

CRM Product Performance Report 2014

Q4 Edition



CRM Quality Pledge

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

Advancing Science for Life.

For almost 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 Q4 2014 report includes data through October 10, 2014.

This report meets or exceeds the AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance, and address recommendations from the Heart Rhythm Society Task Force on Lead Performance. With increased interest in lead performance, our **Product Performance Report** provides the most comprehensive presentation of lead performance data available, including:

- ✓ U.S. Lead survival probability
- ✓ Worldwide malfunction counts and patterns
- ✓ Longitudinal Surveillance Registry lead survival probability
- ✓ Acute (first month) lead observations
- ✓ Chronic (after first month) lead complications
- ✓ Malfunctions reported before and during an implant procedure

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

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

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Statistical Methodology

What Is Device Survival Probability?

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

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

Boston Scientific estimates survival probability in compliance with international standard ISO 5841-2: 2000 (E). Survival probability is calculated at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in the report section entitled U.S. Reason for Out of Service.

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

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets

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

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

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

Criteria for inclusion of product families in this report are in compliance with the *AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*. Survival estimates are provided for product families once they have at least 10,000 cumulative U.S. implant months. The minimum interval sample size is 200 U.S. implanted units. Pulse generator product families with less than 500 total remaining estimated active U.S. devices are not included in this report. Lead product families that received original U.S. market release approval twenty or more years ago are not included in this report. Survival estimates for leads enrolled in the Longitude Surveillance Registry are provided for product families once they have at least 200 enrolled leads. The minimum interval sample size is 50 leads which have been followed for at least 6 months.

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

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

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

To convey implant experience for a product family, average device age and U.S. approval date are provided. The U.S. approval date listed is the earliest date Boston Scientific received approval for one or more of the models in the family. For Longitude Surveillance Registry data, the number of enrolled leads and their cumulative followup months are also provided for context.

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)

Reduction in survival probability for **pulse generators** is due to:

- Devices removed for normal battery depletion
- Device malfunctions occurring while implanted, as confirmed by returned product analysis
- Devices removed from service and reported to have exhibited premature battery depletion, but not confirmed by laboratory analysis, whether returned or not—also known as “unconfirmed reports of premature battery depletions.”

Survival Probability – Malfunctions Only (Pulse Generators)

Reduction in survival probability for **pulse generators** is due only to:

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

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

Survival Probability — Complications and Malfunctions (Leads)

The AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads*, published in May 2009, outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology to all lead families being implanted as of May 2009, and will apply it to all future lead families as they are included in the Product Performance Report. Worldwide malfunctions are not included for older lead families. .

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads and lead segments returned for analysis with reported observations 30 days or more post-implant, but for which analysis was inconclusive or a reported complication was unconfirmed
- Leads removed from service but not returned for laboratory analysis, with reported complications 30 days or more post-implant

Further Adjustments for Device and Lead Survival

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

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

Categorization of Malfunctions for Survival Probability Reporting

Malfunctions represent pulse generators and leads removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. In addition, leads utilize AdvaMed methodology which includes Extrinsic Factor malfunctions occurring 30 days or more post-implant, where laboratory analysis is inconclusive or unconfirmed. 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 root cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples. Improvement implementation may vary by geography due to various factors including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

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

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

Malfunction Details: Overview

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

Category

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

Patterns

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

Each pattern description includes:

- **Clinical Manifestation and Root Cause** – Malfunctions for each product are characterized according to root cause. Descriptions provide clinical observations and/or analysis findings associated with each malfunction pattern listed in this report. Malfunctions listed within “Other” either do not yet have an identified root cause, or are related to a proprietary product feature, such as connectors or seal rings.
- **Improvement Implementation** – All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, improvements have been or will be implemented in response to identified malfunction patterns. Improvements may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications or labeling changes. Improvement implementation may vary by geography due to various factors, including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not completely mitigate or eliminate the potential for additional malfunctions.

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

Therapy Availability

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

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

For lead malfunctions listed in the Extrinsic Factors category, therapy availability may be known, not reported or unable to be determined. When known, these malfunctions are reported in the appropriate therapy availability column. When unknown, because the lead was taken out of service and returned, it is assumed that therapy may have been compromised, and will be reported in the With Compromised Therapy column.

Pulse Generator Confirmed Malfunctions

Pulse generator confirmed 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 Malfunctions

The Boston Scientific Product Performance Report is in compliance with the May 2009 AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

Malfunction Categories for Leads

Lead malfunction categories include Conductor, Insulation, Crimps/Welds/Bonds, Other and Extrinsic Factors, and include the following:

- **Conductor:** Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors), including those associated with clavicle flex fatigue or crush damage.
- **Insulation:** Any lead insulation breach. Examples include: 1) proximal abrasions associated with lead-on-lead or lead-on-PG contact in the pocket, 2) mid-lead insulation damage caused by clavicle flex fatigue or crush, suture or suture sleeve, insulation wear in the region of vein insertion, and 3) distal region wear due to lead-on-lead (intracardiac), lead-on-heart valve or lead-on-other anatomy contact.
- **Crimps/Welds/Bonds:** Any interruption in the conductor or lead body associated with a point of connection. Typically demonstrated by high or low shocking/pacing impedance, undersensing or oversensing.
- **Other:** Includes specific proprietary lead mechanical attributes, such as lead-incorporated sensors, connectors, seal rings or the 4–Site connector, or any malfunction modes not included in the three categories above.
- **Extrinsic Factors:** Lead complication where the identified lead was removed from service and returned for analysis, where analysis was either inconclusive or the complication was not confirmed. Inconclusive includes leads where only portions of the lead were available for return, or the returned lead was damaged by the explantation process. Unconfirmed includes when lab analysis could not determine an out of specification condition (including complaints of malfunction or complications such as dislodgements, perforations or failure to capture).

The categories of Conductor, Insulation, Crimps/Welds/Bonds and Other represent malfunctions for 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 Extrinsic Factors category represents leads with reported complications for which the leads were removed from service and returned, but for which laboratory analysis was inconclusive or the complication was unconfirmed. For the Extrinsic Factors category only, malfunctions are included for leads implanted greater than 30 days.

Supporting Greater Return of Explanted Devices

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

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

Help Us Provide You With More Complete Product Performance Data

Reporting Adverse Events

The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department at:

United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.

International: Please refer to the Country Offices List for local contact information.

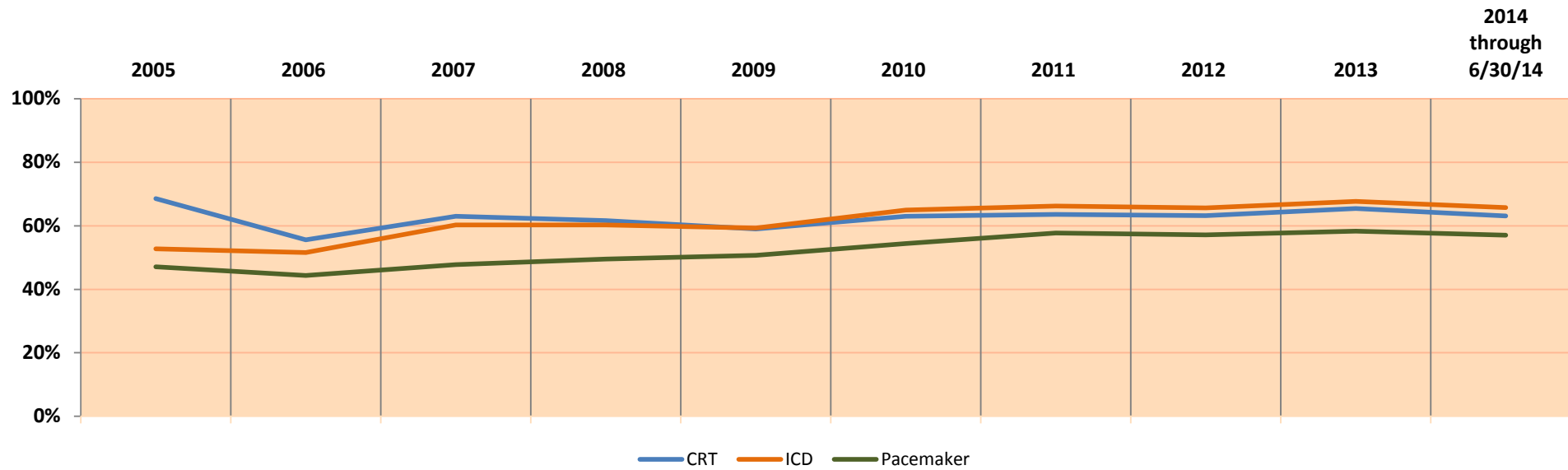
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

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



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




	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014 through 6/30/14
Explants	4528	4391	4697	5298	8159	9030	7490	5907	5429	1716
Returns	3104	2441	2958	3263	4816	5685	4766	3731	3551	1082
% Returned	69%	56%	63%	62%	59%	63%	64%	63%	65%	63%
Explants	16495	10224	11542	15756	20229	20862	17714	13321	13783	7088
Returns	8701	5269	6953	9498	11988	13544	11729	8740	9333	4660
% Returned	53%	52%	60%	60%	59%	65%	66%	66%	68%	66%
Explants	21700	17785	19120	20979	21602	21566	20541	19167	19109	9697
Returns	10223	7882	9131	10389	10946	11723	11859	10943	11150	5531
% Returned	47%	44%	48%	50%	51%	54%	58%	57%	58%	57%

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

AUTOGEN CRT-D

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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AUTOGEN CRT-D Models G160/G161/G164/G166/G168/ G172/G173/G175/G177/G179 			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions


[References](#) cited in table above

DYNAGEN INOGEN ORIGEN CRT-D

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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DYNAGEN INOGEN ORIGEN CRT-D
Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

[References](#) cited in table above

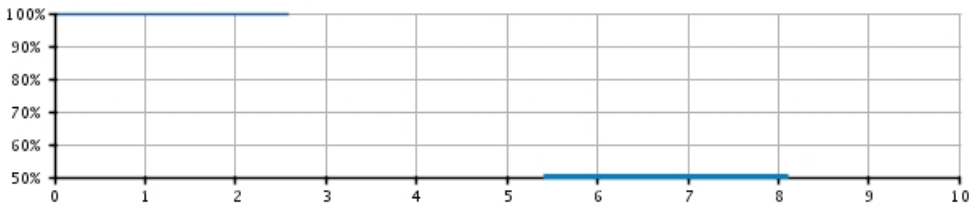
INCEPTA CRT-D 4-Site

Models N160/N162/P162

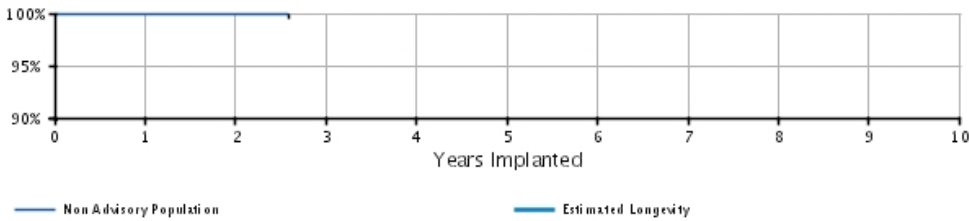
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 8,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 7,000	U.S. Normal Battery Depletions: 3 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:4 Without Compromised Therapy:3 With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.74 @ 31 mo. (-0.4/+0.2)	-	-	-	-	-	-	-	-
	Registered Implants: 8000	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.86 @ 31 mo. (-0.4/+0.1)	-	-	-	-	-	-	-	-
Effective Sample Size		4191	1453	291	-	-	-	-	-	-	-	-

INCEPTA CRT-D 4-Site

Models N160/N162/P162

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA CRT-D 4-Site Models N160/N162/P162			
Worldwide Distribution: 14,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁹ Safety Core-electrocautery	1	-	
⁸⁹ Integrated circuit	-	1	
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	2	-	2
⁹⁰ Memory errors	2	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

[References](#) cited in table above

INCEPTA CRT-D

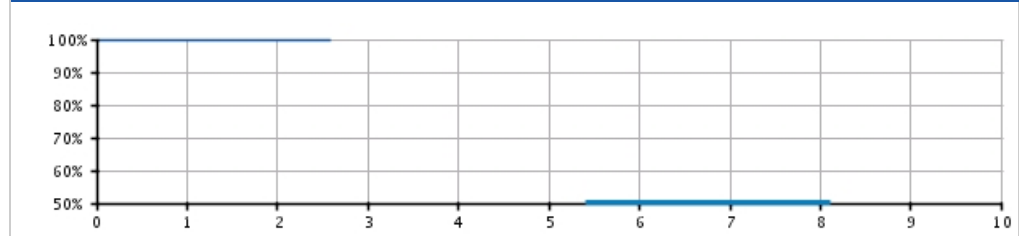
Models N161/N163/N164/N165/P163/
P165

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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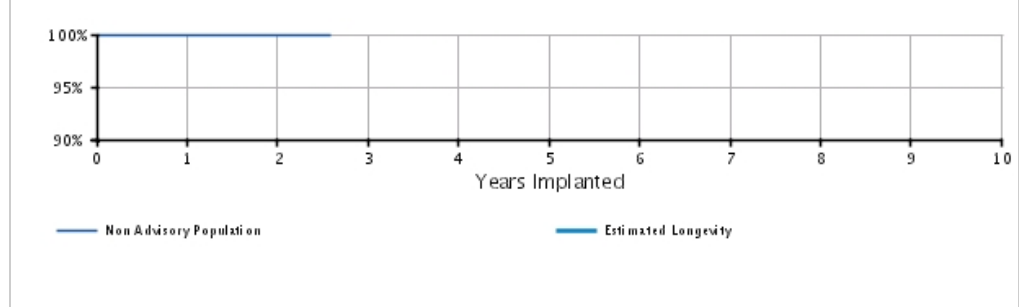
U.S. Summary

U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 6
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:2
	Without Compromised Therapy:0
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.75 @ 31 mo. (-0.3/+0.1)	—	—	—	—	—	—	—
Registered Implants: 11000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 31 mo. (-0.1/+0.0)	—	—	—	—	—	—	—
	Effective Sample Size	5927	1840	222	—	—	—	—	—	—	—

INCEPTA CRT-D

Models N161/N163/N164/N165/P163/
P165

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA CRT-D Models N161/N163/N164/N165/P163/ P165 			
Worldwide Distribution: 16,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁰ High-voltage capacitor	-	1	
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	2	2

[More details](#) about malfunctions

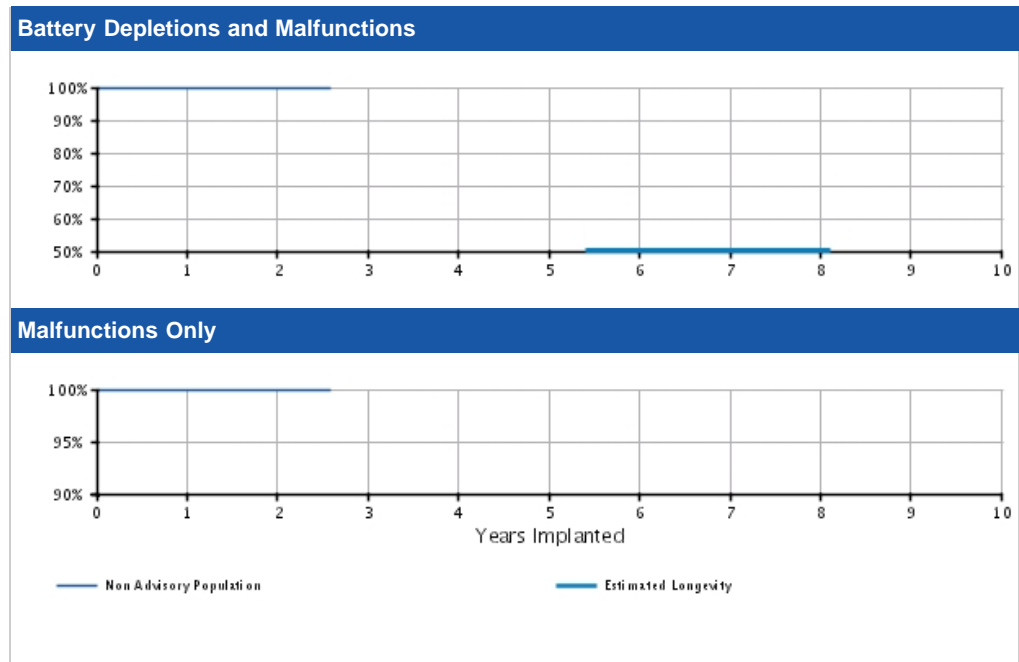
[References](#) cited in table above

ENERGEN CRT-D 4-Site

Models N140/N142/P142

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 12,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 11,000	U.S. Normal Battery Depletions: 1 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:2 Without Compromised Therapy:1 With Compromised Therapy:1



U.S. Survival Probability												
		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 31 mo. (-0.1/+0.0)	—	—	—	—	—	—	—	—
	Registered Implants: 12000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 31 mo. (-0.1/+0.0)	—	—	—	—	—	—	—
		Effective Sample Size	7364	2578	402	—	—	—	—	—	—	—

ENERGEN CRT-D 4-Site

Models N140/N142/P142

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENERGEN CRT-D 4-Site Models N140/N142/P142			
Worldwide Distribution: 18,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸⁹ Integrated circuit	1	-	
Mechanical	-	-	0
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	3	1	4

[More details](#) about malfunctions

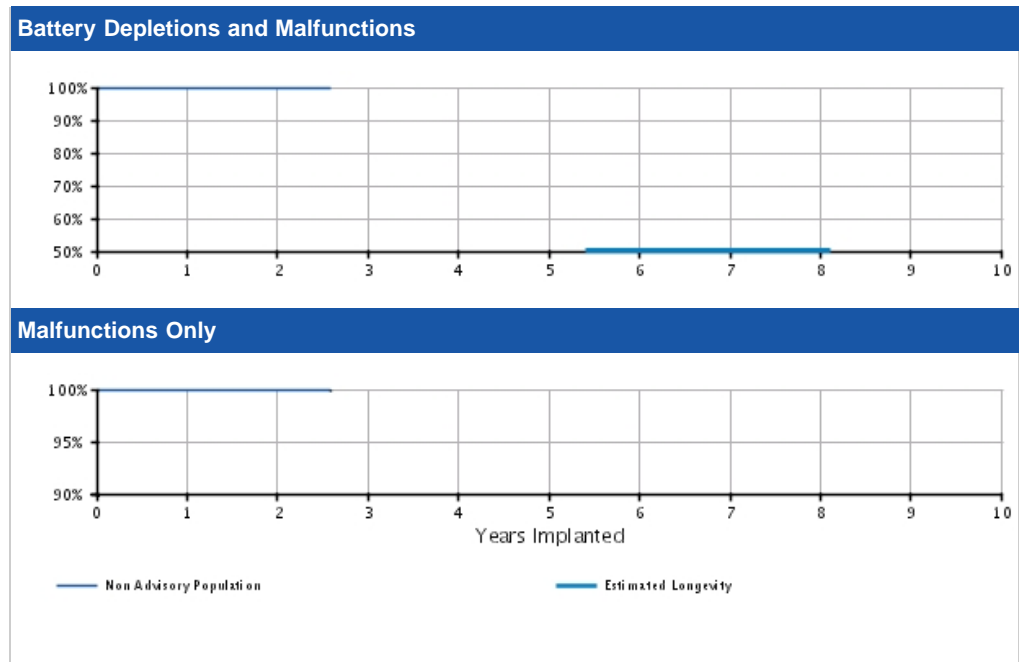
[References](#) cited in table above

ENERGEN CRT-D

Models N141/N143/P143

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 12,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 10,000	U.S. Normal Battery Depletions: 5 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:8 Without Compromised Therapy:4 With Compromised Therapy:4




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.79 (-0.2/+0.1)	99.74 @ 31 mo. (-0.2/+0.1)	-	-	-	-	-	-	-	-
	Registered Implants: 12000	99.91 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.91 @ 31 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
Effective Sample Size		7135	2305	265	-	-	-	-	-	-	-	-

ENERGEN CRT-D

Models N141/N143/P143

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENERGEN CRT-D Models N141/N143/P143 			
Worldwide Distribution: 15,000 Worldwide Confirmed Malfunctions: 10			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	2	4
⁷⁹ Safety Core-electrocautery	1	1	
⁸⁵ Low-voltage capacitors	1	-	
⁸⁹ Integrated circuit	-	1	
Mechanical	-	3	3
⁷³ Transformer	-	3	
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	5	5	10


[More details](#) about malfunctions

[References](#) cited in table above

PUNCTUA CRT-D 4-Site

Models N050/N052/P052

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA CRT-D 4-Site Models N050/N052/P052			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

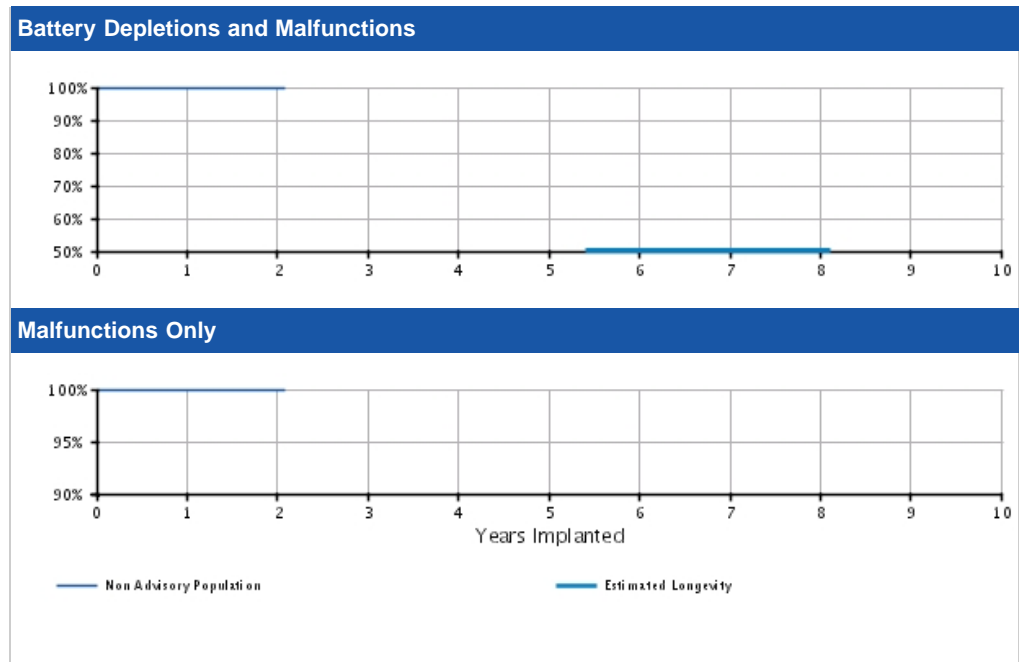
[References](#) cited in table above

PUNCTUA CRT-D

Models N051/N053/P053

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 1,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 1,000	U.S. Normal Battery Depletions: 0 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:0 Without Compromised Therapy:0 With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 25 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 25 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 1000	Effective Sample Size	832	268	226	-	-	-	-	-	-	-	-

PUNCTUA CRT-D

Models N051/N053/P053

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA CRT-D Models N051/N053/P053 			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁹ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2014

COGNIS

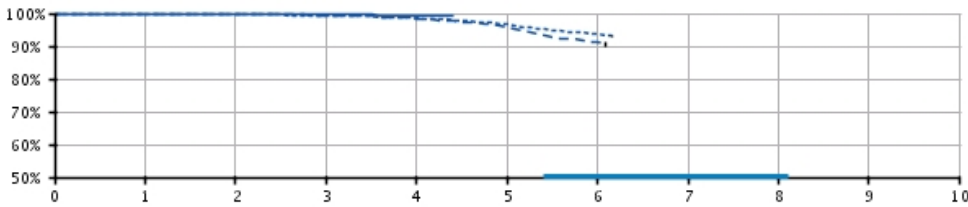
Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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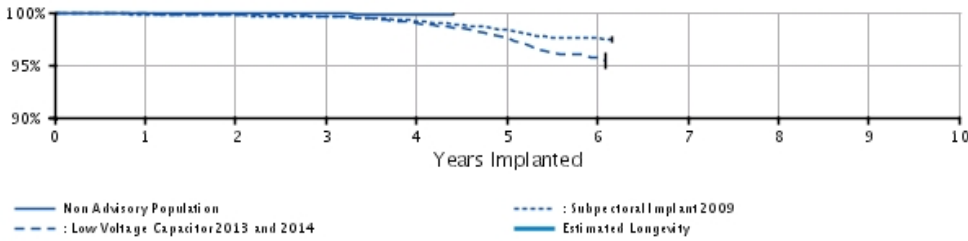
U.S. Summary

U.S. Registered Implants: 75,000	U.S. Normal Battery Depletions: 551
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 45
U.S. Estimated Active Implants: 49,000	U.S. Malfunctions:524
	Without Compromised Therapy:403
	With Compromised Therapy:121

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.67 (-0.1/+0.1)	99.24 (-0.2/+0.1)	99.14 @ 53 mo. (-0.2/+0.2)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.81 (-0.1/+0.1)	99.81 @ 53 mo. (-0.1/+0.1)	-	-	-	-	-
	Effective Sample Size	31537	27823	19469	4412	290	-	-	-	-	-
Subjectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.1)	96.52 (-0.3/+0.3)	93.76 (-0.5/+0.5)	92.32 @ 74 mo. (-0.6/+0.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.71 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.29 (-0.2/+0.2)	97.52 (-0.3/+0.3)	97.41 @ 74 mo. (-0.3/+0.3)	-	-	-
	Effective Sample Size	27513	24398	21699	19208	12958	1520	343	-	-	-
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.47 (-0.1/+0.1)	98.41 (-0.2/+0.2)	95.75 (-0.4/+0.3)	91.16 (-1.3/+1.2)	90.55 @ 73 mo. (-1.3/+1.3)	-	-	-
	Effective Sample Size										


26,000	Malfunctions Only (%)	99.85	99.78	99.65	98.96	97.56	95.51	90.55	-	-	-
	(Confidence Interval)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.3/+0.3)	(-0.8/+0.7)	@ 73 mo. (-0.8/+0.7)			
	Effective Sample Size	22629	20056	17862	15526	6360	337	299	-	-	-

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

COGNIS

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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COGNIS Models N106/N107/N108/N118/N119/ N120/P106/P107/P108 			
Worldwide Distribution: 109,000			
Worldwide Confirmed Malfunctions: 670			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	433	78	511
¹ Low Voltage Capacitor 2014 (Advisory issued)	342	29	
⁷⁹ Safety Core-electrocautery	44	18	
⁸⁰ High-voltage capacitor	1	4	
⁸⁵ Low-voltage capacitors	7	-	
⁸⁹ Integrated circuit	7	19	
⁹¹ High voltage circuit	-	1	
⁹² Battery	17	2	
⁹³ Low-voltage capacitor	15	5	
Mechanical	33	81	114
⁵ Subpectoral implant 2009 (Advisory issued)	13	41	
⁷³ Transformer	-	9	
⁷⁷ Difficulty securing lead	9	9	
⁸³ Header contacts	5	7	
⁹⁹ Header	6	15	
Software	11	-	11
⁸⁴ Safety Core-programming	1	-	
⁸⁷ Alert messages not displayed post-EOL	2	-	
⁹⁰ Memory errors	8	-	
Other	26	8	34
Non-patterned	26	8	
WW Confirmed Malfunctions	503	167	670

[More details](#) about malfunctions

[References](#) cited in table above

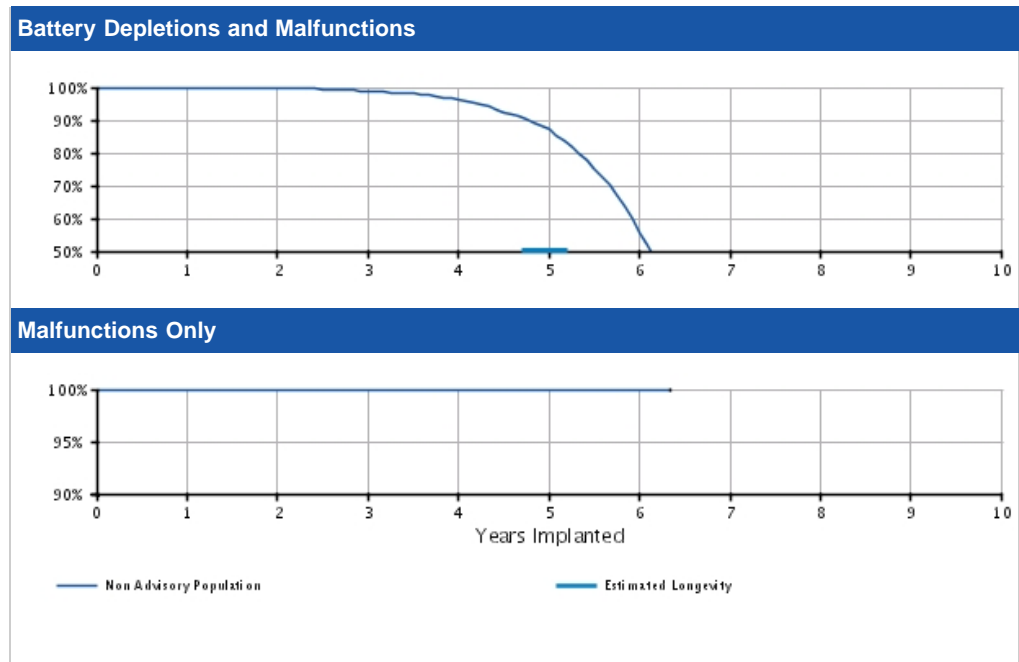
CRM PRODUCT PERFORMANCE REPORT Q4 2014

LIVIAN HE

Models H227/H229/H247/H249

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 1,101
U.S. Approval Date: February 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:4
	Without Compromised Therapy:2
	With Compromised Therapy:2




U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.74	98.92	96.43	87.05	55.63	42.07	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.4/+0.3)	(-0.7/+0.6)	(-1.3/+1.2)	(-2.3/+2.3)	@ 76 mo. (-2.7/+2.7)			
Registered Implants: 6000	Malfunctions Only(%)	99.98	99.92	99.92	99.92	99.92	99.92	99.92	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	@ 76 mo. (-0.1/+0.1)			
	Effective Sample Size	4941	4328	3732	3021	2125	802	291	-	-	-

LIVIAN HE

Models H227/H229/H247/H249

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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LIVIAN HE Models H227/H229/H247/H249 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
³¹ Integrated circuit	1	1	
Mechanical	-	2	2
⁷⁷ Difficulty securing lead	-	2	
Software	-	-	0
Other	1	1	2
Non-patterned	1	-	
³⁹ Battery depletion	-	1	
WW Confirmed Malfunctions	2	4	6

[More details](#) about malfunctions

[References](#) cited in table above

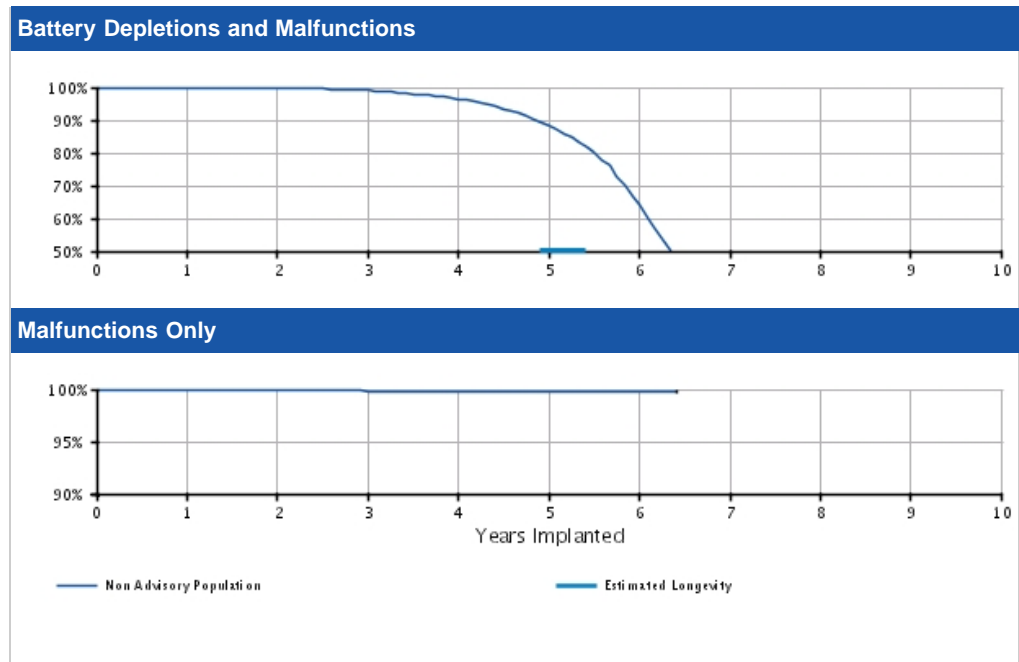
CRM PRODUCT PERFORMANCE REPORT Q4 2014

LIVIAN

Models H220/H225/H240/H245

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 5,000 U.S. Approval Date: February 2008 U.S. Estimated Active Implants: 2,000	U.S. Normal Battery Depletions: 842 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:8 Without Compromised Therapy:5 With Compromised Therapy:3




U.S. Survival Probability												
		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	Registered Implants: 5000	99.95 (-0.1/+0.0)	99.68 (-0.2/+0.1)	99.06 (-0.4/+0.3)	96.43 (-0.7/+0.6)	88.14 (-1.4/+1.2)	64.15 (-2.3/+2.2)	45.99 @ 77 mo. (-3.1/+3.1)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	Effective Sample Size	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.80 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 @ 77 mo. (-0.2/+0.1)	-	-	-
			3997	3486	3027	2515	1839	863	226	-	-	-

LIVIAN

Models H220/H225/H240/H245

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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LIVIAN
Models H220/H225/H240/H245 

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	2	3
³¹ Integrated circuit	1	2	
Mechanical	1	-	1
³⁵ Seal plug	1	-	
Software	-	-	0
Other	3	3	6
Non-patterned	1	3	
³⁹ Battery depletion	2	-	
WW Confirmed Malfunctions	5	5	10

[More details](#) about malfunctions

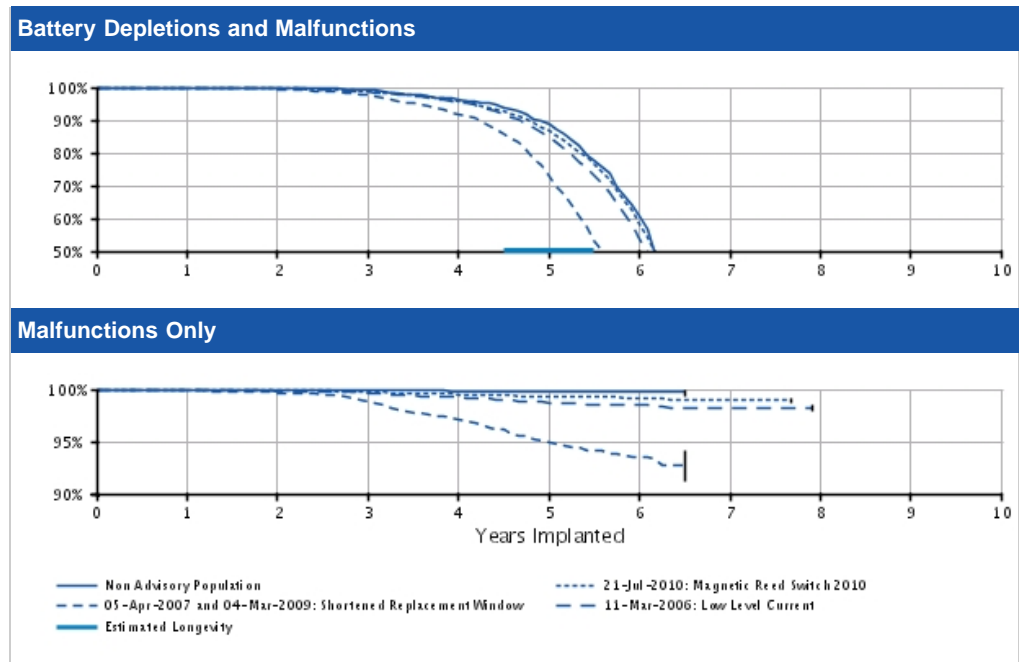
[References](#) cited in table above

CONTAK RENEWAL 3 RF

Models H210/H215

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Normal Battery Depletions: 7,500
U.S. Approval Date: February 2005	U.S. Unconfirmed Reports of Premature Battery Depletion : 29
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:176
	Without Compromised Therapy:157
	With Compromised Therapy:19



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.82 (-0.4/+0.1)	99.17 (-0.6/+0.4)	96.26 (-1.2/+0.9)	88.55 (-2.0/+1.7)	60.71 (-3.2/+3.1)	33.53 @ 78 mo. (-3.4/+3.5)	-	-	-	-
	Registered Implants: 2000											
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.78 (-0.5/+0.2)	99.78 (-0.5/+0.2)	99.78 (-0.5/+0.2)	99.78 @ 78 mo. (-0.5/+0.2)	-	-	-	-
	Effective Sample Size	1735	1524	1321	1126	901	511	202	-	-	-	-
21-Jul-10 Magnetic Reed Switch 2010*	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.75 (-0.1/+0.1)	98.81 (-0.2/+0.2)	95.99 (-0.4/+0.4)	86.55 (-0.7/+0.7)	58.20 (-1.1/+1.1)	21.22 (-1.0/+1.1)	17.10 @ 92 mo. (-1.1/+1.1)	-	-	-
	Registered Implants: 15000											
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.53 (-0.2/+0.1)	99.28 (-0.2/+0.2)	99.19 (-0.2/+0.2)	98.99 (-0.3/+0.2)	98.99 @ 92 mo. (-0.3/+0.2)	-	-	-
	Effective Sample Size	12967	11434	9921	8438	6648	3957	898	236	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.41 (-0.3/+0.2)	97.57 (-0.6/+0.5)	91.86 (-1.2/+1.0)	72.82 (-2.0/+1.9)	30.93 (-2.2/+2.2)	14.74 @ 78 mo. (-1.7/+1.9)	-	-	-	-
	Registered Implants:											
	Malfunctions Only(%)											

4000	Malfunctions Only (%) (Confidence Interval)	99.89 (-0.2/+0.1)	99.66 (-0.3/+0.2)	98.82 (-0.5/+0.3)	97.09 (-0.7/+0.6)	94.91 (-1.0/+0.9)	93.54 (-1.3/+1.1)	92.74 @ 78 mo. (-1.6/+1.4)	-	-	-
	Effective Sample Size	3377	2941	2484	2036	1397	500	204	-	-	-
11-Mar-06 Low Level Current*	Depletions and Malfunctions (%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.67 (-0.1/+0.1)	98.62 (-0.2/+0.2)	95.46 (-0.4/+0.4)	84.69 (-0.7/+0.7)	53.90 (-1.0/+1.0)	19.77 (-0.9/+0.9)	15.62 @ 95 mo. (-0.9/+1.0)	-	-
Registered Implants: 19000	Malfunctions Only (%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.84 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.23 (-0.2/+0.1)	98.73 (-0.2/+0.2)	98.48 (-0.3/+0.2)	98.22 (-0.3/+0.3)	98.22 @ 95 mo. (-0.3/+0.3)	-	-
	Effective Sample Size	16380	14429	12466	10557	8177	4601	1107	224	-	-

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

CONTAK RENEWAL 3 RF

Models H210/H215

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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CONTAK RENEWAL 3 RF Models H210/H215			
Worldwide Distribution: 21,000			
Worldwide Confirmed Malfunctions: 178			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	143	5	148
⁸ Shortened replacement window (Advisory issued)	84	2	
¹⁷ Extended charge time post-mid-life	1	-	
²⁶ Capacitor	2	-	
³¹ Integrated circuit	8	3	
⁴⁶ Capacitor	1	-	
⁵¹ Capacitor	3	-	
⁵⁶ Mid-life display of replacement indicators	13	-	
⁵⁸ High-voltage capacitor	2	-	
⁷⁸ Low-voltage capacitor	29	-	
Mechanical	8	11	19
⁴ Magnetic reed switch 2010 (Advisory issued)	5	6	
¹⁴ Magnetic switch (Advisory issued)	-	1	
³⁵ Seal plug	2	-	
⁶³ Setscrew	1	-	
⁶⁵ Seal plug	-	1	
⁸⁶ Bent flex circuit	-	3	
Software	3	-	3
²⁰ Parameter errors	1	-	
⁵⁵ Memory location	1	-	
⁷⁵ Misaligned markers	1	-	
Other	5	3	8
Non-patterned	-	2	
³⁹ Battery depletion	5	1	
WW Confirmed Malfunctions	159	19	178

[More details](#) about malfunctions

[References](#) cited in table above

CONTAK RENEWAL 4 HE

Models H197/H199

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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CONTAK RENEWAL 4 HE Models H197/H199			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 146			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	130	2	132
⁸ Shortened replacement window (Advisory issued)	67	1	
¹⁰ Premature battery depletion (Advisory issued)	2	-	
¹⁷ Extended charge time post-mid-life	10	-	
²⁶ Capacitor	1	-	
³¹ Integrated circuit	1	1	
⁴⁶ Capacitor	1	-	
⁵⁶ Mid-life display of replacement indicators	26	-	
⁵⁸ High-voltage capacitor	1	-	
⁷⁸ Low-voltage capacitor	21	-	
Mechanical	6	4	10
⁴ Magnetic reed switch 2010 (Advisory issued)	-	1	
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁸ Header	1	1	
³⁵ Seal plug	2	-	
⁶³ Setscrew	1	1	
⁶⁵ Seal plug	1	-	
⁷² Cracked solder joint	1	-	
Software	-	-	0
Other	3	1	4
Non-patterned	1	1	
³⁹ Battery depletion	2	-	
WW Confirmed Malfunctions	139	7	146


[More details](#) about malfunctions

[References](#) cited in table above

CONTAK RENEWAL 4

Models H190/H195

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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CONTAK RENEWAL 4 Models H190/H195 			
Worldwide Distribution: 18,000 Worldwide Confirmed Malfunctions: 354			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	310	11	321
⁸ Shortened replacement window (Advisory issued)	160	5	
¹⁰ Premature battery depletion (Advisory issued)	14	-	
¹⁷ Extended charge time post-mid-life	9	-	
²² Integrated circuit	2	-	
²⁶ Capacitor	-	1	
³¹ Integrated circuit	3	3	
⁴⁶ Capacitor	-	1	
⁵¹ Capacitor	3	-	
⁵⁶ Mid-life display of replacement indicators	63	-	
⁶¹ Integrated circuit	-	1	
⁷⁸ Low-voltage capacitor	56	-	
Mechanical	7	14	21
⁴ Magnetic reed switch 2010 (Advisory issued)	-	3	
⁷ Subpectoral implant (Advisory issued)	-	7	
¹⁴ Magnetic switch (Advisory issued)	-	1	
²⁸ Header	2	-	
³⁵ Seal plug	3	-	
⁴⁵ Circuit connection	-	1	
⁶³ Setscrew	-	1	
⁷¹ Reed switch	1	1	
⁷² Cracked solder joint	1	-	
Software	-	-	0
Other	6	6	12
Non-patterned	2	3	
³⁹ Battery depletion	4	3	
WW Confirmed Malfunctions	323	31	354

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2014

INVIVE

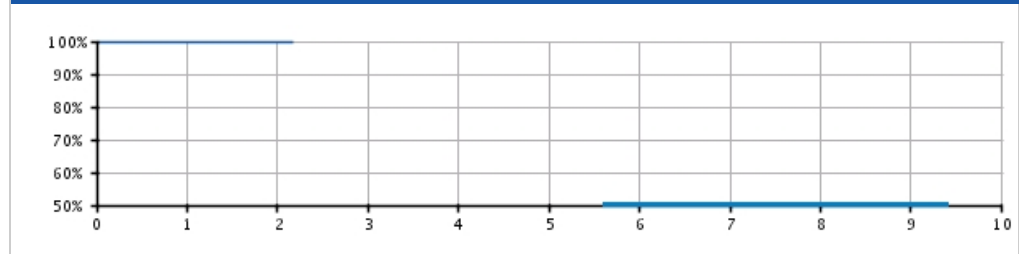
Models V172/V173/V182/V183/W172/
W173

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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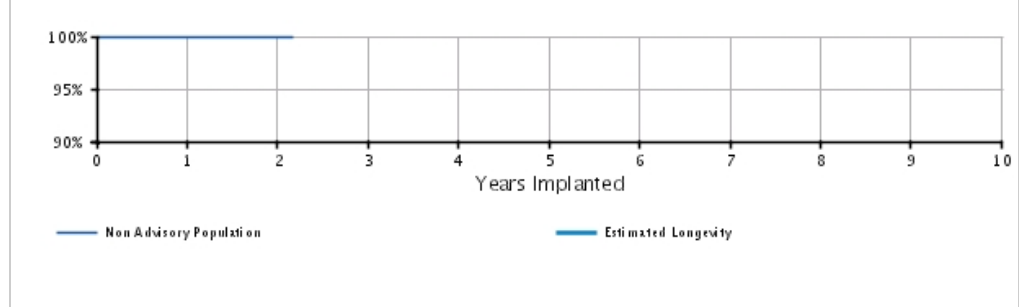
U.S. Summary

U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 26 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
Registered Implants: 6000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 26 mo. (-0.0/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	3224	575	297	-	-	-	-	-	-	-

INVIVE

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INVIVE Models V172/V173/V182/V183/W172/ W173 			
Worldwide Distribution: 14,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁵ Low-voltage capacitors	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1


[More details](#) about malfunctions

[References](#) cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

CONTAK RENEWAL TR 2 Models H140/H145 			
Worldwide Distribution: 31,000			
Worldwide Confirmed Malfunctions: 28			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁶ Capacitor	1	-	
Mechanical	4	-	4
³⁵ Seal plug	1	-	
⁵⁰ Setscrew block	2	-	
⁶⁵ Seal plug	1	-	
Software	12	-	12
⁴⁰ Memory error	1	-	
⁵⁴ Stored EGMs	11	-	
Other	10	1	11
Non-patterned	9	1	
⁶² Alert messages	1	-	
WW Confirmed Malfunctions	27	1	28

[More details](#) about malfunctions

[References](#) cited in table above

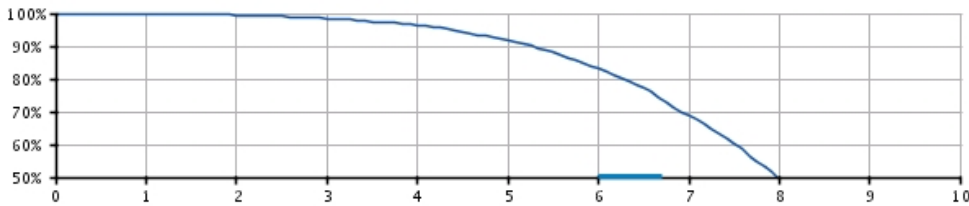
CONTAK RENEWAL TR

Models H120/H125

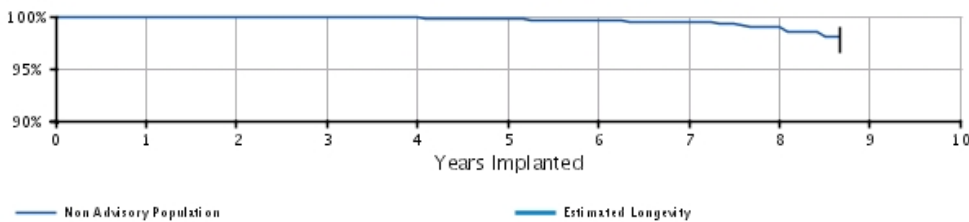
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 19,000	U.S. Normal Battery Depletions: 1,687
U.S. Approval Date: January 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 15
U.S. Estimated Active Implants: 8,000	U.S. Malfunctions:44
	Without Compromised Therapy:42
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.50 (-0.2/+0.2)	96.38 (-0.4/+0.3)	91.71 (-0.7/+0.6)	83.04 (-1.1/+1.1)	68.82 (-1.7/+1.7)	49.12 (-2.5/+2.5)	34.51 @ 104 mo. (-2.9/+3.1)	—
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.72 (-0.1/+0.1)	99.58 (-0.2/+0.1)	99.38 (-0.3/+0.2)	99.00 (-0.7/+0.4)	98.10 @ 104 mo. (-1.6/+0.9)	—
Registered Implants: 19000	Effective Sample Size	15609	13529	10565	7137	4493	2528	1227	465	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

