Boston Scientific
Advancing science for life™

2019

Rhythm Management Product Performance Report

Q1 Edition

ACUITY™ X4
Quadripolar LV Lead

RESONATE™
FAMILY OF ICDs AND CRT-Ds

Emblem™ MRI S-ICD
System

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 2019 report includes data through February 12, 2019.

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,

Renold J. Russie
Vice President, Quality Assurance

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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.

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.

Survival probabilities are statistical estimates subject to uncertainty. To quantify this uncertainty, 95% confidence intervals of survival probabilities are computed. Greenwood's formula is used to estimate the standard error of the calculated survival probabilities, and confidence intervals are constructed using a logit transformation, assuming the transformed values are normally distributed. For example, 99.36% (-0.3/+0.2) represents an interval of 99.06% to 99.56%, and these intervals are constructed such that 95% of the time they will contain the true survival probability. These confidence intervals are not symmetric due to the transformation method described previously.

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets
Pulse generator survival probability is reported for U.S. implanted devices in product families which meet inclusion criteria described below. Lead survival probability is reported for the U.S. Registered Implant population for product families which 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 which 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 United States. 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 believes, however, that U.S. experience is generally 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 less 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. The minimum interval sample size is 50 leads which have been followed for at least 6 months.

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, average device age and U.S. approval date 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
- Devices removed from service and reported to have exhibited premature battery depletion, but not confirmed by laboratory analysis, whether returned or not—also known as “unconfirmed reports of premature battery depletions.”

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 being implanted as of May 2009 and forward. Worldwide malfunctions are not included for older 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 learn about 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 (CAPA) 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 the 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 in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples. 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 characterizing and presenting to our customers an accurate picture of product performance and addressing identified issues in a timely fashion.

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 in existing or subsequent generations, manufacturing process modifications, software updates, educational communications or labeling changes. 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]

In this section of the report, Boston Scientific provides device return rate data with the goal of raising awareness and improving current device explant and return rates. Figure 1 on the following page depicts the percentage of devices reported to have been explanted and then returned to Boston Scientific for various product therapy types.

Help Us Provide You With More Complete Product Performance Data

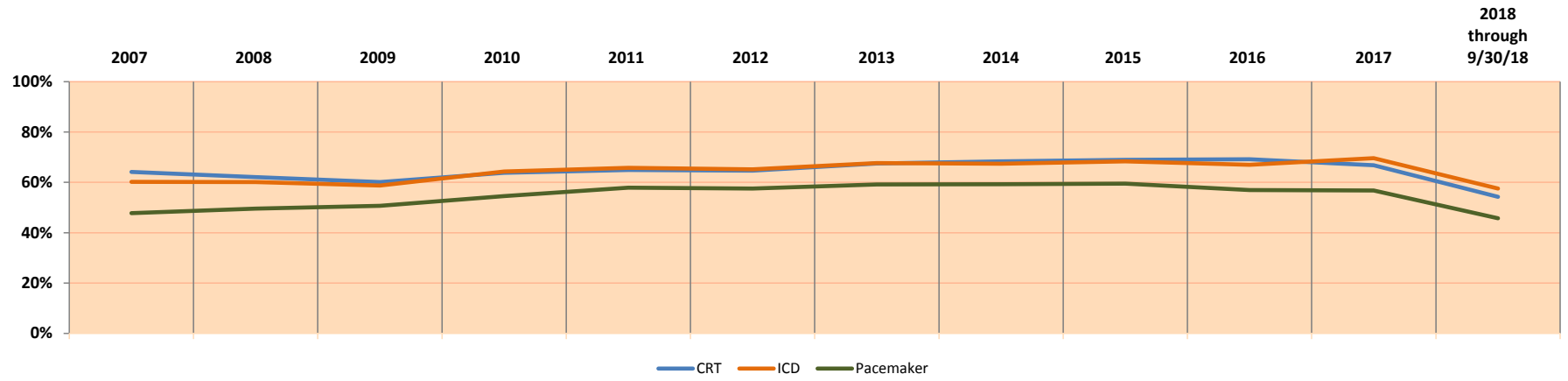
Reporting Adverse Events

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.



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 through 9/30/18
Explants	4248	5682	9273	10494	9341	8071	8349	6940	5084	4661	5252	4495
Returns	2726	3530	5573	6697	6064	5222	5633	4743	3504	3225	3508	2439
% Returned	**64%**	**62%**	**60%**	**64%**	**65%**	**65%**	**67%**	**68%**	**69%**	**69%**	**67%**	**54%**
Explants	11544	15564	19519	19961	16595	12004	11947	11303	10050	8427	7959	5701
Returns	6954	9356	11476	12844	10922	7828	8083	7617	6873	5648	5541	3281
% Returned	**60%**	**60%**	**59%**	**64%**	**66%**	**65%**	**68%**	**67%**	**68%**	**67%**	**70%**	**58%**
Explants	18426	20476	21043	21168	20060	18747	18841	19364	19718	19541	19270	14151
Returns	8798	10152	10660	11546	11608	10784	11143	11473	11734	11125	10941	6473
% Returned	**48%**	**50%**	**51%**	**55%**	**58%**	**58%**	**59%**	**59%**	**60%**	**57%**	**57%**	**46%**

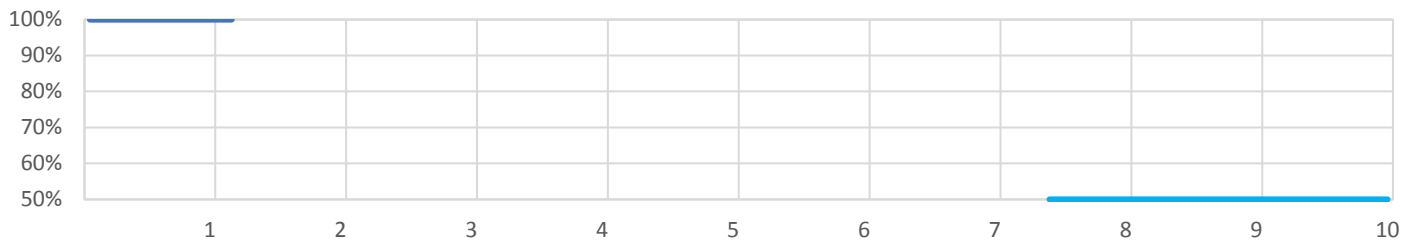
Figure 1. Percentage of U.S. explanted devices as reported and returned to Boston Scientic CRM.

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

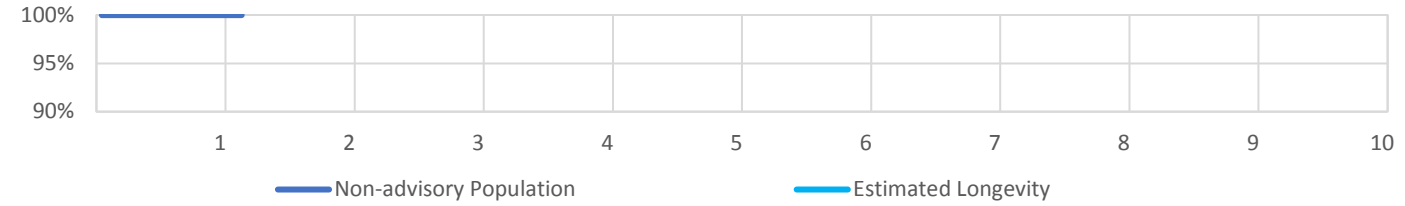
Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/ G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

US Summary			
US Registered Implants:	9,000	US Normal Battery Depletions:	-
US Approval Date:	September 2017	US Malfunctions:	1
US Estimated Active Implants:	9,000	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	100.0%	100.0%	--	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	--	--	--	--	--	--	--	--
9000	Effective Sample Size	1066	299	--	--	--	--	--	--	--	--

@ 15 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	**1**
Worldwide Distribution	**20,000**

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

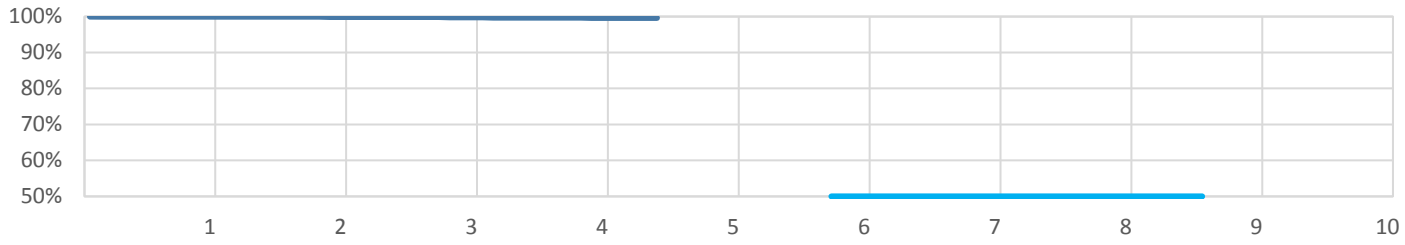
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN CRT-D

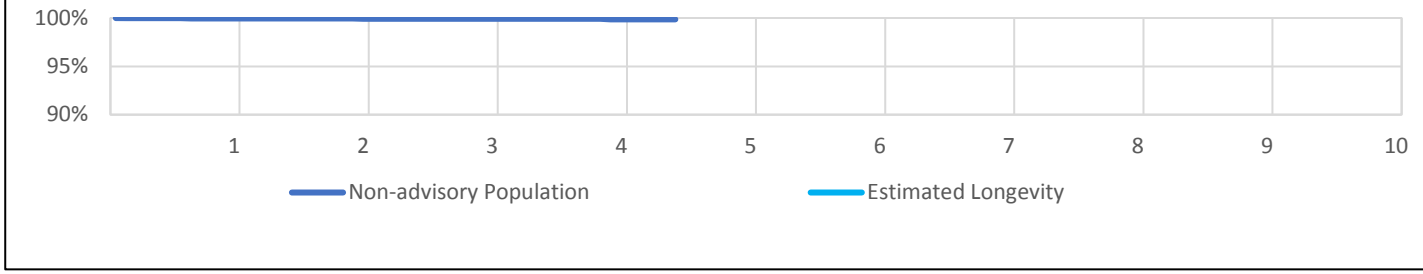
Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

US Summary			
US Registered Implants:	59,000	US Normal Battery Depletions:	29
US Approval Date:	April 2014	US Malfunctions:	32
US Estimated Active Implants:	53,000	Without Compromised Therapy:	26
		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%	99.8%	99.6%	99.6%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--	--
59000	Effective Sample Size	41907	24803	10952	2016	206	--	--	--	--	--

@ 54 months

DYNAGEN/INOGEN/ORIGEN CRT-D

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

Worldwide Confirmed Malfunctions	**50**
Worldwide Distribution	**86,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	6	6	12
Software			
Memory errors (51)	11	1	12
Safety Core-unintended biventricular pacing (64)	1	0	1
Electrical			
High voltage circuit component (62)	11	0	11
Integrated circuit (63)	10	2	12
Low-voltage capacitor (69)	1	0	1
High voltage capacitor (75)	0	1	1
Grand Total	**40**	**10**	**50**

References cited in table above (link)

AUTOGEN CRT-D

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

Worldwide Confirmed Malfunctions	**18**
Worldwide Distribution	**23,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	2	1	3
Electrical			
High voltage circuit component (62)	7	0	7
Integrated circuit (63)	4	2	6
Low-voltage capacitor (69)	1	0	1
Software			
Safety Core-unintended biventricular pacing (64)	1	0	1
Grand Total	**15**	**3**	**18**

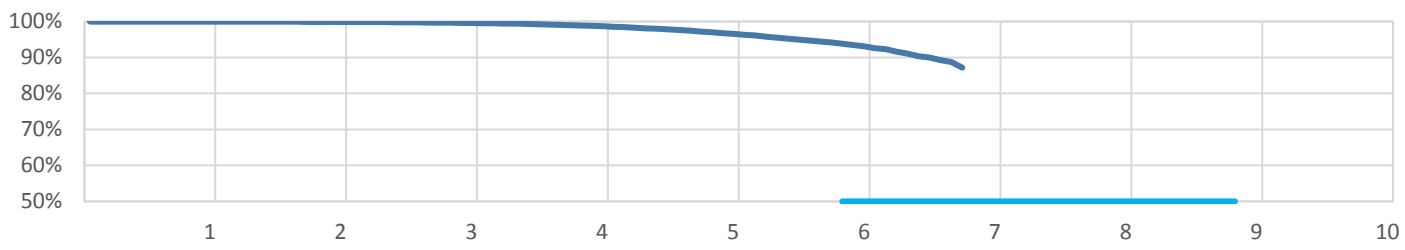
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA CRT-D

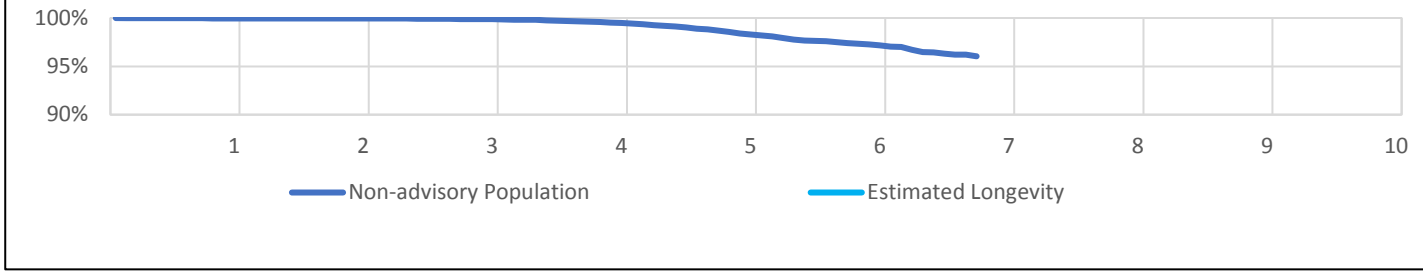
Models: N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/P052/P053/P142/P143/P162/P163/P165

US Summary			
US Registered Implants:	53,000	US Normal Battery Depletions:	849
US Approval Date:	November 2011	US Malfunctions:	600
US Estimated Active Implants:	36,000	Without Compromised Therapy:	584
		With Compromised Therapy:	16

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%	96.8%	93.5%	87.2%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.4%	97.3%	96.0%	--	--	--
52000	Effective Sample Size	46328	41479	36385	29540	17802	6684	611	--	--	--

@ 82 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	**958**
Worldwide Distribution	**81,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	11	5	16
Mechanical			
Transformer (38)	0	6	6
Electrical			
Safety Core-electrocautery (42)	5	1	6
High-voltage capacitor (43)	0	4	4
Low-voltage capacitors (47)	1	0	1
Integrated circuit (50)	2	6	8
Battery (53)	7	1	8
Low-voltage capacitor (54)	895	2	897
Low-voltage capacitor (69)	4	0	4
Software			
Memory errors (51)	8	0	8
Grand Total	**933**	**25**	**958**

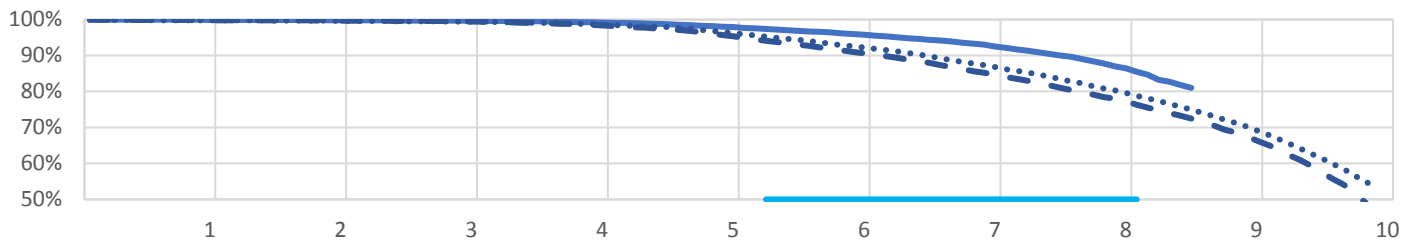
References cited in table above (link)

COGNIS CRT-D

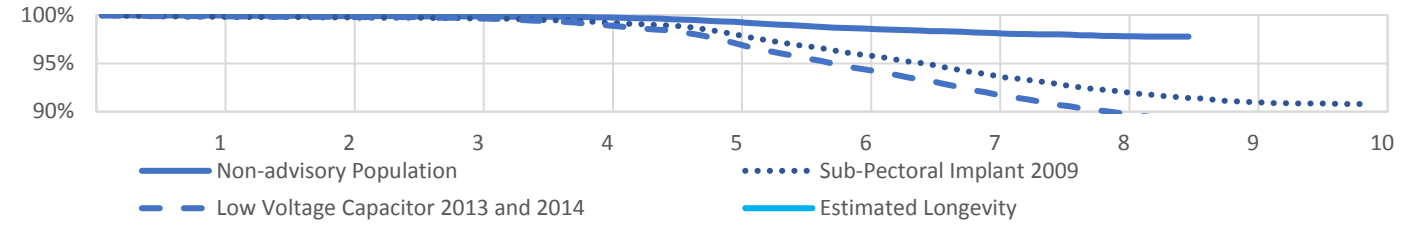
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	6,014
US Approval Date:	March 2008	US Malfunctions:	1,971
US Estimated Active Implants:	29,000	Without Compromised Therapy:	1,783
		With Compromised Therapy:	188

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%	99.2%	98.0%	96.0%	93.0%	87.0%	81.0%	--	
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.2%	97.8%	97.8%	--	
36000	Effective Sample Size	31282	28056	25123	22398	19844	17197	13663	4291	390	--	@ 103 months

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	Depletions and Malfunctions	99.8%	99.7%	99.4%	98.7%	96.6%	92.6%	87.4%	80.3%	70.4%	52.8%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.7%	99.3%	98.2%	96.0%	93.9%	92.2%	91.0%	90.8%
32000	Effective Sample Size	27335	24228	21628	19198	16777	14299	11977	9753	7398	1280
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.5%	95.7%	91.0%	85.2%	78.0%	67.7%	49.0%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.5%	98.5%	95.7%	91.0%	85.2%	78.0%	67.7%	88.0%
26000	Effective Sample Size	22473	19948	17838	15800	13754	11614	9636	7792	3937	429

@ 119 months

*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	**2,734**
Worldwide Distribution	**109,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	33	11	44
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	1583	78	1661
Safety Core-electrocautery (42)	54	25	79
High-voltage capacitor (43)	1	6	7
Low-voltage capacitors (47)	7	0	7
Integrated circuit (50)	8	21	29
High voltage circuit (52)	0	1	1
Battery (53)	47	7	54
Low-voltage capacitor (54)	678	11	689
Low-voltage capacitor (69)	1	0	1
Mechanical			
Transformer (38)	0	9	9
Difficulty securing lead (41)	8	8	16
Header contacts (45)	12	8	20
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	20	47	67
Header (74)	8	23	31
Software			
Safety Core-programming (46)	1	0	1
Alert messages not displayed post-EOL (48)	2	0	2
Memory errors (51)	14	2	16
Grand Total	**2477**	**257**	**2734**

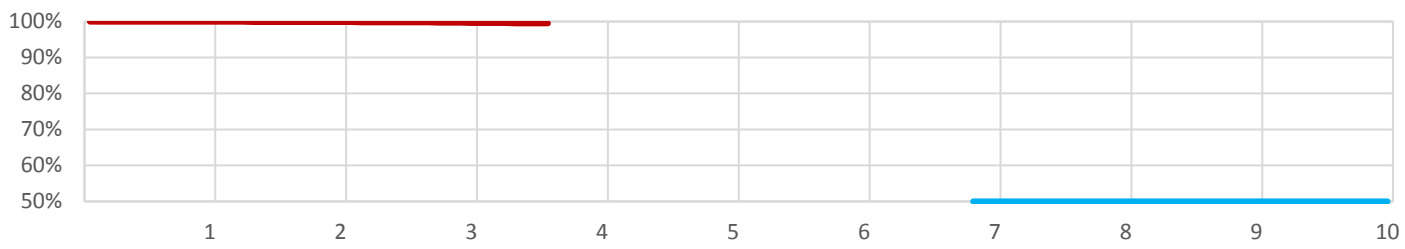
References cited in table above (link)

VISIONIST/VALITUDE

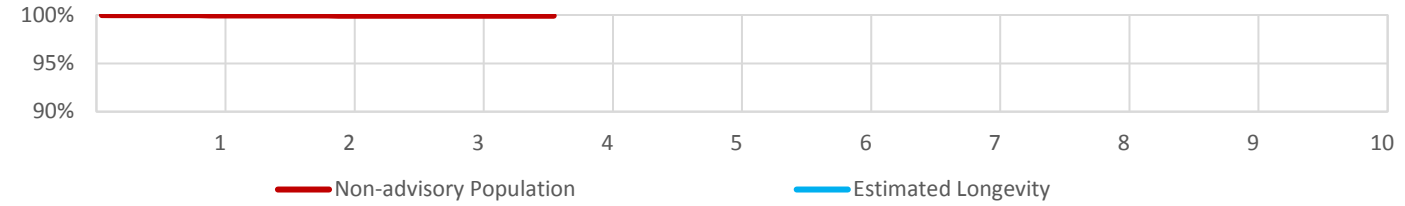
Models: U125/U128/U225/U226/U228

US Summary			
US Registered Implants:	22,000	US Normal Battery Depletions:	13
US Approval Date:	October 2014	US Malfunctions:	16
US Estimated Active Implants:	20,000	Without Compromised Therapy:	15
		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%	99.7%	99.5%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--	--
22000	Effective Sample Size	13947	6980	1866	250	--	--	--	--	--	--

@ 44 months

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**45,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	4	0	4
Electrical			
Low-voltage capacitors (47)	1	0	1
Integrated circuit (63)	5	1	6
Telemetry (68)	1	0	1
Hydrogen induced premature depletion - September 2018 (70)	5	0	5
Software			
Memory errors (51)	3	0	3
Grand Total	**19**	**1**	**20**

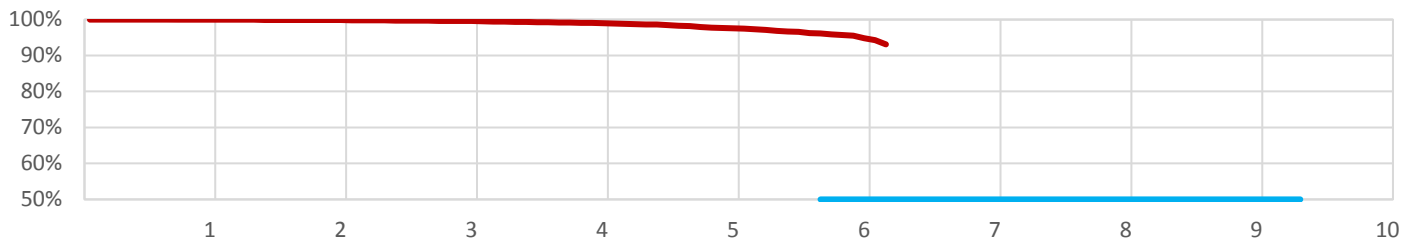
References cited in table above (link)

INVIVE

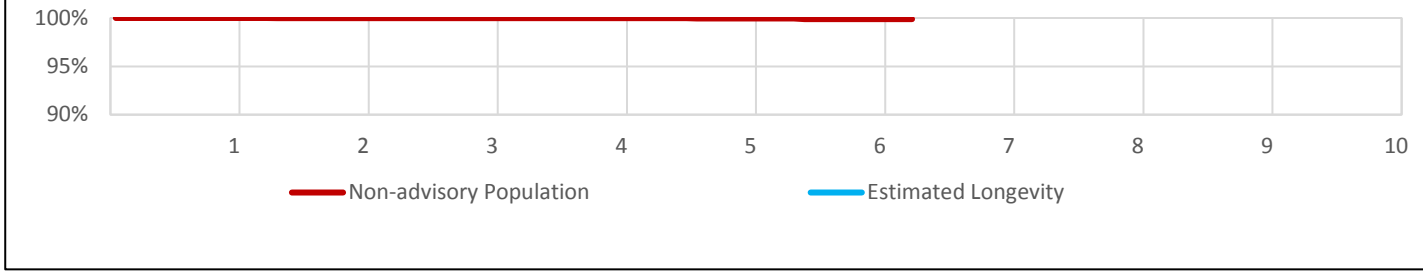
Models: V172/V173/V182/V183/W172/W173

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	123
US Approval Date:	May 2012	US Malfunctions:	3
US Estimated Active Implants:	5,000	Without Compromised Therapy:	3
		With Compromised Therapy:	0

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%	99.1%	97.7%	95.7%	93.1%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	--	--	--
8000	Effective Sample Size	6723	6000	5254	4153	2399	603	245	--	--	--

@ 76 months

INVIVE

Models: V172/V173/V182/V183/W172/W173

Worldwide Confirmed Malfunctions	**6**
Worldwide Distribution	**18,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	1	2
Electrical			
Low-voltage capacitors (47)	0	1	1
Software			
Memory errors (51)	3	0	3
Grand Total	**2**	**4**	**6**

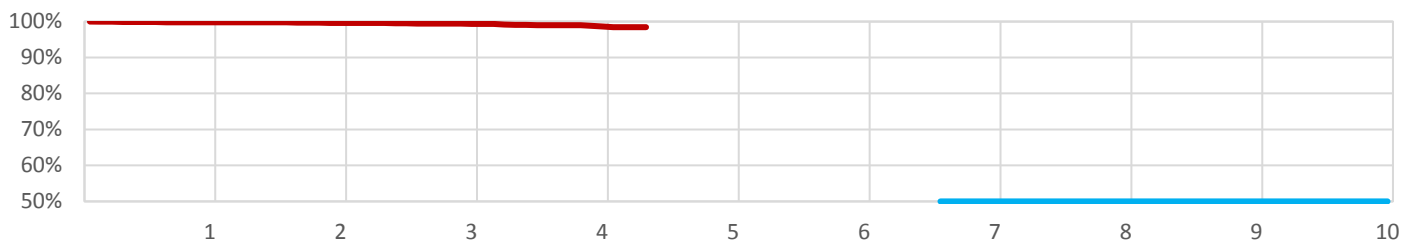
References cited in table above (link)

INTUA

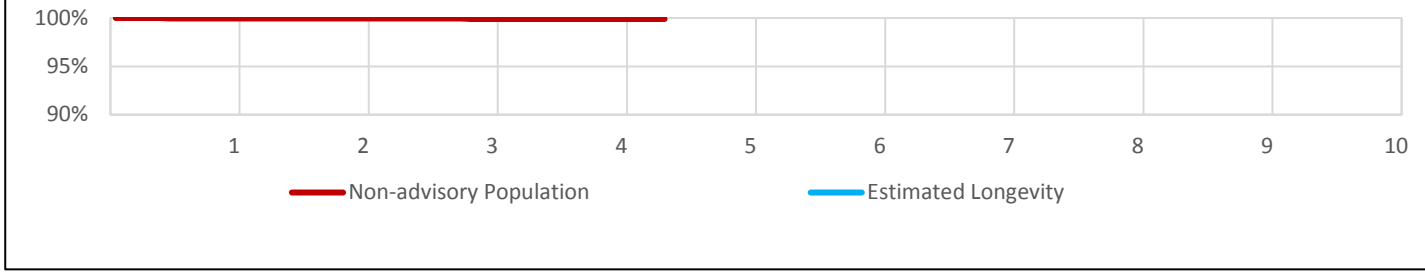
Models: V272/V273/V282/V283/W272/W273

US Summary			
US Registered Implants:	3,000	US Normal Battery Depletions:	21
US Approval Date:	May 2012	US Malfunctions:	2
US Estimated Active Implants:	2,000	Without Compromised Therapy:	1
		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	99.8%	99.6%	99.4%	98.8%	98.4%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	--	--	--	--	--
3000	Effective Sample Size	2268	1983	1599	679	248	--	--	--	--	--

@ 53 months

INTUA

Models: V272/V273/V282/V283/W272/W273

Worldwide Confirmed Mal	**2**
Worldwide Distribution	**3,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	1	2
Grand Total	**1**	**1**	**2**

References cited in table above (link)

