Boston Scientific
Advancing science for life™

2022

Rhythm Management Product Performance Report

Q1 Edition

RESONATE™
Family of ICDs AND CRT-Ds

ACCOLADE™
Family of Pacemakers

INGEVITY™ +
Pacing Lead

CRM Quality Pledge

I improve the quality of patient care and all things Boston Scientific

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q1 2022 report includes data through January 5th, 2022.

Boston Scientific provides performance data for pulse generators and leads that meets or exceeds the 2014 revision of ISO 5841-2: 2014 (E), the AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance, and addresses recommendations from the Heart Rhythm Society Task Force.

This report provides the most comprehensive presentation of rhythm management product performance data available, including:

- ✓ U.S. lead and pulse generator survival probability
- ✓ Worldwide malfunction counts and patterns
- ✓ Worldwide malfunctions during an implant procedure
- ✓ Acute (first month) lead observations
- ✓ Chronic (after first month) lead complications
- ✓ Reasons for out of service
- ✓ Return rates

Your feedback is always welcome, and plays a vital role in our effort to continuously improve our products and services, advancing science to transform the lives of our patients.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

Boston Scientific Reviewers

Alexandra Naughton
Vice President, Quality Assurance

John Kerrigan
Director, Quality Assurance

Olaf Hedrich, M.D.
Vice President of Medical Safety

Monica Degnan, M.S.
Senior Statistician

John Risse
Manager, Product Performance Reporting

Independent Reviewer

Professor Douglas Hawkins, Ph.D.

Editor

Steven Brillhart
Senior Data Analyst

Statistical Methodology

What Is Device Survival Probability?
Medical journals have traditionally used patient survival probability to display information on treatment option effectiveness. In the report, **pulse generator and lead** survival probabilities convey information about long-term performance of implantable cardiac rhythm management products.

Device survival probability shows the percentage of implanted devices that remain implanted and in service at various points in a product's service life, in the absence of competing risks, such as natural mortality or voluntary explants. Conceptually, a pulse generator of high reliability and large battery capacity or low current drain remains near 100% survival until eventually, normal battery depletion begins to cause significant numbers of devices to be removed, and the device survival probability drops rapidly. For example, a device survival probability of 99% indicates that within the stated implant duration, the pulse generator had a 1% risk of removal for battery depletion or for incurring a malfunction that required replacement. Survival probabilities are provided with and without normal battery depletions, depicted as “Battery Depletions and Malfunctions” and “Malfunctions Only,” respectively.

Boston Scientific estimates survival probability in compliance with the 2014 revision of international standard ISO 5841-2: 2014 (E). Survival probability is calculated at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in the report section entitled U.S. Reason for Out of Service.

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets
Pulse generator survival probability is reported for U.S. implanted devices in product families that meet inclusion criteria described below. Lead survival probability is reported for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry, for product families that meet inclusion criteria described below.

To be included in survival probability statistics, a device must first be successfully implanted (defined in this report as occurring upon pocket closure). Prophylactic device removals are tracked as part of the active population up until the time the device is removed from service; devices removed prophylactically and are not identified as malfunctions at the time of explant do not contribute to a reduction in survival probability. Reasons for device explant or out of service, if known, are provided in this report for each pulse generator product/product grouping.

Survival probabilities are based on devices registered as implanted in the U.S. Privacy laws in many other geographies preclude manufacturers from obtaining specific patient implant and explant information, thus device survival probabilities cannot be constructed from these data. Boston Scientific considers U.S. experience representative of worldwide performance. The Malfunction Details for leads and pulse generators reflect worldwide malfunctions, inclusive of U.S. data.

Criteria for inclusion of product families in this report are in compliance with the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*. Survival estimates are provided for product families once they have at least 10,000 cumulative U.S. implant

months. The minimum interval sample size is 200 U.S. implanted units. Pulse generator product families with fewer than 500 total remaining estimated active U.S. devices are not included in this report. Lead product families that received original U.S. market release approval twenty or more years ago are not included in this report.

Estimated Longevity information is provided for pulse generator products in the U.S. Survival Probability - Battery Depletions and Malfunctions graphs, depicted as a blue bar on the x axis for Years Implanted. The estimated longevity values from the Instructions for Use for each product family are used to construct the blue longevity bars on their U.S. Survival Probability graph. They represent the range of estimated longevity based on a variety of programmed settings and therapy usage.

Survival probability data are presented in tabular and graphical formats online at www.bostonscientific.com/ppr. Performance data for Intermedics products may also be found on www.bostonscientific.com/ppr. Specific inclusion criteria for pulse generator and lead survival probability datasets are described here. Not all products may be approved for use in all geographies, as product approval is geography specific.

Worldwide distribution, U.S. registered implant, and U.S. estimated active implant numbers have been rounded to provide population size context.

To convey implant experience for a product family, U.S. approval dates are provided. The U.S. approval date listed is the earliest date Boston Scientific received approval for one or more of the models in the family.

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)
Reduction in survival probability for **pulse generators** is due to:

- Devices removed for normal battery depletion
- Device malfunctions occurring while implanted, as confirmed by returned product analysis

Survival Probability – Malfunctions Only (Pulse Generators)
Reduction in survival probability for **pulse generators** is due only to:

- Device malfunctions occurring while implanted, as confirmed by returned product analysis; premature battery depletions are considered device malfunctions.

In this case, normal battery depletions do not contribute to the reduction in survival probability; rather, reduction in survival probability is due only to confirmed pulse generator malfunctions. Furthermore, unconfirmed reports of premature battery depletions do not reduce “Malfunctions Only” survival probability. Put another way, this information depicts the percentage of confirmed malfunction-free devices remaining in service at various intervals in the product's service life, based on returned product analysis.

Survival Probability — Complications and Malfunctions (Leads)
The 2014 version of ISO 5841-2: 2014(E) outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology for survival probability to all lead families implanted as of May 2009 and forward. Worldwide malfunctions are not included for previous lead families.

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads removed from service with reported complications 30 days or more post-implant, whether returned or not. See the Chronic Lead Complications Table in this report for the observations which are included.

Further Adjustments for Device and Lead Survival
Because underreporting of patient deaths unrelated to device function would result in overestimation of pulse generator or lead survival by overstating the number of devices in service, Boston Scientific addresses this underreporting in two ways. First, regular updates are obtained from the Social Security Administration about deceased persons and compared to Boston Scientific patient data to identify patients who have died but whose deaths had not been reported to Boston Scientific. Second, Boston Scientific uses 10% annual patient mortality as a baseline and adjusts reported patient deaths in any interval for which reports are less than the baseline rate. No adjustment is applied to account for underreporting of malfunctions, as the rate of underreporting is unknown.

Boston Scientific does not make statistical adjustments to account for underreporting of battery depletion. However, as mentioned earlier, Boston Scientific includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions.

Categorization of Malfunctions for Survival Probability Reporting
Malfunctions represent pulse generators and leads removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (such as ionizing therapeutic radiation), are not reported as device malfunctions in survival data. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction. Malfunctions are further classified according to their impact on therapy, as follows:

- **Malfunction With Compromised Therapy —**
  The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

  Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

- **Malfunction Without Compromised Therapy —**
  The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

  Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Categorization of Normal Battery Depletion for Survival Probability Reporting
Per the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*, **Normal Battery Depletion** is defined as the condition when:

a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings and therapeutic use.

Boston Scientific includes within this count both returned *and non-returned* devices removed from service for battery depletion with no associated complaint. In conformance with the AdvaMed guidance document, Boston Scientific performs battery usage analysis, including battery status verification, on all devices returned without a complaint. We continue to include non-returned devices reported by our customers as being removed from service due to normal battery depletion within this count.

Boston Scientific CRM's Corrective and Preventive Actions (CPA) System

Boston Scientific strives to provide implantable devices of high quality and reliability. However, these devices are not perfect and may exhibit malfunctions at a low rate of occurrence. Device performance information is received from many sources through various channels. Boston Scientific monitors information from many sources including suppliers, testing, manufacturing and field performance to identify opportunities for improvement.

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes, manufacturing and supplier process modifications, software updates, educational communications, or labeling changes to preceding, existing, or subsequent generations. Improvement implementation may vary by geography due to various factors including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern and may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

Improvements are closely monitored for effectiveness. Boston Scientific informs regulatory bodies of each significant event that poses potential risk to patient health to meet regulatory obligations, and shares returned product investigation findings with physicians. The malfunction details section for pulse generators and leads includes a summary of these findings.

In summary, thorough investigation of internal and external data coupled with low trigger levels for improvements creates a continuous product improvement system that is very responsive to patient and physician needs. Boston Scientific is committed to sharing an accurate picture of product performance and addressing identified opportunities for improvement in a timely fashion for our customers.

Malfunction Details: Overview

Boston Scientific CRM pursues product quality and reliability with a passion. We therefore continuously monitor product performance to make improvements whenever possible. Worldwide Malfunction tables provide a count and description of malfunctions associated with the majority of actively in-service Boston Scientific products. Intermedics co-branded product data are included in corresponding pacemaker and pacing lead malfunction counts and details. Information presented is based on malfunctions reported to and analyzed by Boston Scientific. Each table contains malfunction counts listed by category, pattern and therapy availability.

Category
Malfunctions are categorized by the nature of their root cause. For example, a malfunction due to the software within a pulse generator is listed in the Software category. There are four pulse generator malfunction categories and four malfunction categories for leads (described below).

Patterns
Patients and physicians have asked for more access to Quality System details; therefore, we provide information on patterns of product performance. Patterns listed are informational and do not represent actions that need to be taken. Boston Scientific is committed to direct communication when predicted product performance fails to achieve design or performance expectations or when actions may be taken to improve patient outcomes. Malfunctions associated with product advisories are denoted. Refer to the Product Advisories section for more information.

Each pattern description includes:

- ***Clinical Manifestation and Root Cause*** – Malfunctions for each product are characterized according to root cause. Descriptions provide clinical observations and/or analysis findings associated with each malfunction pattern listed in this report. Malfunctions listed within “Other” either do not yet have an identified root cause, or are related to a proprietary product feature, such as connectors or seal rings.

- ***Improvement Implementation*** – All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, improvements have been or will be implemented in response to identified malfunction patterns. Improvements may include product design changes, manufacturing process modifications, software updates, educational communications, or labeling changes to preceding, existing, or subsequent generations. Improvement implementation may vary by geography due to various factors, including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not completely mitigate or eliminate the potential for additional malfunctions.

Pattern information in this report is dynamic. Pattern names, superscript number assignments and descriptions may all change from quarter to quarter; as Boston Scientific's investigations progress and improvements are implemented, updated information is provided.

Therapy Availability
Malfunctions are further classified according to their impact on therapy, as follows:

- ***Malfunction With Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

- ***Malfunction Without Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here. Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Pulse Generator Malfunctions
Pulse generator malfunctions represent devices removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (e.g. therapeutic radiation), are not considered device malfunctions. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction.

Lead Confirmed Malfunctions
Lead confirmed malfunctions represent leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Boston Scientific Product Performance Report is in compliance with the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. This version categorizes leads with reported complications which are taken out of service and returned, but for which no malfunction can be confirmed, as Chronic Lead Complications. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

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Supporting Greater Return of Explanted Devices

The Heart Rhythm Society (HRS) Task Force on Device Performance Policies and Guidelines stated that knowledge, confidence, and trust in cardiac rhythm management devices can be strengthened through enhancing systems that increase the return of devices to the manufacturer. Boston Scientific CRM shares in this belief and supports the HRS-specified actions geared toward achieving the goal of greater device return to the manufacturer, including post-mortem device interrogation, explantation and return to the manufacturer.[1] Approximately 60% of ICD, CRT-D, and PM pulse generators are returned for analysis.

Help Us Provide You With More Complete Product Performance Data

Reporting Adverse Events

The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department at:
United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.
International: Please refer to the Country Offices List for local contact information.
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

Boston Scientific provides a Returned Products Kit (Model 6499) that includes proper forms, shipping/packaging (biohazard bags), and a prepaid shipping label. It can be ordered at no charge through Boston Scientific's Customer Service department at 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698, or you can order a Returned Products Kit online at www.bostonscientific.com/ppr.

[1] Carlson et al. Recommendations from the Heart Rhythm Society Task Force. Heart Rhythm. October 2006; 3(special issue):1251 — 1252.

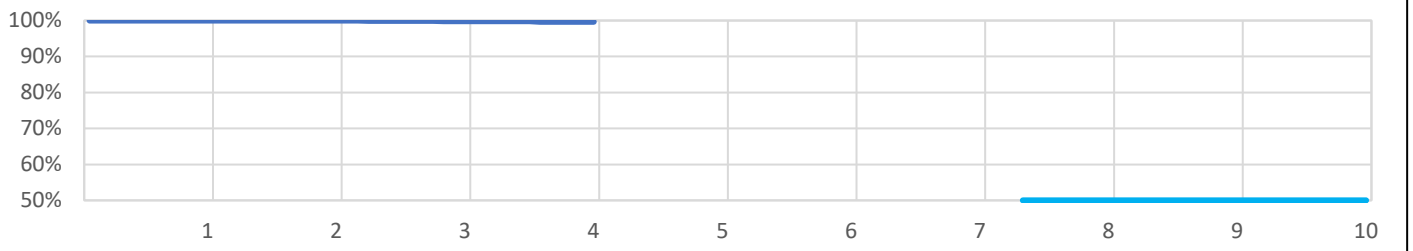
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/ G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

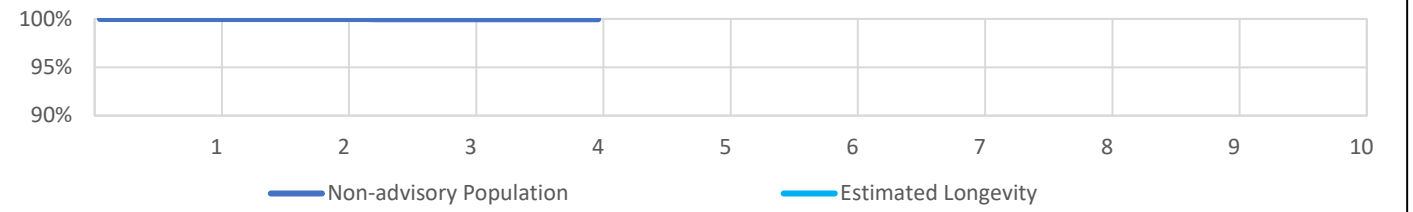
US Summary

US Registered Implants:	49,000	US Normal Battery Depletions:	18
US Approval Date:	September 2017	US Malfunctions:	8
US Estimated Active Implants:	45,000	Without Compromised Therapy:	6
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.6%	99.6%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--
49,000	Effective Sample Size	30191	16429	5837	414	238	--	--	--	--	--

@ 49 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/ G348/G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

Worldwide Confirmed Malfunctions	**17**
Worldwide Distribution	**91,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (63)	0	3	3
Low-voltage capacitor (69)	0	2	2
Battery (53)	1	2	3
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	5	5
Other			
Non-patterned, other	1	2	3
Grand Total	**3**	**14**	**17**

References cited in table above (link)

AUTOGEN CRT-D

Models: G160/G161/G164/G166/G168/G172/G173/G175/G177/G179

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	7	7
Integrated circuit (63)	2	4	6
Low-voltage capacitor (69)	0	1	1
Battery (53)	1	0	1
Software			
Safety Core-unintended biventricular pacing (64)	0	1	1
Other			
Non-patterned, other	1	3	4
Grand Total	**4**	**16**	**20**

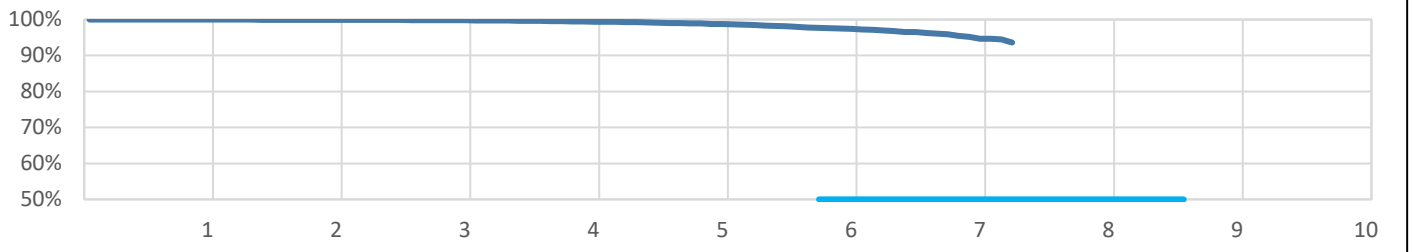
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN CRT-D

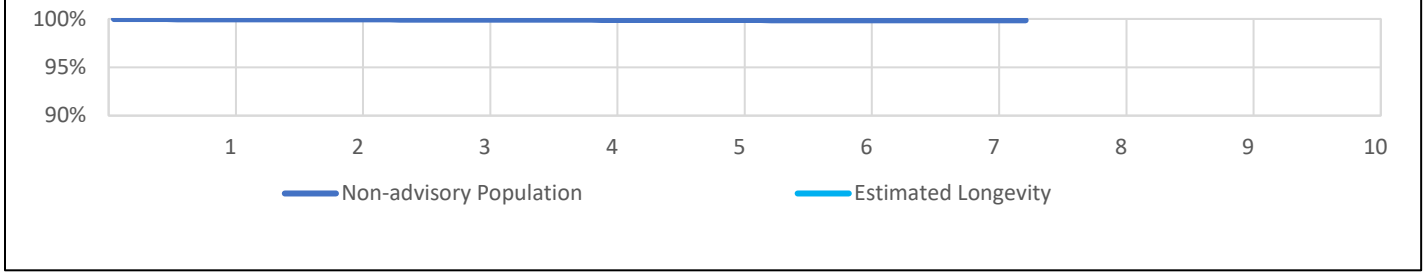
Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

US Summary			
US Registered Implants:	72,000	US Normal Battery Depletions:	525
US Approval Date:	April 2014	US Malfunctions:	57
US Estimated Active Implants:	58,000	Without Compromised Therapy:	48
		With Compromised Therapy:	9

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.8%	97.5%	95.2%	93.6%	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--
72,000	Effective Sample Size	61137	51190	40686	28925	16574	6983	1103	226	--	--

@ 88 months

DYNAGEN/INOGEN/ORIGEN CRT-D

Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

Worldwide Confirmed Malfunctions	**84**
Worldwide Distribution	**118,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	17	17
Integrated circuit (63)	3	11	14
Low-voltage capacitor (69)	0	10	10
High voltage capacitor (75)	1	1	2
Battery (53)	0	5	5
Software			
Memory errors (51)	2	20	22
Safety Core-unintended biventricular pacing (64)	0	2	2
Other			
Non-patterned, other	7	5	12
Grand Total	**13**	**71**	**84**

References cited in table above (link)

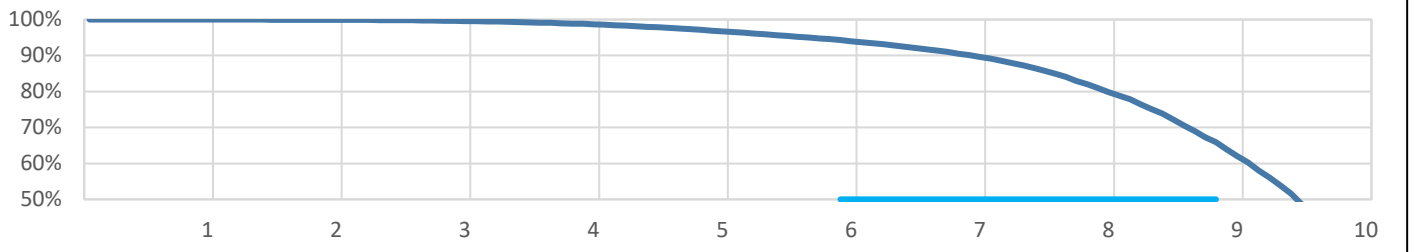
INCEPTA/ENERGEN/PUNCTUA CRT-D

Models: N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/P052/P053/P142/P143/P162/P163/P165

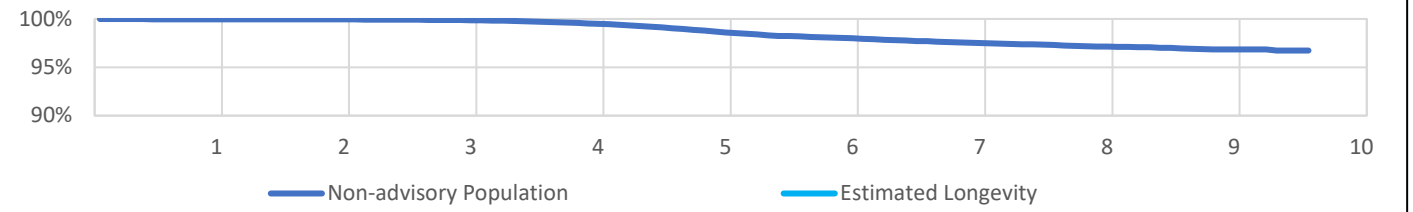
US Summary

US Registered Implants:	53,000	US Normal Battery Depletions:	4,831
US Approval Date:	November 2011	US Malfunctions:	788
US Estimated Active Implants:	27,000	Without Compromised Therapy:	769
		With Compromised Therapy:	19

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.6%	98.8%	96.9%	94.3%	90.1%	80.9%	63.9%	43.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.7%	98.1%	97.5%	97.2%	96.8%	96.7%
53,000	Effective Sample Size	46309	41464	37008	32851	28797	24466	18707	9651	2480	206

@ 116 months

INCEPTA/ENERGEN/PUNCTUA CRT-D

Models: N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/ P052/P053/P142/P143/P162/P163/P165

Worldwide Confirmed Malfunctions	**1,268**
Worldwide Distribution	**81,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Safety Core-electrocautery (42)	1	5	6
High-voltage capacitor (43)	5	0	5
Low-voltage capacitors (47)	0	1	1
Integrated circuit (50)	7	2	9
Battery (53)	1	10	11
Low-voltage capacitor (54)	5	1191	1196
Low-voltage capacitor (69)	0	6	6
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	5	15	20
Grand Total	**30**	**1238**	**1268**

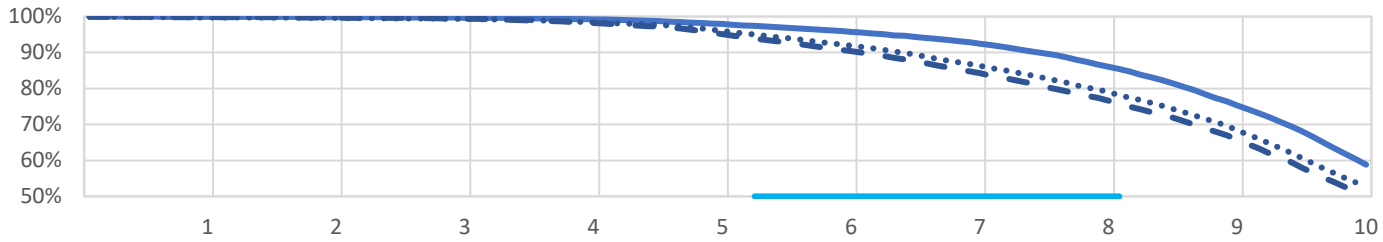
References cited in table above (link)

COGNIS CRT-D

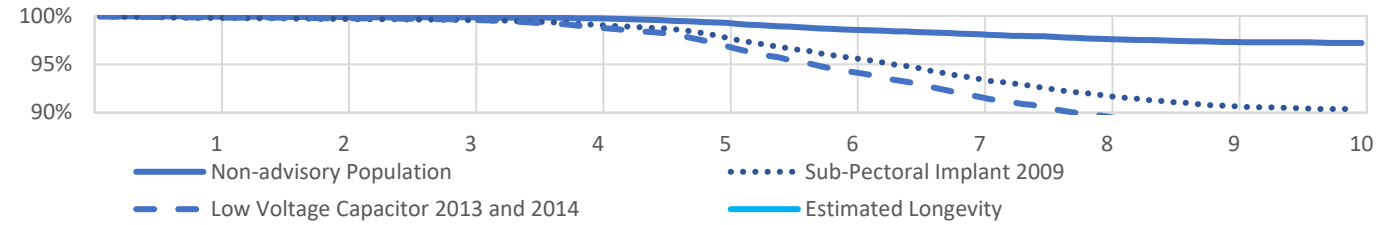
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	14,136
US Approval Date:	March 2008	US Malfunctions:	2,089
US Estimated Active Implants:	17,000	Without Compromised Therapy:	1,896
		With Compromised Therapy:	193

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.0%	96.0%	92.9%	86.6%	76.4%	60.4%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.2%	97.6%	97.3%	97.2%
36,000	Effective Sample Size	31268	28042	25105	22388	19840	17356	14977	12486	9669	5949

COGNIS CRT-D

Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009 Registered Implants: 32,000	Depletions and Malfunctions	99.8%	99.6%	99.4%	98.5%	96.3%	92.2%	86.9%	79.7%	69.6%	53.9%
	Malfunctions Only	99.8%	99.7%	99.6%	99.1%	98.0%	95.8%	93.7%	91.9%	90.7%	90.4%
	Effective Sample Size	27326	24215	21616	19189	16760	14285	11966	9741	7548	5156
Low Voltage Capacitor 2013 and 2014 Registered Implants: 26,000	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.4%	95.6%	90.7%	84.8%	77.4%	67.0%	51.6%
	Malfunctions Only	99.8%	99.8%	99.6%	98.9%	97.2%	94.4%	91.8%	89.8%	88.4%	88.1%
	Effective Sample Size	22464	19941	17828	15779	13729	11594	9619	7778	5976	4031

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

COGNIS CRT-D

Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

Worldwide Confirmed Malfunctions	**2,947**
Worldwide Distribution	**109,000**

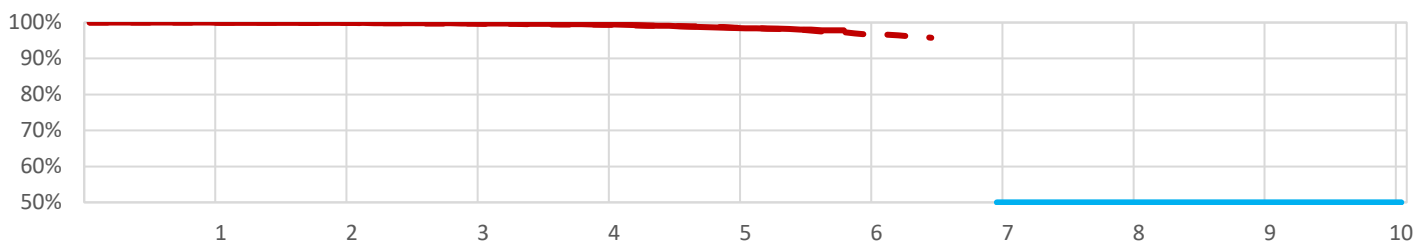
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	83	1617	1700
Safety Core-electrocautery (42)	25	54	79
High-voltage capacitor (43)	6	1	7
Low-voltage capacitors (47)	0	7	7
Integrated circuit (50)	21	8	29
High voltage circuit (52)	1	0	1
Battery (53)	10	51	61
Low-voltage capacitor (54)	12	837	849
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	9	0	9
Difficulty securing lead (41)	8	8	16
Header contacts (45)	8	10	18
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	48	20	68
Header (74)	25	9	34
Software			
Safety Core-programming (46)	0	1	1
Alert messages not displayed post-EOL (48)	0	2	2
Memory errors (51)	2	15	17
Other			
Non-patterned, other	11	36	47
Grand Total	**269**	**2678**	**2947**

VISIONIST/VALITUDE

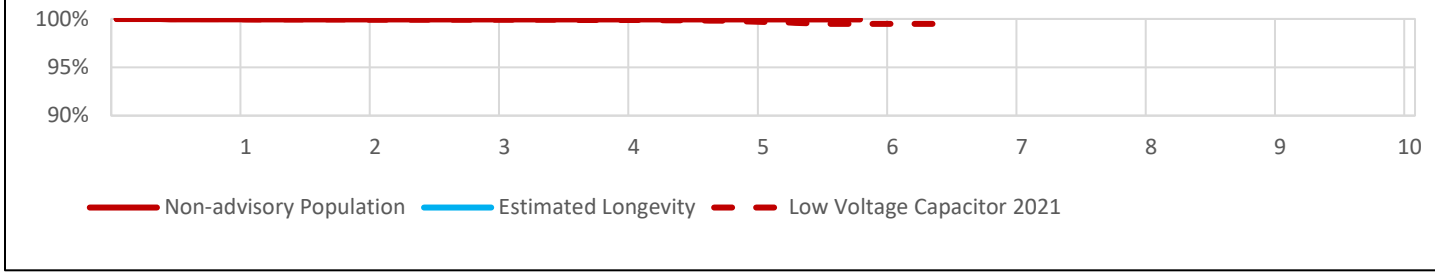
Models: U125/U128/U225/U226/U228

US Summary			
US Registered Implants:	41,000	US Normal Battery Depletions:	174
US Approval Date:	October 2014	US Malfunctions:	44
US Estimated Active Implants:	34,000	Without Compromised Therapy:	42
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.5%	98.5%	97.8%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--	--	--
34,000	Effective Sample Size	24171	16760	10337	5519	1593	229	--	--	--	--

@ 70 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.4%	98.6%	96.7%	95.8%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.7%	99.5%	99.5%	--	--	--
6,000	Effective Sample Size	5917	5285	4686	3857	2892	932	215	--	--	--

