



FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately FDA has posted an announcement by BD (Becton, Dickinson and Company) of an update to their previously announced voluntary recalls issued on August 4, 2020. The recalls have now been updated to FDA Class I and II designation for their BD Alaris System due to the potential for 4 hardware situations relating to keypads, incorrect module types and/or sizes and channel error. These hardware situations may result in the infusion pump not operating as expected.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-announces-fda-classifications-august-4th-recalls-bd-alarism-system-hardware-keypads-incorrect?utm_medium=email&utm_source=govdelivery
- 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.