



M1130-TPS GUARDIAN RADIATION SHIELD

User Guide

M1130-UGD, Rev. B
LBL-119, Rev. B
Date of Issue: June 2025

This document should be stored with or within the immediate vicinity of the M1130-TPS GUARDIAN radiation shield and the medical team using the unit.

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The M1130-TPS GUARDIAN radiation shield is protected in the United States under U.S. patent numbers 11,207,039 and 11,660,056. Additional patents are pending in the United States and in other countries.

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Pursuant to continuous product improvement, Rampart^{IC} reserves the right to change the equipment design and the technology at any time.

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Within the bounds of legal requirements, the manufacturer is only responsible for the technical safety characteristics of this device if the maintenance, repairs, and modifications to this apparatus are performed by Rampart^{IC} or an approved Rampart^{IC} representative.

Manufacturer

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Live Technical Support

Live technical support is available at (855) 236-3777 between the hours of 8 am to 5 pm Central Standard Time (CST), Monday through Friday. Phone calls received outside business hours will be returned as quickly as possible.

Training

A PDF version of this user guide is available at www.RampartIC.com/training.

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Overview

Congratulations on your purchase of the Rampart® M1130-TPS GUARDIAN® Radiation Shield! Rampart^{IC} ensures your team is equipped with the latest, state-of-the-art radiation protection equipment and has freedom of mobility during fluoroscopic procedures. We hope you will **PROTECT THE TEAM™** and **SHED THE LEAD®** associated with lead aprons as you **FIGHT THE GOOD FIGHT®** in the cath lab. We think **YOU ARE WORTH IT™**.

This user guide provides guidance for the proper use of the Rampart^{IC} M1130-TPS GUARDIAN and for training personnel. Please read this document in its entirety, especially the warnings and caution statements identified throughout and summarized under [Safety & General Symbols \(page 4\)](#) before use.



WARNING!

To reduce risk of injury to user(s) and patient(s), user(s) must read and understand this user guide and be trained prior to using the M1130-TPS GUARDIAN.

Intended Use

The Rampart^{IC} M1130-TPS GUARDIAN is a protective radiation shield intended to safeguard users from radiation exposure during fluoroscopic medical procedures. Sterile disposable drapes are placed over each individual panel and attached curtain assembly to maintain a sterile environment.

Safety & Liability

Rampart^{IC} assumes no liability for the safe and reliable operation of the M1130-TPS GUARDIAN radiation protection system where:

- Installation, modifications, or repairs are not performed by Rampart^{IC} technicians or people authorized by Rampart^{IC}.
- Authorized Rampart^{IC} replacement parts are not used.
- Authorized Rampart^{IC} sterility protection accessories are not used.
- The M1130-TPS GUARDIAN has not been installed or set up for a procedure in accordance with the steps in this user guide.
- The M1130-TPS GUARDIAN is not operated in accordance with the steps in this user guide.
- The M1130-TPS GUARDIAN is used in a manner other than its intended use as stated above.

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 in which the user and/or patient is established.

Safety & General Symbols

Please pay special attention to important safety information marked with **WARNING**, **CAUTION**, or **ATTENTION** keywords and symbols.



WARNING!

Indicates a potentially hazardous situation which could result in the *serious risk* of injury or death to the patient or operator, and/or damage to equipment or property.

- To reduce risk of injury to user(s) and patient(s), user(s) must carefully read and understand this user guide and be trained prior to using the M1130-TPS GUARDIAN.
- Repairs must only be performed by Rampart^{IC} authorized personnel.
- The weight of the M1130-TPS GUARDIAN panels and attached curtains must not be altered in any way.
- When positioning, the panels and curtains must be carefully monitored to avoid damage to persons or property.



WARNING: MR-Unsafe

The M1130-TPS GUARDIAN system is MR-unsafe. MR-unsafe items should not be brought into MRI scanner rooms.