CONTAK RENEWAL TR

Models H120/H125

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

CONTAK RENEWAL TR Models H120/H125 			
Worldwide Distribution: 19,000			
Worldwide Confirmed Malfunctions: 44			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁹ Low-voltage capacitor (Advisory issued)	1	-	
²⁶ Capacitor	-	1	
Mechanical	5	-	5
³⁵ Seal plug	5	-	
Software	27	-	27
⁵⁴ Stored EGMs	27	-	
Other	9	1	10
Non-patterned	7	1	
⁶² Alert messages	2	-	
WW Confirmed Malfunctions	42	2	44

[More details](#) about malfunctions


[References](#) cited in table above

AUTOGEN ICD EL DR

Models D162/D163/D176/D177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

AUTOGEN ICD EL DR
Models D162/D163/D176/D177



Worldwide Distribution: 500
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions


[References](#) cited in table above

AUTOGEN ICD EL VR

Models D160/D161/D174/D175

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

AUTOGEN ICD EL VR
Models D160/D161/D174/D175



Worldwide Distribution: 500
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

DYNAGEN/INOGEN/ORIGEN ICD MINI DR 

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

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

DYNAGEN/INOGEN/ORIGEN ICD MINI VR 

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

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

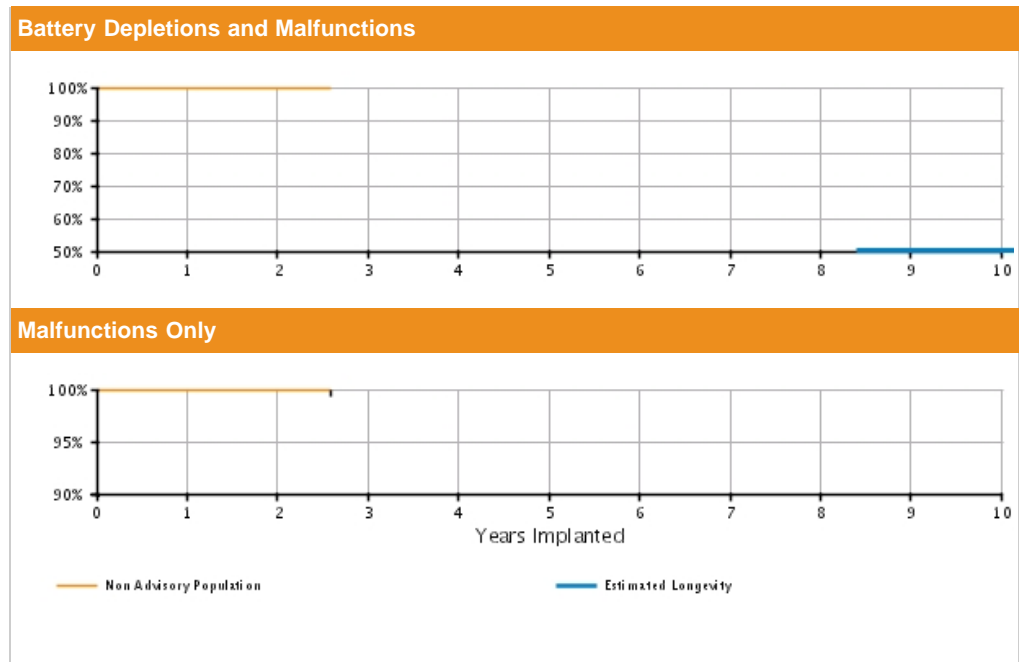
[References](#) cited in table above

INCEPTA ICD DR 4-Site

Models E162/F162

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 9,000	U.S. Normal Battery Depletions: 2
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 9,000	U.S. Malfunctions:3
	Without Compromised Therapy:2
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 @ 31 mo. (-0.5/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.85 @ 31 mo. (-0.5/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 9000	Effective Sample Size	4988	1681	305	-	-	-	-	-	-	-	-

INCEPTA ICD DR 4-Site

Models E162/F162

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INCEPTA ICD DR 4-Site
Models E162/F162



Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁸⁹ Integrated circuit	1	1	
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	2	4

[More details](#) about malfunctions

[References](#) cited in table above

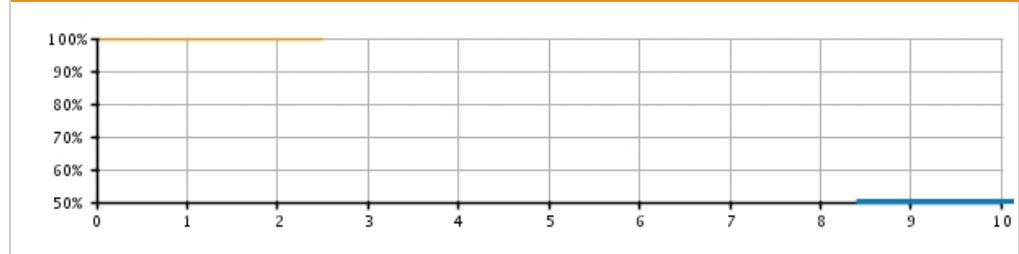
INCEPTA ICD DR

Models E163/F163

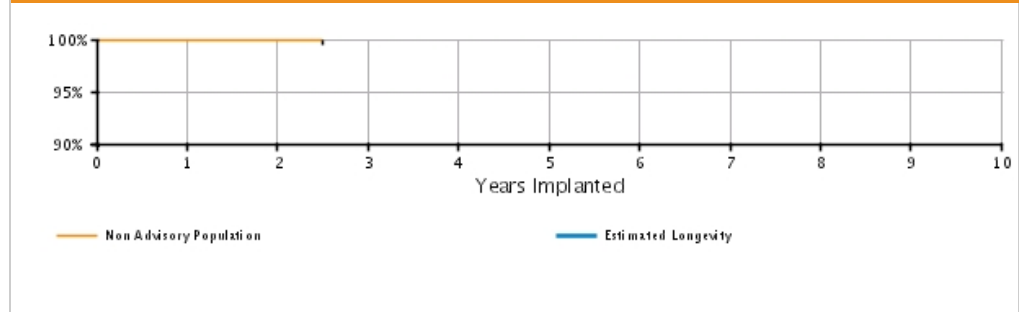
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:3
	Without Compromised Therapy:2
	With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.84 (-0.4/+0.1)	99.84 @ 30 mo. (-0.4/+0.1)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.86 (-0.4/+0.1)	99.86 @ 30 mo. (-0.4/+0.1)	-	-	-	-	-	-	-
Registered Implants: 6000	Effective Sample Size	2898	868	208	-	-	-	-	-	-	-

INCEPTA ICD DR

Models E163/F163

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INCEPTA ICD DR Models E163/F163			
Worldwide Distribution: 9,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	-	3
⁸⁵ Low-voltage capacitors	1	-	
⁸⁹ Integrated circuit	1	-	
⁹⁷ High voltage circuit	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	2	1	3
Non-patterned	2	1	
WW Confirmed Malfunctions	5	1	6

[More details](#) about malfunctions

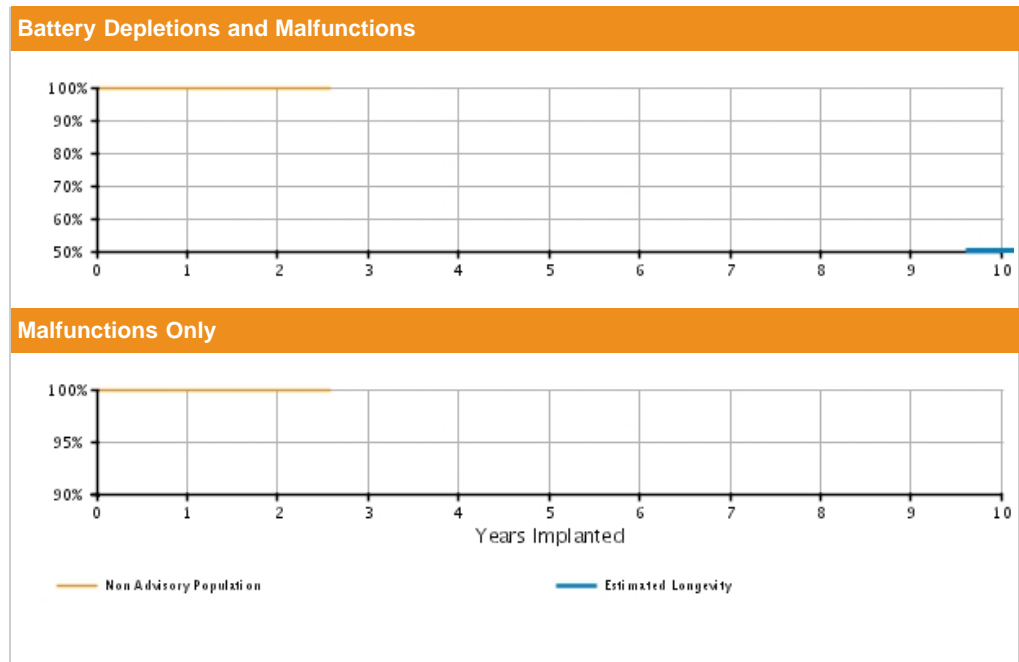
[References](#) cited in table above

INCEPTA ICD VR 4-Site

Models E160/F160

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 8,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 8,000	U.S. Normal Battery Depletions: 3 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:2 Without Compromised Therapy:1 With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.90 (-0.1/+0.1)	99.90 @ 31 mo. (-0.1/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 31 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	4184	1318	244	-	-	-	-	-	-	-	-

INCEPTA ICD VR 4-Site

Models E160/F160

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INCEPTA ICD VR 4-Site
Models E160/F160



Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

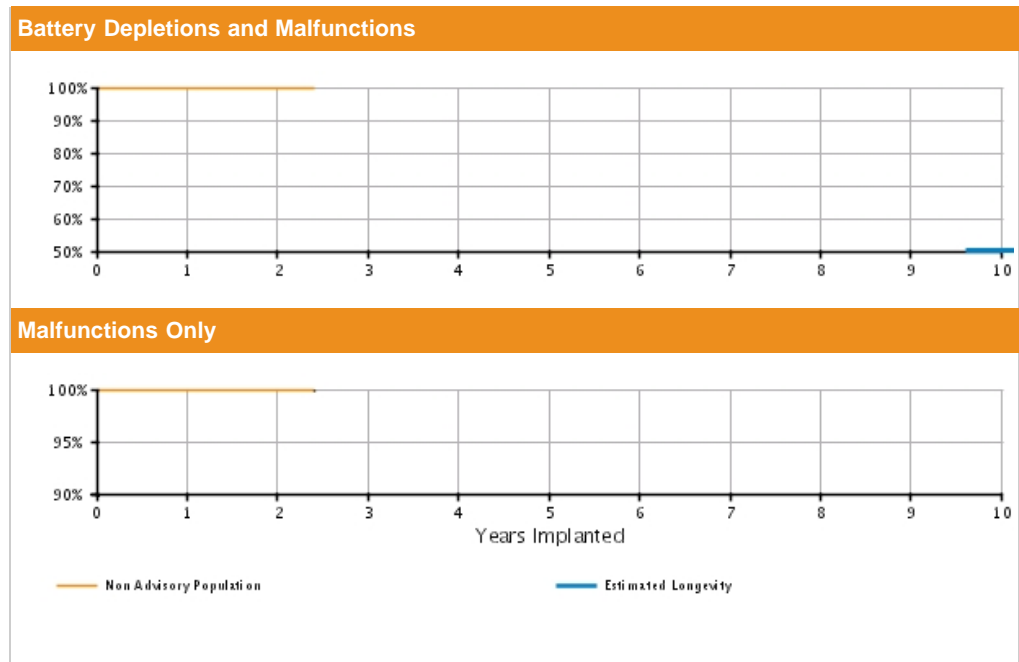
[References](#) cited in table above

INCEPTA ICD VR

Models E161/F161

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 3,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)		99.97 (-0.2/+0.0)	99.91 (-0.3/+0.1)	99.91 @ 29 mo. (-0.3/+0.1)	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)		99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 29 mo. (-0.2/+0.0)	—	—	—	—	—	—	—
Registered Implants: 3000	Effective Sample Size		1775	604	227	—	—	—	—	—	—	—

INCEPTA ICD VR

Models E161/F161

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INCEPTA ICD VR Models E161/F161			
Worldwide Distribution: 6,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁰ High-voltage capacitor	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

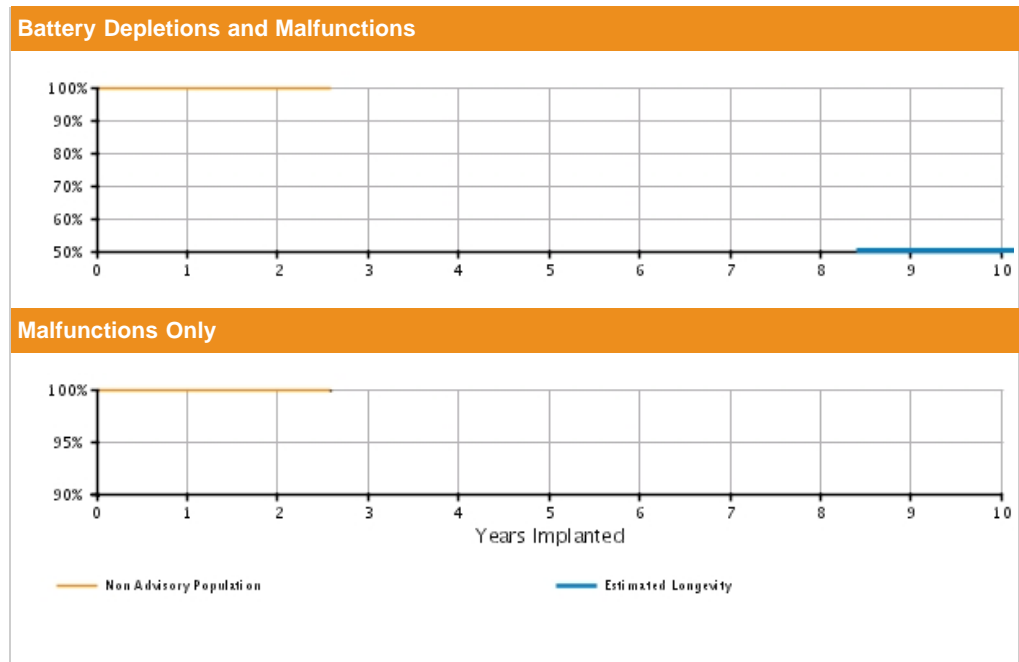
[References](#) cited in table above

ENERGEN ICD DR 4-Site

Models E142/F142

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 12,000	U.S. Normal Battery Depletions: 2
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:5
	Without Compromised Therapy:3
	With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.95	99.93	99.87	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	@ 31 mo. (-0.2/+0.1)								
Registered Implants: 12000	Malfunctions Only(%)	99.96	99.94	99.94	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	@ 31 mo. (-0.1/+0.0)								
	Effective Sample Size	7563	2628	403	—	—	—	—	—	—	—	—

ENERGEN ICD DR 4-Site

Models E142/F142

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENERGEN ICD DR 4-Site
Models E142/F142



Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	2	5
⁸⁵ Low-voltage capacitors	1	-	
⁸⁹ Integrated circuit	2	2	
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

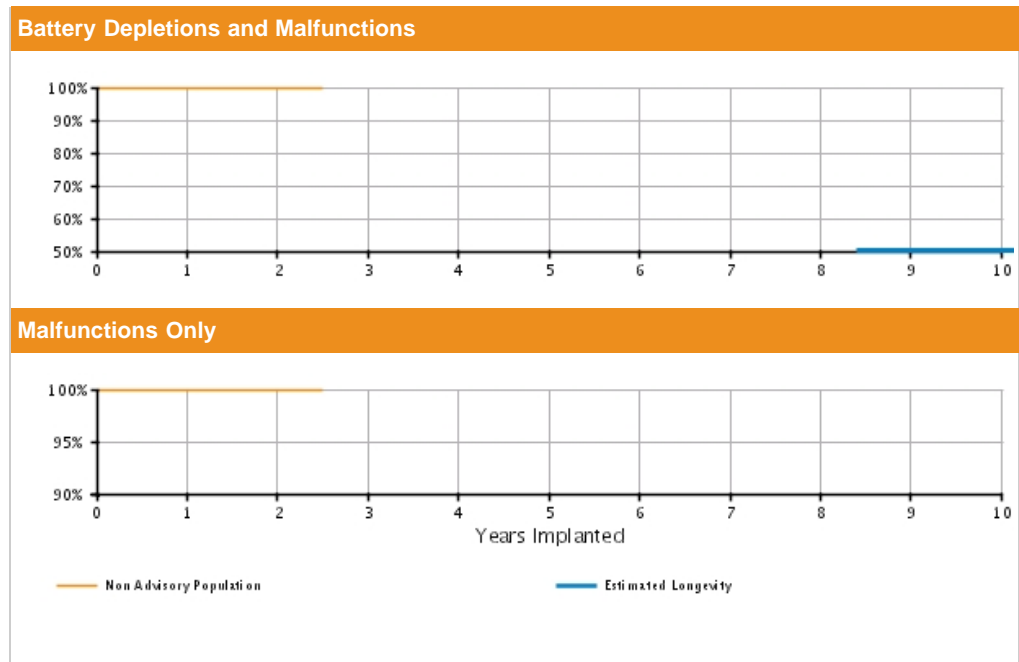
[References](#) cited in table above

ENERGEN ICD DR

Models E143/F143

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 9,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 8,000	U.S. Malfunctions: 1
	Without Compromised Therapy: 1
	With Compromised Therapy: 0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%)	99.96	99.91	99.91	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	@ 30 mo. (-0.1/+0.1)								
Registered Implants: 9000	Malfunctions Only (%)	99.99	99.99	99.99	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	@ 30 mo. (-0.1/+0.0)								
	Effective Sample Size	5405	1615	331	—	—	—	—	—	—	—	—

ENERGEN ICD DR

Models E143/F143

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENERGEN ICD DR
Models E143/F143



Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸⁵ Low-voltage capacitors	1	-	
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

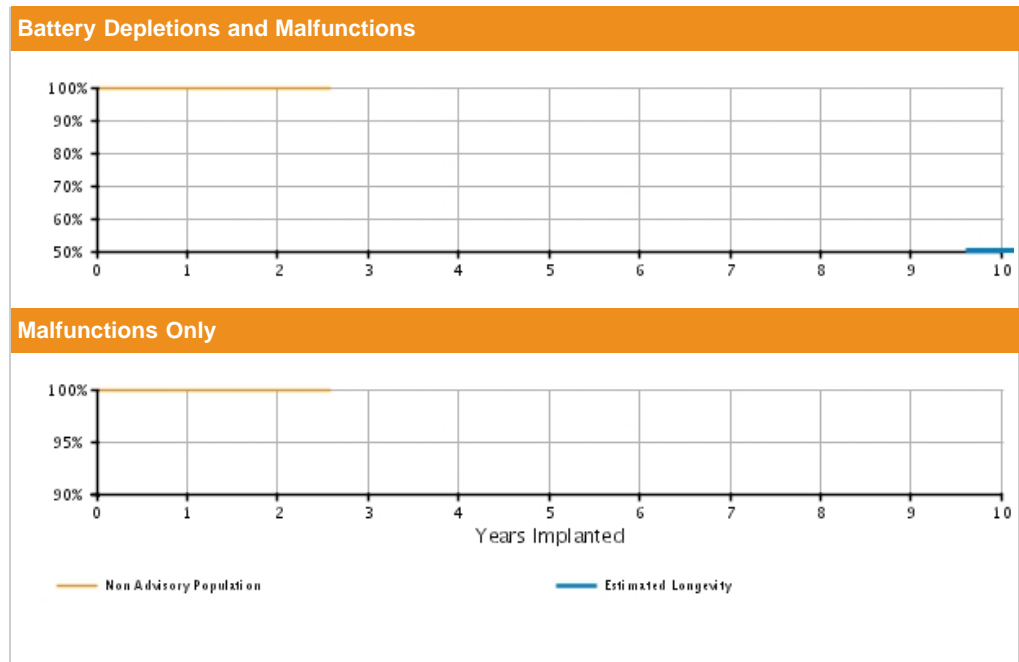
[References](#) cited in table above

ENERGEN ICD VR 4-Site

Models E140/F140

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 13,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 12,000	U.S. Normal Battery Depletions: 9 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:2 Without Compromised Therapy:0 With Compromised Therapy:2



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.84 (-0.2/+0.1)	99.79 @ 31 mo. (-0.2/+0.1)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 31 mo. (-0.1/+0.0)	—	—	—	—	—	—	—	—
Registered Implants: 13000	Effective Sample Size	7340	2353	367	—	—	—	—	—	—	—	—

ENERGEN ICD VR 4-Site

Models E140/F140

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENERGEN ICD VR 4-Site
Models E140/F140

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	1	2	3

[More details](#) about malfunctions

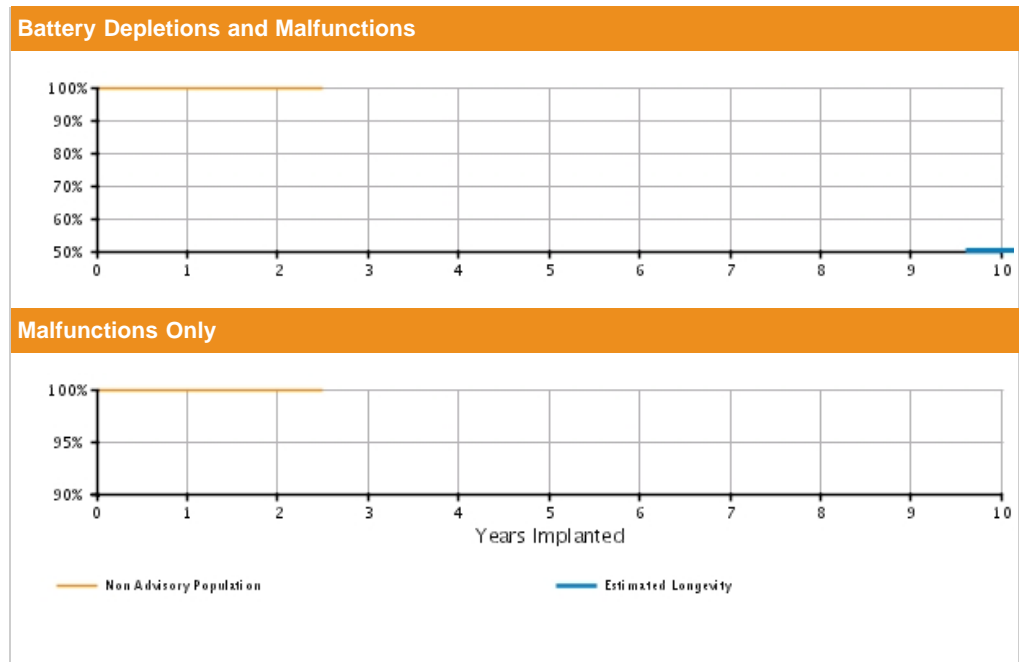
[References](#) cited in table above

ENERGEN ICD VR

Models E141/F141

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 2
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:2
	Without Compromised Therapy:1
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.91 @ 30 mo. (-0.2/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 30 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 6000	Effective Sample Size	3774	1314	308	-	-	-	-	-	-	-	-

ENERGEN ICD VR

Models E141/F141

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENERGEN ICD VR Models E141/F141 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 5			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
⁸⁹ Integrated circuit	-	3	
Mechanical	-	-	0
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	2	3	5

[More details](#) about malfunctions


[References](#) cited in table above

PUNCTUA ICD DR 4-Site

Models E052/F052

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA ICD DR 4-Site
Models E052/F052



Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

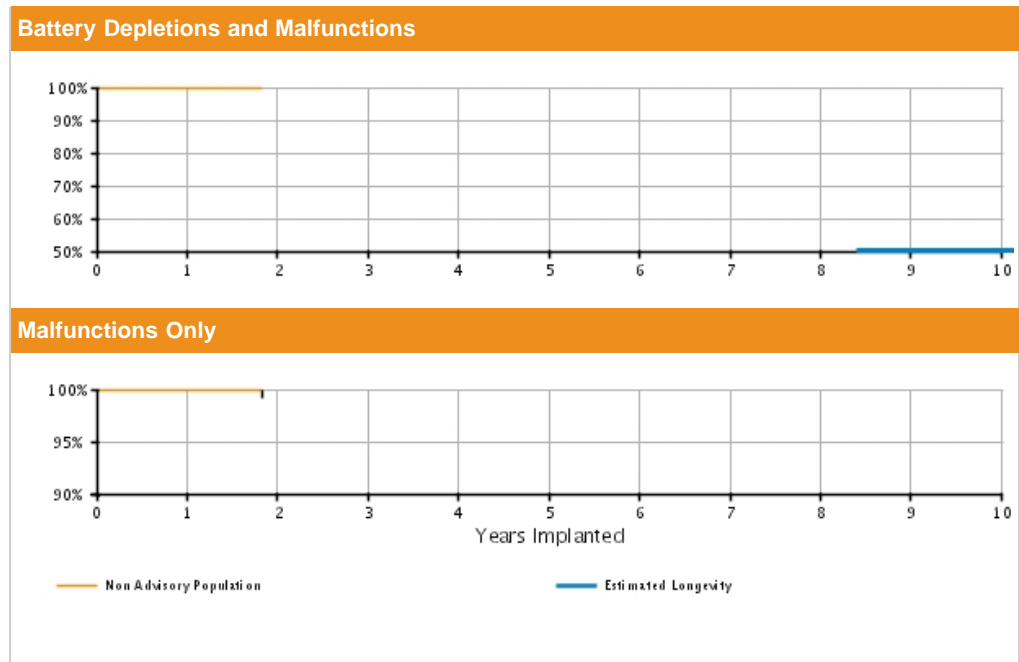
[References](#) cited in table above

PUNCTUA ICD DR

Models E053/F053

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 1,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%) (Confidence Interval)	99.89 (-0.7/+0.1)	99.89 @ 22 mo. (-0.7/+0.1)	-	-	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.89 (-0.7/+0.1)	99.89 @ 22 mo. (-0.7/+0.1)	-	-	-	-	-	-	-	-	-
Registered Implants: 1000	Effective Sample Size	581	220	-	-	-	-	-	-	-	-	-

PUNCTUA ICD DR

Models E053/F053

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA ICD DR
Models E053/F053



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions


[References](#) cited in table above

PUNCTUA ICD VR 4-Site

Models E050/F050

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA ICD VR 4-Site
Models E050/F050



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

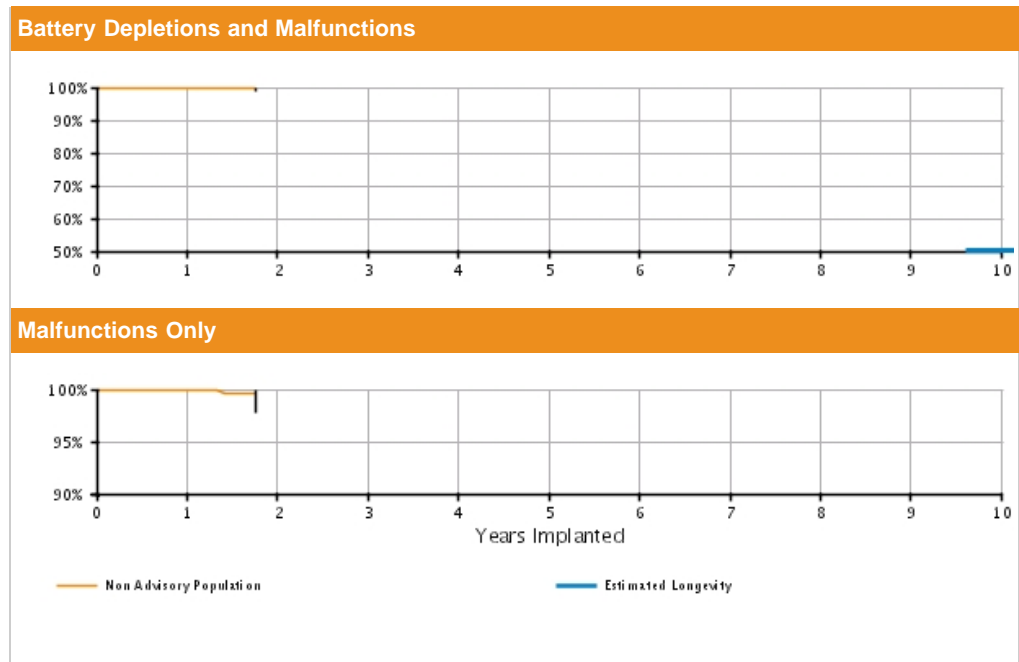
[References](#) cited in table above

PUNCTUA ICD VR

Models E051/F051

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 1,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:1
	Without Compromised Therapy:1
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%)	100.00	99.68	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	@ 21 mo. (-1.9/+0.3)									
Registered Implants: 1000	Malfunctions Only (%)	100.00	99.68	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	@ 21 mo. (-1.9/+0.3)									
	Effective Sample Size	433	214	-	-	-	-	-	-	-	-	-

PUNCTUA ICD VR

Models E051/F051

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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PUNCTUA ICD VR
Models E051/F051



Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁹⁷ High voltage circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

[References](#) cited in table above

SQ-RX Pulse Generator

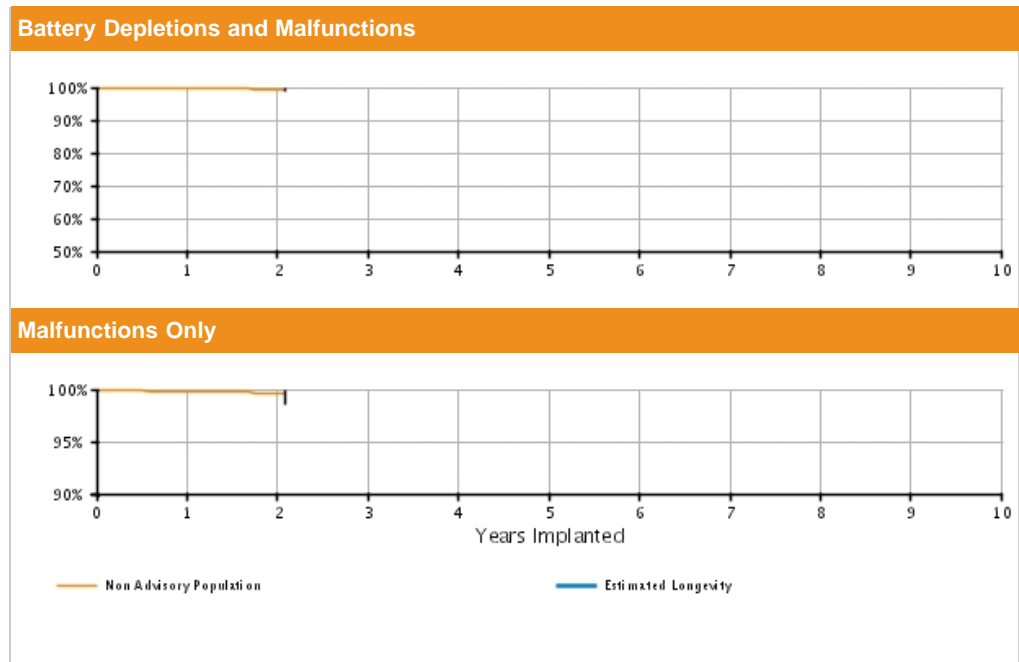
Model 1010

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Approval Date: September 2012

U.S. Normal Battery Depletions: 0
 U.S. Unconfirmed Reports of Premature Battery Depletion : 1
 U.S. Malfunctions:7
 Without Compromised Therapy:2
 With Compromised Therapy:5



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Total Population	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.3/+0.1)	99.36 (-1.2/+0.4)	99.36 @ 25 mo. (-1.2/+0.4)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.3/+0.1)	99.55 (-1.1/+0.3)	99.55 @ 25 mo. (-1.1/+0.3)	-	-	-	-	-	-	-
1-Jun-11 High Cathode Condition*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

This product family may not conform to all AdvaMed/ISO recommended performance reporting data elements.

SQ-RX Pulse Generator

Model 1010

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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SQ-RX Pulse Generator Model 1010			
Worldwide Confirmed Malfunctions: 43			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
² Unintended Fuse Activation 2013 (Advisory issued)	-	3	
Mechanical	11	11	22
³ High cathode condition 2011 (Advisory issued)	1	2	
⁹⁴ Battery depletion	10	9	
Software	2	-	2
⁹⁶ Unintended Battery Depletion Alert	2	-	
Other	9	7	16
Non-patterned	8	6	
⁹⁵ Telemetry	1	1	
WW Confirmed Malfunctions	22	21	43

[More details](#) about malfunctions

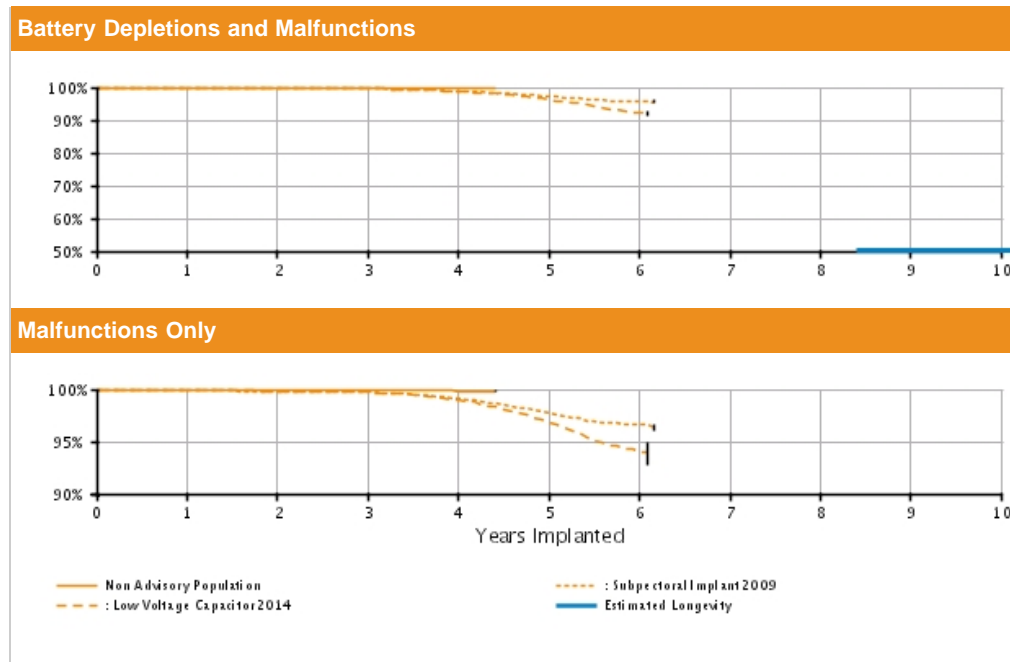
[References](#) cited in table above

TELIGEN DR

Models E110/E111/F110/F111

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 66,000	U.S. Normal Battery Depletions: 107
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 45
U.S. Estimated Active Implants: 47,000	U.S. Malfunctions:554
	Without Compromised Therapy:473
	With Compromised Therapy:81



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.79 (-0.1/+0.1)	99.66 (-0.1/+0.1)	99.66 @ 53 mo. (-0.1/+0.1)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.82 @ 53 mo. (-0.1/+0.1)	-	-	-	-	-	-
	Effective Sample Size	26440	23322	16699	4416	359	-	-	-	-	-	-
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.2)	98.89 (-0.1/+0.3)	97.30 (-0.2/+0.7)	95.72 (-0.6/+1.3)	95.44 @ 74 mo. (-0.6/+1.3)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.74 (-0.2/+0.2)	96.64 (-0.4/+0.3)	96.64 @ 74 mo. (-0.4/+0.3)	-	-	-	-
	Effective Sample Size	22629	20056	17862	15526	6360	337	343	-	-	-	-
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.56 (-0.1/+0.1)	98.19 (-0.2/+0.2)	95.18 (-0.4/+0.3)	92.41 (-1.5/+1.3)	92.04 @ 73 mo. (-1.5/+1.3)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.96 (-0.2/+0.1)	96.86 (-0.3/+0.3)	93.99 (-1.1/+0.9)	93.99 @ 73 mo.	-	-	-	-
	Effective Sample Size	23000	23000	23000	23000	23000	23000	23000	-	-	-	-


						(-1.2/+1.0)			
Effective Sample Size	20718	18223	16017	13895	6117	320	290	-	-

*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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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TELIGEN DR Models E110/E111/F110/F111 			
Worldwide Distribution: 90,000			
Worldwide Confirmed Malfunctions: 753			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	600	51	651
¹ Low Voltage Capacitor 2014 (Advisory issued)	491	16	
⁷⁹ Safety Core-electrocautery	3	-	
⁸⁰ High-voltage capacitor	1	5	
⁸⁵ Low-voltage capacitors	6	-	
⁸⁹ Integrated circuit	14	16	
⁹² Battery	71	14	
⁹³ Low-voltage capacitor	14	-	
Mechanical	17	48	65
⁵ Subpectoral implant 2009 (Advisory issued)	3	6	
⁷³ Transformer	-	20	
⁷⁶ Seal plug	3	-	
⁷⁷ Difficulty securing lead	9	8	
⁸³ Header contacts	1	11	
⁹⁹ Header	1	3	
Software	14	-	14
⁸⁷ Alert messages not displayed post-EOL	3	-	
⁹⁰ Memory errors	11	-	
Other	17	6	23
Non-patterned	17	6	
WW Confirmed Malfunctions	648	105	753

[More details](#) about malfunctions

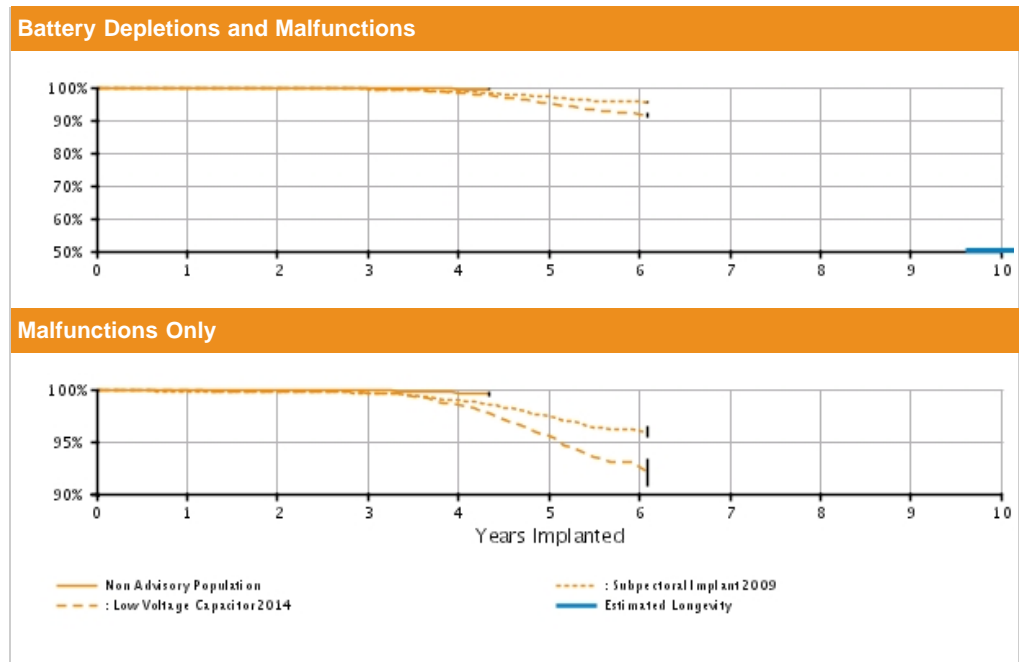
[References](#) cited in table above

TELIGEN VR

Models E102/E103/F102/F103

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 38,000	U.S. Normal Battery Depletions: 56
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Estimated Active Implants: 27,000	U.S. Malfunctions:396
	Without Compromised Therapy:332
	With Compromised Therapy:64



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.46 (-0.3/+0.2)	99.46 @ 52 mo. (-0.3/+0.2)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.59 (-0.3/+0.2)	99.59 @ 52 mo. (-0.3/+0.2)	-	-	-	-	-	-
	Effective Sample Size	16280	14329	9564	1678	252	-	-	-	-	-	-
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.2)	97.02 (-0.4/+0.3)	95.52 (-0.6/+0.5)	95.32 @ 73 mo. (-0.6/+0.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.63 (-0.1/+0.1)	98.93 (-0.2/+0.2)	97.42 (-0.3/+0.3)	96.08 (-0.6/+0.5)	95.88 @ 73 mo. (-0.5/+0.6)	-	-	-	-
	Effective Sample Size	13681	11998	10518	9151	6222	792	464	-	-	-	-
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.2)	98.24 (-0.1/+0.5)	95.18 (-0.2/+0.9)	91.92 (-0.6/+1.8)	91.47 @ 73 mo. (-1.4/+1.1)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.46 (-0.3/+0.2)	95.56 (-0.5/+0.5)	92.64 (-1.3/+1.1)	92.18 @ 73 mo.	-	-	-	-
	Effective Sample Size	12000	12000	12000	12000	12000	12000	12000	-	-	-	-


						(-1.5/+1.2)			
Effective Sample Size	10905	9579	8403	7114	2846	253	202	-	-

*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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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TELIGEN VR Models E102/E103/F102/F103			
Worldwide Distribution: 65,000			
Worldwide Confirmed Malfunctions: 618			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	479	31	510
¹ Low Voltage Capacitor 2014 (Advisory issued)	374	12	
⁷⁹ Safety Core-electrocautery	1	1	
⁸⁰ High-voltage capacitor	-	2	
⁸⁵ Low-voltage capacitors	4	-	
⁸⁹ Integrated circuit	7	12	
⁹² Battery	85	4	
⁹³ Low-voltage capacitor	8	-	
Mechanical	19	60	79
⁵ Subpectoral implant 2009 (Advisory issued)	6	12	
⁴⁴ Transformer	-	1	
⁷³ Transformer	-	14	
⁷⁶ Seal plug	1	-	
⁷⁷ Difficulty securing lead	-	10	
⁸³ Header contacts	11	16	
⁹⁹ Header	1	7	
Software	14	-	14
⁶ Respiratory Sensor Oversensing (Advisory issued)	1	-	
⁸⁷ Alert messages not displayed post-EOL	4	-	
⁹⁰ Memory errors	9	-	
Other	7	8	15
Non-patterned	7	8	
WW Confirmed Malfunctions	519	99	618

[More details](#) about malfunctions

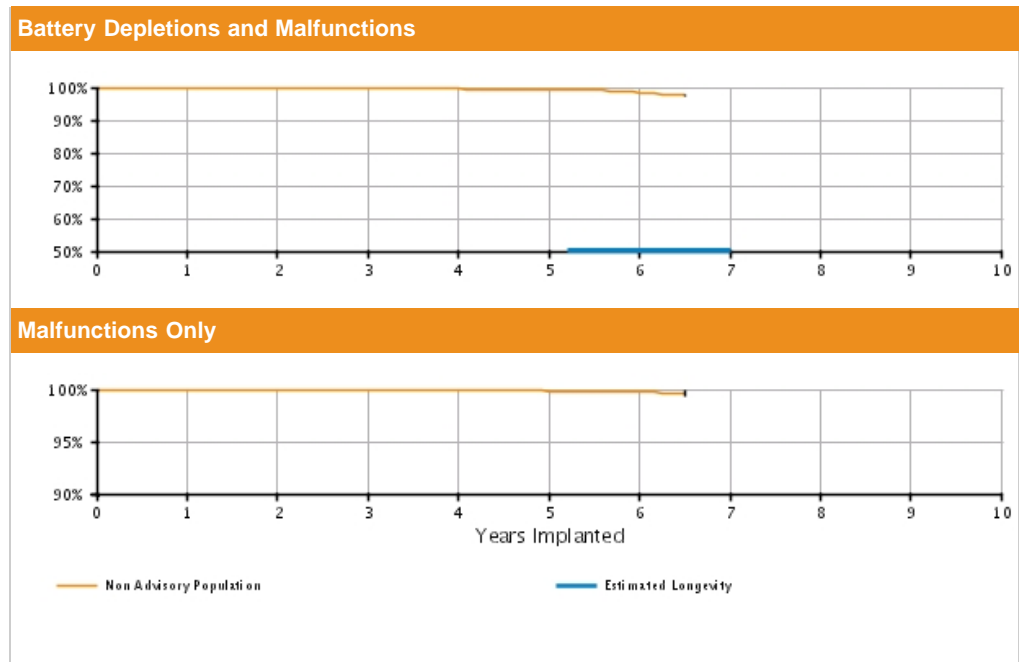
[References](#) cited in table above

CONFIDENT DR

Models E030/F030

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 51
U.S. Approval Date: February 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:10
	Without Compromised Therapy:8
	With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.94	99.89	99.73	99.54	99.34	98.42	97.63	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.2)	(-0.3/+0.2)	(-0.5/+0.4)	@ 78 mo. (-0.8/+0.6)				
Registered Implants: 7000	Malfunctions Only(%)	99.98	99.98	99.98	99.92	99.83	99.74	99.67	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	@ 78 mo. (-0.3/+0.2)				
Effective Sample Size		6165	5398	4678	3938	3142	1962	379	—	—	—	—

CONFIENT DR

Models E030/F030

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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CONFIENT DR Models E030/F030 			
Worldwide Distribution: 8,000			
Worldwide Confirmed Malfunctions: 10			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	6	-	6
²⁶ Capacitor	1	-	
³¹ Integrated circuit	2	-	
⁹³ Low-voltage capacitor	3	-	
Mechanical	-	1	1
⁷³ Transformer	-	1	
Software	-	-	0
Other	2	1	3
Non-patterned	2	-	
³⁹ Battery depletion	-	1	
WW Confirmed Malfunctions	8	2	10

[More details](#) about malfunctions

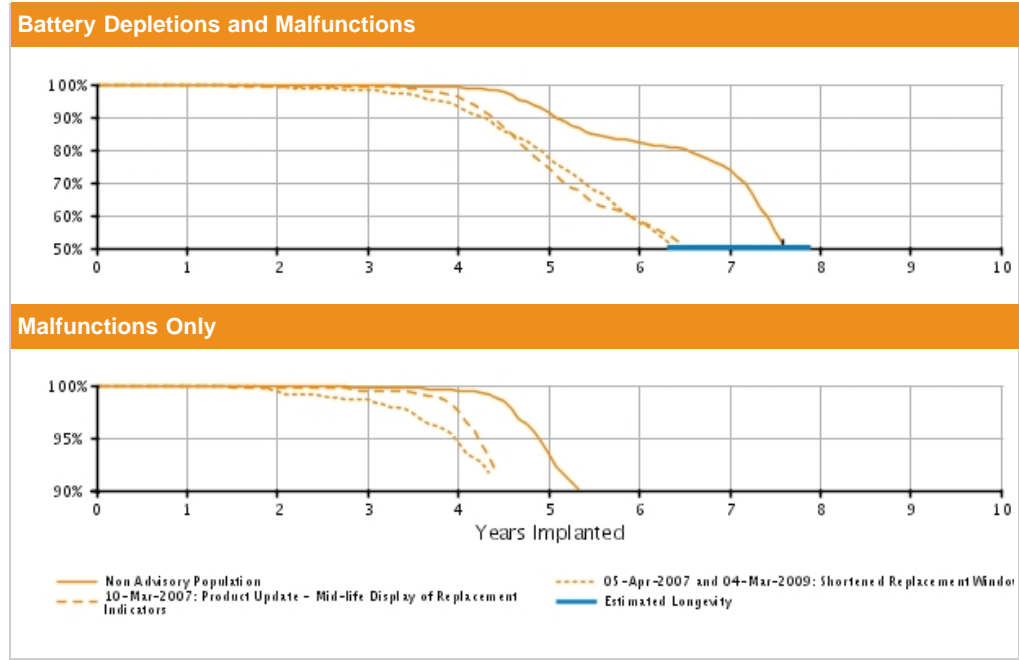
[References](#) cited in table above

VITALITY 2 EL DR

Model T167

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 8,000	U.S. Normal Battery Depletions: 1,495
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions: 764



