carecentrix

Provider Newsflash
March 2022

Company Announcement/Recall – Baxter Infusion Pumps

Purpose of this communication:

We are writing to inform you that the FDA has published a Class I recall by Baxter of their SIGMA Spectrum Infusion Pumps with Master Drug Library (Version 8), Product Code 35700BAX2 and their Spectrum IQ Infusion System with Dose IQ Safety Software (Version 9), Product Code 3570009 distributed from February 5, 2015 to present. The recall is due to the risk of the devices not alarming for repeated upstream occlusion events. If an occlusion is not fully resolved before restarting the infusion, the pump may not re-alarm as expected and may appear to be infusing normally when it may be infusing below the programmed rate or not infusing at all. Patient harm may occur from interruption in therapy (due to full occlusion) and/or under-infusion (due to partial occlusion).

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/baxter-recalls-sigma-spectrum-infusion-pumps-master-drug-library-version-8-and-spectrum-iq-infusion?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 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.