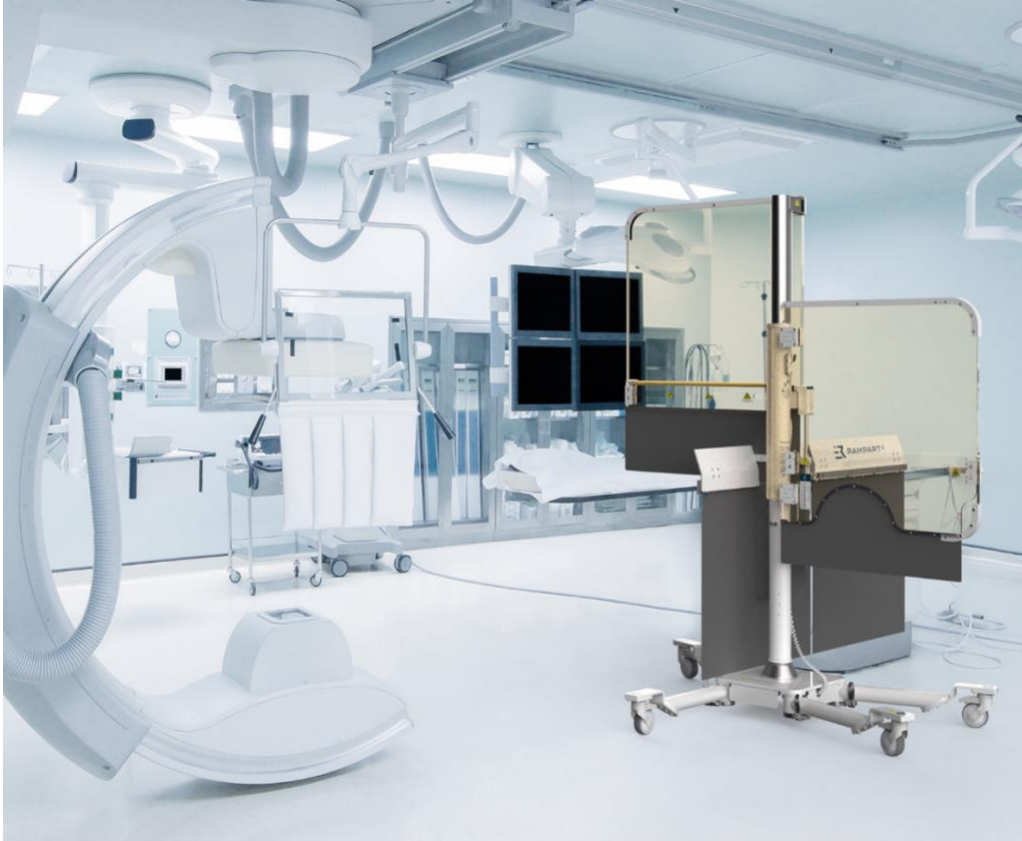




RAMPART IC



DEFENDER M1128 RADIATION SHIELD

RTV[®]-RTV V2 User Guide

This document should be stored with or within the immediate vicinity of the Defender M1128-RTV Radiation Shield and the medical team using the unit.

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The Defender M1128-RTV 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[®] Defender M1128-RTV[®] 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} Defender M1128-RTV 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](#) before use.



WARNING!

To reduce risk of injury to user(s) and patient(s), user(s) must read and understand this guide and be trained prior to using the Defender M1128-RTV.

Intended Use

The Rampart^{IC} Defender M1128-RTV 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 Defender M1128-RTV 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 Defender M1128-RTV has not been installed or set up for a procedure in accordance with the steps in this user guide.
- The Defender M1128-RTV is not operated in accordance with steps in this user guide.
- The Defender M1128-RTV is not moved in accordance with the steps in this user guide.
- The Defender M1128-RTV is moved or transported to another building location without proper moving containers and a Rampart^{IC} authorized technician.
- The Defender M1128-RTV 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 Defender M1128-RTV.
- Repairs must only be performed by Rampart^{IC} authorized personnel.
- Before transport, the Rampart^{IC} Defender M1128-RTV must be placed into *Transit Mode* (page 14) and be disconnected from charging.
- The weight of the Defender M1128-RTV panels and attached curtains must not be altered in any way.
- The base unit and legs must not be altered in any way and must be used only as outlined in this user guide.
- The panels and curtains can only be adjusted up and down using the handset controller provided.
- When positioning, the panels and curtains must be carefully monitored to avoid damage to persons or property.



WARNING: Rare Earth Magnet

Keep rare-earth magnets away from anyone with a pacemaker and away from magnetic media. Dispose of rare-earth magnets in compliance with local, state, and Federal laws.



WARNING: MR-Unsafe

The Defender M1128-RTV system is MR-unsafe. MR-unsafe items should not be brought into MRI scanner rooms.



WARNING:
Tipping
Hazard

- **CONFIGURATION DURING USE:** The Defender M1128-RTV panels and attached curtains can be placed safely at any needed angle during use, so long as one leg is positioned in the general direction of each panel and curtain to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- **CONFIGURATION DURING TRANSIT:** To move the Defender M1128-RTV to another location, the Defender M1128-RTV must be placed into *Transit Mode* (page 14). First, collapse the mast to the lowest position and fold the panels and attached curtains together and lock them forward between legs 1 and 4. Then, position all four legs for transit with leg locks locked into place to prevent the legs from changing angles during transit. The person moving the device must carefully walk on the side of the device with the Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit. When in Transit Mode and moved correctly, the Defender M1128-RTV is narrow enough to fit through standard walkways.



WARNING:
Radiation
Exposure

- Failure to set Defender M1128-RTV lead-equivalent acrylic panels and curtain attachments at the proper height and position may cause radiation exposure. The Defender M1128-RTV 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} Defender M1128-RTV panels provide a protection level of 1 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 to ensure 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 30 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 panel and curtain 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.



CAUTION!
Heavy
Equipment
Injury Risk

- The Defender M1128-RTV is heavy, and caution must be used when handling the system.
- Failure to maintain control when moving the system can result in personal injury or property damage.
- Personnel working with the Defender M1128-RTV system(s) must be properly trained.
- Defender M1128-RTV assembly, repairs, and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}.

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/ajacc.2018.02.016> [accessed August 10, 2019].

The Defender M1128-RTV 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:**

ATTENTION!

- 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
- 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!

- The Defender M1128-RTV must be fully charged at least once every 12 months.
- The Defender M1128-RTV must be charged a minimum of 10 hours to obtain full charge as described in [Charging](#) on page 19.
- Locking the casters during a procedure may cause damage to the Defender M1128-RTV or interfere with its proper use.
- 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 Defender M1128-RTV, 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.
- Place controllers and the Defender M1128-RTV legs in a convenient and safe position so as not to create a tripping hazard for the physician and medical team in the lab.
- Always maintain awareness of the positioning of the Defender M1128-RTV legs and casters to avoid tripping when moving around the Defender M1128-RTV.
- **CONFIGURATION DURING TRANSIT:** To avoid becoming a tripping hazard, the Defender M1128-RTV must be placed into [Transit Mode](#) (page 14). First, collapse the mast to the lowest position and fold the panels and curtain attachments together and lock them forward between legs 1 and 4. Then, position all four legs for transit with leg locks locked into place to prevent the legs from changing angle during transit. When in Transit Mode, the Defender M1128-RTV is stable and narrow enough to fit through standard walkways. The person moving the device should carefully walk on the side of the device with the Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit.