@ 78 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

Worldwide Confirmed Malfunctions	**65**
Worldwide Distribution	**83,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	1	6	7
Telemetry (68)	0	1	1
Hydrogen induced premature depletion - September 2018 (70)	0	16	16
Capacitor (67)	0	1	1
Hydrogen induced premature depletion - June 2021 (83)	1	18	19
Software			
Memory errors (51)	0	7	7
Other			
Non-patterned, other	1	11	12
Grand Total	**3**	**62**	**65**

References cited in table above (link)

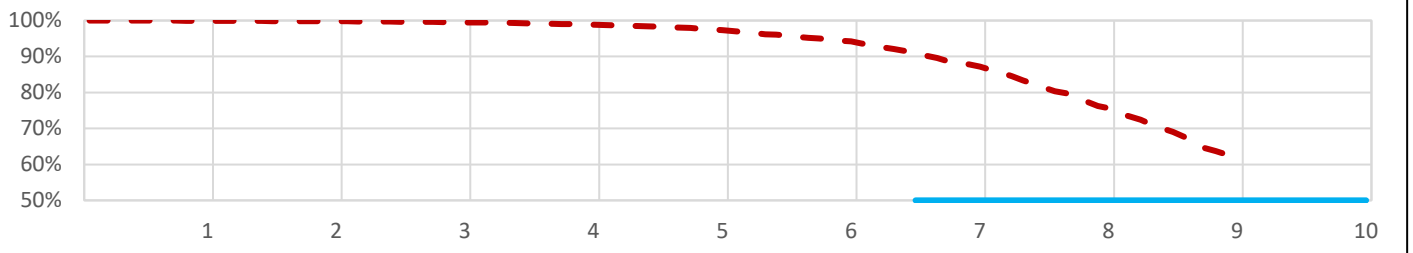
INTUA/INVIVE/INLIVEN

Models: V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/W173/V274/V275/V284/V285/W275

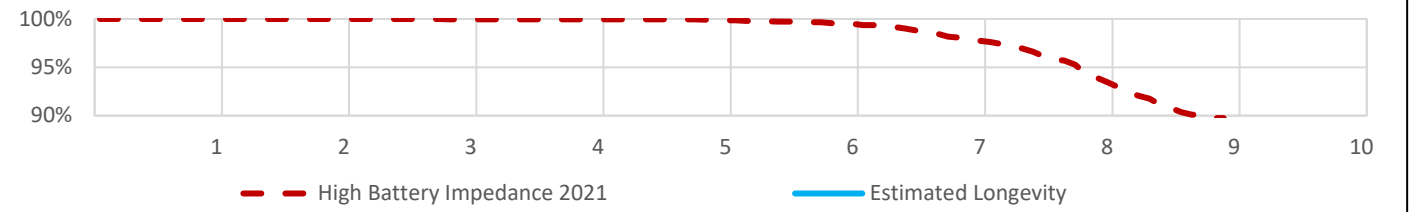
US Summary

US Registered Implants:	10,000	US Normal Battery Depletions:	774
US Approval Date:	May 2013	US Malfunctions:	183
US Estimated Active Implants:	5,000	Without Compromised Therapy:	179
		With Compromised Therapy:	4

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	99.9%	99.8%	99.5%	99.0%	97.5%	94.4%	87.8%	76.2%	62.7%	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.5%	98.0%	93.9%	89.7%	--
10,000	Effective Sample Size	8979	8005	7119	6305	5536	4562	2838	1139	202	--

@ 108 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

INTUA/INVIVE/INLIVEN

Models: V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/W173/V274/V275/V284/V285/W275

Worldwide Confirmed Malfunctions	**263**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High battery impedance initiating safety mode 2021 (82)	2	220	222
Low-voltage capacitors (47)	1	0	1
Other			
Non-patterned, other	4	36	40
Grand Total	**7**	**256**	**263**

References cited in table above (link)

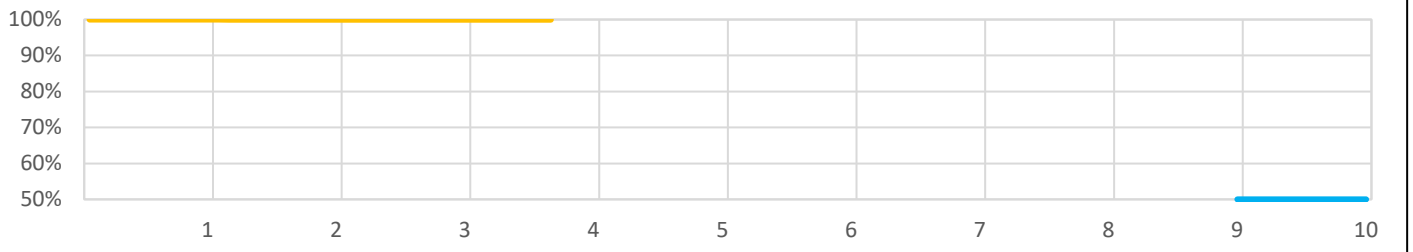
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

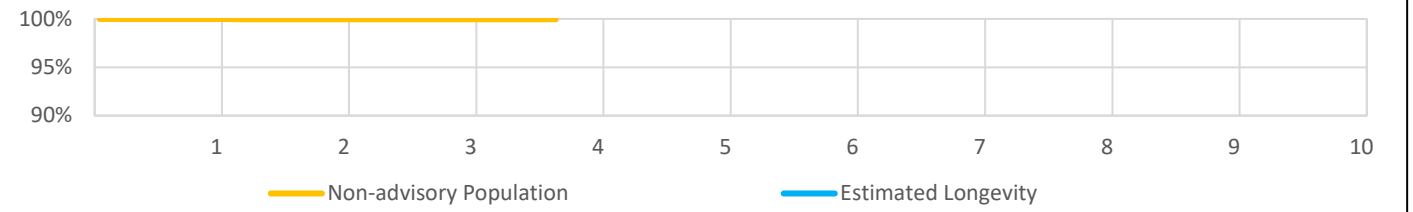
US Summary

US Registered Implants:	28,000	US Normal Battery Depletions:	5
US Approval Date:	July 2017	US Malfunctions:	6
US Estimated Active Implants:	26,000	Without Compromised Therapy:	5
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--	--
28,000	Effective Sample Size	15422	7323	2130	290	--	--	--	--	--	--

@ 45 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**50,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	1	0	1
Integrated circuit (63)	1	0	1
Low-voltage capacitor (69)	0	1	1
Other			
Non-patterned, other	0	2	2
Grand Total	**2**	**3**	**5**

References cited in table above (link)

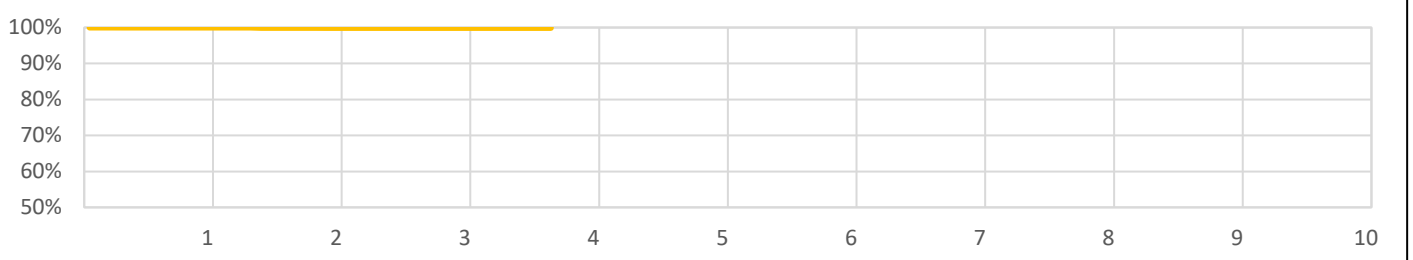
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

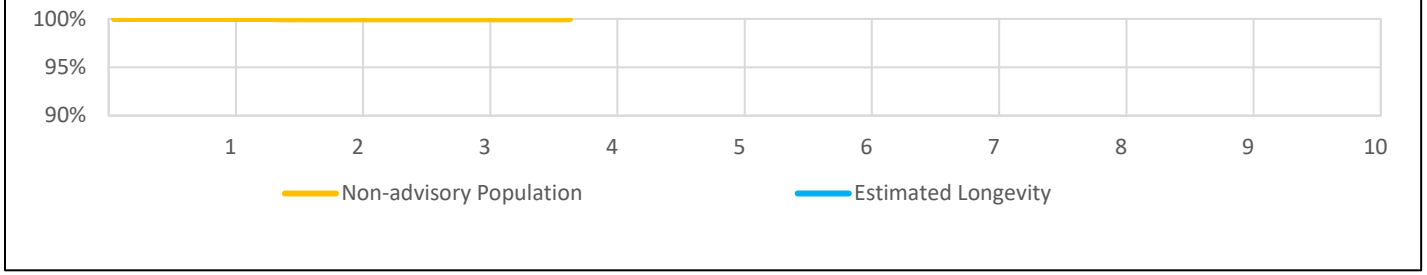
US Summary

US Registered Implants:	16,000	US Normal Battery Depletions:	6
US Approval Date:	July 2017	US Malfunctions:	3
US Estimated Active Implants:	15,000	Without Compromised Therapy:	2
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--	--
16,000	Effective Sample Size	9552	5057	1548	219	--	--	--	--	--	--

@ 45 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**38,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	1	0	1
Integrated circuit (63)	1	0	1
Low-voltage capacitor (69)	0	1	1
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	0	4	4
Grand Total	**2**	**7**	**9**

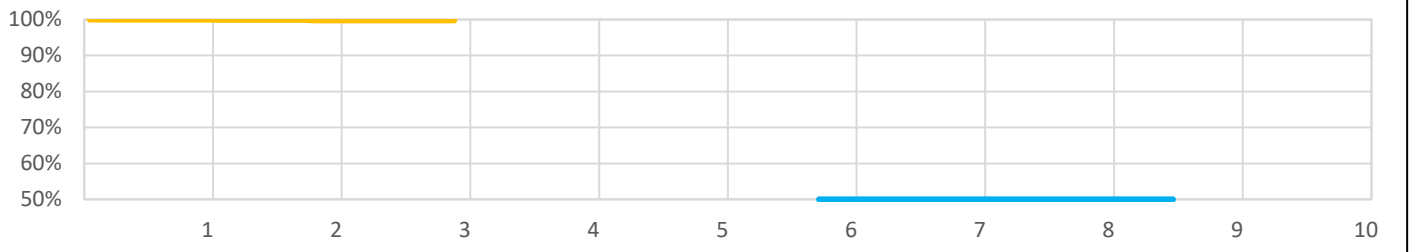
References cited in table above (link)

PERCIVA DR

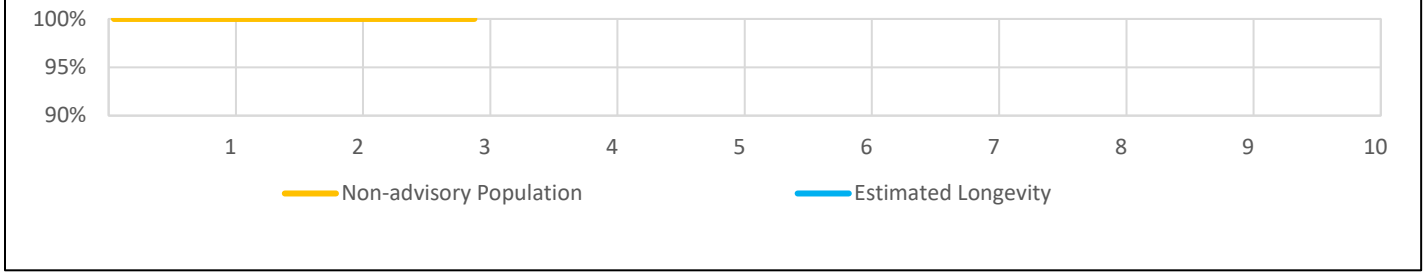
Models: D401/D413/D501/D513

US Summary			
US Registered Implants:	3,000	US Normal Battery Depletions:	3
US Approval Date:	July 2017	US Malfunctions:	-
US Estimated Active Implants:	3,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.8%	99.8%	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	--	--	--	--	--	--	--
3,000	Effective Sample Size	1649	802	219	--	--	--	--	--	--	--

@ 36 months

PERCIVA DR

Models: D401/D413/D501/D513

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**5,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

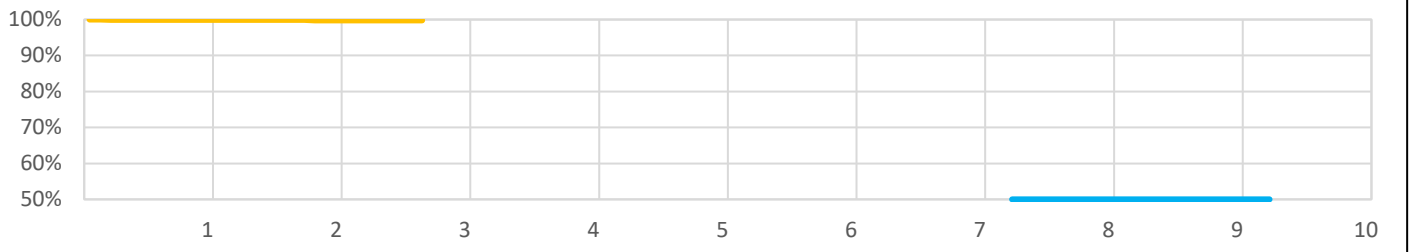
References cited in table above (link)

PERCIVA VR

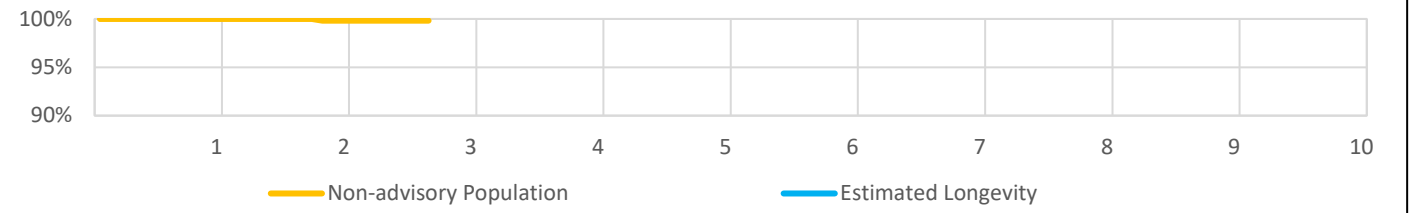
Models: D400/D412/D500/D512

US Summary			
US Registered Implants:	2,000	US Normal Battery Depletions:	1
US Approval Date:	July 2017	US Malfunctions:	1
US Estimated Active Implants:	2,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.8%	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.8%	99.8%	--	--	--	--	--	--	--
2,000	Effective Sample Size	1103	511	215	--	--	--	--	--	--	--

@ 33 months

PERCIVA VR

Models: D400/D412/D500/D512

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**4,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	1	1
Grand Total	**0**	**1**	**1**

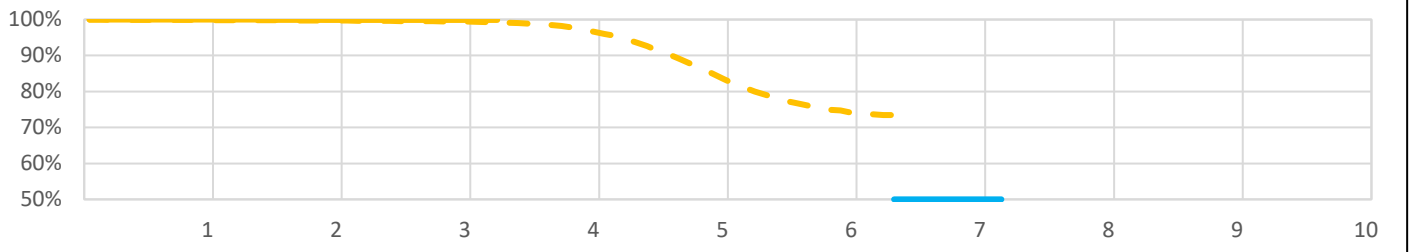
References cited in table above (link)

EMBLEM S-ICD

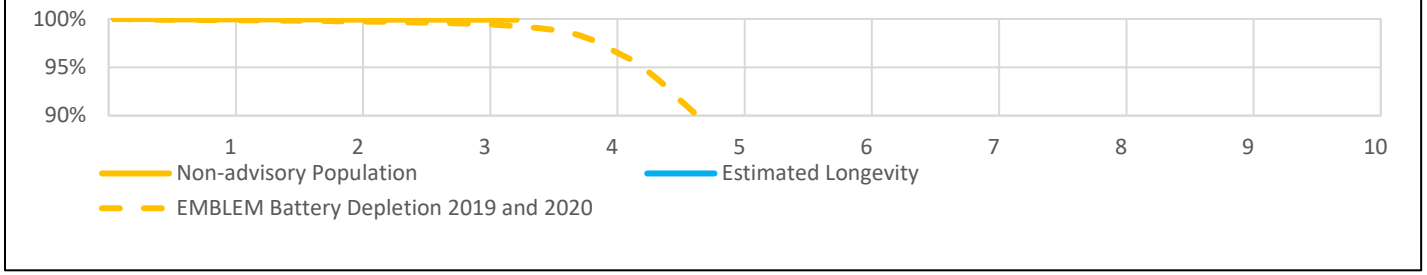
Models: A209/A219

US Summary			
US Registered Implants:	44,000	US Normal Battery Depletions:	242
US Approval Date:	March 2015	US Malfunctions:	1,314
US Estimated Active Implants:	36,000	Without Compromised Therapy:	1,282
		With Compromised Therapy:	32

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--	--
14,000	Effective Sample Size	13155	6587	1352	244	--	--	--	--	--	--

@ 40 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

EMBLEM S-ICD

Models: A209/A219

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Battery Depletion 2019 and 2020	Depletions and Malfunctions	99.9%	99.7%	99.5%	97.2%	85.1%	74.7%	73.4%	--	--	--
Registered Implants: 22,000	Malfunctions Only	99.9%	99.8%	99.5%	97.4%	86.7%	79.4%	78.8%	--	--	--
	Effective Sample Size	18606	16498	14297	9518	4386	1242	209	--	--	--

@ 77 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

EMBLEM S-ICD

Models: A209/A219

Worldwide Confirmed Malfunctions	**2,984**
Worldwide Distribution	**97,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	1	0	1
S-ICD battery depletion 2019 and 2020 (77)	19	2835	2854
Battery depletion (84)	1	1	2
Software			
Memory corruption (65)	1	0	1
Misaligned markers (73)	1	2	3
Memory corruption (85)	6	5	11
Mechanical			
Solder joint (78)	9	0	9
EMBLEM S-ICD electrical overstress 2020 (80)	8	0	8
RF antenna (81)	1	0	1
Other			
Non-patterned, other	23	35	58
Telemetry (56)	14	22	36
Grand Total	**84**	**2900**	**2984**

References cited in table above (link)

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions	**22**
Worldwide Distribution	**16,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	2	0	2
Low-voltage capacitor (69)	0	4	4
Battery (53)	0	5	5
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	1	3	4
Grand Total	**4**	**18**	**22**

References cited in table above (link)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions	**16**
Worldwide Distribution	**17,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	1	0	1
Low-voltage capacitor (69)	0	1	1
Battery (53)	2	7	9
Software			
Memory errors (51)	2	2	4
Other			
Non-patterned, other	0	1	1
Grand Total	**5**	**11**	**16**

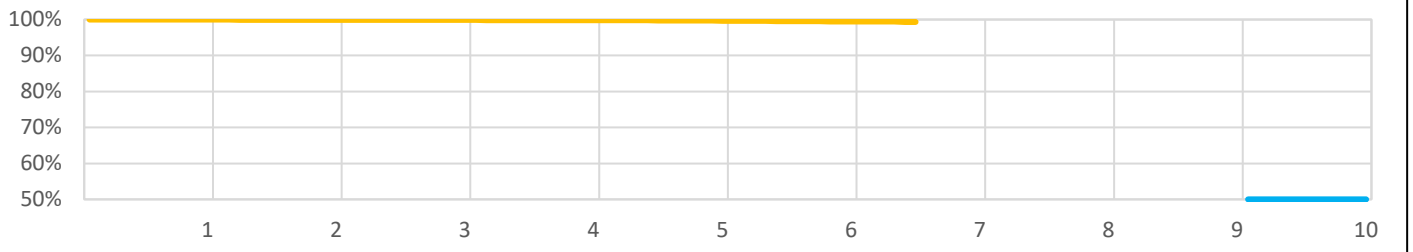
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

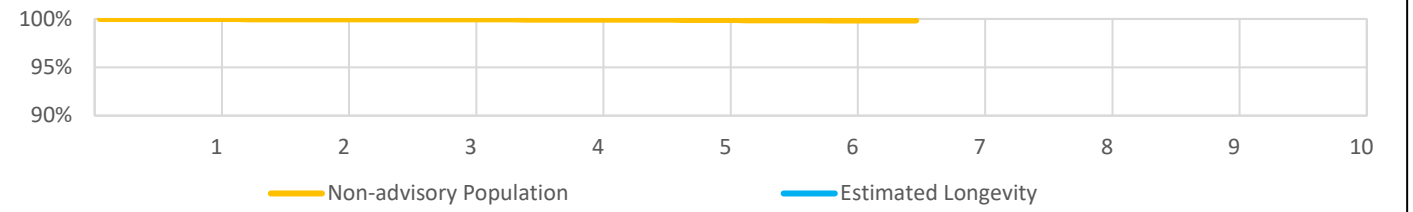
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	46,000	US Normal Battery Depletions:	49
US Approval Date:	April 2014	US Malfunctions:	26
US Estimated Active Implants:	38,000	Without Compromised Therapy:	19
		With Compromised Therapy:	7

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	--	--	--
46,000	Effective Sample Size	37653	30336	22951	14896	7479	2483	341	--	--	--

@ 79 months

DYNAGEN/INOGEN/ORIGEN ICD EL DR

Models: D052/D053/D142/D143/D152/D153

Worldwide Confirmed Malfunctions	**33**
Worldwide Distribution	**70,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	2	1	3
Low-voltage capacitor (69)	0	7	7
High voltage capacitor (75)	5	0	5
Battery (53)	0	3	3
Software			
Memory errors (51)	0	1	1
Other			
Non-patterned, other	3	5	8
Grand Total	**10**	**23**	**33**

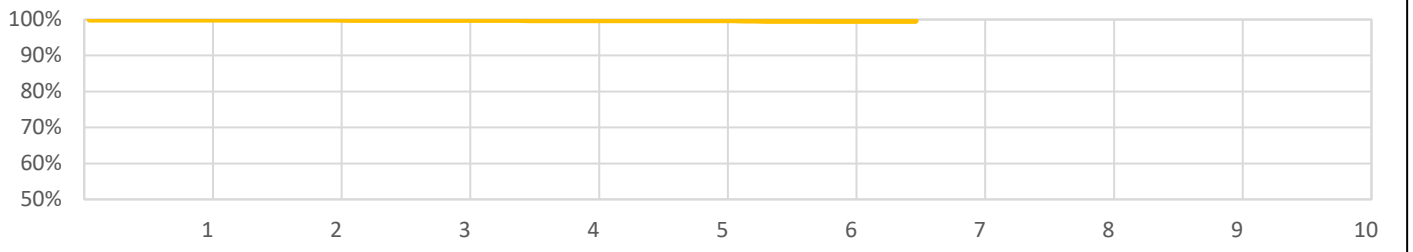
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL VR

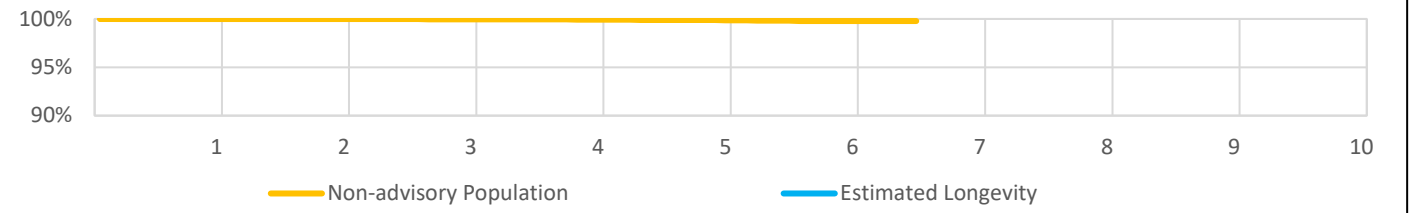
Models: D050/D051/D140/D141/D150/D151

US Summary			
US Registered Implants:	37,000	US Normal Battery Depletions:	24
US Approval Date:	April 2014	US Malfunctions:	25
US Estimated Active Implants:	31,000	Without Compromised Therapy:	24
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	--	--	--
37,000	Effective Sample Size	30910	25537	19625	13187	7131	2493	320	--	--	--

@ 79 months

DYNAGEN/INOGEN/ORIGEN ICD EL VR

Models: D050/D051/D140/D141/D150/D151

Worldwide Confirmed Malfunctions	**43**
Worldwide Distribution	**64,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	1	1
High voltage circuit component (62)	0	2	2
Integrated circuit (63)	0	2	2
Low-voltage capacitor (69)	1	17	18
Battery (53)	1	5	6
Software			
Memory errors (51)	0	5	5
Other			
Non-patterned, other	4	5	9
Grand Total	**6**	**37**	**43**

References cited in table above (link)

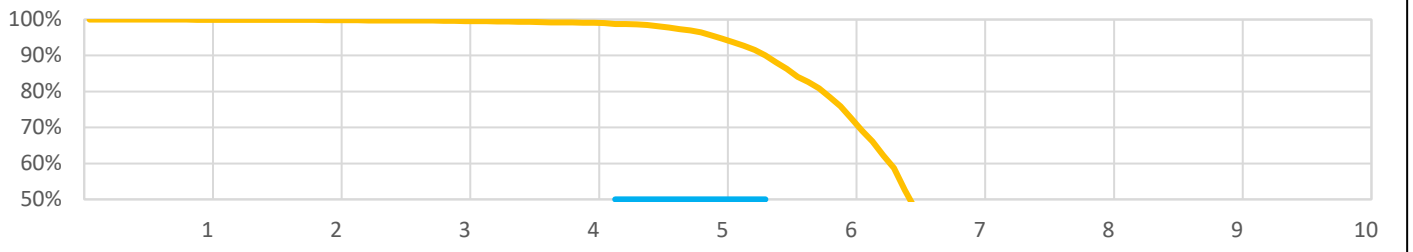
DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models: D002/D003/D012/D013/D022/D023

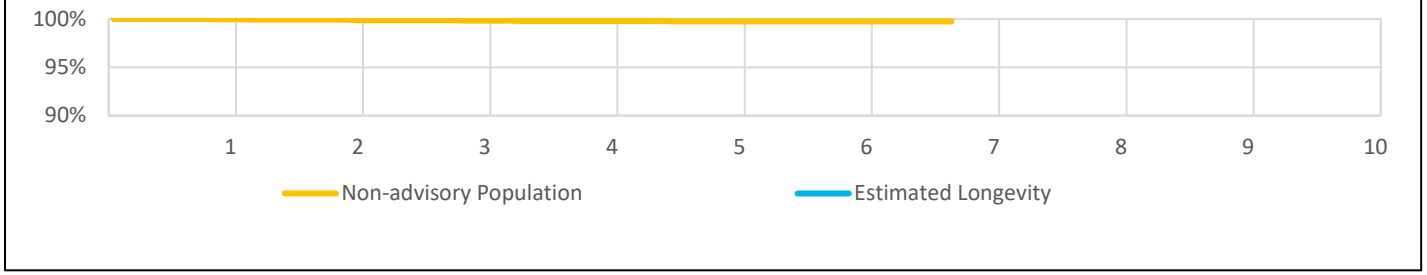
US Summary

US Registered Implants:	10,000	US Normal Battery Depletions:	1,042
US Approval Date:	April 2014	US Malfunctions:	16
US Estimated Active Implants:	7,000	Without Compromised Therapy:	13
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.6%	99.1%	95.5%	75.8%	32.4%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	--	--	--
10,000	Effective Sample Size	8539	6960	5494	3968	2639	1217	267	--	--	--

@ 82 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models: D002/D003/D012/D013/D022/D023

Worldwide Confirmed Malfunctions	**25**
Worldwide Distribution	**29,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	12	12
High voltage capacitor (75)	3	0	3
Integrated circuit (63)	0	1	1
Low-voltage capacitors (47)	1	0	1
Other			
Non-patterned, other	3	5	8
Grand Total	**7**	**18**	**25**

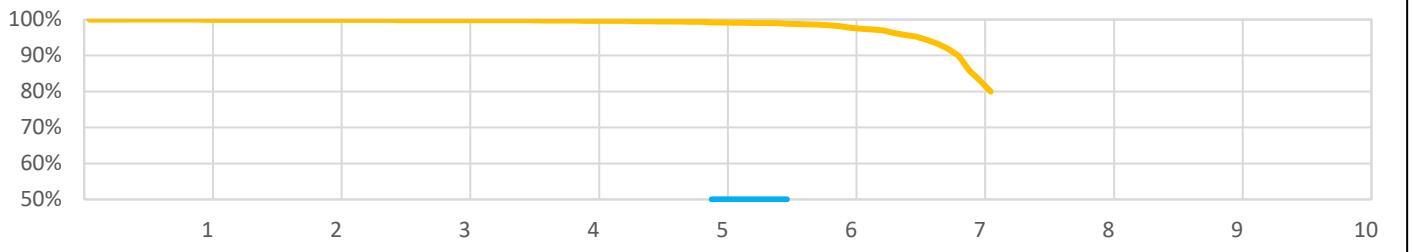
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

