

2023

Rhythm Management Product Performance Report

Q3 Edition



RESONATE™
Family of ICDs AND CRT-Ds



ACCOLADE™
Family of Pacemakers



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 Q3 2023 report includes data through July 5th, 2023.

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

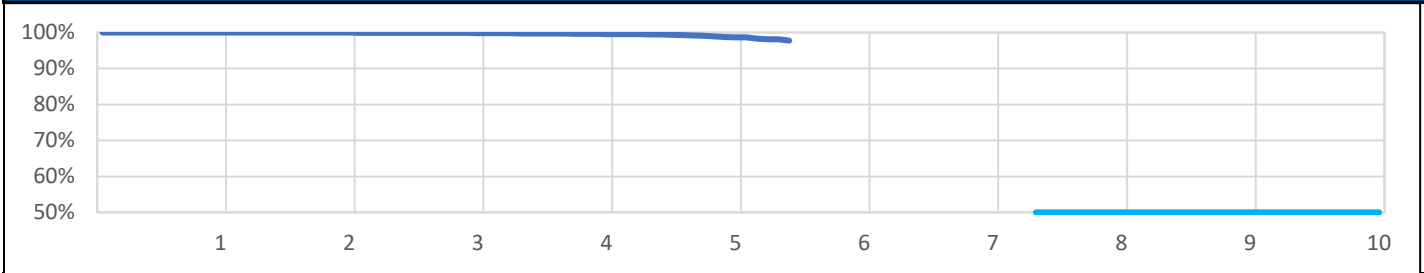
Lead confirmed malfunctions represent leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Boston Scientific Product Performance Report is in compliance with the 2014 version 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.

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

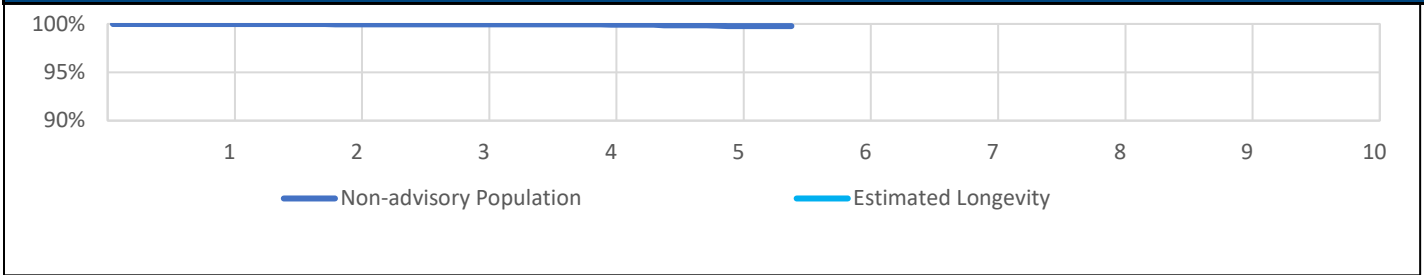
Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/
G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

US Summary			
US Registered Implants:	73,000	US Normal Battery Depletions:	92
US Approval Date:	September 2017	US Malfunctions:	25
US Estimated Active Implants:	66,000	Without Compromised Therapy:	20
		With Compromised Therapy:	5

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.6%	98.7%	97.8%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	--	--	--	--
73,000	Effective Sample Size	50264	32764	18870	8686	1922	239	--	--	--	--

@ 66 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	47
Worldwide Distribution	134,000

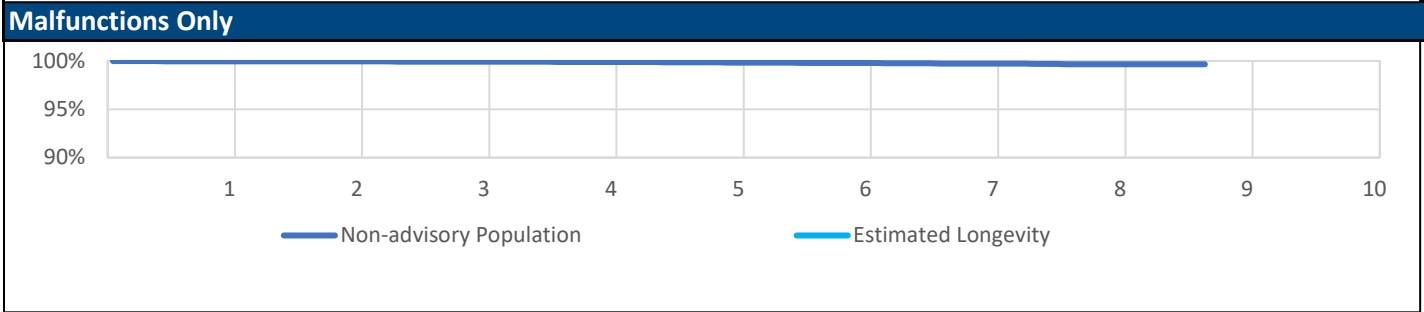
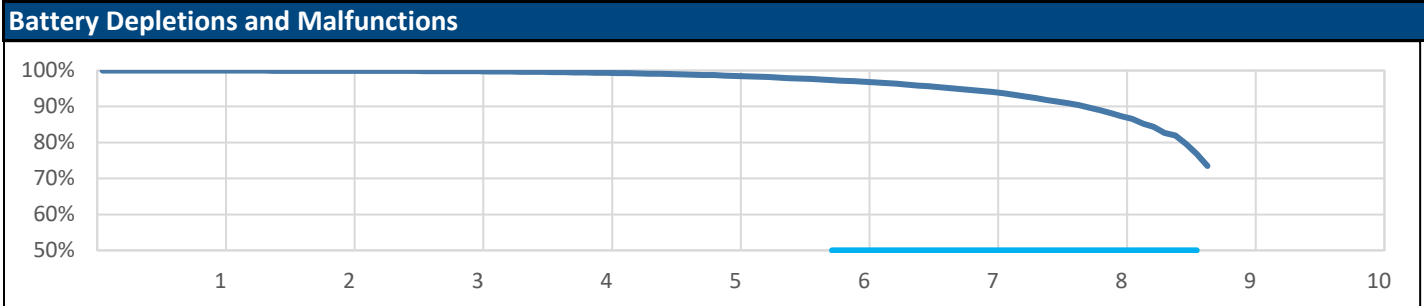
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (63)	1	6	7
Low-voltage capacitor (69)	0	9	9
Battery (53)	2	8	10
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	11	11
Other			
Non-patterned, other	4	5	9
Grand Total	8	39	47

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:	1,638
US Approval Date:	April 2014	US Malfunctions:	100
US Estimated Active Implants:	57,000	Without Compromised Therapy:	88
		With Compromised Therapy:	12



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%	94.3%	88.1%	73.5%	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	--
75,000	Effective Sample Size	64636	55916	47311	38719	29041	18559	9017	2562	207	--

@ 105 months

DYNAGEN/INOGEN/ORIGEN CRT-D

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

Worldwide Confirmed Malfunctions		144	
Worldwide Distribution		129,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	18	18
Integrated circuit (63)	4	11	15
Low-voltage capacitor (69)	0	20	20
High voltage capacitor (75)	2	1	3
Battery (53)	1	30	31
Low-voltage capacitors (47)	0	1	1
Software			
Memory errors (51)	2	27	29
Safety Core-unintended biventricular pacing (64)	0	3	3
Other			
Non-patterned, other	11	13	24
Grand Total	20	124	144

References cited in table above [\(link\)](#)

AUTOGEN CRT-D

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

Worldwide Confirmed Malfunctions		37	
Worldwide Distribution		24,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	7	7
Integrated circuit (63)	2	4	6
Low-voltage capacitor (69)	0	6	6
Battery (53)	3	8	11
Software			
Safety Core-unintended biventricular pacing (64)	0	1	1
Memory errors (51)	0	1	1
Other			
Non-patterned, other	1	4	5
Grand Total	6	31	37

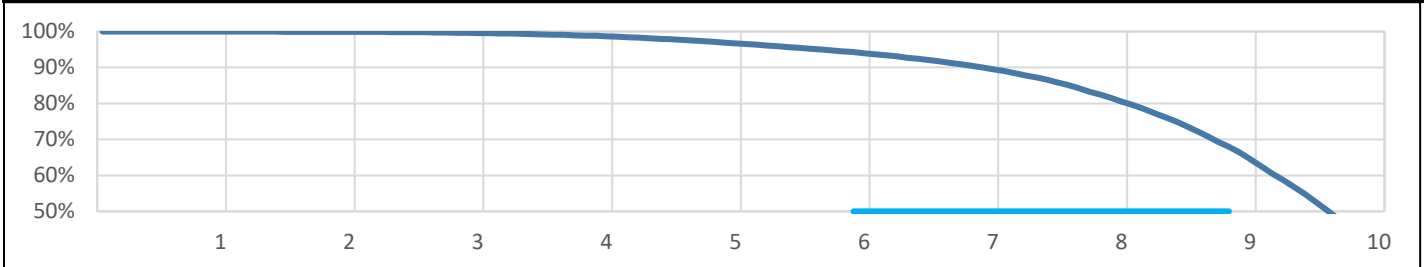
References cited in table above [\(link\)](#)

INCEPTA/ENERGEN/PUNCTUA CRT-D

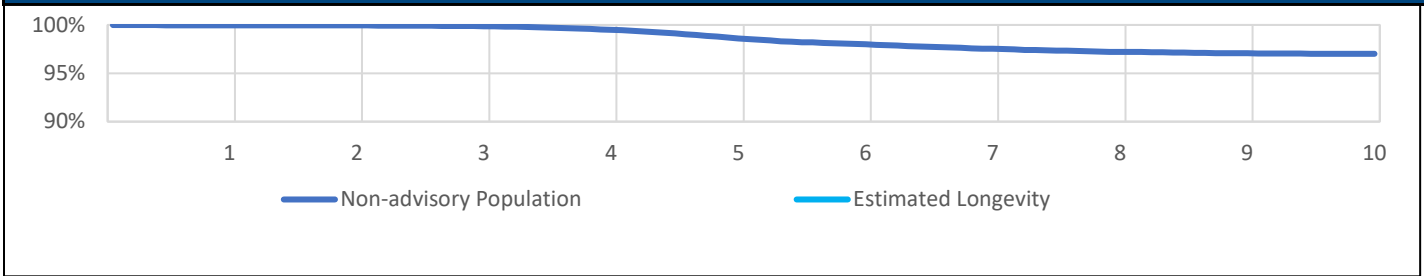
Models: N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/P052/P053/P142/P143/P162/P163/P165

US Summary			
US Registered Implants:	53,000	US Normal Battery Depletions:	9,071
US Approval Date:	November 2011	US Malfunctions:	807
US Estimated Active Implants:	21,000	Without Compromised Therapy:	785
		With Compromised Therapy:	22

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.6%	98.8%	96.9%	94.3%	90.0%	81.6%	66.4%	41.4%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.7%	98.0%	97.6%	97.2%	97.1%	97.0%
53,000	Effective Sample Size	46304	41460	37004	32848	28795	24989	21209	16466	9137	2313

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	1,293
Worldwide Distribution	81,000

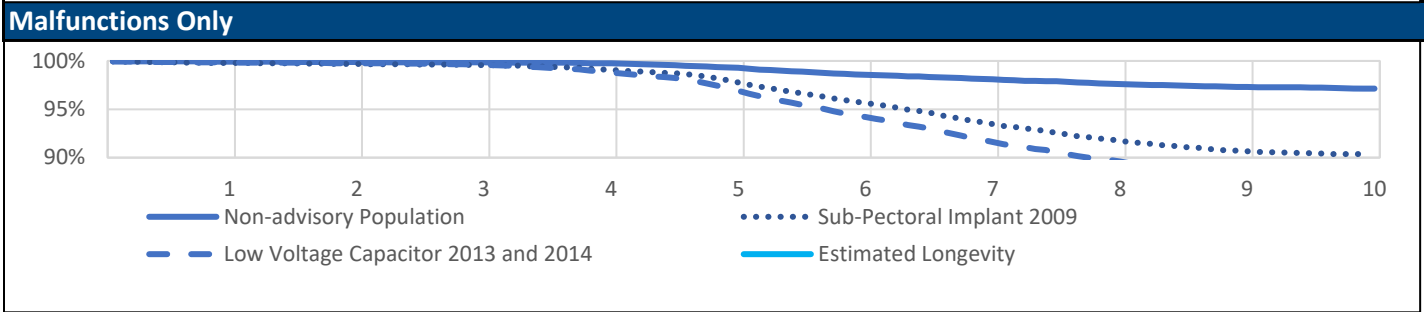
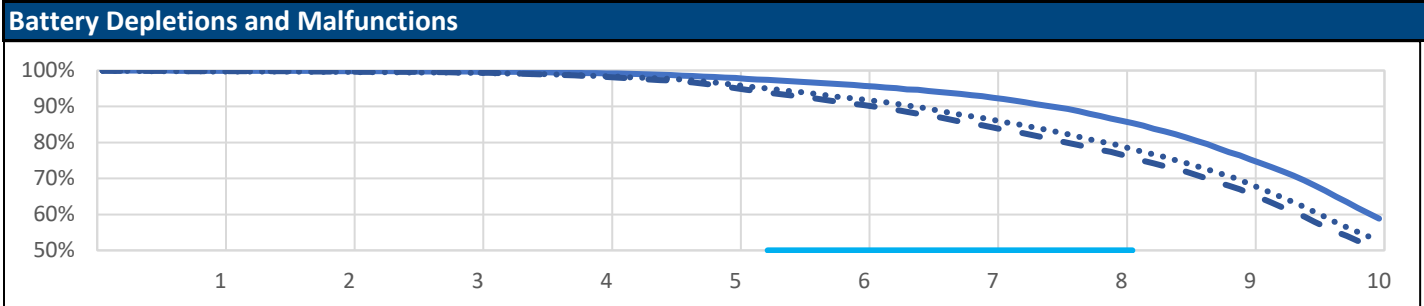
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Safety Core-electrocautery (42)	1	6	7
High-voltage capacitor (43)	5	0	5
Low-voltage capacitors (47)	0	1	1
Integrated circuit (50)	7	2	9
Battery (53)	2	11	13
Low-voltage capacitor (54)	6	1204	1210
Low-voltage capacitor (69)	0	10	10
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	8	16	24
Grand Total	35	1258	1293

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:	15,792
US Approval Date:	March 2008	US Malfunctions:	2,097
US Estimated Active Implants:	15,000	Without Compromised Therapy:	1,904
		With Compromised Therapy:	193



US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.0%	96.0%	92.9%	86.6%	76.4%	60.3%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.2%	97.6%	97.3%	97.1%
36,000	Effective Sample Size	31268	28042	25103	22387	19840	17356	14976	12484	9783	6854

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%	79.7%	69.6%	53.9%
Registered Implants: 32,000	Malfunctions Only	99.8%	99.7%	99.6%	99.1%	98.0%	95.8%	93.7%	91.9%	90.7%	90.4%
	Effective Sample Size	27324	24211	21611	19183	16753	14278	11961	9734	7541	5149
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.4%	95.6%	90.7%	84.8%	77.4%	67.0%	51.5%
Registered Implants: 26,000	Malfunctions Only	99.8%	99.8%	99.6%	98.9%	97.2%	94.4%	91.8%	89.8%	88.4%	88.0%
	Effective Sample Size	22463	19938	17825	15774	13720	11585	9611	7769	5968	4021

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

COGNIS CRT-D

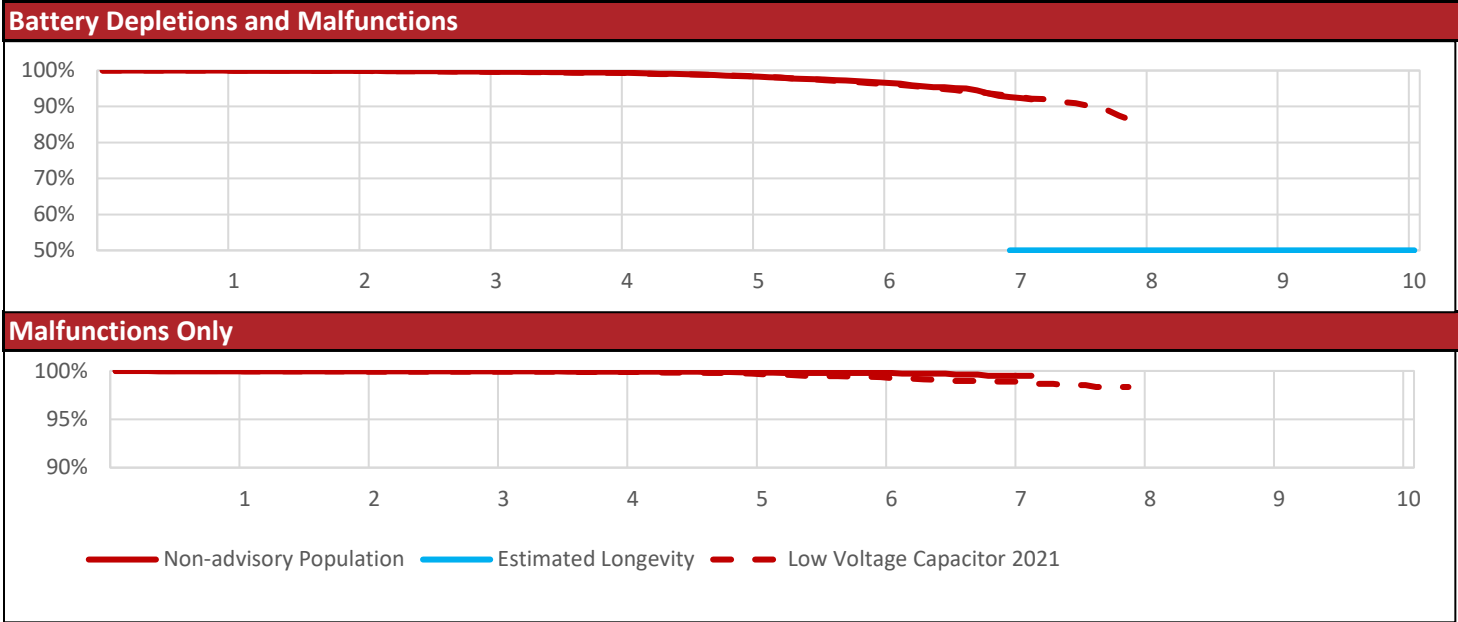
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

Worldwide Confirmed Malfunctions		2,958	
Worldwide Distribution		109,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	83	1617	1700
Safety Core-electrocautery (42)	25	54	79
High-voltage capacitor (43)	6	1	7
Low-voltage capacitors (47)	0	7	7
Integrated circuit (50)	21	8	29
High voltage circuit (52)	1	0	1
Battery (53)	10	51	61
Low-voltage capacitor (54)	12	848	860
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	9	0	9
Difficulty securing lead (41)	8	8	16
Header contacts (45)	8	10	18
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	48	20	68
Header (74)	25	9	34
Software			
Safety Core-programming (46)	0	1	1
Alert messages not displayed post-EOL (48)	0	2	2
Memory errors (51)	2	15	17
Other			
Non-patterned, other	11	36	47
Grand Total	269	2689	2958

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

US Summary			
US Registered Implants:	51,000	US Normal Battery Depletions:	514
US Approval Date:	October 2014	US Malfunctions:	93
US Estimated Active Implants:	42,000	Without Compromised Therapy:	86
		With Compromised Therapy:	7



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%	98.4%	96.7%	92.6%	92.0%	--	--
Registered Implants:	Malfunctions Only		100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.5%	99.5%	--	--
	Effective Sample Size	45,000	33256	24070	16714	10961	6185	2766	466	260	--	--

@ 86 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%	93.0%	86.3%	--	--
Registered Implants: 6,000	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.7%	99.4%	98.9%	98.3%	--	--
	Effective Sample Size	5914	5282	4716	4183	3639	2888	1468	229	--	--

@ 95 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

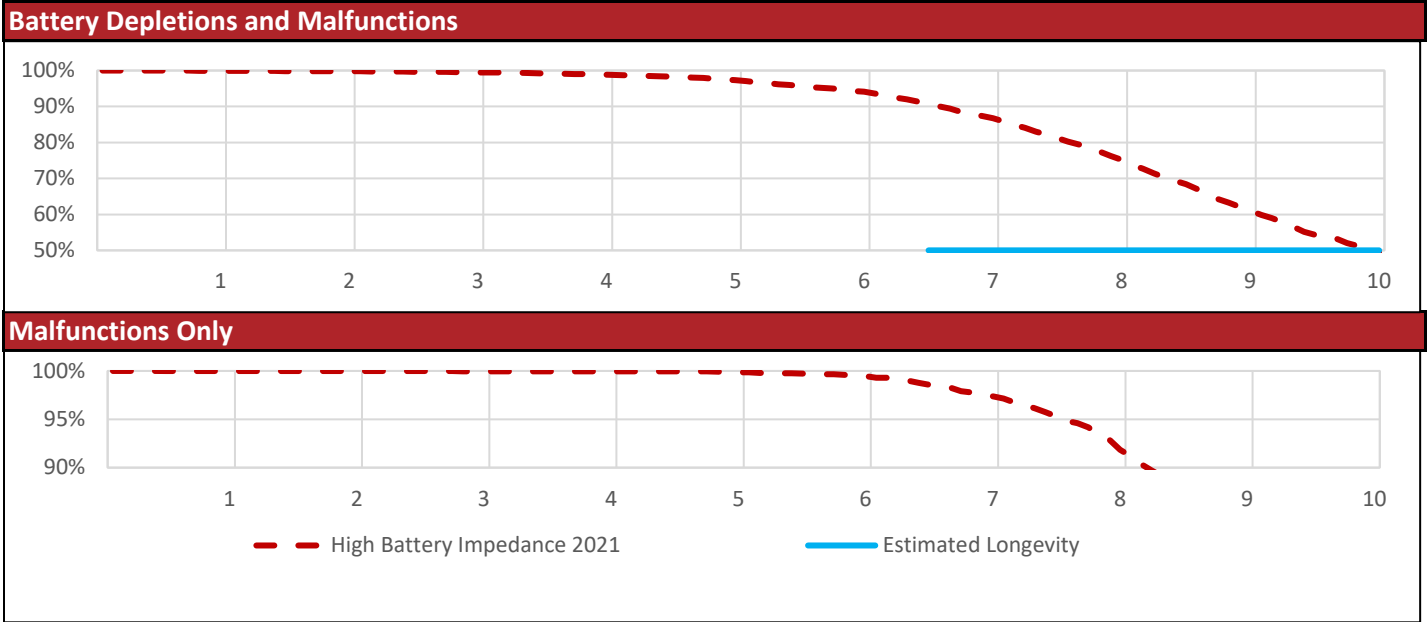
Worldwide Confirmed Malfunctions		156	
Worldwide Distribution		105,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	2	11	13
Telemetry (68)	0	1	1
Hydrogen induced premature depletion - September 2018 (70)	0	19	19
Hydrogen induced premature depletion - June 2021 (83)	2	49	51
High battery impedance (89)	3	14	17
Software			
Memory errors (51)	0	16	16
Other			
Non-patterned, other	5	32	37
Grand Total	12	144	156

