



RAMPART IC

M1128



- *Standalone M1128*
- *M1128 + M1128-RAK*
- *M1128 + M1128-RAK + M1128-CMA*

M1128[®]-RTV RADIATION SHIELD USER GUIDE

This user guide includes assembly and instructions for use for the “standalone” M1128 without accessory kits, the M1128 purchased with the M1128-RAK accessory kit, and the M1128 purchased with the M1128-RAK and M1128-CMA accessory kits.



Standalone M1128



M1128 + M1128-RAK



M1128 + M1128-RAK + M1128-CMA

This document should be stored with or within the immediate vicinity of the M1128 radiation shield and the medical team using the unit.

Rampart[®], M1128[®], Shed the Lead[®], and Fight the Good Fight[®] are trademarks of Rampart^{IC}.

The M1128 radiation shield is protected by patent in the United States under U.S. patent number 11,207,039. Additional patents are pending in the United States and in other countries.

The contents of this publication may not be reproduced, copied or translated in whole or in part without prior consent from Rampart^{IC}.

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.

The Rampart^{IC} M1128 radiation shield is available in the following options:

- Mobile Right Table Version (M1128-RTV)

MANUFACTURER

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LIVE TECHNICAL SUPPORT

Live technical support is available at (833) 978-0052 between the hours of 7 am to 6 pm Central Standard Time (CST), Monday through Friday. Phone calls received outside business hours will be returned as quickly as possible.

TRAINING

Training videos and a PDF version of this user guide are available at www.RampartIC.com/training.

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Overview

Congratulations on your purchase of the Rampart® M1128® radiation shield! Depending on the date of purchase or what you've opted to include with your purchase, you may have received the M1128 with accessory kit enhancements. Please review the table below to identify your M1128 purchase and follow the correct assembly and use instructions in this manual. **Please note that the accessory kits added to enhance the M1128 shown below are available for purchase to perfectly retrofit your M1128*.**

M1128 & Accessory Kit Options	Description
"Standalone" M1128	This is the original M1128 model with all rigid lead-shielding components without accessory kits.
M1128 with M1128-RAK*	In early 2021, we began offering an enhancement option to replace the rigid side drop panel and lower extremity shelf with the M1128-RAK* , a radiation shielding soft accessory kit allowing greater protective adaptability in the cath lab.
M1128 with M1128-RAK* & M1128-CMA*	In late 2021, we introduced another enhancement to further compliment the M1128-RAK* upgrade: an optional articulating center mast accessory kit (M1128-CMA*) which further increases the M1128 protective adaptability and scope.

Rampart makes sure your team is equipped with the latest, state-of-the-art radiation protection and freedom of mobility during fluoroscopic procedures allowing you to **SHED THE LEAD**® associated with lead aprons to best **FIGHT THE GOOD FIGHT**® in the cath lab.

This user guide provides guidance for the proper installation and use of the Rampart^{IC} M1128, 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 (see p. 8)*, 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 M1128.

Note: Training videos and a PDF version of this user guide are available at www.RampartIC.com/training.

INTENDED USE

The Rampart^{IC} M1128 (including accessory kits) is a protective radiation shield intended to safeguard users from radiation exposure during fluoroscopic medical procedures. An optional arm board is available to support a patient's arm during procedures requiring radial access. 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 M1128 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 M1128 has not been installed or set up for a procedure in accordance with the steps in this user guide.
- The M1128 is not moved in accordance with steps in this user guide.
- The M1128 is moved or transported to another building location without proper moving containers and a Rampart^{IC} authorized technician.
- The M1128 is used in a manner other than its intended use as stated above.

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 M1128.
- Repairs must only be performed by Rampart^{IC} authorized personnel.
- Before transport, the Rampart^{IC} M1128 must be placed into *Transit Mode* (p. 38) and be disconnected from charging.
- The weight of the M1128 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 law.



WARNING:
MR-Unsafe

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



WARNING:
Tipping Hazard

- **CONFIGURATION DURING USE:** The M1128 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 M1128 to another location, the M1128 must be placed into *Transit Mode (p. 38)*. First, the mast must be collapsed to the lowest position and the panels and attached curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent 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 M1128 during transit. When in Transit Mode and moved correctly, the M1128 is narrow enough to fit through standard walkways.



WARNING:
Radiation Exposure

- Failure to set M1128 lead-equivalent acrylic panels and curtain attachments at the proper height and position may cause radiation exposure. The M1128 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 Imaging¹*, 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} M1128 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 54 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 M1128 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 M1128 system(s) must be properly trained.
- M1128 assembly, repairs and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}. At least one other individual must also be present to assist with initial assembly due to the size and weight of the M1128 components.

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 M1128 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!
 (Without safety alert symbol)

- Alcohol wipes or Sporicidan² 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 Cellusolve³
- 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 M1128 must be fully charged at least once every 12 months.
- The M1128 must be charged a minimum of 10 hours to obtain full charge. Please see *Charging* on page 43.
- Locking the casters during a procedure may cause damage to the M1128 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 M1128, 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.
























CAUTION:
 Trip Hazard

- Place controllers and the M1128 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 M1128 legs and casters to avoid tripping when moving around the M1128.
- **CONFIGURATION DURING TRANSIT:** To avoid becoming a tripping hazard, the M1128 must be placed into *Transit Mode* (p. 38). First, the mast must be collapsed to the lowest position and the panels and curtain attachments folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent legs from changing angle during transit. When in Transit Mode, the M1128 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 M1128 during transit.

² Sporicidan® is a registered trademark of Contec, Inc.
³ Cellusolve™ is a trademark of the Dow Chemical Company.

Explanation of Symbols

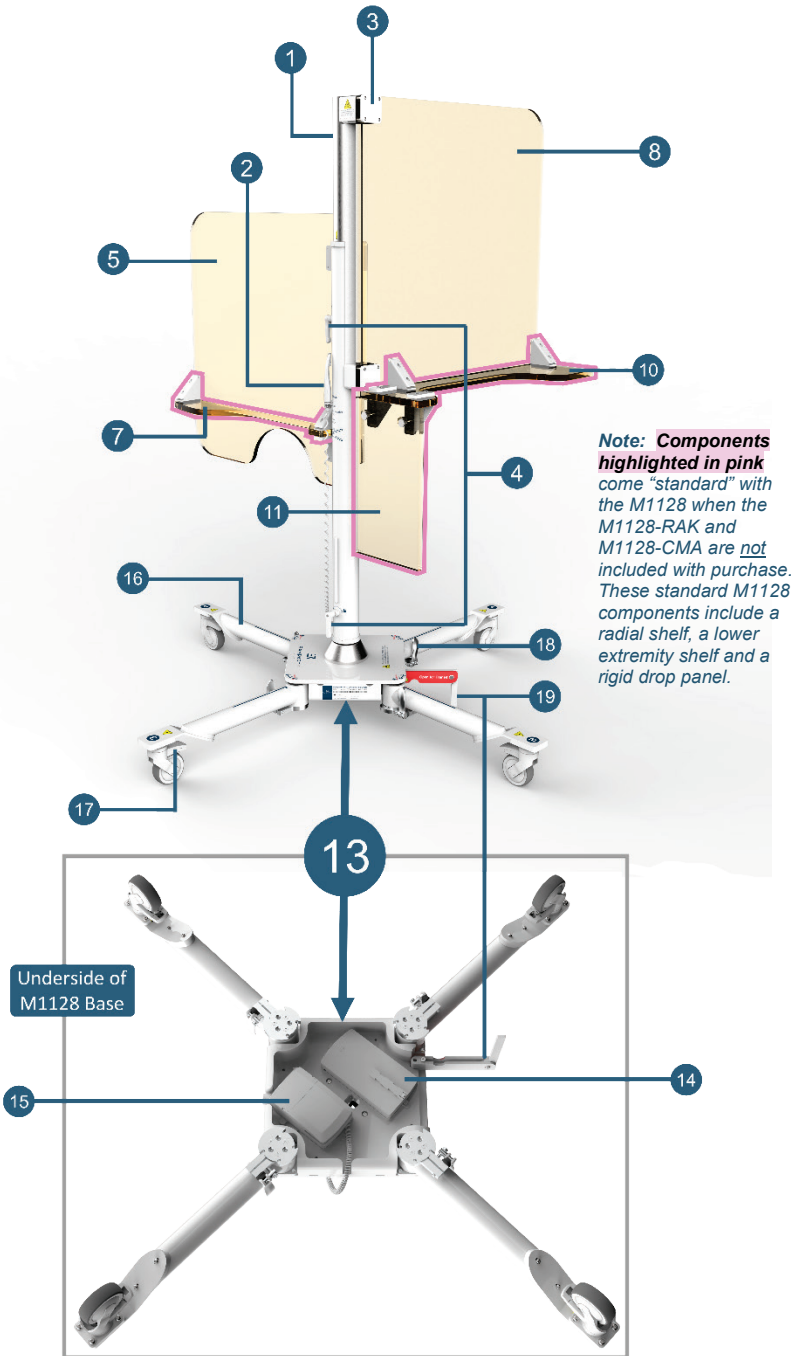
	Reference Number		Use By
	Serial Number		Keep Dry
	Quantity		Consult Instructions for Use
	Batch Number		Complies with Applicable European Union Regulations
	Manufacturer		Prescription Use or Licensed Healthcare Practitioner Use Only
	Manufactured Date		User Guide Must Be Read
	Do Not Re-Sterilize		Transit Mode
	Do Not Use If Package Is Damaged		Leg Angle Indicator
	Do Not Reuse		Lock / Unlock
	Sterilize Using Ethylene Oxide		Leg Number (1 - 4)
	European Authorized Representative		

THREE SYSTEM OVERVIEWS

The Rampart M1128 radiation shield is available for purchase standalone or with optional accessory kits. Three system overviews will go over the three most common purchase scenarios and the components included in each.

1. [***The Standalone M1128 System Overview on p. 12***](#) depicts the original M1128 with all-rigid lead-shielding components including the original radial shelf, a rigid side drop panel and a lower extremity shelf.
2. [***The M1128 + M1128-RAK System Overview on p. 14***](#) depicts the M1128 purchased with the M1128-RAK accessory kit containing two soft radiation shielding curtains and a lower extremity handlebar replacing the side drop panel and a lower extremity shelf.
3. [***The M1128 + M1128-RAK + M1128-CMA System Overview on p. 16***](#) depicts the M1128 purchased with both M1128-RAK and M1128-CMA accessory kits. The M1128-RAK includes two soft radiation shielding curtains and a lower extremity handlebar replacing the side drop panel and a lower extremity shelf. The M1128-CMA includes a center mast accessory and a radial shelf delete handle and bracket replacing the radial shelf.