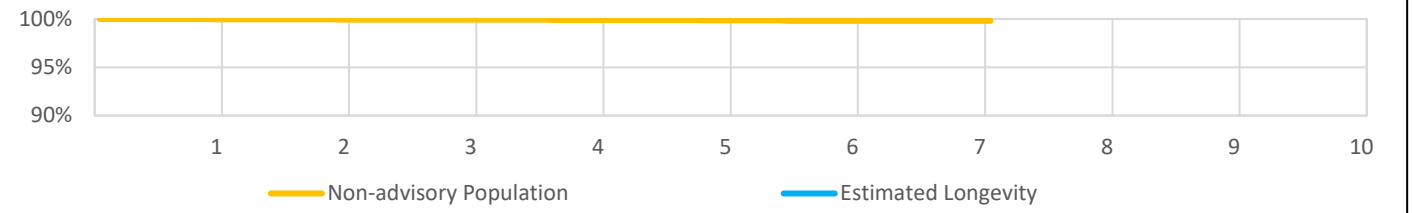
Models: D000/D001/D010/D011/D020/D021

US Summary			
US Registered Implants:	9,000	US Normal Battery Depletions:	157
US Approval Date:	April 2014	US Malfunctions:	9
US Estimated Active Implants:	7,000	Without Compromised Therapy:	8
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.7%	99.2%	98.1%	85.8%	80.0%	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	--	--
9,000	Effective Sample Size	7740	6531	5195	3898	2711	1546	376	219	--	--

@ 86 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

Models: D000/D001/D010/D011/D020/D021

Worldwide Confirmed Malfunctions	**22**
Worldwide Distribution	**30,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	7	7
High voltage capacitor (75)	6	0	6
Low-voltage capacitor (69)	0	1	1
Battery (53)	0	1	1
Software			
Memory errors (51)	1	2	3
Other			
Non-patterned, other	0	2	2
Grand Total	**7**	**15**	**22**

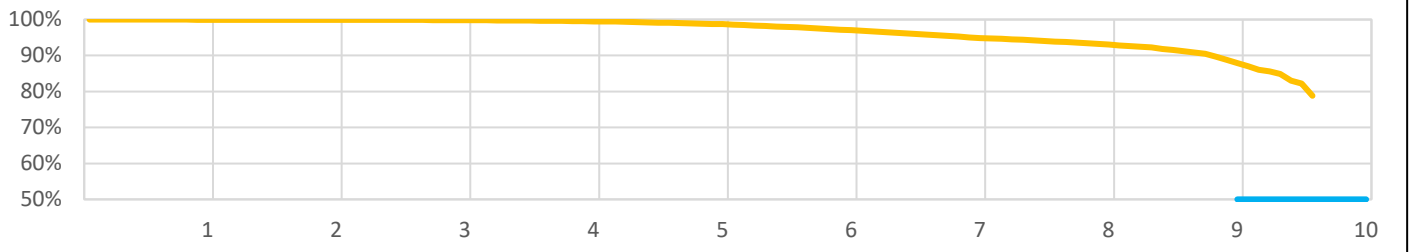
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD DR

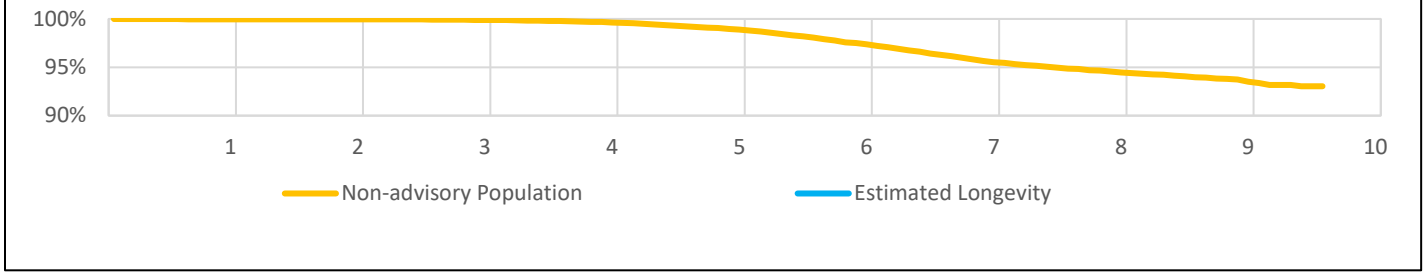
Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

US Summary			
US Registered Implants:	47,000	US Normal Battery Depletions:	499
US Approval Date:	November 2011	US Malfunctions:	1,179
US Estimated Active Implants:	29,000	Without Compromised Therapy:	1,154
		With Compromised Therapy:	25

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	98.8%	97.2%	95.0%	93.2%	88.8%	78.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.5%	95.6%	94.6%	93.7%	93.0%
47,000	Effective Sample Size	41244	36555	32305	28428	24893	21062	15792	8392	2538	288

@ 116 months

INCEPTA/ENERGEN/PUNCTUA ICD DR

Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

Worldwide Confirmed Malfunctions	**1,852**
Worldwide Distribution	**72,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Mechanical			
Transformer (38)	2	0	2
Electrical			
High-voltage capacitor (43)	4	1	5
Low-voltage capacitors (47)	0	4	4
Integrated circuit (50)	5	7	12
Battery (53)	11	81	92
Low-voltage capacitor (54)	9	1678	1687
High voltage circuit (58)	0	1	1
Low-voltage capacitor (69)	0	17	17
Software			
Memory errors (51)	0	7	7
Other			
Non-patterned, other	8	17	25
Grand Total	**39**	**1813**	**1852**

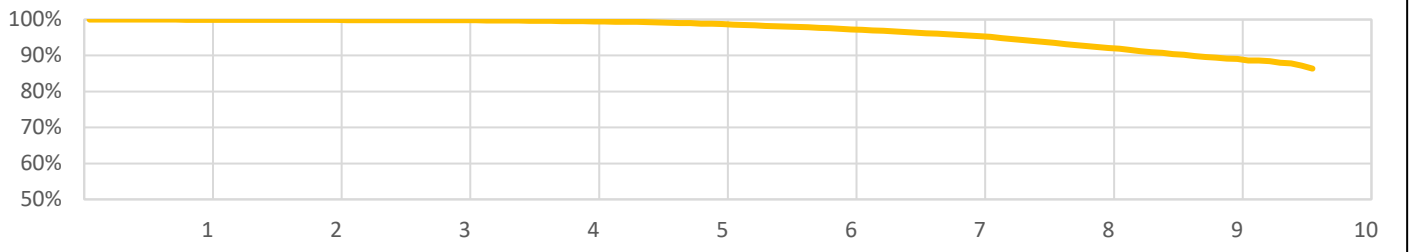
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD VR

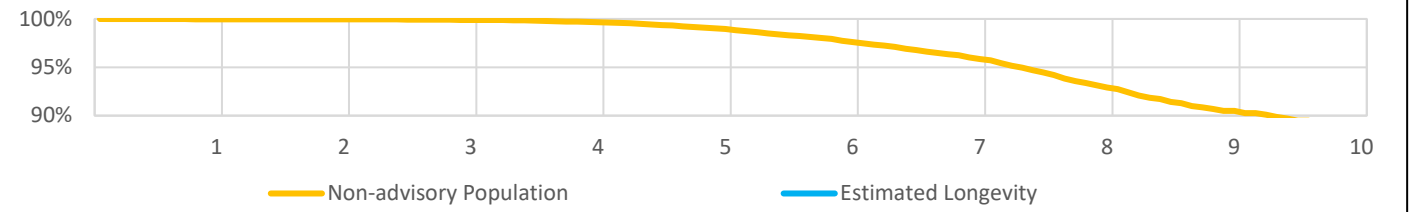
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	179
US Approval Date:	November 2011	US Malfunctions:	1,169
US Estimated Active Implants:	25,000	Without Compromised Therapy:	1,135
		With Compromised Therapy:	34

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.5%	98.8%	97.4%	95.5%	92.4%	89.1%	86.4%	
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.8%	96.0%	93.1%	90.5%	89.5%	
39,000	Effective Sample Size	34701	30726	27148	23904	20915	17782	13139	6728	2042	213	@ 116 months

INCEPTA/ENERGEN/PUNCTUA ICD VR

Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

Worldwide Confirmed Malfunctions	**1,978**
Worldwide Distribution	**68,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	4	1	5
Integrated circuit (50)	5	4	9
Battery (53)	16	122	138
Low-voltage capacitor (54)	14	1771	1785
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	0	4	4
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	1	7	8
Other			
Non-patterned, other	10	12	22
Grand Total	**57**	**1921**	**1978**

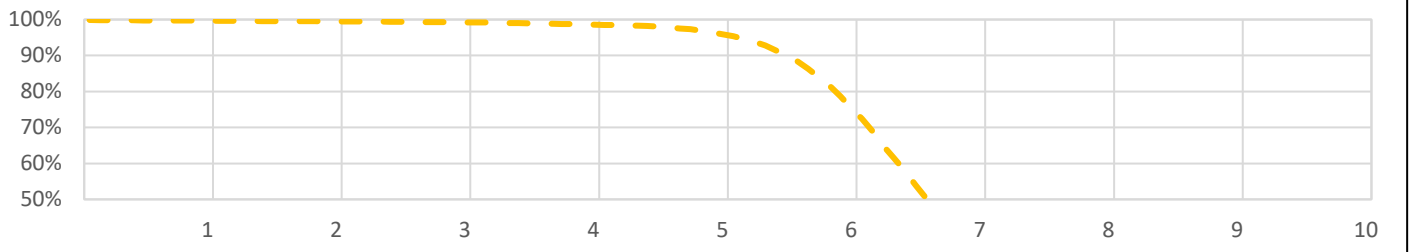
References cited in table above (link)

SQ-RX S-ICD

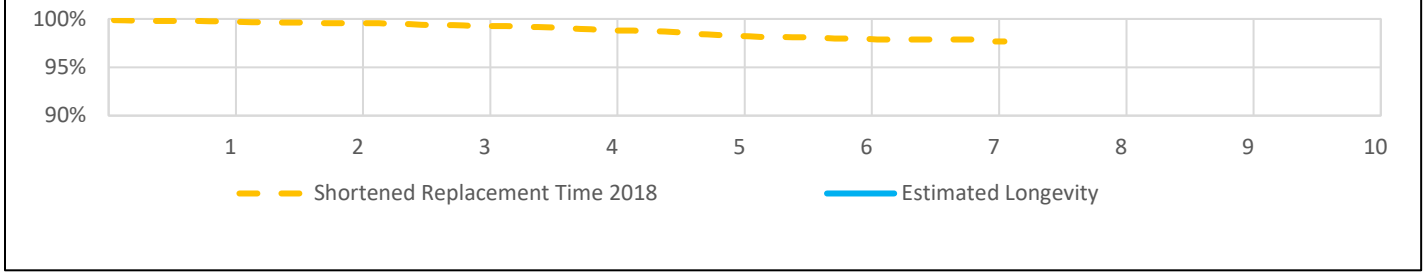
Models: 1010

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	2,011
US Approval Date:	September 2012	US Malfunctions:	100
US Estimated Active Implants:	3,000	Without Compromised Therapy:	42
		With Compromised Therapy:	58

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Shortened Replacement Time 2018	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.6%	96.5%	78.6%	32.7%	24.0%	--	--
Registered Implants:	Malfunctions Only	99.7%	99.5%	99.3%	98.8%	98.3%	98.0%	97.7%	97.7%	--	--
8,000	Effective Sample Size	6404	5642	4985	4376	3687	2663	492	216	--	--

@ 86 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

SQ-RX S-ICD

Models: 1010

Worldwide Confirmed Malfunctions	**210**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Unintended Fuse Activation 2013 (4)	3	0	3
Charge Timeout Alert (61)	1	11	12
Mechanical			
High cathode condition (5)	1	1	2
Shortened replacement time 2018 (55)	61	42	103
Software			
Unintended Battery Depletion Alert (57)	0	10	10
Other			
Telemetry (56)	10	4	14
Non-patterned, other	38	28	66
Grand Total	**114**	**96**	**210**

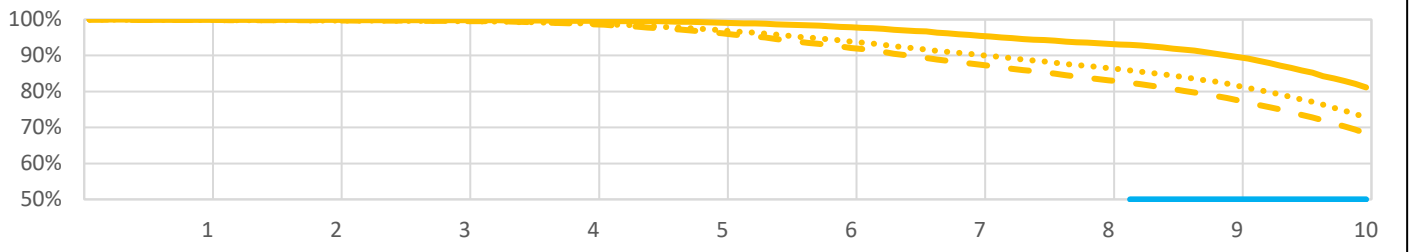
References cited in table above (link)

TELIGEN DR

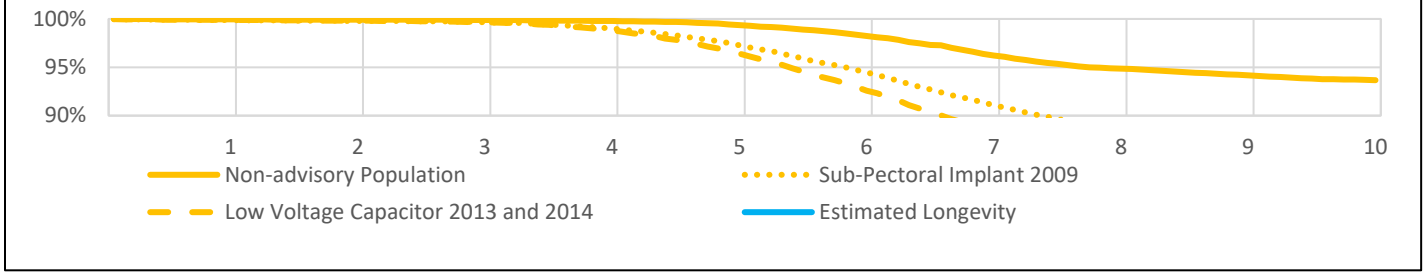
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	7,524
US Approval Date:	March 2008	US Malfunctions:	3,002
US Estimated Active Implants:	21,000	Without Compromised Therapy:	2,844
		With Compromised Therapy:	158

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	99.2%	98.0%	95.7%	93.4%	90.0%	82.1%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.4%	94.9%	94.2%	93.7%
30000	Effective Sample Size	26330	23355	20709	18287	16083	13986	11979	10220	8620	6114

TELIGEN DR

Models: E110/E111/F110/F111

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.9%	97.2%	94.2%	90.4%	86.8%	82.2%	73.8%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.7%	91.3%	88.6%	86.6%	85.3%
30000	Effective Sample Size	26630	23511	20787	18251	15859	13510	11367	9507	7810	6055
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.5%	92.5%	87.8%	83.4%	78.2%	69.4%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	98.9%	96.7%	93.0%	88.7%	85.3%	82.9%	81.3%
23000	Effective Sample Size	20615	18222	16099	14124	12169	10249	8519	7042	5716	4371

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN DR

Models: E110/E111/F110/F111

Worldwide Confirmed Malfunctions	**4,106**
Worldwide Distribution	**91,000**

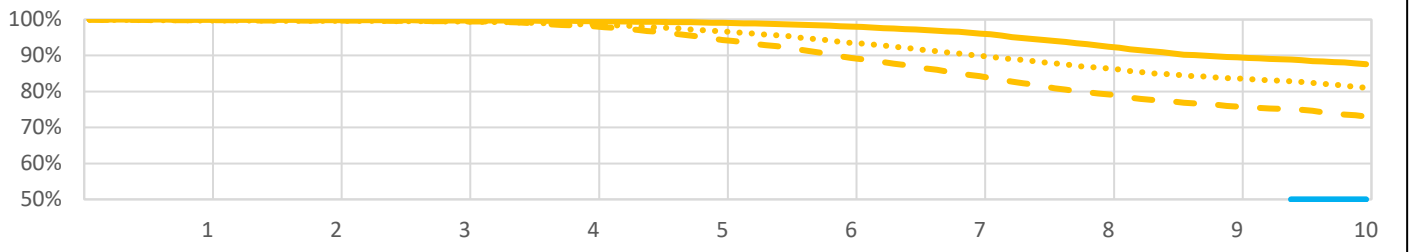
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	51	2294	2345
Safety Core-electrocautery (42)	1	4	5
High-voltage capacitor (43)	8	1	9
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	21	22	43
Battery (53)	42	256	298
Low-voltage capacitor (54)	9	1244	1253
Low-voltage capacitor (69)	0	4	4
Integrated circuit (63)	1	0	1
Mechanical			
Transformer (38)	20	0	20
Seal plug (40)	0	3	3
Difficulty securing lead (41)	8	7	15
Header contacts (45)	12	3	15
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	11	6	17
Header (74)	9	3	12
Software			
Alert messages not displayed post-EOL (48)	0	3	3
Memory errors (51)	0	17	17
Other			
Non-patterned, other	10	28	38
Grand Total	**203**	**3903**	**4106**

TELIGEN VR

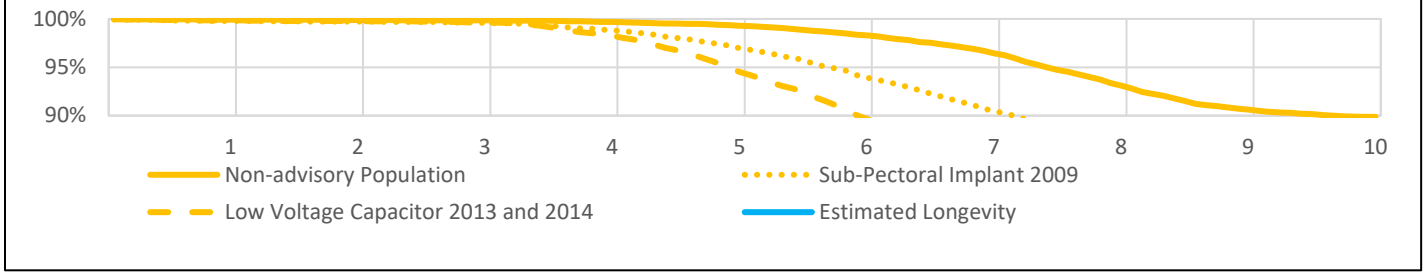
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	884
US Approval Date:	March 2008	US Malfunctions:	2,342
US Estimated Active Implants:	16,000	Without Compromised Therapy:	2,214
		With Compromised Therapy:	128

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.6%	99.1%	98.1%	96.3%	92.8%	89.6%	87.8%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.7%	99.3%	98.4%	96.7%	93.4%	90.7%	89.9%
18000	Effective Sample Size	16199	14330	12650	11154	9789	8516	7303	6105	5120	3760

TELIGEN VR

Models: E102/E103/F102/F103

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.8%	99.6%	99.5%	98.7%	96.9%	93.8%	90.2%	86.6%	83.7%	81.3%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.6%	98.9%	97.2%	94.2%	90.7%	87.4%	84.8%	83.3%
16000	Effective Sample Size	13610	11994	10570	9241	7984	6796	5704	4752	3990	3355
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.2%	94.8%	89.7%	84.6%	79.5%	76.0%	73.4%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.6%	98.4%	95.0%	90.0%	85.1%	80.2%	77.1%	75.5%
12000	Effective Sample Size	10849	9579	8445	7363	6261	5193	4245	3442	2854	2383

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN VR

Models: E102/E103/F102/F103

Worldwide Confirmed Malfunctions	**3,980**
Worldwide Distribution	**66,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	46	1912	1958
Safety Core-electrocautery (42)	1	1	2
High-voltage capacitor (43)	3	0	3
Low-voltage capacitors (47)	0	5	5
Integrated circuit (50)	17	11	28
Battery (53)	52	418	470
Low-voltage capacitor (54)	6	1356	1362
Low-voltage capacitor (69)	0	5	5
Mechanical			
Transformer (24)	1	0	1
Transformer (38)	14	0	14
Seal plug (40)	0	1	1
Difficulty securing lead (41)	9	0	9
Header contacts (45)	22	16	38
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	17	9	26
Header (74)	13	4	17
Software			
Alert messages not displayed post-EOL (48)	0	4	4
Memory errors (51)	0	12	12
Respiratory Sensor Oversensing - March 23, 2009 Voluntary Physician Advisory (7)	0	2	2
Other			
Non-patterned, other	12	11	23
Grand Total	**213**	**3767**	**3980**

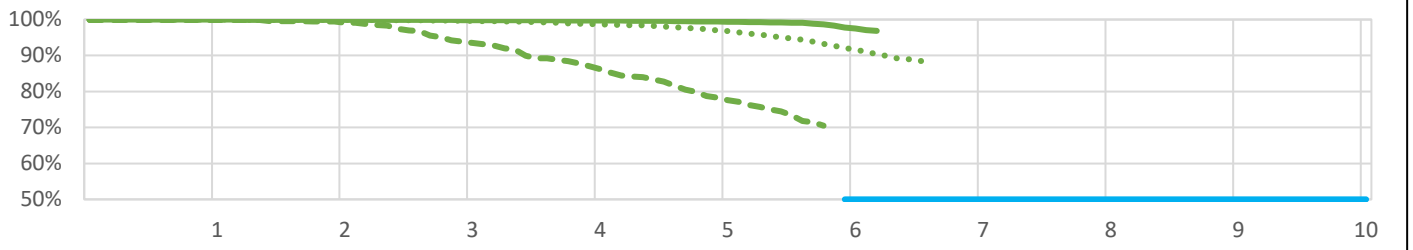
ACCOLADE/PROPONENT/ESSENTIO DR

Models: L101/L111/L201/L211/L301/L311

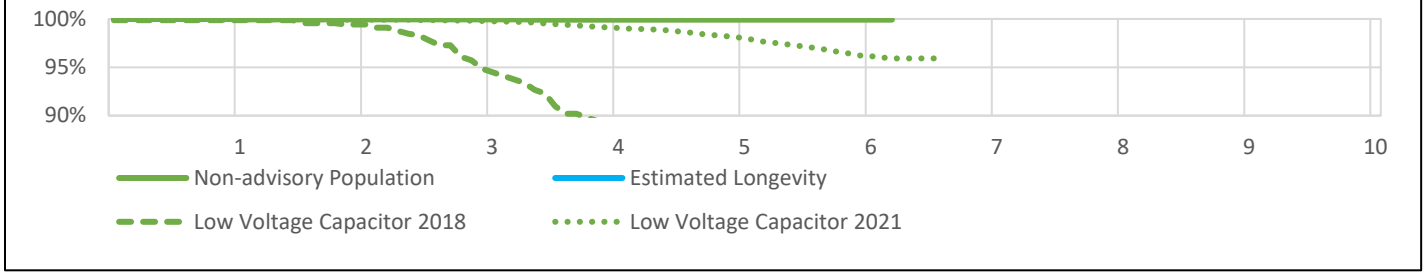
US Summary

US Registered Implants:	224,000	US Normal Battery Depletions:	1,060
US Approval Date:	October 2014	US Malfunctions:	903
US Estimated Active Implants:	189,000	Without Compromised Therapy:	881
		With Compromised Therapy:	22

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.4%	97.8%	96.8%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--	--
181000	Effective Sample Size	134010	97135	63811	35572	11325	1475	453	--	--	--

@ 75 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO DR

Models: L101/L111/L201/L211/L301/L311

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018	Depletions and Malfunctions	99.9%	99.4%	94.2%	87.8%	78.7%	70.5%	--	--	--	--
Registered Implants: 800	Malfunctions Only	99.9%	99.4%	94.9%	88.8%	83.5%	79.3%	--	--	--	--
	Effective Sample Size	713	640	544	450	358	218	--	--	--	--
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	98.8%	97.0%	92.1%	87.8%	--	--	--
Registered Implants: 42000	Malfunctions Only	100.0%	99.9%	99.8%	99.1%	98.1%	96.2%	95.9%	--	--	--
	Effective Sample Size	37244	33200	29454	24923	19804	6777	213	--	--	--

@ 71 months

@ 80 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO DR

Models: L101/L111/L201/L211/L301/L311

Worldwide Confirmed Malfunctions	**1,538**
Worldwide Distribution	**473,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	4	5
Integrated circuit (63)	10	29	39
Capacitor (67)	0	2	2
Telemetry (68)	2	12	14
Hydrogen induced premature depletion - September 2018 (70)	2	186	188
Hydrogen induced premature depletion - June 2021 (83)	16	1160	1176
Capacitor (72)	0	1	1
Software			
Memory errors (51)	0	38	38
Mechanical			
Battery cathode (79)	1	0	1
Other			
Non-patterned, other	19	55	74
Grand Total	**51**	**1487**	**1538**

References cited in table above (link)

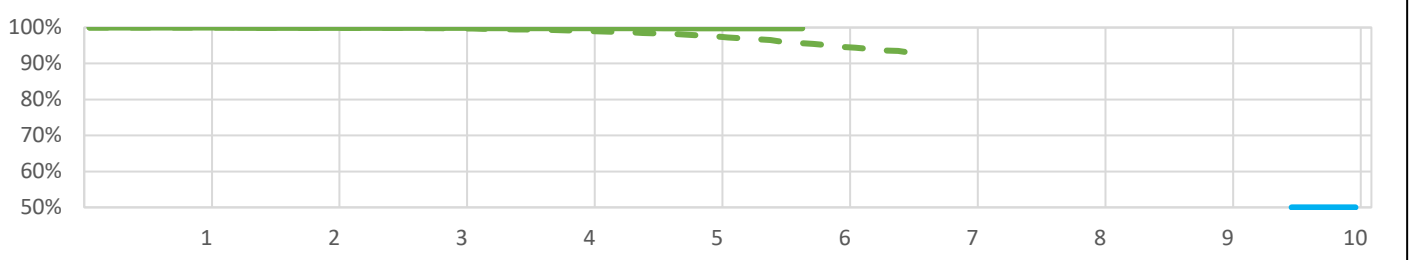
ACCOLADE/PROPONENT/ESSENTIO EL DR

Models: L121/L131/L221/L231/L321/L331

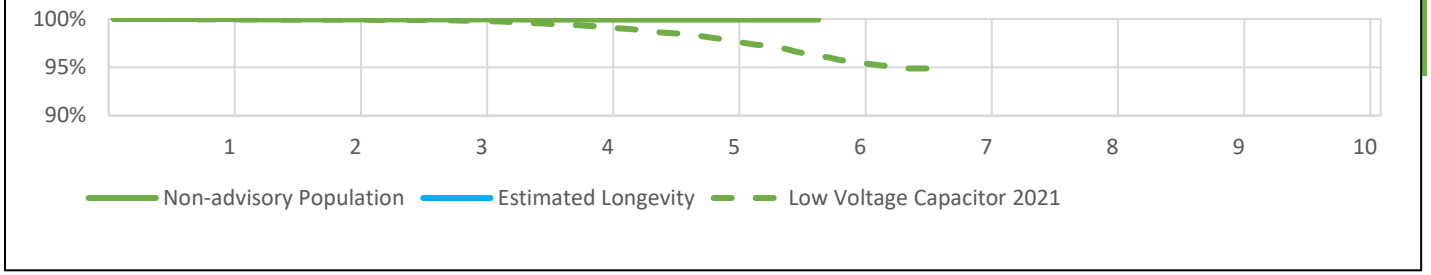
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	117
US Approval Date:	October 2014	US Malfunctions:	410
US Estimated Active Implants:	108,000	Without Compromised Therapy:	404
		With Compromised Therapy:	6

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--
104,000	Effective Sample Size	70913	47298	28157	13692	3017	247	--	--	--	--

@ 69 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO EL DR

Models: L121/L131/L221/L231/L321/L331

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.0%	97.5%	94.6%	93.1%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.1%	97.7%	95.5%	94.9%	--	--	--
17,000	Effective Sample Size	14979	13323	11812	9957	7617	2326	251	--	--	--

@ 79 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO EL DR

Models: L121/L131/L221/L231/L321/L331

Worldwide Confirmed Malfunctions	**902**
Worldwide Distribution	**289,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	10	10
Integrated circuit (63)	1	15	16
Telemetry (68)	1	12	13
Hydrogen induced premature depletion - September 2018 (70)	3	88	91
Hydrogen induced premature depletion - June 2021 (83)	3	707	710
Software			
Memory errors (51)	0	33	33
Mechanical			
Battery cathode (79)	1	0	1
Other			
Non-patterned, other	4	24	28
Grand Total	**13**	**889**	**902**

References cited in table above (link)

