


Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Alaris infusion pump
Device Model	8100
Manufacturer	Becton Dickinson
Country of Origin	USA
Serial No.	14419130
Reference	https://www.bd.com/documents/alerts/IF_Alaris-Pump-model-8100-bezel-post-serparation_CL_EN.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to pumps manufactured between April 2011 to June 2017 contain bezel assemblies that were manufactured from plastic FR-110 plastic and the manufacturing process may have resulted in the weakening of this plastic and as a result the bezel posts has the potential to separate or become damaged.
Action should be taken	In case of having the affected device model, please contact the local agent YMH at me.regulatory@ymh.com.bh / drugregulatory@ymh.com.bh to take the necessary action for replacement.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh