carecentrix

Provider Newsflash Sept 2, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has announced a Class I recall as an update to their previously announced voluntary recall on June 30, 2020 of BD Alaris System Hardware. The hardware issues may cause the infusion pump to not operate as expected. The 4 hardware situations that may result in infusion pump not operating as expected include:

1. Damaged Inter-Unit Interface (IUI) Connectors (Situation 1 – Class I)
2. Broken elements on Alaris™ Pump Module platen (Situation 2 – Class I)
3. Improperly secured PC unit Battery (Situation 3 – Class I)
4. Dim LED Segment(s) on the Alaris™ modules (Situation 4 – Class II)

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-provides-update-previously-disclosed-recall-bd-alaris-system-hardware?utm_campaign=BD%20Provides%20Update%20on%20Previously%20Disclosed%20Recall%20of%20BD%20Alaris%20System%20Hardware&utm_medium=email&utm_source=Eloqua
- Notify impacted patients and facilitate the repair, 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 for your prompt attention and cooperation in this matter.