

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة Safety Communication

To: Healthcare providers	إلى: مقدمي الرعاية الصحية
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Title:	Important Awareness about insulin pump reporting incidents	العنوان:
Medical Device Description	Insulin Pumps	اسم ووصف الجهاز/المستلزم الطبي:
Manufacturer:	All	اسم المصنع:

Potential /Associated Risks	<p>Based on the SFDA's post-market clinical evaluation study to analyze and evaluate multiple safety signals related to the insulin pumps. The study revealed the below issues associated with the insulin pump reporting incidents:</p> <ol style="list-style-type: none">1. Lack of awareness of insulin pump device incident reporting vs. the rapid development in pump technologies.2. There are many cases in which pumps were not returned for investigation based on many manufacturers' evaluations of insulin pump device-related Adverse Events.	المخاطر المحتملة المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<p>Recommendations for healthcare providers:</p> <ul style="list-style-type: none">• Ensure that healthcare practitioners who follow up with patients have updated training.• During clinic visits, inform the patients that if there is a problem with the insulin pump, keep and return the device to facilitate the investigation.• Improve patient-healthcare provider communication and use technology to extend the relationship between patient and healthcare provider between clinic visits. <p>Recommendations for users:</p> <ul style="list-style-type: none">• Read and carefully follow the insulin pump manufacturer's instructions for use.• Be attentive to pump notifications, alarms, and alerts.• Users are highly advised to report any related incident /Adverse Event to SFDA and manufacturer.	التوصيات

For Reporting:				للإبلاغ:
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