


**Safety Communication**

**رسالة سلامة**

**Three key issues could interrupt/ effect the infusion**

<b>Device/ Product Description:</b>	Infusion Pump
<b>Brand:</b>	Alaris System PCU / LVP / SYR / PCA
<b>Affected product:</b>	Check the attachments below
<b>Manufacturer:</b>	Becton Dickinson
<b>Problem:</b>	<p><b><u>Issue 1 – PCU keypad</u></b> The affected BD Alaris PC unit keypad may have one or more keys that become unresponsive or stuck (i.e. constantly pressed state) due to fluid ingress. <a href="#">(Check Here)</a></p> <p><b><u>Issue 2 – LVP keypad</u></b> The affected BD Alaris Pump Module keypads may have one or more keys that become unresponsive or stuck (i.e. constantly pressed state) due to fluid ingress. <a href="#">(Check Here)</a></p> <p><b><u>Issue 3 – Syringe / PCA Sizer sensor</u></b> Excessive force when extending and rotating the syringe barrel clamp either clockwise or counter clockwise can damage the internal mechanism of the syringe barrel clamp. Damage to this mechanism on either the Alaris Syringe Module or Alaris PCA Module may result in the Alaris PC unit displaying incorrect syringe types and/or sizes or display of a “Syringe not Recognized” prompt. <a href="#">(Check Here)</a></p>

<p><b>Recommendation /Actions:</b></p>	<ul style="list-style-type: none"> <li>• Avoid using the Device.</li> <li>• Follow the cleaning instructions provided by the manufacturer.</li> <li>• Contact the Authorized Representative for the required corrective action.</li> </ul> <p>For more information, please check the “NCMDR portal website <a href="#">(1)</a>, <a href="#">(2)</a> and <a href="#">(3)</a>“</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:  <a href="#">NCMDR</a>  <a href="#">Vigilance system</a>  19999 unified call center</p>	
<p><b>Devices/Products photo:</b></p>		
<p><b>Authorized Representative Details</b></p>	<p>AR name:</p>	<p>Becton Dickinson B.V.</p>
	<p>Assigned Contact Person:</p>	<p>Nawaf Alsalmi</p>
	<p>Mobile/Phone:</p>	<p>+(966) 566898822</p>
	<p>Email:</p>	<p>nawaf.m.al.salmie@bd.com</p>