CONTAK RENEWAL TR 2

Models: H140/H145

Worldwide Confirmed Malfunctions	**38**
Worldwide Distribution	**31,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	10	1	11
Electrical			
Capacitor (15)	1	0	1
Memory error (23)	1	0	1
Mechanical			
Seal plug (19)	2	0	2
Setscrew block (25)	2	0	2
Seal plug (33)	1	0	1
Software			
Stored EGMs (28)	20	0	20
Grand Total	**37**	**1**	**38**

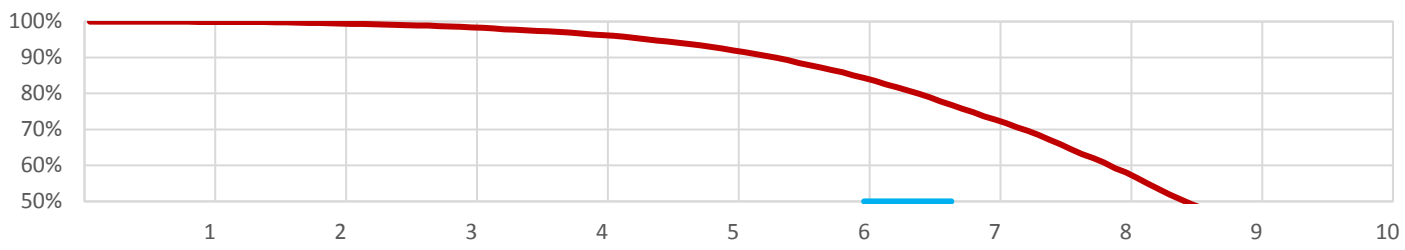
References cited in table above (link)

CONTAK RENEWAL TR

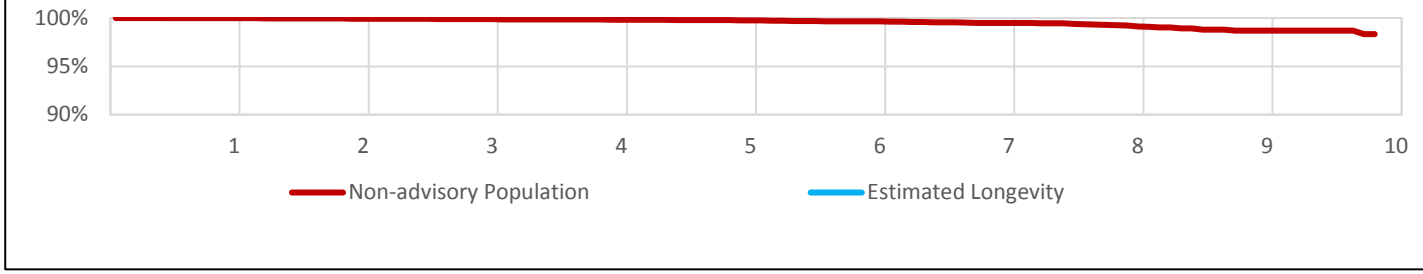
Models: H120/H125

US Summary			
US Registered Implants:	19,000	US Normal Battery Depletions:	3,675
US Approval Date:	January 2004	US Malfunctions:	67
US Estimated Active Implants:	4,000	Without Compromised Therapy:	66
		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%	99.5%	98.6%	96.4%	92.5%	85.0%	73.7%	59.2%	43.2%	30.9%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.5%	99.2%	98.7%	98.3%
19000	Effective Sample Size	15209	13201	11524	9993	8494	6889	4767	2530	932	230

@ 119 months

CONTAK RENEWAL TR

Models: H120/H125

Worldwide Confirmed Malfunctions	**67**
Worldwide Distribution	**19,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	13	0	13
Alert messages (31)	7	0	7
Magnet rate (44)	1	0	1
Electrical			
Capacitor (15)	0	1	1
	1	0	1
Low-voltage capacitor - June 23, 2006			
Voluntary Physician Advisory (8)			
Mechanical			
Seal plug (19)	5	0	5
Software			
Stored EGMs (28)	39	0	39
Grand Total	**66**	**1**	**67**

References cited in table above (link)

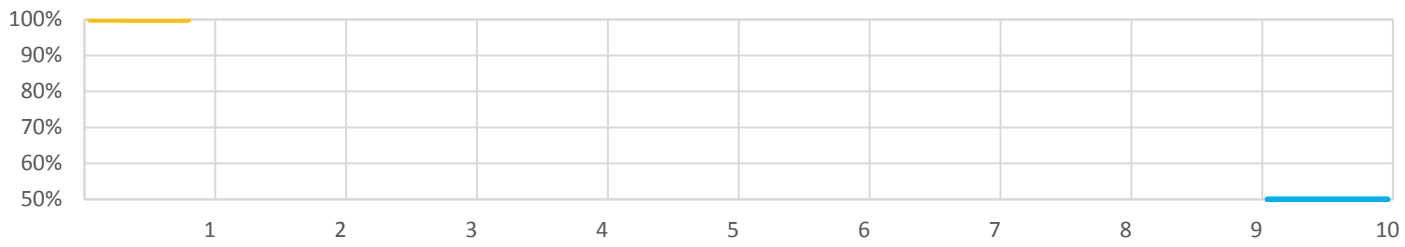
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

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

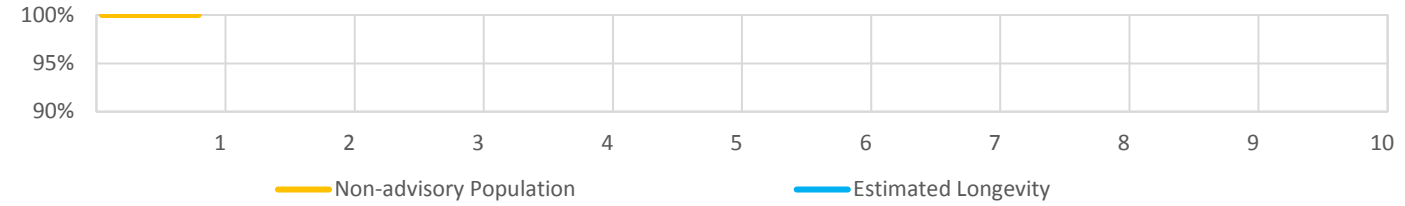
US Summary

US Registered Implants:	3,000	US Normal Battery Depletions:	1
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	99.9%	--	--	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	--	--	--	--	--	--	--	--	--
3000	Effective Sample Size	259	--	--	--	--	--	--	--	--	--

@ 11 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

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

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

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

References cited in table above (link)

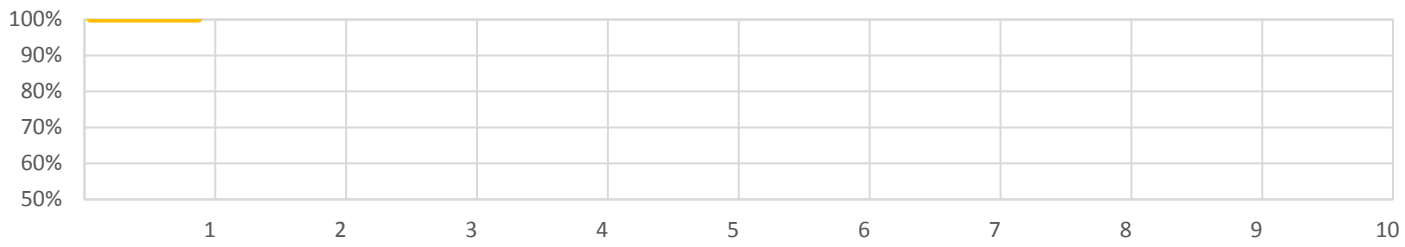
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

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

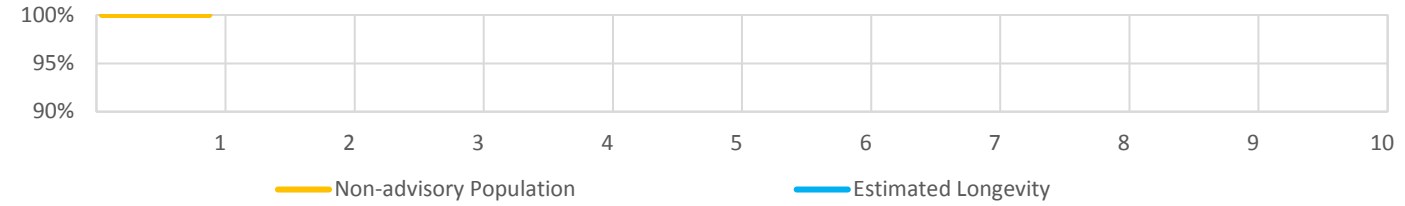
US Summary

US Registered Implants:	4,000	US Normal Battery Depletions:	-
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%	--	--	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	--	--	--	--	--	--	--	--	--
4000	Effective Sample Size	220	--	--	--	--	--	--	--	--	--

@ 12 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

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

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

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

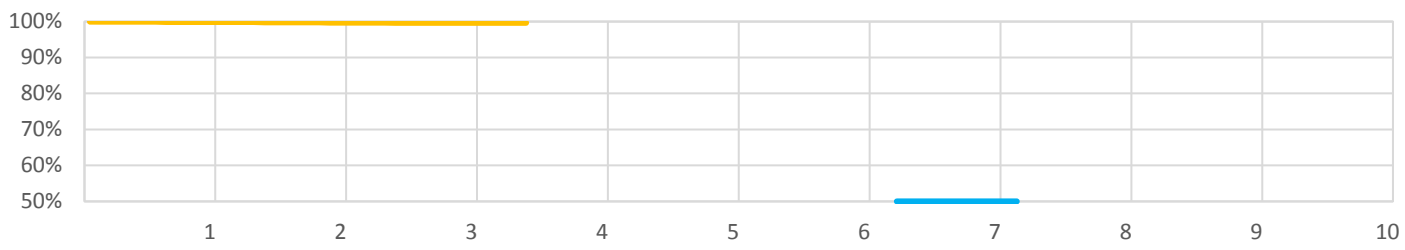
References cited in table above (link)

EMBLEM S-ICD

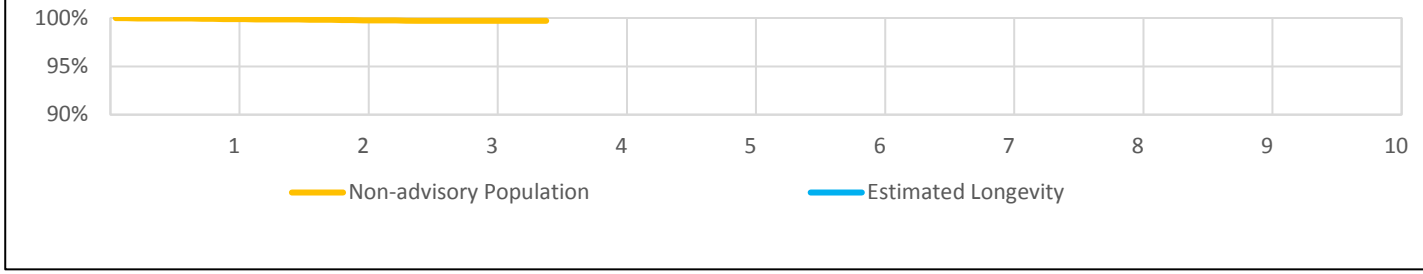
Models: A209/A219

US Summary			
US Registered Implants:	24,000	US Normal Battery Depletions:	7
US Approval Date:	March 2015	US Malfunctions:	35
US Estimated Active Implants:	22,000	Without Compromised Therapy:	19
		With Compromised Therapy:	16

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%	99.7%	99.6%	99.6%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.7%	--	--	--	--	--	--
24000	Effective Sample Size	14489	7700	2399	368	--	--	--	--	--	--

@ 42 months

EMBLEM S-ICD

Models: A209/A219

Worldwide Confirmed Malfunctions	**66**
Worldwide Distribution	**47,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	17	18	35
Telemetry (56)	6	6	12
Electrical			
High-voltage capacitor (43)	0	1	1
Capacitor (72)	16	0	16
Software			
Memory corruption (65)	0	1	1
Misaligned markers (73)	1	0	1
Grand Total	**40**	**26**	**66**

References cited in table above (link)

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**15,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	1	2
Electrical			
High voltage circuit component (62)	3	0	3
Integrated circuit (63)	0	2	2
Low-voltage capacitor (69)	2	0	2
Grand Total	**6**	**3**	**9**

References cited in table above (link)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**16,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other **Software**	1	0	1
Memory errors (51) **Electrical**	0	1	1
High voltage capacitor (75)	0	1	1
Grand Total	**1**	**2**	**3**

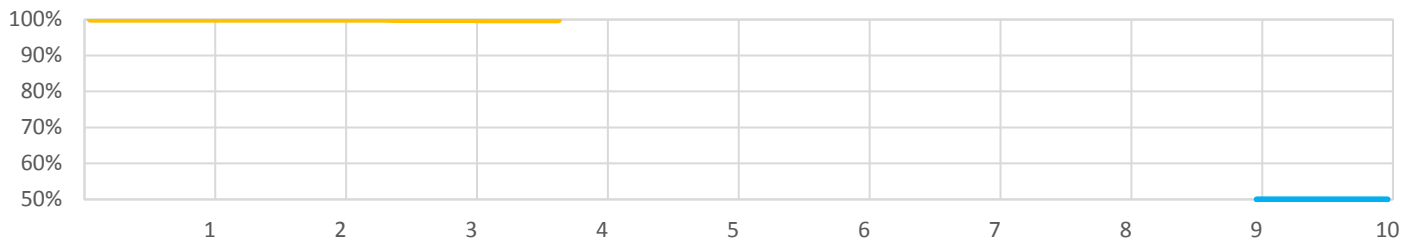
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

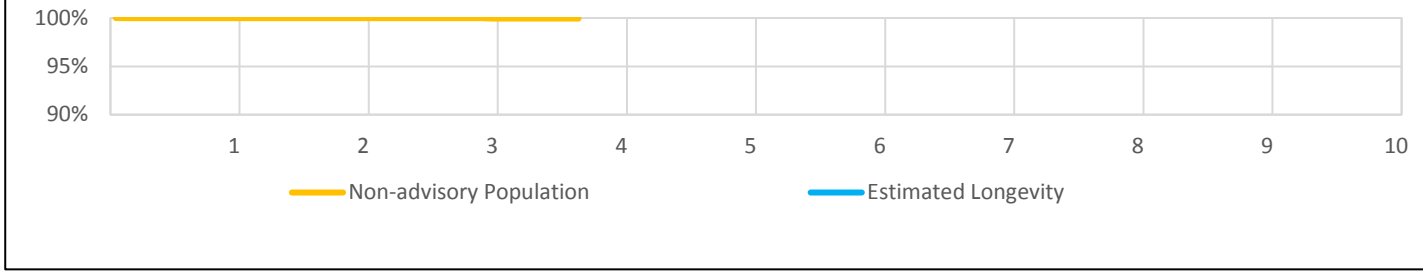
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	34,000	US Normal Battery Depletions:	11
US Approval Date:	April 2014	US Malfunctions:	7
US Estimated Active Implants:	31,000	Without Compromised Therapy:	4
		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%	99.8%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	--	--	--	--	--	--
34000	Effective Sample Size	22681	11831	4200	302	--	--	--	--	--	--

@ 45 months

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

Worldwide Confirmed Malfunctions	**10**
Worldwide Distribution	**47,000**

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

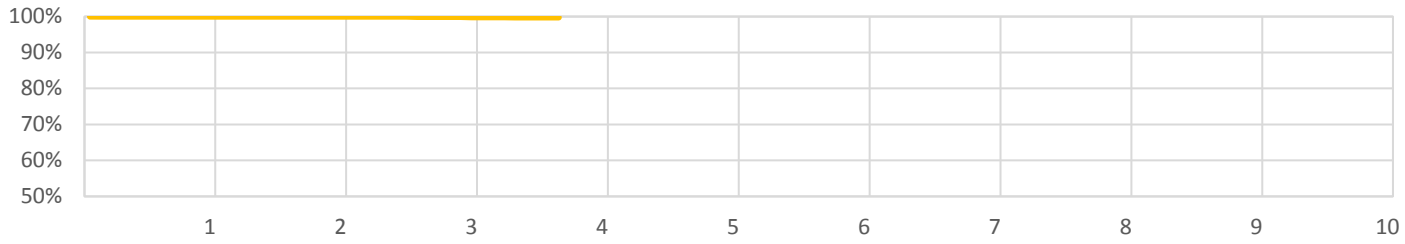
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL VR

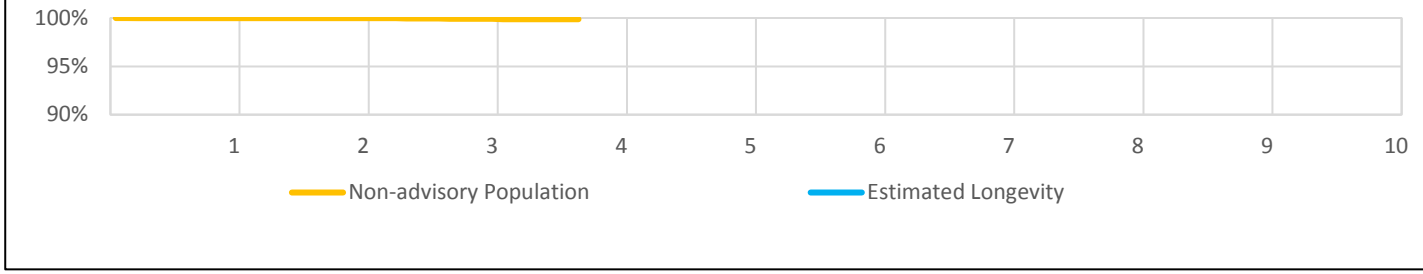
Models: D050/D051/D140/D141/D150/D151

US Summary			
US Registered Implants:	29,000	US Normal Battery Depletions:	8
US Approval Date:	April 2014	US Malfunctions:	10
US Estimated Active Implants:	27,000	Without Compromised Therapy:	10
		With Compromised Therapy:	0

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%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	--	--	--	--	--	--
29000	Effective Sample Size	19907	11074	4182	273	--	--	--	--	--	--

@ 45 months

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

Worldwide Confirmed Malfunctions	**16**
Worldwide Distribution	**46,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	5	1	6
Electrical			
Low-voltage capacitors (47)	1	0	1
High voltage circuit component (62)	1	0	1
Integrated circuit (63)	1	0	1
Low-voltage capacitor (69)	4	0	4
Software			
Memory errors (51)	3	0	3
Grand Total	**15**	**1**	**16**

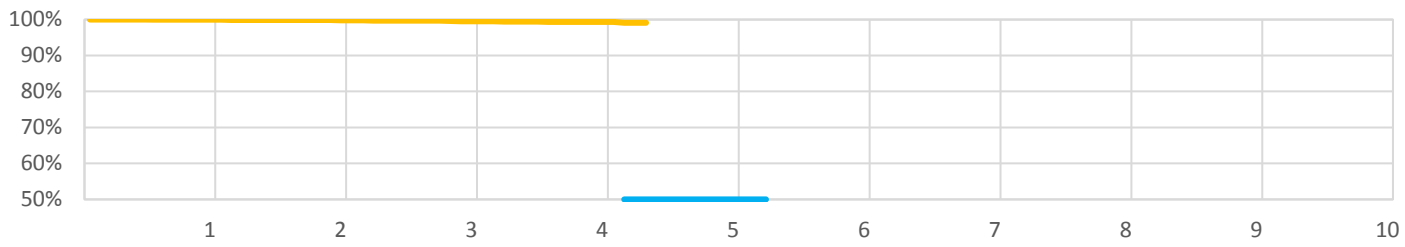
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

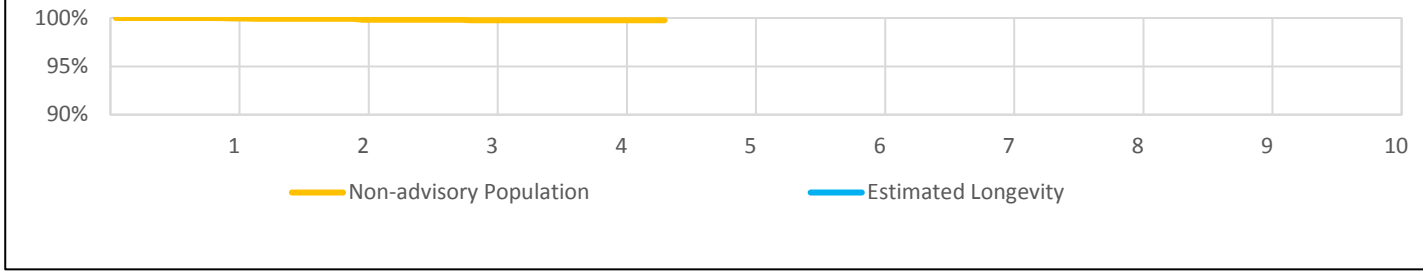
Models: D002/D003/D012/D013/D022/D023

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	14
US Approval Date:	April 2014	US Malfunctions:	10
US Estimated Active Implants:	7,000	Without Compromised Therapy:	8
		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%	99.5%	99.3%	99.1%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.8%	99.8%	--	--	--	--	--
8000	Effective Sample Size	5950	4120	2456	825	270	--	--	--	--	--

@ 53 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

Worldwide Confirmed Malfunctions	**14**
Worldwide Distribution	**20,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	3	1	4
Electrical			
High voltage circuit component (62)	8	0	8
High voltage capacitor (75)	0	2	2
Grand Total	**11**	**3**	**14**

References cited in table above (link)

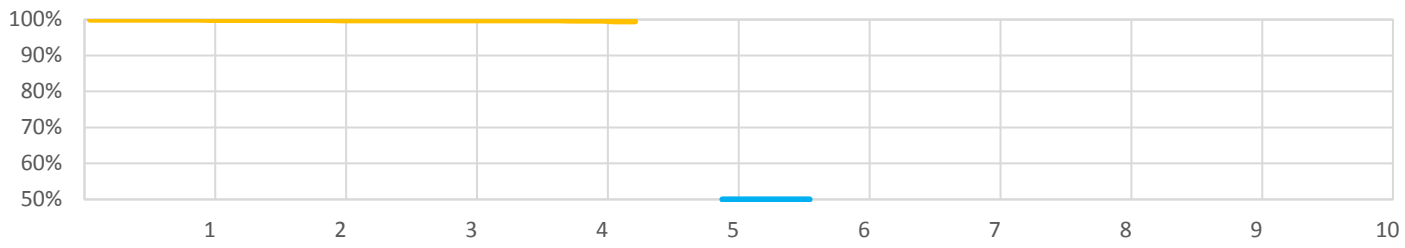
DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

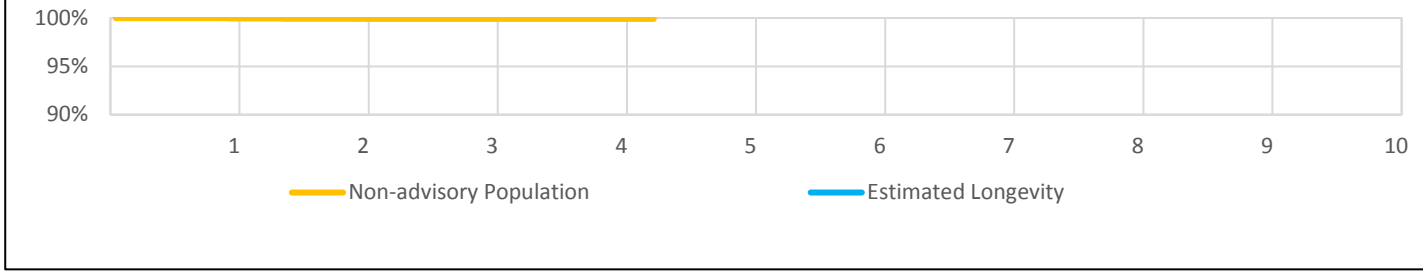
US Summary

US Registered Implants:	8,000	US Normal Battery Depletions:	7
US Approval Date:	April 2014	US Malfunctions:	5
US Estimated Active Implants:	7,000	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%	99.7%	99.5%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--	--
8000	Effective Sample Size	5795	4088	2449	748	297	--	--	--	--	--

@ 52 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

Worldwide Confirmed Malfunctions	**12**
Worldwide Distribution	**21,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	2	0	2
Electrical			
Low-voltage capacitors (47)	2	0	2
High voltage circuit component (62)	4	0	4
High voltage capacitor (75)	0	2	2
Software			
Memory errors (51)	1	1	2
Grand Total	**9**	**3**	**12**

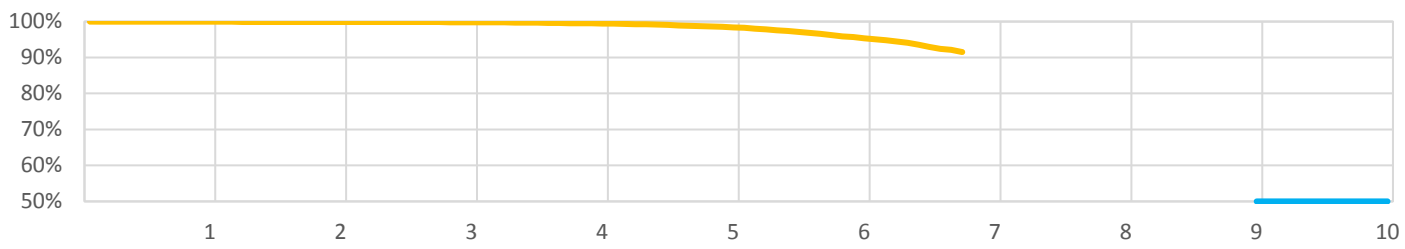
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD DR

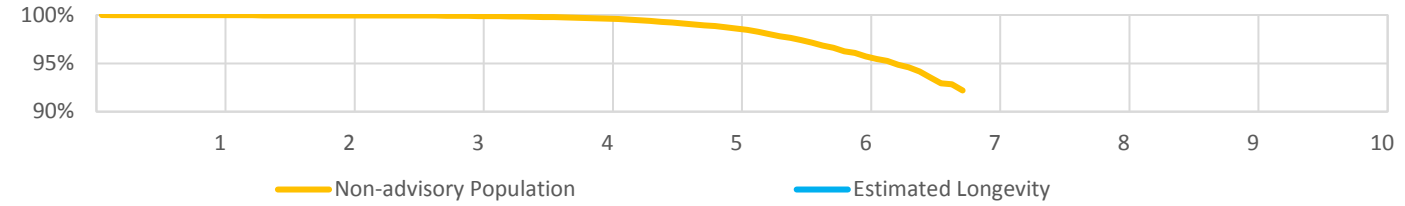
Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

US Summary			
US Registered Implants:	47,000	US Normal Battery Depletions:	84
US Approval Date:	March 2008	US Malfunctions:	612
US Estimated Active Implants:	35,000	Without Compromised Therapy:	598
		With Compromised Therapy:	14

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%	98.5%	95.7%	91.5%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	98.7%	96.1%	92.2%	--	--	--
47000	Effective Sample Size	41227	36539	31742	25191	14573	5379	444	--	--	--

@ 82 months

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

Worldwide Confirmed Malfunctions	**945**
Worldwide Distribution	**72,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	15	5	20
Mechanical			
Transformer (38)	0	2	2
Electrical			
High-voltage capacitor (43)	1	4	5
Low-voltage capacitors (47)	4	0	4
Integrated circuit (50)	7	4	11
Battery (53)	43	5	48
Low-voltage capacitor (54)	844	3	847
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	2	0	2
Software			
Memory errors (51)	5	0	5
Grand Total	**922**	**23**	**945**

