



**RAMPART** IC

FIGHT THE GOOD FIGHT

Basic Training – M1128  
Tanaya G Meaders RN, BSN, CNOR  
VP of Medical Development and Regulatory

# Rampart M1128

Cath Lab radiation protection for the physician and TEAM that addresses both radiation and orthopedic safety, removing the need to wear heavy lead aprons.

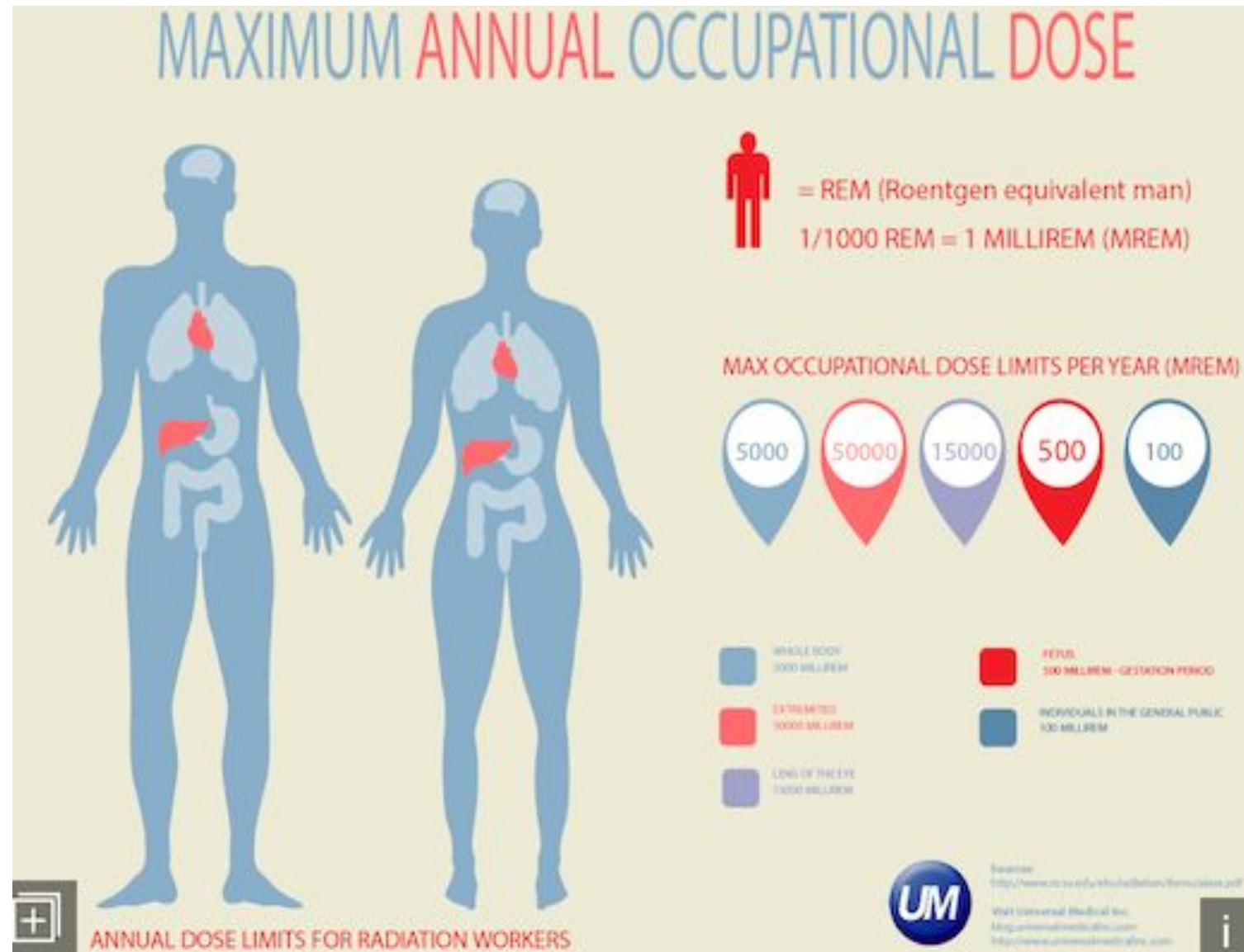
\* when used as directed

- ❑ Based in Birmingham, AL
- ❑ Manufactured in Birmingham, AL
- ❑ Developed by an IC – Dr. Bob Foster out of necessity due to Spinal injury from lead



FDA Yearly Max Dose:  
5 Rem

Reference:  
.3 Rem/year  
Walking around radiation



# Common lead protective gear leaves areas exposed to radiation

Brain

Nasal Canal

Mouth

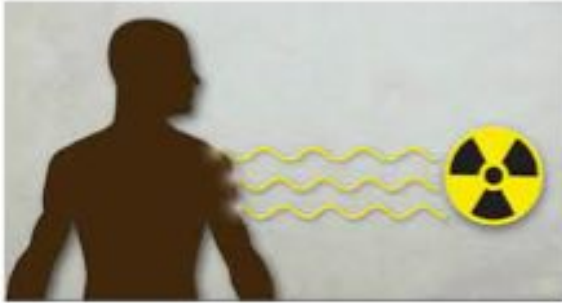
Ear Canals

Shoulders

Arms



# Ionizing Radiation Physics 101



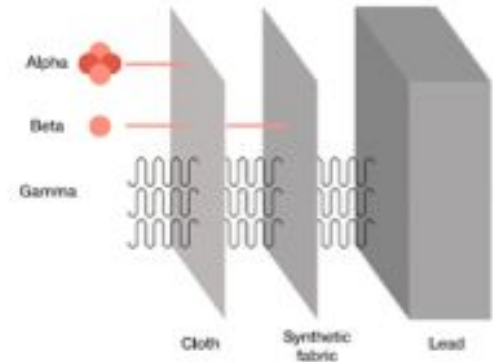
How does Radiation Travel?

X-ray radiation travels in a straight line at the speed of light – it does not bend around corners and there is minimal refraction off of walls, depending on the material in them.



How does Lead ABSORB radiation?

The X-ray radiation gives up its energy to the atoms in the lead, absorbing the X-ray energy and it spreads the energy WITHIN the lead.



How well does a lead apron work?

Depending on the calibration of the X-ray source and amount of lead in the apron, 80 - 95% of radiation is absorbed.

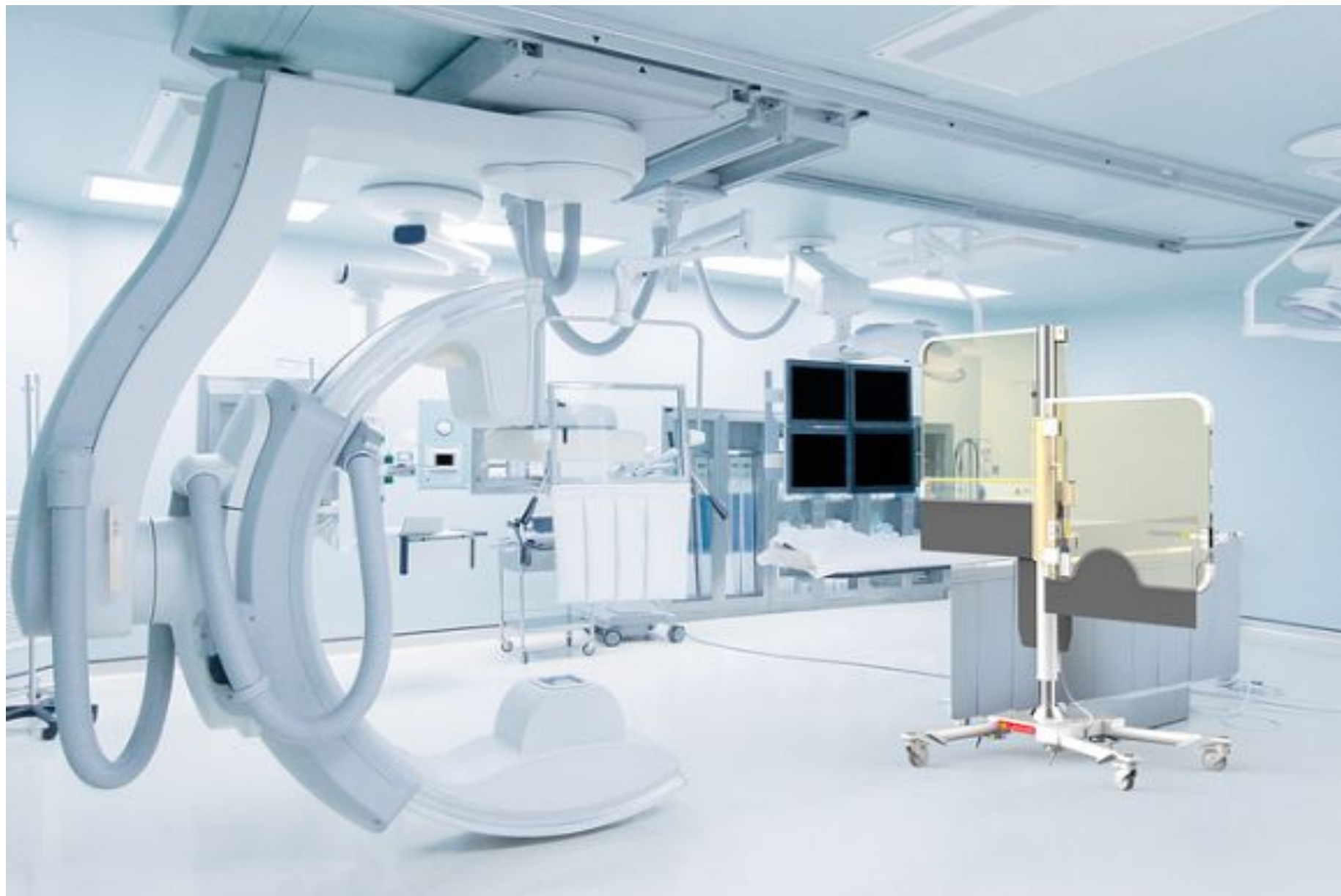
? Is, what about the body parts not covered?

