

Medical Devices Sector  
National Center for Medical Devices Reporting

رسالة سلامة  
**Safety Communication**

To: Healthcare providers	إلى: مقدمي الرعاية الصحية
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<b>Title:</b>	Risk of Decreased flow rate, stopped flow or residual fluid left within the IV bag	العنوان:
<b>Medical Device Description</b>	Level 1 Fast Fluid Flow Fluid Warmers	اسم ووصف الجهاز/المستلزم الطبي:
<b>Medical Device Product Codes</b>	Model: H-1000, H-1025, H-1200 Brand: Level 1 ® H-2 Pressure Chambers	الأرقام لـ الجهاز/المستلزم الطبي
<b>Manufacturer:</b>	Smiths Medical	اسم المصنع:
<b>Authorized Representative</b>	almadar medical Est.	الممثل المعتمد

<b>Medical Devices Marketing Authorization (MDMA)</b>	GHTF-2019-4782	إذن التسويق:
<b>Potential /Associated Risks</b>	Pressure Chambers with the wider hinge assembly can potentially impact the amount of pressure exerted onto the IV fluid bag while contained within the pressure chamber. This may result in decreased flow rate, stopped flow or residual fluid left within the IV bag.	المخاطر المحتملة المرتبطة بالجهاز أو المستلزم الطبي
<b>Recommendations</b>	<p>Recommendations for healthcare providers:</p> <ul style="list-style-type: none"> <li>Identify all affected Level 1 H-2 Pressure Chambers in your possession.</li> <li>If the device has the narrower hinge assembly, then it is not affected, and you can continue to use the device per the instructions in the <a href="#">FSN</a>.</li> <li>If the device has the wider hinge assembly, then it is affected, and the hinge should be replaced. Therefore you may need to contact Smiths Medical supplier for the correction</li> </ul>	التوصيات

**For Reporting:**



**NCMDR**



**للإبلاغ:**