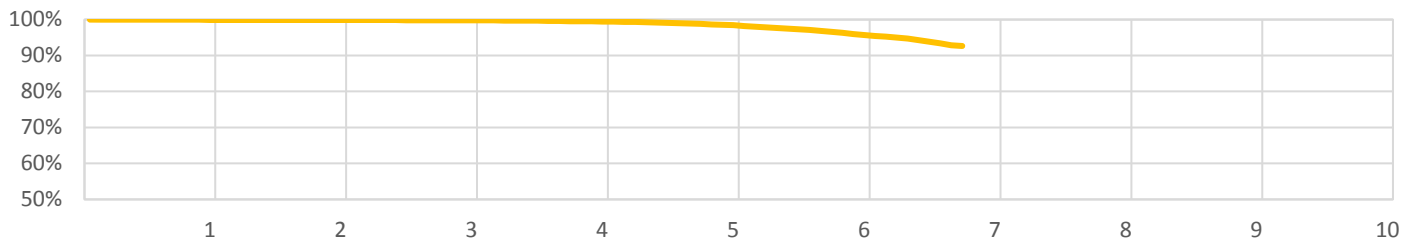
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD VR

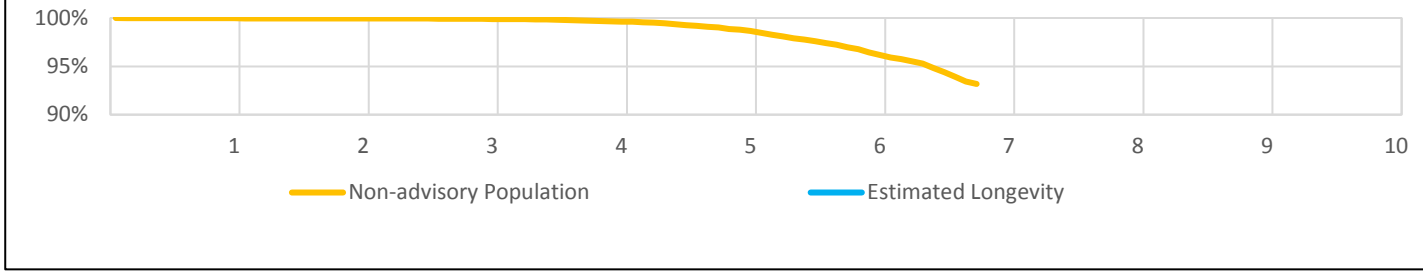
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	77
US Approval Date:	November 2011	US Malfunctions:	458
US Estimated Active Implants:	30,000	Without Compromised Therapy:	433
		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%	99.5%	98.6%	96.0%	92.7%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	98.8%	96.4%	93.2%	--	--	--
39000	Effective Sample Size	34703	30731	26747	21076	11944	4461	395	--	--	--

@ 82 months

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

Worldwide Confirmed Malfunctions	**759**
Worldwide Distribution	**68,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	11	10	21
Mechanical			
Transformer (38)	0	6	6
Electrical			
High-voltage capacitor (43)	1	3	4
Integrated circuit (50)	3	5	8
Battery (53)	52	8	60
Low-voltage capacitor (54)	645	7	652
High voltage circuit (58)	0	1	1
Software			
Memory errors (51)	6	1	7
Grand Total	**718**	**41**	**759**

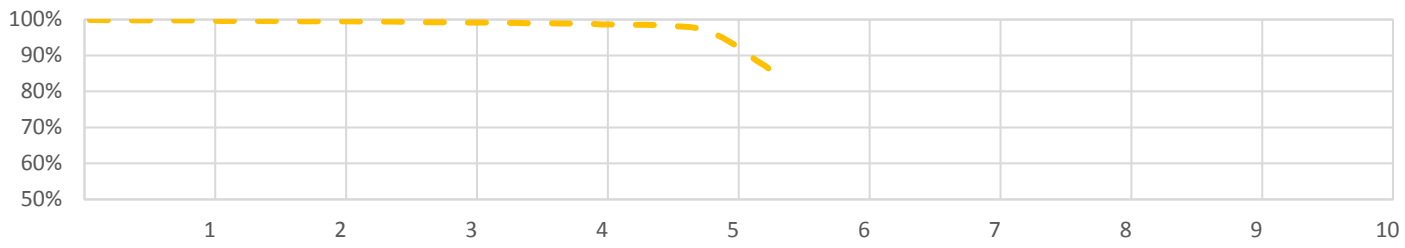
References cited in table above (link)

SQ-RX S-ICD

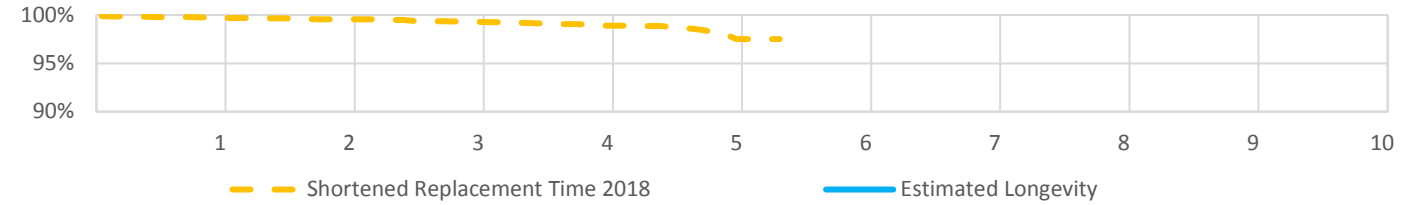
Models: 1010

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	226
US Approval Date:	September 2012	US Malfunctions:	75
US Estimated Active Implants:	6,000	Without Compromised Therapy:	30
		With Compromised Therapy:	45

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%	98.8%	95.0%	84.5%	--	--	--	--
Registered Implants:	Malfunctions Only	99.7%	99.6%	99.3%	99.0%	98.0%	97.5%	--	--	--	--
8000	Effective Sample Size	6460	5692	5020	3106	531	203	--	--	--	--

@ 65 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	**168**
Worldwide Distribution	**11,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	20	35	55
Telemetry (56)	3	10	13
Electrical			
Unintended Fuse Activation 2013 (4)	0	3	3
Charge Timeout Alert (61)	10	0	10
Shortened replacement time 2018 (55)	29	46	75
Mechanical			
High cathode condition (5)	1	1	2
Software			
Unintended Battery Depletion Alert (57)	10	0	10
Grand Total	**73**	**95**	**168**

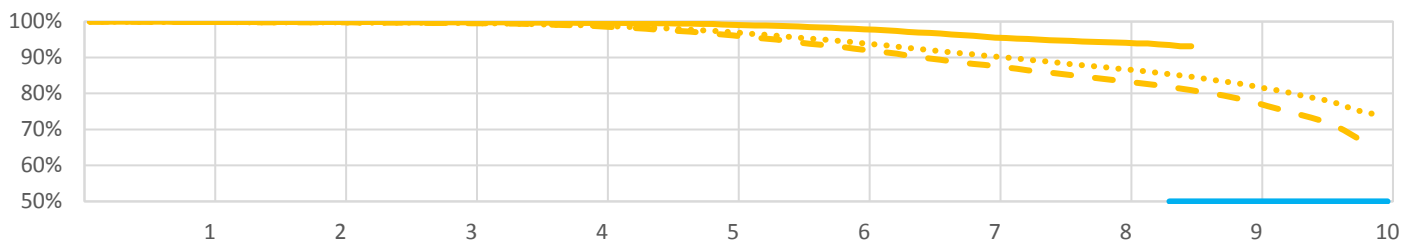
References cited in table above (link)

TELIGEN DR

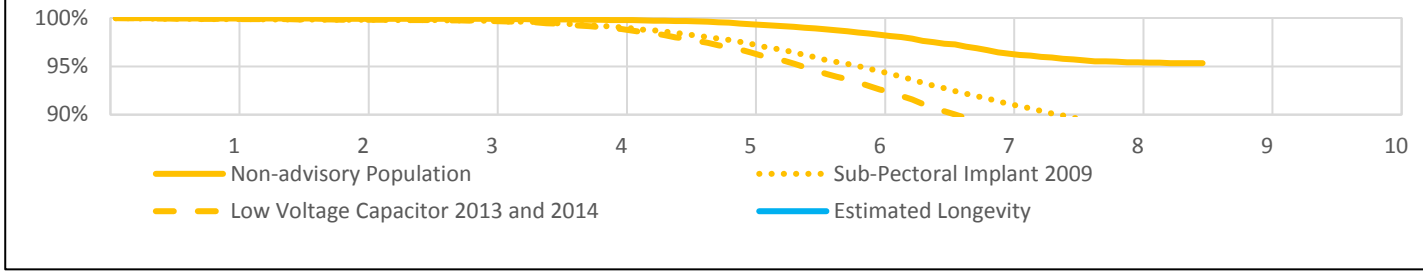
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	1,155
US Approval Date:	March 2008	US Malfunctions:	2,665
US Estimated Active Implants:	33,000	Without Compromised Therapy:	2,535
		With Compromised Therapy:	140

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%	95.8%	94.2%	93.1%	--
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.5%	95.4%	95.3%	--
30000	Effective Sample Size	26322	23344	20697	18277	16078	13979	11243	3997	405	--

@ 103 months

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 Registered Implants: 30000	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.9%	97.2%	94.2%	90.6%	87.0%	82.5%	74.2%
	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.8%	91.4%	88.7%	86.7%	85.8%
	Effective Sample Size	26608	23481	20752	18216	15827	13477	11335	9477	7585	1680
Low Voltage Capacitor 2013 and 2014 Registered Implants: 23000	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.5%	92.5%	87.9%	83.7%	78.2%	66.2%
	Malfunctions Only	99.9%	99.8%	99.6%	98.8%	96.5%	92.5%	87.9%	83.7%	78.2%	80.8%
	Effective Sample Size	20598	18198	16074	14098	12148	10226	8497	7023	3861	224

@ 119 months

*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	**3,569**
Worldwide Distribution	**91,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	31	10	41
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	2183	48	2231
Safety Core-electrocautery (42)	4	1	5
High-voltage capacitor (43)	1	7	8
Low-voltage capacitors (47)	8	0	8
Integrated circuit (50)	20	21	41
Battery (53)	231	32	263
Low-voltage capacitor (54)	873	5	878
Low-voltage capacitor (69)	1	0	1
Mechanical			
Transformer (38)	0	20	20
Seal plug (40)	3	0	3
Difficulty securing lead (41)	7	7	14
Header contacts (45)	3	14	17
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	3	8	11
Header (74)	3	7	10
Software			
Alert messages not displayed post-EOL (48)	3	0	3
Memory errors (51)	15	0	15
Grand Total	**3389**	**180**	**3569**

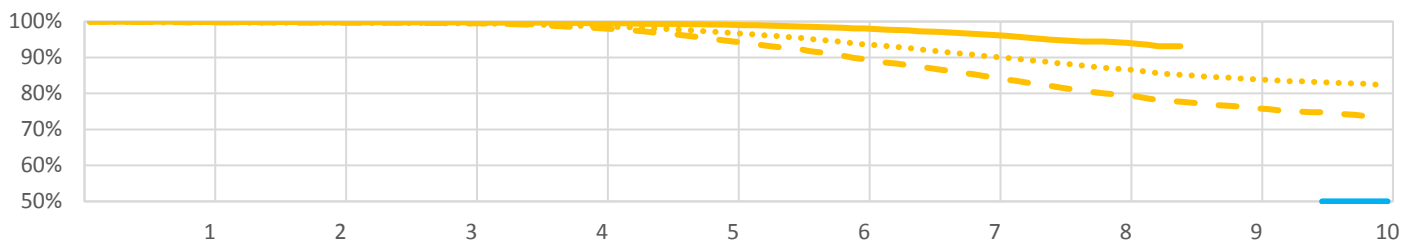
References cited in table above (link)

TELIGEN VR

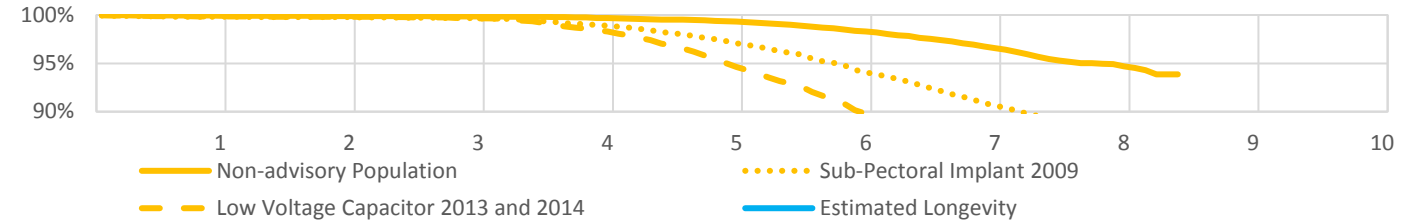
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	161
US Approval Date:	March 2008	US Malfunctions:	1,838
US Estimated Active Implants:	20,000	Without Compromised Therapy:	1,725
		With Compromised Therapy:	113

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%	99.6%	99.1%	98.1%	96.4%	94.3%	93.1%	--
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.7%	99.3%	98.4%	96.7%	94.9%	93.9%	--
18000	Effective Sample Size	16194	14328	12644	11147	9785	8510	6736	1713	233	--

@ 102 months

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%	99.7%	99.5%	98.7%	97.0%	93.9%	90.4%	86.9%	84.1%	82.5%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.7%	99.0%	97.3%	94.3%	90.9%	87.5%	85.0%	84.3%
16000	Effective Sample Size	13607	11985	10556	9230	7972	6784	5694	4741	3878	966
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.3%	94.8%	89.9%	84.8%	79.7%	76.0%	73.7%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.5%	98.3%	94.8%	89.9%	84.8%	79.7%	76.0%	75.5%
12000	Effective Sample Size	10840	9568	8433	7352	6249	5182	4235	3432	1793	207

@ 119 months

*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	**3,026**
Worldwide Distribution	**66,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	13	12	25
Mechanical			
Transformer (24)	0	1	1
Transformer (38)	0	14	14
Seal plug (40)	1	0	1
Difficulty securing lead (41)	0	9	9
Header contacts (45)	16	23	39
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	6	14	20
Header (74)	4	13	17
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	1759	38	1797
Safety Core-electrocautery (42)	1	1	2
High-voltage capacitor (43)	0	3	3
Low-voltage capacitors (47)	5	0	5
Integrated circuit (50)	11	16	27
Battery (53)	352	38	390
Low-voltage capacitor (54)	655	3	658
Low-voltage capacitor (69)	1	0	1
Software			
Alert messages not displayed post-EOL (48)	4	0	4
Memory errors (51)	11	0	11
Respiratory Sensor Oversensing - March 23, 2009 Voluntary Physician Advisory (7)	2	0	2
Grand Total	**2841**	**185**	**3026**

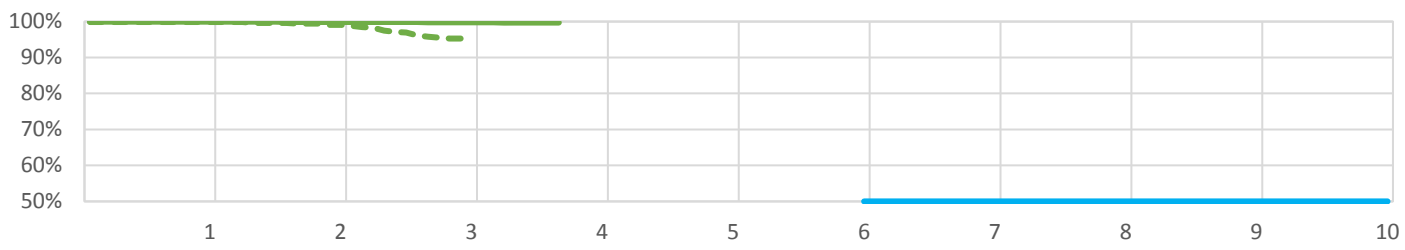
References cited in table above (link)

ACCOLADE/PROPONENT/ESSENTIO DR

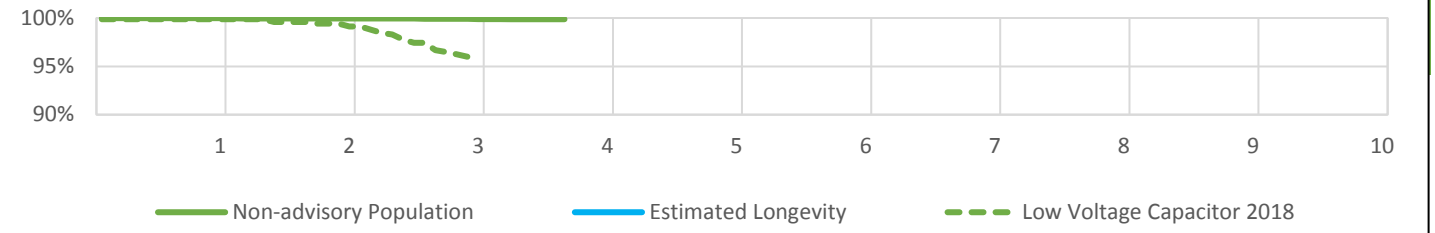
Models: L101/L111/L201/L211/L301/L311

US Summary			
US Registered Implants:	137,000	US Normal Battery Depletions:	63
US Approval Date:	October 2014	US Malfunctions:	83
US Estimated Active Implants:	126,000	Without Compromised Therapy:	76
		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%	99.8%	99.7%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	--	--	--	--	--	--
136000	Effective Sample Size	89646	48176	14914	255	--	--	--	--	--	--

@ 45 months

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%	95.5%	95.3%	--	--	--	--	--	--
Registered Implants: 300	Malfunctions Only	99.9%	99.4%	96.3%	96.0%	--	--	--	--	--	--
	Effective Sample Size	714	640	437	227	--	--	--	--	--	--

@ 38 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	**148**
Worldwide Distribution	**263,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	26	6	32
Electrical			
Low-voltage capacitors (47)	2	0	2
Integrated circuit (63)	15	5	20
Capacitor (67)	30	0	30
Telemetry (68)	8	1	9
Hydrogen induced premature depletion - September 2018 (70)	38	0	38
Software			
Memory errors (51)	17	0	17
Grand Total	**136**	**12**	**148**

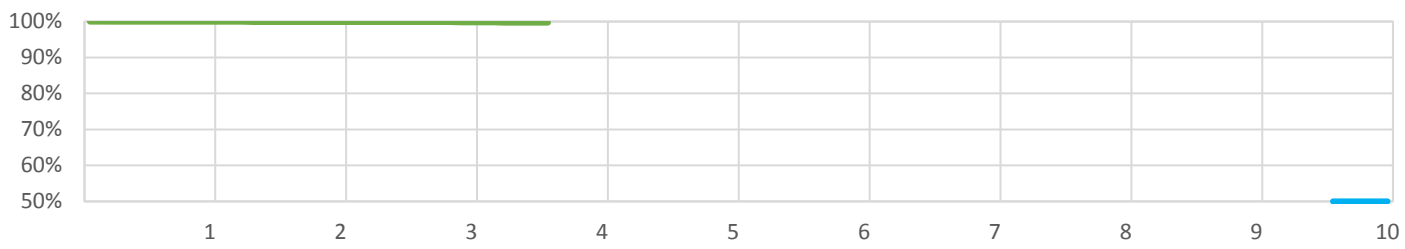
References cited in table above (link)

ACCOLADE/PROPONENT/ESSENTIO DR EL

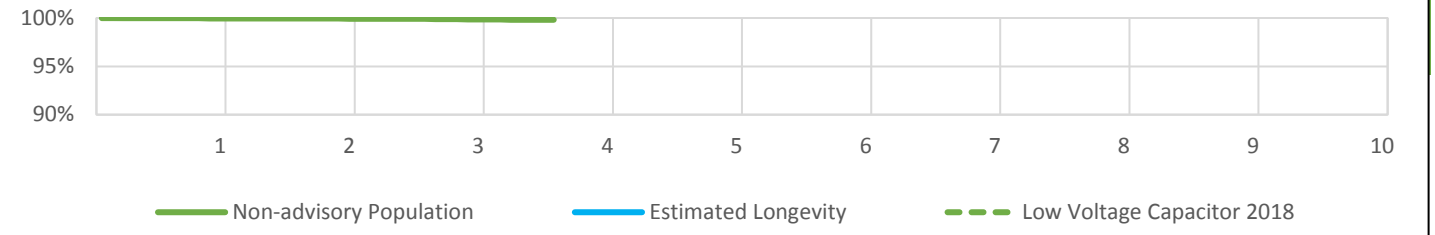
Models: L121/L131/L221/L231/L321/L331

US Summary			
US Registered Implants:	59,000	US Normal Battery Depletions:	11
US Approval Date:	October 2014	US Malfunctions:	35
US Estimated Active Implants:	56,000	Without Compromised Therapy:	33
		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%	99.8%	99.7%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	--	--	--	--	--	--
59000	Effective Sample Size	35587	16818	4368	336	--	--	--	--	--	--

@ 44 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 EL

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

Worldwide Confirmed Malfunctions	**87**
Worldwide Distribution	**137,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	14	1	15
Electrical			
Low-voltage capacitors (47)	2	0	2
Integrated circuit (63)	4	1	5
Capacitor (67)	20	0	20
Telemetry (68)	8	0	8
Hydrogen induced premature depletion - September 2018 (70)	17	2	19
Software			
Memory errors (51)	18	0	18
Grand Total	**83**	**4**	**87**

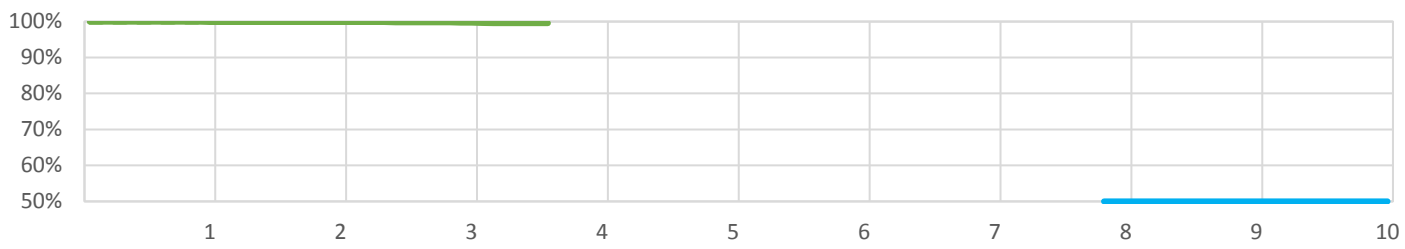
References cited in table above (link)

ACCOLADE/PROPONENT/ESSENTIO SR

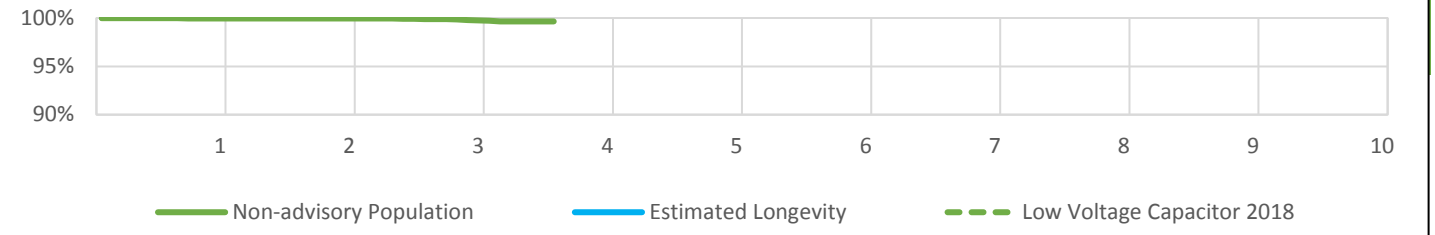
Models: L100/L110/L200/L210/L300/L310

US Summary			
US Registered Implants:	27,000	US Normal Battery Depletions:	13
US Approval Date:	October 2014	US Malfunctions:	25
US Estimated Active Implants:	24,000	Without Compromised Therapy:	23
		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	99.9%	99.9%	99.7%	99.6%	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.8%	99.6%	--	--	--	--	--	--
27000	Effective Sample Size	17518	9299	2683	211	--	--	--	--	--	--

@ 44 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	**56**
Worldwide Distribution	**94,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	4	0	4
Electrical			
Low-voltage capacitors (47)	2	0	2
Integrated circuit (63)	3	4	7
Capacitor (67)	20	0	20
Telemetry (68)	4	0	4
Hydrogen induced premature depletion - September 2018 (70)	14	1	15
Software			
Memory errors (51)	4	0	4
Grand Total	**51**	**5**	**56**

References cited in table above (link)

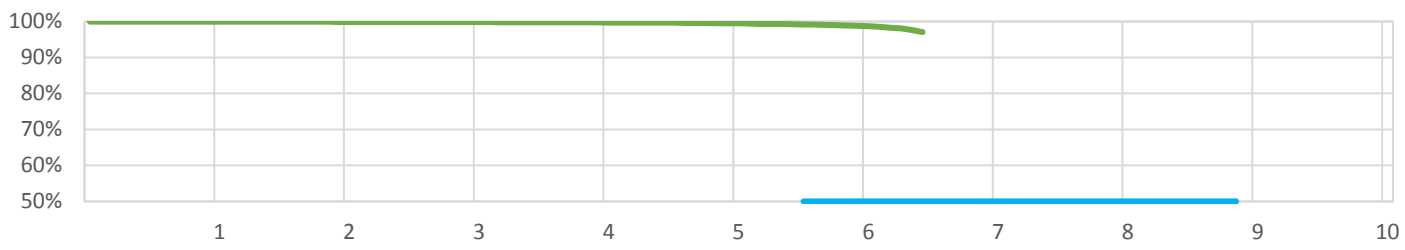
ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

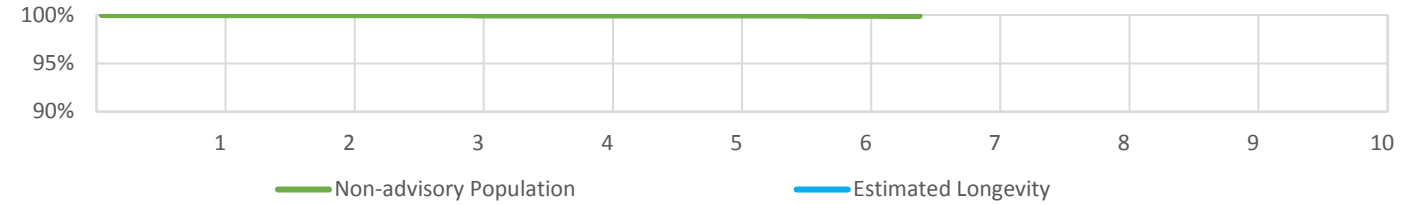
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	292
US Approval Date:	May 2012	US Malfunctions:	53
US Estimated Active Implants:	97,000	Without Compromised Therapy:	42
		With Compromised Therapy:	11

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%	99.5%	98.8%	97.1%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	--	--	--
#REF!	Effective Sample Size	107324	95745	85278	66740	34772	9423	1106	--	--	--

@ 78 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	**88**
Worldwide Distribution	**219,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	36	8	44
Electrical			
Low-voltage capacitors (47)	8	0	8
Integrated circuit (50)	3	7	10
Titanium case material (60)	0	3	3
Software			
Memory errors (51)	22	1	23
Grand Total	**69**	**19**	**88**

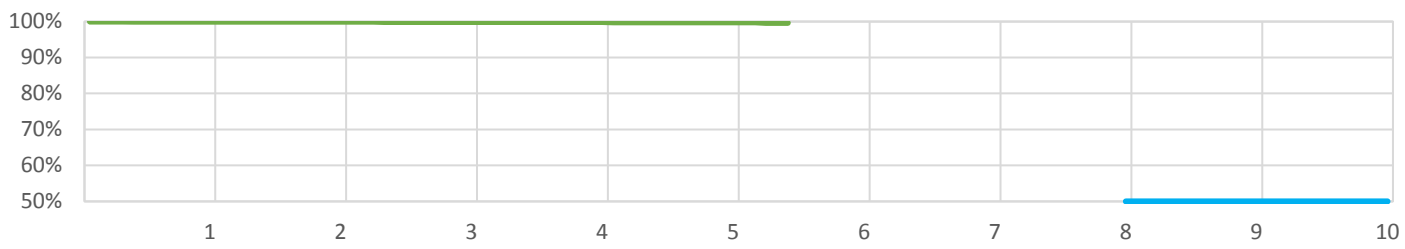
References cited in table above (link)

