Boston Scientific
Advancing science for life™

2024

Rhythm Management Product Performance Report

Q1 Edition

RESONATE™
Family of ICDs AND CRT-Ds

ACCOLADE™
Family of Pacemakers

INGEVITY™ +
Pacing Lead

CRM Quality Pledge

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

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q1 2024 report includes data through January 8th, 2024.

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,

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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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Reduction in survival probability is due to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Malfunction Details: Overview

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

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

Patterns
Patients and physicians have asked for more access to Quality System details; therefore, we provide information on patterns of product performance. Patterns listed are informational and do not represent actions that need to be taken. Boston Scientific is committed to direct communication when predicted product performance fails to achieve design or performance expectations or when actions may be taken to improve patient outcomes. Malfunctions associated with product advisories are denoted. Refer to the Product Advisories section for more information. In cases where more than one malfunction pattern could be applied to a device, a single malfunction pattern is reported, with priority given to patterns associated with an advisory, patterns associated with an existing investigation, and malfunctions that resulted in compromised therapy.

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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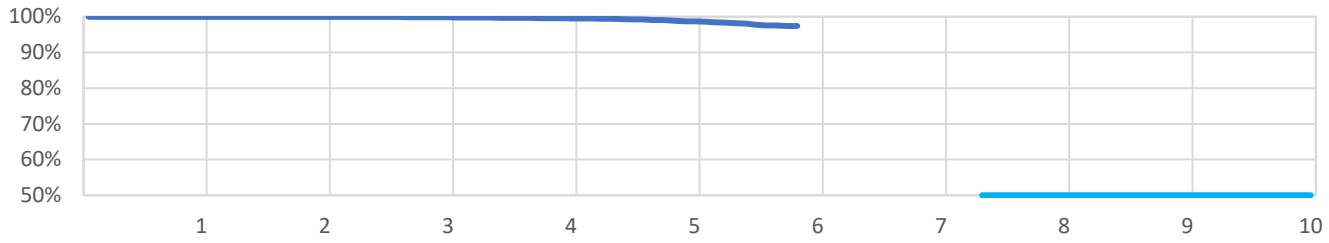
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

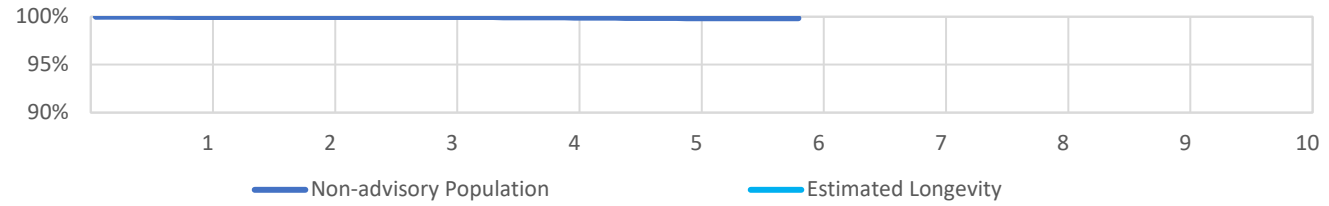
Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/ G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

US Summary			
US Registered Implants:	81,000	US Normal Battery Depletions:	158
US Approval Date:	September 2017	US Malfunctions:	32
US Estimated Active Implants:	73,000	Without Compromised Therapy:	24
		With Compromised Therapy:	8

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%	98.7%	97.4%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	--	--	--	--
81,000	Effective Sample Size	57251	38549	23696	12649	4343	329	--	--	--	--

@ 71 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	**58**
Worldwide Distribution	**149,000**

US Approval Date: September 2017	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (63)	1	8	9
Low-voltage capacitor (69)	0	9	9
Battery (53)	2	10	12
High voltage capacitor (75)	2	0	2
Software			
Memory errors (51)	0	15	15
Other			
Non-patterned, other	6	5	11
Grand Total	**11**	**47**	**58**

References cited in table above (link)

AUTOGEN CRT-D

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

Worldwide Confirmed Malfunctions	**39**
Worldwide Distribution	**25,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	7	7
Integrated circuit (63)	2	4	6
Low-voltage capacitor (69)	0	6	6
Battery (53)	3	8	11
High voltage capacitor (75)	1	0	1
Software			
Safety Core-unintended biventricular pacing (64)	0	1	1
Memory errors (51)	0	1	1
Other			
Non-patterned, other	1	5	6
Grand Total	**7**	**32**	**39**

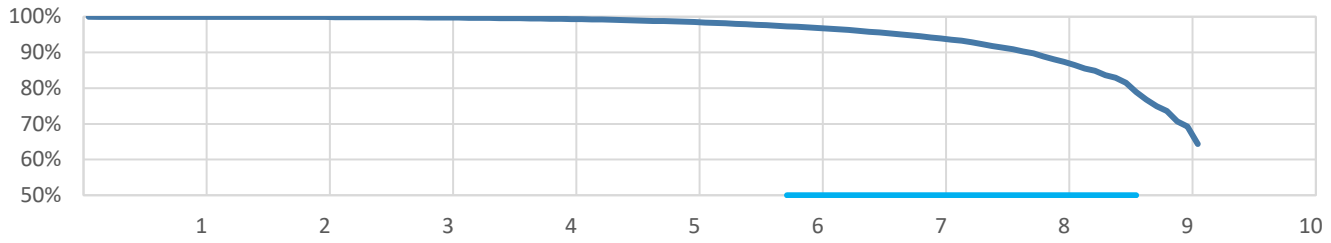
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN CRT-D

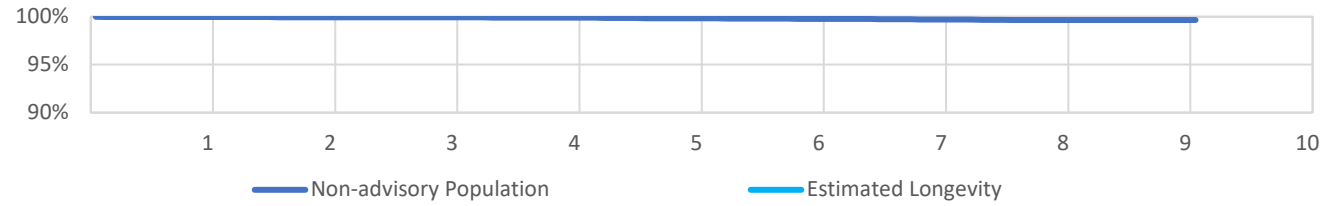
Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	2,247
US Approval Date:	April 2014	US Malfunctions:	112
US Estimated Active Implants:	56,000	Without Compromised Therapy:	99
		With Compromised Therapy:	13

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.6%	97.0%	94.2%	88.1%	70.6%	64.3%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
75,000	Effective Sample Size	65345	56928	48753	40636	31920	22250	12309	4831	522	218

@ 110 months

DYNAGEN/INOGEN/ORIGEN CRT-D

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

Worldwide Confirmed Malfunctions	**161**
Worldwide Distribution	**133,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	19	19
Integrated circuit (63)	4	11	15
Low-voltage capacitor (69)	0	27	27
High voltage capacitor (75)	2	1	3
Battery (53)	2	32	34
Low-voltage capacitors (47)	0	1	1
Software			
Memory errors (51)	2	31	33
Safety Core-unintended biventricular pacing (64)	0	3	3
Other			
Non-patterned, other	13	13	26
Grand Total	**23**	**138**	**161**

References cited in table above (link)

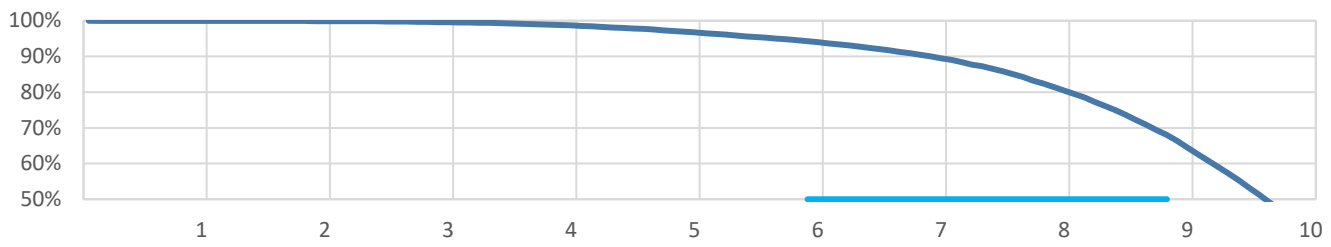
INCEPTA/ENERGEN/PUNCTUA CRT-D

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

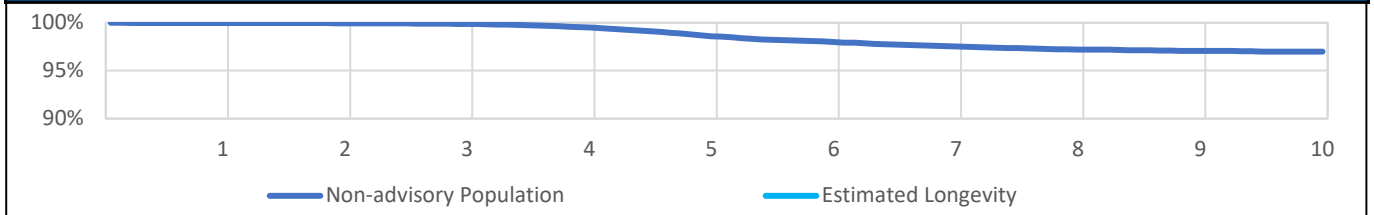
US Summary

US Registered Implants:	53,000	US Normal Battery Depletions:	10,396
US Approval Date:	November 2011	US Malfunctions:	811
US Estimated Active Implants:	20,000	Without Compromised Therapy:	788
		With Compromised Therapy:	23

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.6%	98.8%	96.9%	94.3%	90.0%	81.4%	66.3%	42.7%
Registered Implants: 53,000	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.7%	98.0%	97.5%	97.2%	97.1%	97.0%
	Effective Sample Size	46248	41361	36873	32715	28670	24876	21210	16802	10817	3607

INCEPTA/ENERGEN/PUNCTUA CRT-D

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

Worldwide Confirmed Malfunctions	**1,297**
Worldwide Distribution	**81,000**

US Approval Date: November 2011	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Safety Core-electrocautery (42)	1	6	7
High-voltage capacitor (43)	5	0	5
Low-voltage capacitors (47)	0	2	2
Integrated circuit (50)	7	2	9
Battery (53)	2	11	13
Low-voltage capacitor (54)	7	1204	1211
Low-voltage capacitor (69)	0	11	11
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	8	16	24
Grand Total	**36**	**1261**	**1297**

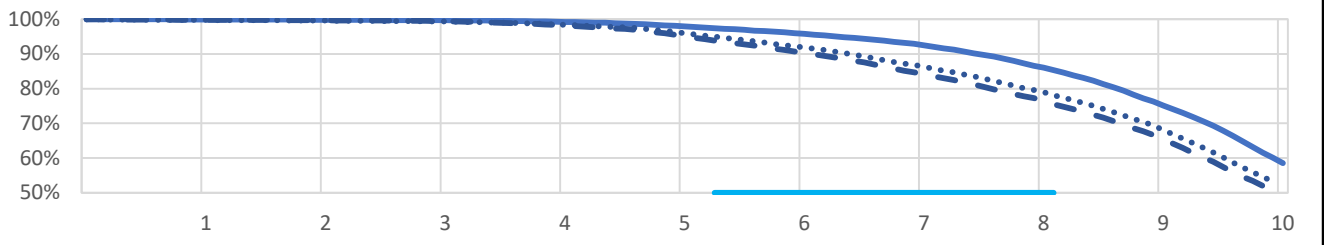
References cited in table above (link)

COGNIS CRT-D

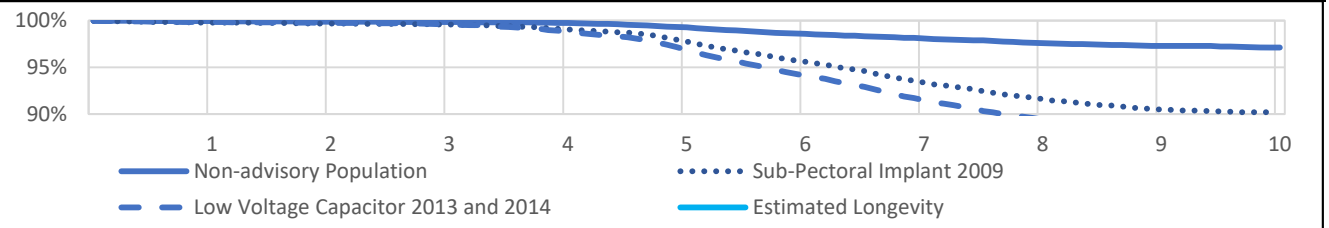
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	15,839
US Approval Date:	March 2008	US Malfunctions:	2,099
US Estimated Active Implants:	14,000	Without Compromised Therapy:	1,906
		With Compromised Therapy:	193

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.1%	96.0%	92.9%	86.6%	76.3%	60.1%
Registered Implants: 36,000	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.1%	97.6%	97.3%	97.1%
	Effective Sample Size	31212	27983	25037	22287	19720	17226	14860	12377	9685	6792

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%	99.6%	99.4%	98.5%	96.3%	92.2%	86.8%	79.6%	69.4%	53.3%
Registered Implants: 32,000	Malfunctions Only	99.8%	99.7%	99.6%	99.1%	98.0%	95.7%	93.6%	91.8%	90.6%	90.2%
	Effective Sample Size	27066	23947	21359	18946	16511	14042	11726	9511	7340	4967
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.3%	95.5%	90.7%	84.7%	77.3%	66.7%	50.8%
Registered Implants: 26,000	Malfunctions Only	99.8%	99.8%	99.6%	98.9%	97.2%	94.3%	91.7%	89.6%	88.2%	87.8%
	Effective Sample Size	22275	19748	17644	15600	13537	11396	9423	7595	5811	3878

*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	**2,962**
Worldwide Distribution	**109,000**

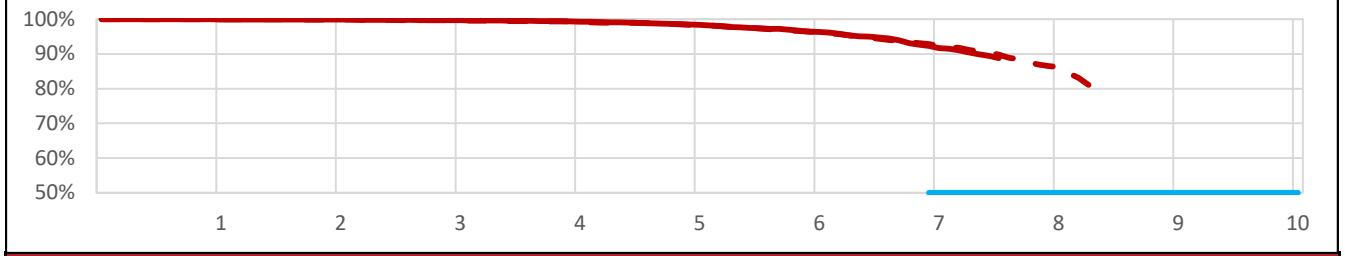
US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	83	1617	1700
Safety Core-electrocautery (42)	25	54	79
High-voltage capacitor (43)	6	1	7
Low-voltage capacitors (47)	0	7	7
Integrated circuit (50)	21	8	29
High voltage circuit (52)	1	0	1
Battery (53)	10	51	61
Low-voltage capacitor (54)	12	851	863
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	9	0	9
Difficulty securing lead (41)	8	8	16
Header contacts (45)	8	10	18
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	48	20	68
Header (74)	25	9	34
Software			
Safety Core-programming (46)	0	1	1
Alert messages not displayed post-EOL (48)	0	2	2
Memory errors (51)	2	15	17
Other			
Non-patterned, other	11	37	48
Grand Total	**269**	**2693**	**2962**

VISIONIST/VALITUDE

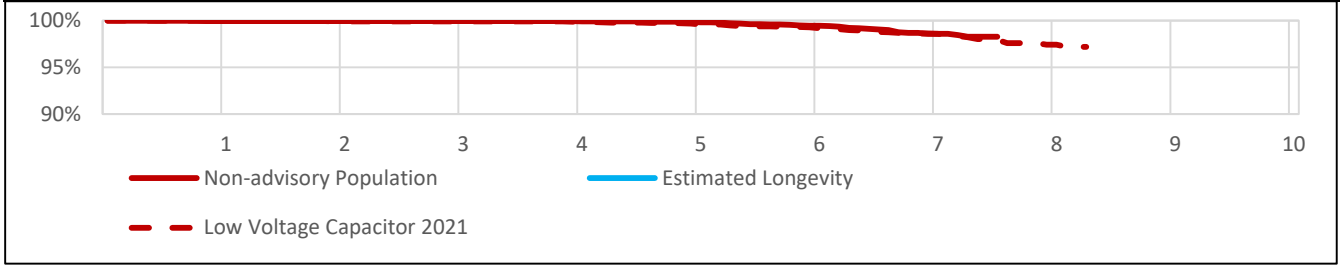
Models: U125/U128/U225/U226/U228

US Summary			
US Registered Implants:	55,000	US Normal Battery Depletions:	674
US Approval Date:	October 2014	US Malfunctions:	157
US Estimated Active Implants:	44,000	Without Compromised Therapy:	146
		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%	99.7%	99.4%	98.5%	96.4%	92.3%	88.8%	--	--	
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.5%	98.6%	98.3%	--	--	
47,000	Effective Sample Size	36105	26748	18803	12858	7765	3990	1032	295	--	--	@ 91 months

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

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.3%	98.4%	96.4%	92.8%	86.5%	81.1%	--
Registered Implants: 6,000	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.7%	99.3%	98.6%	97.4%	97.2%	--
	Effective Sample Size	5897	5266	4702	4185	3679	2968	2144	610	245	--

@ 100 months

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

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

Worldwide Confirmed Malfunctions	**253**
Worldwide Distribution	**113,000**

US Approval Date: October 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	2	14	16
Telemetry (68)	0	1	1
Hydrogen induced premature depletion - September 2018 (70)	0	19	19
Capacitor (67)	0	1	1
Hydrogen induced premature depletion - June 2021 (83)	2	63	65
High battery impedance (89)	4	87	91
Software			
Memory errors (51)	0	20	20
Other			
Non-patterned, other	9	29	38
Grand Total	**17**	**236**	**253**

References cited in table above (link)

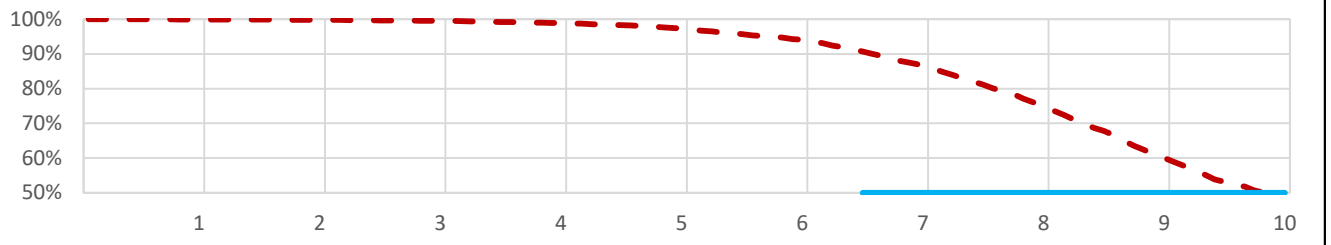
INTUA/INVIVE/INLIVEN

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

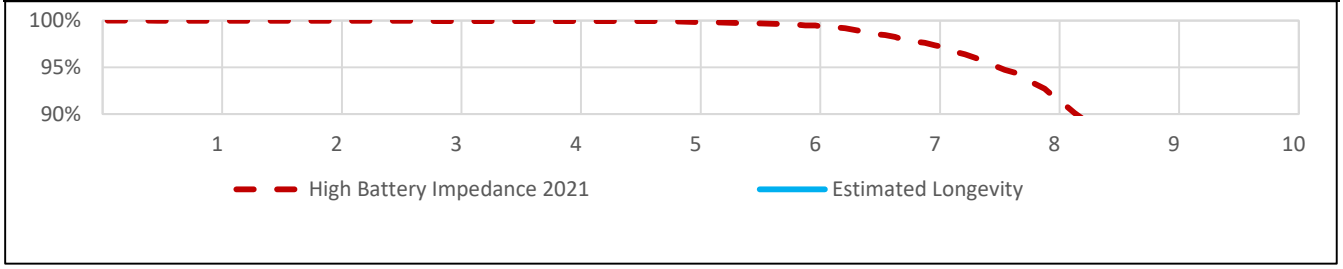
US Summary

US Registered Implants:	10,000	US Normal Battery Depletions:	1,191
US Approval Date:	May 2013	US Malfunctions:	524
US Estimated Active Implants:	3,000	Without Compromised Therapy:	508
		With Compromised Therapy:	16

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	99.9%	99.8%	99.5%	99.0%	97.5%	94.3%	87.3%	76.1%	61.0%	49.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.5%	97.6%	92.7%	84.0%	78.2%
10,000	Effective Sample Size	8945	7960	7076	6272	5526	4736	3750	2657	1327	444

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

INTUA/INVIVE/INLIVEN

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

Worldwide Confirmed Malfunctions	**788**
Worldwide Distribution	**24,000**

US Approval Date: May 2013	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High battery impedance initiating safety mode 2021 (82)	13	696	709
Low-voltage capacitors (47)	1	0	1
Other			
Non-patterned, other	16	62	78
Grand Total	**30**	**758**	**788**

