the Radial Armboard pad to allow for visualization of the upper arm (**See page 18 for details**). Locate the L-Shields as normal. Release the patient-left side of or float the Protego Main Shield over the patient. Acquire access, then lock the Protego Main Shield in place.

Femoral Access - Groin access requires the Protego Main Shield to be unlocked and suspended over the patient. The L-Shields should be positioned near the final resting point. The interventionalist locates and places forceps over anticipated access site. Pan the table with the forceps through the Protego Main Shield aperture and take the image. Relocate forceps if necessary and image. Pan the table back through the Protego Main Shield aperture, locate ultrasound, and achieve access. Lock the Protego Main Shield into magnet locks, re-position L-Shields and place the Disposable Femoral Pad.

Femoral Access Mapping

With the Protego Main Shield floating close above the patient, place L-Shields as illustrated below for a femoral approach. Place forceps. While holding forceps in place, pan table toward patient head until the access site is on the fluoro side of the Protego Main Shield. Remove hand. Fluoro and adjust marker as necessary. When the access site is located, pan table toward patient feet until the Protego Main Shield is aligned with the patient umbilicus. Lock Protego Main Shield into Wing Shield magnet locks. Make access and perform ultrasound. When ready to begin intervention, adjust L-Shields positioning to allow for site access and have them overlap the Protego Main Shield aperture flaps. Place Disposable Femoral Pad over access point, ensure the flap is closed for optimal radiation shielding.

7. PLACE L-SHIELDS

L-Shields are shown without their sterile drapes for clarity.

1. Place the L-Shields

NOTE: Final placement of the L-Shields will take place after the Protego is positioned and before access is attempted.

2. Place the sterile, left-side L-Shield first with the long end toward the feet with the short end **toward the patient's head**. The inside corner should allow for a groin access if needed.
3. Place the right-side L-Shield. The outside edge of the L-Shield should be as close as possible to the radial site.
4. To convert to a groin access, rotate the right-side L-Shield counterclockwise forming the drapes into a "U". Cover the open site with our proprietary disposable **Femoral Pad**. It may be necessary to fold the outside edge of the top L-Shield underneath itself allowing for radial access.
5. When using the disposable Femoral Shield, be sure the flap is covering the access point to block scatter radiation.
6. Place the disposable **Radial Pad** with the tape up on the front of the Protego Main Shield drape.
7. **NOTE:** L-Shields should only be placed and secured in their final position once the patient has been loaded & positioned and your access point is established. (**See "Final Check" section below**)
8. After the access point is located and shortly before the procedure, adhere the L-Shields to the patient's surgical drape by removing the sticky part and lightly pressing to ensure it stays in place during the intervention.

Femoral Approach



Position L-Shield like the left Image and overlap them as shown in the Image



Femoral Pad placement

Radial Approach



Position L-Shield like the left Image and overlap them as shown in the Image



Radial Pad

To convert Radial approach to Femoral, reposition top L-Shield 90°



WARNING: L-Shields, Disposable Femoral Shield, and Disposable Radial Shield must all overlap the Protego Shield aperture flaps.

8. PLACE MOBILE SHIELD

1. Roll the Mobile Shield into place and at an angle to the table. The aluminum spring arm has a passive connection hook that allows for table panning.
2. Important – don't push the shield too far into the back of the surgical site as it could impact panning.

Converting to Femoral Access

In the event that the case converts to femoral access: *(See previous page for Femoral Access details)*

1. Release the shield while keeping it hovering over the table.
2. Rotate the top L-Shield counterclockwise a quarter-turn to open femoral access.
3. Place marker and pan the table towards the head, image, and relocate marker if necessary.
4. Reverse pan, do the ultrasound, gain access, lock Protego Main Shield into Wing Shields
5. Relocate the L-Shields, gain access, and place a disposable Femoral Pad.



9. FINAL CHECK

- The Radial Armboard is seated next to the patient.
- The Protego Main Shield's aperture flaps are bent so the ends are toward the patient's feet, overlapping, and there are no obvious leak points.
- The L-Shields overlap the aperture flaps. Secure with the adhesive strips on bottom of drapes, and extended laterally as far as they can be once access is achieved.
- The Radial Pad is up and taped to the face of the Protego Main Shield.
- The table Side Shields must hang freely and overlap to ensure shield integrity. The C-arm floor foot switch should be clear of the panels.
- The Dosimetry Real-Time Badges are in the proper places on the required team members, reset to zero, and recognized by the system.
- The Protego Main Shield arms must not be straight to ensure proper panning with the table, and the ben arms can point in either direction, depending on the space requirements of the room.

10. FINAL CONTINUOUS MONITORING OF RADIATION DOSE

IMPORTANT! One person must be designated to observe the exposure level during the case and call out when radiation levels are noted by the badge. At no time should the exposure levels exceed the Radiation Safety Officer's determined maximum single procedure dose.

These are the steps to take in the event of an unusually high radiation dose reading.