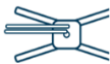









CAUTION:
Trip Hazard

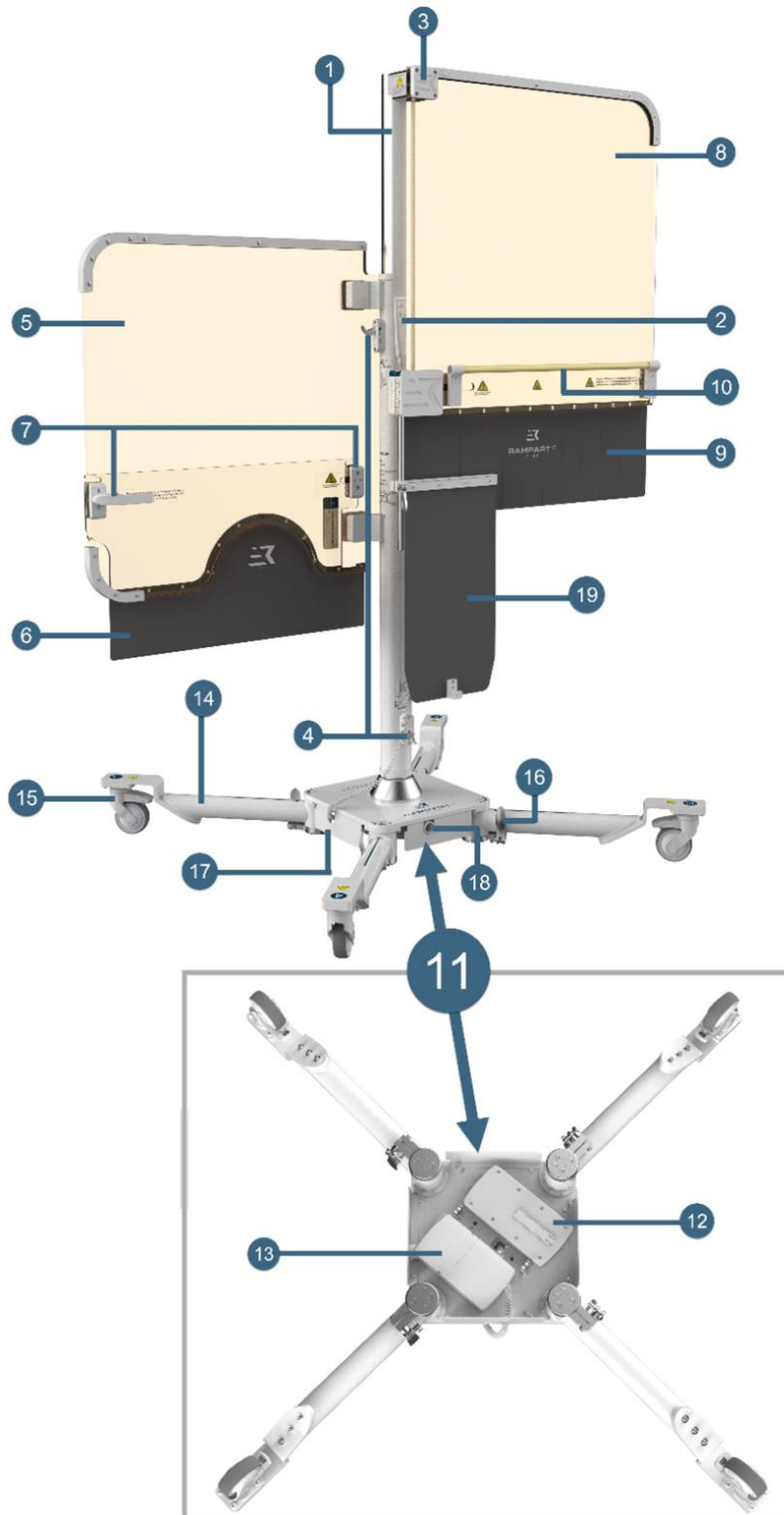
² Sporidican® is a registered trademark of Contec, Inc.

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

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		Use By
	Transit Mode Mast in the lowest position. Panels folded together and locked. Legs in transit position and locked.		Leg Number (1-4)
	Leg 1 Angle Indicator (Transit to 45°)		Leg 2 Angle Indicator (Transit to 45° to 90°)
	Leg 3 Angle Indicator (Transit to 45°)		Leg 4 Angle Indicator (Transit to 45°)
	Lower Rotation Lock (Lock for Transit, Auto-Lock, Unlock)		Upper Rotation Lock (Lock for Transit, Auto-Lock, Unlock)

Defender M1128-RTV System Overview



1	Telescopic Mast: This stainless-steel mast is the backbone of the Defender M1128-RTV, supporting the weight and height adjustment of all attached panels and curtains by control of the handset controller. The total height of the Defender M1128-RTV can be adjusted between 65.7 in. (1669 mm) tall when the mast is fully collapsed and up to 95.2 inches (2419 mm) tall when the mast is fully extended.
2	Handset Controller: Controls the simultaneous up and down movement of the panels and curtains attached to the mast: <ul style="list-style-type: none"> • Top buttons – Raise and lower both the radial and lower extremity panels simultaneously. • Bottom buttons – Raise and lower the lower extremity panel attached to the mast.
3	Panel Mounting Brackets: Durable, acetal plastic brackets of varying shapes are used in Defender M1128-RTV assembly of the panels and shelves, curtains, and handlebar.
4	Rotation Locks: The Defender M1128-RTV comes with two rotation locks: <ul style="list-style-type: none"> • An upper rotation lock which locks and unlocks the movement of the lower extremity panel and curtain. • A lower rotation lock which locks and unlocks the movement of the radial panel and curtain.
5	Radial Panel: An adjustable acrylic panel with a half circle arm cutout and 1 mm lead-equivalent protection. This is one of the two large primary radiation shielding panels motorized for movement via attachment to the mast assembly.
6	Radial Curtain: A pliable curtain with 0.5 mm lead-equivalent protection which attaches to the radial panel and provides flexible, shapeable radiation protection by conforming to a patient's body.
7	Radial Panel Handle and Radial Panel Bracket: A fixed handle and bracket attached to the radial panel that are designed to better facilitate manipulation and positioning of the Defender M1128-RTV.
8	Lower Extremity Panel: An adjustable acrylic panel with 1 mm lead-equivalent protection. This is one of the two large primary radiation shielding panels motorized for movement via attachment to the mast assembly.
9	Lower Extremity Curtain: A pliable curtain with 0.5 mm lead-equivalent protection that attaches to the lower extremity panel.
10	Handlebar: A handlebar attached to the lower extremity panel that helps to steady and position the Defender M1128-RTV.
11	Base Block*: The base of the Defender M1128-RTV comes with four configurable base legs and four base access panels which can swing open to provide access to components in the base. The rechargeable battery, charging cord, and the controller are attached on the underside, and the telescopic mast on top. <i>*Callout image shows the underside of the Defender M1128-RTV base.</i>
12	Rechargeable Battery: The rechargeable battery is attached under the base block for mobile operation. It requires a minimum of 10 hours to fully charge and can remain charging when not in use without damaging the battery. The battery must be charged once every 12 months.
13	Controller: The control box located under the Defender M1128-RTV base receives input from the handset controller to raise or lower the panels and curtains attached to the mast.
14	Base Legs: The base legs are mounted to the Defender M1128-RTV base, adjust to a variety of configurations, and can fold inward to create a minimal footprint for <i>Transit Mode</i> (page 14) or <i>Storage</i> (page 31).

