

# STEMRAD MD

## INSTRUCTIONS FOR USE

### StemRad MD Radiation Protection System

INFORMATION FOR USE

STEMRAD MD

REVISION #002

07/2021

The StemRad MD Exoskeleton Radiation Protection System is a unique personal radiation protection system that offers unmatched radiation protection while being weightless to the user. The StemRad MD provides full mobility and dexterity so that the operator can still perform intricate operations while transferring the weight of the protective apron through the exoskeleton to the ground. The advanced ergonomic design moves naturally in unison with the operator and the customization of the system provides a perfect fit.

#### VISOR



Full head protection allowing you to wear your own prescription glasses.

#### EXO



Proprietary exoskeleton which channels all of the weight to the floor while enabling free movement.

#### APRON



State of the art lead free material.  
Tested: 60kVp-110kVp  
IEC EN 61331 – 1:2014

#### HANGER



Dedicated mobile hanger system enabling easy entry and exit of the system.

## TERMINOLOGY

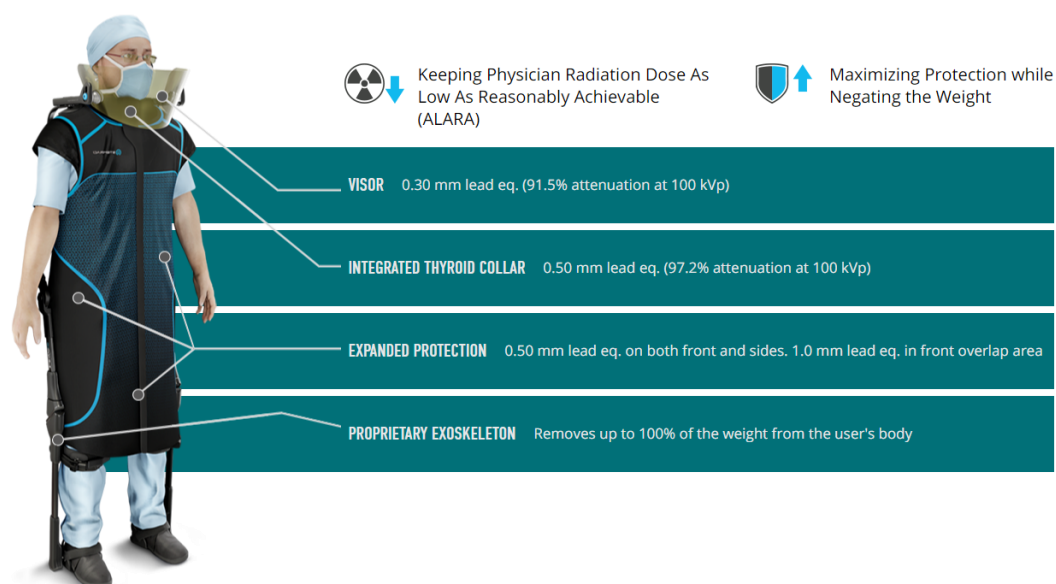
The system is divided into two main areas – the upper section composed from A to C and the lower section composed from D to H.



- A: Visor
- B: Apron
- C: Back System
- D: Pelvis Belt
- E: Thigh Profile
- F: Shin Holder
- G: Shin Profile
- H: Shoe Holster

- 1: Shoulder Pivot
- 2: Hip Pivot
- 3: Knee Pivot
- 4: Ankle Pivot

## PRODUCT SAFETY SPECIFICATIONS



StemRad MD radiation protection garments were tested according to the IEC 61331-1:2014 standard, which provides the criteria for testing a material's lead attenuation equivalent thickness (lead eq.) in a laboratory-based facility. Testing shows that the apron provides at least 0.50 mm lead eq. protection in the front and sides and at least 0.25 mm lead eq. protection in the back @60-110 kVp. The thyroid collar is at least 0.50 mm lead eq. @60-110 kVp.

## WARNINGS AND PRECAUTIONS

The StemRad MD is intended for use in medical x-rays, operating rooms, interventional radiology, and cardiac catheterization labs on an unobstructed and level floor.

Do not permit eating, drinking, smoking, or the use of cosmetics while handling the StemRad MD. Do not attempt to modify the product as this may negatively impact protection and invalidate the warranty.

Movements that are not compatible with the product and should not be attempted are as follows: going up and down stairs, sitting down, running, jumping, and attempting to go through narrow passageways. Avoid contact with sharp objects as these may penetrate the apron's protective core.

Do not continue using the StemRad MD if the user feels it has been improperly installed or fitted. If the product feels too loose or too tight, consult with StemRad's Field Engineers. It is most important that the apron fits properly at the neckline and armhole. Large gaps could result in unnecessary radiation exposure.

After adjustments of the system by the StemRad technician, if additional adjustments are needed, the operator has the ability to adjust the straps that are located on the waist belt, shin holder, and shoe holster for maximum comfort and fitting. Replacing your shoe type may require readjustment of the system. Do not attempt to make any other modification to the system other than what has been described above.

