Safety Communication رسالة سلامة

Infusion Pump software May Exhibit Various Problems

Device/ Product Description:	Infusion Pump Systems
Brand:	Alaris™ System PC Unit
Affected product:	**Model** 8000: software versions 9.5 and prior **Model** 8015: software versions 9.33 and prior
Manufacturer:	BD Diagnostic Systems
Problem:	Manufacturer has identified issues are as follows: Issue 1: Software errors related to System Error Code 255-XX-XXX Issue 2: Delay Options programming Issue 3: Low Battery Alarm Failure Issue 4: Keep Vein Open (KVO) / End of Infusion alarms priority Issue 5: Use Errors related to Custom Concentration programming The identified issues could result in delay to the start of an infusion, an interruption of therapy, sudden stop, or lowering the infusion rate. This may put patient at greatest risk of harm.
Recommendation /Actions:	1. Review this notice and ensure that affected personnel are aware of the contents. 2. Contact the authorized representative for required correction. For more information, Please click here. If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

Devices/Products photo:		
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