15	Lockable Casters: Industrial grade, smooth-rolling casters attached to each leg of the Defender M1128-RTV allow smooth configuration of the base legs and transportation of the Defender M1128-RTV.
16	Leg lock: There are four leg locks, one on each leg. Unlock the individual leg lock on each leg to reposition the legs. Lock to keep legs from changing positions.
17	Base Access Panels: There are four base access panels, one on each vertical side of the base that swing open and closed to allow access to Defender M1128-RTV base block contents.
18	Charging Port: A port that connects the rechargeable battery and controller under the base to the wall outlet.
19	Center Mast Accessory (CMA): The CMA assembly includes a pliable, articulating 1 mm lead-equivalent protection CMA curtain able to adjust in height along a CMA guide shaft and lock into place via the CMA clamping handle, all of which are attached to the lower extremity panel via the white box-shaped CMA mounting bracket. A curtain hook on the bottom of the CMA curtain is used to fold up the curtain for <i>Transit Mode</i> (page 14) or <i>Storage</i> (page 31).

Key Characteristics

- Acrylic panels with a full 1 mm of lead-equivalent protection rotate smoothly around the mast to provide customized protection for most approach positions including bilateral radial, bilateral femoral, and bilateral pedal.
- Panels are adjustable vertically to adapt to table and physician height, using the handset controller.
- Pliable radiation shielding curtains able to conform to patient body shapes attach to the bottom of the radial and lower extremity panels and extend the Defender M1128-RTV protective coverage area.
- The CMA assembly provides height-adjustable articulating radiation protection between the radial and lower extremity panel.
- The Defender M1128-RTV legs are also adjustable to fit most intervention procedure tables.
- The Defender M1128-RTV panels and curtains remain sterile when properly draped.
- The Defender M1128-RTV panels and curtains can be configured into an efficient mobile or storage position when not in use.
- A below-table lead-equivalent protective modular shield, Bunker L148-TMS is available for purchase through Rampart^{IC} and can be used with the Defender M1128-RTV to provide further radiation protection to the physician and lab tech on the shielded side of the table.

Technical Specifications

Power Supply

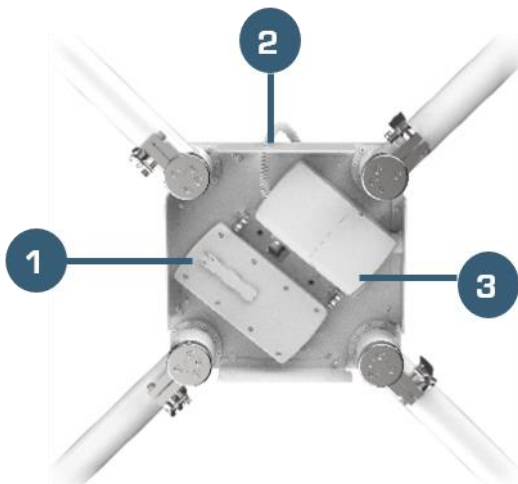
The Defender M1128-RTV uses a rechargeable nickel manganese cobalt lithium-ion oxide battery attached to the underside of the Defender M1128-RTV base.

The battery specifications are:

- 25.9 VDC output voltage
- 10 A maximum discharge current
- 300 mA charging current
- 2.25 Ah / 58.28 Wh battery capacity
- IPX6 washable protection class
- 10-hour full battery charge time
- 10.5 ft (3.2 m) cord length

ATTENTION! The Defender M1128-RTV must be fully charged at least once every 12 months.

The following is the underside of the Defender M1128-RTV:

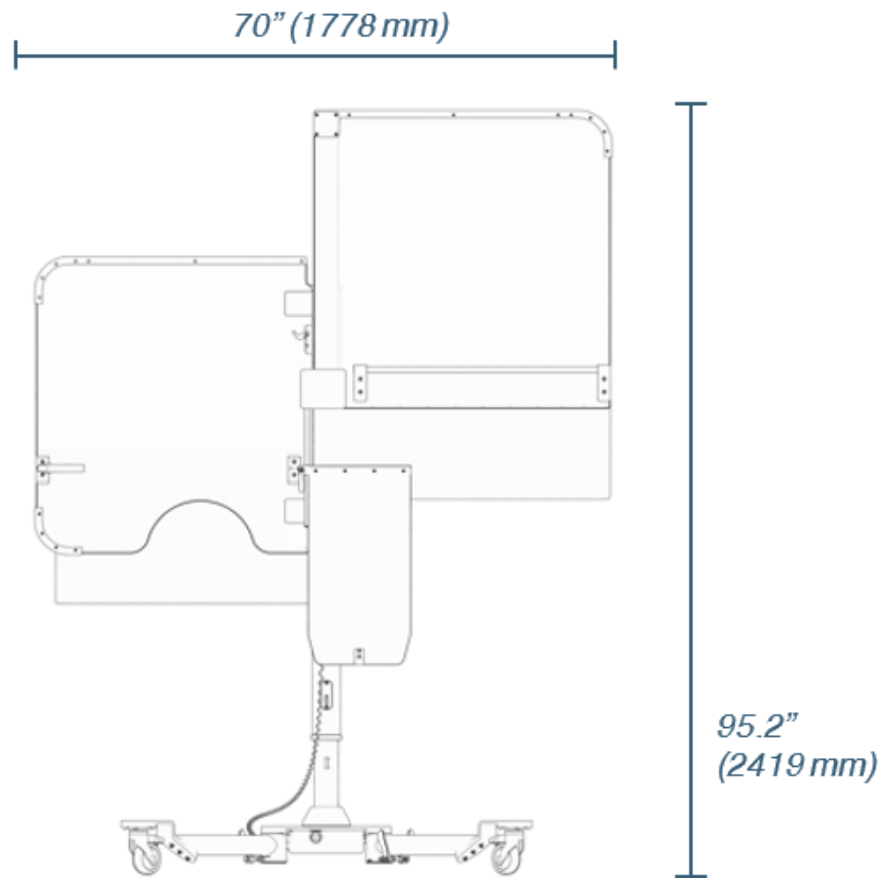


1	Rechargeable Battery
2	Charging Port
3	Controller

Dimensions

The four legs, extendable mast, acrylic panels, and attached radiation shielding curtains of the Defender M1128-RTV can be configured in a variety of ways with the overall measurements varying accordingly.