WARNING: Radiation Exposure

- Failure to set M1130-TPS GUARDIAN lead-equivalent acrylic panels and curtain attachments at the proper height and position may cause radiation exposure. The M1130-TPS GUARDIAN is designed to be used with under-table and above-table lower body protection.
- According to the *Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging*¹, proper radiation protection is in place when a minimum of 0.5 mm lead equivalency is placed between the radiation source and medical personnel. When used correctly, the Rampart^{IC} M1130-TPS GUARDIAN panels provide a protection level of 1.0 mm lead equivalency, and the curtains provide 0.5 mm lead equivalency against radiation exposure.
- The panels and curtain attachments must be handled with care, so they are not damaged due to contact with other objects. If the panels or curtains are damaged, they must be rechecked according to the [Maintenance](#) section on page 14 of this user guide.



CAUTION: Pinch Point

When making final adjustments to the panels and curtains, and while the patient is in position, always monitor the lower edge of the panels and curtains in relation to the patient to prevent injury. Always maintain visual contact with panels, curtains, and other equipment, in relation to the patient, when panel and curtain assemblies or other equipment are being adjusted.



ATTENTION!

The M1130-TPS GUARDIAN acrylic panels and curtain attachments will be permanently damaged if cleaned with abrasive cleaners. **When cleaning acrylic panels and curtain attachments, DO NOT use the following cleaning supplies:**

- Alcohol wipes or Sporidican² disinfectant towelettes, rough or abrasive-faced sponges, brushes, cleaning pads, scrapers, or metal tools, paper towels, linen washcloths
- Strong detergents or abrasives such as scouring powders

¹ J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/j.jacc.2018.02.016> (accessed August 10, 2019).

² Sporidican[®] is a registered trademark of Contec, Inc.

- Aerosol cleaners with Butyl Cellosolve³
- Hydrocarbon or chlorinated solvents, ammonia (more than 0.5%), or strong alkali cleaners
- Cleaners that are designed for grease cutting
- Excessively hot water or steam














Indicates a potentially hazardous situation which could result in a *minor or moderate risk* of injury to the patient or operator, and/or damage to equipment or property.



CAUTION!

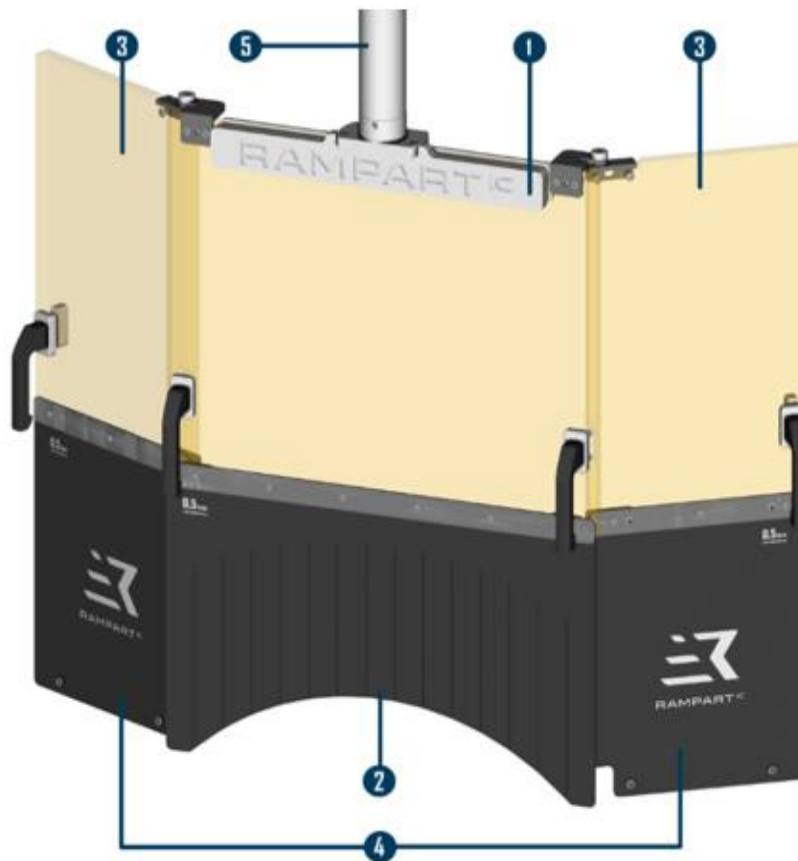
- When cleaning acrylic panels and curtain attachments, never use rough or abrasive sponges, steel wool, brushes, or cleaning pads.
- When cleaning any component of the M1130-TPS GUARDIAN, never use scrapers or metal tools of any kind.
- Potential drag may occur when the radiation shielding curtains are moved during a procedure. Ensure that the curtain flaps are lying flat against the patient's abdomen, pointing towards the patient's head, to allow for best visibility and intervention to access points.