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.66 (-0.2/+0.1)	99.01 (-0.4/+0.3)	91.26 (-1.1/+1.0)	82.27 (-1.5/+1.4)	73.62 (-2.1/+2.0)	51.08 (-3.6/+3.6)	--	--	--
	Registered Implants: 5000											
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.90 (-0.2/+0.1)	99.82 (-0.2/+0.1)	99.50 (-0.3/+0.2)	93.38 (-1.0/+0.9)	87.28 (-1.4/+1.3)	86.56 (-1.4/+1.3)	86.56 (-1.4/+1.3)	--	--	--
	Effective Sample Size	4363	3832	3362	2917	2348	1755	772	219	--	--	--
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.22 (-0.6/+0.3)	98.37 (-0.8/+0.5)	93.39 (-1.5/+1.2)	77.47 (-2.6/+2.4)	57.93 (-3.2/+3.1)	31.68 (-3.2/+3.4)	28.59 (-3.1/+3.3)	--	--	--
	Registered Implants: 2000											
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.41 (-0.5/+0.3)	98.63 (-0.7/+0.5)	94.61 (-1.4/+1.1)	83.49 (-2.4/+2.1)	75.79 (-2.9/+2.6)	73.66 (-3.1/+2.9)	73.66 (-3.1/+2.9)	--	--	--
	Effective Sample Size	1699	1489	1289	1076	782	475	219	201	--	--	--
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.40 (-0.7/+0.3)	99.18 (-0.8/+0.4)	96.23 (-1.5/+1.1)	74.33 (-3.3/+3.1)	58.16 (-3.8/+3.7)	42.77 (-4.0/+4.1)	--	--	--	--
	Registered Implants:											
	Malfunctions Only(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.40 (-0.7/+0.3)	99.18 (-0.8/+0.4)	96.23 (-1.5/+1.1)	74.33 (-3.3/+3.1)	58.16 (-3.8/+3.7)	42.77 (-4.0/+4.1)	--	--	--	--

1000											
	Malfunctions Only (%) (Confidence Interval)	99.92 (-0.5/+0.1)	99.74 (-0.6/+0.2)	99.52 (-0.7/+0.3)	97.51 (-1.3/+0.9)	81.03 (-3.1/+2.8)	70.85 (-3.7/+3.4)	70.61 @ 82 mo. (-3.7/+3.5)	-	-	-
	Effective Sample Size	1171	1024	899	763	501	320	207	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL DR

Model T167

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY 2 EL DR Model T167			
Worldwide Distribution: 14,000			
Worldwide Confirmed Malfunctions: 1055			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1016	10	1026
⁸ Shortened replacement window (Advisory issued)	143	2	
¹⁷ Extended charge time post-mid-life	15	-	
²⁶ Capacitor	1	-	
³¹ Integrated circuit	-	4	
⁴⁶ Capacitor	1	-	
⁵⁶ Mid-life display of replacement indicators	814	-	
⁵⁸ High-voltage capacitor	-	2	
⁶¹ Integrated circuit	-	1	
⁷⁸ Low-voltage capacitor	42	1	
Mechanical	8	3	11
⁷ Subpectoral implant (Advisory issued)	1	1	
²⁸ Header	1	-	
³⁵ Seal plug	5	1	
⁶⁵ Seal plug	1	-	
⁷³ Transformer	-	1	
Software	7	1	8
⁵⁵ Memory location	1	1	
⁷⁵ Misaligned markers	6	-	
Other	3	7	10
Non-patterned	2	3	
²¹ Firmware error	1	4	
WW Confirmed Malfunctions	1034	21	1055

[More details](#) about malfunctions

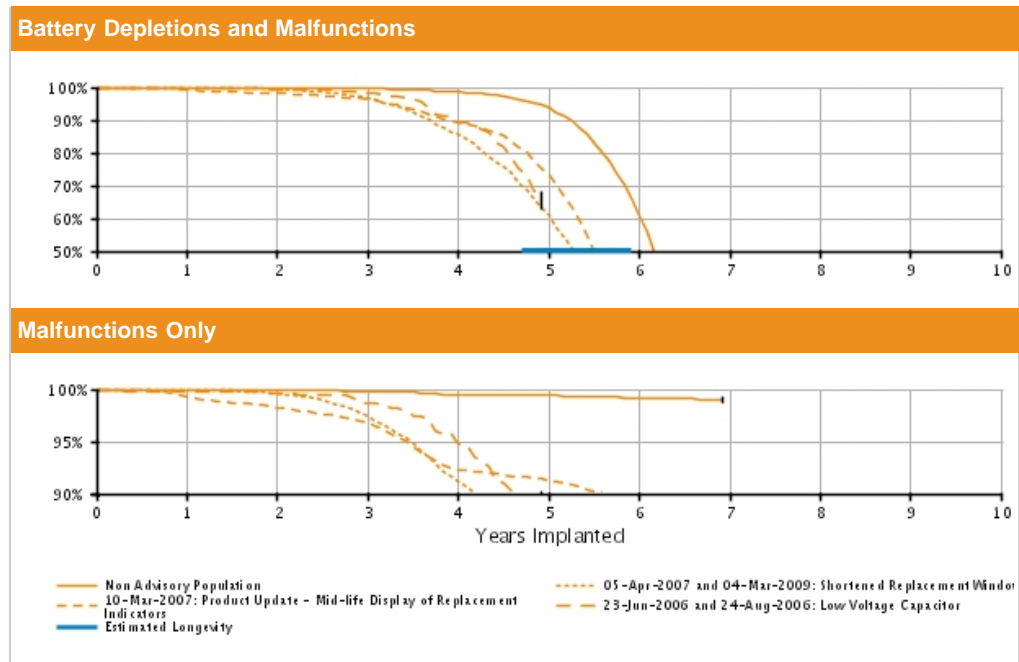
[References](#) cited in table above

VITALITY 2 DR

Model T165

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 31,000	U.S. Normal Battery Depletions: 10,939
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 79
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions: 1139
	Without Compromised Therapy: 1075
	With Compromised Therapy: 64



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions (%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.59 (-0.1/+0.1)	98.58 (-0.2/+0.2)	93.66 (-0.5/+0.5)	60.72 (-1.1/+1.1)	10.43 @ 83 mo. (-1.0/+1.1)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.19 (-0.2/+0.2)	99.01 @ 83 mo. (-0.4/+0.3)	-	-	-	-
	Effective Sample Size	15244	13386	11724	10036	8130	4390	267	-	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 9000	Depletions and Malfunctions (%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.39 (-0.2/+0.2)	96.63 (-0.5/+0.4)	85.51 (-0.9/+0.9)	60.66 (-1.4/+1.4)	17.82 (-1.2/+1.2)	6.63 @ 77 mo. (-0.8/+0.9)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.56 (-0.2/+0.1)	97.36 (-0.4/+0.4)	91.21 (-0.8/+0.7)	86.77 (-1.0/+0.9)	84.75 (-1.2/+1.1)	84.19 @ 77 mo. (-1.5/+1.4)	-	-	-	-
	Effective Sample Size	7844	6862	5805	4450	2719	682	221	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 5000	Depletions and Malfunctions (%) (Confidence Interval)	99.30 (-0.3/+0.2)	98.16 (-0.4/+0.3)	96.34 (-0.6/+0.5)	89.37 (-1.0/+0.9)	73.17 (-1.6/+1.5)	22.53 (-1.6/+1.7)	8.97 @ 76 mo. (-1.1/+1.3)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.19 (-0.2/+0.2)	99.01 @ 83 mo. (-0.4/+0.3)	-	-	-	-
	Effective Sample Size	5000	5000	5000	5000	5000	5000	5000	-	-	-	-

Registered Implants: 6000											
	Malfunctions Only (%) (Confidence Interval)	99.34 (-0.3/+0.2)	98.28 (-0.4/+0.3)	96.80 (-0.6/+0.5)	92.34 (-0.9/+0.8)	91.25 (-1.0/+0.9)	89.29 (-1.3/+1.1)	87.86 @ 76 mo. (-1.8/+1.6)	-	-	-
	Effective Sample Size	4991	4338	3718	2977	2093	542	204	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions (%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.42 (-1.2/+0.4)	98.25 (-1.7/+0.9)	89.37 (-3.5/+2.7)	65.57 @ 59 mo. (-5.3/+5.0)	-	-	-	-	-
Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.63 (-1.1/+0.3)	98.69 (-1.6/+0.7)	94.80 (-2.8/+1.8)	86.94 @ 59 mo. (-4.3/+3.3)	-	-	-	-	-
	Effective Sample Size	555	472	403	321	201	-	-	-	-	-
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 DR

Model T165

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY 2 DR Model T165			
Worldwide Distribution: 43,000			
Worldwide Confirmed Malfunctions: 1371			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1267	46	1313
⁸ Shortened replacement window (Advisory issued)	477	24	
⁹ Low-voltage capacitor (Advisory issued)	1	-	
¹⁰ Premature battery depletion (Advisory issued)	163	1	
¹⁷ Extended charge time post-mid-life	101	1	
²² Integrated circuit	1	1	
²⁵ Reconfirmation after charge	1	-	
²⁶ Capacitor	1	1	
³¹ Integrated circuit	7	11	
⁴⁶ Capacitor	3	1	
⁵¹ Capacitor	4	-	
⁵² Device tones	1	-	
⁵⁶ Mid-life display of replacement indicators	268	-	
⁵⁸ High-voltage capacitor	4	1	
⁶¹ Integrated circuit	1	-	
⁷⁰ Logic errors	-	3	
⁷⁸ Low-voltage capacitor	234	2	
Mechanical	7	6	13
³⁵ Seal plug	4	3	
⁴⁴ Transformer	-	1	
⁶⁵ Seal plug	2	-	
¹⁰⁰ Solder joint	1	2	
Software	2	2	4
⁵³ Memory location	-	2	
⁵⁵ Memory location	1	-	
⁷⁵ Misaligned markers	1	-	
Other	19	22	41
Non-patterned	12	8	
²¹ Firmware error	5	8	
³⁰ Battery depletion	2	5	
⁸¹ Magnet rate	-	1	
WW Confirmed Malfunctions	1295	76	1371

[More details](#) about malfunctions

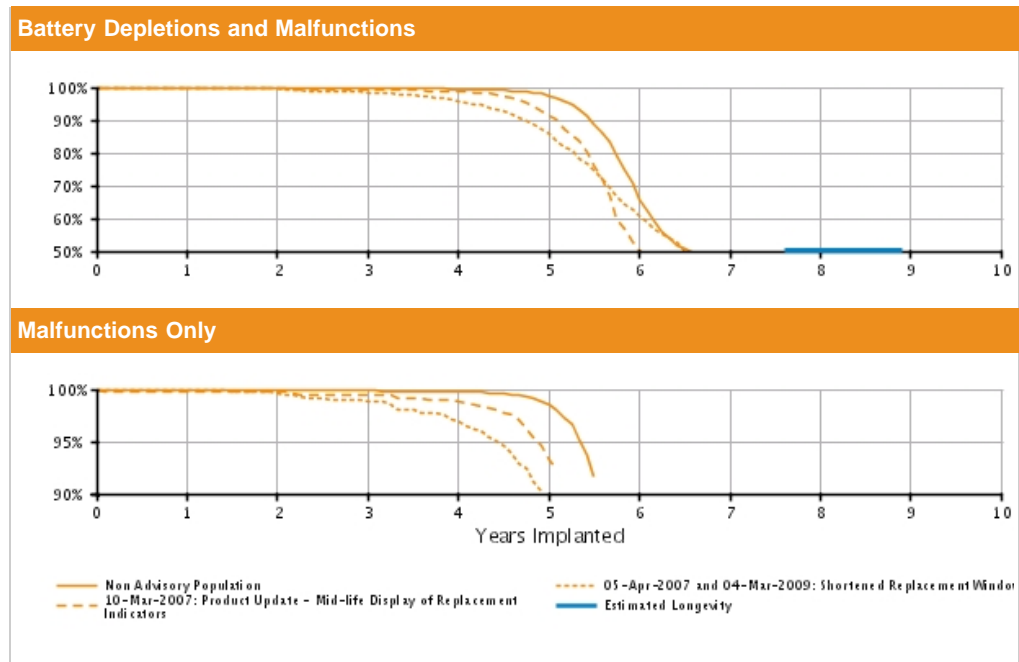
[References](#) cited in table above

VITALITY 2 EL VR

Model T177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 885
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1234
	Without Compromised Therapy:1221
	With Compromised Therapy:13



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.39 (-0.4/+0.2)	97.34 (-0.8/+0.6)	65.80 (-2.2/+2.2)	45.82 (-2.6/+2.6)	43.13 @ 88 mo. (-2.8/+2.8)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.85 (-0.2/+0.1)	99.73 (-0.3/+0.1)	98.47 (-0.6/+0.4)	72.54 (-2.2/+2.1)	57.03 (-2.7/+2.7)	57.03 @ 88 mo. (-2.7/+2.7)	-	-	-
	Effective Sample Size	3631	3176	2771	2396	2037	1168	331	209	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.48 (-0.8/+0.5)	95.88 (-1.2/+1.0)	85.72 (-2.2/+2.0)	60.99 (-3.2/+3.2)	41.55 (-3.4/+3.5)	34.07 @ 88 mo. (-3.4/+3.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.84 (-0.7/+0.4)	97.00 (-1.1/+0.8)	88.94 (-2.1/+1.8)	68.47 (-3.2/+3.1)	61.12 (-3.5/+3.4)	60.60 @ 88 mo. (-3.6/+3.4)	-	-	-
	Effective Sample Size	1687	1474	1279	1087	822	496	278	208	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.48 (-4.4/+4.4)	45.30 @ 74 mo. (-4.4/+4.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.48 (-4.4/+4.4)	45.30 @ 74 mo. (-4.4/+4.5)	-	-	-	-
	Effective Sample Size	1687	1474	1279	1087	822	496	278	208	-	-	-

Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.72 (-0.6/+0.2)	99.72 (-0.6/+0.2)	99.48 (-0.7/+0.3)	98.90 (-1.0/+0.5)	93.22 (-2.3/+1.8)	59.83 (-4.6/+4.4)	54.67 @ 74 mo. (-4.7/+4.6)	-	-	-
	Effective Sample Size	975	854	747	647	527	240	209	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL VR

Model T177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY 2 EL VR Model T177			
Worldwide Distribution: 16,000			
Worldwide Confirmed Malfunctions: 1826			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1785	8	1793
⁸ Shortened replacement window (Advisory issued)	139	1	
⁹ Low-voltage capacitor (Advisory issued)	2	1	
¹⁷ Extended charge time post-mid-life	15	2	
³¹ Integrated circuit	-	3	
⁴⁶ Capacitor	1	-	
⁵¹ Capacitor	2	-	
⁵⁶ Mid-life display of replacement indicators	1559	1	
⁵⁸ High-voltage capacitor	2	-	
⁷⁸ Low-voltage capacitor	65	-	
Mechanical	2	8	10
⁷ Subpectoral implant (Advisory issued)	-	5	
²⁸ Header	-	1	
³⁵ Seal plug	1	-	
⁵⁹ Sensing	1	-	
⁷³ Transformer	-	2	
Software	-	2	2
⁵³ Memory location	-	1	
⁵⁵ Memory location	-	1	
Other	12	9	21
Non-patterned	12	7	
³⁰ Battery depletion	-	2	
WW Confirmed Malfunctions	1799	27	1826

[More details](#) about malfunctions

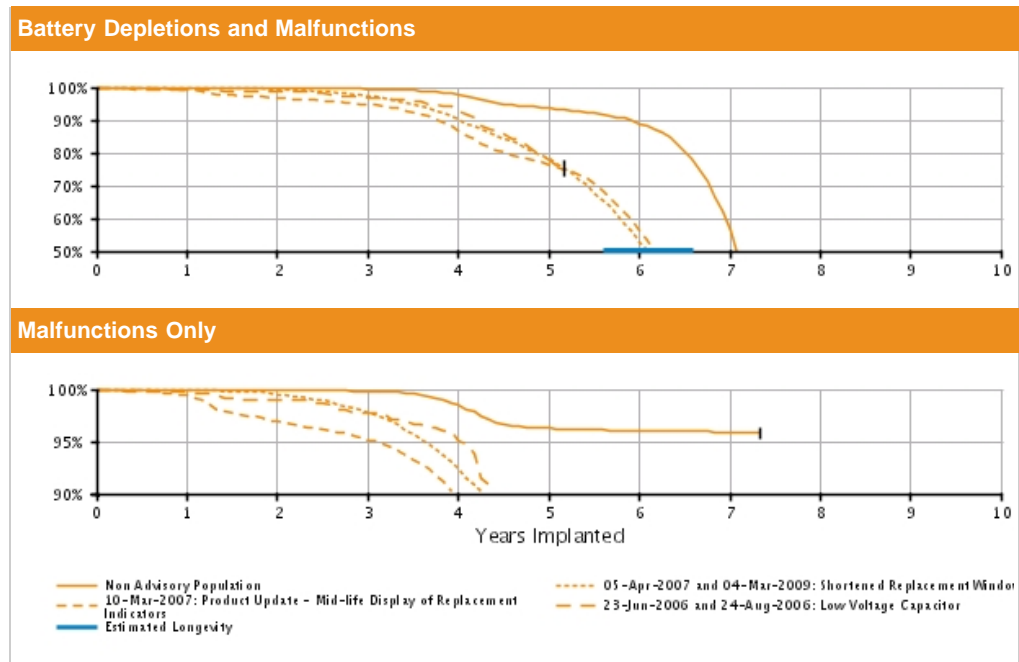
[References](#) cited in table above

VITALITY 2 VR

Model T175

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Normal Battery Depletions: 4,908
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 33
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:1239
	Without Compromised Therapy:1214
	With Compromised Therapy:25



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.49 (-0.2/+0.1)	97.60 (-0.4/+0.3)	93.69 (-0.6/+0.6)	88.97 (-0.9/+0.8)	56.37 (-2.0/+2.0)	26.81 @ 88 mo. (-2.4/+2.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	98.44 (-0.3/+0.3)	96.26 (-0.5/+0.4)	96.07 (-0.5/+0.5)	95.86 (-0.6/+0.5)	95.86 @ 88 mo. (-0.6/+0.5)	-	-	-
	Effective Sample Size	9495	8336	7240	6082	4921	3829	1004	278	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.43 (-0.3/+0.2)	97.47 (-0.5/+0.4)	90.30 (-1.0/+0.9)	78.08 (-1.4/+1.3)	52.56 (-1.8/+1.8)	17.04 (-1.5/+1.6)	9.23 @ 87 mo. (-1.2/+1.3)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.40 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.20 (-1.5/+1.4)	83.20 @ 87 mo. (-1.5/+1.4)	-	-	-
	Effective Sample Size	5392	4692	4023	3237	2376	1375	365	211	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.34 (-0.3/+0.2)	96.85 (-0.6/+0.5)	94.72 (-0.8/+0.7)	86.62 (-1.3/+1.2)	76.43 (-1.7/+1.6)	56.31 (-2.1/+2.1)	16.09 (-1.7/+1.9)	13.76 @ 85 mo. (-1.6/+1.8)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.40 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.20 (-1.5/+1.4)	83.20 @ 87 mo. (-1.5/+1.4)	-	-	-
	Effective Sample Size	5392	4692	4023	3237	2376	1375	365	211	-	-	-


Registered Implants: 4000											
	Malfunctions Only (%) (Confidence Interval)	99.39 (-0.3/+0.2)	96.95 (-0.6/+0.5)	95.13 (-0.8/+0.7)	89.21 (-1.2/+1.1)	84.05 (-1.4/+1.3)	83.38 (-1.5/+1.4)	81.61 (-1.8/+1.7)	81.61 @ 85 mo. (-1.8/+1.7)	-	-
	Effective Sample Size	3907	3331	2852	2263	1681	1059	247	205	-	-
23-Jun-06 and 24- Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions (%) (Confidence Interval)	99.47 (-1.1/+0.4)	98.64 (-1.5/+0.7)	96.88 (-2.1/+1.3)	92.79 (-3.1/+2.2)	77.91 (-4.9/+4.3)	75.29 @ 62 mo. (-5.2/+4.5)	-	-	-	-
Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.82 (-1.1/+0.2)	98.99 (-1.4/+0.6)	97.73 (-1.9/+1.0)	95.08 (-2.7/+1.8)	84.94 (-4.5/+3.6)	84.94 @ 62 mo. (-4.5/+3.6)	-	-	-	-
	Effective Sample Size	504	432	366	307	215	201	-	-	-	-
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 VR

Model T175

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY 2 VR Model T175 			
Worldwide Distribution: 37,000			
Worldwide Confirmed Malfunctions: 1581			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1529	26	1555
⁸ Shortened replacement window (Advisory issued)	347	9	
⁹ Low-voltage capacitor (Advisory issued)	-	1	
¹⁰ Premature battery depletion (Advisory issued)	219	6	
¹⁷ Extended charge time post-mid-life	62	-	
²² Integrated circuit	-	1	
²⁶ Capacitor	1	-	
³¹ Integrated circuit	4	7	
⁴⁶ Capacitor	1	-	
⁵¹ Capacitor	4	-	
⁵⁶ Mid-life display of replacement indicators	771	-	
⁵⁸ High-voltage capacitor	-	1	
⁷⁸ Low-voltage capacitor	120	1	
Mechanical	2	1	3
³⁵ Seal plug	2	1	
Software	-	1	1
⁵⁵ Memory location	-	1	
Other	16	6	22
Non-patterned	14	6	
³⁰ Battery depletion	2	-	
WW Confirmed Malfunctions	1547	34	1581

[More details](#) about malfunctions

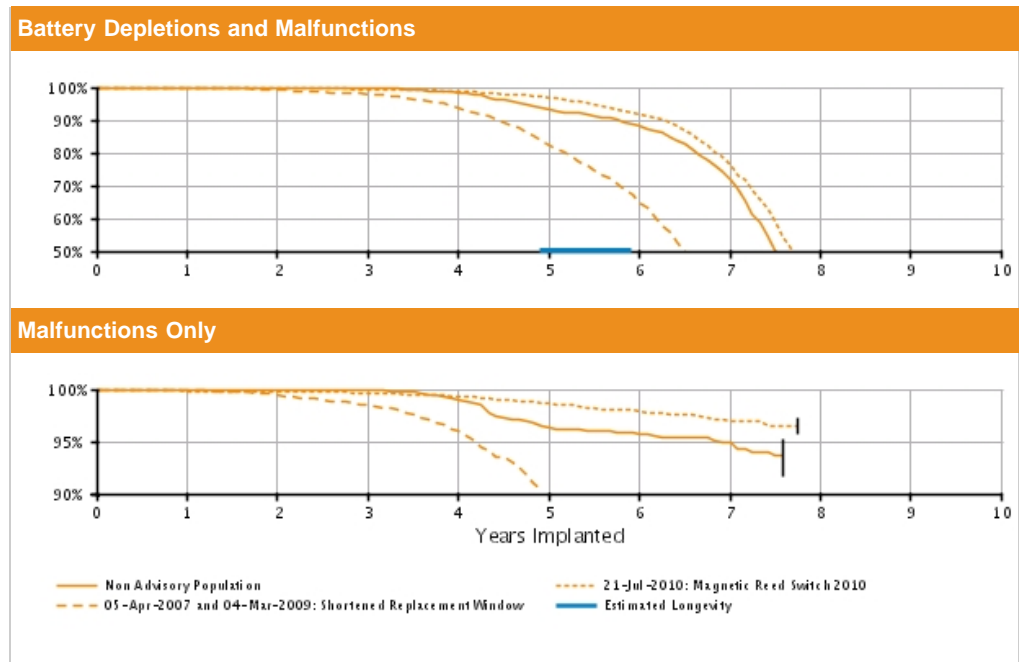
[References](#) cited in table above

VITALITY DR HE

Model T180

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 13,000	U.S. Normal Battery Depletions: 2,144
U.S. Approval Date: May 2005	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:416
	Without Compromised Therapy:387
	With Compromised Therapy:29



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.86 (-0.3/+0.1)	99.76 (-0.3/+0.1)	98.27 (-0.8/+0.5)	93.29 (-1.4/+1.2)	88.23 (-1.9/+1.7)	71.60 (-3.2/+3.0)	47.33 @ 91 mo. (-4.2/+4.2)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.91 (-0.3/+0.1)	99.86 (-0.3/+0.1)	99.01 (-0.6/+0.4)	96.29 (-1.1/+0.9)	95.66 (-1.2/+1.0)	94.86 (-1.5/+1.2)	93.62 @ 91 mo. (-2.0/+1.6)	-	-	-
	Effective Sample Size	2235	1950	1699	1463	1202	957	372	214	-	-	-
21-Jul-10 Magnetic Reed Switch 2010* Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.42 (-0.2/+0.2)	98.78 (-0.3/+0.3)	96.77 (-0.6/+0.5)	91.87 (-0.9/+0.8)	76.09 (-1.6/+1.5)	46.69 @ 93 mo. (-3.0/+3.0)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.81 (-0.1/+0.1)	99.63 (-0.2/+0.1)	99.28 (-0.3/+0.2)	98.60 (-0.4/+0.3)	97.85 (-0.5/+0.4)	96.99 (-0.6/+0.5)	96.53 @ 93 mo. (-0.8/+0.7)	-	-	-
	Effective Sample Size	6979	6087	5305	4598	3915	3208	1617	250	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.86 (-0.2/+0.1)	99.21 (-0.4/+0.3)	97.96 (-0.7/+0.5)	93.65 (-1.2/+1.0)	82.33 (-1.9/+1.7)	64.80 (-2.5/+2.4)	34.53 (-2.7/+2.8)	20.22 @ 91 mo. (-2.3/+2.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.86 (-0.2/+0.1)	99.21 (-0.4/+0.3)	97.96 (-0.7/+0.5)	93.65 (-1.2/+1.0)	82.33 (-1.9/+1.7)	64.80 (-2.5/+2.4)	34.53 (-2.7/+2.8)	20.22 @ 91 mo. (-2.3/+2.5)	-	-	-
	Effective Sample Size	6979	6087	5305	4598	3915	3208	1617	250	-	-	-


3000											
	Malfunctions Only (%) (Confidence Interval)	99.93 (-0.2/+0.1)	99.44 (-0.4/+0.2)	98.51 (-0.6/+0.4)	95.95 (-1.0/+0.8)	89.77 (-1.6/+1.4)	84.83 (-2.0/+1.8)	79.86 (-2.5/+2.3)	78.99 @ 91 mo. (-2.7/+2.5)	-	-
	Effective Sample Size	2673	2314	1995	1653	1239	828	372	202	-	-

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

VITALITY DR HE

Model T180

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY DR HE Model T180 			
Worldwide Distribution: 13,000			
Worldwide Confirmed Malfunctions: 416			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	370	5	375
⁸ Shortened replacement window (Advisory issued)	88	1	
¹⁷ Extended charge time post-mid-life	25	-	
²⁶ Capacitor	2	1	
³¹ Integrated circuit	3	1	
⁴⁶ Capacitor	1	1	
⁵⁶ Mid-life display of replacement indicators	170	-	
⁶¹ Integrated circuit	-	1	
⁷⁸ Low-voltage capacitor	81	-	
Mechanical	6	18	24
⁴ Magnetic reed switch 2010 (Advisory issued)	2	10	
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁸ Header	3	7	
⁶³ Setscrew	1	-	
Software	1	2	3
⁵³ Memory location	-	1	
⁵⁵ Memory location	-	1	
⁷⁵ Misaligned markers	1	-	
Other	10	4	14
Non-patterned	8	3	
³⁰ Battery depletion	1	1	
³⁹ Battery depletion	1	-	
WW Confirmed Malfunctions	387	29	416

[More details](#) about malfunctions

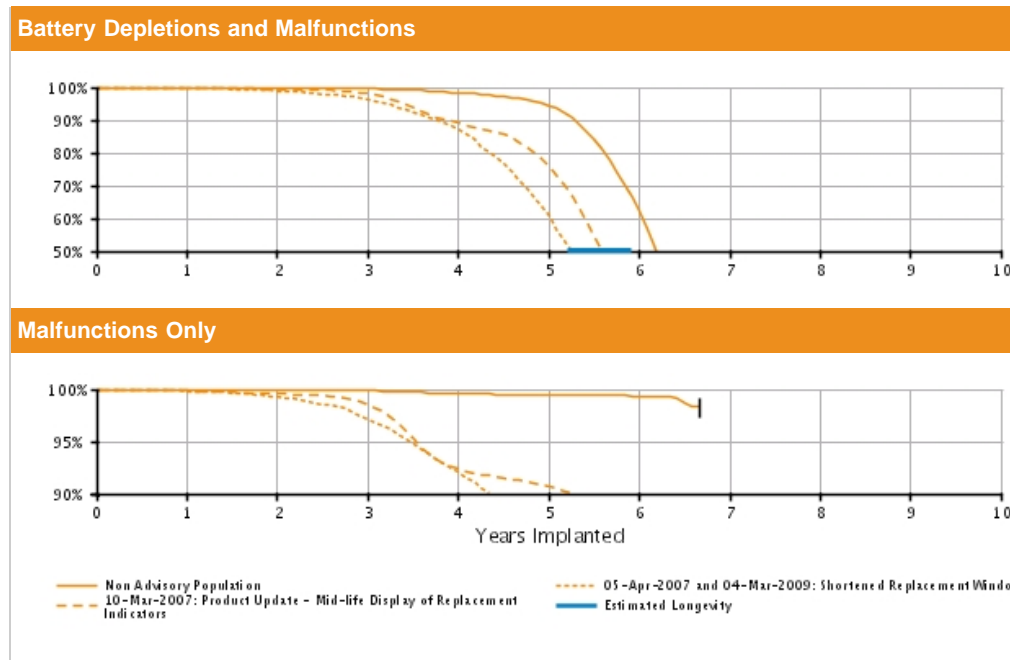
[References](#) cited in table above

VITALITY DS DR

Model T125

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 22,000	U.S. Normal Battery Depletions: 8,044
U.S. Approval Date: July 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 67
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions: 1183
	Without Compromised Therapy: 1145
	With Compromised Therapy: 38



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions (%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.84 (-0.2/+0.1)	99.54 (-0.2/+0.2)	98.38 (-0.4/+0.4)	94.44 (-0.8/+0.7)	62.18 (-1.9/+1.9)	16.36 (-1.7/+1.9)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.86 (-0.2/+0.1)	99.60 (-0.3/+0.2)	99.44 (-0.3/+0.2)	99.26 (-0.4/+0.3)	98.42 (-1.2/+0.7)	-	-	-	-
	Effective Sample Size	5265	4644	4044	3422	2741	1398	251	-	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 5000	Depletions and Malfunctions (%) (Confidence Interval)	99.78 (-0.2/+0.1)	98.97 (-0.4/+0.3)	96.15 (-0.7/+0.6)	87.05 (-1.2/+1.1)	60.70 (-1.9/+1.8)	17.57 (-1.6/+1.7)	10.32 (-1.3/+1.5)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.82 (-0.2/+0.1)	99.24 (-0.3/+0.2)	97.09 (-0.6/+0.5)	92.09 (-1.0/+0.9)	87.89 (-1.3/+1.2)	84.93 (-1.7/+1.6)	84.03 (-2.2/+1.9)	-	-	-	-
	Effective Sample Size	4301	3765	3201	2519	1484	345	205	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 5000	Depletions and Malfunctions (%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.45 (-0.2/+0.1)	98.01 (-0.3/+0.3)	89.10 (-0.7/+0.7)	75.99 (-1.0/+1.0)	29.35 (-1.2/+1.2)	5.98 (-0.7/+0.8)	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.45 (-0.2/+0.1)	98.01 (-0.3/+0.3)	89.10 (-0.7/+0.7)	75.99 (-1.0/+1.0)	29.35 (-1.2/+1.2)	5.98 (-0.7/+0.8)	-	-	-	-
	Effective Sample Size	4301	3765	3201	2519	1484	345	205	-	-	-	-


Registered Implants: 12000											
	Malfunctions Only (%) (Confidence Interval)	99.87 (-0.1/+0.1)	99.56 (-0.1/+0.1)	98.52 (-0.3/+0.2)	92.35 (-0.6/+0.6)	90.69 (-0.7/+0.6)	88.47 (-0.9/+0.8)	86.71 @ 79 mo. (-1.5/+1.4)	-	-	-
	Effective Sample Size	10839	9499	8204	6407	4726	1513	253	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY DS DR

Model T125

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY DS DR Model T125 			
Worldwide Distribution: 22,000			
Worldwide Confirmed Malfunctions: 1184			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1112	23	1135
⁸ Shortened replacement window (Advisory issued)	207	8	
¹⁰ Premature battery depletion (Advisory issued)	68	2	
¹⁷ Extended charge time post-mid-life	144	2	
²² Integrated circuit	1	-	
³¹ Integrated circuit	2	8	
⁵¹ Capacitor	3	-	
⁵⁶ Mid-life display of replacement indicators	589	-	
⁵⁸ High-voltage capacitor	2	1	
⁷⁰ Logic errors	-	1	
⁷⁸ Low-voltage capacitor	96	1	
Mechanical	11	5	16
³⁵ Seal plug	11	3	
⁴⁴ Transformer	-	1	
¹⁰⁰ Solder joint	-	1	
Software	6	-	6
³³ Impedance measurements	2	-	
⁵⁵ Memory location	1	-	
⁷⁵ Misaligned markers	3	-	
Other	17	10	27
Non-patterned	8	3	
²¹ Firmware error	5	7	
³⁰ Battery depletion	4	-	
WW Confirmed Malfunctions	1146	38	1184

[More details](#) about malfunctions

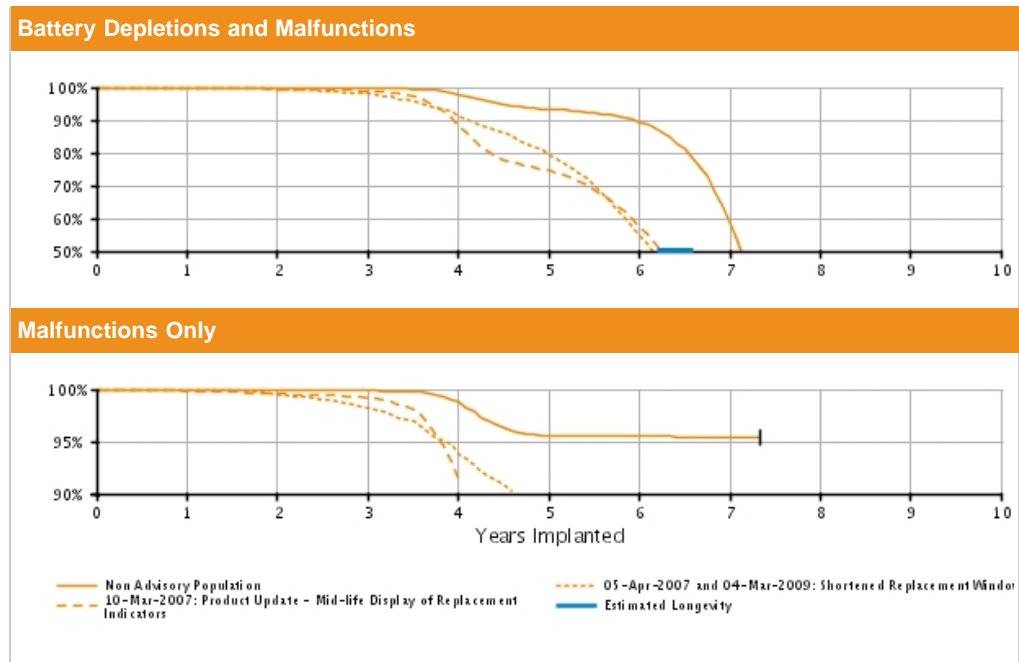
[References](#) cited in table above

VITALITY DS VR

Model T135

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary U.S. Registered Implants: 19,000 U.S. Approval Date: July 2003 U.S. Estimated Active Implants: 3,000	U.S. Normal Battery Depletions: 5,290 U.S. Unconfirmed Reports of Premature Battery Depletion : 39 U.S. Malfunctions:1553 Without Compromised Therapy:1537 With Compromised Therapy:16
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U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.92 (-0.2/+0.1)	99.72 (-0.3/+0.1)	97.94 (-0.6/+0.5)	93.22 (-1.1/+0.9)	89.18 (-1.4/+1.2)	58.15 (-3.0/+2.9)	36.23 @ 88 mo. (-3.4/+3.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.91 (-0.2/+0.1)	98.76 (-0.5/+0.4)	95.59 (-0.9/+0.7)	95.54 (-0.9/+0.8)	95.45 (-0.9/+0.8)	95.45 @ 88 mo. (-0.9/+0.8)	-	-	-
	Effective Sample Size	3863	3373	2947	2493	1993	1501	495	207	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.2/+0.0)	99.40 (-0.4/+0.2)	98.02 (-0.6/+0.5)	91.28 (-1.2/+1.1)	79.24 (-1.8/+1.7)	54.58 (-2.3/+2.3)	19.07 (-2.0/+2.1)	16.06 @ 85 mo. (-1.9/+2.1)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.46 (-0.3/+0.2)	98.24 (-0.6/+0.4)	93.88 (-1.0/+0.9)	88.87 (-1.4/+1.3)	87.10 (-1.6/+1.4)	86.57 (-1.7/+1.5)	86.16 @ 85 mo. (-1.9/+1.7)	-	-	-
	Effective Sample Size	3237	2836	2447	1979	1476	867	253	210	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.76 (-0.1/+0.1)	99.49 (-0.2/+0.1)	98.88 (-0.2/+0.2)	88.44 (-0.8/+0.7)	74.53 (-1.1/+1.0)	57.40 (-1.3/+1.3)	20.94 (-1.2/+1.2)	5.46 @ 90 mo. (-0.7/+0.8)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.46 (-0.3/+0.2)	98.24 (-0.6/+0.4)	93.88 (-1.0/+0.9)	88.87 (-1.4/+1.3)	87.10 (-1.6/+1.4)	86.57 (-1.7/+1.5)	86.16 @ 85 mo. (-1.9/+1.7)	-	-	-
	Effective Sample Size	3237	2836	2447	1979	1476	867	253	210	-	-	-

Registered Implants: 12000											
	Malfunctions Only (%) (Confidence Interval)	99.84 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.16 (-0.2/+0.2)	91.52 (-0.7/+0.6)	83.12 (-0.9/+0.9)	81.67 (-1.0/+1.0)	80.37 (-1.1/+1.1)	79.11 @ 90 mo. (-1.6/+1.5)	-	-
	Effective Sample Size	10129	8847	7670	6031	4225	2793	850	301	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY DS VR

Model T135

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY DS VR Model T135			
Worldwide Distribution: 19,000			
Worldwide Confirmed Malfunctions: 1554			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1524	11	1535
⁸ Shortened replacement window (Advisory issued)	122	1	
⁹ Low-voltage capacitor (Advisory issued)	2	-	
¹⁰ Premature battery depletion (Advisory issued)	61	4	
¹⁷ Extended charge time post-mid-life	70	-	
²⁶ Capacitor	2	1	
³¹ Integrated circuit	-	1	
⁴⁶ Capacitor	3	1	
⁵¹ Capacitor	2	1	
⁵⁶ Mid-life display of replacement indicators	1210	-	
⁵⁸ High-voltage capacitor	3	1	
⁷⁸ Low-voltage capacitor	49	1	
Mechanical	4	2	6
³⁵ Seal plug	3	1	
⁶⁵ Seal plug	-	1	
⁷² Cracked solder joint	1	-	
Software	2	-	2
³³ Impedance measurements	2	-	
Other	8	3	11
Non-patterned	6	1	
³⁰ Battery depletion	2	2	
WW Confirmed Malfunctions	1538	16	1554

[More details](#) about malfunctions

[References](#) cited in table above

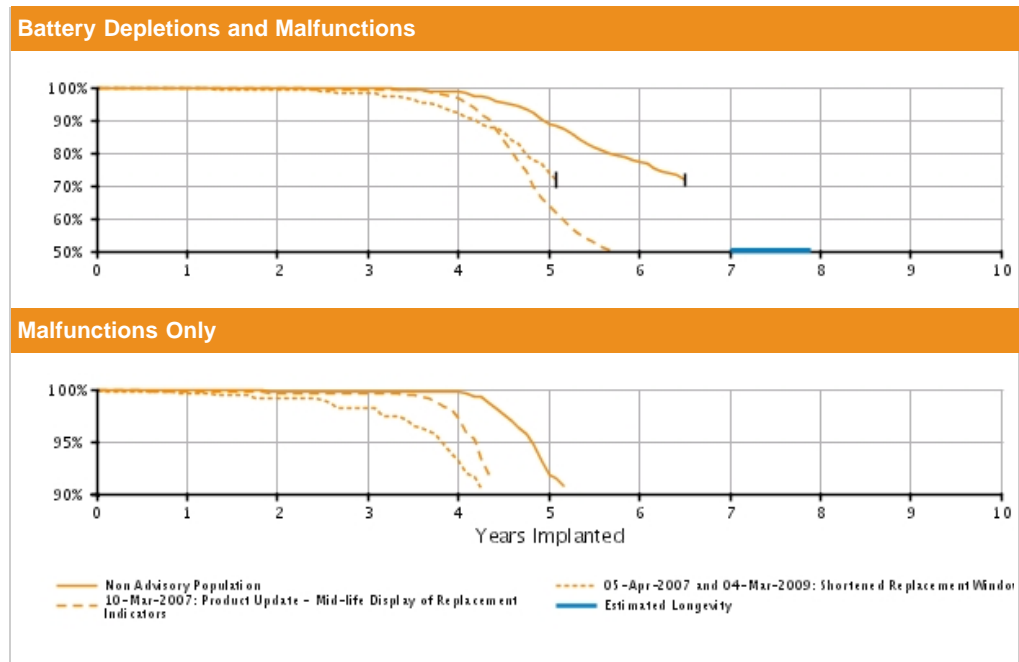
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VITALITY EL

Model T127

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Normal Battery Depletions: 881
U.S. Approval Date: July 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions: 617
	Without Compromised Therapy: 610
	With Compromised Therapy: 7



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.68	99.55	99.55	98.72	88.85	77.08	71.81	-	-	-	-
	(Confidence Interval)	(-0.7/+0.2)	(-0.8/+0.3)	(-0.8/+0.3)	(-1.2/+0.6)	(-3.0/+2.4)	(-4.0/+3.6)	@ 78 mo. (-4.5/+4.1)				
	Registered Implants: 1000											
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%)	99.63	99.21	98.21	92.36	73.65	71.82	-	-	-	-	-
	(Confidence Interval)	(-1.1/+0.3)	(-1.3/+0.5)	(-1.8/+0.9)	(-3.2/+2.3)	(-5.2/+4.6)	@ 61 mo. (-5.3/+4.8)					
	Registered Implants: 1000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%)	99.82	99.60	99.36	96.68	63.84	45.80	28.93	-	-	-	-
	(Confidence Interval)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.5/+0.3)	(-1.1/+0.8)	(-2.8/+2.7)	(-3.0/+3.0)	@ 63 mo. (-2.9/+3.1)				
	Registered Implants: 1000											
Effective Sample Size		857	750	654	564	439	291	210	-	-	-	-
Effective Sample Size		506	437	372	300	212	200	-	-	-	-	-

Registered Implants: 2000											
	Malfunctions Only (%) (Confidence Interval)	99.82 (-0.3/+0.1)	99.65 (-0.4/+0.2)	99.60 (-0.4/+0.2)	97.27 (-1.0/+0.7)	69.88 (-2.7/+2.6)	59.96 (-3.0/+3.0)	58.32 @ 83 mo. (-3.1/+3.1)	-	-	-
	Effective Sample Size	2028	1770	1549	1311	732	412	204	-	-	-
23-Jun-06 and 24- Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY EL

Model T127

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY EL Model T127			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 618			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	600	2	602
⁸ Shortened replacement window (Advisory issued)	30	-	
¹⁷ Extended charge time post-mid-life	6	-	
²² Integrated circuit	-	1	
³¹ Integrated circuit	2	1	
⁵¹ Capacitor	1	-	
⁵⁶ Mid-life display of replacement indicators	547	-	
⁷⁸ Low-voltage capacitor	14	-	
Mechanical	5	4	9
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁸ Header	-	2	
³⁵ Seal plug	4	1	
⁶³ Setscrew	1	-	
Software	2	-	2
³³ Impedance measurements	1	-	
⁷⁵ Misaligned markers	1	-	
Other	4	1	5
Non-patterned	2	1	
²¹ Firmware error	1	-	
³⁰ Battery depletion	1	-	
WW Confirmed Malfunctions	611	7	618


[More details](#) about malfunctions

[References](#) cited in table above

VITALITY DR

Model 1871

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY DR Model 1871			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 734			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	711	2	713
¹⁷ Extended charge time post-mid-life	168	1	
²⁶ Capacitor	6	-	
³¹ Integrated circuit	-	1	
⁵⁶ Mid-life display of replacement indicators	536	-	
⁶¹ Integrated circuit	1	-	
Mechanical	9	2	11
²⁸ Header	2	1	
³⁵ Seal plug	7	-	
¹⁰⁰ Solder joint	-	1	
Software	3	-	3
⁴² Reset during charge	1	-	
⁶⁰ Software download	2	-	
Other	3	4	7
Non-patterned	3	3	
³⁰ Battery depletion	-	1	
WW Confirmed Malfunctions	726	8	734


[More details](#) about malfunctions

[References](#) cited in table above

VITALITY VR

Model 1870

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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VITALITY VR Model 1870				
Worldwide Distribution: 10,000				
Worldwide Confirmed Malfunctions: 1142				
	Without Compromised Therapy	With Compromised Therapy	Total	
Electrical	1127	2	1129	
¹⁷ Extended charge time post-mid-life	102	-		
²² Integrated circuit	1	-		
²⁶ Capacitor	7	-		
³¹ Integrated circuit	-	2		
⁵⁶ Mid-life display of replacement indicators	1017	-		
Mechanical	1	2	3	
²⁸ Header	-	1		
³⁵ Seal plug	1	-		
⁶³ Setscrew	-	1		
Software	1	-	1	
⁶⁰ Software download	1	-		
Other	6	3	9	
Non-patterned	4	2		
³⁰ Battery depletion	2	1		
WW Confirmed Malfunctions	1135	7	1142	