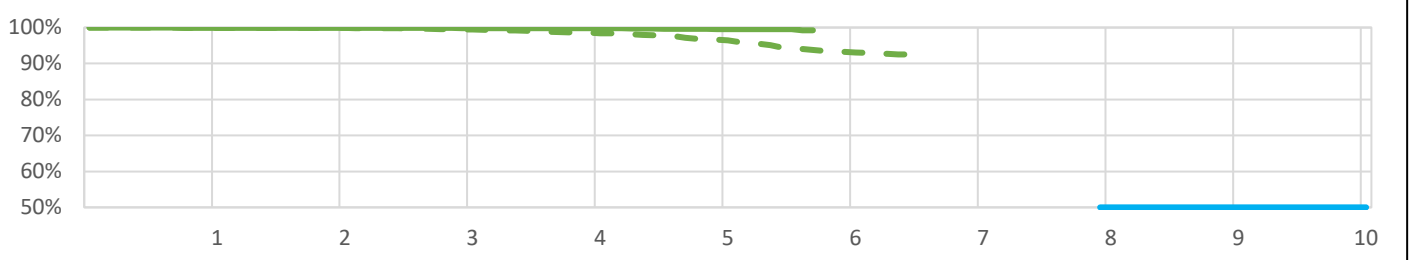
ACCOLADE/PROPONENT/ESSENTIO SR

Models: L100/L110/L200/L210/L300/L310

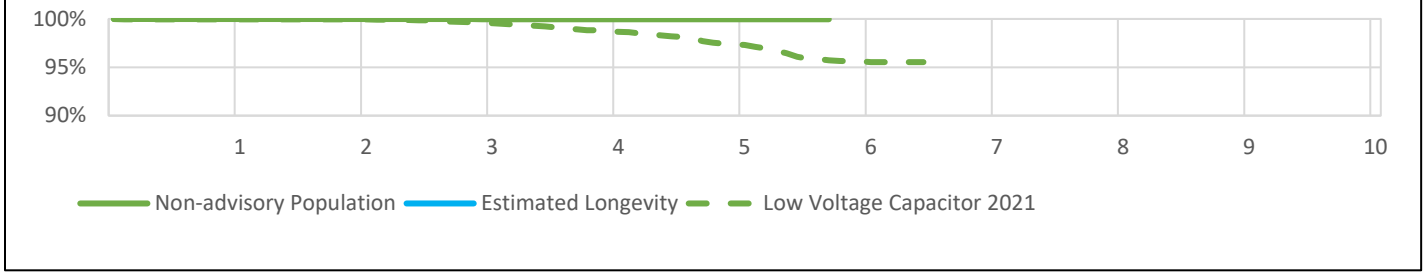
US Summary

US Registered Implants:	43,000	US Normal Battery Depletions:	137
US Approval Date:	October 2014	US Malfunctions:	270
US Estimated Active Implants:	32,000	Without Compromised Therapy:	265
		With Compromised Therapy:	5

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.9%	99.8%	99.6%	99.2%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	--	--	--	--
31,000	Effective Sample Size	22003	15712	9803	4961	1203	204	--	--	--	--

@ 69 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO SR

Models: L100/L110/L200/L210/L300/L310

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	99.9%	99.9%	99.5%	98.5%	96.6%	93.3%	92.5%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.6%	98.8%	97.4%	95.6%	95.5%	--	--	--
12,000	Effective Sample Size	10319	9160	8087	6748	4768	1427	291	--	--	--

@ 78 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ACCOLADE/PROPONENT/ESSENTIO SR

Models: L100/L110/L200/L210/L300/L310

Worldwide Confirmed Malfunctions	**669**
Worldwide Distribution	**172,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	2	3
Integrated circuit (63)	5	5	10
Telemetry (68)	0	4	4
Hydrogen induced premature depletion - September 2018 (70)	2	55	57
Hydrogen induced premature depletion - June 2021 (83)	12	559	571
Software			
Memory errors (51)	0	11	11
Other			
Non-patterned, other	1	12	13
Grand Total	**21**	**648**	**669**

References cited in table above (link)

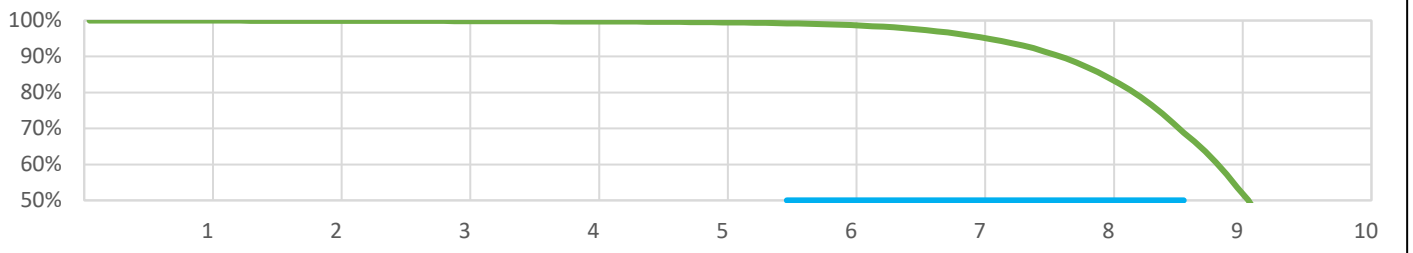
ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models: J063/J066/J173/J176/J273/J276/J278/J279/K063/K066/K083/K086/K173/K176/K183/K186/K273/K276/K278/K279/K283/K286/K288/K289

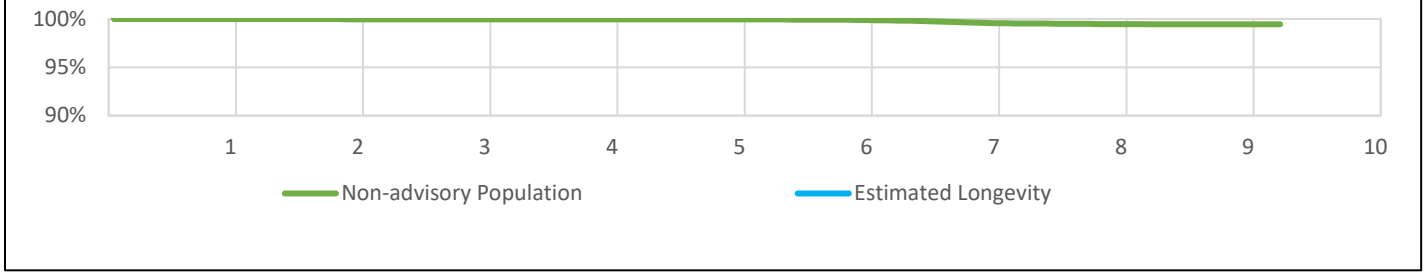
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	8,677
US Approval Date:	May 2012	US Malfunctions:	281
US Estimated Active Implants:	72,000	Without Compromised Therapy:	269
		With Compromised Therapy:	12

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.5%	98.9%	95.8%	85.7%	57.2%	39.0%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.6%	99.5%	99.4%	99.4%
121,000	Effective Sample Size	107338	95759	85393	76116	67676	59855	43768	19360	2850	251

@ 112 months

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models: J063/J066/J173/J176/J273/J276/J278/J279/K063/K066/K083/K086/K173/K176/K183/K186/K273/K276/ K278/K279/K283/K286/K288/K289

Worldwide Confirmed Malfunctions	**322**
Worldwide Distribution	**218,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	7	3	10
Titanium case material (60)	3	0	3
Software			
Memory errors (51)	1	27	28
Other			
Non-patterned, other	10	263	273
Grand Total	**21**	**301**	**322**

References cited in table above (link)

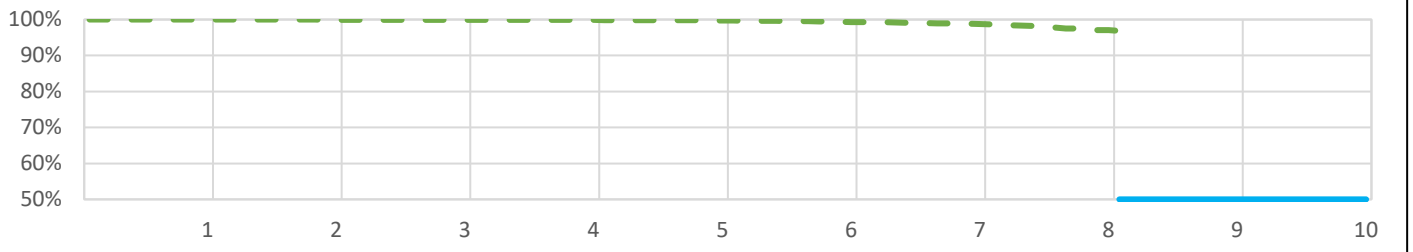
ADVANTIO/INGENIO/VITALIO EL DR

Models: J064/J067/J174/J177/J274/J277/K064/K067/K084/K087/K174/K177/K184/K187/K274/K277/K284/K287

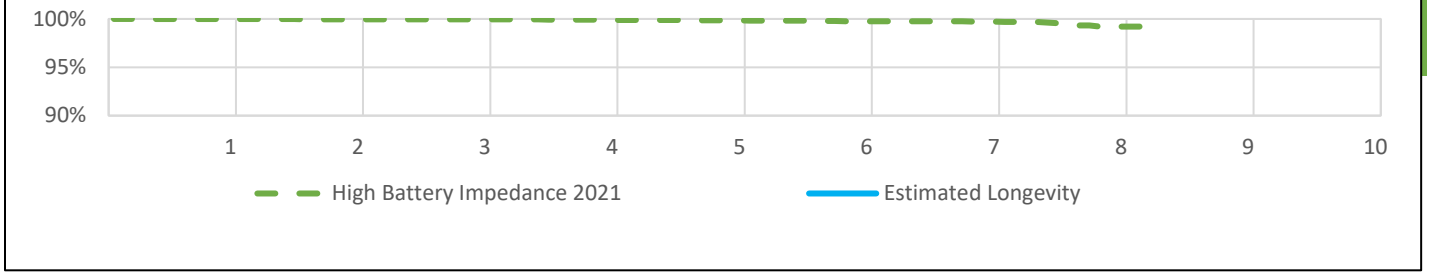
US Summary

US Registered Implants:	11,000	US Normal Battery Depletions:	68
US Approval Date:	May 2012	US Malfunctions:	26
US Estimated Active Implants:	8,000	Without Compromised Therapy:	24
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	99.8%	99.4%	98.8%	97.1%	96.8%	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.2%	99.2%	--
11,000	Effective Sample Size	9676	8589	7640	6794	6039	5208	3214	606	286	--

@ 99 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

ADVANTIO/INGENIO/VITALIO/FORMIO EL DR

Models: J064/J067/J174/J177/J274/J277/K064/K067/K084/K087/K174/K177/K184/K187/K274/K277/K284/K287

Worldwide Confirmed Malfunctions	**164**
Worldwide Distribution	**76,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	5	6
Integrated circuit (50)	2	0	2
Titanium case material (60)	2	0	2
High battery impedance initiating safety mode 2021 (82)	0	14	14
Software			
Memory errors (51)	1	5	6
Respiratory sensor (59)	0	1	1
Other			
Non-patterned, other	5	128	133
Grand Total	**11**	**153**	**164**

References cited in table above (link)

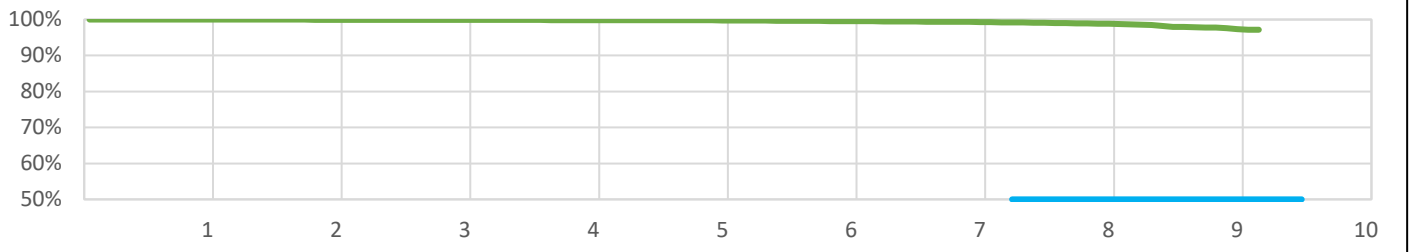
ADVANTIO/INGENIO/VITALIO/FORMIO SR

Models: J062/J065/J172/J175/J272/J275/K062/K065/K082/K085/K172/K175/K182/K185/K272/K275/K282/K285

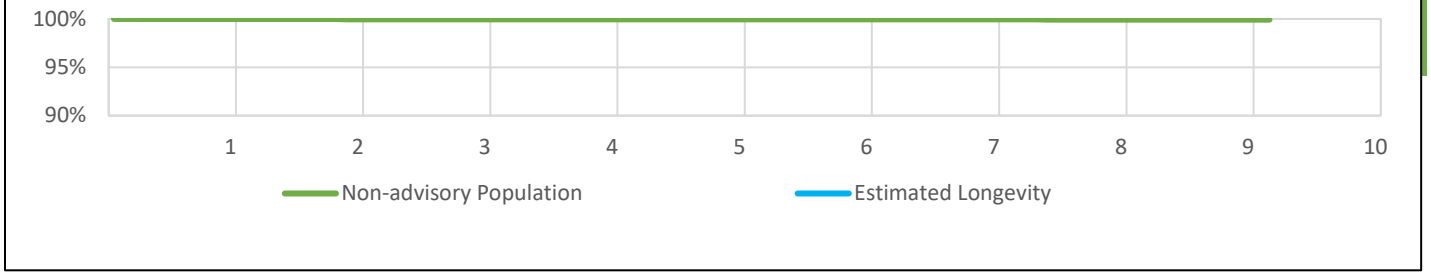
US Summary

US Registered Implants:	27,000	US Normal Battery Depletions:	145
US Approval Date:	May 2012	US Malfunctions:	12
US Estimated Active Implants:	15,000	Without Compromised Therapy:	11
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.3%	98.9%	97.6%	97.2%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
27,000	Effective Sample Size	22815	20289	18097	16156	14396	12545	8904	4373	965	377

@ 111 months

ADVANTIO/INGENIO/VITALIO SR

Models: J062/J065/J172/J175/J272/J275/K062/K065/K082/K085/K172/K175/K182/K185/K272/K275/K282/K285

Worldwide Confirmed Malfunctions	**25**
Worldwide Distribution	**86,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (50)	3	2	5
Titanium case material (60)	1	0	1
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	3	3	6
Grand Total	**8**	**17**	**25**

References cited in table above (link)

ALTRUA 2 DR

Models: S702

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	1	1
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	6	6
Grand Total	**0**	**7**	**7**

References cited in table above (link)

ALTRUA 2 EL DR

Models: S722

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**7,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

ALTRUA 2 SR

Models: S701

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	8	8
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**9**	**9**

References cited in table above (link)

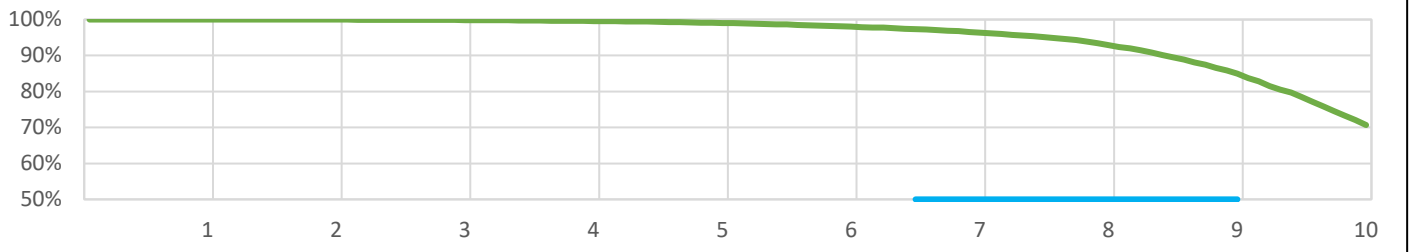
ALTRUA 60 DR

Model: S602

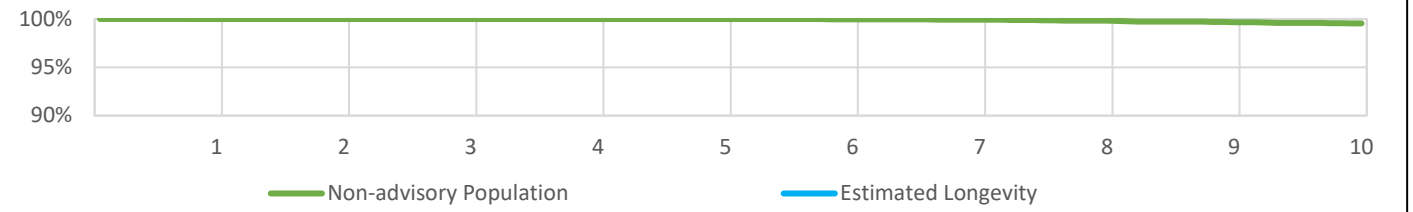
US Summary

US Registered Implants:	22,000	US Normal Battery Depletions:	4,001
US Approval Date:	April 2008	US Malfunctions:	40
US Estimated Active Implants:	7,000	Without Compromised Therapy:	37
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.6%	99.1%	98.1%	96.6%	93.4%	85.8%	72.0%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%
22,000	Effective Sample Size	19220	17184	15327	13623	12039	10569	9239	7843	6270	4306

ALTRUA 60 DR

Models: S602

Worldwide Confirmed Malfunctions	**68**
Worldwide Distribution	**56,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Mechanical			
Capacitor array (16)	0	1	1
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	1	1	2
Battery status (49)	0	56	56
Non-patterned, other	3	4	7
Grand Total	**5**	**63**	**68**

References cited in table above (link)

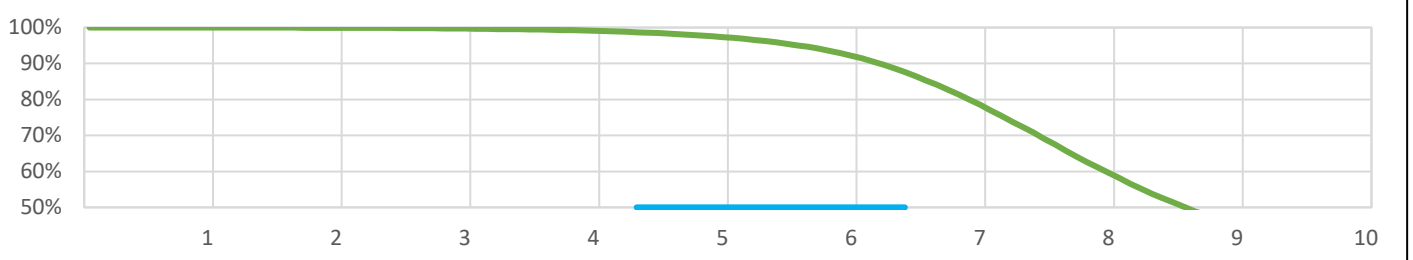
ALTRUA 60 DR (Downsize)

Model: S603

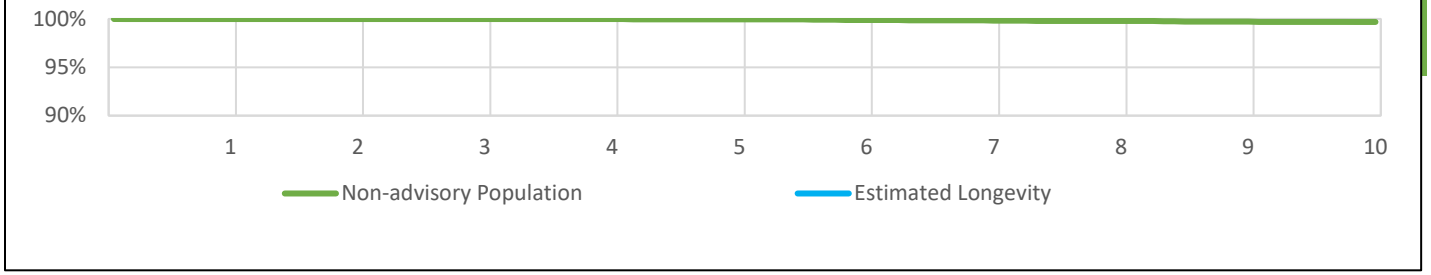
US Summary

US Registered Implants:	90,000	US Normal Battery Depletions:	25,137
US Approval Date:	April 2008	US Malfunctions:	101
US Estimated Active Implants:	22,000	Without Compromised Therapy:	91
		With Compromised Therapy:	10

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.2%	97.6%	92.9%	79.9%	61.1%	45.5%	32.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.7%
90,000	Effective Sample Size	78569	70274	62759	55844	49154	41776	32054	21297	13272	6124

ALTRUA 60 DR (Downsize)

Models: S603

Worldwide Confirmed Malfunctions	**130**
Worldwide Distribution	**132,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	7	4	11
Integrated circuit (30)	1	1	2
Mechanical			
Difficulty securing lead (41)	0	1	1
Connector block (39)	0	1	1
Software			
Underestimation of battery status (34)	0	1	1
Other			
Battery depletion (26)	1	3	4
Battery status (49)	0	99	99
Magnet response (21)	0	2	2
Non-patterned, other	4	5	9
Grand Total	**13**	**117**	**130**

References cited in table above (link)

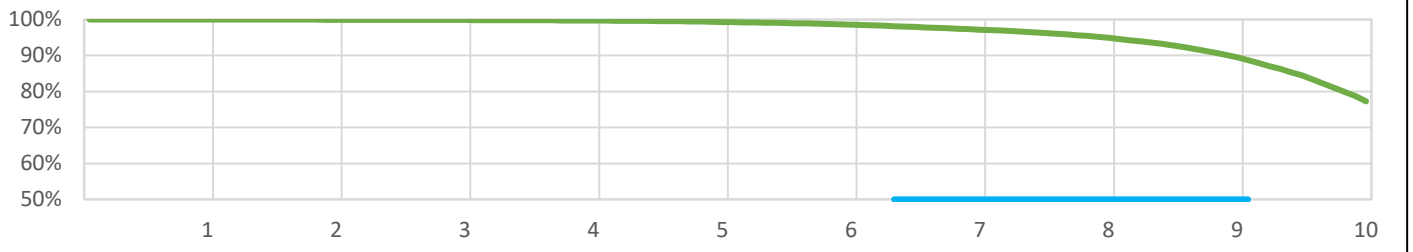
ALTRUA 60 EL DR

Model: S606

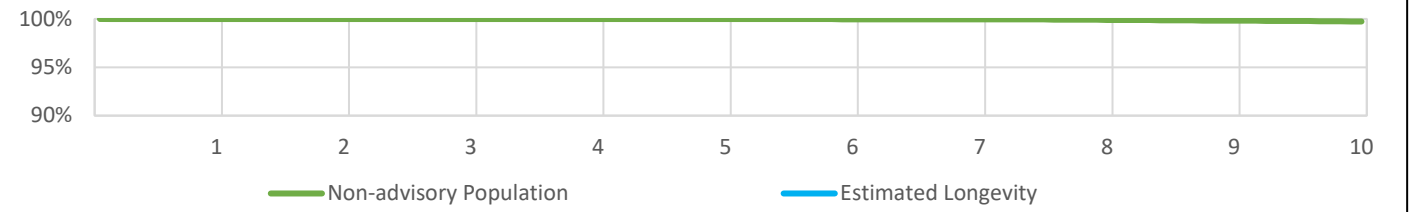
US Summary

US Registered Implants:	59,000	US Normal Battery Depletions:	6,842
US Approval Date:	April 2008	US Malfunctions:	60
US Estimated Active Implants:	27,000	Without Compromised Therapy:	54
		With Compromised Therapy:	6

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.4%	98.6%	97.3%	95.2%	90.1%	78.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%
59,000	Effective Sample Size	52504	46923	41880	37333	33242	29397	25845	22472	18463	10778

ALTRUA 60 EL DR

Models: S606

Worldwide Confirmed Malfunctions	**87**
Worldwide Distribution	**90,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	3	3
Integrated circuit (17)	0	1	1
Mechanical			
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	2	0	2
Battery status (49)	2	72	74
Magnet rate (44)	0	1	1
Non-patterned, other	2	3	5
Grand Total	**7**	**80**	**87**

References cited in table above (link)

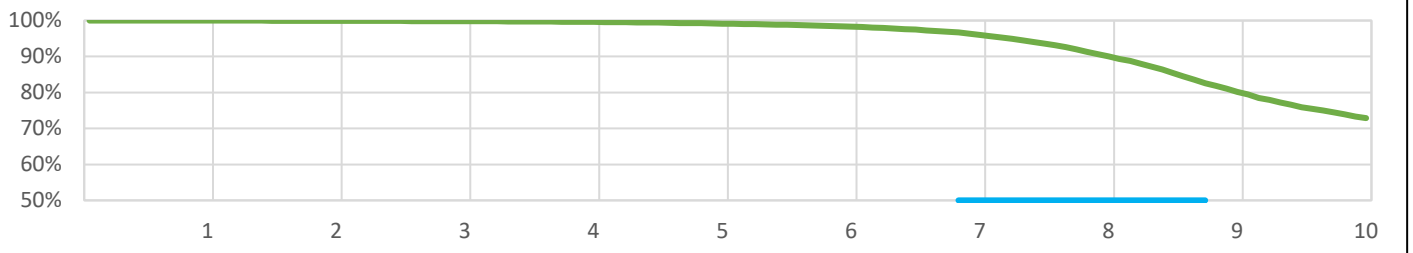
ALTRUA 60 SR

Model: S601

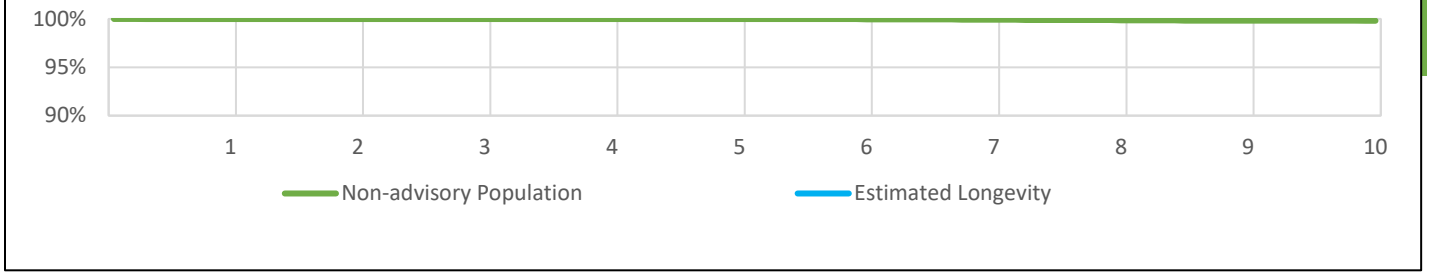
US Summary

US Registered Implants:	32,000	US Normal Battery Depletions:	3,424
US Approval Date:	April 2008	US Malfunctions:	22
US Estimated Active Implants:	9,000	Without Compromised Therapy:	19
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.6%	99.2%	98.4%	96.3%	90.6%	81.0%	73.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
32,000	Effective Sample Size	26282	23045	20422	18182	16193	14346	12588	10507	8022	5079

ALTRUA 60 SR

Models: S601

Worldwide Confirmed Malfunctions	**42**
Worldwide Distribution	**68,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	2	0	2
Other			
Battery depletion (26)	1	0	1
Battery status (49)	1	32	33
Non-patterned, other	2	1	3
Grand Total	**8**	**34**	**42**

References cited in table above (link)

ALTRUA 50 DR (Downsize)

Models: S502

Worldwide Confirmed Malfunctions	**39**
Worldwide Distribution	**48,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	1	2	3
Integrated circuit (30)	0	1	1
Other			
Battery depletion (26)	0	2	2
Battery status (49)	0	31	31
Non-patterned, other	1	1	2
Grand Total	**2**	**37**	**39**

References cited in table above (link)

ALTRUA 50 DDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	**13**
Worldwide Distribution	**12,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	3	0	3
Battery status (49)	0	9	9
Non-patterned, other	0	1	1
Grand Total	**3**	**10**	**13**

References cited in table above (link)

ALTRUA 50 SR

Models: S501

Worldwide Confirmed Malfunctions	**16**
Worldwide Distribution	**25,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	4	1	5
Other			
Battery depletion (26)	2	0	2
Battery status (49)	0	8	8
Non-patterned, other	1	0	1
Grand Total	**7**	**9**	**16**

References cited in table above (link)

ALTRUA 50 SSI

Models: S508

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	1	0	1
Battery status (49)	0	4	4
Grand Total	**1**	**4**	**5**

References cited in table above (link)

ALTRUA 50 VDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery status (49)	0	7	7
Grand Total	**0**	**7**	**7**

References cited in table above (link)