Explanation of Symbols

	Catalogue Number		Keep Dry
	Serial Number		Instructions for Use Found at www.RampartIC.com
	Quantity		Complies with Applicable European Union Regulations
	Batch Code		Prescription User or Licensed Healthcare Practitioner Use Only
	Manufacturer		Authorized Representative in the European Community/European Union
	Date of Manufacture		Do Not Use If Package is Damaged and Consult Instructions for Use Found at www.RampartIC.com
	Medical Device		

³ Butyl Cellosolve™ is a trademark of the Dow Chemical Company.

M1130-TPS GUARDIAN System Overview

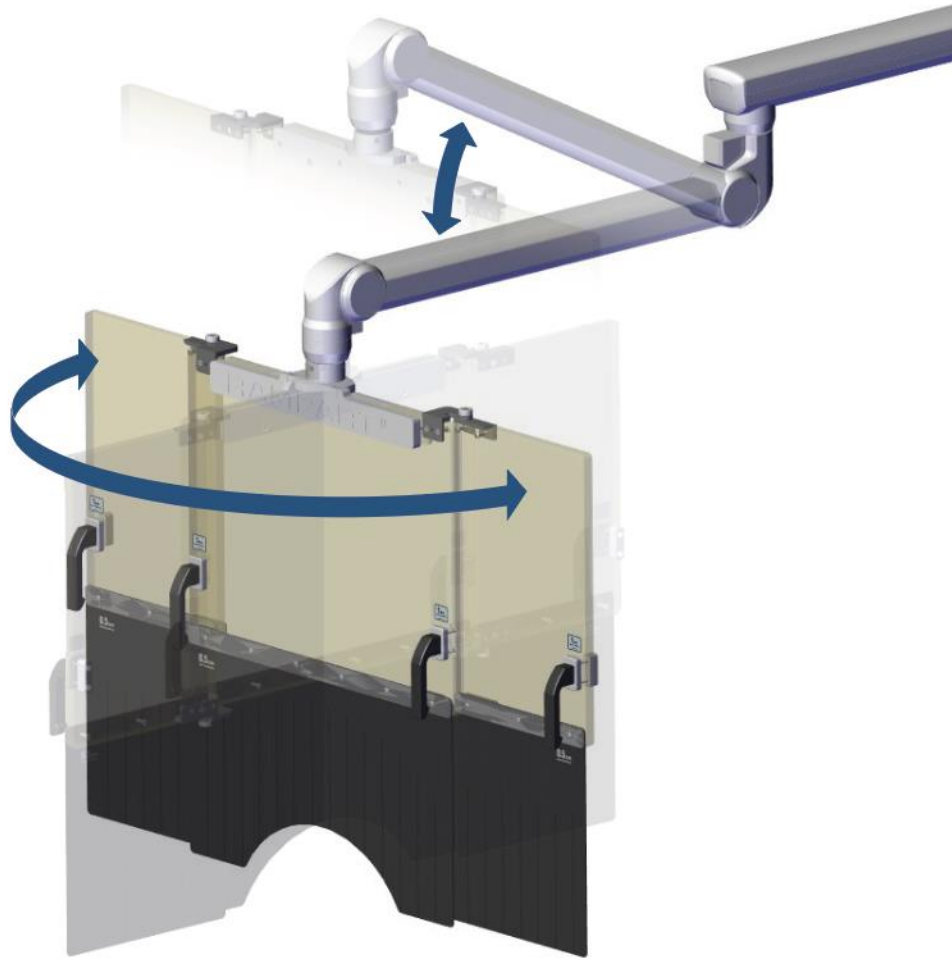


M1130-TPS GUARDIAN System Overview Key

1	Center Panel Assembly: The center panel assembly serves as the M1130-TPS GUARDIAN's primary radiation shield. This panel rotates 360 degrees about the arm and provides 1.0 mm lead-equivalent protection. Two ergonomic handles are attached to this panel to aid in positioning of the shield.
2	Center Panel Curtain: A pliable two-layer curtain with 0.5 mm lead-equivalent protection which attaches to the center panel and provides flexible, shapeable, radiation protection by conforming to the patient's body.
3	Side Panel Assemblies: The acrylic side panel assemblies provide 1.0 mm lead-equivalent protection and rotate 210 degrees about the center panel assembly. An ergonomic handle is attached to each panel to aid in positioning of the shields.
