


Safety Communication

رسالة سلامة

Infusion Pumps might trigger a safety alarm and the infusion will be interrupted

Device/ Product Description:	Infusion Pump											
Brand:	<ul style="list-style-type: none"> - Volumed μVP7000 - Syramed μSP6000 											
AFFECTED PRODUCTS:	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Model Name</th> <th style="width: 33%;">Serial Number</th> <th style="width: 33%;">Production date</th> </tr> </thead> <tbody> <tr> <td>Syramed μSP6000</td> <td>ending with xxxx1605 and higher</td> <td>from 05/2016 till 10/2019</td> </tr> <tr> <td>Volumed μVP7000</td> <td>NA</td> <td>from 07/2019 till 09/2019</td> </tr> </tbody> </table>			Model Name	Serial Number	Production date	Syramed μ SP6000	ending with xxxx1605 and higher	from 05/2016 till 10/2019	Volumed μ VP7000	NA	from 07/2019 till 09/2019
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Manufacturer:	Arcomed AG											
Problem:	<p>Manufacturer clarified that the above mentioned devices would signal a safety alarm due to interference in the main PCB. During the alarm the devices stop the infusion until reset and restarted by the user.</p>											
Recommendation/ Actions:	<ol style="list-style-type: none"> 1. Review this notice and ensure that affected personnel are aware of the contents. 2. Make sure replacement equipment is available and the procedures are in place for an exchange in case a technical defect should happen on a device. 3. If you had devices that displayed safety alarms and in particular could only be switched off with the 15 seconds reset function, make sure these devices are not used until checked and updated by your technical support. 4. If you have affected product at your facility, contact the authorized representative for required correction. <p>For more information, Please click here.</p>											

	<p>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</p>	
<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Alfaisaliah Medical Systems</p>
	<p>Assigned Contact Person:</p>	<p>Alaa Babgi</p>
	<p>Mobile/Phone:</p>	<p>0553237989</p>
	<p>Email:</p>	<p>FMS-SFDA@Alfaisaliah.com</p>