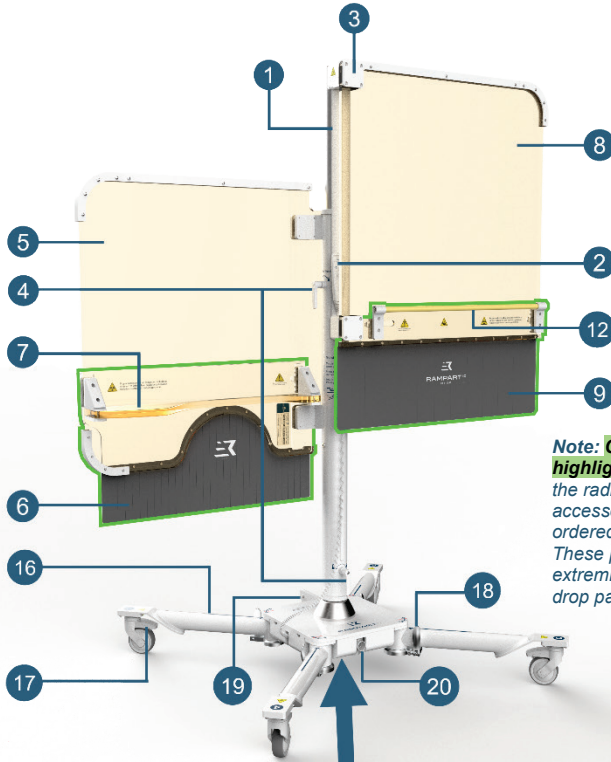
Standalone M1128 System Overview



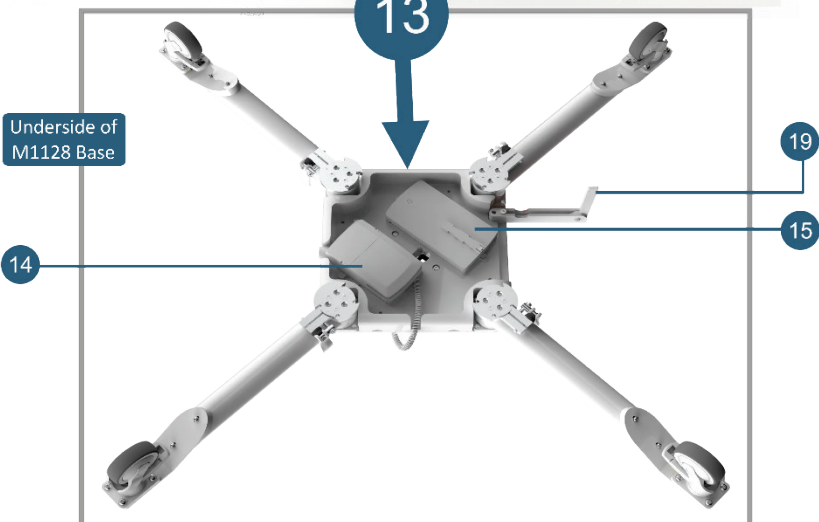
Standalone M1128 System Overview Key

1	Telescopic Mast: This stainless-steel mast is the backbone of the M1128, supporting the weight and height adjustment of all attached panels and curtains by control of the handset controller. The total height of the M1128 can be adjusted between 65.5 inches (1664 mm) tall when the mast is fully collapsed and up to 95 inches (2414 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"> • <i>Top buttons</i> – raise and lower both the radial and lower extremity panels simultaneously. • <i>Bottom buttons</i> – 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 M1128 assembly of the acrylic panels and shelves, curtains and handlebar.
4	Mast Locks: Two locks located along the mast can be locked to keep panels and attached curtain assemblies pointed in the desired direction and to prevent repositioning during transit. Both mast locks must be unlocked when adjusting the angle of the panels and curtains.
5	Radial Panel: Adjustable acrylic panel with a half circle arm cutout and 1 mm lead-equivalent protection. An optional, separately purchased arm board may be inserted during radial access procedures. This is one of the two large primary radiation shielding panels motorized for movement via attachment to the mast assembly.
7	Radial Shelf: Shelf with 0.5 mm lead-equivalent protection which attaches to the radial panel. <i>This part is included when the CMA Accessory (M1128-CMA) is not purchased with the M1128.</i>
8	Lower Extremity Panel: 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. Depending on purchase, this panel may include a shelf and drop panel attachment or a curtain and handlebar attachment.
10	Lower Extremity Shelf: Shelf with 0.5 mm lead-equivalent protection which attaches to the lower extremity panel. <i>This part is included when the radiation shielding soft accessory kit (M1128-RAK) is not purchased with the M1128.</i>
11	Side drop panel: Rigid rectangular panel that attaches to the bottom of the lower extremity shelf. This panel includes 1 mm lead-equivalent protection and <i>is included when the radiation shielding soft accessory kit (M1128-RAK) is not purchased with the M1128.</i>
13	Base Block: The base of the M1128 with four configurable legs. The rechargeable battery, charging cord and the deployable outrigger leg are attached on the underside, and the telescopic mast is attached on top.
14	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 plugged in to charge when not in use without damaging the battery. The battery must be charged once every 12 months.
15	Controller: The control box located under the M1128 base receives input from the handset controller to raise or lower the panels and curtains attached to the mast.
16	Base Legs: The base legs are mounted to the M1128 base, adjustable to a variety of user configurations and can fold inward to create a minimal footprint for <i>Transit Mode (p. 38)</i> or <i>Storage (p. 56.)</i>
17	Lockable Casters: Industrial grade, smooth-rolling casters attached to each leg of the M1128 allow smooth configuration of the base legs, transportation of the M1128, and are lockable.
18	Leg lock: There are four leg locks, one on each leg. Unlock the individual leg lock on each leg to reposition legs. Lock to keep legs from changing positions.
19	Outrigger Leg: This steel leg attached to the underside of the M1128 base is a safeguard to be deployed during <i>Transit Mode (p. 38)</i> and during fluoroscopic procedures.
20	Charging Port: Connects the rechargeable battery and controller under the base of the mast to the wall outlet.

M1128 + M1128-RAK System Overview



Note: Components highlighted in green are from the radiation shielding soft accessory kit (M1128-RAK) ordered with the M1128. These parts replace the lower extremity shelf and rigid side drop panel.

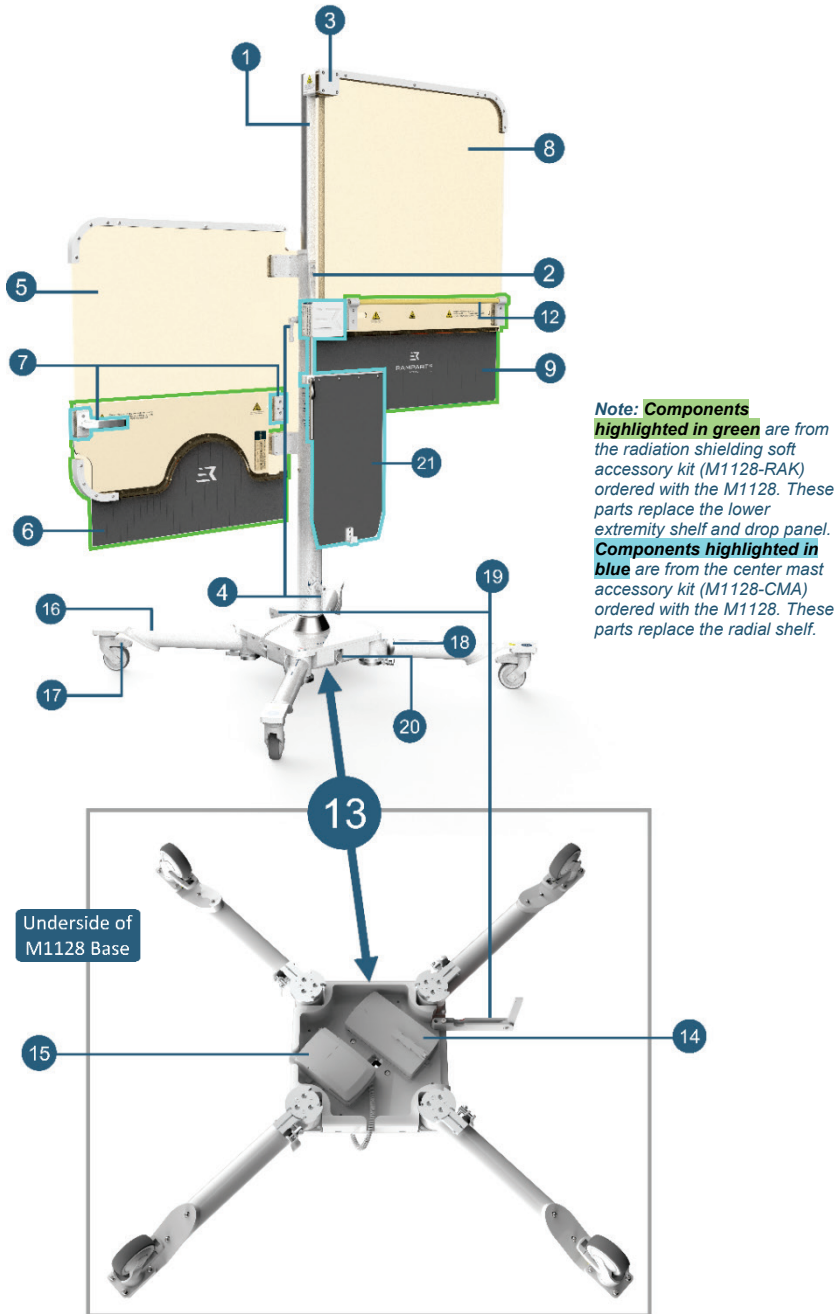


Underside of M1128 Base

M1128 + M1128-RAK System Overview Key

1	Telescopic Mast: This stainless-steel mast is the backbone of the M1128, supporting the weight and height adjustment of all attached panels and curtains by control of the handset controller. The total height of the M1128 can be adjusted between 65.5 inches (1664 mm) tall when the mast is fully collapsed and up to 95 inches (2414 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"> • <i>Top buttons</i> – raise and lower both the radial and lower extremity panels simultaneously. • <i>Bottom buttons</i> – 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 M1128 assembly of the panels and shelves, curtains and handlebar.
4	Mast Locks: Two locks located along the mast can be locked to keep panels and attached curtain assemblies pointed in the desired direction and to prevent repositioning during transit. Both mast locks must be unlocked when adjusting the angle of the panels and curtains.
5	Radial Panel: Adjustable acrylic panel with a half circle arm cutout and 1 mm lead-equivalent protection. An optional, separately purchased arm board may be inserted during radial access procedures. This is one of the two large primary radiation shielding panels motorized for movement via attachment to the mast assembly.
6	Radial Curtain: 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. <i>This part is included only with purchase of the M1128 with radiation shielding soft accessory kit (M1128-RAK).</i>
7	Radial Shelf: Shelf with 0.5 mm lead-equivalent protection which attaches to the radial panel.
8	Lower Extremity Panel: 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. Depending on purchase, this panel may include a shelf and drop panel attachment or a curtain and handlebar attachment.
9	Lower Extremity Curtain: Pliable curtain with 0.5 mm lead-equivalent protection which attaches to the lower extremity panel. <i>This part is included only with purchase of the M1128 with radiation shielding soft accessory kit (M1128-RAK).</i>
12	Handlebar: A handlebar attached to the lower extremity panel aids in steadying and positioning the M1128. <i>This part is included only with purchase of the M1128 with the radiation shielding soft accessory kit (M1128-RAK).</i>
13	Base Block: The base of the M1128 with four configurable legs. The rechargeable battery, charging cord and the deployable outrigger leg are attached on the underside, and the telescopic mast is attached on top.
14	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 plugged in to charge when not in use without damaging the battery. The battery must be charged once every 12 months.
15	Controller: The control box located under the M1128 base receives input from the handset controller to raise or lower the panels and curtains attached to the mast.
16	Base Legs: The base legs are mounted to the M1128 base, adjustable to a variety of user configurations and can fold inward to create a minimal footprint for <i>Transit Mode (p. 38)</i> or <i>Storage (p. 56.)</i>
17	Lockable Casters: Industrial grade, smooth-rolling casters attached to each leg of the M1128 allow smooth configuration of the base legs, transportation of the M1128, and are lockable.
18	Leg lock: There are four leg locks, one on each leg. Unlock the individual leg lock on each leg to reposition legs. Lock to keep legs from changing positions.
19	Outrigger Leg: This steel leg attached to the underside of the M1128 base is a safeguard to be deployed during <i>Transit Mode (p. 38)</i> and during fluoroscopic procedures.
20	Charging Port: Connects the rechargeable battery and controller under the base of the mast to the wall outlet.