The Defender M1128-RTV at its maximum dimensions is positioned with both upper and lower mast actuators extended, panels positioned at a 180-degree angle, and a leg positioned generally under each panel and attached curtain. This configuration allows for proper weight distribution and balance while the Defender M1128-RTV is at its largest configured size of 95.2 in. (2419 mm) tall by 70 in. (1778 mm) wide.



Operating Environment

The Defender M1128-RTV 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).

Weight

- The assembled Defender M1128-RTV radiation shield is over 300 lbs. (136 kg).
- The Defender M1128-RTV handset controller is 1.10 lbs. (0.5 kg).

IP Protection Class

The Defender M1128-RTV radiation shield is rated in the IPX6 washable protection class.

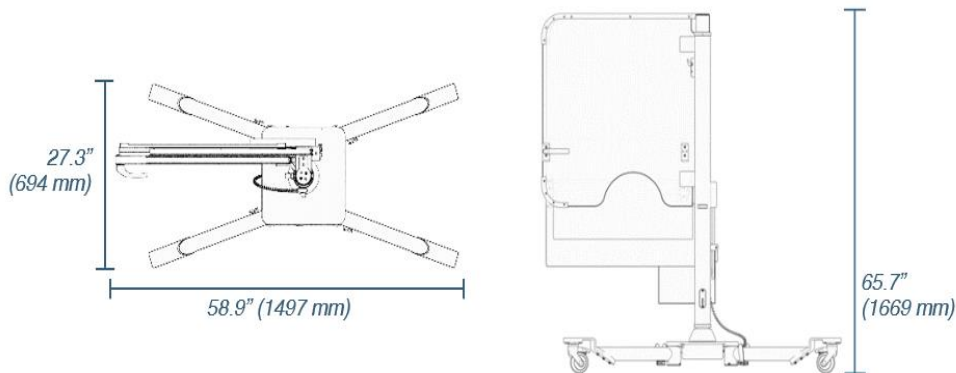
Identification Tag

An identification tag can be found at the base of the Defender M1128-RTV identifying key information about your product that may need to be referenced during service calls.

- Product Name
- Reference Number
- Serial Number
- Bar Code
- Manufacturer Name
- Manufacturer City, State and Zip
- Manufacturer Website
- Manufacturer Phone

Transit Mode

The Defender M1128-RTV must be placed into Transit Mode to be safely and efficiently moved. Transit Mode consists of configuring the Defender M1128-RTV to its smallest profile while maintaining stability. When in Transit Mode, the Defender M1128-RTV upper and lower mast actuators are collapsed and the panels and attached curtains are folded so that the Defender M1128-RTV dimensions are 65.7 in. (1669 mm) tall by 58.9 in. (1497 mm) long and 27.3 in. (694 mm) wide. This allows the Defender M1128-RTV to easily fit through standard hospital doorways.



WARNING!

Before transport, the Rampart^{IC} Defender M1128-RTV must be in Transit Mode and disconnected from charging.



WARNING: Tipping Hazard

- **CONFIGURATION DURING USE:** Panels and attached curtains can be placed safely at any needed angle during use, as long as one leg is positioned in the general direction of each panel to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- **CONFIGURATION DURING TRANSIT:** To move the Defender M1128-RTV to another location, the Defender M1128-RTV must be placed into Transit Mode. Collapse the mast to the lowest position, fold the panels and curtains together, and lock forward between legs 1 and 4. Then, position all four legs for transit with the leg locks locked into place to prevent the legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit. When in Transit Mode and moved correctly, the Defender M1128-RTV is narrow enough to fit through standard walkways.



CAUTION:
Heavy
Equipment-
Injury Risk

- The Defender M1128-RTV is heavy and caution must be used when handling the system.
- Failure to maintain control when moving the system can result in personal injury or property damage.
- Personnel working with the Defender M1128-RTV system(s) must be properly trained.



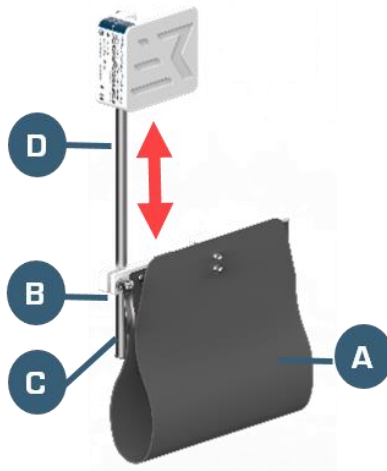
CAUTION:
Tripping
Hazard

- **CONFIGURATION DURING TRANSIT:** To avoid becoming a tripping hazard, the Defender M1128-RTV must be placed into Transit Mode. Collapse the mast to the lowest position, fold the panels and curtains together, and lock forward between legs 1 and 4. Then, position all four legs for transit with the leg locks locked into place to prevent the legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit.
- Always maintain awareness of the positioning of Defender M1128-RTV legs and casters to avoid tripping when moving around the Defender M1128-RTV.

Note: A training video demonstrating configuration into Transit Mode is available at www.RampartIC.com/training.

Move the M1128-RTV in Transit Mode

1. Remove and set aside the charging cord.
2. **Fold up the CMA curtain (A)** by hooking the **curtain hook** located on the bottom of the curtain onto the **CMA curtain bar (B)**.
3. Unlock the CMA curtain (A) for movement by turning the CMA clamping handle (C) **up**.
4. **Raise the CMA curtain (A)** to the highest vertical position on the guide shaft (D).
5. Lock the CMA clamping handle (C) by turning it **down**.



6. Put both rotation locks on the mast into **mid-position auto lock mode**.



Lower Rotation Lock

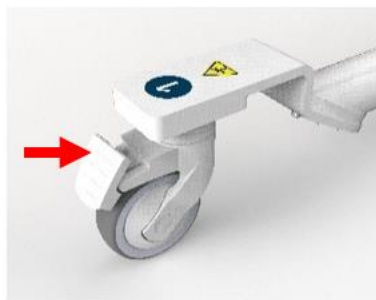


Upper Rotation Lock

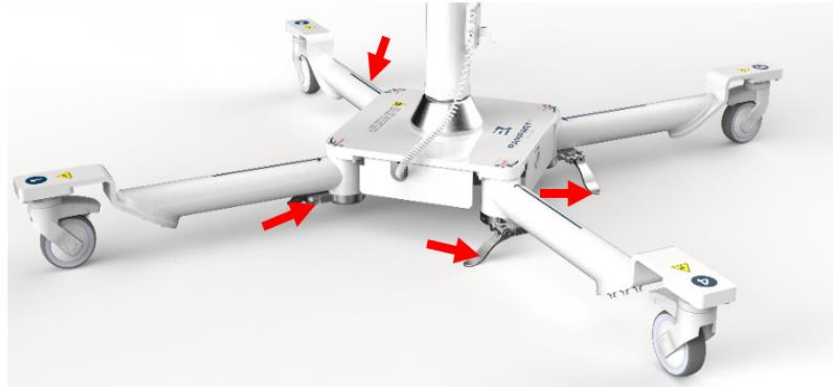
7. **Lower all panels and curtains** using the [Handset Controller](#) (page 24).
8. Fold the radial panel, the lower extremity panel, and CMA curtain together between legs 1 and 4. Both rotation locks will automatically lock when panels are in the correct position.