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:	1,090
US Approval Date:	May 2013	US Malfunctions:	439
US Estimated Active Implants:	4,000	Without Compromised Therapy:	430
		With Compromised Therapy:	9



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%	87.4%	76.3%	62.1%	50.7%
Registered Implants:	Malfunctions Only		100.0%	100.0%	100.0%	100.0%	99.9%	99.5%	97.6%	92.9%	84.9%	80.0%
	Effective Sample Size	10,000	8980	8006	7121	6313	5563	4771	3738	2426	1026	272

*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

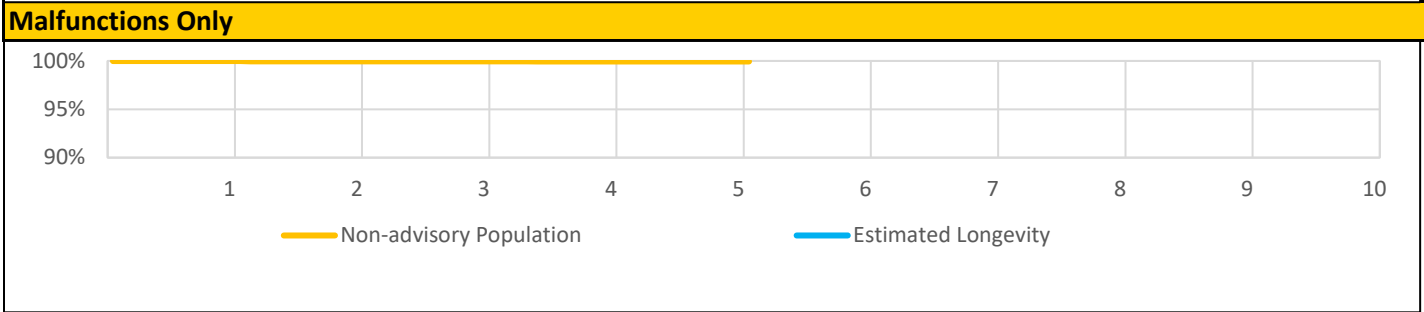
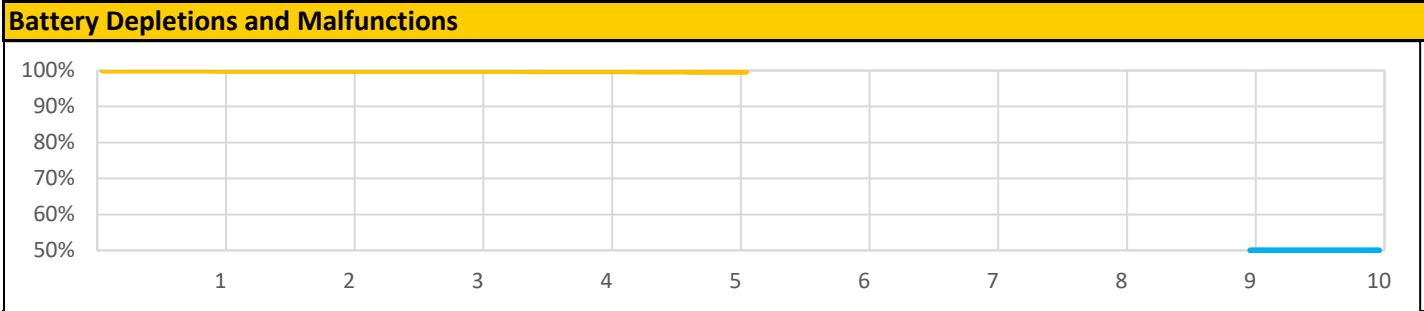
Worldwide Confirmed Malfunctions	649		
Worldwide Distribution	24,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High battery impedance initiating safety mode 2021 (82)	10	576	586
Low-voltage capacitors (47)	1	0	1
Other			
Non-patterned, other	5	57	62
Grand Total	16	633	649

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:	45,000	US Normal Battery Depletions:	24
US Approval Date:	July 2017	US Malfunctions:	13
US Estimated Active Implants:	41,000	Without Compromised Therapy:	9
		With Compromised Therapy:	4



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.9%	99.8%	99.6%	99.6%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	--	--	--	--
45,000	Effective Sample Size	29520	17567	8778	3424	546	269	--	--	--	--

@ 62 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

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

Worldwide Confirmed Malfunctions		21	
Worldwide Distribution		82,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Integrated circuit (63)	0	4	4
Low-voltage capacitor (69)	0	1	1
Battery (53)	0	1	1
Software			
Memory errors (51)	0	7	7
Mechanical			
Solder joint (88)	1	0	1
Other			
Non-patterned, other	2	3	5
Grand Total	5	16	21

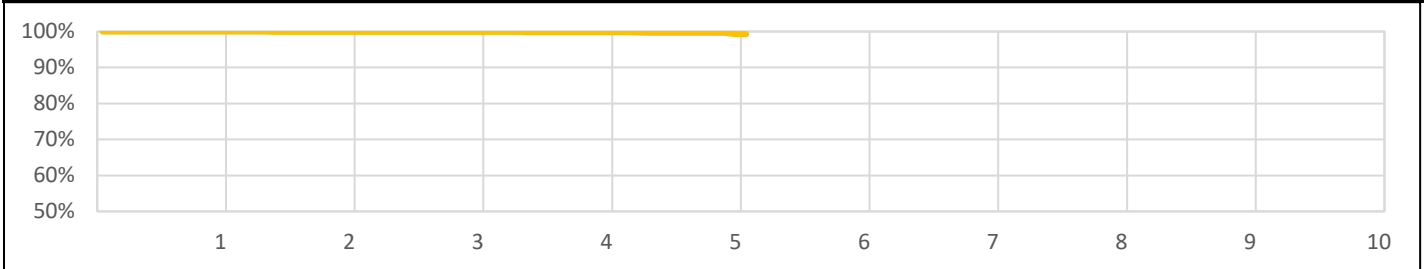
References cited in table above [\(link\)](#)

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

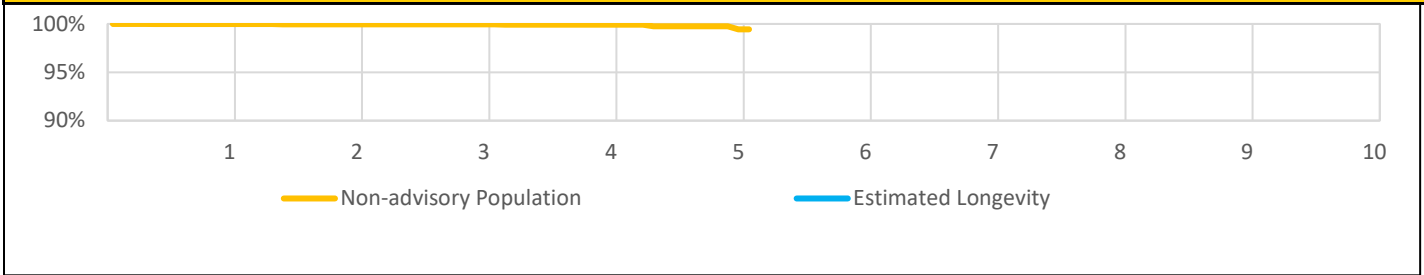
Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

US Summary			
US Registered Implants:	25,000	US Normal Battery Depletions:	12
US Approval Date:	July 2017	US Malfunctions:	11
US Estimated Active Implants:	23,000	Without Compromised Therapy:	10
		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%	99.6%	99.3%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.4%	--	--	--	--
25,000	Effective Sample Size	16422	10402	5741	2467	404	215	--	--	--	--

@ 62 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

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

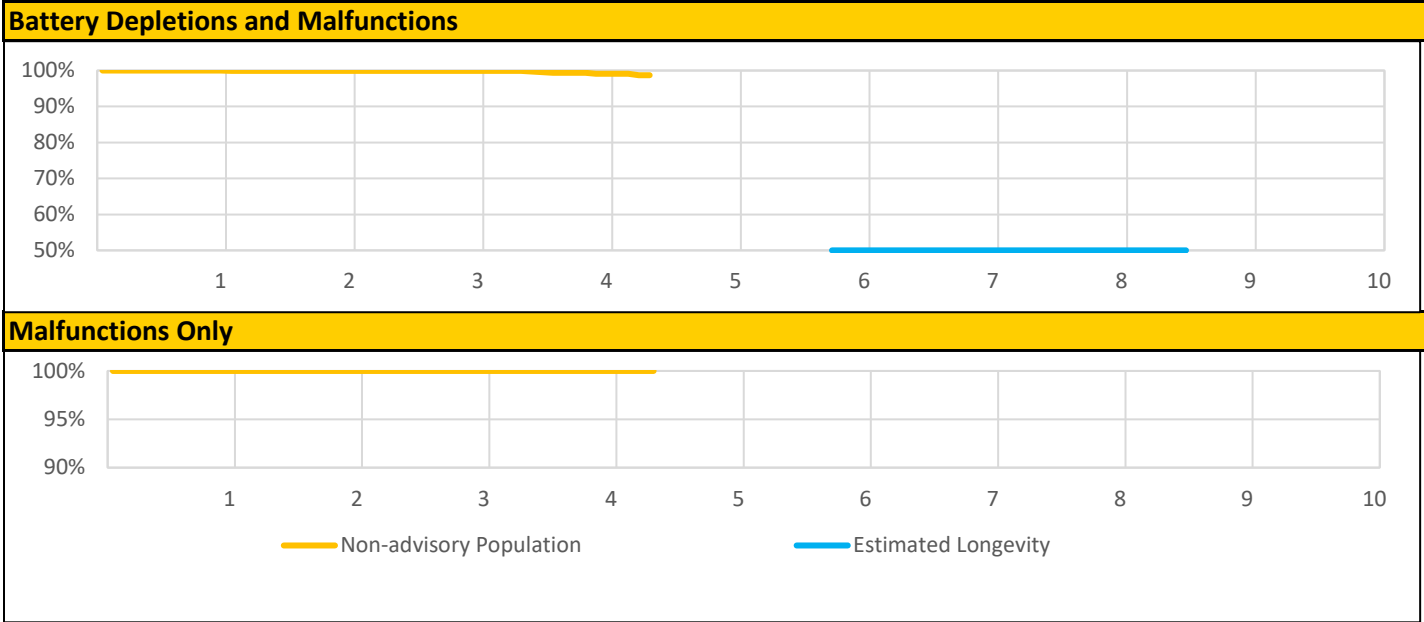
Worldwide Confirmed Malfunctions		21	
Worldwide Distribution		59,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	1	0	1
Integrated circuit (63)	1	0	1
Low-voltage capacitor (69)	0	2	2
Low-voltage capacitors (47)	0	1	1
Battery (53)	0	3	3
Software			
Memory errors (51)	0	6	6
Other			
Non-patterned, other	1	6	7
Grand Total	3	18	21

References cited in table above [\(link\)](#)

PERCIVA DR

Models: D401/D413/D501/D513

US Summary			
US Registered Implants:	5,000	US Normal Battery Depletions:	13
US Approval Date:	July 2017	US Malfunctions:	-
US Estimated Active Implants:	4,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-



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%	99.1%	98.7%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	--	--	--	--	--
5,000	Effective Sample Size	3098	1866	945	370	202	--	--	--	--	--

@ 53 months

PERCIVA DR

Models: D401/D413/D501/D513

Worldwide Confirmed Malfunctions	0		
Worldwide Distribution	8,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	0	0	0

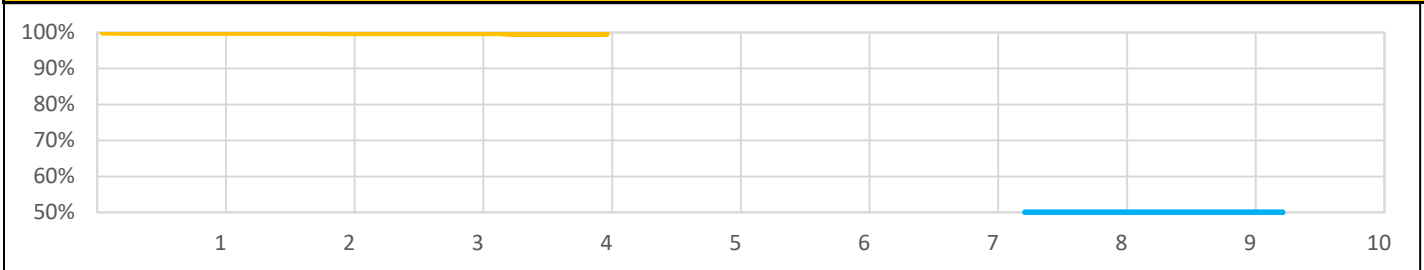
References cited in table above [\(link\)](#)

PERCIVA VR

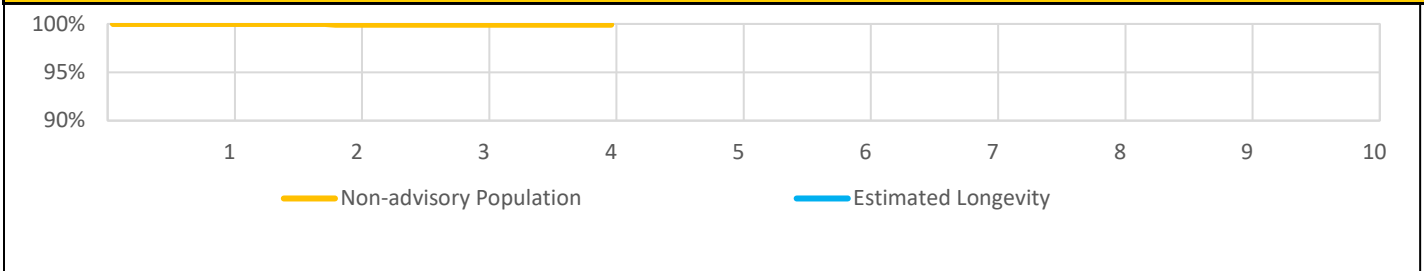
Models: D400/D412/D500/D512

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

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.8%	99.6%	99.6%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--	--
	3,000 Effective Sample Size	2047	1205	640	223	203	--	--	--	--	--

@ 49 months

PERCIVA VR

Models: D400/D412/D500/D512

Worldwide Confirmed Malfunctions	1		
Worldwide Distribution	6,000		
	With	Without	
	Compromised	Compromised	
	Therapy	Therapy	Total
Software			
Memory errors (51)	0	1	1
Grand Total	0	1	1

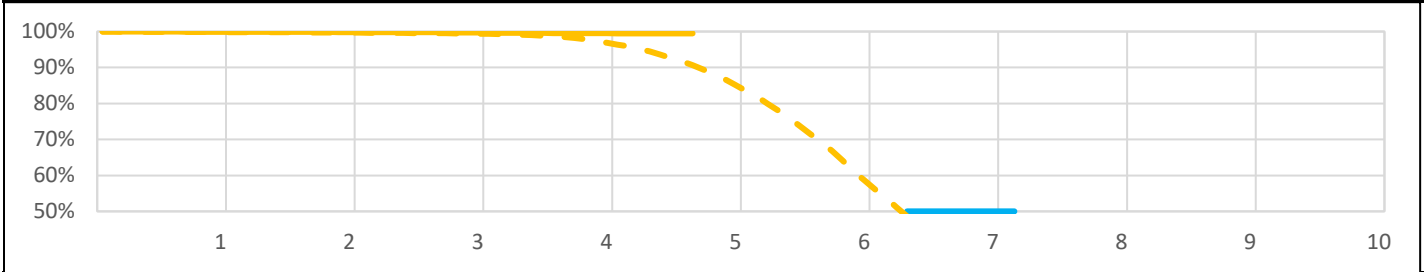
References cited in table above [\(link\)](#)

EMBLEM S-ICD

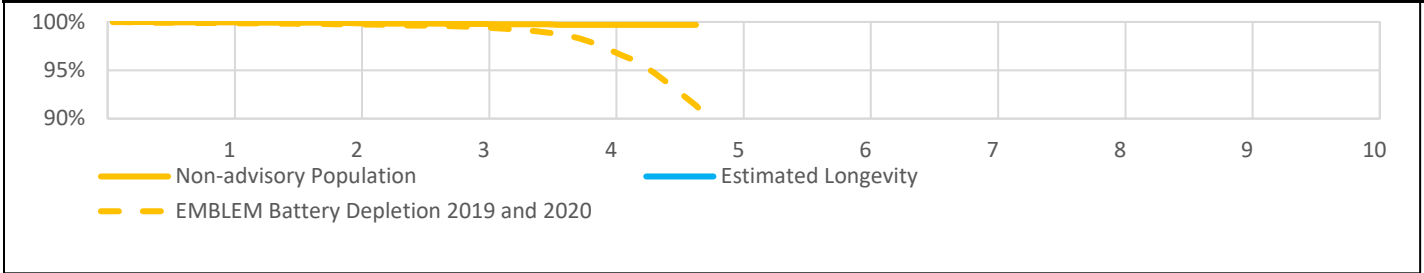
Models: A209/A219

US Summary			
US Registered Implants:	56,000	US Normal Battery Depletions:	969
US Approval Date:	March 2015	US Malfunctions:	3,730
US Estimated Active Implants:	44,000	Without Compromised Therapy:	3,629
		With Compromised Therapy:	101

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions		99.9%	99.9%	99.7%	99.5%	99.5%	--	--	--	--	--
Registered Implants:	Malfunctions Only		99.9%	99.9%	99.8%	99.7%	99.7%	--	--	--	--	--
32,000	Effective Sample Size		23101	14154	7662	3009	291	--	--	--	--	--

@ 57 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 Registered Implants: 22,000	Depletions and Malfunctions	99.9%	99.7%	99.4%	97.4%	86.7%	61.1%	35.9%	25.6%	--	--
	Malfunctions Only	99.9%	99.8%	99.5%	97.5%	87.9%	66.6%	46.5%	39.3%	--	--
	Effective Sample Size	18532	16453	14588	12612	8998	3272	1219	318	--	--

@ 93 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		7,718	
Worldwide Distribution		127,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	3	0	3
S-ICD battery depletion 2019 and 2020 (77)	91	7380	7471
Battery depletion (84)	1	2	3
Software			
Memory corruption (65)	1	0	1
Misaligned markers (73)	1	3	4
Memory corruption (85)	4	8	12
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)	14	1	15
Header (87)	1	0	1
Other			
Non-patterned, other	37	102	139
Telemetry (56)	16	30	46
Grand Total	191	7527	7718

References cited in table above ([link](#))

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions		49	
Worldwide Distribution		16,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	2	0	2
Low-voltage capacitor (69)	0	15	15
Battery (53)	0	18	18
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	5	5
Other			
Non-patterned, other	1	3	4
Grand Total	4	45	49

References cited in table above [\(link\)](#)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions		37	
Worldwide Distribution		17,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Low-voltage capacitor (69)	0	6	6
Battery (53)	4	18	22
Integrated circuit (63)	0	1	1
Software			
Memory errors (51)	2	2	4
Other			
Non-patterned, other	0	2	2
Grand Total	8	29	37

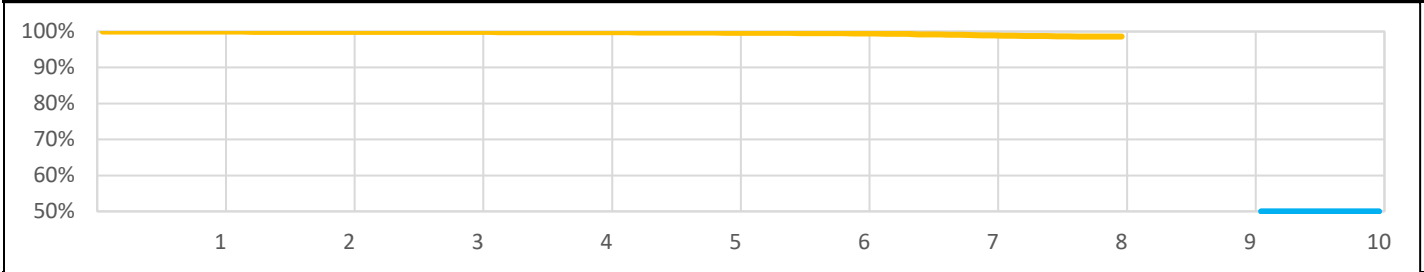
References cited in table above [\(link\)](#)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

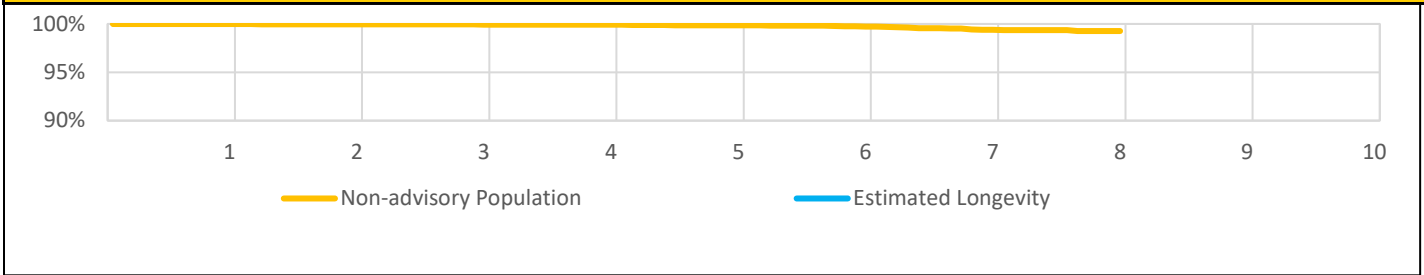
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	49,000	US Normal Battery Depletions:	75
US Approval Date:	April 2014	US Malfunctions:	72
US Estimated Active Implants:	40,000	Without Compromised Therapy:	56
		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%	99.8%	99.7%	99.5%	98.9%	98.6%	98.6%	--
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.4%	99.3%	99.3%	--
49,000	Effective Sample Size		41365	34602	28014	22045	15473	8770	3613	424	215	--

@ 97 months

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

Worldwide Confirmed Malfunctions		93	
Worldwide Distribution		80,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	4	1	5
Low-voltage capacitor (69)	0	22	22
High voltage capacitor (75)	8	0	8
Battery (53)	3	31	34
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	6	10	16
Grand Total	21	72	93

References cited in table above [\(link\)](#)

