

Safety Communication

رسالة سلامة

Potential to Display an Inaccurate Remaining Longevity Estimate

Device/ Product Description:	Cardiac pulse generator programmer, Pacemaker, Implantable Defibrillator.
Affected Programmers :	2090 CareLink™ Programmer 29901 Encore™ Programmer CareLink Network Application Software 2491 CareLink SmartSync™ Device Manager MyCareLink Heart™ Mobile Application
Affected Devices:	Claria MRI™ /Amplia MRI™ /Compia MRI™ /Viva™ /Brava™ CRT-Ds Visia AF™ / Visia AF MRI™ /Evera™ / Evera MRI™/ Primo MRI™ /Mirro MRI™ ICDs Azure™ /Astra™ IPGs Percepta™ /Serena™ /Solara™ CRT-Ps Micra™ TPS
Manufacturer:	Medtronic
Problem:	<p>Potential for the mentioned programmers to display an inaccurate remaining longevity estimate for a subset of implanted cardiac device models. This issue does not influence device functionality. Furthermore, the Recommended Replacement Time (RRT) remains an accurate indicator for device replacement.</p> <p>The inaccurate longevity estimation is limited to a well-defined subset of devices manufactured between October 2018 and April 2019, and only occurs in the middle (plateau) phase of the device life.</p>

<p>Recommendation/Actions:</p>	<ul style="list-style-type: none"> Prophylactic device replacement is not recommended, as device functionality and the RRT indicator are not impacted by the inaccurate longevity estimate. <p>Until the software update becomes available:</p> <ul style="list-style-type: none"> Continue normal patient follow-up in accordance with standard practice. Per labeling, continue to use the RRT notification to identify when device replacement should be scheduled. Where available, utilize the low battery voltage RRT audible alert or wireless CareAlert™. At any time, if a lower-than-expected remaining longevity estimate occurs, contact Medtronic Technical Services for assistance – additional analysis of stored device information will be required to assess if the decreased longevity estimate is due to this issue. <p>Note: For Azure IPG or Percepta/Serena/Solara CRT-P patients remotely monitored via the MyCareLink Heart mobile app, patients' mobile app longevity estimates will not change until the software update has been released.</p> <p>You can find more information and recommendations from (HERE).</p>	
<p>Devices/Products photo:</p>		
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