carecentrix

Provider Newsflash
February 2026

FDA Early Alert – Fresenius Kabi Large Volume Pump Ivenix

Purpose of this communication:

We are writing to inform you that Fresenius Kabi has issued an Urgent Medical Device Correction for Ivenix Large Volume Pump (Product Code: LVP-SW-0005) relating to the software. Fresenius Kabi stated that the affected software (Version: 5.10.1 and earlier) contains anomalies that could cause serious patient harm or death. These issues may cause delays or interruptions to infusion. The extent of harm resulting from delayed or interrupted therapy depends on the time taken to identify and resolve the issue, the patient's underlying medical condition, and the criticality of the administered therapy.

As of November 18, Fresenius Kabi has reported two serious injuries and no deaths associated with this issue.

What do I need to do?

- Please review the following recall notice from the FDA here.
- Notify impacted patients that the software should be corrected prior to continued use for the Ivenix Large Volume Pump to software version: 5.10.2. This new software release addresses the anomalies.
- Confirm if you have any CareCentrix patients affected by this FDA Early Alert and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.