4	Side Panel Curtains: Pliable curtains with 0.5 mm lead-equivalent protection that attach to the side panel assemblies and provide flexible radiation protection.
5	Arm Assembly: The arm assembly serves as the mounting fixture for the M1130-TPS GUARDIAN.

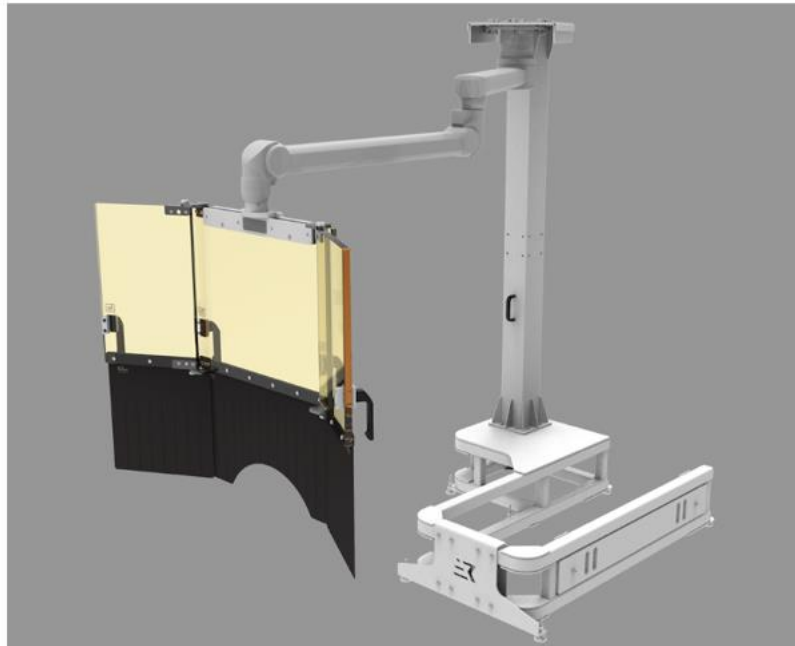
Key Characteristics

- Acrylic panels with a full 1.0 mm of lead-equivalent protection rotate smoothly about the arm to provide customized protection for most approach positions including bilateral radial, bilateral femoral, and bilateral pedal.
- Panels can be adjusted vertically to adapt to table and physician height, by repositioning the arm.
- Pliable radiation shielding curtains that can conform to patient body shapes attach to the bottom of the panels and extend the M1130-TPS GUARDIAN protective coverage area.
- The M1130-TPS GUARDIAN panels and curtains remain sterile when properly draped.
- The M1130-TPS GUARDIAN panels and curtains can be configured into storage position when not in use.
- A below-table lead-equivalent protective shield is available for purchase through Rampart^{IC} and can be used with the M1130-TPS GUARDIAN to provide further radiation protection to the physician and lab tech on both sides of the table.



Vertical Movement and Rotation Around the Arm

- The M1130-TPS GUARDIAN Guardian can be purchased with the M1130-FLS Liberty Floor Stand accessory.



