Provider Newsflash
March 2024

FDA Recall – InfuTronix, LLC

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has posted notice of a voluntary recall by InfuTronix, LLC of the Nimbus Ambulatory Infusion Pump System, including Nimbus II PainPro, Nimbus II Flex, Nimbus II Plus, Nimbus II EpiD and Nimbus II EMS distributed from October 17, 2014 to February 21, 2024. InfuTronix is seeking to remove the system from the US Market due to a high number of customer complaints related to the Nimbus Infusion Pump Systems from May 2019 to August 2023. Evaluation of the complaint data identified several potential product issues. As a result, InfuTronix has determined that the best corrective and preventive action to address the identified product issues and potential outcomes is a redesign of the Nimbus Infusion Pump system. As such, InfuTronix is seeking to remove the system from the market while these improvements and design changes are being made and new clearance(s) is obtained.

What do I need to do?

- Please review the following recall notice: Voluntary Removal Announcement for the InfuTronix Nimbus Ambulatory Infusion Pump System | FDA
- Notify impacted patients and facilitate the 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.