# Radiation Safety / M1128

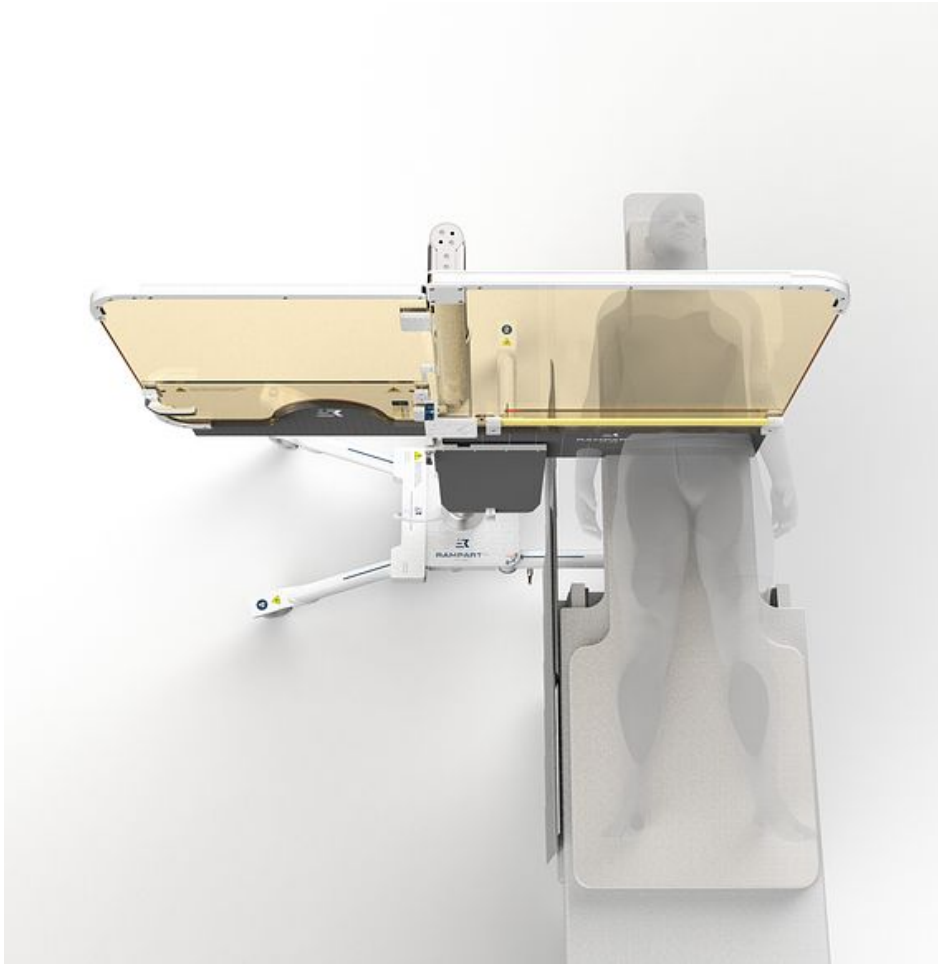
- Situational awareness of your team, yourself, and your patient is key to Rampart IC M1128 radiation attenuation
    - ✓ MUST have right side below table lead curtains where staff is standing x 2
    - ✓ MUST have above table lead panel (abdomen protector)
    - ✓ look for radiation draft opportunities “close gaps” – 2 hands above abdomen
    - ✓ position M1128 as close to patient without engaging pinch points
    - ✓ Snug M1128 up when floating table
  - Rampart is 1mm lead equivalent thick in protection
  - WEAR your badge!
- \*per IFU configurations