## **RECOMMENDATIONS AND LIMITATIONS OF USE**

The StemRad MD is custom-fitted to a specific user and should not be used by anyone other than the original user.

The StemRad MD is designed to be worn over the operator's scrubs and under the sterile gown. It is recommended to use a bigger sterile gown size, compared to what you would ordinarily use. We recommend Level 4, size 3 XL sterile gowns.

The StemRad MD should only be used with closed shoes. Shoe covers should be worn after donning the system, use high-top shoe covers to cover the feet, lower leg, and the system, all the way up to the sterile gown. Use the shoe holster only while wearing the system to avoid damage to obstacles or people.

## **CARE, MAINTENANCE & INSPECTION**

With careful use and proper storage of the StemRad MD on the dedicated hanger system, the useful life of the StemRad MD will be several years. The warranty of the apron is 2 years from the date of manufacture. Regular inspections of the apron, at least annually, are recommended.

Please make sure that before inspecting the StemRad MD apron under fluoroscopy, the apron is disassembled from the exoskeleton unit, instructions are provided below (Appendix B). Lines may indicate cracks while dots may appear, suggesting air bubbles that do not compromise the protective properties of the apron. Please consult your institution's Radiation Safety Officer for additional information and guidance.

Do not use solvents or harsh cleaners of any kind on the StemRad MD. If the exoskeleton, apron, or hanger needs cleaning, use only Clorox Hydrogen Peroxide Cleaner Disinfectant Spray/Wipes or Super Sani-Cloth Germicidal Disposable Wipes for cleaning and disinfection (or equivalent). Gently rub the system clean and rinse well, use non-scratch fabric to avoid any chance of damage.

Do not iron, dry clean, autoclave, bleach, use alkali detergent or modify the apron, as this may affect the protective abilities of the product and invalidate the warranty.

Always use the two handles to lift the visor carefully from the hanger system. Lifting the visor with only one handle could damage the visor and cause unnecessary pressure on the visor. After connecting the visor to your StemRad MD system, please ensure that the visor is tightly secured before proceeding any further.

When handling the visor, it is advised to first clean both hands and do not touch the lead-acrylic directly when possible. The lead acrylic might be negatively affected by solvent. Clean the surface of the visor only using water, neutral detergent, or ethanol, while only using a non-abrasive cleaning cloth.

## STORAGE

When not in use, aprons should always be placed on its StemRad MD designated hanger. Store the StemRad MD in a clean, dry room. Do not expose the product to excessive heat, above 50°C ,and/or humidity levels exceeding 80%.

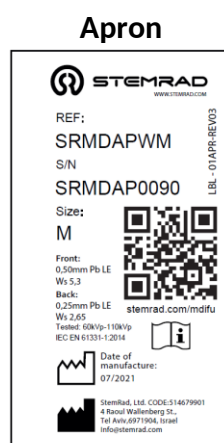
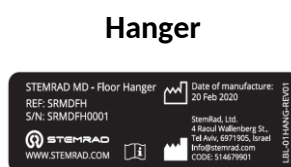
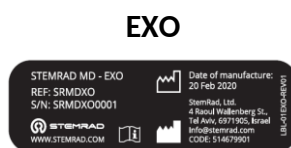
## TRANSPORTATION

When transporting the StemRad MD system, it is critical that the dedicated mobile hanger system be used. When you are ready to transport the system on the hanger system, use the handle to tilt it back slightly and start the process of rolling it, keeping that positioning until you reach your desired destination. Once there, carefully tilt it back down to its original leveled positioning. Please make sure that the hanger system braking mechanisms are activated when the system is not being transported. It is also very important to ensure that the protective visor is properly secured in its dedicated storage channel. It is best to only transport the StemRad MD on a level surface and to avoid inclines, stairs and ramps. Lastly, when parking the StemRad MD, please position the back of the hanger system against a flat wall to ensure maximum stability.



## LABELING/MARKINGS

On the system, you will find labels like the ones that are shown below, which identify the serial number, size, and protection values of the StemRad MD apron.



### Symbols



Manufacturer



Consult Instructions For Use

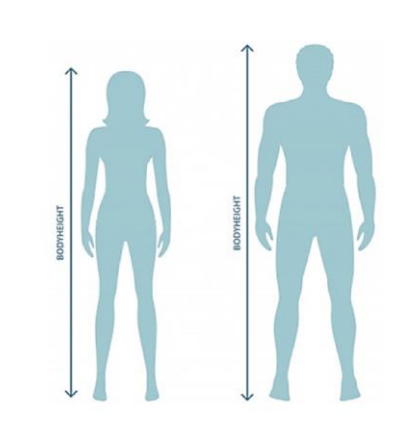


Date of Manufacture

## FIT & SIZING

The StemRad MD is custom-fitted to the exact measurements of the specific user. It is required that a certified StemRad MD Field Engineer provide the initial fitting and proper set-up before the operator's first use. An Improper fitting might result in inadequate radiation protection, maybe uncomfortable, may stress or damage the material, and may lead to premature cracking of the core .

