

2015

Rhythm Management Product Performance Report

Q2 Edition



CRM Quality Pledge

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

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2015 report includes data through April 10, 2015.

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

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

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

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

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

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Statistical Methodology

What Is Device Survival Probability?

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

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

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

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

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets

Pulse generator survival probability is reported for U.S. implanted devices in product families which meet inclusion criteria described below. Lead survival probability is reported for 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 2014 version of ISO 5841-2: 2014(E) outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology for survival probability to all lead families being implanted as of May 2009, and forward. . Worldwide malfunctions are not included for older lead families.

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads removed from service with reported complications 30 days or more post-implant, whether returned or not.

Further Adjustments for Device and Lead Survival

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

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

Categorization of Malfunctions for Survival Probability Reporting

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

Malfunction With Compromised Therapy —

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

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

Malfunction Without Compromised Therapy —

The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

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

Categorization of Normal Battery Depletion for Survival Probability Reporting

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

- a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or
- b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings and therapeutic use.

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

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

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

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine 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 four malfunction categories for leads (described below).

Patterns

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

Each pattern description includes:

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

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

Therapy Availability

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

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

Pulse Generator Malfunctions

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

Lead Confirmed Malfunctions

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

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.

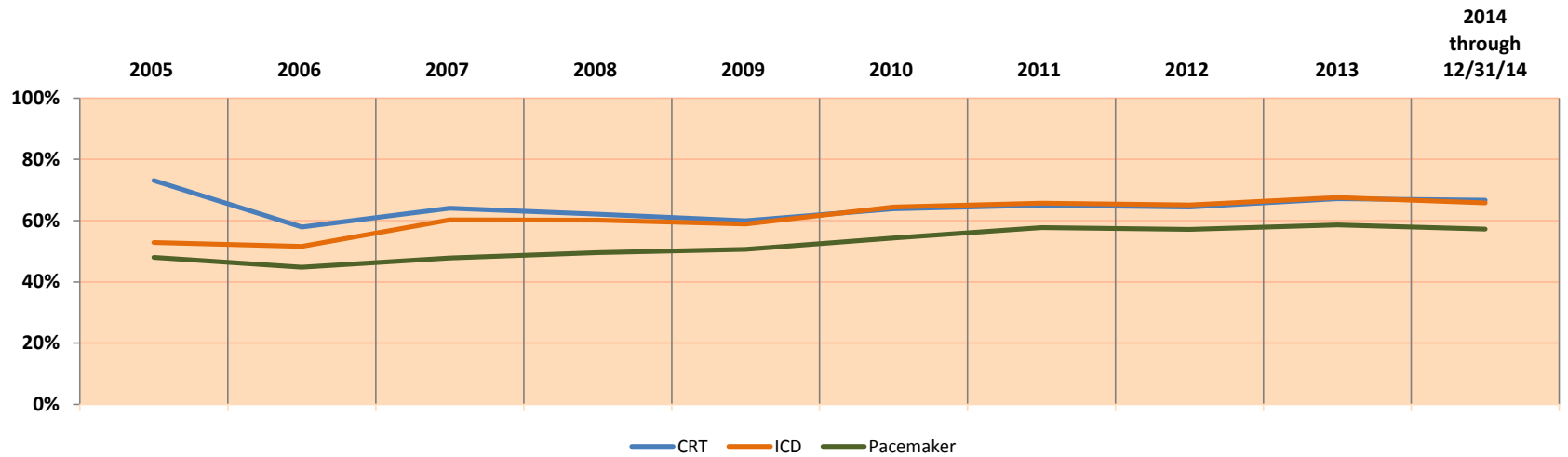
E-mail: crmevent@bsci.com

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 12/31/14
Explants	3847	3345	4239	5656	9238	10418	9260	7975	8194	6690
Returns	2813	1936	2716	3511	5539	6652	6016	5137	5499	4461
% Returned	73%	58%	64%	62%	60%	64%	65%	64%	67%	67%
Explants	16419	10171	11516	15519	19444	19826	16479	11859	11731	10853
Returns	8674	5251	6939	9330	11444	12767	10827	7722	7924	7144
% Returned	53%	52%	60%	60%	59%	64%	66%	65%	68%	66%
Explants	20604	16912	18335	20363	20917	20980	19858	18502	18489	18669
Returns	9881	7572	8755	10082	10576	11401	11451	10573	10823	10686
% Returned	48%	45%	48%	50%	51%	54%	58%	57%	59%	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: 5,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

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DYNAGEN/INOGEN/ORIGEN CRT-D

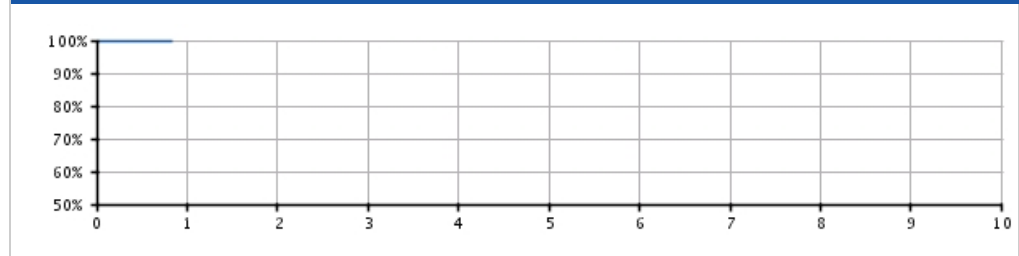
Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

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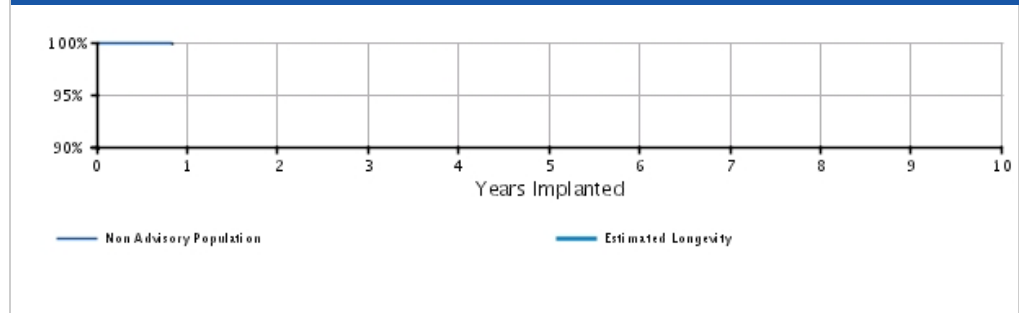
U.S. Summary

U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:1
	Without Compromised Therapy:1
	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)	99.94 @ 10 mo. (-0.2/+0.0)	-	-	-	-	-	-	-	-	-
Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	99.97 @ 10 mo. (-0.2/+0.0)	-	-	-	-	-	-	-	-	-
	Effective Sample Size	205	-	-	-	-	-	-	-	-	-

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: 9,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	1	1
⁷⁹ Memory errors	-	1	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

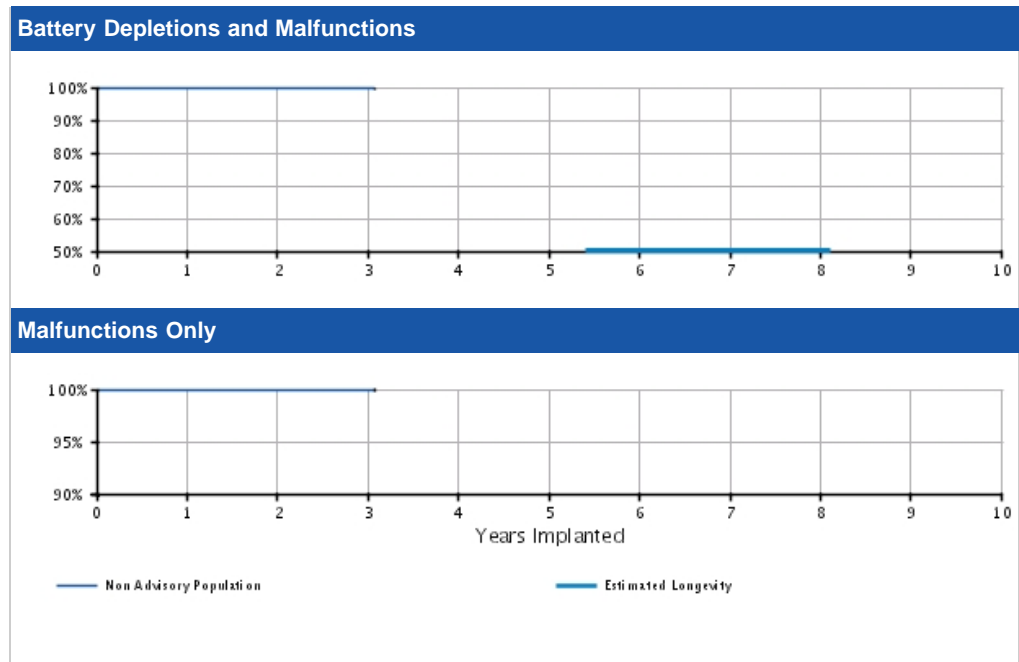
[References](#) cited in table above

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: 9,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 8,000	U.S. Normal Battery Depletions: 5 U.S. Unconfirmed Reports of Premature Battery Depletion : 2 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)	99.88 (-0.2/+0.1)	99.59 (-0.7/+0.3)	99.59 @ 37 mo. (-0.7/+0.3)	—	—	—	—	—	—	—
	Registered Implants: 9000	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.91 (-0.2/+0.1)	99.91 @ 37 mo. (-0.2/+0.1)	—	—	—	—	—	—
Effective Sample Size		5682	2498	417	274	—	—	—	—	—	—	—

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: 16,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁰ Safety Core-electrocautery	1	-	
⁷⁸ Integrated circuit	-	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

[References](#) cited in table above

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INCEPTA CRT-D

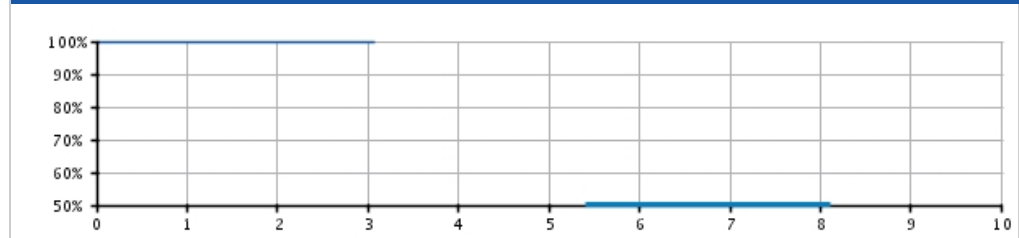
Models N161/N163/N164/N165/P163/
P165

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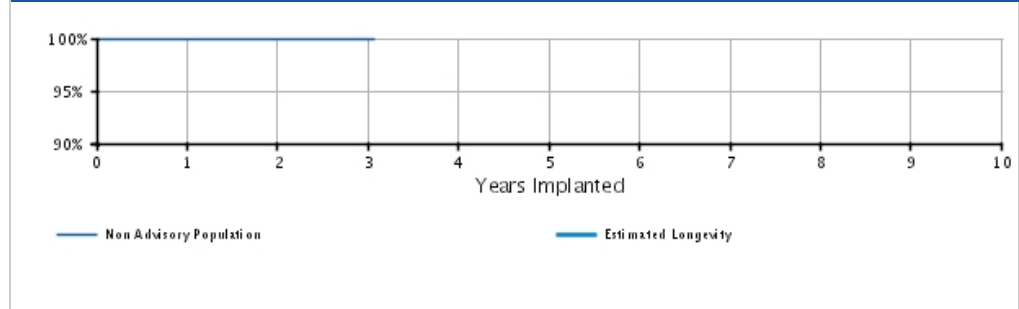
U.S. Summary

U.S. Registered Implants: 12,000	U.S. Normal Battery Depletions: 8
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 11,000	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(%)	99.94	99.85	99.79	99.79	-	-	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	@ 37 mo. (-0.2/+0.1)						
Registered Implants: 12000	Malfunctions Only(%)	99.98	99.98	99.98	99.98	-	-	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	@ 37 mo. (-0.1/+0.0)						
	Effective Sample Size	7754	3520	372	205	-	-	-	-	-	-

INCEPTA CRT-D

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

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

INCEPTA CRT-D Models N161/N163/N164/N165/P163/ P165 			
Worldwide Distribution: 17,000 Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷¹ High-voltage capacitor	-	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	2	2

[More details](#) about malfunctions

[References](#) cited in table above

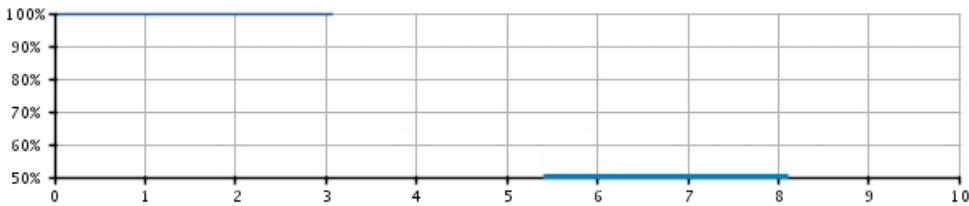
ENERGEN CRT-D 4-Site

Models N140/N142/P142

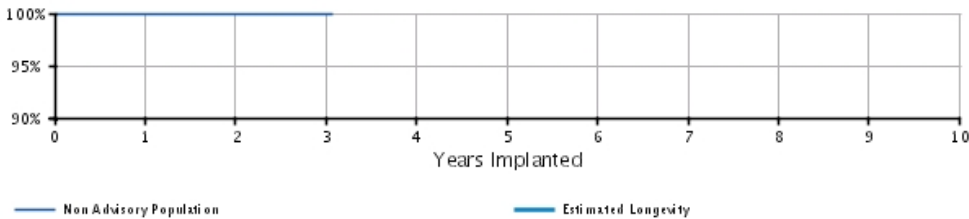
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

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: 4 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:2 Without Compromised Therapy:1 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)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.81 (-0.4/+0.1)	99.81 @ 37 mo. (-0.4/+0.1)	-	-	-	-	-	-	-
	Registered Implants: 13000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 37 mo. (-0.1/+0.0)	-	-	-	-	-	-
Effective Sample Size		9315	4537	657	377	-	-	-	-	-	-	-

ENERGEN CRT-D 4-Site

Models N140/N142/P142

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

ENERGEN CRT-D 4-Site Models N140/N142/P142 			
Worldwide Distribution: 19,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁷⁸ Integrated circuit	1	-	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ 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

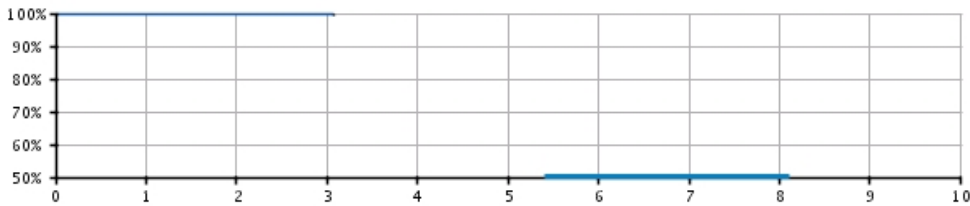
ENERGEN CRT-D

Models N141/N143/P143

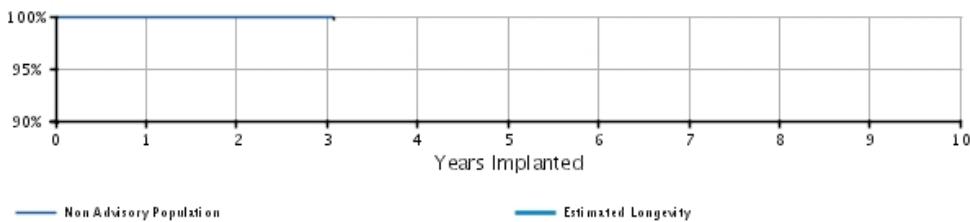
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 13,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 11,000	U.S. Normal Battery Depletions: 6 U.S. Unconfirmed Reports of Premature Battery Depletion : 3 U.S. Malfunctions:9 Without Compromised Therapy:5 With Compromised Therapy:4