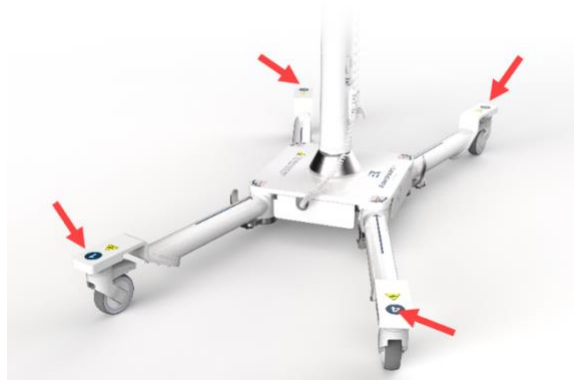
9. **Unlock all casters** by pressing the top half of the tab on each caster lock.



10. **Unlock all four legs** by turning the leg lock **down** on each leg.



11. **Position all four legs into Transit position** according to the **leg angle labels** adhered to the base of the Defender M1128-RTV. When positioned according to these labels, the legs fully support the panels and curtains while properly balancing the Defender M1128-RTV for transit.



12. **Lock the legs** into place by turning the leg lock **up** on each leg.



13. Make sure all doors between the current location and the destination are unlocked and opened.
14. Make sure that the pathway to the destination is unobstructed.
15. Alert individuals in proximity that equipment is coming through.

16. Stand on the side of the Defender M1128-RTV with the Rampart^{IC} logo.
17. Secure the equipment by placing one hand on the **mast** and the other hand on the **folded panels**.
18. Walk with the Defender M1128-RTV, guiding and pushing it to the desired location.
19. Lock casters upon arriving at the destination.

Charging

The Defender M1128-RTV is powered by a rechargeable battery designed to be charged only when the Defender M1128-RTV is not in use or in transit.

- Though it takes 10 hours for the Defender M1128-RTV to fully charge, it is recommended that the Defender M1128-RTV remain plugged in continuously—if not in use or in transit—to maintain a full charge.
- Continuous beeping from the battery indicates a low charge and the need to charge the battery. Continuously charging a Defender M1128-RTV in storage does not damage the battery.
- It is important to battery life to charge the Defender M1128-RTV in full at least once every 12 months.

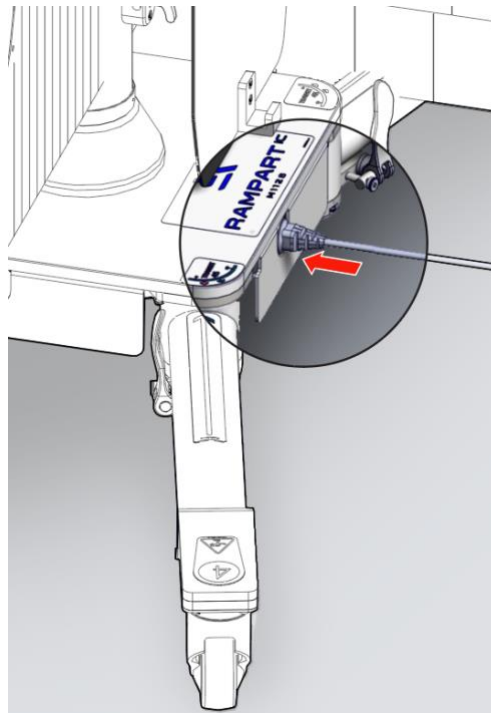


CAUTION!

- The Defender M1128-RTV must be fully charged at least once every 12 months.
- The Defender M1128-RTV must be charged 10 hours to obtain full charge.
- Always unplug the Defender M1128-RTV radiation shield prior to transport and before use.

Charge the Defender M1128-RTV

1. Move the Defender M1128-RTV radiation shield to [Storage](#) (page 31) or another safe location out of the way of foot traffic and activity, and where there is a standard wall outlet. See [Transit Mode](#) (page 14) for directions on how to safely move the Defender M1128-RTV.
2. Connect the charging cord to the base of the Defender M1128-RTV.



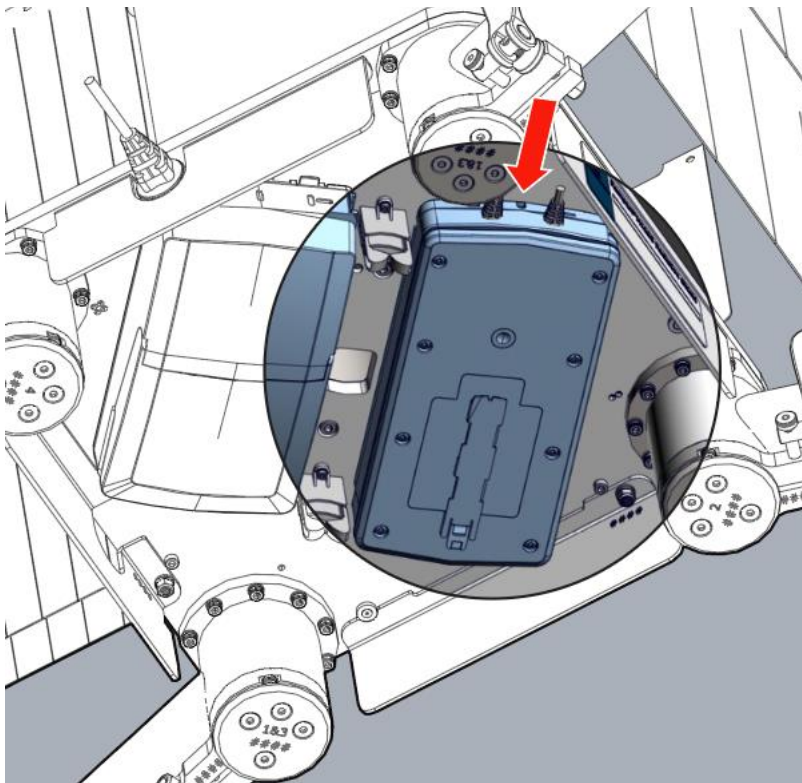
3. Connect the other end of charging cord to the wall outlet.
4. Charge for a **minimum of 10 hours** to obtain a full charge.

Note: *The Defender M1128-RTV can remain plugged in whenever not in use to safely maintain a full charge.*

5. When charged and needed, unplug the Defender M1128-RTV before moving and place in *Transit Mode* (page 14).

LED Indicator – Battery Status

There is an LED indicator on the edge of the battery affixed to the bottom-side of the Defender M1128-RTV base.



The appearance of the LED indicates battery charge status as follows:

LED	Battery Status Indication
Solid Light	Battery is charging.
Light Off	Battery is fully charged.
Flashing Light	There is a charging error.