Please contact StemRad's Technical Support Service Team if you are not fully satisfied with the StemRad MD. Do not attempt to readjust or modify the system yourself in any way that is not described in this manual. The StemRad MD system is custom-made for you and should only be worn by the original user.

Apron Size	Height	Weight	
<b>SMALL</b>	168 -173 5'6"-5'8"	120-159 54-72 Kg	
<b>MEDIUM</b>	175 - 180 5'9"-5'11"	160-199 72-90 kg	
<b>LARGE</b>	183-188 6' - 6'2"	200-240 90-110 Kg	
<b>EXTRA LARGE</b>	183-193 6' - 6'4"	200-240 90-110 Kg	

## CONTACT US

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## APPENDIX A

### DONNING THE SYSTEM

1. Before donning the system please have your scrubs on.
2. Start from the bottom of the StemRad MD and work your way to the top.
3. As a first step, put on the shoe holsters and adjust/tighten them to your shoes.
4. Attach the exoskeleton legs to the shoe holster clamps and then close the shin holders while the system is attached to the hanger system.
5. Insert your hands into the apron and close the buckle of the waist belt.
6. Attach the inside clips, close the zipper, and attach the thyroid collar magnet.
7. After ensuring you have properly put the StemRad MD on, you are ready to disconnect it from the hanger system.
8. Put both hands on the shoulder connectors, disconnect them and exit the hanger system.
9. Put on a sterile Level 4 surgical gown large enough to cover the footprint of the system.
- After the gown has been applied, you are now ready to attach the visor.
10. Make sure to hold the visor from its connectors on both sides.





## DOFFING THE SYSTEM

1. After the procedure, please have the operator carefully remove the system by first standing inside the StemRad MD Hanger system. Start from the top to the bottom.
2. First disconnect the visor and remove the sterile gown. Place the visor in his designated place on the hanger.
3. Connect the apron with both shoulder connectors to the hanger.
4. Open the thyroid collar magnet, then open the zipper and the inside clips.
5. Insert your hands into the apron and open the buckle of the waist belt.
6. Pull both quick releases handles on the exoskeleton legs sides at the same time.
7. The quick-release disconnects the shin holders and shoe holsters.
8. You can now walk out of the Hanger system.
9. Sit down and remove the shoe holsters.
10. Make sure to thoroughly clean the system after each procedure.



A



B



C



D



E



F



G



H



I



J



K



L

## **APPENDIX B**

### **DISASSEMBLE THE APRON**

1. Disconnect the Pelvis Joint from the belt inside the Apron by inserting a screwdriver to the hole on the Pelvis Joint side and pulling it towards you.
2. Make the same action to both sides left and right. After the belt is disconnected hang it on the hanger handle.
3. After disconnecting the Pelvis Joint mechanism and the belt please remove the Apron from the Hanger system and hang it on a chair.
4. Disconnect the Exo shoulders from the Apron by inserting a screwdriver to the shoulders hole mechanism. Pull it back to open and forward to close.
5. Make the same action to both sides left and right. After the Apron is removed from the Exo shoulders hang the Exo back on the Hanger system.

### **ASSEMBLE THE APRON**

1. Place the Apron on a chair. Remove the Exo from the hanger and place the Exo shoulders according to the Apron shoulders.
2. Connect the Exo shoulders to the Apron by inserting a screwdriver to the shoulders hole mechanism. Pull it back to open and forward to close.
3. Make the same action to both sides left and right. After connecting the Exo shoulders please hang the Exo with the Apron on the Hanger.
4. Remove the belt from the Hanger and connect it to the Pelvis Joint. Make sure the belt is position on the right orientation label facing upwards.
5. Connect the Pelvis Joint to the belt inside the Apron by inserting a screwdriver to the hole on the Pelvis Joint side and pulling it towards you. Make the same action to both sides left and right.

Pictures attached below to illustrate the actions. Detailed video instructions of the assembly/disassembly process can be seen on our website: <http://stemrad.com/mdifu>





A



B



C



D



E



F



G



H



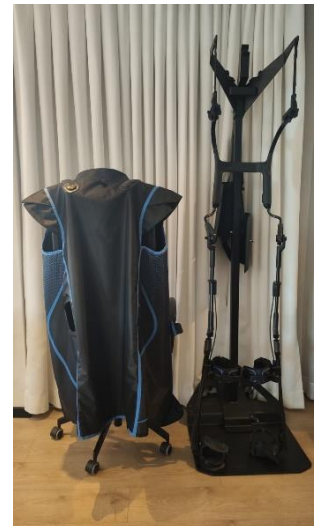
I



J



K



L