ADVANTIO/INGENIO/VITALIO EL DR

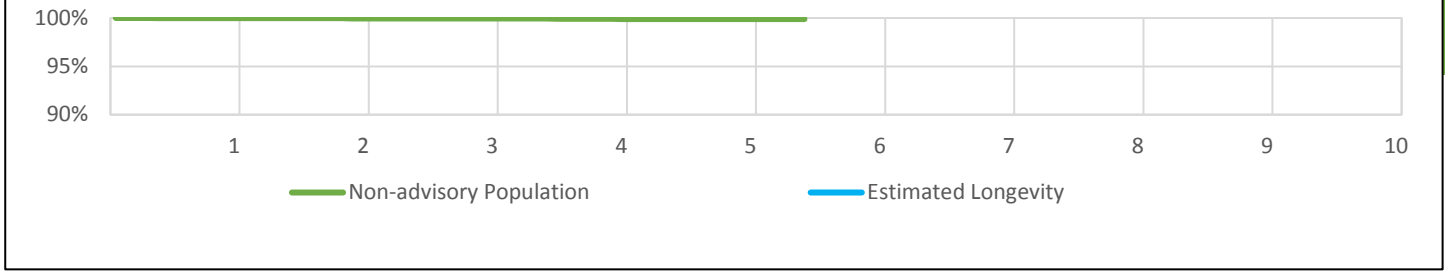
Models: J064/J067/J174/J177/J274/J277/K064/K067/K084/K087/K174/K177/K184/K187/K274/K277/K284/K287

US Summary			
US Registered Implants:	11,000	US Normal Battery Depletions:	5
US Approval Date:	March 2008	US Malfunctions:	8
US Estimated Active Implants:	9,000	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%	99.9%	99.9%	99.9%	99.8%	99.6%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--
11000	Effective Sample Size	9674	8584	7466	5047	1158	257	--	--	--	--

@ 66 months

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	**48**
Worldwide Distribution	**75,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	29	4	33
Electrical			
Low-voltage capacitors (47)	5	1	6
Integrated circuit (50)	0	2	2
Titanium case material (60)	0	2	2
Software			
Memory errors (51)	4	0	4
Respiratory sensor (59)	1	0	1
Grand Total	**39**	**9**	**48**

References cited in table above (link)

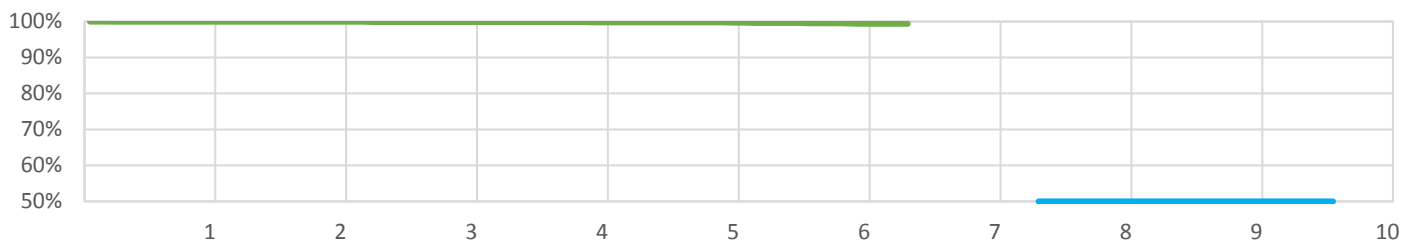
ADVANTIO/INGENIO/VITALIO SR

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

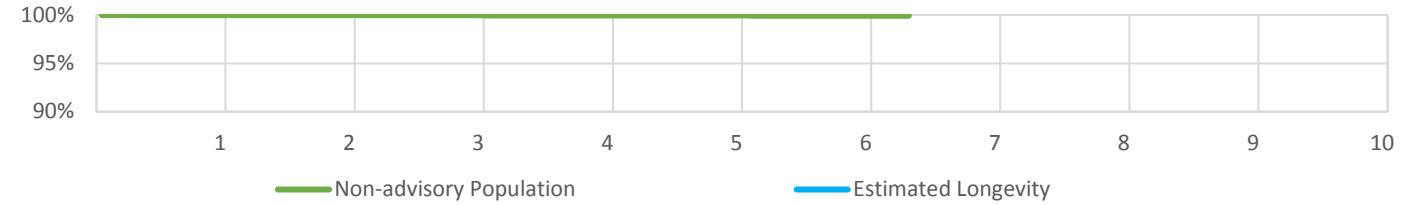
US Summary

US Registered Implants:	27,000	US Normal Battery Depletions:	41
US Approval Date:	May 2012	US Malfunctions:	11
US Estimated Active Implants:	18,000	Without Compromised Therapy:	10
		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%	99.5%	99.4%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	--	--	--
27000	Effective Sample Size	22943	20415	17867	13223	6679	1716	360	--	--	--

@ 77 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	**24**
Worldwide Distribution	**86,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	2	3	5
Electrical			
Low-voltage capacitors (47)	3	1	4
Integrated circuit (50)	2	3	5
Titanium case material (60)	0	1	1
Software			
Memory errors (51)	9	0	9
Grand Total	**16**	**8**	**24**

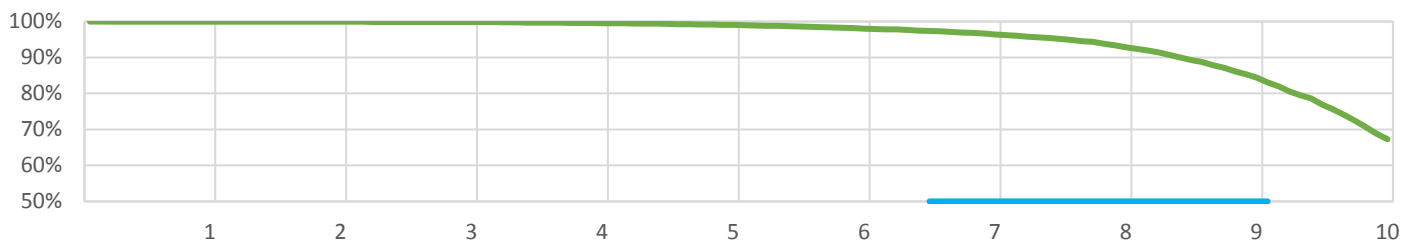
References cited in table above (link)

ALTRUA 60 DR

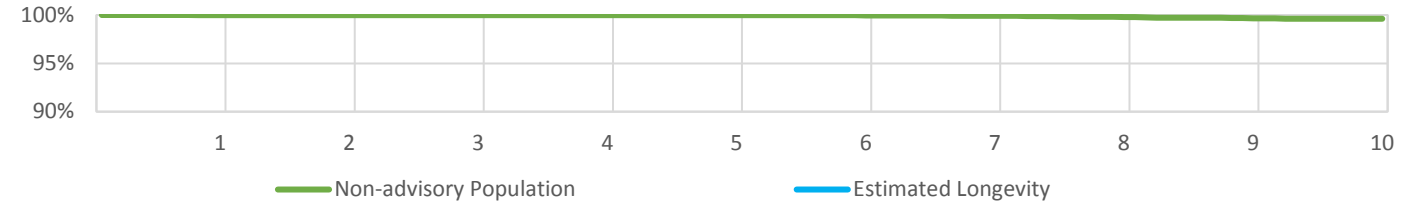
Model: S602

US Summary			
US Registered Implants:	22,000	US Normal Battery Depletions:	1,796
US Approval Date:	March 2008	US Malfunctions:	29
US Estimated Active Implants:	11,000	Without Compromised Therapy:	27
		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%	99.9%	99.6%	99.1%	98.2%	96.6%	93.4%	85.4%	68.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%
22000	Effective Sample Size	19576	17447	15497	13712	12044	10450	8770	6749	4587	1260

ALTRUA 60 DR

Models: S602

Worldwide Confirmed Malfunctions	**44**
Worldwide Distribution	**56,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	2	2	4
Battery depletion (26)	1	1	2
Battery status (49)	35	0	35
Electrical			
Capacitor (15)	1	0	1
Mechanical			
Capacitor array (16)	1	0	1
Difficulty securing lead (41)	0	1	1
Grand Total	**40**	**4**	**44**

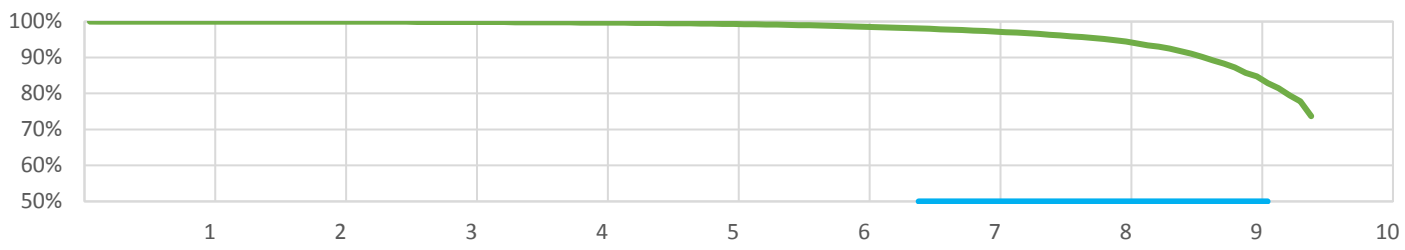
References cited in table above (link)

ALTRUA 60 EL DR

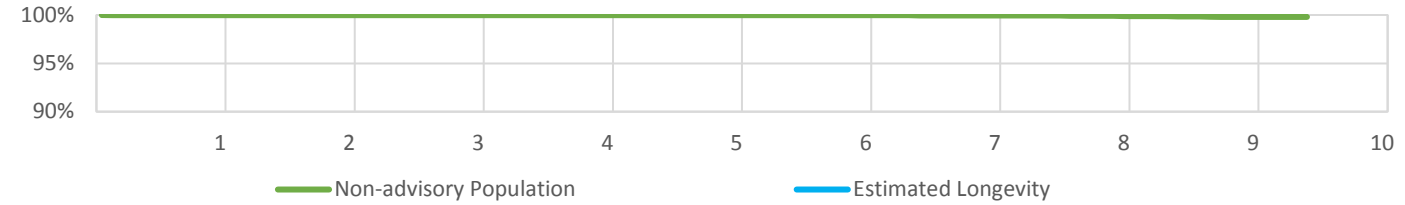
Model: S606

US Summary			
US Registered Implants:	59,000	US Normal Battery Depletions:	1,724
US Approval Date:	April 2008	US Malfunctions:	27
US Estimated Active Implants:	37,000	Without Compromised Therapy:	22
		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	100.0%	99.9%	99.9%	99.7%	99.4%	98.6%	97.4%	94.8%	85.8%	73.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
59000	Effective Sample Size	52510	46931	41889	37343	33203	28786	20388	10032	2277	219

@ 114 months

ALTRUA 60 DR EL

Models: S606

Worldwide Confirmed Malfunctions	**33**
Worldwide Distribution	**90,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	2	3
Battery depletion (26)	0	2	2
Battery status (49)	22	0	22
Magnet rate (44)	1	0	1
Electrical			
Capacitor (15)	3	0	3
Integrated circuit (17)	1	0	1
Mechanical			
Difficulty securing lead (41)	0	1	1
Grand Total	**28**	**5**	**33**

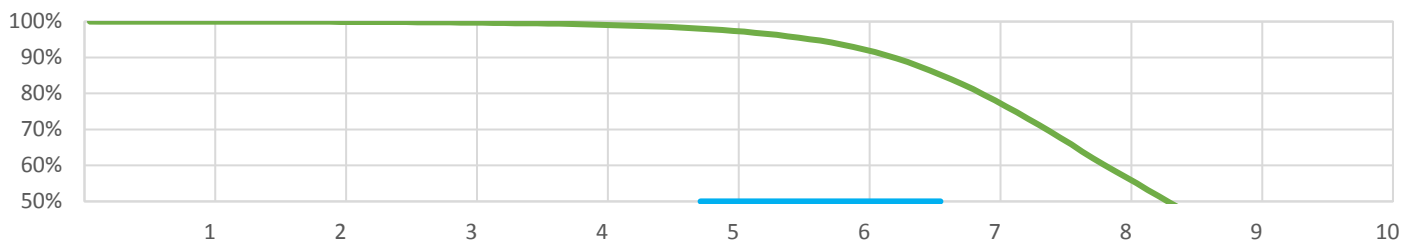
References cited in table above (link)

ALTRUA 60 DR (Downsize)

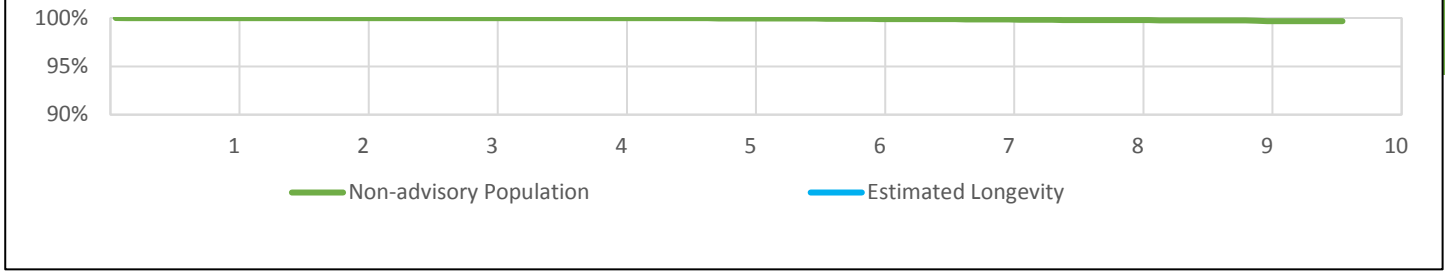
Model: S603

US Summary			
US Registered Implants:	90,000	US Normal Battery Depletions:	17,787
US Approval Date:	April 2008	US Malfunctions:	88
US Estimated Active Implants:	34,000	Without Compromised Therapy:	78
		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%	93.0%	79.6%	58.4%	38.0%	18.0%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
89000	Effective Sample Size	78576	70273	62753	55833	49083	41066	27068	11981	3217	327

@ 116 months

ALTRUA 60 DR (Downsize)

Models: S603

Worldwide Confirmed Malfunctions	**115**
Worldwide Distribution	**132,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	4	4	8
Battery depletion (26)	3	1	4
Battery status (49)	85	0	85
Magnet response (21)	2	0	2
Electrical			
Capacitor (15)	4	7	11
Integrated circuit (30)	1	1	2
Mechanical			
Difficulty securing lead (41)	1	0	1
Connector block (39)	1	0	1
Software			
Underestimation of battery status (34)	1	0	1
Grand Total	**102**	**13**	**115**

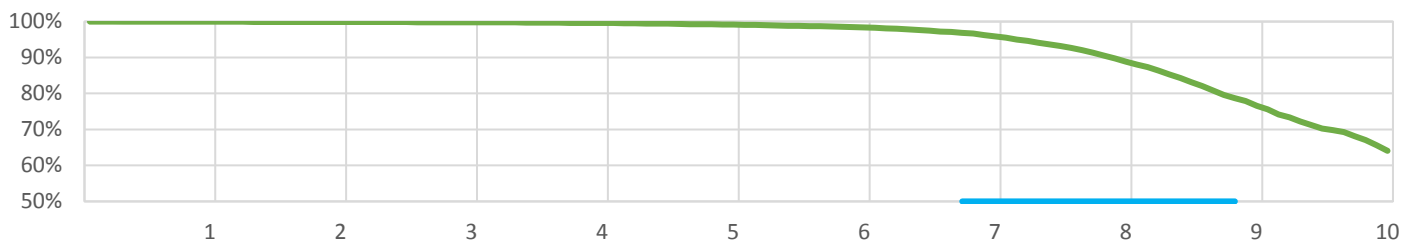
References cited in table above (link)

ALTRUA 60 SR

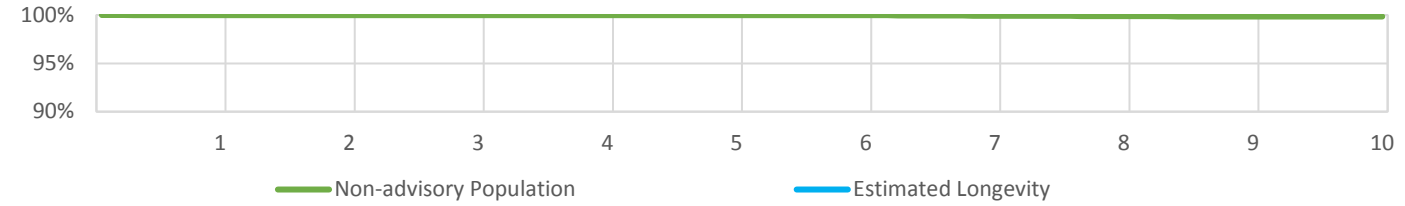
Model: S601

US Summary			
US Registered Implants:	32,000	US Normal Battery Depletions:	1,801
US Approval Date:	April 2008	US Malfunctions:	16
US Estimated Active Implants:	13,000	Without Compromised Therapy:	14
		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	99.9%	99.9%	99.8%	99.6%	99.2%	98.4%	96.2%	89.7%	77.9%	65.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
31000	Effective Sample Size	26349	23169	20624	18401	16337	14108	10405	5883	2342	358

ALTRUA 60 SR

Models: S601

Worldwide Confirmed Malfunctions	**29**
Worldwide Distribution	**68,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	2	3
Battery depletion (26)	0	1	1
Battery status (49)	20	0	20
Electrical			
Capacitor (15)	1	2	3
Integrated circuit (30)	0	2	2
Grand Total	**22**	**7**	**29**

References cited in table above (link)

ALTRUA 50 DR (Downsize)

Models: S502

Worldwide Confirmed Malfunctions	**32**
Worldwide Distribution	**48,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	0	1
Battery depletion (26)	2	0	2
Battery status (49)	25	0	25
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	1	0	1
Grand Total	**31**	**1**	**32**

References cited in table above (link)

ALTRUA 50 SR

Models: S501

Worldwide Confirmed Malfunctions	**12**
Worldwide Distribution	**25,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Battery depletion (26)	0	2	2
Battery status (49)	4	0	4
Electrical			
Capacitor (15)	1	4	5
Grand Total	**5**	**7**	**12**

References cited in table above (link)

ALTRUA 50 DDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**12,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery depletion (26)	0	3	3
Battery status (49)	6	0	6
Grand Total	**6**	**3**	**9**

References cited in table above (link)

ALTRUA 50 VDD (Downsize)

Models: S504

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

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery status (49)	5	0	5
Grand Total	**5**	**0**	**5**

References cited in table above (link)

ALTRUA 50 SSI

Models: S508

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

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	0	1	1
Battery status (49)	3	0	3
Grand Total	**3**	**1**	**4**

References cited in table above (link)

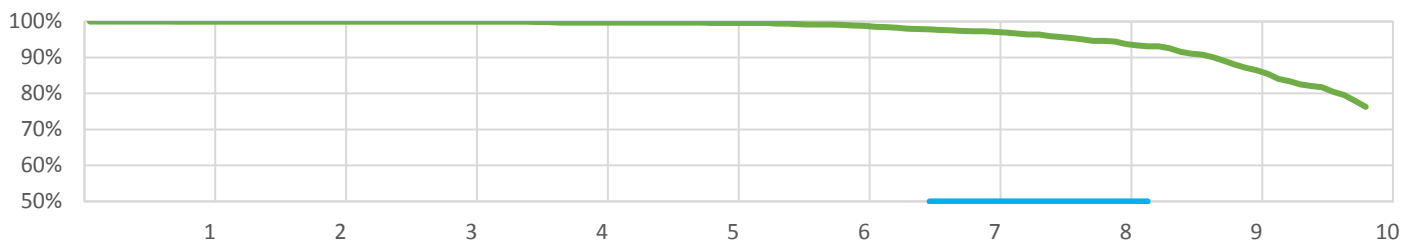
ALTRUA 40 DR

Model: S402

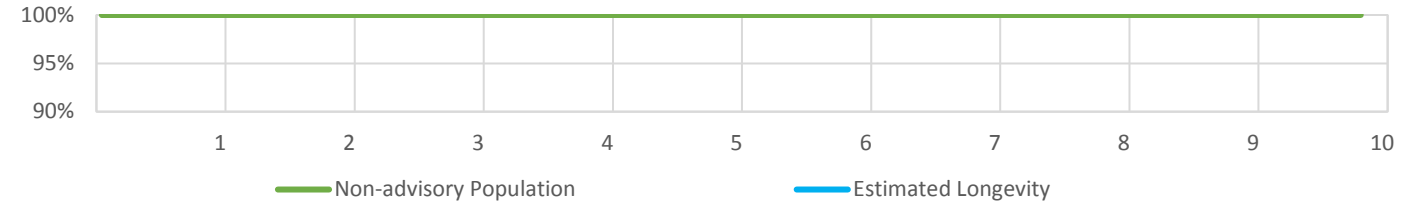
US Summary

US Registered Implants:	2,000	US Normal Battery Depletions:	143
US Approval Date:	April 2008	US Malfunctions:	-
US Estimated Active Implants:	1,000	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	99.9%	99.9%	99.9%	99.7%	99.6%	98.9%	97.3%	94.5%	87.1%	76.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
2000	Effective Sample Size	1468	1302	1151	1027	916	811	710	615	497	229

@ 119 months

ALTRUA 40 DR

Models: S402

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**3,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery depletion (26)	0	1	1
Grand Total	**0**	**1**	**1**

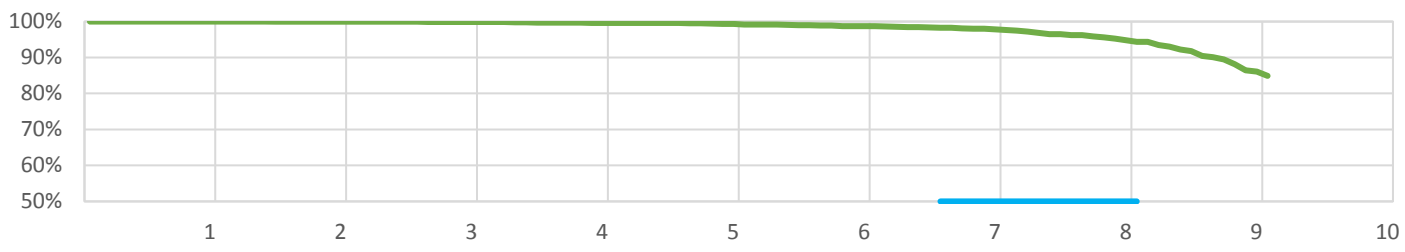
References cited in table above (link)

ALTRUA 40 DR EL

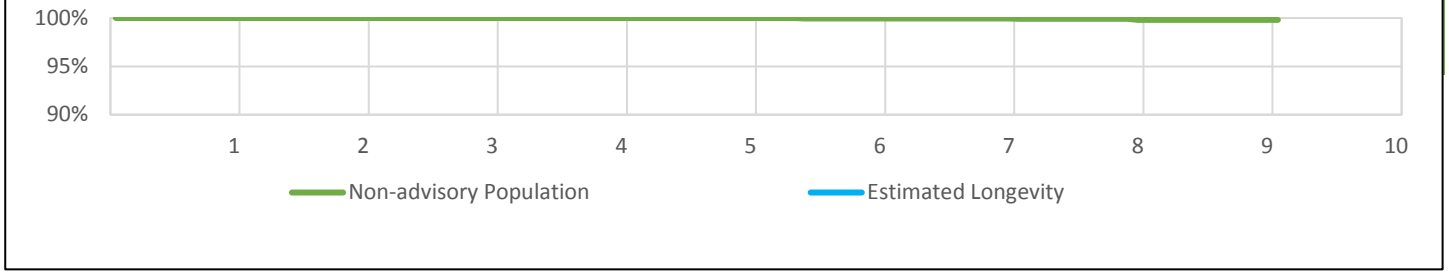
Model: S404

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	159
US Approval Date:	April 2008	US Malfunctions:	3
US Estimated Active Implants:	3,000	Without Compromised Therapy:	3
		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%	99.3%	98.7%	98.0%	95.2%	86.4%	84.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
5000	Effective Sample Size	4431	3964	3559	3180	2840	2502	1917	1065	315	214

@ 110 months

ALTRUA 40 DR EL

Models: S404

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**11,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery status (49)	3	0	3
Electrical			
Capacitor (15)	1	0	1
Grand Total	**4**	**0**	**4**

References cited in table above (link)

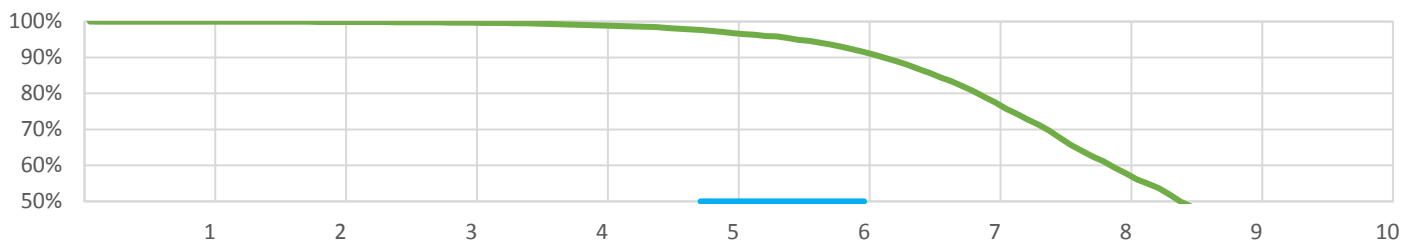
ALTRUA 40 DR (Downsize)

Model: S403

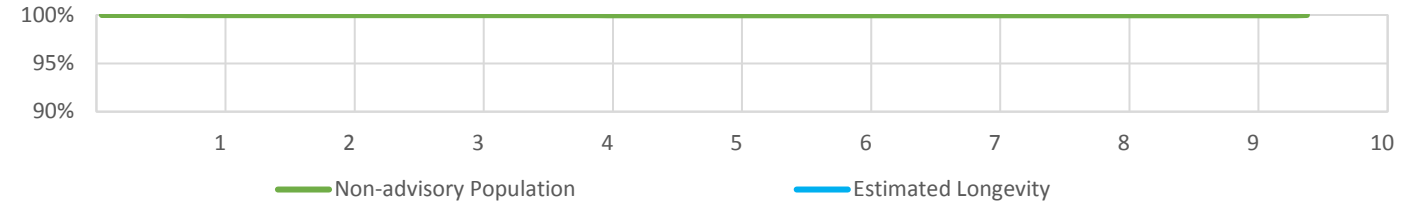
US Summary

US Registered Implants:	14,000	US Normal Battery Depletions:	2,807
US Approval Date:	March 2008	US Malfunctions:	3
US Estimated Active Implants:	5,000	Without Compromised Therapy:	3
		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%	99.9%	99.7%	99.0%	97.1%	92.2%	79.1%	59.3%	40.2%	33.4%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
14000	Effective Sample Size	12424	11127	9936	8842	7769	6584	4472	1962	512	219

@ 113 months

ALTRUA 40 DR (Downsize)

Models: S403

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**16,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery status (49)	2	0	2
Mechanical			
Seal plug (40)	1	0	1
Difficulty securing lead (41)	1	0	1
Grand Total	**4**	**0**	**4**

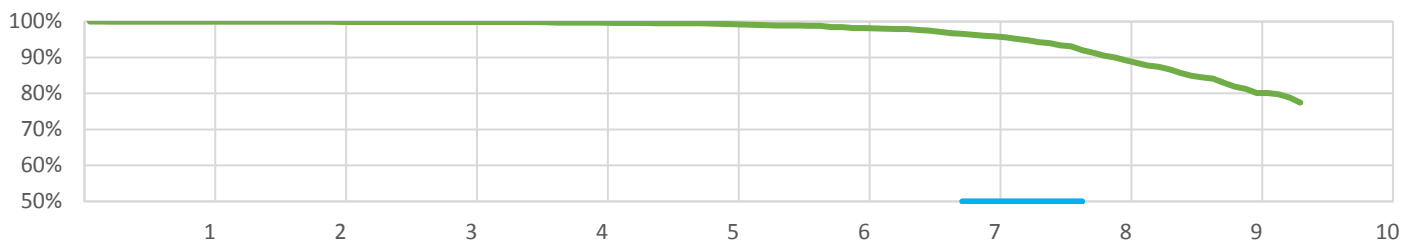
References cited in table above (link)

