

Safety Communication

رسالة سلامة

Potential inaccurate longevity estimate

Device/ Product Description:	Pacemakers (IPGs) , and Cardiac Resynchronization Therapy pacemakers (CRT-Ps)
Affected Devices:	<p>IPGs: Azure™ XT DR MRI SureScan™, Azure™ S DR MRI SureScan™, Azure™ XT SR MRI SureScan™, Azure™ S SR MRI SureScan™, Astra™ XT DR MRI SureScan™, Astra™ XT SR MRI SureScan™</p> <p>CRT-Ps: Percepta™ CRT-P MRI SureScan™, Percepta™ Quad CRT-P MRI SureScan™, Serena™ CRT-P MRI SureScan™, Serena™ Quad CRT-P MRI SureScan™, Solara™ CRT-P MRI SureScan™, Solara™ Quad CRT-P MRI SureScan™</p>
Affected Programmers and Remote Monitoring Software Apps:	<p>2090 CareLink™ Programmer 29901 Encore™ Programmer CareLink SmartSync™ Device Manager CareLink™ Network Application Software 2491 MyCareLink Heart™ Mobile Application</p>
Manufacturer:	Medtronic
Problem:	Longevity estimation error associated with unipolar pacing configurations. If the software update is not applied to the programmer, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention.
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document is reached to the end-users. • Contact the authorized representative for the required corrective action.

For more information please click [here](#) and [here](#) .

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

Devices/Products photo:



Authorized Representative Details

AR name:	Medtronic Saudi Arabia
Assigned Contact Person:	Nahar Alsurayi
Mobile/Phone:	0503226812
Email:	nahar.s.alsurayi@medtronic.com