1. Check the L-Shields for possible migration during the case. Reposition if necessary.
2. Verify that aperture flaps of the Protego Main Shield are overlapped and there are no separations causing the radiation leak.
3. The table Side Shields must be overlapping and unhindered by other equipment in the room. The C-arm angle or floor foot switch could be causing a shield not to hang correctly.
4. If radiation levels exceed the allowable benchmark as set by RSO and the leak cannot be resolved, team members must put on appropriate personal protective lead apron.



DO NOT USE the Protego Radiation Protection System without a Real-Time Dosimetry System to monitor radiation exposure levels and protection.



Failure to monitor radiation exposure levels without a Real-Time Dosimetry System is a misuse of Protego Radiation Protection System and can result in serious injury or death.



Radiation exposure is dangerous and cumulative. The protection afforded by the Protego Radiation Protection System cannot reduce the amount of radiation to which an individual has already been exposed or undo any damage an individual has already sustained from previous exposure.

THE PROTEGO SHIELD AND EMERGENT SITUATIONS

The Protego Main Shield can be moved or removed, depending on the emergent situation as well as facility protocol.

INCREASE PATIENT VISUALIZATION

Move the Mobile Shield away from the table and off to the side to increase patient visualization and provide a wider path to the patient.

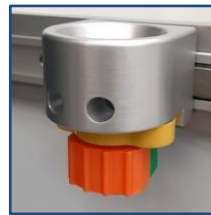


WARNING: Moving the Mobile Shield will reduce the size of the apron-free zone.



INCREASING ACCESS AND ANGULATION

To release the left side of the Protego Main Shield. Unlock the Magnet Lock on the patient-left side of the table only. Move the Protego Main Shield toward the patient's feet without disrupting the intervention which allows space for increased caudal angulations or emergent compressions if needed.



Twist knob 180° to
UNLOCK Magnet
Lock and release
Protego Main Shield

At the handle, move Protego
Main Shield toward patient feet
to create more room at the head-
end of the table.

WHEN INTERVENTION BECOMES STABILIZATION

Gripping the Protego Main Shield sides, firmly tug upward to release magnets or unlock magnet locks by pulling upwards. This releases the Protego Main Shield from the Wing Shields magnets and allows for moving the shield out of the way.



Firmly tug upwards or unlock magnet
locks to release Main Shield



Lift straight up, clearing the patient. Pull toward
patient's right side and store out of the way

CLEANING

Cleaning Agents for Radiation Shield, Metals, and Plastics

We recommend Scrubbles® for cleaning, disinfecting, and deodorizing, IDI Part # C000-1504, 32 oz. (spray bottle and brush)
The following list of cleaners and disinfecting agents are approved.

- Scrubbles® for cleaning, disinfecting, and deodorizing
- Disinfecting Wipes (Lysol or equivalent), Ammonium Chloride 0.2 to 0.5%
- Precise Hospital Foam Cleaner Disinfect
- Envirocide® Disinfectant and Cleaner.
- Dish detergent Soap (Used on Acrylic Window Panels)

Cleaning Directions on Radiation Shields and other Components

Apply recommended cleaner on one area at a time. Scrub the area with a soft bristle brush if needed. With use of a damp cloth, wipe area with circle motion. Do not let the solution dry before rinsing. Rinse with damp cloth and repeat as needed with cleaner and damp cloth where needed.

- Shield panels can be cleaned in a fixed position but should be lifted off and removed from location when possible. Lay shield assembly or partition on a flat surface when using the recommended cleaners.
- NOTE: The Protego Main Shield is not removable; cleaning must be done while hanging from the suspension arm.
- Clean the Protego System handles, magnet lock knobs and position lock plunger knobs area and accessories using an approved cleaner listed above.
- Clean the articulating arms and components from either the mobile stand platform or ceiling mount systems with an approved cleaner listed above.

Cleaning Directions on Acrylic Windows Panels

Acrylic windows are easily scratched. Care for them is specific. Only use the following when cleaning the acrylic windows and be sure to read the following warnings.

- Standard Dish washing liquid, one drip to a quart. Use only a soft non-abrasive or microfiber damp cloth. Wet the cloth directly in the soapy mild water solution. With careful, minimal pressure motion, clean acrylic surfaces.
- Use a new or separate cloth to wipe acrylic window after cleaning.



It is possible to scratch acrylic, so NEVER use any scouring compounds or chemical cleaners such as Windex or other glass cleaners (even if they are environmentally friendly, organic, or non-scented).



Never use the same cloth that you clean other items with – it can retain dirt, grit, and chemical residues that may harm your acrylic windows. Do not use paper towels, scrub pads, or other abrasive cleaning tools. We recommend using a new or separate cloth for your acrylic care.



AVOID ammonia or vinegar-based cleaners and any use of isopropyl alcohol which can cause fogging and tiny cracks in window.

DISPOSAL OF COMPONENTS



The Protego System is constructed with components made of steel, aluminum and shielding materials. Steel and aluminum are easily recycled. Shielding materials will be considered waste disposal products. Components must be disassembled before recycling.