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: 13000	99.93 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.55 (-0.4/+0.2)	99.55 @ 37 mo. (-0.4/+0.2)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.85 (-0.3/+0.1)	99.85 @ 37 mo. (-0.3/+0.1)	-	-	-	-	-	-	-
Effective Sample Size		9001	4270	470	243	-	-	-	-	-	-	-

ENERGEN CRT-D

Models N141/N143/P143

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

ENERGEN CRT-D Models N141/N143/P143 			
Worldwide Distribution: 17,000 Worldwide Confirmed Malfunctions: 11			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	2	5
⁷⁰ Safety Core-electrocautery	1	1	
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	-	1	
⁸² Low-voltage capacitor	1	-	
Mechanical	-	3	3
⁶⁴ Transformer	-	3	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	6	5	11


[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
---------------------------	-------------------------------	--------------------

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

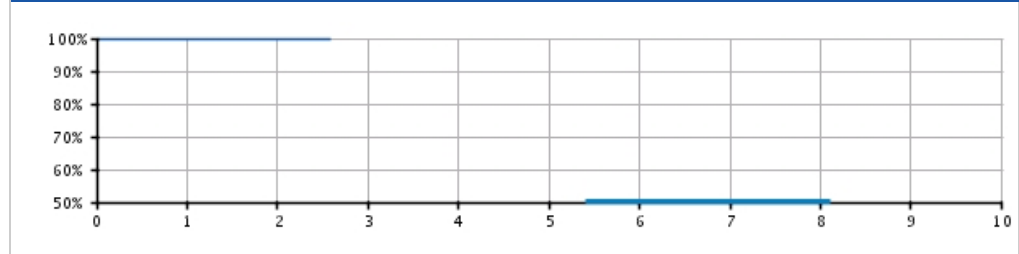
PUNCTUA CRT-D

Models N051/N053/P053

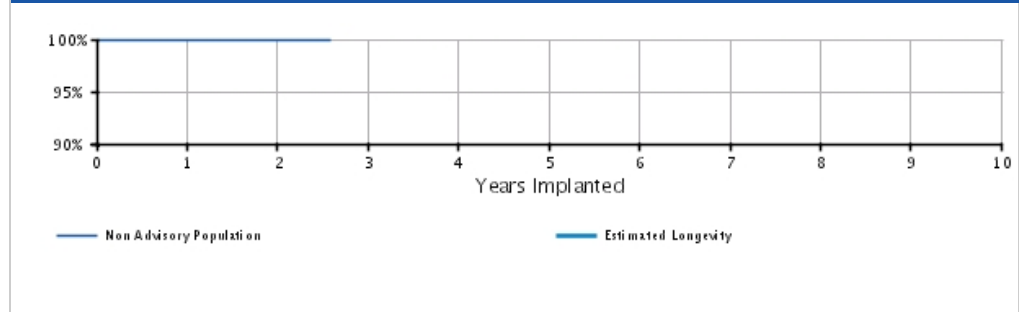
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

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

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)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 31 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Registered Implants: 1000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 31 mo. (-0.0/+0.0)	-	-	-	-	-	-	-
Effective Sample Size		1036	503	211	-	-	-	-	-	-	-	-

PUNCTUA CRT-D

Models N051/N053/P053

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

PUNCTUA CRT-D Models N051/N053/P053 			
Worldwide Distribution: 5,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷⁸ 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

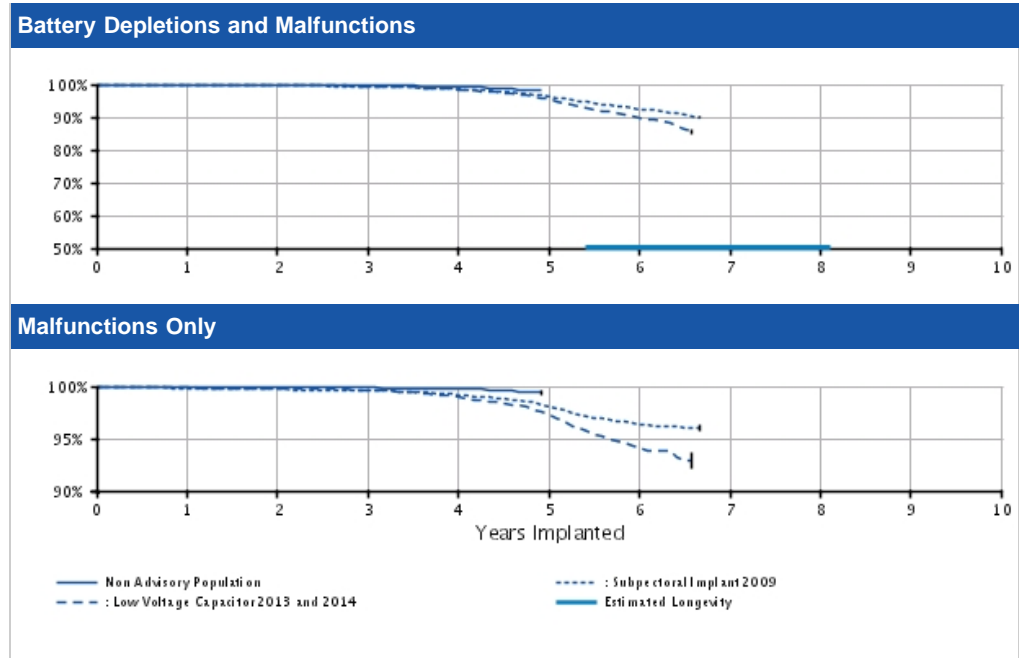
CRM PRODUCT PERFORMANCE REPORT Q2 2015

COGNIS

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

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

U.S. Summary	
U.S. Registered Implants: 75,000	U.S. Normal Battery Depletions: 803
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 59
U.S. Estimated Active Implants: 46,000	U.S. Malfunctions: 798



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)	99.19 (-0.1/+0.1)	98.35 @ 59 mo. (-0.4/+0.3)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.45 @ 59 mo. (-0.3/+0.2)	-	-	-	-	-
	Effective Sample Size	31541	27993	24169	10920	267	-	-	-	-	-
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.1)	96.38 (-0.3/+0.3)	92.42 (-0.5/+0.5)	89.94 @ 80 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)	98.12 (-0.2/+0.2)	96.38 (-0.3/+0.3)	96.05 @ 80 mo. (-0.3/+0.3)	-	-	-
	Effective Sample Size	27509	24393	21695	19204	16736	5717	313	-	-	-
Low Voltage Capacitor 2013 and 2014* Registered Implants: 26,000	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)	95.53 (-0.4/+0.3)	89.68 (-1.3/+1.2)	85.63 @ 79 mo. (-1.3/+1.3)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.2/+0.1)	97.31 (-0.3/+0.3)	94.10 (-0.8/+0.7)	92.94 @ 79 mo.	-	-	-
	Effective Sample Size	26000	26000	26000	26000	26000	26000	26000	-	-	-


(Confidence Interval)						(-0.8/+0.7)				
Effective Sample Size	22626	20049	17856	15771	11362	2120	268	-	-	-

*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
---------------------------	-------------------------------	--------------------

COGNIS Models N106/N107/N108/N118/N119/ N120/P106/P107/P108 			
Worldwide Distribution: 109,000			
Worldwide Confirmed Malfunctions: 1032			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	767	98	865
¹ Low Voltage Capacitor 2014 (Advisory issued)	631	46	
⁷⁰ Safety Core-electrocautery	46	18	
⁷¹ High-voltage capacitor	1	4	
⁷⁵ Low-voltage capacitors	7	-	
⁷⁸ Integrated circuit	7	19	
⁸⁰ High voltage circuit	-	1	
⁸¹ Battery	23	4	
⁸² Low-voltage capacitor	52	6	
Mechanical	36	83	119
⁵ Subpectoral implant 2009 (Advisory issued)	14	42	
⁶⁴ Transformer	-	9	
⁶⁸ Difficulty securing lead	9	9	
⁷³ Header contacts	7	7	
⁹¹ Header	6	16	
Software	14	-	14
⁷⁴ Safety Core-programming	1	-	
⁷⁶ Alert messages not displayed post-EOL	2	-	
⁷⁹ Memory errors	11	-	
Other	26	8	34
Non-patterned	26	8	
WW Confirmed Malfunctions	843	189	1032

[More details](#) about malfunctions

[References](#) cited in table above

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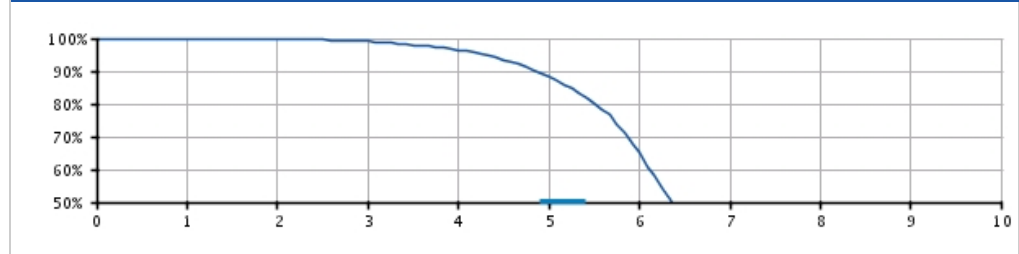
LIVIAN

Models H220/H225/H240/H245

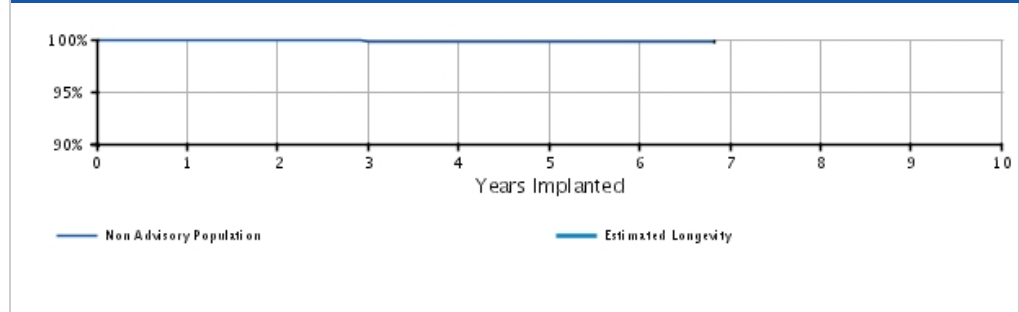
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 1,158
U.S. Approval Date: February 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:8
	Without Compromised Therapy:5
	With Compromised Therapy:3

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)	99.95 (-0.1/+0.0)	99.68 (-0.2/+0.1)	99.06 (-0.4/+0.3)	96.47 (-0.7/+0.6)	88.17 (-1.3/+1.2)	65.32 (-2.1/+2.1)	31.11 @ 82 mo. (-2.6/+2.7)	-	-	-	-
	Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	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 @ 82 mo. (-0.2/+0.1)	-	-	-
Effective Sample Size		3997	3486	3040	2572	1955	1074	207	-	-	-	-

LIVIAN

Models H220/H225/H240/H245

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

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
²⁷ Integrated circuit	1	2	
Mechanical	1	-	1
³¹ Seal plug	1	-	
Software	-	-	0
Other	3	3	6
Non-patterned	1	3	
³⁴ Battery depletion	2	-	
WW Confirmed Malfunctions	5	5	10

[More details](#) about malfunctions

[References](#) cited in table above

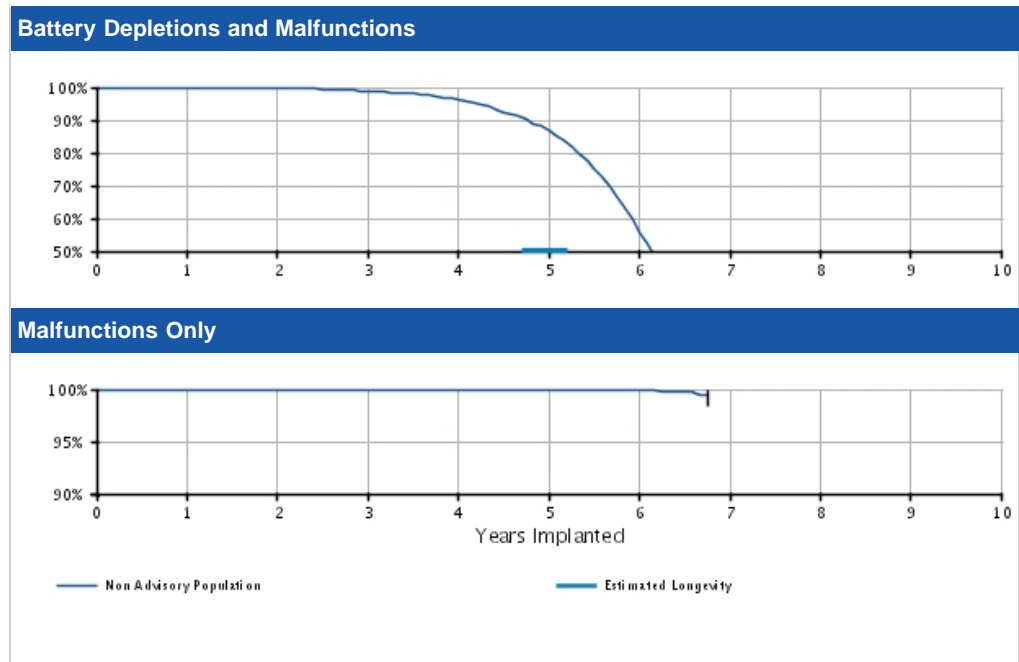
CRM PRODUCT PERFORMANCE REPORT Q2 2015

LIVIAN HE

Models H227/H229/H247/H249

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

U.S. Summary	
U.S. Registered Implants: 6,000 U.S. Approval Date: February 2008 U.S. Estimated Active Implants: 2,000	U.S. Normal Battery Depletions: 1,447 U.S. Unconfirmed Reports of Premature Battery Depletion : 4 U.S. Malfunctions:6 Without Compromised Therapy:3 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)	99.98 (-0.1/+0.0)	99.74 (-0.2/+0.1)	98.92 (-0.4/+0.3)	96.44 (-0.7/+0.6)	86.98 (-1.3/+1.2)	55.88 (-2.1/+2.1)	29.24 @ 81 mo. (-2.3/+2.4)	-	-	-	-
	Registered Implants: 6000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.49 @ 81 mo. (-1.2/+0.4)	-	-	-
Effective Sample Size		4940	4325	3786	3138	2279	1051	262	-	-	-	-

LIVIAN HE

Models H227/H229/H247/H249

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

LIVIAN HE Models H227/H229/H247/H249 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	2	3
²⁷ Integrated circuit	1	1	
⁸² Low-voltage capacitor	-	1	
Mechanical	-	2	2
⁶⁸ Difficulty securing lead	-	2	
Software	1	-	1
⁴⁷ Memory location	1	-	
Other	1	1	2
Non-patterned	1	-	
³⁴ Battery depletion	-	1	
WW Confirmed Malfunctions	3	5	8


[More details](#) about malfunctions

[References](#) cited in table above

CONTAK RENEWAL 4

Models H190/H195

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

CONTAK RENEWAL 4 Models H190/H195 			
Worldwide Distribution: 18,000			
Worldwide Confirmed Malfunctions: 356			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	311	11	322
⁸ Shortened replacement window (Advisory issued)	160	5	
¹⁰ Premature battery depletion (Advisory issued)	14	-	
¹⁵ Extended charge time post-mid-life	9	-	
¹⁹ Integrated circuit	2	-	
²³ Capacitor	-	1	
²⁷ Integrated circuit	3	3	
³⁸ Capacitor	-	1	
⁴¹ Capacitor	3	-	
⁴⁸ Mid-life display of replacement indicators	63	-	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	57	-	
Mechanical	8	14	22
⁴ Magnetic reed switch 2010 (Advisory issued)	-	3	
⁷ Subpectoral implant (Advisory issued)	-	7	
¹³ Magnetic switch (Advisory issued)	-	1	
²⁴ Header	2	-	
³¹ Seal plug	4	-	
⁴⁰ Circuit connection	-	1	
⁵⁵ Setscrew	-	1	
⁶² Reed switch	1	1	
⁶³ Cracked solder joint	1	-	
Software	-	-	0
Other	6	6	12
Non-patterned	2	3	
³⁴ Battery depletion	4	3	
WW Confirmed Malfunctions	325	31	356