# 180 degree Configuration







Peripheral - Antegrade Set Up

Peripheral - Pedal Set Up



# M1128 Protected Areas

Head of bed &  
left side of table are  
**NOT** protected

**NOT** Protected



\*Ray Safe i3 real time  
dosimetry system is utilized  
during evaluation periods for  
collection of radiation  
attenuation data

Shadow of Protection: From the right of the mast  
– down to the foot of the table

Everyone pictured below is protected by the M1128.... Including ME



# Rampart Emergency Protocol

180 degree configuration allows access to patient on both sides, and head of patient for anesthesia/airway support

Option to leave Rampart in and continue working in a code situation as usual.

**OR**

Remove Rampart and have emergency lead in the room and ready to be thrown on in case of an emergency



**RAMPART** IC

FIGHT THE GOOD FIGHT

\*Rampart will need to be removed for an emergent pericardiocentesis



# Secure Sheaths

When using the M1128  
-proper securing of the  
sheaths are recommended to  
avoid dislodgement during  
procedural movement.





# Shielding and Leg Configurations

What leg goes where?

- One leg in the general direction of the shields at all times
- Leave legs 1, 3, 4 **LOCKED** in transit position
- Move Leg 2 to the 90 degree position and **lock in place**
- Leg 3 goes under the bed



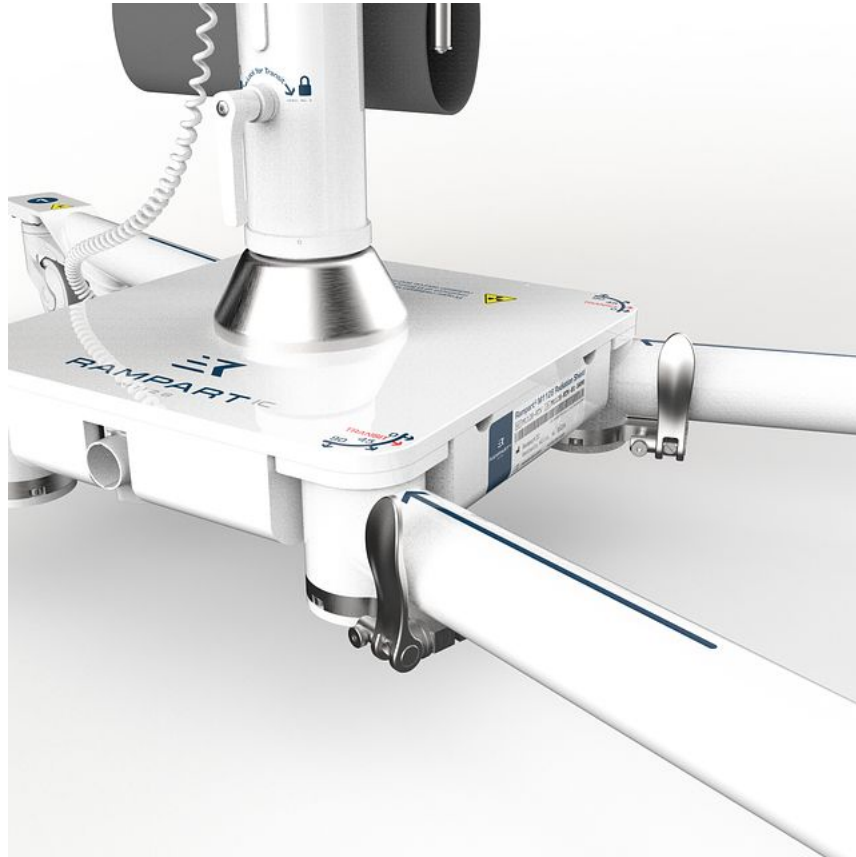
# Rampart Legs

- **Leave legs 1 & 4 locked at all times.**
- **Unlock Leg 2, move it to 90 degrees for procedure and lock in place (leg lock facing UP)**