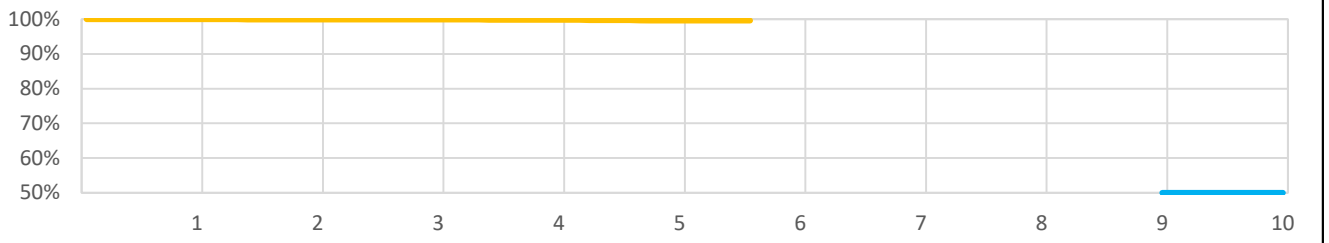
References cited in table above (link)

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

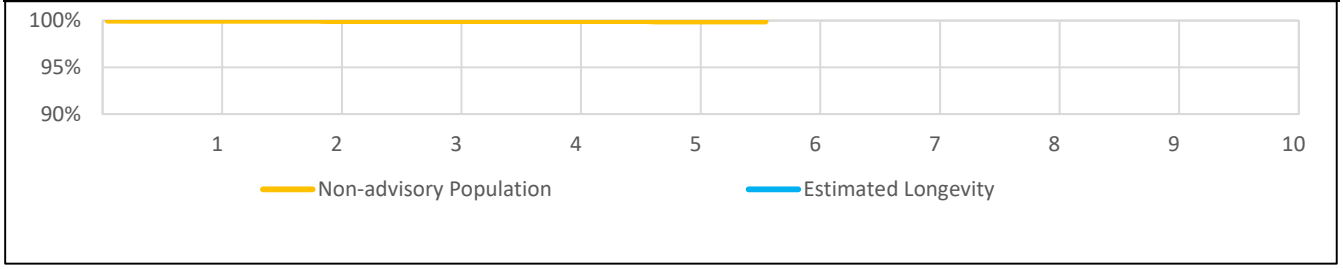
Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

US Summary			
US Registered Implants:	51,000	US Normal Battery Depletions:	32
US Approval Date:	July 2017	US Malfunctions:	16
US Estimated Active Implants:	47,000	Without Compromised Therapy:	12
		With Compromised Therapy:	4

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%	99.6%	99.6%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	--	--	--	--
51,000	Effective Sample Size	34489	21707	11807	5460	1485	212	--	--	--	--

@ 68 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

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

Worldwide Confirmed Malfunctions	**27**
Worldwide Distribution	**94,000**

US Approval Date: July 2017	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Integrated circuit (63)	0	6	6
Low-voltage capacitor (69)	0	3	3
Battery (53)	0	2	2
Software			
Memory errors (51)	0	8	8
Mechanical			
Solder joint (88)	1	0	1
Other			
Non-patterned, other	2	3	5
Grand Total	**5**	**22**	**27**

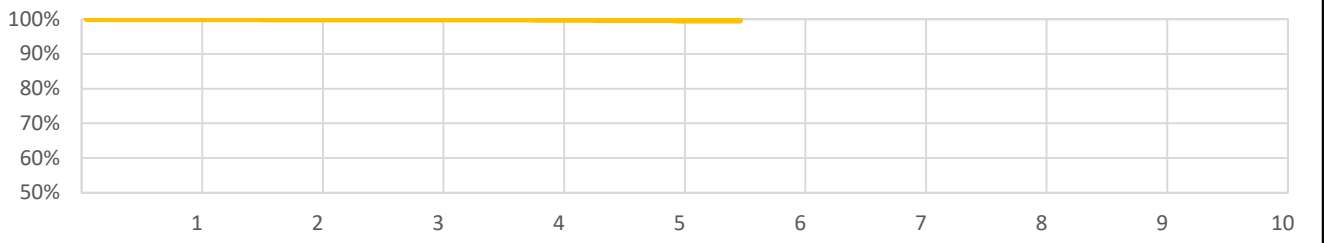
References cited in table above (link)

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

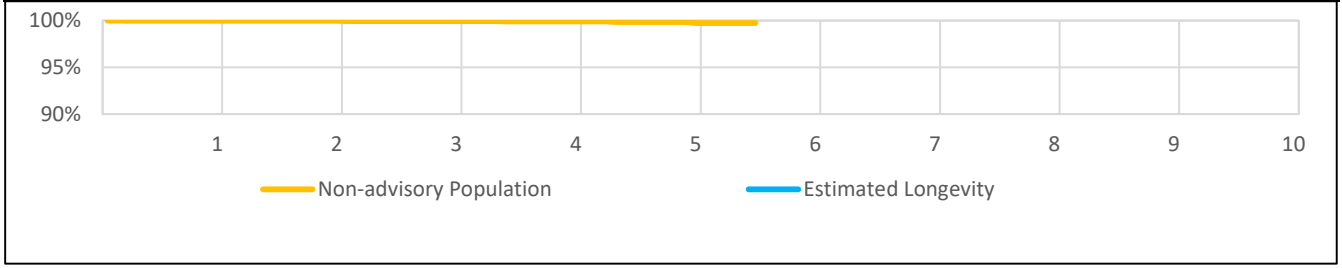
Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

US Summary			
US Registered Implants:	28,000	US Normal Battery Depletions:	13
US Approval Date:	July 2017	US Malfunctions:	12
US Estimated Active Implants:	26,000	Without Compromised Therapy:	11
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	--	--	--	--
28,000	Effective Sample Size	19081	12331	7338	3798	1095	256	--	--	--	--

@ 67 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

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

Worldwide Confirmed Malfunctions	**23**
Worldwide Distribution	**67,000**

US Approval Date: July 2017	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Integrated circuit (63)	1	0	1
Low-voltage capacitor (69)	0	2	2
Low-voltage capacitors (47)	0	1	1
Battery (53)	0	3	3
Software			
Memory errors (51)	0	7	7
Other			
Non-patterned, other	1	6	7
Grand Total	**4**	**19**	**23**

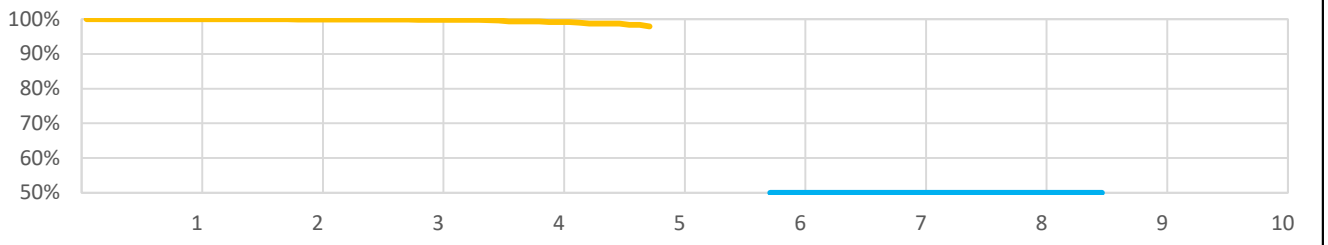
References cited in table above (link)

PERCIVA DR

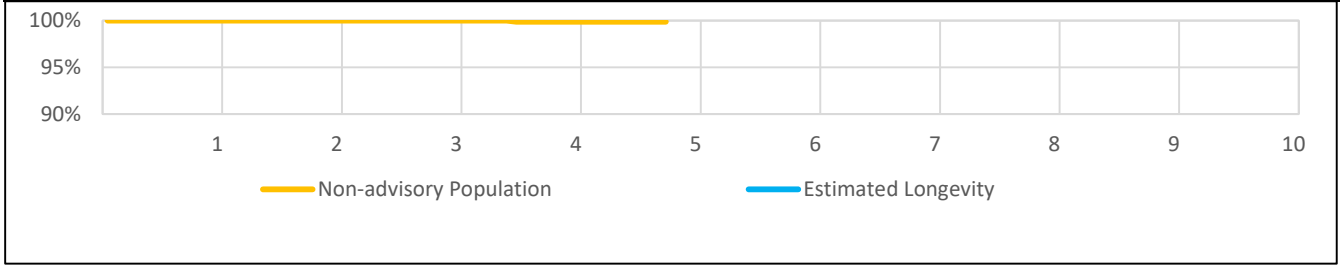
Models: D401/D413/D501/D513

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	21
US Approval Date:	July 2017	US Malfunctions:	1
US Estimated Active Implants:	4,000	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%	99.9%	99.8%	99.2%	97.9%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	--	--	--	--	--
5,000	Effective Sample Size	3559	2324	1272	597	211	--	--	--	--	--

@ 58 months

PERCIVA DR

Models: D401/D413/D501/D513

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**9,000**

US Approval Date: July 2017	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Battery (53)	0	1	1
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**1**	**1**

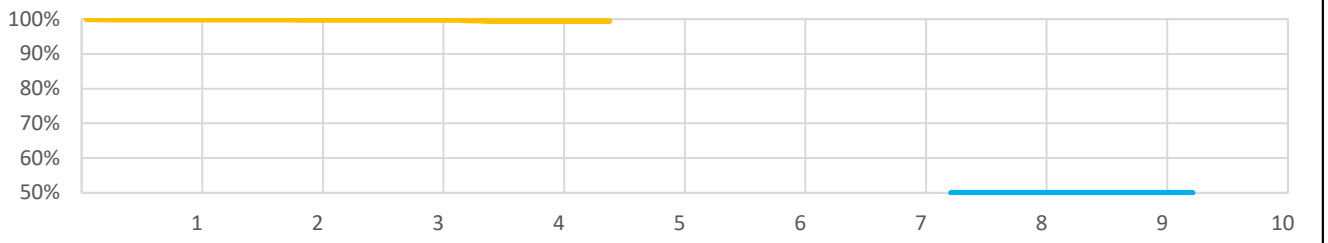
References cited in table above (link)

PERCIVA VR

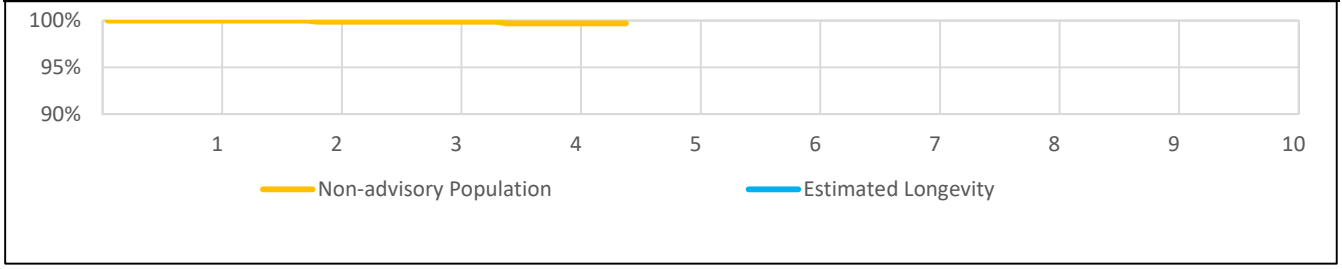
Models: D400/D412/D500/D512

US Summary			
US Registered Implants:	4,000	US Normal Battery Depletions:	5
US Approval Date:	July 2017	US Malfunctions:	3
US Estimated Active Implants:	3,000	Without Compromised Therapy:	2
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.8%	99.5%	99.5%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.7%	99.7%	--	--	--	--	--
4,000	Effective Sample Size	2459	1459	836	371	205	--	--	--	--	--

@ 54 months

PERCIVA VR

Models: D400/D412/D500/D512

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**7,000**

US Approval Date: July 2017	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	2	2
Electrical			
Integrated circuit (63)	1	0	1
High voltage capacitor (75)	1	0	1
Grand Total	**2**	**2**	**4**

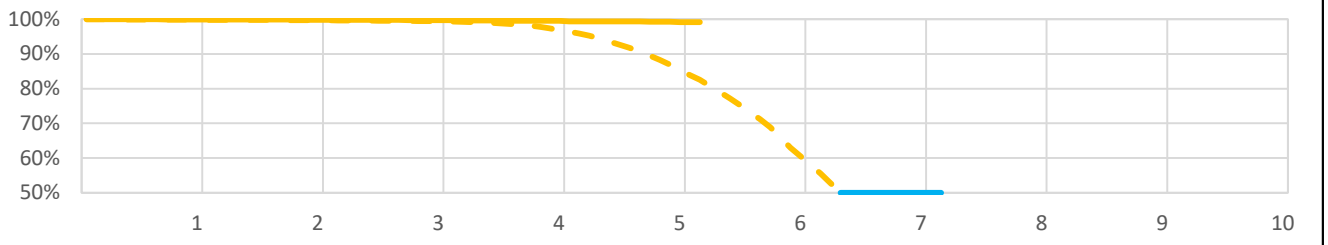
References cited in table above (link)

EMBLEM S-ICD

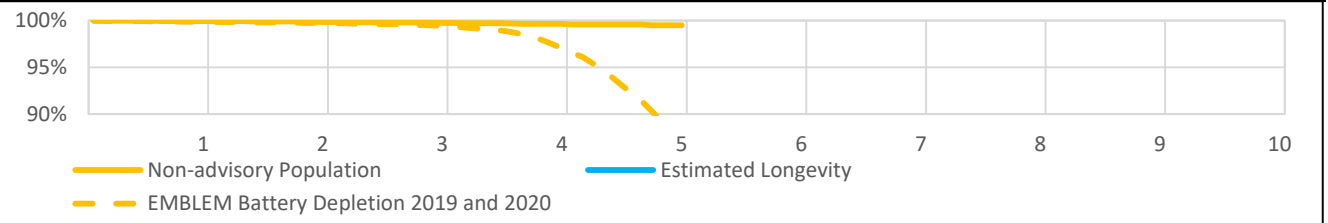
Models: A209/A219

US Summary			
US Registered Implants:	60,000	US Normal Battery Depletions:	1,141
US Approval Date:	March 2015	US Malfunctions:	4,374
US Estimated Active Implants:	46,000	Without Compromised Therapy:	4,241
		With Compromised Therapy:	133

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%	99.5%	99.3%	99.1%	--	--	--	--
Registered Implants: 32,000	Malfunctions Only	99.9%	99.9%	99.8%	99.6%	99.5%	99.5%	--	--	--	--
	Effective Sample Size	26771	17007	10111	4989	941	224	--	--	--	--

@ 63 months

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

EMBLEM S-ICD

Models: A209/A219

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Battery Depletion 2019 and 2020	Depletions and Malfunctions	99.9%	99.7%	99.4%	97.4%	87.0%	63.0%	34.7%	18.8%	17.2%	--
Registered Implants: 22,000	Malfunctions Only	99.9%	99.7%	99.5%	97.5%	88.1%	67.7%	44.3%	32.1%	31.3%	--
	Effective Sample Size	18477	16404	14543	12654	9815	4346	1197	399	262	--

@ 98 months

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

EMBLEM S-ICD

Models: A209/A219

Worldwide Confirmed Malfunctions	**8,910**
Worldwide Distribution	**138,000**

US Approval Date: March 2015	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	3	0	3
S-ICD battery depletion 2019 and 2020 (77)	124	8480	8604
Battery depletion (84)	1	2	3
Software			
Memory corruption (65)	1	0	1
Misaligned markers (73)	1	3	4
Memory corruption (85)	4	11	15
Mechanical			
Solder joint (78)	13	1	14
EMBLEM S-ICD electrical overstress 2020 (80)	8	0	8
RF antenna (81)	1	0	1
Cracked case (86)	16	1	17
Header (87)	1	0	1
Other			
Non-patterned, other	42	148	190
Telemetry (56)	17	32	49
Grand Total	**232**	**8678**	**8910**

References cited in table above (link)

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions	**59**
Worldwide Distribution	**16,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	2	0	2
Low-voltage capacitor (69)	0	19	19
Battery (53)	0	23	23
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	6	6
Other			
Non-patterned, other	1	3	4
Grand Total	**4**	**55**	**59**

References cited in table above (link)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions	**44**
Worldwide Distribution	**17,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Low-voltage capacitor (69)	0	8	8
Battery (53)	4	23	27
Integrated circuit (63)	0	1	1
Software			
Memory errors (51)	2	2	4
Other			
Non-patterned, other	0	2	2
Grand Total	**8**	**36**	**44**

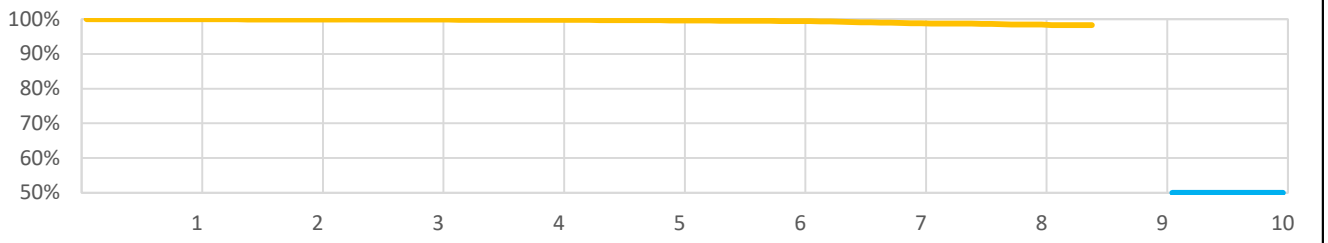
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

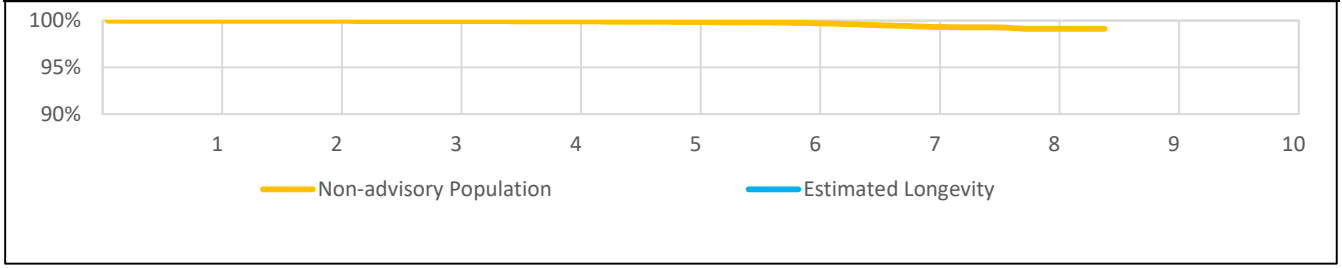
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	50,000	US Normal Battery Depletions:	91
US Approval Date:	April 2014	US Malfunctions:	95
US Estimated Active Implants:	40,000	Without Compromised Therapy:	78
		With Compromised Therapy:	17

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	98.8%	98.5%	98.3%	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.3%	99.1%	99.1%	--
50,000	Effective Sample Size	42270	35657	29375	23538	17654	11262	5487	1729	338	--

@ 102 months

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

Worldwide Confirmed Malfunctions	**121**
Worldwide Distribution	**83,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	4	1	5
Low-voltage capacitor (69)	0	35	35
High voltage capacitor (75)	8	0	8
Battery (53)	4	43	47
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	6	12	18
Grand Total	**22**	**99**	**121**

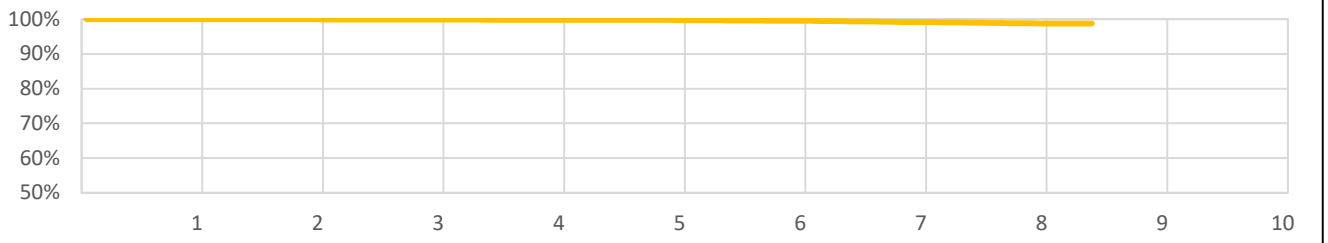
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL VR

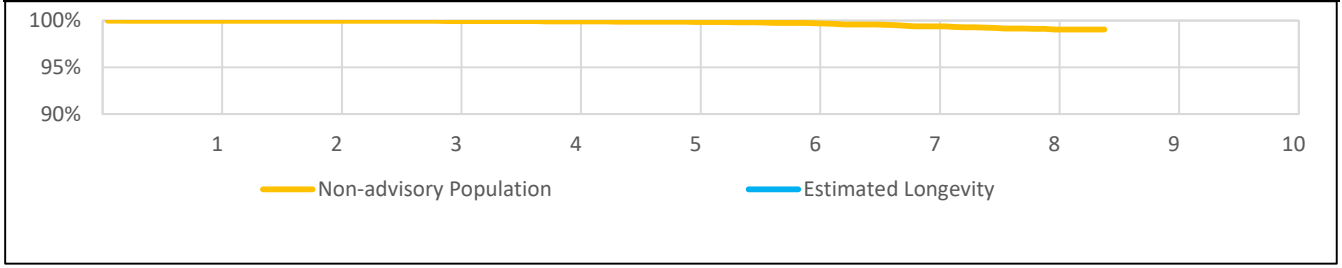
Models: D050/D051/D140/D141/D150/D151

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	42
US Approval Date:	April 2014	US Malfunctions:	81
US Estimated Active Implants:	31,000	Without Compromised Therapy:	74
		With Compromised Therapy:	7