[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
---------------------------	-------------------------------	--------------------

CONTAK RENEWAL 4 HE Models H197/H199 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 147			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	131	2	133
⁸ Shortened replacement window (Advisory issued)	68	1	
¹⁰ Premature battery depletion (Advisory issued)	2	-	
¹⁵ Extended charge time post-mid-life	10	-	
²³ Capacitor	1	-	
²⁷ Integrated circuit	1	1	
³⁸ Capacitor	1	-	
⁴⁸ Mid-life display of replacement indicators	26	-	
⁴⁹ High-voltage capacitor	1	-	
⁶⁹ Low-voltage capacitor	21	-	
Mechanical	6	4	10
⁴ Magnetic reed switch 2010 (Advisory issued)	-	1	
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁴ Header	1	1	
³¹ Seal plug	2	-	
⁵⁵ Setscrew	1	1	
⁵⁶ Seal plug	1	-	
⁶³ Cracked solder joint	1	-	
Software	-	-	0
Other	3	1	4
Non-patterned	1	1	
³⁴ Battery depletion	2	-	
WW Confirmed Malfunctions	140	7	147

[More details](#) about malfunctions

[References](#) cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

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

VISIONIST/VALITUDE Models U125/U128/U225/U226/U228			
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

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INVIVE

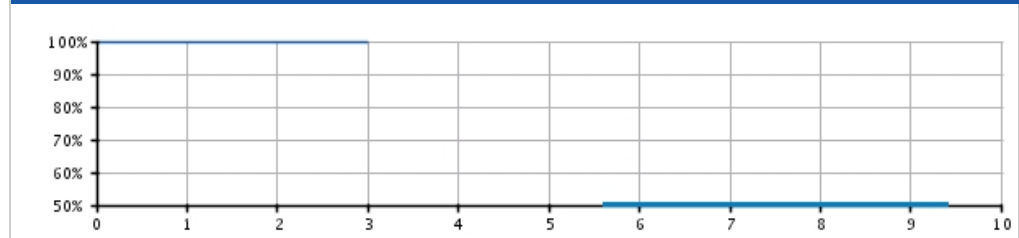
Models V172/V173/V182/V183/W172/
W173

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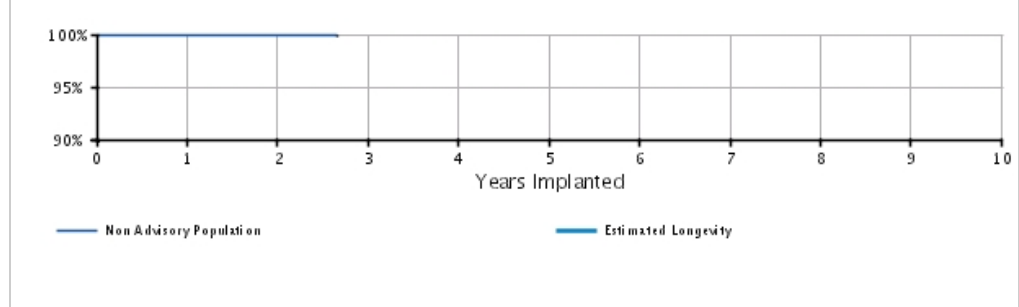
U.S. Summary

U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 5
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:1
	Without Compromised Therapy:1
	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)	99.96 (-0.1/+0.0)	99.82 (-0.3/+0.1)	99.82 @ 32 mo. (-0.3/+0.1)	-	-	-	-	-	-	-
Registered Implants: 7000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 32 mo. (-0.2/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	4644	1577	281	-	-	-	-	-	-	-

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: 16,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷⁵ Low-voltage capacitors	-	1	
Mechanical	-	-	0
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3


[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
²³ Capacitor	1	-	
Mechanical	4	-	4
³¹ Seal plug	1	-	
⁴⁴ Setscrew block	2	-	
⁵⁶ Seal plug	1	-	
Software	12	-	12
³⁶ Memory error	1	-	
⁴⁶ Stored EGMs	11	-	
Other	10	1	11
Non-patterned	9	1	
⁵⁴ Alert messages	1	-	
WW Confirmed Malfunctions	27	1	28

[More details](#) about malfunctions

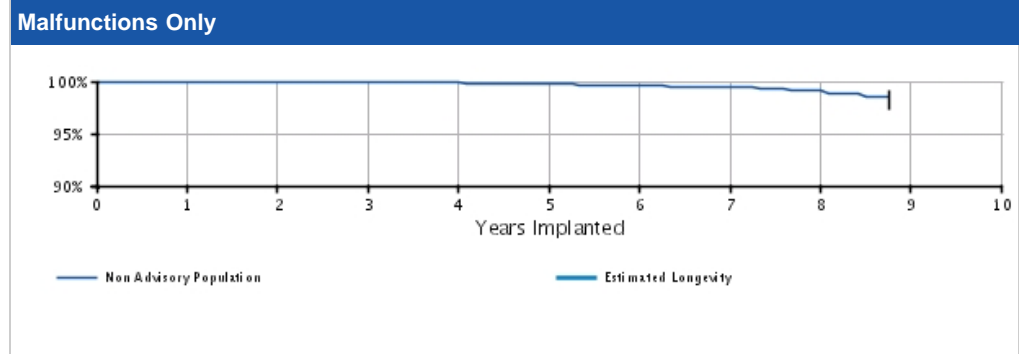
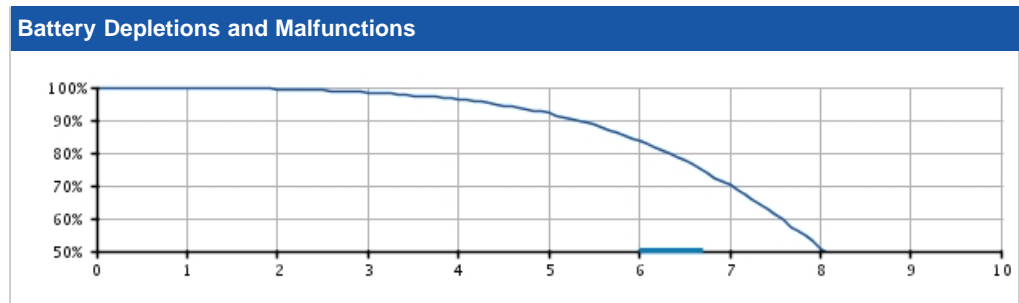
[References](#) cited in table above

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: 1,897
U.S. Approval Date: January 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Estimated Active Implants: 8,000	U.S. Malfunctions:44
	Without Compromised Therapy:42
	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)	99.91 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.37 (-0.4/+0.3)	92.01 (-0.6/+0.6)	83.64 (-1.0/+1.0)	70.20 (-1.6/+1.5)	50.97 (-2.2/+2.2)	36.14 @ 105 mo. (-2.7/+2.8)	-
Registered Implants: 19000	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)	99.74 (-0.1/+0.1)	99.62 (-0.2/+0.1)	99.45 (-0.3/+0.2)	99.13 (-0.5/+0.3)	98.45 @ 105 mo. (-1.2/+0.7)	-
	Effective Sample Size	15604	13624	11411	8287	5170	2954	1493	589	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.										

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	-	
²³ Capacitor	-	1	
Mechanical	5	-	5
³¹ Seal plug	5	-	
Software	27	-	27
⁴⁶ Stored EGMs	27	-	
Other	9	1	10
Non-patterned	7	1	
⁵⁴ 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: 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

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: 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

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

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

DYNAGEN/INOGEN/ORIGEN ICD EL DR
Models D052/D053/D142/D143/D152/
D153 

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 EL VR

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

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

DYNAGEN/INOGEN/ORIGEN ICD EL VR
Models D050/D051/D140/D141/D150/
D151 

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 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: 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

CRM PRODUCT PERFORMANCE REPORT Q2 2015

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: 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

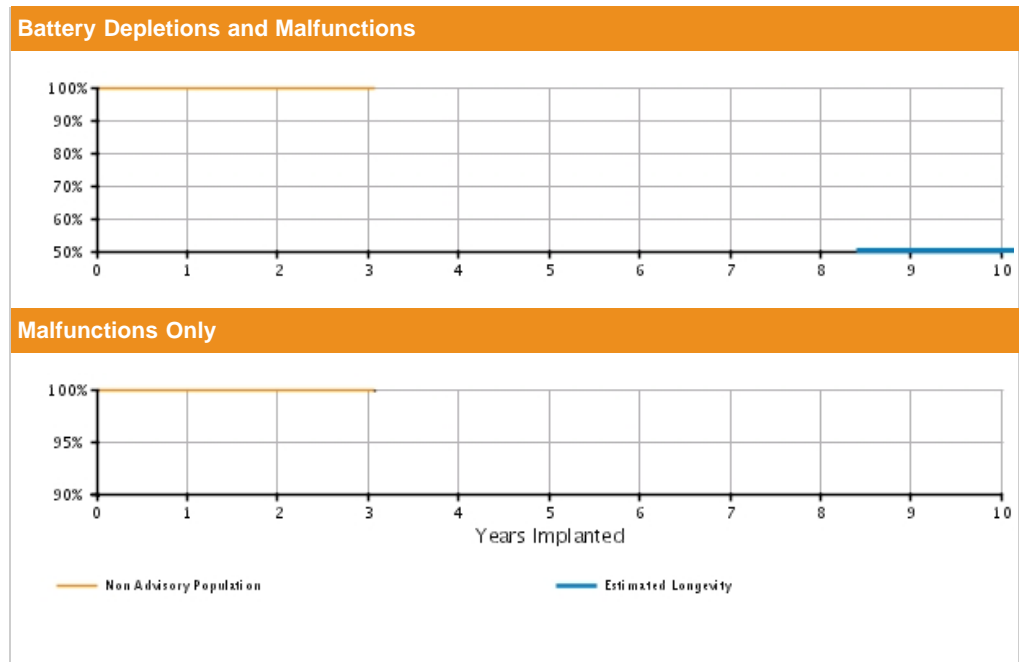
[References](#) cited in table above

INCEPTA ICD DR 4-Site

Models E162/F162

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

U.S. Summary	
U.S. Registered Implants: 11,000	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: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(%)	99.98	99.92	99.87	99.87	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	@ 37 mo. (-0.2/+0.1)							
Registered Implants: 11000	Malfunctions Only(%)	99.98	99.95	99.90	99.90	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	@ 37 mo. (-0.2/+0.1)							
	Effective Sample Size	6741	2965	450	284	—	—	—	—	—	—	—

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: 19,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁷¹ High-voltage capacitor	1	-	
⁷⁸ Integrated circuit	1	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	3	2	5

[More details](#) about malfunctions

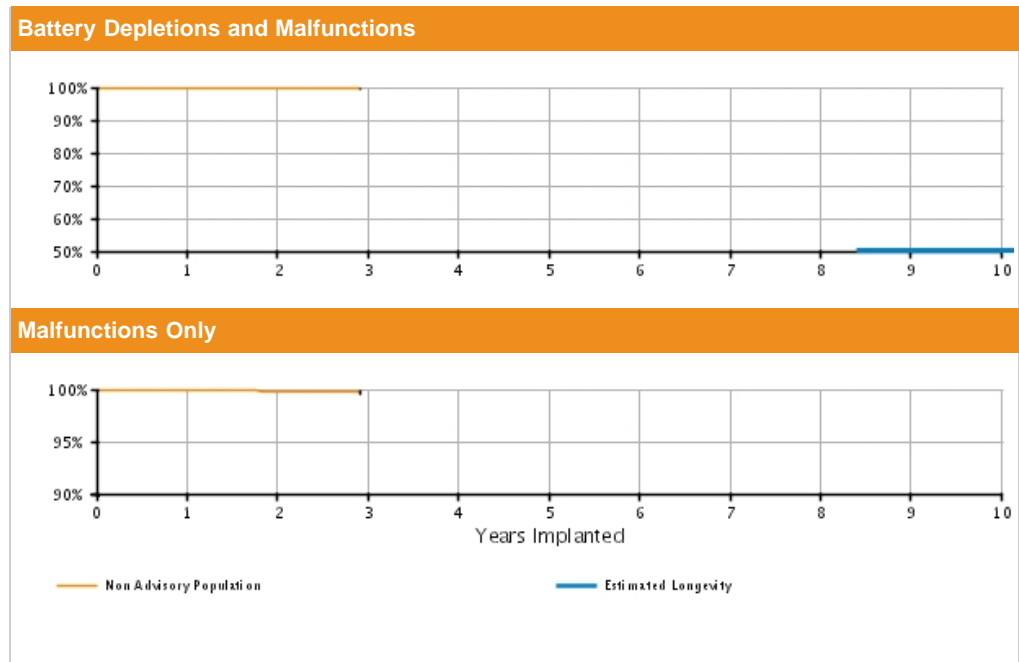
[References](#) cited in table above

INCEPTA ICD DR

Models E163/F163

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

U.S. Summary	
U.S. Registered Implants: 7,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 6,000	U.S. Normal Battery Depletions: 3 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:5 Without Compromised Therapy:4 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)	99.73 (-0.3/+0.1)	99.62 @ 35 mo. (-0.5/+0.2)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.83 (-0.3/+0.1)	99.83 @ 35 mo. (-0.3/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 7000	Effective Sample Size	3888	1657	281	-	-	-	-	-	-	-	-

INCEPTA ICD DR

Models E163/F163

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

INCEPTA ICD DR Models E163/F163			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	-	
⁸⁶ High voltage circuit	1	-	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	2	1	3
Non-patterned	2	1	
WW Confirmed Malfunctions	7	1	8

[More details](#) about malfunctions

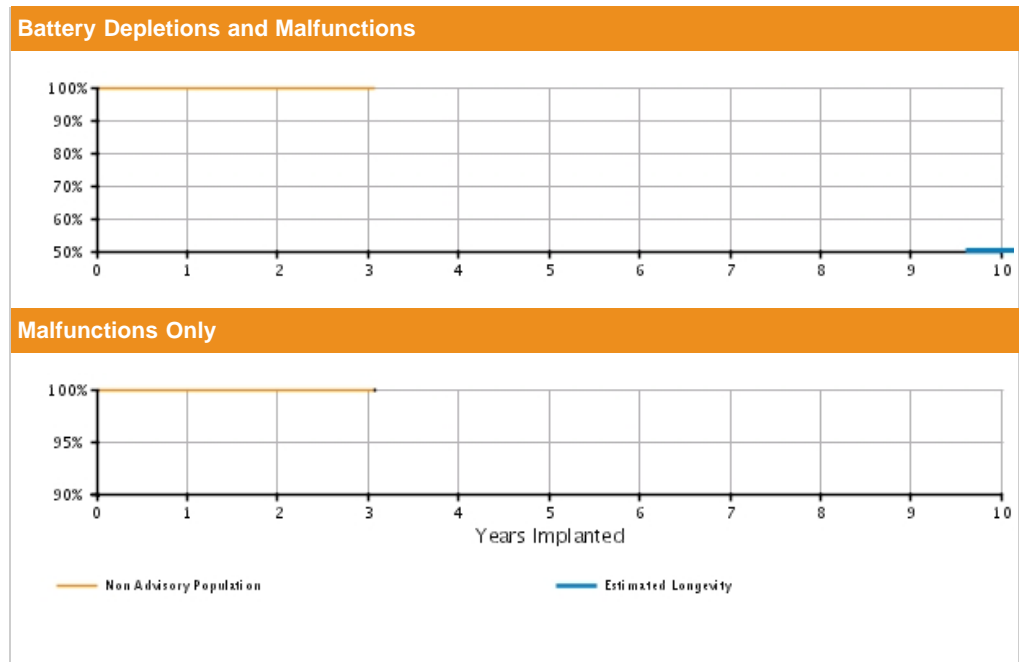
[References](#) cited in table above

INCEPTA ICD VR 4-Site

Models E160/F160

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

U.S. Summary	
U.S. Registered Implants: 10,000	U.S. Normal Battery Depletions: 3
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 Registered Implants: 10000	Depletions and Malfunctions (%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.87 @ 37 mo. (-0.2/+0.1)	—	—	—	—	—	—	—
	Malfunctions Only (%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.92 (-0.2/+0.1)	99.92 @ 37 mo. (-0.2/+0.1)	—	—	—	—	—	—	—
	Effective Sample Size	5730	2406	354	226	—	—	—	—	—	—	—