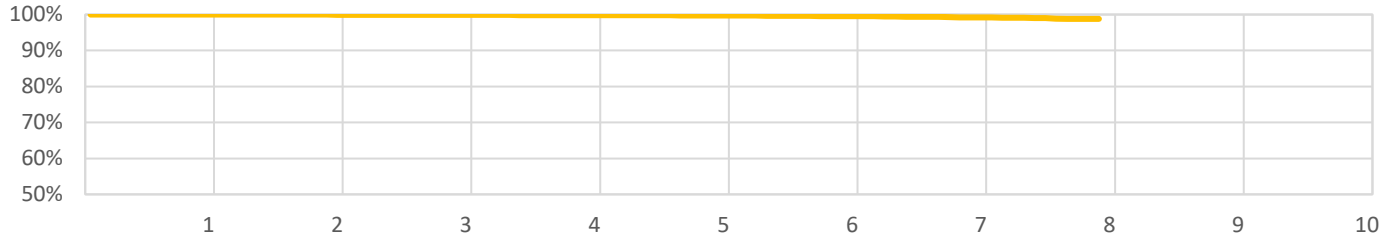
DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

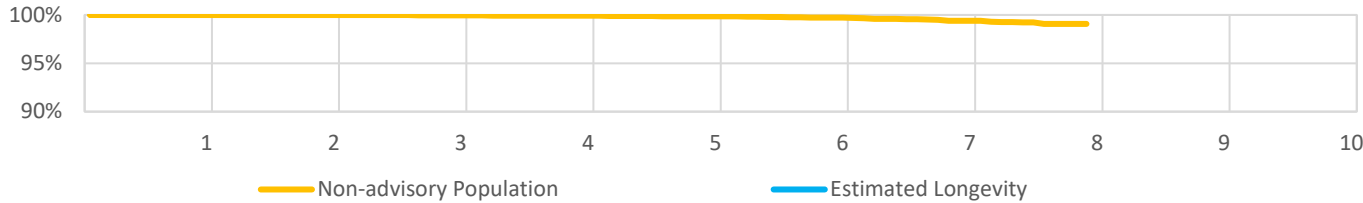
US Summary

US Registered Implants:	38,000	US Normal Battery Depletions:	36
US Approval Date:	April 2014	US Malfunctions:	67
US Estimated Active Implants:	31,000	Without Compromised Therapy:	61
		With Compromised Therapy:	6

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%	--	--
Registered Implants:	Malfunctions Only		100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	99.1%	--	--
38,000	Effective Sample Size		32807	27989	23348	18673	13530	8076	3666	396	--	--

@ 96 months

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

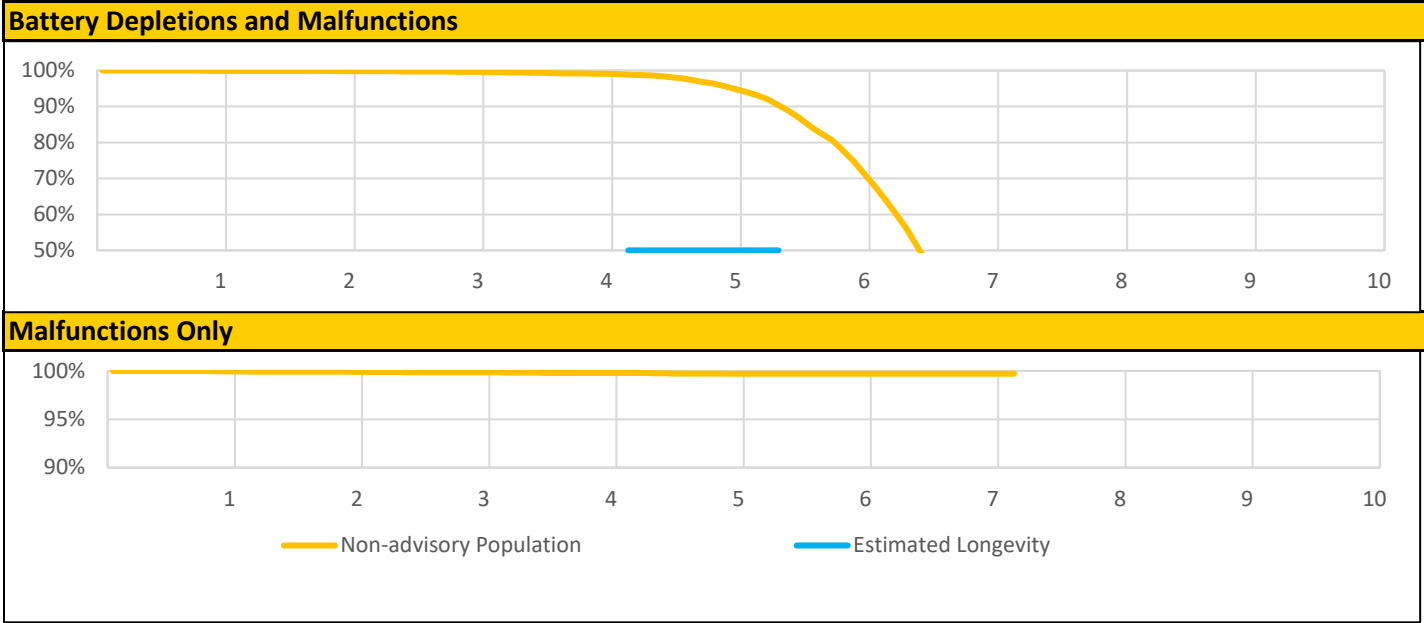
Worldwide Confirmed Malfunctions		106	
Worldwide Distribution		72,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	1	1
High voltage circuit component (62)	0	2	2
Integrated circuit (63)	0	2	2
Low-voltage capacitor (69)	1	37	38
Battery (53)	6	34	40
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	6	8	14
Grand Total	14	92	106

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:	1,956
US Approval Date:	April 2014	US Malfunctions:	19
US Estimated Active Implants:	6,000	Without Compromised Therapy:	16
		With Compromised Therapy:	3



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%	95.6%	74.8%	26.6%	17.7%	--	--
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		9275	7785	6402	5099	3758	2041	455	220	--	--

@ 87 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

Worldwide Confirmed Malfunctions		30	
Worldwide Distribution		32,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	12	12
High voltage capacitor (75)	3	0	3
Integrated circuit (63)	0	2	2
Low-voltage capacitors (47)	1	0	1
Battery (53)	0	3	3
Low-voltage capacitor (69)	0	1	1
Other			
Non-patterned, other	3	5	8
Grand Total	7	23	30

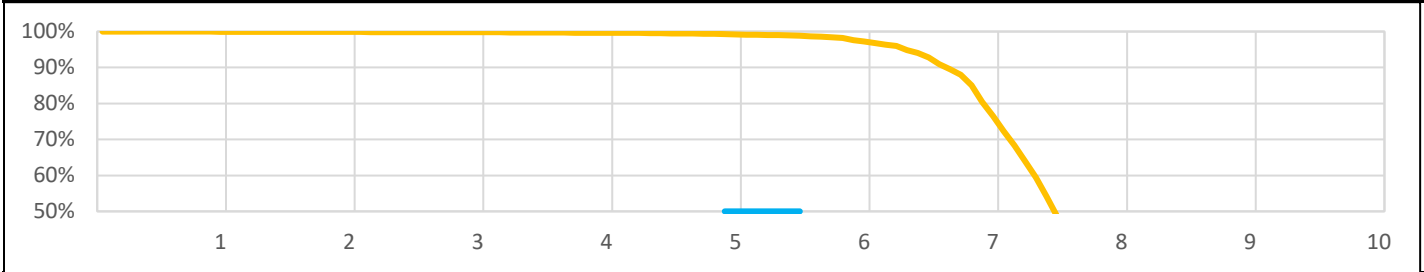
References cited in table above [\(link\)](#)

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

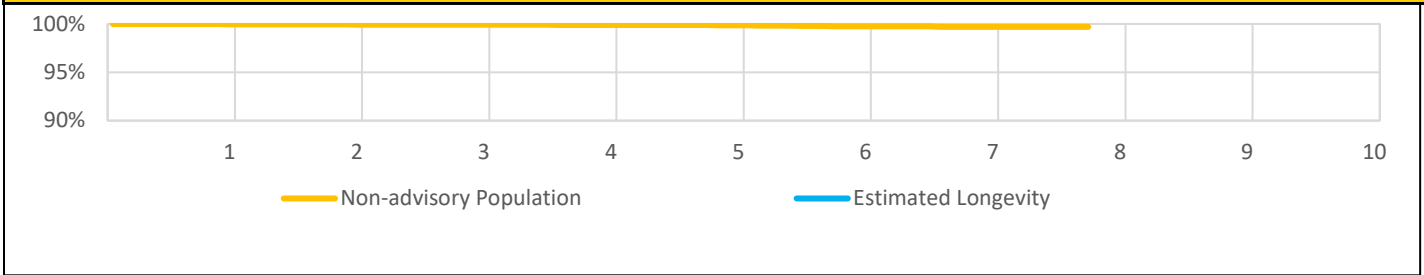
Models: D000/D001/D010/D011/D020/D021

US Summary			
US Registered Implants:	9,000	US Normal Battery Depletions:	1,126
US Approval Date:	April 2014	US Malfunctions:	13
US Estimated Active Implants:	6,000	Without Compromised Therapy:	12
		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%	99.2%	97.6%	80.4%	26.2%	--	--
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	--	--
	9,000 Effective Sample Size		8052	6915	5874	4829	3716	2633	1484	277	--	--

@ 95 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

Worldwide Confirmed Malfunctions		29	
Worldwide Distribution		34,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	7	7
High voltage capacitor (75)	6	0	6
Low-voltage capacitor (69)	0	3	3
Battery (53)	1	4	5
Software			
Memory errors (51)	1	2	3
Other			
Non-patterned, other	0	3	3
Grand Total	8	21	29

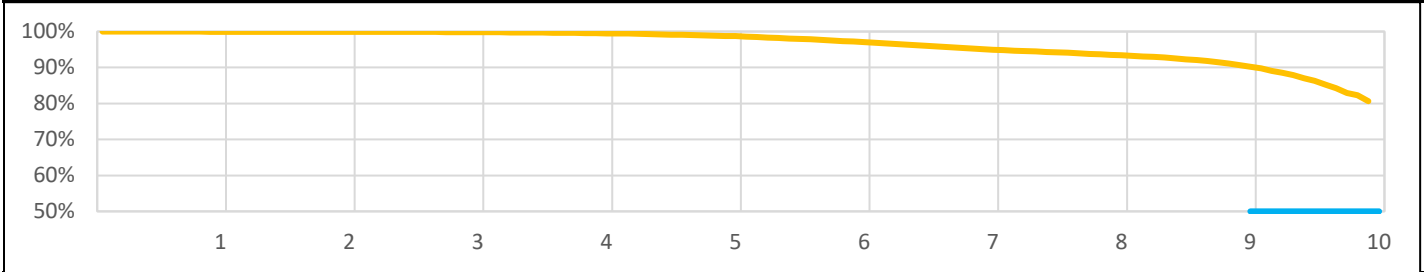
References cited in table above [\(link\)](#)

INCEPTA/ENERGEN/PUNCTUA ICD DR

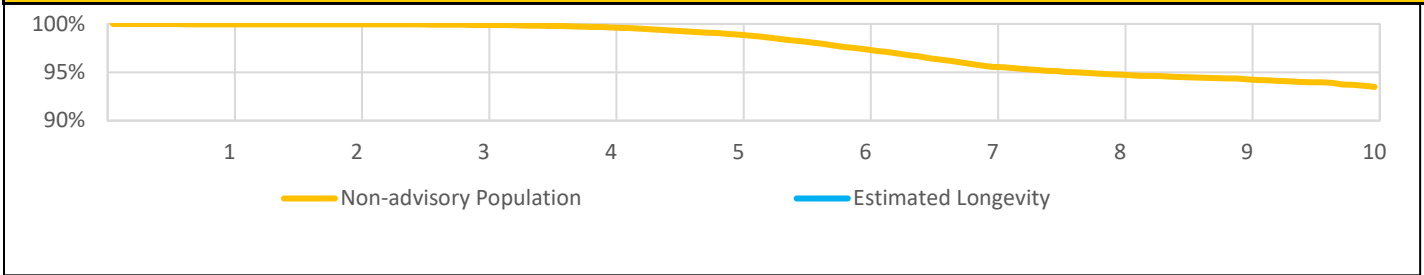
Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

US Summary			
US Registered Implants:	47,000	US Normal Battery Depletions:	1,591
US Approval Date:	November 2011	US Malfunctions:	1,279
US Estimated Active Implants:	26,000	Without Compromised Therapy:	1,245
		With Compromised Therapy:	34

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability												
		Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions		99.9%	99.9%	99.8%	99.6%	98.8%	97.2%	95.1%	93.5%	90.7%	80.6%
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.7%	99.0%	97.5%	95.7%	94.8%	94.3%	93.6%
	47,000 Effective Sample Size		41224	36536	32288	28413	24881	21513	18347	15152	9181	3401

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

Worldwide Confirmed Malfunctions	1,987
Worldwide Distribution	72,000

	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)	5	7	12
Battery (53)	14	90	104
Low-voltage capacitor (54)	14	1776	1790
High voltage circuit (58)	0	1	1
Low-voltage capacitor (69)	0	33	33
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	10	17	27
Grand Total	50	1937	1987

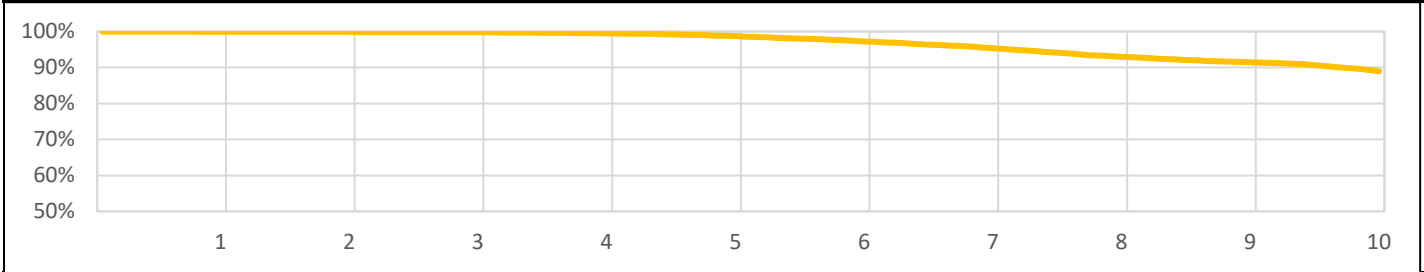
References cited in table above [\(link\)](#)

INCEPTA/ENERGEN/PUNCTUA ICD VR

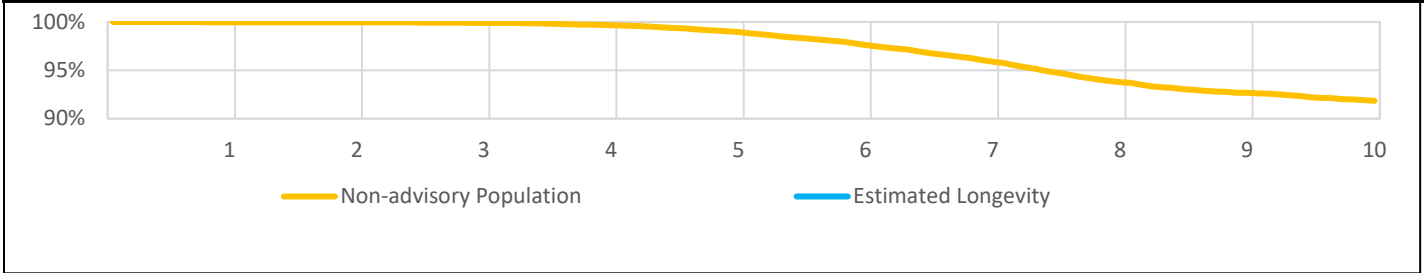
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	371
US Approval Date:	November 2011	US Malfunctions:	1,280
US Estimated Active Implants:	24,000	Without Compromised Therapy:	1,240
		With Compromised Therapy:	40

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%	95.6%	93.1%	91.5%	89.3%
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.7%	99.0%	97.8%	96.1%	93.9%	92.7%	91.9%
	39,000 Effective Sample Size		34701	30726	27149	23901	20912	18142	15462	12567	7566	2938

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

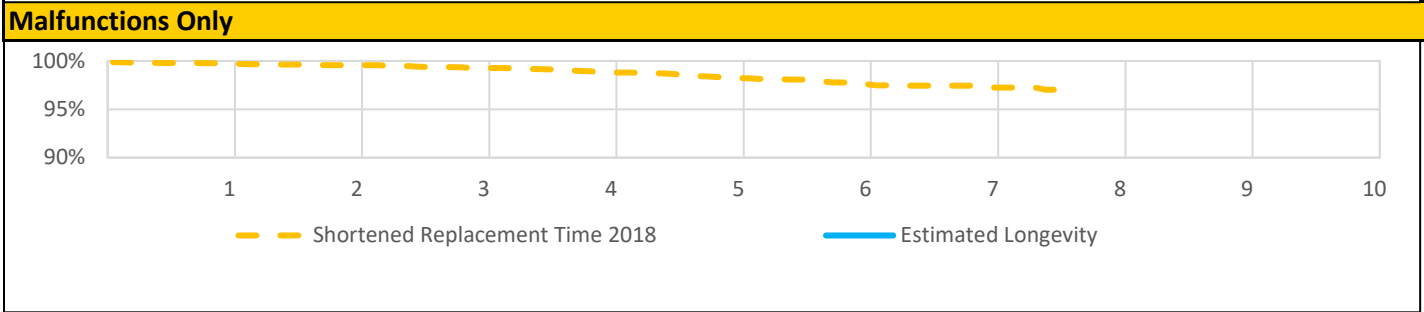
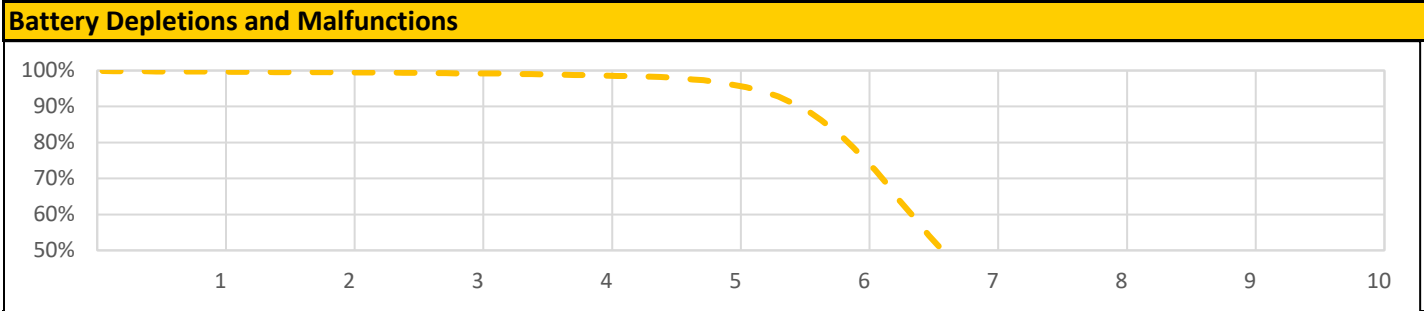
Worldwide Confirmed Malfunctions		2,161	
Worldwide Distribution		68,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	4	1	5
Integrated circuit (50)	5	4	9
Battery (53)	22	143	165
Low-voltage capacitor (54)	16	1905	1921
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	0	18	18
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	1	8	9
Other			
Non-patterned, other	10	17	27
Grand Total	65	2096	2161

References cited in table above [\(link\)](#)

SQ-RX S-ICD

Models: 1010

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	2,912
US Approval Date:	September 2012	US Malfunctions:	114
US Estimated Active Implants:	2,000	Without Compromised Therapy:	48
		With Compromised Therapy:	66



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%	35.8%	8.8%	--	--
	Malfunctions Only	99.7%	99.5%	99.3%	98.8%	98.3%	97.8%	97.3%	97.0%	--	--
Registered Implants:	Effective Sample Size	6403	5641	4984	4375	3686	2669	1086	215	--	--

@ 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		225	
Worldwide Distribution		11,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Unintended Fuse Activation 2013 (4)	3	0	3
Charge Timeout Alert (61)	1	11	12
Mechanical			
High cathode condition (5)	1	1	2
Shortened replacement time 2018 (55)	69	46	115
Software			
Unintended Battery Depletion Alert (57)	0	10	10
Other			
Telemetry (56)	10	4	14
Non-patterned, other	39	30	69
Grand Total	123	102	225

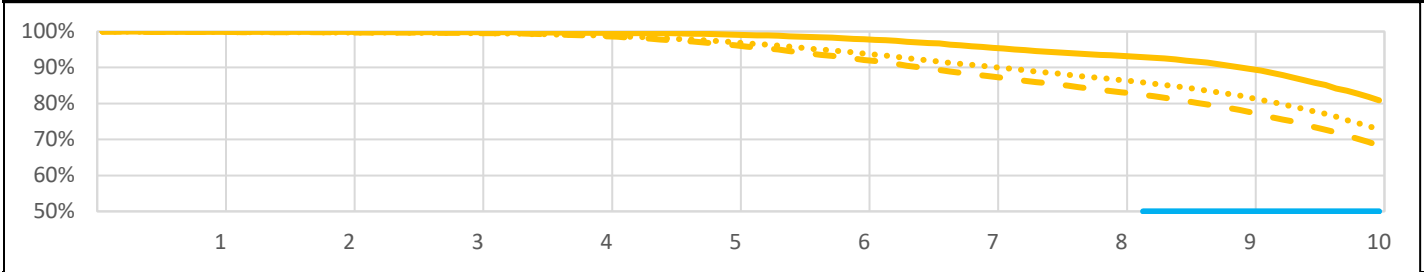
References cited in table above [\(link\)](#)

TELIGEN DR

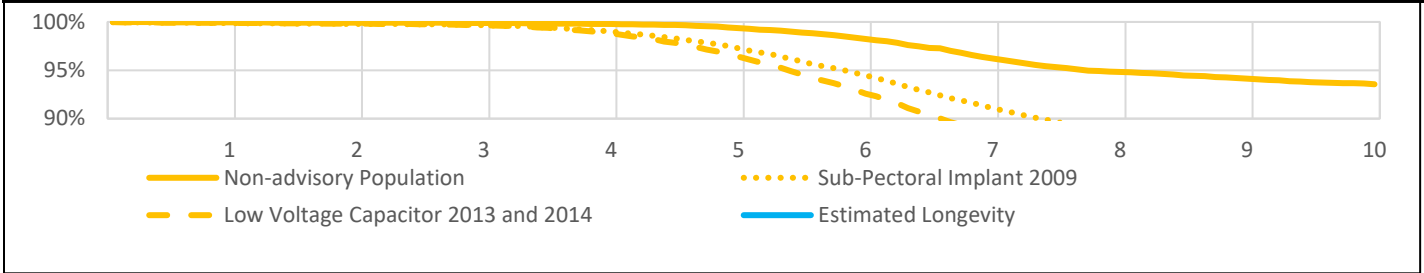
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	11,497
US Approval Date:	March 2008	US Malfunctions:	3,042
US Estimated Active Implants:	16,000	Without Compromised Therapy:	2,877
		With Compromised Therapy:	165