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.2%	98.8%	98.7%	--	
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	99.1%	99.0%	--	
39,000	Effective Sample Size	33234	28499	24068	19779	15110	10011	5303	1748	298	--	@ 102 months

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

Worldwide Confirmed Malfunctions	**124**
Worldwide Distribution	**74,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	1	1
High voltage circuit component (62)	0	2	2
Integrated circuit (63)	0	2	2
Low-voltage capacitor (69)	1	43	44
Battery (53)	7	43	50
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	6	9	15
Grand Total	**15**	**109**	**124**

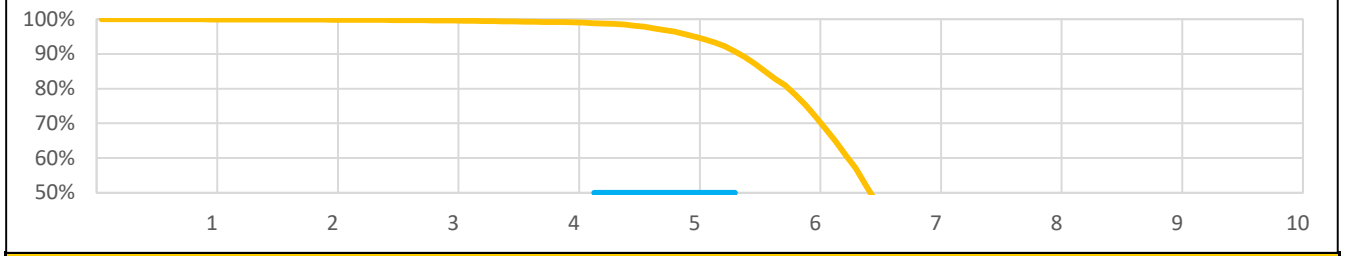
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

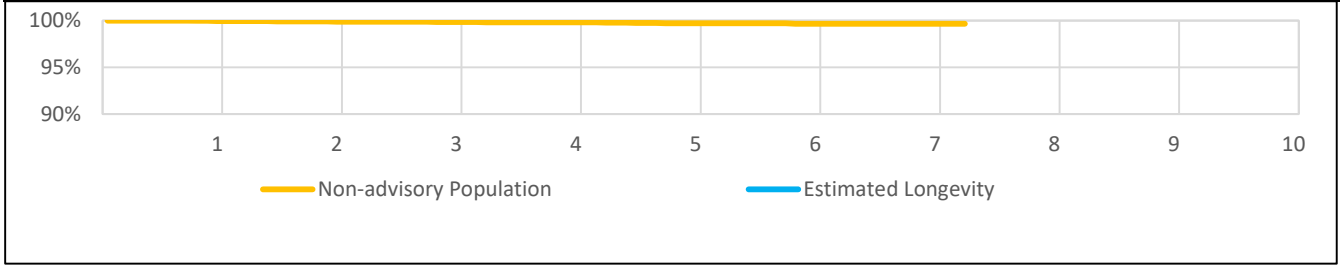
Models: D002/D003/D012/D013/D022/D023

US Summary			
US Registered Implants:	11,000	US Normal Battery Depletions:	2,159
US Approval Date:	April 2014	US Malfunctions:	21
US Estimated Active Implants:	6,000	Without Compromised Therapy:	18
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.6%	99.1%	95.7%	75.3%	27.6%	16.3%	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%	99.7%	--	--
11,000	Effective Sample Size	9473	7972	6648	5364	4116	2303	524	233	--	--

@ 89 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

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

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	12	12
High voltage capacitor (75)	3	0	3
Integrated circuit (63)	0	2	2
Low-voltage capacitors (47)	1	0	1
Battery (53)	0	4	4
Low-voltage capacitor (69)	0	3	3
Other			
Non-patterned, other	3	5	8
Grand Total	**7**	**26**	**33**

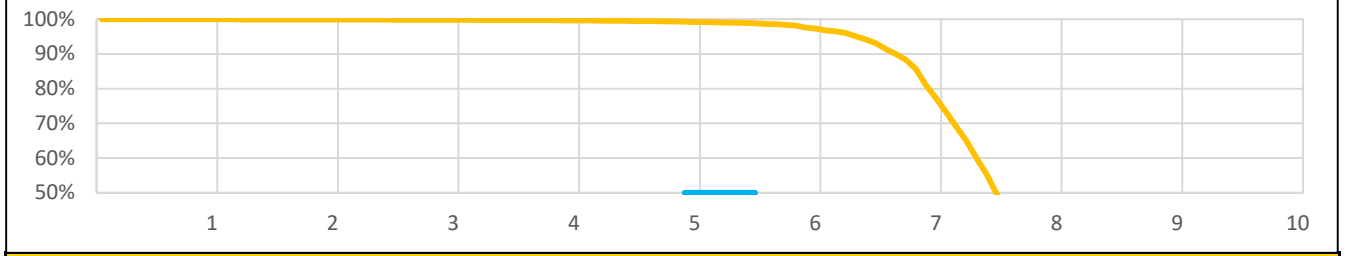
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

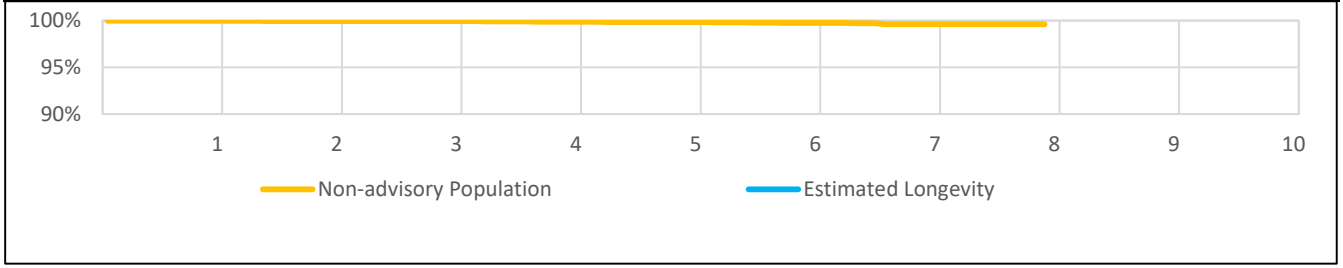
Models: D000/D001/D010/D011/D020/D021

US Summary			
US Registered Implants:	10,000	US Normal Battery Depletions:	1,350
US Approval Date:	April 2014	US Malfunctions:	16
US Estimated Active Implants:	6,000	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%	99.8%	99.6%	99.3%	97.6%	81.1%	24.5%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	--	--
10,000	Effective Sample Size	8127	6989	5969	5040	3986	2925	1719	278	--	--

@ 96 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

Worldwide Confirmed Malfunctions	**35**
Worldwide Distribution	**35,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	7	7
High voltage capacitor (75)	7	0	7
Low-voltage capacitor (69)	0	4	4
Battery (53)	1	6	7
Software			
Memory errors (51)	1	2	3
Other			
Non-patterned, other	2	3	5
Grand Total	**11**	**24**	**35**

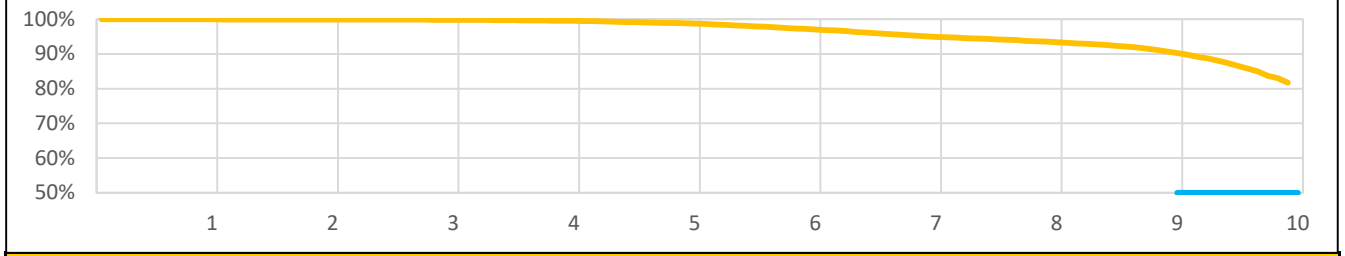
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD DR

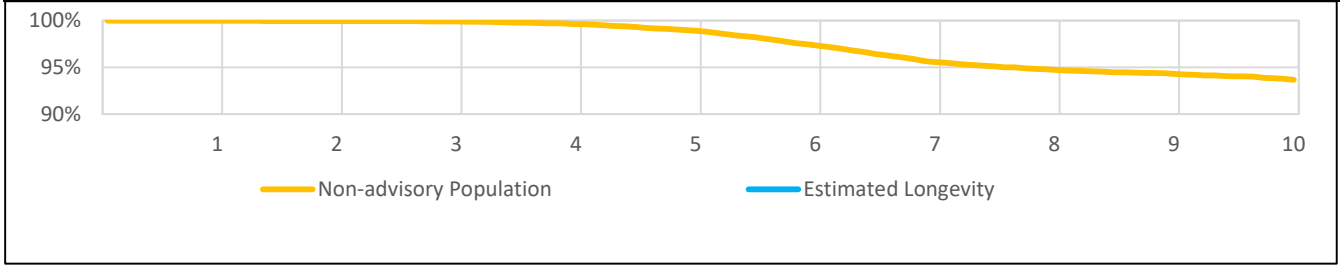
Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

US Summary			
US Registered Implants:	47,000	US Normal Battery Depletions:	2,204
US Approval Date:	November 2011	US Malfunctions:	1,291
US Estimated Active Implants:	25,000	Without Compromised Therapy:	1,256
		With Compromised Therapy:	35

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	98.8%	97.2%	95.1%	93.5%	90.7%	81.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.5%	95.7%	94.8%	94.4%	93.8%
47,000	Effective Sample Size	41187	36470	32192	28308	24787	21427	18402	15477	11309	5201

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

Worldwide Confirmed Malfunctions	**2,000**
Worldwide Distribution	**72,000**

US Approval Date: November 2011	With Compromised Therapy	Without Compromised Therapy	Total
Mechanical			
Transformer (38)	2	0	2
Electrical			
High-voltage capacitor (43)	5	1	6
Low-voltage capacitors (47)	0	4	4
Integrated circuit (50)	6	7	13
Battery (53)	15	92	107
Low-voltage capacitor (54)	14	1782	1796
High voltage circuit (58)	0	1	1
Low-voltage capacitor (69)	0	35	35
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	10	17	27
Grand Total	**52**	**1948**	**2000**

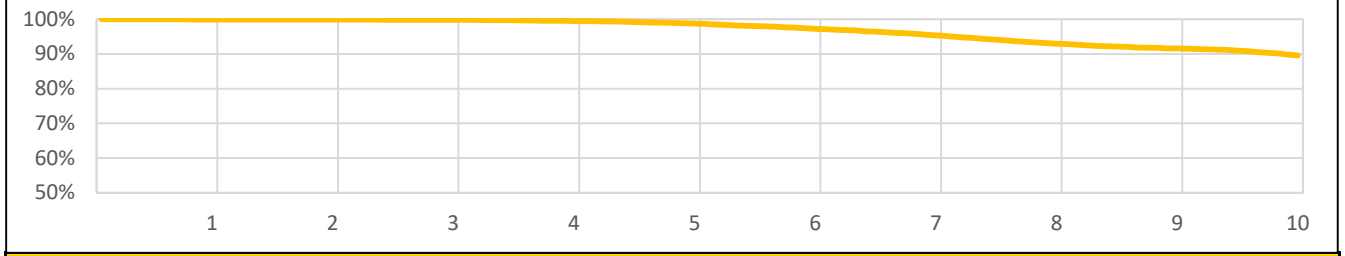
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD VR

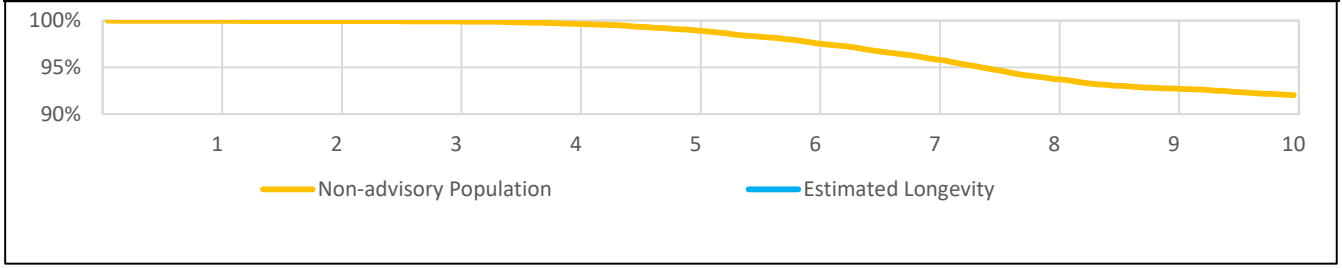
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	487
US Approval Date:	November 2011	US Malfunctions:	1,310
US Estimated Active Implants:	23,000	Without Compromised Therapy:	1,267
		With Compromised Therapy:	43

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.5%	98.8%	97.4%	95.5%	93.1%	91.6%	89.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.8%	96.0%	93.9%	92.7%	92.1%
39,000	Effective Sample Size	34676	30678	27085	23833	20849	18085	15489	12901	9357	4539

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

Worldwide Confirmed Malfunctions	**2,207**
Worldwide Distribution	**68,000**

US Approval Date: November 2011	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	4	1	5
Integrated circuit (50)	5	4	9
Battery (53)	26	152	178
Low-voltage capacitor (54)	19	1926	1945
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	0	26	26
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	1	9	10
Other			
Non-patterned, other	11	16	27
Grand Total	**73**	**2134**	**2207**

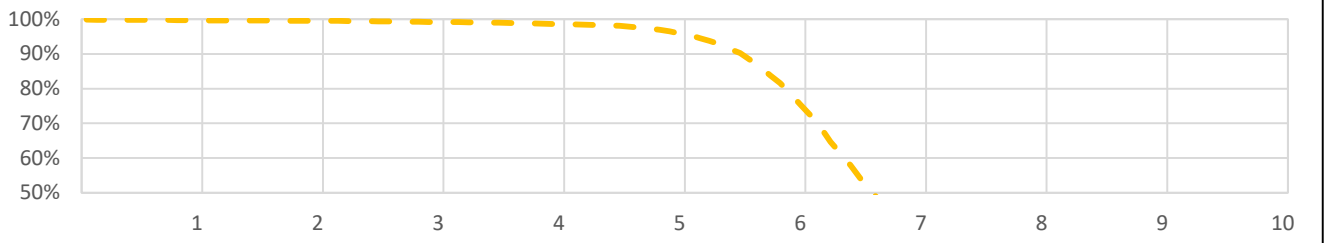
References cited in table above (link)

SQ-RX S-ICD

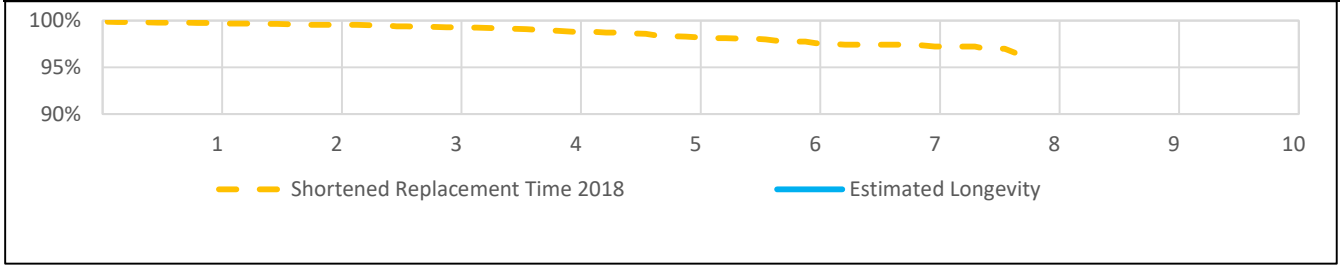
Models: 1010

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	2,958
US Approval Date:	September 2012	US Malfunctions:	116
US Estimated Active Implants:	2,000	Without Compromised Therapy:	49
		With Compromised Therapy:	67

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Shortened Replacement Time 2018	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.6%	96.5%	78.6%	35.5%	8.6%	--	--
Registered Implants:	Malfunctions Only	99.7%	99.5%	99.3%	98.8%	98.3%	97.8%	97.3%	96.6%	--	--
8,000	Effective Sample Size	6380	5616	4962	4355	3667	2652	1069	224	--	--

@ 93 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	**227**
Worldwide Distribution	**11,000**

US Approval Date: September 2012	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Unintended Fuse Activation 2013 (4)	3	0	3
Charge Timeout Alert (61)	1	11	12
Mechanical			
High cathode condition (5)	1	1	2
Shortened replacement time 2018 (55)	69	46	115
Software			
Unintended Battery Depletion Alert (57)	0	10	10
Other			
Telemetry (56)	10	4	14
Non-patterned, other	40	31	71
Grand Total	**124**	**103**	**227**

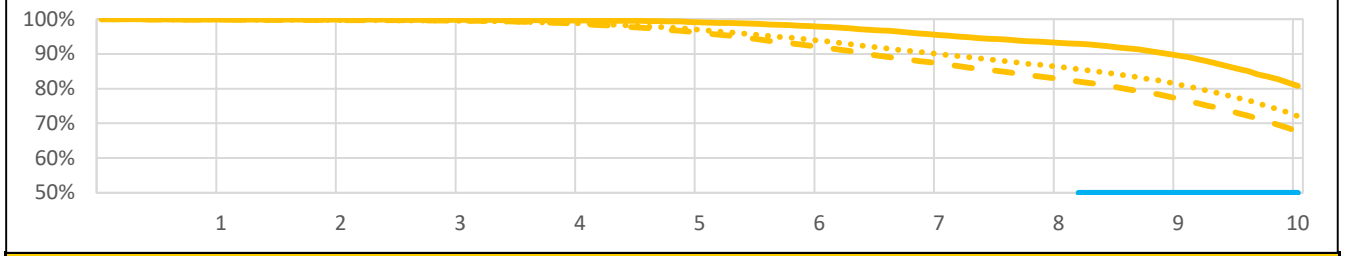
References cited in table above (link)

TELIGEN DR

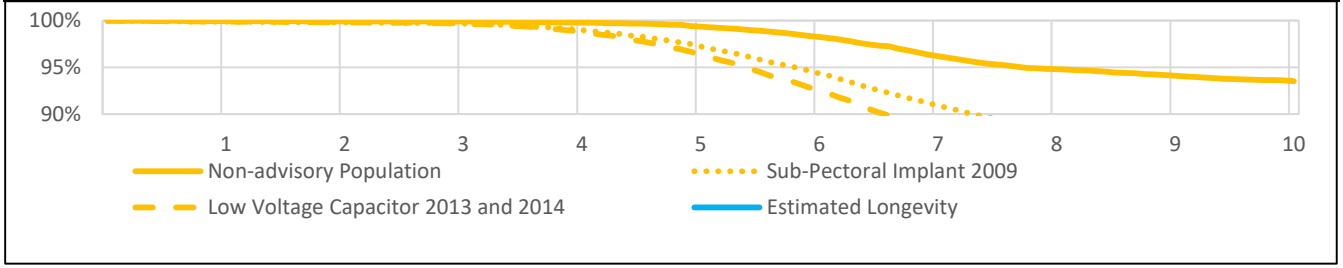
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	12,392
US Approval Date:	March 2008	US Malfunctions:	3,044
US Estimated Active Implants:	15,000	Without Compromised Therapy:	2,878
		With Compromised Therapy:	166

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	99.2%	98.0%	95.7%	93.4%	90.0%	81.7%
Registered Implants: 30000	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.4%	94.8%	94.2%	93.6%
	Effective Sample Size	26319	23340	20679	18240	16013	13908	11907	10157	8560	6792

TELIGEN DR

Models: E110/E111/F110/F111

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.9%	99.7%	99.6%	98.9%	97.2%	94.1%	90.3%	86.6%	81.8%	73.1%
Registered Implants: 30000	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.6%	91.2%	88.4%	86.3%	84.9%
	Effective Sample Size	26254	23134	20442	17936	15553	13211	11075	9234	7562	5830
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.4%	92.4%	87.6%	83.1%	77.8%	68.7%
Registered Implants: 23000	Malfunctions Only	99.9%	99.8%	99.7%	98.9%	96.7%	92.9%	88.5%	85.0%	82.5%	80.9%
	Effective Sample Size	20371	17989	15885	13926	11971	10046	8317	6858	5549	4217