[More details](#) about malfunctions

[References](#) cited in table above

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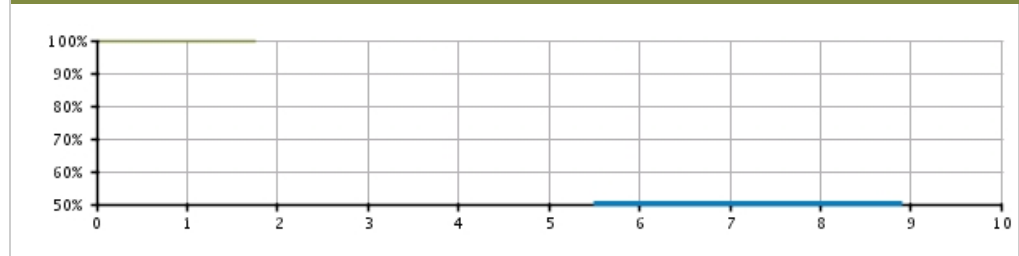
ADVANTIO DR

Models J063/J066/K063/K066/K083

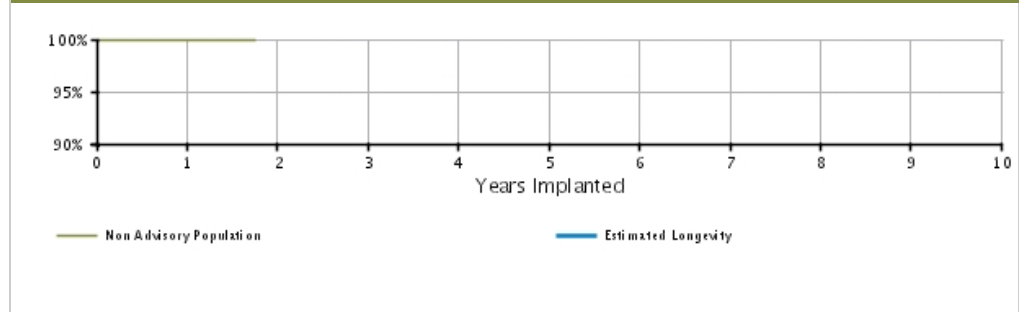
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 40,000	U.S. Normal Battery Depletions: 6
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 38,000	U.S. Malfunctions:9
	Without Compromised Therapy:8
	With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 40000	Depletions and Malfunctions (%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.92 @ 28 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 28 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	22143	4106	245	-	-	-	-	-	-	-

ADVANTIO DR

Models J063/J066/K063/K066/K083

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ADVANTIO DR
Models J063/J066/K063/K066/K083



Worldwide Distribution: 57,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	1	4
⁸⁵ Low-voltage capacitors	1	-	
⁸⁹ Integrated circuit	2	1	
Mechanical	-	-	0
Software	3	-	3
⁹⁰ Memory errors	3	-	
Other	3	-	3
Non-patterned	3	-	
WW Confirmed Malfunctions	9	1	10

[More details](#) about malfunctions

[References](#) cited in table above

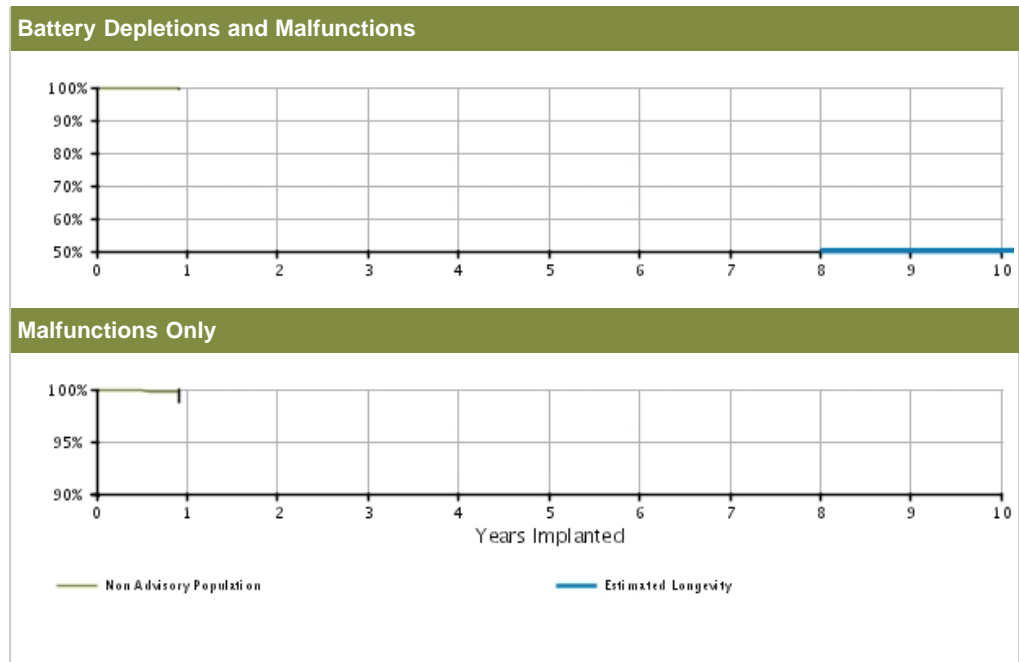
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ADVANTIO EL DR

Models J064/K064/K067/K084

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1
	Without Compromised Therapy:1
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.87 (-0.8/+0.1)	99.50 @ 13 mo. (-1.8/+0.4)	-	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.87 (-0.8/+0.1)	99.87 @ 13 mo. (-0.8/+0.1)	-	-	-	-	-	-	-	-	-
Registered Implants: 2000	Effective Sample Size	346	269	-	-	-	-	-	-	-	-	-

ADVANTIO EL DR

Models J064/K064/K067/K084

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ADVANTIO EL DR
Models J064/K064/K067/K084



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁵ Low-voltage capacitors	-	1	
Mechanical	-	-	0
Software	1	-	1
⁹⁸ Respiratory sensor	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

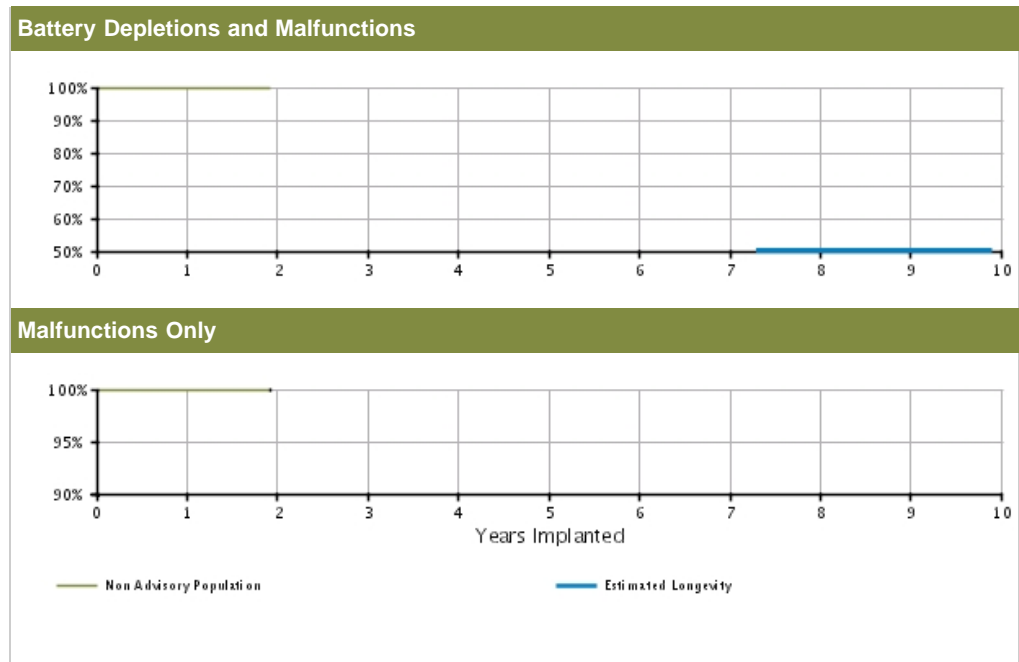
[References](#) cited in table above

ADVANTIO SR

Models J062/J065/K062/K065/K082

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 9,000	U.S. Normal Battery Depletions: 3
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 8,000	U.S. Malfunctions:4
	Without Compromised Therapy:3
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 @ 26 mo. (-0.1/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.92 @ 26 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 9000	Effective Sample Size	4735	808	328	-	-	-	-	-	-	-	-

ADVANTIO SR

Models J062/J065/K062/K065/K082

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

ADVANTIO SR Models J062/J065/K062/K065/K082 			
Worldwide Distribution: 22,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	3	5
⁸⁵ Low-voltage capacitors	2	-	
⁸⁹ Integrated circuit	-	3	
Mechanical	-	-	0
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	3	3	6

[More details](#) about malfunctions

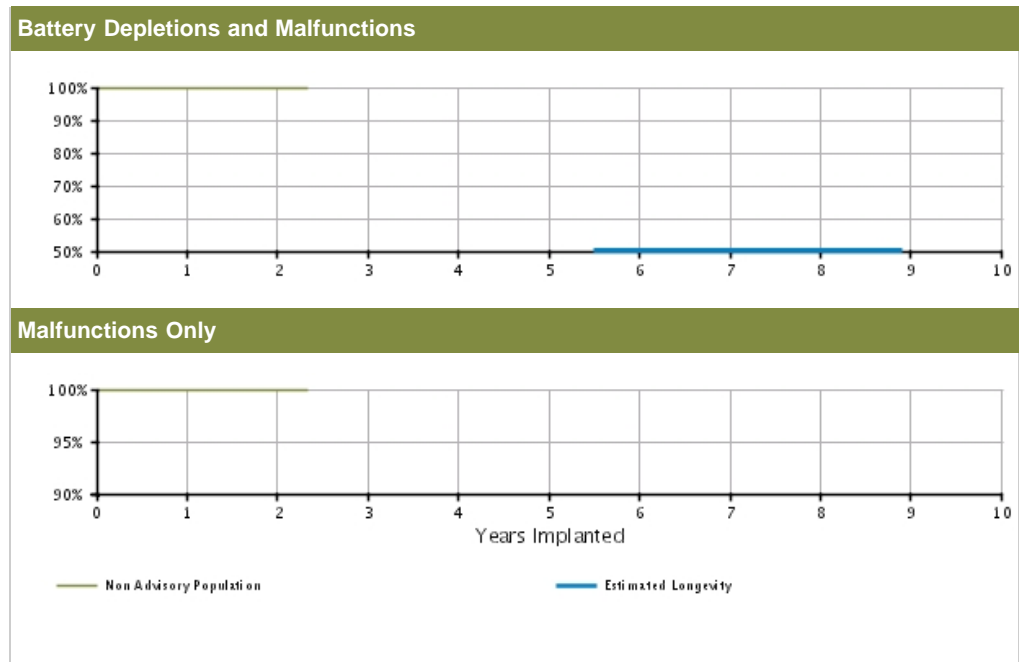
[References](#) cited in table above

INGENIO DR

Models J173/J176/K173/K176/K183

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 52,000	U.S. Normal Battery Depletions: 11
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 50,000	U.S. Malfunctions:6
	Without Compromised Therapy:5
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.93 @ 28 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 @ 28 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	24314	4403	465	-	-	-	-	-	-	-	-

INGENIO DR

Models J173/J176/K173/K176/K183

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGENIO DR Models J173/J176/K173/K176/K183			
Worldwide Distribution: 84,000			
Worldwide Confirmed Malfunctions: 11			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸⁵ Low-voltage capacitors	1	-	
Mechanical	-	-	0
Software	4	1	5
⁹⁰ Memory errors	4	1	
Other	5	-	5
Non-patterned	5	-	
WW Confirmed Malfunctions	10	1	11

[More details](#) about malfunctions

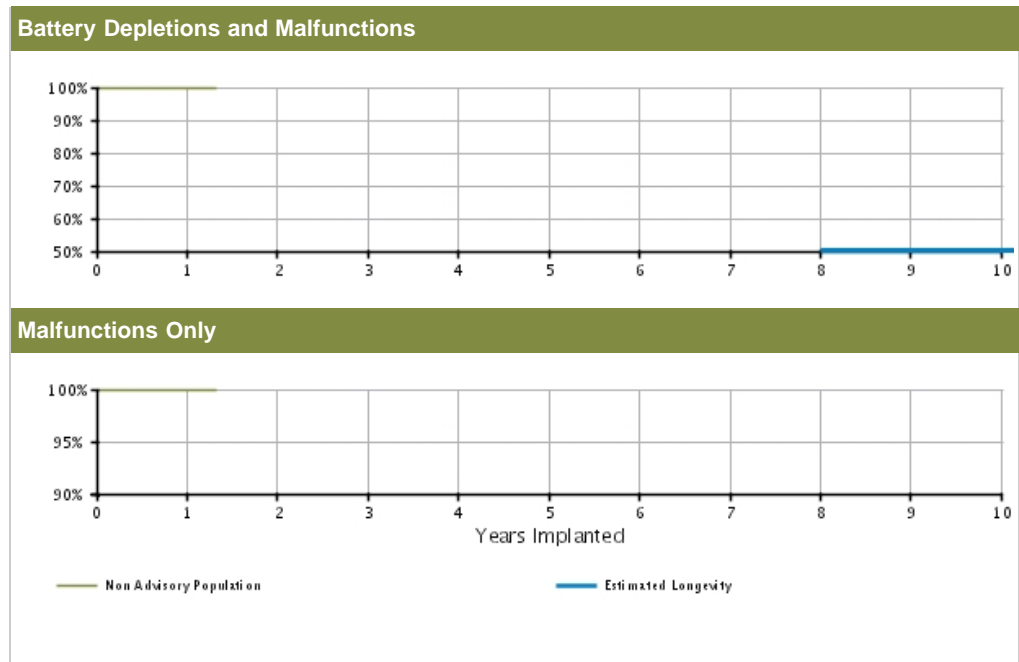
[References](#) cited in table above

INGENIO EL DR

Models J174/J177/K174/K177/K184

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 16 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 16 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
Registered Implants: 4000	Effective Sample Size	689	215	-	-	-	-	-	-	-	-	-

INGENIO EL DR

Models J174/J177/K174/K177/K184

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGENIO EL DR Models J174/J177/K174/K177/K184			
Worldwide Distribution: 22,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	-	2
⁸⁵ Low-voltage capacitors	2	-	
Mechanical	-	-	0
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

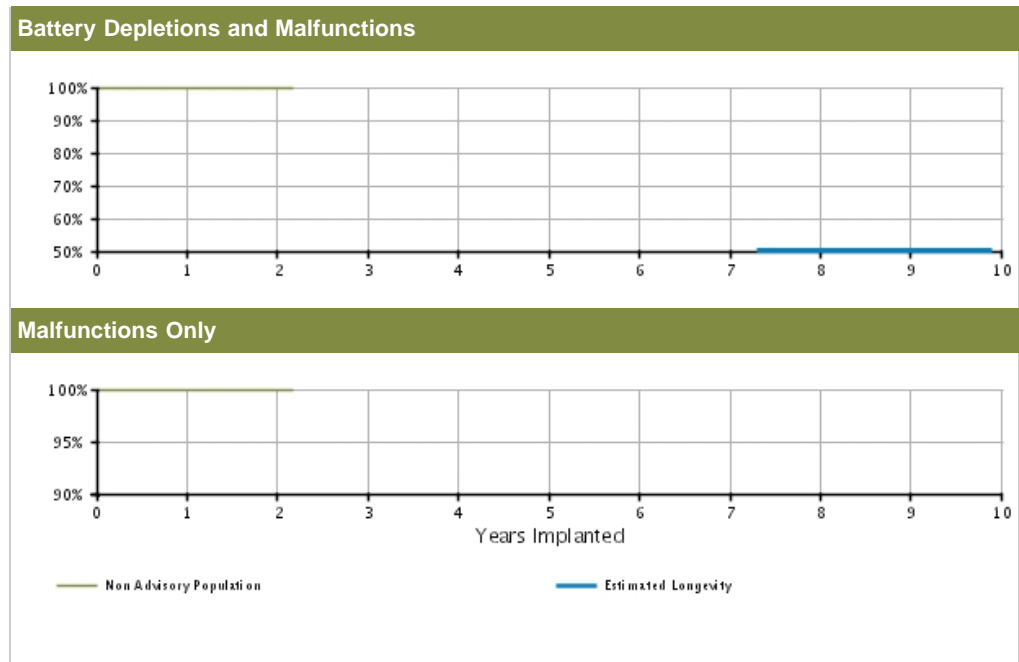
[References](#) cited in table above

INGENIO SR

Models J172/J175/K172/K175/K182

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 10,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 9,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 10000	Depletions and Malfunctions (%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.99 (-0.1/+0.0)	99.99 @ 26 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 26 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	4201	681	317	-	-	-	-	-	-	-	-

INGENIO SR

Models J172/J175/K172/K175/K182

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGENIO SR Models J172/J175/K172/K175/K182			
Worldwide Distribution: 25,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	-	1
⁹⁰ Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions


[References](#) cited in table above

VITALIO DR

Models J273/J276/K273/K276

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

VITALIO DR
Models J273/J276/K273/K276



Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions


[References](#) cited in table above

VITALIO EL DR

Models J274/J277/K274

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

VITALIO EL DR
Models J274/J277/K274



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

VITALIO SR

Models J272/J275/K272/K275

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

VITALIO SR
Models J272/J275/K272/K275 

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	1	1


[More details](#) about malfunctions

[References](#) cited in table above

FORMIO DR

Models J278/J279/K278/K279

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

FORMIO DR Models J278/J279/K278/K279 			
Worldwide Distribution: 1,000 Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

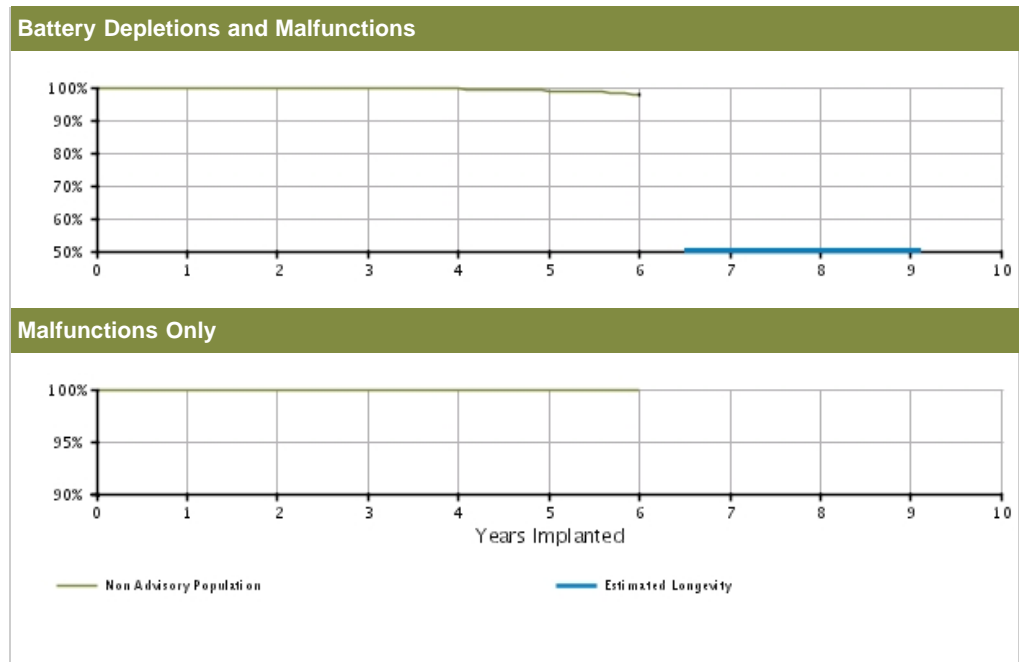
[References](#) cited in table above

ALTRUA 60 DR

Model S602

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 22,000	U.S. Normal Battery Depletions: 162
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 16,000	U.S. Malfunctions:3
	Without Compromised Therapy:2
	With Compromised Therapy:1




U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.99	99.94	99.85	99.52	99.02	97.96	97.45	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.4/+0.3)	@ 75 mo. (-0.7/+0.5)			
Registered Implants: 22000	Malfunctions Only(%)	99.99	99.98	99.98	99.98	99.98	99.98	99.98	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	@ 75 mo. (-0.0/+0.0)			
	Effective Sample Size	19198	16756	13981	11168	8121	1882	391	-	-	-

ALTRUA 60 DR

Model S602

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 60 DR Model S602			
Worldwide Distribution: 55,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁶ Capacitor	1	-	
Mechanical	1	1	2
²⁹ Capacitor array	1	-	
⁷⁷ Difficulty securing lead	-	1	
Software	-	-	0
Other	2	1	3
Non-patterned	1	1	
⁴⁷ Battery depletion	1	-	
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

[References](#) cited in table above

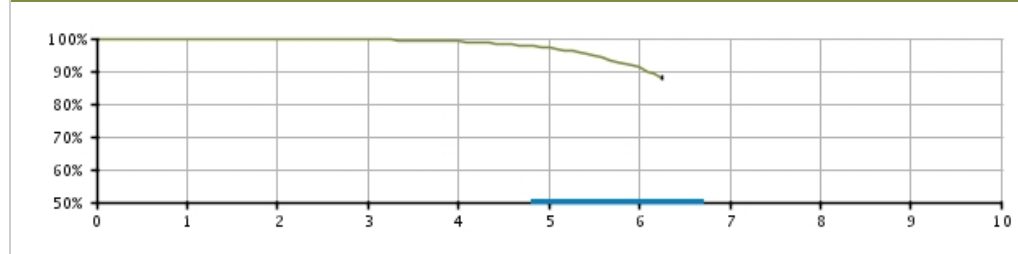
ALTRUA 60 DR (Downsize)

Model S603

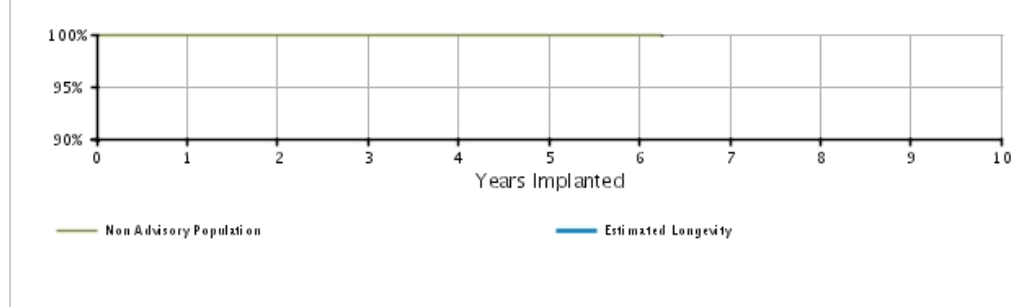
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 90,000	U.S. Normal Battery Depletions: 1,437
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 29
U.S. Estimated Active Implants: 66,000	U.S. Malfunctions: 22
	Without Compromised Therapy: 14
	With Compromised Therapy: 8

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.65 (-0.1/+0.0)	99.01 (-0.1/+0.1)	97.06 (-0.2/+0.2)	91.08 (-0.6/+0.6)	87.95 @ 75 mo. (-1.3/+1.2)	-	-	-	-
	Registered Implants: 90000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 75 mo. (-0.1/+0.0)	-	-	-
		Effective Sample Size	79256	68896	51238	33157	16962	3038	601	-	-	-

ALTRUA 60 DR (Downsize)

Model S603

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 60 DR (Downsize) Model S603 			
Worldwide Distribution: 132,000			
Worldwide Confirmed Malfunctions: 24			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	5	6	11
²⁶ Capacitor	4	5	
⁶¹ Integrated circuit	1	1	
Mechanical	2	-	2
⁷⁴ Connector block	1	-	
⁷⁷ Difficulty securing lead	1	-	
Software	-	-	0
Other	8	3	11
Non-patterned	-	2	
⁴⁷ Battery depletion	3	1	
⁸⁸ Battery status	5	-	
WW Confirmed Malfunctions	15	9	24

[More details](#) about malfunctions

[References](#) cited in table above

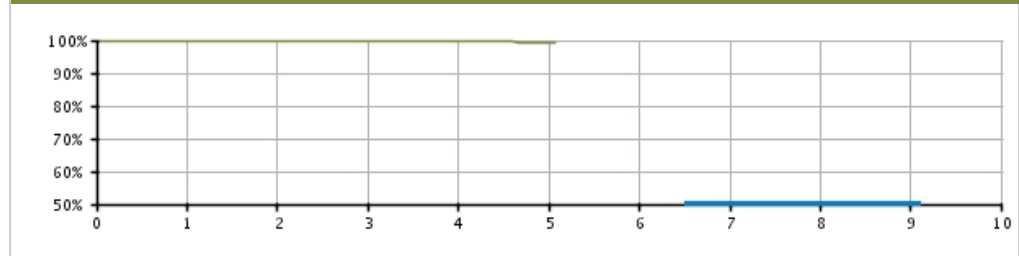
ALTRUA 60 DR EL

Model S606

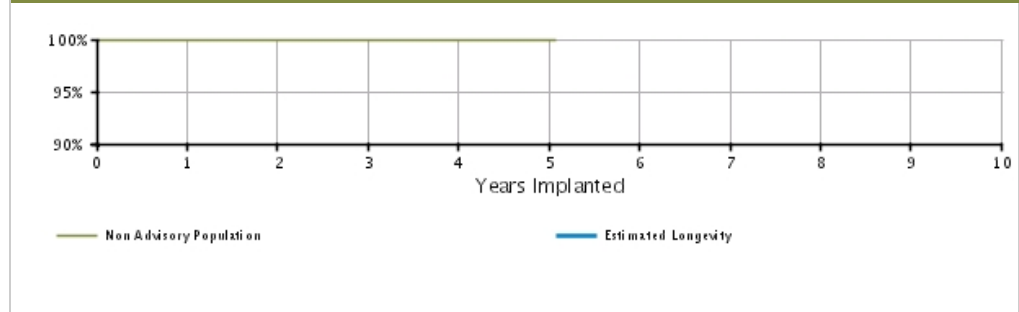
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 59,000	U.S. Normal Battery Depletions: 102
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 6
U.S. Estimated Active Implants: 49,000	U.S. Malfunctions:6
	Without Compromised Therapy:4
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.72 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.10 @ 64 mo. (-0.4/+0.3)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 @ 64 mo. (-0.0/+0.0)	-	-	-	-	-
Registered Implants: 59000	Effective Sample Size	52586	45343	29613	14141	2690	501	-	-	-	-	-

ALTRUA 60 DR EL

Model S606

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

ALTRUA 60 DR EL Model S606 			
Worldwide Distribution: 90,000			
Worldwide Confirmed Malfunctions: 7			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
²⁶ Capacitor	3	-	
³¹ Integrated circuit	1	-	
Mechanical	-	1	1
⁷⁷ Difficulty securing lead	-	1	
Software	-	-	0
Other	1	1	2
Non-patterned	1	-	
⁴⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	5	2	7

[More details](#) about malfunctions

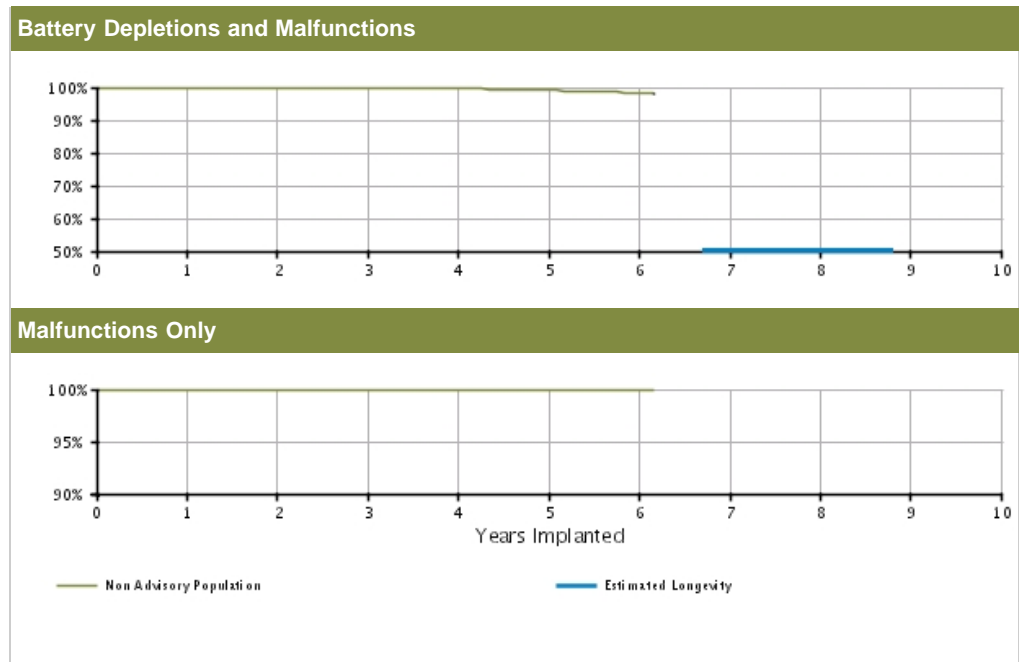
[References](#) cited in table above

ALTRUA 60 SR

Model S601

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 121
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 21,000	U.S. Malfunctions:3
	Without Compromised Therapy:1
	With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.08 (-0.2/+0.2)	98.26 (-0.5/+0.4)	98.08 @ 74 mo. (-0.7/+0.5)	-	-	-	-
	Registered Implants: 32000											
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 74 mo. (-0.1/+0.0)	-	-	-	-
	Effective Sample Size	26757	22882	16236	9940	4573	782	319	-	-	-	-

ALTRUA 60 SR

Model S601

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 60 SR Model S601 			
Worldwide Distribution: 68,000			
Worldwide Confirmed Malfunctions: 9			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	3	5
²⁶ Capacitor	2	1	
⁶¹ Integrated circuit	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	2	
⁴⁷ Battery depletion	-	1	
⁸⁸ Battery status	1	-	
WW Confirmed Malfunctions	3	6	9


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 DR (Downsize)

Model S502

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 50 DR (Downsize) Model S502 			
Worldwide Distribution: 42,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	-	3
²⁶ Capacitor	2	-	
⁶¹ Integrated circuit	1	-	
Mechanical	-	1	1
⁷⁷ Difficulty securing lead	-	1	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁴⁷ Battery depletion	1	-	
⁸⁸ Battery status	1	-	
WW Confirmed Malfunctions	5	1	6


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 SR

Model S501

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 50 SR Model S501			
Worldwide Distribution: 24,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	2	3
²⁶ Capacitor	1	2	
Mechanical	-	-	0
Software	-	-	0
Other	-	3	3
Non-patterned	-	1	
⁴⁷ Battery depletion	-	2	
WW Confirmed Malfunctions	1	5	6


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 50 DDD (Downsize) Model S503 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	-	
⁴⁷ Battery depletion	-	3	
⁸⁸ Battery status	1	-	
WW Confirmed Malfunctions	1	3	4


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 VDD (Downsize)

Model S504

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 50 VDD (Downsize) Model S504 			
Worldwide Distribution: 6,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 SSI

Model S508

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 50 SSI Model S508 			
Worldwide Distribution: 6,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
⁴⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

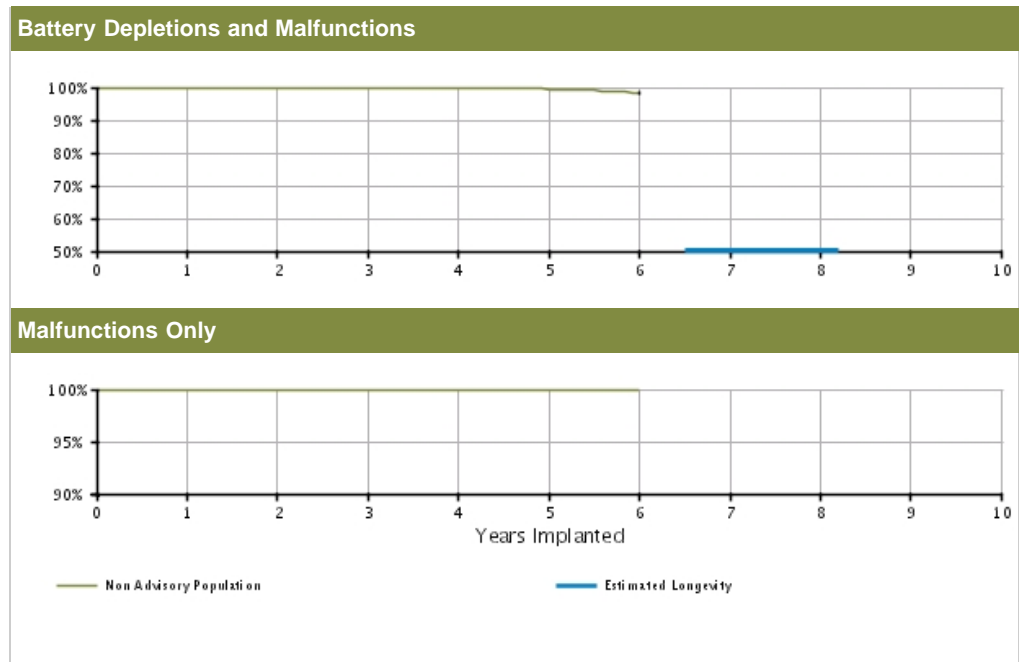
[References](#) cited in table above

ALTRUA 40 DR

Model S402

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 12
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.66 (-0.6/+0.2)	99.45 (-0.7/+0.3)	98.46 (-1.3/+0.7)	-	-	-	-	-
	Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	-	-	-	-
Effective Sample Size		1517	1346	1194	1064	927	264	-	-	-	-	-

ALTRUA 40 DR

Model S402

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 40 DR
Model S402



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
⁴⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

[References](#) cited in table above

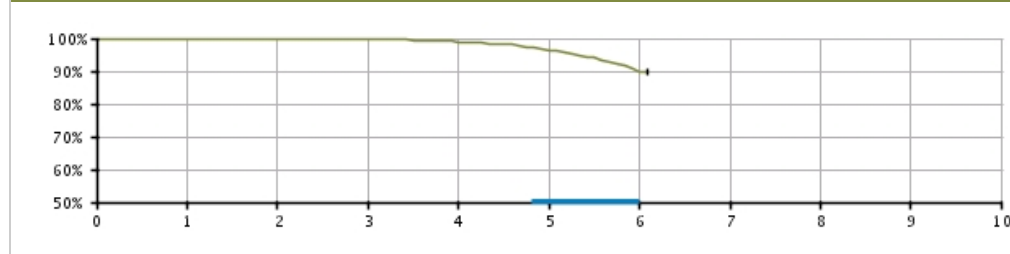
ALTRUA 40 DR (downsize)

Model S403

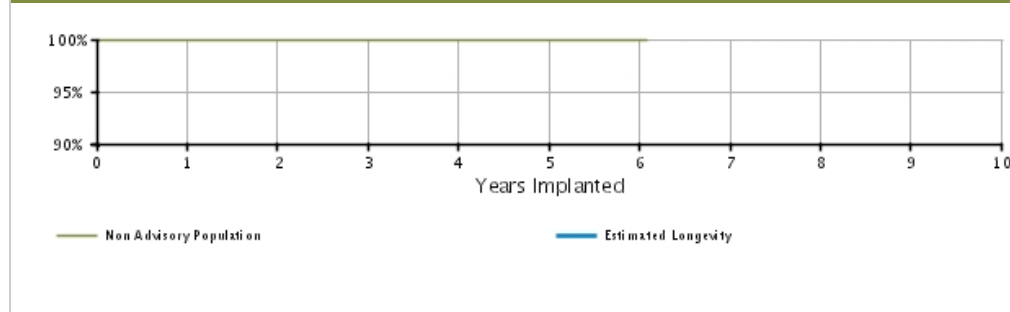
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 231
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:3
	Without Compromised Therapy:3
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	Registered Implants: 14000	99.98 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.68 (-0.1/+0.1)	98.96 (-0.3/+0.2)	96.43 (-0.6/+0.6)	90.00 (-1.9/+1.7)	89.67 @ 73 mo. (-2.1/+1.8)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 73 mo. (-0.1/+0.0)	-	-	-	
Effective Sample Size		12513	11128	8365	5177	2429	379	269	-	-	-	

ALTRUA 40 DR (downsize)

Model S403

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 40 DR (downsize)
Model S403

Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	2	-	2
⁷⁶ Seal plug	1	-	
⁷⁷ Difficulty securing lead	1	-	
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
⁸⁸ Battery status	1	-	
WW Confirmed Malfunctions	3	0	3

[More details](#) about malfunctions

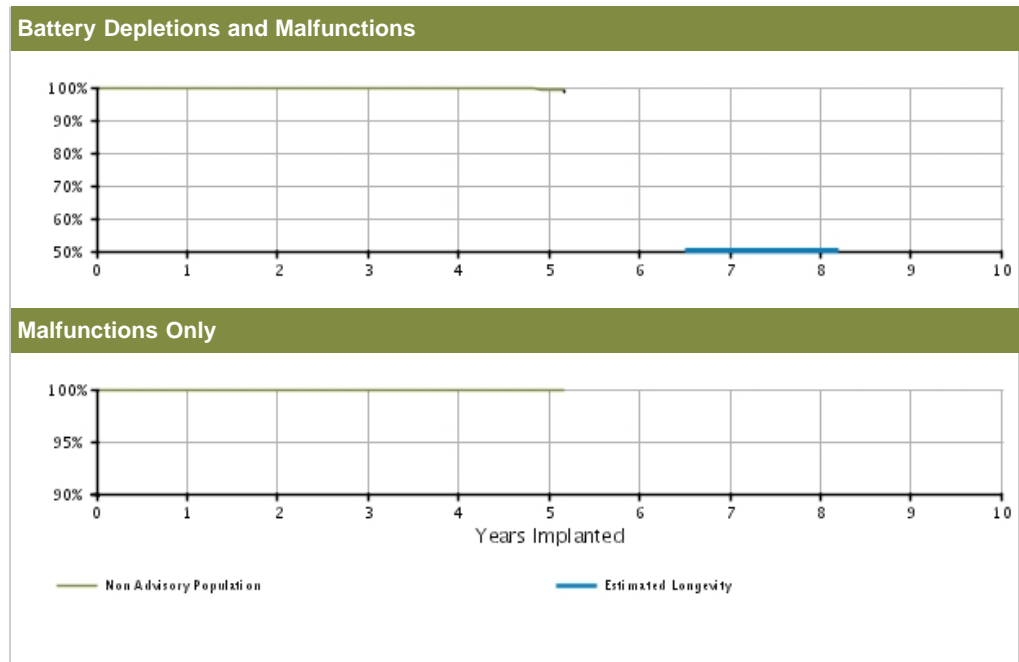
[References](#) cited in table above

ALTRUA 40 DR EL

Model S404

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 9
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	Registered Implants: 5000	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.70 (-0.3/+0.2)	99.08 (-1.2/+0.5)	99.08 @ 62 mo. (-1.2/+0.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 62 mo. (-0.0/+0.0)	-	-	-	-
Effective Sample Size		4471	3948	2831	1564	363	213	-	-	-	-	-

ALTRUA 40 DR EL

Model S404

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 40 DR EL
Model S404



Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁶ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

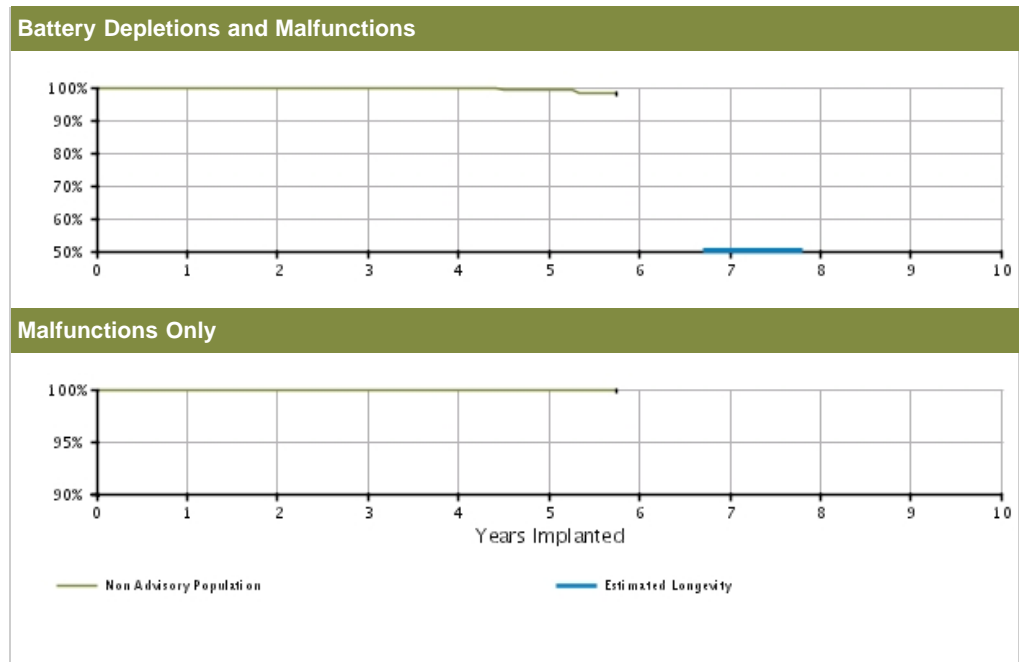
[References](#) cited in table above

ALTRUA 40 SR

Model S401

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 17
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:2
	Without Compromised Therapy:2
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	Registered Implants: 5000	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.66 (-0.3/+0.2)	99.42 (-0.5/+0.3)	98.17 @ 69 mo. (-1.5/+0.8)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	Effective Sample Size	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.92 (-0.3/+0.1)	99.92 (-0.3/+0.1)	99.92 @ 69 mo. (-0.3/+0.1)	-	-	-	-
			3962	3459	2534	1541	742	216	-	-	-	-

ALTRUA 40 SR

Model S401

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ALTRUA 40 SR Model S401 			
Worldwide Distribution: 9,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
²⁶ Capacitor	2	-	
⁶¹ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

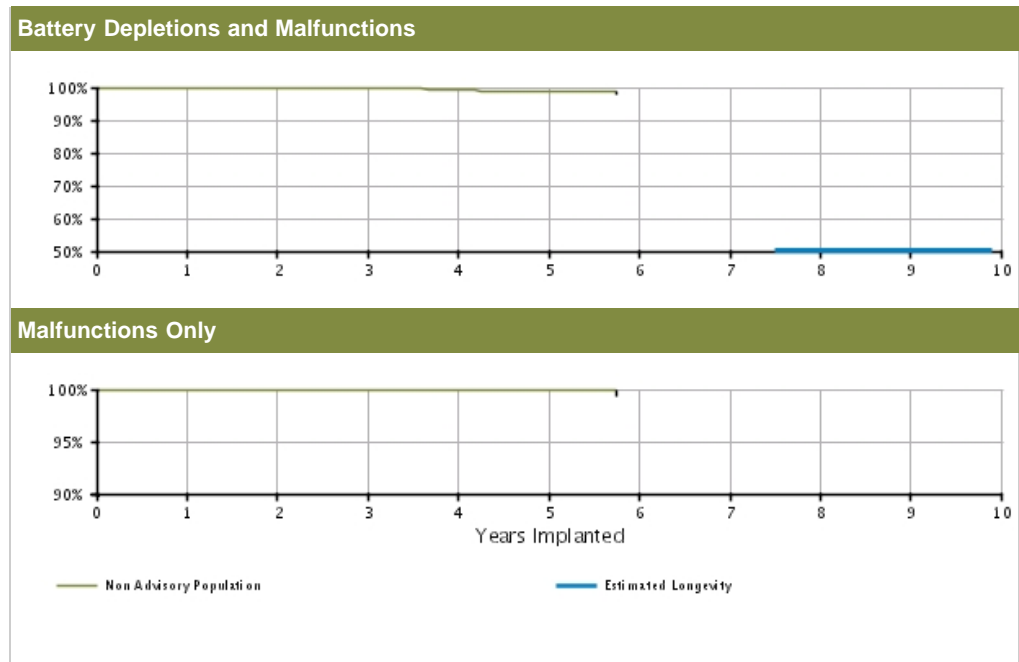
[References](#) cited in table above

ALTRUA 20 DR

Models S202/S205

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 17
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:1
	Without Compromised Therapy:1
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	100.00	100.00	99.83	99.43	98.72	97.47	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.5/+0.1)	(-0.7/+0.3)	(-1.0/+0.6)	@ 71 mo. (-1.8/+1.1)					
Registered Implants: 2000	Malfunctions Only(%)	100.00	100.00	100.00	99.90	99.90	99.90	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.6/+0.1)	(-0.6/+0.1)	@ 71 mo. (-0.6/+0.1)					
	Effective Sample Size	1475	1278	1080	902	732	243	-	-	-	-	-

ALTRUA 20 DR

Models S202/S205

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 DR
Models S202/S205



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
⁸¹ Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

[References](#) cited in table above

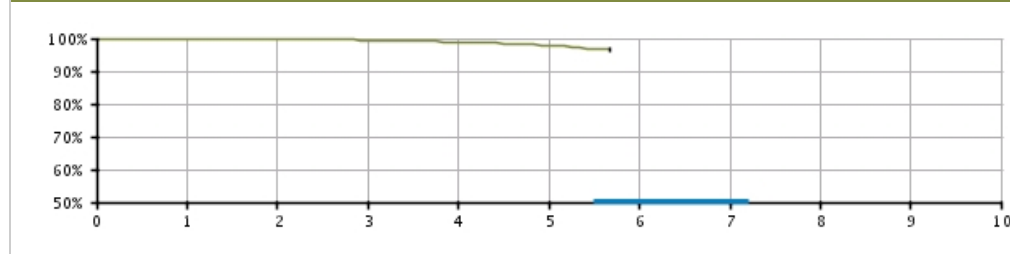
ALTRUA 20 DR (downsize)

Model S203

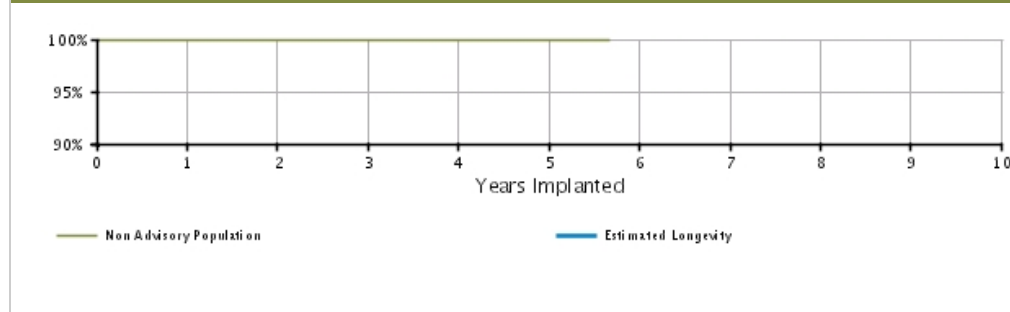
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 53
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.83	99.46	98.82	97.88	96.35	-	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.5/+0.3)	(-0.8/+0.6)	@ 70 mo. (-1.6/+1.1)					
Registered Implants: 5000	Malfunctions Only(%)	100.00	100.00	100.00	100.00	100.00	100.00	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	@ 70 mo. (-0.0/+0.0)				
Effective Sample Size		4416	3888	2976	1893	923	243	-	-	-	-	-

ALTRUA 20 DR (downsize)

Model S203

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 DR (downsize)
Model S203



Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	-	2
²⁶ Capacitor	2	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
⁴⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