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%	81.8%
	Malfunctions Only		99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.4%	94.9%	94.2%	93.6%
Registered Implants:	Effective Sample Size	30000	26329	23354	20709	18286	16080	13984	11977	10220	8618	6844

TELIGEN DR

Models: E110/E111/F110/F111

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.9%	97.2%	94.2%	90.4%	86.8%	82.2%	73.7%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.7%	91.3%	88.6%	86.6%	85.3%
30000	Effective Sample Size	26630	23511	20787	18251	15859	13509	11366	9504	7807	6051
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.5%	92.5%	87.8%	83.4%	78.2%	69.3%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	98.9%	96.7%	93.0%	88.7%	85.3%	82.9%	81.2%
23000	Effective Sample Size	20616	18223	16099	14124	12170	10248	8518	7041	5714	4366

*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

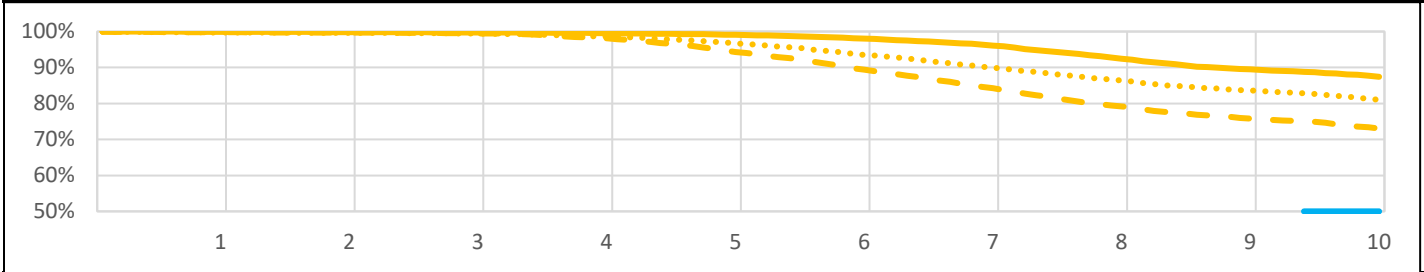
Worldwide Confirmed Malfunctions		4,183	
Worldwide Distribution		91,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	54	2299	2353
Safety Core-electrocautery (42)	1	4	5
High-voltage 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)	13	1298	1311
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	213	3970	4183

TELIGEN VR

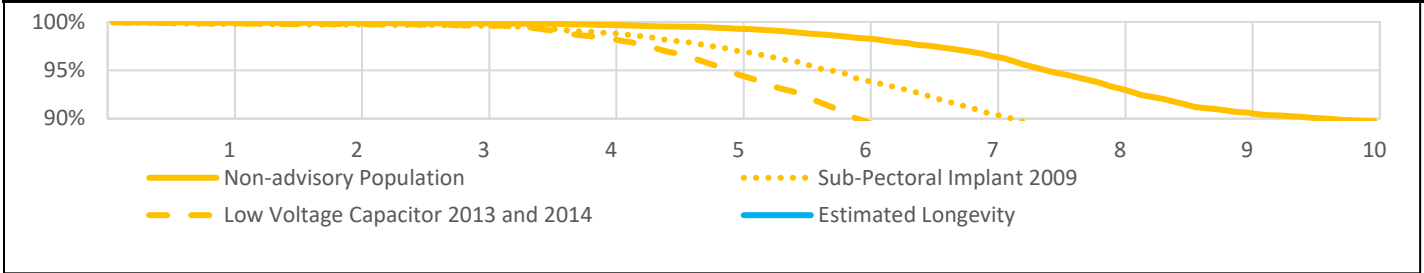
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	2,661
US Approval Date:	March 2008	US Malfunctions:	2,408
US Estimated Active Implants:	13,000	Without Compromised Therapy:	2,273
		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%	99.6%	99.1%	98.1%	96.3%	92.8%	89.6%	87.7%
Registered Implants:	Malfunctions Only		99.9%	99.9%	99.9%	99.7%	99.3%	98.4%	96.7%	93.4%	90.7%	89.8%
18000	Effective Sample Size		16198	14328	12648	11152	9789	8515	7303	6105	5119	4400

TELIGEN VR

Models: E102/E103/F102/F103

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.8%	99.6%	99.5%	98.7%	96.9%	93.8%	90.2%	86.6%	83.7%	81.3%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.6%	98.9%	97.2%	94.2%	90.7%	87.4%	84.8%	83.4%
16000	Effective Sample Size	13607	11991	10568	9239	7984	6794	5701	4749	3988	3353
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.2%	94.8%	89.7%	84.6%	79.5%	76.0%	73.4%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.6%	98.4%	95.0%	90.1%	85.1%	80.2%	77.1%	75.5%
12000	Effective Sample Size	10847	9577	8443	7362	6261	5193	4243	3440	2853	2382

*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		4,079	
Worldwide Distribution		66,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	47	1923	1970
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	422	477
Low-voltage capacitor (54)	12	1425	1437
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	11	29
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	12	25
Grand Total	225	3854	4079

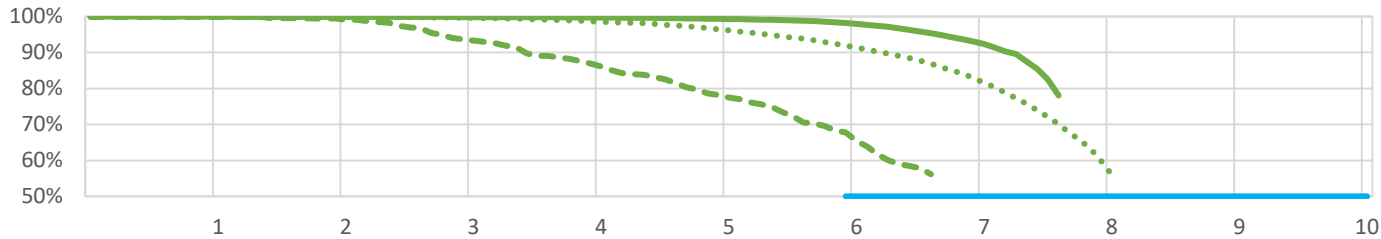
ACCOLADE/PROPONENT/ESSENTIO DR

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

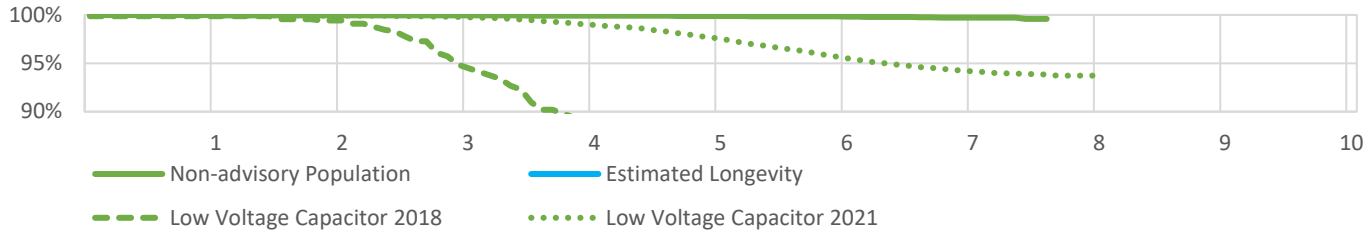
US Summary

US Registered Implants:	270,000	US Normal Battery Depletions:	4,410
US Approval Date:	October 2014	US Malfunctions:	1,542
US Estimated Active Implants:	219,000	Without Compromised Therapy:	1,480
		With Compromised Therapy:	62

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%	98.2%	93.1%	78.1%	--	--
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	--	--
219000	Effective Sample Size		174644	130806	94969	65928	39657	18205	4089	403	--	--

@ 92 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%	87.7%	78.6%	68.3%	56.1%	--	--	--
Registered Implants: 800	Malfunctions Only	99.9%	99.4%	94.8%	88.8%	83.5%	77.2%	71.8%	--	--	--
	Effective Sample Size	713	640	543	449	361	272	203	--	--	--
Low Voltage Capacitor 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	98.7%	96.5%	91.9%	82.9%	59.8%	56.0%	--
Registered Implants: 42000	Malfunctions Only	100.0%	99.9%	99.8%	99.0%	97.7%	95.7%	94.2%	93.7%	93.7%	--
	Effective Sample Size	37246	33201	29505	26056	22598	17755	8675	654	233	--

@ 81 months

@ 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

Worldwide Confirmed Malfunctions 2,545
Worldwide Distribution 596,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	2	4	6
Integrated circuit (63)	16	46	62
Capacitor (67)	0	2	2
Telemetry (68)	2	14	16
Hydrogen induced premature depletion - September 2018 (70)	4	221	225
Hydrogen induced premature depletion - June 2021 (83)	31	1902	1933
High battery impedance (89)	11	60	71
Software			
Memory errors (51)	0	57	57
Mechanical			
Battery cathode (79)	5	4	9
Other			
Non-patterned, other	50	114	164
Grand Total	121	2424	2545

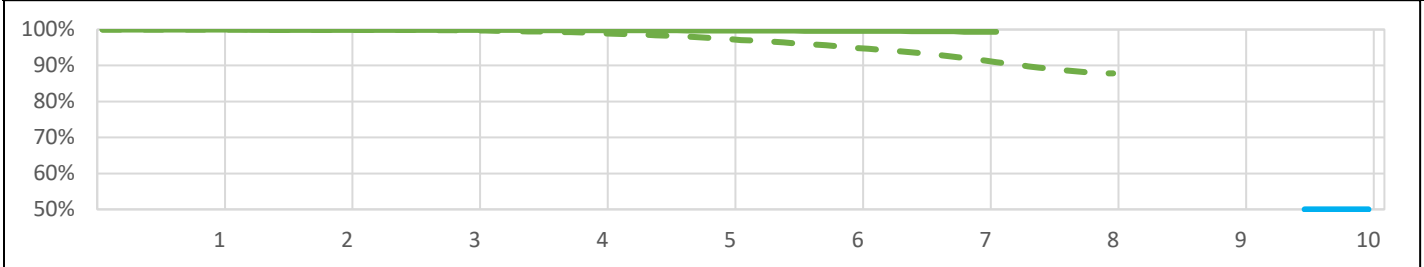
References cited in table above ([link](#))

ACCOLADE/PROPONENT/ESSENTIO EL DR

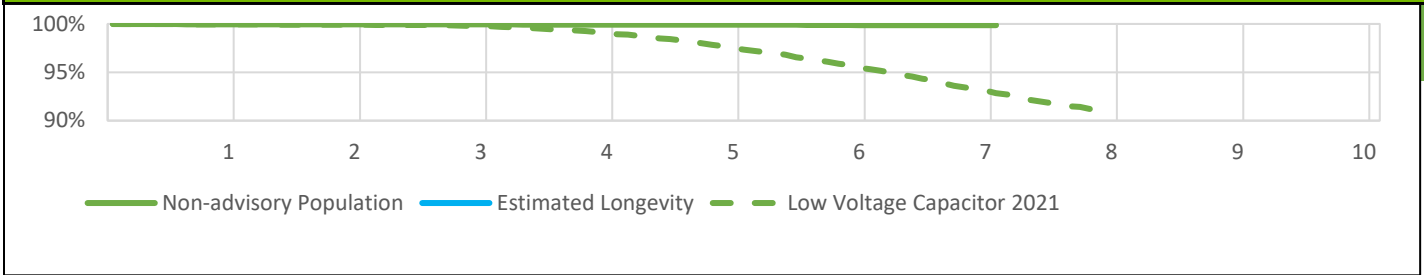
Models: L121/L131/L221/L231/L321/L331

US Summary			
US Registered Implants:	162,000	US Normal Battery Depletions:	256
US Approval Date:	October 2014	US Malfunctions:	721
US Estimated Active Implants:	143,000	Without Compromised Therapy:	712
		With Compromised Therapy:	9

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.4%	99.4%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--
117,000	Effective Sample Size	104105	71976	47883	30311	16474	6166	656	244	--	--

@ 86 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%	94.8%	91.4%	87.8%	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.0%	97.5%	95.5%	93.1%	91.0%	--	--
17,000	Effective Sample Size	14978	13322	11847	10461	9065	7063	3434	312	--	--

@ 96 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	1,588
Worldwide Distribution	390,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	10	10
Integrated circuit (63)	3	29	32
Telemetry (68)	1	13	14
Hydrogen induced premature depletion - September 2018 (70)	3	120	123
Hydrogen induced premature depletion - June 2021 (83)	8	1305	1313
High battery impedance (89)	1	4	5
Software			
Memory errors (51)	0	51	51
Mechanical			
Battery cathode (79)	2	0	2
Other			
Non-patterned, other	5	33	38
Grand Total	23	1565	1588

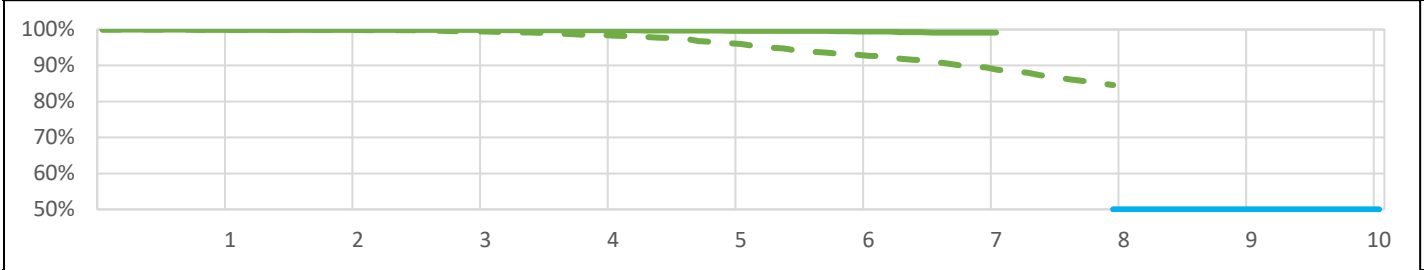
References cited in table above ([link](#))

ACCOLADE/PROPONENT/ESSENTIO SR

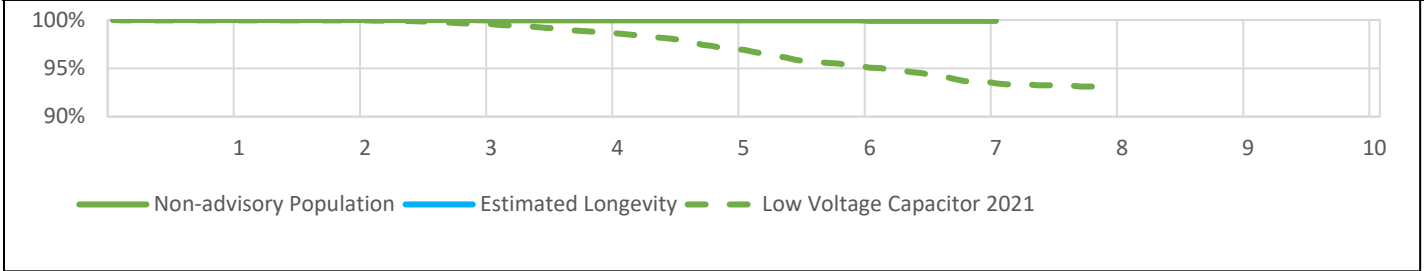
Models: L100/L110/L200/L210/L300/L310

US Summary			
US Registered Implants:	50,000	US Normal Battery Depletions:	330
US Approval Date:	October 2014	US Malfunctions:	431
US Estimated Active Implants:	36,000	Without Compromised Therapy:	421
		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		99.9%	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	99.1%	--	--
Registered Implants:	Malfunctions Only		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	--	--
	33,000 Effective Sample Size		28289	21339	15391	10459	5845	2203	377	285	--	--

@ 85 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%	96.2%	93.0%	89.5%	84.6%	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.6%	98.7%	97.0%	95.3%	93.6%	93.1%	--	--
12,000	Effective Sample Size	10313	9156	8122	7156	6177	4782	2182	221	--	--

@ 96 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	1,038
Worldwide Distribution	214,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (63)	5	5	10
Telemetry (68)	0	4	4
Hydrogen induced premature depletion - September 2018 (70)	3	64	67
Hydrogen induced premature depletion - June 2021 (83)	25	894	919
High battery impedance (89)	0	1	1
Software			
Memory errors (51)	0	13	13
Other			
Non-patterned, other	5	15	20
Grand Total	39	999	1038

References cited in table above [\(link\)](#)

ALTRUA 2 DR

Models: S702

Worldwide Confirmed Malfunctions	11
Worldwide Distribution	12,000

	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	1	1
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	10	10
Grand Total	0	11	11

References cited in table above [\(link\)](#)

ALTRUA 2 EL DR

Models: S722

Worldwide Confirmed Malfunctions	2
Worldwide Distribution	8,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Hydrogen induced premature depletion - June 2021 (83)	0	1	1
Other			
Non-patterned, other	0	1	1
Grand Total	0	2	2

References cited in table above [\(link\)](#)

ALTRUA 2 SR

Models: S701

Worldwide Confirmed Malfunctions	13
Worldwide Distribution	10,000

	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

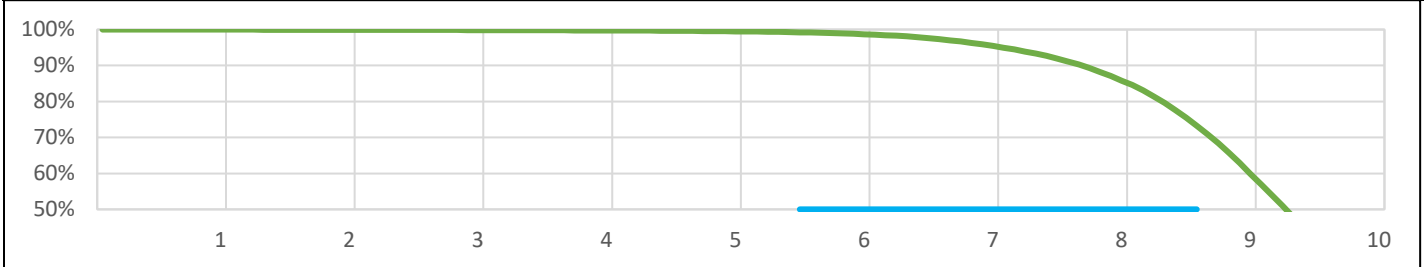
References cited in table above ([link](#))

ADVANTIO/INGENIO/VITALIO/FORMIO DR

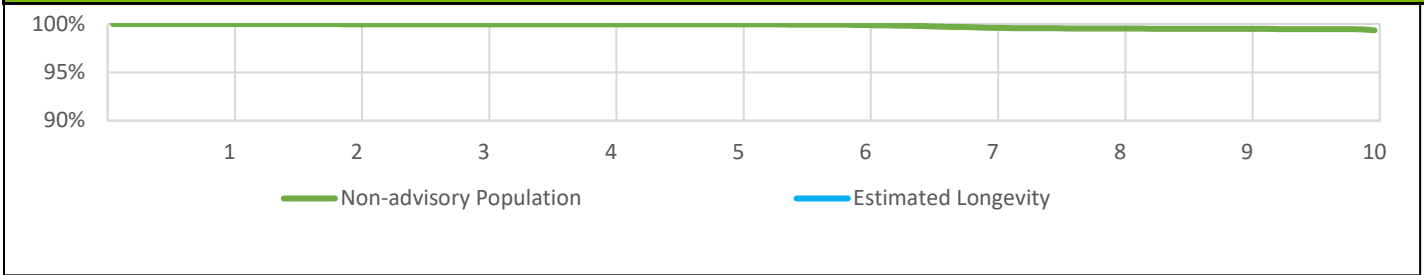
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K283/K286/K288/K289

US Summary			
US Registered Implants:	121,000	US Normal Battery Depletions:	20,991
US Approval Date:	May 2012	US Malfunctions:	293
US Estimated Active Implants:	55,000	Without Compromised Therapy:	278
		With Compromised Therapy:	15

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions		100.0%	99.9%	99.9%	99.7%	99.5%	98.9%	95.9%	87.1%	62.9%	25.9%
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		107339	95759	85390	76115	67672	59969	51861	41118	16613	1884

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	337
Worldwide Distribution	218,000

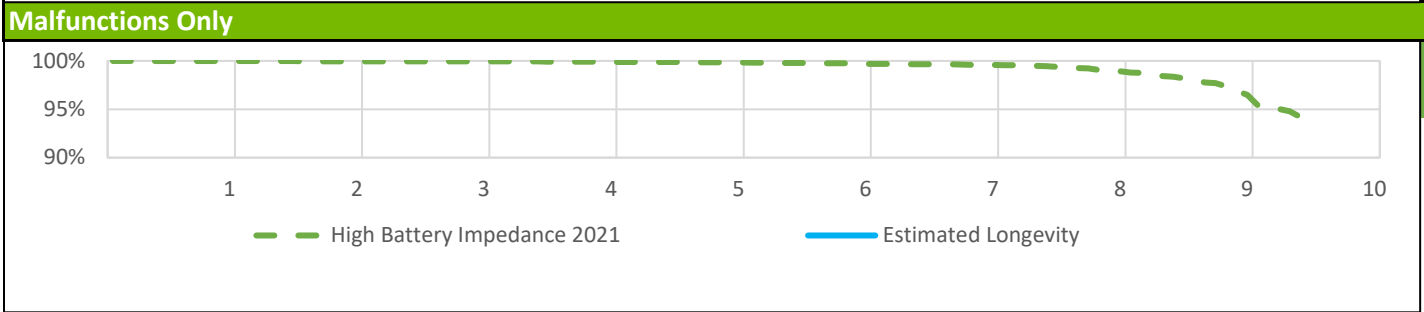
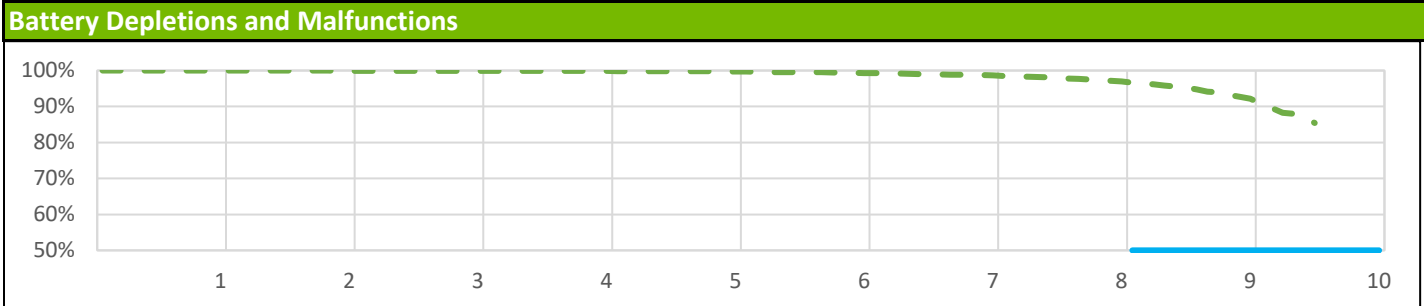
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	7	3	10
Titanium case material (60)	3	0	3
High battery impedance initiating safety mode 2021 (82)	0	1	1
Software			
Memory errors (51)	1	28	29
Other			
Non-patterned, other	13	273	286
Grand Total	24	313	337