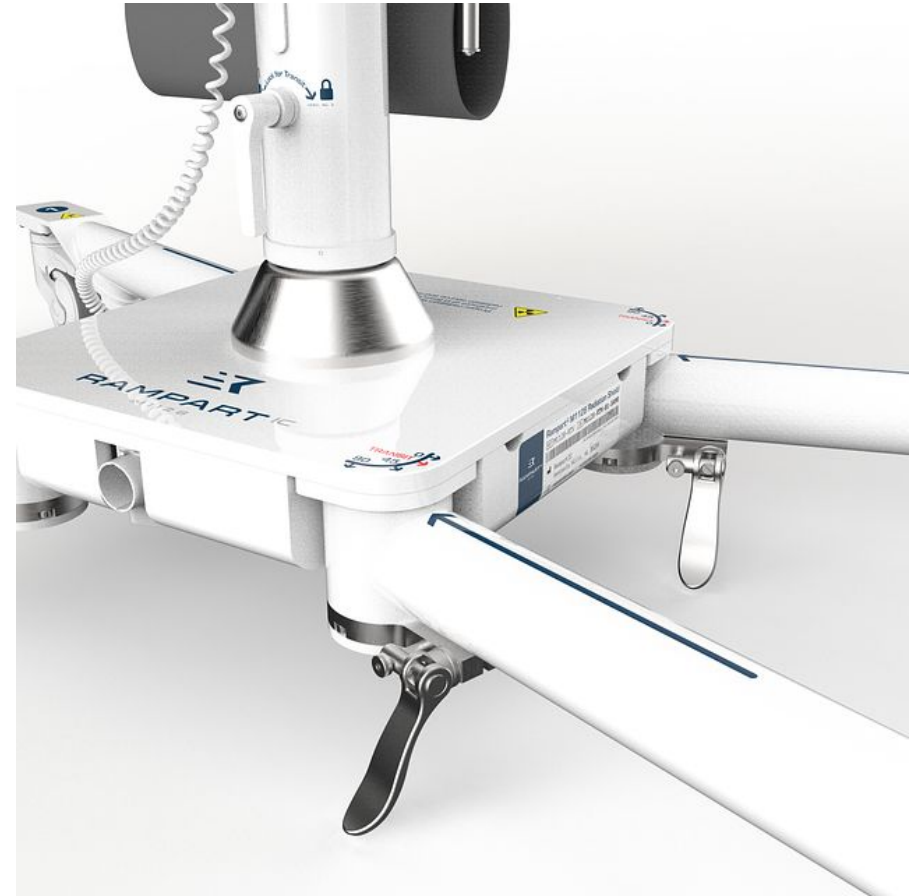


# Leg Locks

- Legs are **LOCKED** when leg lock is **UP**



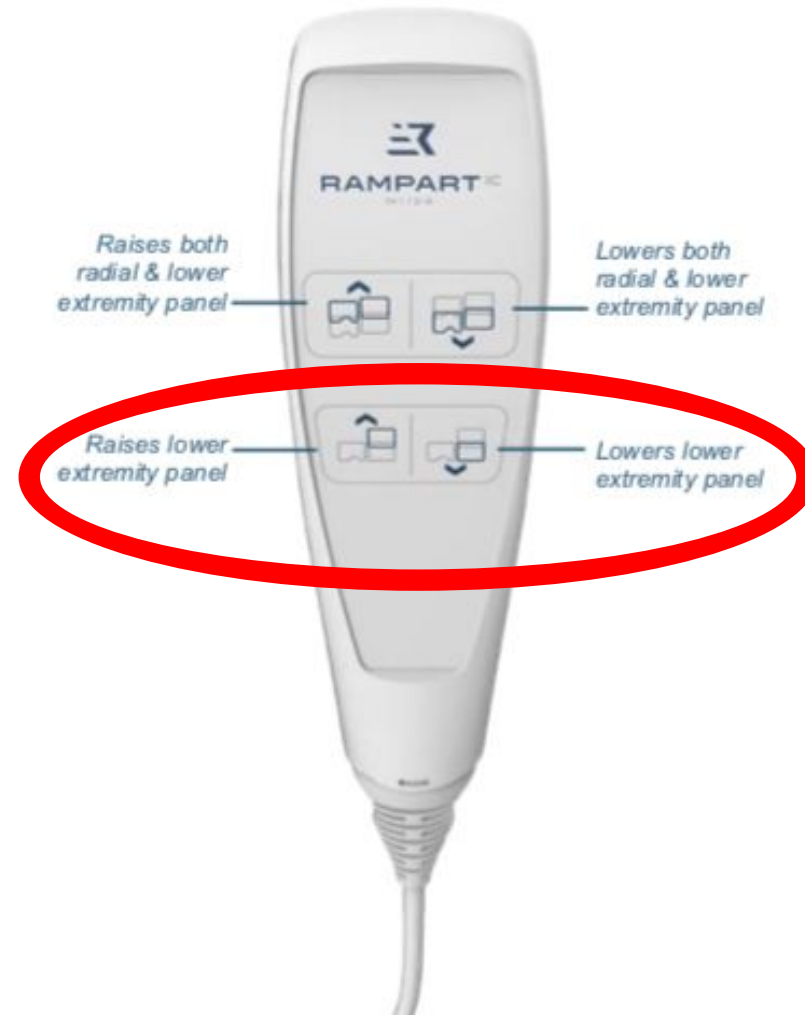
- Legs are **UNLOCKED** when leg lock is **DOWN**



