

Safety Communication

رسالة سلامة

Various hardware problems could result in serious injury and death

Device/ Product Description:	Infusion Pump System
Brand:	Alaris™
Affected product:	Alaris™ System PC Unit Model 8000 Alaris™ System PC Unit Model 8015 Alaris™ Pump Module Model 8100 Alaris™ Syringe Module Model 8110 Alaris™ PCA Module Model 8120 Alaris™ EtCO2 Module Model 8300 Alaris™ SpO2 Module Model 8210 and Model 8220
Manufacturer:	Becton Dickinson & Co. (BD)
Problem:	Four hardware situations that require attention and actions. The potential risks associated with these issues have resulted in serious injury and death: <ol style="list-style-type: none"> 1- Damaged Inter-Unit Interface (IUI) Connectors 2- Broken elements on Alaris™ Pump Module platen 3- Improperly secured PC unit Battery 4- Dim Segment
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document, with accompanying FSNs, are reached to the end-users. • Inspect the devices for the above-mentioned issues in accordance with the information given in Appendix 1 in the FSN issued by the manufacturer (Click here) • If you experience any of the above-mentioned issues with the device, the device should be taken out service and contact the authorized representative for replacement parts.

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

Devices/Products photo:



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