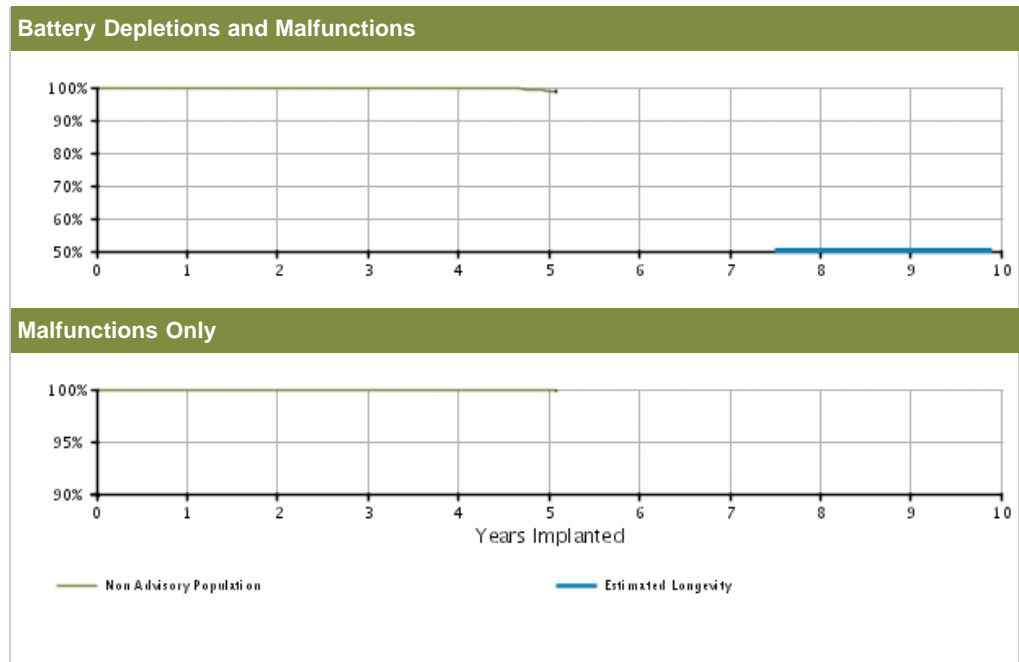
[References](#) cited in table above

ALTRUA 20 DR EL

Model S208

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 3,000	U.S. Normal Battery Depletions: 9
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.93	99.86	99.75	99.59	98.96	98.96	-	-	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-1.5/+0.6)	@ 61 mo. (-1.5/+0.6)					
Registered Implants: 3000	Malfunctions Only(%)	99.97	99.97	99.97	99.97	99.97	99.97	-	-	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	@ 61 mo. (-0.2/+0.0)					
	Effective Sample Size	2775	2439	1699	902	264	208	-	-	-	-	-

ALTRUA 20 DR EL

Model S208

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 DR EL
Model S208

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
²⁶ Capacitor	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

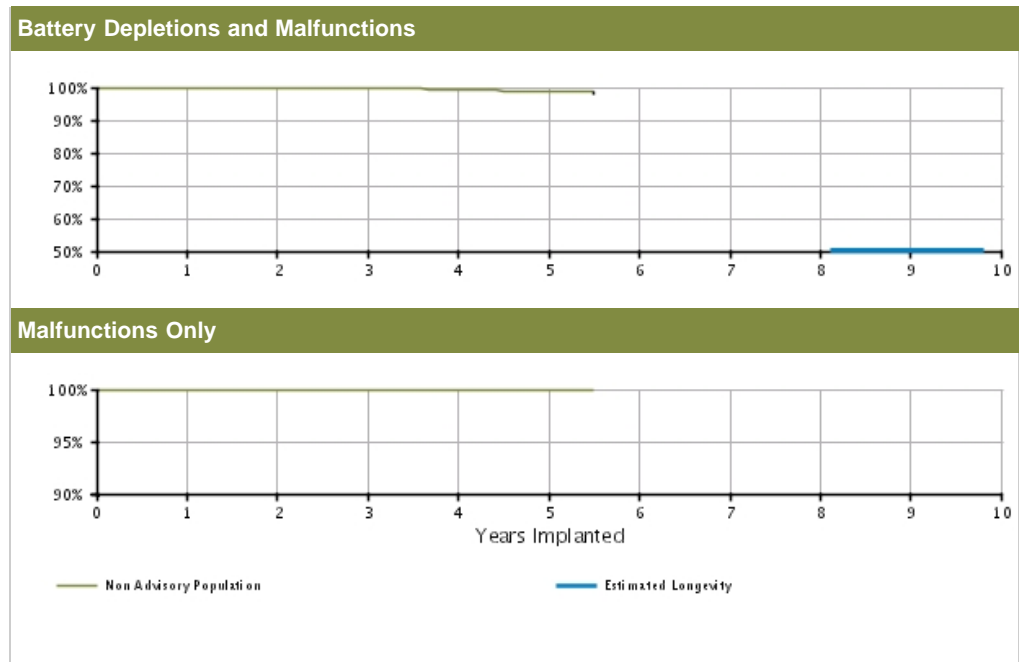
[References](#) cited in table above

ALTRUA 20 SR

Models S201/S204

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Normal Battery Depletions: 21
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.65 (-0.3/+0.2)	99.34 (-0.5/+0.3)	98.57 (-0.9/+0.6)	98.39 @ 68 mo. (-1.0/+0.6)	-	-	-	-	-
	Registered Implants: 4000											
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 68 mo. (-0.0/+0.0)	-	-	-	-	-
	Effective Sample Size	3559	2973	2185	1346	596	236	-	-	-	-	-

ALTRUA 20 SR

Models S201/S204

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 SR
Models S201/S204



Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁶ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 20 DDD

Model S207

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 DDD
Model S207

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 20 SSI

Model S206

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 SSI Model S206 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

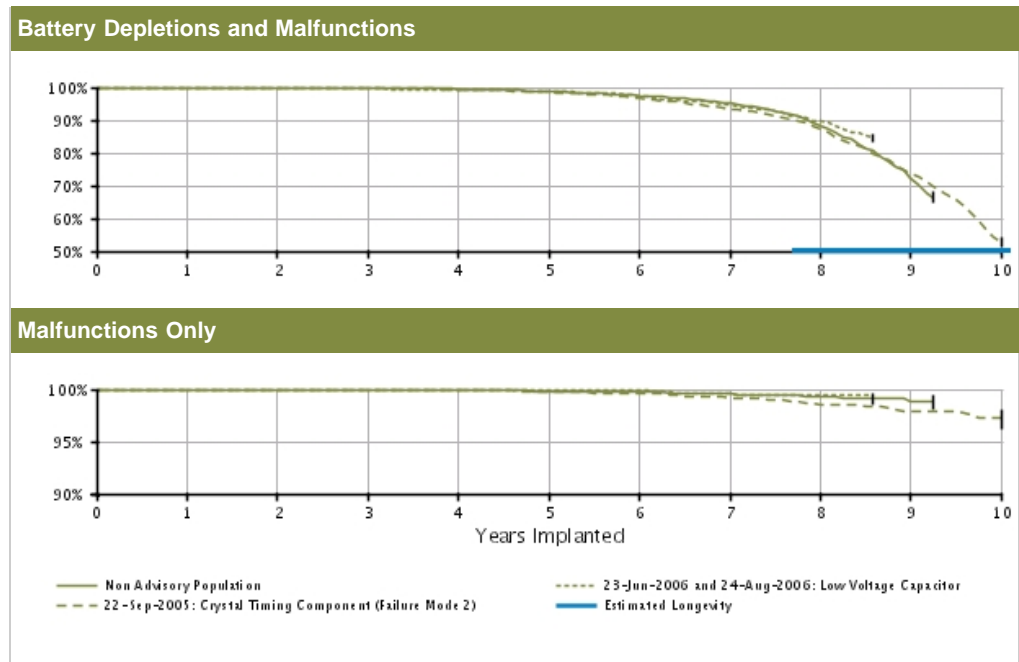
[References](#) cited in table above

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 1,833
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 19
U.S. Estimated Active Implants: 16,000	U.S. Malfunctions:122
	Without Compromised Therapy:113
	With Compromised Therapy:9



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.50 (-0.1/+0.1)	98.71 (-0.2/+0.2)	97.44 (-0.3/+0.3)	95.07 (-0.4/+0.4)	88.17 (-1.0/+0.9)	72.44 (-2.8/+2.6)	66.36 (-3.6/+3.4)	@ 111 mo. (-0.9/+0.5)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.30 (-0.3/+0.2)	98.89 (-0.9/+0.5)	98.89 (-0.9/+0.5)	@ 111 mo. (-0.9/+0.5)
	Effective Sample Size	21006	18660	16562	14651	12904	11249	5991	1890	307	203	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.48 (-1.1/+0.8)	94.64 (-1.5/+1.2)	89.58 (-2.1/+1.8)	84.62 (-2.8/+2.5)	—	@ 103 mo. (-2.8/+2.5)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.63 (-0.6/+0.2)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)	—	@ 103 mo. (-0.8/+0.3)
	Effective Sample Size	1878	1659	1461	1287	1134	987	850	701	220	—	
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.59 (-0.7/+0.6)	93.45 (-0.9/+0.8)	87.21 (-1.3/+1.2)	73.60 (-1.8/+1.7)	52.84 (-3.2/+3.2)	
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.59 (-0.7/+0.6)	93.45 (-0.9/+0.8)	87.21 (-1.3/+1.2)	73.60 (-1.8/+1.7)	52.84 (-3.2/+3.2)	
	Effective Sample Size											

6000											
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.96 (-0.7/+0.5)	97.28 (-1.1/+0.8)
	Effective Sample Size	5702	5045	4467	3940	3453	2980	2556	2098	1461	226


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

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Ultra DR Model 1291 			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 152			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	7	5	12
⁹ Low-voltage capacitor (Advisory issued)	-	2	
²³ Capacitor	1	-	
²⁶ Capacitor	4	2	
⁶¹ Integrated circuit	2	1	
Mechanical	7	5	12
³⁵ Seal plug	5	4	
³⁶ Header	1	1	
⁶³ Setscrew	1	-	
Software	4	-	4
⁶⁷ Underestimation of battery status	3	-	
⁶⁹ Pacing rate limit	1	-	
Other	120	4	124
Non-patterned	7	3	
¹⁹ Longevity labeling	72	-	
³⁸ Magnet response	1	-	
⁴⁷ Battery depletion	2	1	
⁸⁸ Battery status	38	-	
WW Confirmed Malfunctions	138	14	152

[More details](#) about malfunctions

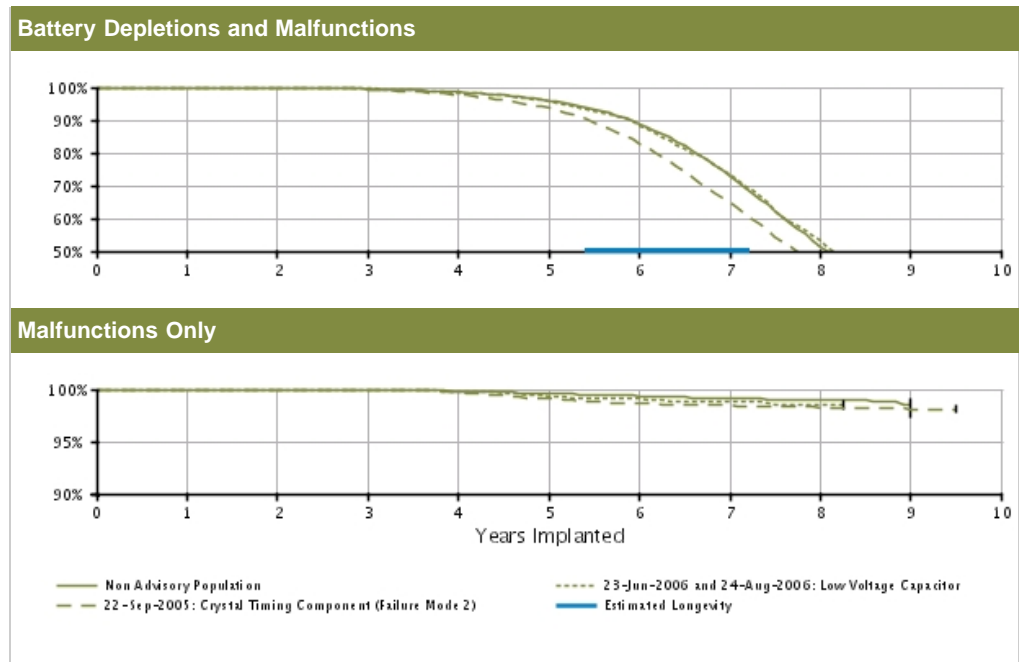
[References](#) cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 76,000	U.S. Normal Battery Depletions: 14,793
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 110
U.S. Estimated Active Implants: 23,000	U.S. Malfunctions:404
	Without Compromised Therapy:393
	With Compromised Therapy:11



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.48 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.93 (-0.4/+0.4)	72.97 (-0.6/+0.6)	51.30 (-1.0/+1.0)	30.02 (-1.7/+1.8)	26.58 @ 110 mo. (-1.9/+2.0)	
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.17 (-0.1/+0.1)	99.07 (-0.1/+0.1)	98.68 (-0.8/+0.5)	98.68 @ 110 mo. (-0.8/+0.5)	
	Effective Sample Size	47638	42291	37445	32964	28497	23363	10990	2770	281	238	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.2/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.3/+0.2)	98.41 (-0.5/+0.4)	95.67 (-0.8/+0.7)	88.20 (-1.4/+1.2)	73.26 (-1.9/+1.8)	53.08 (-2.3/+2.3)	43.38 @ 102 mo. (-2.4/+2.4)	-	
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.37 (-0.4/+0.2)	99.10 (-0.5/+0.3)	98.76 (-0.6/+0.4)	98.59 (-0.6/+0.4)	98.59 @ 102 mo. (-0.6/+0.4)	-	
	Effective Sample Size	4025	3553	3142	2733	2340	1909	1380	861	310	-	
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.											
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.38 (-0.2/+0.1)	97.77 (-0.3/+0.3)	93.65 (-0.5/+0.5)	82.84 (-0.8/+0.8)	64.59 (-1.1/+1.1)	44.72 (-1.2/+1.2)	28.12 (-1.2/+1.2)	19.30 @ 117 mo.	

Component (Failure Mode 2)*	(Confidence Interval)										(-1.3/+1.4)
Registered Implants: 17000											
	Malfunctions Only (%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.09 (-0.2/+0.2)	98.67 (-0.3/+0.2)	98.45 (-0.3/+0.2)	98.25 (-0.3/+0.3)	98.12 (-0.4/+0.3)	98.12 @ 117 mo. (-0.4/+0.3)
	Effective Sample Size	14977	13298	11732	10224	8613	6644	4423	2603	1248	214


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

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR (downsize)

Model 1290

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Ultra DR (downsize) Model 1290 			
Worldwide Distribution: 124,000			
Worldwide Confirmed Malfunctions: 548			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	9	18
⁹ Low-voltage capacitor (Advisory issued)	1	5	
²⁶ Capacitor	7	3	
⁶¹ Integrated circuit	1	1	
Mechanical	6	2	8
¹³ Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²⁴ Setscrew thread depth	1	-	
³⁵ Seal plug	4	1	
⁴⁵ Circuit connection	1	-	
Software	12	-	12
⁴⁰ Memory error	2	-	
⁴¹ Rate fault declaration	1	-	
⁶⁷ Underestimation of battery status	8	-	
⁶⁹ Pacing rate limit	1	-	
Other	503	7	510
Non-patterned	22	5	
¹⁹ Longevity labeling	399	-	
⁴⁷ Battery depletion	6	2	
⁸⁸ Battery status	76	-	
WW Confirmed Malfunctions	530	18	548

[More details](#) about malfunctions

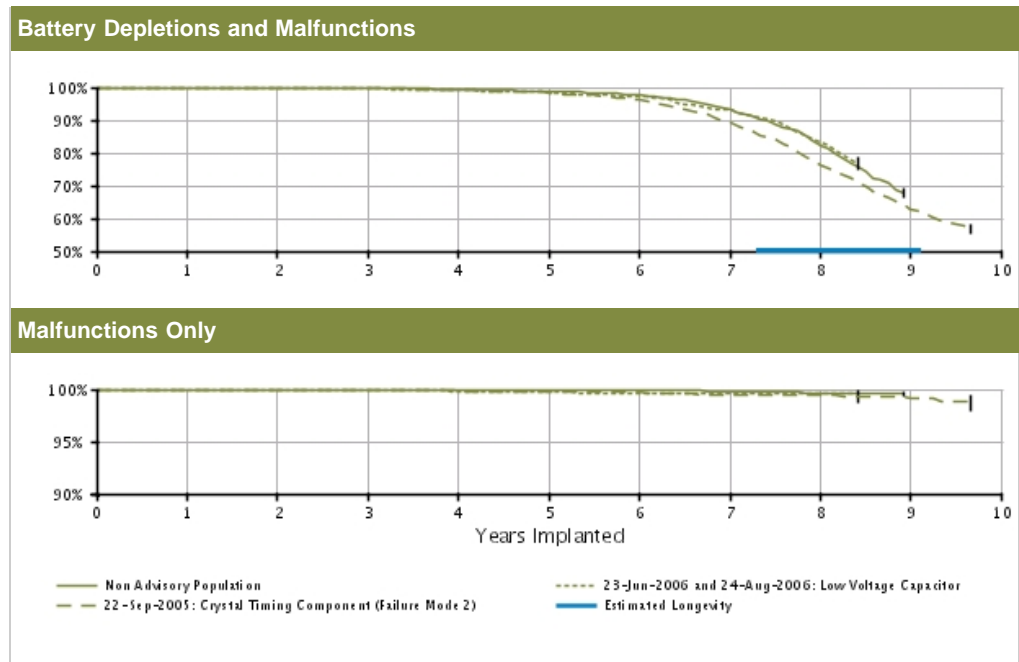
[References](#) cited in table above

INSIGNIA Ultra SR

Model 1190

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Normal Battery Depletions: 1,451
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 7,000	U.S. Malfunctions:34
	Without Compromised Therapy:30
	With Compromised Therapy:4



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.71 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.73 (-0.3/+0.2)	97.57 (-0.4/+0.3)	93.07 (-0.7/+0.6)	82.25 (-1.5/+1.4)	67.75 @ 107 mo. (-3.2/+3.0)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.77 (-0.2/+0.1)	99.60 (-0.3/+0.2)	99.60 @ 107 mo. (-0.3/+0.2)	-	-
	Effective Sample Size	14153	12092	10314	8875	7736	6709	3650	1123	206	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.11 (-0.9/+0.5)	98.47 (-1.2/+0.7)	97.21 (-1.6/+1.0)	93.27 (-2.5/+1.8)	83.26 (-3.7/+3.2)	76.68 @ 101 mo. (-4.3/+3.8)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 @ 101 mo. (-0.9/+0.3)	-	-
	Effective Sample Size	1148	963	812	700	589	503	422	334	219	-	-
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.											
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.23 (-0.4/+0.3)	98.28 (-0.6/+0.4)	96.25 (-0.9/+0.7)	89.36 (-1.5/+1.3)	76.36 (-2.2/+2.0)	62.80 (-2.6/+2.5)	56.79 @ 116 mo.	-

Component (Failure Mode 2)*	(Confidence Interval)										(-3.0/+3.0)
Registered Implants: 5000											
Malfunctions Only (%)	100.00	99.98	99.98	99.87	99.83	99.78	99.47	99.40	99.15	98.88	
(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.5/+0.3)	(-0.7/+0.4)	@ 116 mo. (-1.0/+0.5)	
Effective Sample Size	4144	3558	3002	2530	2113	1770	1420	1040	684	207	


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

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra SR

Model 1190

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Ultra SR Model 1190			
Worldwide Distribution: 48,000			
Worldwide Confirmed Malfunctions: 54			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	5	7
⁹ Low-voltage capacitor (Advisory issued)	1	3	
²⁶ Capacitor	1	-	
⁶¹ Integrated circuit	-	2	
Mechanical	3	1	4
³⁵ Seal plug	3	-	
³⁶ Header	-	1	
Software	1	-	1
⁴⁰ Memory error	1	-	
Other	42	-	42
Non-patterned	1	-	
¹⁹ Longevity labeling	23	-	
⁴⁷ Battery depletion	1	-	
⁸⁸ Battery status	17	-	
WW Confirmed Malfunctions	48	6	54

[More details](#) about malfunctions

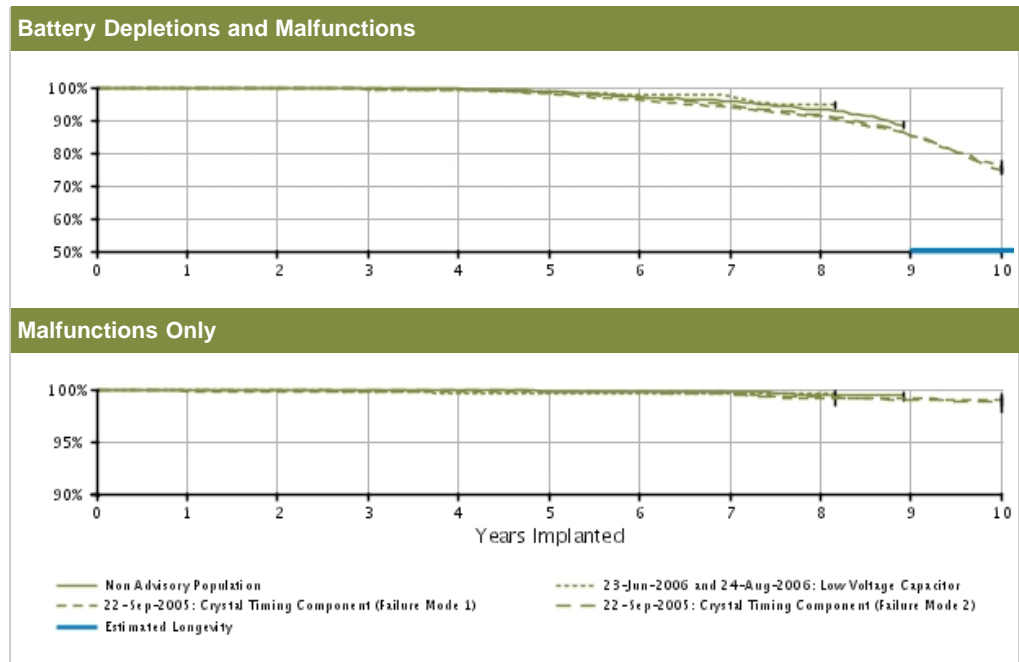
[References](#) cited in table above

INSIGNIA Entra DR

Models 1294/1295

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 17,000	U.S. Normal Battery Depletions: 1,041
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:59
	Without Compromised Therapy:52
	With Compromised Therapy:7



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.2/+0.2)	98.72 (-0.4/+0.3)	97.03 (-0.6/+0.5)	95.68 (-0.7/+0.6)	93.35 (-1.1/+1.0)	87.42 (-2.6/+2.2)	85.32 @ 109 mo. (-3.2/+2.7)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.74 (-0.2/+0.1)	99.42 (-0.5/+0.3)	99.25 (-0.7/+0.4)	99.25 @ 109 mo. (-0.7/+0.4)	
	Effective Sample Size	6259	5547	4915	4356	3806	3252	2066	890	225	205	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.45 (-1.1/+0.4)	99.24 (-1.3/+0.5)	98.76 (-1.5/+0.7)	97.66 (-2.0/+1.1)	97.33 (-2.1/+1.2)	94.55 (-3.0/+2.0)	94.55 @ 100 mo. (-3.0/+2.0)		-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 @ 100 mo. (-1.2/+0.3)	
	Effective Sample Size	693	607	529	452	394	338	294	249	231		-
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.69 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.19 (-0.7/+0.4)	98.09 (-1.0/+0.7)	96.06 (-1.4/+1.1)	93.81 (-1.8/+1.4)	91.04 (-2.2/+1.8)	85.33 (-2.9/+2.5)	75.31 (-3.7/+3.4)	
	Malfunctions Only(%) (Confidence Interval)											
	Effective Sample Size											

2000	Malfunctions Only (%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.19 (-1.0/+0.5)	99.19 (-1.0/+0.5)	98.95 (-1.2/+0.6)
	Effective Sample Size	1675	1453	1213	1063	923	785	662	554	452	326
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.31 (-0.3/+0.2)	98.40 (-0.4/+0.3)	96.92 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.56 (-1.0/+0.9)	85.59 (-1.4/+1.3)	74.72 (-2.1/+2.0)
Registered Implants: 7000	Malfunctions Only (%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.47 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.98 (-0.5/+0.3)	98.90 (-0.5/+0.3)
	Effective Sample Size	6210	5482	4824	4230	3694	3188	2680	2268	1811	724

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

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR

Models 1294/1295

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Entra DR Models 1294/1295			
Worldwide Distribution: 36,000			
Worldwide Confirmed Malfunctions: 69			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
²² Integrated circuit	-	1	
²⁶ Capacitor	-	1	
⁶¹ Integrated circuit	-	1	
Mechanical	3	7	10
¹² Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
³⁵ Seal plug	3	-	
³⁶ Header	-	2	
Software	-	-	0
Other	54	2	56
Non-patterned	4	2	
¹⁹ Longevity labeling	48	-	
⁸⁸ Battery status	2	-	
WW Confirmed Malfunctions	57	12	69

[More details](#) about malfunctions

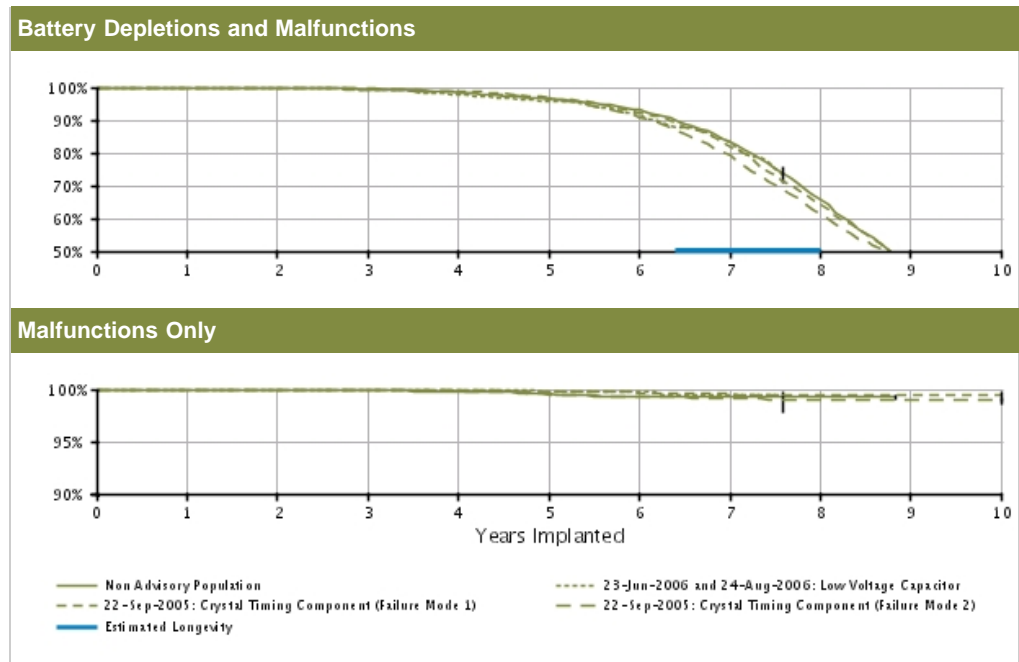
[References](#) cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Normal Battery Depletions: 4,237
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:95
	Without Compromised Therapy:89
	With Compromised Therapy:6



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.43 (-0.2/+0.2)	98.43 (-0.4/+0.3)	96.58 (-0.5/+0.5)	93.02 (-0.8/+0.7)	83.24 (-1.3/+1.2)	65.78 (-2.2/+2.1)	47.84 @ 106 mo. (-3.3/+3.3)	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.99 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.57 (-0.2/+0.2)	99.37 (-0.3/+0.2)	99.31 (-0.3/+0.2)	99.24 (-0.3/+0.2)	99.24 @ 106 mo. (-0.3/+0.2)	-	-
	Effective Sample Size	7138	6279	5496	4779	4117	3474	2029	742	206	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.70 (-0.9/+0.2)	99.20 (-1.1/+0.5)	97.84 (-1.6/+0.9)	95.61 (-2.2/+1.5)	91.90 (-3.0/+2.2)	83.01 (-4.2/+3.5)	73.28 @ 91 mo. (-5.1/+4.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.75 (-1.5/+0.2)	99.75 (-1.5/+0.2)	99.43 (-1.7/+0.4)	99.43 @ 91 mo. (-1.7/+0.4)	-	-	-
	Effective Sample Size	763	657	563	476	402	329	253	205	-	-	-
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.03 (-1.5/+1.3)	81.79 (-2.2/+2.0)	64.06 (-2.9/+2.8)	45.84 (-3.2/+3.2)	32.02 (-3.1/+3.3)	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.75 (-1.5/+0.2)	99.75 (-1.5/+0.2)	99.43 (-1.7/+0.4)	99.43 @ 91 mo. (-1.7/+0.4)	-	-	-
	Effective Sample Size	763	657	563	476	402	329	253	205	-	-	-

3000	Malfunctions Only (%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2736	2405	2071	1813	1515	1227	934	597	361	205
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.56 (-0.2/+0.1)	98.52 (-0.3/+0.3)	96.46 (-0.5/+0.4)	90.85 (-0.8/+0.7)	79.03 (-1.2/+1.1)	61.27 (-1.5/+1.5)	45.10 (-1.6/+1.6)	36.13 (-1.8/+1.8)
Registered Implants: 11000	Malfunctions Only (%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.52 (-0.2/+0.1)	99.26 (-0.3/+0.2)	99.14 (-0.3/+0.2)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)
	Effective Sample Size	9584	8452	7365	6366	5505	4512	3340	2174	1307	524

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

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR (downsize)

Model 1296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Entra DR (downsize) Model 1296			
Worldwide Distribution: 47,000			
Worldwide Confirmed Malfunctions: 117			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
⁹ Low-voltage capacitor (Advisory issued)	-	1	
²⁶ Capacitor	1	-	
⁶¹ Integrated circuit	-	3	
Mechanical	-	3	3
¹² Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
¹⁶ Solder bond	-	1	
Software	4	-	4
³² Memory error	1	-	
⁶⁷ Underestimation of battery status	1	-	
⁶⁸ Interrupted telemetry	2	-	
Other	103	2	105
Non-patterned	4	2	
¹⁹ Longevity labeling	96	-	
⁴⁷ Battery depletion	1	-	
⁸⁸ Battery status	2	-	
WW Confirmed Malfunctions	108	9	117

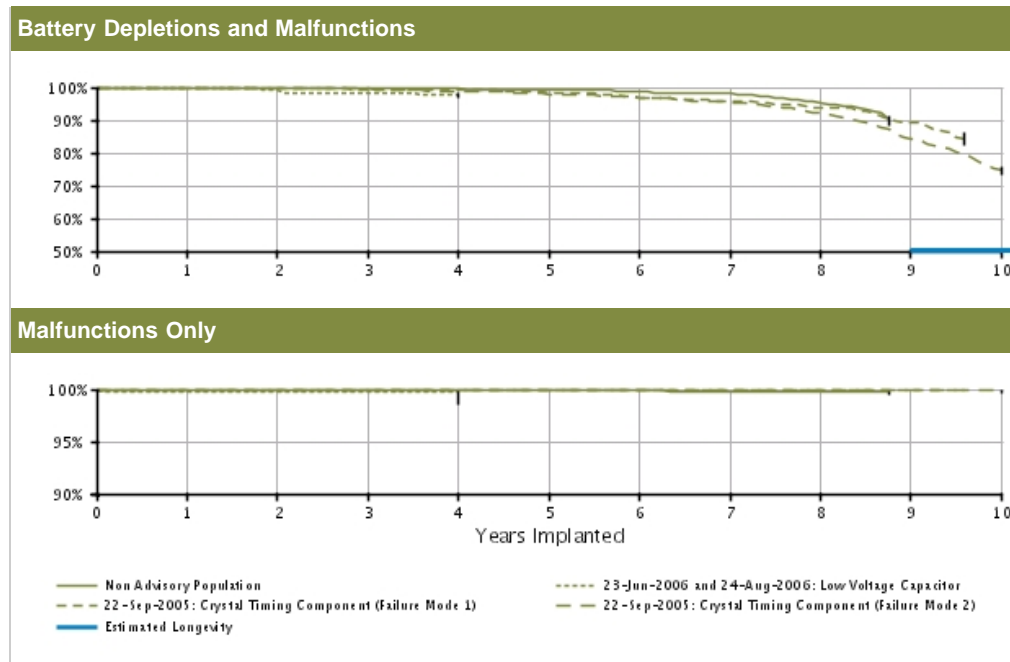
[More details](#) about malfunctions[References](#) cited in table above

INSIGNIA Entra SR

Models 1195/1198

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 551
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:9
	Without Compromised Therapy:7
	With Compromised Therapy:2



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.85 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.74 (-0.5/+0.4)	98.06 (-0.7/+0.5)	95.32 (-1.5/+1.1)	90.09 @ 105 mo. (-3.3/+2.6)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.80 (-0.3/+0.1)	99.80 (-0.3/+0.1)	99.80 @ 105 mo. (-0.3/+0.1)	-	-
	Effective Sample Size	4709	3873	3253	2747	2332	1964	1208	488	201	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 500	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.10 (-1.9/+0.6)	98.39 (-2.2/+0.9)	97.94 (-2.5/+1.1)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	-	-	-	-	-	-	-
	Effective Sample Size	348	284	237	204	-	-	-	-	-	-	-
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.21 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.96 (-1.8/+1.1)	95.73 (-2.1/+1.4)	93.95 (-2.6/+1.9)	89.46 (-3.6/+2.8)	84.37 @ 115 mo. (-4.5/+3.6)	-
	Malfunctions Only(%) (Confidence Interval)	-	-	-	-	-	-	-	-	-	-	-
	Effective Sample Size	-	-	-	-	-	-	-	-	-	-	-

	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 115 mo. (-0.0/+0.0)
	Effective Sample Size	1216	999	807	662	550	447	356	298	244	204
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.95 (-0.6/+0.5)	96.95 (-0.8/+0.6)	95.27 (-1.0/+0.8)	92.21 (-1.3/+1.2)	84.15 (-2.0/+1.8)	74.60 (-2.7/+2.6)
Registered Implants: 6000											
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)
	Effective Sample Size	4579	3829	3178	2643	2185	1831	1542	1289	979	445


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

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra SR

Models 1195/1198

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Entra SR Models 1195/1198 			
Worldwide Distribution: 52,000			
Worldwide Confirmed Malfunctions: 26			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	4	7
⁹ Low-voltage capacitor (Advisory issued)	-	2	
²⁶ Capacitor	2	2	
⁶¹ Integrated circuit	1	-	
Mechanical	1	6	7
¹² Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
¹³ Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²⁹ Capacitor array	-	2	
³⁵ Seal plug	-	2	
⁶⁵ Seal plug	-	1	
Software	-	-	0
Other	11	1	12
Non-patterned	1	1	
¹⁹ Longevity labeling	6	-	
⁸⁸ Battery status	4	-	
WW Confirmed Malfunctions	15	11	26

[More details](#) about malfunctions

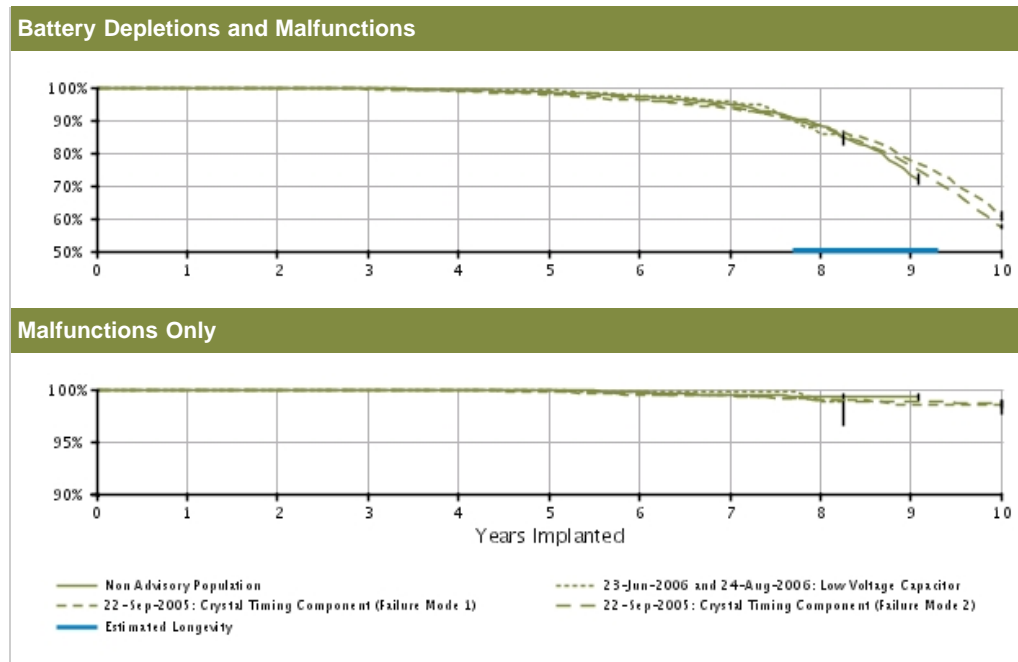
[References](#) cited in table above

INSIGNIA Plus DR

Model 1297

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 3,519
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Estimated Active Implants: 8,000	U.S. Malfunctions:125
	Without Compromised Therapy:116
	With Compromised Therapy:9



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.75 (-0.2/+0.1)	99.26 (-0.3/+0.2)	98.51 (-0.4/+0.3)	97.18 (-0.5/+0.5)	94.91 (-0.8/+0.7)	88.47 (-1.6/+1.4)	73.03 (-3.5/+3.3)	71.99 @ 109 mo. (-3.7/+3.4)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.45 (-0.3/+0.2)	99.29 (-0.4/+0.3)	99.29 (-0.4/+0.3)	99.29 @ 109 mo. (-0.4/+0.3)	
	Effective Sample Size	6560	5831	5161	4546	3997	3475	2140	882	235	210	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.19 (-1.3/+0.5)	99.19 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.64 (-2.7/+1.7)	85.99 (-4.5/+3.5)	84.78 @ 99 mo. (-4.7/+3.7)		
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.86 (-2.4/+0.8)	98.86 @ 99 mo. (-2.4/+0.8)		
	Effective Sample Size	664	580	510	442	386	333	285	223	211		
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.10 (-1.7/+1.5)	77.84 (-2.2/+2.1)	60.66 (-2.8/+2.7)	
	Malfunctions Only(%) (Confidence Interval)											
	Effective Sample Size											

4000	Malfunctions Only (%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.4/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3515	3073	2598	2281	1973	1705	1459	1211	931	608
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.55 (-0.1/+0.1)	99.10 (-0.2/+0.2)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.79 (-0.8/+0.8)	76.12 (-1.2/+1.1)	57.39 (-1.5/+1.5)
Registered Implants: 14000	Malfunctions Only (%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.1)	99.58 (-0.2/+0.1)	99.38 (-0.2/+0.2)	99.05 (-0.3/+0.2)	98.80 (-0.3/+0.3)	98.68 (-0.4/+0.3)
	Effective Sample Size	12753	11250	9911	8722	7618	6597	5631	4617	3428	1664

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

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus DR

Model 1297

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Plus DR Model 1297			
Worldwide Distribution: 47,000			
Worldwide Confirmed Malfunctions: 148			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁹ Low-voltage capacitor (Advisory issued)	1	1	
²⁶ Capacitor	2	1	
⁶¹ Integrated circuit	-	1	
Mechanical	13	7	20
¹² Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
¹³ Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
¹⁶ Solder bond	1	-	
²⁹ Capacitor array	1	-	
³⁵ Seal plug	5	-	
³⁶ Header	5	4	
Software	7	-	7
⁶⁷ Underestimation of battery status	4	-	
⁶⁸ Interrupted telemetry	2	-	
⁶⁹ Pacing rate limit	1	-	
Other	113	2	115
Non-patterned	6	2	
¹⁹ Longevity labeling	87	-	
⁴⁷ Battery depletion	2	-	
⁸⁸ Battery status	18	-	
WW Confirmed Malfunctions	136	12	148

[More details](#) about malfunctions

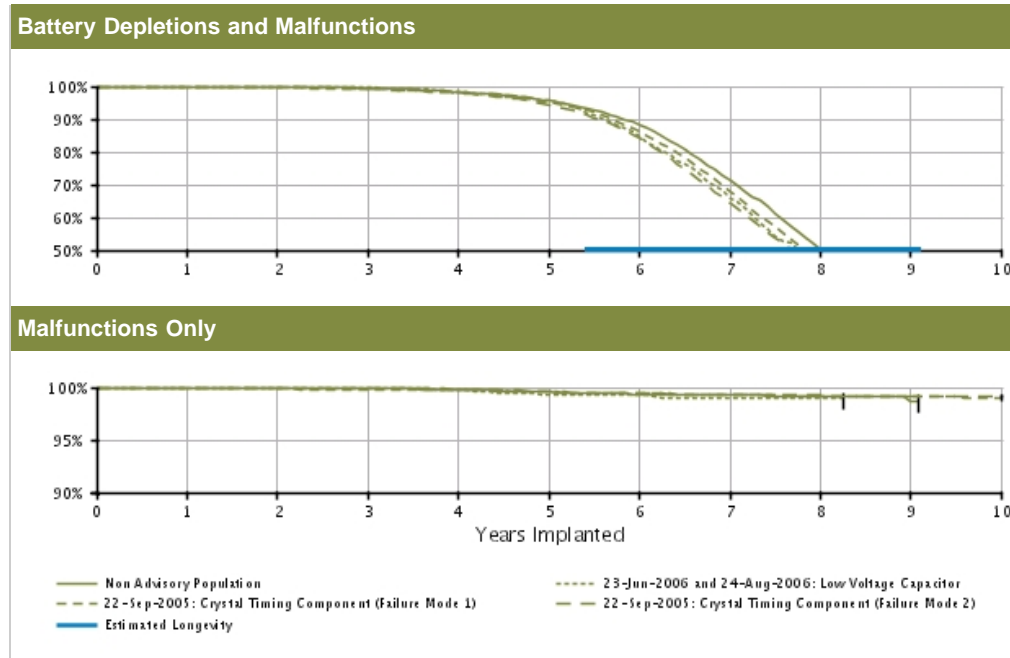
[References](#) cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 90,000	U.S. Normal Battery Depletions: 24,936
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 113
U.S. Estimated Active Implants: 12,000	U.S. Malfunctions: 371



U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.41 (-0.1/+0.1)	98.27 (-0.2/+0.2)	95.61 (-0.4/+0.4)	88.26 (-0.6/+0.6)	71.17 (-1.0/+1.0)	50.16 (-1.4/+1.4)	29.65 (-2.0/+2.1)	28.06 (-2.1/+2.2) @ 109 mo.
	Registered Implants: 19000										
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.35 (-0.2/+0.1)	99.25 (-0.2/+0.2)	99.13 (-0.3/+0.2)	98.72 (-1.2/+0.6)	98.72 (-1.2/+0.6) @ 109 mo.
	Effective Sample Size	16864	14980	13240	11653	10064	8172	4332	1388	244	218
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.86 (-0.4/+0.1)	99.77 (-0.5/+0.2)	98.12 (-1.0/+0.7)	95.80 (-1.5/+1.1)	84.87 (-2.6/+2.3)	65.93 (-3.5/+3.4)	45.70 (-3.8/+3.9)	39.35 (-3.8/+3.9) @ 99 mo.	—
	Registered Implants: 2000										
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.70 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5) @ 99 mo.	—
	Effective Sample Size	1420	1250	1112	964	825	642	435	258	214	—
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.13 (-0.2/+0.2)	98.03 (-0.3/+0.2)	95.05 (-0.5/+0.4)	86.19 (-0.8/+0.7)	67.68 (-1.1/+1.1)	47.02 (-1.3/+1.3)	31.93 (-1.3/+1.3)	22.09 (-1.2/+1.3)
	Registered Implants: 16000										
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.57 (-0.2/+0.1)	99.38 (-0.2/+0.1)	99.32 (-0.2/+0.2)	99.19 (-0.2/+0.2)	99.13 (-0.3/+0.2)	99.03 (-0.4/+0.3)

	Effective Sample Size	13683	12074	10375	9055	7729	6115	4097	2348	1305	740
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.80 (-0.0/+0.0)	99.26 (-0.1/+0.1)	97.91 (-0.2/+0.1)	94.47 (-0.3/+0.2)	84.13 (-0.4/+0.4)	64.21 (-0.6/+0.6)	44.20 (-0.7/+0.7)	29.98 (-0.7/+0.7)	20.67 (-0.7/+0.7)
Registered Implants: 54000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.30 (-0.1/+0.1)	99.22 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.14 (-0.1/+0.1)
	Effective Sample Size	47026	41685	36743	32066	27289	21114	13687	7797	4317	1878


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

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus DR (downsize)

Model 1298

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Plus DR (downsize) Model 1298 			
Worldwide Distribution: 140,000			
Worldwide Confirmed Malfunctions: 446			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	11	10	21
⁹ Low-voltage capacitor (Advisory issued)	-	3	
²³ Capacitor	-	1	
²⁶ Capacitor	6	2	
³¹ Integrated circuit	-	1	
⁶¹ Integrated circuit	5	3	
Mechanical	21	22	43
¹² Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
¹³ Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
¹⁶ Solder bond	1	-	
²⁹ Capacitor array	3	1	
³⁵ Seal plug	3	1	
³⁶ Header	5	-	
⁶⁵ Seal plug	1	-	
Software	11	-	11
⁴⁰ Memory error	1	-	
⁶⁶ Interrogation at EOL	2	-	
⁶⁷ Underestimation of battery status	6	-	
⁶⁸ Interrupted telemetry	1	-	
⁶⁹ Pacing rate limit	1	-	
Other	360	11	371
Non-patterned	27	9	
¹⁹ Longevity labeling	310	-	
³⁴ Battery depletion	2	1	
³⁸ Magnet response	1	-	
⁴⁷ Battery depletion	11	1	
⁸⁸ Battery status	9	-	
WW Confirmed Malfunctions	403	43	446

[More details](#) about malfunctions

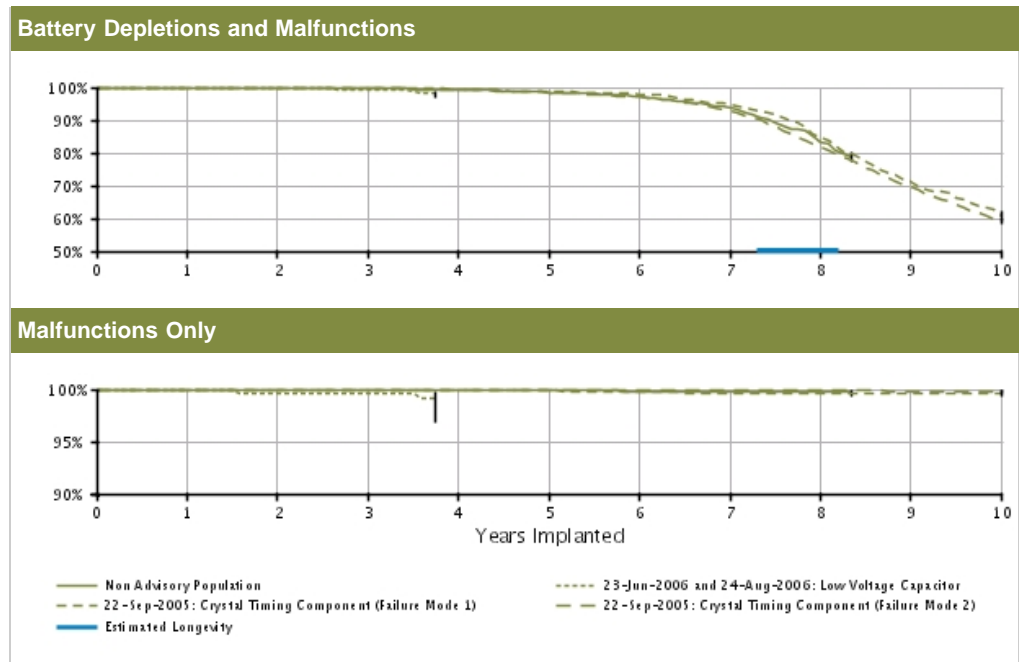
[References](#) cited in table above

INSIGNIA Plus SR

Model 1194

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 2,809
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 7
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:27
	Without Compromised Therapy:19
	With Compromised Therapy:8