M1128 + M1128-RAK + M1128-CMA System Overview



M1128 + M1128-RAK + M1128-CMA System Overview Key

1	Telescopic Mast: This stainless-steel mast is the backbone of the M1128, supporting the weight and height adjustment of all attached panels and curtains by control of the handset controller. The total height of the M1128 can be adjusted between 65.5 inches (1664 mm) tall when the mast is fully collapsed and up to 95 inches (2414 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"> • <i>Top buttons</i> – raise and lower both the radial and lower extremity panels simultaneously. • <i>Bottom buttons</i> – raise and lower the lower extremity panel attached to the mast.
3	Panel Mounting Brackets: Durable, acetel plastic brackets of varying shapes are used in M1128 assembly of the panels and shelves, curtains and handlebar.
4	Mast Locks: Two locks located along the mast can be locked to keep panels and attached curtain assemblies pointed in the desired direction and to prevent repositioning during transit. Both mast locks must be unlocked when adjusting the angle of the panels and curtains.
5	Radial Panel: Adjustable acrylic panel with a half circle arm cutout and 1 mm lead-equivalent protection. An optional, separately purchased arm board may be inserted during radial access procedures. This is one of the two large primary radiation shielding panels motorized for movement via attachment to the mast assembly.
6	Radial Curtain: 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. <i>This part is included only with purchase of the M1128 with radiation shielding soft accessory kit (M1128-RAK).</i>
7	Radial Shelf Delete Handle and Radial Shelf Delete Bracket: A fixed handle and bracket attached to the radial panel replacing the original radial shelf. These parts are designed to better facilitate manipulation and positioning of the M1128. This radial shelf delete handle and radial shelf delete bracket come with purchase of the optional center mast accessory (M1128-CMA) enhancement.
8	Lower Extremity Panel: 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. Depending on purchase, this panel may include a shelf and drop panel attachment or a curtain and handlebar attachment.
9	Lower Extremity Curtain: Pliable curtain with 0.5 mm lead-equivalent protection which attaches to the lower extremity panel. <i>This part is included only with purchase of the M1128 with radiation shielding soft accessory kit (M1128-RAK).</i>
12	Handlebar: A handlebar attached to the lower extremity panel aids in steadying and positioning the M1128. <i>This part is included only with purchase of the M1128 with the radiation shielding soft accessory kit (M1128-RAK).</i>
13	Base Block: The base of the M1128 with four configurable legs. The rechargeable battery, charging cord and the deployable outrigger leg are attached on the underside, and the telescopic mast on top.
14	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.
15	Controller: The control box located under the M1128 base receives input from the handset controller to raise or lower the panels and curtains attached to the mast.
16	Base Legs: The base legs are mounted to the M1128 base, adjusts to a variety of configurations and can fold inward to create a minimal footprint for <i>Transit Mode (p. 38)</i> or <i>Storage (p. 56.)</i>
17	Lockable Casters: Industrial grade, smooth-rolling casters attached to each leg of the M1128 allow smooth configuration of the base legs, transportation of the M1128, and are lockable.
18	Leg lock: There are four leg locks, one on each leg. Unlock the individual leg lock on each leg to reposition legs. Lock to keep legs from changing positions.
19	Outrigger Leg: This steel leg attached to the underside of the M1128 base is a safeguard to be deployed during <i>Transit Mode (p. 38)</i> and during fluoroscopic procedures.
20	Charging Port: Connects the rechargeable battery and controller under the base to the wall outlet.
21	Center Mast Accessory (CMA): The CMA assembly includes a pliable, articulating 1 mm lead-equivalent protection <i>CMA curtain</i> able to adjust in height along a <i>CMA guide shaft</i> and lock into place via the <i>CMA clamping handle</i> , all of which are attached to the lower extremity panel via the white box-shaped <i>CMA mounting bracket</i> . A <i>curtain hook</i> on the bottom of the CMA curtain is used to foldup the curtain for <i>Transit Mode (p. 38)</i> or <i>Storage (p. 56.)</i> .

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, by use of a handset controller.
- If ordered, 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 M1128 protective coverage area.
- If ordered, the CMA assembly provides height-adjustable articulating radiation protection between the radial and lower extremity panel.
- The M1128 legs are also adjustable to fit most intervention procedure tables.
- The M1128 panels and curtains remain sterile when properly draped.
- The M1128 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, is available for purchase through RampartIC, and can be used with the M1128 to provide further radiation protection to the physician and lab tech on the shielded side of the table.

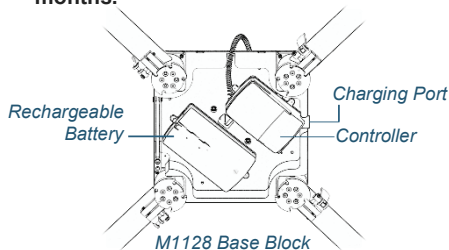
TECHNICAL SPECIFICATIONS

Power Supply

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

- 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 feet (3.2 meter) cord length

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

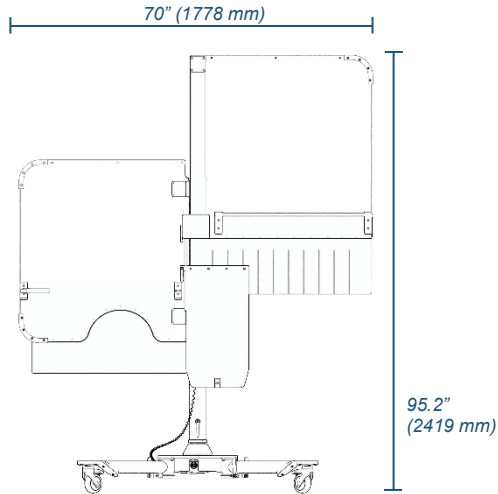


Dimensions

After *M1128 Assembly* (see p. 21) the four legs, extendable mast, acrylic panels and attached radiation shielding curtains of the M1128 can be configured in a variety of ways with the overall measurements varying accordingly:

- *Instructions for Use* (p. 44)
- *Transit Mode* (p. 38)
- *Maintenance section* (p. 54)

The M1128 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 M1128 is at its largest configured size: 95.2 inches (2419 mm) tall by 70 inches (1778 mm) wide



Operating Environment

The M1128 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. Storage temperature is between 14°F (-10°C) to 104°F (40°C).

Weight

- The assembled M1128 radiation shield is over 300 pounds (>136 kg).
- The M1128 handset controller is 1.10 pounds (0.5 kg).

IP Protection Class

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

OPTIONAL M1128 LOWERING KIT



Rampart^{IC} offers the M1128 lowering kit (part number M1128-LWK) for separate purchase to reduce the overall M1128 radiation shield height by 62 mm. This is done with the provision of a base block with modified legs that lower the M1128 center of gravity. Installation of the lowering kit would reduce the maximum and minimum adjusted radiation shield heights by 62 mm.

The benefits of installing the lowering kit include the following:

- Allows the M1128 radiation shield to accommodate a wider range of C-Arm procedure positions to better-achieve all camera angles.
- Reduces user interaction with the M1128 base during left anterior oblique (LAO) procedures for certain C-Arm types.

Contact Rampart^{IC} at <https://www.RampartIC.com/contact-us> to purchase the lowering kit. Purchase of the lowering kit will include professional installation according to the *Rampart^{IC} Assembly and Service Guide*.

IDENTIFICATION TAG

An identification tag can be found at the base of the M1128 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

M1128 Assembly

Assembly instructions must be performed by a Rampart^{IC} authorized individual. As an assembled M1128 radiation shield is over 300 pounds (>136 kg), the presence of at least one assistant is required for safe assembly. A 5 mm Allen wrench (long handle, ball end) is not included with your M1128 purchase and will be required for assembly.

Note: Training videos and a PDF version of this user guide are available at www.RampartIC.com/training.



CAUTION:
Heavy
Equipment-Injury
Risk

- The M1128 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 M1128 system(s) must be properly trained.
- M1128 assembly, repairs and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}. At least one other individual must also be present to assist with initial assembly due to the size and weight of the M1128 components.

Assembly will begin with building the essential M1128 frame. This includes the base, mast and two primary large lead-shielding panels. **Assembly directions and components THEN DIVERGE according to whether your M1128 purchase includes accessory kits.**



- **A standalone M1128 purchased *without* accessory kits** will involve completing assembly with a radial shelf, a rigid side drop panel and lower extremity shelf.
- **An M1128 purchased *with* M1128-RAK** (radiation shielding soft accessory kit) will involve completing assembly with two lead-equivalent curtains and a handlebar in lieu of the rigid side drop panel and lower extremity shelf.
- **An M1128 purchased *with both* the M1128-RAK** (radiation shielding soft accessory kit) and the **M1128-CMA** (center mast accessory kit) will involve completing assembly with the two lead-equivalent curtains and the handlebar from the M1128-RAK in lieu of the rigid side drop panel and lower extremity shelf as well as a center mast accessory and radial shelf delete handle and bracket from the M1128-CMA, in lieu of the radial shelf.

FIRST ASSEMBLE THE ESSENTIAL M1128 FRAME

1. Move the **packaged M1128** into a **well-lit room** with a level floor that is at least 8 feet tall and 10 feet by 10 feet wide. This ensures a stable surface, adequate visibility and enough space to accommodate the potential maximum dimensions (*see p. 19*) of the M1128 radiation shield at 95.2 inches (2419 mm) tall and 70 inches (1778 mm) wide.
2. Make sure to have a 5 mm Allen wrench (long handle, ball end) to assemble the M1128.
3. **Unpack the M1128 cases** and ensure all parts are present. *What Comes Out-of-the-Box* will differ according to whether you also purchased accessory kits with your M1128.

What Comes Out-of-the-Box

- **Standalone M1128 purchased *without* accessory kits**, includes the full *standalone M1128 components* listed in the table below.
- **M1128 + M1128-RAK purchases** includes the standalone M1128 components **excluding** the lower extremity shelf* and rigid side drop panel* and **including** all M1128-RAK contents below.
- **M1128 + M1128-RAK + M1128-CMA purchases** includes the *standalone M1128 components* **excluding** the lower extremity shelf*, rigid side drop panel* and radial shelf* while **including** all M1128-RAK and M1128-CMA contents below.

Standalone M1128 Components	Optional Accessory Kit Components
<ul style="list-style-type: none"> • One (1) mast assembly • One (1) radial panel • One (1) radial shelf* • One (1) lower extremity panel • One (1) lower extremity shelf* • One (1) rigid side drop panel* • Two (2) shelf brackets • Eight (8) RIC001-01-08 compression plates • One (1) base and legs assembly • One (1) handset controller • One (1) actuator control box with battery • One (1) charging cord • Two (2) stainless steel knobs • Thirty-six (36) M6x40 SHCS • Twenty (20) M6 nylon insert locknuts (<i>referenced as "M6 locknuts" in user guide</i>) • Four (4) M6x30 SHCS, 18-8SS, locking • Four (4) M6 flat washer, zinc plated steel • Four (4) thumb screws • Four (4) M6x45 SHC* (<i>*for all double-stacked panel configurations only</i>) 	<p><u>M1128-RAK accessory kit contents</u></p> <ul style="list-style-type: none"> • One (1) radial curtain • One (1) lower extremity curtain • Two (2) bracket A • One (1) bracket B • One (1) bracket C • Three (3) F-locks • One (1) slide-lock • Two (2) lower extremity handlebar brackets (<i>a counterbored hole is additionally included for all double-stacked panel configurations only</i>) • One (1) lower extremity handlebar <p><u>M1128-CMA accessory kit contents:</u></p> <ul style="list-style-type: none"> • One (1) center mast accessory (CMA) (<i>comes preassembled together with the CMA curtain bar, CMA curtain, CMA mounting bracket, CMA clamping handle and CMA guide shaft</i>) • One (1) radial shelf delete handle • One (1) radial shelf delete bracket

Base Legs Assembly

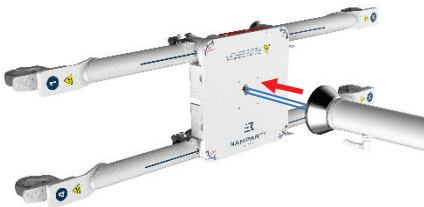
4. Remove the **base and legs assembly** from the transportation case and place it on the floor with wheels resting on the ground.
5. **Adjust and lock the four legs** of the base and leg assembly so that two legs are fully folded together on each side.



6. Flip the base and legs assembly *on its side*.

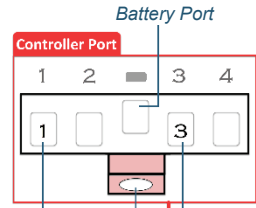


Install Mast onto Base Legs Assembly

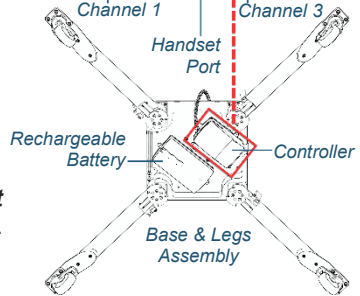


7. **Feed the two actuator cables** through the passageway in the center of the base and legs assembly.
8. Together with the assistant(s), **position the mast assembly** on the center of the base and legs assembly. (Align the lower mast lock to the side with the base charging port.)
9. **Secure the mast assembly** by tightening four M6x30 screws (stainless steel socket head cap screws with a locking nylon patch) through the base and legs assembly, and into the bottom of the mast assembly. Use the 5 mm Allen wrench to tighten.
10. **Connect the handset controller cable to the handset port** of the controller found on the underside of the M1128 base block.

11. Connect the *numerically labeled* actuator cables to these numerically labeled channels:
 - a. Insert the plug for actuator cable 1 into **channel 1** of the controller.
 - b. Insert the plug for actuator cable 2 into **channel 3** of the controller.



12. **Install the controller and the battery** to the underside of the base and legs assembly using the four thumb screws provided.

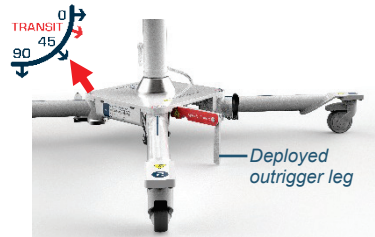


13. **Flip the M1128 base block to its upright position** with wheels touching the ground.

14. **Position M1128 legs in preparation for remaining assembly.**

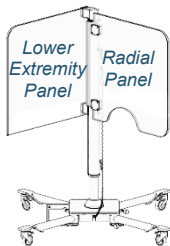
To adjust each leg individually:

- a. **Unlock each leg** by turning **down** the leg lock on each leg.
- b. **Move all four legs** to the 45-degree mark.
- c. **Lock each leg** by turning **up** the leg lock on each leg.
- d. **Deploy the outrigger leg** to help maintain stability.