Disposal Considerations for shielding materials – Waste Disposal: Classified in Europe as non-hazardous under EWC code 12 01 99. It should be disposed of in registered landfill sites in accordance with local authority regulations.

COMPONENT	ITEM	RECYCLING GROUP
Frame & Rail Supports	Pipe Weldment & Lower Shield Rail Supports	Metal (Steel and Aluminum)
Mobile Platforms & Suspension Components	Arms & Frames	Metal, Plastic
Lead Acrylic Windows & Shield Panels	Window Shield Partitions / Radiation Shield Panels	Heavy Metal Composites

TECHNICAL SPECIFICATIONS

Technical Specifications	
Description	Protego Radiation Protection System
Models	A800-0250 -XX, A800-0532-XX
MDR Classification	Class 1 per Annex VIII Rule 13
Service Life	5 Years and beyond with extension through maintenance.
Power Source Input	120V , 50/60 Hz, 1.5 Amp WARNING
Terminal Block (Power Enclosure Box)	3 Pole, 12-20 AWG, Rating per IEC/EN - 500V, 6 kV, 32 Amp RoHS Compliance, Cert.: CCA, CSA, ENEC 15, KEMA/KEUR, UL 1059
Operating Temperature	10 Deg. C to 35 Deg. C
Operating Humidity	20% to 80%
Transport & Storage Temperature	-20 Deg. C to 60 Deg. C
Transport & Storage Humidity	10% to 90%
Transport & Storage Altitude	70 to 110 kPa
Operating Altitude	3000 m (Max)
Ingress Protection	IPX0
Certification & Compliance	• Intertek Classification CDR. No 10606608BOX-003 • 217/745 EU (Medical Device Regulation) • MDMA Certification: MDMDA-202025-2186 (Kindom of Saudi Arabia)
Standards	IEC 60601-1:2005 Ed.3+A1:A2 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) IEC 60601-1-6:2010 ED.3+A1:A2 (Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance) EN ISO 13485:2016+A11:2021 (Medical Devices - Quality Management Systems - Requirements and Regulatory Purposes) EN ISO 14971:2019+A11:2021 (Medical Devices - Application of Risk Management to Medical Devices) EN ISO 15223-1:2021 (Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied)
WARNING: To reduce the risk of electric shock, this equipment must be connected to a mains socket with protective earth before use. No user-serviceable parts inside. Service to be performed on this equipment by qualified personnel only.	

REORDER LIST

CONSUMABLE DISPOSABLE DRAPES FOR USE WITH SYSTEM

A800-0310	Protego ProKits	Each box contains 25 kits that consist of one Drape for the Protego Shield and two L-Shield Drapes. All drapes are sterile and disposable.
C000-1717	Drape, Protego Shield Monitor	Each box contains 25 sterile, disposable drapes. (Optional)
X800-0117	Drape, Protego Main Shield	Each box contains 15 sterile, disposable drapes.
X800-0288	Drape, L-Shield	Each box contains 25 sterile, disposable drapes.

PREMIUM DISPOSABLE SCATTER SHIELD PADS (OPTIONAL)

X800-0147	Radial Pad	Each box contains 15 sterile, single-use scatter pads that are 0.25mm lead equivalent radiation protection. (12" x 17")
X800-0251	Femoral Pad	Each box contains 15 sterile, single-use scatter pads that are 0.25mm lead equivalent radiation protection. (12" x 17")

REUSEABLE COMPONENTS OF THE SYSTEM

Z800-0285	Flexi-Shield	A reusable shield that bends into the shape needed and retains that shape. To be used when needed. Dimensions are 14" x 24", lead equivalence is 0.5mm. Sold individually.
Z800-0286	L-Shield	A reusable shield placed over the patient to protect personnel from scatter radiation. Dimensions are 24" x 24", lead equivalence is 0.5mm. Sold individually.
A610-0295	Radial Palm Restraint Assembly	Stabilizes palm for easier radial access. Sold Individually. (Comes with Strap)
Z610-0297	Radial Palm Restraint Strap	Replacement strap for the Radial Palm Restraint Assy A610-0295. Sold Individually.
Z610-0349	Tabletop Shield	Dimensions are 26" x 32", lead equivalency is 0.5mm. Sold individually.
A610-0358	Patient Side Shield	Dimensions are 7.5" x 32", lead equivalence is 0.5mm. Sold Individually.
A610-0461	Brachial Insert Shield	Dimensions are 6.75" x 12", lead equivalency is 0.5mm. Sold individually. (Used on Right Radial Armboard under pad)

WARRANTY

Warranty details for IDI Products can be obtained directly from Image Diagnostics, Inc



Image Diagnostics, Inc
310 Authority Drive
Fitchburg, MA 01420
United States of America



ORDER: sales@imagediagnostics.com
SUPPORT: techsupport@imagediagnostics.com



WEBSITE: <https://imagediagnostics.com/protego/>



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