

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific Corporation ACCOLADE, ESSENTIO, and PROPONENT DR Pacemaker, and VALITUDE CRT-P

Recall Date	Product Description	Recalling Firm	Recall Reason
01/10/2025	ACCOLADE DR Pacemaker SL (Model Number L301) SL MRI (Model Number L311) EL (Model Number L321) EL MRI (Model Number L331) ESSENTIO DR Pacemaker SL (Model Number L101) SL MRI (Model Number L111) EL (Model Number L121) EL MRI (Model Number L131) PROPONENT DR Pacemaker SL (Model Number L201) (VDD) SL (Model Number L209) SL MRI (Model Number L211) EL (Model Number L221) EL MRI (Model Number L231) VALITUDE CRT-P EL (Model Number U125) EL MRI (Model Number U128)	Boston Scientific Corporation	A subset of devices from the ACCOLADE Family of Pacemakers and CRT-Ps, built before September 2018, have an increased potential to initiate Safety Mode during telemetry or other normal, higher-power operations due to latent high battery impedance.

Recall Class	Product Identification	Distribution	Affected Dates
I	L301 UDI-DI: 00802526559174, 00802526559181 Serial Numbers: 100752 - 765525 L311 UDI-DI: 00802526559228, 00802526559235, 00802526576461, 00802526578076 Serial Numbers: 102370 - 283457 L321 UDI-DI: 00802526559242, 00802526559259 Serial Numbers: 100290 - 345837 L331 UDI-DI: 00802526559273, 00802526576485, 00802526578083, 00802526592201, 00802526559266 Serial Numbers: 701130 - 777988 L101 UDI- DI: 00802526558924 and 00802526558931, 00802526576317, 00802526576812 Serial Numbers: 100683 - 768169 L111 UDI-DI: 00802526558962 and 00802526558979, 00802526576331, 00802526576836 Serial Numbers: 200737 - 345405 L121 UDI-DI: 00802526558986 and 00802526558993, 00802526576348, 00802526593277	59,937 units nationwide	December and prior

	Serial Numbers: 100262 - 723447 L131 UDI-DI: 00802526559006, 00802526559013, 00802526576355 Serial Numbers: 702777 L201 UDI-DI: 00802526559044, 00802526578014, 00802526576379, 00802526576874 Serial Number: 760500 - 701203 L211 UDI-DI: 00802526578038, 00802526559105, 00802526576409, 00802526576904 Serial Numbers: 251896 - 345845 L221 UDI-DI: 00802526576416, 00802526578045, 00802526593307 Serial Numbers: 100263 - 723521 L231 UDI-DI: 00802526578052, 00802526559143, 00802526576423 Serial Numbers: 727921 - 778206 U125 UDI-DI: 00802526559389, 00802526559396, 00802526577109, 00802526578793, 00802526577024 Serial Numbers: 100319 - 707801 U128 UDI-DI: 00802526559402, 00802526559419, 00802526576522, 00802526578120, 00802526577031,		
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	00802526593284 Serial Numbers: 100719 - 727978		
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For additional information, please visit: [FDA Website \(Accolade\)](#), [FDA Website \(Essentio\)](#), [FDA Website \(Proponent\)](#), and [FDA Website \(Valitude\)](#).