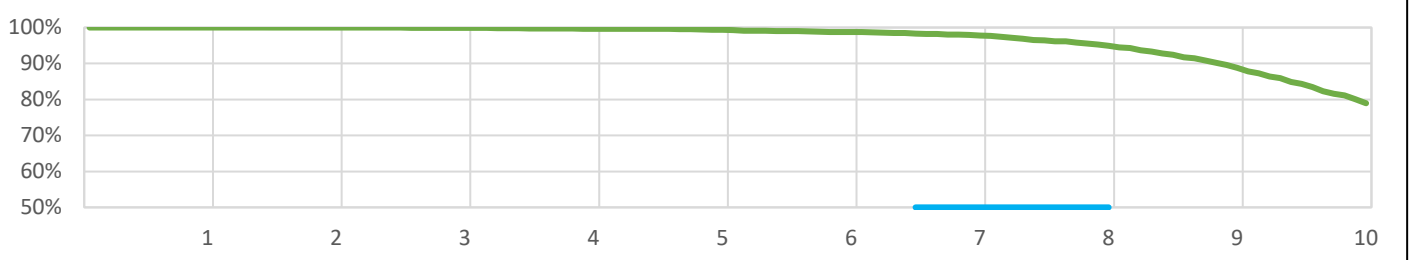
ALTRUA 40 EL DR

Model: S404

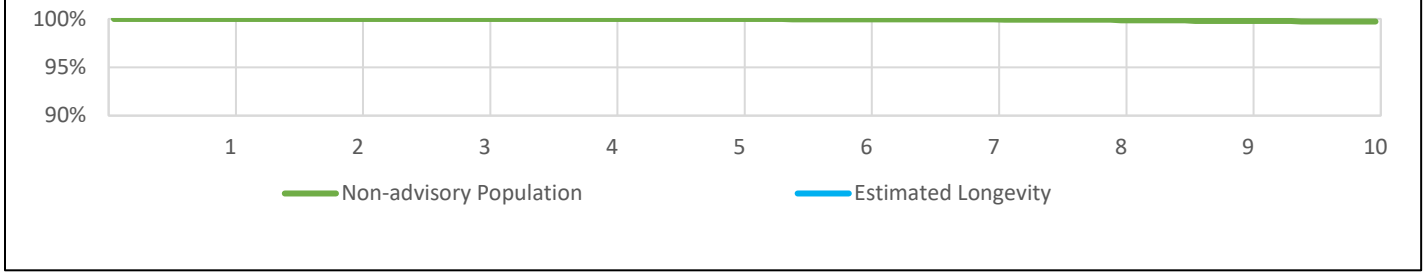
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	578
US Approval Date:	April 2008	US Malfunctions:	5
US Estimated Active Implants:	2,000	Without Compromised Therapy:	5
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.7%	99.4%	98.7%	98.0%	95.3%	89.6%	80.1%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%
5,000	Effective Sample Size	4429	3960	3555	3176	2835	2511	2223	1923	1598	1046

ALTRUA 40 EL DR

Models: S404

Worldwide Confirmed Malfunctions	**6**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Other			
Battery status (49)	0	5	5
Grand Total	**0**	**6**	**6**

References cited in table above (link)

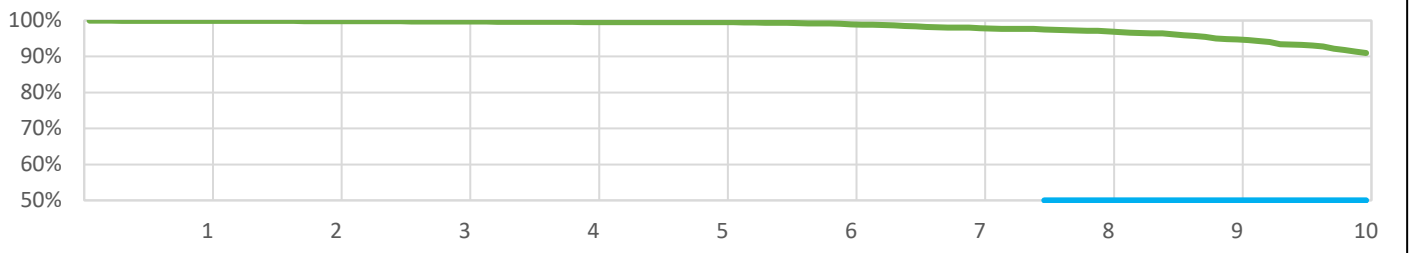
ALTRUA 20 EL DR

Model: S208

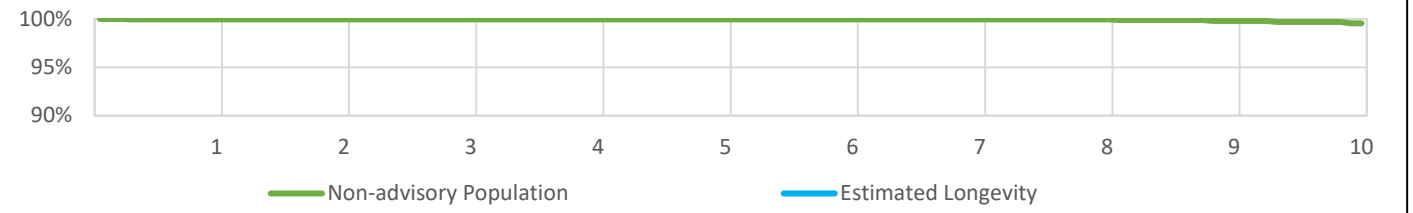
US Summary

US Registered Implants:	3,000	US Normal Battery Depletions:	173
US Approval Date:	April 2008	US Malfunctions:	5
US Estimated Active Implants:	1,000	Without Compromised Therapy:	4
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	99.5%	99.1%	98.0%	97.2%	94.8%	91.4%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.5%
3,000	Effective Sample Size	2762	2472	2200	1968	1745	1553	1369	1209	1045	745

ALTRUA 20 EL DR

Models: S208

Worldwide Confirmed Malfunctions	**8**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	0	2
Other			
Battery status (49)	0	5	5
Non-patterned, other	1	0	1
Grand Total	**3**	**5**	**8**

References cited in table above (link)

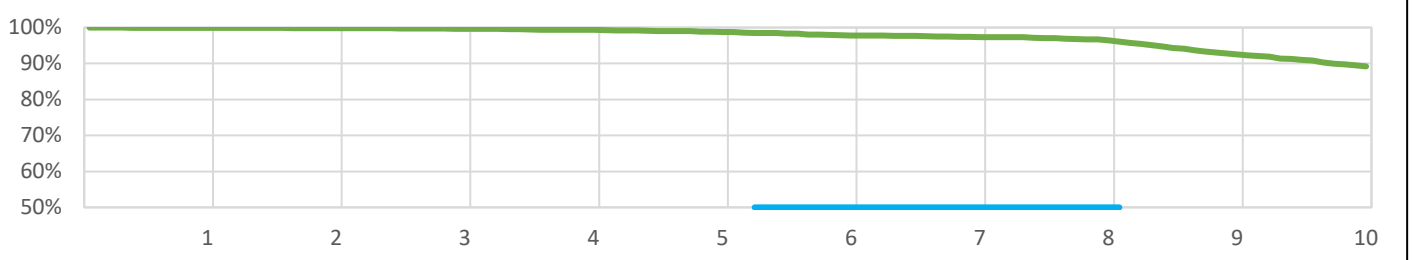
ALTRUA 20 SR

Model: S201/S204

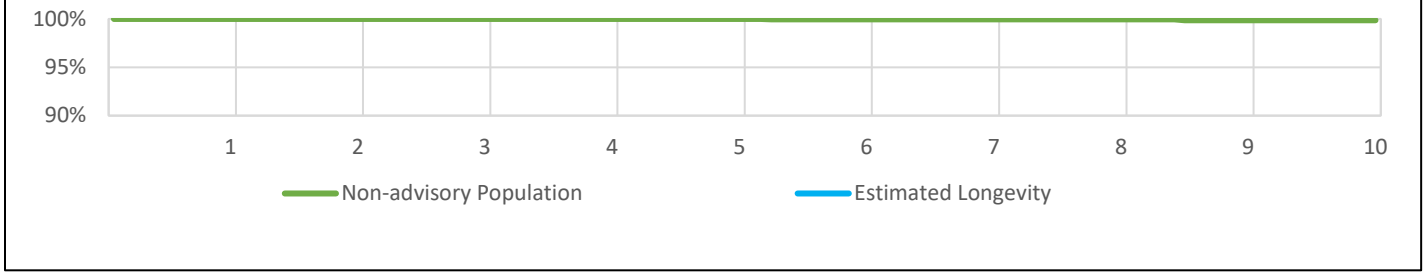
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	224
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	1,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.8%	97.9%	97.4%	96.7%	92.8%	89.5%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
5,000	Effective Sample Size	3566	3032	2604	2276	1997	1741	1528	1338	1112	800

ALTRUA 20 SR

Models: S201/S204

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Other			
Non-patterned, other	1	0	1
Battery status (49)	0	3	3
Grand Total	**1**	**4**	**5**

References cited in table above (link)

ALTRUA 20 DDD

Models: S207

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**1,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

ALTRUA 20 SSI

Models: S206

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterend, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

Confirmed Malfunction Details: Pulse Generator References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each pulse generator confirmed malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

3. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory.*Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
4. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory*.Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
5. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory.*Premature battery depletion. Misaligned battery component. Improvement implemented.
6. **Subpectoral implant 2009**— *December 01, 2009 Voluntary Physician Advisory.*Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subpectorally. Weakened bond between header and titanium case. Improvement implemented.
7. **Respiratory Sensor Oversensing**— *March 23, 2009 Voluntary Physician Advisory.*Oversensing, noise, inappropriate shock, pacing inhibition. When Respiratory Sensor is ON, RV lead or system complications may cause oversensing or noise. Improvement implemented.
8. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory.*Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
9. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.*Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
10. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.*At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
11. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
12. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
13. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
14. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
15. **Capacitor**— No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.
16. **Capacitor array**— Loss of device output, loss of capture, inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.
17. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
18. **Battery depletion**— Premature battery depletion and loss of capture.
19. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
20. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
21. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
22. **Battery depletion**— Premature battery depletion.
23. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
24. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
25. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
26. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.

27. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
28. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
29. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
30. **Integrated circuit**— Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing, loss of shock therapy. Damage to integrated circuit. Improvement implemented.
31. **Alert messages**— During programmer interactions, alert messages appear which are able to be cleared. In one case, an alert message occurred with two memory errors after multiple device resets.
32. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
33. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
34. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
35. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
36. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
37. **Solder joint**— Inappropriate shocks, beeping, fallback mode, errors or inability to interrogate or program. Cracked solder joint due to repetitive mechanical stress-induced component damage, only when implanted subpectorally with serial number facing the ribs.
38. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
39. **Connector block**— Connector block can be moved out of alignment or displaced from header. Prolonged implant procedure, high impedance, no pacing, no sensing. Improvement implemented.
40. **Seal plug**— Non-cardiac signals on electrograms may result in loss of pacing or inappropriate shocks. Seal plug allows air in lead port to escape.
41. **Difficulty securing lead**— Noise, high impedance, inappropriate shocks or loss of therapy due to crossthreaded setscrews, intermittent or lack of contact between lead and header. Improvement implemented.
42. S**afety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
43. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
44. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
45. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
46. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
47. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
48. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
49. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
50. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
51. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
52. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
53. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
54. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
55. **Shortened replacement time 2018** *November 2018 Voluntary Physician Advisory.* Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
56. **Telemetry**— Inability to interrogate, premature battery depletion.
57. **Unintended Battery Depletion Alert**— Beeping tones, Battery Depletion alert during followup despite normal battery depletion. Alert may be cleared without impact to battery status or therapy availability. Improvement implemented.
58. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
59. **Respiratory sensor**— Temporary increase or decrease in pacing rate as a result of respiratory sensor response to non-respiratory signals. No loss of pacing output.
60. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.
61. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
62. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
63. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented

64. **Safety Core-unintended biventricular pacing**— *Dec 2017 Voluntary Physician Advisory.* Device enters Safety Core after detecting unintended asynchronous biventricular pacing due to software issue.
65. **Memory corruption** - *Jun 2017 Voluntary Physician Advisory.* Atypical energy delivery, error messages upon interrogation, loss of tachy therapy. Memory corruption. Improvement implemented.
67. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.
68. **Telemetry**— Alert message during followup, inability to interrogate, premature battery depletion, loss of pacing therapy. Telemetry component.
69. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion.
70. **Hydrogen induced premature depletion - September 2018 -** *September 2018 Voluntary Physician Advisory*. Premature battery depletion. Diminished low voltage capacitor performance.
71. **Battery –** Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
72. **Capacitor**— Premature battery depletion. Diminished capacitor performance
73. **Misaligned markers**— Stored episode markers do not match recorded EGM.
74. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement Implemented.
75. **High voltage capacitor**— Charge time alert message, end of life (EOL) indicator displayed, beeping tones. Loss of tachy therapy without loss of brady therapy. Internal high-voltage capacitor issue. Improvement implemented.
76. **Internal insulation**— Beeping tones, loss of telemetry, premature battery depletion, loss of tachy therapy. Internal insulation issue.
77. **S-ICD battery depletion 2019 and 2020 –** *August 2019 and December 2020 Voluntary Physician Advisory.* Premature battery depletion. Diminished capacitor performance.
78. **Solder joint**— Beeping tones, device errors, loss of tachy therapy. Cracked solder joint.
79. **Battery cathode—** Safety mode operation, inability to interrogate, loss of brady therapy. Internal battery cathode issue.
80. **EMBLEM S-ICD electrical overstress 2020—** *December 2020 Voluntary Physician Advisory*. Beeping tones, loss of telemetry, loss of sensing, premature battery depletion, loss of tachy therapy.
81. **RF antenna—** Beeping tones, loss of telemetry, loss of sensing, premature battery depletion, loss of tachy therapy. Exposed antenna issue.
82. **High battery impedance initiating safety mode 2021—** *June 2021 Voluntary Physician Advisory.* Safety mode operation, system resets. Temporary reduction in battery voltage later in device life.
83. **Hydrogen induced premature depletion June 2021—** *June 2021 Voluntary Physician Advisory*. Premature battery depletion. Diminished low voltage capacitor performance.
84. **Battery depletion—** Beeping tones, device errors, premature battery depletion.
85. **Memory corruption**— Inability to interrogate, error messages upon interrogation, inappropriate shocks, loss of tachy therapy, and/or inaccurate patient information. Product returned with evidence of transient memory corruption.

Before/During Implant Procedure - Worldwide Malfunctions: Pulse Generators

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling (e.g. radiation) is not reported as device malfunction here.
The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.

CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/ G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/ G447/G448/G524/G525/G526/G528/G537/G547/G548	91,000	1	2	4	8	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	24,000	3	0	0	4	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	118,000	3	4	5	16	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	83,000	5	0	2	3	0	0
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	24,000	0	0	1	4	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	7	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	50,000	0	1	2	3	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	38,000	1	3	2	1	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	17,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	16,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	64,000	1	0	3	4	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	70,000	0	3	2	3	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	30,000	1	0	4	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	29,000	2	0	0	3	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	97,000	1	0	5	62	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	27	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	289,000	7	3	4	13	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	473,000	6	0	9	22	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	172,000	3	1	2	15	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	76,000	1	1	0	4	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	218,000	4	0	1	15	0	0
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	86,000	0	0	1	5	0	0

U.S. Reason for Out of Service

As requested by the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Boston Scientific provides reasons for device explant or out of service, if known. The reasons consist of normal battery depletion, unconfirmed premature battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical condition, (such as infection), or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.

The counts for normal battery depletion, unconfirmed premature battery depletion, and device malfunction are reflected in the U.S. survival probability data. Reason for device explant or out of service may either be confirmed through laboratory analysis (as in the case of device malfunction) or it may be reported to Boston Scientific with no associated device return or laboratory analysis. Although a device may be indicated by the health care provider to have been taken out of service for more than one reason, the table below indicates only one reason per device in category counts.

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548	49000	18	156	8	536	3142
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/ G156/G158	72000	519	358	60	1123	11657
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/ N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	53000	4822	425	798	925	18764
COGNIS N118/N119/N120/P106/P107/P108	75000	14117	426	2101	1662	39498

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
VISIONIST/VALITUDE U125/U128/U225/U226/U228	41000	174	842	44	293	5533
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	10000	773	212	184	77	4274
CONTAK RENEWAL TR H120/H125	19000	4288	207	67	208	11985

S-ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
EMBLEM S-ICD A209, A219	44000	241	452	1316	887	4369
SQ-RX S-ICD 1010	8000	2006	206	100	250	1890

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	28000	5	442	6	246	1170
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	16000	6	293	3	145	633
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	46000	49	1749	26	586	5003
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	37000	23	1592	25	460	3740
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	10000	1038	374	16	125	1763
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	9000	155	386	9	123	1416
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	175	2144	1174	553	10117
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	492	2455	1183	676	12955

ICD/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
TELIGEN VR E102/E103/F102/F103	38000	879	1787	2350	657	16555
TELIGEN DR E110/E111/F110/F111	66000	7498	2797	3013	1141	30362

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	121000	116	2909	410	582	8785
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	224000	1048	4906	906	1083	26994
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	43000	133	1238	270	207	8474
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	68	425	26	53	2692
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	121000	8625	3580	283	549	36083
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	145	674	13	108	11202

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 60 SR S601	32000	3419	479	22	144	18397
ALTRUA 60 DR (Downsize) S603	90000	25127	1251	101	469	40395
ALTRUA 60 DR S602	22000	3998	468	40	160	10111
ALTRUA 60 DR EL S606	59000	6825	1354	60	354	23939
ALTRUA 40 SR S401	5000	485	52	2	17	2994
ALTRUA 40 DR (downsize) S403	14000	3943	164	4	63	6810
ALTRUA 40 DR S402	2000	286	32	1	7	951
ALTRUA 40 DR EL S404	5000	577	86	5	33	2493
ALTRUA 20 SR S201/S204	5000	222	42	2	31	2985
ALTRUA 20 DR EL S208	3000	173	47	5	10	1659

[1] Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned.. U.S. confirmed malfunction counts are reflected in U.S. survival probability.

[2] System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.

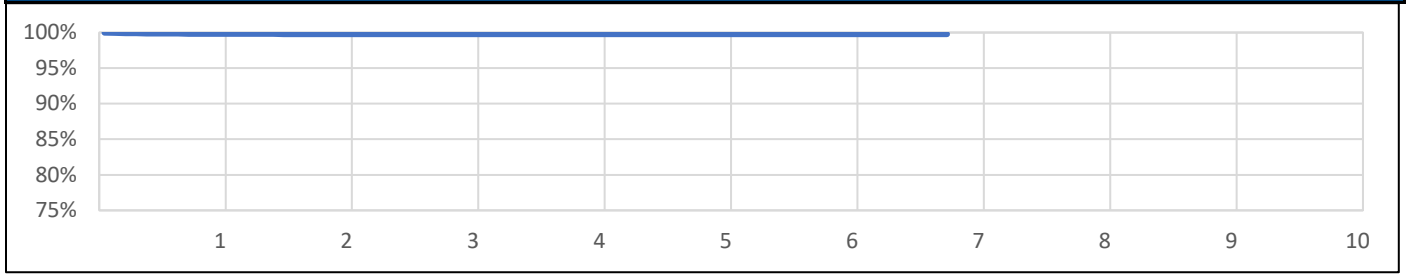
[3] Other consists of: patient death, electrive replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

ACUITY X4 Spiral L

Models: 4677/4678

US Summary			
US Registered Implants:	16,000	US Chronic Complications	32
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	14,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	--	--	--	
Registered Implants: 16000	Effective Sample Size	12569	9489	6477	3767	1718	344	215	--	--	--	@ 81 months

ACUITY X4 Spiral L

Models: 4677/4678

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**39,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

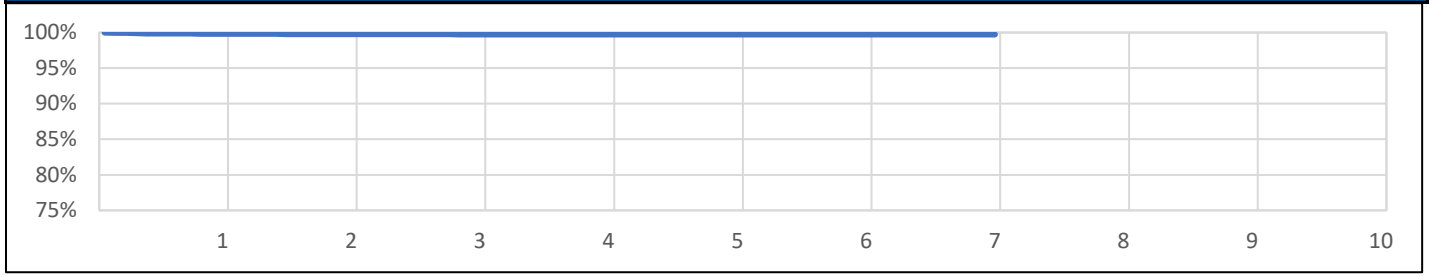
References cited in table above (link)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	47,000	US Chronic Complications	98
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	42,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	--	--	--	
Registered Implants: 47000	Effective Sample Size	35362	25718	16798	9638	4016	517	211	--	--	--	@ 84 months

ACUITY X4 Spiral S

Models: 4674/4675

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**99,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

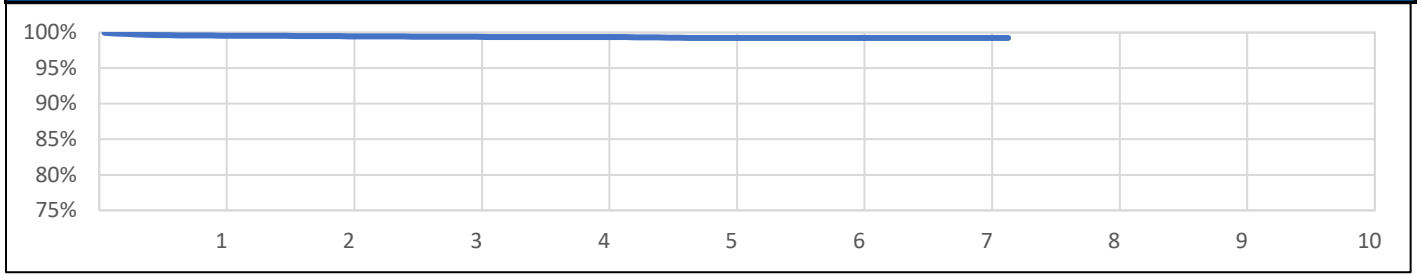
References cited in table above (link)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	36,000	US Chronic Complications	181
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	31,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.6%	99.5%	99.4%	99.4%	99.2%	99.2%	99.2%	99.2%	--	--	
Registered Implants: 36000	Effective Sample Size	26431	18882	12098	6746	2716	484	249	216	--	--	@ 86 months

ACUITY X4 Straight

Models: 4671/4672

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**80,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

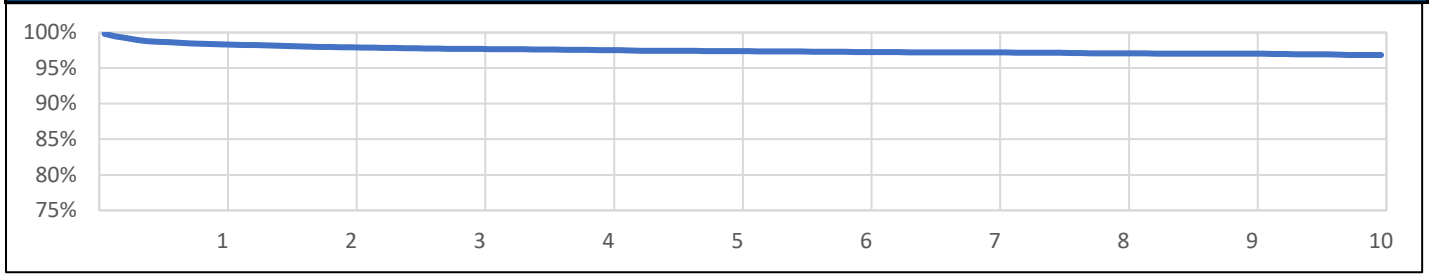
References cited in table above (link)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	24,000	US Chronic Complications	569
US Approval Date:	May 2008	US Malfunctions:	9
US Estimated Active Implants:	12,000	Without Compromised Therapy:	5
		With Compromised Therapy:	4

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.3%	97.9%	97.7%	97.5%	97.4%	97.3%	97.2%	97.1%	97.0%	96.8%
Registered Implants: 24000	Effective Sample Size	19927	17666	15681	13857	12218	10626	8833	6803	4952	3423

ACUITY Spiral

Models: 4591/4592/4593

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**46,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	5	9
Grand Total	**4**	**5**	**9**

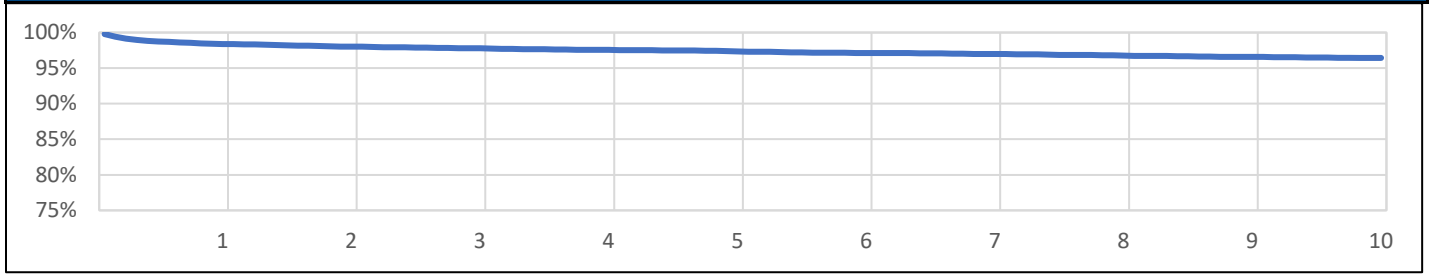
References cited in table above (link)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	738
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	13,000	Without Compromised Therapy:	12
		With Compromised Therapy:	21

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.4%	98.0%	97.8%	97.6%	97.3%	97.1%	97.0%	96.8%	96.6%	96.4%
Registered Implants: 29000	Effective Sample Size	24533	21930	19647	17630	15802	14020	12027	9733	7568	5771

ACUITY Steerable

Models: 4554/4555/4556

Worldwide Confirmed Malfunctions	**57**
Worldwide Distribution	**65,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	8	36
Other			
Non-patterned, other	10	11	21
Grand Total	**38**	**19**	**57**

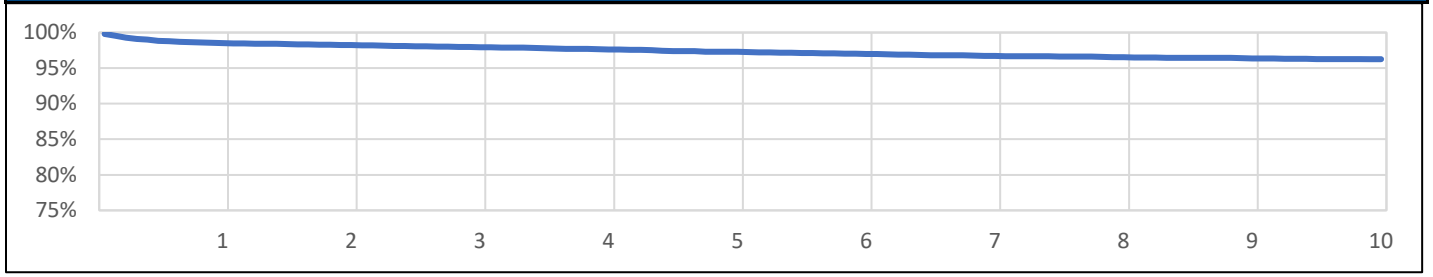
References cited in table above (link)

EASYTRAK 3

Models: 4522/4524/4525/4527/4548/4549/4550

US Summary			
US Registered Implants:	22,000	US Chronic Complications	564
US Approval Date:	August 2004	US Malfunctions:	32
US Estimated Active Implants:	8,000	Without Compromised Therapy:	9
		With Compromised Therapy:	23

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.5%	98.2%	97.9%	97.6%	97.3%	97.0%	96.7%	96.5%	96.4%	96.3%
Registered Implants: 22000	Effective Sample Size	18418	16447	14726	13167	11746	10419	9024	7497	6034	4831

EASYTRAK 3

Models: 4522/4524/4525/4527/4548/4549/4550

Worldwide Confirmed Malfunctions	**52**
Worldwide Distribution	**43,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	6	34
Other			
Non-patterned, other	7	11	18
Grand Total	**35**	**17**	**52**

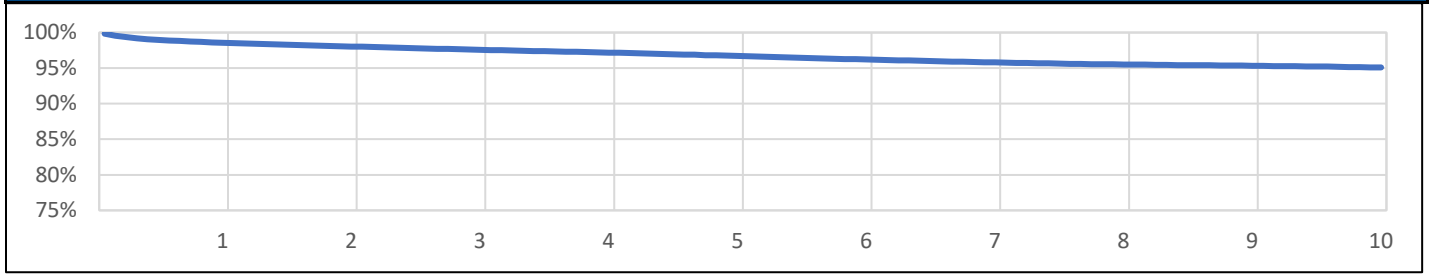
References cited in table above (link)

EASYTRAK 2

Models: 4515/4517/4518/4520/4542/4543/4544

US Summary			
US Registered Implants:	97,000	US Chronic Complications	2,938
US Approval Date:	August 2004	US Malfunctions:	405
US Estimated Active Implants:	33,000	Without Compromised Therapy:	146
		With Compromised Therapy:	259