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

TELIGEN DR

Models: E110/E111/F110/F111

Worldwide Confirmed Malfunctions	**4,186**
Worldwide Distribution	**91,000**

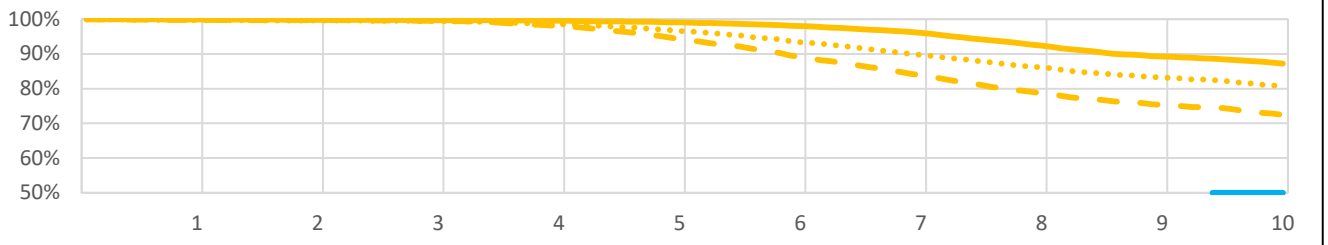
US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	54	2299	2353
Safety Core-electrocautery (42)	1	4	5
High-voltage capacitor (43)	8	1	9
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	22	22	44
Battery (53)	43	256	299
Low-voltage capacitor (54)	14	1300	1314
Low-voltage capacitor (69)	0	7	7
Mechanical			
Transformer (38)	20	0	20
Seal plug (40)	0	3	3
Difficulty securing lead (41)	7	7	14
Header contacts (45)	13	3	16
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	12	9	21
Header (74)	9	3	12
Software			
Alert messages not displayed post-EOL (48)	0	3	3
Memory errors (51)	0	19	19
Other			
Non-patterned, other	11	28	39
Grand Total	**214**	**3972**	**4186**

TELIGEN VR

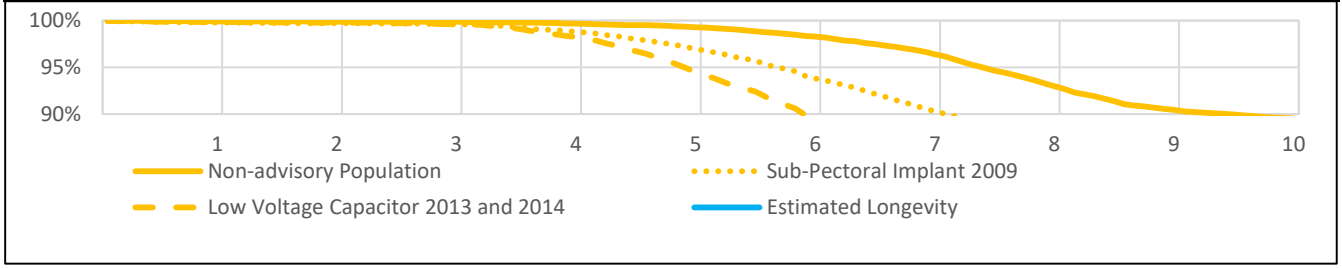
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	3,313
US Approval Date:	March 2008	US Malfunctions:	2,416
US Estimated Active Implants:	12,000	Without Compromised Therapy:	2,281
		With Compromised Therapy:	135

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%	99.5%	99.1%	98.1%	96.3%	92.6%	89.4%	87.5%
Registered Implants: 18000	Malfunctions Only	99.9%	99.9%	99.9%	99.7%	99.3%	98.3%	96.6%	93.3%	90.5%	89.6%
	Effective Sample Size	16037	14180	12501	10996	9636	8374	7175	5989	5015	4305

TELIGEN VR

Models: E102/E103/F102/F103

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.8%	99.6%	99.5%	98.7%	96.9%	93.7%	90.0%	86.3%	83.4%	80.9%
Registered Implants: 16000	Malfunctions Only	99.8%	99.7%	99.6%	98.9%	97.2%	94.1%	90.5%	87.1%	84.4%	83.0%
	Effective Sample Size	13422	11801	10395	9082	7829	6646	5561	4620	3871	3246
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.2%	94.7%	89.6%	84.3%	79.0%	75.5%	72.8%
Registered Implants: 12000	Malfunctions Only	99.8%	99.8%	99.6%	98.4%	94.9%	89.9%	84.8%	79.8%	76.7%	75.0%
	Effective Sample Size	10713	9447	8325	7251	6151	5079	4136	3342	2764	2302

*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	**4,099**
Worldwide Distribution	**66,000**

US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	47	1924	1971
Safety Core-electrocautery (42)	1	1	2
High-voltage capacitor (43)	3	0	3
Low-voltage capacitors (47)	0	5	5
Integrated circuit (50)	17	11	28
Battery (53)	55	421	476
Low-voltage capacitor (54)	12	1443	1455
Low-voltage capacitor (69)	0	5	5
Mechanical			
Transformer (24)	1	0	1
Transformer (38)	14	0	14
Seal plug (40)	0	1	1
Difficulty securing lead (41)	9	0	9
Header contacts (45)	22	16	38
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	18	12	30
Header (74)	13	4	17
Software			
Alert messages not displayed post-EOL (48)	0	4	4
Memory errors (51)	0	12	12
Respiratory Sensor Oversensing - March 23, 2009 Voluntary Physician Advisory (7)	0	2	2
Other			
Non-patterned, other	13	13	26
Grand Total	**225**	**3874**	**4099**

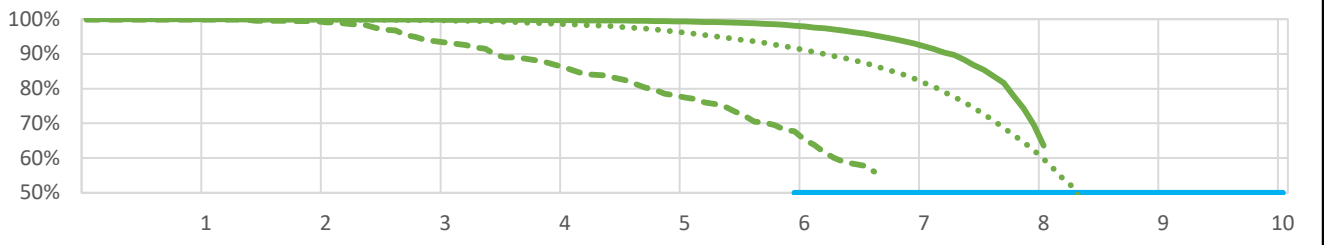
ACCOLADE/PROPONENT/ESSENTIO DR

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

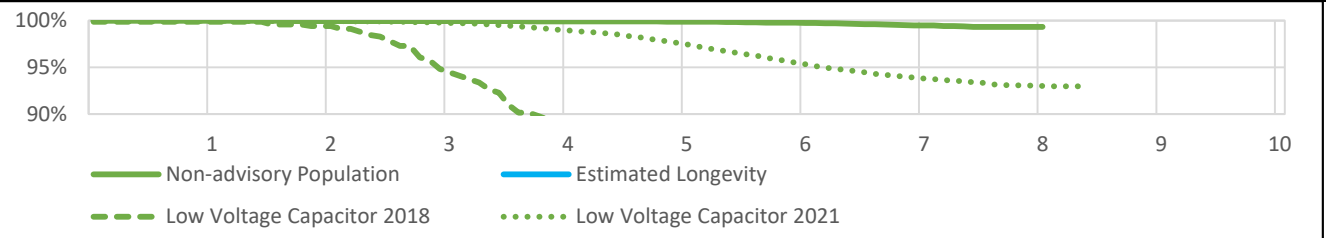
US Summary

US Registered Implants:	285,000	US Normal Battery Depletions:	6,610
US Approval Date:	October 2014	US Malfunctions:	1,771
US Estimated Active Implants:	229,000	Without Compromised Therapy:	1,697
		With Compromised Therapy:	74

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%	98.1%	93.0%	69.6%	63.6%	--	
Registered Implants: 219000	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.5%	99.3%	99.3%	--	
	Effective Sample Size	188020	142617	104789	75336	48841	26502	7586	534	322	--	@ 97 months

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

ACCOLADE/PROPONENT/ESSENTIO DR

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

US Survival Probability (cont.)												
	Year	1	2	3	4	5	6	7	8	9	10	
Low Voltage Capacitor 2018	Depletions and Malfunctions	99.9%	99.4%	94.0%	87.6%	78.5%	68.2%	56.1%	--	--	--	
Registered Implants: 800	Malfunctions Only	99.9%	99.4%	94.8%	88.8%	83.5%	77.2%	71.7%	--	--	--	
	Effective Sample Size	711	638	542	447	359	272	204	--	--	--	@ 81 months
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	98.7%	96.4%	91.7%	82.9%	62.3%	46.3%	--	
Registered Implants: 42000	Malfunctions Only	100.0%	99.9%	99.8%	99.0%	97.6%	95.5%	93.9%	93.1%	93.0%	--	
	Effective Sample Size	37161	33124	29434	26011	22628	18350	13379	3031	562	--	@ 101 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	**2,881**
Worldwide Distribution	**639,000**

US Approval Date: October 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	2	4	6
Integrated circuit (63)	17	50	67
Capacitor (67)	0	3	3
Telemetry (68)	2	14	16
Hydrogen induced premature depletion - September 2018 (70)	4	221	225
Hydrogen induced premature depletion - June 2021 (83)	37	2057	2094
High battery impedance (89)	15	205	220
Software			
Memory errors (51)	0	67	67
Mechanical			
Battery cathode (79)	5	5	10
Other			
Non-patterned, other	58	115	173
Grand Total	**140**	**2741**	**2881**

References cited in table above (link)

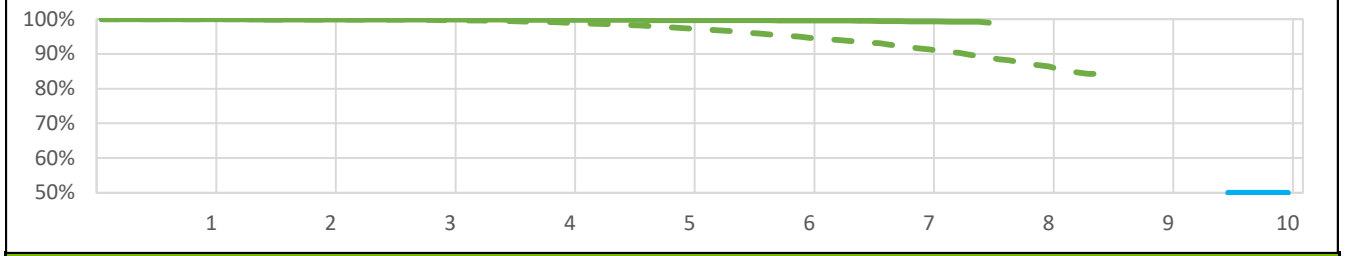
ACCOLADE/PROPONENT/ESSENTIO EL DR

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

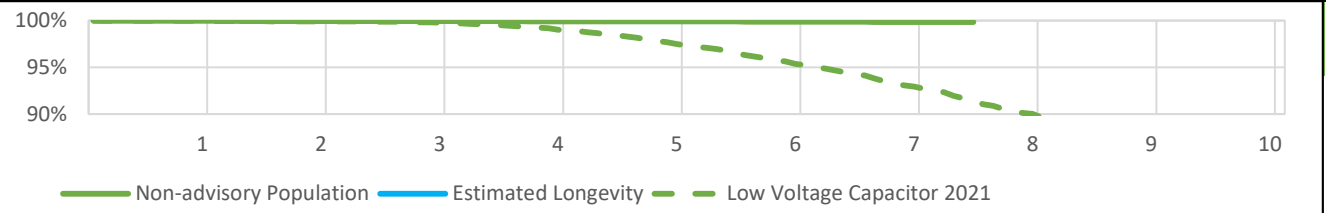
US Summary

US Registered Implants:	177,000	US Normal Battery Depletions:	337
US Approval Date:	October 2014	US Malfunctions:	853
US Estimated Active Implants:	156,000	Without Compromised Therapy:	835
		With Compromised Therapy:	18

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.3%	99.0%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	--	--
117,000	Effective Sample Size	115966	81882	55258	36553	21506	10213	1945	383	--	--

@ 91 months

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

ACCOLADE/PROPONENT/ESSENTIO EL DR

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

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	98.9%	97.3%	94.7%	91.3%	86.4%	84.3%	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.0%	97.5%	95.4%	93.0%	90.0%	89.2%	--
17,000	Effective Sample Size	14948	13295	11822	10454	9101	7446	5521	1467	220	--

@ 102 months

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

ACCOLADE/PROPONENT/ESSENTIO EL DR

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

Worldwide Confirmed Malfunctions	**1,788**
Worldwide Distribution	**428,000**

US Approval Date: October 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	10	10
Integrated circuit (63)	3	38	41
Telemetry (68)	1	13	14
Hydrogen induced premature depletion - September 2018 (70)	3	125	128
Hydrogen induced premature depletion - June 2021 (83)	19	1458	1477
High battery impedance (89)	2	9	11
Software			
Memory errors (51)	0	64	64
Mechanical			
Battery cathode (79)	2	0	2
Other			
Non-patterned, other	7	34	41
Grand Total	**37**	**1751**	**1788**

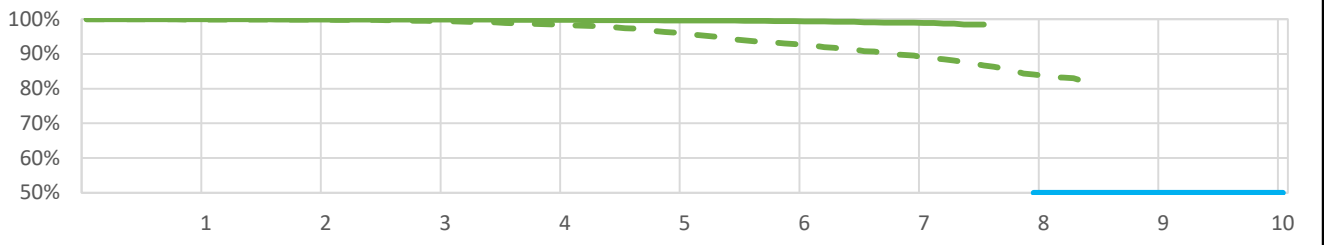
References cited in table above (link)

ACCOLADE/PROPONENT/ESSENTIO SR

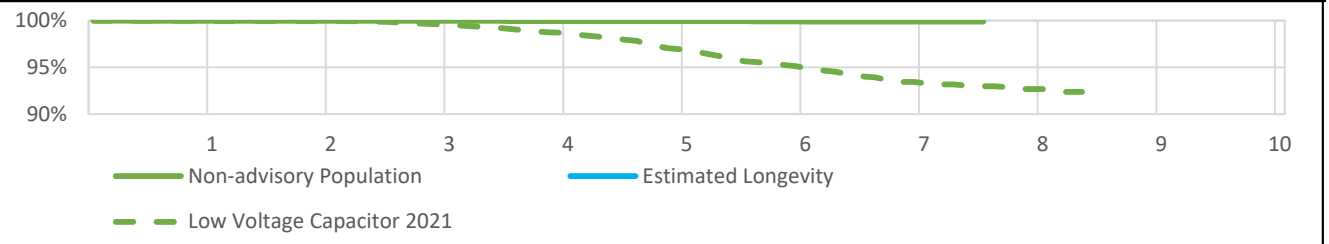
Models: L100/L110/L200/L210/L300/L310

US Summary			
US Registered Implants:	52,000	US Normal Battery Depletions:	426
US Approval Date:	October 2014	US Malfunctions:	474
US Estimated Active Implants:	38,000	Without Compromised Therapy:	462
		With Compromised Therapy:	12

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.6%	99.4%	99.0%	98.5%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	--	--
33,000	Effective Sample Size	30202	23160	17089	12119	7473	3687	817	241	--	--

@ 91 months

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

ACCOLADE/PROPONENT/ESSENTIO SR

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

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2021	Depletions and Malfunctions	99.9%	99.9%	99.5%	98.5%	96.1%	92.8%	89.5%	84.1%	82.1%	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.6%	98.7%	97.0%	95.1%	93.4%	92.7%	92.4%	--
12,000	Effective Sample Size	10295	9139	8107	7161	6216	5058	3476	968	294	--

@ 101 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	**1,120**
Worldwide Distribution	**228,000**

US Approval Date: October 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (63)	5	5	10
Capacitor (67)	0	2	2
Telemetry (68)	0	4	4
Hydrogen induced premature depletion - September 2018 (70)	3	67	70
Hydrogen induced premature depletion - June 2021 (83)	27	960	987
High battery impedance (89)	0	6	6
Software			
Memory errors (51)	0	16	16
Other			
Non-patterned, other	7	14	21
Grand Total	**43**	**1077**	**1120**

References cited in table above (link)

ALTRUA 2 DR

Models: S702

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

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	2	2
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	10	10
Grand Total	**0**	**12**	**12**

References cited in table above (link)

ALTRUA 2 EL DR

Models: S722

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

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	2	2
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**3**	**3**

References cited in table above (link)

ALTRUA 2 SR

Models: S701

Worldwide Confirmed Malfunctions	**13**
Worldwide Distribution	**11,000**

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	11	11
Other			
Non-patterned, other	1	1	2
Grand Total	**1**	**12**	**13**

References cited in table above (link)

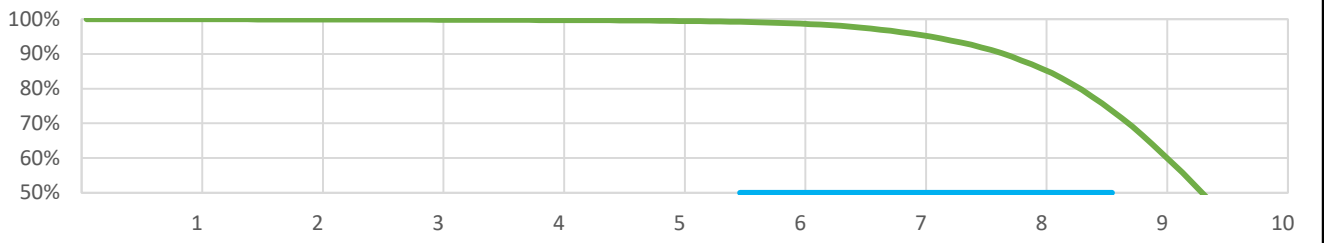
ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

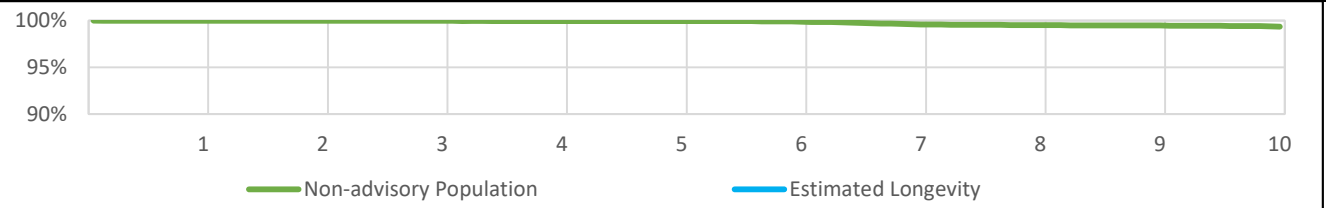
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	24,608
US Approval Date:	May 2012	US Malfunctions:	307
US Estimated Active Implants:	51,000	Without Compromised Therapy:	291
		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%	99.9%	99.7%	99.5%	98.9%	95.9%	87.0%	64.0%	29.5%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.6%	99.5%	99.5%	99.4%
121,000	Effective Sample Size	107156	95494	85094	75826	67411	59732	51650	41679	22187	3896

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	**352**
Worldwide Distribution	**218,000**

US Approval Date: May 2012	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	7	3	10
Titanium case material (60)	3	0	3
Software			
Memory errors (51)	1	29	30
Other			
Non-patterned, other	14	287	301
Grand Total	**25**	**327**	**352**

References cited in table above (link)

ADVANTIO/INGENIO/VITALIO EL DR

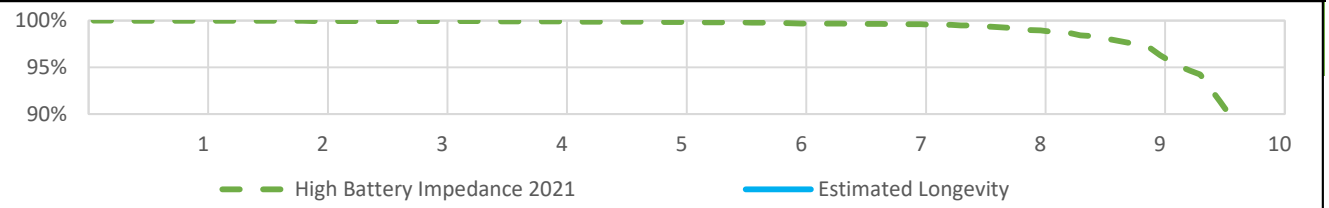
Models: J064/J067/J174/J177/J274/J277/K064/K067/K084/K087/K174/K177/K184/K187/K274/K277/K284/K287

US Summary

US Registered Implants:	11,000	US Normal Battery Depletions:	243
US Approval Date:	May 2012	US Malfunctions:	212
US Estimated Active Implants:	6,000	Without Compromised Therapy:	207
		With Compromised Therapy:	5

Battery Depletions and Malfunctions

Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	99.8%	99.3%	98.7%	97.0%	92.9%	69.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.0%	97.1%	82.2%
11,000	Effective Sample Size	9659	8568	7622	6777	6026	5319	4596	3712	1975	220

@ 119 months

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

ADVANTIO/INGENIO/VITALIO/FORMIO EL DR

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

Worldwide Confirmed Malfunctions	**691**
Worldwide Distribution	**76,000**

US Approval Date: May 2012	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	5	6
Integrated circuit (50)	2	0	2
Titanium case material (60)	2	0	2
High battery impedance initiating safety mode 2021 (82)	12	332	344
Software			
Memory errors (51)	1	11	12
Respiratory sensor (59)	0	1	1
Other			
Non-patterned, other	13	311	324
Grand Total	**31**	**660**	**691**

References cited in table above (link)

