Provider Newsflash
April 2024

FDA Recall – InfuTronix, LLC

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class I recall of InfuTronix, LLC's Nimbus and Nimbus II Infusion Pump Shystems. On February 21, 2024, the firm initiated a voluntary recall of the Nimbus Administration Set, Nimbus Flex, Nimbus PainPro (aka Halo Ambulatory Infusion System), Nimbus II Infusion Systems, Nimbus ii PainPro, Nimbus II Flex and Nimbus II Plus Infusion systems. The recall is due to multiple potential failure modes that may include battery failure, upstream blockage (occlusion), system errors, drug product leakage, high or low flow rate, of damaged housing. The devices will not be available or supported after June 20, 2024. Use of these products may lead to serious injury or death.

What do I need to do?

- Please review the following recall notice: InfuTronix, LLC Recalls Nimbus and Nimbus II Infusion Pump Systems for Multiple Device Failures That May Cause Severe Injury and Death | FDA
- 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.