



Product Information Letter

HeartMate 3™ LVAS - Electrostatic Discharge Awareness

July 2024

Dear Valued Customer,

Every year, Abbott sends out a refresher communication to remind customers about the **potential risks of Electrostatic Discharge (ESD)** and the potential impact ESD may cause to the **HeartMate 3™ LVAS**. **This letter enhances the information already on the Instructions for Use (IFU) by bringing specific awareness on air fluidized specialty beds manufactured by third parties as a potential source of static electricity.** Please note that **it is safe to continue using your HeartMate 3™ LVAS** when following the Instructions for Use.

Air fluidized specialty beds are used to aid in wound healing by distributing the patient's load and reducing pressure points while lying on the specialty bed. The fluidization technology is based on air moving through a bed of silicone beads to create a fluid effect. A side effect of this technology is that the beds can be a source of high static electricity (due to the movement of the silicone beads) and can affect HeartMate 3™ LVAS operation. Although specialty beds are not specifically listed in the IFU as a source of ESD, the current general guidance to avoid activities that may cause ESD applies. It is recommended to avoid air fluidized specialty beds as their technology is a potential source of ESD.

WHAT YOU NEED TO KNOW:

It is safe to continue using your HeartMate 3™ LVAS when following the Instructions for Use which includes avoiding activities that may cause ESD including air fluidized beds. High levels of static electricity may damage or harm the HeartMate 3™ LVAS system and may cause the pump to stop. HeartMate 3™ LVAS utilizes Magnetic-Levitation technology and is designed with hardware reset and software automatic restart algorithms that automatically restart the pump following an electrostatic discharge.

HeartMate II™ LVAS is not in scope of this product information letter as it does not utilize Magnetic-Levitation technology and thus does not require reset and automatic restart mechanisms.

Air fluidized specialty beds are a potential source of high static electricity that can affect the HeartMate 3 pump while a patient is lying on them. As indicated in the IFU, ESD can lead to damage or harm to the system and may cause a pump reset. As of March 20, 2024, Abbott has received six (6) complaints reporting HeartMate 3™ (HM3) pump reset associated with Electrostatic Discharge (ESD) event/strike when HeartMate 3 LVAD patient was lying on a specialty bed. These were reported since the launch of HeartMate 3™ LVAS to March 20, 2024. To avoid ESD events, alternatives to the Air Fluidized Specialty Beds should be considered when using the HeartMate 3™ LVAS.

For additional information about ESD and the HeartMate 3™ LVAS, please refer to the IFU Chapter 6- Patient Care and Management.

Remember, **it is safe to continue using your System when following the Instructions for Use.** Should you have any questions about this communication, please contact Abbott Technical Support at 1-800-456-1477 or your local Abbott representative.

Instructions for Use are available for the HeartMate 3™ LVAS model numbers 106524US, 106524INT and 106524 on the Abbott website (<https://manuals.eifu.abbott/en/index.html>).

Safety and satisfaction are a top priority for Abbott. We appreciate the privilege to provide high quality products and support to you.