M1130 Guardian with the M1130-FLS Floor Stand Accessory

Operating Environment

- The M1130-TPS GUARDIAN system is designed for indoor use and storage only and must not be subjected to weathering, UV light, or corrosive environments.
- The working environment defined for this device is a clinical or hospital surgical suite with a working temperature range of 50°F (10°C) to 77°F (25°C) at 20% to 75% non-condensing humidity.
- The storage temperature is between 14°F (-10°C) to 104°F (40°C).

IP Protection Class

The M1130-TPS GUARDIAN radiation shield is rated in the IPX6 washable protection class.

Identification Tag

An identification tag can be found at the upper portion of the center panel assembly, near its arm mount. This tag identifies key information about your product that may need to be referenced during service calls:

- Product Name
- Reference Number
- Serial Number
- Data Matrix
- Manufacturer Name
- Manufacturer City, State, and Zip Code
- Manufacturer Website

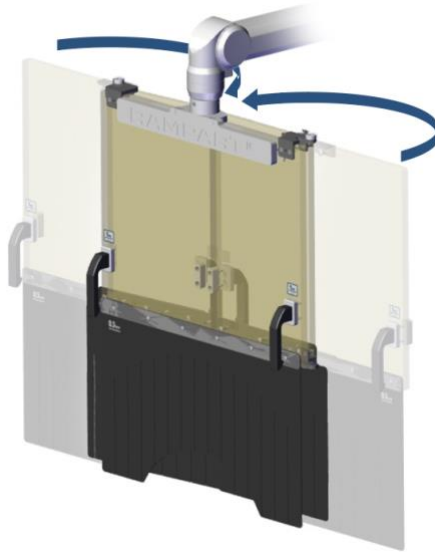
- Manufacturer Phone

Storage Mode

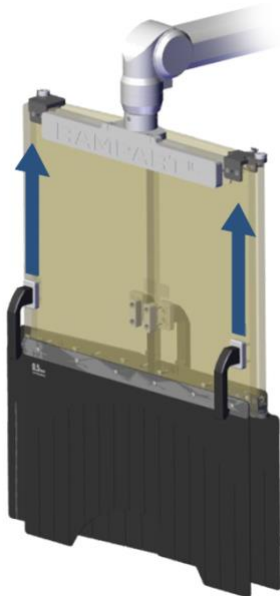
The M1130-TPS GUARDIAN radiation shield must be placed into storage mode when not in use to ensure the system remains free of damage. When in storage mode, the arm is raised to its maximum height, and the panels and attached curtains are folded.

Place the Unit in Storage Mode

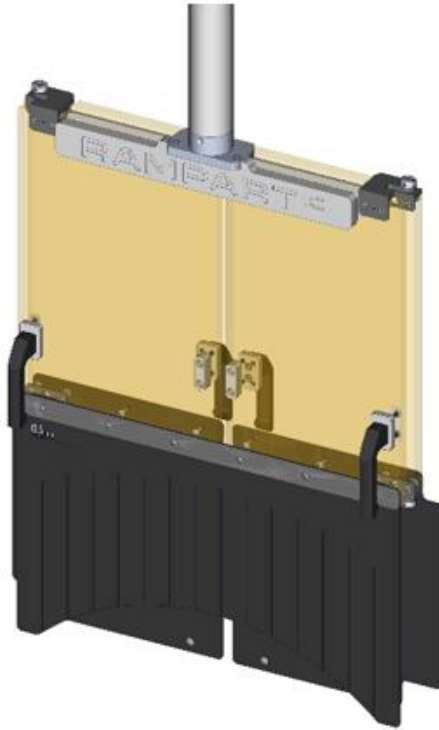
1. **Fold the left and right-side panels toward the rear of the center panel** so that both side panels are nested against the center panel.



2. **Raise the arm** by lifting the handles attached to the center panel.



3. **Reposition** the M1130-TPS GUARDIAN and the arm to the desired location.