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.6%	98.0%	97.6%	97.2%	96.7%	96.2%	95.8%	95.5%	95.3%	95.1%
Registered Implants: 97000	Effective Sample Size	82256	73306	65439	58464	52061	45909	39508	32955	26936	21824

EASYTRAK 2

Models: 4515/4517/4518/4520/4542/4543/4544

Worldwide Confirmed Malfunctions	**548**
Worldwide Distribution	**180,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (25)	329	149	478
Other			
Non-patterned, other	39	31	70
Grand Total	**368**	**180**	**548**

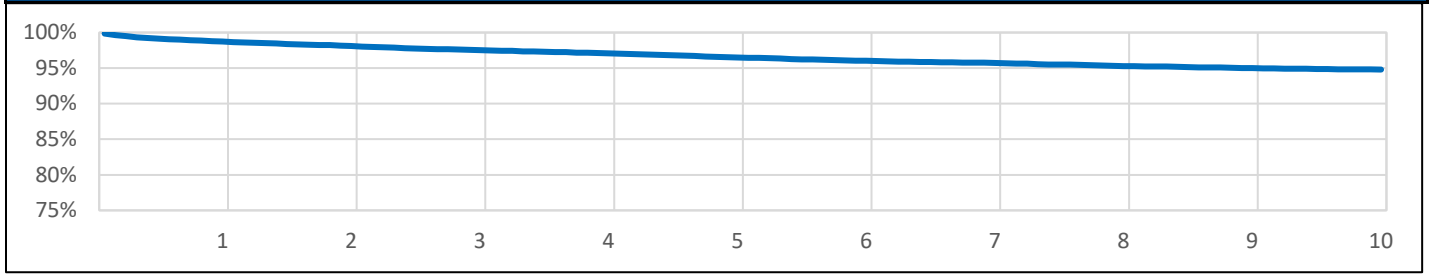
References cited in table above (link)

EASYTRAK

Models: 4510/4511/4512/4513/4535/4536/4537/4538

US Summary			
US Registered Implants:	38,000	US Chronic Complications	1,133
US Approval Date:	May 2002	US Malfunctions:	94
US Estimated Active Implants:	5,000	Without Compromised Therapy:	9
		With Compromised Therapy:	85

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.7%	98.1%	97.5%	97.1%	96.5%	96.0%	95.7%	95.3%	95.0%	94.8%
Registered Implants: 38000	Effective Sample Size	30327	26080	22383	19248	16434	14056	12055	10487	9252	8214

EASYTRAK

Models: 4510/4511/4512/4513/4535/4536/4537/4538

Worldwide Confirmed Malfunctions	**106**
Worldwide Distribution	**53,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	96	10	106
Grand Total	**96**	**10**	**106**

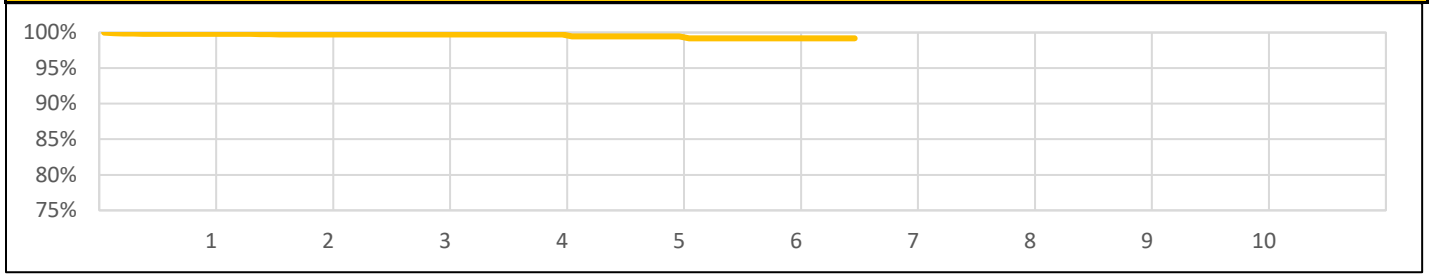
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0653/0658/0675/0676/0695/0696

US Summary			
US Registered Implants:	7,000	US Chronic Complications	17
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	7,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.7%	99.7%	99.5%	99.2%	99.2%	--	--	--	
Registered Implants: 7000	Effective Sample Size	4495	2115	479	381	340	291	206	--	--	--	@ 78 months

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0653/0658/0675/0676/0695/0696

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**25,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	0	4
Grand Total	**4**	**0**	**4**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

Models: 0636/0651/0655/0665/0685/0686

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**1,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

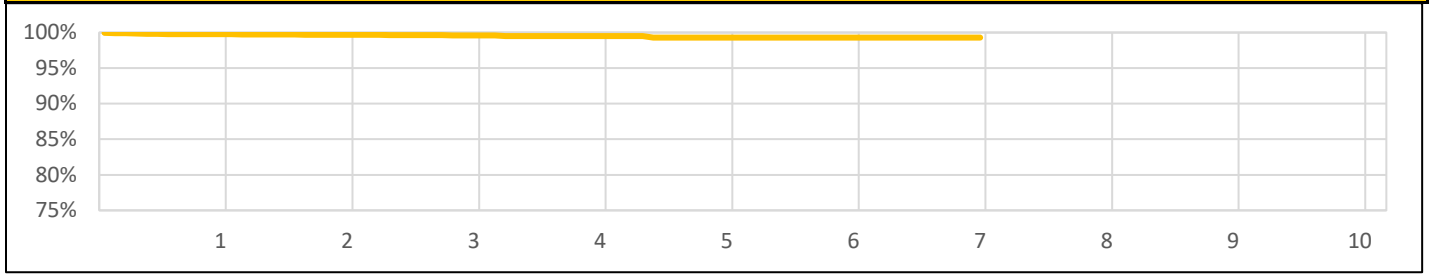
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Summary			
US Registered Implants:	49,000	US Chronic Complications	114
US Approval Date:	May 2018	US Malfunctions:	8
US Estimated Active Implants:	46,000	Without Compromised Therapy:	-
		With Compromised Therapy:	8

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.3%	99.3%	99.3%	--	--	--	
	Effective Sample Size	28371	12581	1487	921	825	718	239	--	--	--	@ 84 months
Registered Implants: 49000												

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0652/ 0657/0672/0673/0692/0693

Worldwide Confirmed Malfunctions	**62**
Worldwide Distribution	**165,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	23	0	23
Other			
Non-patterned, other	36	3	39
Grand Total	**59**	**3**	**62**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

Models: 0650/0654/0662/0663/0682/0683

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	1	0	1
Grand Total	**1**	**0**	**1**

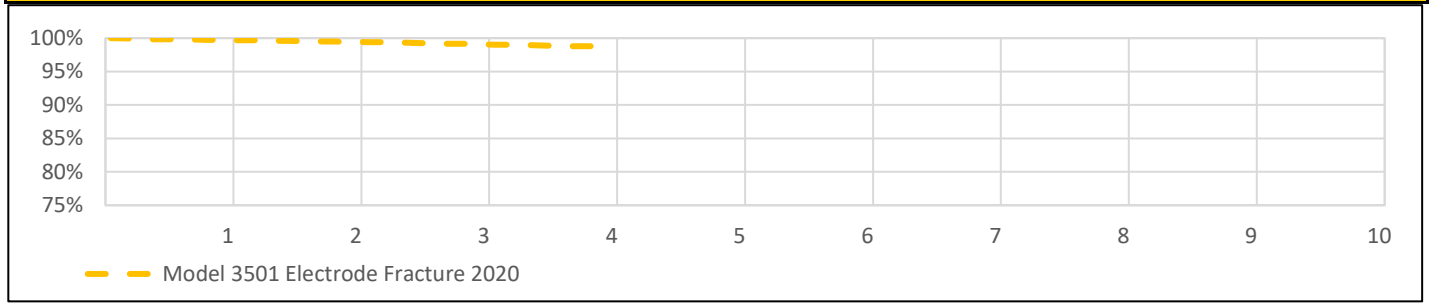
References cited in table above (link)

EMBLEM S-ICD Electrode

Models: 3501

US Summary			
US Registered Implants:	23,000	US Chronic Complications	82
US Approval Date:	September 2017	US Malfunctions:	35
US Estimated Active Implants:	21,000	Without Compromised Therapy:	-
		With Compromised Therapy:	35

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Model 3501 Electrode Fracture 2020	Complications and Malfunctions	99.7%	99.5%	99.1%	98.8%	--	--	--	--	--	--	
Registered Implants: 21000	Effective Sample Size	15744	9680	4140	276	--	--	--	--	--	--	@ 48 months

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

**The enhanced version (non-advisory population) of the Model 3501 EMBLEM S-ICD Electrode has not reached sufficient age for the survival probability to be included in this report. We anticipate inclusion in subsequent reports.

EMBLEM S-ICD Electrode

Models: 3501

Worldwide Confirmed Malfunctions	**100**
Worldwide Distribution	**57,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Model 3501 electrode fracture 2020 (42)	50	0	50
Electrode conductor fracture in or near the pocket (44)	46	1	47
Other			
Non-patterned, other	3	0	3
Grand Total	**99**	**1**	**100**

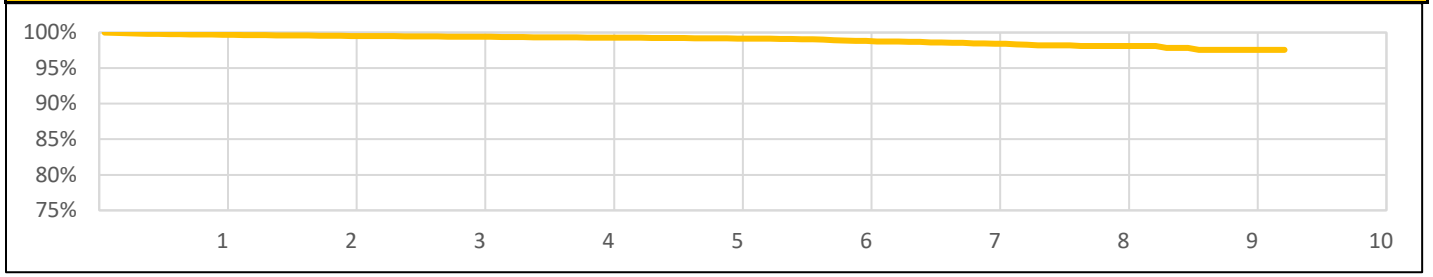
References cited in table above (link)

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

US Summary			
US Registered Implants:	24,000	US Chronic Complications	178
US Approval Date:	September 2012	US Malfunctions:	17
US Estimated Active Implants:	19,000	Without Compromised Therapy:	2
		With Compromised Therapy:	15

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.4%	99.3%	99.2%	98.8%	98.4%	98.1%	97.6%	97.6%	
Registered Implants: 24000	Effective Sample Size	21035	18703	16597	14143	9060	4881	1987	506	294	256	@ 111 months

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

Worldwide Confirmed Malfunctions	**48**
Worldwide Distribution	**43,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Electrode conductor fracture in or near the pocket (44)	21	1	22
Crimp/Weld/Bond			
Weld fracture (37)	3	0	3
Other			
Non-patterned, other	18	5	23
Grand Total	**42**	**6**	**48**

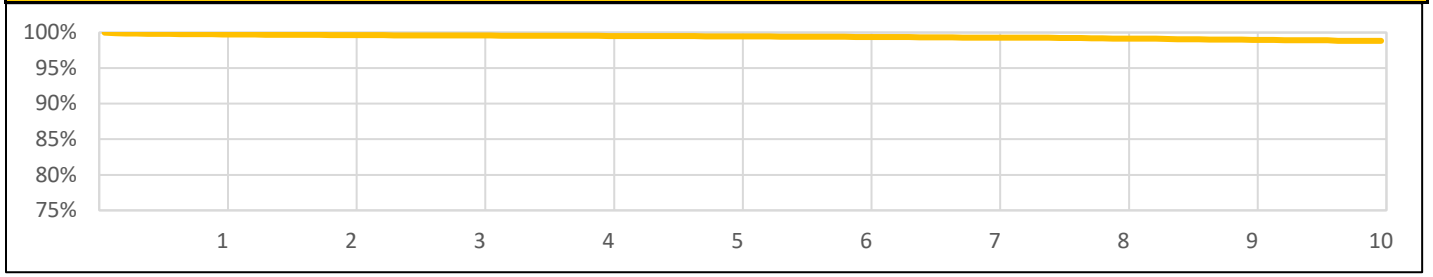
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Summary			
US Registered Implants:	77,000	US Chronic Complications	385
US Approval Date:	November 2010	US Malfunctions:	30
US Estimated Active Implants:	58,000	Without Compromised Therapy:	5
		With Compromised Therapy:	25

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.5%	99.4%	99.3%	99.2%	99.0%	98.8%
Registered Implants: 77000	Effective Sample Size	67508	59480	50945	41509	33263	25594	18277	11379	4777	253

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

Worldwide Confirmed Malfunctions	**65**
Worldwide Distribution	**124,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Non-patterned, other	50	12	62
Grand Total	**53**	**12**	**65**

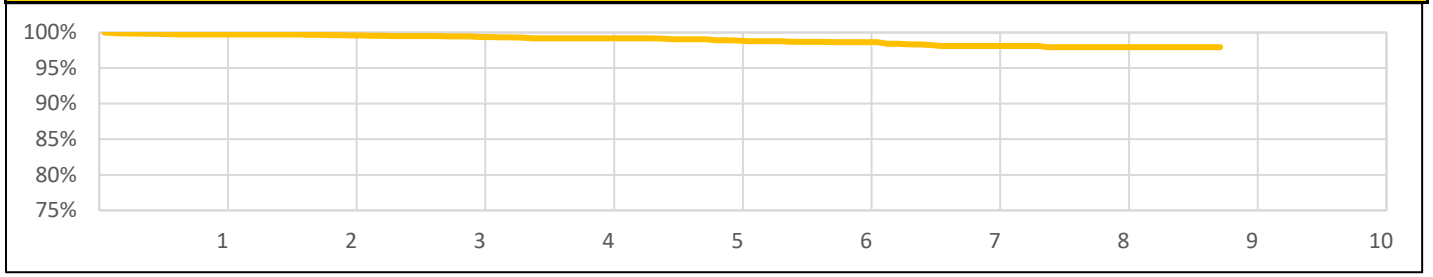
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Summary			
US Registered Implants:	3,000	US Chronic Complications	33
US Approval Date:	Novemeber 2010	US Malfunctions:	2
US Estimated Active Implants:	3,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.4%	99.2%	98.9%	98.6%	98.1%	97.9%	97.9%	--	
Registered Implants: 3000	Effective Sample Size	2937	2562	2166	1768	1410	1071	739	397	209	--	@ 105 month

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	3	3
Grand Total	**0**	**3**	**3**

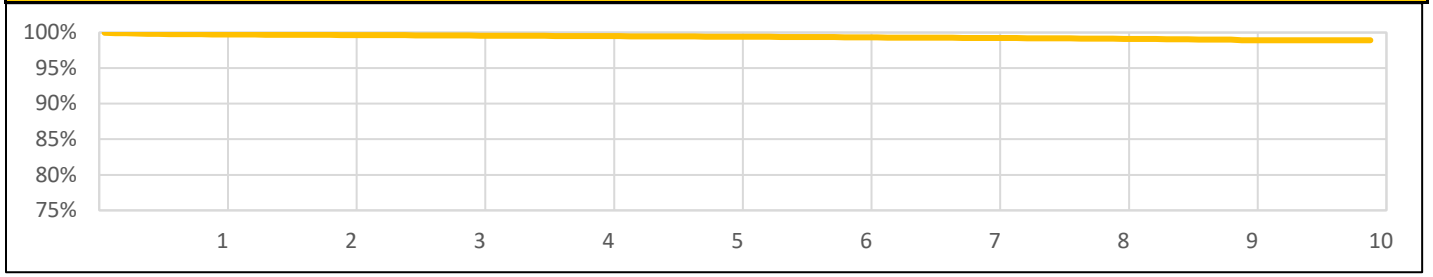
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Summary			
US Registered Implants:	119,000	US Chronic Complications	587
US Approval Date:	November 2010	US Malfunctions:	42
US Estimated Active Implants:	98,000	Without Compromised Therapy:	9
		With Compromised Therapy:	33

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%	98.9%	
Registered Implants: 119000	Effective Sample Size	105129	93387	79064	55633	38054	24621	14293	6983	2399	400	@ 119 months

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

Worldwide Confirmed Malfunctions	**86**
Worldwide Distribution	**206,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	9	0	9
Other			
Non-patterned, other	62	15	77
Grand Total	**71**	**15**	**86**

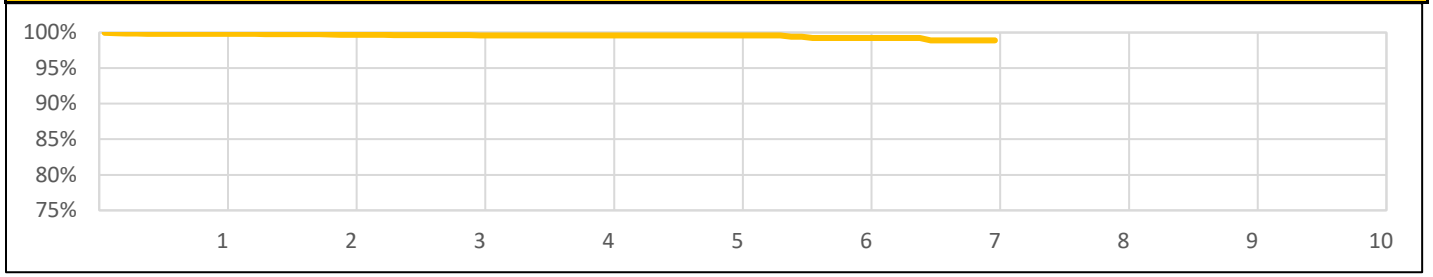
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Summary			
US Registered Implants:	16,000	US Chronic Complications	15
US Approval Date:	November 2010	US Malfunctions:	4
US Estimated Active Implants:	15,000	Without Compromised Therapy:	-
		With Compromised Therapy:	4

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.6%	99.6%	99.2%	98.9%	--	--	--	
Registered Implants: 16000	Effective Sample Size	10112	5310	1537	1067	686	407	206	--	--	--	@ 84 months

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	3	1	4
Grand Total	**3**	**1**	**4**

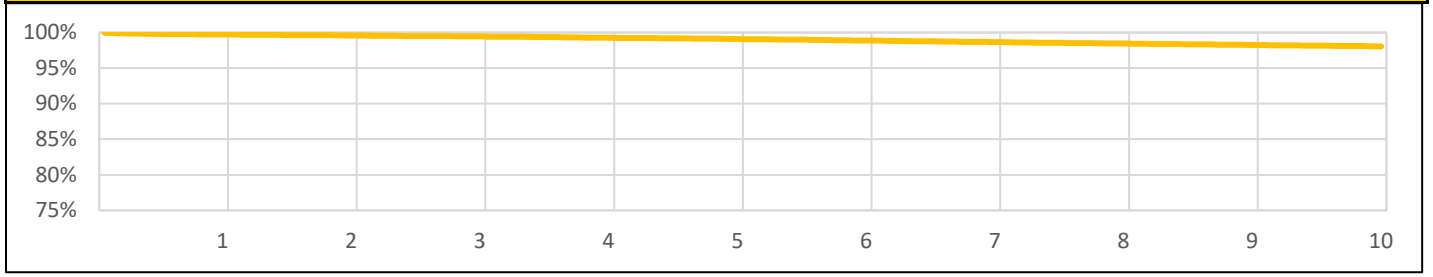
References cited in table above (link)

ENDOTAK RELIANCE Dual Coil, Active Fixation

Models: 0157/0158/0159/0164/0165/0166/0167/0184/0185/0186/0187

US Summary			
US Registered Implants:	287,000	US Chronic Complications	3,579
US Approval Date:	July 2002	US Malfunctions:	383
US Estimated Active Implants:	108,000	Without Compromised Therapy:	122
		With Compromised Therapy:	261

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.4%	99.3%	99.1%	98.9%	98.6%	98.5%	98.2%	98.0%
Registered Implants: 287000	Effective Sample Size	252093	226251	203159	182290	163444	146206	130415	116031	102363	88555

ENDOTAK RELIANCE Dual Coil, Active Fixation

Models: 0157/0158/0159/0164/0165/0166/0167/0184/0185/0186/0187

Worldwide Confirmed Malfunctions	**582**
Worldwide Distribution	**381,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	106	0	106
Crimp/Weld/Bond			
Seal rings (5)	2	2	4
Other			
Non-patterned, other	270	202	472
Grand Total	**378**	**204**	**582**

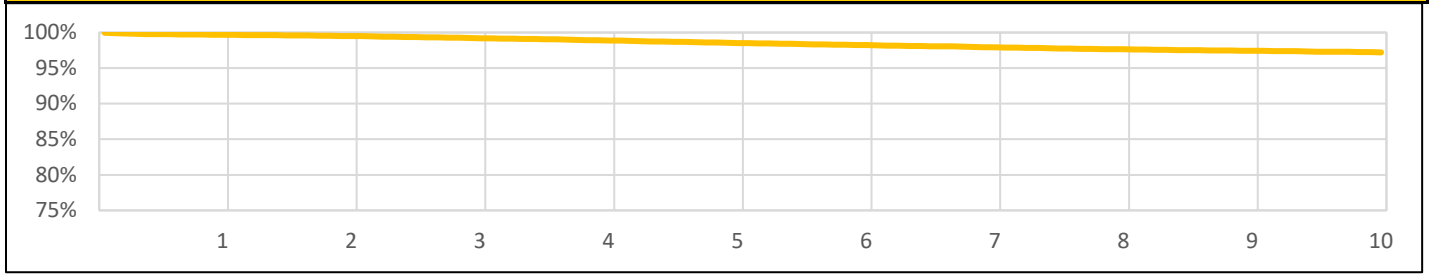
References cited in table above (link)

ENDOTAK RELIANCE Dual Coil, Passive Fixation

Models: 0147/0148/0149/0174/0175/0176/0177

US Summary			
US Registered Implants:	47,000	US Chronic Complications	893
US Approval Date:	October 2000	US Malfunctions:	60
US Estimated Active Implants:	14,000	Without Compromised Therapy:	14
		With Compromised Therapy:	46

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.2%	98.9%	98.5%	98.2%	97.9%	97.6%	97.4%	97.2%
Registered Implants: 47000	Effective Sample Size	40555	36391	32649	29240	26160	23393	20874	18630	16499	14456

ENDOTAK RELIANCE Dual Coil, Passive Fixation

Models: 0147/0148/0149/0174/0175/0176/0177

Worldwide Confirmed Malfunctions	**165**
Worldwide Distribution	**109,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	20	0	20
Crimp/Weld/Bond			
Conductor connection (36)	3	0	3
Other			
Non-patterned, other	86	55	141
Manufacturing material (6)	1	0	1
Grand Total	**110**	**55**	**165**

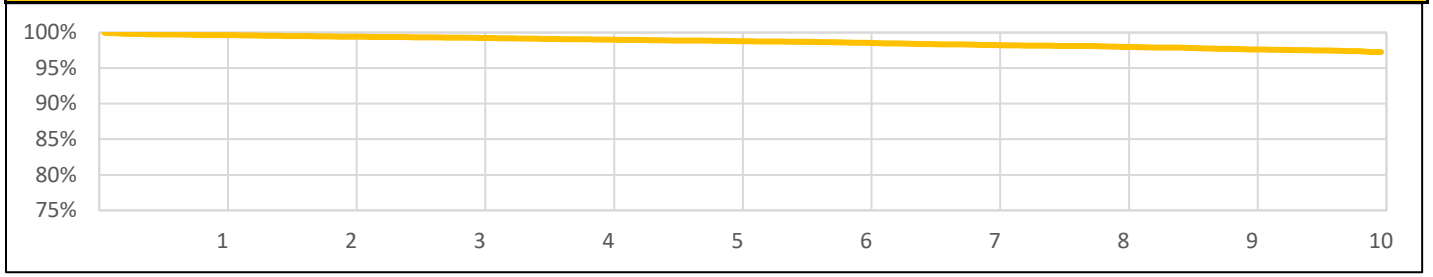
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Active Fixation

Models: 0137/0138/0160/0161/0162/0180/0181/0182

US Summary			
US Registered Implants:	34,000	US Chronic Complications	459
US Approval Date:	October 2000	US Malfunctions:	85
US Estimated Active Implants:	21,000	Without Compromised Therapy:	23
		With Compromised Therapy:	62

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.6%	99.4%	99.2%	99.0%	98.8%	98.5%	98.2%	98.0%	97.6%	97.3%
Registered Implants: 34000	Effective Sample Size	29370	26007	23006	20296	17826	15455	12929	10565	8337	6214

ENDOTAK RELIANCE Single Coil, Active Fixation

Models: 0137/0138/0160/0161/0162/0180/0181/0182

Worldwide Confirmed Malfunctions	**207**
Worldwide Distribution	**76,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	62	1	63
Other			
Non-patterned, other	88	56	144
Grand Total	**150**	**57**	**207**

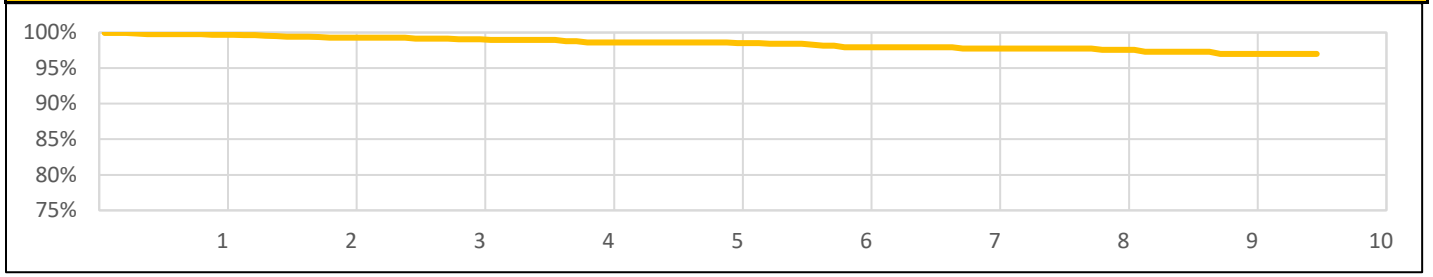
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Passive Fixation

Models: 0127/0128/0170/0171/0172/0173

US Summary			
US Registered Implants:	2,000	US Chronic Complications	34
US Approval Date:	October 2000	US Malfunctions:	4
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		With Compromised Therapy:	3

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.3%	99.1%	98.6%	98.5%	97.9%	97.8%	97.6%	97.0%	97.0%	
Registered Implants: 2000	Effective Sample Size	1548	1372	1216	1071	942	770	581	435	269	205	@ 114 month

ENDOTAK RELIANCE Single Coil, Passive Fixation

Models: 0127/0128/0170/0171/0172/0173

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Non-patterned, other	9	8	17
Grand Total	**12**	**8**	**20**

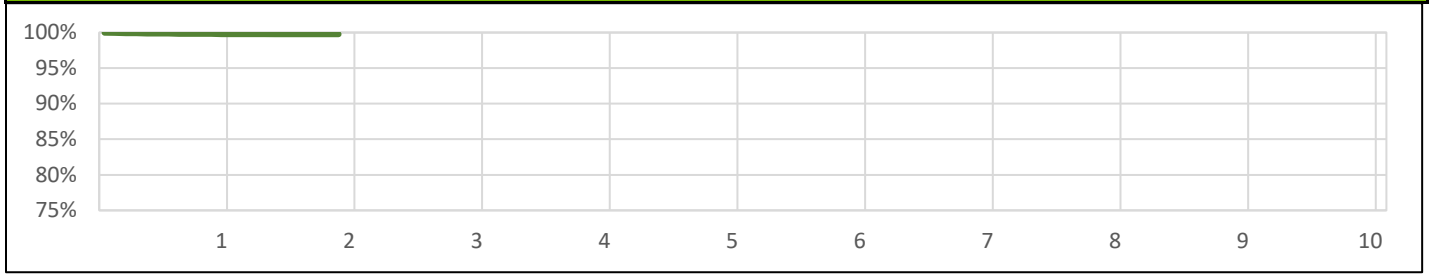
References cited in table above (link)

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

US Summary			
US Registered Implants:	150,000	US Chronic Complications	222
US Approval Date:	December 2019	US Malfunctions:	15
US Estimated Active Implants:	144,000	Without Compromised Therapy:	9
		With Compromised Therapy:	6

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	--	--	--	--	--	--	--	--	
Registered Implants: 150000	Effective Sample Size	51931	330	--	--	--	--	--	--	--	--	@ 23 months

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

Worldwide Confirmed Malfunctions	**15**
Worldwide Distribution	**174,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	1	3	4
Other			
Non-patterned, other	5	6	11
Grand Total	**6**	**9**	**15**