INCEPTA ICD VR 4-Site

Models E160/F160

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA ICD VR 4-Site
Models E160/F160



Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

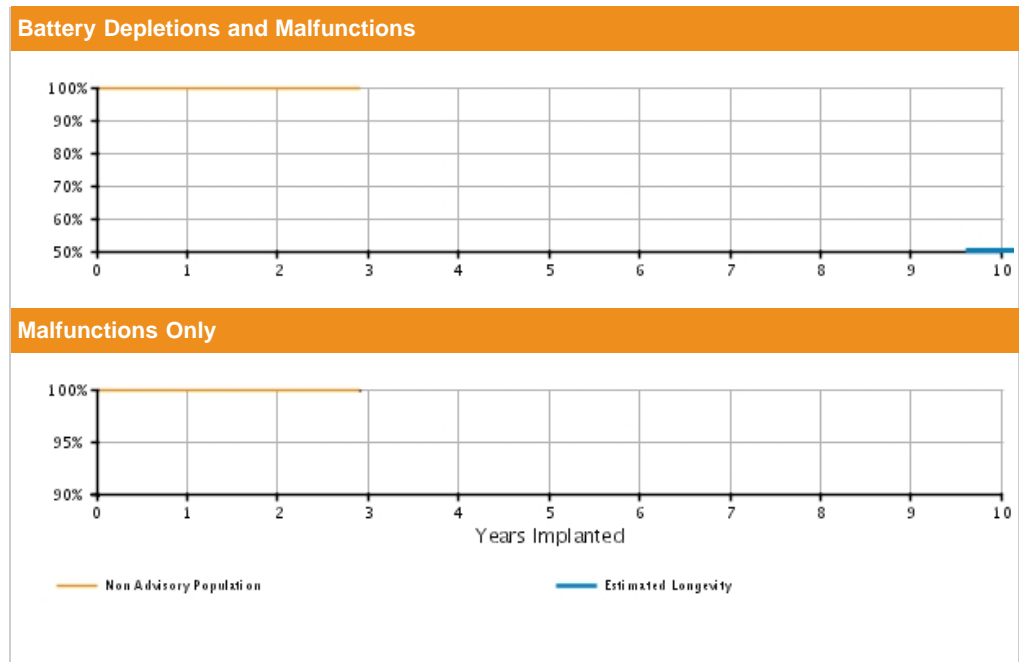
[References](#) cited in table above

INCEPTA ICD VR

Models E161/F161

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

U.S. Summary	
U.S. Registered Implants: 4,000	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: 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)	99.95 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.90 @ 35 mo. (-0.2/+0.1)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 35 mo. (-0.2/+0.0)	—	—	—	—	—	—	—	—
Registered Implants: 4000	Effective Sample Size	2314	1098	211	—	—	—	—	—	—	—	—

INCEPTA ICD VR

Models E161/F161

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

INCEPTA ICD VR
Models E161/F161



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷¹ High-voltage capacitor	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

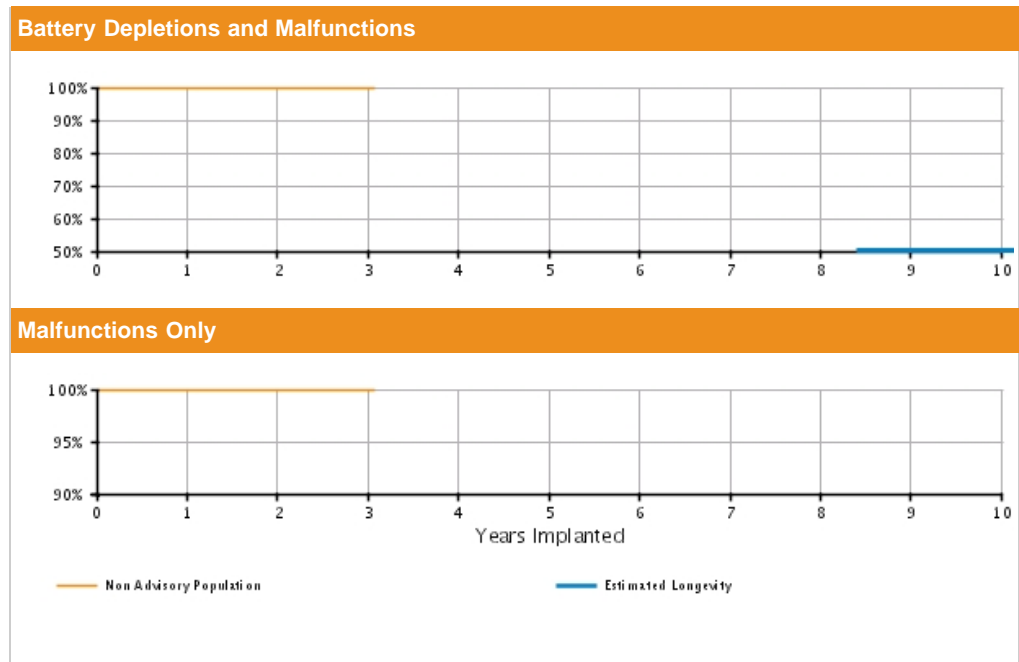
[References](#) cited in table above

ENERGEN ICD DR 4-Site

Models E142/F142

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

U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 5
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 13,000	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(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.85 @ 37 mo. (-0.1/+0.1)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 37 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
Registered Implants: 14000	Effective Sample Size	9423	4658	646	374	-	-	-	-	-	-	-

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: 20,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	2	5
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	2	
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

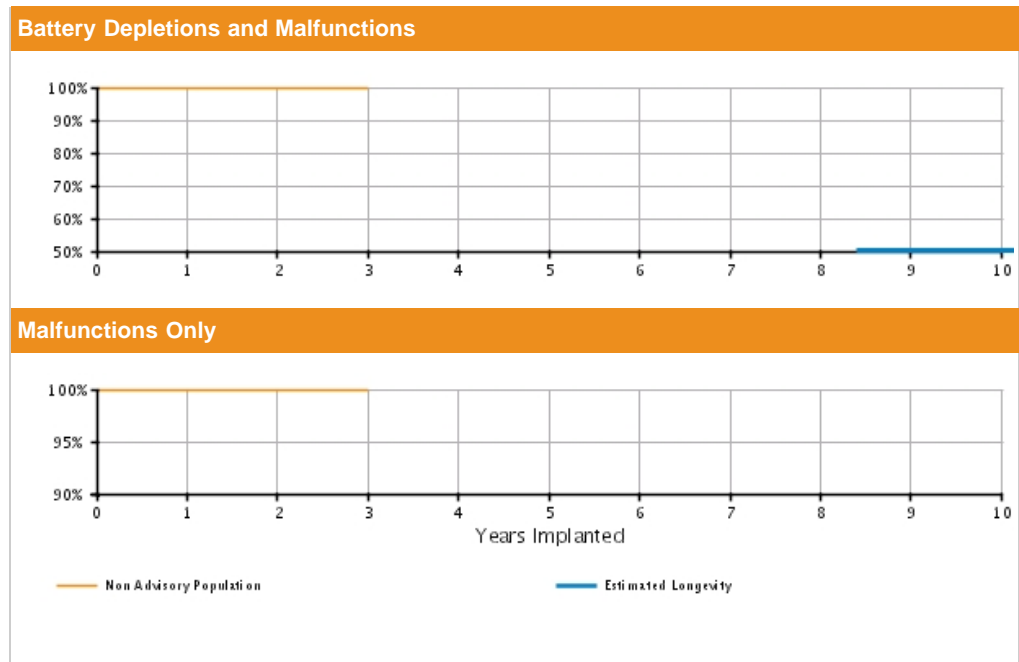
[References](#) cited in table above

ENERGEN ICD DR

Models E143/F143

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

U.S. Summary	
U.S. Registered Implants: 10,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 9,000	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	99.92	99.92	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)								
Registered Implants: 10000	Malfunctions Only (%)	99.99	99.99	99.99	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)								
	Effective Sample Size	6871	3187	310	—	—	—	—	—	—	—	—

ENERGEN ICD DR

Models E143/F143

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

ENERGEN ICD DR
Models E143/F143



Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁷⁵ Low-voltage capacitors	1	-	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

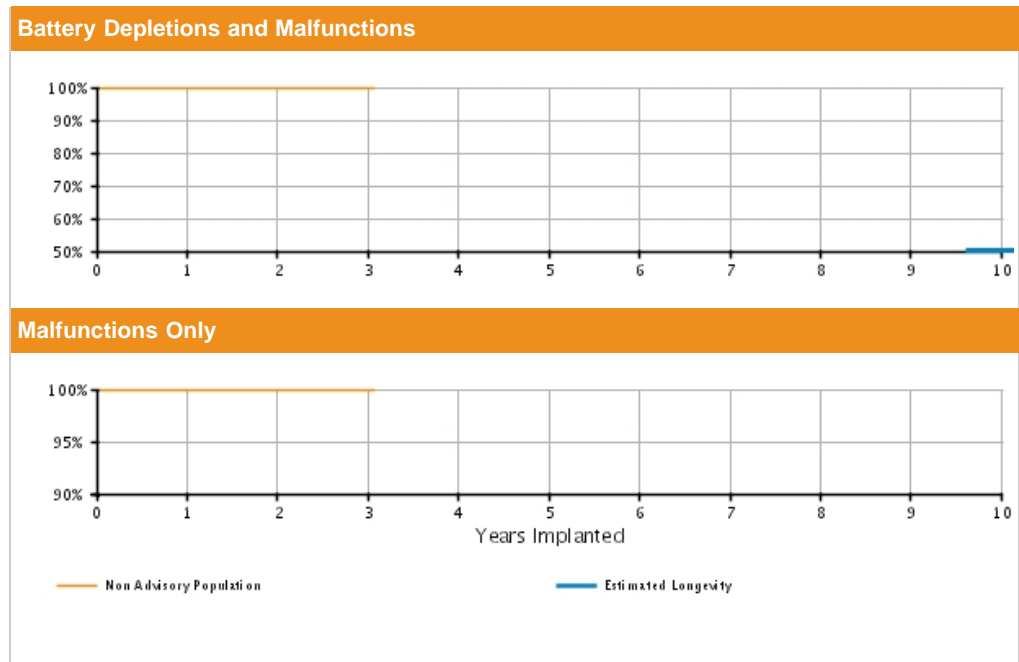
[References](#) cited in table above

ENERGEN ICD VR 4-Site

Models E140/F140

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

U.S. Summary	
U.S. Registered Implants: 14,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 13,000	U.S. Normal Battery Depletions: 11 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:4 Without Compromised Therapy:0 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)	99.93 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.78 (-0.2/+0.1)	99.78 @ 37 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 37 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
Registered Implants: 14000	Effective Sample Size	9533	4289	556	343	-	-	-	-	-	-	-

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: 21,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸¹ Battery	1	-	
Mechanical	-	2	2
⁶⁴ Transformer	-	2	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	-	2	2
Non-patterned	-	2	
WW Confirmed Malfunctions	2	4	6

[More details](#) about malfunctions

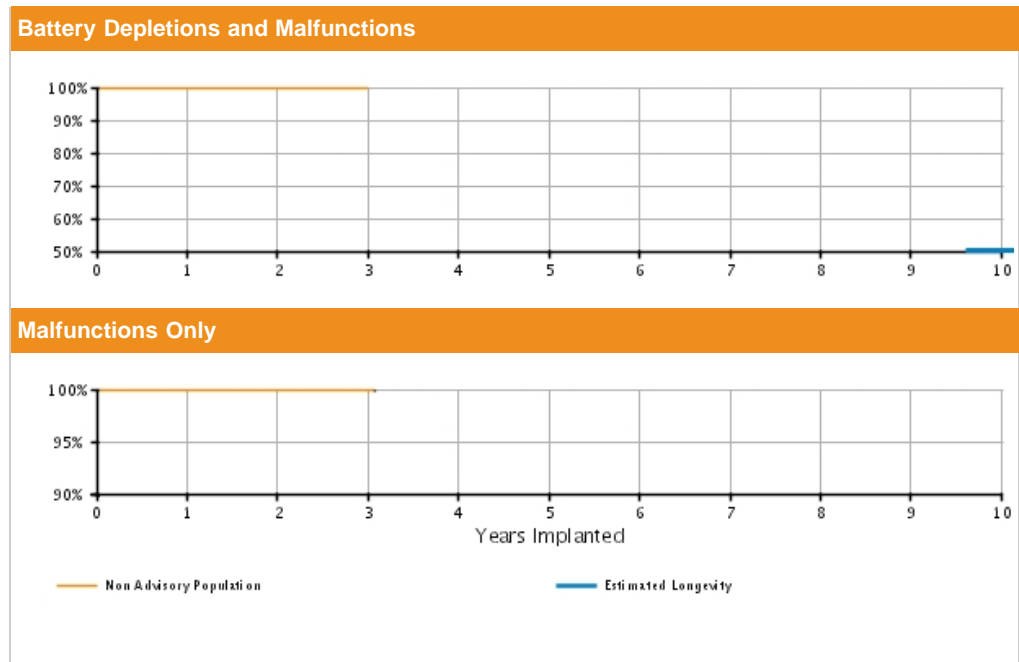
[References](#) cited in table above

ENERGEN ICD VR

Models E141/F141

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

U.S. Summary	
U.S. Registered Implants: 7,000	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: 6,000	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(%)	99.90	99.84	99.84	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)								
Registered Implants: 7000	Malfunctions Only(%)	99.94	99.94	99.94	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)								
Effective Sample Size		4799	2335	290	—	—	—	—	—	—	—	—

ENERGEN ICD VR

Models E141/F141

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

ENERGEN ICD VR
Models E141/F141



Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
⁷⁸ Integrated circuit	-	3	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	2	4	6

[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
---------------------------	-------------------------------	--------------------

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

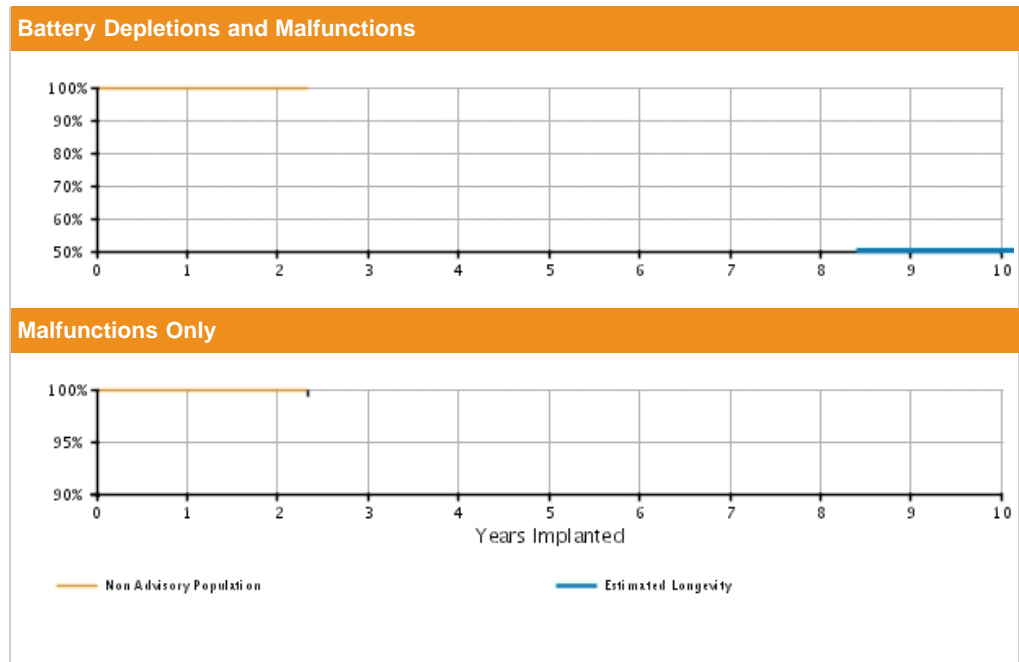
[References](#) cited in table above

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)	99.90 (-0.6/+0.1)	99.90 (-0.6/+0.1)	99.90 @ 28 mo. (-0.6/+0.1)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.6/+0.1)	99.90 (-0.6/+0.1)	99.90 @ 28 mo. (-0.6/+0.1)	—	—	—	—	—	—	—	—
Registered Implants: 1000	Effective Sample Size	719	335	205	—	—	—	—	—	—	—	—