ALTRUA 40 SR

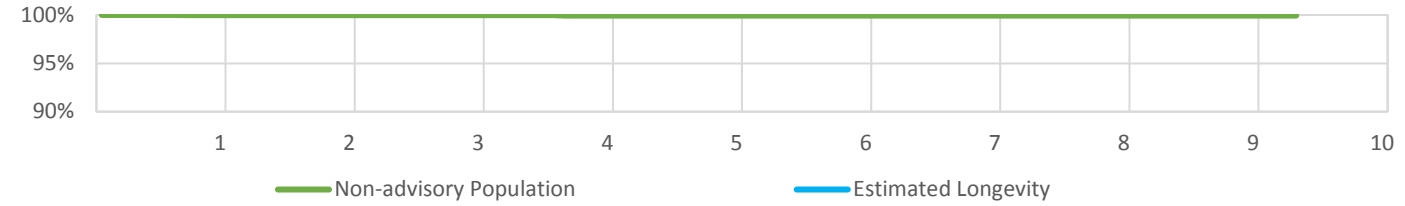
Model: S401

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	246
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	2,000	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%	99.9%	99.9%	99.7%	99.4%	98.2%	96.1%	90.0%	81.3%	77.5%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
5000	Effective Sample Size	3886	3406	2978	2646	2340	2062	1594	901	369	222

@ 113 months

ALTRUA 40 SR

Models: S401

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**9,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical			
Capacitor (15)	2	0	2
Integrated circuit (30)	0	1	1
Grand Total	**2**	**1**	**3**

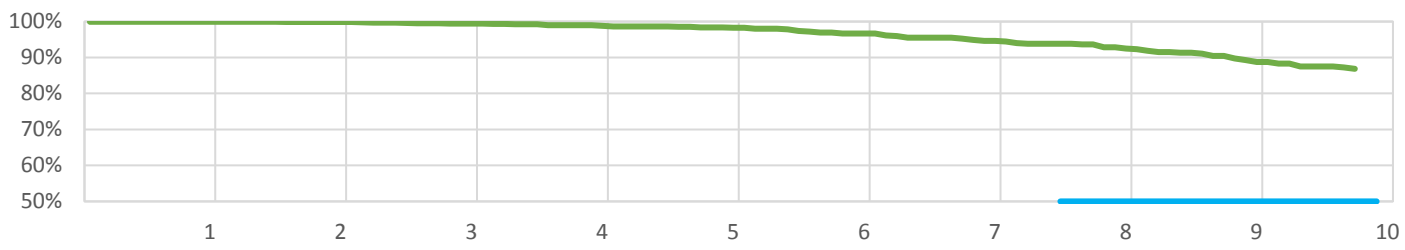
References cited in table above (link)

ALTRUA 20 DR

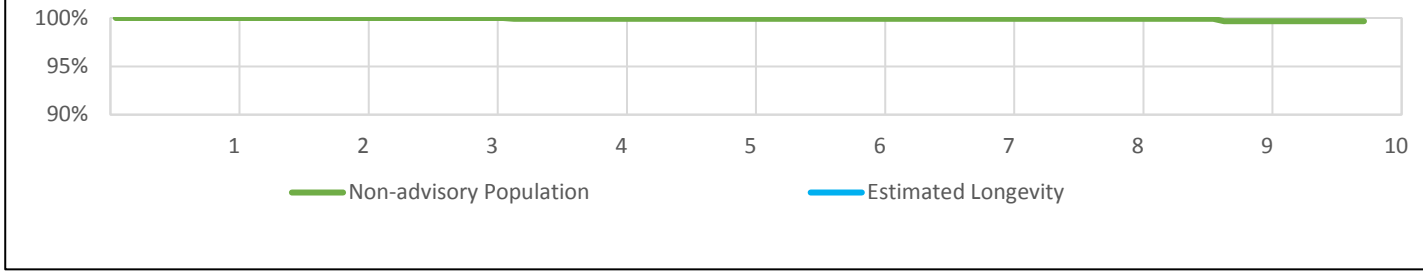
Model: S202/S205

US Summary			
US Registered Implants:	2,000	US Normal Battery Depletions:	87
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		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%	99.5%	99.0%	98.4%	96.7%	94.6%	92.9%	89.3%	86.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.7%	99.7%
2000	Effective Sample Size	1515	1336	1160	1013	869	730	608	497	386	232

@ 118 months

ALTRUA 20 DR

Models: S202/S205

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

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery depletion (26)	0	1	1
Magnet rate (44)	1	0	1
Battery status (49)	1	0	1
Grand Total	**2**	**1**	**3**

References cited in table above (link)

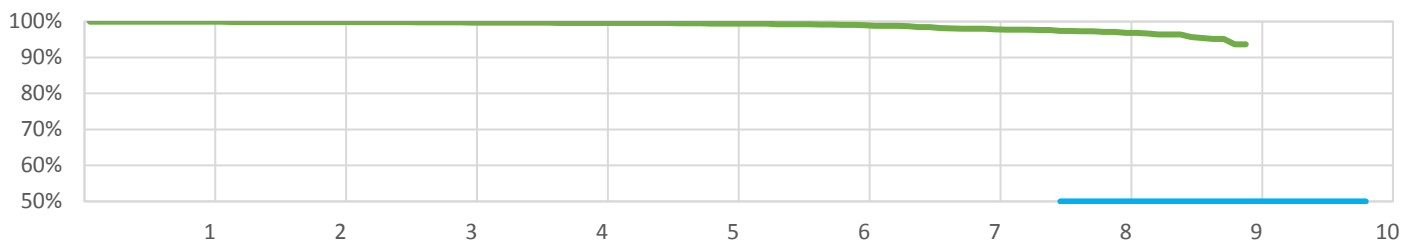
ALTRUA 20 EL DR

Model: S208

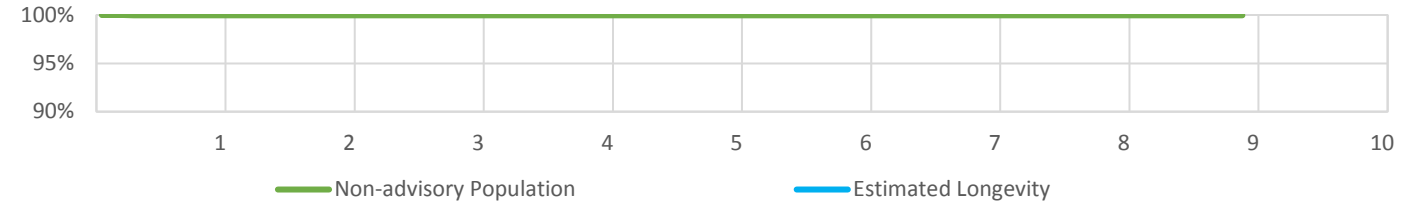
US Summary

US Registered Implants:	3,000	US Normal Battery Depletions:	46
US Approval Date:	April 2008	US Malfunctions:	1
US Estimated Active Implants:	2,000	Without Compromised Therapy:	-
		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%	99.0%	98.0%	97.1%	93.7%	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	--
3000	Effective Sample Size	2761	2471	2198	1970	1749	1555	1176	659	222	--

@ 108 months

ALTRUA 20 DR EL

Models: S208

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

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

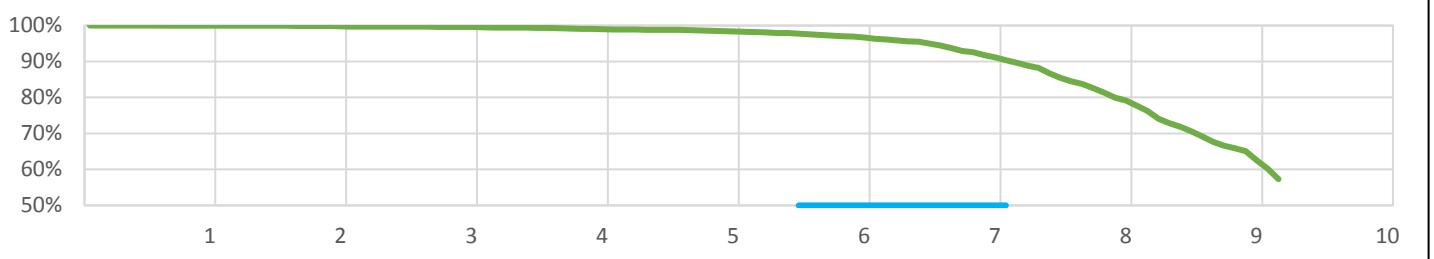
References cited in table above (link)

ALTRUA 20 DR (downsize)

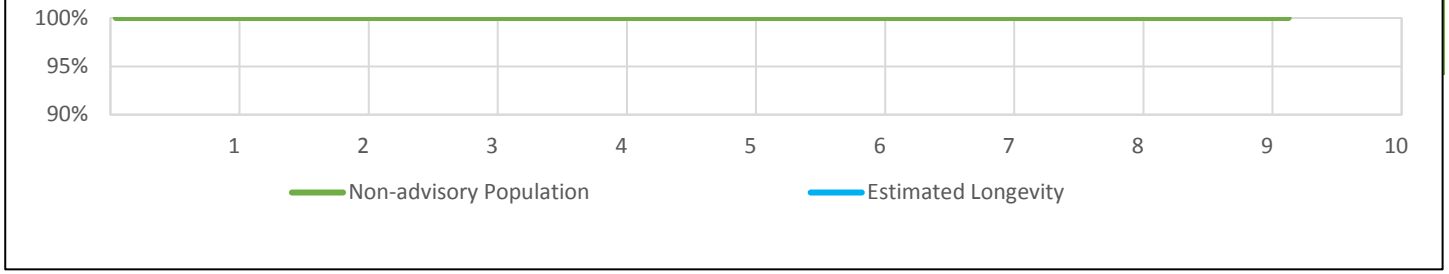
Model: S203

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	566
US Approval Date:	April 2008	US Malfunctions:	-
US Estimated Active Implants:	2,000	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%	99.9%	99.6%	99.0%	98.4%	96.9%	91.8%	80.0%	65.1%	57.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
5000	Effective Sample Size	4315	3818	3400	3020	2687	2353	1803	979	333	225

@ 111 months

ALTRUA 20 DR (downsize)

Models: S203

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**16,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery depletion (26)	0	1	1
Battery status (49)	1	0	1
Electrical			
Capacitor (15)	2	0	2
Grand Total	**3**	**1**	**4**

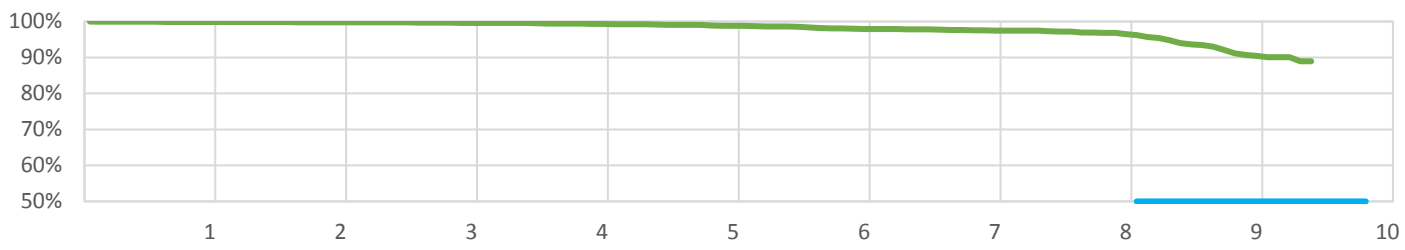
References cited in table above (link)

ALTRUA 20 SR

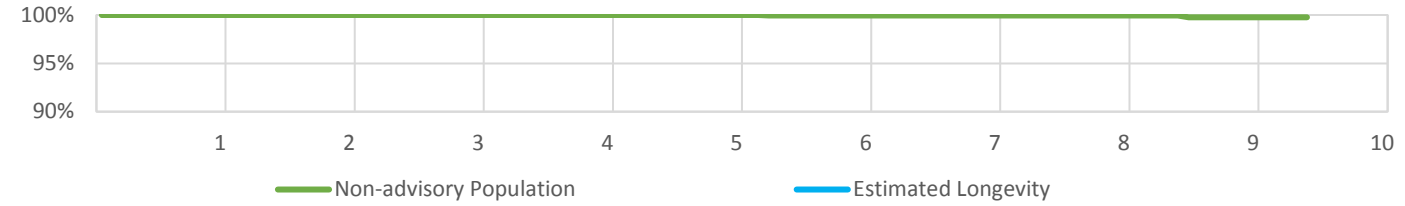
Model: S201/S204

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	100
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	2,000	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%	99.4%	98.8%	98.0%	97.6%	96.9%	90.7%	89.0%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%
4000	Effective Sample Size	3571	3044	2610	2273	1978	1692	1321	806	357	206

@ 114 months

ALTRUA 20 SR

Models: S201/S204

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**24,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Battery status (49)	2	0	2
Electrical			
Capacitor (15)	1	0	1
Grand Total	**3**	**1**	**4**

References cited in table above (link)

ALTRUA 20 SSI

Models: S206

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**8,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Battery depletion (26)	0	1	1
Battery status (49)	3	0	3
Grand Total	**3**	**1**	**4**

References cited in table above (link)

ALTRUA 20 DDD

Models: S207

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

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

References cited in table above (link)

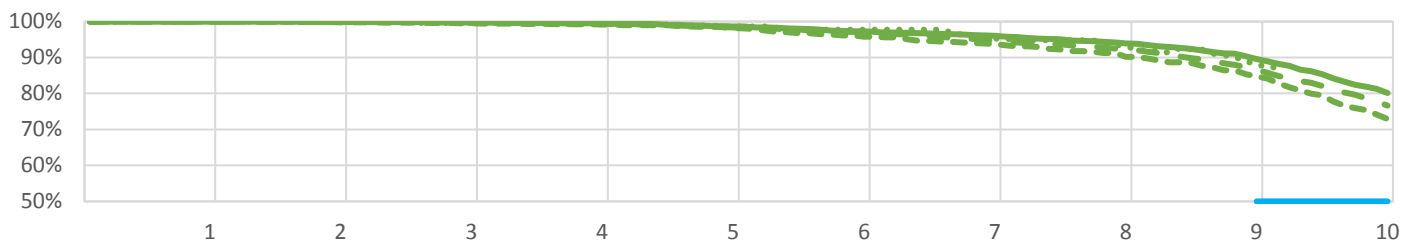
INSIGNIA Entra DR

Model: 1294/1295

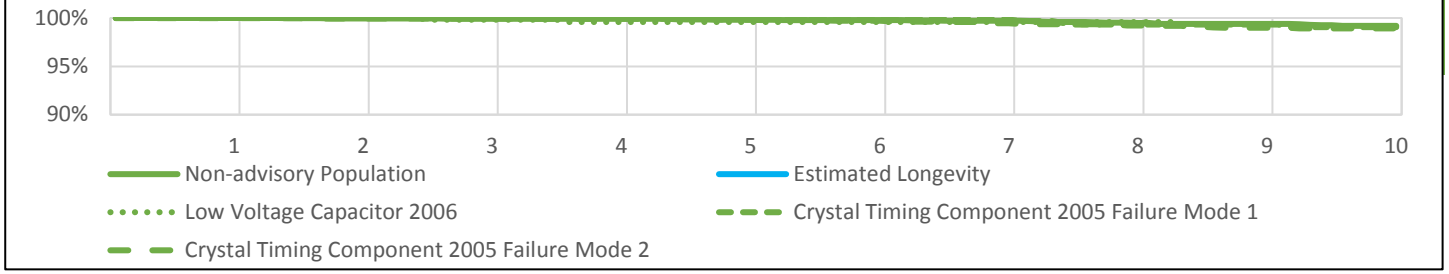
US Summary

US Registered Implants:	17,000	US Normal Battery Depletions:	2,369
US Approval Date:	March 2008	US Malfunctions:	71
US Estimated Active Implants:	3,000	Without Compromised Therapy:	64
		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%	99.8%	99.5%	98.7%	97.3%	96.2%	94.2%	90.4%	81.2%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.5%	99.4%	99.2%
7000	Effective Sample Size	6110	5421	4806	4264	3727	3246	2848	2496	2131	1659

INSIGNIA Entra DR

Model: 1294/1295

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2006	Depletions and Malfunctions	100.0%	100.0%	99.6%	99.4%	98.9%	97.7%	97.0%	94.8%	90.6%	87.3%
Registered Implants: 35000	Malfunctions Only	100.0%	100.0%	99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	--
	Effective Sample Size	658	571	499	427	369	316	277	234	221	201
Crystal Timing Component 2005 Failure Mode 1	Depletions and Malfunctions	100.0%	99.9%	99.5%	99.3%	98.4%	96.1%	93.9%	91.2%	85.4%	74.2%
Registered Implants: 29000	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.3%	99.3%	99.1%
	Effective Sample Size	1592	1382	1154	1012	879	736	617	511	414	300
Crystal Timing Component 2005 Failure Mode 2	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.5%	97.1%	95.0%	92.5%	87.3%	77.9%
Registered Implants: 29000	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	99.0%	98.9%
	Effective Sample Size	6130	5433	4782	4212	3684	3175	2674	2271	1852	1410

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

INSIGNIA Entra DR

Models: 1294/1295

Worldwide Confirmed Malfunctions	**91**
Worldwide Distribution	**37,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	3	7	10
Longevity labeling (11)	50	0	50
Battery status (49)	15	0	15
Electrical			
Integrated circuit (13)	0	1	1
Capacitor (15)	0	1	1
Integrated circuit (30)	0	1	1
Mechanical			
Seal plug (19)	3	0	3
Header (20)	0	2	2
Seal plug (33)	1	0	1
Crystal timing component Failure Mode 1 - September 22, 2005 Voluntary Physician Advisory (9)	0	5	5
Software			
Underestimation of battery status (34)	2	0	2
Grand Total	**74**	**17**	**91**

References cited in table above (link)

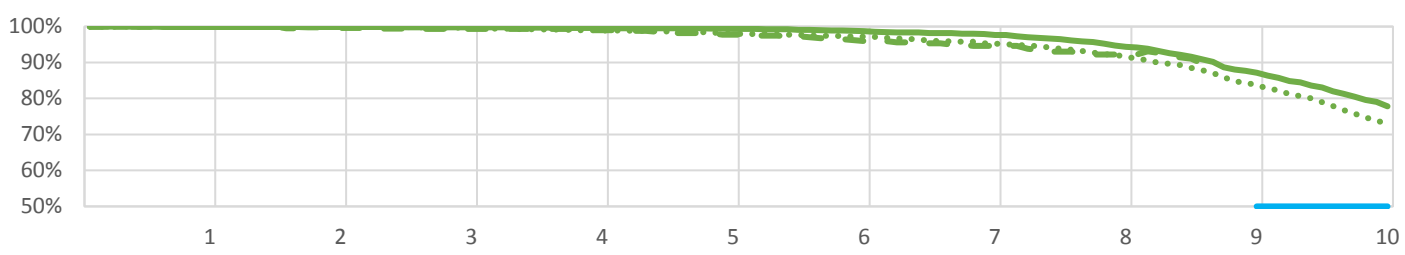
INSIGNIA Entra SR

Model: 1195/1198

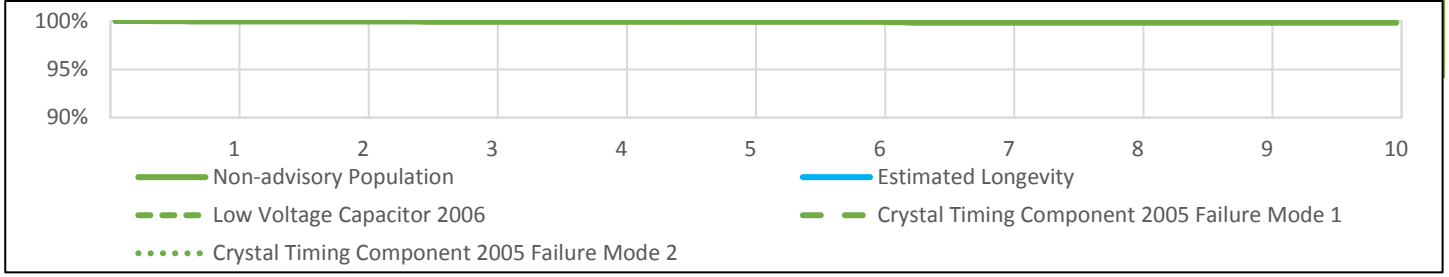
US Summary

US Registered Implants:	14,000	US Normal Battery Depletions:	1,145
US Approval Date:	March 2002	US Malfunctions:	7
US Estimated Active Implants:	1,000	Without Compromised Therapy:	6
		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%	99.8%	99.8%	99.6%	99.4%	98.8%	97.9%	94.7%	87.7%	79.1%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
6000	Effective Sample Size	4620	3791	3173	2661	2240	1905	1649	1410	1149	895

INSIGNIA Entra SR

Model: 1194/1195

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2006	Depletions and Malfunctions	100.0%	99.5%	--	--	--	--	--	--	--	--
Registered Implants: 500	Malfunctions Only	100.0%	100.0%	--	--	--	--	--	--	--	--
	Effective Sample Size	257	203	--	--	--	--	--	--	--	--
Crystal Timing Component 2005 Failure Mode 1	Depletions and Malfunctions	99.9%	99.8%	99.3%	99.0%	97.8%	96.2%	94.6%	92.2%	88.5%	--
Registered Implants: 1000	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	--
	Effective Sample Size	1101	890	700	560	450	351	260	206	206	--
Crystal Timing Component 2005 Failure Mode 2	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.0%	98.1%	97.2%	95.4%	92.1%	84.4%	73.9%
Registered Implants: 6000	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
	Effective Sample Size	4483	3738	3093	2553	2097	1744	1454	1216	953	720

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

INSIGNIA Entra SR

Models: 1195/1198

Worldwide Confirmed Malfunctions	**28**
Worldwide Distribution	**52,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	2	3
Longevity labeling (11)	6	0	6
Battery depletion (26)	0	1	1
Battery status (49)	5	0	5
Electrical			
Capacitor (15)	2	2	4
Low-voltage capacitor - June 23, 2006 Voluntary Physician Advisory (8)	0	2	2
Mechanical			
Capacitor array (16)	0	2	2
Seal plug (19)	0	2	2
Seal plug (33)	0	1	1
Crystal timing component Failure Mode 1 - September 22, 2005 Voluntary Physician Advisory (9)	1	0	1
Crystal timing component Failure Mode 2 - September 22, 2005 Voluntary Physician Advisory (10)	0	1	1
Grand Total	**15**	**13**	**28**

References cited in table above (link)

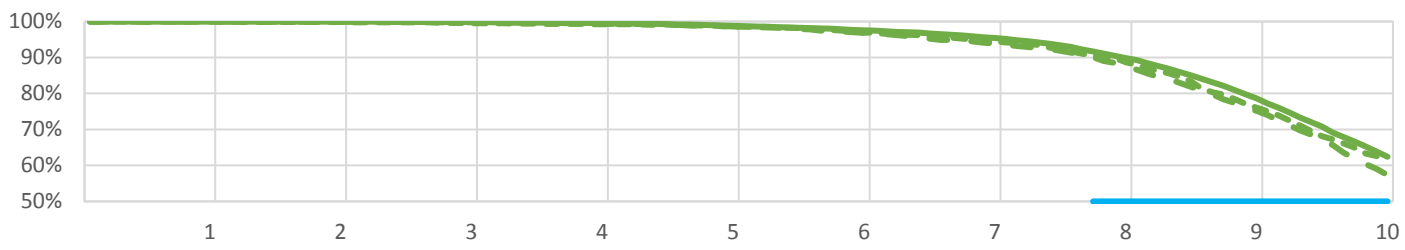
INSIGNIA Ultra DR

Model: 1291

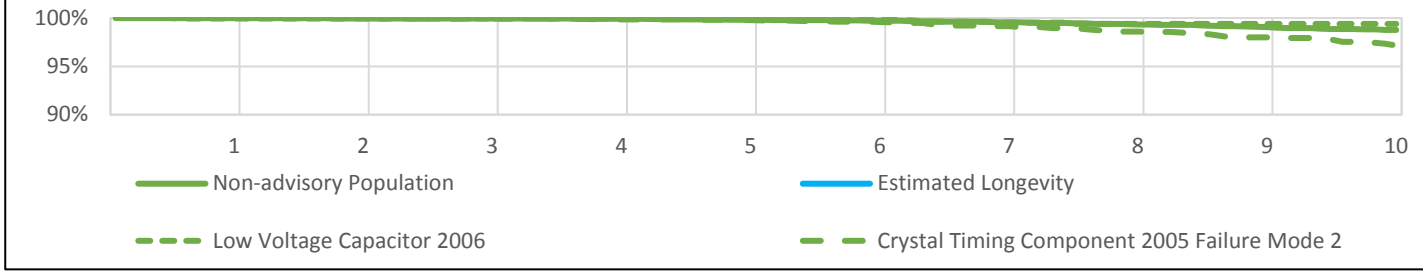
US Summary

US Registered Implants:	32,000	US Normal Battery Depletions:	6,708
US Approval Date:	November 2003	US Malfunctions:	202
US Estimated Active Implants:	7,000	Without Compromised Therapy:	187
		With Compromised Therapy:	15

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population Registered Implants: 23000	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.6%	98.9%	97.7%	95.7%	90.4%	79.8%	63.9%
	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%	99.4%	99.1%	98.8%
	Effective Sample Size	20772	18542	16540	14705	13018	11455	9978	8367	6509	4538

INSIGNIA Ultra DR

Model: 1291

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2006	Depletions and Malfunctions	99.9%	99.9%	99.6%	99.3%	98.9%	97.5%	95.0%	90.2%	78.4%	63.3%
Registered Implants: 2000	Malfunctions Only	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.5%	99.4%	99.4%	99.4%
	Effective Sample Size	1865	1654	1463	1291	1139	992	857	711	543	375
Crystal Timing Component 2005 Failure Mode 2	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.7%	97.1%	94.1%	88.5%	76.2%	59.0%
Registered Implants: 6000	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.6%	99.2%	98.6%	98.0%	97.4%
	Effective Sample Size	5578	4959	4409	3903	3439	2983	2569	2120	1592	1041

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

INSIGNIA Ultra DR

Models: 1291

Worldwide Confirmed Malfunctions	**260**
Worldwide Distribution	**51,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	8	10	18
Longevity labeling (11)	83	0	83
Magnet response (21)	1	0	1
Battery depletion (26)	3	1	4
Battery status (49)	126	0	126
Electrical			
Capacitor (14)	1	0	1
Capacitor (15)	4	2	6
Integrated circuit (30)	2	1	3
Low-voltage capacitor - June 23, 2006	0	2	2
Voluntary Physician Advisory (8)			
Mechanical			
Seal plug (19)	5	4	9
Header (20)	2	1	3
Software			
Underestimation of battery status (34)	3	0	3
Pacing rate limit (36)	1	0	1
Grand Total	**239**	**21**	**260**

References cited in table above (link)

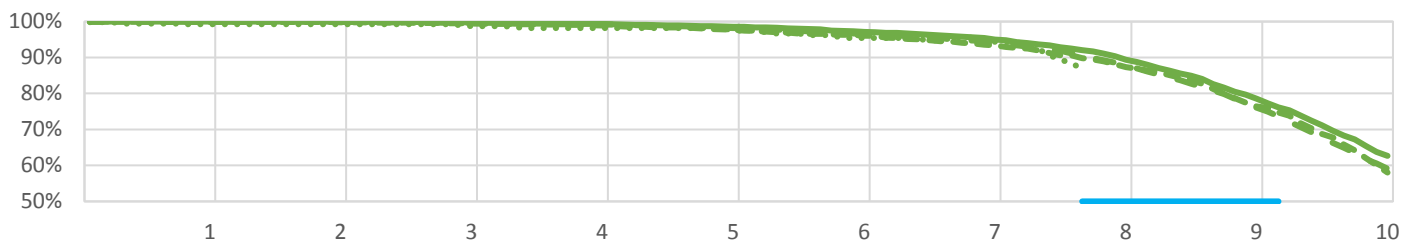
INSIGNIA Plus DR

Model: 1297

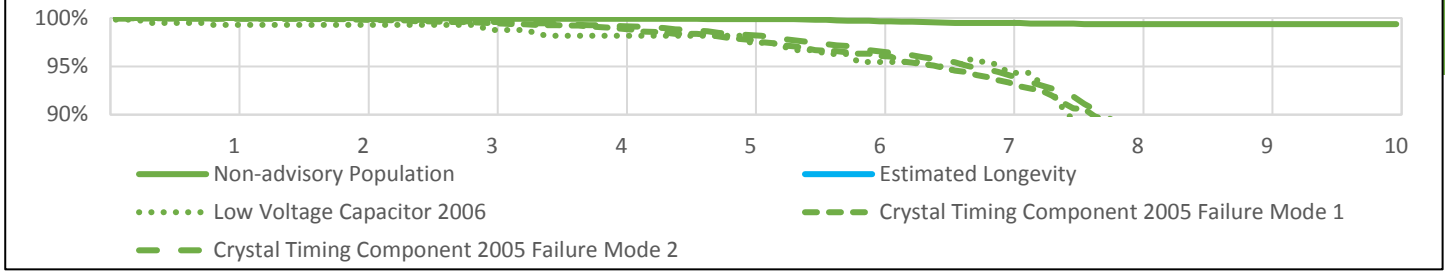
US Summary

US Registered Implants:	27,000	US Normal Battery Depletions:	6,091
US Approval Date:	March 2008	US Malfunctions:	137
US Estimated Active Implants:	3,000	Without Compromised Therapy:	126
		With Compromised Therapy:	11

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%	99.3%	98.7%	97.3%	95.4%	90.3%	79.7%	63.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.5%	99.4%	99.4%	99.4%
7000	Effective Sample Size	6422	5725	5086	4491	3968	3488	3043	2564	1990	1395

INSIGNIA Plus DR

Model: 1297

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2006	Depletions and Malfunctions	99.3%	99.3%	99.0%	98.2%	98.2%	95.4%	95.5%	86.8%	--	--
Registered Implants: 35000	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.6%	99.7%	99.2%	--	--
	Effective Sample Size	508	433	377	315	269	228	255	205	--	--
Crystal Timing Component 2005 Failure Mode 1	Depletions and Malfunctions	99.9%	99.8%	99.5%	99.0%	97.8%	96.3%	93.6%	88.1%	77.5%	60.1%
Registered Implants: 29000	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.5%	99.5%	99.1%	98.6%	98.5%
	Effective Sample Size	3293	2886	2440	2146	1855	1605	1374	1137	865	550
Crystal Timing Component 2005 Failure Mode 2	Depletions and Malfunctions	100.0%	99.9%	99.6%	99.2%	98.3%	96.7%	94.4%	88.6%	77.2%	60.6%
Registered Implants: 29000	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.6%	99.4%	99.0%	98.8%	98.7%
	Effective Sample Size	12507	11089	9811	8676	7594	6603	5685	4689	3548	2342

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

INSIGNIA Plus DR

Models: 1297

Worldwide Confirmed Malfunctions	**179**
Worldwide Distribution	**47,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	5	9	14
Longevity labeling (11)	97	0	97
Battery depletion (26)	1	0	1
Battery status (49)	28	0	28
Mechanical			
Solder bond (12)	1	0	1
Capacitor array (16)	1	0	1
Seal plug (19)	6	0	6
Header (20)	8	6	14
Crystal timing component Failure Mode 1 - September 22, 2005 Voluntary Physician Advisory (9)	1	2	3
Crystal timing component Failure Mode 2 - September 22, 2005 Voluntary Physician Advisory (10)	0	1	1
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	0	1	1
Low-voltage capacitor - June 23, 2006 Voluntary Physician Advisory (8)	1	1	2
Software			
Underestimation of battery status (34)	4	0	4
Interrupted telemetry (35)	2	0	2

Pacing rate limit (36)	1	0	1
Grand Total	**158**	**21**	**179**

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.