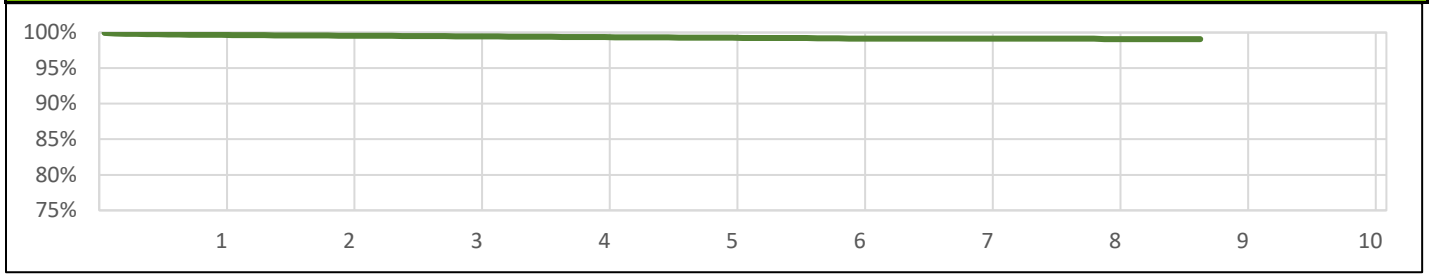
References cited in table above (link)

INGEVITY Positive Fixation

Models: 7640/7641/7642/7740/7741/7742

US Summary			
US Registered Implants:	365,000	US Chronic Complications	1,651
US Approval Date:	April 2016	US Malfunctions:	249
US Estimated Active Implants:	315,000	Without Compromised Therapy:	134
		With Compromised Therapy:	115

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.5%	99.4%	99.3%	99.1%	99.1%	99.1%	99.1%	--	
Registered Implants: 365000	Effective Sample Size	321643	267106	174004	96372	32205	1983	1779	1535	1370	--	@ 104 months

INGEVITY Positive Fixation

Models: 7640/7641/7642/7740/7741/7742

Worldwide Confirmed Malfunctions	**377**
Worldwide Distribution	**1,032,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	9	7	16
Extracardiac fracture (41)	93	113	206
Other			
Insulation (43)	2	16	18
Non-patterned, other	67	70	137
Grand Total	**171**	**206**	**377**

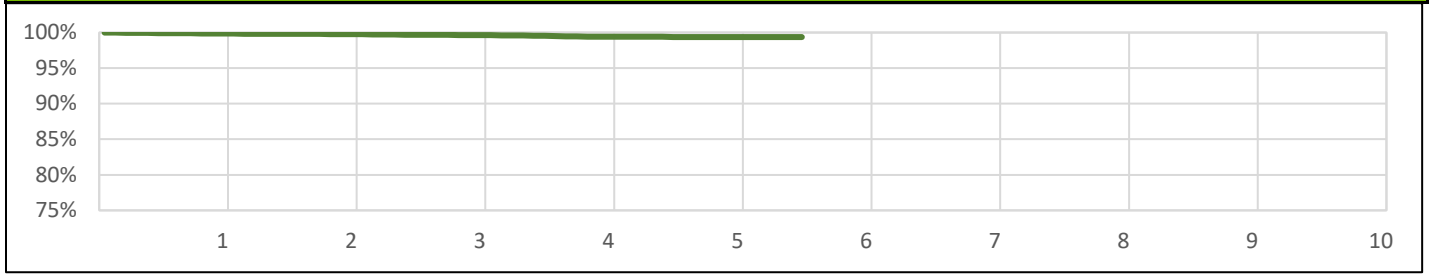
References cited in table above (link)

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary			
US Registered Implants:	24,000	US Chronic Complications	63
US Approval Date:	April 2016	US Malfunctions:	12
US Estimated Active Implants:	21,000	Without Compromised Therapy:	1
		With Compromised Therapy:	11

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.6%	99.4%	99.4%	99.4%	--	--	--	--	
Registered Implants: 24000	Effective Sample Size	17923	13317	8772	4895	1667	311	--	--	--	--	@ 66 months

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	**17**
Worldwide Distribution	**111,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	6	0	6
Other			
Insulation (43)	0	1	1
Non-patterned, other	10	0	10
Grand Total	**16**	**1**	**17**

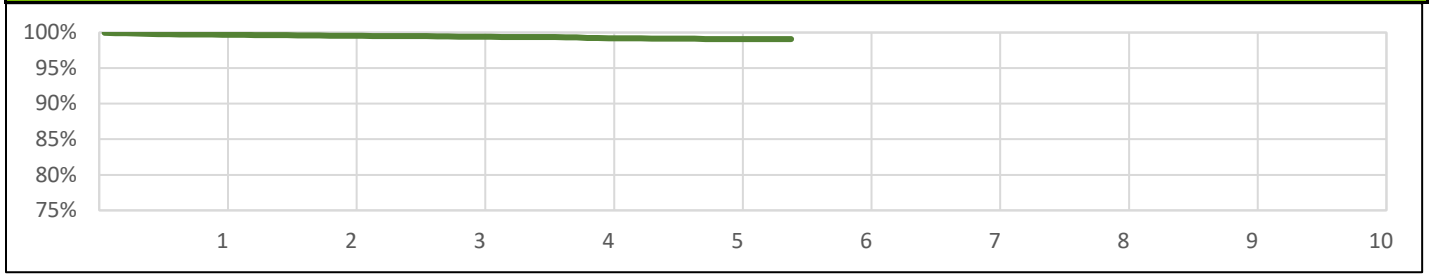
References cited in table above (link)

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	14,000	US Chronic Complications	61
US Approval Date:	April 2016	US Malfunctions:	7
US Estimated Active Implants:	12,000	Without Compromised Therapy:	7
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.4%	99.2%	99.1%	99.1%	--	--	--	--	
Registered Implants: 14000	Effective Sample Size	10286	7625	5019	2719	892	288	--	--	--	--	@ 65 months

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	**13**
Worldwide Distribution	**99,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	8	8
Crimp/Weld/Bond			
Weld (40)	0	1	1
Other			
Non-patterned, other	0	4	4
Grand Total	**0**	**13**	**13**

References cited in table above (link)

FLEXTEND 2 Positive Fixation

Models: 4095/4096/4097

Worldwide Confirmed Malfunctions	**127**
Worldwide Distribution	**185,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	17	6	23
Electrical			
Inner insulation abrasion (2)	2	5	7
Other			
Non-patterned, other	2	9	11
Conductor damage (32)	23	63	86
Grand Total	**44**	**83**	**127**

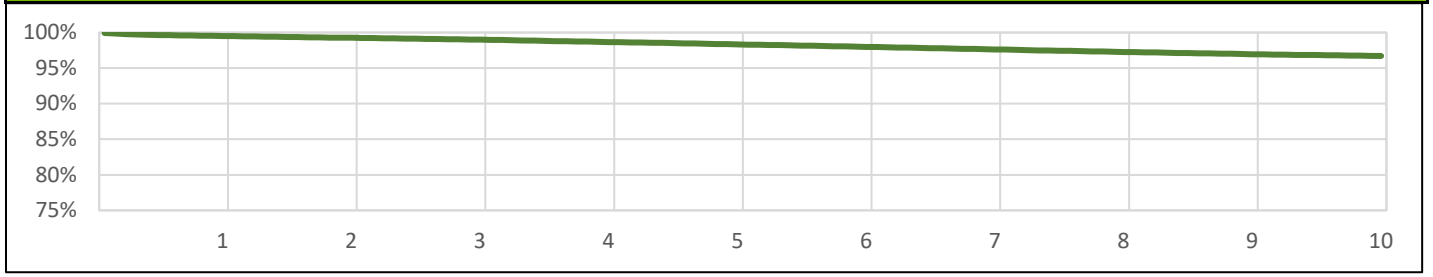
References cited in table above (link)

FLEXTEND Positive Fixation

Models: 4086/4087/4088

US Summary			
US Registered Implants:	235,000	US Chronic Complications	4,782
US Approval Date:	February 2002	US Malfunctions:	375
US Estimated Active Implants:	75,000	Without Compromised Therapy:	153
		With Compromised Therapy:	222

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.5%	99.3%	99.0%	98.7%	98.3%	98.0%	97.6%	97.3%	96.9%	96.7%
Registered Implants: 235000	Effective Sample Size	200306	179358	160701	143816	128488	113524	98615	84985	72695	61754

FLEXTEND Positive Fixation

Models: 4086/4087/4088

Worldwide Confirmed Malfunctions	**405**
Worldwide Distribution	**290,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	88	19	107
Electrical			
Inner insulation abrasion (2)	18	23	41
Other			
Non-patterned, other	11	18	29
Conductor damage (32)	123	105	228
Grand Total	**240**	**165**	**405**

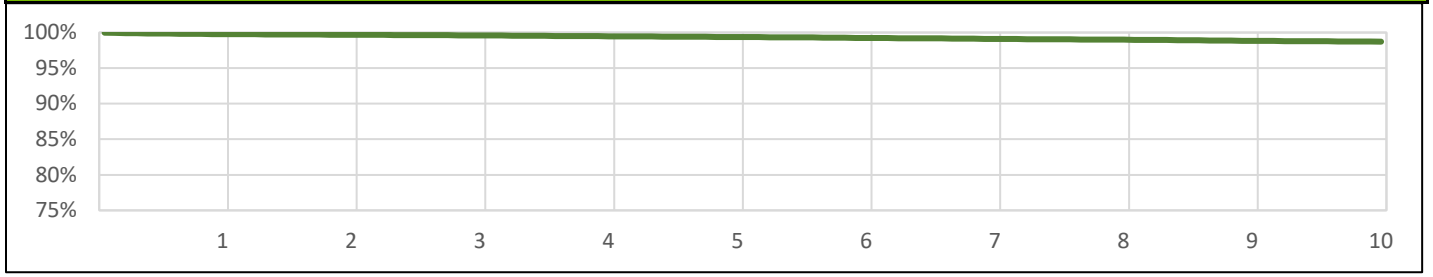
References cited in table above (link)

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models: 4463/4464/4465/4469/4470/4471

US Summary			
US Registered Implants:	505,000	US Chronic Complications	3,736
US Approval Date:	January 2000	US Malfunctions:	169
US Estimated Active Implants:	253,000	Without Compromised Therapy:	51
		With Compromised Therapy:	118

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.4%	99.2%	99.1%	99.0%	98.8%	98.7%
Registered Implants: 505000	Effective Sample Size	438752	386786	338249	295033	257173	221053	184796	152261	123544	98719

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models: 4463/4464/4465/4469/4470/4471

Worldwide Confirmed Malfunctions	**202**
Worldwide Distribution	**796,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	66	17	83
Crimp/Weld/Bond			
Terminal weld (23)	1	0	1
Other			
Lead body (4)	71	31	102
Non-patterned, other	8	8	16
Grand Total	**146**	**56**	**202**

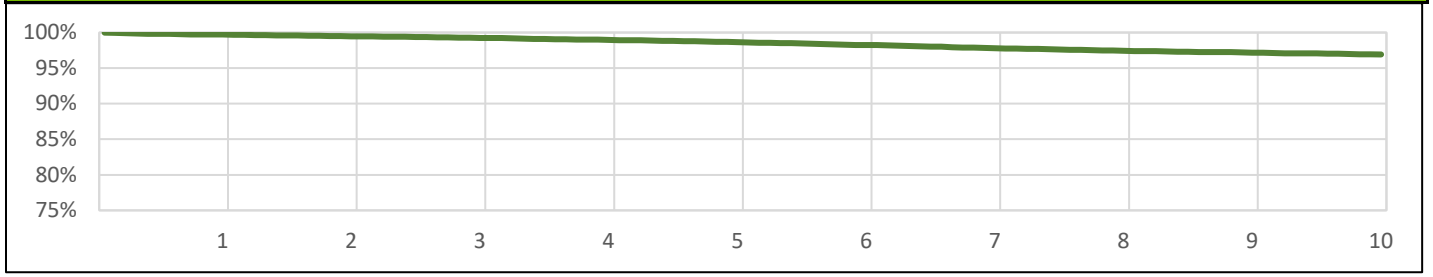
References cited in table above (link)

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models: 4466/4467/4468/4472/4473/4474

US Summary			
US Registered Implants:	53,000	US Chronic Complications	908
US Approval Date:	January 2000	US Malfunctions:	152
US Estimated Active Implants:	20,000	Without Compromised Therapy:	37
		With Compromised Therapy:	115

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.3%	99.0%	98.6%	98.3%	97.8%	97.4%	97.2%	96.9%
Registered Implants: 53000	Effective Sample Size	46311	41442	36973	32978	29341	25699	22047	18774	15747	13095

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models: 4466/4467/4468/4472/4473/4474

Worldwide Confirmed Malfunctions	**192**
Worldwide Distribution	**144,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	90	13	103
Other			
Conductor damage (32)	55	23	78
Lead body (4)	0	1	1
Non-patterned, other	3	7	10
Grand Total	**148**	**44**	**192**

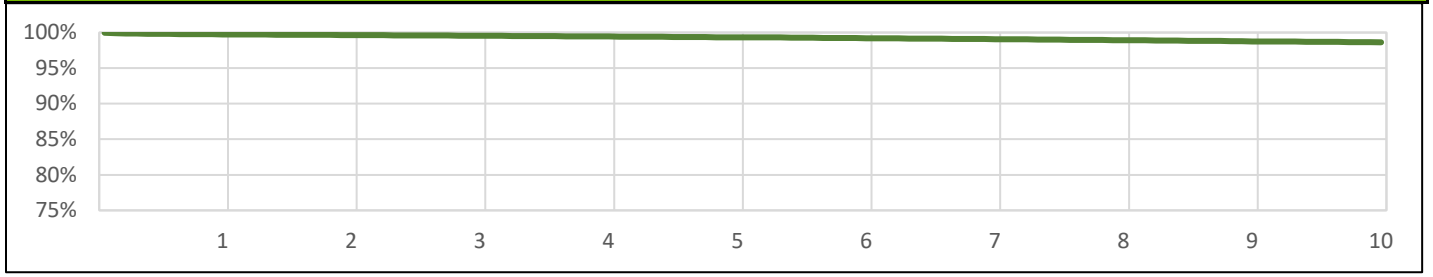
References cited in table above (link)

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

US Summary			
US Registered Implants:	196,000	US Chronic Complications	1,641
US Approval Date:	January 2000	US Malfunctions:	45
US Estimated Active Implants:	76,000	Without Compromised Therapy:	3
		With Compromised Therapy:	42

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%	98.8%	98.6%
Registered Implants: 196000	Effective Sample Size	169146	150912	134179	119109	105515	92001	77948	65113	53742	43897

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	**68**
Worldwide Distribution	**551,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	18	0	18
Other			
Lead body (4)	41	3	44
Non-patterned, other	5	1	6
Grand Total	**64**	**4**	**68**

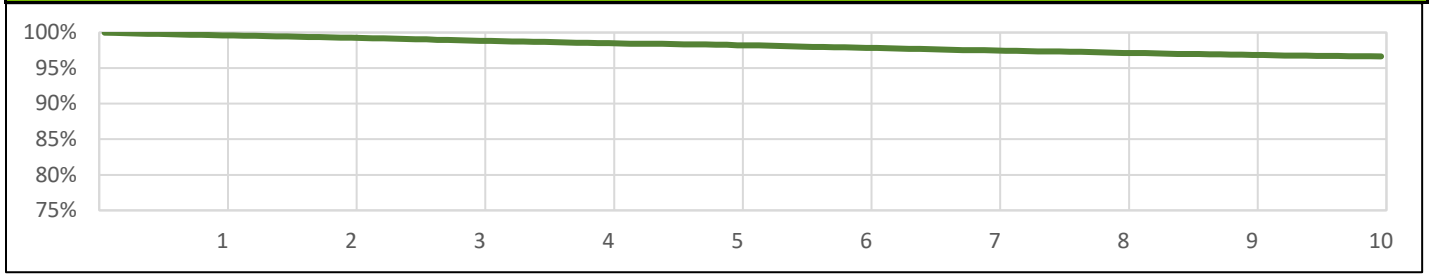
References cited in table above (link)

FINELINE II EZ/FINELINE II Sterox Passive Fixation (Silicone)

Models: 4454/4455/4458/4459

US Summary			
US Registered Implants:	14,000	US Chronic Complications	316
US Approval Date:	January 2000	US Malfunctions:	23
US Estimated Active Implants:	4,000	Without Compromised Therapy:	-
		With Compromised Therapy:	23

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.6%	99.3%	98.8%	98.5%	98.2%	97.8%	97.5%	97.1%	96.8%	96.6%
Registered Implants: 14000	Effective Sample Size	12303	11010	9805	8696	7733	6806	5928	5122	4421	3740

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models: 4454/4455/4458/4459

Worldwide Confirmed Malfunctions	**60**
Worldwide Distribution	**105,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	20	0	20
Other			
Conductor damage (32)	35	3	38
Non-patterned, other	2	0	2
Grand Total	**57**	**3**	**60**

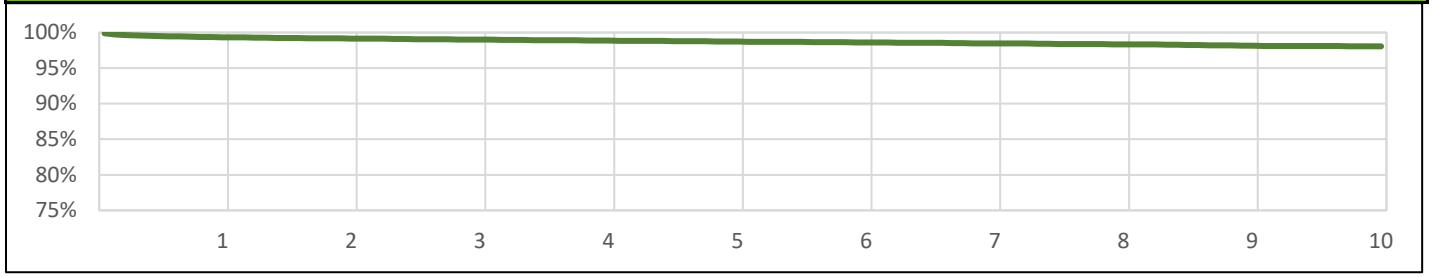
References cited in table above (link)

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary			
US Registered Implants:	63,000	US Chronic Complications	834
US Approval Date:	January 2000	US Malfunctions:	39
US Estimated Active Implants:	26,000	Without Compromised Therapy:	20
		With Compromised Therapy:	19

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.3%	99.2%	99.0%	98.9%	98.7%	98.6%	98.5%	98.3%	98.1%	98.1%
Registered Implants: 63000	Effective Sample Size	54844	49103	43948	39206	34855	30368	25653	21372	17516	14159

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	**79**
Worldwide Distribution	**320,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	5	2	7
Other			
J-shape (22)	26	30	56
Lead body (4)	8	3	11
Non-patterned, other	3	2	5
Grand Total	**42**	**37**	**79**

References cited in table above (link)

Confirmed Malfunction Details: Leads References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each confirmed lead malfunction pattern listed in this report. All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

1. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
4. **Lead body**— Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
5. **Seal rings**— Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.
6. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
11. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
12. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
13. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
14. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **DF-1 terminal pin**— Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.
18. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
19. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
22. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-onlead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle first rib entrapment. Damage to lead body may expose conductor.

34. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.
35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.
36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
37. **Weld fracture**— Noise, loss of sensing. Fractured weld.
38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high voltage cable. Improvement implemented.
39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.
40. **Weld**— Out of range impedance measurements, noise, oversensing. Incomplete weld.
41. **Extracardiac fracture**— High impedance, noise, oversensing, loss of capture, loss of pacing. Flex fatigue leading to discontinuity of outer conductor.
42. **Model 3501 electrode fracture 2020**— *December 2020 Voluntary Physician Advisory.* High shock impedance, loss of tachy therapy. Fractured electrode conductor immediately distal to the proximal sense electrode. Note: per ISO 5841-2:2(E), only returned and confirmed failures are included in this table. All failures associated with this pattern – including reports that are not returned - are included in rate calculations and projections updated in the advisory section.
43. **Insulation**— High pacing impedance, noise, undersensing. Insulation issue.
44. **Electrode conductor fracture in or near pocket**— High shock impedance, loss of tachy therapy. Fractured electrode conductor proximal to the proximal sense electrode.

U.S. Chronic Lead Complications (Occurring After the First Month of Service)

Boston Scientific strives to provide meaningful detail in describing the performance of our products. U.S. Chronic Lead Complications are reported in compliance with ISO 5841-2: 2014 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations (as listed in the table) occurring after the first month of implant, and have been removed from service surgically or electronically. The lead either was not returned for analysis, or was returned but had no confirmation of a malfunction.

While multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY+ Positive Fixation 7840/7841/7842	150,000	28	32	126	24	7	4	0	1	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	110	495	557	211	86	23	40	101	0	28
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	14,000	0	15	28	8	4	1	2	3	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	24,000	1	15	13	14	3	3	1	13	0	0
FLEXTEND Active Fixation 4086/4087/4088	235,000	82	1056	1019	1017	616	140	227	570	0	55
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	196,000	5	486	249	296	75	35	213	263	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	505,000	21	801	886	513	196	151	598	539	0	31
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	1	124	368	138	29	34	79	53	0	8
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	2	126	20	70	30	5	24	38	0	1
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474	53,000	0	303	96	121	109	23	105	149	0	2

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	16,000	0	0	20	4	1	0	0	0	0	7
ACUITY X4 Spiral S 4674/4675	47,000	1	0	75	5	1	0	0	0	0	16

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	36,000	1	1	106	19	0	0	1	4	0	49
ACUITY Steerable 4554/4555/4556	29,000	3	43	461	67	6	2	18	40	0	98
ACUITY Spiral 4591/4592/4593	24,000	0	23	341	52	0	1	5	11	0	136
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	2	43	314	63	5	2	16	24	0	95
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	1	423	1370	379	15	8	117	178	0	447
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	2	91	488	149	4	1	77	53	0	268

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	49,000	14	11	56	8	12	5	0	2	5	1
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	7,000	2	2	10	1	2	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	77,000	22	54	120	34	65	12	13	22	34	7
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	0	3	9	1	6	0	0	12	1	1
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	132,000	33	70	202	58	96	24	11	36	45	12
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	2	3	1	4	1	0	0	3	1	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	33	763	429	233	878	103	166	450	494	30
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	4	156	75	86	157	13	48	268	79	7
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	34,000	13	104	62	38	84	3	8	54	89	4
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	5	5	3	7	0	1	10	3	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM S-ICD Electrode 3501	23,000	0	4	3	0	69	3	0	0	3
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	24,000	0	3	19	0	129	14	4	0	9

U.S. Acute Lead Observations

Boston Scientific strives to provide meaningful detail reflective of real-world product experience. In the first weeks following lead implantation, physiologic responses and lead performance can vary until chronic lead stability is attained. Acute lead performance may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques.

Because acute implant time contributes to overall clinical experience. Boston Scientific provides specific information regarding acute lead performance. To be included in the Acute Lead Observations table, a lead must first be successfully implanted, with clinical observations occurring within the first month of implant. These reports may or may not have resulted in clinical action and/or product return to Boston Scientific. The categories are consistent with the AdvaMed guidance for *Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads*. Although multiple observations are possible for any given lead, only one observation is reported per lead. The observation reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Acute Lead Observations are not included in calculation of lead survival probability.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY+ Positive Fixation 7840/7841/7842	150,000	139	22	410	95	19	26	1	15	0	1
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	358	428	950	248	77	51	8	52	0	33
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	14,000	0	0	31	6	1	0	0	1	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	24,000	1	0	36	11	0	3	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235,000	170	265	1011	291	46	55	25	92	0	30
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	196,000	9	10	401	102	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	0	10	396	51	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	505,000	54	49	676	145	86	67	28	79	0	26
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	0	1	28	10	0	0	3	4	0	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/4473/4474	53,000	2	13	90	13	3	8	6	4	0	3

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	16,000	0	0	28	33	9	0	0	6	0	21
ACUITY X4 Spiral S 4674/4675	47,000	0	2	56	41	7	0	0	21	1	54

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	36,000	2	0	121	24	4	1	0	11	0	58
ACUITY Steerable 4554/4555/4556	29,000	1	1	291	22	13	1	1	21	0	162
ACUITY Spiral 4591/4592/4593	24,000	1	2	172	28	5	0	3	9	0	168
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	0	1	240	23	8	1	3	17	0	128
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	7	4	806	84	30	4	14	64	0	512
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	4	4	168	23	11	1	10	20	0	141

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	49,000	39	7	95	17	13	3	1	5	3	1
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	7,000	3	1	14	7	2	0	0	1	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	77,000	55	18	252	42	29	3	2	27	7	6
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	2	0	10	1	0	0	0	5	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	132,000	97	19	351	70	51	15	6	31	13	20
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	2	1	6	1	1	1	0	7	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	82	137	510	130	223	12	17	178	108	44
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	5	4	92	36	41	4	3	47	5	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	34,000	31	7	69	14	19	3	2	18	23	9

ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	0	3	1	2	0	0	1	0	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM S-ICD Electrode 3501	23,000	1	0	20	0	183	5	0	0	6
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401	24,000	1	0	20	0	207	6	1	0	15

Before/During Implant Procedure - Worldwide Malfunctions: Leads

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling is not reported as device malfunction here.
The Conductor category includes any conductor break or damage with complete or intermittent loss of continuity that could interrupt current flow, including clavicle fatigue or crush damage. The Insulation category includes any lead insulation breach, such as damage due to lead-on-lead or lead-on-anatomy contact, or clavicle fatigue or crush. The Crimp/Weld/Bond category includes any interruption in the conductor or lead body associated with a point of connection. The Other category includes malfunctions for which the root cause does not fit within other categories or has not yet been determined. The Labeling and Packaging categories include product identification issues and damage to sterile packaging, respectively. The Implant Accessory category includes lead malfunctions due to catheter, guidewire or sheath issues.

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	39,000	0	0	0	2	0	0	0
ACUITY X4 Spiral S 4674/4675	99,000	0	0	0	4	0	0	0
ACUITY X4 Straight 4671/4672	80,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	65,000	0	0	0	5	0	2	0
ACUITY Spiral 4591/4592/4593	46,000	0	0	0	2	1	0	0

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	25,000	0	0	0	4	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	165,000	3	1	0	29	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0682/0663/0683	6,000	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	124,000	0	0	0	89	0	1	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0265/0266/0285/0286	11,000	0	0	0	7	15	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	206,000	0	0	0	54	0	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	6,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	382,000	0	0	92	571	1	3	10
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	109,000	1	0	20	108	0	3	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	77,000	0	0	15	73	0	1	1
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	0	0	1	6	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM S-ICD Electrode 3501	57,000	0	0	0	1	0	0	0
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	43,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY+ Positive Fixation 7840/7841/7842	174,000	0	0	0	1	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	1,032,000	2233	0	0	3220	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	99,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	111,000	1	0	1	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	185,000	0	0	11	136	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	290,000	0	0	66	636	1	1	4
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457*	551,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	796,000	0	0	6	727	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	321,000	0	0	1	144	6	18	0
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459*	105,000	0	0	2	2	1	1	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	144,000	0	0	0	233	4	6	0

*Counts consist of Boston Scientific and Intermedics co-branded pacing leads data.

Product Advisories

A Product Advisory is a voluntary letter issued to inform physicians of an anomalous device behavior identified by Boston Scientific's Quality System. A Product Advisory is issued when there is a material elevation in risk to patient safety with potential for compromised lifesaving therapy, or when Boston Scientific can provide meaningful guidance to improve patient outcomes or device performance. Boston Scientific considers many perspectives in the decision to issue a Product Advisory, including internal expertise and guidance from an independent Patient Safety Advisory Board (PSAB).