The handset controller accompanying the M1128 is used to raise and lower the lead acrylic panels along the mast to accommodate different procedures and circumstances.

# Handset Controller

- The **top row of buttons** raises or lowers both lead acrylic panels 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.



\*Use bottom row 1<sup>st</sup>  
Move to top row if  
more height is needed

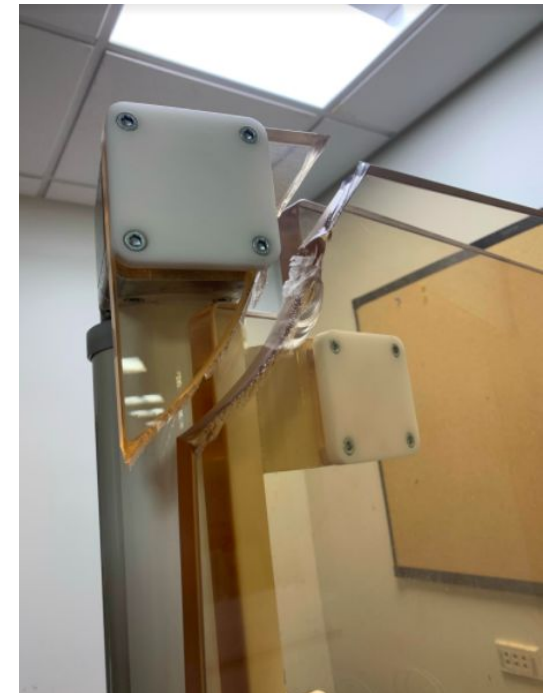
# TRANSIT / STORAGE

1. **Bring both panels to lowest position FIRST!!!!**
2. Ensure legs support panels
3. Fold panels together – do not force together – watch legs/adjust if needed
4. Lock Mast x 2
5. Reference arrows on base sticker – align legs to “transit” position – lock each leg with lock
6. Push from the side with logo on base– legs 1& 4 in front (right hand on mast / left hand on radial shelf) – have kick out stand engaged



When the mast is up and you try to FORCE panels to close – you will crack the shield

If you feel resistance – STOP & ensure mast is all the way down





# CMA – CENTER MAST ACCESSORY

The CMA provides an additional layer of protection between mast of rampart and the patient for various angles, X-ray equipment, or radial set ups.

## Features:

- 1.0mm Pb equivalency
- Easily attachable to extremity panel
- Articulating design to be able to maintain highly configurable platform
- Adjustable in height to accommodate specific patient / table / access / operator preferences
- Fold up for Transit/Storage mode
- Utilizes drape #2 from Drape Kit



# Draping

- Under 2 min drape time
- 5 pieces
- Drape #1, #2, #3, #4
- Ideal to have draped and in place prior to physician



Drape 1 – Left Drape = Radial Panel

Drape 2 - Drop Panel – Center Mast Accessory (CMA)

Drape 3 – Right Drape – Extremity Panel

Drape 4 – Flat drape – use like U drape / allow lag for mast to extend up

Drape 5 – through onto sterile field for boom remote if desired

# Tips For Success

- Configurability to accommodate access points – **BI-RADIAL / BI-FEMORAL / PEDAL**
- Keep armboards / sleds as close to patient body as safely possible
- Open both panels to a minimum 90 degrees before raising either shield
- When raising the table, raise the height of the M1128 (watch for pinch points)
- Check under bed for cords that could obstruct Rampart legs / move anti-fatigue mats
- Fluoro Driver – when going into an LAO or Cranial (depending on camera approach) – anticipate movement of M1128 / tap CARM into position