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	20,000	0	0	0	1	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	23,000	3	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	86,000	3	1	3	13	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	45,000	5	0	1	1	0	0
INTUA V272/V273/V282/V283/W272/W273	3,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	18,000	0	0	1	3	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	0	0	0	0	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	6,000	0	0	2	0	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	5,000	0	0	1	0	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	16,000	0	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	15,000	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	46,000	1	0	2	2	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	47,000	0	0	2	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	21,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	20,000	2	0	0	2	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	47,000	0	0	2	37	0	0
SQ-RX S-ICD 1010	11,000	10	0	21	27	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	137,000	5	0	3	2	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	263,000	2	0	4	16	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	94,000	1	0	1	11	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	75,000	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	219,000	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	9000	0	13	1	64	181
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158	59000	28	158	34	787	4478
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	848	233	608	1087	13536
COGNIS N118/N119/N120/P106/P107/P108	75000	6004	259	1927	1899	35437

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	22000	13	338	16	168	1619
INTUA V272/V273/V282/V283/W272/W273	3000	21	53	2	29	476
INVIVE V172/V173/V182/V183/W172/W173	8000	123	105	3	71	2140
CONTAK RENEWAL TR H120/H125	19000	3673	203	66	268	10772

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	24000	7	110	35	502	1263
SQ-RX S-ICD 1010	8000	226	100	75	280	1324

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	4000	0	15	0	20	39
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	3000	1	9	0	15	22
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	34000	11	641	7	348	1644
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	29000	7	587	10	275	1253
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	8000	14	159	10	95	784
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	8000	6	185	5	99	699
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	73	1238	461	595	7199
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	78	1452	615	733	9054

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	159	1246	1822	721	14422
TELIGEN DR E110/E111/F110/F111	66000	1150	1920	2658	1262	26170

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	59000	10	870	35	273	2084
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	137000	62	1818	84	715	8000
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	27000	12	512	25	144	2854
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	5	272	8	61	1406
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	461	2239	55	800	23903
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	41	462	12	152	8203

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	1797	391	16	180	16532
ALTRUA 60 DR (Downsize) S603	90000	17778	1086	88	595	35804
ALTRUA 60 DR S602	22000	1795	363	29	208	8718
ALTRUA 60 DR EL S606	59000	1719	933	27	455	19522
ALTRUA 40 SR S401	5000	246	38	2	24	2660
ALTRUA 40 DR (downsize) S403	14000	2807	139	3	81	5953
ALTRUA 40 DR S402	2000	143	27	0	8	834
ALTRUA 40 DR EL S404	5000	158	61	3	44	2061
ALTRUA 20 SR S201/S204	5000	98	31	2	36	2731
ALTRUA 20 DR (downsize) S203	5000	565	37	0	39	2589
ALTRUA 20 DR S202/S205	2000	86	13	2	15	920
ALTRUA 20 DR EL S208	3000	56	36	1	11	1437
INSIGNIA Ultra SR 1190 [4]	24000	2990	230	47	147	17037
INSIGNIA Ultra DR 1291 [4]	32000	6702	460	202	321	17484
INSIGNIA Entra SR 1195/1198 [4]	14000	1139	102	7	75	10932
INSIGNIA Entra DR 1294/1295 [4]	17000	2366	164	71	187	11792
INSIGNIA Plus DR 1297 [4]	27000	6081	303	133	263	16426

[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.

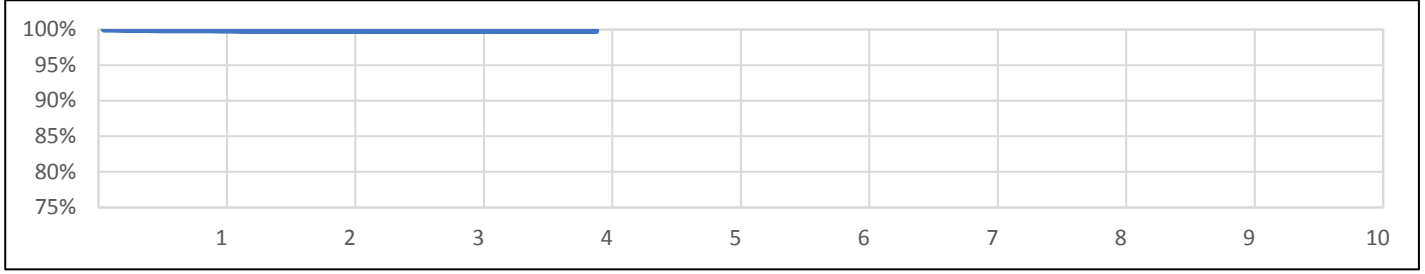
[4] Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

ACUITY X4 Spiral L

Models: 4677/4678

US Summary			
US Registered Implants:	9,000	US Chronic Complications	13
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	9,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



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%	99.8%	--	--	--	--	--	--
	Effective Sample Size	5500	2573	409	216	--	--	--	--	--	--
Registered Implants: 9000											

@ 47 months

ACUITY X4 Spiral L

Models: 4677/4678

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**22,000**

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

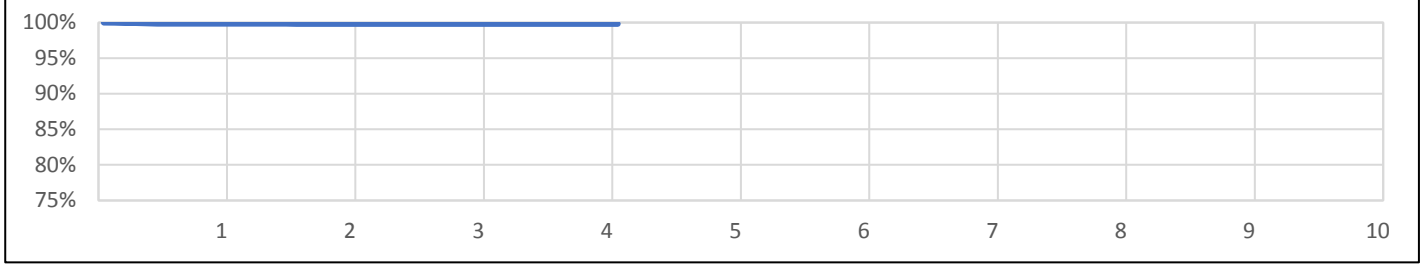
References cited in table above (link)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	24,000	US Chronic Complications	35
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	23,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.8%	99.8%	99.8%	99.8%	--	--	--	--	--
	Effective Sample Size	14899	6762	738	277	240	--	--	--	--	--
Registered Implants: 24000											

@ 49 months

ACUITY X4 Spiral S

Models: 4674/4675

Worldwide Confirmed Malfunctions	**-**
Worldwide Distribution	**51,000**

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

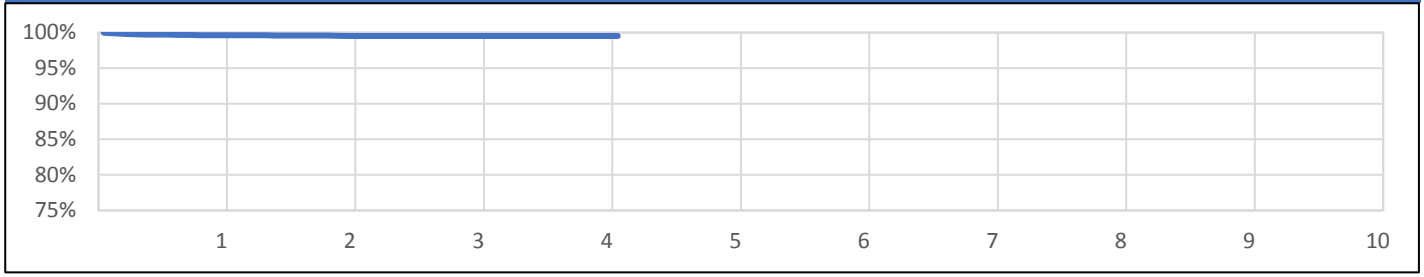
References cited in table above (link)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	18,000	US Chronic Complications	61
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	16,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.5%	99.5%	99.5%	99.5%	--	--	--	--	--
	Effective Sample Size	9791	4086	515	224	200	--	--	--	--	--

Registered Implants: 18000

@ 49 months

ACUITY X4 Straight

Models: 4671/4672

Worldwide Confirmed Malfunctions	**-**
Worldwide Distribution	**41,000**

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

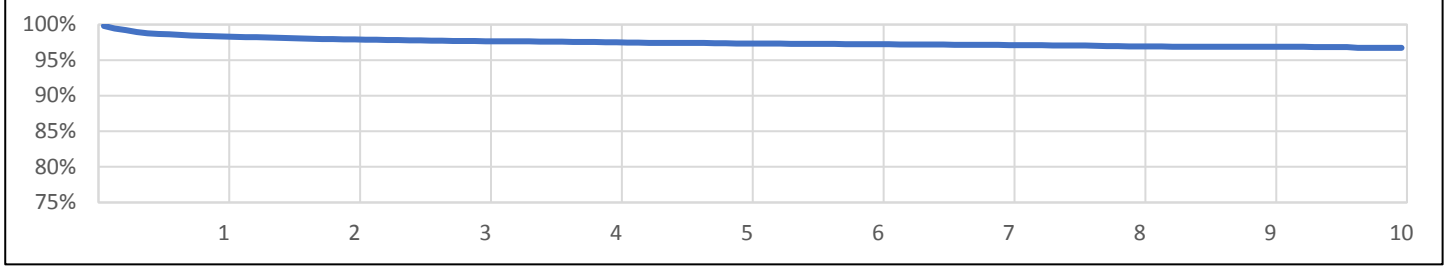
References cited in table above (link)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	23,000	US Chronic Complications	540
US Approval Date:	May 2008	US Malfunctions:	7
US Estimated Active Implants:	14,000	Without Compromised Therapy:	3
		With Compromised Therapy:	4

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.3%	97.9%	97.7%	97.5%	97.3%	97.2%	97.1%	96.9%	96.9%	96.7%
Registered Implants: 23000	Effective Sample Size	19456	17133	15002	12552	9876	7315	5161	3242	1793	581

ACUITY Spiral

Models: 4591/4592/4593

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**45,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	3	4	7
Grand Total	**3**	**4**	**7**

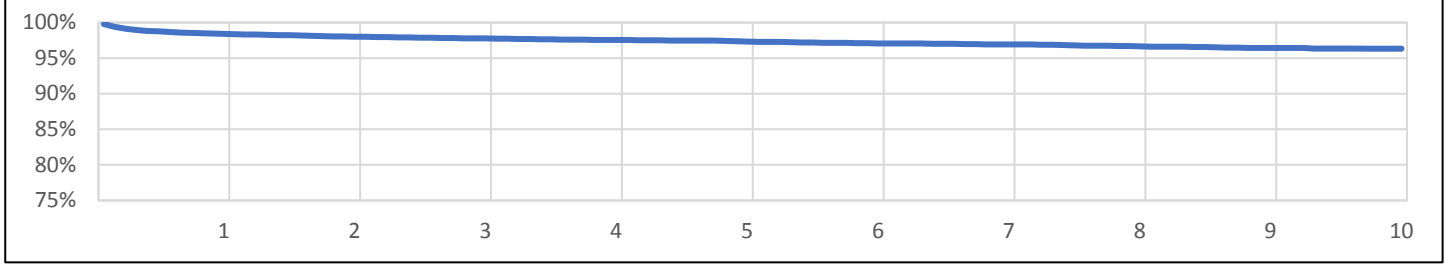
References cited in table above (link)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	700
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	15,000	Without Compromised Therapy:	12
		With Compromised Therapy:	21

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.4%	98.0%	97.8%	97.6%	97.3%	97.1%	96.9%	96.7%	96.4%	96.3%
	Effective Sample Size	24538	21899	19484	16859	13872	10928	8475	6282	4326	2449
Registered Implants: 29000											

ACUITY Steerable

Models: 4554/4555/4556

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

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

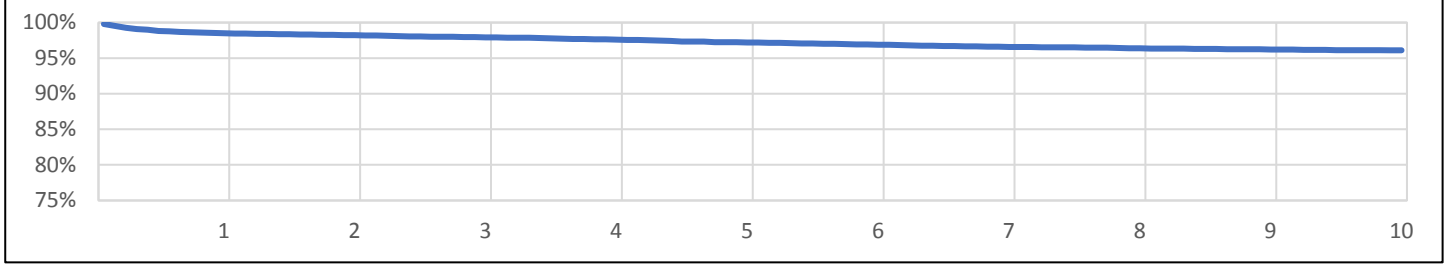
References cited in table above (link)

EASYTRAK 3

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

US Summary			
US Registered Implants:	22,000	US Chronic Complications	545
US Approval Date:	May 2002	US Malfunctions:	32
US Estimated Active Implants:	9,000	Without Compromised Therapy:	9
		With Compromised Therapy:	23

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.5%	98.2%	97.9%	97.6%	97.2%	96.9%	96.6%	96.4%	96.2%	96.1%
	Effective Sample Size	18250	16289	14504	12615	10581	8612	6979	5685	4557	3494

Registered Implants: 22000

EASYTRAK 3

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

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

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

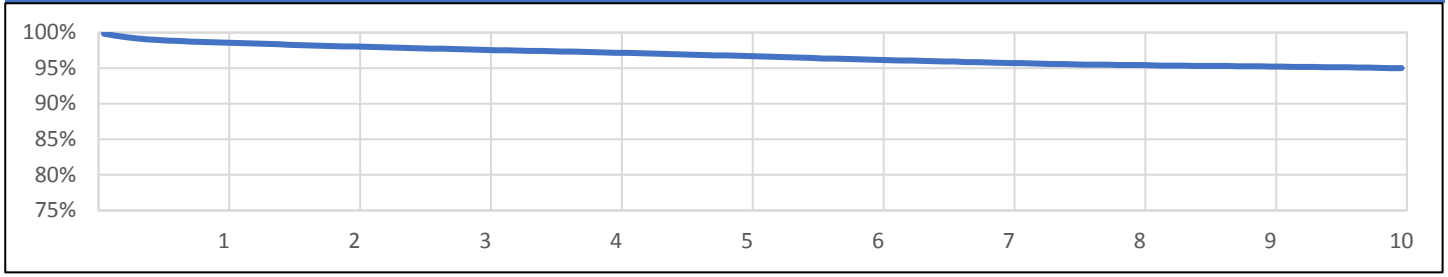
References cited in table above (link)

EASYTRAK 2

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

US Summary			
US Registered Implants:	97,000	US Chronic Complications	2,782
US Approval Date:	May 2002	US Malfunctions:	387
US Estimated Active Implants:	39,000	Without Compromised Therapy:	128
		With Compromised Therapy:	259

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.6%	98.0%	97.6%	97.2%	96.7%	96.1%	95.7%	95.4%	95.2%	95.0%
	Effective Sample Size	82358	73254	64957	56353	47471	39018	31911	25641	19960	14741

Registered Implants: 97000

EASYTRAK 2

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

Worldwide Confirmed Malfunctions	**530**
Worldwide Distribution	**179,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (25)	133	329	462
Other			
Non-patterned, other	29	39	68
Grand Total	**162**	**368**	**530**

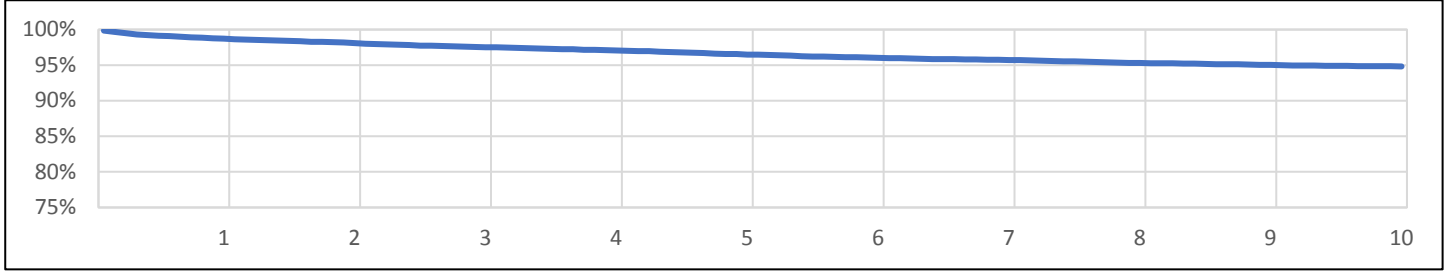
References cited in table above (link)

EASYTRAK

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

US Summary			
US Registered Implants:	38,000	US Chronic Complications	1,118
US Approval Date:	May 2002	US Malfunctions:	94
US Estimated Active Implants:	6,000	Without Compromised Therapy:	9
		With Compromised Therapy:	85

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.7%	98.1%	97.5%	97.1%	96.5%	96.0%	95.7%	95.3%	95.0%	94.8%
	Effective Sample Size	30356	26117	22429	19299	16495	14125	12134	10587	9373	8354

Registered Implants: 38000

EASYTRAK

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

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

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

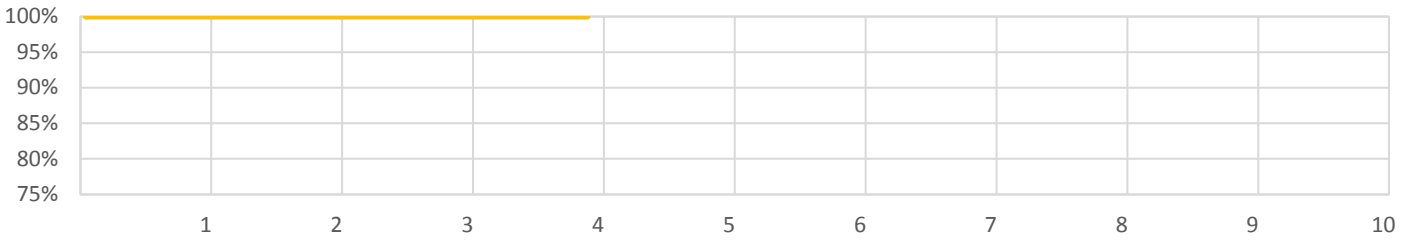
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0658/0695/0696

US Summary			
US Registered Implants:	1,000	US Chronic Complications	-
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	1,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--	--
	Effective Sample Size	554	501	469	208	--	--	--	--	--	--

Registered Implants: 1000

@ 47 mont

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0658/0695/0696

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**13,000**

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

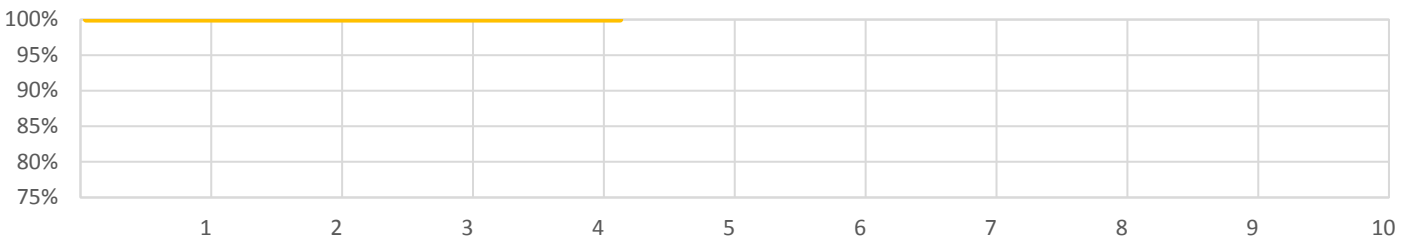
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0692/0693

US Summary			
US Registered Implants:	1,000	US Chronic Complications	-
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	1,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--	
	Effective Sample Size	1257	1127	1009	345	234	--	--	--	--	--	@ 50 months
Registered Implants: 1000												

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0692/0693

Worldwide Confirmed Malfunctions	**33**
Worldwide Distribution	**63,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	0	14	14
Other			
Non-patterned, other	2	17	19
Grand Total	**2**	**31**	**33**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

Models: 0655/0685/0686

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

	Without Compromised Therapy	With 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 Passive Fixation

Models: 0654/0682/0683

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

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

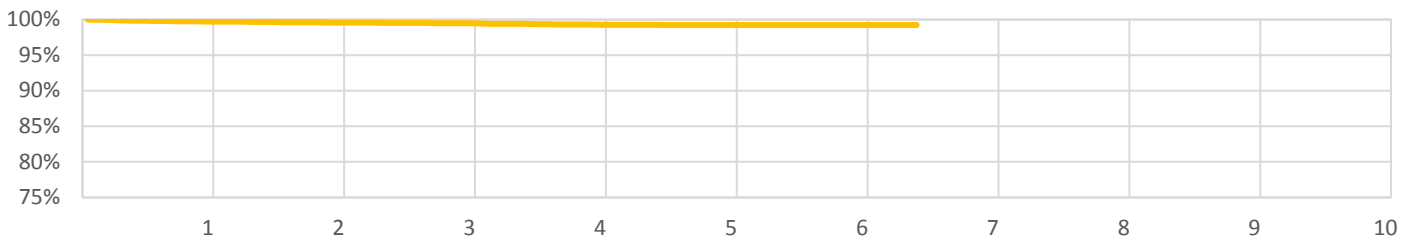
References cited in table above (link)

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401/3501

US Summary			
US Registered Implants:	27,000	US Chronic Complications	94
US Approval Date:	September 2012	US Malfunctions:	2
US Estimated Active Implants:	24,000	Without Compromised Therapy:	-
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.5%	99.3%	99.2%	99.2%	99.2%	--	--	--	
	Effective Sample Size	20813	13409	7509	3198	756	376	263	--	--	--	@ 77 months
Registered Implants: 31000												

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401/3501

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**57,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Crimp/Weld/Bond			
Weld fracture (37)	0	3	3
Other			
Non-patterned, other	1	16	17
Grand Total	**1**	**19**	**20**

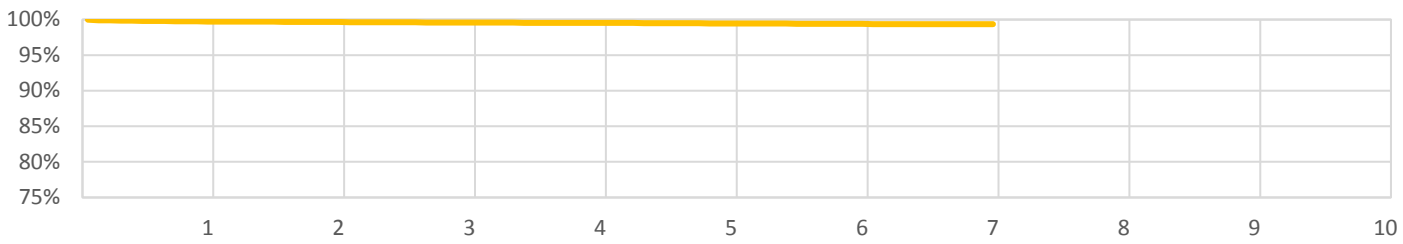
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Summary			
US Registered Implants:	72,000	US Chronic Complications	267
US Approval Date:	November 2010	US Malfunctions:	23
US Estimated Active Implants:	60,000	Without Compromised Therapy:	2
		With Compromised Therapy:	21

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.5%	99.4%	99.4%	--	--	--	
	Effective Sample Size	58126	46757	36240	26369	16900	7694	303	--	--	--	@ 84 months
Registered Implants: 72000												

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

Worldwide Confirmed Malfunctions	**55**
Worldwide Distribution	**113,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	0	1	1
Other			
Non-patterned, other	9	45	54
Grand Total	**9**	**46**	**55**