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

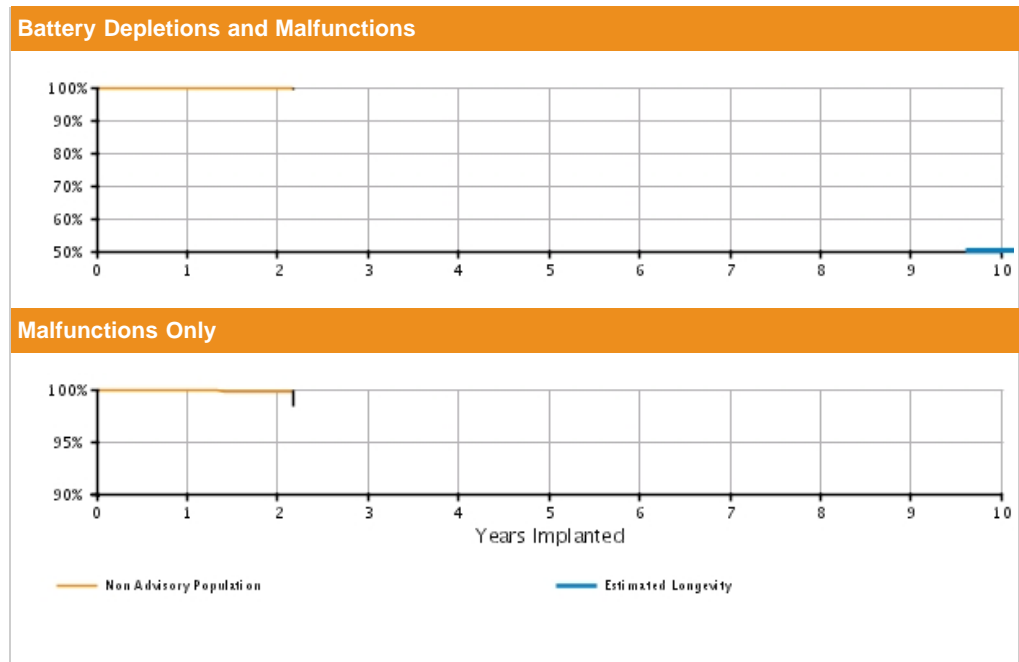
[References](#) cited in table above

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(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.76 (-1.4/+0.2)	99.76 @ 26 mo. (-1.4/+0.2)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.76 (-1.4/+0.2)	99.76 @ 26 mo. (-1.4/+0.2)	-	-	-	-	-	-	-	-
Registered Implants: 1000	Effective Sample Size	537	269	221	-	-	-	-	-	-	-	-

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
⁸⁶ High voltage circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

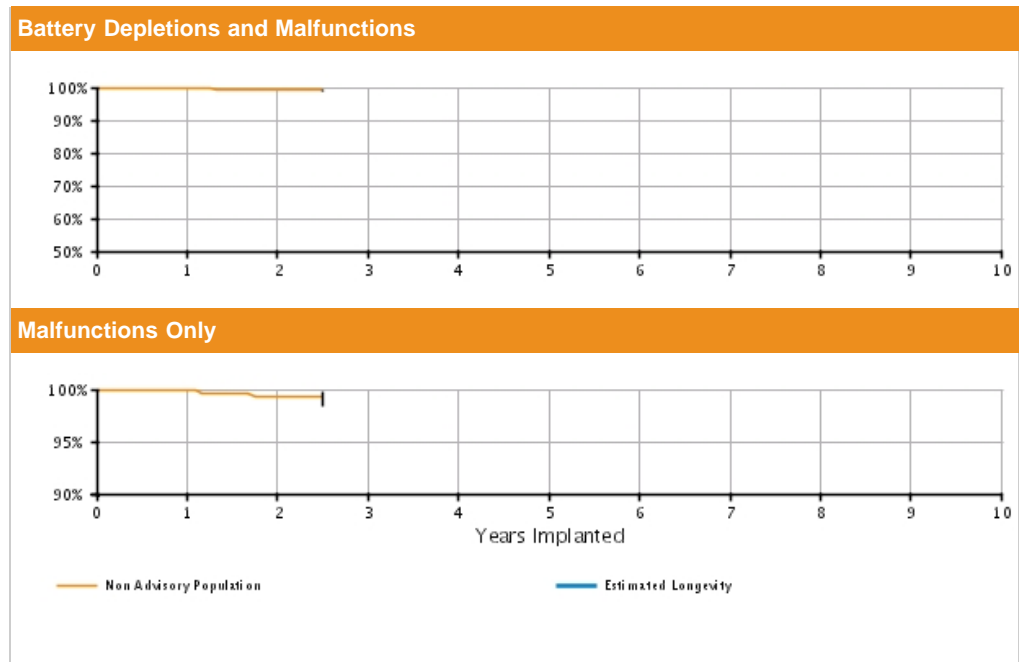
[References](#) cited in table above

SQ-RX S-ICD

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: 2 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:14 Without Compromised Therapy:7 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(%) (Confidence Interval)	99.81 (-0.2/+0.1)	99.28 (-0.9/+0.4)	99.28 @ 30 mo. (-0.9/+0.4)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.2/+0.1)	99.32 (-0.9/+0.4)	99.32 @ 30 mo. (-0.9/+0.4)	—	—	—	—	—	—	—	—
		—	—	—	—	—	—	—	—	—	—	—


*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 S-ICD

Model 1010

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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SQ-RX S-ICD Model 1010 			
Worldwide Confirmed Malfunctions: 53			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
² Unintended Fuse Activation 2013 (Advisory issued)	-	3	
⁸⁹ Charge Timeout Alert	3	-	
Mechanical	11	11	22
³ High cathode condition 2011 (Advisory issued)	1	2	
⁸³ Battery depletion	10	9	
Software	2	-	2
⁸⁵ Unintended Battery Depletion Alert	2	-	
Other	11	12	23
Non-patterned	9	7	
⁸⁴ Telemetry	2	5	
WW Confirmed Malfunctions	27	26	53

[More details](#) about malfunctions

[References](#) cited in table above

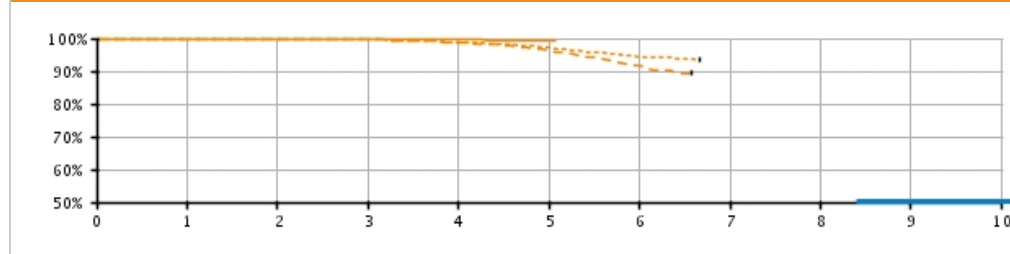
TELIGEN DR

Models E110/E111/F110/F111

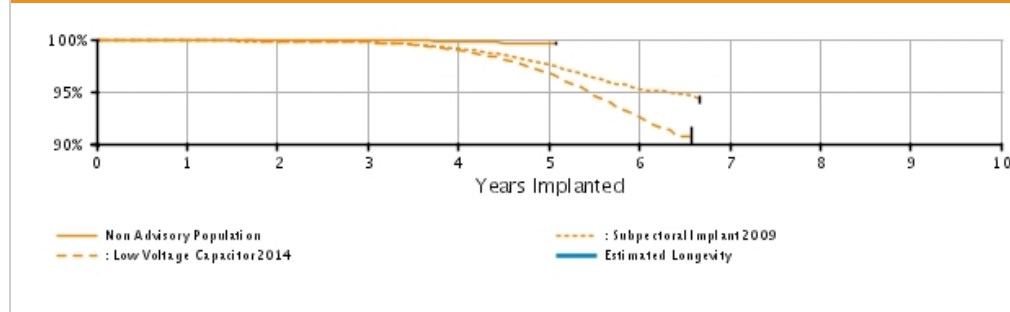
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 66,000	U.S. Normal Battery Depletions: 135
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 47
U.S. Estimated Active Implants: 45,000	U.S. Malfunctions:839
	Without Compromised Therapy:751
	With Compromised Therapy:88

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: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.79 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.21 @ 59 mo. (-0.3/+0.2)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.78 (-0.1/+0.1)	99.60 @ 59 mo. (-0.2/+0.1)	-	-	-	-	-
	Effective Sample Size	26439	23338	20209	9806	329	-	-	-	-	-
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)	97.20 (-0.2/+0.7)	94.48 (-0.6/+1.3)	93.36 @ 80 mo. (-0.8/+1.8)	-	-	-
	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)	97.58 (-0.2/+0.2)	95.29 (-0.4/+0.3)	94.30 @ 80 mo. (-0.4/+0.3)	-	-	-
	Effective Sample Size	26747	23501	20672	18054	15606	5657	307	-	-	-
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.74 (-0.2/+0.2)	96.35 (-0.4/+0.3)	91.59 (-1.5/+1.3)	89.43 @ 79 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)	98.95 (-0.2/+0.1)	96.62 (-0.3/+0.3)	92.62 (-1.1/+0.9)	90.66 @ 79 mo.	-	-	-
	Effective Sample Size										


						(-1.2/+1.0)			
Effective Sample Size	20716	18220	16012	13977	10456	2187	262	-	-

*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: 1121			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	952	58	1010
¹ Low Voltage Capacitor 2014 (Advisory issued)	788	21	
⁷⁰ Safety Core-electrocautery	3	-	
⁷¹ High-voltage capacitor	1	5	
⁷⁵ Low-voltage capacitors	6	-	
⁷⁸ Integrated circuit	16	18	
⁸¹ Battery	97	14	
⁸² Low-voltage capacitor	41	-	
Mechanical	19	49	68
⁵ Subpectoral implant 2009 (Advisory issued)	3	7	
⁶⁴ Transformer	-	20	
⁶⁷ Seal plug	3	-	
⁶⁸ Difficulty securing lead	9	8	
⁷³ Header contacts	2	11	
⁹¹ Header	2	3	
Software	15	-	15
⁷⁶ Alert messages not displayed post-EOL	3	-	
⁷⁹ Memory errors	12	-	
Other	20	8	28
Non-patterned	20	8	
WW Confirmed Malfunctions	1006	115	1121

[More details](#) about malfunctions

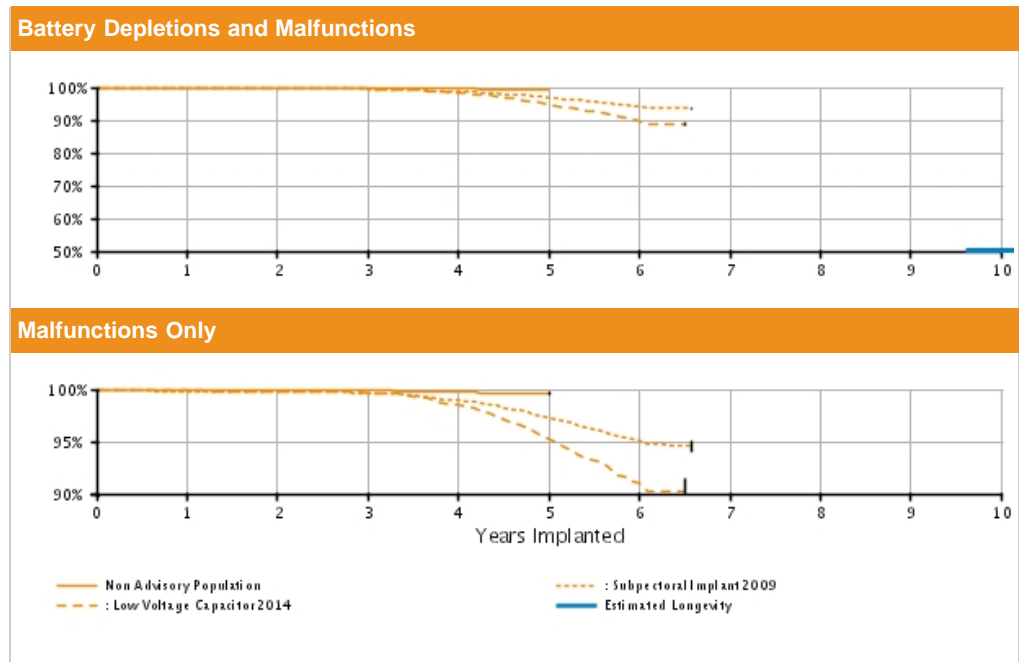
[References](#) cited in table above

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: 63
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 33
U.S. Estimated Active Implants: 26,000	U.S. Malfunctions:559
	Without Compromised Therapy:490
	With Compromised Therapy:69



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)	99.75 (-0.1/+0.1)	99.55 (-0.2/+0.1)	99.37 @ 58 mo. (-0.2/+0.2)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.59 @ 58 mo. (-0.2/+0.1)	-	-	-	-	-	-
	Effective Sample Size	16279	14332	12365	4785	233	-	-	-	-	-	-
Subpectoral Implant 2009* Registered Implants: 16,000	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)	96.93 (-0.4/+0.3)	94.27 (-0.6/+0.5)	93.67 @ 79 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)	97.33 (-0.3/+0.3)	95.01 (-0.6/+0.5)	94.55 @ 79 mo. (-0.5/+0.6)	-	-	-	-
	Effective Sample Size	13683	11999	10517	9152	7862	2937	432	-	-	-	-
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)	98.23 (-0.1/+0.5)	94.79 (-0.2/+0.9)	89.92 (-0.6/+1.8)	88.74 @ 78 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)	98.45 (-0.3/+0.2)	95.23 (-0.5/+0.5)	90.95 (-1.3/+1.1)	90.23 @ 78 mo.	-	-	-	-
	Effective Sample Size	12000	12000	12000	12000	12000	12000	12000	-	-	-	-


						(-1.5/+1.2)			
Effective Sample Size	10905	9580	8404	7291	4926	1041	235	-	-

*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
----------------------------------	--------------------------------------	---------------------------

TELIGEN VR Models E102/E103/F102/F103 			
Worldwide Distribution: 65,000			
Worldwide Confirmed Malfunctions: 861			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	710	37	747
¹ Low Voltage Capacitor 2014 (Advisory issued)	558	17	
⁷⁰ Safety Core-electrocautery	1	1	
⁷¹ High-voltage capacitor	-	2	
⁷⁵ Low-voltage capacitors	4	-	
⁷⁸ Integrated circuit	8	13	
⁸¹ Battery	117	4	
⁸² Low-voltage capacitor	22	-	
Mechanical	20	62	82
⁵ Subpectoral implant 2009 (Advisory issued)	5	14	
³⁹ Transformer	-	1	
⁶⁴ Transformer	-	14	
⁶⁷ Seal plug	1	-	
⁶⁸ Difficulty securing lead	-	10	
⁷³ Header contacts	12	16	
⁹¹ Header	2	7	
Software	15	-	15
⁶ Respiratory Sensor Oversensing	1	-	
⁷⁶ Alert messages not displayed post-EOL	4	-	
⁷⁹ Memory errors	10	-	
Other	7	10	17
Non-patterned	7	10	
WW Confirmed Malfunctions	752	109	861