This report section includes summaries of Product Advisories for which significant, active U.S. device populations exist. In general, this includes advisories for which the estimated active U.S. advisory population is at least 200. Physician and patient letters, as well as Advisory Updates, are available at www.bostonscientific.com. With respect to the number of reported events listed in the summaries below, Boston Scientific recognizes that the actual number of clinical malfunctions may be greater than the number reported. Information reported in the Current Status section of each summary represents Boston Scientific's most current understanding of the data presented, but is not necessarily updated in every report. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION **Jun 2021 – High Battery Impedance Initiating Safety Mode in INGENIO EL Pacemakers and CRT-Ps**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INLIVEN CRT-P** Models: V284, V285, W274, W275 **INTUA CRT-P** Models: V272, V273, W273 **INVIVE CRT-P** Models: V172, V173, V182, V183, W172, W173 **VITALIO DR EL Pacemaker** Models: J274, J277, K274, K277, K284 **INGENIO DR EL Pacemaker** Models: J174, J177, K174, K184, K187 **ADVANTIO DR EL Pacemaker** Models: J064, J067, K064, K084, K087 Safety Mode, Physician Letter, June 2021 Safety Mode, Patient Letter, June 2021	Voluntary Physician Advisory FDA Classification: Class I Affected devices built with the EL battery have the potential to transition to Safety Mode during interrogation attempts by either a programmer or a LATITUDE™ communicator. The EL battery impedance of affected devices may increase over time causing a device to exhibit transient voltage decreases during the high-power consumption associated with telemetry communication via programmer or LATITUDE communicator. If the battery voltage drops below a minimum threshold during communication attempts, the device will temporarily halt telemetry, and a system reset will be performed. Subsequent telemetry attempts may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to immediately enter Safety Mode to maintain back-up pacing with pre-defined non-programmable settings. Once a device is in Safety Mode, it cannot be reprogrammed and must be replaced. There is a high degree of detectability when a device is operating in Safety Mode based on displayed programmer warning screen and/or LATITUDE alert condition. Although the most common clinical outcome has been early device replacement, Safety Mode parameters may result in unintended clinical impact for certain patients. Prior to device replacement, some patients may experience the following due to non-programmable Safety Mode pacing parameters: myopotential oversensing resulting in pacing inhibition, phrenic nerve stimulation; and/or loss of AV/VV synchrony. The most common clinical impact has been early device replacement. No patient deaths have been reported. No affected devices remain available for implant. Estimated Rate It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator. The potential for life-threatening harm due to loss of pacing (occurring because of prolonged inhibition) over a device's lifetime is estimated to be less than 1 in 15,000. Standard Warranty program available, please contact your local representative for terms and conditions. CURRENT STATUS **05-Jan-22** *Estimated Rate of Occurrence* It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator. The potential for life-threatening harm due to loss of pacing (occurring because of prolonged inhibition) over a device's lifetime is estimated to be less than 1 in 15,000. The INGENIO devices built with the standard life (SL) battery, as well as all contemporary Boston Scientific pacemakers and CRT-Ps, have different batteries and have not exhibited this latent battery condition. CURRENT RECOMMENDATION **05-Jan-22** • As noted above, Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. When assessing potential risk for a patient if their device initiates Safety Mode prior to the Explant indicator, consider patient-specific physiological factors (which may vary over time), including: adequacy of underlying escape rhythm and/or the need for AV/VV pacing for cardiac synchrony. • If a device enters Safety Mode, schedule replacement. Boston Scientific does not recommend general prophylactic replacement for affected devices. However, for individual patients, factors such as those listed above and shared decision-making may support consideration of device replacement to mitigate unintended clinical impact(s) due to potential entry into Safety Mode prior to the Explant indicator. In these cases, the following guidance should be considered: - For EL pacemakers, replace with a longevity remaining of 4 years (or less, if the device currently indicates fewer than 4 years longevity remaining). - For CRT-Ps, replace with a longevity remaining of 3 years (or less, if the device currently indicates fewer than 3 years longevity remaining). • Follow-up interval. Perform a system follow-up via remote or in-office interrogation at least every 12 months. For patients who may not require early device replacement, continue with existing follow-up protocols until the longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated (in accordance with the device's instructions for use). • For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT	ORIGINAL COMMUNICATION **Sep 2018 and Jun 2021 – Hydrogen-Induced Premature Depletion**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **VALITUDE CRT-P** Models U125, U128 **VISIONIST CRT-P** Models U225, U226, U228 **ACCOLADE Pacemaker** Models L300, L301, L310, L311, L321, L331 **PROPONENT Pacemaker** Models L200, L201, L209, L210, L211, L221, L231 **ESSENTIO Pacemaker** Models L100, L101, L110, L111, L121, **ALTRUA 2 Pacemaker** Models S701, S702, S722 Hydrogen Induced Premature Depletion, Physician Letter, September 2018 Hydrogen Induced Premature Depletion, Patient Letter, September 2018 Hydrogen Induced Premature Depletion, Physician Letter, June 2021 Hydrogen Induced Premature Depletion, Patient Letter, June 2021	Voluntary Physician Advisory FDA Classification: Sep 2018 – Class II; Jun 2021 - Class II This advisory discusses two separate, distinct subsets of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) with a potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion. The 2018 advisory population included approximately 2,900 active pacemakers, and the 2021 advisory population included approximately 125,000 active pacemakers. Latent release of small amounts of hydrogen within the pacemaker may compromise electrical function of a low voltage capacitor over time, resulting in accelerated depletion of the battery. The susceptibility of a pacemaker to this hydrogen-induced accelerated battery depletion mechanism is dependent upon the amount of hydrogen accumulation within the device and the susceptibility of the low voltage capacitors to hydrogen. The 2018 population is composed of pacemakers built with specific batches/lots of a liner component exhibiting a higher likelihood for this behavior. The 2021 population is composed of pacemakers built with a discontinued/original low voltage capacitor that is susceptible to compromised electrical performance in the presence of hydrogen. The use of the original low voltage capacitor in pacemaker and production of pacemakers from these advisory populations ceased in Nov 2017, and therefore they are no longer available for implantation. The most common clinical outcome has been device replacement. There have been no reported deaths associated with this behavior. *Estimated Rate of Occurrence* In June 2021 Boston Scientific identified an additional population of devices and the rate of occurrence at that time is described for each population below. • The 2018 advisory subset was composed of approximately 2,100 active pacemakers. The observed malfunction rate for this behavior was 11.0% at 5 years with a potential for life-threatening harm of 1 in 500,000 (0.0002%) at 5 years. • The 2021 advisory subset was composed of approximately 125,000 active pacemakers. The observed malfunction rate for this behavior was 1.3% at 5 years with a potential for life-threatening harm of 1 in 5,000,000 (0.00002%) at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **18-Oct-21**
	Estimated Rate of Occurrence • The 2018 advisory subset is composed of approximately 2,100 active pacemakers. The observed malfunction rate for this behavior is 12.3% at 5 years with a potential for life-threatening harm of 1 in 250,000 (0.0004%) at 5 years. • The 2021 advisory subset is composed of approximately 125,000 active pacemakers. The observed malfunction rate for this behavior is 1.6% at 5 years with a potential for life-threatening harm of 1 in 1,670,000 (0.00006%) at 5 years. 98.9% of all hydrogen-induced confirmed events have been replaced before the battery reached a depleted state; therefore, normal battery assessment during labeled 12-month follow-ups is effective and recommended for both the 2018 and 2021 advisory populations. A polymer material, designed to remove excess hydrogen within the pulse generator, was added to this device family in March 2018 and is intended to mitigate hydrogen-induced accelerated battery depletion due to the low voltage capacitors. Additionally, improvements were implemented in the liner component starting in May 2021 intended to further reduce the device's overall capacity to generate hydrogen. Over 800,000 pacemakers built with contemporary low voltage capacitors have zero hydrogen-induced malfunctions with up to 74 implant months.
	CURRENT RECOMMENDATION **05-Jan-22**
	• Per labeling, perform a system follow-up via remote or in-office interrogation every 12 months until One-Year-Remaining and then every three (3) months thereafter until replacement is indicated. • Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. • Replace 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. • For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT	ORIGINAL COMMUNICATION **Dec 2020 — Model 3501 Electrode Fracture**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM Subcutaneous Electrode** Model 3501 Model 3501 Electrode Fracture, Physician Letter, December 2020 Model 3501 Electrode Fracture, Patient Letter, December 2020	Voluntary Physician Advisory FDA Classification: Class I This advisory discusses the performance of approximately 47,000 EMBLEM S-ICD Subcutaneous Electrodes (Model 3501). During assembly of the EMBLEM S-ICD Subcutaneous Electrode, a small amount of adhesive is applied to a location just distal to the proximal sense ring. Over time, mechanical stresses on the electrode body at this location may create the potential for a fatigue crack to initiate from the outer lumen. This crack then propagates inward toward the center-oriented distal sense conductor, eventually resulting in a fracture of the two high voltage conductors. The cumulative occurrence rate for this specific electrode body fracture location is 0.2% at 41 months with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years. The physician letter (link provided) details device programming considerations and troubleshooting and detection techniques. Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **05-Jan-22**

Estimated Rate of Occurrence

The occurrence rate for EMBLEM S-ICD Subcutaneous Electrode (Model 3501) body fractures at a location just distal to the proximal sense ring is 0.28% at 54 months and the potential for life-threatening harm is 1 in 25,000 (0.004%) at 10 years. This rate was derived by including all reports of this failure mode, whether or not the product was returned.

An enhanced version of the EMBLEM Electrode has been developed to address the risks associated with this device behavior. Based on accelerated, extreme laboratory test, the enhanced EMBLEM Electrode design has demonstrated statistical survival of the electrode body around the sense ring to 10 implant years. Contact your local Boston Scientific sales professionals for availability.

CURRENT RECOMMENDATION **05-Jan-22**

1. Remote monitoring. Enroll and monitor patients through LATITUDE remote monitoring to facilitate detection of high electrode impedance alert or non-physiologic, mechanical artifacts on stored S-ECGs during the interval between in-office device checks. Instruct patients to comply with weekly remote interrogations.
2. Follow-up interval. Perform a system follow-up every three months via remote or in-office interrogation.
3. During follow-ups. For every remote or in-office follow-up:
  3.1. Promptly investigate any high impedance alerts in-clinic, as this may indicate an electrode body fracture and an inability of the system to provide therapy.
  3.2. Review stored episode S-ECGs for non-physiologic, mechanical artifacts, as this may indicate onset of electrode body fracture.
  3.3. During in-clinic follow-up, capture all sensing vectors, and review for the following conditions, any of which may indicate onset of electrode body fracture:
    3.3.1. cardiac signals on the S-ECGs of the Primary and Secondary sensing vector look nearly identical; or
    3.3.2. flatline S-ECGs in the Alternate sensing vector.
  3.4. Assess sensing performance in-clinic during isometrics and/or posture changes if any of the following is observed: non-physiologic, mechanical artifacts and/or high electrode impedance alerts. If isometrics and/or posture changes provoke non-physiologic, mechanical artifacts, this may indicate onset of an electrode body fracture.
4. Imaging. If an electrode body fracture is suspected, perform chest radiography in PA and left lateral viewprojections, ensuring the entire electrode length can be visualized to enable differential diagnosis of competing causes of high impedance or artifact signals. Portable X-ray images typically provide insufficient clarity to evaluate electrode integrity. In the absence of any indications of electrode fracture, surveillance X-rays are not recommended.
5. Shocks and beeping tones. During the next in-office follow-up visit, demonstrate the device beeper tothe patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
- For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan, as strong magnetic fields may cause permanent loss of beeper volume; and
- Remind all patients to promptly contact their physician if beeping tones are heard from their device or if a shock is delivered.
6. Evaluate risk. The potential for life-threatening harm due to an electrode body fracture is greatest for:
- patients with a history of life-threatening ventricular arrhythmias such as secondary preventionindication or previous appropriate shock for VT/VF;
- patients who are unable to be reliably followed remotely or in person every three months; or
- patients who are not monitored via LATITUDE and are unable to hear beeping tones
7. Replacement. Following consultation with Boston Scientific Technical Services, promptly replace any electrode that is indicated to have compromised integrity as evidenced by non-physiologic, mechanical artifacts, high impedance alert, and/or X-ray. Routine prophylactic replacement of an electrode without evidence of fracture is not recommended. Return explanted devices to Boston Scientific.
8. De novo and replacement S-ICD candidates. Consider overall S-ICD performance with respect to the competing risks for transvenous ICDs. The Product Performance Report includes up-to-date performance data on Boston Scientific transvenous leads and subcutaneous electrodes.

PRODUCT	ORIGINAL COMMUNICATION **Dec 2020 — EMBLEM S-ICD Electrical Overstress**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM S-ICD** Models A209, A219 EMBLEM Electrical Overstress, Physician Letter, December 2020 EMBLEM Electrical Overstress, Patient Letter, December 2020	Voluntary Physician Advisory FDA Classification: Class I This advisory discusses the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress (i.e., damage to the device caused by electrical shorting). Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations. *Estimated Rate of Occurrence* • Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported. • The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide needed defibrillation therapy, as it is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **05-Jan-22** *Estimated Rate of Occurrence* • The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. • We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years
	CURRENT RECOMMENDATION **05-Jan-22** 1. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations. 2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation. 3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. 4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu. - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan as strong magnetic fields may cause permanent loss of beeper volume; and - Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI. 5. Evaluate risk. The potential for life-threatening harm due to accelerated depletion is greatest for: - Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for ventricular arrhythmias; - Patients who are unable to be reliably followed remotely or in person every 3 months; or - Patients who are not monitored via LATITUDE and are unable to hear beeping tones. 6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. - In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making. - Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2019 and Dec 2020 — EMBLEM S-ICD Premature Depletion**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM S-ICD** Models A209, A219 EMBLEM Premature Depletion, Physician Letter, August 2019 EMBLEM Premature Depletion, Patient Letter, August 2019 EMBLEM Premature Battery Depletion Physician Letter Update, December 2020 EMBLEM Premature Depletion, Patient Letter Update, December 2020 EMBLEM Premature Battery Depletion Physician Letter Update, February 2022 EMBLEM Premature Depletion, Patient Letter Update, February 2022	Voluntary Physician Advisory FDA Classification August 2019: Class II FDA Classification December 2020: Class II In August 2019, a physician communication discussed a subset of EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) that may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion. In December 2020, the advisory population was expanded to a total of approximately 42,000 distributed EMBLEM S-ICDs with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion. This behavior can be detected if an unexpected decrease in remaining battery capacity is observed between remote/in-clinic follow-ups. Progression of accelerated depletion eventually produces a battery status replacement indicator (ERI) which is detectable through ambulatory beeping tones, remote monitoring, or in-clinic follow-up. Devices exhibiting this accelerated depletion behavior are capable of providing therapy for a minimum of 21 days after ERI independent of when EOL is initiated. The most common clinical outcome associated with this device behavior is early replacement. In August 2018, Boston Scientific transitioned S-ICDs to an alternative low voltage capacitor. All EMBLEM S-ICDs with the original low voltage capacitor are included in either the original or the expanded advisory population and none are available for implantation. *Estimated Rate of Occurrence* • The August 2019 advisory subset is comprised of approximately 400 distributed worldwide devices manufactured in July 2017. The August 2019 advisory subset has a projected rate of accelerated depletion of 15.1% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 50,000 at 5 years. • The December 2020 advisory subset is comprised of approximately 42,000 distributed worldwide devices manufactured before August 2018. The December 2020 advisory subset has a projected rate of accelerated depletion of 3.7% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 250,000 at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **05-Jan-22**
	The existing BD alert has been enhanced to enable detection of hydrogen-induced accelerated battery depletion in Model A209 and A219 EMBLEM S-ICDs. Affected devices must be interrogated by a programmer with updated software. This software is available in the U.S. and will become available in other countries once approved by local Regulatory Authorities. *Estimated Rate of Occurrence* Because the 5-year malfunction rate for the August 2019 and December 2020 populations has converged, a single malfunction rate will be reported for the combined populations. There are approximately 29,300 active worldwide devices. The malfunction rate is 11.6% at 5 years with a projected potential for life-threatening harm of approximately 1 in 200,000 at 5 years. There have been zero deaths associated with this behavior. There have been zero malfunctions for this behavior in devices manufactured with contemporary low-voltage capacitors.

CURRENT RECOMMENDATION **05-Jan-22**

Recommendations for countries where enhanced BD alert software upgrade is available. Contact your local Boston Scientific sales representative to determine availability of software in your country.

1. Programmer Software Upgrade. Confirm programmers at your center have been upgraded.
- Model 3300 LATITUDE Programmers are supported with Model 3877 v1.03 application
- Model 3200 EMBLEM Programmers are supported with Model 2877 v4.09 application
2. Next Follow-up. Boston Scientific continues to recommend 3-month follow-ups per labeling. Bearing in mind the risk versus benefits of in-person visits in the setting of the global COVID-19 pandemic, consider an in-person visit at the next scheduled follow-up, so the enhanced BD alert can be enabled in each affected device.
- When an EMBLEM S-ICD is first interrogated by an upgraded programmer, an S-ICD software update will be performed. Per labeling, monitor the patient and have external defibrillation equipment available as tachycardia therapy is suspended during a S-ICD software update.
- If a BD alert occurs, follow screen prompts and contact Technical Services. Using device data, Technical Services can provide a replacement interval.
3. Update Records. For each patient with an affected EMBLEM S-ICD, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

Follow-up Recommendations:

1. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations.
2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation.
3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed.
4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
- For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan as strong magnetic fields may cause permanent loss of beeper volume; and
- Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI.
5. Evaluate risk. The potential for life-threatening harm due to accelerated depletion is greatest for:
- Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for ventricular arrhythmias;
- Patients who are unable to be reliably followed remotely or in person every 3 months; or
- Patients who are not monitored via LATITUDE and are unable to hear beeping tones.
6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE.
- In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
- Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

PRODUCT	ORIGINAL COMMUNICATION **November 2018 — SQ-RX 1010 Shortened Replacement Time**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **S-ICD** Model 1010 SQ-RX 1010 Shortened Replacement Time, Physician Letter, November 2018 SQ-RX 1010 Shortened Replacement Time, Patient Letter, November 2018	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the potential for a shortened replacement interval after a Charge Time (CT) / Battery Depletion (BD) alert has occurred or after the battery status reaches Elective Replacement Indicator (ERI) in the first-generation Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) system's SQ-RX™ Model 1010 Pulse Generator (PG). The SQ-RX Model 1010 PG provides an Elective Replacement Indicator (ERI) as the PG approaches the end of its expected battery service life. When the battery reaches ERI through normal use, there is sufficient capacity to support up to 90 days of continued operation, including up to 6 maximum energy charges/shocks before fully depleting. However, if the PG experiences a latent battery malfunction resulting in accelerated battery depletion, the reserve battery capacity available beyond ERI may not be sufficient to support the full 90-day interval or additional shock therapy before depleting. The rate of depletion for a latent battery malfunctions varies. The SQ-RX model 1010 PGs include separate monitors for charging and battery performance. The Charge Time (CT) alert is designed to detect unsuccessful charging of the high voltage capacitors within 44 seconds. The Battery Depletion (BD) alert is designed to detect higher rates of accelerated battery depletion. When an alert condition occurs, the patient is notified through beeping tones and the clinician user is notified through programmer messages. Most battery malfunctions exhibit a sufficient rate of accelerated depletion to be detected by one of these alerts. Some battery malfunctions exhibit a slower rate of accelerated depletion, which is not detected as an alert condition. Based on an analysis of accelerated battery depletion events where only ERI presented (no alert condition), at least one maximum energy shock has been determined to be available for at least 20 days after ERI. *Estimated Rate of Occurrence* The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years. There have been no reports of injuries or deaths associated with this behavior. Laboratory analysis of returned PGs with latent battery malfunctions has shown some depletions to a level at which therapy would not have been available if not replaced in accordance with the recommendations above. Based on a 3-month follow-up interval, the potential for life threatening harm for this behavior is 0.006% (1 in 16,667) at 5 years. However, the potential for life-threatening harm is greater for secondary prevention patients or those who have received appropriate therapy previously, patients with longer follow-up intervals, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **05-Jan-22**
	Estimated Rate of Occurrence The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years. There have been no reports of injuries or deaths associated with this behavior.
	CURRENT RECOMMENDATION **05-Jan-22**
	• Follow-Up. Consistent with the SQ-RX Model 1010 PG User Manual: - Perform in-clinic checks every 3 months as the PG is not capable of remote patient management; - If it has been more than 3 months since a patient's last in-clinic follow-up, schedule a follow-up within the next month and every 3 months thereafter; - During the next follow-up visit, demonstrate the beeper by applying a magnet over the PG to elicit beeping tones; and - Remind patients to promptly contact their physician if beeping tones are heard from their PG as this may be an indication of a CT / BD alert or ERI. - Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of their PG • Evaluate Risk. The potential for life-threatening harm is greater for patients who have experienced life-threatening ventricular arrhythmias, patients not followed every 3 months, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction • CT / BD Alerts. Promptly investigate any beeping tones, CT alerts, or BD alerts and report them to Boston Scientific Technical Services. Using saved PG data, Technical Services can determine if an accelerated battery depletion exists and provide guidance for replacement. • ERI. To mitigate the rare potential for undetected accelerated battery depletion, replace SQ-RX Model 1010 PGs within 20 days of ERI. If a longer replacement interval is desired, save PG data and contact Technical Service to determine a recommended replacement interval. Note: CT / BD Alerts appearing before or after ERI should always be reported to Technical Services for evaluation

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

ACCOLADE Pacemaker
Models L300, L301, L310, L311, L321, L331

PROPONENT Pacemaker
Models L200, L201, L209, L210, L211, L221, L231

ESSENTIO Pacemaker
L131

ALTRUA 2 Pacemaker
Models S701, S702, S722

Minute Ventialtion Signal Oversensing, Physician Letter, December 2017

Minute Ventialtion Signal Oversensing, Patient Letter, December 2017

Minute Ventialtion Signal Oversensing, Update letter, January 2019

ORIGINAL COMMUNICATION **December 2017 — Minute Ventilation Signal Oversensing**

Voluntary Physician Advisory

This advisory discusses intermittent oversensing of the Minute Ventilation (MV) sensor signal with certain Boston Scientific pacemaker and cardiac resynchronization therapy pacemaker systems (pacemakers). MV sensor signal oversensing may cause pre-syncope or syncope due to periods of pacing inhibition. This MV behavior may occur with any manufacturer's pacing lead system, but Boston Scientific has determined it to be more likely for affected Boston Scientific pacemakers using Medtronic or Abbott/St. Jude (Abbott) leads implanted in either the right atrium (RA) or right ventricle (RV).

The MV sensor in Boston Scientific pacemakers can be used for RightRate™ (rate adaptive pacing), Respiratory Rate Trend, or AP Scan. When the RA/RV pacing leads and lead terminal connections are operating as intended, the MV sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on electrograms (EGMs). However, intermittency related to the lead or pacemaker-lead connection has the potential to create a transient high impedance condition. A high impedance condition may subsequently alter the MV sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels. For a technical description of the Boston Scientific's MV sensor, please refer to Appendix A in the December 2017 physician letter.

Engineering analysis and testing, as well as evaluation of post-market surveillance data, demonstrates an elevated potential for oversensing of the MV sensor signal in certain pacemaker systems connected to Medtronic or Abbott pacing leads. Although all leads evaluated in simulated testing environments comply with appropriate connector standards, we have discovered subtle differences amongst lead manufacturers in the surface finish of the lead terminal ring and amount of axial and radial terminal ring motion within the pacemaker header. These factors may result in intermittent increases in impedance leading to oversensing of the MV sensor signal or changes in daily impedance test measurements.

Estimated Rate of Occurrence

behavior is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

Affected pacemaker systems connected to the following RA/RV pacing leads[4]:	Probability of Injury at 5 years	Probability of Life Threatening Harm at 5 years
Medtronic or Abbott pacing leads	0.0005 (1 in 2,000)	0.00001 (1 in 100,000)
Boston Scientific pacing leads (including DEXTRUS)	0.00003 (1 in 33,333)	0.0000008 (1 in 1,250,000)
All pacing leads combined[5]	0.00008 (1 in 12,500)	0.000002 (1 in 500,000)

CURRENT STATUS **05-Jan-22**

Estimated Rate of Occurrence

Boston Scientific investigation has shown that the probability of harm associated with MV sensor signal oversensing behavior is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

Affected pacemaker systems connected to the following RA/RV pacing leads[4]:	Probability of Injury at 5 years	Probability of Life Threatening Harm at 5 years
Medtronic or Abbott pacing leads	0.0005 (1 in 2,000)	0.00001 (1 in 100,000)
Boston Scientific pacing leads (including DEXTRUS)	0.00003 (1 in 33,333)	0.0000008 (1 in 1,250,000)
All pacing leads combined[5]	0.00008 (1 in 12,500)	0.000002 (1 in 500,000)

CURRENT RECOMMENDATION **05-Jan-22**

Software is available in most countries to address the potential for pacing inhibition due to MV sensor signal oversensing in affected pacemakers. The software adds the Signal Artifact Monitor (SAM) to Boston Scientific's proprietary suite of Safety Architecture diagnostics. When enabled, the SAM continuously monitors electrograms for MV sensor signal artifacts and measures MV vector lead impedance values. If artifacts are detected or the MV vector lead impedance is out of range, the monitor either switches to the right ventricular vector or disables the MV sensor in approximately one second. In this manner, the SAM promptly eliminates the clinical risk of pacing inhibition associated with MV sensor signal oversensing.

Programmer	Software Model	Software Version
Model 3120 ZOOM Programmer	2869	2.06
Model 3300 LATITUDE Programmer	3869	1.05

If software is not available in your country, continue to follow advisory recommendations.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected.

A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

RESONATE CRT-D
Models G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548

VIGILANT CRT-D
Models G224, G225, G228, G237, G247, G248

MOMENTUM CRT-D
Models G124, G125, G126, G128, G138

CHARISMA CRT-D
G337, G347, G348

AUTOGEN CRT-D
Models G172, G173, G175, G177, G179

DYNAGEN CRT-D
Models G150, G151, G156, G158

INOGEN CRT-D
Models G140, G141, G146, G148

ORIGEN CRT-D
Models G050, G051, G056, G058

CRT Positive LV Offset and TPP Interaction, Physician Letter, Dec 2017

CRT Positive LV Offset and TPP Interaction, Patient Letter, December 2017

CRT Positive LV Offset and TPP Interaction, Update Letter, January 2019

ORIGINAL COMMUNICATION **December 2017 — CRT Positive LV Offset and TPP Interaction**

Voluntary Physician Advisory
FDA Classification: Unclassified

This advisory discusses unintended asynchronous biventricular (BiV) pacing behavior when tracking elevated atrial intrinsic rhythms in certain Boston Scientific Cardiac Resynchronization Therapy (CRT) pacemakers (CRT-Ps) and defibrillators (CRT-Ds). Repeated detection of this unintended asynchronous BiV pacing behavior may result in the implanted device reverting to a permanent Safety Mode (Safety Core™) status thus requiring early replacement. The unintended asynchronous BiV pacing behavior can only occur when an infrequent combination of parameters are programmed, specifically:

• Left Ventricular (LV) Offset programmed to a positive value which exceeds the Atrial Blank after Ventricular Pace (A-Blank after V-Pace) interval; and
• Tracking Preference = ON (nominal).

Observed Rate
Of the 60,500 CRT devices distributed worldwide, Boston Scientific estimates approximately 300 CRT devices are programmed with the combination of parameters which may lead to this device behavior. There have been two confirmed instances of early device replacement due to this device behavior (0.7%). Of the two cases, a single patient death occurred due to complications related to the replacement procedure.

CURRENT STATUS **05-Jan-22**

Confirmed Malfunctions (worldwide)
There have been four confirmed instances of early device replacement due to this device behavior.

CURRENT RECOMMENDATION **05-Jan-22**

Software is available in most countries to addresses the rare potential for early replacement due to permanent Safety Mode status. The software imposes an interactive limit which prevents programming the device into a susceptible manner. Affected devices interrogated by an updated programmer are no longer susceptible to this issue.

Programmer	Device Therapy	Software Model	Software Version
Model 3120 ZOOM Programmer	CRT-Ps	2869	2.06
Model 3300 LATITUDE Programmer	CRT-Ps	3869	1.05
Model 3120 ZOOM Programmer	CRT-Ds	2868	4.07
Model 3300 LATITUDE Programmer	CRT-Ds	3868	1.07

If software is not available in your country, continue to follow advisory recommendations.

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available here:

Device Lookup Tool

COGNIS
Models N106/N107/N108/N118/ N119/N120/P106/P107/P108

TELIGEN VR
Models E102/E103/F102/F103

TELIGEN DR
Models E110/E111/F110/F111

Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014

Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014

Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013

ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor**

Voluntary Physician Advisory
FDA Classification August 2013: Class II
FDA Classification September 2014: Class II

In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. It also informed physicians how to identify and respond to a Safety Architecture low voltage alert. In September 2014, a second subset of devices was identified that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset. The second communication also discussed improvements to Safety Architecture's low voltage alert, which were released through a programmer software update.

The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.

The most common alert is a yellow programmer screen that states, “Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003”. LATITUDE issues a corresponding yellow alert (nominally configured “On”). In other instances, diminished LV capacitor performance can result in an early “Explant” battery status indicator (ERI) and a replacement window that may be less than 3 months.
Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.

Advisory population
Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.

CURRENT STATUS **05-Jan-22**

Estimated Rate of Occurrence
• COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.8% at 60 months, 5.8% at 72 months, 8.6% at 84 months, 10.9% at 96 months, 12.2% at 108 months, and 12.9% at 120 months. The potential for life-threatening harm from loss of therapy is approximately 1 in 200,000 (0.0005%) at 60 months.

• COGNIS CRT-D and TELIGEN ICD populations (advisory and non-advisory) - The overall rate of occurrence is approximately 1.1% at 60 months, 2.4% at 72 months, 3.9% at 84 months, 5.2% at 96 months, 6.0% at 108 months, and 6.2% at 120 months . Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy is approximately 2.2%. The potential for life-threatening harm from loss of therapy is approximately 1 in 500,000 (0.0002%) at 60 months.

• INCEPTA, ENERGEN and PUNCTUA CRT-Ds and ICDs - The rate of occurrence is 1.1% at 60 months, 2.0% at 72 months, 3.0% at 84 months, 3.8% at 96 months, 4.3% at 108 months, and 4.5% at 120 months. The portion of malfunctions with compromised therapy is approximately 0.3%. The potential for life-threatening harm from loss of therapy is approximately 1 in 2,500,000 (0.00004%) at 60 months.

CURRENT RECOMMENDATION **05-Jan-22**

Updated Software
In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.

LATITUDE Patient Management System
Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert “Voltage was too low for projected remaining capacity” is configured “On”.

Additional Recommendations
- After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling.
- Device replacement is not recommended for advisory devices displaying normal behavior.
- Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.
This advisory is limited to those models listed below implanted subpectorally.	Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.
COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108 **TELIGEN VR** Models E102/F102 **TELIGEN DR** Models E110/E111/F110/F111	A weakened header bond can result in one or more of the following device behaviors: – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.
Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
	CURRENT STATUS **05-Jan-22**
	Reported events (worldwide) 106 reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.
	CURRENT RECOMMENDATION **05-Jan-22**
	If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended. **For affected devices implanted in a subpectoral location:** – Follow patient at least once every three months as recommended in device instructions for use. – Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation. – Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.
	Standard Warranty program available, please contact your local representative for terms and conditions.

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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
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1.866.484.3268

CRM-373910-AD