Instructions for Use

The four legs, extendable mast, acrylic panels, and attached curtains of the Defender M1128-RTV 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. The Defender M1128-RTV can also be folded down to *Transit Mode* (page 14), providing a minimal footprint for safe and efficient movement between rooms.

The Defender M1128-RTV operates on battery power only.

Intended User Group

The intended user group for the Rampart Defender M1128-RTV radiation shield are physicians and their staff.

Intended Patient Populations

The Rampart Defender M1128-RTV is indicated for any interventional procedure that utilizes fluoroscopy where an operator stands on the right side of the procedure table and uses the following specific access points:

- Bi-radial
- Bi-femoral
- Pedal
- Popliteal
- Prachial

Contraindications, Warnings, and Cautions

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



WARNING:
Radiation
Exposure

- Failure to set Defender M1128-RTV lead-equivalent acrylic panels and curtain attachments at the proper height and position may cause radiation exposure. The Defender M1128-RTV 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} Defender M1128-RTV panels provide a protection level of 1 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 30 of this user guide.

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/j.jacc.2018.02.016> [accessed August 10, 2019].



WARNING:
MR-Unsafe

The Defender M1128-RTV system is MR-unsafe. MR-unsafe items should not be brought into MRI scanner rooms.



CAUTION:
Heavy
Equipment-
Injury Risk

- The Defender M1128-RTV is heavy and caution must be used when handling the system.
- Failure to maintain control when moving the system can result in personal injury or property damage.
- Personnel working with the Defender M1128-RTV system(s) must be properly trained.



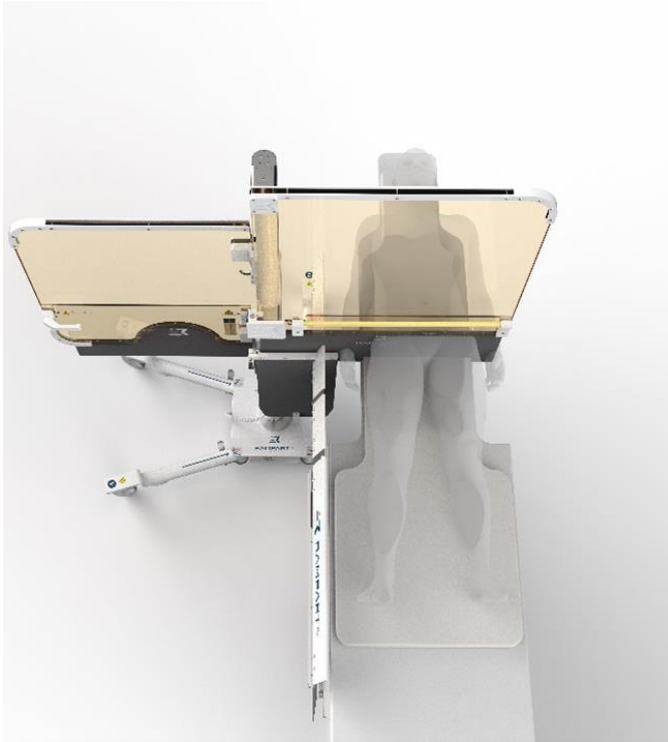
CAUTION

Potential drag may occur when the curtain or the table are moved during a procedure. Ensure that the soft shield flaps are lying flat against the patient's body and pointing towards the operator. Securing the sheath with adhesive or suture is recommended.

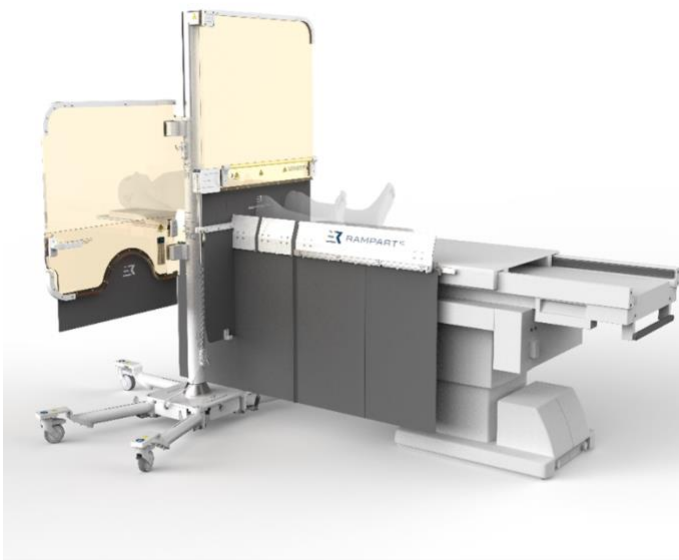
Sample Configurations



Transit Mode with mast fully collapsed and panels and curtains folded together between legs 1 and 4



Panels and curtains at 180° for radial (bi-radial) and femoral procedures and to accommodate biplane angles



Panels and curtains at 180° pedal configuration

Handset Controller

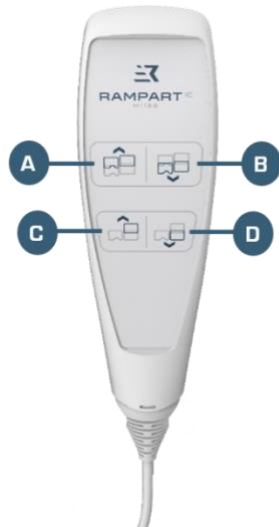


WARNING:
Rare Earth
Magnet

Keep rare-earth magnets away from anyone with a pacemaker and away from magnetic media. Dispose of rare-earth magnets in compliance with local, state, and Federal laws.

The handset controller accompanying the Defender M1128-RTV is used to raise and lower the panels and curtains:

- The **top row of buttons** raises or lowers both panels and curtains simultaneously.
- The **bottom row of buttons** raises or lowers the lower extremity panel only.
- The controller has a magnet on the back to increase placement options and convenience.



A	Raises both radial and lower extremity panels
B	Lowers both radial and lower extremity panels
C	Raises lower extremity panel
D	Lowers lower extremity panel

Reset the Handset Controller

An intermittent beeping sound coming from the controller and inability to move panels upwards indicates the handset controller is overloaded and needs to be reset.

To reset the handset controller:

1. Hold down both bottom buttons on the handset controller for a few seconds until you hear two beeps.
2. Confirm that the overload error has cleared by attempting to lower or raise the lower extremity panel.

3. Repeat step 1 as necessary.

Operate the Defender M1128-RTV



WARNING: Radiation Exposure

- Failure to set Defender M1128-RTV lead-equivalent acrylic panels and curtain attachments at the proper height and position may cause radiation exposure. The Defender M1128-RTV 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*⁵, 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} Defender M1128-RTV panels provide a protection level of 1 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 30 of this user guide.



CAUTION!

Locking the casters during a procedure may cause damage to the Defender M1128-RTV or interfere with its proper use.

1. **Unlock the Defender M1128-RTV casters** if they are locked.