[More details](#) about malfunctions

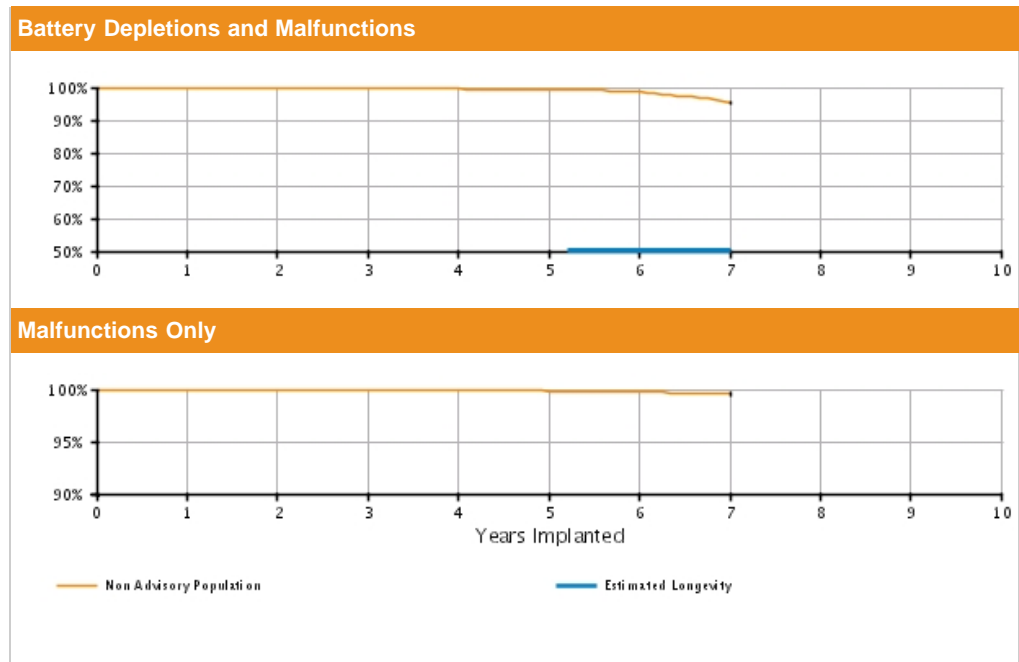
[References](#) cited in table above

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: 85
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:13
	Without Compromised Therapy:10
	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)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.54 (-0.2/+0.2)	99.35 (-0.3/+0.2)	98.57 (-0.5/+0.4)	95.32 (-1.3/+1.0)	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.84 (-0.2/+0.1)	99.76 (-0.2/+0.1)	99.56 (-0.3/+0.2)	—	—	—	—
Registered Implants: 7000	Effective Sample Size	6165	5398	4704	4044	3311	2431	339	—	—	—	—

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: 13			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	-	9
²³ Capacitor	1	-	
²⁷ Integrated circuit	2	-	
⁸² Low-voltage capacitor	6	-	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	1	2	3
Non-patterned	1	1	
³⁴ Battery depletion	-	1	
WW Confirmed Malfunctions	10	3	13

[More details](#) about malfunctions

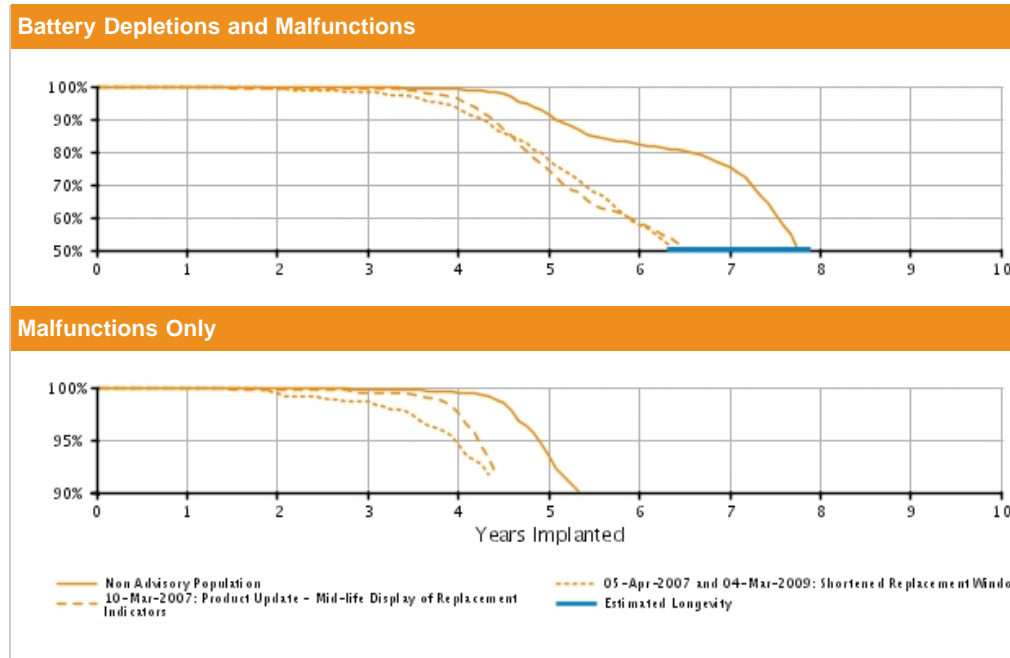
[References](#) cited in table above

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: 1,707
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions: 765



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)	91.28 (-1.1/+1.0)	82.33 (-1.5/+1.4)	75.02 (-1.9/+1.8)	45.41 (-3.3/+3.3)	–	–	–
	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)	93.40 (-1.0/+0.9)	87.32 (-1.4/+1.3)	86.71 (-1.4/+1.3)	86.61 (-1.4/+1.3)	–	–	–
	Effective Sample Size	4362	3831	3362	2919	2357	1801	1153	247	–	–	–
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)	93.31 (-1.5/+1.3)	77.40 (-2.6/+2.4)	57.88 (-3.2/+3.1)	31.65 (-3.2/+3.4)	28.57 (-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	NaN	–	–	–
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: 1058			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1019	10	1029
⁸ Shortened replacement window (Advisory issued)	143	2	
¹⁵ Extended charge time post-mid-life	15	-	
²³ Capacitor	1	-	
²⁷ Integrated circuit	-	4	
³⁸ Capacitor	1	-	
⁴⁸ Mid-life display of replacement indicators	817	-	
⁴⁹ High-voltage capacitor	-	2	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	42	1	
Mechanical	8	3	11
⁷ Subpectoral implant (Advisory issued)	1	1	
²⁴ Header	1	-	
³¹ Seal plug	5	1	
⁵⁶ Seal plug	1	-	
⁶⁴ Transformer	-	1	
Software	7	1	8
⁴⁷ Memory location	1	1	
⁶⁶ Misaligned markers	6	-	
Other	3	7	10
Non-patterned	2	3	
¹⁸ Firmware error	1	4	
WW Confirmed Malfunctions	1037	21	1058

[More details](#) about malfunctions

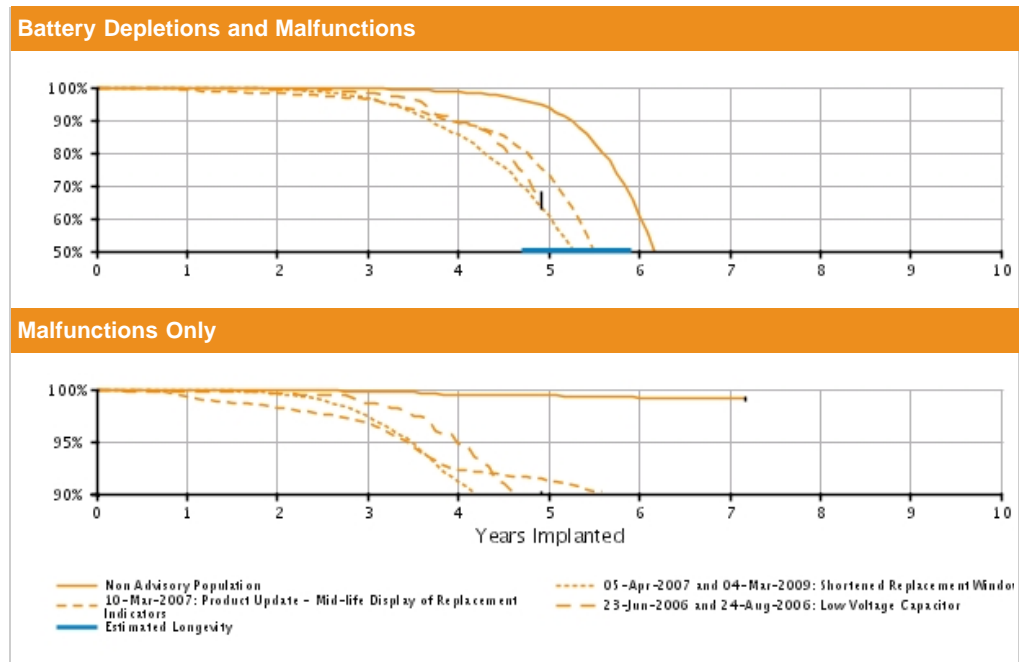
[References](#) cited in table above

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: 11,647
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 79
U.S. Estimated Active Implants: 4,000	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)	93.65 (-0.5/+0.5)	60.95 (-1.1/+1.1)	10.54 (-0.8/+0.8)	8.22 @ 86 mo. (-0.8/+0.8)	-	-	-
	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)	99.40 (-0.2/+0.1)	99.20 (-0.2/+0.2)	99.08 (-0.3/+0.2)	99.08 @ 86 mo. (-0.3/+0.2)	-	-	-
	Effective Sample Size	15245	13387	11743	10102	8246	4570	460	231	-	-	-
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)	17.76 (-1.2/+1.2)	6.53 @ 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)	84.17 @ 77 mo. (-1.5/+1.4)	-	-	-	-
	Effective Sample Size	7844	6862	5805	4450	2718	679	218	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 4000	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)	99.92 (-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)	84.17 @ 77 mo. (-1.5/+1.4)	-	-	-	-
	Effective Sample Size	4000	4000	4000	4000	4000	4000	4000	4000	-	-	-

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	NaN	-	-	-
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	NaN	-	-	-	-	-
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	
¹⁵ Extended charge time post-mid-life	101	1	
¹⁹ Integrated circuit	1	1	
²² Reconfirmation after charge	1	-	
²³ Capacitor	1	1	
²⁷ Integrated circuit	7	11	
³⁸ Capacitor	3	1	
⁴¹ Capacitor	4	-	
⁴² Device tones	1	-	
⁴⁸ Mid-life display of replacement indicators	268	-	
⁴⁹ High-voltage capacitor	4	1	
⁵³ Integrated circuit	1	-	
⁶¹ Logic errors	-	3	
⁶⁹ Low-voltage capacitor	234	2	
Mechanical	7	6	13
³¹ Seal plug	4	3	
³⁹ Transformer	-	1	
⁵⁶ Seal plug	2	-	
¹⁰⁰ Solder joint (Advisory issued)	1	2	
Software	2	2	4
⁴⁵ Memory location	-	2	
⁴⁷ Memory location	1	-	
⁶⁶ Misaligned markers	1	-	
Other	19	22	41
Non-patterned	12	8	
¹⁸ Firmware error	5	8	
²⁵ Battery depletion	2	5	
⁷² Magnet rate	-	1	
WW Confirmed Malfunctions	1295	76	1371

[More details](#) about malfunctions

[References](#) cited in table above

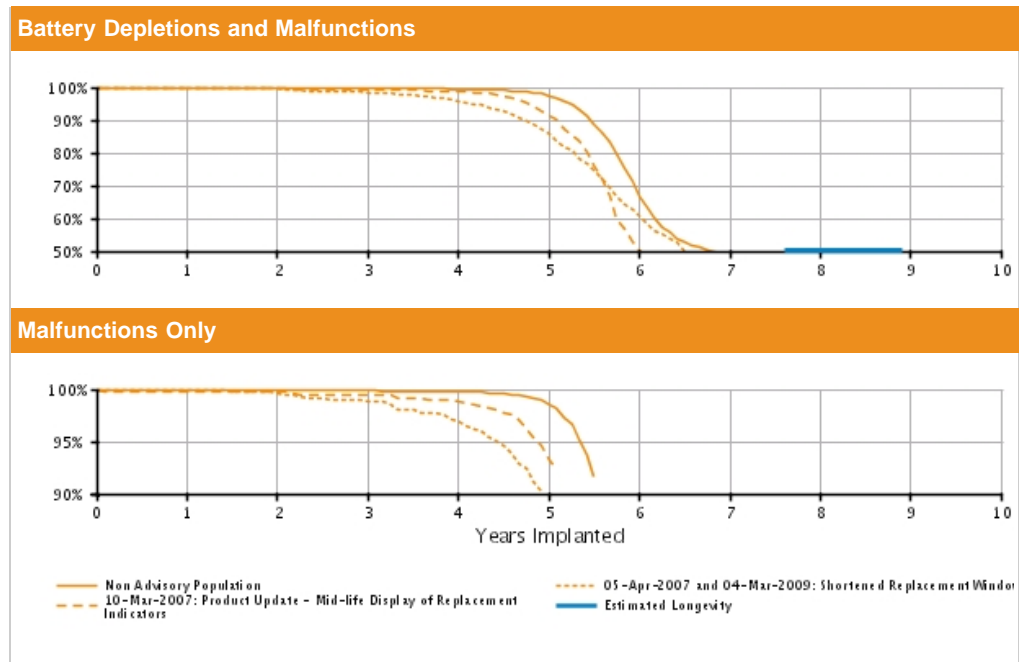
CRM PRODUCT PERFORMANCE REPORT Q2 2015

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. Approval Date: March 2004 U.S. Estimated Active Implants: 2,000	U.S. Normal Battery Depletions: 990 U.S. Unconfirmed Reports of Premature Battery Depletion : 9 U.S. Malfunctions:1255 Without Compromised Therapy:1242 With Compromised Therapy:13
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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)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.39 (-0.4/+0.2)	97.35 (-0.7/+0.6)	66.64 (-2.2/+2.1)	48.77 (-2.4/+2.4)	42.29 @ 92 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)	73.23 (-2.1/+2.0)	59.14 (-2.5/+2.4)	57.83 @ 92 mo. (-2.6/+2.6)	-	-	-
	Effective Sample Size	3631	3176	2774	2402	2049	1242	508	216	-	-	-
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)	60.87 (-3.2/+3.2)	41.42 (-3.4/+3.5)	33.95 @ 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)	68.34 (-3.2/+3.1)	60.99 (-3.5/+3.4)	60.46 @ 88 mo. (-3.6/+3.4)	-	-	-
	Effective Sample Size	1687	1474	1279	1087	822	495	277	207	-	-	-
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	495	277	207	-	-	-

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: 1861			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1821	8	1829
⁸ Shortened replacement window (Advisory issued)	139	1	
⁹ Low-voltage capacitor (Advisory issued)	2	1	
¹⁵ Extended charge time post-mid-life	15	2	
²⁷ Integrated circuit	-	3	
³⁸ Capacitor	1	-	
⁴¹ Capacitor	2	-	
⁴⁸ Mid-life display of replacement indicators	1595	1	
⁴⁹ High-voltage capacitor	2	-	
⁶⁹ Low-voltage capacitor	65	-	
Mechanical	2	8	10
⁷ Subpectoral implant (Advisory issued)	-	5	
²⁴ Header	-	1	
³¹ Seal plug	1	-	
⁵¹ Sensing	1	-	
⁶⁴ Transformer	-	2	
Software	-	2	2
⁴⁵ Memory location	-	1	
⁴⁷ Memory location	-	1	
Other	11	9	20
Non-patterned	11	7	
²⁵ Battery depletion	-	2	
WW Confirmed Malfunctions	1834	27	1861

