

## Important Medical Device Advisory Expansion

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**Performance Update - June 2021:** Hydrogen-Induced Accelerated Battery Depletion in ACCOLADE™, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 pacemakers and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps) originally communicated in September 2018.<sup>1</sup>

In September 2018, Boston Scientific advised physicians about a population of pacemakers and CRT-Ps (collectively pacemakers) exhibiting hydrogen-induced accelerated battery depletion. Since that time, additional confirmed depletion events have been reported and described within Boston Scientific's Product Performance Report (PPR) for both the 2018 advisory and the non-advisory population. Latent release of small amounts of hydrogen within the pacemaker may cause a low voltage capacitor to become electrically compromised over time resulting in accelerated battery depletion of the battery and associated progression of displayed battery depletion indicators. Boston Scientific's ongoing investigation has determined that any pacemaker built with a specific, discontinued low voltage capacitor is potentially susceptible to this behavior. Therefore, Boston Scientific is expanding the advisory population to make customers aware of all potentially susceptible pacemakers to this behavior (Appendix A). The production of pacemakers from these advisory populations ceased in November 2017, and therefore they are no longer available for implantation. Pacemakers built with contemporary low voltage capacitors have not exhibited this behavior and are not included in this expansion.

Ongoing monitoring, aligned with labeled instructions for use, has continued to validate the high degree of detectability and low risk of life-threatening harm due to this behavior. To date, 99.5% of the total 1,776 pacemakers confirmed to have exhibited this behavior were replaced before the battery reached a depleted state. The likelihood of this behavior occurring in the 2021 expanded population is an order of magnitude lower which contributes to a proportionally lower potential for life-threatening harm of a battery reaching a depleted state: 1 in 500,000 at 5 years for the approximate 2,100 active devices in the 2018 population and 1 in 5,000,000 at 5 years for the approximate 125,000 active devices in the expanded 2021 population. As communicated in the 2018 advisory, the most common clinical impact of this behavior is early device replacement. There have been no reported deaths associated with this behavior.

Based on the high degree of early detectability of this behavior, normal battery assessment during labeled 12-month follow-ups has been effective and is recommended for the 2018 and 2021 advisory populations. If you are following Boston Scientific pacemakers every 12-months in person or via remote monitoring, there are no new actions for you to take. Continue to evaluate battery performance at each follow-up and contact Boston Scientific if you observe accelerated battery depletion.

### Recommendations

1. Follow-up interval. Per labeling, perform a system follow-up via remote or in-office interrogation at least every 12 months until One-Year-Remaining and then 3 months thereafter until replacement is indicated. Note: this is a change to the recommendations originally communicated for the 2018 population.

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<sup>1</sup>Boston Scientific's Product Performance Report (PPR) includes advisory information at [www.BostonScientific.com/ppr](http://www.BostonScientific.com/ppr)

## Boston Scientific Performance Update: Hydrogen Induced Accelerated Battery Depletion

### Appendix A: Affected Product Model/Part Numbers

2. During follow-ups. Assess battery for accelerated depletion by comparing the device's 'Approximate Time to Explant' between two follow-up intervals. If the change in longevity significantly exceeds the interval between follow-ups, the device may be exhibiting accelerated depletion. Contact Boston Scientific Technical Services for assistance verifying if there is accelerated depletion or if the observed change in longevity remaining is expected based on changes in device power usage.
3. Replacement. Replace and return to Boston Scientific any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery depletion.
4. Medical records. For each patient with an affected pacemaker, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the pacemaker.

Please distribute this update to all other physicians and healthcare professionals within or outside your organization who need to be aware of this topic. Enclosed is a list of affected pacemakers. Adverse reactions or quality problems experienced with the use of these or any devices should be reported to Boston Scientific and your local and your local regulatory authority, as applicable.

Up-to-date product performance information about this topic, including a device lookup tool<sup>2</sup>, is available within our Product Performance Resource Center at [www.bostonscientific.com/ppr](http://www.bostonscientific.com/ppr). If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

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<sup>2</sup>Available at [www.BostonScientific.com/lookup](http://www.BostonScientific.com/lookup)

# Boston Scientific Performance Update: Hydrogen Induced Accelerated Battery Depletion

## Appendix A: Affected Product Model/Part Numbers

Affected product models/GTIN numbers that compose the subset of hydrogen-induced accelerated battery depletion advisory populations: Sep 2018 advisory population composed of ~2,100 active pacemakers and Jun 2021 advisory population composed of ~125,000 active pacemakers.

