

Safety Communication

رسالة سلامة

untested barrier methods to reduce skin reactions

Device/ Product Description:	Gluucose Monitor Sensor G6
Affected Lot Number:	STS-GS-003 ;
Manufacturer:	Dexcom, Inc.
Problem:	Due to adverse skin reactions under the sensor which may result in symptoms such as itching; burning; and/or rashes at the site of adhesive patch application, some patients tend to use 3rd party barrier creams or patches to reduce skin reactions. These solutions have not been tested or validated and it could affect the way the sensor works.
Recommendation /Actions:	<ul style="list-style-type: none"> Identify patients who have skin reactions, which may include erythema, itching and blistering. Consider if continued use of this device for patients with skin reactions is suitable. Consider use of alternative glucose monitoring systems for these patients. <p>For more information, Please see click here.</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: NCMDR Vigilance system (19999) unified call center</p>

Devices/Products photo:		
Authorized Representative Details	AR name:	Bio Standards LLC
	Assigned Contact Person:	Ahmed Al Shareef
	Mobile/Phone:	+(966) 502923399
	Email:	info@bio-standards.com