**WARNING!**

# **ALL STAFF MUST BE TRAINED ON RAMPART & PASS COMPETENCY TESTING PRIOR TO USING / MOVING RAMPART UNITS**

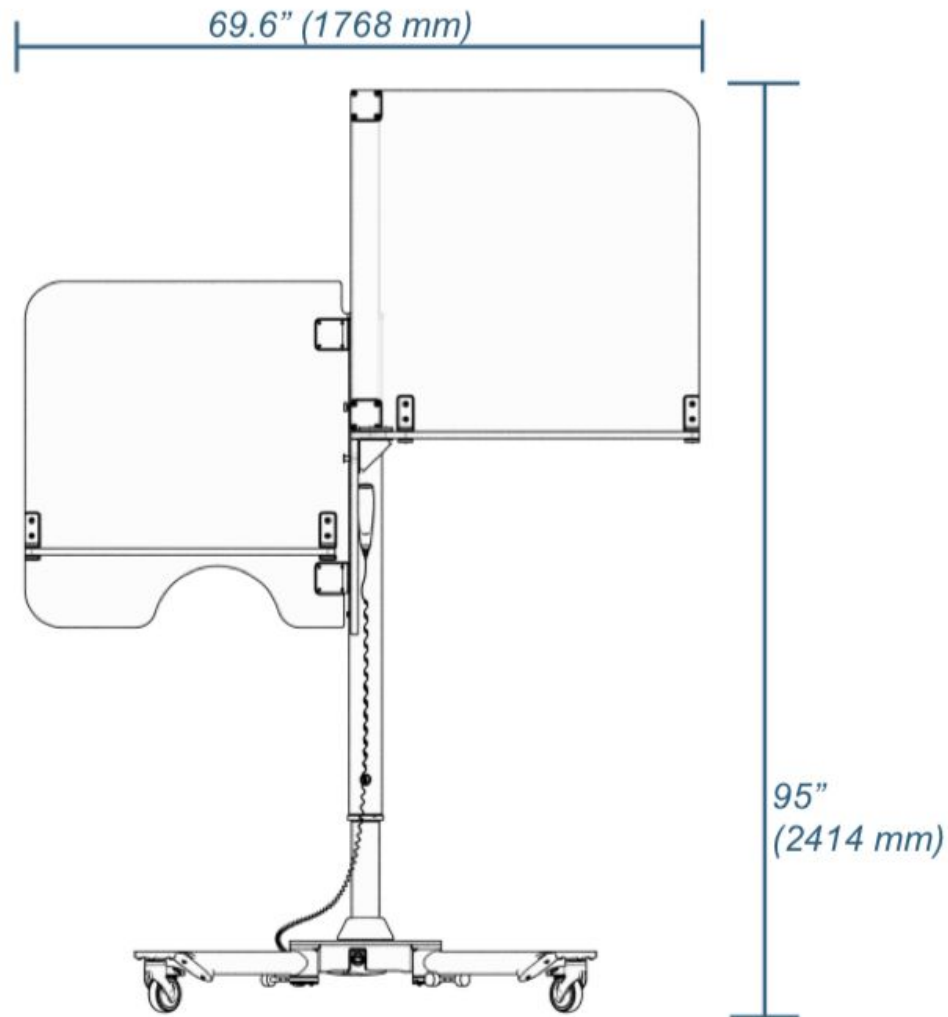


**WARNING:  
Tipping  
Hazard**

#	Items to Complete	Initials	Date
1.	Read the Rampart M1128 USER GUIDE.		
2.	Log into the <a href="http://www.RAMPARTic.com/Training">www.RAMPARTic.com/Training</a> website.		
3.	Watch the Demonstration video at <a href="http://www.RAMPARTic.com/Training">www.RAMPARTic.com/Training</a> .		
4.	Watch the TRANSIT MODE video at <a href="http://www.RAMPARTic.com/Training">www.RAMPARTic.com/Training</a> .		
5.	Watch M1128 Drape Video at <a href="http://www.RAMPARTic.com/Training">www.RAMPARTic.com/Training</a>		
6.	Review the Basic Training Document at <a href="http://www.RAMPARTic.com/Training">www.RAMPARTic.com/Training</a> .		
7.	Complete Competency Test (one per trained staff member) turn into trainer		
8.	Simulate a procedure set-up and sequencing using the Rampart M1128.		
9.	Sign and date this TRAINING TRACKING WORKSHEET and <u>provide copy to manager</u> and trainer.		

**NOTE \* CL MANAGEMENT TO COMMUNICATE LIST OF NEW HIRES/NEW TRAVELERS TO RAMPART PERSONNEL & DISCUSS TRAINING PLAN**

The M1128 is at its **maximum dimensions** with both upper and lower mast actuators extended, lead acrylic panels positioned at an 180 degree angle, and a leg positioned generally under each panel for proper weight distribution and balance, the M1128 is at its largest configured size: **95 inches (2414 mm) tall by 69.6 inches (1768 mm) wide**





# Warnings

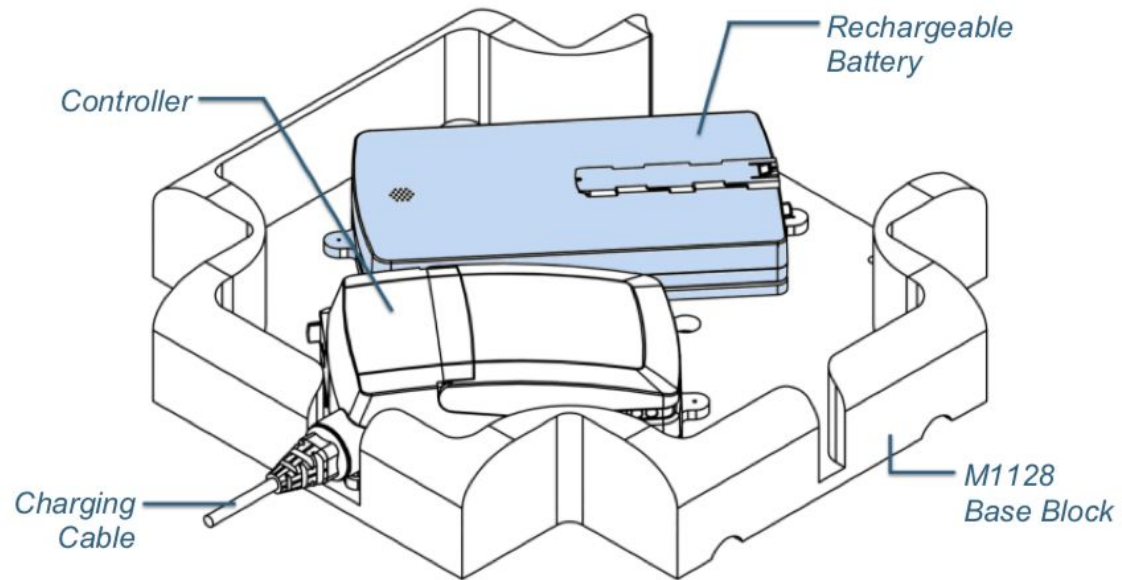


**WARNING:**  
**Tipping  
Hazard**

- **CONFIGURATION DURING USE:** The M1128 lead acrylic panels 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* (see p. 24). First, the mast must be collapsed to the lowest position and the panels folded together and locked forward in the direction of travel. Then, all four legs should be positioned according to the leg angle label adhered to the base of the M1128 and locked into place to prevent legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with Rampart<sup>IC</sup> 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.

# CHARGING

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



Takes 10 hours to achieve a full charge

# Cleaning

## CLEANING

The Rampart<sup>IC</sup> 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<sup>IC</sup> personnel or people authorized by Rampart<sup>IC</sup>.



**CAUTION!**

- When cleaning lead acrylic panels, 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.

## Cleaning Panels

Clean and disinfect the panels by wiping them with **microfiber towels** using one of the following:

- Water solution with mild dish soap
- Windex<sup>10</sup> multi-surface antibacterial spray
- 70% isopropyl alcohol (Use only when disinfection is needed, drying panels immediately after application.)

# ORDERING

- PO process
- Email to:  
[orders@iflproducts.com](mailto:orders@iflproducts.com)
- M1128 RDK -Drape Kits –  
10/case
- 1 drape kit / procedure



# SERVICE

- 1 year warranty at purchase – manufacturing defects
- Service plan (PM) available
- 833-987-0052 – service hotline



# Training Check List

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# Questions and Competency Test