Note: The two primary M1128 panels—the radial panel and lower extremity panel—may include bumpers and/or a tension bar depending upon when you purchased your M1128. Accordingly, the images displayed throughout this user guide may depict radial and lower extremity panels with and without a tension bar and bumpers.

Install Acrylic Panels onto Telescopic Mast



15. **Install the radial panel** onto the mounting surface of the telescopic mast using the zinc-plated M6x40 socket head cap screws and the RIC001-01-08-panel compression plates. Tighten using a 5 mm Allen wrench.

Note: **In double-stack panel configurations**, ensure that radial panel is set to the highest possible position before securing. Additionally, install the RIC001-01-08 panel compression plates with the counterbored hole facing towards the panel to ensure a proper fit over all shoulder bolts.

16. Install the lower extremity panel on to the lower extremity panel hanger using the zinc-plated M6x40 socket head cap screws and the RIC001-01-08 panel compression plates. Tighten using a 5 mm Allen wrench.

Note: *In double-stack panel configurations, use four M6x45 socket head cap screws on the top mount. Ensure that the tension bar is flush/lightly resting on the top tube. Do not allow the tension bar to hold the full weight of the lower extremity panel. Additionally, install the RIC001-01-08 panel compression plates with the counterbored hole facing towards the panel to ensure a proper fit over all shoulder bolts.*

The essential M1128 frame is assembled. Remaining M1128 assembly steps depend on whether you purchased the M1128 with accessory kits.

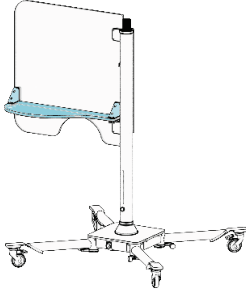


COMPLETING M1128 ASSEMBLY **Did You Purchase Accessory Kits?**

- If you purchased the M1128 without accessory kits, go to page **26** to **Complete the Standalone M1128 Assembly**.
- If you purchased the M1128 + M1128-RAK accessory kit, go to page **27** to **Complete the M1128 + M1128-RAK Assembly**.
- If you purchased the M1128 + M1128-RAK + M1128-CMA accessory kits, go to page **32** to **Complete the M1128 + M1128-RAK + M1128-CMA Assembly**.

COMPLETE THE STANDALONE M1128 ASSEMBLY

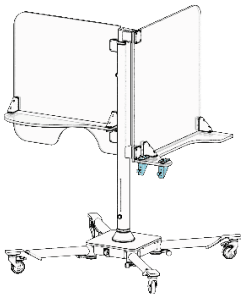
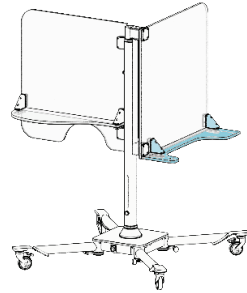
These directions are for M1128 radiation shields purchased **without** either the radiation shielding soft accessory kit (M1128-RAK) or the center mast accessory kit (M1128-CMA). Follow these directions to complete M1128 assembly by attaching the radial shelf, lower extremity shelf and the rigid side drop panel.



1. **Install two of the shelf brackets** onto the radial panel using the shelf bracket back plates, Use M6x40 socket head caps screws and M6 locknuts.

2. **Mount the radial shelf** on to the shelf brackets installed in the previous step. Use the shelf bracket back plates, M6x40 socket head caps screws and M6 locknuts.

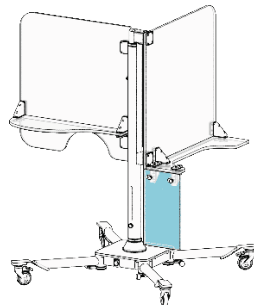
3. **Install two of the shelf brackets** onto the lower extremity panel using the shelf bracket back plates, M6x40 socket head caps screws, and M6 locknuts.
4. **Mount the lower extremity shelf** to the shelf brackets installed in the previous step. Use the shelf bracket back plates, M6x40 socket head caps screws, and M6 locknuts.



5. **Install two of the shelf brackets** onto the lower extremity panel using the shelf bracket back plates, M6x40 socket head caps screws, and M6 locknuts.

6. **Mount the rigid side drop panel** to the shelf brackets installed in the previous step using the two stainless steel knobs.

7. Proceed to *Quality Check* on page 38.

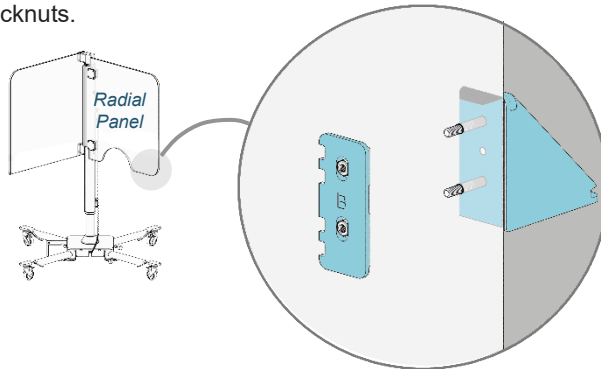


COMPLETE THE M1128 + M1128-RAK ASSEMBLY

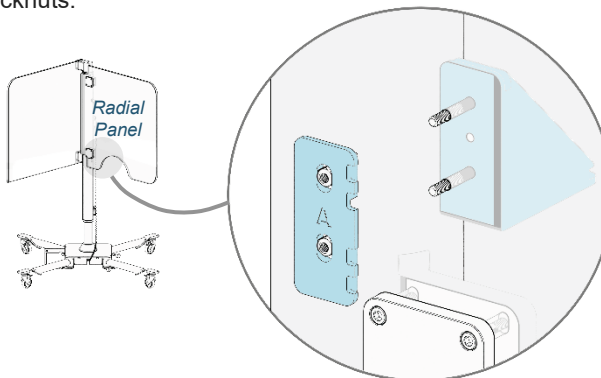
Follow these directions to complete assembly for M1128 radiation shields purchased **with** the radiation shielding soft accessory kit (M1128-RAK).

Install Brackets on Radial Panel

1. Install **bracket B** and a **shelf bracket** onto the **outer edge** (edge **furthest** from the mast) of the radial panel.
 - Line up the brackets so that the panel is sandwiched in between and the threaded holes receiving screws are lined up.
 - Secure brackets to panel using M6x40 socket head cap screws and M6 locknuts.

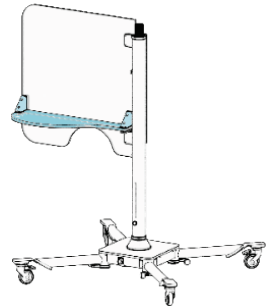


2. Install **bracket A** and a **shelf bracket** onto the **inner edge** of the radial panel using M6x40 socket head cap screws and M6 locknuts.
 - Line up the brackets so that the panel is sandwiched in between and the threaded holes receiving screws are lined up.
 - Secure brackets to panel using M6x40 socket head cap screws and M6 locknuts.



Install Radial Shelf

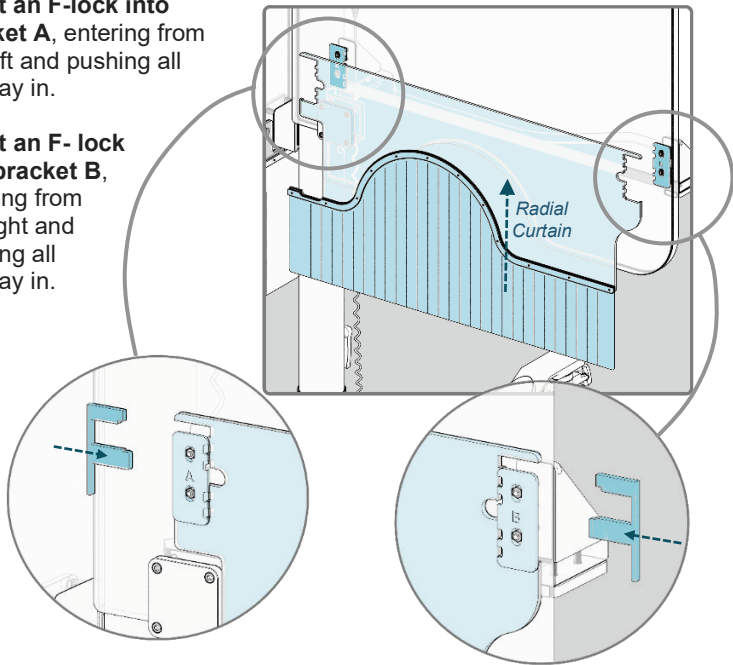
3. **Mount the radial shelf** on to the shelf brackets installed in the previous step. Use the shelf bracket back plates, M6x40 socket head caps screws and M6 locknuts.



Install Radial Curtain

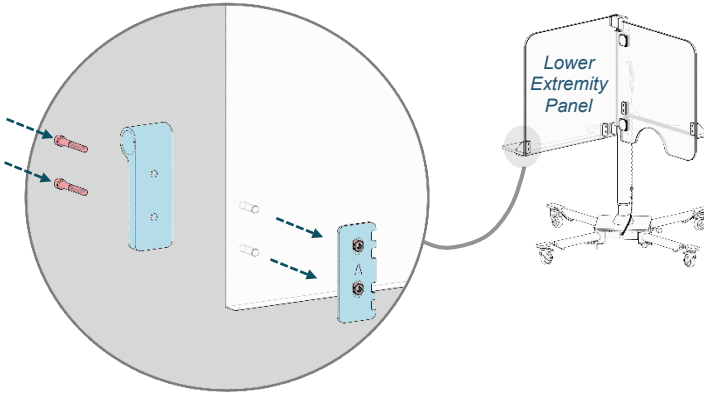
4. **Hang the radial (R) curtain** with the puzzle-like bracket cutouts onto brackets A and B.
5. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and B. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.

6. **Insert an F-lock into bracket A**, entering from the left and pushing all the way in.
7. **Insert an F-lock into bracket B**, entering from the right and pushing all the way in.

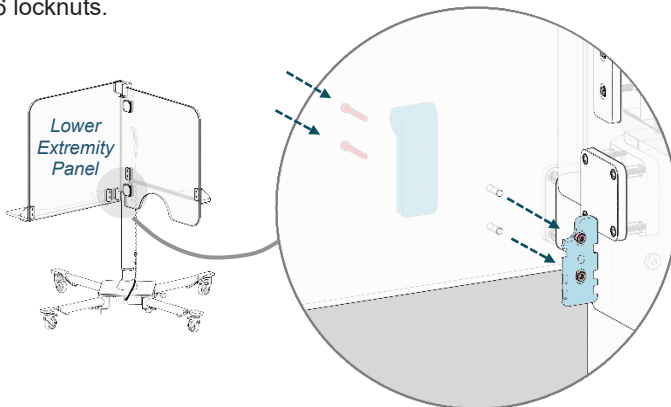


Install Brackets on Lower Extremity Panel

8. **Install bracket A** and a **handlebar bracket** to the **outer edge** (edge **furthest** from the mast) of the lower extremity panel:
- Line up the brackets so that the panel is sandwiched in between and the threaded holes to receiving screws are lined up.
 - Secure brackets to panel using M6x40 socket head cap screws and M6 locknuts.
 - **For double-stack panel configurations**, install the handlebar bracket with the counterbored hole facing towards the panel to ensure a proper fit over the shoulder bolt.



9. **Install bracket C** and a **handlebar bracket** onto the **inner edge** of the lower extremity panel (edge closest to mast):
- Line up the brackets so that the panel is sandwiched in between and the threaded holes receiving screws are lined up.
 - Secure brackets to panel using M6x40 socket head cap screws and M6 locknuts.