Storage Mode with Side Panels in Nested Position

Instructions for Use

The M1130-TPS GUARDIAN acrylic panels and attached curtains can be arranged in a variety of configurations to accommodate patient positions, specific access points, technician location, multiple procedure table types, and other lab equipment in various procedures.

Using the M1130-TPS GUARDIAN

To access instructions related to the storage and use of the M1130-TPS GUARDIAN, please visit www.RampartIC.com.

Intended User Group

The intended user group for the Rampart M1130-TPS GUARDIAN radiation shield are physicians and their staff.

Contraindications, Warnings, and Cautions

Contraindications include internal jugular and axillary access points and emergent TAP procedures.



**WARNING:
Radiation
Exposure**

- Failure to set M1130-TPS GUARDIAN panels and curtains at the proper height and position may cause unwanted radiation exposure. The M1130-TPS GUARDIAN is designed to be used with under-table and above-table lower body protection.
- According to the *Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging*⁴, proper radiation protection is in place when a minimum of 0.5 mm lead equivalency is placed between the radiation source and medical personnel. When used correctly, the Rampart^{IC} M1130-TPS GUARDIAN acrylic panels provide a protection level of 1.0 mm lead equivalency, and the curtains provide 0.5 mm lead equivalency against radiation exposure.
- The acrylic panels and curtains must be handled with care, so they are not damaged due to contact with other objects. If the panels or curtains are damaged, they must be rechecked according to the [Maintenance](#) section on page 14.



**WARNING:
MR-Unsafe**

The M1130-TPS GUARDIAN system is MR-unsafe. MR-unsafe items should not be brought into MRI scanner rooms.



CAUTION

Potential drag may occur when the radiation shielding curtains are moved during a procedure. Ensure that the curtain flaps are lying flat against the patient's abdomen, pointing towards the patient's head, to allow for best visibility and intervention to access points.

⁴ J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/ajacc.2018.02.016> [accessed August 10, 2019].

Maintenance

The Rampart^{IC} M1130-TPS GUARDIAN requires post-procedure cleaning, routine inspections, and repairs by Rampart^{IC} authorized personnel to maintain optimal performance.

Cleaning

The Rampart^{IC} M1130-TPS GUARDIAN must be thoroughly cleaned and disinfected in accordance with standard operating room practices and CDC guidelines. Clean each component after use and prior to maintenance. Always use disposable drape kits to maintain sterility during procedures and dispose of them after each use.



CAUTION!

- When cleaning acrylic panels and curtains, never use rough or abrasive-faced sponges, steel wool, brushes, or cleaning pads.
- When cleaning any component of the M1130-TPS GUARDIAN, never use scrapers or metal tools of any kind.



ATTENTION!

The M1130-TPS GUARDIAN acrylic panels and curtains will be permanently damaged if cleaned with abrasive cleaners. **When cleaning acrylic panels and curtains, DO NOT clean with the following cleaning supplies:**

- Paper towels or linen washcloths
- Alcohol wipes
- Sporidican⁵ Disinfectant Towelettes
- Rough or abrasive-faced sponges, brushes, cleaning pads, scrapers, or metal tools
- Strong detergents or abrasives such as scouring powders
- Aerosol cleaners with Butyl Cellosolve⁶
- Hydrocarbon or chlorinated solvents, ammonia (more than 0.5%), or strong alkali cleaners
- Cleaners that are designed for grease cutting
- Excessively hot water or steam

Clean the M1130-TPS GUARDIAN by wiping it with a soft cloth and a neutral pH enzymatic detergent (typically pH 6-8) diluted in water.

Disinfection

Disinfect the M1130-TPS GUARDIAN using one of the following:

- 70% or less isopropyl alcohol (dry panels and curtains immediately after application.)
- Sani-HyPerCide⁷ Germicidal Disposable Wipe
- Super Sani-Cloth⁸ Germicidal Disposable Wipes
- CaviWipes⁹ 2.0 Disinfecting Wipes

⁵ Sporidican[®] is a registered trademark of Contec, Inc.

