carecentrix

Provider Newsflash
December 2024

FDA Recall – ICU Medical

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued notice of a Class I recall by ICU Medical for removal of some CSB batteries intended for use with their Plum 360, Plum A+ and Plum A+3 infusion systems after receiving reports of allegedly counterfeit, untested batteries being used with the infusion pumps. The affected and allegedly counterfeit products are named: Batteries for use in Plum 360, Plum A+, and Plum A+3 Infusion Systems, are missing information including ICU Medical Test Label or CE Mark and have a Date code (yellow label found on side of battery): W2401xxxx – W2406xxx. Preliminary reports suggest that the batteries fail to hold charge, and the pump may display battery replacement messages earlier than expected. The batteries and replacement batteries for these infusion systems are used when the pump is not plugged into AC power, for example when a patient is being transported. The use of affected products may cause serious injury or death to patients due to interruption, under-infusion, or delays in the delivery of critical fluids, blood products, and medications.
- The recall is only for removal of the allegedly counterfeit batteries and does not include removal of Plum Infusion Systems. This recall notice is an extension of an Urgent Medical Device Safety Alert issued by ICU Medical to all affected customers on October 22, 2024, and includes the following instructions:
    - Make sure batteries currently used in Plum 360, Plum A+, and Plum A+3 Infusion Systems are not part of this recall.
    - Do not use batteries that do not have an ICU Medical Test Label or CE Mark on the label
    - Ensure that any entity providing service or repair for Plum Infusion Systems uses only parts authorized by ICU Medical.

What do I need to do?

- Please review the following recall notice: Infusion Pump Battery Recall: ICU Medical Removes Some CSB Batteries Intended For Use With Plum 360, A+, and A+3 Infusion Systems Due to Reports of Allegedly Counterfeit, Untested Batteries In Use | FDA
- Notify impacted patients and facilitate the replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall 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.