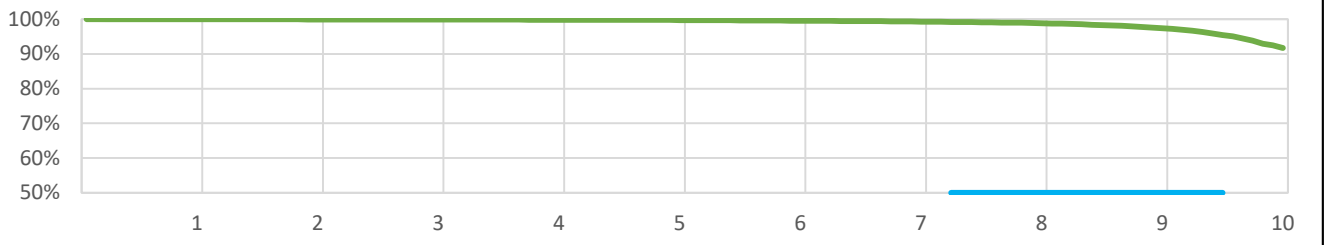
ADVANTIO/INGENIO/VITALIO/FORMIO SR

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

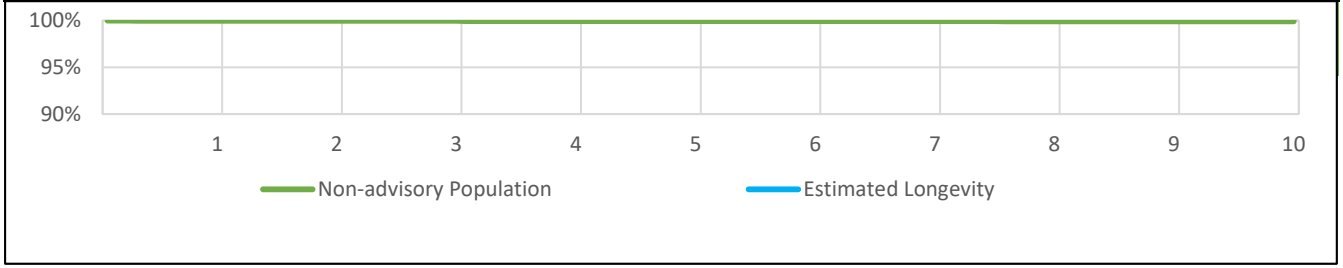
US Summary

US Registered Implants:	27,000	US Normal Battery Depletions:	774
US Approval Date:	May 2012	US Malfunctions:	14
US Estimated Active Implants:	13,000	Without Compromised Therapy:	13
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	97.6%	92.4%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
27,000	Effective Sample Size	22766	20210	17999	16063	14321	12760	11376	9907	6843	3120

ADVANTIO/INGENIO/VITALIO SR

Models: J062/J065/J172/J175/J272/J275/K062/K065/K082/K085/K172/K175/K182/K185/K272/K27

Worldwide Confirmed Malfunctions	**29**
Worldwide Distribution	**86,000**

US Approval Date: May 2012	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (50)	3	2	5
Titanium case material (60)	1	0	1
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	3	7	10
Grand Total	**8**	**21**	**29**

References cited in table above (link)

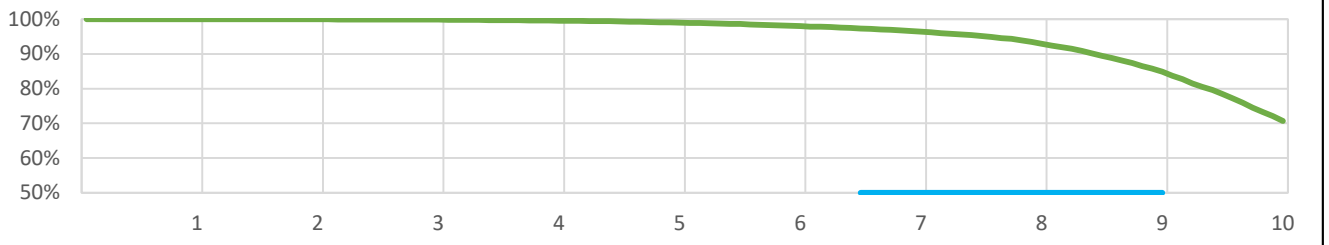
ALTRUA 60 DR

Model: S602

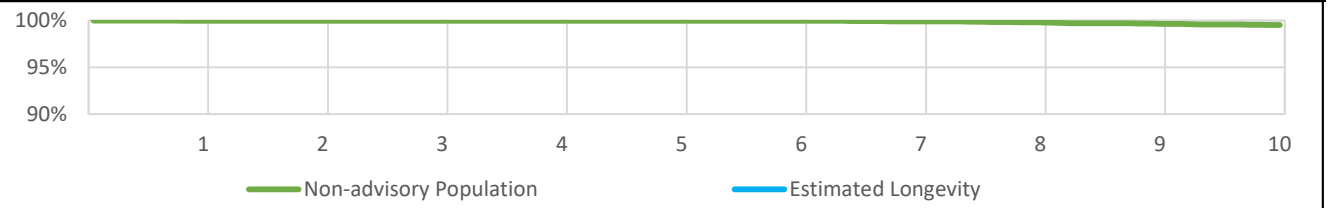
US Summary

US Registered Implants:	22,000	US Normal Battery Depletions:	4,802
US Approval Date:	April 2008	US Malfunctions:	46
US Estimated Active Implants:	6,000	Without Compromised Therapy:	42
		With Compromised Therapy:	4

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.6%	99.1%	98.1%	96.6%	93.4%	85.8%	72.1%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%
22,000	Effective Sample Size	19049	16978	15134	13449	11906	10484	9172	7817	6317	4582

ALTRUA 60 DR

Models: S602

Worldwide Confirmed Malfunctions	**79**
Worldwide Distribution	**56,000**

US Approval Date: April 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Mechanical			
Capacitor array (16)	0	1	1
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	1	1	2
Battery status (49)	1	66	67
Non-patterned, other	3	4	7
Grand Total	**6**	**73**	**79**

References cited in table above (link)

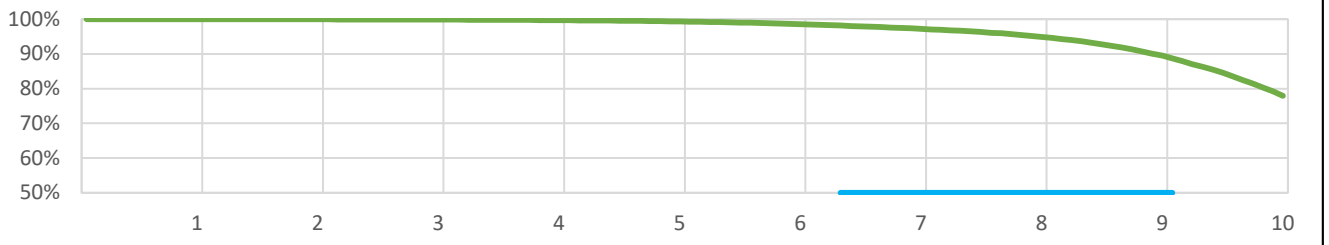
ALTRUA 60 EL DR

Model: S606

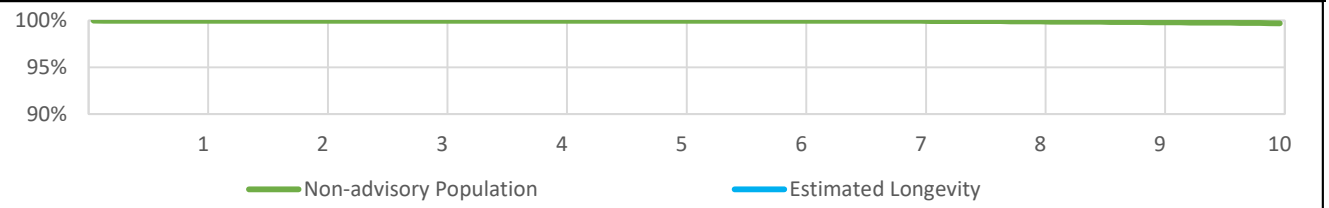
US Summary

US Registered Implants:	59,000	US Normal Battery Depletions:	10,503
US Approval Date:	April 2008	US Malfunctions:	91
US Estimated Active Implants:	22,000	Without Compromised Therapy:	85
		With Compromised Therapy:	6

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.4%	98.6%	97.4%	95.2%	90.1%	79.2%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%
59,000	Effective Sample Size	52382	46800	41730	37156	33042	29202	25662	22352	18835	14616

ALTRUA 60 EL DR

Models: S606

Worldwide Confirmed Malfunctions	**129**
Worldwide Distribution	**90,000**

US Approval Date: April 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	3	3
Integrated circuit (17)	0	1	1
Mechanical			
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	2	0	2
Battery status (49)	2	113	115
Magnet rate (44)	0	1	1
Non-patterned, other	2	4	6
Grand Total	**7**	**122**	**129**

References cited in table above (link)

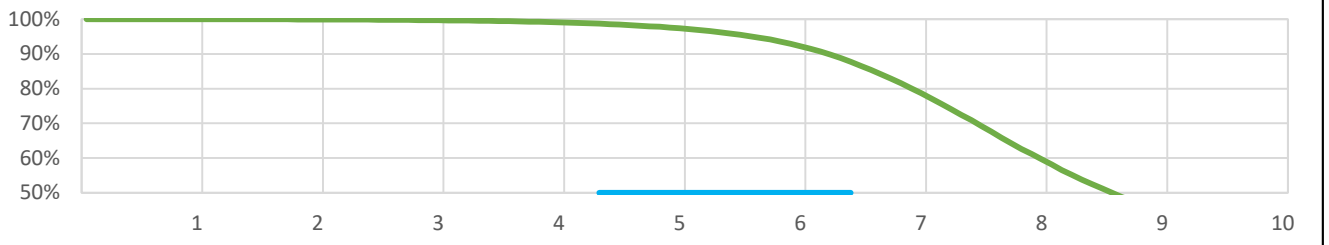
ALTRUA 60 DR (Downsize)

Model: S603

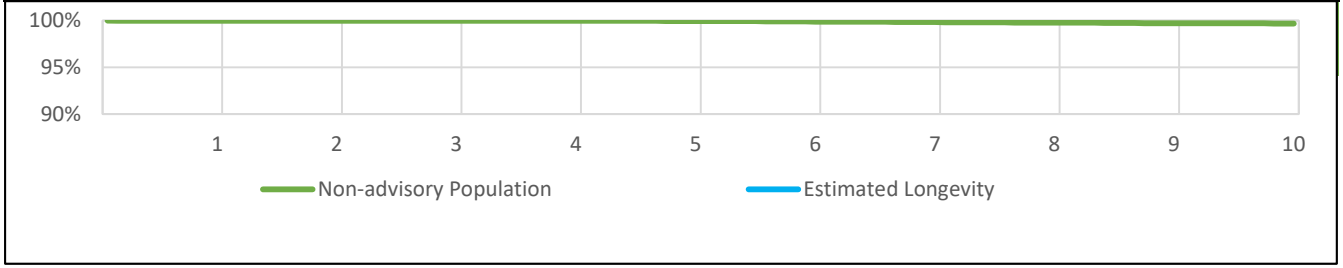
US Summary

US Registered Implants:	90,000	US Normal Battery Depletions:	25,820
US Approval Date:	April 2008	US Malfunctions:	103
US Estimated Active Implants:	20,000	Without Compromised Therapy:	93
		With Compromised Therapy:	10

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.2%	97.6%	92.9%	80.1%	61.2%	45.3%	32.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.7%
90,000	Effective Sample Size	78171	69832	62326	55402	48701	41307	31598	20916	13331	8241

ALTRUA 60 DR (Downsize)

Models: S603

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

US Approval Date: April 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	7	4	11
Integrated circuit (30)	1	1	2
Mechanical			
Difficulty securing lead (41)	0	1	1
Connector block (39)	0	1	1
Software			
Underestimation of battery status (34)	0	1	1
Other			
Battery depletion (26)	1	3	4
Battery status (49)	0	101	101
Magnet response (21)	0	2	2
Non-patterned, other	4	5	9
Grand Total	**13**	**119**	**132**

References cited in table above (link)

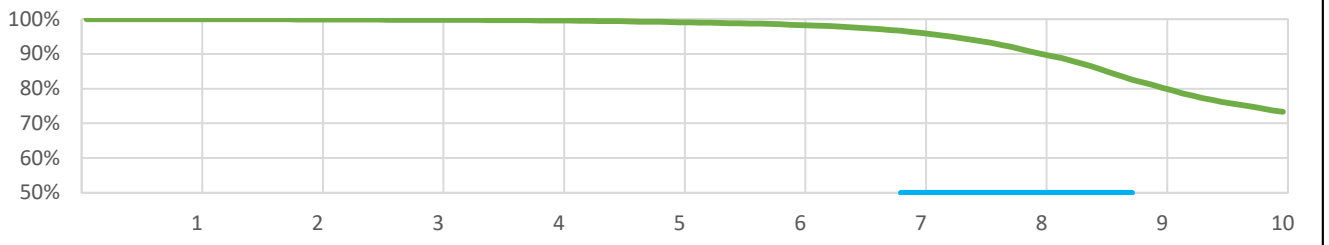
ALTRUA 60 SR

Model: S601

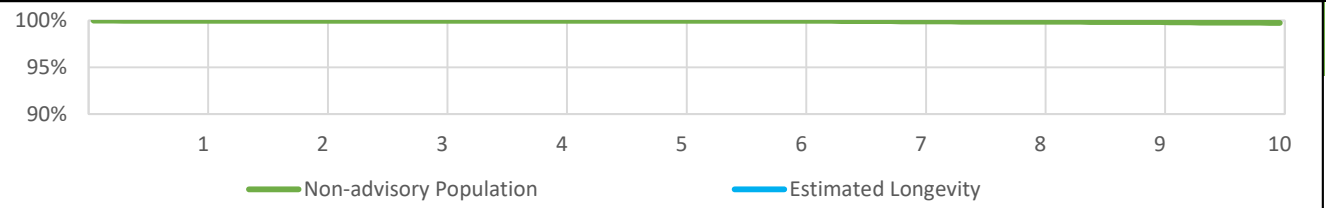
US Summary

US Registered Implants:	32,000	US Normal Battery Depletions:	3,836
US Approval Date:	April 2008	US Malfunctions:	31
US Estimated Active Implants:	8,000	Without Compromised Therapy:	28
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.6%	99.2%	98.4%	96.4%	90.6%	81.1%	73.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
32,000	Effective Sample Size	26233	22983	20339	18085	16083	14231	12479	10461	8278	6633

ALTRUA 60 SR

Models: S601

Worldwide Confirmed Malfunctions	**54**
Worldwide Distribution	**68,000**

US Approval Date: April 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	2	0	2
Other			
Battery depletion (26)	1	0	1
Battery status (49)	1	44	45
Non-patterned, other	2	1	3
Grand Total	**8**	**46**	**54**

References cited in table above (link)

ALTRUA 50 DR (Downsize)

Models: S502

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

CE Mark Date: March 2016	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	1	2	3
Integrated circuit (30)	0	1	1
Other			
Battery depletion (26)	0	2	2
Battery status (49)	0	31	31
Non-patterned, other	1	1	2
Grand Total	**2**	**37**	**39**

References cited in table above (link)

ALTRUA 50 SR

Models: S501

Worldwide Confirmed Malfunctions	**17**
Worldwide Distribution	**25,000**

CE Mark Date: March 2016	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	4	1	5
Other			
Battery depletion (26)	2	0	2
Battery status (49)	0	9	9
Non-patterned, other	1	0	1
Grand Total	**7**	**10**	**17**

References cited in table above (link)

ALTRUA 50 DDD (Downsize)

Models: S504

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

CE Mark Date: March 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	3	0	3
Battery status (49)	0	9	9
Non-patterned, other	0	1	1
Grand Total	**3**	**10**	**13**

References cited in table above (link)

ALTRUA 50 SSI

Models: S508

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

CE Mark Date: March 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	1	0	1
Battery status (49)	0	4	4
Grand Total	**1**	**4**	**5**

References cited in table above (link)

ALTRUA 50 VDD (Downsize)

Models: S504

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

CE Mark Date: March 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery status (49)	0	7	7
Grand Total	**0**	**7**	**7**

References cited in table above (link)

Confirmed Malfunction Details: Pulse Generator References

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

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

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

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

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

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	149,000	1	2	7	14	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	25,000	3	0	0	4	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	133,000	3	4	5	17	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	113,000	5	0	2	5	0	0
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	24,000	0	0	1	6	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	7	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	94,000	0	2	7	6	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	67,000	1	5	2	3	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	17,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	16,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	74,000	1	0	3	4	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	83,000	0	3	2	3	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	35,000	1	0	4	2	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	33,000	2	0	0	3	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	138,000	1	0	5	124	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	27	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	428,000	7	3	10	18	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	639,000	6	0	14	29	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	228,000	2	1	7	19	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	76,000	1	1	0	4	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	218,000	4	0	1	15	0	0
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	86,000	0	0	1	5	0	0

U.S. Reason for Out of Service

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

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

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548	81000	158	335	32	1005	6273
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/ G156/G158	75000	2245	498	116	1311	14695
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	10401	508	821	948	20156
COGNIS N118/N119/N120/P106/P107/P108	75000	15899	446	2111	1624	40253

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	55000	674	1261	157	417	7977
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	10000	1191	229	525	78	4915
CONTAK RENEWAL TR H120/H125	19000	4292	195	67	198	12132

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	60000	1140	811	4380	1218	6426
SQ-RX S-ICD 1010	8000	2963	229	116	251	1984

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	51000	32	1174	16	505	2550
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	28000	13	735	12	288	1333
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	50000	91	2514	95	722	6590
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	39000	41	2274	81	554	4873
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	11000	2159	487	22	148	2148
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	10000	1350	515	16	143	1751
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	483	2661	1315	582	11054
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	2200	2998	1295	729	14232

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	3311	2117	2424	657	17296
TELIGEN DR E110/E111/F110/F111	66000	12397	3050	3055	1130	31515

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	176000	336	5098	853	931	13902
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	285000	6607	7624	1781	1479	38974
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	52000	425	1862	475	259	11491
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	243	512	212	58	3837
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	24606	4194	309	577	40609
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	774	758	15	111	12192

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	3846	491	31	140	18839
ALTRUA 60 DR (Downsize) S603	90000	26095	1255	103	455	41428
ALTRUA 60 DR S602	22000	4813	498	46	158	10478
ALTRUA 60 DR EL S606	59000	10514	1521	91	356	25312
ALTRUA 40 SR S401	5000	536	53	2	17	3054
ALTRUA 40 DR (downsize) S403	14000	4072	165	5	61	6960
ALTRUA 40 DR S402	2000	316	32	2	7	978
ALTRUA 40 DR EL S404	5000	791	92	7	36	2617
ALTRUA 20 SR S201/S204	5000	289	46	3	31	3036
ALTRUA 20 DR EL S208	3000	296	52	6	10	1722

[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.

