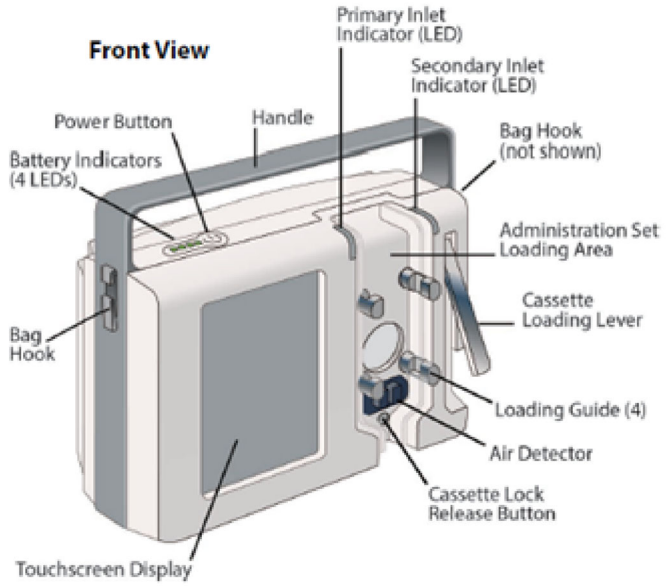
# Early Alert: Infusion Pump Issue from Fresenius Kabi USA

*This communication is part of the Communications Pilot to Enhance the Medical Device Recall Program (/medical-devices/medical-devices-news-and-events/cdrh-announces-communications-pilot-enhance-medical-device-recall-program). The FDA has become aware of a potentially high-risk device issue. The FDA will keep the public informed and update this web page as significant new information becomes available.*

## Affected Product




The FDA is aware that Fresenius Kabi USA has issued a letter to affected health care providers indicating a subset of Ivenix large-volume pumps are to be removed from use for repair.

- Ivenix large-volume pump, LVP-0004
- UDI 00811505030320

### Serial Numbers

## What to Do

- On December 5, 2024, Fresenius Kabi USA sent all affected customers a letter recommending the following actions to be taken until the affected LVPs are returned for pneumatic valve repair:
    - Review the list of affected Serial Numbers and post the list in a public place. If possible, remove and isolate all affected devices from circulation to prevent

inadvertent use.

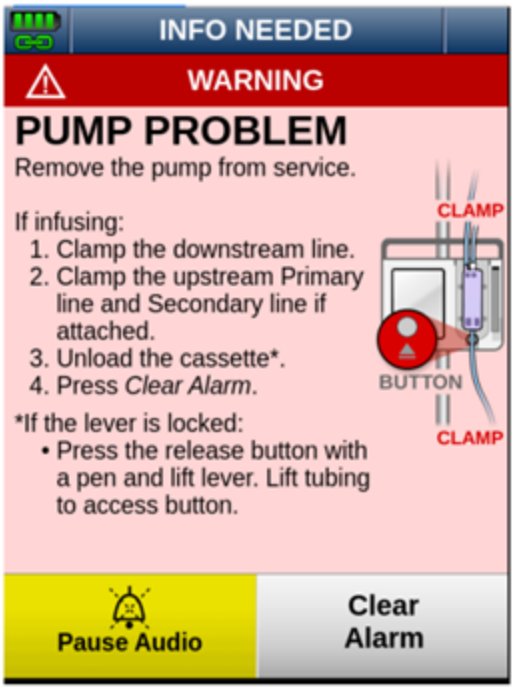
- If removing all or some of the devices from active use is not feasible (that is, no alternative pumps are available and patient care would be compromised), proceed with caution as outlined below:
  - If the Ivenix LVP is being used to **deliver life-sustaining medications**, enhance clinical monitoring during use and ensure an additional LVP is available for situations where an interruption in infusion could be dangerous. If a problem is encountered, remove the pump from circulation, use the backup LVP to continue, and report the event to Fresenius Kabi.
  - For **Pump Problem alarm during set up**, use another LVP and report the issue to your institution's biomedical engineers. Remove the pump from circulation and report the event to Fresenius Kabi.
  - For **Pump Problem alarm during use**, reprogram the infusion on another LVP and report the issue to your institution's biomedical engineers. Remove the pump from circulation and report the event to Fresenius Kabi.
  - Post the steps above and the list of affected Serial Numbers at each nursing station.
- Inform potential users of the product within your organization of this notification.

- Check this page for updates. The FDA is currently collecting information about this potentially high-risk device issue and will keep the public informed as significant new information becomes available

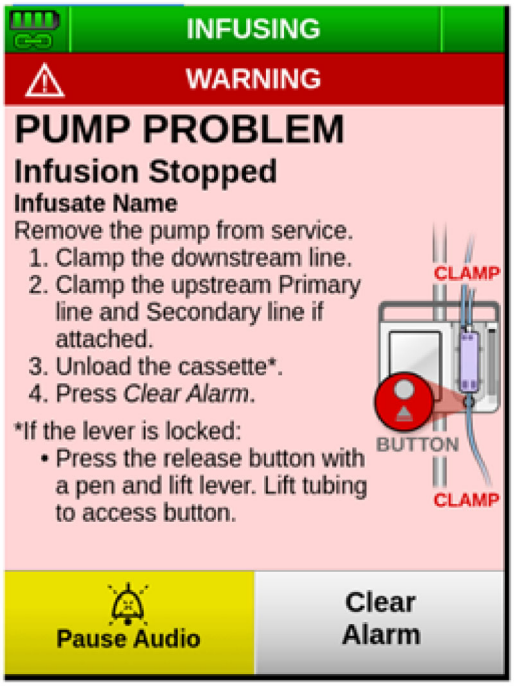
## Reason for Early Alert

Fresenius Kabi USA reports that a subset of pneumatic valves installed in some Ivenix LVPs have an increased chance of issuing a non-recoverable pump problem alarm. All devices with the affected valves, should be removed from use, as described in the What to do section above, to be evaluated and returned to Fresenius Kabi's facility for repair.

- If the pneumatic valve fails, a Pump Problem alarm will be raised.
- If this failure occurs during LVP setup, this could potentially delay therapy. (See Image 1 below)




- If this failure occurs during an active infusion and flow is interrupted, this could lead to an underdose. (See Image 2 below)




- Delay or interruption of a life-sustaining infusion may result in permanent disability or death.

The pump problem alarms are working as intended and will arise indicating when to act, if the malfunction occurs.

The firm has not reported any injuries or deaths associated with this issue.

## Device Use

The Ivenix LVP is a large volume infusion pump designed to deliver fluids and medications from one of two inlet source containers to the patient through a single outlet. When loaded with an administration set, the LVP delivers infusion therapy to an individual patient.

## Contact Information

Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Fresenius Kabi USA at Ivenix_support@fresenius-kabi.com (mailto:Ivenix_support@fresenius-kabi.com) or 1-855-354-6387.

## Unique Device Identifier (UDI)

The unique device identifier (UDI) helps identify individual medical devices sold in the United States from distribution to use. The UDI allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that devices can be identified more quickly, and as a result, problems potentially resolved more quickly.

- How do I recognize a UDI on a label? (/medical-devices/unique-device-identification-system-udi-system/udi-basics)
- AccessGUDID database - Identify Your Medical Device (https://accessgudid.nlm.nih.gov/)
- Benefits of a UDI System (/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.