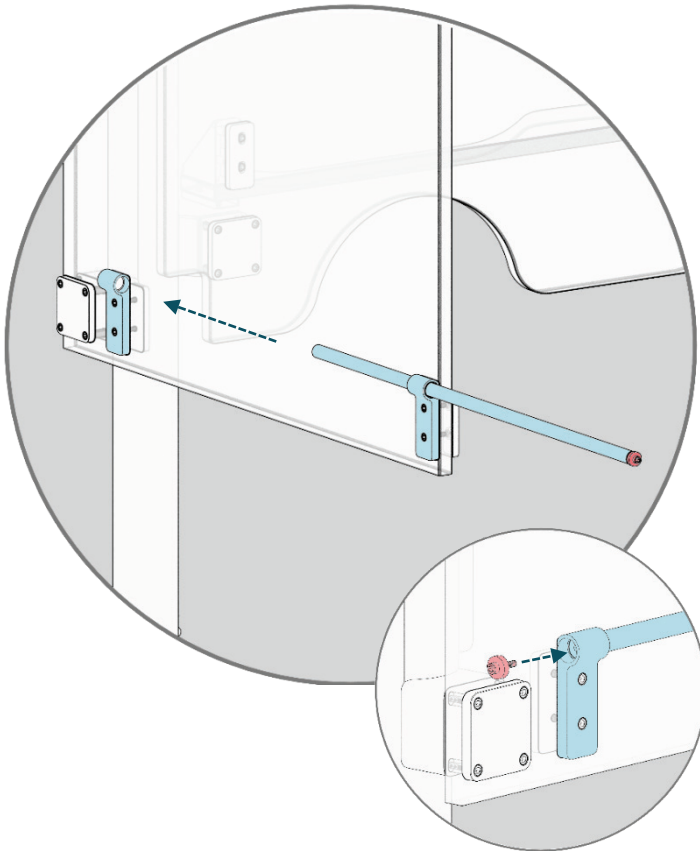


Install Handlebar

10. Remove a screw and washer from one end of the handlebar.
 - Removing the screw and washer from one end allows handlebar to slide through the handlebar brackets.
 - Save the screw and washer to secure the handlebar in **step 12**.

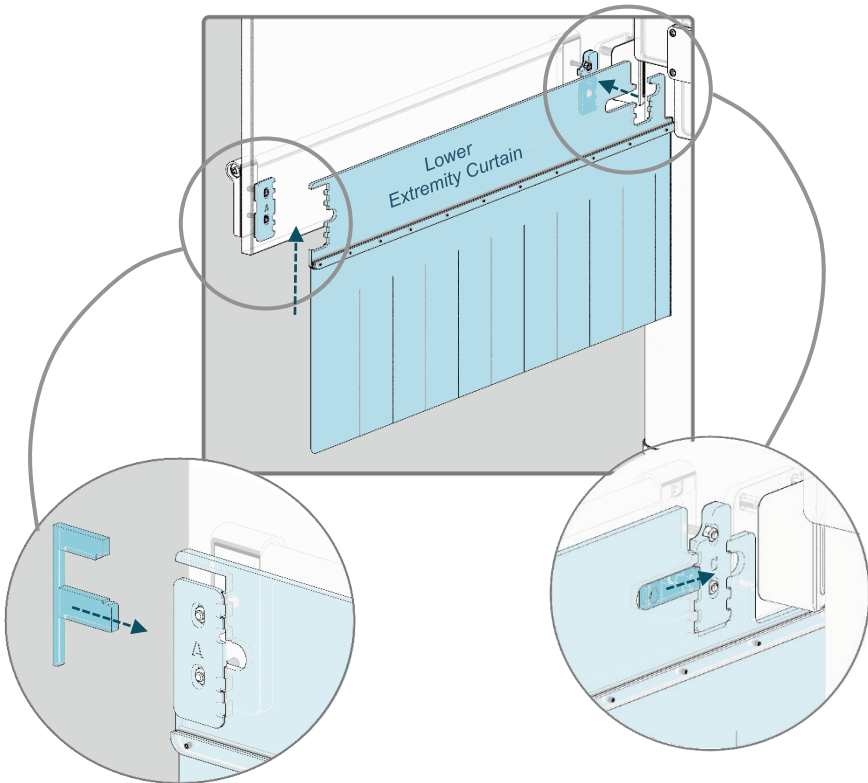


11. **Slide the handlebar end without screw and washer** through both handlebar brackets on the lower extremity panel.
12. Replace and tighten the saved screw through the saved washer from **step 10** into the handlebar (end without screw and washer).
13. Tighten the screw and washer on the opposite side of the handlebar if loose.



Install Lower Extremity Curtain

14. **Hang the lower extremity (LE) curtain** with the puzzle-like bracket cutouts onto brackets A and C.
15. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and C. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.
16. **Insert an F-lock into bracket A**, entering from the left and pushing all the way in.
17. **Insert the slide lock into bracket C**, entering from the left and pushing all the way in.



18. Proceed to *Quality Check* on page 38.

COMPLETE THE M1128 + M1128-RAK + M1128-CMA ASSEMBLY

Follow these directions to complete assembly for M1128 radiation shields purchased ***with both*** the **radiation shielding soft accessory kit (M1128-RAK)** and the **center mast accessory kit (M1128-CMA)**.

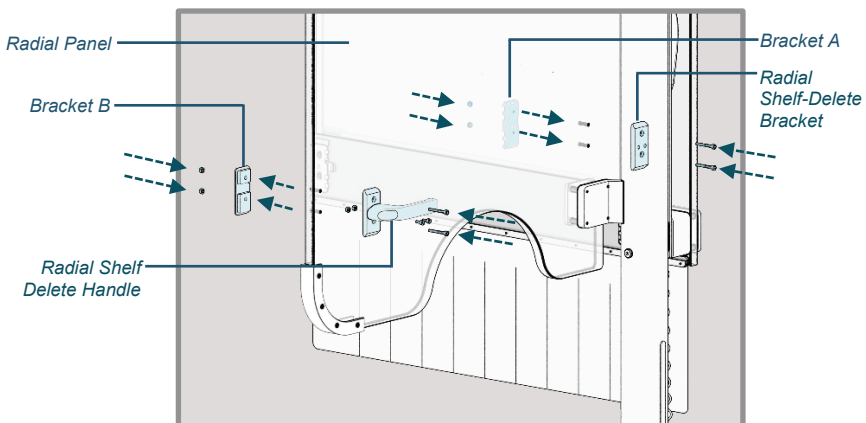
Install Radial Shelf Delete Handle & Bracket, and Brackets A & B onto the Radial Panel

1. Face the **outer edge** of the **radial panel** (side **furthest** from the mast) to be properly oriented for installation. There will be two pairs of screw holes:
 - a. First pair of screw holes is closer to the outer edge of the radial panel furthest from the mast.
 - b. Second pair of screw holes on the radial panel is closer to the mast.

2. Addressing the first pair of outer screw holes, position the radial shelf delete handle on the ***right outer edge*** of the radial panel so that:
 - a. The grip of the handle is pointed towards the center mast.
 - b. The screw holes in the **radial shelf delete handle base** and **radial panel** are aligned in preparation to receive screws through both.

3. Position **RAK bracket B** (letter facing outward) to the left of the radial panel so the screw holes in bracket B also line up with the screw holes in **step 2**. The **radial panel** ***should be sandwiched between*** **bracket B** and the **radial shelf delete handle**.

4. Insert **two M6x40 socket head cap screws** through the aligned screw holes of the **radial shelf delete handle base**, through the **radial panel** and into **bracket B** and secure components together with **two M6 locknuts**.



5. Addressing the second pair of inner screw holes:
 - a. Position the shelf delete bracket on the right inner edge of the radial panel.
 - b. Position **bracket A** (letter facing outward) on the left inner edge of the radial panel.
 - c. Make sure the two screw holes in each of these components are aligned in preparation to receive screws through both.
 - d. The radial panel should be sandwiched between bracket A and the radial shelf-delete bracket.

6. Insert **two M6x40 socket head cap screws** through the aligned screw holes of the **shelf delete bracket**, the **radial panel** and **bracket A** and secure components together with **two M6 locknuts**.

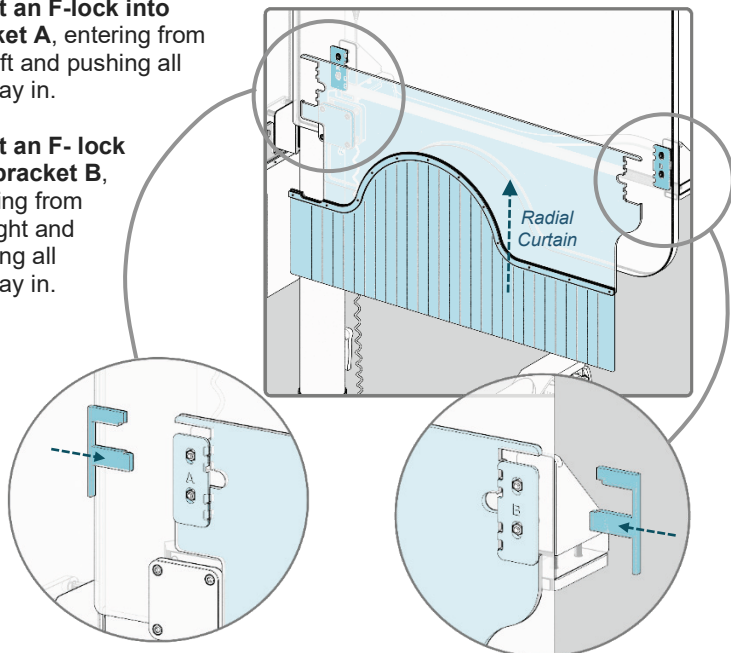
Install Radial Curtain

7. **Hang the radial (R) curtain** with the puzzle-like bracket cutouts onto brackets A and B.

8. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and B. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.

9. **Insert an F-lock into bracket A**, entering from the left and pushing all the way in.

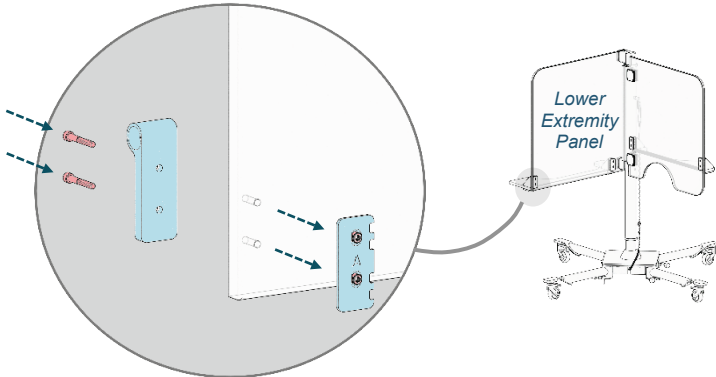
10. **Insert an F-lock into bracket B**, entering from the right and pushing all the way in.



Install Brackets on Lower Extremity Panel

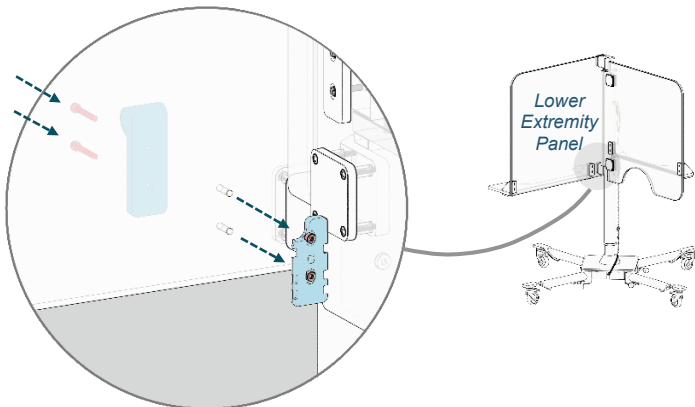
11. **Install bracket A** and a **handlebar bracket** to the **outer edge** (edge **furthest** from mast) of the lower extremity panel:

- Line up the brackets so that the panel is sandwiched in between and the threaded holes to receiving screws are lined up.
- Secure brackets to panel using M6x40 socket head cap screws and M6 locknuts.
- **For double-stack panel configurations**, install the handlebar bracket with the counterbored hole facing towards the panel to ensure a proper fit over the shoulder bolt.



12. **Install bracket C** and a **handlebar bracket** onto the **inner edge** of the lower extremity panel (edge **closest** to mast):

- Line up the brackets so that the panel is sandwiched in between and the threaded holes receiving screws are lined up.
- Secure brackets to panel using 6x40 socket head cap screws and M6 locknuts.