Product Name	Model	GTIN	Product Name	Model	GTIN
ESSENTIO Pacemaker	L100	00802526558900	ACCOLADE Pacemaker	L310	00802526559204
		00802526558917			00802526559211
		00802526571923			00802526572364
		00802526576300			00802526576454
		00802526576805			00802526576959
		00802526593109			00802526578069
ESSENTIO Pacemaker	L101	00802526558924	ACCOLADE Pacemaker	L311	00802526559228
		00802526558931			00802526559235
		00802526576317			00802526572395
		00802526576812			00802526576461
ESSENTIO Pacemaker	L110	00802526558948	ACCOLADE Pacemaker	L321	00802526578076
		00802526558955			00802526559242
		00802526571985			00802526559259
		00802526576324			00802526572425
ESSENTIO Pacemaker	L111	00802526576829	ACCOLADE Pacemaker	L331	00802526572432
		00802526558962			00802526576478
		00802526558979			00802526559266
		00802526572012			00802526559273
ESSENTIO Pacemaker	L121	00802526576331	ALTRUA 2 Pacemaker	S701	00802526572456
		00802526576836			00802526576485
		00802526558986			00802526578083
		00802526558993			00802526592201
ESSENTIO Pacemaker	L131	00802526572043	ALTRUA 2 Pacemaker	S702	0080252659327
		00802526576348			00802526559334
		00802526576843			00802526572487
		00802526559006			00802526576492
PROPONENT Pacemaker	L200	00802526559013	ALTRUA 2 Pacemaker	S722	00802526576997
		00802526572081			00802526578090
		00802526576355			00802526559341
		00802526559020			00802526559358
PROPONENT Pacemaker	L201	00802526559037	VALITUDE CRT-P	U125	00802526576508
		00802526572104			00802526559365
		00802526576362			00802526559372
		00802526578007			00802526576515
PROPONENT Pacemaker	L201	00802526559044			00802526577017
		00802526559051			00802526578113
PROPONENT Pacemaker	L209	00802526576379			00802526559389
		00802526576874			00802526559396
PROPONENT Pacemaker	L209	00802526578014			
		00802526559068			
PROPONENT Pacemaker	L209	00802526559068			
		00802526576386			

**United States Technical Services**

1.800.CARDIAC (227.3422) tech.services@bsci.com

**FDA MedWatch**

1.800.FDA.1088 (332.1088) www.fda.gov/MedWatch/report.htm

**Boston Scientific Performance Update: Hydrogen Induced Accelerated Battery Depletion**

**Appendix A: Affected Product Model/Part Numbers**

<b>Product Name</b>	<b>Model</b>	<b>GTIN</b>	<b>Product Name</b>	<b>Model</b>	<b>GTIN</b>
PROPONENT Pacemaker	L210	00802526559082	VALITUDE CRT-P	U125	00802526573101
		00802526572180			00802526577109
		00802526576393			00802526578793
		00802526576898	VALITUDE CRT-P	U128	00802526559402
		00802526578021			00802526559419
PROPONENT Pacemaker	L211	00802526559105	VALITUDE CRT-P	U128	00802526572609
		00802526572210			00802526572616
		00802526576409			00802526576522
		00802526576904			00802526577031
		00802526578038			00802526578120
PROPONENT Pacemaker	L221	00802526559129	VISIONIST CRT-P	U225	00802526559433
		00802526576416			00802526572630
		00802526576911			00802526577048
		00802526578045			00802526577116
		00802526593307			00802526578809
PROPONENT Pacemaker	L231	00802526559136	VISIONIST CRT-P	U226	00802526559457
		00802526559143			00802526559464
		00802526572272			00802526577062
		00802526576423	VISIONIST CRT-P	U228	00802526577123
		00802526576928			00802526559471
		00802526578052			00802526559488
ACCOLADE Pacemaker	L300	00802526559150	VISIONIST CRT-P	U228	00802526572692
		00802526559167			00802526577055
		00802526572302			00802526577130
ACCOLADE Pacemaker	L301	00802526559174			00802526578830
		00802526559181			
		00802526572333			
		00802526572340			
		00802526576447			
		00802526576942			