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:	169
US Approval Date:	May 2012	US Malfunctions:	115
US Estimated Active Implants:	7,000	Without Compromised Therapy:	113
		With Compromised Therapy:	2



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%	97.1%	92.7%	85.4%
Registered Implants:	Malfunctions Only		100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.0%	96.9%	92.7%
11,000	Effective Sample Size		9674	8587	7639	6792	6040	5331	4584	3544	1048	246

@ 115 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 456
Worldwide Distribution 76,000

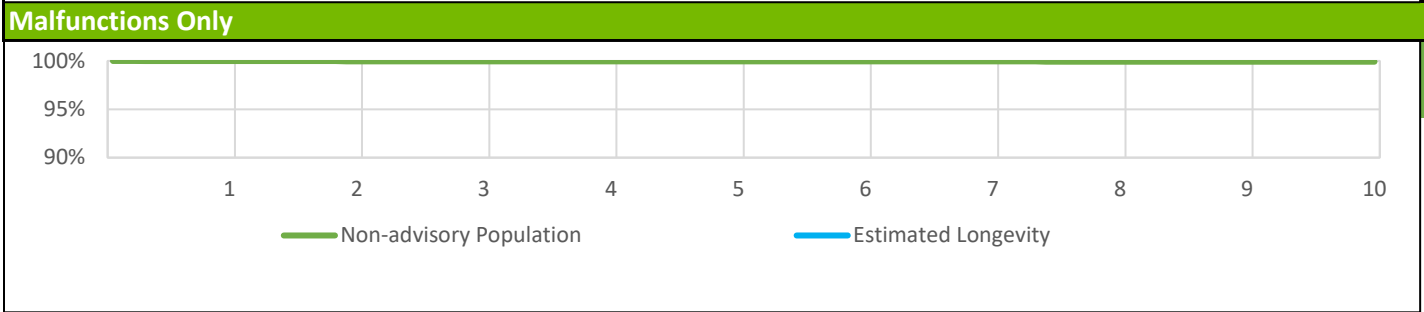
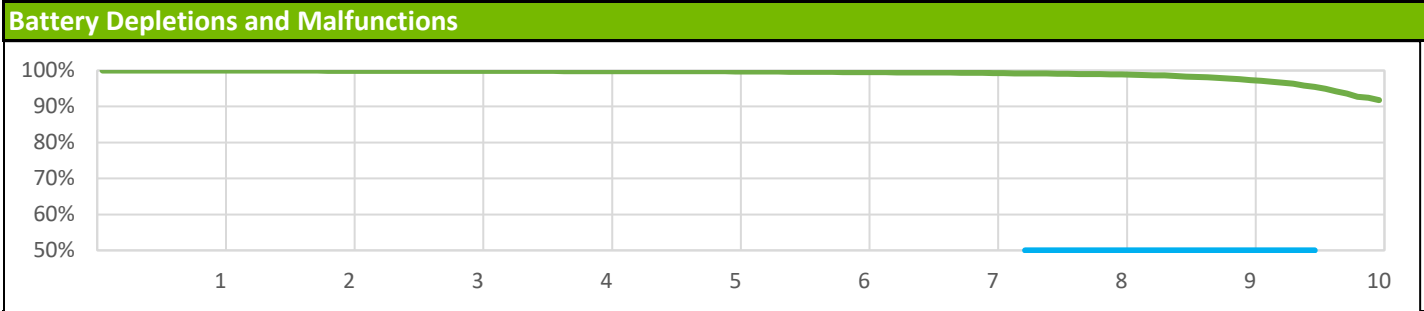
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	5	6
Integrated circuit (50)	2	0	2
Titanium case material (60)	2	0	2
High battery impedance initiating safety mode 2021 (82)	3	154	157
Software			
Memory errors (51)	1	6	7
Respiratory sensor (59)	0	1	1
Other			
Non-patterned, other	6	275	281
Grand Total	15	441	456

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:	482
US Approval Date:	May 2012	US Malfunctions:	14
US Estimated Active Implants:	13,000	Without Compromised Therapy:	13
		With Compromised Therapy:	1



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%
	Effective Sample Size	27,000	22798	20269	18077	16140	14391	12823	11377	9452	5381	1857

ADVANTIO/INGENIO/VITALIO SR

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

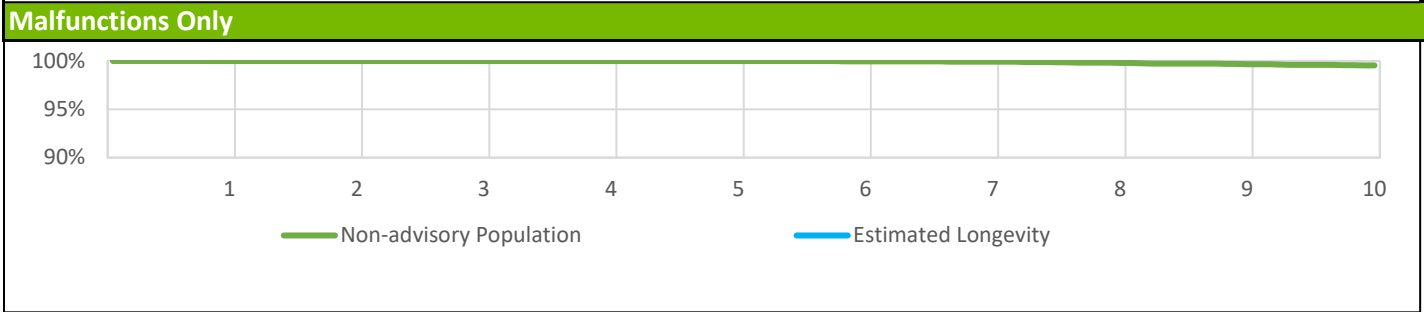
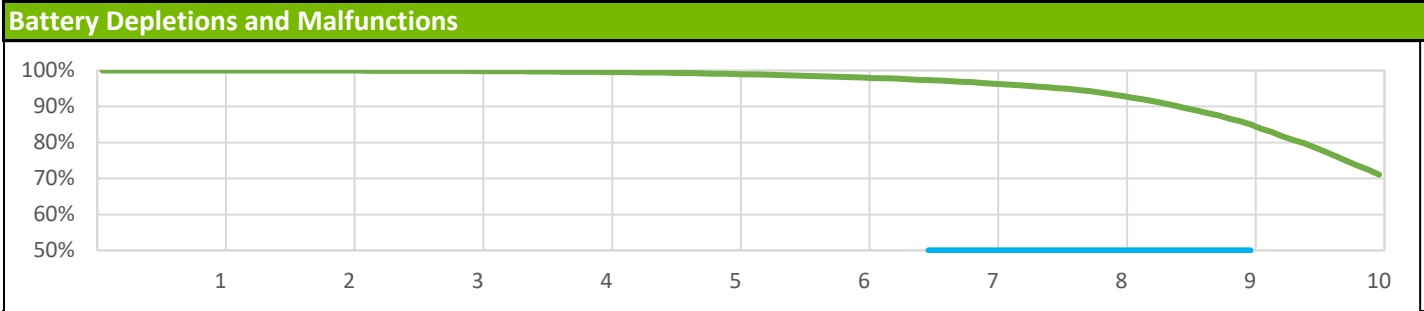
Worldwide Confirmed Malfunctions	29		
Worldwide Distribution	86,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (50)	3	2	5
Titanium case material (60)	1	0	1
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	3	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:	4,658
US Approval Date:	April 2008	US Malfunctions:	43
US Estimated Active Implants:	6,000	Without Compromised Therapy:	39
		With Compromised Therapy:	4



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%	85.9%	72.4%
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	19221	17184	15327	13629	12085	10642	9316	7955	6434	4670

ALTRUA 60 DR

Models: S602

Worldwide Confirmed Malfunctions	76
Worldwide Distribution	56,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Mechanical			
Capacitor array (16)	0	1	1
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	1	1	2
Battery status (49)	1	63	64
Non-patterned, other	3	4	7
Grand Total	6	70	76

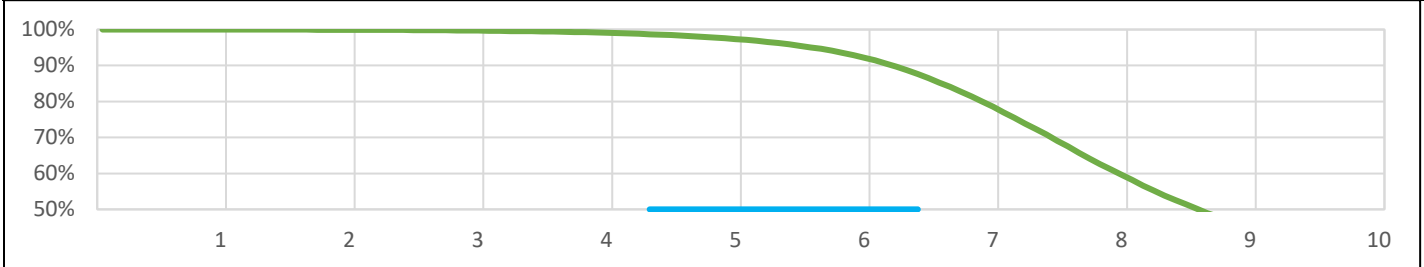
References cited in table above [\(link\)](#)

ALTRUA 60 DR (Downsize)

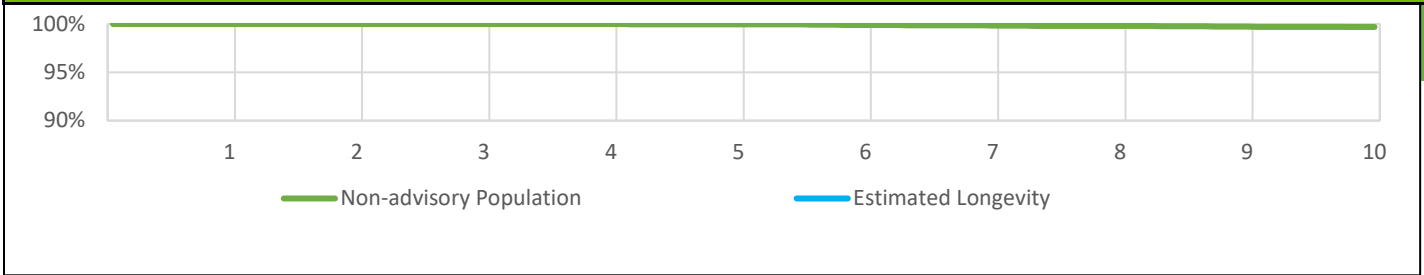
Model: S603

US Summary			
US Registered Implants:	90,000	US Normal Battery Depletions:	26,022
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%	79.9%	61.1%	45.5%	33.4%
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		78558	70264	62750	55836	49143	41763	32037	21320	13692	8481

ALTRUA 60 DR (Downsize)

Models: S603

Worldwide Confirmed Malfunctions		132	
Worldwide Distribution		132,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	7	4	11
Integrated circuit (30)	1	1	2
Mechanical			
Difficulty securing lead (41)	0	1	1
Connector block (39)	0	1	1
Software			
Underestimation of battery status (34)	0	1	1
Other			
Battery depletion (26)	1	3	4
Battery status (49)	0	101	101
Magnet response (21)	0	2	2
Non-patterned, other	4	5	9
Grand Total	13	119	132

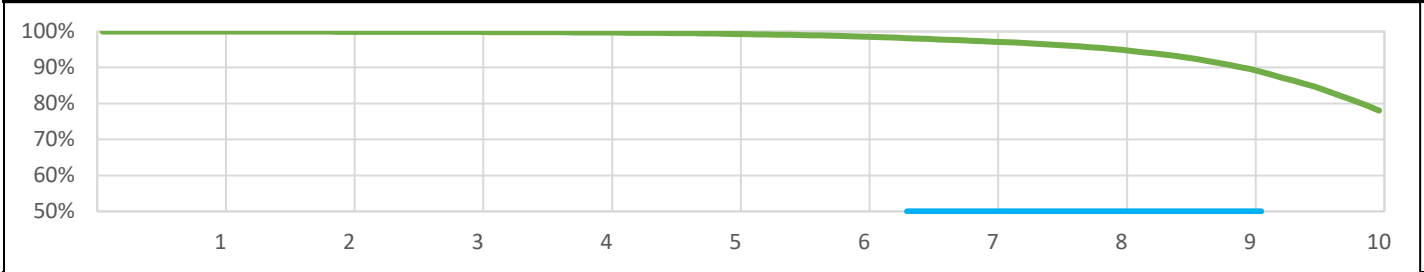
References cited in table above [\(link\)](#)

ALTRUA 60 EL DR

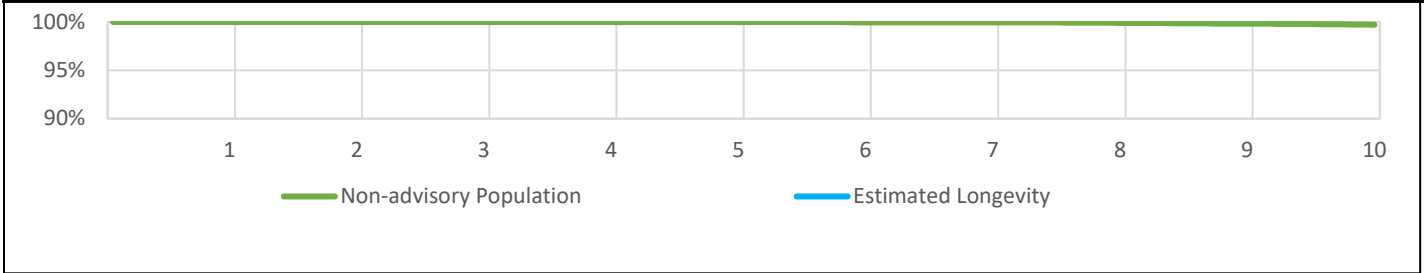
Model: S606

US Summary			
US Registered Implants:	59,000	US Normal Battery Depletions:	9,808
US Approval Date:	April 2008	US Malfunctions:	85
US Estimated Active Implants:	22,000	Without Compromised Therapy:	79
		With Compromised Therapy:	6

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.4%	98.6%	97.3%	95.2%	90.1%	79.3%
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	52505	46924	41880	37332	33241	29397	25846	22518	18977	14630

ALTRUA 60 EL DR

Models: S606

Worldwide Confirmed Malfunctions	121
Worldwide Distribution	90,000

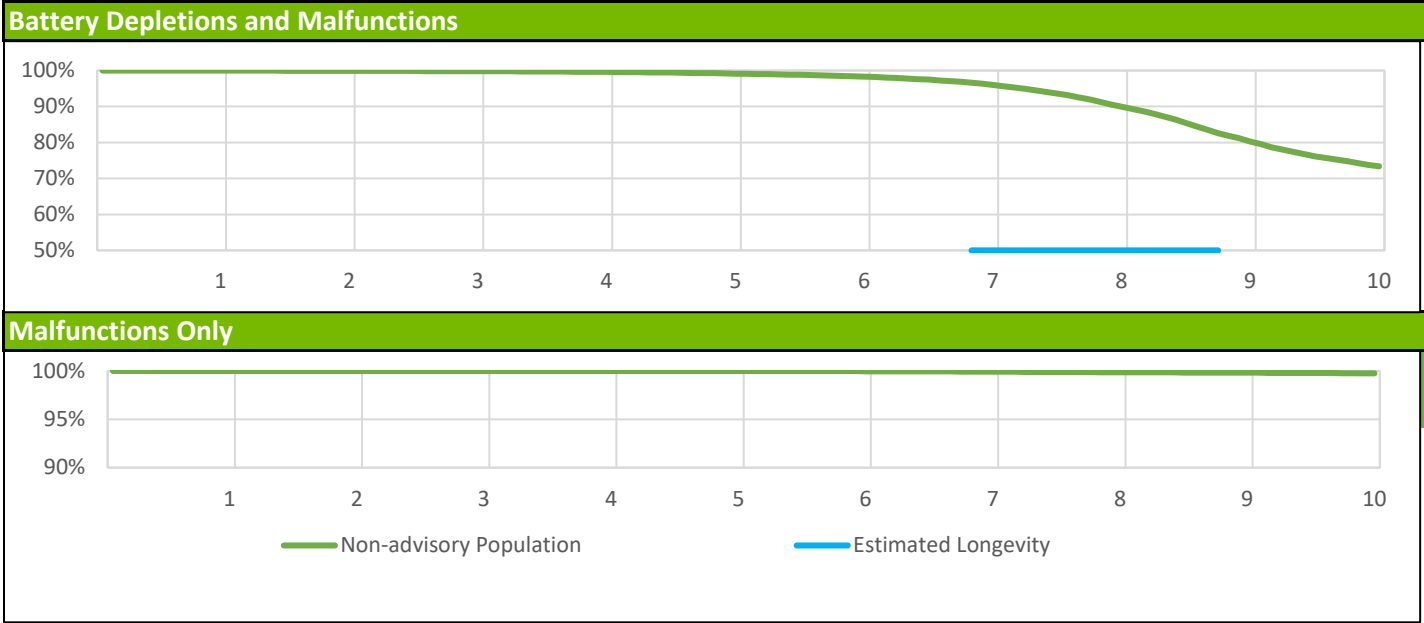
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	3	3
Integrated circuit (17)	0	1	1
Mechanical			
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	2	0	2
Battery status (49)	2	106	108
Magnet rate (44)	0	1	1
Non-patterned, other	2	3	5
Grand Total	7	114	121

References cited in table above [\(link\)](#)

ALTRUA 60 SR

Model: S601

US Summary			
US Registered Implants:	32,000	US Normal Battery Depletions:	3,763
US Approval Date:	April 2008	US Malfunctions:	30
US Estimated Active Implants:	8,000	Without Compromised Therapy:	27
		With Compromised Therapy:	3



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.6%	99.2%	98.4%	96.3%	90.6%	81.1%	73.8%
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	26266	23016	20374	18124	16138	14297	12545	10524	8327	6589

ALTRUA 60 SR

Models: S601

Worldwide Confirmed Malfunctions	52
Worldwide Distribution	68,000

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	2	0	2
Other			
Battery depletion (26)	1	0	1
Battery status (49)	1	42	43
Non-patterned, other	2	1	3
Grand Total	8	44	52

References cited in table above [\(link\)](#)

ALTRUA 50 DR (Downsize)

Models: S502

Worldwide Confirmed Malfunctions	39		
Worldwide Distribution	48,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	1	2	3
Integrated circuit (30)	0	1	1
Other			
Battery depletion (26)	0	2	2
Battery status (49)	0	31	31
Non-patterned, other	1	1	2
Grand Total	2	37	39

References cited in table above [\(link\)](#)

ALTRUA 50 SR

Models: S501

Worldwide Confirmed Malfunctions	16
Worldwide Distribution	25,000

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

References cited in table above [\(link\)](#)

ALTRUA 50 DDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	13
Worldwide Distribution	12,000

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

References cited in table above ([link](#))

ALTRUA 50 SSI

Models: S508

Worldwide Confirmed Malfunctions	5
Worldwide Distribution	6,000

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

References cited in table above [\(link\)](#)

ALTRUA 50 VDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	7		
Worldwide Distribution	6,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery status (49)	0	7	7
Grand Total	0	7	7

References cited in table above [\(link\)](#)

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. **Safety 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	134,000	1	2	7	12	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	129,000	3	4	5	17	0	0
CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	105,000	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	82,000	0	2	6	6	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	59,000	1	4	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	72,000	1	0	3	4	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	80,000	0	3	2	3	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	34,000	1	0	4	2	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	32,000	2	0	0	3	0	0
S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	127,000	1	0	5	104	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	390,000	7	3	10	18	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	596,000	6	0	14	27	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	214,000	2	1	7	18	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	72000	92	269	25	862	5516
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158	75000	1636	463	104	1256	14124
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	9069	488	817	942	19934
COGNIS N118/N119/N120/P106/P107/P108	75000	15782	444	2109	1666	40116

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	51000	514	1148	93	381	7475
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	10000	1090	227	440	78	4613
CONTAK RENEWAL TR H120/H125	19000	4324	210	67	208	12057

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	56000	968	702	3736	1136	5950
SQ-RX S-ICD 1010	8000	2912	229	114	251	1971

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	45000	24	960	13	418	2223
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	25000	12	598	11	246	1159
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	49000	75	2327	72	691	6283
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	38000	35	2102	67	533	4652
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	11000	1956	468	19	144	2075
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	9000	1126	489	13	139	1696
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	367	2529	1285	573	10919
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	1585	2874	1283	718	14014

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	2658	2071	2416	668	17157
TELIGEN DR E110/E111/F110/F111	66000	11490	3020	3053	1155	31318

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/PROONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	161000	255	4495	721	835	12797
ACCOLADE/PROONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	270000	4406	6903	1550	1362	36526
ACCOLADE/PROONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	50000	329	1696	432	243	10914
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	169	489	115	58	3328
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	20987	4095	295	571	39910
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	482	737	15	110	12042

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	3759	495	30	144	18786
ALTRUA 60 DR (Downsize) S603	90000	26016	1262	103	470	41274
ALTRUA 60 DR S602	22000	4657	493	43	163	10437
ALTRUA 60 DR EL S606	59000	9804	1485	85	361	25109
ALTRUA 40 SR S401	5000	529	55	2	17	3048
ALTRUA 40 DR (downsize) S403	14000	4066	166	5	63	6940
ALTRUA 40 DR S402	2000	309	33	2	7	976
ALTRUA 40 DR EL S404	5000	745	90	7	35	2606
ALTRUA 20 SR S201/S204	5000	277	47	3	31	3026
ALTRUA 20 DR EL S208	3000	271	51	6	11	1714

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.