2. **Position the Defender M1128-RTV legs** according to the type of procedure, planned panel and curtain assembly orientation, and in a way where each panel and curtain will be directly supported by a leg.

To adjust each leg individually:

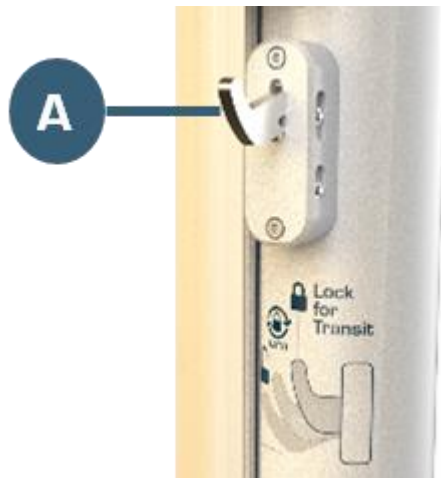
⁵ J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/j.jacc.2018.02.016> (accessed August 10, 2019).



- a. **Unlock the legs** by turning the leg lock down on each leg.
- b. **Move the legs** into the desired positions.
 - **Legs 1, 3, and 4** can be adjusted between 17.8 and 45 degrees.
 - **Leg 2** can be adjusted between 17.8 and 90 degrees.
- c. **Lock the legs** by turning the leg lock up on each leg.

Note: It is recommended that Defender M1128-RTV legs are placed in the optimal position prior to advancing to the table as predetermined and optimized for the operator and access point. The Defender M1128-RTV leg position can be configured to fit most procedures, table types, and the comfort of the medical team, and is positioned by feet to maintain hand sterility.

3. **Unlock the lower extremity panel** by pulling the upper rotation lock (A) to its furthest position out away from the mast.



4. Rotate the lower extremity panel into the desired position. The lower extremity panel can open a maximum of 210 degrees.

Note: The upper rotation lock must be unlocked and the lower extremity panel opened to at least a 90-degree angle before panels can be raised. Once raised, the lower extremity panel cannot be rotated less than

90-degrees. The panels must be lowered all the way with the handset controller before panels can be folded together into transit position.

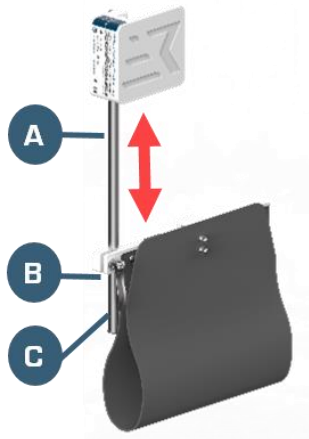
5. **Using the handset controller, adjust the Defender M1128-RTV panels and curtain attachments** to the approximate height of the anticipated access site (radial, femoral, pedal, or otherwise) when the patient is eventually positioned.
6. Place or attach the handset controller in a location that is convenient on the Defender M1128-RTV.
7. Adjust the rotation of the lower extremity and radial panel so that they are in the correct position for the procedure.

- **CONFIGURATION DURING USE:** Panels and attached curtains can be placed safely at any needed angle during use, as long as one leg is positioned in the general direction of each panel to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- **CONFIGURATION DURING TRANSIT:** To move the Defender M1128-RTV to another location, the Defender M1128-RTV must be placed into *Transit Mode* (page 14). First, collapse the mast to the lowest position, fold the panels and curtains together, and lock them forward between legs 1 and 4. Then, position all four legs for transit with leg locks locked into place to prevent the legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with the Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit. When in Transit Mode and moved correctly, the Defender M1128-RTV is narrow enough to fit through standard walkways.



WARNING:
Tipping
Hazard

8. **Unlock the CMA curtain** for vertical adjustment by turning the CMA clamping handle (C) straight up. The unlocked CMA curtain bar (B) can be adjusted up and down the CMA guide shaft (A).



9. Vertically adjust the CMA curtain by moving the CMA curtain bar to the anticipated height needed and **lock** the curtain by turning the CMA clamping handle straight down.
10. **Orient the CMA accessory curtain** to the anticipated position reflecting the access site and patient position.

11. Apply the sterile drapes.

Note: *Drape kits are sold separately at Rampart^{IC} and not included with purchase of the Defender M1128-RTV.*

12. Further adjust the radial panel, the lower extremity panel, and attached curtains with the handset controller while considering the access site, patient position and size, table height, and physician's preference.
13. Ensure proper lower table and lower body radiation protection is in place at the procedure table.

Note: *Rampart^{IC} recommends using under-table lead-equivalent curtains that fully extend between the radiation source and the positions of the medical team during a procedure.*

14. Position the patient for the procedure.
15. Drape the patient and table as usual.
16. **Lower the procedure table** in preparation for precise positioning of the Defender M1128-RTV, as necessary.
17. Roll the Defender M1128-RTV to adjust physical orientation, as necessary.
18. **Raise the procedure table** to meet the Defender M1128-RTV radiation shield, as necessary.
19. Further customize the positioning of the Defender M1128-RTV mast, panels, and curtains after the patient, staff, other equipment, and the physician are in position.



CAUTION:
Pinch Point

When making final adjustments to the Defender M1128-RTV and while the patient is in position, always monitor the lower edge of the panel and curtain in relation to the patient to prevent injury. Always maintain visual contact with panels, curtains, and other equipment, in relation to the patient, when panels, curtains, or other equipment are being adjusted.

20. **Position Rampart^{IC} anti-fatigue mat(s)** according to the comfort of physicians and staff.

Note: *A Rampart^{IC} anti-fatigue mat is provided with each Defender M1128-RTV. To purchase additional anti-fatigue mats, email info@RampartIC.com.*

21. Place scrub table and fluoroscopy handset controllers and control pedals in place on the floor keeping in mind the location of the Defender M1128-RTV leg position, physician preference, and safety.



CAUTION:
Trip Hazard

- Failure to place controllers and the Defender M1128-RTV legs in a convenient and safe position can result in a tripping hazard for the physician and medical team in the lab.

- Always maintain awareness of the positioning of Defender M1128-RTV legs and casters to avoid tripping when moving around the Defender M1128-RTV.

22. **Conduct a safety check** to ensure all radiation protection equipment is in place and radiation gaps below the table and around the Defender M1128-RTV are minimized.
23. **Make final adjustments** to the Defender M1128-RTV as necessary.
24. Conduct the fluoroscopic procedure.
25. When the procedure is complete, **adjust the Defender M1128-RTV mast, panels, and curtains with the handset controller so that it can be pulled away** from the procedure table without harming the patient or equipment.



WARNING:
Tipping Hazard

- **CONFIGURATION DURING USE:** Defender M1128-RTV panels and attached curtain assemblies can be placed safely at any needed angle during use, as long as one leg is positioned in the general direction of each panel and curtain to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- **CONFIGURATION DURING TRANSIT:** To move the Defender M1128-RTV to another location, the Defender M1128-RTV must be placed into *Transit Mode* (page 14). First, collapse the mast to the lowest position, fold the panels and curtains together, and lock them forward between legs 1 and 4. Then, position all four legs for transit with leg locks locked into place to prevent the legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with the Rampart^{IC} logo to push and guide the Defender M1128-RTV during transit. When in Transit Mode and moved correctly, the Defender M1128-RTV is stable and narrow enough to fit through standard walkways.