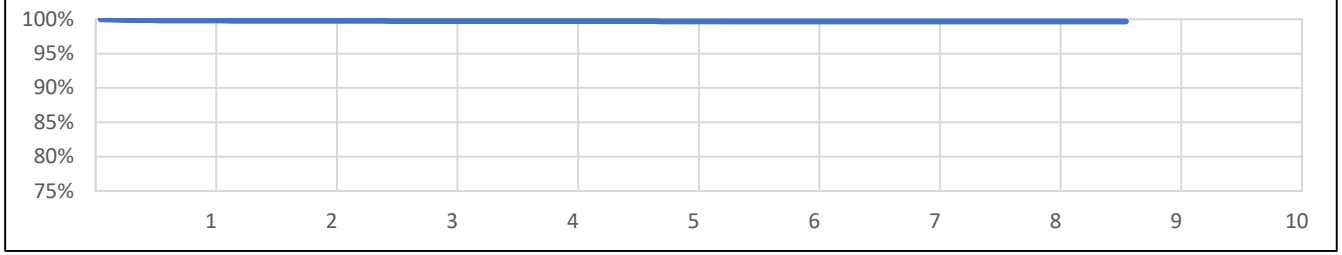
[3] Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

ACUITY X4 Spiral L

Models: 4677/4678

US Summary			
US Registered Implants:	21,000	US Chronic Complications	51
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	18,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	--	
Registered Implants: 21000	Effective Sample Size	16621	13078	10045	7536	5093	2919	1314	293	211	--	@ 103 months

ACUITY X4 Spiral L

Models: 4677/4678

Worldwide Confirmed Malfunctions	**2**
Worldwide Distribution	**51,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**2**	**2**

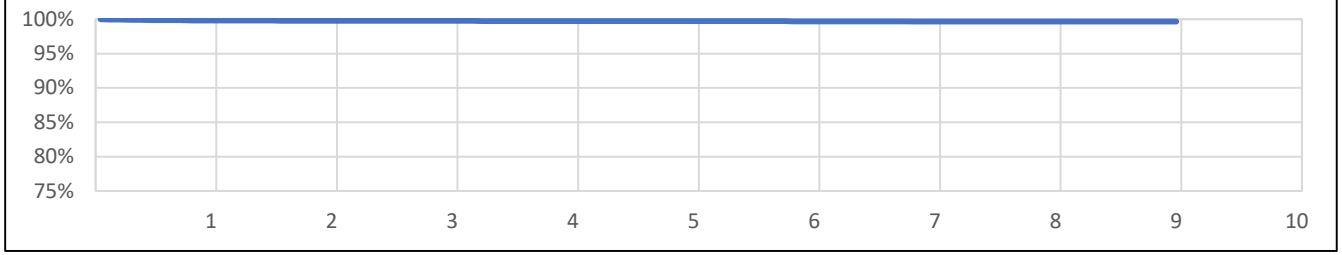
References cited in table above (link)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	63,000	US Chronic Complications	142
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	55,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	--	
Registered Implants: 63000	Effective Sample Size	49049	37736	28212	20373	13196	7512	3085	465	215	--	@ 108 months

ACUITY X4 Spiral S

Models: 4674/4675

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**134,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

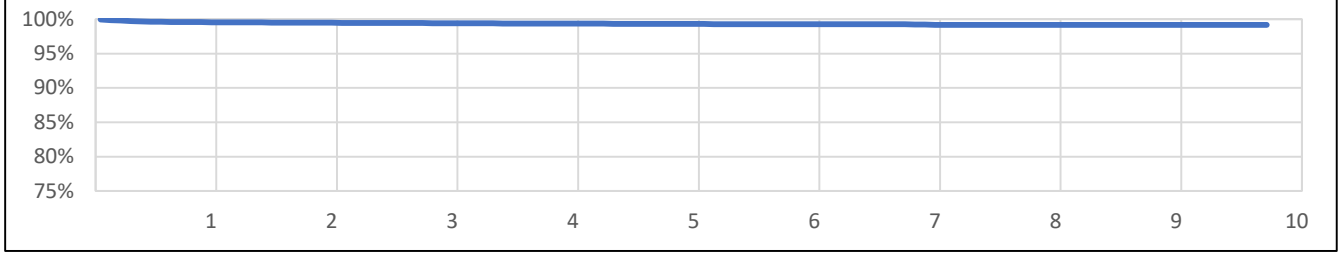
References cited in table above (link)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	48,000	US Chronic Complications	256
US Approval Date:	February 2016	US Malfunctions:	2
US Estimated Active Implants:	40,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.6%	99.5%	99.4%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%	99.2%	
Registered Implants: 48000	Effective Sample Size	36980	28403	20992	14910	9484	5254	2109	473	279	213	@ 117 months

ACUITY X4 Straight

Models: 4671/4672

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**105,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	4	4
Grand Total	**0**	**4**	**4**

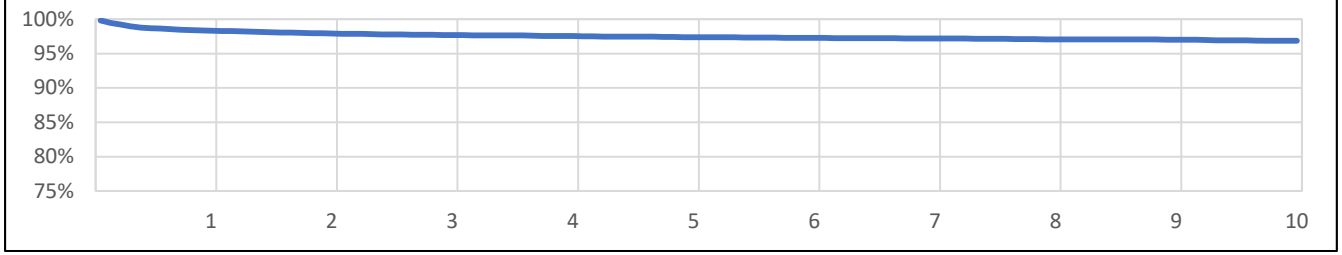
References cited in table above (link)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	24,000	US Chronic Complications	583
US Approval Date:	May 2008	US Malfunctions:	9
US Estimated Active Implants:	12,000	Without Compromised Therapy:	5
		With Compromised Therapy:	4

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.3%	97.9%	97.7%	97.5%	97.4%	97.3%	97.2%	97.1%	97.0%	96.9%
Registered Implants: 24000	Effective Sample Size	19994	17754	15796	14051	12458	10952	9618	8319	6850	5220

ACUITY Spiral

Models: 4591/4592/4593

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**47,000**

US Approval Date: May 2008	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	5	9
Grand Total	**4**	**5**	**9**

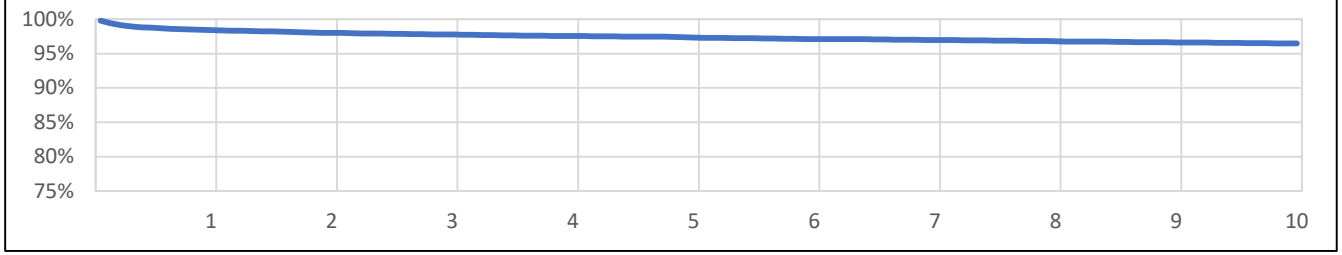
References cited in table above (link)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	751
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	12,000	Without Compromised Therapy:	12
		With Compromised Therapy:	21

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.4%	98.0%	97.8%	97.5%	97.3%	97.1%	97.0%	96.8%	96.6%	96.5%
Registered Implants: 29000	Effective Sample Size	24388	21718	19437	17436	15639	13994	12496	11076	9463	7540

ACUITY Steerable

Models: 4554/4555/4556

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

US Approval Date: May 2008	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	8	36
Other			
Non-patterned, other	10	11	21
Grand Total	**38**	**19**	**57**

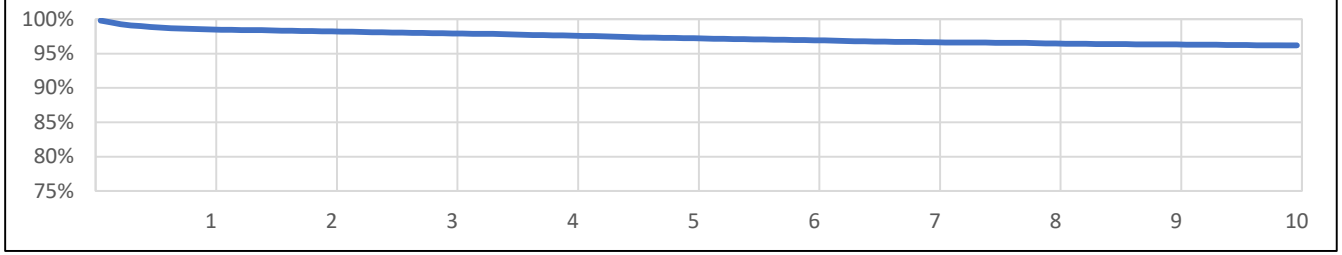
References cited in table above (link)

EASYTRAK 3

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

US Summary			
US Registered Implants:	22,000	US Chronic Complications	573
US Approval Date:	August 2004	US Malfunctions:	32
US Estimated Active Implants:	7,000	Without Compromised Therapy:	9
		With Compromised Therapy:	23

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.5%	98.2%	97.9%	97.6%	97.2%	96.9%	96.6%	96.5%	96.3%	96.2%
Registered Implants: 22000	Effective Sample Size	18189	16065	14214	12627	11238	10021	8950	7962	6867	5628

EASYTRAK 3

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

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

US Approval Date: August 2004	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	6	34
Other			
Non-patterned, other	7	11	18
Grand Total	**35**	**17**	**52**

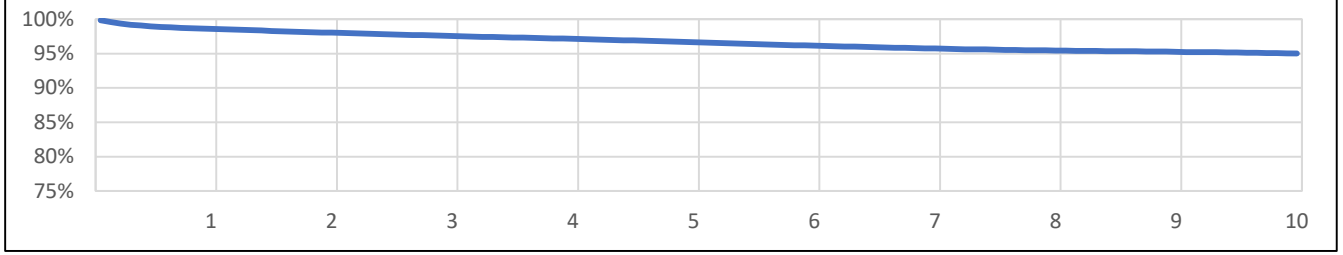
References cited in table above (link)

EASYTRAK 2

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

US Summary			
US Registered Implants:	97,000	US Chronic Complications	3,005
US Approval Date:	August 2004	US Malfunctions:	408
US Estimated Active Implants:	31,000	Without Compromised Therapy:	149
		With Compromised Therapy:	259

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.6%	98.0%	97.6%	97.1%	96.7%	96.1%	95.7%	95.4%	95.3%	95.0%
Registered Implants: 97000	Effective Sample Size	81794	71922	63545	56438	50178	44604	39674	35024	30019	24804

EASYTRAK 2

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

Worldwide Confirmed Malfunctions	**551**
Worldwide Distribution	**180,000**

US Approval Date: August 2004	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (25)	329	149	478
Other			
Non-patterned, other	39	34	73
Grand Total	**368**	**183**	**551**

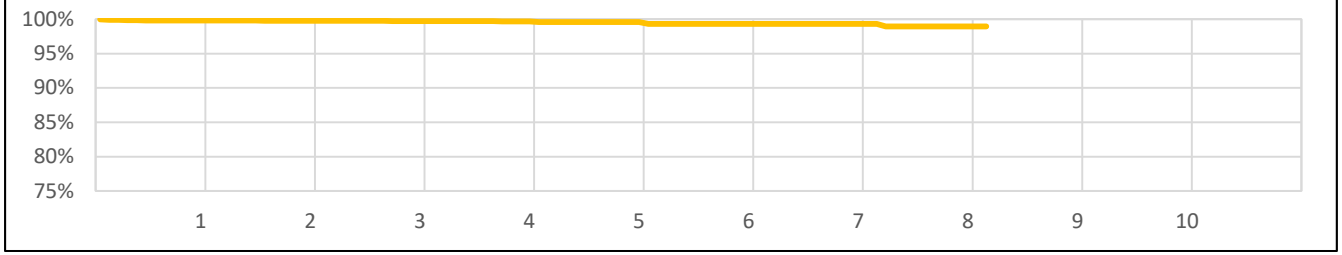
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

US Summary			
US Registered Implants:	12,000	US Chronic Complications	30
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	11,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.7%	99.7%	99.6%	99.3%	99.3%	98.9%	98.9%	--	
Registered Implants: 12000	Effective Sample Size	8629	5966	3555	1650	375	300	269	225	209	--	@ 98 months

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**33,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	5	0	5
Grand Total	**5**	**0**	**5**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

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

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**2,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

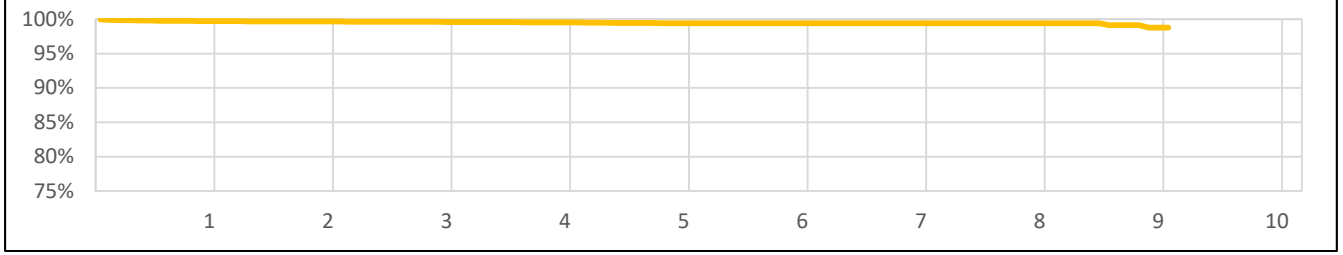
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Summary			
US Registered Implants:	87,000	US Chronic Complications	257
US Approval Date:	May 2018	US Malfunctions:	20
US Estimated Active Implants:	81,000	Without Compromised Therapy:	3
		With Compromised Therapy:	17

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%	99.4%	98.8%	98.8%	
Registered Implants: 87000	Effective Sample Size	59947	39455	22631	9921	1198	793	711	614	251	217	@ 109 months

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

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

Worldwide Confirmed Malfunctions	**90**
Worldwide Distribution	**266,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	24	0	24
Other			
Non-patterned, other	56	10	66
Grand Total	**80**	**10**	**90**

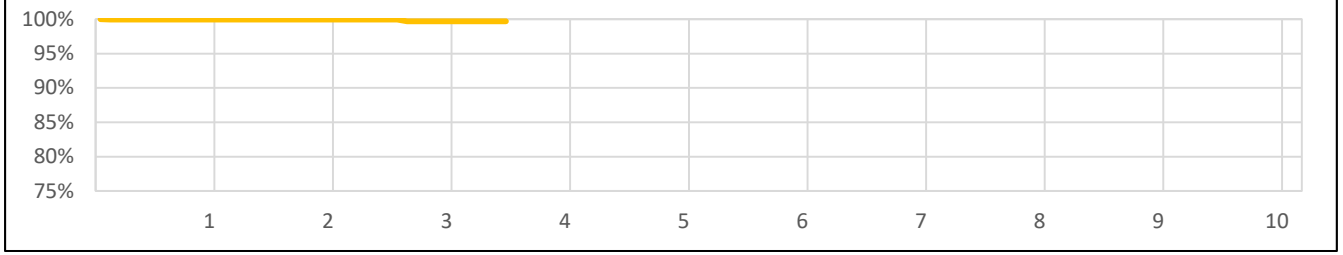
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

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

US Summary			
US Registered Implants:	1,000	US Chronic Complications	2
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	1,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.9%	99.9%	99.7%	99.7%	--	--	--	--	--	--	
Registered Implants: 1000	Effective Sample Size	947	604	334	217	--	--	--	--	--	--	@ 42 months

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

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

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**8,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	1	0	1
Grand Total	**1**	**0**	**1**

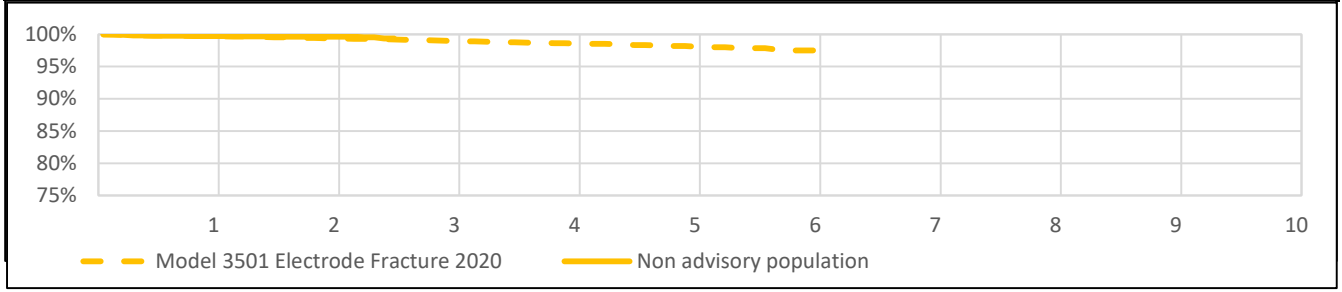
References cited in table above (link)

EMBLEM S-ICD Electrode

Models: 3501

US Summary			
US Registered Implants:	35,000	US Chronic Complications	197
US Approval Date:	September 2017	US Malfunctions:	77
US Estimated Active Implants:	30,000	Without Compromised Therapy:	6
		With Compromised Therapy:	71

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non advisory population	Complications and Malfunctions	99.8%	99.6%	99.2%	--	--	--	--	--	--	--	
Registered Implants: 9000	Effective Sample Size	7349	2194	270	--	--	--	--	--	--	--	@ 30 months

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

EMBLEM S-ICD Electrode

Models: 3501

US Survival Probability (cont.)												
Year		1	2	3	4	5	6	7	8	9	10	
Model 3501 Electrode Fracture 2020	Complications and Malfunctions	99.7%	99.4%	99.0%	98.6%	98.1%	97.5%	--	--	--	--	
Registered Implants: 21000	Effective Sample Size	17551	15536	12313	7526	3192	216	--	--	--	--	@ 72 months

EMBLEM S-ICD Electrode

Models: 3501

Worldwide Confirmed Malfunctions	**195**
Worldwide Distribution	**87,000**

US Approval Date: September 2017	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Model 3501 electrode fracture 2020 (42)	80	2	82
Electrode conductor fracture in or near the pocket (44)	95	9	104
Other			
Non-patterned, other	8	1	9
Grand Total	**183**	**12**	**195**

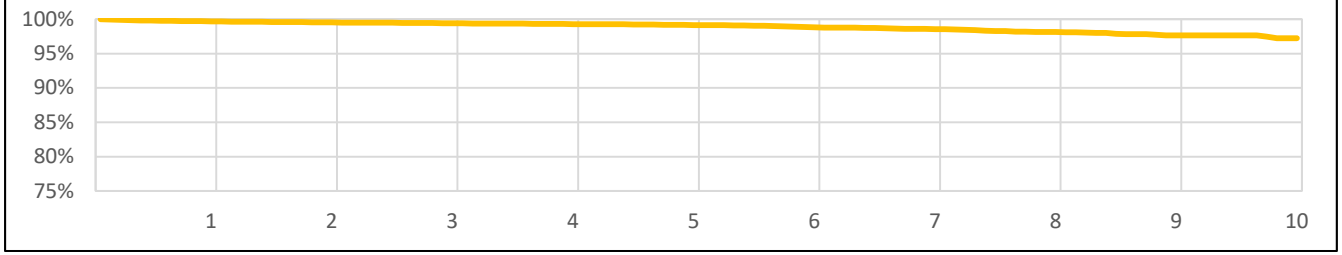
References cited in table above (link)

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

US Summary			
US Registered Implants:	24,000	US Chronic Complications	228
US Approval Date:	September 2012	US Malfunctions:	29
US Estimated Active Implants:	18,000	Without Compromised Therapy:	4
		With Compromised Therapy:	25

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.4%	99.3%	99.1%	98.8%	98.6%	98.1%	97.7%	97.2%
Registered Implants: 24000	Effective Sample Size	20971	18642	16589	14746	12968	10804	6749	3556	1428	363

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

Worldwide Confirmed Malfunctions	**85**
Worldwide Distribution	**43,000**

US Approval Date: September 2012	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Electrode conductor fracture in or near the pocket (44)	38	4	42
Crimp/Weld/Bond			
Weld fracture (37)	3	0	3
Other			
Non-patterned, other	29	11	40
Grand Total	**70**	**15**	**85**

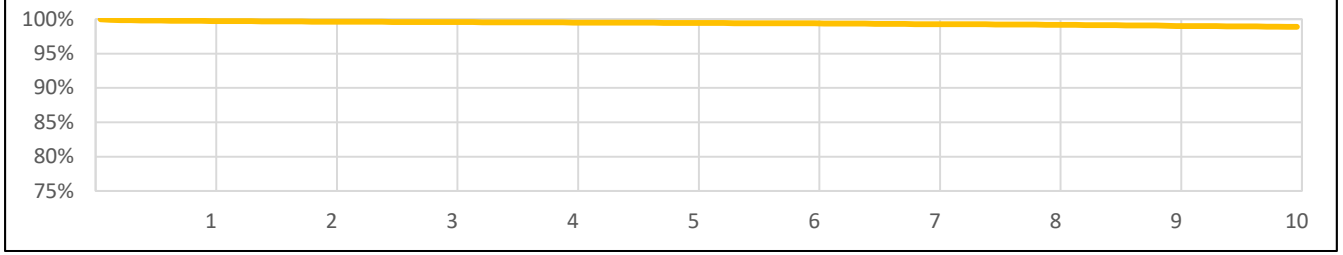
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Summary			
US Registered Implants:	78,000	US Chronic Complications	460
US Approval Date:	November 2010	US Malfunctions:	31
US Estimated Active Implants:	56,000	Without Compromised Therapy:	6
		With Compromised Therapy:	25

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.5%	99.4%	99.3%	99.2%	99.0%	98.9%
Registered Implants: 78000	Effective Sample Size	68419	60933	54214	47759	40847	33051	26262	20029	14075	8591

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

Worldwide Confirmed Malfunctions	**68**
Worldwide Distribution	**126,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Non-patterned, other	52	13	65
Grand Total	**55**	**13**	**68**

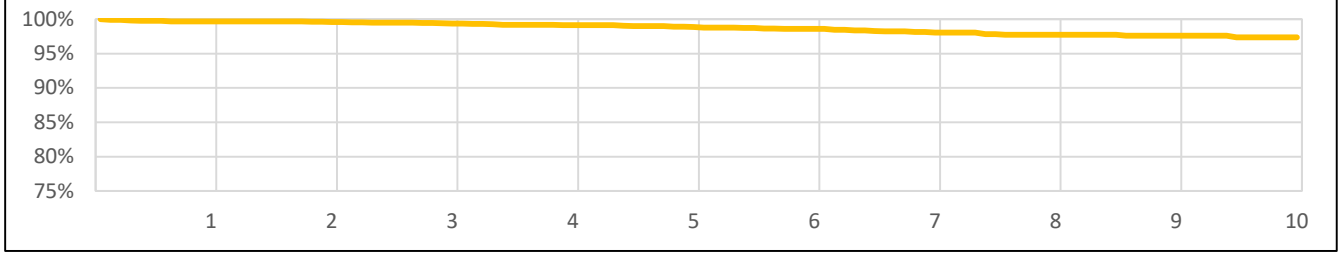
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Summary			
US Registered Implants:	3,000	US Chronic Complications	44
US Approval Date:	November 2010	US Malfunctions:	2
US Estimated Active Implants:	3,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.3%	99.1%	98.8%	98.6%	98.0%	97.7%	97.6%	97.4%
Registered Implants: 3000	Effective Sample Size	3001	2663	2355	2052	1722	1394	1111	832	564	297