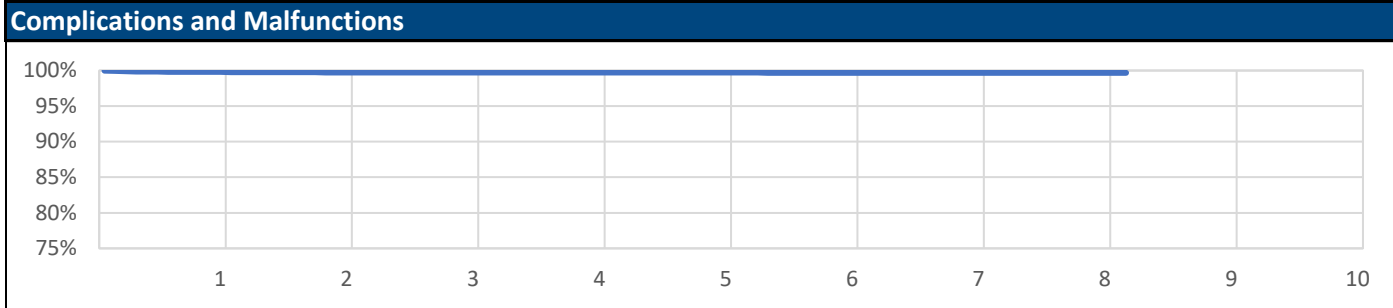
² System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.

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

ACUITY X4 Spiral L

Models: 4677/4678

US Summary			
US Registered Implants:	20,000	US Chronic Complications	47
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	17,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-



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%	99.7%	99.7%	99.7%	99.7%	99.7%	--
Registered Implants: 20000	Effective Sample Size	15652	12171	9222	6720	4256	2242	742	237	206	--

@ 98 months

ACUITY X4 Spiral L

Models: 4677/4678

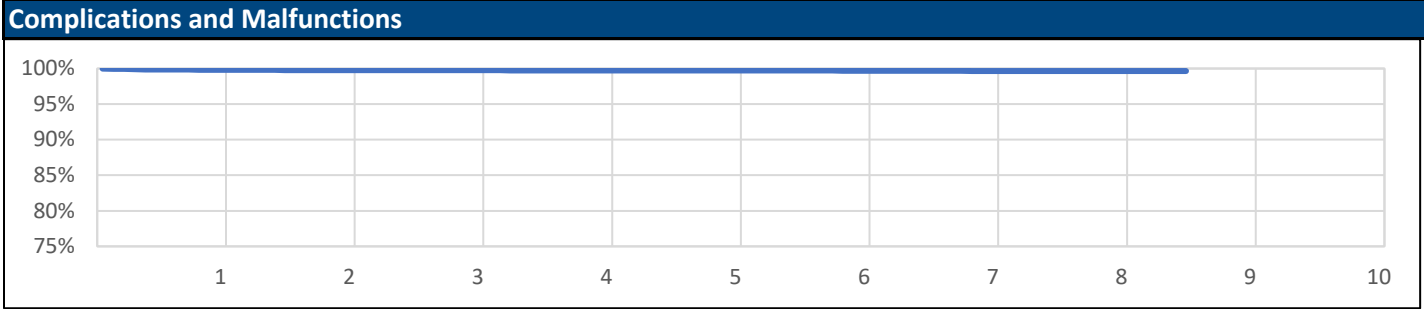
Worldwide Confirmed Malfunctions		2	
Worldwide Distribution		48,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	2	2
Grand Total	0	2	2

References cited in table above [\(link\)](#)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	59,000	US Chronic Complications	128
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	51,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%	99.6%	--
Registered Implants: 59000	Effective Sample Size	45670	34719	25511	17607	10843	5573	1496	338	212	--

@ 102 month

ACUITY X4 Spiral S

Models: 4674/4675

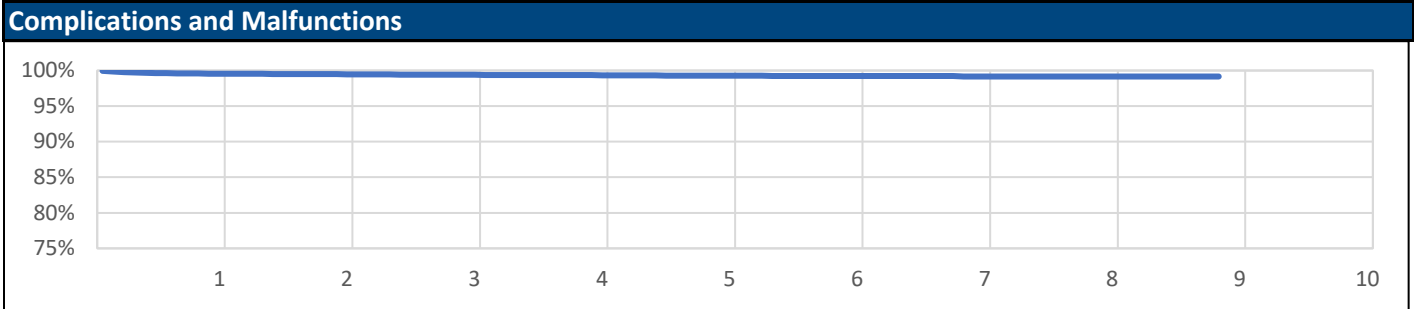
Worldwide Confirmed Malfunctions		1	
Worldwide Distribution		125,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	0	1	1

References cited in table above [\(link\)](#)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	45,000	US Chronic Complications	242
US Approval Date:	February 2016	US Malfunctions:	2
US Estimated Active Implants:	38,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-



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%	99.3%	99.3%	99.2%	99.2%	99.2%	99.2%	--
Registered Implants: 45000	Effective Sample Size	34460	26114	18864	12900	7695	3921	993	360	210	--

@ 106 month

ACUITY X4 Straight

Models: 4671/4672

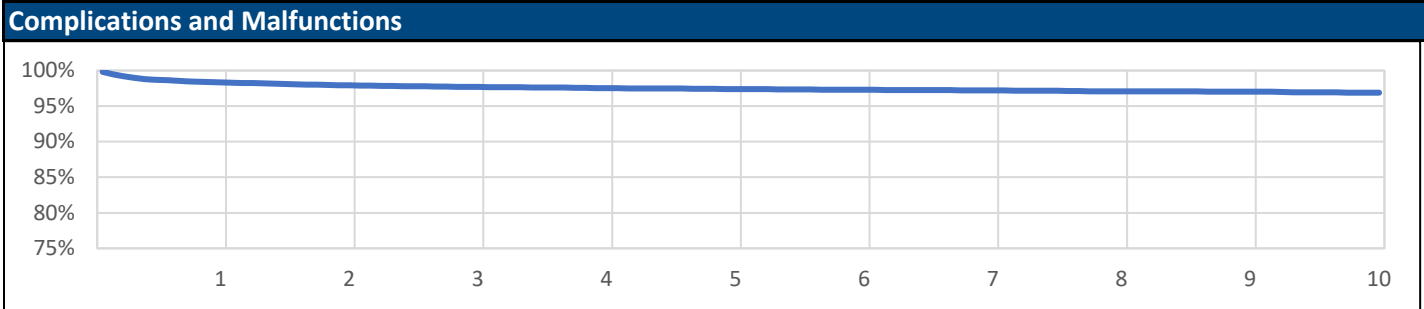
Worldwide Confirmed Malfunctions		4		
Worldwide Distribution		99,000		
	With Compromised Therapy	Without Compromised Therapy	Total	
Other				
Non-patterned, other	0	4	4	
Grand Total	0	4	4	

References cited in table above [\(link\)](#)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	24,000	US Chronic Complications	580
US Approval Date:	May 2008	US Malfunctions:	9
US Estimated Active Implants:	12,000	Without Compromised Therapy:	5
		With Compromised Therapy:	4



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	20056	17819	15852	14099	12468	10984	9634	8143	6492	4803

ACUITY Spiral

Models: 4591/4592/4593

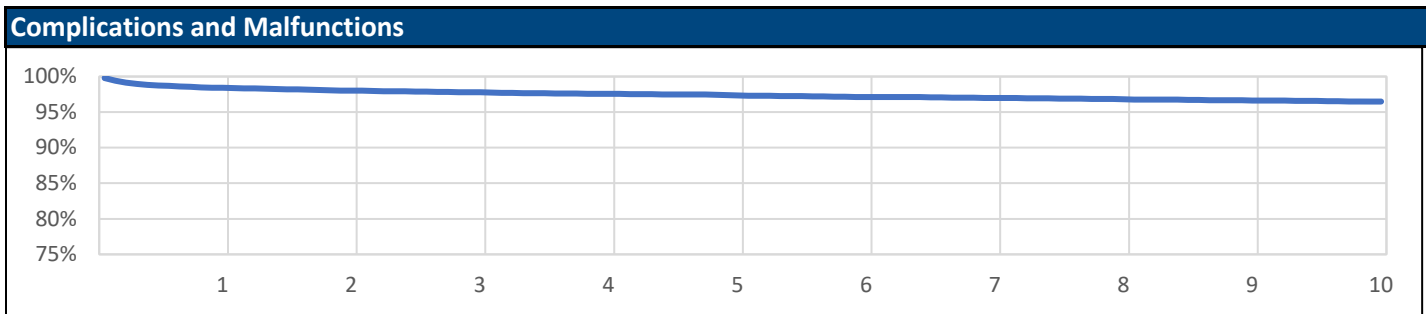
Worldwide Confirmed Malfunctions	9		
Worldwide Distribution	47,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	5	9
Grand Total	4	5	9

References cited in table above [\(link\)](#)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	748
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	12,000	Without Compromised Therapy:	12
		With Compromised Therapy:	21



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.4%	98.0%	97.8%	97.6%	97.4%	97.1%	97.0%	96.8%	96.6%	96.5%
Registered Implants: 29000	Effective Sample Size	24522	21920	19645	17638	15825	14171	12637	11054	9222	7163

ACUITY Steerable

Models: 4554/4555/4556

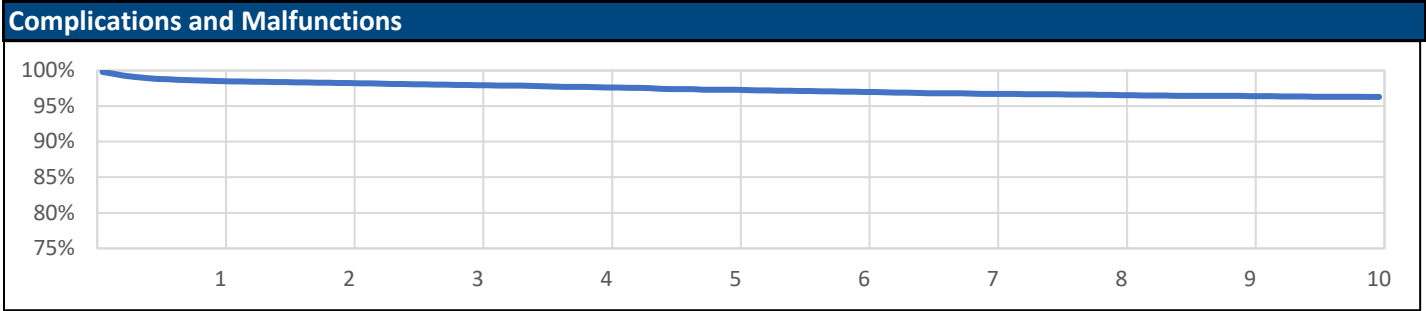
Worldwide Confirmed Malfunctions		57	
Worldwide Distribution		65,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	8	36
Other			
Non-patterned, other	10	11	21
Grand Total	38	19	57

References cited in table above [\(link\)](#)

EASYTRAK 3

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

US Summary			
US Registered Implants:	22,000	US Chronic Complications	570
US Approval Date:	August 2004	US Malfunctions:	32
US Estimated Active Implants:	7,000	Without Compromised Therapy:	9
		With Compromised Therapy:	23



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.5%	98.2%	97.9%	97.6%	97.3%	97.0%	96.7%	96.5%	96.4%	96.3%
Registered Implants: 22000	Effective Sample Size	18406	16435	14715	13158	11744	10487	9363	8240	6999	5653

EASYTRAK 3

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

Worldwide Confirmed Malfunctions	52
Worldwide Distribution	43,000

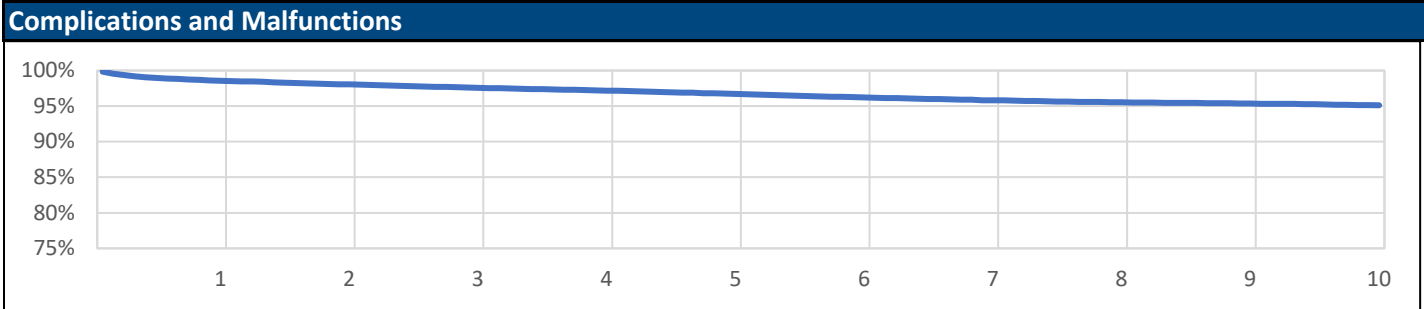
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	6	34
Other			
Non-patterned, other	7	11	18
Grand Total	35	17	52

References cited in table above ([link](#))

EASYTRAK 2

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

US Summary			
US Registered Implants:	97,000	US Chronic Complications	2,992
US Approval Date:	August 2004	US Malfunctions:	408
US Estimated Active Implants:	31,000	Without Compromised Therapy:	149
		With Compromised Therapy:	259



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	98.6%	98.0%	97.6%	97.2%	96.7%	96.2%	95.8%	95.5%	95.4%	95.1%
Registered Implants: 97000	Effective Sample Size	82245	73297	65437	58483	52170	46423	41253	35988	30487	24944

EASYTRAK 2

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

Worldwide Confirmed Malfunctions	551
Worldwide Distribution	180,000

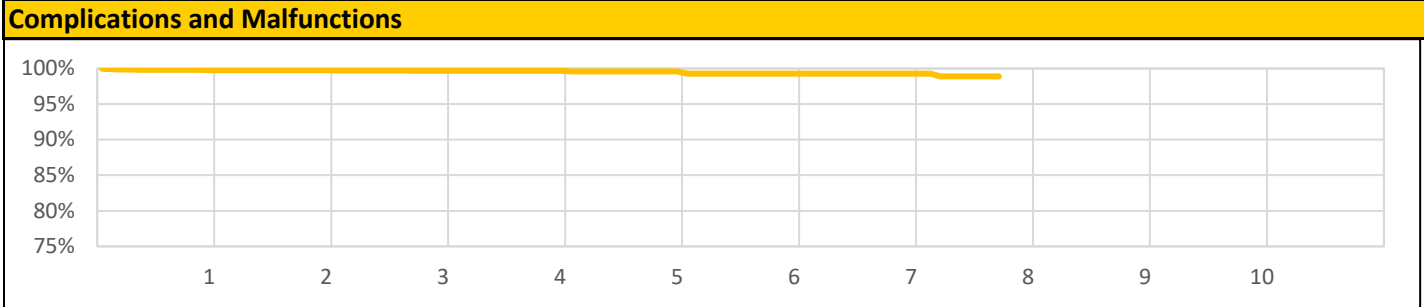
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (25)	329	149	478
Other			
Non-patterned, other	39	34	73
Grand Total	368	183	551

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:	11,000	US Chronic Complications	28
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	10,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-



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%	--	--
Registered Implants: 11000	Effective Sample Size	7712	4999	2683	866	335	298	268	209	--	--

@ 93 months

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

Worldwide Confirmed Malfunctions	5		
Worldwide Distribution	31,000		
	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

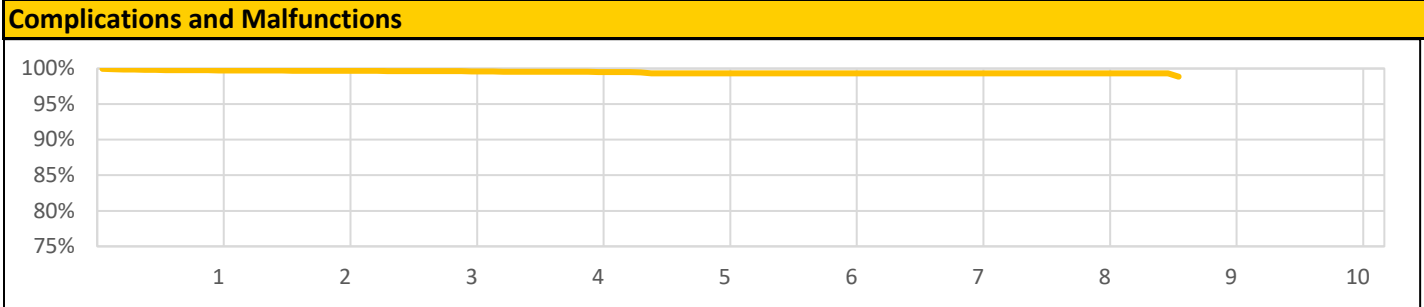
Worldwide Confirmed Malfunctions	0		
Worldwide Distribution	1,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	0	0	0

References cited in table above [\(link\)](#)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Summary			
US Registered Implants:	77,000	US Chronic Complications	214
US Approval Date:	May 2018	US Malfunctions:	16
US Estimated Active Implants:	71,000	Without Compromised Therapy:	2
		With Compromised Therapy:	14



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%	99.3%	99.3%	99.3%	99.3%	98.9%	--
	Effective Sample Size	51977	32667	16474	4886	856	765	687	422	206	--

Registered Implants: 77000

@ 103 months

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

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

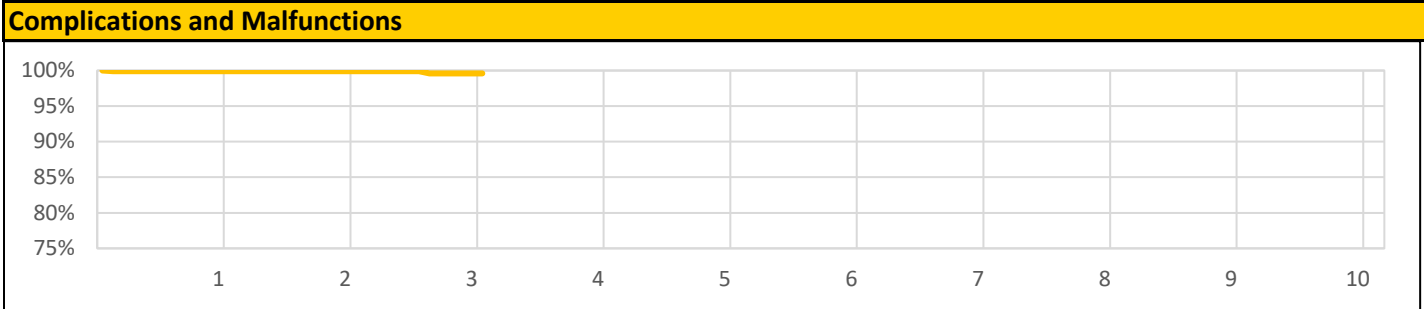
Worldwide Confirmed Malfunctions		83	
Worldwide Distribution		240,000	
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	24	0	24
Other			
Non-patterned, other	51	8	59
Grand Total	75	8	83

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:	-



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.9%	99.9%	99.6%	99.6%	--	--	--	--	--	--
	Effective Sample Size	796	486	232	210	--	--	--	--	--	--

Registered Implants: 1000

@ 37 months

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

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

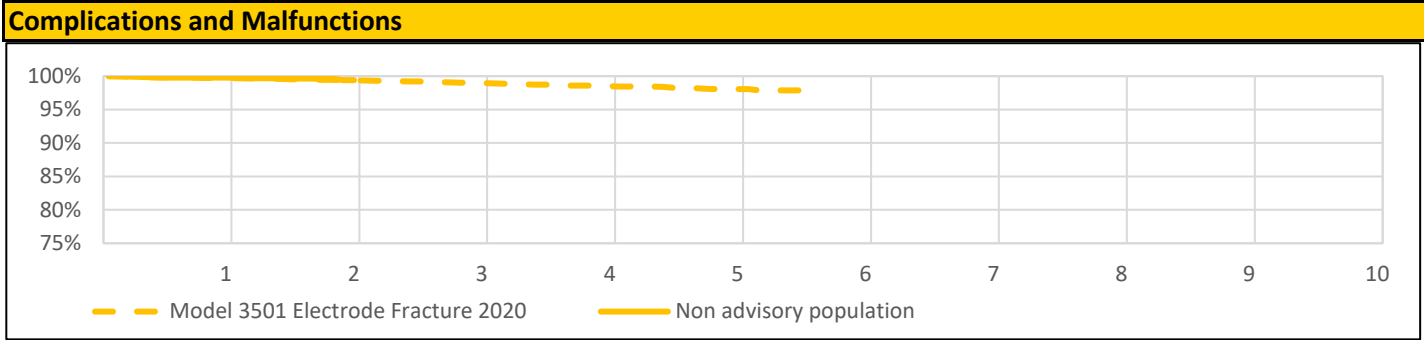
Worldwide Confirmed Malfunctions	1		
Worldwide Distribution	8,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	1	0	1
Grand Total	1	0	1

References cited in table above [\(link\)](#)

EMBLEM S-ICD Electrode

Models: 3501

US Summary			
US Registered Implants:	32,000	US Chronic Complications	174
US Approval Date:	September 2017	US Malfunctions:	68
US Estimated Active Implants:	28,000	Without Compromised Therapy:	4
		With Compromised Therapy:	64



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non advisory population	Complications and Malfunctions	99.8%	99.4%	--	--	--	--	--	--	--	--
Registered Implants: 9000	Effective Sample Size	4887	271	--	--	--	--	--	--	--	--

@ 24 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%	98.5%	98.1%	97.9%	--	--	--	--
Registered Implants: 21000	Effective Sample Size	17551	15535	10286	5595	1584	245	--	--	--	--

