

Safety Communication

رسالة سلامة

Medfusion Syringe Pumps May Deliver Inappropriate Dose

Device/ Product Description:	Medfusion 3500 and 4000 Syringe Infusion Pumps	
Affected product:	Affected Model	Affected Firmware Version
	Medfusion 3500	6.0.0
	Medfusion 4000	1.5.0, 1.5.1, 1.6.0, 1.6.1, 1.7.0
Manufacturer:	Smiths Medical International Limited.	
Problem:	Medfusion 3500 and 4000 Syringe Infusion Pumps May Deliver Inappropriate Dose under Certain Circumstances. This inappropriate delivery (over or under-delivery of a bolus or loading dose) may lead to serious injury or possibly death, depending on the type of treatment being administered and the patient's condition.	
Recommendation /Actions:	<p>1. Smiths Medical developed an Operators Manual Insert. 2. Smiths Medical is developing software updates to fix this software defect.</p> <p>For more information, please check the "FSCA"</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>	

Devices/Products photo:		
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