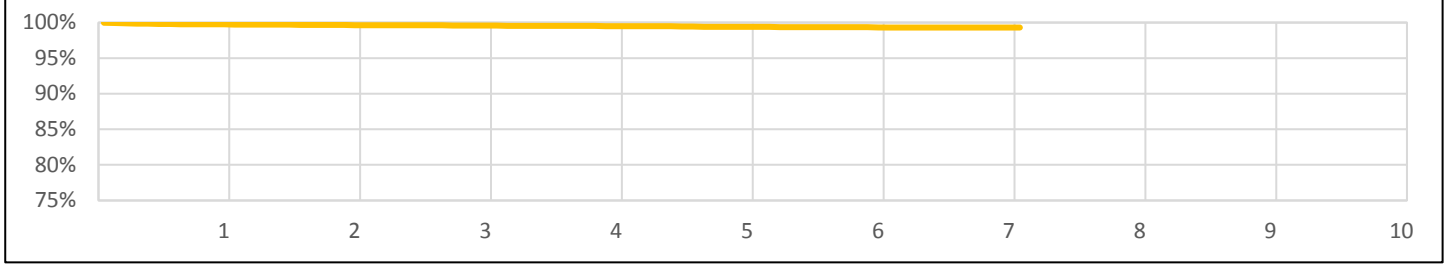
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0292/0293

US Summary			
US Registered Implants:	112,000	US Chronic Complications	365
US Approval Date:	November 2010	US Malfunctions:	22
US Estimated Active Implants:	101,000	Without Compromised Therapy:	1
		With Compromised Therapy:	21

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	--	--	
	Effective Sample Size	79247	54537	35717	21064	10479	3693	338	305	--	--	@ 85 months
Registered Implants: 112000												

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0292/0293

Worldwide Confirmed Malfunctions	**48**
Worldwide Distribution	**168,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	0	4	4
Other			
Non-patterned, other	3	41	44
Grand Total	**3**	**45**	**48**

References cited in table above (link)

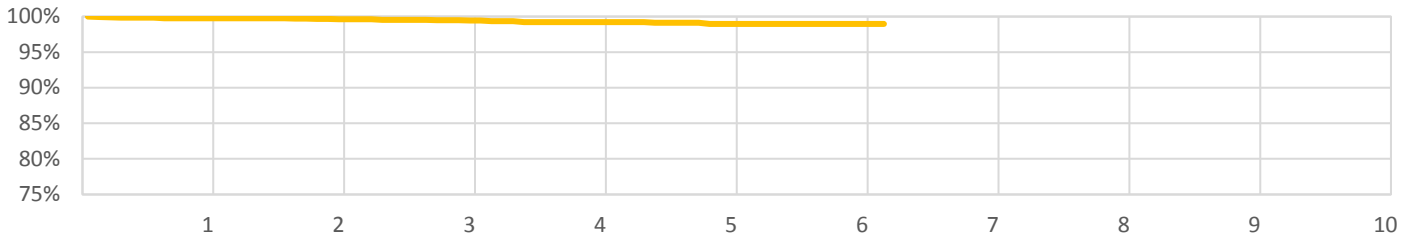
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Summary

US Registered Implants:	3,000	US Chronic Complications	18
US Approval Date:	Novemeber 2010	US Malfunctions:	-
US Estimated Active Implants:	3,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.6%	99.4%	99.2%	99.0%	99.0%	99.0%	--	--	--
	Effective Sample Size	2496	2018	1556	1104	617	262	208	--	--	--

Registered Implants: 3000

@ 74 months

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

Worldwide Confirmed Malfunctions	**89**
Worldwide Distribution	**10,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Inner conductor break(39)	3	6	9
Other			
Non-patterned, other	45	35	80
Grand Total	**48**	**41**	**89**

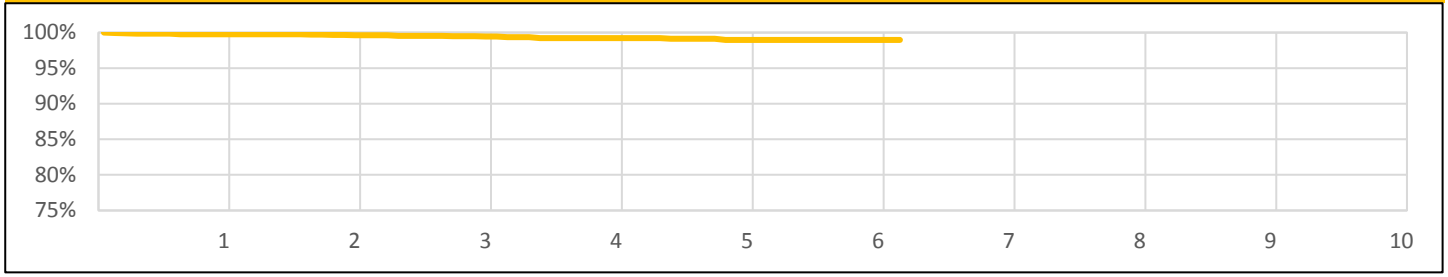
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0282/0283

US Summary			
US Registered Implants:	3,000	US Chronic Complications	18
US Approval Date:	Novemeber 2010	US Malfunctions:	-
US Estimated Active Implants:	3,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.6%	99.4%	99.2%	99.0%	99.0%	99.0%	--	--	--
	Effective Sample Size	2496	2018	1556	1104	617	262	208	--	--	--

Registered Implants: 3000

@ 74 mont

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0282/0283

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**5,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	1	2	3
Grand Total	**1**	**2**	**3**

References cited in table above (link)

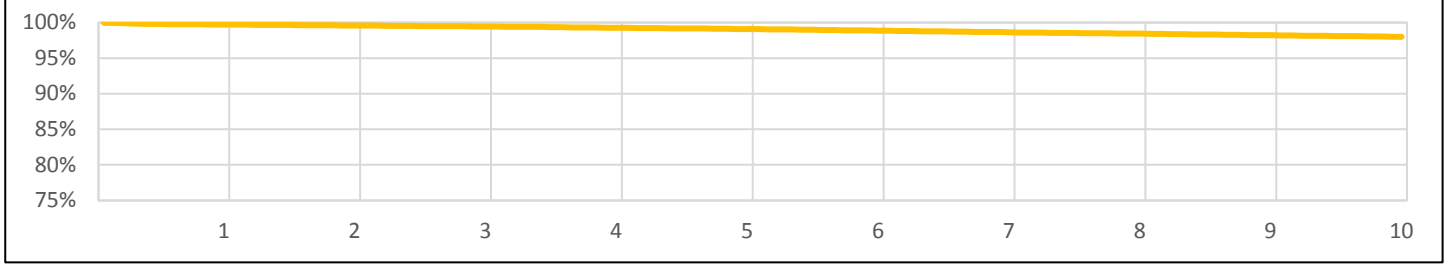
ENDOTAK RELIANCE Dual Coil, Active Fixation

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

US Summary

US Registered Implants:	287,000	US Chronic Complications	3,165
US Approval Date:	July 2002	US Malfunctions:	360
US Estimated Active Implants:	124,000	Without Compromised Therapy:	116
		With Compromised Therapy:	244

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.4%	99.3%	99.1%	98.9%	98.6%	98.4%	98.2%	98.0%
	Effective Sample Size	251535	225556	202275	180893	161292	142716	124690	100470	79123	58130
Registered Implants: 286000											

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**553**
Worldwide Distribution	**377,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	0	102	102
Crimp/Weld			
Seal rings (5)	2	2	4
Other			
Non-patterned, other	193	254	447
Grand Total	**195**	**358**	**553**

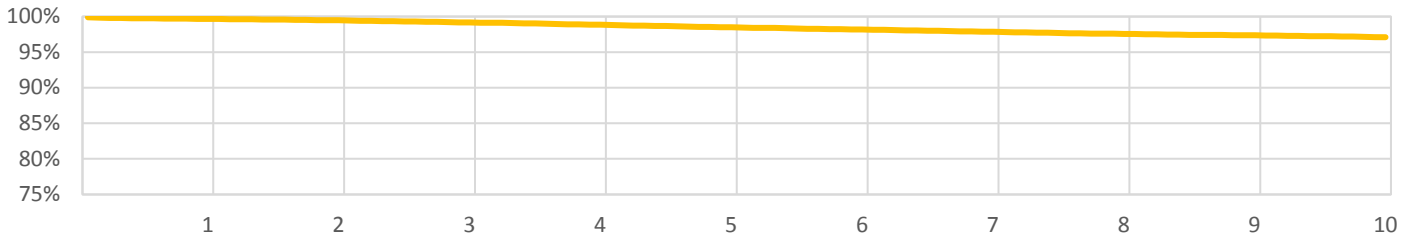
References cited in table above (link)

ENDOTAK RELIANCE Dual Coil, Passive Fixation

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

US Summary			
US Registered Implants:	47,000	US Chronic Complications	839
US Approval Date:	October 2000	US Malfunctions:	56
US Estimated Active Implants:	15,000	Without Compromised Therapy:	13
		With Compromised Therapy:	43

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.9%	98.5%	98.2%	97.9%	97.6%	97.4%	97.1%
	Effective Sample Size	40178	36029	32273	28810	25682	22752	19995	17223	14708	12362

Registered Implants: 46000

ENDOTAK RELIANCE Dual Coil, Passive Fixation

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

Worldwide Confirmed Malfunctions	**158**
Worldwide Distribution	**109,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	0	18	18
Crimp/Weld/Bond			
Conductor connection (36)	0	3	3
Other			
Non-patterned, other	52	84	136
Manufacturing material (6)	0	1	1
Grand Total	**52**	**106**	**158**

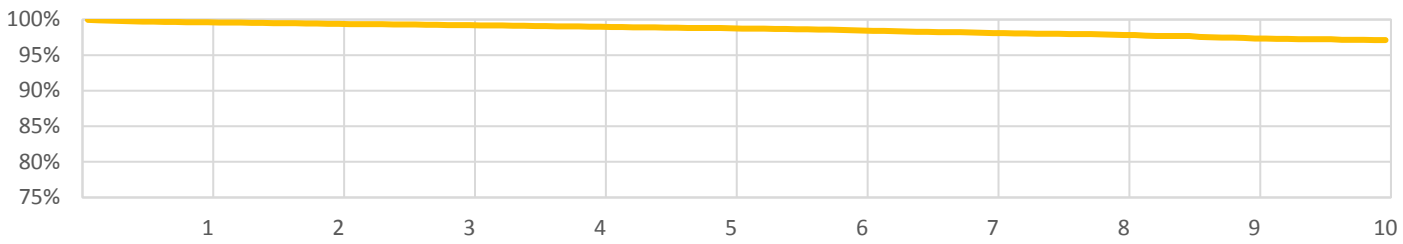
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Active Fixation

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

US Summary			
US Registered Implants:	33,000	US Chronic Complications	360
US Approval Date:	October 2000	US Malfunctions:	78
US Estimated Active Implants:	22,000	Without Compromised Therapy:	22
		With Compromised Therapy:	56

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.4%	99.2%	99.0%	98.8%	98.5%	98.1%	97.8%	97.3%	97.1%
	Effective Sample Size	28261	24882	21697	18369	15164	12190	9500	5696	3475	1854

Registered Implants: 33000

ENDOTAK RELIANCE Single Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**188**
Worldwide Distribution	**72,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	0	59	59
Other			
Non-patterned, other	53	76	129
Grand Total	**53**	**135**	**188**

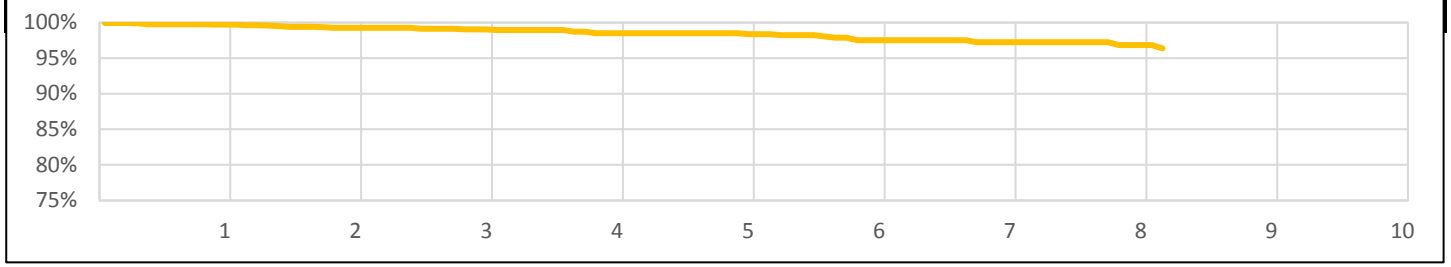
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Passive Fixation

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

US Summary			
US Registered Implants:	2,000	US Chronic Complications	32
US Approval Date:	October 2000	US Malfunctions:	4
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.3%	99.0%	98.5%	98.4%	97.5%	97.3%	96.8%	96.4%	--
	Effective Sample Size	1519	1333	1119	890	704	496	334	216	203	--

Registered Implants: 2000

@ 98 mont

ENDOTAK RELIANCE Single Coil, Passive Fixation

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

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

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

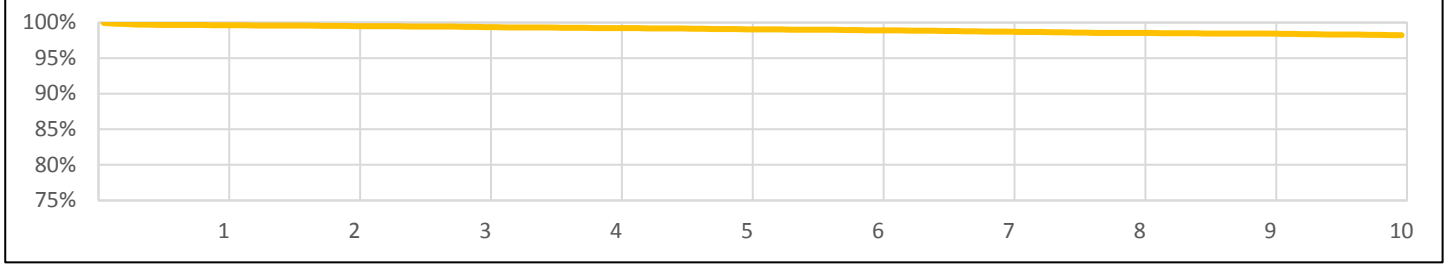
References cited in table above (link)

ENDOTAK ENDURANCE EZ Active Fixation

Models: 0154/0155/0156

US Summary			
US Registered Implants:	29,000	US Chronic Complications	366
US Approval Date:	June 1999	US Malfunctions:	25
US Estimated Active Implants:	6,000	Without Compromised Therapy:	10
		With Compromised Therapy:	15

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.5%	99.4%	99.2%	99.1%	98.9%	98.7%	98.5%	98.4%	98.2%
	Effective Sample Size	23898	21389	19140	17115	15292	13630	12148	10856	9682	8621

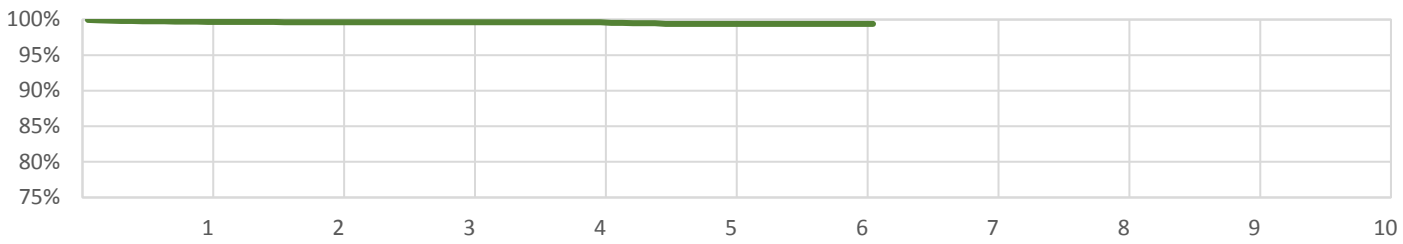
Registered Implants: 28000

INGEVITY Positive Fixation

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

US Summary			
US Registered Implants:	253,000	US Chronic Complications	633
US Approval Date:	April 2016	US Malfunctions:	79
US Estimated Active Implants:	237,000	Without Compromised Therapy:	33
		With Compromised Therapy:	46

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.6%	99.6%	99.4%	99.4%	99.4%	--	--	--	
	Effective Sample Size	141268	50829	1540	1381	1118	733	723	--	--	--	@ 75 months
Registered Implants: 253000												

INGEVITY Positive Fixation

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

Worldwide Confirmed Malfunctions	**130**
Worldwide Distribution	**600,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Inner conductor break (39)	7	4	11
Extracardiac fracture (41)	32	45	77
Other			
Non-patterned, other	17	25	42
Grand Total	**56**	**74**	**130**

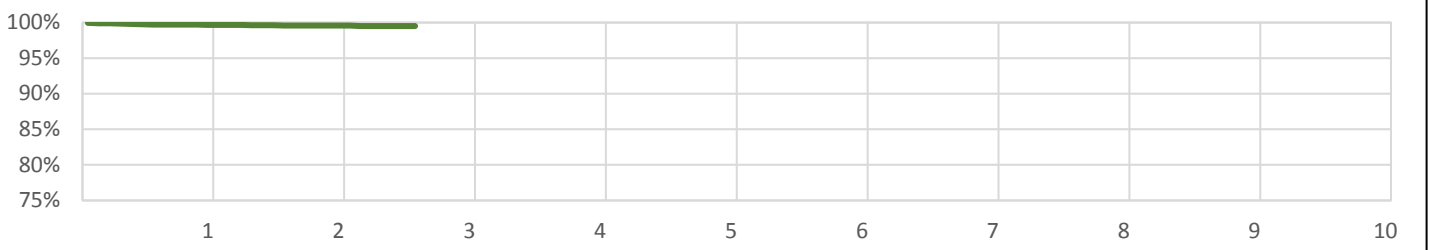
References cited in table above (link)

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	7,000	US Chronic Complications	20
US Approval Date:	April 2016	US Malfunctions:	2
US Estimated Active Implants:	7,000	Without Compromised Therapy:	2
		With Compromised Therapy:	0

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.5%	--	--	--	--	--	--	--
	Effective Sample Size	4013	1423	246	--	--	--	--	--	--	--

Registered Implants: 7000

@ 31 months

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**56,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	3	0	3
Crimp/Weld			
Weld (40)	1	0	1
Other			
Non-patterned, other	1	0	1
Grand Total	**5**	**0**	**5**

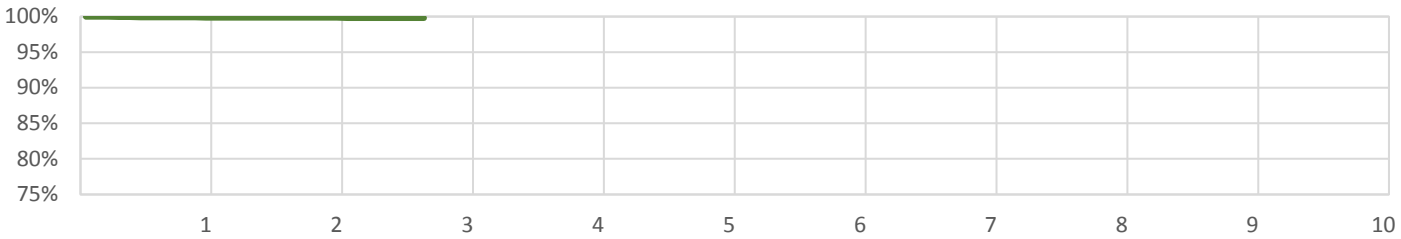
References cited in table above (link)

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary			
US Registered Implants:	13,000	US Chronic Complications	12
US Approval Date:	April 2016	US Malfunctions:	4
US Estimated Active Implants:	12,000	Without Compromised Therapy:	-
		With Compromised Therapy:	4

Battery Depletions and Malfunctions



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%	--	--	--	--	--	--	--
	Effective Sample Size	7307	2734	229	--	--	--	--	--	--	--

Registered Implants: 13000

@ 32 months

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**66,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	5	5
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**7**	**7**

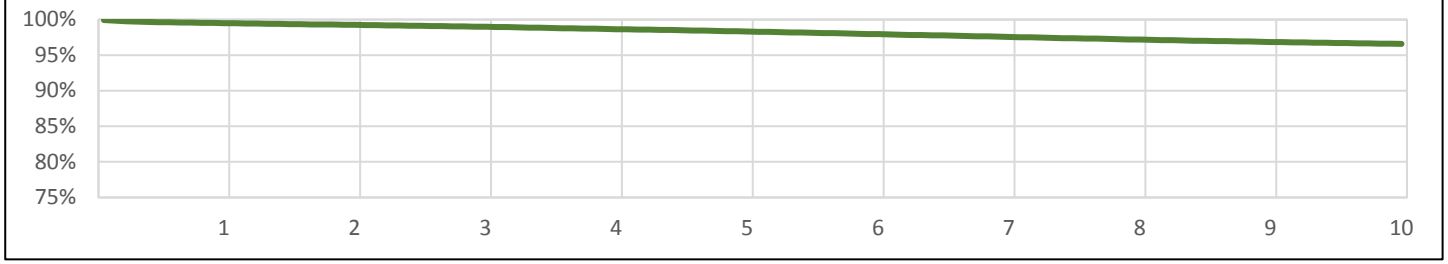
References cited in table above (link)

FLEXTEND Active Fixation

Models: 4086/4087/4088

US Summary			
US Registered Implants:	235,000	US Chronic Complications	4,508
US Approval Date:	February 2002	US Malfunctions:	358
US Estimated Active Implants:	88,000	Without Compromised Therapy:	141
		With Compromised Therapy:	217

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.5%	99.3%	99.0%	98.7%	98.3%	98.0%	97.6%	97.2%	96.8%	96.6%
Registered Implants: 232000	Effective Sample Size	200357	179155	159099	139078	120875	104188	89059	75200	62313	51027

FLEXTEND Active Fixation

Models: 4086/4087/4088

Worldwide Confirmed Malfunctions	**385**
Worldwide Distribution	**291,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	15	86	101
Electrical			
Inner insulation abrasion (2)	20	15	35
Other			
Non-patterned, other	17	11	28
Conductor damage (32)	99	122	221
Grand Total	**151**	**234**	**385**

References cited in table above (link)

FLEXTEND 2 Active Fixation

Models: 4095/4096/4097

Worldwide Confirmed Malfunctions	**120**
Worldwide Distribution	**185,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	4	17	21
Electrical			
Inner insulation abrasion (2)	5	1	6
Other			
Non-patterned, other	9	2	11
Conductor damage (32)	60	22	82
Grand Total	**78**	**42**	**120**

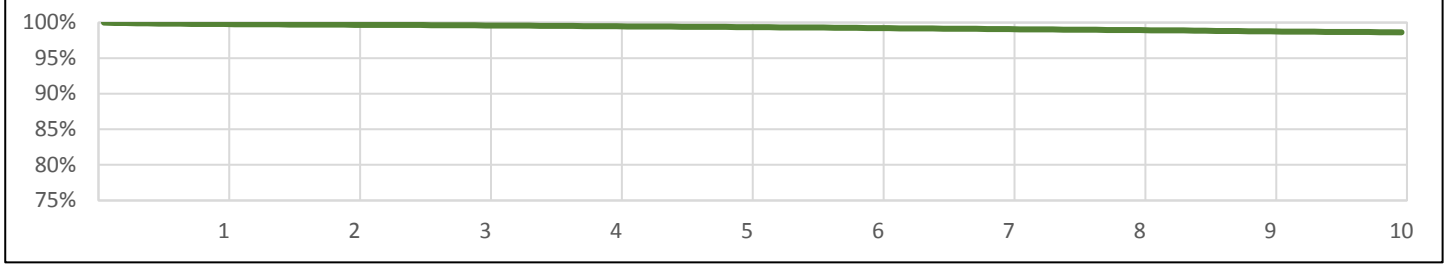
References cited in table above (link)

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

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

US Summary			
US Registered Implants:	477,000	US Chronic Complications	3,384
US Approval Date:	January 2000	US Malfunctions:	150
US Estimated Active Implants:	255,000	Without Compromised Therapy:	35
		With Compromised Therapy:	115

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.4%	99.2%	99.1%	98.9%	98.8%	98.6%
	Effective Sample Size	403095	353282	301659	254328	212223	174795	141667	111776	85132	63636
Registered Implants: 469000											

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

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

Worldwide Confirmed Malfunctions	**180**
Worldwide Distribution	**741,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	11	64	75
Crimp/Weld/Bond			
Terminal weld (23)	0	1	1
Other			
Non-patterned, other	5	7	12
Lead body (4)	24	68	92
Grand Total	**40**	**140**	**180**

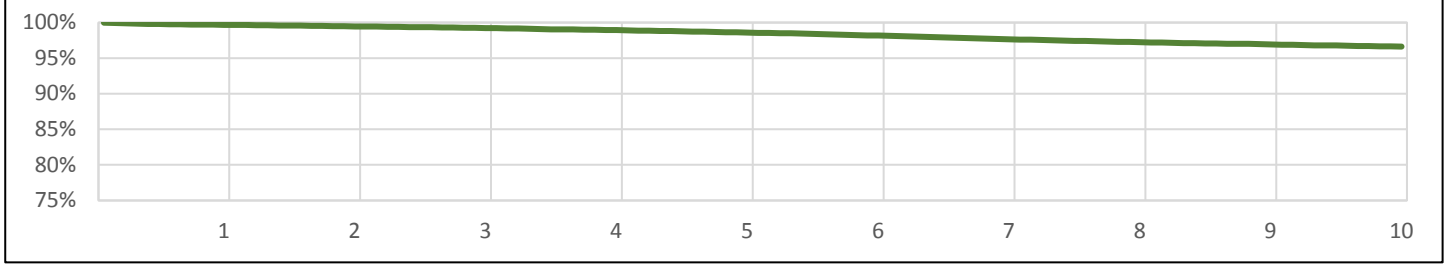
References cited in table above (link)

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

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

US Summary			
US Registered Implants:	52,000	US Chronic Complications	861
US Approval Date:	January 2000	US Malfunctions:	140
US Estimated Active Implants:	23,000	Without Compromised Therapy:	27
		With Compromised Therapy:	113

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.9%	98.6%	98.2%	97.7%	97.2%	96.9%	96.6%
	Effective Sample Size	45684	40732	35986	31177	26772	22617	18953	15646	12633	10048

Registered Implants: 52000

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

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

Worldwide Confirmed Malfunctions	**176**
Worldwide Distribution	**142,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	7	89	96
Other			
Non-patterned, other	6	3	9
Conductor damage (32)	19	53	72
Lead body (4)	1	0	1
Grand Total	**33**	**145**	**178**

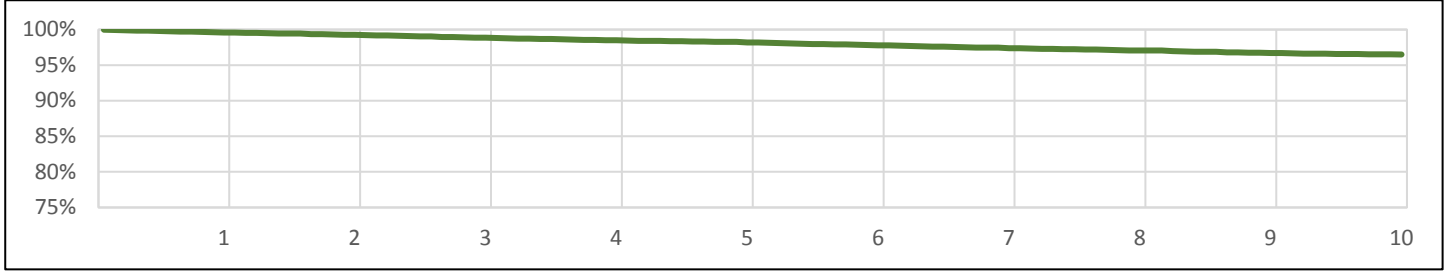
References cited in table above (link)

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

Models: 4454/4455/4458/4459

US Summary			
US Registered Implants:	14,000	US Chronic Complications	292
US Approval Date:	January 2000	US Malfunctions:	23
US Estimated Active Implants:	4,000	Without Compromised Therapy:	-
		With Compromised Therapy:	23