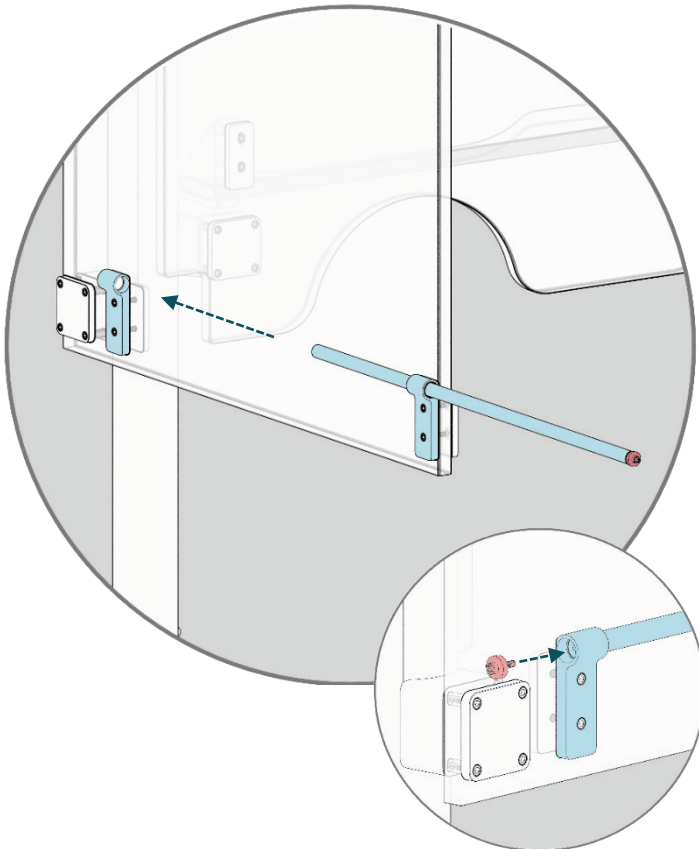


Install Handlebar

13. Remove a screw and washer from one end of the handlebar.
 - Removing the screw and washer from one end allows handlebar to slide through the handlebar brackets.
 - Save the screw and washer to secure the handlebar in **step 15**.

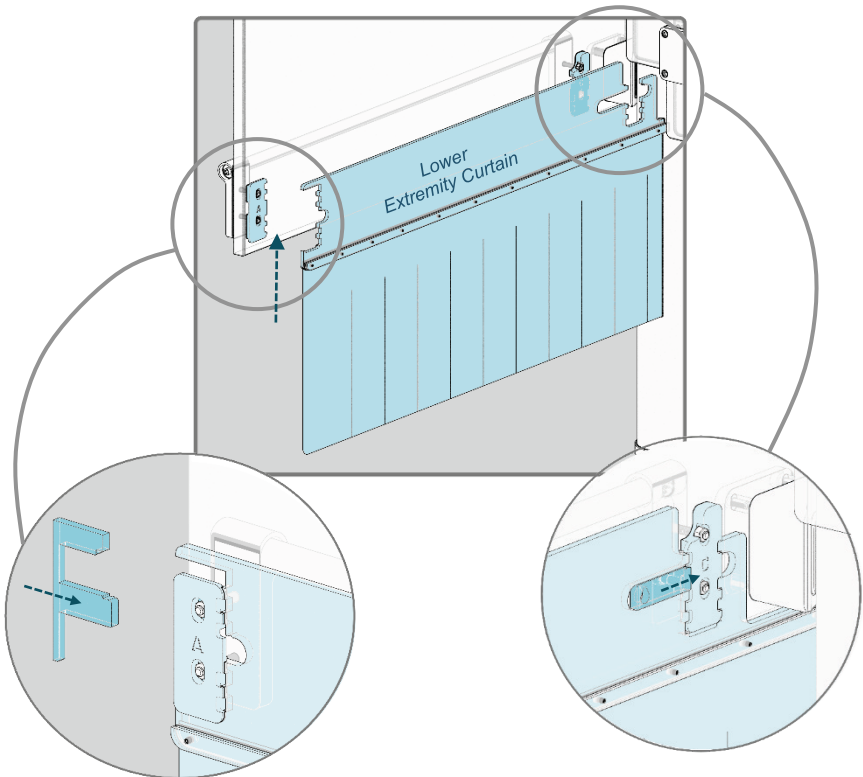


14. **Slide the handlebar end without screw and washer** through both handlebar brackets on the lower extremity panel.
15. Replace and tighten the saved screw through the saved washer from **step 13** into the handlebar (end without screw and washer).
16. Tighten the screw and washer on the opposite side of the handlebar if loose.



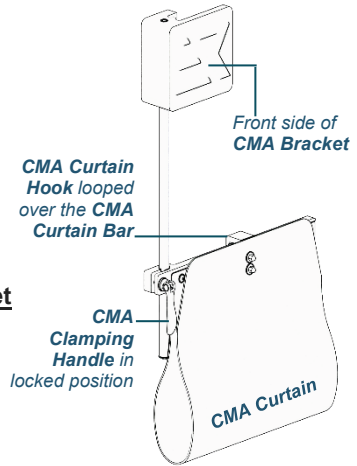
Install Lower Extremity Curtain

17. Hang the **lower extremity (LE) curtain** with the puzzle-like bracket cutouts onto brackets A and C.
18. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and C. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.
19. Insert an **F-lock into bracket A**, entering from the left and pushing all the way in.
20. Insert the **slide lock into bracket C**, entering from the left and pushing all the way in.

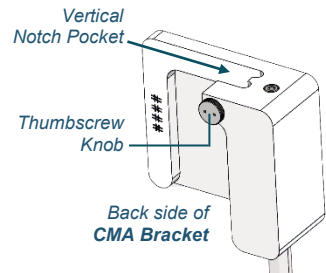


Install Center Mast Accessory (CMA)

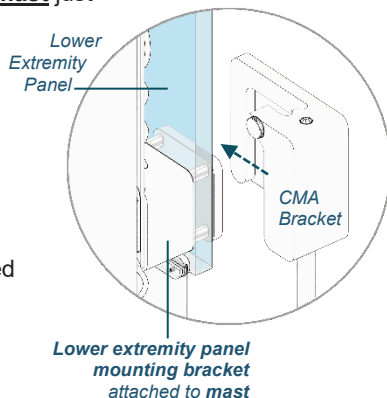
21. Prepare CMA for installation.
 - a. Ensure the **CMA clamping handle** is in the locked position (handle turned **downwards**).
 - b. Loop the **CMA curtain hook** over the **CMA curtain bar** so the curtain is neatly folded up for easier install.
 - c. Retract the **thumbscrew knob** from the backside of the white box-shaped **CMA mounting bracket** (side opposite the Rampart logo) so that the screw end is slightly receded from the interior surface of the mounting bracket. This is to prevent the sharp end of the screw from scratching or catching during installation. The screw will later be tightened when the CMA is properly mounted.



22. Position the CMA for installation by locating the vertical notch pocket on the back side of the white box-shaped CMA bracket.
 - a. The notch is on the same side as the thumbscrew knob and opposite the side with the Rampart logo.
 - b. This vertical notch is shaped to perfectly catch onto the lower extremity panel without tools.



23. Hook the CMA bracket onto the inner side of the **lower extremity panel** closest to the **mast** just a little above the **mounting bracket** which connects the lower extremity panel to the mast.
 - a. The lower extremity panel should slip easily into the vertical notch pocket.
 - b. The large Rampart logo on the opposite side of the CMA bracket displays when the CMA is properly positioned on the lower extremity panel.
 - c. Continue to **step 24** without letting go of this positioning.



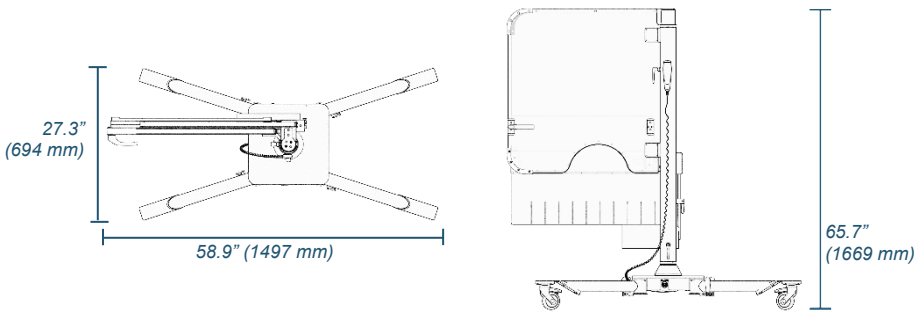
24. Slide the **CMA bracket** down the lower extremity panel until it sits upon the mounting bracket that connects the lower extremity panel to the mast.
25. Tighten the **thumbscrew knob** on the backside of the CMA mounting bracket, securing the CMA assembly to the lower extremity panel.
26. Proceed to *Quality Check* on page 38.

QUALITY CHECK

1. Ensure that the M1128 is working properly:
 - The casters are adjusted so that each wheel is in contact with the floor.
 - The leg locking mechanism is working properly.
 - The mast rotates smoothly.
 - All casters roll smoothly.
 - Verify the panels and curtain attachments can move up and down with use of the *Handset Controller* (p. 46).
 - Verify panels and curtain attachments can fold together for *Transit Mode* (p. 38).
2. The Rampart^{IC} authorized assembler and individual receiving the assembled product need to **complete, sign and submit the *M1128 Assembly Checklist*** on p. 61 according to directions on the page in order to register the M1128.

Transit Mode

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



WARNING!

Before transport, the Rampart^{IC} M1128 must be in *Transit Mode* (p. 38) and disconnected from charging.



**WARNING:
Tipping
Hazard**

- **CONFIGURATION DURING USE:** 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* to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- **CONFIGURATION DURING TRANSIT:** To move the M1128 to another location, the M1128 must be placed into *Transit Mode* (p. 38). First, the mast must be collapsed to the lowest position and the panels and curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent 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 M1128 during transit. When in Transit Mode and moved correctly, the M1128 is narrow enough to fit through standard walkways.



CAUTION:
Heavy
Equipment-
Injury Risk

- The M1128 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 M1128 system(s) must be properly trained.



CAUTION:
Trip Hazard

- **CONFIGURATION DURING TRANSIT:** To avoid becoming a tripping hazard, the M1128 must be placed into *Transit Mode* (p. 38). First, the mast must be collapsed to the lowest position and the panels and curtain attachments folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent legs from changing angle during transit. When in Transit Mode, the M1128 is stable, narrow enough to fit through standard walkways. The person moving the device should carefully walk on the side of the device with Rampart^{IC} logo to push and guide the M1128 during transit.
- Always maintain awareness of the positioning of M1128 legs and casters to avoid tripping when moving around the M1128.

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

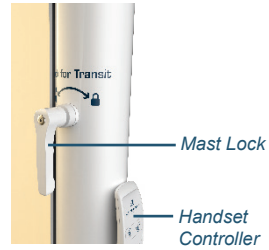
TO MOVE IN TRANSIT MODE

1. Remove and set aside the charging cord.
2. **Fold up the CMA curtain** by hooking the **curtain hook** located on the bottom of the curtain onto the **CMA curtain bar**.
3. **Unlock the CMA curtain** for movement by turning the CMA clamping handle straight **up**.
4. Raise the CMA curtain to the highest vertical position.
5. Lock the CMA clamping handle by turning it straight **down**.
6. **Lower all panels and curtains** using the *Handset Controller* (p. 46).
7. Fold the radial panel, the lower extremity panel and CMA curtain together in the direction of travel.

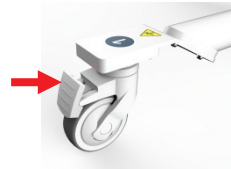


- Lock the panels and curtains so they will not rotate during transit by turning both mast locks clockwise until tight.

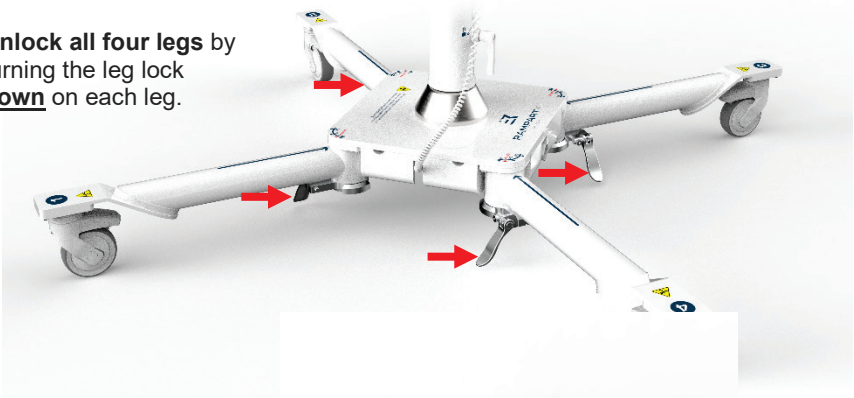
Note: *The mast locks must be unlocked before the mast can lower, raise or rotate.*



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



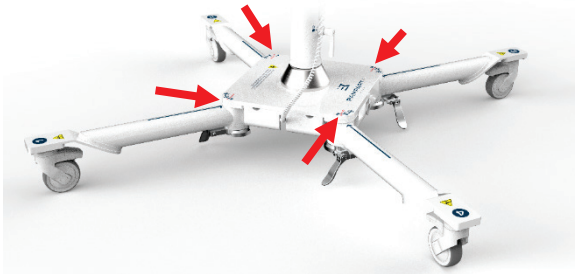
- Unlock all four legs** by turning the leg lock down on each leg.