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 panel and curtain in relation to the patient to prevent injury. Always maintain visual contact with panels, curtains, and other equipment, in relation to the patient, when the panel and curtain assembly or other equipment are being adjusted.

26. Carefully roll the Defender M1128-RTV away for safe patient removal..
27. **Remove the patient** from the procedure room and **dispose of the used drape kit** according to standard biohazard guidelines.
28. **Clean** (see *Cleaning* on page 30) and **store** (see *Storage* on page 31) the Defender M1128-RTV.

Maintenance

The Rampart^{IC} Defender M1128-RTV requires post-procedure cleaning, routine inspections, and repairs by Rampart^{IC} authorized personnel to maintain optimal performance.



CAUTION:
Heavy
Equipment-
Injury Risk

- The Defender M1128-RTV is heavy and caution must be used when handling the system.
- Failure to maintain control when moving the system can result in personal injury or property damage.
- Personnel working with the Defender M1128-RTV system(s) must be properly trained.
- Defender M1128-RTV assembly, repairs, and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}.

Cleaning

The Rampart^{IC} Defender M1128-RTV 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.



CAUTION:
Heavy
Equipment-
Injury Risk

- The Defender M1128-RTV is heavy and caution must be used when handling the system.
- Failure to maintain control when moving the system can result in personal injury or property damage.
- Personnel working with the Defender M1128-RTV system(s) must be properly trained.
- Defender M1128-RTV assembly, repairs, and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}.



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 Defender M1128-RTV, never use scrapers or metal tools of any kind.

The Defender M1128-RTV 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:**

ATTENTION!

- Paper towels or linen washcloths
- Alcohol wipes
- Sporidican⁶ 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 Cellosolve⁷
- 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

⁶ Sporidican[®] is a registered trademark of Contec, Inc.

⁷ Butyl Cellosolve[™] is a trademark of the Dow Chemical Company.

Clean the Defender M1128-RTV

Clean the Defender M1128-RTV by wiping it with a soft cloth and a neutral pH enzymatic detergent (typically pH 6-8) diluted in water.

Disinfect the Defender M1128-RTV

Disinfect the Defender M1128-RTV using one of the following:

- 70% or less isopropyl alcohol
(Dry panels and curtains immediately after application.)
- Sani-HyPerCide⁸ Germicidal Disposable Wipe
- Super Sani-Cloth⁹ Germicidal Disposable Wipes
- CaviWipes¹⁰ 2.0 Disinfecting Wipes

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 Defender M1128-RTV panels and curtains and are available for purchase. To purchase, email info@RampartIC.com.*

Storage

Rampart^{IC} recommends transporting and storing the Defender M1128-RTV in *Transit Mode* (page 14) due to the stability and minimal space footprint of this configuration.

1. Make sure the Defender M1128-RTV is cleaned (see *Cleaning* on page 30) before storage.
2. Move the Defender M1128-RTV in *Transit Mode* (page 14) to a dedicated storage room, to the side of the cath lab or other suitable location where there is minimal foot traffic and activity, and where there is a standard wall outlet.
3. Plug in the rechargeable battery to charge when the Defender M1128-RTV is not in use. See *Charging* on page 19.

Note: *The Defender M1128-RTV should remain plugged in whenever it is not in use to safely maintain a full charge.*



CAUTION!

- The Defender M1128-RTV must be fully charged at least once every 12 months.
- The Defender M1128-RTV must be charged 10 hours to obtain full charge.
- Always unplug the Defender M1128-RTV prior to transport and before use.

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

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

¹⁰ CaviWipes[®] is a registered trademark of Metrex Research LLC.

Preventative Inspection

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

1. Make sure the Defender M1128-RTV is cleaned (see [Cleaning](#) on page 30) before performing preventative inspection.
2. Inspect the panels, curtains, mast, and mobile unit to ensure:
 - a. All parts are fastened tightly.
 - b. The casters roll smoothly.
 - c. The support legs adjust easily.
 - d. There are no cracks or damage to any of the panels and curtains.
 - e. The panels and curtain attachments rotate easily around the mast.
 - f. The actuators function well in raising and lowering each panel and curtain attachment.
3. Preventative maintenance following the equipment specific maintenance plan will default to the policies and procedures of the institution related to inspecting shielding. The Rampart^{IC} 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
M1128-RTV-RTV	Defender M1128-RTV Radiation Shield Right Table Version V2
M1128-RTV-CDK	Defender M1128-RTV Drape Kit
M1128-RTV-UIG	Defender M1128-RTV User and Installation Guide
M1128-RTV-AFM	Defender M1128-RTV Antifatigue Mat
M1128-RTV-RCC	Defender M1128-RTV Rampart Cleaning Cloth

Suggestions

Adjustable Legs

The legs of the Defender M1128-RTV are adjustable to accommodate several needs and scenarios. Rampart^{IC} has added leg numbers and leg angle indicator labels to the Defender M1128-RTV base for easy reference. It may be helpful and more efficient for staff to use the angle indicator labels and numbering on the legs to note the leg placement preferences of different physicians and what works best for different procedures.

Before transit, all four legs should be moved into the transit position and locked to prevent them from changing angles during movement. Upon arrival at the cath lab, the leg locks can be unlocked for adjustment as necessary. The physician or technician can keep their hands sterile by adjusting unlocked legs with their feet.

Under and Above Table Lower Body Protection

Rampart^{IC} requires the use of a below-table lead-equivalent protective shield in conjunction with the Defender M1128-RTV radiation shield such as the Rampart^{IC} L148 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.

Transit Mode

To ensure easy transportation from room to room, the Defender M1128-RTV should always be configured into *Transit Mode* (page 14) prior to being moved. This position is when the radial panel, lower extremity panel, and attached curtains are in their lowest position and folded in together pointing forward. All four legs should be placed in Transit Mode as indicated by the leg arrow and the leg angle label, and the legs should be locked. Transit Mode is also the ideal storage position due to its maximum stability and smaller footprint.

Reposition out of Transit Mode

When repositioning the Defender M1128-RTV out of Transit Mode:

1. Unlock the legs.
2. Move all legs to the 45° angle as shown on the leg angle labels.
3. Move the panels and attached curtains into the desired position.

Note: *Legs can be placed in position for the procedure after panel and curtain positioning, but there must always be one leg positioned in the general direction of each panel and curtain to ensure proper Defender M1128-RTV balance and stability.*

Disposal



WARNING:
Rare Earth
Magnet

Keep rare-earth magnets away from anyone with a pacemaker and away from magnetic media. Dispose of rare-earth magnets in compliance with local, state, and Federal laws.

The Rampart^{IC} Defender M1128-RTV system contains lead-equivalent panels, lead-equivalent curtains, rare earth magnets, and a rechargeable battery. The system and all components should be disposed of 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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M1128

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