⁶ Butyl Cellosolve[™] is a trademark of the Dow Chemical Company.

⁸ Sani-HyPerCide[®] is a registered trademark of PDI.

⁹ Super Sani-Cloth[®] is a registered trademark of PDI.

⁹ CaviWipes[®] is a registered trademark of Metrex Research LLC.

Notes:

- Always use detergent or wipe products according to safety precautions and use directions provided by the manufacturer.
- The use of disinfecting products may cause panel discoloration over time.
- Rampart^{IC} cleaning cloths are designed for safely cleaning M1130-TPS GUARDIAN panels and curtains and are available for purchase. To purchase, email info@RampartIC.com.

Storage

Rampart^{IC} recommends placing the M1130-TPS GUARDIAN in *Storage Mode (page 11)* when not in use due to the minimal footprint of this configuration.

1. Make sure the M1130-TPS GUARDIAN is cleaned as described in *Cleaning* on page 14 before storage.
2. Place the M1130-TPS GUARDIAN in *Storage Mode (page 11)* and reposition to the side of the cath lab or other suitable location where there is minimal foot traffic and activity.

Preventative Inspection

Rampart^{IC} recommends an annual preventative maintenance inspection by a Rampart^{IC} authorized representative.

1. Make sure the M1130-TPS GUARDIAN is cleaned as described in *Cleaning* on page 14 before performing preventative inspection.
2. Inspect panels and curtains to ensure:
 - a. All parts are fastened tightly.
 - b. There are no cracks or damage to any of the panels and curtains.
 - c. The side panels rotate easily around the center panel.
 - d. The M1130-TPS GUARDIAN rotates easily around the arm assembly.
3. Preventative maintenance following the equipment specific maintenance plan will default to the policies and procedures of the institution related to inspecting shielding. Rampart service team will perform a visual inspection of attenuating components to determine appropriateness. If institution participation is available to operate fluoroscopic equipment, such testing will be performed via institution staff.
4. The Rampart^{IC} authorized representative will perform or schedule repairs necessary including ordering replacement parts.

Parts and Accessories

Part Number	Description
M1130-TPS	Guardian Tri-Panel Shield
M1130-FLS	Liberty Floor Stand
M1130-CDK	Guardian Drape Kit
M1130-UIG	Guardian User Guide

M1130-AFM	Guardian Anti-Fatigue Mat
M1130-RCC	Guardian Rampart Cleaning Cloth

Suggestions

Under & Above Table Lower Body Protection

Rampart^{IC} requires the use of a below-table lead-equivalent protective shield in conjunction with the M1130-TPS GUARDIAN radiation shield such as the Rampart^{IC} L148-TMS Bunker, table-mounted shield available for purchase through Rampart^{IC}. When used in the correct configuration, the physician and the lab technician will be shielded from 98% to 99.9% radiation exposure. This facilitates freedom of movement during a procedure for the staff and physician.

Storage Mode

To ensure minimal footprint, always configure the M1130-TPS GUARDIAN into [Storage Mode \(page 11\)](#) when not in use. This position is when the side panel curtains are snapped in the up position and both side panels are nested against the center panel. Raise the arm assembly to its maximum height and reposition the M1130-TPS GUARDIAN to an area of the lab where minimal foot traffic occurs.

Disposal

The Rampart^{IC} M1130-TPS GUARDIAN system contains lead-equivalent panels and lead-equivalent curtains. Dispose of the system and all components in an environmentally safe manner per local, state, and Federal laws.

Limited Warranty

Rampart^{IC} warrants to Customer that this product, manufactured by Rampart^{IC} and sold to Customer, will be free from defects in materials and workmanship for a period of one (1) year after delivery to Customer. This warranty shall not apply to any products which have been subjected to misuse, improper installation or repair, alteration, neglect, accident, abnormal conditions of operation, or use under conditions other than those for which the products were designed.

EXCEPT FOR THE FOREGOING LIMITED WARRANTY, SELLER MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ALL WARRANTIES OF FITNESS OR OF MERCHANTABILITY.



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