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.61 (-0.3/+0.2)	99.33 (-0.3/+0.2)	98.47 (-0.5/+0.4)	97.29 (-0.7/+0.6)	93.55 (-1.2/+1.0)	83.50 (-2.4/+2.1)	73.24 @ 105 mo. (-3.7/+3.4)	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.85 (-0.3/+0.1)	99.74 (-0.3/+0.1)	99.74 (-0.3/+0.1)	99.74 @ 105 mo. (-0.3/+0.1)	-	-
	Effective Sample Size	4727	4035	3452	2889	2472	2108	1260	524	210	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 400	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.27 (-2.2/+0.6)	98.33 @ 45 mo. (-2.7/+1.0)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.66 (-2.0/+0.3)	99.18 @ 45 mo. (-2.5/+0.6)	-	-	-	-	-	-	-
	Effective Sample Size	326	277	240	201	-	-	-	-	-	-	-
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.89 (-0.2/+0.1)	99.74 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.74 (-0.6/+0.4)	98.00 (-0.7/+0.5)	94.86 (-1.2/+1.0)	84.90 (-2.2/+1.9)	71.08 (-2.8/+2.7)	60.82 (-3.2/+3.1)	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)
	Effective Sample Size	-	-	-	-	-	-	-	-	-	-	-

4000	Malfunctions Only (%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.92 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.76 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)
	Effective Sample Size	3454	2919	2422	2071	1744	1437	1173	878	621	457
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.24 (-0.2/+0.2)	98.49 (-0.3/+0.2)	97.09 (-0.4/+0.4)	92.87 (-0.7/+0.6)	81.86 (-1.1/+1.0)	69.70 (-1.3/+1.3)	58.46 (-1.6/+1.6)
Registered Implants: 17000	Malfunctions Only (%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 (-0.1/+0.1)	99.82 (-0.2/+0.1)	99.82 (-0.2/+0.1)
	Effective Sample Size	13687	11697	10067	8523	7167	6028	4919	3655	2588	1466

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

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus SR

Model 1194

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Plus SR Model 1194			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 35			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁹ Low-voltage capacitor (Advisory issued)	1	2	
²⁶ Capacitor	2	2	
³¹ Integrated circuit	-	1	
⁶¹ Integrated circuit	1	-	
Mechanical	1	6	7
¹² Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
²⁹ Capacitor array	1	-	
³⁵ Seal plug	-	1	
Software	1	-	1
⁶⁹ Pacing rate limit	1	-	
Other	17	1	18
Non-patterned	4	-	
¹⁹ Longevity labeling	10	-	
³⁴ Battery depletion	-	1	
⁴⁷ Battery depletion	1	-	
⁸⁸ Battery status	2	-	
WW Confirmed Malfunctions	23	12	35


[More details](#) about malfunctions

[References](#) cited in table above

INSIGNIA AVT

Models 0482/0882/0982/1192/1292

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA AVT Models 0482/0882/0982/1192/1292 			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 75			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	5	5
⁹ Low-voltage capacitor (Advisory issued)	-	3	
²⁶ Capacitor	-	1	
⁶¹ Integrated circuit	-	1	
Mechanical	2	-	2
³⁵ Seal plug	1	-	
³⁶ Header	1	-	
Software	-	-	0
Other	66	2	68
Non-patterned	2	1	
¹⁹ Longevity labeling	40	-	
⁴⁷ Battery depletion	-	1	
⁸⁸ Battery status	24	-	
WW Confirmed Malfunctions	68	7	75

[More details](#) about malfunctions

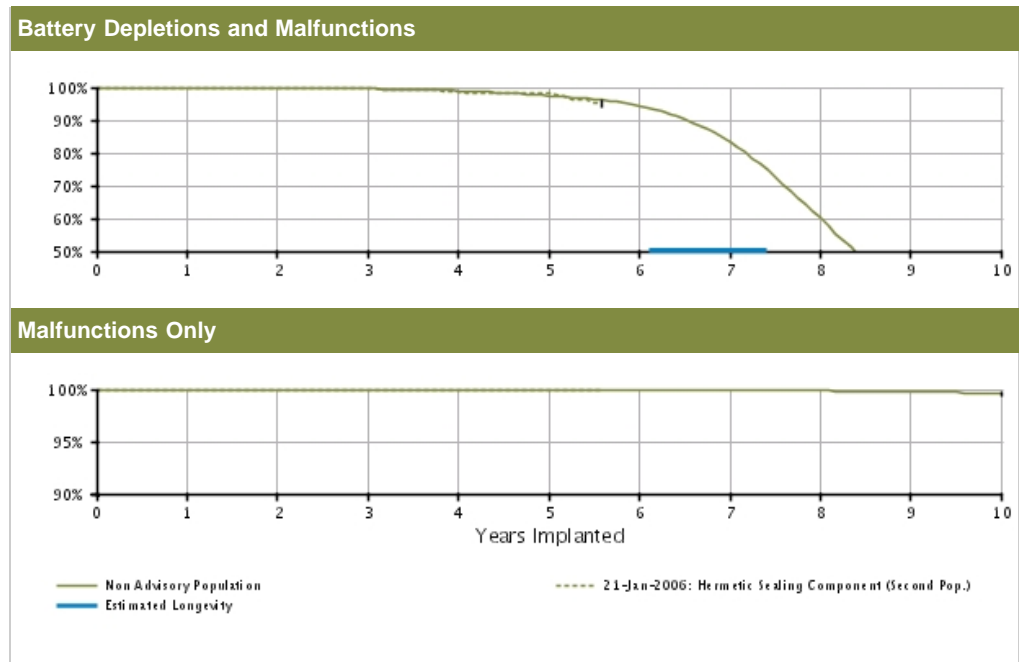
[References](#) cited in table above

DISCOVERY II DR

Models 1284/1286

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 23,000	U.S. Normal Battery Depletions: 5,898
U.S. Approval Date: March 2000	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:21
	Without Compromised Therapy:15
	With Compromised Therapy:6




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.96	99.84	99.60	98.94	97.50	94.45	83.35	60.07	37.04	26.05	
	(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.3/+0.3)	(-0.4/+0.4)	(-0.7/+0.7)	(-1.0/+1.0)	(-1.1/+1.1)	(-1.1/+1.1)	
	Registered Implants: 22000											
21-Jan-06 Hermetic Sealing Component (Second Pop.)*	Malfunctions Only(%)	99.99	99.99	99.98	99.96	99.96	99.95	99.94	99.89	99.70	99.63	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.3/+0.2)	
	Registered Implants: 1000											
Effective Sample Size		19377	17254	15236	13364	11590	9848	7535	4498	2111	1069	
21-Jan-06 and 18-Jul-05 Hermetic Sealing Component (Original Pop.)*	Depletions and Malfunctions(%)	100.00	100.00	99.72	98.77	98.03	95.42	-	-	-	-	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-1.7/+0.2)	(-2.0/+0.8)	(-2.4/+1.1)	@ 67 mo. (-3.4/+2.0)					
	Registered Implants: 1000											
Effective Sample Size		442	386	340	282	239	201	-	-	-	-	
Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.												

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

DISCOVERY II DR

Models 1284/1286

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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DISCOVERY II DR Models 1284/1286 			
Worldwide Distribution: 37,000			
Worldwide Confirmed Malfunctions: 32			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁶¹ Integrated circuit	-	1	
Mechanical	7	4	11
¹¹ Hermetic sealing component Original Population (Advisory issued)	5	2	
²⁷ Feedthrough wires	-	1	
³⁷ Telemetry or atrial noise	1	-	
⁴⁹ Internal device connection	1	-	
⁵⁰ Setscrew block	-	1	
Software	3	1	4
¹⁵ Overestimation of battery status	-	1	
⁴⁰ Memory error	1	-	
⁸² Battery status	2	-	
Other	13	3	16
Non-patterned	4	3	
¹⁸ Longevity Remaining error	6	-	
⁴⁷ Battery depletion	3	-	
WW Confirmed Malfunctions	23	9	32

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2014

Confirmed Malfunction Details: Pulse Generators

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.

1. **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.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory*. Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
3. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory*. Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **Magnetic reed switch 2010**— *July 21, 2010 Voluntary Physician Advisory*. Upon magnet removal, magnetic reed switch remains closed and device tones do not cease. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON.
5. **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.
6. **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.
7. **Subpectoral implant**— *May 12, 2006 and January 04, 2008 Voluntary Physician Advisory*. Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications, loss of pacing (intermittent or permanent) and/or loss of shock therapy. Repetitive mechanical stress-induced component damage, only when implanted subpectorally with the serial number facing the ribs. Improvement implemented.
8. **Shortened replacement window**— *April 05, 2007 and March 04, 2009 Voluntary Physician Advisory*. Accelerated battery depletion may reduce time between elective replacement (ERI) and end of life (EOL) indicators to less than three months. Device replacement indicators continue to function normally. Degradation of low-voltage capacitor. Improvement implemented.
9. **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.
10. **Premature battery depletion**— *May 12, 2006 Voluntary Physician Advisory*. Premature battery depletion, significantly shortened longevity and duration between elective replacement (ERI) and end of life (EOL) indicators. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
11. **Hermetic sealing component Original Population**— *July 18, 2005 and January 21, 2006 Voluntary Physician*. Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.
12. **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.
13. **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.
14. **Magnetic switch**— *June 23, 2005 Voluntary Physician Advisory*. Inhibition of tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. Magnetic switch stuck in closed position. Improvement implemented.
15. **Overestimation of battery status**— *May 06, 2003 Voluntary Physician Advisory*. Improvement in battery status between follow-up visits and/or overestimation of remaining longevity. Very specific conditions involving the use of an atrial tachycardia response feature. Software upgrade distributed late November 2003 eliminated the possibility of battery status overestimation. Improvement implemented.
16. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate.

Improvement implemented.

17. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.
18. **Longevity Remaining error**— When near ERT, Longevity Remaining Estimate is incorrect when amplitude is reprogrammed to a higher value. Gas gauge display is not affected.
19. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
20. **Parameter errors**— During RF interrogation, parameter errors occur, requiring manual parameter correction. Corruption in telemetry logic. Improvement implemented.
21. **Firmware error**— Device beeping unaffected by magnet application, missing EGMs, loss of telemetry, loss of tachy therapy. Multiple resets due to firmware error. Improvement implemented.
22. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
23. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
24. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
25. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.
26. **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.
27. **Feedthrough wires**— High impedance and/or loss of pacing therapy. Broken wire connecting header to internal circuitry. Improvement implemented.
28. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.
29. **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.
30. **Battery depletion**— Premature battery depletion.
31. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
32. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
33. **Impedance measurements**— High impedance value (generally >3000 ohms) recorded and displayed as weekly average impedance. Low daily impedance recordings cause error in calculating weekly average impedance due to memory storage limitations. Device fully capable of therapy delivery as programmed. Improvement implemented.
34. **Battery depletion**— Premature battery depletion and loss of capture.
35. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
36. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
37. **Telemetry or atrial noise**— Noise during telemetry and/or atrial sensing. Inappropriate contact between telemetry coil and device case. Improvement implemented.
38. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
39. **Battery depletion**— Premature battery depletion.
40. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
41. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
42. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.
43. **Adhesive consistency**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Bubbles or voids in adhesive. Improvement implemented.
44. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
45. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
46. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
47. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
48. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
49. **Internal device connection**— Intermittent or no telemetry. Telemetry coil connection. Improvement implemented.
50. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
51. **Capacitor**— Premature battery depletion, significantly shortened ERI to EOL time. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
52. **Device tones**— Inappropriately sustained device tone. Magnet removal or initialization of programming event during specific timing window. Device fully capable of therapy delivery as programmed. Improvement implemented.

53. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
54. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
55. **Memory location**— Loss of pacing and/or shock therapy, premature battery depletion, inability to perform diagnostic testing, loss of telemetry, and/or incorrect diagnostic information. Incorrect data within a specific memory location.
56. **Mid-life display of replacement indicators**— Extended charge time resulting in early occurrence of ERI or EOL, or shortened ERI to EOL time. Please reference the ERI Charge Time Limit Extended During Mid-Life Product Update for more details. Improvement implemented.
57. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
58. **High-voltage capacitor**— In most cases, temporary long capform charge time; in some cases delayed therapy or loss of tachy therapy. Extended charge time could prompt EOL declaration. High-voltage capacitor issue.
59. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
60. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.
61. **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.
62. **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.
63. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
64. **Charge time limit**— Early appearance of elective replacement indicator (ERI). Incorrect extended charge time limit. Improvement implemented.
65. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
66. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
67. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
68. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
69. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
70. **Logic errors**— Unable to complete diagnostic, cap reform or daily shock lead measurement processes; loss of pacing output, loss of shock therapy. Logic errors when device is performing capacitor reforms or shock impedance measurements.
71. **Reed switch**— While implanted, continuous device tone or beeping occurs. During interrogation, magnet presence dialog box appears. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON. Reed switch stuck in closed position. Improvement implemented.
72. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.
73. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
74. **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.
75. **Misaligned markers**— Stored episode markers do not match recorded EGM. Software error when ventricular episode begins during ATR episode. New software was released in 2006 which prevents misaligned markers. Improvement implemented.
76. **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.
77. **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.
78. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
79. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
80. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
81. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
82. **Battery status**— Battery status readings below BOL at or soon after implant caused by exposure to below room temperatures before implant. Actual battery status and longevity are not affected. Improvement implemented.
83. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
84. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
85. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
86. **Bent flex circuit**— Charge time-out and/or EOL declaration, due to bent flex circuit. Improvement implemented.
87. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
88. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are

inconsistent.

89. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
90. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
91. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
92. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
93. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
94. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
95. **Telemetry**— Inability to interrogate, premature battery depletion.
96. **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.
97. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy.
98. **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.
99. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement implemented.
100. **Solder joint**— Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications. Cracked solder joint due to repetitive mechanical stress-induced component damage when implanted subpectorally with the serial number facing the ribs.

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
AUTOGEN CRT-D G160/G161/G164/G166/G172/G173/G175/ G177/G179	3,000	0	2	0	0	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	3,000	0	0	0	0	0	0
INCEPTA CRT-D 4-Site N160/N162/P162	14,000	0	0	0	1	0	0
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	16,000	2	0	0	0	0	0
ENERGEN CRT-D 4-Site N140/N142/P142	18,000	2	0	0	3	0	0
ENERGEN CRT-D N141/N143/P143	15,000	3	0	0	3	0	0
PUNCTUA CRT-D 4-Site N050/N052/P052	2,000	0	0	0	0	0	0
PUNCTUA CRT-D N051/N053/P053	4,000	1	0	0	1	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	23	50	4	26	0	0
LIVIAN HE H227/H229/H247/H249	7,000	3	1	0	2	0	0
LIVIAN H220/H225/H240/H245	6,000	0	1	0	2	0	0

CRT-D/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL 4 HE H197/H199	7,000	7	7	0	0	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0
CONTAK RENEWAL 3 RF H210/H215	21,000	493	9	1	7	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INVIVE V172/V173/V182/V183/W172/W173	14,000	0	0	0	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN ICD EL VR D160/D161/D174/D175	500	0	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	500	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	1,000	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	1,000	0	0	0	0	0	0

ICD/Model, continued...	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA ICD VR 4-Site E160/F160	14,000	0	0	0	3	0	0
INCEPTA ICD DR 4-Site E162/F162	16,000	0	0	0	0	0	0
INCEPTA ICD VR E161/F161	6,000	0	0	0	1	0	0
INCEPTA ICD DR E163/F163	9,000	0	0	0	0	0	0
ENERGEN ICD VR 4-Site E140/F140	18,000	1	0	0	3	0	0
ENERGEN ICD DR 4-Site E142/F142	18,000	1	0	0	1	0	0
ENERGEN ICD VR E141/F141	10,000	2	0	0	1	0	0
ENERGEN ICD DR E143/F143	12,000	2	1	0	1	0	0
PUNCTUA ICD VR 4-Site E050/F050	3,000	0	0	0	0	0	0
PUNCTUA ICD DR 4-Site E052/F052	2,000	1	0	0	0	0	0
PUNCTUA ICD VR E051/F051	5,000	0	0	0	1	0	0
PUNCTUA ICD DR E053/F053	3,000	1	0	0	0	0	0
TELIGEN VR E102/E103/F102/F103	65,000	7	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	90,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO EL DR J064/K064/K067/K084	7,000	0	0	0	0	0	0
ADVANTIO SR J062/J065/K062/K065/K082	22,000	0	0	0	1	0	0
ADVANTIO DR J063/J066/K063/K066/K083	57,000	4	0	0	2	0	0
INGENIO EL DR J174/J177/K174/K177/K184	22,000	1	0	0	1	0	0
INGENIO SR J172/J175/K172/K175/K182	25,000	0	0	0	1	0	0
INGENIO DR J173/J176/K173/K176/K183	84,000	0	0	0	4	0	0
INGENIO VDD J178/J179/K188	1,000	0	0	0	21	0	0
FORMIO DR J278/J279/K278/K279	1,000	0	0	0	0	0	0
VITALIO DR J273/J276/K273/K276	5,000	0	0	0	1	0	0
VITALIO EL DR J274/J277/K274	4,000	0	0	0	0	0	0
VITALIO SR J272/J275/K272/K275	2,000	0	0	0	0	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	55,000	1	11	0	2	0	0
ALTRUA 50 SR S501	24,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	42,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	10,000	1	1	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0
ALTRUA 50 SSI S508	6,000	0	0	0	1	0	0
ALTRUA 40 SR S401	9,000	0	2	0	0	0	0
ALTRUA 40 DR (Downsize) S403	22,000	0	4	0	2	0	0
ALTRUA 40 DR S402	3,000	1	3	0	0	0	0
ALTRUA 40 DR EL S404	9,000	0	0	0	0	0	0
ALTRUA 20 SR S201/S204	24,000	0	2	0	0	0	0
ALTRUA 20 DR (Downsize) S203	16,000	0	1	0	0	0	0
ALTRUA 20 DR S202/S205	3,000	1	0	0	1	0	0
ALTRUA 20 DR EL S208	10,000	0	0	0	0	0	0
ALTRUA 20 DDD S207	1,000	0	0	0	0	0	0
ALTRUA 20 SSI S206	7,000	0	0	0	0	0	0
INSIGNIA Ultra SR 1190*	48,000	3	3	1	4	0	0
INSIGNIA Ultra DR (Downsize) 1290*	124,000	3	3	1	6	0	0
INSIGNIA Ultra DR 1291*	51,000	1	8	1	4	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INSIGNIA Entra SR 1195/1198*	52,000	1	0	3	5	0	0
INSIGNIA Entra DR (Downsize) 1296*	47,000	1	7	6	3	0	0
INSIGNIA Entra DR 1294/1295*	36,000	0	6	3	9	0	0
INSIGNIA Plus SR 1194*	51,000	1	5	13	5	0	0
INSIGNIA Plus DR (Downsize) 1298*	140,000	3	16	30	7	0	1
INSIGNIA Plus DR 1297*	47,000	0	7	8	6	0	1
INSIGNIA AVT 0482/0882/0982/1192/1292*	51,000	1	1	0	3	0	0

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

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	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INCEPTA CRT-D 4-Site N160/N162/P162	8000	3	1	0	4	82	503
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	11000	6	1	0	2	121	862
ENERGEN CRT-D 4-Site N140/N142/P142	12000	1	1	2	2	130	932
ENERGEN CRT-D N141/N143/P143	12000	5	1	1	8	136	1107
COGNIS N118/N119/N120/P106/P107/P108	75000	551	45	7	524	1483	23310
LIVIAN HE H227/H229/H247/H249	6000	1101	4	2	4	174	2440
LIVIAN H220/H225/H240/H245	5000	842	0	3	8	119	2026
CONTAK RENEWAL 3 RF H210/H215	21000	7500	29	13	176	529	10967

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INVIVE V172/V173/V182/V183/W172/W173	6000	1	0	1	0	33	513
CONTAK RENEWAL TR H120/H125	19000	1687	15	132	44	250	8677
S-ICD/Model		Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
SQ-RX Pulse Generator 1010		0	1	1	11	66	145
ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INCEPTA ICD VR 4-Site E160/F160	8000	3	0	4	2	56	395
INCEPTA ICD DR 4-Site E162/F162	9000	2	0	7	3	73	480
INCEPTA ICD VR E161/F161	3000	1	0	1	1	34	204
INCEPTA ICD DR E163/F163	6000	1	0	1	3	42	313
ENERGEN ICD VR 4-Site E140/F140	13000	9	0	5	2	111	688
ENERGEN ICD DR 4-Site E142/F142	12000	2	0	5	5	120	805
ENERGEN ICD VR E141/F141	6000	2	0	2	2	41	416
ENERGEN ICD DR E143/F143	9000	4	0	3	1	60	631
PUNCTUA ICD VR E051/F051	1000	0	0	0	1	1	48

ICD/Model, continued...	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature 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	56	14	313	396	572	9083
TELIGEN DR E110/E111/F110/F111	66000	107	45	440	554	1009	16714
CONFIENT DR E030/F030	7000	51	2	91	10	140	2487
VITALITY 2 EL VR T177	7000	885	9	147	1234	108	2506
VITALITY 2 EL DR T167	8000	1495	13	141	764	130	3074
VITALITY 2 VR T175	21000	4908	33	378	1239	296	8965
VITALITY 2 DR T165	31000	10939	79	526	1139	453	13144
VITALITY DR HE T180	13000	2144	13	230	416	303	6265
VITALITY DS DR T125	22000	8044	67	361	1183	305	10133
VITALITY DS VR T135	19000	5290	39	319	1553	252	8694
VITALITY EL T127	4000	881	9	60	617	69	1526

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
ADVANTIO SR J062/J065/K062/K065/K082	9000	3	0	8	4	38	789
ADVANTIO DR J063/J066/K063/K066/K083	40000	6	1	9	9	187	1950
ADVANTIO EL DR J064/K064/K067/K084	2000	1	0	1	1	3	37
INGENIO SR J172/J175/K172/K175/K182	10000	1	0	4	0	37	709
INGENIO DR J173/J176/K173/K176/K183	52000	11	1	12	6	203	1998

Pacemaker/Model, continued...	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
ALTRUA 60 SR S601	32000	121	1	158	3	154	10595
ALTRUA 60 DR (Downsize) S603	90000	1437	29	338	22	526	21328
ALTRUA 60 DR S602	22000	162	2	121	3	169	5396
ALTRUA 60 DR EL S606	59000	102	6	181	6	365	9819
ALTRUA 40 SR S401	5000	17	0	14	2	21	1769
ALTRUA 40 DR (downsize) S403	14000	231	1	34	3	75	3557
ALTRUA 40 DR S402	2000	12	1	14	0	6	581
ALTRUA 40 DR EL S404	5000	9	1	20	0	39	1137
ALTRUA 20 SR S201/S204	4000	21	1	15	0	34	1872
ALTRUA 20 DR (downsize) S203	5000	53	2	18	0	35	1610
ALTRUA 20 DR S202/S205	2000	17	0	5	1	12	605
ALTRUA 20 DR EL S208	3000	9	0	12	1	8	803
INSIGNIA Ultra SR 1190 ⁴	24000	1451	9	193	36	140	15184
INSIGNIA Ultra DR (Downsize) 1290 ⁴	76000	14793	110	529	417	587	36585
INSIGNIA Ultra DR 1291 ⁴	32000	1833	19	282	124	296	13635

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INSIGNIA Entra SR 1195/1198 ⁴	14000	551	10	81	9	72	9963
INSIGNIA Entra DR (Downsize) 1296 ⁴	24000	4237	25	128	96	148	14773
INSIGNIA Entra DR 1294/1295 ⁴	17000	1041	10	114	59	178	9931
INSIGNIA Plus SR 1194 ⁴	27000	2809	7	222	27	156	19957
INSIGNIA Plus DR (Downsize) 1298 ⁴	90000	24936	113	529	373	693	50704
INSIGNIA Plus DR 1297 ⁴	27000	3519	20	247	127	253	14032
DISCOVERY II DR 1284/1286 ⁴	23000	5898	9	123	21	168	15032

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.

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

ACUITY X4 Spiral L

Models 4677/4678

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ACUITY X4 Spiral L Models 4677/4678 			
Worldwide Distribution: 1,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

ACUITY X4 Spiral S

Models 4674/4675

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ACUITY X4 Spiral S Models 4674/4675			
Worldwide Distribution: 1,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

ACUITY X4 Straight

Models 4671/4672

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ACUITY X4 Straight Models 4671/4672			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

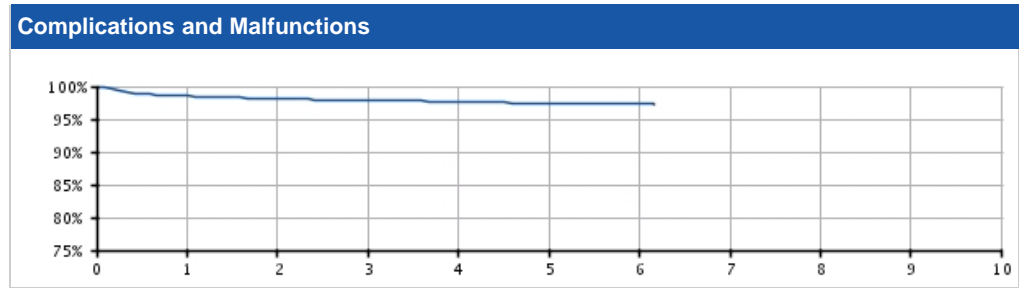
[References](#) cited in table above

ACUITY Spiral

Models 4591/4592/4593

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Chronic Lead Complications: 283
U.S. Approval Date: May 2008	U.S. Malfunctions:90
U.S. Estimated Active Implants: 15,000	Without Compromised Therapy:3
	With Compromised Therapy:87




U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.53 (-0.2/+0.2)	98.16 (-0.2/+0.2)	97.86 (-0.2/+0.2)	97.60 (-0.3/+0.2)	97.43 (-0.3/+0.3)	97.31 (-0.4/+0.3)	97.31 @ 74 mo. (-0.4/+0.3)	--	--	--
Registered Implants: 19000										
Effective Sample Size	15390	11429	8131	4977	2503	555	316	--	--	--

ACUITY Spiral

Models 4591/4592/4593

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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ACUITY Spiral Models 4591/4592/4593				
Worldwide Distribution: 1,000				
Worldwide Confirmed Malfunctions: 100				
	Without Compromised Therapy	With Compromised Therapy	Total	
Conductor	1	3	4	
²⁸ Non-patterned, Conductor	1	3		
Crimp/Weld/Bond	-	-	0	
Extrinsic	-	93	93	
³⁰ Unconfirmed Extrinsic	-	93		
Insulation	-	1	1	
²⁹ Non-patterned, Insulation	-	1		
Other	2	-	2	
²⁷ Non-patterned, Other	2	-		
WW Confirmed Malfunctions	3	97	100	

[More details](#) about malfunctions

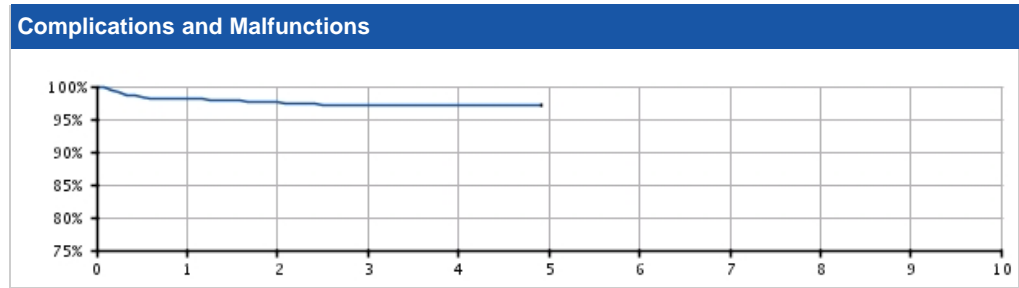
[References](#) cited in table above

ACUITY Spiral Longitude*

Models 4591/4592/4593

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

Longitude Registry Summary Data	
Leads Enrolled: 1329	Chronic Lead Complications: 20
Leads Active: 999	Malfunctions:10
Cumulative Followup Months : 33,398	Without Compromised Therapy:0
	With Compromised Therapy:10



Longitude Registry Survival Probability

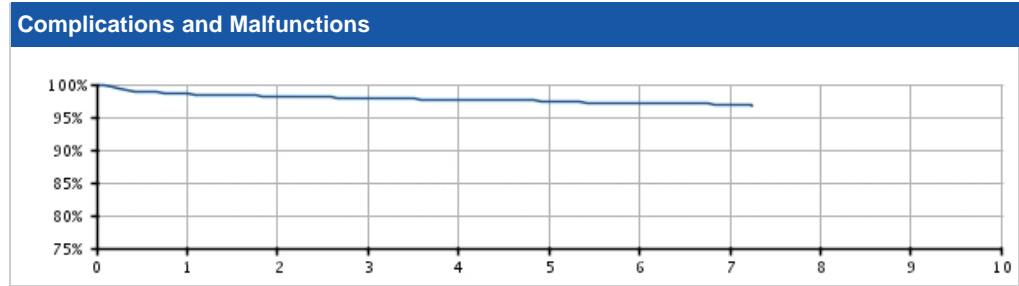
Year	1	2	3	4	5	6	7	8	9	10
Longitude	98.07 (-1.0/+0.7)	97.61 (-1.1/+0.8)	97.19 (-1.2/+0.9)	97.19 (-1.2/+0.9)	97.19 @ 59 mo. (-1.2/+0.9)	--	--	--	--	--
Registered Implants: 1329										
Effective Sample Size	985	766	537	281	52	--	--	--	--	--

ACUITY Steerable

Models 4554/4555/4556

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 27,000	U.S. Chronic Lead Complications: 348
U.S. Approval Date: May 2008	U.S. Malfunctions: 187
U.S. Estimated Active Implants: 18,000	Without Compromised Therapy: 10
	With Compromised Therapy: 177




U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.55 <small>(-0.2/+0.1)</small>	98.19 <small>(-0.2/+0.2)</small>	97.91 <small>(-0.2/+0.2)</small>	97.69 <small>(-0.2/+0.2)</small>	97.39 <small>(-0.3/+0.2)</small>	97.10 <small>(-0.3/+0.3)</small>	96.83 <small>(-0.5/+0.4)</small>	96.83 @ 87 mo. <small>(-0.5/+0.4)</small>	--	--
Registered Implants: 27000										
Effective Sample Size	21211	16892	13139	9612	6424	3335	765	239	--	--

ACUITY Steerable

Models 4554/4555/4556

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ACUITY Steerable Models 4554/4555/4556 			
Worldwide Distribution: 59,000			
Worldwide Confirmed Malfunctions: 244			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	7	35	42
²⁸ Non-patterned, Conductor	4	9	
³⁵ Extracardiac fracture	3	26	
Crimp/Weld/Bond	-	-	0
Extrinsic	2	192	194
³⁰ Unconfirmed Extrinsic	-	191	
³¹ Inconclusive Extrinsic	2	1	
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	6	1	7
²⁷ Non-patterned, Other	6	1	
WW Confirmed Malfunctions	15	229	244

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 3

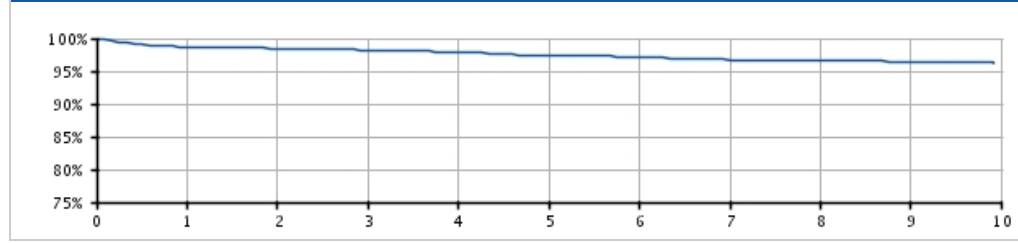
Models 4522/4524/4525/4527/4548/
4549/4550

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary

U.S. Registered Implants: 21,000 U.S. Approval Date: August 2004 U.S. Estimated Active Implants: 11,000	U.S. Chronic Lead Complications: 331 U.S. Malfunctions: 104 Without Compromised Therapy: 7 With Compromised Therapy: 97
--	--

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.68 (-0.2/+0.2)	98.49 (-0.2/+0.2)	98.25 (-0.2/+0.2)	97.90 (-0.2/+0.2)	97.46 (-0.3/+0.3)	97.14 (-0.3/+0.3)	96.74 (-0.4/+0.3)	96.66 (-0.4/+0.3)	96.47 (-0.4/+0.4)	96.28 @ 119 mo. (-0.5/+0.5)
Registered Implants: 21000										
Effective Sample Size	16757	13806	11345	9290	7411	5627	4207	2627	1226	217

EASYTRAK 3

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

EASYTRAK 3 Models 4522/4524/4525/4527/4548/ 4549/4550			
Worldwide Distribution: 40,000 Worldwide Confirmed Malfunctions: 131			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	8	34	42
²⁸ Non-patterned, Conductor	5	5	
³⁵ Extracardiac fracture	3	29	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	84	84
³⁰ Unconfirmed Extrinsic	-	84	
Insulation	3	1	4
²⁹ Non-patterned, Insulation	3	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	12	119	131

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 2

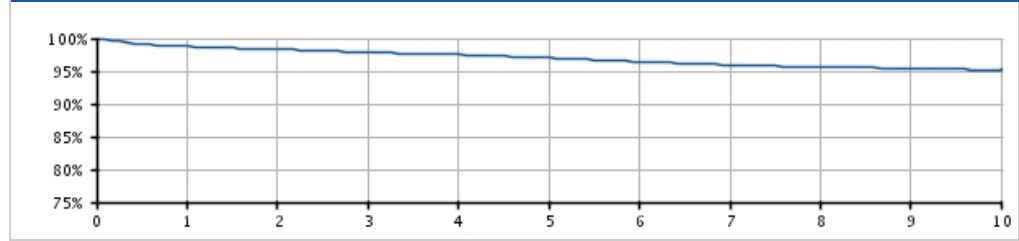
Models 4515/4517/4518/4520/4542/
4543/4544

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary

U.S. Registered Implants: 93,000 U.S. Approval Date: August 2004 U.S. Estimated Active Implants: 47,000	U.S. Chronic Lead Complications: 1,617 U.S. Malfunctions: 643 Without Compromised Therapy: 37 With Compromised Therapy: 606
--	--

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.78 (-0.1/+0.1)	98.31 (-0.1/+0.1)	97.89 (-0.1/+0.1)	97.53 (-0.1/+0.1)	97.03 (-0.1/+0.1)	96.44 (-0.2/+0.2)	95.96 (-0.2/+0.2)	95.63 (-0.2/+0.2)	95.40 (-0.2/+0.2)	95.19 (-0.3/+0.3)
Registered Implants: 93000										
Effective Sample Size	74473	61755	50896	40933	31801	23353	16548	10316	5098	692

EASYTRAK 2

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

EASYTRAK 2
Models 4515/4517/4518/4520/4542/
4543/4544

Worldwide Distribution: 168,000
Worldwide Confirmed Malfunctions: 832

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	35	356	391
²⁶ Conductor fracture	31	310	
²⁸ Non-patterned, Conductor	4	46	
Crimp/Weld/Bond	-	-	0
Extrinsic	5	414	419
³⁰ Unconfirmed Extrinsic	-	404	
³¹ Inconclusive Extrinsic	5	10	
Insulation	9	2	11
²⁹ Non-patterned, Insulation	9	2	
Other	6	5	11
²⁷ Non-patterned, Other	6	5	
WW Confirmed Malfunctions	55	777	832

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK

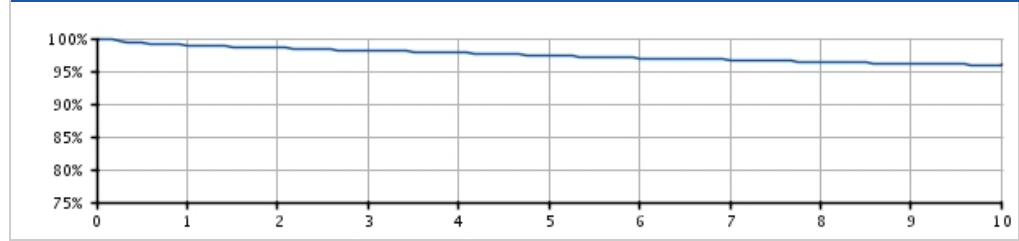
Models 4510/4511/4512/4513/4535/
4536/4537/4538

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary

U.S. Registered Implants: 38,000	U.S. Chronic Lead Complications: 719
U.S. Approval Date: May 2002	U.S. Malfunctions:186
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy:10
	With Compromised Therapy:176

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.75 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.93 (-0.3/+0.3)
Registered Implants: 38000										
Effective Sample Size	30543	26257	22527	19361	16534	14119	11877	9944	8374	7008

EASYTRAK

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

EASYTRAK Models 4510/4511/4512/4513/4535/ 4536/4537/4538			
Worldwide Distribution: 53,000			
Worldwide Confirmed Malfunctions: 203			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	13	13
²⁸ Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	176	176
³⁰ Unconfirmed Extrinsic	-	176	
³¹ Inconclusive Extrinsic	-	-	
Insulation	3	3	6
²⁹ Non-patterned, Insulation	3	3	
Other	7	1	8
²⁷ Non-patterned, Other	7	1	
WW Confirmed Malfunctions	10	193	203

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation
Models 0658/0695/0696



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	5	5
³⁰ Unconfirmed Extrinsic	-	5	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	5	5

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation

Models 0657/0692/0693

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation
Models 0657/0692/0693



Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	1	1
³⁸ Conductor cable fracture	-	1	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	1	1
³⁰ Unconfirmed Extrinsic	-	1	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	2	2

[More details](#) about malfunctions

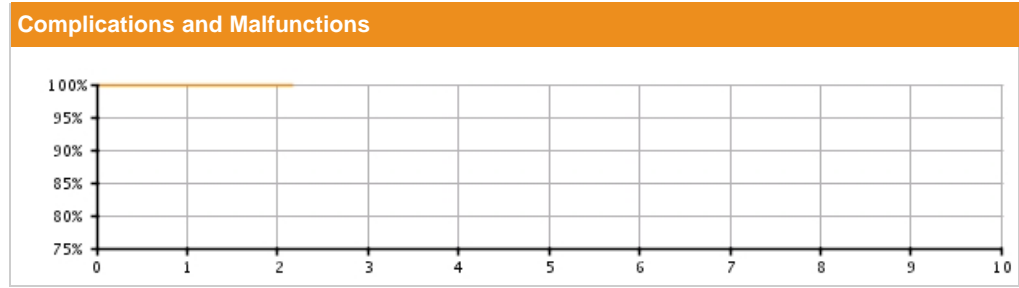
[References](#) cited in table above

Q-TRAK SQ Electrode

Model 3010

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Approval Date: September 2012	U.S. Chronic Lead Complications: 1 U.S. Malfunctions:0 Without Compromised Therapy:0 With Compromised Therapy:0




U.S. Survival Probability											
Year	1	2	3	4	5	6	7	8	9	10	
Non Advisory Population	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 @ 26 mo. (-0.3/+0.0)	--	--	--	--	--	--	--	

This product family may not conform to all AdvaMed/ISO recommended performance reporting data elements.

Q-TRAK SQ Electrode

Model 3010

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

Q-TRAK SQ Electrode Model 3010 			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	1	1
<small>³⁷Weld fracture</small>	-	1	
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Active Fixation**

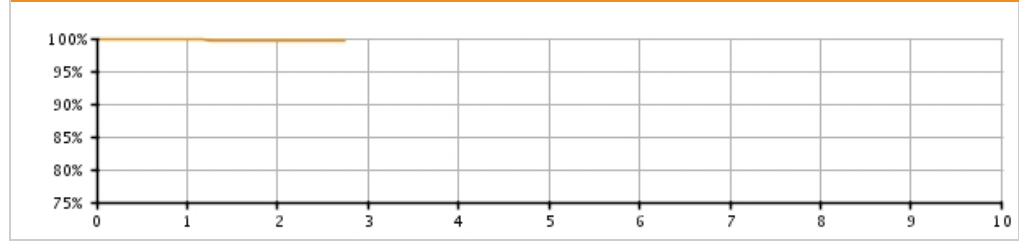
Models 0295/0296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
----------------------------------	--------------------------------------	---------------------------	---------------------------------------

U.S. Summary

U.S. Registered Implants: 35,000	U.S. Chronic Lead Complications: 48
U.S. Approval Date: November 2010	U.S. Malfunctions:25
U.S. Estimated Active Implants: 33,000	Without Compromised Therapy:0
	With Compromised Therapy:25

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.78 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.67 @ 33 mo. (-0.1/+0.1)	--	--	--	--	--	--	--
Registered Implants: 35000										
Effective Sample Size	21713	8047	210	--	--	--	--	--	--	--

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Active Fixation**

Models 0295/0296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation Models 0295/0296 			
Worldwide Distribution: 63,000			
Worldwide Confirmed Malfunctions: 90			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁸ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	66	66
³⁰ Unconfirmed Extrinsic	-	66	
Insulation	7	11	18
²⁹ Non-patterned, Insulation	7	11	
Other	2	1	3
²⁷ Non-patterned, Other	2	1	
WW Confirmed Malfunctions	9	81	90

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Active Fixation Longitude***

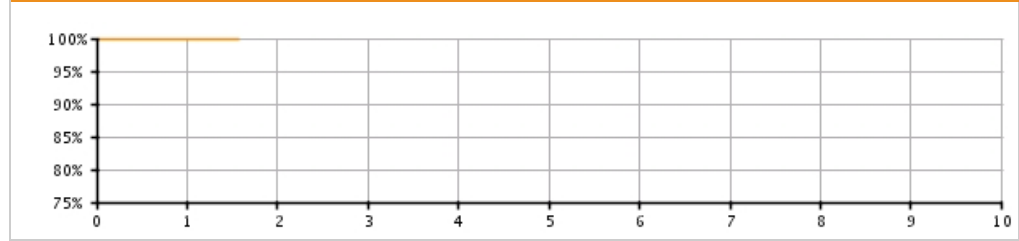
Models 0295/0296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

Longitude Registry Summary Data

Leads Enrolled: 650	Chronic Lead Complications: 0
Leads Active: 614	Malfunctions: 0
Cumulative Followup Months : 5,098	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	100.00 (-0.0/+0.0)	100.00 @ 19 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 650										
Effective Sample Size	138	51	-	-	-	-	-	-	-	-

ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation

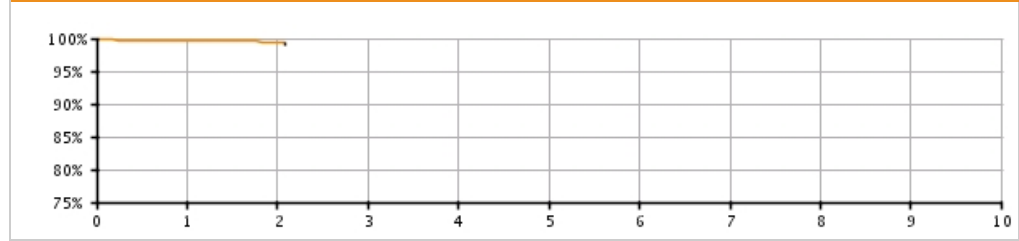
Models 0285/0286

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 4
U.S. Approval Date: November 2010	U.S. Malfunctions: 1
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy: 0
	With Compromised Therapy: 1

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.63 (-0.6/+0.2)	99.30 (-1.3/+0.5)	99.30 @ 25 mo. (-1.3/+0.5)	--	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	673	233	202	--	--	--	--	--	--	--

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Passive Fixation**

Models 0285/0286

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**ENDOTAK RELIANCE G 4-Site
Dual Coil, Passive Fixation
Models 0285/0286**



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	3	3
³⁰ Unconfirmed Extrinsic	-	3	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	3	3

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Active Fixation**

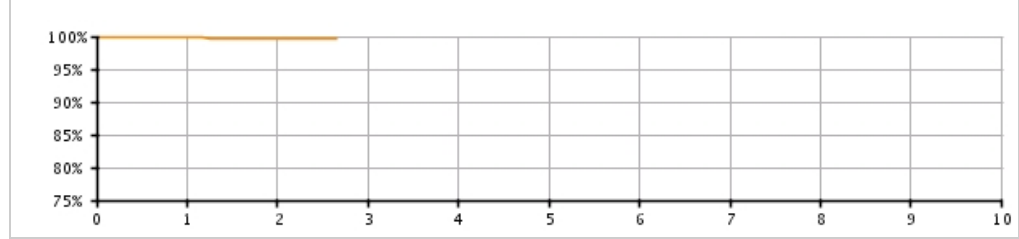
Models 0292/0293

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
----------------------------------	--------------------------------------	---------------------------	---------------------------------------

U.S. Summary

U.S. Registered Implants: 29,000	U.S. Chronic Lead Complications: 35
U.S. Approval Date: November 2010	U.S. Malfunctions:20
U.S. Estimated Active Implants: 27,000	Without Compromised Therapy:1
	With Compromised Therapy:19

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.78 (-0.1/+0.1)	99.71 (-0.1/+0.1)	99.71 @ 32 mo. (-0.1/+0.1)	--	--	--	--	--	--	--
Registered Implants: 28000										
Effective Sample Size	13654	3824	306	--	--	--	--	--	--	--

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Active Fixation**

Models 0292/0293

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Active Fixation
Models 0292/0293**



Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 46

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	1	1
²⁸ Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	36	36
³⁰ Unconfirmed Extrinsic	-	36	
Insulation	2	5	7
²⁹ Non-patterned, Insulation	2	5	
Other	-	2	2
²⁷ Non-patterned, Other	-	2	
WW Confirmed Malfunctions	2	44	46

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Active Fixation Longitude***

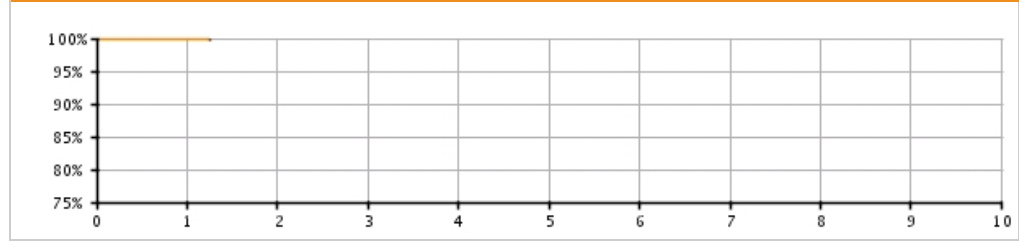
Models 0292/0293

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

Longitude Registry Summary Data

Leads Enrolled: 984	Chronic Lead Complications: 0
Leads Active: 921	Malfunctions: 1
Cumulative Followup Months : 6,445	Without Compromised Therapy: 0
	With Compromised Therapy: 1

Complications and Malfunctions



Longitude Registry Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Longitude	99.87 (-0.8/+0.1)	97.19 @ 15 mo. (-0.8/+0.1)	--	--	--	--	--	--	--	--
Registered Implants: 984										
Effective Sample Size	130	51	--	--	--	--	--	--	--	--

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Passive Fixation**

Models 0282/0283

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

**ENDOTAK RELIANCE SG 4-Site
Single Coil, Passive Fixation
Models 0282/0283**



Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	2	1	3
³⁰ Unconfirmed Extrinsic	-	1	
³¹ Inconclusive Extrinsic	2	-	
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	-	-	0
WW Confirmed Malfunctions	2	2	4