@ 66 months

EMBLEM S-ICD Electrode

Models: 3501

Worldwide Confirmed Malfunctions	178
Worldwide Distribution	79,000

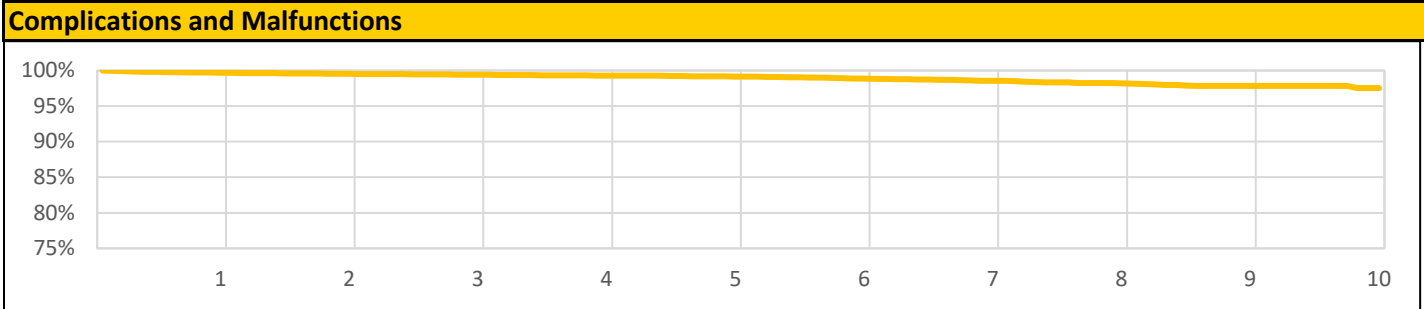
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Model 3501 electrode fracture 2020 (42)	75	1	76
Electrode conductor fracture in or near the pocket (44)	86	9	95
Other			
Non-patterned, other	6	1	7
Grand Total	167	11	178

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	210
US Approval Date:	September 2012	US Malfunctions:	28
US Estimated Active Implants:	18,000	Without Compromised Therapy:	3
		With Compromised Therapy:	25



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%	98.9%	98.6%	98.2%	97.8%	97.5%
Registered Implants: 24000	Effective Sample Size	21028	18697	16640	14786	12906	9360	5519	2542	888	324

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

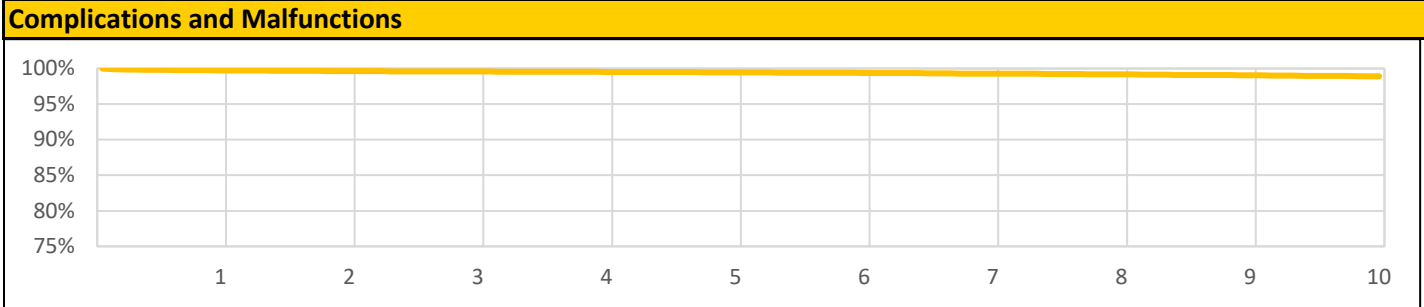
Worldwide Confirmed Malfunctions	78		
Worldwide Distribution	43,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Electrode conductor fracture in or near the pocket (44)	34	4	38
Crimp/Weld/Bond			
Weld fracture (37)	3	0	3
Other			
Non-patterned, other	29	8	37
Grand Total	66	12	78

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	438
US Approval Date:	November 2010	US Malfunctions:	31
US Estimated Active Implants:	56,000	Without Compromised Therapy:	6
		With Compromised Therapy:	25



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	68255	60826	53911	47060	39117	31438	24544	18330	12115	6456

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

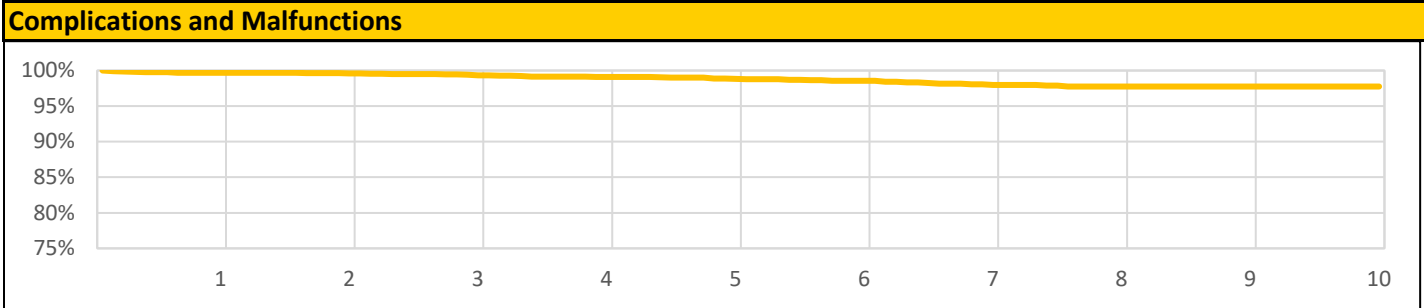
Worldwide Confirmed Malfunctions	67		
Worldwide Distribution	126,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Non-patterned, other	51	13	64
Grand Total	54	13	67

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	40
US Approval Date:	November 2010	US Malfunctions:	2
US Estimated Active Implants:	3,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-



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%	97.8%	97.8%	97.8%
Registered Implants: 3000	Effective Sample Size	2993	2651	2332	2008	1660	1330	1028	760	455	213

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

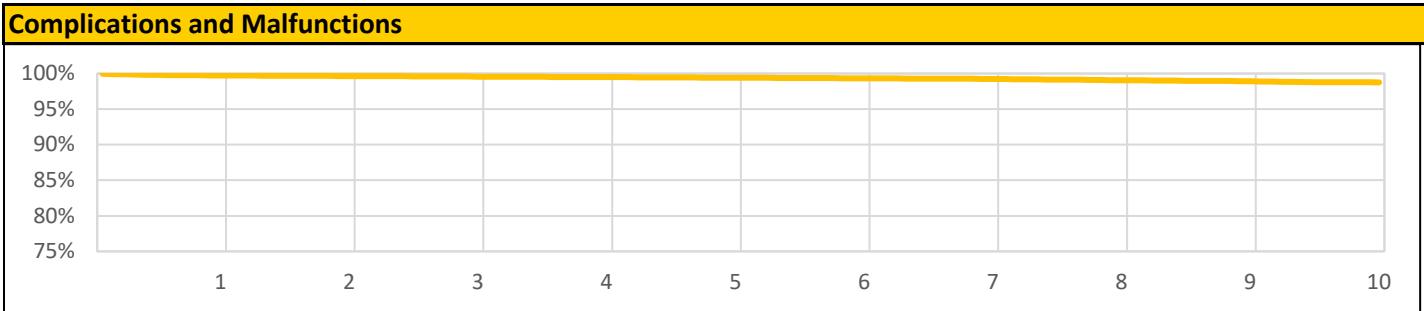
Worldwide Confirmed Malfunctions	3		
Worldwide Distribution	11,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	3	3
Grand Total	0	3	3

References cited in table above [\(link\)](#)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Summary			
US Registered Implants:	120,000	US Chronic Complications	653
US Approval Date:	November 2010	US Malfunctions:	55
US Estimated Active Implants:	95,000	Without Compromised Therapy:	12
		With Compromised Therapy:	43



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	105516	94535	84467	74089	56641	38862	25916	15845	8362	3577

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

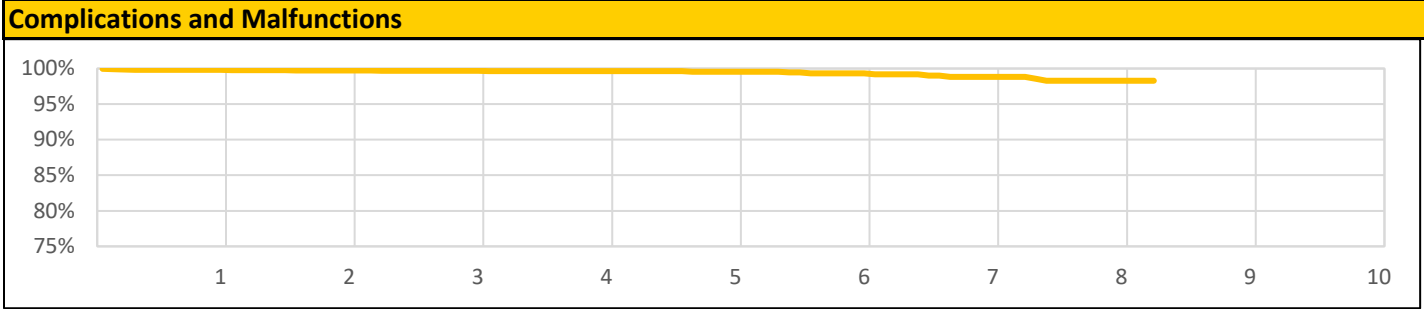
Worldwide Confirmed Malfunctions	100		
Worldwide Distribution	218,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	12	0	12
Other			
Non-patterned, other	70	18	88
Grand Total	82	18	100

References cited in table above [\(link\)](#)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Summary			
US Registered Implants:	23,000	US Chronic Complications	63
US Approval Date:	November 2010	US Malfunctions:	5
US Estimated Active Implants:	21,000	Without Compromised Therapy:	-
		With Compromised Therapy:	5



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%	99.6%	99.5%	99.3%	98.8%	98.3%	98.3%	--
Registered Implants: 23000	Effective Sample Size	16235	10968	6283	2611	1084	720	461	254	207	--

@ 99 months

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

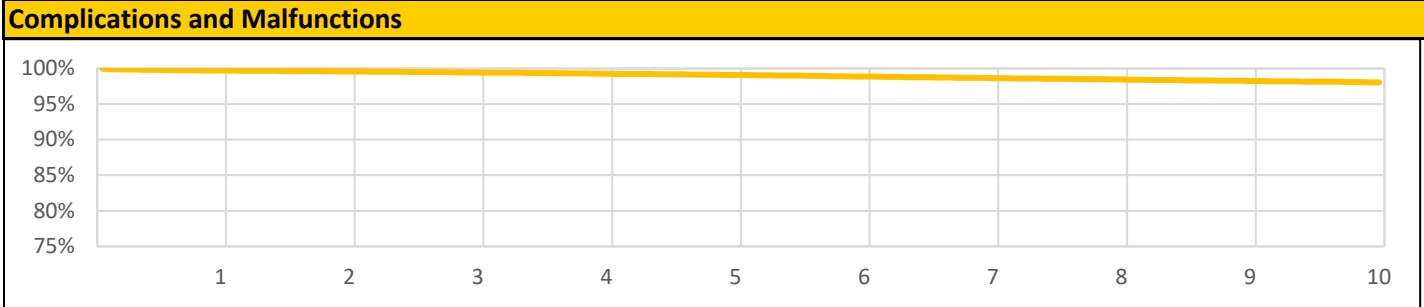
Worldwide Confirmed Malfunctions	10		
Worldwide Distribution	7,000		
	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	9	1	10
Grand Total	9	1	10

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	3,759
US Approval Date:	July 2002	US Malfunctions:	395
US Estimated Active Implants:	104,000	Without Compromised Therapy:	126
		With Compromised Therapy:	269



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.4%	99.3%	99.1%	98.9%	98.7%	98.5%	98.3%	98.1%
Registered Implants: 287000	Effective Sample Size	252214	226419	203388	182560	163708	146616	131191	117166	104275	92385

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

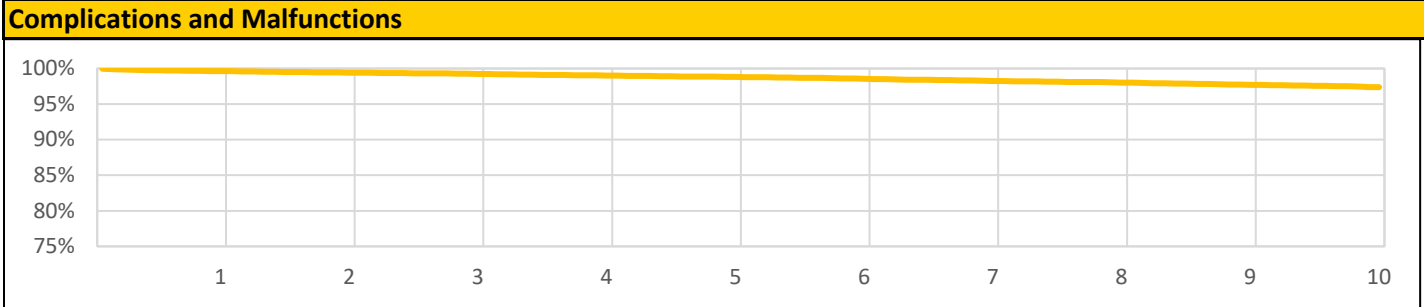
Worldwide Confirmed Malfunctions		596		
Worldwide Distribution		383,000		
	With Compromised Therapy	Without Compromised Therapy	Total	
Conductor				
Conductor fracture (24)	106	0	106	
Crimp/Weld/Bond				
Seal rings (5)	2	2	4	
Other				
Non-patterned, other	279	207	486	
Grand Total	387	209	596	

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	501
US Approval Date:	October 2000	US Malfunctions:	92
US Estimated Active Implants:	20,000	Without Compromised Therapy:	25
		With Compromised Therapy:	67



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%	98.6%	98.3%	98.0%	97.7%	97.4%
Registered Implants: 34000	Effective Sample Size	29841	26439	23418	20722	18271	16051	13988	11900	9739	7747

ENDOTAK RELIANCE Single Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	216
Worldwide Distribution	80,000

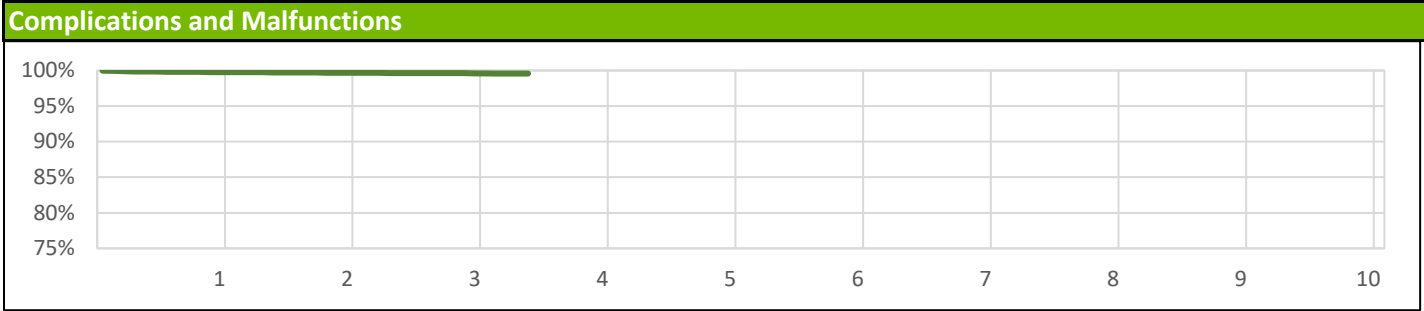
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	62	1	63
Other			
Non-patterned, other	94	59	153
Grand Total	156	60	216

References cited in table above ([link](#))

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

US Summary			
US Registered Implants:	297,000	US Chronic Complications	624
US Approval Date:	December 2019	US Malfunctions:	75
US Estimated Active Implants:	280,000	Without Compromised Therapy:	44
		With Compromised Therapy:	31



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.6%	--	--	--	--	--	--
Registered Implants: 297000	Effective Sample Size	178738	84046	11230	647	--	--	--	--	--	--

@ 41 months

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

Worldwide Confirmed Malfunctions	83
Worldwide Distribution	476,000

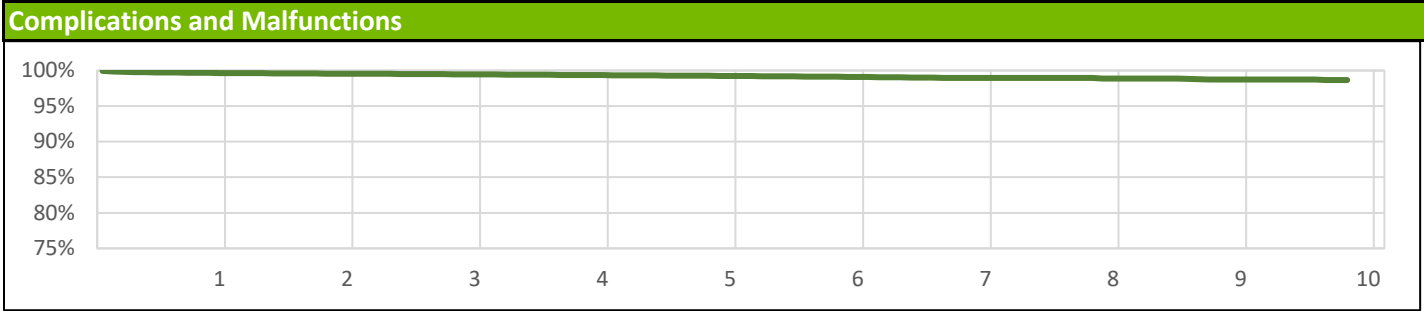
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	9	20	29
Other			
Non-patterned, other	24	30	54
Grand Total	33	50	83

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	2,015
US Approval Date:	April 2016	US Malfunctions:	318
US Estimated Active Implants:	302,000	Without Compromised Therapy:	183
		With Compromised Therapy:	135



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%	98.9%	98.7%	98.7%
Registered Implants: 365000	Effective Sample Size	322023	288569	257030	184297	111833	52131	5464	1909	1702	1489

@ 118 months

INGEVITY Positive Fixation

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

Worldwide Confirmed Malfunctions	475
Worldwide Distribution	1,093,000

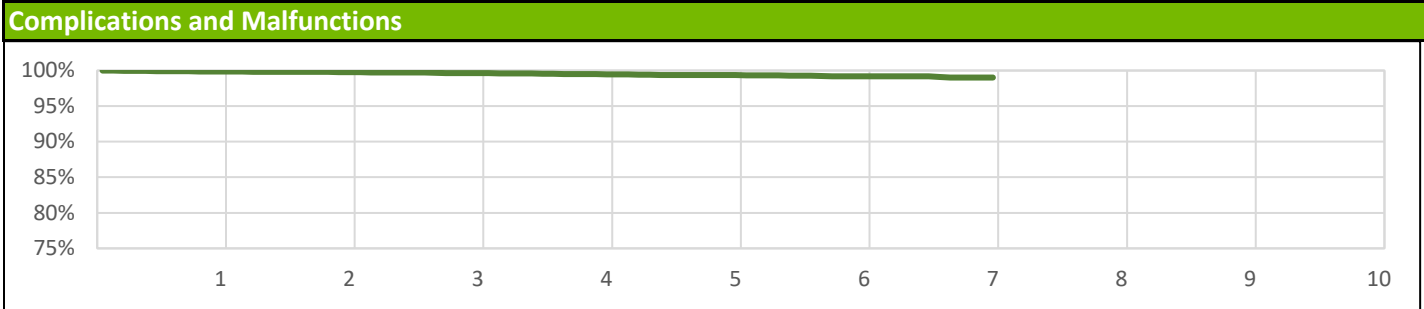
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	9	9	18
Extracardiac fracture (41)	113	145	258
Other			
Insulation (43)	2	22	24
Non-patterned, other	75	100	175
Grand Total	199	276	475

References cited in table above ([link](#))

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary			
US Registered Implants:	28,000	US Chronic Complications	93
US Approval Date:	April 2016	US Malfunctions:	16
US Estimated Active Implants:	24,000	Without Compromised Therapy:	4
		With Compromised Therapy:	12



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.9%	99.8%	99.6%	99.5%	99.3%	99.2%	99.0%	--	--	--
Registered Implants: 28000	Effective Sample Size	22534	17532	13011	9048	5578	2643	234	--	--	--

@ 84 months

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	21
Worldwide Distribution	129,000

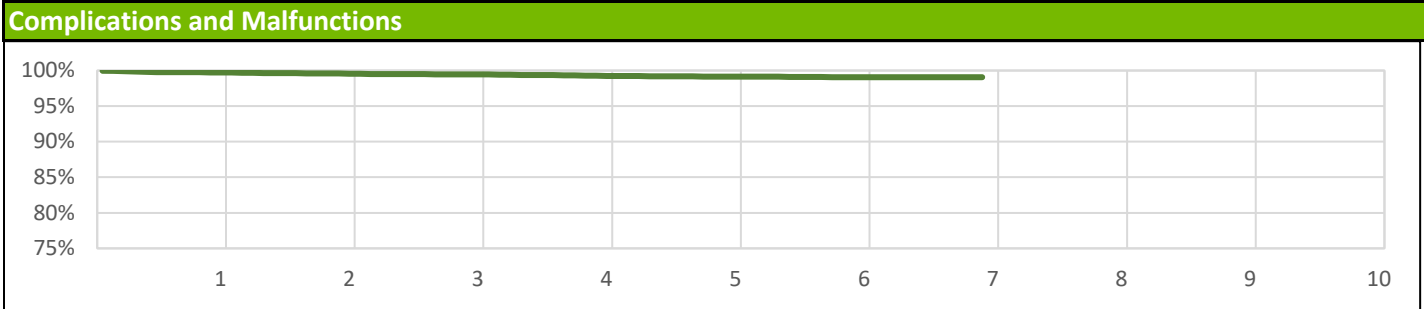
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	6	0	6
Other			
Insulation (43)	0	1	1
Non-patterned, other	11	3	14
Grand Total	17	4	21

References cited in table above ([link](#))

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	16,000	US Chronic Complications	81
US Approval Date:	April 2016	US Malfunctions:	8
US Estimated Active Implants:	15,000	Without Compromised Therapy:	8
		With Compromised Therapy:	-



US Survival Probability											
Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.4%	99.2%	99.2%	99.1%	99.1%	--	--	--
Registered Implants: 16000	Effective Sample Size	13008	10163	7533	5250	3197	1439	235	--	--	--

@ 83 months

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	15
Worldwide Distribution	118,000

