

Date: 23 July 2023

Reference Number: SG-2307-407-H



قطاع الأجهزة والمستلزمات الطبية  
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector  
National Center for Medical Devices Reporting

رسالة سلامة  
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
<b>Title</b>	A potential for reduced- or no-energy output during high voltage (HV) therapy when programmed AX>B	العنوان
<b>Medical Device Description</b>	Cobalt™ XT/Cobalt™/Crome™ ICDs and CRT-Ds	اسم ووصف الجهاز/المستلزم الطبي
<b>Medical Device Products Identifier</b>	Cobalt™ XT/Cobalt™/Crome™ ICDs and CRT-Ds A subset of: Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava™ CRT-Ds A subset of: Visia AF™/Visia AF MRI™/Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs With glassed feedthrough (manufactured after July 2017).	الأرقام للجهاز/المستلزم الطبي
<b>Manufacturer</b>	Medtronic	اسم المصنع
<b>Authorized Representative</b>	شركة ميدترونك العربية السعودية	الممثل المعتمد

<b>Medical Devices Marketing Authorization (MDMA)</b>	ME0000000256SFDA00045	ME0000000256SFDA00215	إذن التسويق
	ME0000000256SFDA00046	ME0000000256SFDA00217	
	ME0000000256SFDA00047	ME0000000256SFDA00219	
	ME0000000256SFDA00048	ME0000000256SFDA00236	
	ME0000000256SFDA00049	ME0000000256SFDA00237	
	ME0000000256SFDA00050	ME0000000256SFDA00238	
	ME0000000256SFDA00505	ME0000000256SFDA00239	
	ME0000000256SFDA00507	ME0000000256SFDA00945	
	ME0000000256SFDA00942	ME0000000256SFDA00946	
	ME0000000256SFDA00943	ME0000000256SFDA00947	
	ME0000000256SFDA00944	ME0000000256SFDA00948	
	ME0000000256SFDA00949	ME0000000256SFDA00953	
<b>Potential /Associated risks</b>	Failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي	
<b>Recommendations</b>	Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:  • Prophylactic device replacement is NOT recommended.	التوصيات	

	<ul style="list-style-type: none"> <li>• Program all HV therapy pathways B&gt;AX in all therapy zones to minimize the risk for this issue. Note:             <ol style="list-style-type: none"> <li>1. Using “Get Medtronic Nominals” will require manual reprogramming of Rx5 and Rx6 to B&gt;AX for all ventricular therapies.</li> <li>2. For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX&gt;B.</li> </ol> </li> <li>• Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX&gt;B.</li> <li>• For remaining patients with AX&gt;B programming in any HV therapy sequence, schedule (with appropriate discretion) the next follow-up for in-clinic reprogramming, to minimize potential for reduced- or no-energy HV therapies to occur.</li> <li>• Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered:             <ol style="list-style-type: none"> <li>1. Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.</li> <li>2. Verify delivered energy is consistent with programmed energy in the Episode Summary.</li> </ol> </li> </ul>	
<p><b>For Reporting</b></p>	<div style="display: flex; justify-content: space-around; align-items: center;"> <div data-bbox="462 821 695 905" style="border: 1px solid black; padding: 5px;">  <p>SFDA 19999 مركز الاتصال الموحد</p> </div> <div data-bbox="745 821 967 905" style="border: 1px solid black; padding: 5px;"> <p><b>NCMDR</b></p> </div> <div data-bbox="1016 821 1230 905" style="border: 1px solid black; padding: 5px;">  <p>تيقظ Saudi Vigilance</p> </div> </div>	<p>للإبلاغ:</p>