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation**

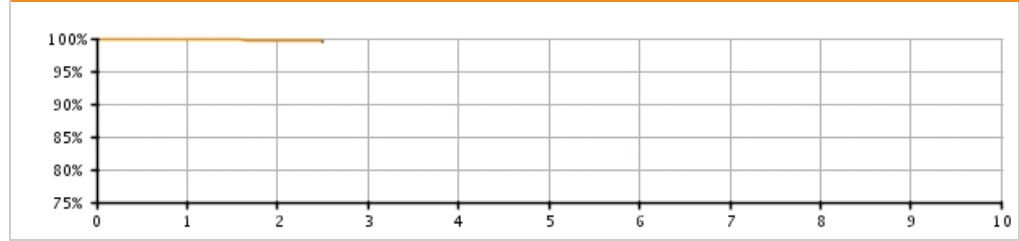
Models 0275/0276

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 5
U.S. Approval Date: November 2010	U.S. Malfunctions: 3
U.S. Estimated Active Implants: 3,000	Without Compromised Therapy: 0
	With Compromised Therapy: 3

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.83 (-0.2/+0.1)	99.59 (-0.5/+0.2)	99.59 @ 30 mo. (-0.5/+0.2)	--	--	--	--	--	--	--
Registered Implants: 3000										
Effective Sample Size	2041	822	234	--	--	--	--	--	--	--

**ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation**

Models 0275/0276

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation Models 0275/0276			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	3	3
³⁰ Unconfirmed Extrinsic	-	3	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	3	3

[More details](#) about malfunctions


[References](#) cited in table above

**ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation**

Models 0265/0266

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

**ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation
Models 0265/0266**



Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE G
Dual Coil, Active Fixation**

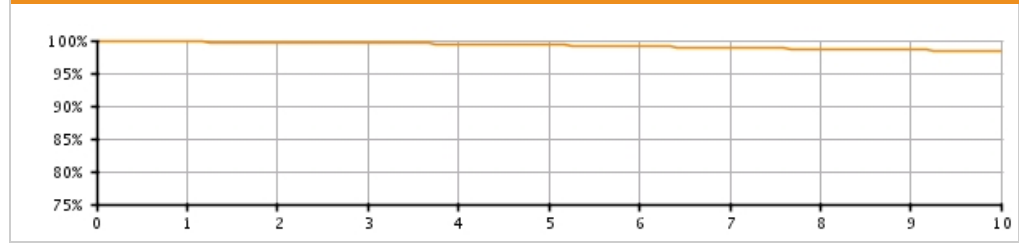
Models 0164/0165/0166/0167/0184/
0185/0186/0187

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
----------------------------------	--------------------------------------	---------------------------	---------------------------------------

U.S. Summary

U.S. Registered Implants: 187,000	U.S. Chronic Lead Complications: 605
U.S. Approval Date: May 2004	U.S. Malfunctions:631
U.S. Estimated Active Implants: 114,000	Without Compromised Therapy:85
	With Compromised Therapy:546

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.30 (-0.0/+0.0)	99.09 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.69 (-0.1/+0.1)	98.55 (-0.1/+0.1)	98.32 (-0.2/+0.2)
Registered Implants: 187000										
Effective Sample Size	163966	144161	122494	96601	73578	51351	33216	20470	10541	2294

**ENDOTAK RELIANCE G
Dual Coil, Active Fixation**

Models 0164/0165/0166/0167/0184/
0185/0186/0187

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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**ENDOTAK RELIANCE G
Dual Coil, Active Fixation
Models 0164/0165/0166/0167/0184/
0185/0186/0187**



**Worldwide Distribution: 253,000
Worldwide Confirmed Malfunctions: 910**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	84	86
²⁵ Conductor fracture	-	54	
²⁸ Non-patterned, Conductor	2	30	
Crimp/Weld/Bond	2	-	2
³² Non-patterned, Crimp, Weld, Bond	2	-	
Extrinsic	11	596	607
³⁰ Unconfirmed Extrinsic	-	594	
³¹ Inconclusive Extrinsic	11	2	
Insulation	113	66	179
²⁹ Non-patterned, Insulation	113	66	
Other	21	15	36
²⁷ Non-patterned, Other	21	15	
WW Confirmed Malfunctions	149	761	910

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE G
Dual Coil, Active Fixation Longitude***

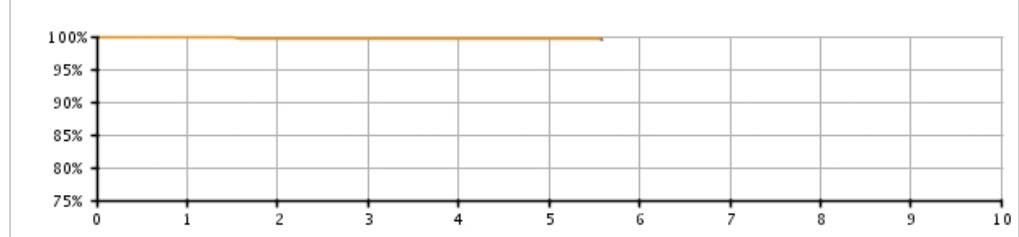
Models 0164/0165/0166/0167/0184/
0185/0186/0187

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
---------------------------	-------------------------------	--------------------	--------------------------------

Longitude Registry Summary Data

Leads Enrolled: 627	Chronic Lead Complications: 1
Leads Active: 461	Malfunctions:1
Cumulative Followup Months : 18,857	Without Compromised Therapy:0
	With Compromised Therapy:1

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	100.00 (-0.0/+0.0)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 @ 67 mo. (-1.2/+0.3)	—	—	—	—
Registered Implants: 627										
Effective Sample Size	542	464	381	244	79	50	—	—	—	—

ENDOTAK RELIANCE G
Dual Coil, Passive Fixation

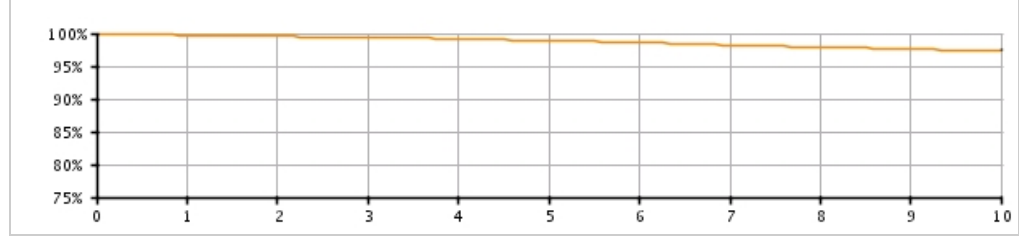
Models 0174/0175/0176/0177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 87
U.S. Approval Date: May 2004	U.S. Malfunctions:56
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy:8
	With Compromised Therapy:48

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.73 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.17 (-0.2/+0.2)	98.89 (-0.2/+0.2)	98.63 (-0.3/+0.2)	98.18 (-0.4/+0.3)	97.88 (-0.5/+0.4)	97.53 (-0.6/+0.5)	97.41 (-0.6/+0.5)
Registered Implants: 14000										
Effective Sample Size	11854	10307	8729	7054	5547	4137	2864	1912	1089	337

ENDOTAK RELIANCE G
Dual Coil, Passive Fixation

Models 0174/0175/0176/0177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE G Dual Coil, Passive Fixation Models 0174/0175/0176/0177 			
Worldwide Distribution: 39,000			
Worldwide Confirmed Malfunctions: 155			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	16	16
²⁵ Conductor fracture	-	13	
²⁸ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	1	1
³⁶ Conductor connection	-	1	
Extrinsic	8	95	103
³⁰ Unconfirmed Extrinsic	-	90	
³¹ Inconclusive Extrinsic	8	5	
Insulation	16	13	29
²⁹ Non-patterned, Insulation	16	13	
Other	6	-	6
²⁷ Non-patterned, Other	6	-	
WW Confirmed Malfunctions	30	125	155

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

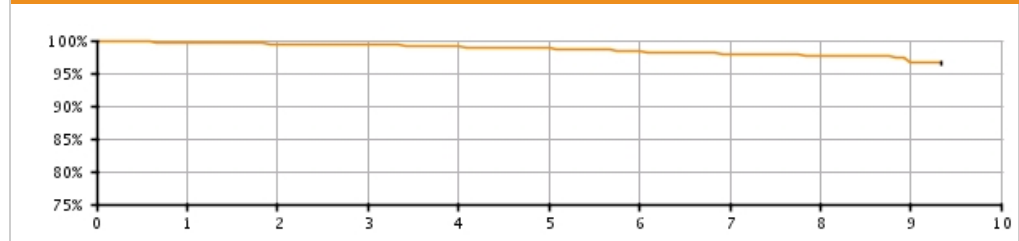
Models 0160/0161/0162/0180/0181/
 0182

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 26,000	U.S. Chronic Lead Complications: 80
U.S. Approval Date: May 2004	U.S. Malfunctions:128
U.S. Estimated Active Implants: 20,000	Without Compromised Therapy:18
	With Compromised Therapy:110

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-0.1/+0.1)	99.47 (-0.1/+0.1)	99.33 (-0.1/+0.1)	99.06 (-0.2/+0.1)	98.77 (-0.2/+0.2)	98.33 (-0.3/+0.3)	97.96 (-0.5/+0.4)	97.72 (-0.6/+0.5)	96.58 (-1.5/+1.1)	96.58 @ 112 mo. (-1.5/+1.1)
Registered Implants: 26000										
Effective Sample Size	21408	17311	12791	7725	4778	2574	1166	631	282	212

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

Models 0160/0161/0162/0180/0181/
 0182

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE SG
Single Coil, Active Fixation
 Models 0160/0161/0162/0180/0181/
 0182



Worldwide Distribution: 56,000
Worldwide Confirmed Malfunctions: 272

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	46	47
²⁵ Conductor fracture	1	40	
²⁸ Non-patterned, Conductor	-	6	
Crimp/Weld/Bond	-	-	0
Extrinsic	1	150	151
³⁰ Unconfirmed Extrinsic	-	150	
³¹ Inconclusive Extrinsic	1	-	
Insulation	43	19	62
²⁹ Non-patterned, Insulation	43	19	
Other	7	5	12
²⁷ Non-patterned, Other	7	5	
WW Confirmed Malfunctions	52	220	272

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

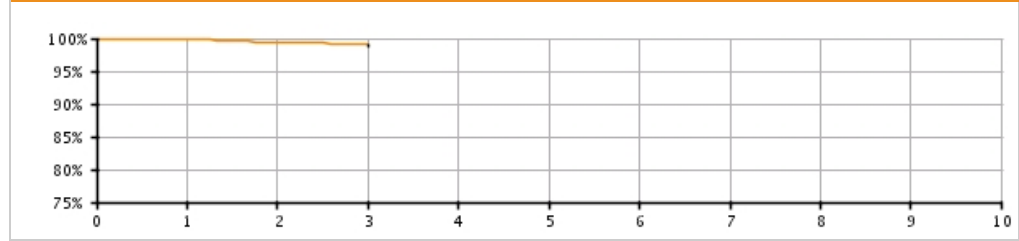
Models 0170/0171/0172/0173

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 1
U.S. Approval Date: May 2004	U.S. Malfunctions:3
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy:1
	With Compromised Therapy:2

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 (-0.8/+0.1)	99.42 (-1.3/+0.4)	99.03 (-1.7/+0.6)	-	-	-	-	-	-	-
Registered Implants: 1000										
Effective Sample Size	559	358	208	-	-	-	-	-	-	-

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation
Models 0170/0171/0172/0173



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 20

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	2	3
²⁵ Conductor fracture	1	2	
Crimp/Weld/Bond	-	-	0
Extrinsic	3	11	14
³⁰ Unconfirmed Extrinsic	-	10	
³¹ Inconclusive Extrinsic	3	1	
Insulation	3	-	3
²⁹ Non-patterned, Insulation	3	-	
Other	-	-	0
WW Confirmed Malfunctions	7	13	20

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

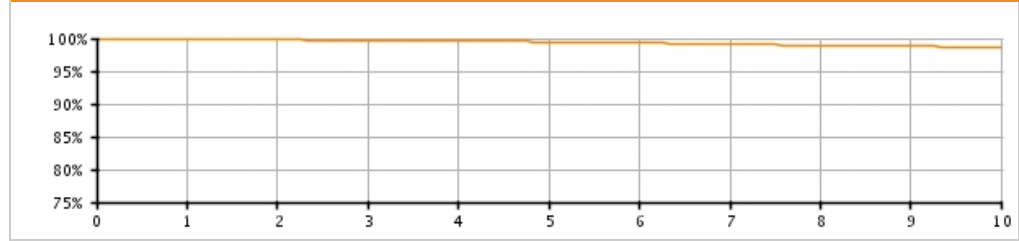
Models 0157/0158/0159

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 97,000	U.S. Chronic Lead Complications: 394
U.S. Approval Date: July 2002	U.S. Malfunctions: 256
U.S. Estimated Active Implants: 41,000	Without Compromised Therapy: 31
	With Compromised Therapy: 225

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.84 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.47 (-0.1/+0.1)	99.32 (-0.1/+0.1)	99.11 (-0.1/+0.1)	98.96 (-0.1/+0.1)	98.80 (-0.1/+0.1)	98.67 (-0.1/+0.1)
Registered Implants: 97000										
Effective Sample Size	84934	75464	66307	57041	48471	40210	33038	26866	21142	15115

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE Dual Coil, Active Fixation Models 0157/0158/0159 			
Worldwide Distribution: 113,000			
Worldwide Confirmed Malfunctions: 290			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	19	19
²⁵ Conductor fracture	-	13	
²⁸ Non-patterned, Conductor	-	6	
Crimp/Weld/Bond	3	1	4
⁵ Seal rings	2	1	
³² Non-patterned, Crimp, Weld, Bond	1	-	
Extrinsic	1	202	203
³⁰ Unconfirmed Extrinsic	-	201	
³¹ Inconclusive Extrinsic	1	1	
Insulation	30	22	52
²⁹ Non-patterned, Insulation	30	22	
Other	8	4	12
²⁷ Non-patterned, Other	8	4	
WW Confirmed Malfunctions	42	248	290

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

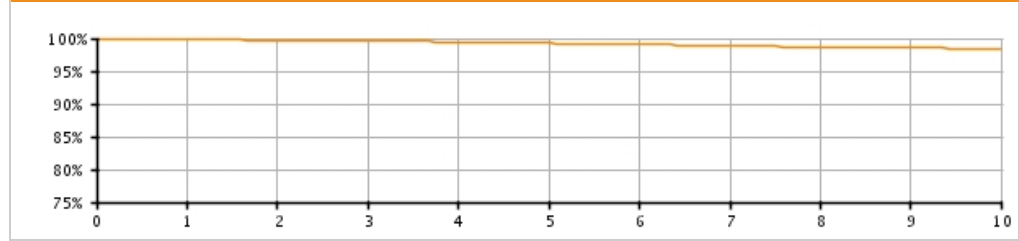
Models 0147/0148/0149

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 33,000	U.S. Chronic Lead Complications: 233
U.S. Approval Date: October 2000	U.S. Malfunctions:95
U.S. Estimated Active Implants: 12,000	Without Compromised Therapy:7
	With Compromised Therapy:88

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.79 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.60 (-0.1/+0.1)	99.44 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.08 (-0.1/+0.1)	98.87 (-0.2/+0.1)	98.66 (-0.2/+0.2)	98.55 (-0.2/+0.2)	98.38 (-0.2/+0.2)
Registered Implants: 33000										
Effective Sample Size	28518	25411	22576	19945	17521	15347	13324	11508	9810	8217

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE Dual Coil, Passive Fixation Models 0147/0148/0149 			
Worldwide Distribution: 67,000			
Worldwide Confirmed Malfunctions: 200			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	11	11
²⁵ Conductor fracture	-	3	
²⁸ Non-patterned, Conductor	-	8	
Crimp/Weld/Bond	-	2	2
³⁶ Conductor connection	-	2	
Extrinsic	8	128	136
³⁰ Unconfirmed Extrinsic	-	126	
³¹ Inconclusive Extrinsic	8	2	
Insulation	22	24	46
²⁹ Non-patterned, Insulation	22	24	
Other	1	4	5
⁶ Manufacturing material	-	1	
²⁷ Non-patterned, Other	1	3	
WW Confirmed Malfunctions	31	169	200

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE S
Single Coil, Active Fixation

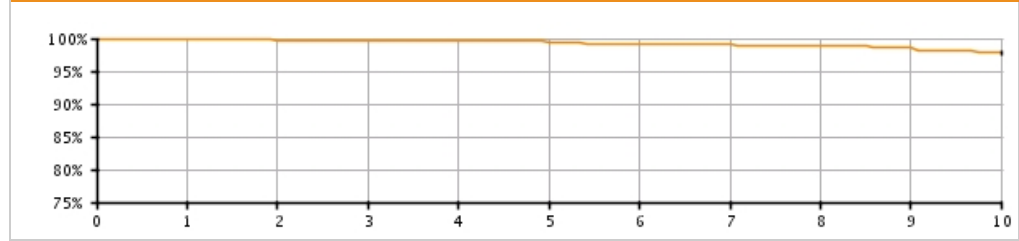
Models 0137/0138

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 2,000	U.S. Chronic Lead Complications: 7
U.S. Approval Date: July 2002	U.S. Malfunctions:9
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy:2
	With Compromised Therapy:7

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.3/+0.1)	99.71 (-0.4/+0.2)	99.64 (-0.4/+0.2)	99.56 (-0.5/+0.2)	99.44 (-0.6/+0.3)	99.17 (-0.8/+0.4)	99.01 (-0.9/+0.5)	98.80 (-1.0/+0.6)	98.52 (-1.3/+0.7)	97.79 (-1.9/+1.0)
Registered Implants: 2000										
Effective Sample Size	2088	1734	1392	1097	845	637	484	380	302	229

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE S Single Coil, Active Fixation Models 0137/0138 			
Worldwide Distribution: 5,000			
Worldwide Confirmed Malfunctions: 18			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁵ Conductor fracture	-	2	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	9	9
³⁰ Unconfirmed Extrinsic	-	9	
Insulation	5	1	6
²⁹ Non-patterned, Insulation	5	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	6	12	18

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE S

Single Coil, Passive Fixation

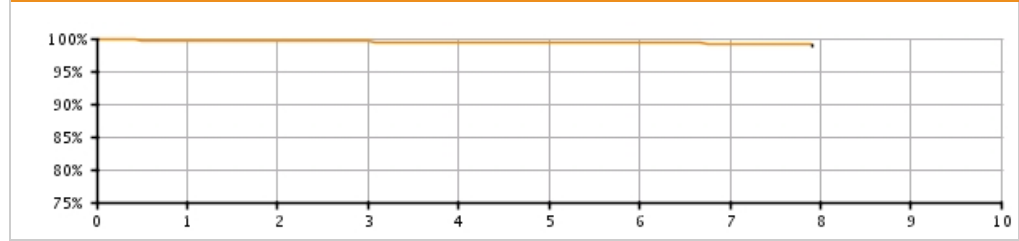
Models 0127/0128

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 4
U.S. Approval Date: October 2000	U.S. Malfunctions:4
U.S. Estimated Active Implants: 200	Without Compromised Therapy:0
	With Compromised Therapy:4

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-1.0/+0.2)	99.67 (-1.0/+0.2)	99.67 (-1.0/+0.2)	99.44 (-1.2/+0.4)	99.44 (-1.2/+0.4)	99.44 (-1.2/+0.4)	99.04 (-1.8/+0.6)	99.04 @ 95 mo. (-1.8/+0.6)	--	--
Registered Implants: 1000										
Effective Sample Size	566	489	430	373	328	277	235	202	--	--

ENDOTAK RELIANCE S Single Coil, Passive Fixation

Models 0127/0128

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

ENDOTAK RELIANCE S Single Coil, Passive Fixation Models 0127/0128 			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 23			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁸ Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	-	-	0
Extrinsic	1	13	14
³⁰ Unconfirmed Extrinsic	-	13	
³¹ Inconclusive Extrinsic	1	-	
Insulation	3	3	6
²⁹ Non-patterned, Insulation	3	3	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	5	18	23

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK DSP
Passive Fixation**

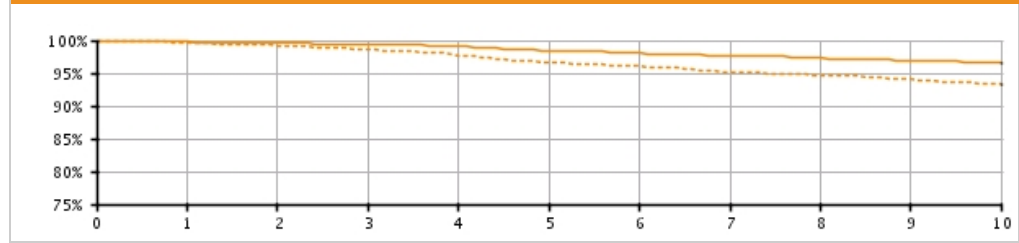
Models 0094/0095/0125

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 36,000	U.S. Chronic Lead Complications: 1,327
U.S. Approval Date: November 1995	U.S. Malfunctions: 172
U.S. Estimated Active Implants: 7,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.10 (-0.2/+0.2)	98.47 (-0.3/+0.2)	98.05 (-0.3/+0.3)	97.70 (-0.3/+0.3)	97.33 (-0.4/+0.3)	96.95 (-0.4/+0.4)	96.60 (-0.4/+0.4)
Registered Implants: 16000										
Effective Sample Size	13504	12009	10700	9498	8336	7384	6519	5765	5074	4439
19-Jul-99 "Long" IS-1 Terminal Pin*	99.66 (-0.1/+0.1)	99.22 (-0.1/+0.1)	98.60 (-0.2/+0.2)	97.74 (-0.2/+0.2)	96.62 (-0.3/+0.3)	96.01 (-0.3/+0.3)	95.19 (-0.4/+0.4)	94.70 (-0.4/+0.4)	94.05 (-0.5/+0.4)	93.36 (-0.5/+0.5)
Registered Implants: 21000										
Effective Sample Size	18130	16101	14289	12617	11013	9641	8418	7361	6435	5637

*Devices subject to an advisory. Refer to the Advisories for more details.

ENDOTAK ENDURANCE
Passive Fixation

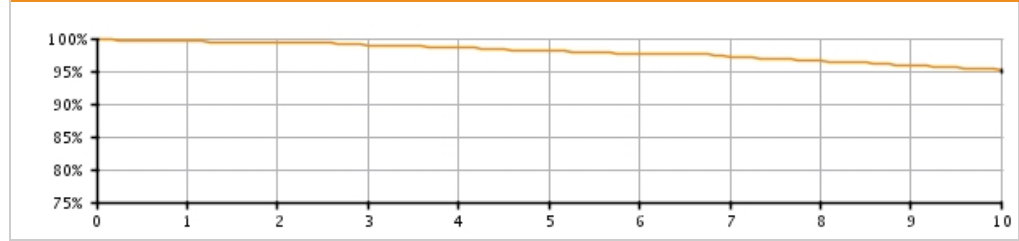
Models 0134/0135/0136

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 107
U.S. Approval Date: August 1998	U.S. Malfunctions: 3
U.S. Estimated Active Implants: 1,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.53 (-0.4/+0.2)	99.35 (-0.4/+0.3)	98.98 (-0.5/+0.3)	98.57 (-0.6/+0.4)	98.12 (-0.7/+0.5)	97.68 (-0.8/+0.6)	97.17 (-0.9/+0.7)	96.60 (-1.1/+0.8)	95.95 (-1.2/+0.9)	95.08 (-1.4/+1.1)
Registered Implants: 3000										
Effective Sample Size	2332	2067	1829	1608	1426	1251	1103	961	831	728

ENDOTAK ENDURANCE EZ
Active Fixation

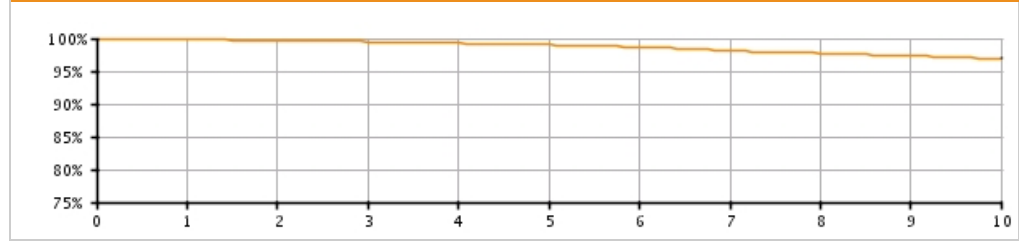
Models 0154/0155/0156

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 29,000	U.S. Chronic Lead Complications: 540
U.S. Approval Date: June 1999	U.S. Malfunctions: 22
U.S. Estimated Active Implants: 8,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.73 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.96 (-0.3/+0.3)
Registered Implants: 29000										
Effective Sample Size	24454	21795	19402	17267	15334	13604	12057	10719	9499	8411

ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting

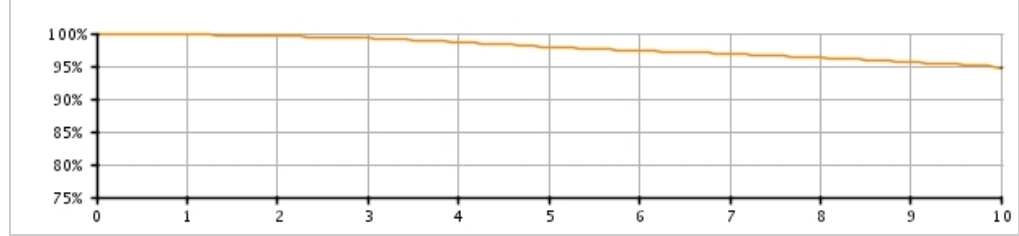
Models 0144/0145/0146

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

<p>U.S. Registered Implants: 18,000 U.S. Approval Date: January 1999 U.S. Estimated Active Implants: 4,000</p>	<p>U.S. Chronic Lead Complications: 653 U.S. Malfunctions: 23</p>
--	--

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 <small>(-0.1/+0.1)</small>	99.61 <small>(-0.1/+0.1)</small>	99.26 <small>(-0.2/+0.1)</small>	98.65 <small>(-0.2/+0.2)</small>	97.92 <small>(-0.3/+0.2)</small>	97.39 <small>(-0.3/+0.3)</small>	96.85 <small>(-0.3/+0.3)</small>	96.26 <small>(-0.4/+0.4)</small>	95.65 <small>(-0.4/+0.4)</small>	94.69 <small>(-0.5/+0.5)</small>
Registered Implants: 18000										
Effective Sample Size	15630	13939	12419	10990	9682	8567	7601	6726	5922	5206

ENDOTAK PLUS
Passive Fixation

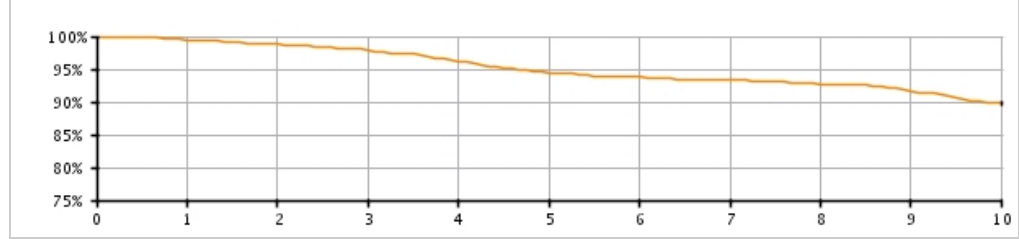
Models 0073/0075/0113/0115

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

<p>U.S. Registered Implants: 4,000 U.S. Approval Date: May 1995 U.S. Estimated Active Implants: 1,000</p>	<p>U.S. Chronic Lead Complications: 263 U.S. Malfunctions: 50</p>
---	--

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.48 <small>(-0.3/+0.2)</small>	98.76 <small>(-0.4/+0.3)</small>	97.98 <small>(-0.5/+0.4)</small>	96.19 <small>(-0.7/+0.6)</small>	94.47 <small>(-0.9/+0.8)</small>	93.79 <small>(-1.0/+0.8)</small>	93.38 <small>(-1.0/+0.9)</small>	92.68 <small>(-1.1/+1.0)</small>	91.66 <small>(-1.2/+1.1)</small>	89.86 <small>(-1.5/+1.3)</small>
Registered Implants: 4000										
Effective Sample Size	3848	3397	2986	2591	2209	1908	1628	1363	1125	913

**ENDOTAK SQ
Array and SQ Array XP**

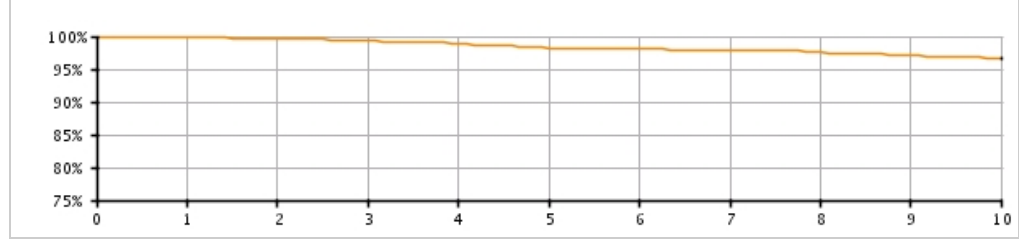
Models 0048/0049/0085

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 66
U.S. Approval Date: April 1995	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.2/+0.1)	99.51 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.85 (-0.5/+0.3)	98.16 (-0.6/+0.5)	98.09 (-0.7/+0.5)	97.86 (-0.7/+0.5)	97.55 (-0.8/+0.6)	97.06 (-1.0/+0.7)	96.61 (-1.2/+0.9)
Registered Implants: 4000										
Effective Sample Size	3125	2745	2411	2059	1727	1409	1132	900	719	551

**ENDOTAK SQ
Patch**

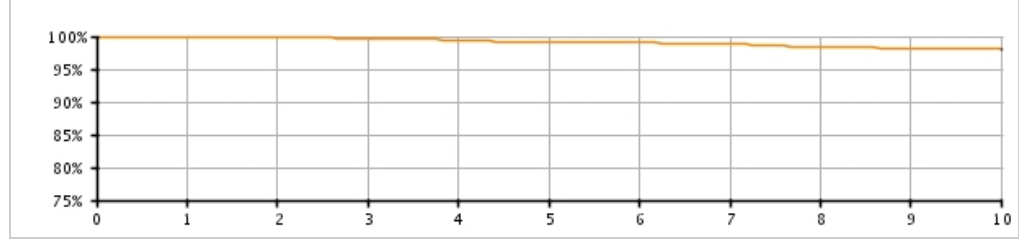
Models 0047/0063

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 36
U.S. Approval Date: August 1993	U.S. Malfunctions: 2
U.S. Estimated Active Implants: 200	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.86 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.65 (-0.3/+0.2)	99.38 (-0.4/+0.3)	99.19 (-0.5/+0.3)	99.04 (-0.6/+0.4)	98.77 (-0.7/+0.4)	98.32 (-0.8/+0.6)	98.19 (-0.9/+0.6)	98.01 (-1.0/+0.7)
Registered Implants: 3000										
Effective Sample Size	2752	2390	2063	1711	1427	1212	1019	832	679	528

INGEVITY Positive Fixation

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGEVITY Positive Fixation Models 7640/7641/7642/7740/7741/ 7742			
Worldwide Distribution: 15,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	1	1
³⁹ Inner conductor fracture	-	1	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

[References](#) cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGEVITY Passive Fixation Models 7631/7632/7731/7732			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

[References](#) cited in table above

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

INGEVITY Atrial J Passive Fixation Models 7635/7636/7735/7736			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0


[More details](#) about malfunctions

[References](#) cited in table above

FLEXTEND 2 Active Fixation

Models 4095/4096/4097

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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FLEXTEND 2 Active Fixation Models 4095/4096/4097 			
Worldwide Distribution: 160,000			
Worldwide Confirmed Malfunctions: 203			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	3	32	35
⁷ Lead conductor	2	18	
³³ Conductor damage	1	14	
Crimp/Weld/Bond	-	-	0
Extrinsic	1	105	106
³⁰ Unconfirmed Extrinsic	-	105	
³¹ Inconclusive Extrinsic	1	-	
Insulation	46	6	52
² Inner insulation abrasion	3	-	
²⁹ Non-patterned, Insulation	4	-	
³⁴ Insulation damage	39	6	
Other	10	-	10
²⁷ Non-patterned, Other	10	-	
WW Confirmed Malfunctions	60	143	203

[More details](#) about malfunctions

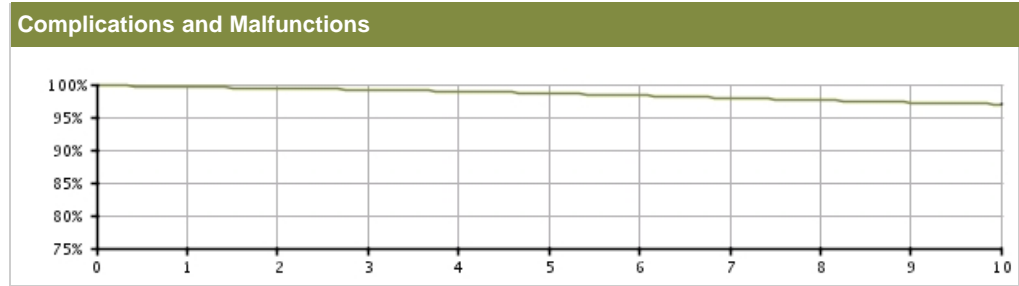
[References](#) cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 227,000	U.S. Chronic Lead Complications: 2,461
U.S. Approval Date: February 2002	U.S. Malfunctions: 808
U.S. Estimated Active Implants: 106,000	Without Compromised Therapy: 119
	With Compromised Therapy: 689




U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.19 (-0.0/+0.0)	98.92 (-0.1/+0.0)	98.64 (-0.1/+0.1)	98.29 (-0.1/+0.1)	97.93 (-0.1/+0.1)	97.58 (-0.1/+0.1)	97.25 (-0.1/+0.1)	96.98 (-0.1/+0.1)
Registered Implants: 227000										
Effective Sample Size	191059	165186	142084	120800	101138	83576	68328	50342	34632	20684

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

FLEXTEND Active Fixation Models 4086/4087/4088 			
Worldwide Distribution: 277,000			
Worldwide Confirmed Malfunctions: 894			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	11	168	179
⁷ Lead conductor	6	78	
²⁸ Non-patterned, Conductor	-	7	
³³ Conductor damage	5	83	
Crimp/Weld/Bond	-	-	0
Extrinsic	2	575	577
³⁰ Unconfirmed Extrinsic	-	572	
³¹ Inconclusive Extrinsic	2	3	
Insulation	100	22	122
² Inner insulation abrasion	19	4	
²⁹ Non-patterned, Insulation	8	-	
³⁴ Insulation damage	73	18	
Other	14	2	16
²⁷ Non-patterned, Other	14	2	
WW Confirmed Malfunctions	127	767	894

[More details](#) about malfunctions

[References](#) cited in table above

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

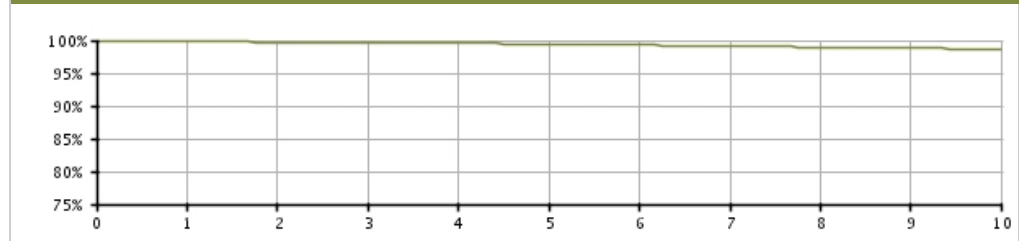
Models 4463/4464/4465/4469/4470/
4471

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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U.S. Summary

U.S. Registered Implants: 411,000	U.S. Chronic Lead Complications: 1,764
U.S. Approval Date: January 2000	U.S. Malfunctions:444
U.S. Estimated Active Implants: 244,000	Without Compromised Therapy:20
	With Compromised Therapy:424

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.0/+0.0)	99.73 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.44 (-0.0/+0.0)	99.29 (-0.0/+0.0)	99.12 (-0.0/+0.0)	98.98 (-0.1/+0.1)	98.82 (-0.1/+0.1)	98.67 (-0.1/+0.1)
Registered Implants: 410000										
Effective Sample Size	342586	285552	235494	190666	150562	115399	87766	64392	44985	29039


Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

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

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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**FINELINE II EZ/FINELINE II Sterox EZ
Positive Fixation (Polyurethane)
Models 4463/4464/4465/4469/4470/
4471**



Worldwide Distribution: 617,000
Worldwide Confirmed Malfunctions: 498

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	9	111	120
⁷ Lead conductor	5	53	
²⁸ Non-patterned, Conductor	-	5	
³³ Conductor damage	4	53	
Crimp/Weld/Bond	-	2	2
²⁴ Terminal weld	-	1	
³² Non-patterned, Crimp, Weld, Bond	-	1	
Extrinsic	-	352	352
³⁰ Unconfirmed Extrinsic	-	346	
³¹ Inconclusive Extrinsic	-	6	
Insulation	9	6	15
³⁴ Insulation damage	9	6	
Other	7	2	9
²⁷ Non-patterned, Other	7	2	
WW Confirmed Malfunctions	25	473	498

[More details](#) about malfunctions

[References](#) cited in table above

**FINELINE II EZ
Positive Fixation (poly) Longitude***

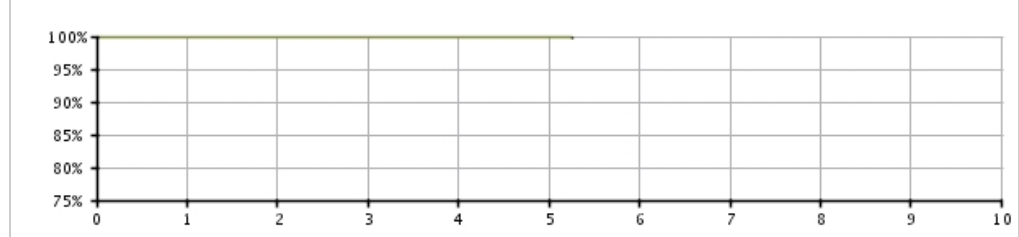
Models 4463/4464/4465/4469/4470/
4471

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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Longitude Registry Summary Data

Leads Enrolled: 844	Chronic Lead Complications: 0
Leads Active: 708	Malfunctions:1
Cumulative Followup Months : 15,012	Without Compromised Therapy:0
	With Compromised Therapy:1

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	99.86 (-0.9/+0.1)	99.86 (-0.9/+0.1)	99.86 (-0.9/+0.1)	99.86 (-0.9/+0.1)	99.86 (-0.9/+0.1)	99.86 @ 63 mo. (-0.9/+0.1)	—	—	—	—
Registered Implants: 844										
Effective Sample Size	432	339	253	164	64	50	—	—	—	—

**FINELINE II/FINELINE II Sterox
Passive Fixation (Polyurethane)**

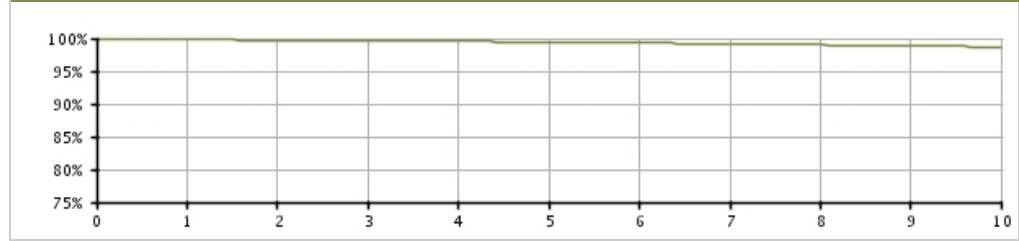
Models 4452/4453/4456/4457

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 175,000	U.S. Chronic Lead Complications: 870
U.S. Approval Date: January 2000	U.S. Malfunctions: 115
U.S. Estimated Active Implants: 89,000	Without Compromised Therapy: 5
	With Compromised Therapy: 110

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.80 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.63 (-0.0/+0.0)	99.54 (-0.0/+0.0)	99.44 (-0.0/+0.0)	99.33 (-0.1/+0.0)	99.15 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.82 (-0.1/+0.1)	98.71 (-0.1/+0.1)
Registered Implants: 175000										
Effective Sample Size	144554	121734	101713	83958	68048	53794	42243	32638	24461	17401

Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

**FINELINE II/FINELINE II Sterox
Passive Fixation (Polyurethane)**

Models 4452/4453/4456/4457

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) Models 4452/4453/4456/4457 			
Worldwide Distribution: 473,000			
Worldwide Confirmed Malfunctions: 153			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	42	43
⁷ Lead conductor	-	14	
²⁸ Non-patterned, Conductor	-	2	
³³ Conductor damage	1	26	
Crimp/Weld/Bond	-	-	0
Extrinsic	1	95	96
³⁰ Unconfirmed Extrinsic	-	93	
³¹ Inconclusive Extrinsic	1	2	
Insulation	2	7	9
³⁴ Insulation damage	2	7	
Other	4	-	4
²⁷ Non-patterned, Other	4	-	
WW Confirmed Malfunctions	8	145	153

[More details](#) about malfunctions

[References](#) cited in table above

**FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)**

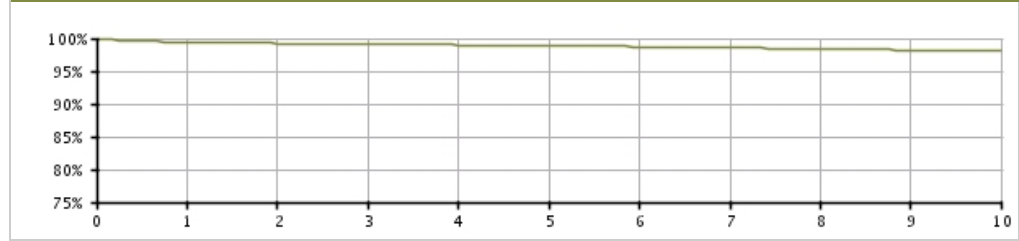
Models 4477/4478/4479/4480

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 57,000	U.S. Chronic Lead Complications: 513
U.S. Approval Date: January 2000	U.S. Malfunctions: 89
U.S. Estimated Active Implants: 31,000	Without Compromised Therapy: 18
	With Compromised Therapy: 71

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.41 (-0.1/+0.1)	99.25 (-0.1/+0.1)	99.12 (-0.1/+0.1)	98.99 (-0.1/+0.1)	98.88 (-0.1/+0.1)	98.71 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.39 (-0.2/+0.1)	98.17 (-0.2/+0.2)	98.09 (-0.2/+0.2)
Registered Implants: 57000										
Effective Sample Size	46919	39443	32917	27156	22009	17376	13585	10435	7763	5387

Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

**FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)**

Models 4477/4478/4479/4480

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) Models 4477/4478/4479/4480			
Worldwide Distribution: 260,000			
Worldwide Confirmed Malfunctions: 148			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	10	12
⁷ Lead conductor	-	3	
³³ Conductor damage	2	7	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	99	99
³⁰ Unconfirmed Extrinsic	-	98	
³¹ Inconclusive Extrinsic	-	1	
Insulation	-	1	1
³⁴ Insulation damage	-	1	
Other	32	4	36
²³ J-shape	30	4	
²⁷ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	34	114	148

[More details](#) about malfunctions

[References](#) cited in table above

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

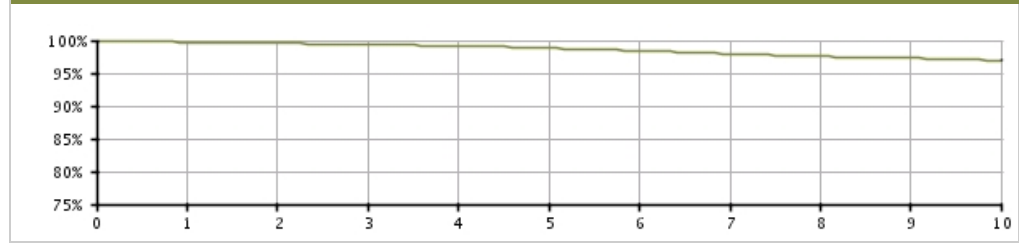
Models 4466/4467/4468/4472/4473/
4474

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 49,000	U.S. Chronic Lead Complications: 468
U.S. Approval Date: January 2000	U.S. Malfunctions:175
U.S. Estimated Active Implants: 25,000	Without Compromised Therapy:16
	With Compromised Therapy:159

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.73 (-0.1/+0.0)	99.56 (-0.1/+0.1)	99.38 (-0.1/+0.1)	99.16 (-0.1/+0.1)	98.84 (-0.1/+0.1)	98.40 (-0.2/+0.1)	97.96 (-0.2/+0.2)	97.54 (-0.2/+0.2)	97.31 (-0.2/+0.2)	97.00 (-0.3/+0.3)
Registered Implants: 49000										
Effective Sample Size	41973	35893	30477	25503	20965	16999	13643	10655	7887	5494


Data are representative of Boston Scientific FINELINE II (silicone) and Intermedics Thinline II (silicone) lead performance.

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

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**FINELINE II EZ/FINELINE II Sterox EZ
Positive Fixation (Silicone)**
Models 4466/4467/4468/4472/4473/
4474



Worldwide Distribution: 132,000
Worldwide Confirmed Malfunctions: 223

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	3	121	124
⁷ Lead conductor	1	75	
²⁸ Non-patterned, Conductor	-	2	
³³ Conductor damage	2	44	
Crimp/Weld/Bond	1	-	1
³² Non-patterned, Crimp, Weld, Bond	1	-	
Extrinsic	-	72	72
³⁰ Unconfirmed Extrinsic	-	70	
³¹ Inconclusive Extrinsic	-	2	
Insulation	8	8	16
²⁹ Non-patterned, Insulation	2	-	
³⁴ Insulation damage	6	8	
Other	5	2	7
²⁷ Non-patterned, Other	5	2	
WW Confirmed Malfunctions	17	206	223

[More details](#) about malfunctions

[References](#) cited in table above

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

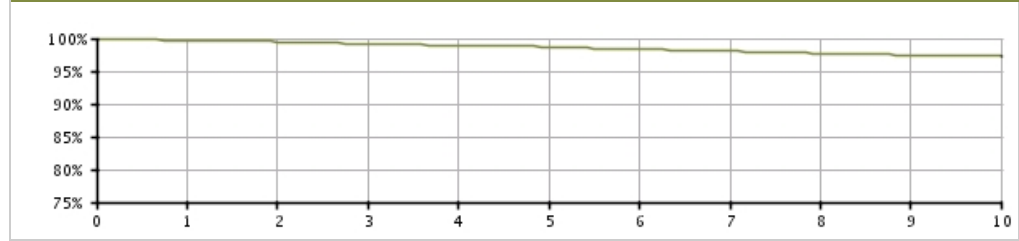
Models 4454/4455/4458/4459

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 167
U.S. Approval Date: January 2000	U.S. Malfunctions: 31
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy: 0
	With Compromised Therapy: 31

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.18 (-0.2/+0.2)	98.89 (-0.2/+0.2)	98.72 (-0.2/+0.2)	98.39 (-0.3/+0.2)	98.02 (-0.3/+0.3)	97.69 (-0.4/+0.3)	97.44 (-0.4/+0.4)	97.30 (-0.5/+0.4)
Registered Implants: 14000										
Effective Sample Size	11885	10330	8848	7489	6270	5209	4330	3585	2866	2148


Data are representative of Boston Scientific FINELINE II (silicone) and Intermedics Thinline II (silicone) lead performance.

