Product Safety Information Letter

RE: **Envella** Air Fluidized Therapy System – Electrostatic Discharge Awareness

June 16, 2026

Dear Valued Customer:

Baxter is aware that manufacturers of certain life-sustaining devices, such as Ventricular Assist Devices (VAD), provide routine communication to customers regarding the potential impact of electrostatic discharge (ESD) on device performance. For example, in July 2024, Abbott issued a product advisory recommending that patients with a HeartMate 3™ Left Ventricular Assist System follow the device Instructions for Use (IFU) and avoid activities that may cause ESD, including the use of air fluidized specialty hospital beds.

While it is safe to continue using Baxter's **Envella** Air Fluidized Therapy System consistent with the product IFU, Baxter is issuing this letter to re-emphasize the importance of vigilant patient monitoring when certain devices are used concurrently. A list of devices where there have been reports of potential ESD impact while in use with Baxter's air fluidized specialty beds is included in Appendix A.

The **Envella** Air Fluidized Therapy System is a patient management system that combines air fluidized therapy and pressure redistribution technologies together on a low-height frame. The lower body section provides air fluidized therapy, and the upper body section provides pressure redistribution. The lower body portion of the bed provides the maximum pressure relief of air fluidized therapy via the bed's air fluidization chamber containing silicone-coated microspheres (beads). Due to the movement of the silicone beads, the beds can be a source of static electricity and can affect other medical devices, including those listed in Appendix A.

What You Need to Know:

It is safe to continue using your **Envella** Air Fluidized Therapy System consistent with the product IFU. Per the **Envella** Air Fluidized Therapy System IFU, "Fluidizing beads can generate Electrostatic Charge. Consult the Instructions for Use of any critical devices used in direct contact with the air fluidized section of this bed to determine if they are susceptible to interference from ESD. Take all precautions as indicated by the manufacturer of this equipment."

It is important that equipment used on or within proximity to the **Envella** Air Fluidized Therapy System also meets IEC 61000-4-2 for ESD immunity. This can be found by reviewing the device manufacturer's labeling or IFU.

Using the **Envella** Air Fluidized Therapy System in the prescribed temperature and humidity environment is a major consideration in electrostatic generation. Lower humidity conditions tend to enhance the ability of static electricity to build up, which can lead to electrostatic discharges. The IFU recommends that the operating environment includes a minimum of 20% relative humidity (RH) and that the bed be placed on wood, concrete or ceramic tile floors. If, however, there is synthetic flooring, then the IFU recommends that the RH be at least 30%. Specifically:

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The P0819 is intended for use in the electromagnetic environment specified below. The customer or the user of the P0819 should make sure it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV Air	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Envella Air Fluidized Therapy System, IFU Revision 8, pg. 80; can be accessed here: Envella Bed: Air Fluidized Therapy Hospital Bed | Hillrom.

Further Information and Support

For general questions regarding this communication, please contact Baxter Technical Support at 800-445-3720, option 2, between the hours of 8:00 am and 6:00 pm Eastern Time, Monday through Friday.

We thank you for your attention to this important product information.

Appendix A

Device List: Potential ESD Impacts with **Envella** Air Fluidized Therapy System (Product Code P0819A) 2017 – 2026

Potentially Impacted Products	**Quantity**	**Reported Issue**
Ventricular Assist Systems	3	Device pump stops, brief power down events, malfunctioning equipment
Infusion/IV Pumps	43	Pump not working, shorting out of the IV pumps, error messages on pumps, pump interference, pumps turning off, malfunctioning pumps
Portable Cardiac Telemetry Monitoring Devices and Heart Rate Monitors	3	Interruptions in heart rate and interference when bed is turned on
Feeding Pumps	1	Interference with feeding pump
Electrical Stimulation Devices	1	Not working while bed is turned on
Ventilators*	0	Not confirmed
Sequential Compression Devices (SCD) / SCD Boots*	0	Not confirmed

- There was no patient/user injury, medical intervention, symptom, or adverse event resulting in patient harm reported to be associated with any of these complaints.
- Most complaints were resolved by reinforcement of the IFU regarding the importance of equipment used on or within proximity to the **Envella** Air Fluidized Therapy System meeting IEC 61000-4-2 for ESD immunity.
- *Devices reported in MedWatch received from the FDA as concomitant products; however, follow up with the customer did not identify these products as impacted by ESD when used with the Envella Air Fluidized Therapy System.