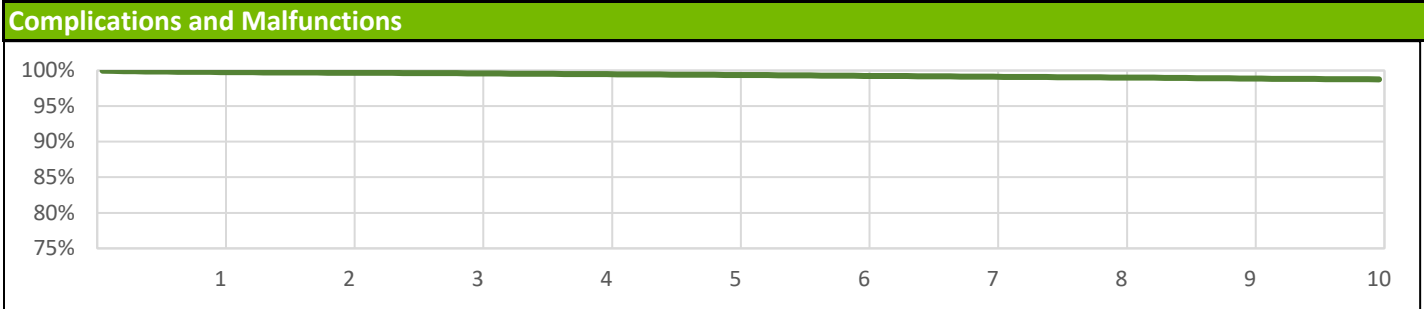
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	9	9
Crimp/Weld/Bond			
Weld (40)	0	1	1
Other			
Non-patterned, other	0	5	5
Grand Total	0	15	15

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:	519,000	US Chronic Complications	3,896
US Approval Date:	January 2000	US Malfunctions:	172
US Estimated Active Implants:	256,000	Without Compromised Therapy:	54
		With Compromised Therapy:	118



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%	99.3%	99.1%	99.0%	98.9%	98.8%
Registered Implants: 519000	Effective Sample Size	450313	397438	350314	306842	267135	231842	201210	168654	138617	112224

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

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

Worldwide Confirmed Malfunctions	205
Worldwide Distribution	821,000

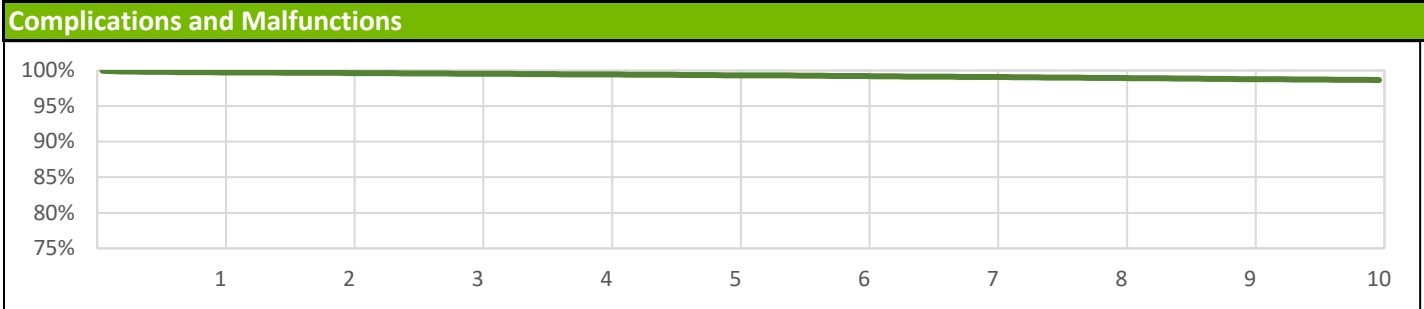
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	66	17	83
Crimp/Weld/Bond			
Terminal weld (23)	1	0	1
Other			
Lead body (4)	71	32	103
Non-patterned, other	8	10	18
Grand Total	146	59	205

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	1,683
US Approval Date:	January 2000	US Malfunctions:	47
US Estimated Active Implants:	74,000	Without Compromised Therapy:	3
		With Compromised Therapy:	44



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%	98.8%	98.7%
Registered Implants: 198000	Effective Sample Size	170751	152347	135917	120998	107357	94951	83763	71382	59652	49125

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	70
Worldwide Distribution	557,000

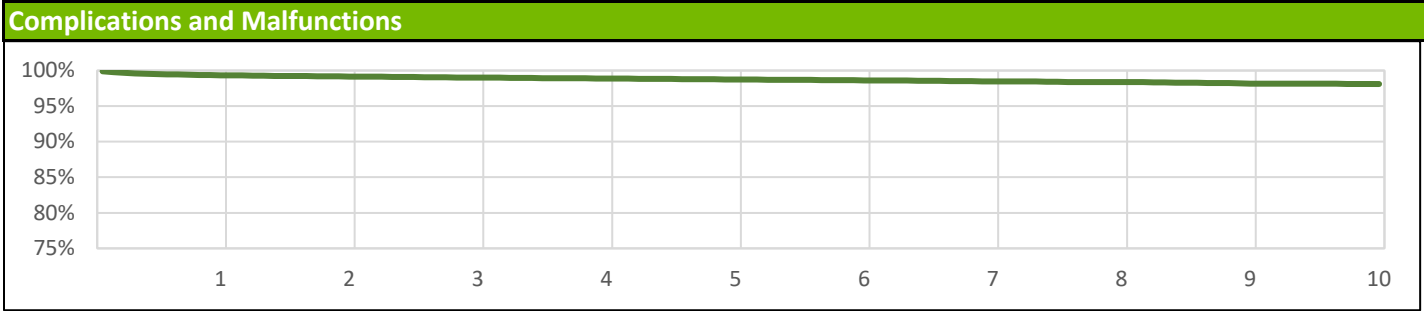
	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	20	0	20
Other			
Lead body (4)	41	3	44
Non-patterned, other	5	1	6
Grand Total	66	4	70

References cited in table above ([link](#))

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary			
US Registered Implants:	63,000	US Chronic Complications	848
US Approval Date:	January 2000	US Malfunctions:	39
US Estimated Active Implants:	26,000	Without Compromised Therapy:	20
		With Compromised Therapy:	19



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%	98.4%	98.2%	98.1%
Registered Implants: 63000	Effective Sample Size	55140	49400	44256	39633	35395	31401	27748	23498	19545	15995

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	79
Worldwide Distribution	327,000

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

References cited in table above ([link](#))

Confirmed Malfunction Details: Leads References

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

1. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
4. **Lead body**— Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
5. **Seal rings**— Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.
6. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
11. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
12. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
13. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
14. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **DF-1 terminal pin**— Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.
18. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
19. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
22. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead 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	295,000	84	93	324	71	16	11	2	21	0	2
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	151	642	586	258	116	28	52	157	0	25
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	16,000	0	18	41	10	3	2	2	5	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	28,000	2	28	16	21	8	3	1	14	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	198,000	5	497	250	305	79	36	217	275	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	518,000	27	840	916	541	212	159	613	557	0	31
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	1	128	369	142	31	34	81	54	0	8
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	2	127	20	73	30	5	24	39	0	1
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474	53,000	0	319	97	124	110	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	20,000	0	0	32	7	1	0	0	0	0	7
ACUITY X4 Spiral S 4674/4675	59,000	1	2	92	12	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	45,000	1	1	155	25	0	0	1	5	0	54
ACUITY Steerable 4554/4555/4556	29,000	5	44	464	69	6	2	18	42	0	98
ACUITY Spiral 4591/4592/4593	24,000	0	26	343	55	0	1	5	12	0	138
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	2	46	315	65	5	2	16	24	0	95
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	2	447	1376	389	15	8	119	187	0	449
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	2	92	489	152	4	1	77	54	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	76,000	27	34	97	19	16	7	0	6	5	3
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	11,000	3	2	14	3	2	0	1	0	2	1
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	78,000	24	61	123	36	81	15	16	30	45	7
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	1	3	9	4	7	0	0	13	2	1
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	139,000	39	89	215	68	111	26	18	57	60	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	808	437	246	906	104	169	471	553	30
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	6	162	76	86	162	13	48	276	83	7
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	34,000	14	117	63	38	88	4	9	59	105	4
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	5	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	31,000	0	9	11	0	138	7	0	0	9
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	24,000	0	6	24	0	149	17	4	0	10

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	295,000	357	44	772	161	46	45	3	26	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	16,000	1	0	39	8	1	1	0	1	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	28,000	1	0	43	12	0	3	0	0	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	198,000	9	11	403	102	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	0	10	397	52	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	518,000	56	49	708	151	88	69	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	20,000	0	0	35	39	9	0	0	8	0	21
ACUITY X4 Spiral S 4674/4675	59,000	0	2	76	60	8	0	0	26	0	56

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	45,000	2	0	159	43	7	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	172	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	806	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	76,000	66	12	170	24	18	3	1	9	3	3
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	11,000	8	1	22	7	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	139,000	101	20	366	70	58	15	6	32	13	21
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	4	1	6	0	1	1	0	7	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	82	137	510	130	223	12	17	178	108	44
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	5	4	92	36	41	4	3	47	5	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	34,000	31	7	70	15	19	3	2	18	25	9

ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	0	3	1	2	0	0	1	0	0
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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	31,000	1	1	30	0	261	9	0	2	9
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401	24,000	1	0	21	0	207	6	1	0	15

Before/During Implant Procedure - Worldwide Malfunctions: Leads

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling is not reported as device malfunction here.

The Conductor category includes any conductor break or damage with complete or intermittent loss of continuity that could interrupt current flow, including clavicle fatigue or crush damage. The Insulation category includes any lead insulation breach, such as damage due to lead-on-lead or lead-on-anatomy contact, or clavicle fatigue or crush. The Crimp/Weld/Bond category includes any interruption in the conductor or lead body associated with a point of connection. The Other category includes malfunctions for which the root cause does not fit within other categories or has not yet been determined. The Labeling and Packaging categories include product identification issues and damage to sterile packaging, respectively. The Implant Accessory category includes lead malfunctions due to catheter, guidewire or sheath issues.

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	48,000	0	0	0	2	0	0	0
ACUITY X4 Spiral S 4674/4675	125,000	0	0	0	5	0	0	0
ACUITY X4 Straight 4671/4672	99,000	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	31,000	0	0	0	8	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	240,000	3	1	0	82	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0682/0663/0683	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	218,000	0	0	0	64	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	80,000	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	79,000	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/Weid/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY+ Positive Fixation 7840/7841/7842	476,000	0	0	0	27	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	1,093,000	2515	0	0	3327	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	118,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	129,000	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*	557,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	821,000	0	0	6	728	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	327,000	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.	Voluntary Physician Advisory FDA Classification: Class I
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Affected devices built with the EL battery have the potential to transition to Safety Mode during interrogation attempts by either a programmer or a LATITUDE™ communicator. The EL battery impedance of affected devices may increase over time causing a device to exhibit transient voltage decreases during the high-power consumption associated with telemetry communication via programmer or LATITUDE communicator. If the battery voltage drops below a minimum threshold during communication attempts, the device will temporarily halt telemetry, and a system reset will be performed. Subsequent telemetry attempts may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to immediately enter Safety Mode to maintain back-up pacing with pre-defined non-programmable settings.
INLIVEN CRT-P Models: V284, V285, W274, W275	Once a device is in Safety Mode, it cannot be reprogrammed and must be replaced. There is a high degree of detectability when a device is operating in Safety Mode based on displayed programmer warning screen and/or LATITUDE alert condition. Although the most common clinical outcome has been early device replacement, Safety Mode parameters may result in unintended clinical impact for certain patients. Prior to device replacement, some patients may experience the following due to non-programmable Safety Mode pacing parameters: myopotential oversensing resulting in pacing inhibition, phrenic nerve stimulation; and/or loss of AV/VV synchrony. The most common clinical impact has been early device replacement. No patient deaths have been reported. No affected devices remain available for implant.
INTUA CRT-P Models: V272, V273, W273	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.
INVIVE CRT-P Models: V172, V173, V182, V183, W172, W173	Standard Warranty program available, please contact your local representative for terms and conditions.
VITALIO DR EL Pacemaker Models: J274, J277, K274, K277, K284	CURRENT STATUS 05-Jul-23 <i>Estimated Rate of Occurrence</i> 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 26,000.
INGENIO DR EL Pacemaker Models: J174, J177, K174, K184, K187	CURRENT RECOMMENDATION 05-Jul-23 <ul style="list-style-type: none"> As noted above, Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. When assessing potential risk for a patient if their device initiates Safety Mode prior to the Explant indicator, consider patient-specific physiological factors (which may vary over time), including: adequacy of underlying escape rhythm and/or the need for AV/VV pacing for cardiac synchrony. If a device enters Safety Mode, schedule replacement. Boston Scientific does not recommend general prophylactic replacement for affected devices. However, for individual patients, factors such as those listed above and shared decision-making may support consideration of device replacement to mitigate unintended clinical impact(s) due to potential entry into Safety Mode prior to the Explant indicator. In these cases, the following guidance should be considered: <ul style="list-style-type: none"> For EL pacemakers, replace with a longevity remaining of 4 years (or less, if the device currently indicates fewer than 4 years longevity remaining). For CRT-Ps, replace with a longevity remaining of 3 years (or less, if the device currently indicates fewer than 3 years longevity remaining). Follow-up interval. Perform a system follow-up via remote or in-office interrogation at least every 12 months. For patients who may not require early device replacement, continue with existing follow-up protocols until the longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated (in accordance with the device's instructions for use). For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.
ADVANTIO DR EL Pacemaker Models: J064, J067, K064, K084, K087 Safety Mode, Physician Letter, June 2021 Safety Mode, Patient Letter, June 2021	

PRODUCT	ORIGINAL COMMUNICATION Sep 2018 and Jun 2021 – Hydrogen-Induced Premature Depletion
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory FDA Classification: Sep 2018 – Class II; Jun 2021 - Class II
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	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.
VALITUDE CRT-P Models U125, U128	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.
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,	<i>Estimated Rate of Occurrence</i> 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.
ALTRUA 2 Pacemaker Models S701, S702, S722	<ul style="list-style-type: none"> 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.
Hydrogen Induced Premature Depletion, Physician Letter, September 2018	Standard Warranty program available, please contact your local representative for terms and conditions.
Hydrogen Induced Premature Depletion, Patient Letter, September 2018	CURRENT STATUS 05-Jul-23 <i>Estimated Rate of Occurrence</i> 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.
Hydrogen Induced Premature Depletion, Physician Letter, June 2021	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.
Hydrogen Induced Premature Depletion, Patient Letter, June 2021	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 05-Jul-23 <ul style="list-style-type: none"> Per labeling, perform a system follow-up via remote or in-office interrogation every 12 months until One-Year-Remaining and then every three (3) months thereafter until replacement is indicated. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. Replace any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery depletion. For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT

ORIGINAL COMMUNICATION Dec 2020 — Model 3501 Electrode Fracture

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

EMBLEM Subcutaneous Electrode
Model 3501

[Model 3501 Electrode Fracture, Physician Letter, December 2020](#)
[Model 3501 Electrode Fracture, Patient Letter, December 2020](#)

Voluntary Physician Advisory
FDA Classification: Class I

This advisory discusses the performance of approximately 47,000 EMBLEM S-ICD Subcutaneous Electrodes (Model 3501). During assembly of the EMBLEM S-ICD Subcutaneous Electrode, a small amount of adhesive is applied to a location just distal to the proximal sense ring. Over time, mechanical stresses on the electrode body at this location may create the potential for a fatigue crack to initiate from the outer lumen. This crack then propagates inward toward the center-oriented distal sense conductor, eventually resulting in a fracture of the two high voltage conductors.

The cumulative occurrence rate for this specific electrode body fracture location is 0.2% at 41 months with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years.

The physician letter (link provided) details device programming considerations and troubleshooting and detection techniques.

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

CURRENT STATUS 05-Jul-23

Estimated Rate of Occurrence

The occurrence rate for EMBLEM S-ICD Subcutaneous Electrode (Model 3501) body fractures at a location just distal to the proximal sense ring is 0.30% at 72 months and the potential for life-threatening harm is 1 in 32,000 (0.0031%) at 10 years. This rate was derived by including all reports of this failure mode, whether or not the product was returned.

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

CURRENT RECOMMENDATION 05-Jul-23

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 view projections, 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 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 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 prevention indication 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

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](#)

ORIGINAL COMMUNICATION Dec 2020 — EMBLEM S-ICD Electrical Overstress

Voluntary Physician Advisory
FDA Classification: Class I

This advisory discusses the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress (i.e., damage to the device caused by electrical shorting).

Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations.

Estimated Rate of Occurrence

- Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported.

- The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide needed defibrillation therapy, as it is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years

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

CURRENT STATUS 05-Jul-23

Estimated Rate of Occurrence

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

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

CURRENT RECOMMENDATION 05-Jul-23

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
<p>Identifiable by serial number. Not all serial numbers are affected.</p> <p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p> <p>EMBLEM S-ICD Models A209, A219</p> <p>EMBLEM Premature Depletion, Physician Letter, August 2019</p> <p>EMBLEM Premature Depletion, Patient Letter, August 2019</p> <p>EMBLEM Premature Battery Depletion, Physician Letter Update, December 2020</p> <p>EMBLEM Premature Depletion, Patient Letter Update, December 2020</p> <p>EMBLEM Premature Battery Depletion, Physician Letter Update, February 2022</p> <p>EMBLEM Premature Depletion, Patient Letter Update, February 2022</p>	<p>Voluntary Physician Advisory FDA Classification August 2019: Class II FDA Classification December 2020: Class II</p> <p>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.</p> <p>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.</p> <p>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.</p> <p><i>Estimated Rate of Occurrence</i></p> <ul style="list-style-type: none"> • 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. <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>
	<p>CURRENT STATUS 05-Jul-23</p> <p>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.</p> <p><i>Estimated Rate of Occurrence</i></p> <p>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.</p> <p>The malfunction rate is 10.4% at 5 years, 24.1% at 6 years, and 33.8% at 7 years. The projected potential for life-threatening harm is approximately 1 in 125,000 at 5 years.</p> <p>There have been zero deaths associated with this behavior. There have been zero malfunctions for this behavior in devices manufactured with contemporary low-voltage capacitors.</p>

CURRENT RECOMMENDATION 05-Jul-23

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
<p>Identifiable by serial number. Not all serial numbers are affected.</p> <p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p> <p>S-ICD Model 1010</p> <p>SQ-RX 1010 Shortened Replacement Time, Physician Letter, November 2018</p> <p>SQ-RX 1010 Shortened Replacement Time, Patient Letter, November 2018</p>	<p>Voluntary Physician Advisory FDA Classification: Unclassified</p> <p>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).</p> <p>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.</p> <p>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.</p> <p><i>Estimated Rate of Occurrence</i></p> <p>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.</p> <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>
	<p>CURRENT STATUS 05-Jul-23</p>
	<p><i>Estimated Rate of Occurrence as of October 2018</i></p> <p>The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years.</p>
	<p>CURRENT RECOMMENDATION 05-Jul-23</p> <ul style="list-style-type: none"> • <u>Follow-Up</u>. Consistent with the SQ-RX Model 1010 PG User Manual: <ul style="list-style-type: none"> - 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 • <u>Evaluate Risk</u>. 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 • <u>CT / BD Alerts</u>. 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. • <u>ERI</u>. 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

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)

[Minute Ventilation Signal Oversensing, Physician Letter, December 2017](#)

[Minute Ventilation Signal Oversensing, Patient Letter, December 2017](#)

[Minute Ventilation Signal Oversensing, Update letter, January 2019](#)

CURRENT STATUS 05-Jul-23

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 05-Jul-23

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.

Voluntary Physician Advisory
FDA Classification: Unclassified

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

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:

VALITUDE CRT-P

Models U125, U128

- 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).

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

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.

VIGILANT CRT-D

Models G224, G225, G228, G237, G247, G248

CURRENT STATUS 05-Jul-23**MOMENTUM CRT-D**

Models G124, G125, G126, G128, G138

Confirmed Malfunctions (worldwide)

There have been five confirmed instances of early device replacement due to this device behavior.

CHARISMA CRT-D

G337, G347, G348

CURRENT RECOMMENDATION 05-Jul-23

Software is available in most countries to address 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.

AUTOGEN CRT-D

Models G172, G173, G175, G177, G179

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

DYNAGEN CRT-D

Models G150, G151, G156, G158

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

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](#)

PRODUCT

ORIGINAL COMMUNICATION Aug 2013 and Sep 2014 — Low Voltage Capacitor

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

[Device Lookup Tool](#)

COGNIS

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

TELIGEN VR

Models E102/E103/F102/F103

TELIGEN DR

Models E110/E111/F110/F111

[Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014](#)

[Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014](#)

[Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013](#)

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

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

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

The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months.

Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.

Advisory population

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

CURRENT STATUS 05-Jul-23

Estimated Rate of Occurrence as of January 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 05-Jul-23

Updated Software

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

LATITUDE Patient Management System

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

Additional Recommendations

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

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

PRODUCT	ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p> <p><i>This advisory is limited to those models listed below implanted subpectorally.</i></p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>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.</p> <p>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.</p>
<p>COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108</p>	<p>A weakened header bond can result in one or more of the following device behaviors:</p> <ul style="list-style-type: none"> – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy
<p>TELIGEN VR Models E102/F102</p>	<ul style="list-style-type: none"> – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy
<p>TELIGEN DR Models E110/E111/F110/F111</p>	<p>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.</p> <p><i>Rate of Occurrence</i> 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.</p>
<p>Subpectoral Implant 2009 Physician Letter, Dec 01, 2009</p> <p>Subpectoral Implant 2009 Patient Letter, Dec 01, 2009</p>	<p>The following factors may also impact the risk of failure if implanted in a subpectoral location:</p> <ul style="list-style-type: none"> – 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)
	<p>CURRENT STATUS 05-Jul-23</p>
	<p><i>Reported events (worldwide)</i></p> <p>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.</p> <p>There have been no reported patient deaths associated with this advisory.</p>
	<p>CURRENT RECOMMENDATION 05-Jul-23</p> <p>If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended.</p> <p>For affected devices implanted in a subpectoral location:</p> <ul style="list-style-type: none"> – 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.
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

Trademarks

The following are trademarks of Boston Scientific Corporation, CRM Division (doing business as Cardiac Pacemakers, Inc., a Boston Scientific Company) used in connection with the goods or services indicated:

ACCOLADE	EQUIO	LUX-DX
ACUITY	ENDOTAK ENDURANCE	MOMENTUM
ACUITY X4	ENDOTAK ENDURANCE EZ	ORIGEN
ADVANTIO	ENDOTAK ENDURANCE RX	PERCIVA
ALTITUDE	ENDOTAK RELIANCE	PROPONENT
ALTRUA	ENERGEN	PUNCTUA
AUTOGEN	ESSENTIO	RELIANCE 4-FRONT
AVT	FINELINE	RESONATE
CHARISMA	FLEXTEND	SELUTE
COGNIS	FORMIO	SWEET PICOTIP
CONFIENT	INSIGNIA	SWEET TIP
CONTAK	INGENIO	TELIGEN
CONTAK RENEWAL	INGEVITY	VIGILANT
CONTAK RENEWAL TR	INCEPTA	VISIONIST
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Q-TRAK	SQ-RX	S-ICD
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