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

Models 4454/4455/4458/4459

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**FINELINE II/FINELINE II Sterox
Passive Fixation (Silicone)
Models 4454/4455/4458/4459**



Worldwide Distribution: 99,000
Worldwide Confirmed Malfunctions: 68

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	38	38
⁷ Lead conductor	-	15	
³³ Conductor damage	-	23	
Crimp/Weld/Bond	-	-	0
Extrinsic	-	21	21
³⁰ Unconfirmed Extrinsic	-	21	
³¹ Inconclusive Extrinsic	-	-	
Insulation	2	4	6
³⁴ Insulation damage	2	4	
Other	-	3	3
²⁷ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	66	68

[More details](#) about malfunctions

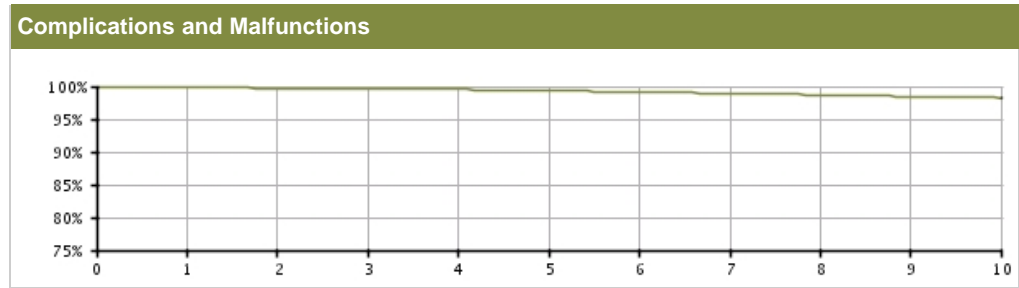
[References](#) cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Chronic Lead Complications: 274
U.S. Approval Date: July 1999	U.S. Malfunctions: 10
U.S. Estimated Active Implants: 6,000	



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.15 (-0.2/+0.1)	98.95 (-0.2/+0.2)	98.71 (-0.2/+0.2)	98.47 (-0.2/+0.2)	98.24 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20911	18708	16690	14867	13217	11631	10250	9041	7934	7002

FINELINE Passive Fixation

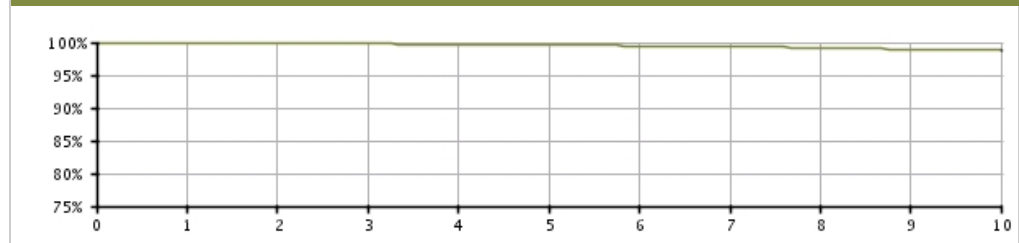
Models 4450/4451

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 42,000	U.S. Chronic Lead Complications: 317
U.S. Approval Date: November 1996	U.S. Malfunctions: 10
U.S. Estimated Active Implants: 8,000	

Complications and Malfunctions



U.S. Survival Probability

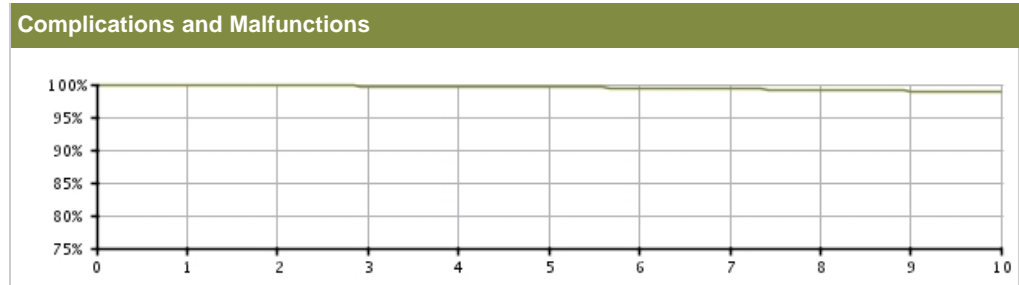
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.91 (-0.0/+0.0)	99.84 (-0.0/+0.0)	99.79 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.98 (-0.1/+0.1)	98.79 (-0.2/+0.1)
Registered Implants: 42000										
Effective Sample Size	35812	32054	28642	25425	22480	19785	17349	15314	13496	11904

FINELINE Atrial J

Models 4475/4476

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 101
U.S. Approval Date: November 1996	U.S. Malfunctions: 6
U.S. Estimated Active Implants: 3,000	



U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 <small>(-0.1/+0.0)</small>	99.83 <small>(-0.1/+0.1)</small>	99.75 <small>(-0.1/+0.1)</small>	99.68 <small>(-0.1/+0.1)</small>	99.61 <small>(-0.1/+0.1)</small>	99.45 <small>(-0.2/+0.1)</small>	99.31 <small>(-0.2/+0.2)</small>	99.16 <small>(-0.2/+0.2)</small>	98.98 <small>(-0.3/+0.2)</small>	98.89 <small>(-0.3/+0.2)</small>
Registered Implants: 14000										
Effective Sample Size	12442	11149	9968	8891	7907	6972	6148	5431	4758	4162

SELUTE
Passive Fixation

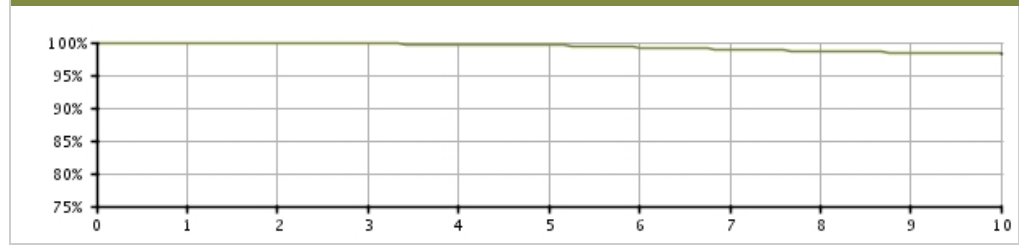
Models 4185/4285

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 48,000	U.S. Chronic Lead Complications: 458
U.S. Approval Date: May 1996	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 8,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.68 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.25 (-0.1/+0.1)	98.94 (-0.1/+0.1)	98.66 (-0.2/+0.1)	98.43 (-0.2/+0.2)	98.30 (-0.2/+0.2)
Registered Implants: 48000										
Effective Sample Size	40978	36614	32655	28946	25599	22380	19583	17096	14881	12898

SELUTE PICOTIP
Passive Fixation

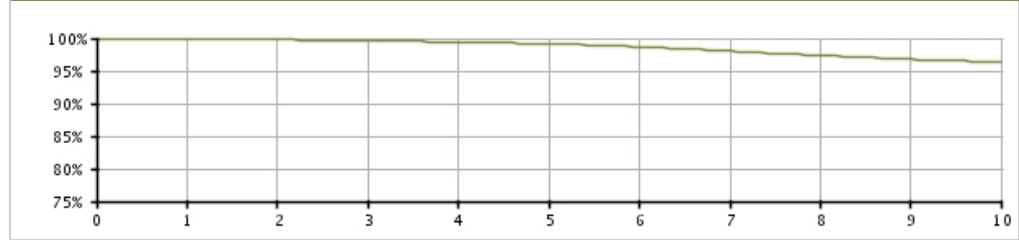
Models 4030/4031/4032/4033/4034/
 4035

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 58,000	U.S. Chronic Lead Complications: 1,061
U.S. Approval Date: April 1998	U.S. Malfunctions: 34
U.S. Estimated Active Implants: 14,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.86 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.04 (-0.2/+0.1)	97.36 (-0.2/+0.2)	96.77 (-0.2/+0.2)	96.36 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49285	43972	39184	34816	30808	26990	23346	20113	17064	14424

SELUTE PICOTIP Atrial J

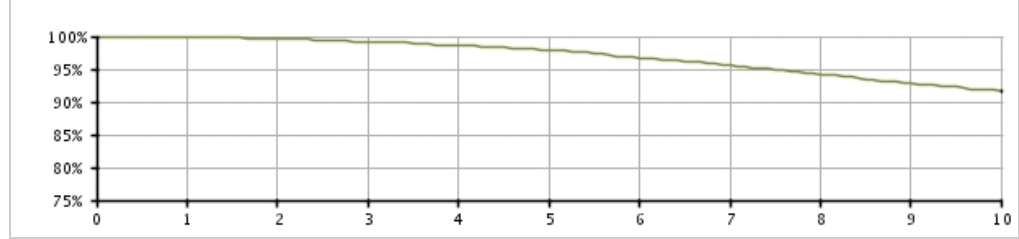
Models 4040/4041/4042/4043/4044/
4045/4063/4064

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 10,000	U.S. Chronic Lead Complications: 406
U.S. Approval Date: May 2000	U.S. Malfunctions: 21
U.S. Estimated Active Implants: 3,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 (-0.1/+0.1)	99.65 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.61 (-0.3/+0.2)	97.90 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.56 (-0.6/+0.5)	94.19 (-0.7/+0.6)	92.83 (-0.8/+0.7)	91.67 (-0.9/+0.8)
Registered Implants: 10000										
Effective Sample Size	8579	7645	6794	6024	5319	4650	3953	3337	2765	2222

SWEET PICOTIP Rx
Positive Fixation

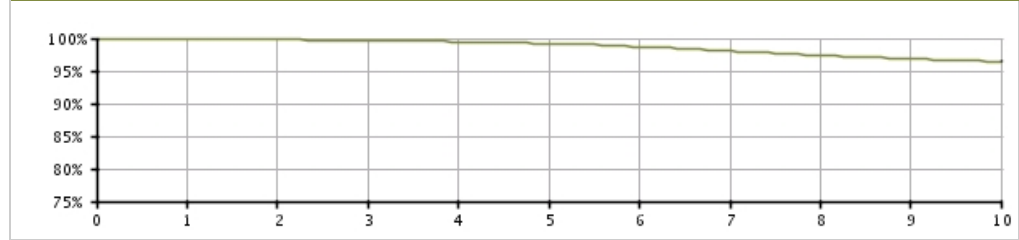
Models 4050/4051/4052/4053/4054/
 4055

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 41,000	U.S. Chronic Lead Complications: 660
U.S. Approval Date: April 1999	U.S. Malfunctions: 54
U.S. Estimated Active Implants: 13,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.91 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.69 (-0.2/+0.1)	98.04 (-0.2/+0.2)	97.38 (-0.2/+0.2)	96.85 (-0.3/+0.2)	96.45 (-0.3/+0.3)
Registered Implants: 41000										
Effective Sample Size	35767	31935	28498	25358	22429	19449	16251	13464	10944	8745

SWEET TIP
Positive Fixation

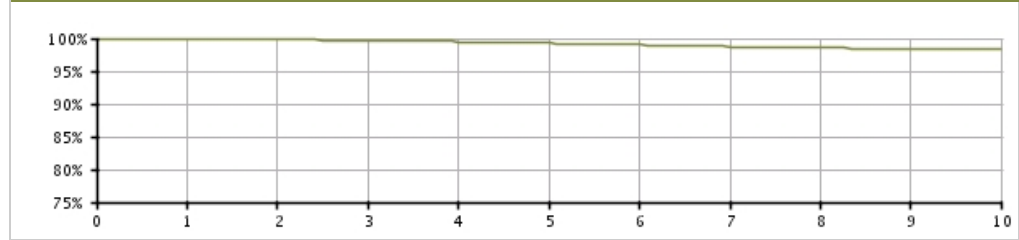
Models 4165/4168/4169/4268/4269

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 89,000	U.S. Chronic Lead Complications: 943
U.S. Estimated Active Implants: 16,000	U.S. Malfunctions: 159

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.88 (-0.0/+0.0)	99.79 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.50 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.41 (-0.1/+0.1)	98.28 (-0.1/+0.1)
Registered Implants: 89000										
Effective Sample Size	77719	69456	62068	55312	49107	43278	38074	33563	29655	26159

SWEET TIP RX
Positive Fixation

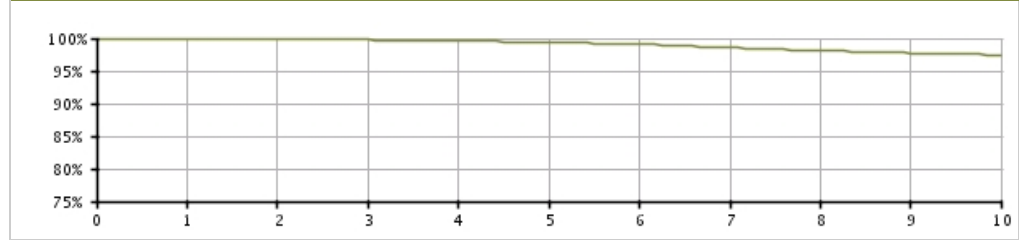
Models 4143/4144/4145/4243/4244/
 4245

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary

U.S. Registered Implants: 34,000	U.S. Chronic Lead Complications: 457
U.S. Approval Date: October 1998	U.S. Malfunctions: 26
U.S. Estimated Active Implants: 9,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.09 (-0.1/+0.1)	98.58 (-0.2/+0.2)	98.10 (-0.2/+0.2)	97.75 (-0.2/+0.2)	97.42 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29682	26537	23705	21101	18666	16341	14055	11979	10236	8643

CRM PRODUCT PERFORMANCE REPORT Q4 2014

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**— July 19, 1999 *Voluntary Physician Advisory*. 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. **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.
4. **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.
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 conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
11. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
12. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. 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. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
17. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
18. **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.
19. **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.
20. **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.
21. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
22. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
23. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
24. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
25. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.

26. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
27. **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.
28. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
29. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.
30. **Unconfirmed Extrinsic**— Lead complication after 30 days of implant time with lead return, where analysis could not identify an out of specification condition. Includes complications such as dislodgement, perforation or failure to capture.
31. **Inconclusive Extrinsic**— Lead complication after 30 days of implant time with lead return, where analysis was inconclusive. Includes partial lead returns and leads damaged by the explantation process.
32. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.
33. **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.
34. **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.
35. **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.
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.
39. **Inner conductor fracture**— High impedance, loss of capture, loss of sensing. Inner conductor fracture. Commonly associated with helix extension/retraction difficulties at implant.

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. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations occurring after the first month of implant, and have been removed from service surgically or electronically, but not returned for laboratory analysis. The categories are consistent with the AdvaMed guidance for *Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads*. Although multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	227000	50	583	619	501	181	64	129	282	0	52
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	175000	0	252	155	144	20	15	133	130	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	411000	12	376	466	229	33	59	321	242	0	26
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	57000	0	71	251	92	5	10	49	29	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	78	16	33	9	2	12	15	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	49000	0	175	59	60	28	9	60	75	0	2
CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	27000	2	13	226	15	1	1	5	9	0	76
ACUITY Spiral 4591/4592/4593	21000	0	7	148	14	0	1	0	4	0	110

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
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	1	23	190	29	0	1	5	5	0	77
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	93000	0	183	814	147	1	3	34	53	0	382
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	45	311	76	1	0	30	20	0	235

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 G 4-Site Dual Coil, Active Fixation 0295/0296	35000	0	4	27	3	4	4	2	0	3	1
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	29000	6	1	17	4	2	2	1	2	0	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	1	1	1	1	0	0	0	0	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	11	120	151	49	99	23	34	52	50	16
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	0	15	20	9	8	2	4	20	7	2
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	26000	3	15	19	8	17	0	4	9	4	1
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	4	92	52	24	92	18	31	56	20	5
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	3	50	27	20	32	3	19	65	12	2

Defibrillation 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
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	2000	0	4	0	0	0	0	0	2	0	1
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	0	2	1	1	0	0	0	0	0

S-ICD Electrodes/Model

		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
Q-TRAK SQ Electrode 3010		0	0	0	0	1	0	0	0	0	0

Longitude Surveillance Registry

	Leads Enrolled	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 Spiral 4591/4592/4593	1329	0	0	11	1	0	0	0	0	0	8
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	627	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	650	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	984	0	0	0	0	0	0	0	0	0	1
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	844	0	0	0	0	0	0	0	0	0	0

U.S. Acute Lead Observations

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	227000	229	189	1320	414	72	87	54	211	0	49
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	175000	15	12	422	162	7	26	23	37	0	19
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	411000	75	77	647	231	97	89	57	229	0	37
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	57000	1	18	434	90	7	28	17	17	0	8
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	33	15	1	3	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	49000	3	16	98	26	9	8	21	12	0	6
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 Steerable 4554/4555/4556	27000	1	2	315	46	25	2	7	134	0	231
ACUITY Spiral 4591/4592/4593	21000	5	4	190	64	8	1	9	37	0	223

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
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	4	2	262	40	12	2	8	45	0	180
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	93000	13	7	890	128	47	9	26	194	0	687
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	18	34	0	186

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 G 4-Site Dual Coil, Active Fixation 0295/0296	35000	28	25	108	61	37	10	5	51	12	5
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	2	0	3	1	2	0	0	13	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	29000	27	36	73	26	37	11	3	54	54	14
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	3	2	4	2	5	1	0	9	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	117	124	481	122	249	34	45	256	190	61
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	4	2	47	28	15	3	0	102	15	1
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	26000	27	15	71	26	30	12	3	49	110	7
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	1	0	1	0	9	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	30	62	163	44	116	20	24	102	43	18
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	28	25	108	61	37	10	5	51	12	5

Defibrillation Leads/Model continued...	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 S Single Coil, Active Fixation 0137/0138	2000	0	1	2	2	2	1	0	5	7	0
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	0	1	0	1	1	0	1	0	0

S-ICD Electrodes/Model	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
Q-TRAK SQ Electrode 3010	0	0	4	0	45	3	0	1	7	0

Longitude Surveillance Registry	Leads Enrolled	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 Spiral 4591/4592/4593	1329	0	0	10	12	1	0	0	3	0	45
RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	650	0	2	10	0	0	0	1	2	0	0
RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	984	6	1	7	2	4	2	0	2	0	2
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	627	0	0	1	0	1	0	1	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	844	0	0	1	1	0	0	0	0	0	0

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	1,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	1,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	2,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	59,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	38,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	40,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	168,000	0	5	0	7	1	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	4	0	0	3

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation 0658/0695/0696	4,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	8,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil Active Fixation 0295/0296	63,000	0	0	0	44	0	1	0
ENDOTAK RELIANCE G 4-Site Dual Coil Passive Fixation 0285/0286	7,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Active Fixation 0292/0293	53,000	0	0	0	8	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Passive Fixation 0282/0283	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276	4,000	0	0	0	6	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G Dual Coil Active Fixation 0164/0165/0166/0167/0184/0185/0186/0187	253,000	0	0	27	355	0	3	14
ENDOTAK RELIANCE G Dual Coil Passive Fixation 0174/0175/0176/0177	39,000	0	0	3	56	0	2	0
ENDOTAK RELIANCE SG Single Coil Active Fixation 0160/0161/0162/0180/0181/0182	56,000	0	0	6	58	0	1	3
ENDOTAK RELIANCE SG Single Coil Passive Fixation 0170/0171/0172/0173	3,000	0	0	0	2	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	113,000	0	0	16	130	0	0	0
ENDOTAK RELIANCE Dual Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	67,000	0	1	0	30	0	1	0
ENDOTAK RELIANCE S Single Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	5,000	0	0	1	3	0	0	0
ENDOTAK RELIANCE S Single Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	4,000	0	0	0	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Passive Fixation 7631/7632/7731/7732	2,000	0	0	0	0	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	15,000	0	0	0	27	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	2,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	160,000	0	0	9	109	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	277,000	0	0	55	582	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	473,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	617,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	260,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	99,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	99,000	0	0	2	1	1	1	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). The Board includes cardiac electrophysiology, engineering, statistics, risk management and bioethics experts.

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 actually reported. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION 17-Nov-2014 - AUTOGEN RVAT November 2014
<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>Voluntary Physician Advisory</p>
<p>AUTOGEN CRT-D Models G172/G173/G175/ G177/G179</p>	<p>AUTOGEN DR ICD and CRT-D devices include the option of enabling a Right Ventricular Automatic Threshold (RVAT) test to determine the RV pacing threshold and adjust amplitude in an ambulatory setting. If the RVAT test feature is enabled and noise signals are continuously sensed within a brief RV noise window following an Atrial pace, a patient may not receive effective pacing support until the RVAT test ends (i.e., up to 20 cardiac cycles). Although no patients have been harmed in the cases reported to date, brief periods of dizziness were reported in one case. Note that there is no additional risk for patients in whom the RVAT feature is disabled.</p>
<p>AUTOGEN ICD MINI DR Models D046/D047</p>	<p>Single-chamber AUTOGEN ICDs (VR models) have not demonstrated this behavior. The Left Ventricular Auto Threshold (LVAT) test (for AUTOGEN CRT-Ds) and the Right Atrial Auto Threshold (RAAT) test (for AUTOGEN CRT-Ds and dual-chamber ICDs) are not subject to this device behavior and are performing as intended. In addition, Boston Scientific pacemaker and CRT-P models with similar automatic pacing threshold test features are performing as intended and thus are not subject to this device behavior.</p>
<p>AUTOGEN ICD EL DR Models D176/D177</p>	<p>Boston Scientific is developing a software solution that will prevent this device behavior from occurring when the RVAT test feature is enabled. Following geography-specific regulatory approval, this software solution will be implemented via a non-invasive download from the programmer.</p>
<p>AUTOGEN RVAT November 2014 Physician Letter, Nov 17, 2014</p> <p>AUTOGEN RVAT November 2014 Patient Letter, Nov 17, 2014</p>	<p>CURRENT STATUS 17-Nov-14</p> <p><i>Reported events (worldwide)</i> Three (3) reports have been received worldwide of ineffective pacing support during an RVAT test.</p> <p>There have been no reported patient deaths associated with this advisory.</p>
	<p>CURRENT RECOMMENDATION 17-Nov-14</p> <p>The RVAT test can be used in-clinic to run an automatic threshold test (nominally enabled) or it can be enabled for ambulatory use (nominally not enabled). Until a software solution can be implemented, Boston Scientific recommends the following:</p> <ol style="list-style-type: none"> For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use: <ul style="list-style-type: none"> Select the SETTINGS tab Select the SETTINGS SUMMARY tab In the BRADY section, select the NORMAL SETTINGS details icon In the PACING and SENSING section, select the desired pacing RV Amplitude (do not select Auto) Ensure that DAILY TREND is not selected Press PROGRAM to implement the selected fixed amplitude pacing output. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilizing the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude). <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT	ORIGINAL COMMUNICATION Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014
<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>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. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.</p>
<p>COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108</p>	<p>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.</p>
<p>TELIGEN VR Models E102/E103/F102/F103</p>	<p>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.</p>
<p>TELIGEN DR Models E110/E111/F110/F111</p>	<p>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.</p>
<p>Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014</p>	<p><u>Advisory population</u> Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.</p>
<p>Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014</p>	<p>CURRENT STATUS 10-Oct-14 Advisory devices have not been available for implant for more than three years.</p>
<p>Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 1,263 malfunctions have been confirmed from the advisory population. Approximately 49,000 devices from the advisory population remain in service.</p>
	<p>There have been no reported patient deaths associated with this advisory.</p>
	<p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for advisory population devices is approximately 2.9% at 60 months.</p>
	<p>CURRENT RECOMMENDATION 10-Oct-14</p>
	<p><u>Updated Software</u> Boston Scientific introduced updated programmer software (Model 2868, version 3.04) that enhances the effectiveness of the Safety Architecture tools later in device life. Patients with a device in the advisory population should be scheduled for an in-clinic follow-up at first opportunity, but within 3 months, using a programmer with the new software. In-clinic interrogation with an updated programmer will automatically download Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.</p>
	<p><u>LATITUDE Patient Management System</u> Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity" is configured "On".</p>
	<p><u>Additional Recommendations</u></p> <ul style="list-style-type: none"> - 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. Note that "Approximate time to Explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a low voltage alert.
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT

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

[Device Lookup Tool](#)

SQ-RX S-ICD

Model1010

[High Cathode Condition Physician Letter, Jun 01, 2011](#)

[High Cathode Condition Patient Letter, Jun 01, 2011](#)

ORIGINAL COMMUNICATION 01-Jun-11 — High Cathode Condition

Voluntary Physician Advisory
FDA Classification: Pending

Boston Scientific has determined that a specific subset of SQ-RX pulse generators may not achieve the five (5) year typical longevity due to premature battery depletion. Although the longevity of these devices may be shortened, therapy remains available through the onset of the Elective Replacement Indicator (ERI). This subset of devices also has the potential for the time between the onset of the ERI and End of Life (EOL) indicators to be less than the nominal three (3) months. The risk for premature battery depletion is due to a specific condition within an individual battery cell. No affected devices remain available for implant.

Rate of Occurrence

Cameron Health has confirmed one (1) occurrence of a device experiencing premature battery depletion due to this condition.

Cameron Health conducted a systematic analysis of all implanted devices worldwide and identified two populations at risk for premature battery depletion due to this condition:

- Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date.
- Population II consists of 386 devices for which manufacturing records cannot exclude the possibility of the condition existing within a battery cell. Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There have been zero (0) confirmed occurrences in this population to date.

CURRENT STATUS 10-Oct-14

No devices in the advisory population remain available for implant.

Confirmed Malfunctions (worldwide)

Three (3) malfunctions have been confirmed worldwide of devices experiencing High Cathode Condition.

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

Projected Rate of Occurrence

- Population I – Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity.
- Population II - Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity.

CURRENT RECOMMENDATION 10-Oct-14

- If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible.
 - Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone.
- For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.

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

PRODUCT	ORIGINAL COMMUNICATION July 2010— Magnetic Reed Switch 2010
<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>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Some Boston Scientific defibrillators include a component referred to as a “magnetic reed switch,” designed to sense the presence of a magnet. If Enable Magnet Use is programmed to On (nominally On) and a magnet is applied in emergent situations or during a medical/surgical procedure, the switch is designed to close and temporarily prevent delivery of undesired tachy therapy. When the magnet is removed, the magnetic switch is designed to open and thereby restore ability to deliver programmed tachy therapy.</p>
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p>Magnetic reed switch technology has historically demonstrated a very low but non-zero rate of failing to open upon magnet removal. However, certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007 have exhibited a somewhat higher rate of magnetic reed switch failure.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	<p>Approximately 34,000 of these devices remain actively implanted; no devices in this population are available for implant. Devices manufactured after November of 2007 have returned to historic performance rates and are not included in this advisory</p>
<p>CONTAK RENEWAL 3 RF Models H210/H215</p>	<p>No patient deaths or injuries have been reported as a result of this issue, although some devices have been replaced. Most devices with a magnetic reed switch confirmed to be stuck in a closed position have remained implanted after “Enable Magnet Use” was programmed to Off (see Recommendations).</p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>Rate of Occurrence A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.</p>
<p>CONTAK RENEWAL 4 Models H190/H195/H197/H199</p>	
<p>CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179</p>	<p>CURRENT STATUS 10-Oct-14</p> <p>There have been no reported patient deaths associated with this advisory.</p> <p><i>Projected Rate of Occurrence</i></p>
<p>CONTAK RENEWAL 4 RF Models H230/H235/H239</p>	<p>The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.</p>
<p>VITALITY DR HE Model T180</p>	<p>CURRENT RECOMMENDATION 10-Oct-14</p> <p>Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device. In addition, Boston Scientific recommends:</p>
<p>Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010</p>	<p>1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.</p>
<p>Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010</p>	<p>2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]</p>

July 2010— Magnetic Reed Switch 2010, continued...

CURRENT RECOMMENDATION, continued...

3) If a stuck magnetic switch is confirmed, program the Enable Magnet Use feature to Off, which ensures that programmed therapy will be provided to treat tachyarrhythmias. However, if Enable Magnet Use is programmed Off:

- A magnet will no longer inhibit tachy therapy.
- The Patient Triggered Monitor feature will no longer be available.

Contact Boston Scientific Technical Services (1-800-CARDIAC) for assistance to re-activate Daily Measurements for devices with a stuck magnetic switch.

4) After consultation with our Independent Patient Safety Advisory Board, **Boston Scientific does not recommend prophylactic explant.** We further advise that physicians **do not routinely program Enable Magnet Use to Off in the absence of a confirmed stuck magnetic reed switch** because the benefits of magnet use to disable tachy therapy in emergent situations outweigh the probability of patient harm associated with a stuck reed switch.

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

PRODUCT

ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant 2009

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

This advisory is limited to those models listed below implanted subpectorally.

COGNIS

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

TELIGEN VR

Models E102/F102

TELIGEN DR

Models E110/E111/F110/F111

[Subpectoral Implant 2009 Physician Letter, Dec 01, 2009](#)

[Subpectoral Implant 2009 Patient Letter, Dec 01, 2009](#)

Voluntary Physician Advisory
FDA Classification: Class II

This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.

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.

A weakened header bond can result in one or more of the following device behaviors:

- Significant changes in measured lead impedance
- Noise on real-time or stored electrograms
- Intermittent inhibition of pacing
- Inappropriate anti-tachy pacing or shock therapy
- Loss of pacing therapy
- Loss of anti-tachy pacing and shock therapy

No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.

Rate of Occurrence

The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

The following factors may also impact the risk of failure if implanted in a subpectoral location:

- Exact location of the patient's ribs relative to the device
- Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients)
- Activity level and/or occupation of the patient (risk may increase for more active patients)

CURRENT STATUS 10-Oct-14

COGNIS and TELIGEN devices are available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired.

Reported events (worldwide)

Eighty-seven (87) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

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

Rate of Occurrence

An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.6% at 60 months.

01-Dec-09 — Subpectoral Implant 2009, continued...

CURRENT RECOMMENDATION 10-Oct-14

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

For affected devices implanted in a subpectoral location:

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

COGNIS and TELIGEN devices are now available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired.

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

ORIGINAL COMMUNICATION 05-Apr-07 and 04-Mar-09— Shortened Replacement Window

PRODUCT

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

Voluntary Physician Advisory
FDA Classification: Class II

Low-voltage capacitors may be subject to degradation. These capacitors may cause accelerated battery depletion and may reduce the time between Elective Replacement Indicator (ERI) and End Of Life (EOL) to less than three months. Device replacement indicators continue to function normally.

CONTAK RENEWAL 4 RF HE

Model H239

In April 2007, Boston Scientific CRM communicated with physicians regarding a population of devices subject to this failure mechanism. As of March 2009, the April 2007 advisory population has not experienced any clinically significant changes to either the rate of occurrence or patient management recommendations.

CONTAK RENEWAL 4 RF

Models H230/H235

CONTAK RENEWAL 4 HE

Models H197/H199

In March 2009, a second population was identified of 856 active ICDs and CRT-Ds manufactured with capacitors from the same supplier that may be subject to the same failure mechanism. The cumulative failure rate for accelerated depletion within this population is approximately 6% at 42 months and is projected to increase. Recommendations described in April 2007 have been 99.9% successful in identifying susceptible devices and ensuring replacement at ERI in the original population, and will minimize patient risk associated with a shortened replacement window when applied to this second population. No devices from this population have been registered as implanted after April 2007. No devices in this subset remain available for implant.

CONTAK RENEWAL 4

Models H190/H195

CONTAK RENEWAL 4

AVT / AVT HE

Models M170/M175/M177/M179

CURRENT STATUS 10-Oct-14

Confirmed Malfunctions (worldwide)

CONTAK RENEWAL 3 RF HE

Models H217/H219

April 2007 Population

2,565 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices.

CONTAK RENEWAL 3 RF

Models H210/H215

115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).

CONTAK RENEWAL 3 HE

Models H177/H179

March 2009 Population

116 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).

CONTAK RENEWAL 3

Models H170/H175

There have been no reported patient deaths associated with either advisory population.

CONTAK RENEWAL 3

AVT / AVT HE

Models M155/M159

No devices currently being distributed are susceptible to this malfunction mode.

Rate of Occurrence

VITALITY 2 EL VR/DR

Models T177/T167

April 2007 Population

The cumulative rate of occurrence for accelerated battery depletion for the April 2007 advisory population is approximately 5.0% at 60 months.

VITALITY 2 VR/DR

Models T175/T165

March 2009 Population

The cumulative rate of occurrence for accelerated battery depletion for the March 2009 advisory population is approximately 15.8% at 60 months.

VITALITY DR HE

Model T180

Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.

VITALITY DS VR/DR

Model T135/T125

05-Apr-07 and 04-Mar-09— Shortened Replacement Window, continued...

CURRENT RECOMMENDATION 10-Oct-14

VITALITY EL

Model T127

VITALITY AVT A155

Model A155

[Shortened Replacement Window
Physician Letter, Mar 04, 2009](#)

[Shortened Replacement Window
Patient Letter, Mar 04, 2009](#)

[Shortened Replacement Window
Physician Letter, Apr 5, 2007](#)

[Shortened Replacement Window
Patient Letter, Apr 5, 2007](#)

Patient management recommendations from the April 5, 2007 physician communication remain unchanged.

If a patient has a device with a degraded capacitor, the time from implant to 2.65 volts (Middle of Life 2 / MOL2) will be reduced.

To determine whether a patient may be at risk for a reduced ERI to EOL time, note when 2.65 volts (MOL2) was observed. For each patient:

1. Review patient records to assess battery voltage.
2. If battery voltage is **above** 2.65 volts (MOL2), continue to follow patient every three months per device labeling.
3. If battery voltage is **at or below** 2.65 volts (MOL2), determine the time between device implant and this observation.
4. If the time from implant to 2.65 volts (MOL2) is greater than 27 months (32 months for VITALITY® EL / 2 EL / HE devices), the patient is not at risk for a shortened ERI to EOL time, and **this advisory no longer applies.**
5. If the time from implant to 2.65 volts (MOL2) is 27 months or less (32 months for VITALITY® EL / 2 EL / HE devices), **the patient should be followed monthly until ERI.** For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed as ERI to EOL time may be shortened.

NOTE: If it is not clear when a battery voltage of less than 2.65 volts (MOL2) was reached, conduct a memory "Save to Disk" and return (mail or e-mail) to Boston Scientific CRM for prompt analysis. Contact your local Boston Scientific representative or Technical Services for further assistance

In geographies where available, the LATITUDE® Patient Management System can facilitate remote patient monitoring and provide automatic notification when the device reaches a battery status of ERI.

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

PRODUCT	ORIGINAL COMMUNICATION 10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	FDA Classification: Devices in Table 1, Column 1 of this <i>Product Update</i> were classified as Class II (27-November-07)
CONTAK RENEWAL 4 RF HE Model H239	Certain devices may display ERI or EOL during mid-life (typically 24–48 months), even though battery voltage (typically greater than or equal to 2.65 volts) and capacity remain available. This behavior is caused by high battery impedance rather than low battery voltage.
CONTAK RENEWAL 4 RF / HE Models H230/H235/H197/H199	Devices that have triggered charge time-based ERI or EOL during mid-life have several months, and in most cases more than one year of remaining battery voltage and capacity, which allows the devices to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled.
CONTAK RENEWAL 4 and 4 AVT / AVT HE Models H190/H195/M170/M175/M177/M179	<i>Rate Projection</i> Certain devices, typically implanted prior to July 2005 (Table 1, Column 1 of the Product Update) are projected to exhibit Mid-Life Display of Replacement Indicators as indicated below:
CONTAK RENEWAL 3 RF HE Models H217/H219	– VITALITY AVT (Model A135), VITALITY VR/DR, VITALITY DR+ (Projected rate: 8–10%) – VITALITY AVT (Model A155), VITALITY DS VR/DR, VITALITY 2 VR/DR, ASSURE (Projected rate: 4–7%)
CONTAK RENEWAL 3 RF / HE Models H210/H215/H177/H179	– VITALITY EL; VITALITY 2 EL DR/VR; VITALITY DR HE; CONTAK RENEWAL 3/4/3HE/4HE; CONTAK RENEWAL 3 RF/4RF/3RF HE/4RF HE; CONTAK RENEWAL 3 AVT/4AVT/3AVT HE/4AVT HE (Projected rate: 1–2%)
CONTAK RENEWAL 3 and 3 AVT / AVT HE Models H170/H175/M155/M159	Continuous manufacturing improvements intended to reduce variability in battery performance have been implemented by our battery supplier, which mitigate the occurrence of mid-life display of replacement indicators.
VITALITY 2 EL VR/DR Models T177/T167	CURRENT STATUS 10-Oct-14
VITALITY 2 VR/DR Models T175/T165	<i>Confirmed Malfunctions (worldwide)</i> For confirmed malfunction counts related to a specific product family, refer to the Confirmed Malfunction Details section of the Product Performance Report and see pattern titled “Mid-life display of replacement indicators.”
VITALITY DR HE and EL Model T180 and Model T127	<i>Projected Rate of Occurrence</i> For projected rates of occurrence see device-specific ranges listed above. Some performance differences have been observed between product families. For example, dual chamber devices have generally performed better than single chamber devices within the same product family. For current performance of a specific product family, refer to the U.S. Survival Probability section of the Product Performance Report and see population titled “10–Mar-07 Product Update — Mid-Life Display of Replacement Indicators.”
VITALITY DS VR/DR Model T135/T125	
VITALITY AVT A135 / A155 Models A135/A155	
VITALITY VR/DR and DR+ Models 1871/1870/1872	CURRENT RECOMMENDATION 10-Oct-14
ASSURE Model B301	<u>Patient management recommendations from the March 10, 2007 Product Update remain unchanged.</u>
Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007	<i>Patient Management Considerations</i> – Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled. – Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL. – Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI. – Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding a manual capacitor reform may be helpful in characterizing the current charge time.
Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 23-Jun-06 and 24-Aug-06— Low Voltage Capacitor
<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>Voluntary Physician Advisory FDA Classification: Class II</p>
<p>INSIGNIA Ultra SR Models 1190/1390</p>	<p>Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue.</p>
<p>INSIGNIA Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490</p>	<p><i>Reported Events (worldwide)</i></p>
<p>INSIGNIA Entra SR Models 1195/1198/1395/1398</p>	<p>At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing.</p>
<p>INSIGNIA Entra DR (downsize) Models 1296/1466</p>	<p><i>Projected Rate of Occurrence</i> While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future.</p>
<p>INSIGNIA Entra DR Models 1294/1295/1494/1495</p>	<p>CURRENT STATUS 10-Oct-14</p>
<p>INSIGNIA Entra SSI Models 0484/0485/1325/1326</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation.</p>
<p>INSIGNIA Entra DDD Models 0985/0986/1426</p>	<p>There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode.</p>
<p>INSIGNIA Plus SR Models 1194/1394</p>	<p><i>Projected Rate of Occurrence</i> The rate of occurrence is projected to range between 0.10% and 0.22%.</p>
<p>INSIGNIA Plus DR and Plus DR Downsize Models 1297/1467/1298/1468</p>	<p>CURRENT RECOMMENDATION 10-Oct-14</p>
<p>INSIGNIA AVT Models 0482/0882/0982 1192/1292/1392/1428/1432/1492</p>	<p><u>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</u></p>
<p>CONTAK RENEWAL TR / TR2 Models H120/H125/H140/H145</p>	<p>– Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients when making medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>Device Behavior</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p>Pacemakers: INSIGNIA/NEXUS</p>
<p>VITALITY DR HE Model T180</p>	<p>– Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant</p>
<p>VITALITY DS VR/DR Models T135/T125</p>	
<p>VITALITY VR/DR and EL Models 1870/1871/T127</p>	

23-Jun-06 and 24-Aug-06— Low Voltage Capacitor, continued...

VENTAK PRIZM 2 VR/DR

Models 1860/1861

[Low Voltage Capacitor, Physician Letter, Aug 24, 2006](#)

[Low Voltage Capacitor, Patient Letter, Aug 24, 2006](#)

[Low Voltage Capacitor, Physician Letter, Jun 23, 2006](#)

CURRENT RECOMMENDATION, continued...

CRT-Ps: RENEWAL TR/TR2

- ERI or EOL indicator message displayed earlier than expected
- Fault Code 11 message (high current indicator)
- A gas gauge less than BOL within six months of implant

ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2

- ERI or EOL indicator message displayed earlier than expected
- A battery voltage **less than 3.10V** within six months of implant

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

PRODUCT	ORIGINAL COMMUNICATION 12-May-06 and 04-Jan-08 Subpectoral Implant
<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 with the serial number facing the ribs..</i></p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up.</p>
<p>CONTAK RENEWAL 4 HE Models H197/H199</p>	<p>This failure mechanism can result in one or more of the following device behaviors:</p> <ul style="list-style-type: none"> - Loss of shock therapy - Loss of pacing therapy (intermittent or permanent) - Loss of telemetry communications - Beeping (16 tones every six hours), and a programmer warning screen upon interrogation
<p>CONTAK RENEWAL 4 Models H190/H195</p>	
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p><i>Reported Events</i> Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p><i>Rate of Occurrence</i> The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	<p>CURRENT STATUS 10-Oct-14</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u> Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation.</p>
<p>VITALITY DR HE Model T180</p>	<p><u>January 4, 2008 Population</u> Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation.</p>
<p>VITALITY EL Model T127</p>	
<p>VITALITY DR+ Model 1872</p>	<p>There have been no reported patient deaths associated with this advisory.</p>
	<p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.</p>
	<p>CURRENT RECOMMENDATION 10-Oct-14</p>
<p>Subpectoral Implant, Physician Letter, Jan 04, 2008</p>	<p>Patient management recommendations for both populations remain unchanged from the <u>May 12, 2006 physician communication.</u></p>
<p>Subpectoral Implant, Patient Letter, Jan 04, 2008</p>	<ul style="list-style-type: none"> - For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
	<ul style="list-style-type: none"> - For subpectoral implants, use an AP radiograph to determine specific device orientation. <ul style="list-style-type: none"> - If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary.

12-May-06 and 04-Jan-08 Subpectoral Implant, continued...

CURRENT RECOMMENDATION, continued...

If the device is in a susceptible orientation (serial number facing the ribs):

- Advise patient of the potential for device failure.
- Follow patient at 3 month intervals in accordance with device labeling.
- Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.
- For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.

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

PRODUCT	ORIGINAL COMMUNICATION 22-Sep-05 — Crystal Timing Component
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory FDA Classification: Class II
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of September 22, 2005, the root cause of the second failure mode had not yet been determined and analysis was ongoing. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component.
INSIGNIA Ultra SR Models 1190/1390	<i>Reported Events</i>
INSIGNIA Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490	Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004.
INSIGNIA Entra SR Models 1195/1198/1395/1398	Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths.
INSIGNIA Entra DR (downsize) Models 1296/1466	<i>Rate Projection</i>
INSIGNIA Entra DR Models 1294/1295/1494/1495	Failure Mode 1—As of the September 22, 2005 communication, Guidant's modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
INSIGNIA Entra SSI Models 0484/0485/1325/1326	CURRENT STATUS 10-Oct-14
INSIGNIA Entra DDD Models 0985/0986/1426	<i>Confirmed Malfunctions (worldwide)</i>
INSIGNIA Plus SR Models 1194/1394	Failure Mode 1— 62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory.
INSIGNIA Plus DR and Plus DR Downsize Models 1297/1467/1298/1468	Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory.
INSIGNIA AVT Models 0482/0882/0982 1192/1292/1392/1428/1432/1492	None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode.
Crystal Timing Component, Physician Letter, Dec 12, 2005	<i>Projected Rate of Occurrence</i> Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 6,000 is projected to range between 0.027% and 0.038%.
Crystal Timing Component, Patient Letter, Oct 03, 2005	CURRENT RECOMMENDATION 10-Oct-14
Crystal Timing Component, Physician Letter, Sep 22, 2005	Failure Mode 1— <u>Patient management recommendations from the September 22, 2005 physician communication remain unchanged.</u>
	Failure Mode 2— <u>Patient management recommendations supersede those originally communicated on September 22, 2005.</u>
	<ul style="list-style-type: none"> – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory (18-Jul-05) 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	Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I
CONTAK TR Model 1241	A hermetic sealing component utilized in a subset of pacemakers may experience a gradual degradation, resulting in higher than normal moisture content within the pacemaker case late in the device's service life; this could lead to a variety of inappropriate clinical behaviors.
DISCOVERY II SR (downsize) Models 1184/1384	The original July 18, 2005 physician communication bounded the population to approximately 78,000 devices manufactured between November 25, 1997 and October 26, 2000; this number was further refined to 77,500 devices manufactured between October 27, 1997 and October 26, 2000.
DISCOVERY II SR Models 1186/1187/1385	The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated at that time to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis.
DISCOVERY II DR (downsize) Models 1283/1483	A Second Population of 54,000 devices was subsequently identified to be at risk of hermetic seal degradation (but at a much lower rate than the original population). This was communicated in the January 21, 2006 letter.
DISCOVERY II DR Models 1284/1286/1484/1485	<u>Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u> ; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).
DISCOVERY II SSI (downsize) Models 0481/1349	Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.
DISCOVERY II DDD Models 0981/1285/1499	<i>Rate Projection</i> Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 had increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and was projected to range between 0.31% and 0.88% over the remaining device lifetime.
PULSAR MAX II SR (downsize) Models 1180/1380	Second Population—For the remaining lifetime of the estimated worldwide 19,300 active devices, the projected rate of occurrence for reported events was estimated to be between 0.02% and 0.06%.
PULSAR MAX II SR / DR Models 1181/1290/1480	CURRENT STATUS 10-Oct-14
DISCOVERY SR/SR (downsize) Models 1174/1175	<i>Reported Events (worldwide)</i> Refined Original Population— 342 malfunctions have been confirmed out of the 77,500 advisory population devices.
DISCOVERY DR/DR (downsize) Models 1274/1275/1273	Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices.
PULSAR MAX SR (downsize) Model 1170	<i>Projected Rate of Occurrence</i> Refined Original Population—The rate of occurrence for the estimated worldwide active device population of 3,000 is projected to range between 0.31% and 0.88% over the remaining device lifetime, as communicated in the January 21, 2006 Advisory Update letter.
PULSAR MAX SR / DR Model 1171/1270	Second Population—The rate of occurrence for the estimated worldwide active device population of 2,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.
PULSAR Models 1272/0470/0870/0970/ 0972/1172	
MERIDIAN SSI / DDD Models 0476/0976	
MERIDIAN SR / DR Models 1176/1276	

18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component, continued...

CURRENT RECOMMENDATION 10-Oct-14

[Hermetic Sealing Component, Physician Letter, Jan 21, 2006](#)

[Hermetic Sealing Component, Patient Letter, Jan 21, 2006](#)

[Hermetic Sealing Component, Physician Letter, Jul 18, 2005](#)

Original Population— **Patient management recommendations from the July 18, 2005 physician letter remain unchanged**; however, physicians should reassess patients in light of the increased projected rate of occurrence communicated in the January 21, 2006 Advisory Update letter.

Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.

- Consider replacing devices for pacemaker-dependent patients.
- Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure.
- Select a suitable Maximum Sensor Rate (MSR) setting, given the rare possibility that inappropriate sustained pacing at MSR can occur

OR

– Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR.
– Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a malfunction that has already occurred, but does not guarantee that the device will not exhibit this malfunction mode in the future. At each patient follow-up:

- Evaluate for the clinical behaviors described in the July 18, 2005 letter.
- Evaluate battery status for signs of early or rapid depletion between sequential follow-up visits.
- Evaluate the accelerometer rate response (for devices with this feature).
 - Accelerometer ON:
 - Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit (LRL) while the patient is at rest.
 - Look for lack of rate response with activity (i.e., isometrics, short hall walk).
 - Accelerometer OFF:
 - *Temporarily* program the accelerometer ON and evaluate as described above

– Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.

– If any of these device behaviors are observed, contact your local representative or Technical Services for troubleshooting and recommendations.

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