

Provider Newsflash April 19, 2021

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately, the FDA has issued notice of a Class 1 recall by CareFusion 303, Inc. of their BD Alaris Infusion Pump Module, model 8100 manufactured 1/15/2019 to 12/5/2019 and distributed 1/23/2019 to 12/5/2019. This recall was issued because of the risk of the keyboard lifting up due to fluid entry which could lead to keys that become stuck or unresponsive. This may lead to an infusion delay or interruption or prevent clinicians from changing fluid or medication infusions on the affected devices.

What do I need to do?

- Please review the following recall notice:
- <u>https://www.fda.gov/medical-devices/medical-device-recalls/carefusion-303-inc-recalls-bd-alaris-pump-module-model-8100-due-risk-stuck-or-unresponsive-keys?utm_medium=email&utm_source=govdelivery</u>
- 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.