[More details](#) about malfunctions

[References](#) cited in table above

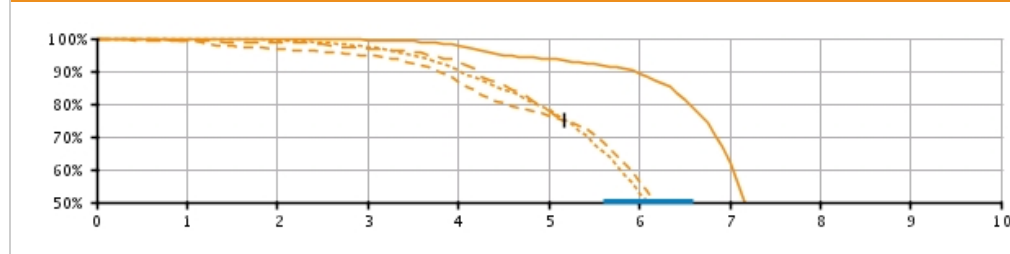
VITALITY 2 VR

Model T175

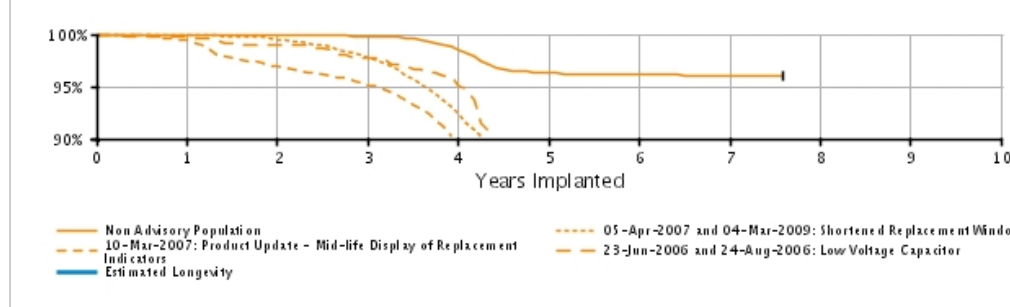
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Normal Battery Depletions: 5,452
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 35
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:1240
	Without Compromised Therapy:1215
	With Compromised Therapy:25

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: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.49 (-0.2/+0.1)	97.62 (-0.4/+0.3)	93.76 (-0.6/+0.6)	89.11 (-0.9/+0.8)	61.89 (-1.6/+1.6)	14.45 @ 91 mo. (-1.8/+2.0)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	98.46 (-0.3/+0.3)	96.30 (-0.5/+0.4)	96.12 (-0.5/+0.5)	95.98 (-0.5/+0.5)	95.98 @ 91 mo. (-0.5/+0.5)	-	-
	Effective Sample Size	9497	8337	7262	6163	4987	3997	1850	NaN	-	-
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)	78.07 (-1.4/+1.3)	52.55 (-1.8/+1.8)	16.95 (-1.5/+1.6)	9.13 @ 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)	86.39 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.19 (-1.5/+1.4)	83.19 @ 87 mo. (-1.5/+1.4)	-	-
	Effective Sample Size	5391	4691	4022	3236	2376	1374	364	NaN	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 4000	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)	56.30 (-2.1/+2.1)	15.99 (-1.7/+1.9)	13.66 @ 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)	86.39 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.19 (-1.5/+1.4)	83.19 @ 87 mo. (-1.5/+1.4)	-	-
	Effective Sample Size	4000	3500	3000	2500	2000	1500	1000	500	-	-

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)	81.60 (-1.8/+1.7)	81.60 @ 85 mo. (-1.8/+1.7)	-	-
	Effective Sample Size	3907	3331	2852	2262	1680	1059	245	204	-	-
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)	96.87 (-2.1/+1.3)	92.76 (-3.1/+2.2)	77.80 (-5.0/+4.3)	75.17 @ 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)	97.72 (-1.9/+1.1)	95.06 (-2.7/+1.8)	84.87 (-4.5/+3.6)	84.87 @ 62 mo. (-4.5/+3.6)	-	-	-	-
	Effective Sample Size	503	430	364	305	214	NaN	-	-	-	-
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: 1583			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1530	26	1556
⁸ Shortened replacement window (Advisory issued)	347	9	
⁹ Low-voltage capacitor (Advisory issued)	-	1	
¹⁰ Premature battery depletion (Advisory issued)	219	6	
¹⁵ Extended charge time post-mid-life	63	-	
¹⁹ Integrated circuit	-	1	
²³ Capacitor	1	-	
²⁷ Integrated circuit	4	7	
³⁸ Capacitor	1	-	
⁴¹ Capacitor	4	-	
⁴⁸ Mid-life display of replacement indicators	771	-	
⁴⁹ High-voltage capacitor	-	1	
⁶⁹ Low-voltage capacitor	120	1	
Mechanical	2	1	3
³¹ Seal plug	2	1	
Software	-	1	1
⁴⁷ Memory location	-	1	
Other	17	6	23
Non-patterned	15	6	
²⁵ Battery depletion	2	-	
WW Confirmed Malfunctions	1549	34	1583

[More details](#) about malfunctions

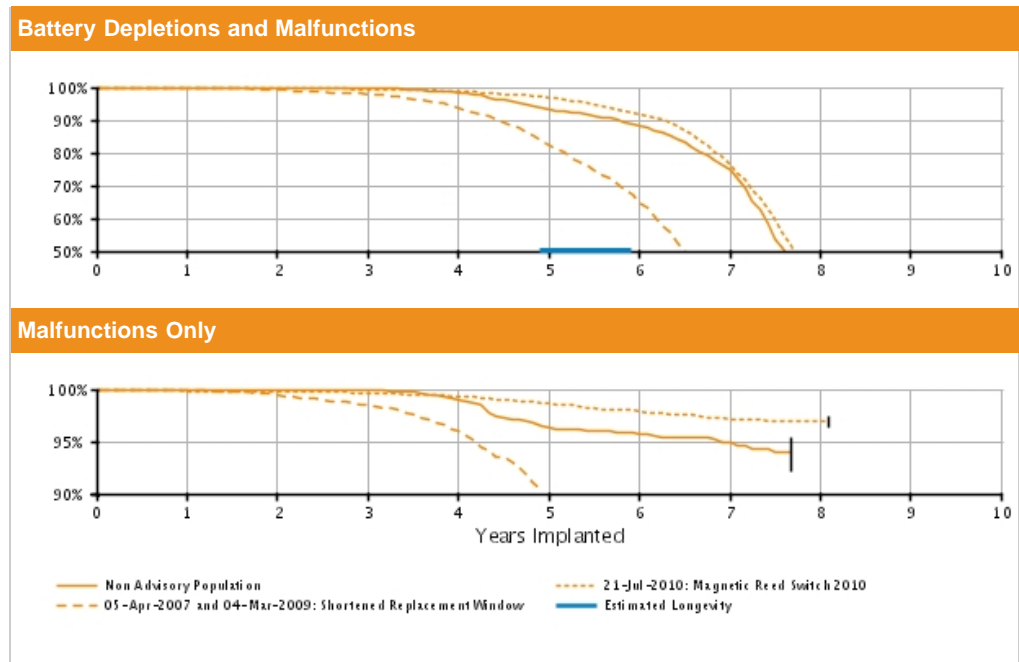
[References](#) cited in table above

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: 2,715
U.S. Approval Date: May 2005	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:416
	Without Compromised Therapy:386
	With Compromised Therapy:30



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)	93.30 (-1.4/+1.2)	88.28 (-1.9/+1.6)	74.58 (-2.7/+2.5)	46.76 @ 92 mo. (-4.1/+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)	95.67 (-1.2/+1.0)	94.94 (-1.4/+1.1)	93.95 @ 92 mo. (-1.8/+1.4)	-	-	
	Effective Sample Size	2235	1950	1699	1464	1203	980	630	202	-	-	
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)	76.49 (-1.5/+1.4)	35.58 (-2.4/+2.5)	31.51 @ 97 mo. (-2.5/+2.6)	-	
	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)	97.09 (-0.6/+0.5)	96.90 (-0.6/+0.5)	96.90 @ 97 mo. (-0.6/+0.5)	-	
	Effective Sample Size	6979	6087	5304	4598	3914	3207	2278	346	255	-	
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)	82.32 (-1.9/+1.7)	64.78 (-2.5/+2.4)	34.48 (-2.7/+2.8)	21.78 @ 90 mo. (-2.4/+2.6)	-	-	
	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)	82.32 (-1.9/+1.7)	64.78 (-2.5/+2.4)	34.48 (-2.7/+2.8)	21.78 @ 90 mo. (-2.4/+2.6)	-	-	
	Effective Sample Size	6979	6087	5304	4598	3914	3207	2278	346	255	-	


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)	89.76 (-1.6/+1.4)	84.82 (-2.0/+1.8)	79.85 (-2.5/+2.3)	78.97 @ 90 mo. (-2.7/+2.5)	-	-
	Effective Sample Size	2673	2314	1995	1652	1238	827	371	210	-	-

*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	369	5	374
⁸ Shortened replacement window (Advisory issued)	88	1	
¹⁵ Extended charge time post-mid-life	24	-	
²³ Capacitor	2	1	
²⁷ Integrated circuit	3	1	
³⁸ Capacitor	1	1	
⁴⁸ Mid-life display of replacement indicators	170	-	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	81	-	
Mechanical	6	19	25
⁴ Magnetic reed switch 2010 (Advisory issued)	2	10	
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁴ Header	3	7	
⁵⁵ Setscrew	1	-	
⁶² Reed switch	-	1	
Software	1	2	3
⁴⁵ Memory location	-	1	
⁴⁷ Memory location	-	1	
⁶⁶ Misaligned markers	1	-	
Other	10	4	14
Non-patterned	8	3	
²⁵ Battery depletion	1	1	
³⁴ Battery depletion	1	-	
WW Confirmed Malfunctions	386	30	416

[More details](#) about malfunctions

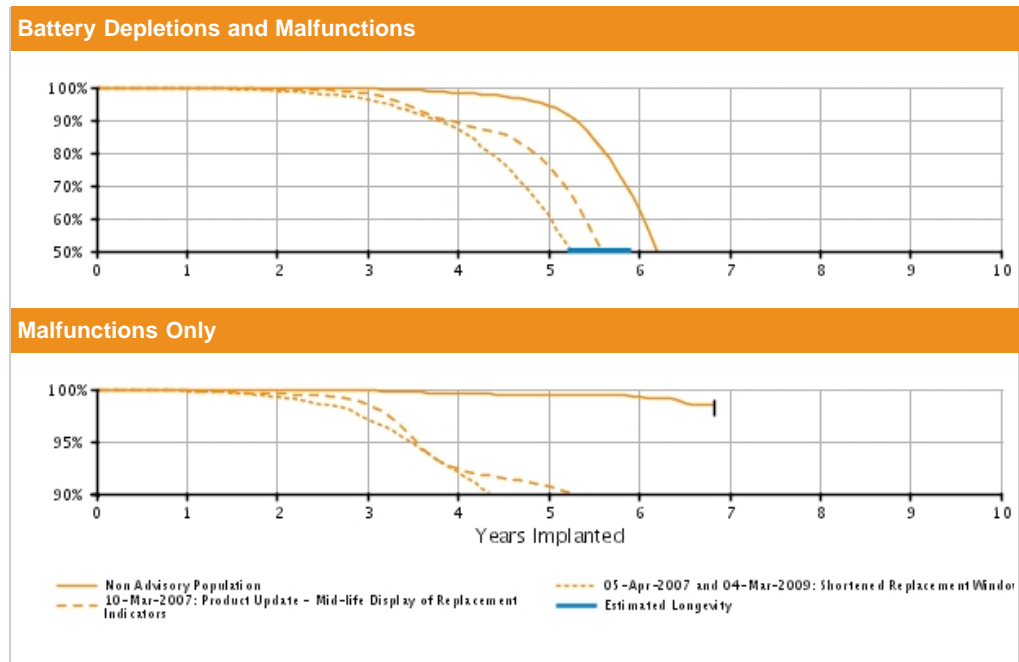
[References](#) cited in table above

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: 8,273
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:1187
	Without Compromised Therapy:1148
	With Compromised Therapy:39



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)	98.39 (-0.4/+0.4)	94.50 (-0.8/+0.7)	62.75 (-1.9/+1.8)	11.38 @ 82 mo. (-1.4/+1.6)	-	-	-	-
	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)	99.28 (-0.4/+0.2)	98.44 @ 82 mo. (-1.0/+0.6)	-	-	-	-
	Effective Sample Size	5265	4644	4049	3459	2811	1526	201	-	-	-	-
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)	96.16 (-0.7/+0.6)	87.05 (-1.2/+1.1)	60.74 (-1.9/+1.8)	17.54 (-1.6/+1.7)	10.27 @ 75 mo. (-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)	84.02 @ 75 mo. (-2.2/+1.9)	-	-	-	-
	Effective Sample Size	4302	3766	3202	2519	1484	344	NaN	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 2000	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)	29.31 (-1.2/+1.2)	5.89 @ 79 mo. (-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)	29.31 (-1.2/+1.2)	5.89 @ 79 mo. (-0.7/+0.8)	-	-	-	-
	Effective Sample Size	2000	2000	2000	2000	2000	2000	2000	-	-	-	-


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)	86.69 @ 79 mo. (-1.5/+1.4)	-	-	-
	Effective Sample Size	10839	9499	8204	6406	4723	1510	249	-	-	-
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: 1188			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1114	23	1137
⁸ Shortened replacement window (Advisory issued)	207	8	
¹⁰ Premature battery depletion (Advisory issued)	68	2	
¹⁵ Extended charge time post-mid-life	146	2	
¹⁹ Integrated circuit	1	-	
²⁷ Integrated circuit	2	8	
⁴¹ Capacitor	3	-	
⁴⁸ Mid-life display of replacement indicators	589	-	
⁴⁹ High-voltage capacitor	2	1	
⁶¹ Logic errors	-	1	
⁶⁹ Low-voltage capacitor	96	1	
Mechanical	11	5	16
³¹ Seal plug	11	3	
³⁹ Transformer	-	1	
¹⁰⁰ Solder joint (Advisory issued)	-	1	
Software	6	-	6
²⁸ Impedance measurements	2	-	
⁴⁷ Memory location	1	-	
⁶⁶ Misaligned markers	3	-	
Other	18	11	29
Non-patterned	8	3	
¹⁸ Firmware error	5	8	
²⁵ Battery depletion	5	-	
WW Confirmed Malfunctions	1149	39	1188

[More details](#) about malfunctions

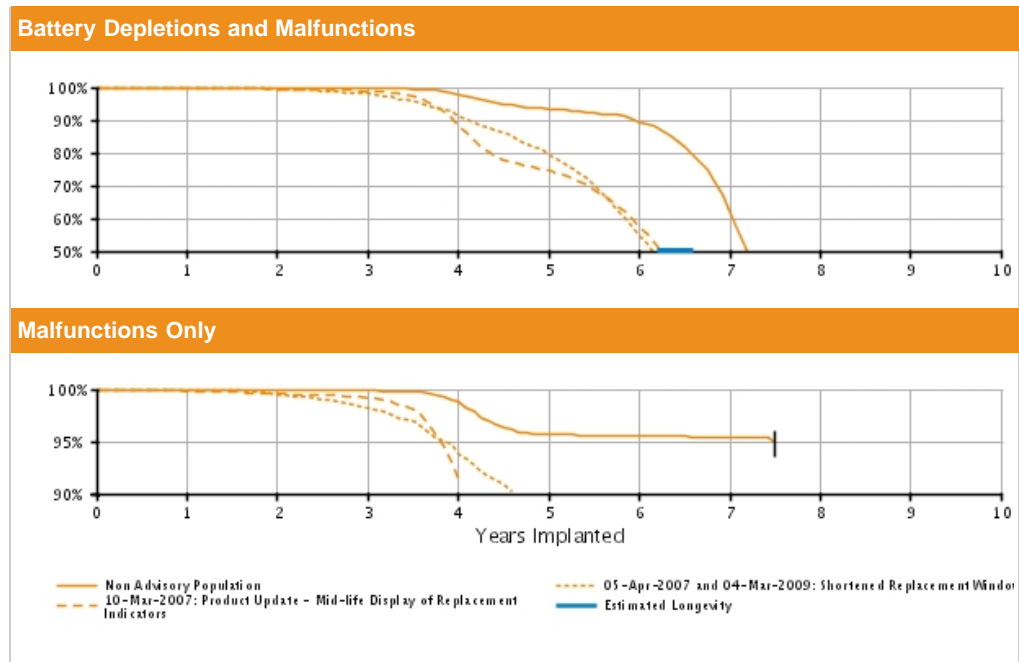
[References](#) cited in table above

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. Normal Battery Depletions: 5,506
U.S. Approval Date: July 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 39
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1555
	Without Compromised Therapy:1539
	With Compromised Therapy:16



