Provider Newsflash
December 2023

FDA Recall – Eitan Medical, Ltd

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class I recall notice of Eitan Medical Ltd's Sapphire Infusion Pumps running software version Rev 16.10. Product Models include the Sapphire Multi-Therapy Infusion Pump (REF 15031-000-0028), the Sapphire Epidural Infusion pump (REF 15032-000-0027), and the Sapphire Plus Infusion Pump (REF 15038-000-0001). Pumps with this software version may fail to detect air in the line when running on battery power and in some cases may not sound an alarm when there is air in the line.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/eitan-medical-ltd-recalls-sapphire-infusion-pumps-failure-detect-air-line?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 in advance for your cooperation and continued partnership.