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

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

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	3	3
Grand Total	**0**	**3**	**3**

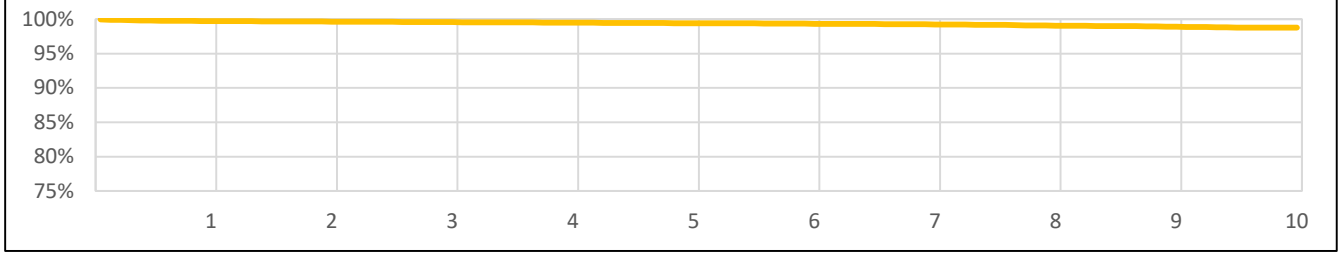
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Summary			
US Registered Implants:	120,000	US Chronic Complications	677
US Approval Date:	November 2010	US Malfunctions:	57
US Estimated Active Implants:	95,000	Without Compromised Therapy:	13
		With Compromised Therapy:	44

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%	98.8%
Registered Implants: 120000	Effective Sample Size	105552	94560	84702	75254	63437	44234	30003	19165	10921	5249

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

Worldwide Confirmed Malfunctions	**102**
Worldwide Distribution	**220,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	12	0	12
Other			
Non-patterned, other	71	19	90
Grand Total	**83**	**19**	**102**

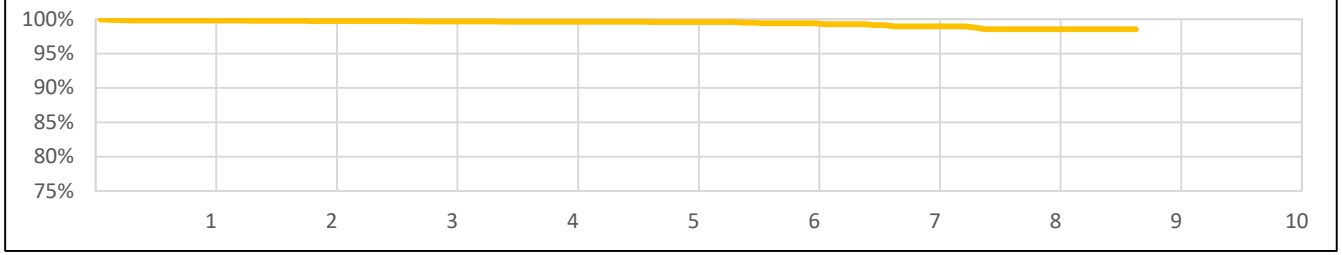
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Summary			
US Registered Implants:	24,000	US Chronic Complications	67
US Approval Date:	November 2010	US Malfunctions:	5
US Estimated Active Implants:	22,000	Without Compromised Therapy:	-
		With Compromised Therapy:	5

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.7%	99.7%	99.6%	99.4%	99.0%	98.5%	98.5%	--	
Registered Implants: 24000	Effective Sample Size	18184	12785	8011	4173	1208	834	538	315	208	--	@ 104 months

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

Worldwide Confirmed Malfunctions	**10**
Worldwide Distribution	**7,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	9	1	10
Grand Total	**9**	**1**	**10**

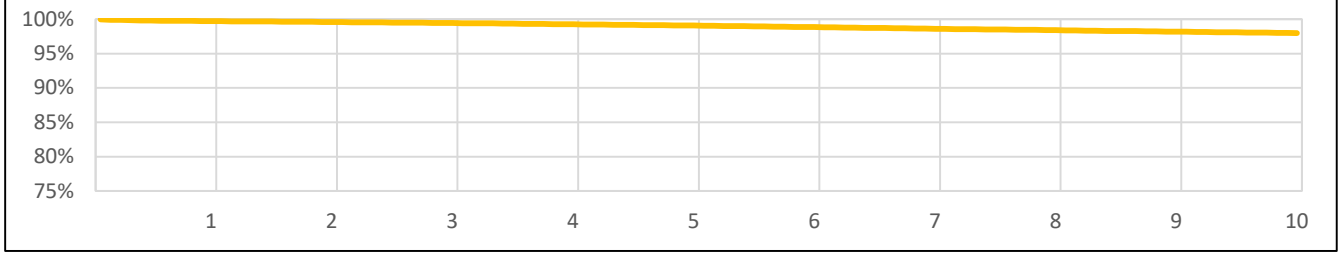
References cited in table above (link)

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	3,814
US Approval Date:	July 2002	US Malfunctions:	396
US Estimated Active Implants:	103,000	Without Compromised Therapy:	126
		With Compromised Therapy:	270

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.4%	99.3%	99.1%	98.8%	98.6%	98.4%	98.2%	98.0%
Registered Implants: 287000	Effective Sample Size	249575	221489	196895	175004	155896	139041	124141	110831	98609	87489

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**597**
Worldwide Distribution	**383,000**

US Approval Date: July 2002	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	106	0	106
Crimp/Weld/Bond			
Seal rings (5)	2	2	4
Other			
Non-patterned, other	280	207	487
Grand Total	**388**	**209**	**597**

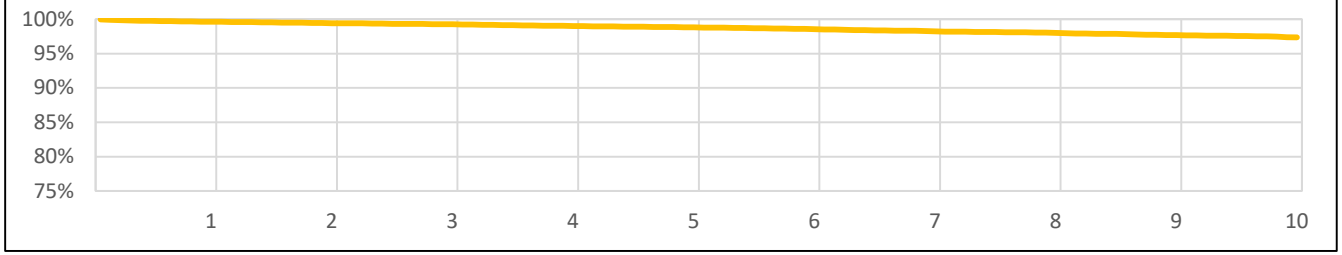
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Active Fixation

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

US Summary			
US Registered Implants:	34,000	US Chronic Complications	521
US Approval Date:	October 2000	US Malfunctions:	94
US Estimated Active Implants:	20,000	Without Compromised Therapy:	26
		With Compromised Therapy:	68

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.6%	99.4%	99.3%	99.0%	98.8%	98.5%	98.2%	98.0%	97.7%	97.4%
Registered Implants: 34000	Effective Sample Size	29863	26389	23329	20581	18121	15921	13909	12013	9967	8036

ENDOTAK RELIANCE Single Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**218**
Worldwide Distribution	**81,000**

US Approval Date: October 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	62	1	63
Other			
Non-patterned, other	95	60	155
Grand Total	**157**	**61**	**218**

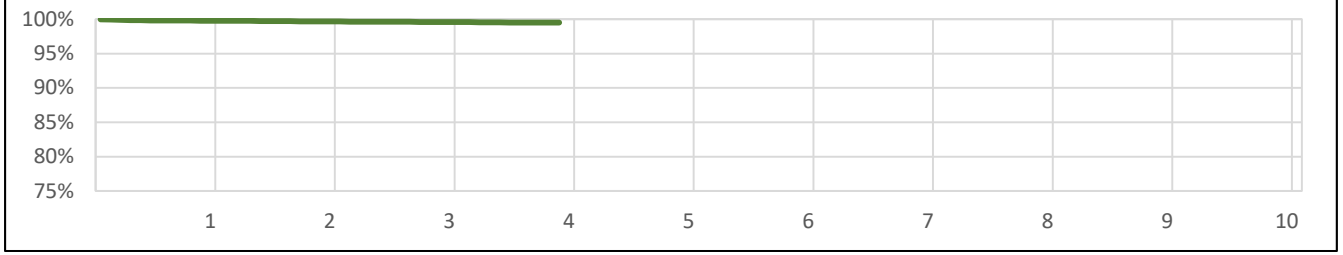
References cited in table above (link)

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

US Summary			
US Registered Implants:	349,000	US Chronic Complications	829
US Approval Date:	December 2019	US Malfunctions:	99
US Estimated Active Implants:	327,000	Without Compromised Therapy:	57
		With Compromised Therapy:	42

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	--	--	--	--	--	--	
Registered Implants: 349000	Effective Sample Size	221378	121251	41300	720	--	--	--	--	--	--	@ 47 months

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

Worldwide Confirmed Malfunctions	**108**
Worldwide Distribution	**598,000**

US Approval Date: December 2019	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	16	32	48
Other			
Non-patterned, other	28	30	58
Insulation (43)	0	2	2
Grand Total	**44**	**64**	**108**

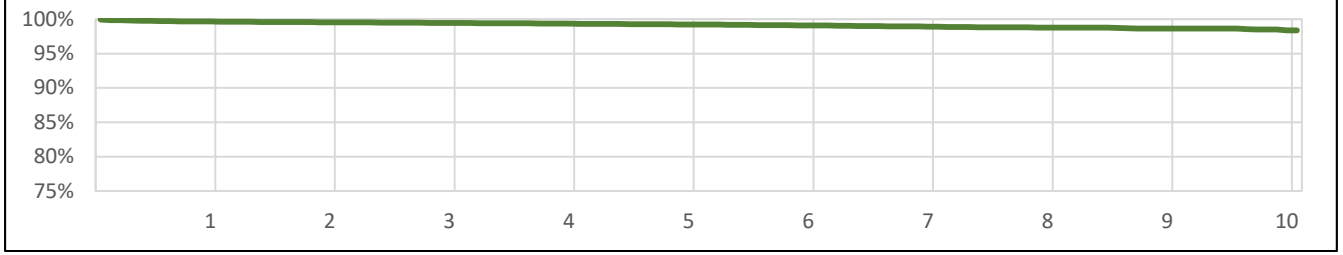
References cited in table above (link)

INGEVITY Positive Fixation

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

US Summary			
US Registered Implants:	365,000	US Chronic Complications	2,142
US Approval Date:	April 2016	US Malfunctions:	338
US Estimated Active Implants:	299,000	Without Compromised Therapy:	194
		With Compromised Therapy:	144

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.5%	99.3%	99.2%	99.1%	98.9%	98.8%	98.6%	98.4%
Registered Implants: 365000	Effective Sample Size	321995	288639	258699	214126	138471	75807	24777	2020	1806	1587

INGEVITY Positive Fixation

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

Worldwide Confirmed Malfunctions	**502**
Worldwide Distribution	**1,108,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	9	11	20
Extracardiac fracture (41)	120	156	276
Other			
Insulation (43)	2	24	26
Non-patterned, other	79	101	180
Grand Total	**210**	**292**	**502**

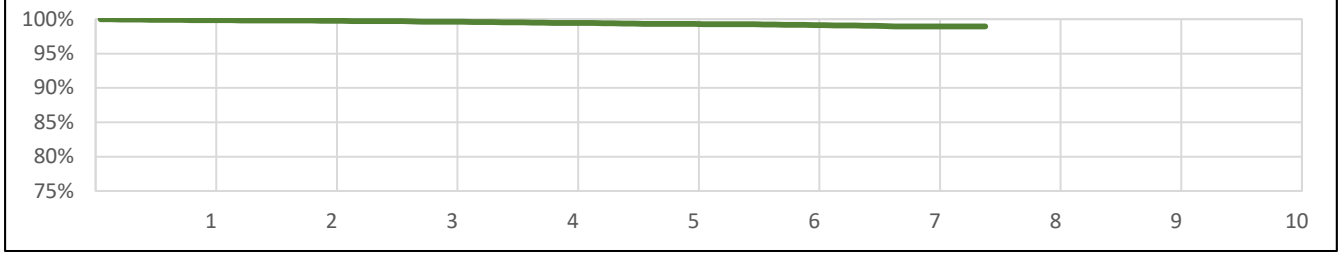
References cited in table above (link)

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary			
US Registered Implants:	30,000	US Chronic Complications	112
US Approval Date:	April 2016	US Malfunctions:	16
US Estimated Active Implants:	25,000	Without Compromised Therapy:	3
		With Compromised Therapy:	13

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.6%	99.4%	99.3%	99.1%	98.9%	98.9%	--	--	
Registered Implants: 30000	Effective Sample Size	23838	18899	14214	10482	6827	3755	1250	339	--	--	@ 89 months

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	**22**
Worldwide Distribution	**134,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	7	0	7
Other			
Insulation (43)	0	1	1
Non-patterned, other	12	2	14
Grand Total	**19**	**3**	**22**

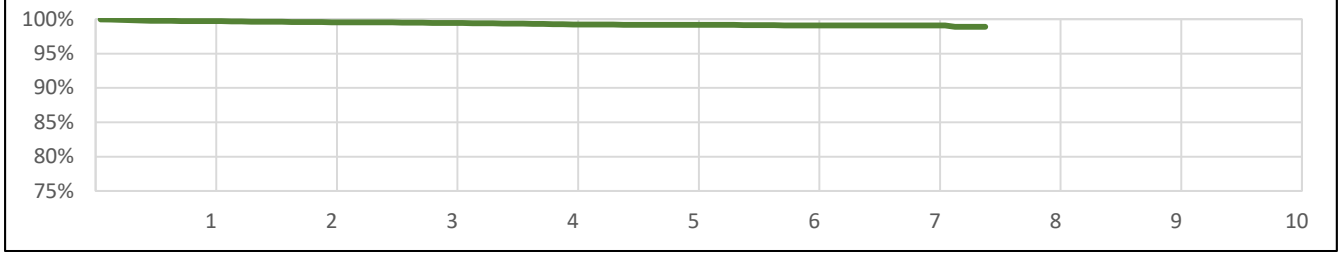
References cited in table above (link)

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	17,000	US Chronic Complications	89
US Approval Date:	April 2016	US Malfunctions:	8
US Estimated Active Implants:	15,000	Without Compromised Therapy:	8
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.5%	99.2%	99.2%	99.1%	99.1%	98.9%	--	--	
Registered Implants: 17000	Effective Sample Size	13769	10946	8265	6074	3977	2130	688	212	--	--	@ 89 months

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	**15**
Worldwide Distribution	**126,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	9	9
Crimp/Weld/Bond			
Weld (40)	0	1	1
Other			
Non-patterned, other	0	5	5
Grand Total	**0**	**15**	**15**

References cited in table above (link)

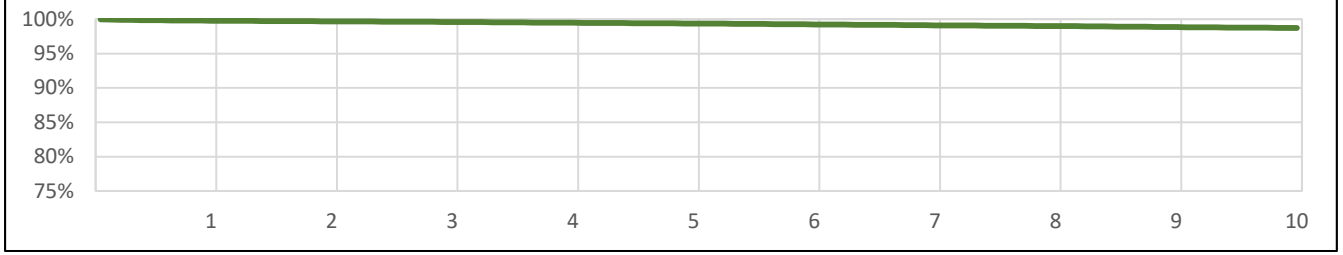
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

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

US Summary

US Registered Implants:	523,000	US Chronic Complications	3,944
US Approval Date:	January 2000	US Malfunctions:	173
US Estimated Active Implants:	258,000	Without Compromised Therapy:	55
		With Compromised Therapy:	118

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.4%	99.2%	99.1%	99.0%	98.8%	98.7%
Registered Implants: 523000	Effective Sample Size	450736	395317	345876	302020	261372	225535	194579	165404	136256	110546

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

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

Worldwide Confirmed Malfunctions	**206**
Worldwide Distribution	**830,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	66	19	85
Crimp/Weld/Bond			
Terminal weld (23)	1	0	1
Other			
Lead body (4)	71	33	104
Non-patterned, other	8	8	16
Grand Total	**146**	**60**	**206**

References cited in table above (link)

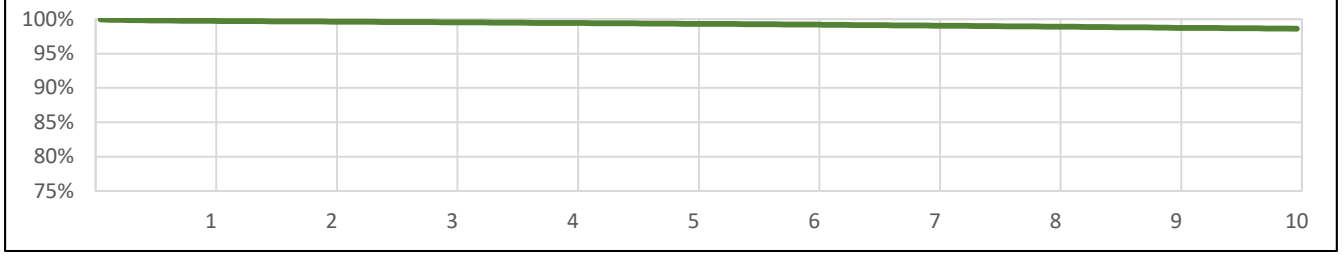
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

US Summary

US Registered Implants:	198,000	US Chronic Complications	1,694
US Approval Date:	January 2000	US Malfunctions:	47
US Estimated Active Implants:	74,000	Without Compromised Therapy:	3
		With Compromised Therapy:	44

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.7%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%	98.7%	98.6%
Registered Implants: 198000	Effective Sample Size	170237	150538	132887	117240	103190	90539	79442	68650	57508	47415

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	**70**
Worldwide Distribution	**559,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	20	0	20
Other			
Lead body (4)	41	3	44
Non-patterned, other	5	1	6
Grand Total	**66**	**4**	**70**

References cited in table above (link)

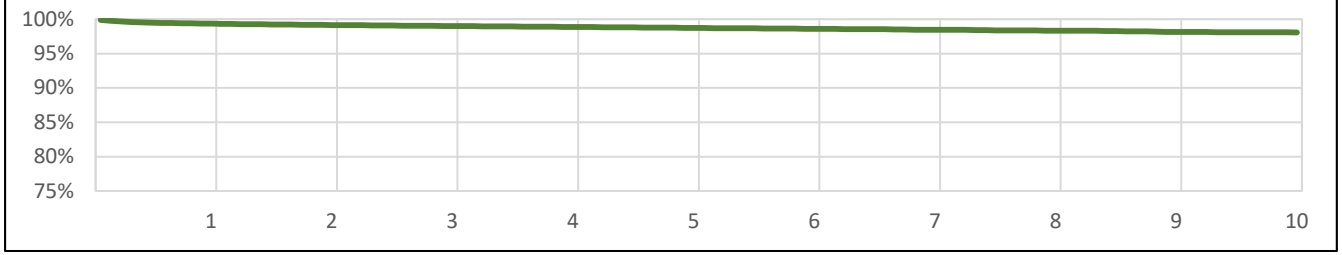
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary

US Registered Implants:	64,000	US Chronic Complications	851
US Approval Date:	January 2000	US Malfunctions:	39
US Estimated Active Implants:	26,000	Without Compromised Therapy:	20
		With Compromised Therapy:	19

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.3%	99.2%	99.0%	98.9%	98.7%	98.6%	98.5%	98.3%	98.1%	98.1%
Registered Implants: 64000	Effective Sample Size	54884	48763	43293	38425	34102	30106	26507	22844	19029	15604

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	**79**
Worldwide Distribution	**329,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	5	2	7
Other			
J-shape (22)	26	30	56
Lead body (4)	8	3	11
Non-patterned, other	3	2	5
Grand Total	**42**	**37**	**79**

References cited in table above (link)

Confirmed Malfunction Details: Leads References

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

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

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

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

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY+ Positive Fixation 7840/7841/7842	347,000	103	134	430	89	21	16	3	31	0	2
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	151	703	598	278	130	29	58	170	0	25
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	17,000	0	20	44	12	3	2	3	5	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	30,000	2	36	17	24	8	3	1	21	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	198,000	5	499	250	310	80	36	218	277	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	523,000	27	857	922	549	215	164	615	564	0	31
FINELINE II Atrial J (poly) 4477/4478/4479/4480	64,000	1	128	369	143	31	35	81	55	0	8
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	2	129	20	73	30	5	24	41	0	1
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474	53,000	0	320	97	124	111	25	108	154	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	21,000	0	0	33	9	1	0	0	0	0	8
ACUITY X4 Spiral S 4674/4675	63,000	1	2	104	14	2	0	0	1	0	18