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.3%	98.8%	98.5%	98.2%	97.8%	97.4%	97.0%	96.7%	96.5%
	Effective Sample Size	12240	10938	9688	8458	7351	6342	5397	4553	3795	3178

Registered Implants: 14000

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models: 4454/4455/4458/4459

Worldwide Confirmed Malfunctions	**58**
Worldwide Distribution	**104,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	0	19	19
Other			
Non-patterned, other	0	2	2
Conductor damage (32)	2	35	37
Grand Total	**2**	**56**	**58**

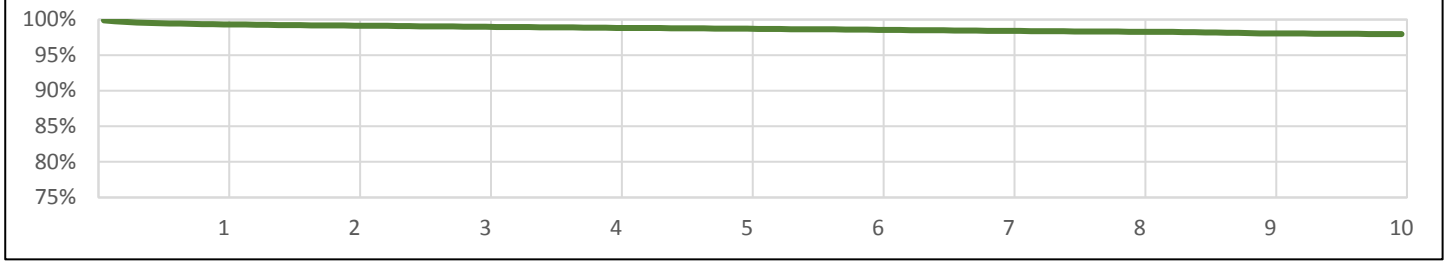
References cited in table above (link)

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary			
US Registered Implants:	62,000	US Chronic Complications	796
US Approval Date:	January 2000	US Malfunctions:	38
US Estimated Active Implants:	29,000	Without Compromised Therapy:	19
		With Compromised Therapy:	19

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.3%	99.1%	99.0%	98.8%	98.7%	98.6%	98.4%	98.3%	98.1%	98.0%
	Effective Sample Size	54002	48028	42194	36090	30537	25486	20996	17121	13563	10508

Registered Implants: 62000

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	**78**
Worldwide Distribution	**308,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	1	5	6
Other			
Non-patterned, other	2	3	5
J-shape (22)	30	26	56
Lead body (4)	3	8	11
Grand Total	**36**	**42**	**78**

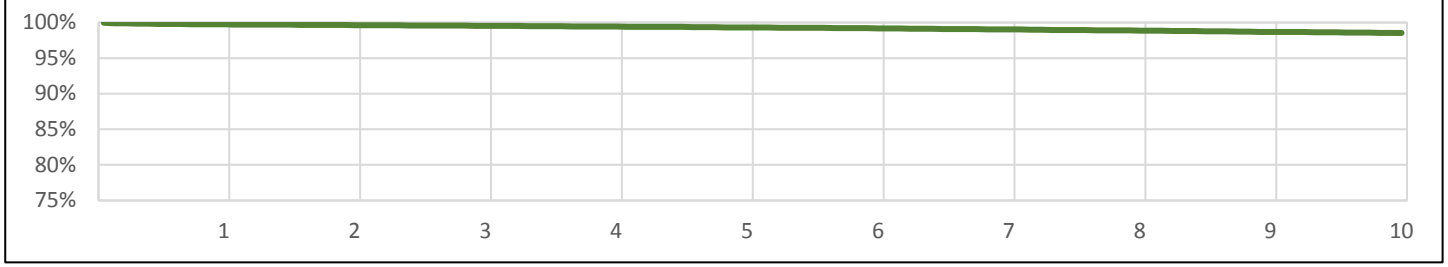
References cited in table above (link)

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

US Summary			
US Registered Implants:	192,000	US Chronic Complications	1,513
US Approval Date:	January 2000	US Malfunctions:	44
US Estimated Active Implants:	83,000	Without Compromised Therapy:	3
		With Compromised Therapy:	41

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.0%	98.9%	98.7%	98.5%
	Effective Sample Size	164912	146331	128453	110015	93117	77961	64675	52943	42345	33044

Registered Implants: 192000

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	**67**
Worldwide Distribution	**538,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Lead conductor (7)	0	17	17
Other			
Non-patterned, other	1	5	6
Lead body (4)	3	41	44
Grand Total	**4**	**63**	**67**

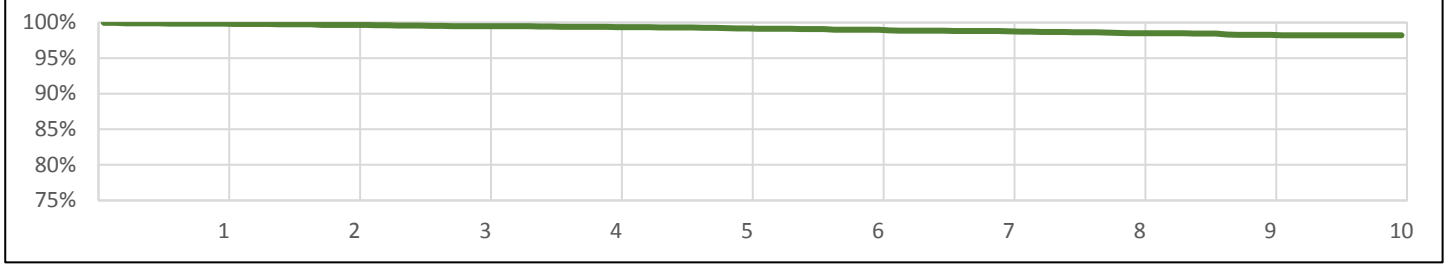
References cited in table above (link)

FINELINE EZ Positive Fixation

Models: 4460/4461/4462

US Summary			
US Registered Implants:	6,000	US Chronic Complications	63
US Approval Date:	July 1999	US Malfunctions:	4
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.7%	99.5%	99.4%	99.2%	99.0%	98.8%	98.5%	98.3%	98.2%
	Effective Sample Size	4904	4346	3845	3395	3013	2600	2272	1961	1679	1433

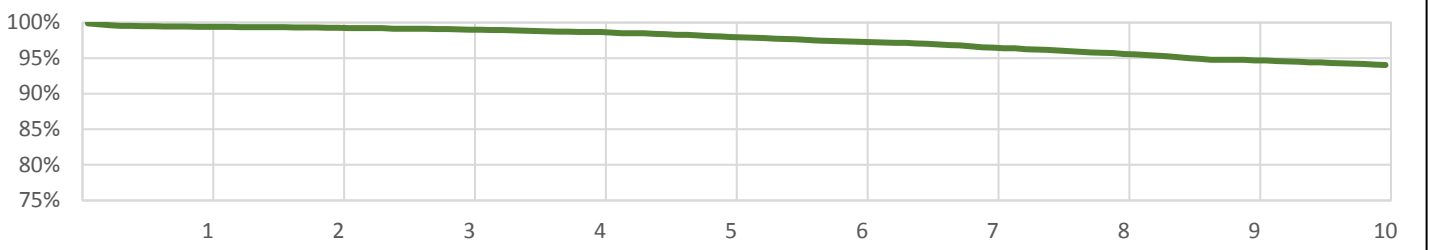
Registered Implants: 6000

SELUTE PICOTIP Atrial J

Models: 4040/4041/4042/4043/4044/4045/4063/4064

US Summary			
US Registered Implants:	10,000	US Chronic Complications	371
US Approval Date:	May 2000	US Malfunctions:	25
US Estimated Active Implants:	2,000	Without Compromised Therapy:	16
		With Compromised Therapy:	9

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.4%	99.3%	99.0%	98.7%	98.0%	97.3%	96.5%	95.6%	94.7%	0.94035
	Effective Sample Size	8524	7652	6856	6130	5466	4854	4245	3712	3241	2862.083

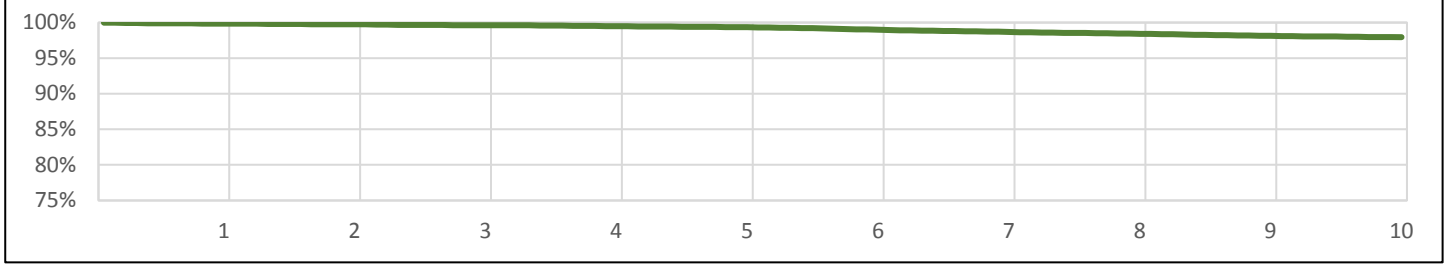
Registered Implants: 10000

SWEET PICOTIP Rx Positive Fixation

Models: 4050/4051/4052/4053/4054/4055

US Summary			
US Registered Implants:	41,000	US Chronic Complications	495
US Approval Date:	April 1999	US Malfunctions:	57
US Estimated Active Implants:	10,000	Without Compromised Therapy:	29
		With Compromised Therapy:	28

Battery Depletions and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.6%	99.5%	99.3%	99.0%	98.7%	98.4%	98.1%	97.9%
	Effective Sample Size	35697	32066	28783	25794	23074	20526	18188	16159	14371	12634

Registered Implants: 41000

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.

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. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

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 7640/7641/7642/7740/7741/7742	253,000	60	237	221	60	11	7	16	10	0	11
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	7,000	0	6	12	2	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	13,000	0	2	4	2	1	1	0	2	0	0
FLEXTEND Active Fixation 4086/4087/4088	235,000	82	1028	1005	962	497	128	221	531	0	52
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	192,000	5	448	237	271	55	34	207	235	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	477,000	22	739	820	461	141	134	581	457	0	27
FINELINE II Atrial J (poly) 4477/4478/4479/4480	62,000	1	119	358	136	21	30	77	47	0	7
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	2	124	19	63	26	4	22	32	0	1
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474	52,000	0	293	96	111	98	24	100	137	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	9,000	0	0	8	2	1	0	0	0	0	2
ACUITY X4 Spiral S 4674/4675	24,000	1	0	26	2	1	0	0	0	0	5

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	18,000	0	0	37	5	0	0	1	4	0	14
ACUITY Steerable 4554/4555/4556	29,000	3	36	451	59	5	2	16	33	0	94
ACUITY Spiral 4591/4592/4593	23,000	0	21	328	45	0	1	5	10	0	130
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	2	38	312	58	5	2	16	21	0	93
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	1	386	1350	333	9	8	115	141	0	436
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	2	88	487	147	4	1	73	52	0	267

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 0657/0692/0693	1,000	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0675/0676/0658/0695/0696	1,000	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	72,000	18	38	104	23	32	10	12	15	11	4
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	0	1	6	1	3	0	0	7	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	112,000	24	44	150	41	42	15	8	15	19	7
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	2,000	1	0	1	1	1	0	0	2	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	32	695	428	204	773	96	157	391	361	29
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	4	152	75	79	145	12	48	251	67	6
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	33,000	12	83	57	30	68	2	9	41	54	4
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	5	5	3	7	0	1	9	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/Q-TRAK S-ICD Electrode 3010, 3401, 3501	31,000	0	2	12	0	75	5	3	0	8

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. Observations for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are included.

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 7640/7641/7642/7740/7741/7742	253000	272	306	563	131	54	37	5	40	0	25
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	7000	0	0	16	2	1	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	13000	0	0	19	5	0	2	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	174	276	1014	296	46	55	25	92	0	30
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	192000	9	10	389	100	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4463/4464/4465/4469/4470/4471	62000	0	13	403	48	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4477/4478/4479/4480	477000	55	55	609	148	84	63	31	77	0	26
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14000	0	1	28	9	0	0	3	4	0	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/4473/4474	52000	2	13	94	16	3	9	6	3	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	9000	0	0	14	12	6	0	0	3	0	14
ACUITY X4 Spiral S 4674/4675	24000	0	1	28	9	4	0	0	14	0	31

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	18000	1	0	58	7	2	0	0	7	0	25
ACUITY Steerable 4554/4555/4556	29000	1	1	291	22	13	1	1	21	0	162
ACUITY Spiral 4591/4592/4593	23000	1	2	172	28	5	0	3	9	0	168
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	0	1	240	23	8	1	3	17	0	128
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	7	4	805	84	30	4	14	63	0	513
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	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 0657/0692/0693	1000	0	0	0	0	0	0	0	0	1	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0675/0676/0658/0695/0696	1000	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	72000	52	18	231	37	23	3	1	25	5	6
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3000	2	0	8	1	0	0	0	6	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	112000	79	19	303	58	36	12	5	28	13	16
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	2000	2	1	4	0	1	1	0	6	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287000	83	140	513	131	223	12	18	180	108	44
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47000	5	4	93	36	41	4	3	47	5	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation	33000	29	7	65	14	19	3	2	18	21	9

0137/0138/0160/0161/0162/0180/0181/0182											
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	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/Q-TRAK S-ICD Electrode 3010/3401/3501	31000	1	0	20	0	239	7	1	0	16

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	22,000	0	0	0	1	0	0	0
ACUITY X4 Spiral S 4674/4675	51,000	0	0	0	3	0	0	0
ACUITY X4 Straight 4671/4672	41,000	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	45,000	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 0658/0695/0696	13,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0657/0692/0693	63,000	3	1	0	1	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0654/0682/0683	4,000	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	113,000	0	0	0	69	0	1	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0265/0266/0285/0286	10,000	0	0	0	5	15	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	168,000	0	0	0	24	0	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	5,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	379,000	0	0	92	568	1	3	10
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	109,000	0	0	20	109	0	3	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	72,000	0	0	15	71	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/Q-TRAK S-ICD Electrode 3010, 3401, 3501	57,000	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 7640/7641/7642/7740/7741/7742	600,000	1595	0	0	2962	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	56,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	66,000	0	0	0	1	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	291,000	0	0	66	636	1	1	4
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457*	538,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	741,000	0	0	6	725	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	308,000	0	0	1	144	6	18	0
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459*	104,000	0	0	2	2	1	1	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	142,000	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. 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 **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 **12-Feb-19** *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 **12-Feb-19** • 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	ORIGINAL COMMUNICATION **September 2018 — Hydrogen Induced Premature Depletion**
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory FDA Classification: Unclassified

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, L131

This advisory discusses a subset of 2900 pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) with an elevated potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion.

The pacemaker manual describes how increases in pacing requirements or changes in programmed parameters may result in an expected longevity reduction and are considered normal battery depletion. However, hydrogen exposure within the pacemaker's circuitry may compromise the electrical performance of low voltage capacitors causing current leakage and a moderate acceleration in the rate of battery depletion.

Because this accelerated depletion does not occur rapidly, a follow-up interval of no more than six months is recommended. Boston Scientific has determined a liner component to be the source of hydrogen and identified a subset of 2900 previously distributed pacemakers that have an elevated potential for exhibiting this behavior. Boston Scientific pacemakers include automated diagnostic tools, including battery status assessment and estimated longevity predictions, that dynamically adjust based on power consumption. It is important to emphasize that the accuracy of battery status and longevity estimates are not affected by this behavior.

Estimated Rate of Occurrence
The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is 1.4% at 2.5 years which is 233 times higher than the non-advisory population. Because this behavior is highly detectable through regular pacemaker follow-up care, the projected potential for life-threatening harm is 0.0003% (1 in 333,333) at 5 years. There are no devices within this advisory subset that are still available for implant.

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

Hydrogen Induced Premature Depletion, Physician Letter, Septemeber 2018

Hydrogen Induced Premature Depletion, Patient Letter, September 2018

CURRENT STATUS **12-Feb-19**

Estimated Rate of Occurrence
The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is 1.4% at 2.5 years which is 233 times higher than the non-advisory population. Because this behavior is highly detectable through regular pacemakerfollow-up care, the projected potential for life-threatening harm is 0.0003% (1 in 333,333) at 5 years. There are no devices within this advisory subset that are still available for implant.

CURRENT RECOMMENDATION **14-Feb-19**

- Boston Scientific recommends following patients implanted with any affected pacemaker from the advisory subset at intervals no greater than every six (6) months either in-clinic or via LATITUDE in accordance with the best practices outlined in international societal guidelines
- Promptly investigate any suspected indication of accelerated depletion. Before surgical intervention, contact Boston Scientific Technical Services for verification of accelerated depletion and to determine an appropriate timeframe for pacemaker replacement. Please note, if accelerated depletion is identified, the Save to Disk feature or LATITUDE is necessary to perform an engineering assessment.
- Prophylactic replacement is NOT recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated depletion.

PRODUCT

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

Voluntary Physician Advisory

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, L131

ALTRUA 2 Pacemaker
Models S701, S702, S722

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

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)

Minute Ventialtion Signal Oversensing, Physician Letter,

Minute Ventialtion Signal Oversensing, Patient Letter, December 2017

CURRENT STATUS **12-Feb-19**

Estimated Rate of Occurrence

Minute Ventialtion Signal Oversensing, Update letter, January 2019

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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
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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 **12-Feb-19**

Boston Scientific has now received approval for Model 2869 v2.06 software. Once this software upgrade is complete, the MV sensor may be enabled for those patients who are likely to benefit clinically from RightRate™, Respiratory Rate Trend, or AP Scan™ . Please refer to the Minute Ventialtion Signal Oversensing, Update letter, January 2019 for instructions.

Until software is available to automatically resolve MV sensor signal oversensing, Boston Scientific recommends managing the risk for patients implanted with affected pacemaker systems as follows:

•For pacemaker-dependent patients, turn the MV sensor “OFF”. Note when programmed to passive, the MV sensor signal is enabled and may be oversensed. See Appendix B for details on turning the MV sensor “OFF”.
•For all other patients, evaluate the risks of oversensing the MV sensor signal against the benefits of MV sensor indicated pacing. If the risk outweighs the benefit, turn the MV sensor “OFF” (see Appendix B).
•If transient, abrupt changes or any out-of-range RA/RV pacing impedance measurements are observed, contact Boston Scientific Technical Services to explore all non-invasive programming options prior to surgical intervention. In most cases, management of the system can be done non-invasively through programming changes.
•In accordance with the pacemaker manual, if MV sensor signal artifacts are observed on EGMs and leads are performing appropriately, consider programming the sensor to “OFF” to prevent oversensing.
•For patients with the MV sensor enabled, periodically re-assess for pacemaker dependence.
•Enroll and follow patients using the LATITUDE™ NXT Remote Patient Management System.

PRODUCT	ORIGINAL COMMUNICATION **December 2017 — CRT Positive LV Offset and TPP Interaction**
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** Models G324, G325, G328, 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	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 **12-Feb-19** *Confirmed Malfunctions (worldwide)* There have been three confirmed instances of early device replacement due to this device behavior. CURRENT RECOMMENDATION **12-Feb-19** Boston Scientific has received approval of Model 2868 v4.07 for CRT-Ds and Model 2869 v2.06 software for CRT-Ps to resolve this behavior. Please refer to the CRT Positive LV Offset and TPP Interaction, Update Letter, January 2019 for instructions. Until software is available to prevent programming of a susceptible combination of parameters, eliminate the risk associated with early replacement due to this unintended asynchronous BiV pacing behavior by performing the following steps: 1. Review programming records of patients implanted with the CRT devices included in Appendix B of the December 2017 physician letter 2. If the LV Offset parameter is programmed to Zero or a Negative value, the device is not at risk of this behavior. 3. If the LV Offset parameter is programmed to a Positive value, determine if the following conditions are met: A. The positive LV Offset value exceeds the A-Blank after V-Pace interval, where “Smart” blanking is equivalent to a value of 37.5 ms; and B. Tracking Preference programmed to ON 4. For patients whose device has a positive LV Offset value exceeding A-Blank after V-Pace value and Tracking Preference is programmed to ON, schedule a clinic appointment to reprogram the CRT device as follows according to the patient’s individual medical needs: A. Either program the CRT device such that the A-Blank after V-Pace value is greater than the positive LV Offset value; or B. Disable Tracking Preference by programming it to a value of “OFF”. 5. Devices with an A-Blank after V-Pace value exceeding the positive LV Offset value are not affected and are not at risk of this behavior. 6. Patients whose device has Tracking Preference programmed OFF are not affected and are not at risk of this behavior. Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT

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

Device Lookup Tool

S-ICD

Models 1010, A209, A219

S-ICD Memory Corruption, Physician Letter, Jun 29, 2017

S-ICD Memory Corruption, Patient Letter, Jun 29, 2017

S-ICD Software v4.04 Programmer Commands and Memory Corruption August 2017

ORIGINAL COMMUNICATION **June 2017 — S-ICD Memory Corruption**

Voluntary Physician Advisory
FDA Classification: Class II

This advisory discusses a single, isolated S-ICD event that resulted in a device-related patient death.

Boston Scientific engineers have determined that this patient's S-ICD repeatedly delivered an atypical amount of energy (similar to the arrhythmia induction function) because a specific memory location was corrupted by radiation within the environment. This repeated atypical energy delivery prevented S-ICD arrhythmia detection/treatment and ultimately contributed to the patient death.

Estimated Rate of Occurrence

This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide.

Given the rarity of this single event observed to date, a precise projection of occurrence cannot be derived with confidence. Engineering analysis of S-ICD device memory design and recorded instances of SEUs in fielded devices was conducted during our root cause investigation of this event. Based on this analysis, the probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.

CURRENT STATUS **12-Feb-19**

This experience represents one (1) observed event in approximately 60,000 S-ICDs distributed worldwide.

Estimated Rate of Occurrence

The probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.

CURRENT RECOMMENDATION **12-Feb-19**

In consultation with our Patient Safety Advisory Board, Boston Scientific recommends NO changes to clinical follow-up due to this single event. Specifically, for patients with S-ICD systems:

- Continue using the S-ICD system to detect and treat life-threatening ventricular tachyarrhythmias;
- Keep scheduled LATITUDE™ and/or in clinic follow-ups; and
- Follow the precautions identified in the S-ICD user's manual when radiation therapy is prescribed.

Furthermore, Boston Scientific does NOT recommend the following:

- Early or off-cycle follow-ups are not recommended. This type of memory corruption cannot be detected, thus additional S-ICD checks do not reduce the potential for this device behavior.
- Prophylactic S-ICD replacement or explant is not recommended. The risks associated with such an additional surgical procedure significantly outweigh the risk of reoccurrence of this device behavior. Until the software mitigation update is available, this S-ICD behavior represents an additional, small risk that should be considered when evaluating the relative risks associated with all available ICD therapy options.

Boston Scientific is now releasing programmer software version 4.04 to address the behavior for S-ICDs and a local Boston Scientific representative will arrange to update each programmer. This advisory no longer applies after an S-ICD is interrogated by any programmer updated with version 4.04 software.

Recommendations for S-ICD and Programmers

- Confirm all Model 3200 S-ICD programmers are upgraded with version 4.04 software.
- Once your Model 3200 S-ICD programmers are upgraded, perform a standard in-clinic S-ICD followup for all patients implanted with an S-ICD at their earliest convenience. The January 2017 recommendation to perform a second interrogation is no longer required.

Note: The programmer will upgrade each S-ICD's software which takes less than 5 minutes.

- Thereafter, standard in-clinic S-ICD follow-up checks may resume at normal frequency with programmers upgraded with version 4.04 software.

Note: When an S-ICD's software has been upgraded, it can only be interrogated with programmers installed with version 4.04 or greater software. Appendix A shows how the software model and version number can be identified through the programmer or an S-ICD summary report.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor**
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	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 **12-Feb-19**
	Advisory devices have not been available for implant for more than seven years. *Confirmed Malfunctions (worldwide)* 5,685 malfunctions have been confirmed from the advisory population. Approximately 32,000 devices from the advisory populations remain in service. There have been two reported patient deaths due to complications with the replacement of an advisory device. *Projected Rate of Occurrence* • COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.9% at 60 months, 6.0% at 72 months, 8.9% at 84 months and 11.2% at 96 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, 2.5% at 72 months and 3.7% at 84 months. The projected rate of occurrence is 5.0% at 96 months. Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy has decreased to approximately 1.6%. 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% at 60 months. The projected rate of occurrence is 1.8% at 72 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 5,000,000 (0.00002%) at 60 months.
	CURRENT RECOMMENDATION **12-Feb-19**
	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	*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.
Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	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 **12-Feb-19**
	Reported events (worldwide) 101 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 **12-Feb-19**
	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.

PRODUCT	ORIGINAL COMMUNICATION **23-Jun-06 and 24-Aug-06— Low Voltage Capacitor**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492 **CONTAK RENEWAL TR / TR2** Models H120/H125/H140/H145 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE** Model T180 **VITALITY DS VR/DR** Models T135/T125 **VITALITY VR/DR and EL** Models 1870/1871/T127 **VENTAK PRIZM 2 VR/DR** Models 1860/1861 Low Voltage Capacitor, Physician Low Voltage Capacitor, Patient Letter, Low Voltage Capacitor, Physician Letter, Jun 23, 2006	Voluntary Physician Advisory FDA Classification: Class II Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue. *Reported Events (worldwide)* At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing. *Projected Rate of Occurrence* While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future. CURRENT STATUS **12-Feb-19** *Confirmed Malfunctions (worldwide)* 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation. There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* The rate of occurrence is projected to range between 0.10% and 0.22%. CURRENT RECOMMENDATION **12-Feb-19** Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged. – Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients when making medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation. **Device Behavior** **Pacemakers: INSIGNIA** – Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **12-May-06 and 04-Jan-08 Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool *This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..* **CONTAK RENEWAL 4 HE** Models H197/H199 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 AVT / AVT HE** Models M170/M175/M177/M179 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 AVT / AVT HE** Models M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY DR HE** Model T180 **VITALITY EL** Model T127 **VITALITY DR+** Model 1872	Voluntary Physician Advisory FDA Classification: Class II Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up. This failure mechanism can result in one or more of the following device behaviors: – Loss of shock therapy – Loss of pacing therapy (intermittent or permanent) – Loss of telemetry communications – Beeping (16 tones every six hours), and a programmer warning screen upon interrogation *Reported Events* Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism. *Rate of Occurrence* The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.
	CURRENT STATUS **12-Feb-19**
	Confirmed Malfunctions (worldwide) May 12, 2006 Population Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation. January 4, 2008 Population Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.
	CURRENT RECOMMENDATION **12-Feb-19**
Subpectoral Implant, Physician Letter, Jan 04, 2008 Subpectoral Implant, Patient Letter, Dec 01, 2009	Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication. – For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. – For subpectoral implants, use an AP radiograph to determine specific device orientation. - If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary. If the device is in a susceptible orientation (serial number facing the ribs): – Advise patient of the potential for device failure. – Follow patient at 3 month intervals in accordance with device labeling. – Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy. – For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **22-Sep-05 — Crystal Timing Component**
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 **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492	Voluntary Physician Advisory FDA Classification: Class II Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component. *Reported Events* Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004. Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths. *Rate Projection* Failure Mode 1—As of the September 22, 2005 communication, Modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
	CURRENT STATUS **12-Feb-19**
	Confirmed Malfunctions (worldwide) Failure Mode 1— 62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory. Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 3,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **12-Feb-19**
Crystal Timing Component, Physician Letter, Dec 12, 2005 Crystal Timing Component, Patient Letter, Oct 03, 2005 Crystal Timing Component, Physician Letter, Sep 22, 2005	Failure Mode 1— Patient management recommendations from the September 22, 2005 physician communication remain unchanged. Failure Mode 2— Patient management recommendations supersede those originally communicated on September 22, 2005. – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
	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

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1.800.CARDIAC (227.3422)
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