FDA MedWatch: BodyGuard Infusion Pump System by CME America - Class I Recall

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- BodyGuard Infusion Pump Systems
- All Serial Numbers of Affected Model Numbers
- Model Numbers:
  - BG 323 Pump*
  - BodyGuard 121 Twins Pump*
  - BodyGuard 545 ColorVision Pump *
  - BodyGuard 575 Pump*
  - CMExpress Pumps*
  * Includes refurbished versions

- Manufacturing Dates: March 06, 2009 to November 26, 2019
- Distribution Dates: March 6, 2009 to November 29, 2019
- Devices Recalled in the U.S.: 28,448
- Date Initiated by Firm: January 7, 2020
Device Use

The BodyGuard Infusion Pump System delivers fluids and medications into a patient's body in controlled amounts. The pump provides fluids through an infusion tubing set into a patient's vein or through other cleared routes of administration. The system can be used in hospitals and home care environments.

Reason for Recall

CME America is recalling the BodyGuard Infusion Pump Systems because the pumps may have a slower than expected delivery of medication (under-infusion), and faster than expected delivery of medication (over-infusion). The reason for the infusion errors is not known.

The use of the affected infusion pumps may cause serious adverse health consequences including death. There have been 158 complaints regarding this device issue. There have been no injuries or deaths.

Who May be Affected

- Health care providers using the BodyGuard Infusion Pump System
- Home care providers using the BodyGuard Infusion Pump System
- Patients who may receive fluids or medications delivered by the BodyGuard Infusion Pump System

What to Do

On January 7, 2020 CME America, a subsidiary of Becton Dickinson sent a letter to distributors and customers informing them of the issue and provided the following instructions:

- Assess the fluid container for volumes infused, volumes remaining in the container at the end of the infusion, and ensure the total volume of medicine is delivered.
- Determine if the devices have been calibrated within the last 12 months.
- If calibration has not occurred within that time frame, customers should contact their Authorized Service Provider to schedule a calibration.
- Complete the Customer Response Form attached to the letter and return it to the CME America, whether the product was in inventory or not.
- Report any adverse events to the FDA’s MedWatch Adverse Event Reporting program.

The FDA recommends health care professionals take the following actions:
• Do not use the pump to administer critical medications (e.g., vasopressors) or medications such as insulin where infusion accuracy is important. Testing indicates that pumps may have a delivery inaccuracy of up to ±13%.
• Depending on your therapy needs, if higher accuracy is required, consider an alternate infusion device.
• When clinically appropriate, perform periodic pump and patient monitoring to ensure that the infusion is proceeding as intended.
• If this pump is used in a home care setting, the prescribing clinician, patient and home healthcare provider should determine the appropriateness of the pump for use, and pump / patient monitoring strategies.
• Notify CME America if your pump is malfunctioning.

Contact Information
Consumers with questions may contact Customer/Technical Support by phone at (877) 263-0111, Monday through Friday between 9:00 am and 5:00 pm Mountain Time.

Additional Resources:
• Medical Device Recall Database Entry
• CME America Recall Notice
• CME America Recall Customer Letter

How do I report a problem?
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.