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	48,000	1	1	165	28	1	0	1	5	0	54
ACUITY Steerable 4554/4555/4556	29,000	5	45	465	70	6	2	18	42	0	98
ACUITY Spiral 4591/4592/4593	24,000	0	27	343	57	0	1	5	12	0	138
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	2	47	316	66	5	2	16	24	0	95
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	2	455	1378	390	15	8	119	189	0	449
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	2	92	489	152	4	1	78	55	0	269

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	87,000	32	43	110	28	18	7	0	8	8	3
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	12,000	3	2	15	3	3	0	1	0	2	1
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	78,000	25	65	125	38	87	15	17	32	49	7
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	1	3	9	4	9	0	0	15	2	1
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	141,000	39	97	218	72	115	26	18	61	65	12
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	2	5	3	5	1	0	0	4	1	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	35	827	437	252	914	106	169	477	567	30
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	6	167	76	86	164	13	48	278	83	7
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	34,000	14	124	63	39	92	4	9	63	109	4
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	7	5	3	7	0	1	10	5	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM S-ICD Electrode 3501	35,000	0	10	12	0	154	8	0	2	11
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	24,000	0	9	25	0	155	18	4	1	16

U.S. Acute Lead Observations

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY+ Positive Fixation 7840/7841/7842	347,000	408	50	909	197	58	50	3	30	0	6
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	457	421	944	220	77	50	8	51	0	31
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	17,000	1	0	44	10	1	1	0	1	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	30,000	2	0	44	12	0	3	0	0	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	198,000	9	11	403	103	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4477/4478/4479/4480	64,000	0	10	397	52	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	523,000	57	49	716	152	89	70	29	80	0	26
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	0	1	28	10	0	0	3	4	0	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/4473/4474	53,000	2	13	90	13	3	8	6	4	0	3

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	21,000	0	0	38	41	9	0	0	8	0	21
ACUITY X4 Spiral S 4674/4675	63,000	0	2	85	67	8	0	0	28	0	57

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	48,000	2	0	175	51	8	1	0	13	0	59
ACUITY Steerable 4554/4555/4556	29,000	1	1	291	22	13	1	1	21	0	162
ACUITY Spiral 4591/4592/4593	24,000	1	2	173	29	5	0	3	9	0	167
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	0	1	240	23	8	1	3	17	0	128
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	7	4	807	84	30	4	14	64	0	512
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	4	4	168	24	11	1	10	20	0	141

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	87,000	78	14	192	31	22	4	1	13	5	3
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	12,000	10	1	29	9	3	0	0	2	2	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	78,000	56	18	253	42	29	3	2	27	7	6
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	2	0	10	1	0	0	0	4	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	141,000	101	20	370	71	59	15	6	32	13	21
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	4	1	6	0	1	1	0	8	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	82	137	510	130	223	12	17	178	108	44
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	5	4	92	36	41	4	3	47	5	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation	34,000	31	7	70	15	20	3	2	18	25	9

0137/0138/0160/0161/0162/0180/0181/0182											
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	0	3	1	2	0	0	1	0	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM S-ICD Electrode 3501	35,000	1	1	33	0	290	10	0	4	10
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401	24,000	1	0	21	0	208	6	1	0	15

Before/During Implant Procedure - Worldwide Malfunctions: Leads

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

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	51,000	0	0	0	3	0	0	0
ACUITY X4 Spiral S 4674/4675	134,000	0	0	0	5	0	0	0
ACUITY X4 Straight 4671/4672	105,000	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	47,000	0	0	0	2	1	0	0

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	33,000	0	0	0	8	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	266,000	3	1	0	88	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0682/0663/0683	8,000	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	126,000	0	0	0	90	0	1	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0265/0266/0285/0286	11,000	0	0	0	7	15	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	220,000	0	0	0	65	0	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	7,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	383,000	0	0	92	571	1	3	10
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	109,000	1	0	20	108	0	3	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	81,000	0	0	15	81	0	1	1
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	0	0	1	6	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM S-ICD Electrode 3501	87,000	0	0	0	1	0	0	0
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	43,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY+ Positive Fixation 7840/7841/7842	598,000	0	0	0	35	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	1,108,000	2553	0	0	3318	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	126,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	134,000	1	0	1	2	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	185,000	0	0	11	136	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	290,000	0	0	66	636	1	1	4
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457*	559,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	830,000	0	0	6	728	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	329,000	0	0	1	144	6	18	0
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459*	105,000	0	0	2	2	1	1	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	144,000	0	0	0	233	4	6	0

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

Product Advisories

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

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

PRODUCT	ORIGINAL COMMUNICATION **Jun 2021 – High Battery Impedance Initiating Safety Mode in INGENIO EL Pacemakers and CRT-Ps**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INLIVEN CRT-P** Models: V284, V285, W274, W275 **INTUA CRT-P** Models: V272, V273, W273 **INVIVE CRT-P** Models: V172, V173, V182, V183, W172, W173 **VITALIO DR EL Pacemaker** Models: J274, J277, K274, K277, K284 **INGENIO DR EL Pacemaker** Models: J174, J177, K174, K184, K187 **ADVANTIO DR EL Pacemaker** Models: J064, J067, K064, K084, K087 Safety Mode, Physician Letter, June 2021 Safety Mode, Patient Letter, June 2021 Safety Mode, Physician Letter, December 2023 Update Safety Mode, Patient Letter, December 2023 Update	Voluntary Physician Advisory FDA Classification: June 2021 - Class I; Nov 2023 - Pending Affected devices built with the extended life (EL) battery have the potential to transition to Safety Mode during periods of high-power consumption (e.g., interrogation by a programmer). If the battery voltage drops below a minimum threshold during a high-power state, a system reset is automatically performed, and the conditions of the high-power state are interrupted. Subsequent high-power states may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to enter Safety Mode to maintain back-up pacing with pre-defined non-programmable settings. When a device is in Safety Mode, users are directed to contact Boston Scientific via a programmer warning screen and LATITUDE alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode is increased when an affected device reaches approximately three (CRT-P) or four (DR EL) years of remaining battery longevity. Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The non-programmable Safety Mode pacing parameters may not provide optimal support of a patient's cardiac condition (e.g., adequacy of underlying escape rhythm, the need for AV/VV pacing for cardiac synchrony, and/or the potential for pacing inhibition due to myopotential oversensing). The most common clinical outcome has been early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure prior to device replacement. The worst-case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. No affected devices remain available for implant. Estimated Rate It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator. The potential for life-threatening harm due to loss of pacing (occurring because of prolonged inhibition) over a device's lifetime is estimated to be less than 1 in 15,000. November 2023 update: Since June 2021, the affected device population has aged, and additional post-market surveillance data has been collected. Most Safety Mode reports continue to be associated with telemetry operations involving an external device. However, approximately 3.5% of reports are unrelated to telemetry operations with an external device and may occur in an ambulatory setting by transient voltage drops during normal, higher power device operations such as automatic radio frequency telemetry circuit enablement and automatic memory checks. There have been 15 reports of a pause in pacing for older devices with less battery capacity experiencing extended transitions into Safety Mode (up to approximately 20 seconds) during telemetry operations with an external device. Thirteen (13) were associated with in-person programmer/Consult interrogations, and two (2) were associated with a LATITUDE patient initiated interrogation (PII). When Safety Mode is initiated due to this behavior, previously reported battery time remaining estimates are invalid because they were determined without accounting for Safety Mode's increased outputs or the battery's high impedance state. There have been three (3) deaths in pacemaker-dependent patients associated with this behavior; all were within the recommended replacement interval. Estimated Rate The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years. The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below. Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **08-Jan-24**

Estimated Rate of Occurrence - as of 11/2023

The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years.

The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below.

CURRENT RECOMMENDATION **08-Jan-24**

Identify patients who are at risk of harm due to Safety Mode's non-programmable parameters.

If a device enters Safety Mode, perform emergent replacement for patients who are at risk of harm. For other patients, non-emergent replacement is recommended. When choosing a replacement interval, do not rely on previously reported battery time remaining estimates which do not account for Safety Mode's increased outputs nor the battery's high impedance state.

General prophylactic replacement is not recommended. For patients who are at risk of harm, device replacement is recommended as follows:
–For DR EL pacemakers, schedule replacement when the longevity remaining is 4 years or less.
–For CRT-Ps, schedule replacement when the longevity remaining is 3 years or less.

Note: There is a potential for pacing pauses during in-person checks and LATITUDE PII in patients at risk of harm who remain implanted beyond the recommended replacement interval. During in-person device checks, consider patient recumbency and availability of resuscitation equipment with qualified personnel. Consider disabling PII for patients on LATITUDE.

Follow-up interval. Per instructions for use, perform a system follow-up via remote or in-office interrogation at least every 12 months. When longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated.

For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT	ORIGINAL COMMUNICATION **Sep 2018 and Jun 2021 – Hydrogen-Induced Premature Depletion**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **VALITUDE CRT-P** Models U125, U128 **VISIONIST CRT-P** Models U225, U226, U228 **ACCOLADE Pacemaker** Models L300, L301, L310, L311, L321, L331 **PROPONENT Pacemaker** Models L200, L201, L209, L210, L211, L221, L231 **ESSENTIO Pacemaker** Models L100, L101, L110, L111, L121, **ALTRUA 2 Pacemaker** Models S701, S702, S722 Hydrogen Induced Premature Depletion, Physician Letter, September 2018 Hydrogen Induced Premature Depletion, Patient Letter, September 2018 Hydrogen Induced Premature Depletion, Physician Letter, June 2021 Hydrogen Induced Premature Depletion, Patient Letter, June 2021	Voluntary Physician Advisory FDA Classification: Sep 2018 – Class II; Jun 2021 - Class II This advisory discusses two separate, distinct subsets of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) with a potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion. The 2018 advisory population included approximately 2,900 active pacemakers, and the 2021 advisory population included approximately 125,000 active pacemakers. Latent release of small amounts of hydrogen within the pacemaker may compromise electrical function of a low voltage capacitor over time, resulting in accelerated depletion of the battery. The susceptibility of a pacemaker to this hydrogen-induced accelerated battery depletion mechanism is dependent upon the amount of hydrogen accumulation within the device and the susceptibility of the low voltage capacitors to hydrogen. The 2018 population is composed of pacemakers built with specific batches/lots of a liner component exhibiting a higher likelihood for this behavior. The 2021 population is composed of pacemakers built with a discontinued/original low voltage capacitor that is susceptible to compromised electrical performance in the presence of hydrogen. The use of the original low voltage capacitor in pacemaker and production of pacemakers from these advisory populations ceased in Nov 2017, and therefore they are no longer available for implantation. The most common clinical outcome has been device replacement. There have been no reported deaths associated with this behavior. *Estimated Rate of Occurrence* In June 2021 Boston Scientific identified an additional population of devices and the rate of occurrence at that time is described for each population below. • The 2018 advisory subset was composed of approximately 2,100 active pacemakers. The observed malfunction rate for this behavior was 11.0% at 5 years with a potential for life-threatening harm of 1 in 500,000 (0.0002%) at 5 years. • The 2021 advisory subset was composed of approximately 125,000 active pacemakers. The observed malfunction rate for this behavior was 1.3% at 5 years with a potential for life-threatening harm of 1 in 5,000,000 (0.00002%) at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions. CURRENT STATUS **08-Jan-24** *Estimated Rate of Occurrence - as of 06/2023* The combined 2018 and 2021 advisories subset is composed of approximately 100,000 active pacemakers. The observed malfunction rate for this behavior is 2.2% at 5 years, and 3.8% at 7 years. The observed potential for life-threatening harm is 1 in 1,000,000 (0.0001%) at 5 years. More than 98% of hydrogen-induced confirmed events have been replaced before the battery reached a depleted state; therefore, normal battery assessment during labeled 12-month follow-ups is effective and recommended for both advisory populations. A polymer material, designed to remove excess hydrogen within the pulse generator, was added to this device family in March 2018 and is intended to mitigate hydrogen-induced accelerated battery depletion due to the low voltage capacitors. Additionally, improvements were implemented in the liner component starting in May 2021 intended to further reduce the device's overall capacity to generate hydrogen. CURRENT RECOMMENDATION **08-Jan-24** • Per labeling, perform a system follow-up via remote or in-office interrogation every 12 months until One-Year-Remaining and then every three (3) months thereafter until replacement is indicated. • Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. • Replace any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery depletion. • For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

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

CURRENT STATUS **08-Jan-24**

Estimated Rate of Occurrence - as of 01/2024

The occurrence rate for EMBLEM S-ICD Subcutaneous Electrode (Model 3501) body fractures at a location just distal to the proximal sense ring is 0.32% at 78 months and the potential for life-threatening harm is 1 in 33,000 (0.0030%) at 10 years. This rate was derived by including all reports of this failure mode, whether or not the product was returned.

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

CURRENT RECOMMENDATION **08-Jan-24**

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

PRODUCT	ORIGINAL COMMUNICATION **Dec 2020 — EMBLEM S-ICD Electrical Overstress**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM S-ICD** Models A209, A219 EMBLEM Electrical Overstress, Physician Letter, December 2020 EMBLEM Electrical Overstress, Patient Letter, December 2020	Voluntary Physician Advisory FDA Classification: Class I This advisory discusses the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress (i.e., damage to the device caused by electrical shorting). Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations. *Estimated Rate of Occurrence* • Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported. • The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide needed defibrillation therapy, as it is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **08-Jan-24**

Estimated Rate of Occurrence - as of 08/2021

• The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement.

• We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years

CURRENT RECOMMENDATION **08-Jan-24**

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

PRODUCT	ORIGINAL COMMUNICATION **Aug 2019 and Dec 2020 — EMBLEM S-ICD Premature Depletion**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM S-ICD** Models A209, A219 EMBLEM Premature Depletion, Physician Letter, August 2019 EMBLEM Premature Depletion, Patient Letter, August 2019 EMBLEM Premature Battery Depletion Physician Letter Update, December 2020 EMBLEM Premature Depletion, Patient Letter Update, December 2020 EMBLEM Premature Battery Depletion Physician Letter Update, February 2022 EMBLEM Premature Depletion, Patient Letter Update, February 2022	Voluntary Physician Advisory FDA Classification August 2019: Class II FDA Classification December 2020: Class II In August 2019, a physician communication discussed a subset of EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) that may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion. In December 2020, the advisory population was expanded to a total of approximately 42,000 distributed EMBLEM S-ICDs with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion. This behavior can be detected if an unexpected decrease in remaining battery capacity is observed between remote/in-clinic follow-ups. Progression of accelerated depletion eventually produces a battery status replacement indicator (ERI) which is detectable through ambulatory beeping tones, remote monitoring, or in-clinic follow-up. Devices exhibiting this accelerated depletion behavior are capable of providing therapy for a minimum of 21 days after ERI independent of when EOL is initiated. The most common clinical outcome associated with this device behavior is early replacement. In August 2018, Boston Scientific transitioned S-ICDs to an alternative low voltage capacitor. All EMBLEM S-ICDs with the original low voltage capacitor are included in either the original or the expanded advisory population and none are available for implantation. *Estimated Rate of Occurrence* • The August 2019 advisory subset is comprised of approximately 400 distributed worldwide devices manufactured in July 2017. The August 2019 advisory subset has a projected rate of accelerated depletion of 15.1% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 50,000 at 5 years. • The December 2020 advisory subset is comprised of approximately 42,000 distributed worldwide devices manufactured before August 2018. The December 2020 advisory subset has a projected rate of accelerated depletion of 3.7% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 250,000 at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions.
CURRENT STATUS **08-Jan-24**	
The existing Battery Depletion (BD) alert has been enhanced to enable detection of hydrogen-induced accelerated battery depletion in Model A209 and A219 EMBLEM S-ICDs. Affected devices must be interrogated by a programmer with updated software. *Estimated Rate of Occurrence - as of 09/2023* Because the 5-year malfunction rate for the August 2019 and December 2020 populations has converged, a single malfunction rate is reported for the combined populations. There are approximately 22,000 active worldwide devices. The malfunction rate is 10.2% at 5 years, 23.7% at 6 years, and 33.6% at 7 years. The projected potential for life-threatening harm is approximately 1 in 110,000 at 5 years.	

CURRENT RECOMMENDATION **08-Jan-24**

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

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

Follow-up Recommendations:

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

PRODUCT	ORIGINAL COMMUNICATION **November 2018 — SQ-RX 1010 Shortened Replacement Time**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **S-ICD** Model 1010 SQ-RX 1010 Shortened Replacement Time, Physician Letter, November 2018 SQ-RX 1010 Shortened Replacement Time, Patient Letter, November 2018	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the potential for a shortened replacement interval after a Charge Time (CT) / Battery Depletion (BD) alert has occurred or after the battery status reaches Elective Replacement Indicator (ERI) in the first-generation Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) system's SQ-RX™ Model 1010 Pulse Generator (PG). The SQ-RX Model 1010 PG provides an Elective Replacement Indicator (ERI) as the PG approaches the end of its expected battery service life. When the battery reaches ERI through normal use, there is sufficient capacity to support up to 90 days of continued operation, including up to 6 maximum energy charges/shocks before fully depleting. However, if the PG experiences a latent battery malfunction resulting in accelerated battery depletion, the reserve battery capacity available beyond ERI may not be sufficient to support the full 90-day interval or additional shock therapy before depleting. The rate of depletion for a latent battery malfunctions varies. The SQ-RX model 1010 PGs include separate monitors for charging and battery performance. The Charge Time (CT) alert is designed to detect unsuccessful charging of the high voltage capacitors within 44 seconds. The Battery Depletion (BD) alert is designed to detect higher rates of accelerated battery depletion. When an alert condition occurs, the patient is notified through beeping tones and the clinician user is notified through programmer messages. Most battery malfunctions exhibit a sufficient rate of accelerated depletion to be detected by one of these alerts. Some battery malfunctions exhibit a slower rate of accelerated depletion, which is not detected as an alert condition. Based on an analysis of accelerated battery depletion events where only ERI presented (no alert condition), at least one maximum energy shock has been determined to be available for at least 20 days after ERI. *Estimated Rate of Occurrence* The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years. There have been no reports of injuries or deaths associated with this behavior. Laboratory analysis of returned PGs with latent battery malfunctions has shown some depletions to a level at which therapy would not have been available if not replaced in accordance with the recommendations above. Based on a 3-month follow-up interval, the potential for life threatening harm for this behavior is 0.006% (1 in 16,667) at 5 years. However, the potential for life-threatening harm is greater for secondary prevention patients or those who have received appropriate therapy previously, patients with longer follow-up intervals, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction. Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **08-Jan-24**

Estimated Rate of Occurrence - as of 10/2018
The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years.

CURRENT RECOMMENDATION **08-Jan-24**

• 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 **December 2017 — Minute Ventilation Signal Oversensing**

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

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

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

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

ESSENTIO Pacemaker
L131

ALTRUA 2 Pacemaker
Models S701, S702, S722

Minute Ventialtion Signal Oversensing, Physician Letter, December 2017

Minute Ventialtion Signal Oversensing, Patient Letter, December 2017

Minute Ventialtion Signal Oversensing, Update letter, January 2019

Voluntary Physician Advisory

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

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

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

Estimated Rate of Occurrence

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

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

CURRENT STATUS **08-Jan-24**

Software has been developed that eliminates the risk of pacing inhibition due to Minute Ventilation (MV) sensor signal oversensing in pacemakers and cardiac resynchronization therapy pacemaker (CRT-P) systems. The software includes a Signal Artifact Monitor (SAM) which further expands our proprietary suite of Safety Architecture automatic self-diagnostics. Once programmers are upgraded with this software, the SAM is automatically enabled whenever the MV sensor is enabled and continuously monitors electrograms for MV sensor signal artifacts. If MV artifacts are detected, the SAM either switches to the right ventricular vector or disables the MV sensor in approximately one second thus eliminating the risk of pacing inhibition due to MV sensor signal oversensing. Contact your local Boston Scientific sales representative to find out if this software is available in your country.

CURRENT RECOMMENDATION **08-Jan-24**

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

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

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

PRODUCT	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** 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 **08-Jan-24** *Confirmed Malfunctions (worldwide)* There have been five confirmed instances of early device replacement due to this device behavior. CURRENT RECOMMENDATION **08-Jan-24** Software is available in most countries to addresses the rare potential for early replacement due to permanent Safety Mode status. The software imposes an interactive limit which prevents programming the device into a susceptible manner. Affected devices interrogated by an updated programmer are no longer susceptible to this issue. If software is not available in your country, continue to follow advisory recommendations.

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

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. <u>Advisory population</u> 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 **08-Jan-24**

Estimated Rate of Occurrence - as of 01/2022

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

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

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

CURRENT RECOMMENDATION **08-Jan-24**

<u>Updated Software</u>

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.

<u>LATITUDE Patient Management System</u>

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”.

<u>Additional Recommendations</u>

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

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

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.
This advisory is limited to those models listed below implanted subpectorally.	Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.
COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108 **TELIGEN VR** Models E102/F102 **TELIGEN DR** Models E110/E111/F110/F111	A weakened header bond can result in one or more of the following device behaviors: – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.
Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)

CURRENT STATUS **08-Jan-24**

Reported events (worldwide)

106 reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

There have been no reported patient deaths associated with this advisory.

CURRENT RECOMMENDATION **08-Jan-24**

If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended.

For affected devices implanted in a subpectoral location:
– Follow patient at least once every three months as recommended in device instructions for use.
– Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.
– Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

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

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