

Date: 27-9-2022

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قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة
Safety Communication

To: Healthcare Providers	إلى: مقدمي الرعاية الصحية
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Title	Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event	العنوان
Medical Device Description	All Cobalt XT, Cobalt and Crome Models - Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	اسم ووصف الجهاز/المستلزم الطبي
Medical Device Products Identifier:	All	الأرقام للجهاز/المستلزم الطبي:
Manufacturer	Medtronic	اسم المصنع:
Authorized Representative	Medtronic Saudi Arabia	الممثل المعتمد:

Medical Devices Marketing Authorization (MDMA)	GHTF-2020-0332 , GHTF-2020-1330	إذن التسويق
Potential /Associated risks	An intermittent, second-phase Short Circuit Protection (SCP) event during high-voltage (HV) therapy delivery that will deliver approximately 79% of programmed energy as a monophasic waveform.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none"> All SmartSync tablets in your facility require an updated with application software D00U005 version 7.1.1 (or higher) refer to Appendix A in the FSN here Patients will require an in-clinic visit for the update to be installed into their device via interrogation with an updated SmartSync tablet. 	التوصيات

For Reporting	  	للإبلاغ
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