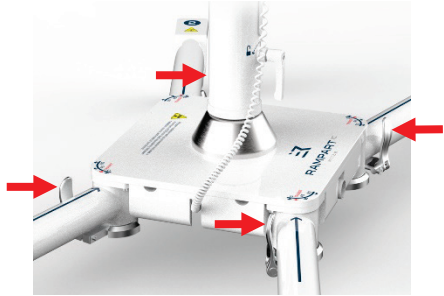
- Position all four legs into Transit position** according to the leg angle labels



adhered to the base of the M1128. When positioned according to these labels, the legs fully support the panels and curtains while properly balancing the M1128 for transit.



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



13. **Deploy the recessed outrigger leg** by folding it outward away from the base and downward toward the ground until it snaps into position.

***Note:** When in transit, only use the outrigger leg when rolling the device over completely flat surfaces without obstacles that may catch on the leg.*

14. Make sure all doors between the current location and the destination are unlocked and opened.
15. Make sure that the pathway to the destination is unobstructed.
16. Alert individuals in proximity that equipment is coming through.
17. Stand on the side of the M1128 with the **Rampart^{IC} logo**.
18. Secure the equipment by placing one hand on the **mast** and the other hand on the **folded panels**.
19. Walk with the M1128, guiding and pushing it to the desired location.
20. Lock casters upon arriving to destination.

Charging

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

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



CAUTION!

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

1. Move the M1128 radiation shield to *Storage (see p. 56)* or another safe location out of the way of foot traffic and activity, and where there is a standard wall outlet. See *Transit Mode (p. 38)* for directions on how to safely move the M1128.
2. Connect the charging cord to the base of the M1128.
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 M1128 can remain plugged in whenever not in use to safely maintain a full charge.
5. When charged and needed, unplug the M1128 radiation shield before moving and place in *Transit Mode (p. 38)*.

LED INDICATOR - BATTERY STATUS

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

After *M1128 Assembly* (p. 21) the four legs, extendable mast, acrylic panels and attached curtains of the M1128 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 M1128 can also be folded down to *Transit Mode* (p. 38), providing a minimal footprint for safe and efficient movement between rooms.

The M1128 is intended to operate on battery power only.

Note: A training video demonstrating usage tips is available at www.RampartIC.com/training.



WARNING:
Radiation
Exposure

- Failure to set M1128 panels and curtains at the proper height and position may cause unwanted radiation exposure. The M1128 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} M1128 acrylic panels provide a protection level of 1 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 *Maintenance* (p. 54).



WARNING:
MR-Unsafe

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



CAUTION:
Heavy Equipment-
Injury Risk

- The M1128 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 M1128 system(s) must be properly trained.

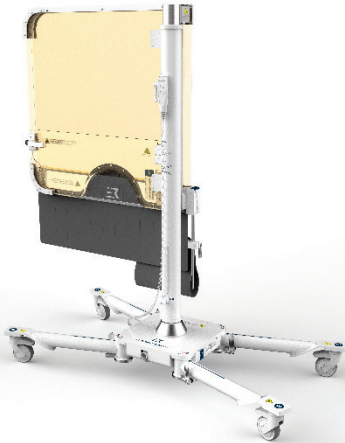


CAUTION

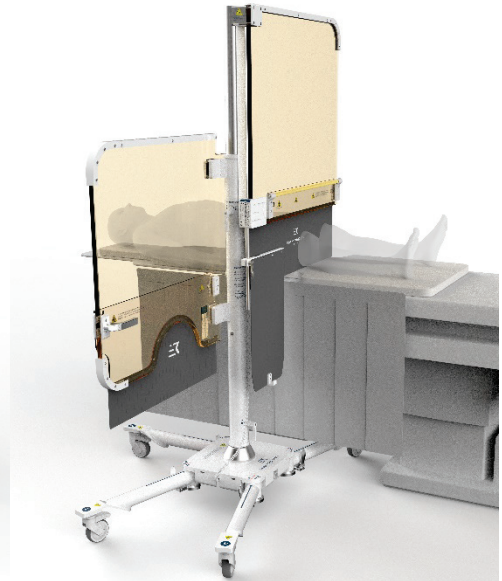
Potential drag may occur when the curtain is moved during a procedure. Ensure that the soft shield flaps are lying flat against the patient's abdomen, pointing towards the patient's head, to allow for the best visibility and intervention to access points.

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).

SAMPLE CONFIGURATIONS



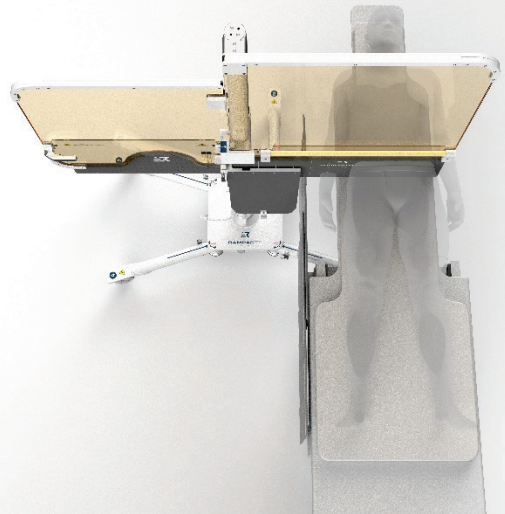
Transit Mode with mast fully collapsed, panels and curtains folded together in the direction of travel and legs in transit mode



Panels and curtains at 90° pedal configuration



(bi-radial) and femoral procedures



Panels and curtains at 180° to accommodate biplane angles

HANDSET CONTROLLER

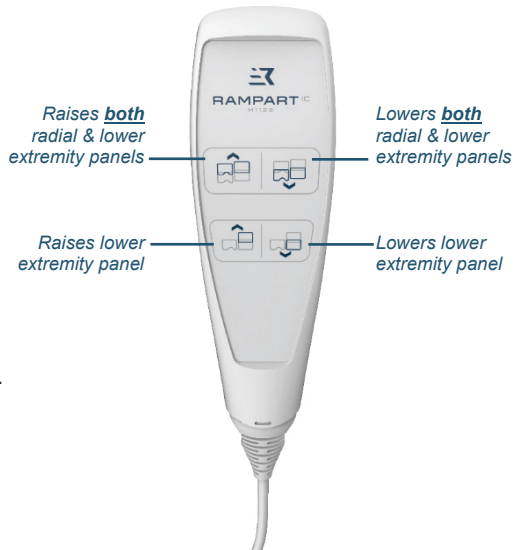


WARNING:
Rare Earth Magnet

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 law.

The handset controller accompanying the M1128 is used to raise and lower the procedures and circumstances.

- 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.



Resetting 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.

USING THE M1128

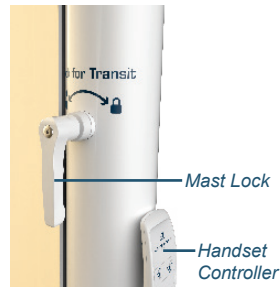


WARNING:
Radiation
Exposure

- Failure to set M1128 panels and curtain attachments at the proper height and position may cause radiation exposure. The M1128 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} M1128 panels provide a protection level of 1 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 54 of this user guide.

1. **Unlock the panels** by turning the mast locks counterclockwise.

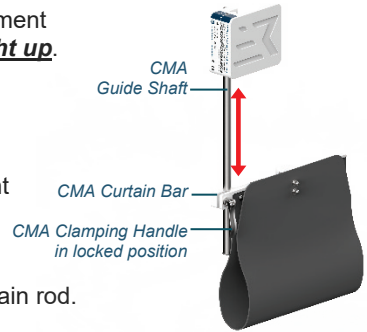
Note: *The mast must be unlocked and the radial and lower extremity panels positioned at an approximate 45-degree angle before panels can be raised, lowered or rotated. The 45-degree positioning ensures panels are wide enough apart to clear the hanger bar.*



2. **Using the handset controller**, adjust the M1128 panels and curtain attachments to the approximate height of the anticipated access site (radial, femoral, pedal, or otherwise) when the patient is eventually positioned.
3. Place or attach the handset controller in a location that is convenient on the M1128.
4. Proceed to **step 5** if you purchased the M1128 with the CMA and RAK accessories. Otherwise, go to **step 9** to continue adjusting the standalone M1128 without CMA and RAK accessories.

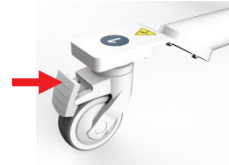
5 J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/ajacc.2018.02.016> (accessed August 10,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

5. **Unlock the CMA curtain** for vertical adjustment by turning the CMA clamping handle **straight up**. The unlocked CMA curtain can be adjusted up and down the CMA guide shaft.



6. 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**.
7. Unhook the CMA curtain from the CMA curtain rod.
8. **Orient the CMA accessory curtain** to the anticipated position reflecting the access site and patient position.

9. Unlock the M1128 casters if they are locked.

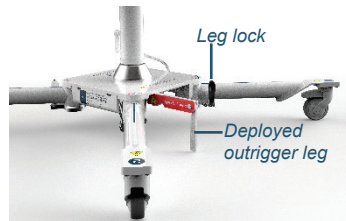


CAUTION!

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

10. **Position M1128 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:

- a. **Unlock the legs** by turning the leg lock **down** on each leg.
- b. **Move legs into 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.
- d. **Deploy the outrigger leg** as needed or helpful to maintain stability.

Note: It is recommended that M1128 legs are placed in the optimal position prior to advancing to the table as predetermined and optimized for the particular operator and access point. The M1128 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.



WARNING:
Tipping Hazard

- **CONFIGURATION DURING USE:** Panels and curtain attachments 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 M1128 to another location, the M1128 must be placed into *Transit Mode* (p. 38). First, the mast must be collapsed to the lowest position and the panels and curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent 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 M1128 during transit. When in Transit Mode and moved correctly, the M1128 is stable, narrow enough to fit through standard walkways.

11. Apply the sterile drape kit according to the appropriate instructions, then return to **step 12** below.

- ***Drape Application Steps for Standalone M1128*** on page 52.
- ***Drape Application Steps for M1128*** purchased with M1128-RAK on page 53.

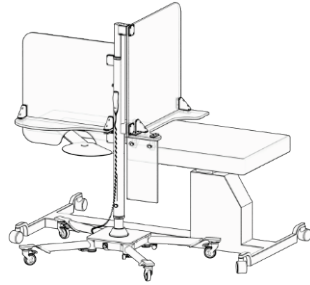


12. **Further adjust the radial panel, the lower extremity panel and attached curtains** with the handset controller while considering the access site, patient position and size, table height, and physician's preference.

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. **Position the arm board** as needed, if preparing for radial access.
16. Drape the patient and table as usual.
17. **Lower the procedure table** in preparation for precise positioning of the M1128, as necessary.



18. Roll the M1128 to adjust physical orientation, as necessary.
19. **Raise the procedure table** to meet the M1128 radiation shield, as necessary.
20. **Further customize the positioning of the M1128** 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 M1128 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.

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

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

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



CAUTION:
Trip Hazard

- Failure to place controllers and the M1128 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 M1128 legs and casters to avoid tripping when moving around the M1128.

23. **Conduct a safety check** to ensure all radiation protection equipment is in place and radiation gaps below table and around the M1128 radiation shield are minimized.
24. **Make final adjustments** to the M1128 as necessary.
25. Conduct fluoroscopic procedure.

26. When the procedure is complete, **adjust the M1128 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:** M1128 panels and attached curtain assemblies 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 M1128 to another location, the M1128 must be placed into *Transit Mode (p. 38)*. First, the mast must be collapsed to the lowest position and the panels and curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned for Transit with leg locks locked into place and the outrigger leg deployed as appropriate to prevent 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 M1128 during transit. When in Transit Mode and moved correctly, the M1128 is stable, 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 panel and curtain assembly or other equipment are being adjusted.

27. Carefully roll the M1128 away from the patient enough so patient can be safely removed.
28. **Remove patient** from the procedure room.
29. **Dispose used drape kit** according to standard biohazard guidelines.
30. **Clean** (see *Cleaning on p. 54*) and store (see *Storage on p. 56*) the M1128.
31. Follow directions in this user guide for moving the M1128 in *Transit Mode (p. 38)*.

DRAPE APPLICATION STEPS FOR STANDALONE M1128

These directions are for draping M1128 radiation shields purchased without the radiation shielding soft accessory kit (M1128-RAK).

- **Remove all drapes from package** and place them on the scrub table. The drapes are packaged and numbered in the order they should be applied with application instructions on the labels.
- **Apply drapes in numerical order** and according to the application instructions on the labels.

<u>Drape 1:</u> Left Drape	<ol style="list-style-type: none"> 1. Place Drape 1 over the <u>radial panel</u>. 2. Tighten the blue vertical drawstring around the opening. 3. Tighten the gray drawstring around the radial shelf. <i>Note: Make sure the cord lock and drawstring do not touch the mast.</i>
<u>Drape 2:</u> Right Lower Drape	<ol style="list-style-type: none"> 4. Pull Drape 2 up and over the <u>drop panel</u> and the end of the lower extremity shelf. 5. Tighten the blue drawstring.
<u>Drape 3:</u> Right Drape	<ol style="list-style-type: none"> 6. Slide Drape 3 about $\frac{3}{4}$ of the way over the <u>lower extremity panel</u> and stop. 7. Grab the bottom loop of the blue drawstring and pull under the drop panel being careful to not touch the mast. 8. Continue to pull Drape 3 over the drop panel and over the mast. 9. Tighten the horizontal blue drawstring around the lower extremity shelf. 10. Tighten the vertical gray drawstring around opening and mast. <i>Note: Make sure the cord lock and drape cord do not touch the mast.</i>
<u>Drape 4:</u> Center Drape	<ol style="list-style-type: none"> 11. Remove the top left adhesive tape backing from Drape 4. 12. Place the left adhesive on the top back of the radial panel, about 8" from the <u>mast</u>. 13. Remove the top right adhesive tape backing from Drape 4. 14. Place the right adhesive tape on the top back of the lower extremity panel, about 8" from the mast, making sure to maintain slack along the top of Drape 4 and between the left and right adhesive. <i>Note: Maintaining slack at the top of Drape 4 allows for adjustability of the mast and avoids causing tension on the adhesive tabs. Once in final position, the draw cord at the top of Drape 4 can be tightened.</i> 15. Remove the rest of the adhesive backings from Drape 4. 16. Secure the rest of the Drape 4 backings to completely cover the mast. 17. Tighten the blue drawstring to cover the top of the mast as necessary.
<u>Drape 5:</u> Handset Drape	<ol style="list-style-type: none"> 18. Place Drape 5 over the <u>handset controller and cord</u>. 19. Tighten the blue drawstring to secure the controller and cord within the drape.

Note: Drapes are sold separately at Rampart^{IC} and not included with purchase of the M1128. A training video demonstrating how to use the drape kit is available at www.RampartIC.com/training.

DRAPE APPLICATION STEPS FOR M1128 + M1128-RAK + M1128-CMA

These directions are for draping M1128 radiation shields purchased with the radiation shielding soft accessory kit (M1128-RAK), and if purchased, the center mast accessory (M1128-CMA). **Skip steps 4 and 5 for Drape 2 if the center mast accessory is not included in your purchase.**

- **Remove drapes 1, 2, 3 and 4 from package** and place them on the scrub table. The drapes are packaged and numbered in the order they should be applied with application instructions on the labels.
- **Apply drapes 1, 2, 3 and 4** according to the application instructions on the labels.
- Do not over cinch the pull cords.
- Allow the drape to adequately encompass the curtains without compressing the curtain flaps.

<u>Drape 1:</u> Left Drape	<ol style="list-style-type: none"> 1. Place drape 1 over the <u>radial panel</u> and the <u>radial curtain</u>. 2. Tighten the blue vertical drawstring around the opening. 3. Tighten the gray drawstring around the radial shelf. <p>Note: <i>Make sure the cord lock and drawstring do not touch the mast.</i></p>
<u>Drape 2:</u> Lower Drape	<ol style="list-style-type: none"> 4. Place drape 2 over the entire <u>CMA assembly</u> starting from the bottom of the accessory moving up over the top. 5. Tighten the gray drawstring on top of the CMA assembly.
<u>Drape 3:</u> Right Drape	<ol style="list-style-type: none"> 6. Place drape 3 over the <u>lower extremity panel, top of mast, and the lower extremity curtain</u>. 7. Tighten the blue drawstring. 8. Tighten the gray drawstring. <p>Note: <i>Make sure the cord lock and drape cord do not touch the mast.</i></p>
<u>Drape 4:</u> Center Drape	<ol style="list-style-type: none"> 9. Remove the top left adhesive tape backing from drape 4. 10. Place the left adhesive on the top back of the radial panel and curtain, about 8" from the <u>mast</u>. 11. Remove the top right adhesive tape backing from drape 4. 12. Place the right adhesive tape on the top back of the lower extremity panel and curtain, about 8" from the mast, making sure to maintain slack along the top of drape 4 and between the left and right adhesive. <p>Note: <i>Maintaining slack at the top of drape 4 allows for adjustability of the mast and avoids causing tension on the adhesive tabs. Once in final position, the draw cord at the top of Drape 4 can be tightened.</i></p> <ol style="list-style-type: none"> 13. Remove the rest of the adhesive backings from drape 4. 14. Secure the rest of the drape 4 backings to completely cover the mast. 15. Tighten the blue drawstring to cover the top of the mast as necessary.

Note: *Drapes are sold separately at Rampart^{IC} and not included with purchase of the M1128. A training video demonstrating how to use the drape kit is available at www.RampartIC.com/training.*

Maintenance

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



CAUTION:
Heavy
Equipment-Injury
Risk

- The M1128 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 M1128 system(s) must be properly trained.
- M1128 assembly, repairs and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}.

CLEANING

The Rampart^{IC} M1128 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 M1128 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 M1128 system(s) must be properly trained.
- M1128 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 M1128, never use scrapers or metal tools of any kind.

The M1128 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

Cleaning

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

Disinfection

Disinfect the M1128 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 M1128 panels and curtains and are available for purchase. To purchase, email info@RampartIC.com.*

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

⁷ Cellusolve™ 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.

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

STORAGE

Rampart^{IC} recommends transporting and storing the M1128 in *Transit Mode* (p. 38) due to the stability and minimal space footprint of this configuration.

1. Make sure the M1128 is cleaned (see Cleaning on p. 54) before storage.
2. Move the M1128 in *Transit Mode* (p. 38) 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 M1128 is not in use. See *Charging* on page 43.

Note: *The M1128 should remain plugged in whenever not in use to safely maintain a full charge.*



CAUTION!

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

PREVENTATIVE INSPECTION

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

1. Make sure the M1128 is cleaned (see Cleaning on p. 54) before performing preventative inspection.
2. Inspect 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. Inspect all panels and curtains for visible cracks and fissures according to fluoroscopy inspection procedures a minimum of once a year.
4. Clean the M1128 if necessary. See *Cleaning* on p. 54.
5. The Rampart^{IC} authorized representative will perform or schedule repairs necessary including ordering replacement parts.

PARTS AND ACCESSORIES

Part Number	Description
M1128-RTV	M1128 Radiation Shield Right Table Version
M1128-HSC	M1128 Handset Controller
M1128-BAT	M1128 Rechargeable Battery
M1128-CON	M1128 Controller
M1128-ECC	M1128 Electrical Charge Cable
M1128-UMA	M1128 Upper Mast Actuator
M1128-LMA	M1128 Lower Mast Actuator
M1128-LEG	M1128 Leg
M1128-RRP	M1128 Right Radial Panel
M1128-RRS	M1128 Right Radial Shelf
M1128-RBP	M1128 Right Lower Extremity Panel
M1128-RBS	M1128 Right Lower Extremity Shelf
M1128-RDP	M1128 Right Drop Panel
M1128-RLK	M1128 Right Table Label Kit
M1128-LLH	M1128 Leg lock
M1128-MLH	M1128 Mast Lock
M1128-SDK	M1128 Side Drop Knob
M1128-CAB	M1128 Custom Arm Board Assembly
M1128-ABB	M1128 Custom Arm Board Base
M1128-ABR	M1128 Custom Arm Board Rotating Platform
M1128-ABC	M1128 Custom Arm Board Clip
M1128-ABP	M1128 Custom Arm Board Pin
M1128-RDK	M1128 Right Table Version Drape Kit
M1128-ODK	M1128 Right Table Version Drape Kit (CE)
M1128-UIG	M1128 User and Installation Guide
M1128-AFM	M1128 Antifatigue Mat
M1128-RCC	M1128 Rampart Cleaning Cloth
M1128-RAK	M1128-RTV Radiation Shielding Soft Accessory Kit
M1128-RCT	M1128-RTV Radial Curtain (RC) (includes proximal and distal sheets)
M1128-LEC	M1128-RTV Lower Extremity Curtain (LEC) (includes proximal and distal sheets)
M1128-RCM	M1128-RTV RC Mount (includes the RC Retainer)
M1128-LCM	M1128-RTV LEC Mount (includes the LE Retainer)
M1128-RBK	M1128-RTV RAK Bracket and Lock Kit (includes all RAK Brackets and Locks)
M1128-HBK	M1128-RTV LE Handlebar Kit (includes LE Handlebar, Brackets and Hardware)
M1128-LAK	M1128-RTV RAK Label Kit
M1128-CMA	M1128-RTV Center Mast Accessory Kit
M1128-CCB	M1128-RTV CMA Curtain Bar
M1128-CMB	M1128-RTV CMA Mounting Bracket
M1128-CMC	M1128-RTV CMA Curtain
M1128-CGS	M1128-RTV CMA Guide Shaft
M1128-CCH	M1128-RTV CMA Clamping Handle
M1128-RSB	M1128-RTV Radial Shelf Delete Bracket
M1128-RSH	M1128-RTV Radial Shelf Delete Handle
M1128-LWK	M1128 Lowering Kit
M1128-UIG	M1128-RTV Radiation Shield User Guide
M1128-RUG	M1128-RTV Radiation Shielding Soft Accessory Kit User Guide

SUGGESTIONS

Adjustable Legs

The legs of the M1128 are adjustable to accommodate a number of needs and scenarios. Rampart^{IC} has added leg numbers and leg angle indicator labels to the M1128 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 Transit position and locked to prevent them from changing angles during movement. Upon arrival to 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 & Above Table Lower Body Protection

RAMPART^{IC} recommends using a below-table lead-equivalent protective modular shield in conjunction with the M1128 radiation shield such as the Mavig UT70 available for purchase through Rampart^{IC}. When used in the correct configuration, the physician and the lab technician will be shielded from a little over 95% of radiation exposure. This facilitates freedom of movement during a procedure for the staff and physician.

Arm Board

An optional M1128 component that supports the patient's arm during procedures involving radial access is available sold separately. The arm board can be placed along the patient's side for radial by the hip approach or under the arm port of the radial panel. The arm board includes a rotating surface configuration according to the needs of the procedure or physician.

Transit Mode

To ensure easy transportation from room to room, the M1128 should always be configured into *Transit Mode* (p. 38) 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 the Transit Mode as indicated by the leg arrow and the leg angle label, and the legs should be locked. The outrigger leg should then be deployed. Transit Mode is also the ideal storage position due to its maximum stability and smaller footprint.

When repositioning the M1128 out of Transit Mode, first unlock the legs. Then move all legs to the 45° angle as shown on the leg angle labels. Panels and attached curtains can then be moved into desired position. 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 M1128 balance and stability.

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.

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 law.

The Rampart^{IC} M1128 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.

M1128 Assembly Checklist

Email scanned or a clear photo of completed page to: info@RampartIC.com

OR

Mail completed page to: **Rampart^{IC}**
Attn: Installation Checklist
1500 Urban Center Dr., Ste. 140
Birmingham, AL 35242 USA

Rampart^{IC} M1128 Serial Number:

I hereby certify that this M1128 system is functionally acceptable at the current time and that the following items have been checked and verified:

- The Rampart^{IC} M1128 is completely assembled with all parts used so that there is a working M1128 with handset controller.
- The M1128 rolls easily.
- The casters on the M1128 lock and solidly hold the M1128 in place.
- Both panels and attached curtains rotate easily around the mast within the normal limits.
- The radial panel and curtain raise and lower smoothly.
- The lower extremity panel and curtain raise and lower smoothly.
- The M1128 is in storage position with the battery in charging state.
- The receiving person was shown how to properly store the M1128 in a safe place and was instructed to not use or operate the M1128 without being fully trained by a Rampart representative.
- The M1128 charging cord is included and present with the M1128.

CUSTOMER RECEIVING M1128

Printed Name: _____ Signature: _____
Date: _____ Location: _____

RAMPART^{IC} AUTHORIZED ASSEMBLER

Printed Name: _____ Signature: _____
Telephone: _____ Email: _____
Assembly Date & Time: _____

Thank you for registering your M1128! Training videos and a PDF version of this user guide are available at www.RampartIC.com/training.



RAMPART IC

M1128

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