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.92	99.72	97.95	93.31	89.40	61.38	25.67	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.6/+0.5)	(-1.1/+0.9)	(-1.4/+1.2)	(-2.6/+2.5)	@ 90 mo. (-2.8/+3.1)			
	Registered Implants: 4000											
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%)	99.94	99.40	98.02	91.28	79.23	54.56	19.09	16.08	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.4/+0.2)	(-0.6/+0.5)	(-1.2/+1.1)	(-1.8/+1.7)	(-2.3/+2.3)	(-2.0/+2.1)	@ 85 mo. (-1.9/+2.1)			
	Registered Implants: 4000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%)	99.76	99.49	98.88	88.44	74.53	57.39	20.92	5.43	-	-	-
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.2)	(-0.8/+0.7)	(-1.1/+1.0)	(-1.3/+1.3)	(-1.2/+1.2)	@ 90 mo. (-0.7/+0.8)			
	Registered Implants: 4000											
		Effective Sample Size	3863	3373	2952	2527	2036	1599	740	NaN	-	-
		Effective Sample Size	3237	2836	2447	1979	1475	866	254	211	-	-


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	4224	2792	849	NaN	-	-
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: 1556			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1525	11	1536
⁸ Shortened replacement window (Advisory issued)	122	1	
⁹ Low-voltage capacitor (Advisory issued)	2	-	
¹⁰ Premature battery depletion (Advisory issued)	61	4	
¹⁵ Extended charge time post-mid-life	70	-	
²³ Capacitor	2	1	
²⁷ Integrated circuit	-	1	
³⁸ Capacitor	3	1	
⁴¹ Capacitor	2	1	
⁴⁸ Mid-life display of replacement indicators	1211	-	
⁴⁹ High-voltage capacitor	3	1	
⁶⁹ Low-voltage capacitor	49	1	
Mechanical	4	2	6
³¹ Seal plug	3	1	
⁵⁶ Seal plug	-	1	
⁶³ Cracked solder joint	1	-	
Software	2	-	2
²⁸ Impedance measurements	2	-	
Other	9	3	12
Non-patterned	7	1	
²⁵ Battery depletion	2	2	
WW Confirmed Malfunctions	1540	16	1556


[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
¹⁵ Extended charge time post-mid-life	168	1	
²³ Capacitor	6	-	
²⁷ Integrated circuit	-	1	
⁴⁸ Mid-life display of replacement indicators	536	-	
⁵³ Integrated circuit	1	-	
Mechanical	9	2	11
²⁴ Header	2	1	
³¹ Seal plug	7	-	
¹⁰⁰ Solder joint (Advisory issued)	-	1	
Software	3	-	3
³⁵ Reset during charge	1	-	
⁵² Software download	2	-	
Other	3	4	7
Non-patterned	3	3	
²⁵ 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
---------------------------	-------------------------------	--------------------

VITALITY VR Model 1870				
Worldwide Distribution: 10,000				
Worldwide Confirmed Malfunctions: 1144				
	Without Compromised Therapy	With Compromised Therapy	Total	
Electrical	1129	2	1131	
¹⁵ Extended charge time post-mid-life	103	-		
¹⁹ Integrated circuit	1	-		
²³ Capacitor	7	-		
²⁷ Integrated circuit	-	2		
⁴⁸ Mid-life display of replacement indicators	1018	-		
Mechanical	1	2	3	
²⁴ Header	-	1		
³¹ Seal plug	1	-		
⁵⁵ Setscrew	-	1		
Software	1	-	1	
⁵² Software download	1	-		
Other	6	3	9	
Non-patterned	4	2		
²⁵ Battery depletion	2	1		
WW Confirmed Malfunctions	1137	7	1144	

[More details](#) about malfunctions

[References](#) cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ACCOLADE/PROPONENT/ESSENTIO DR EL

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

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

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ACCOLADE/PROPONENT/ESSENTIO DR

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

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

ACCOLADE/PROPONENT/ESSENTIO DR 

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

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

ACCOLADE/PROPONENT/ESSENTIO SR

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

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

ACCOLADE/PROPONENT/ESSENTIO SR 

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

Worldwide Distribution: 400
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

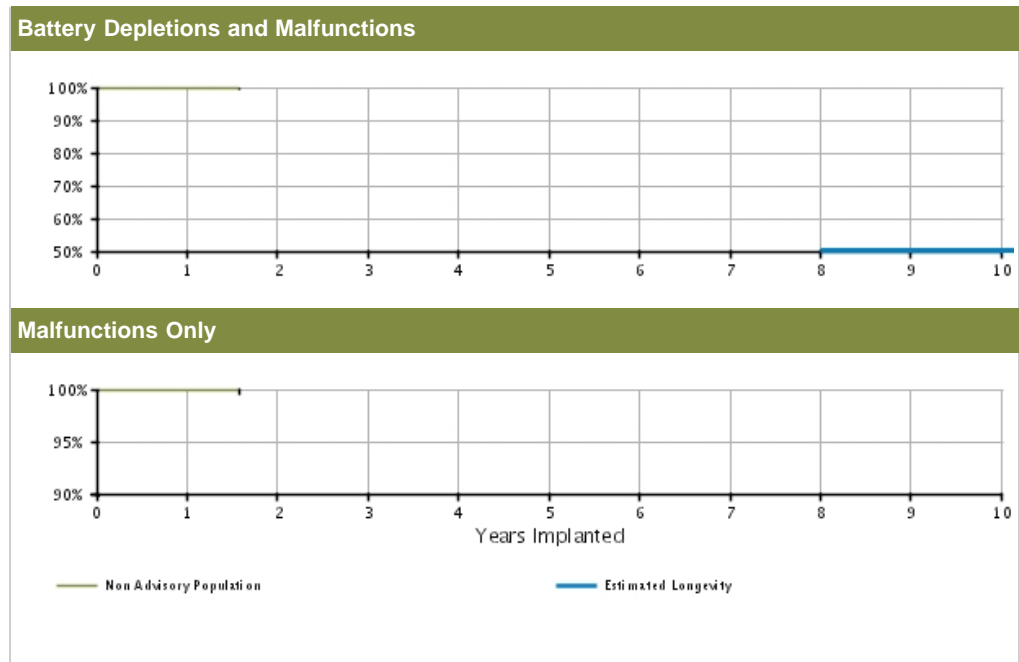
[References](#) cited in table above

ADVANTIO EL DR

Models J064/K064/K067/K084

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

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(%)	99.93	99.80	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.4/+0.1)	@ 19 mo. (-0.7/+0.2)									
Registered Implants: 2000	Malfunctions Only(%)	99.93	99.93	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.4/+0.1)	@ 19 mo. (-0.4/+0.1)									
	Effective Sample Size	849	251	-	-	-	-	-	-	-	-	-

ADVANTIO EL DR

Models J064/K064/K067/K084

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ADVANTIO EL DR
Models J064/K064/K067/K084

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁵ Low-voltage capacitors	1	1	
Mechanical	-	-	0
Software	1	-	1
⁸⁷ Respiratory sensor	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

[References](#) cited in table above

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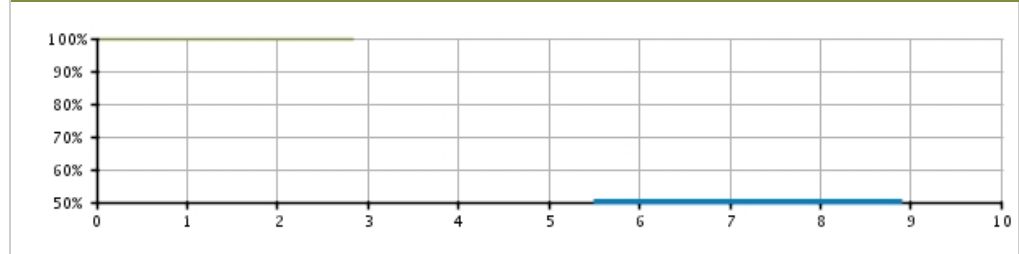
ADVANTIO DR

Models J063/J066/K063/K066/K083

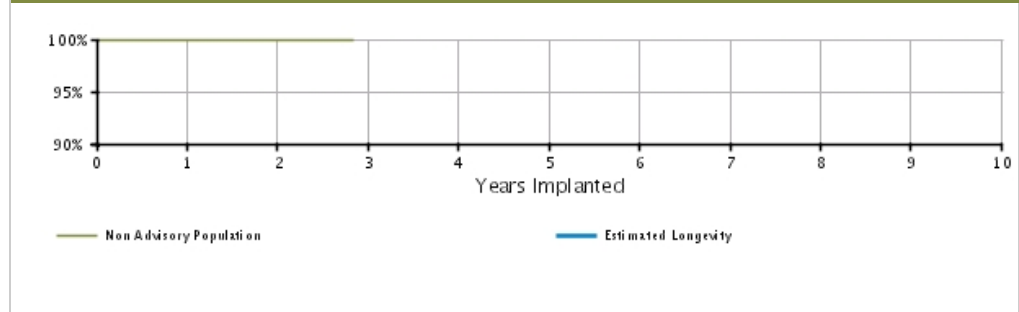
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 45,000	U.S. Normal Battery Depletions: 12
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 42,000	U.S. Malfunctions:11
	Without Compromised Therapy:8
	With Compromised Therapy:3

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)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.87 @ 34 mo. (-0.1/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.95 @ 34 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 45000	Effective Sample Size	29412	11473	229	-	-	-	-	-	-	-	-

ADVANTIO DR

Models J063/J066/K063/K066/K083

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

ADVANTIO DR
Models J063/J066/K063/K066/K083



Worldwide Distribution: 69,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	2	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	4	-	4
⁷⁹ Memory errors	4	-	
Other	5	1	6
Non-patterned	5	1	
WW Confirmed Malfunctions	12	4	16

[More details](#) about malfunctions

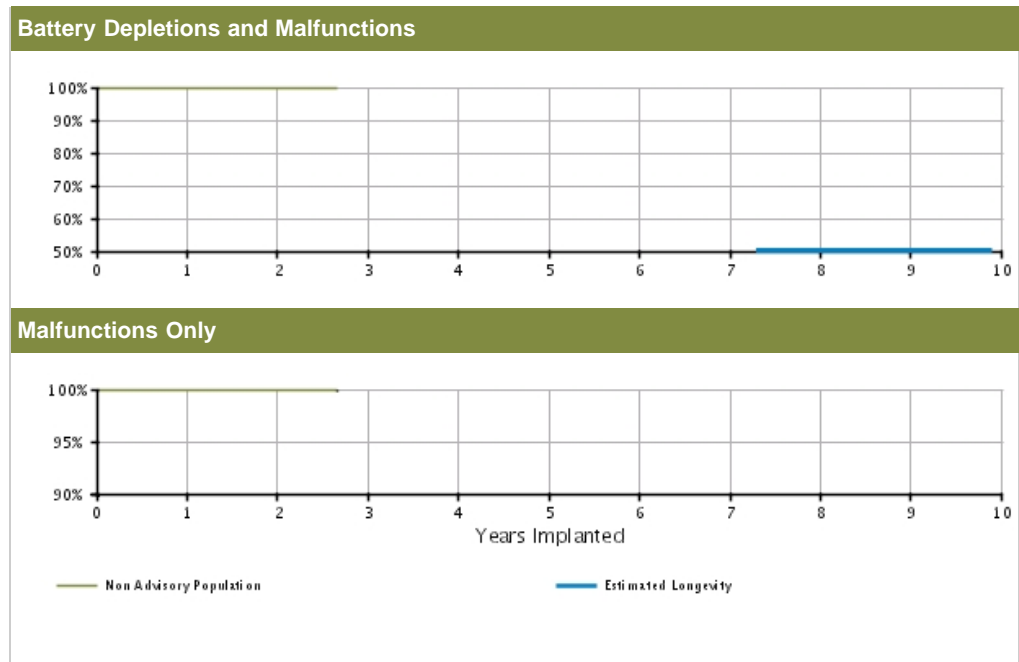
[References](#) cited in table above

ADVANTIO SR

Models J062/J065/K062/K065/K082

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

U.S. Summary	
U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:5
	Without Compromised Therapy:4
	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)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.84 @ 32 mo. (-0.2/+0.1)	-	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.89 @ 32 mo. (-0.2/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 11000	Effective Sample Size	6522	2297	306	-	-	-	-	-	-	-	-

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: 28,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁷⁵ Low-voltage capacitors	3	-	
⁷⁸ Integrated circuit	-	3	
Mechanical	-	-	0
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	5	3	8

[More details](#) about malfunctions

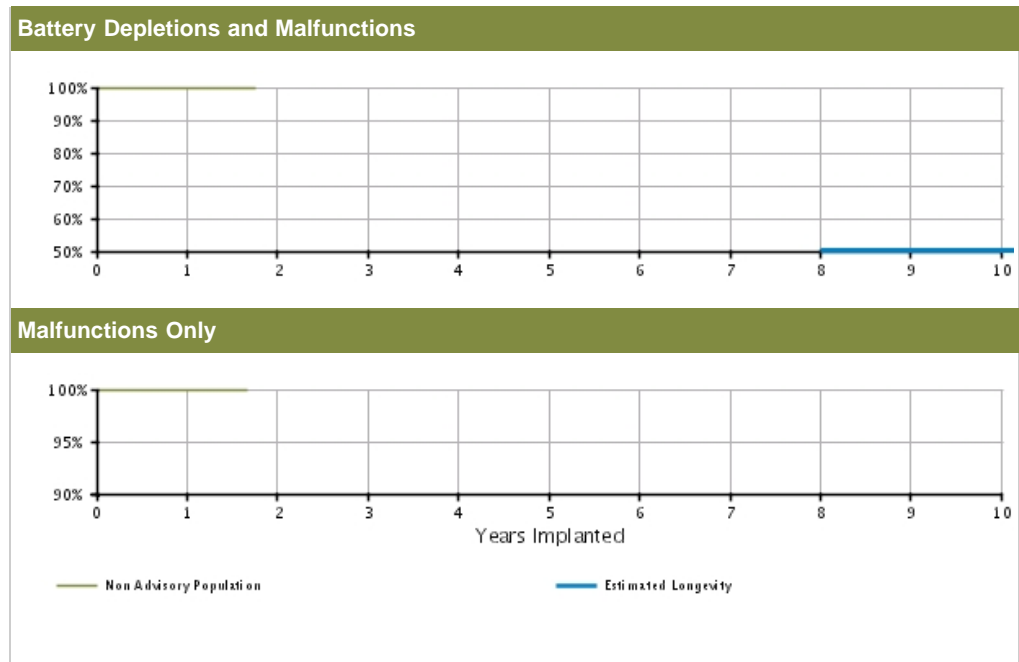
[References](#) cited in table above

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: 5,000	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: 5,000	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 (%)	100.00	100.00	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	@ 21 mo. (-0.0/+0.0)									
Registered Implants: 5000	Malfunctions Only (%)	100.00	100.00	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	@ 21 mo. (-0.0/+0.0)									
	Effective Sample Size	1695	277	-	-	-	-	-	-	-	-	-

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: 28,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁷⁵ Low-voltage capacitors	2	-	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	1	5

[More details](#) about malfunctions

[References](#) cited in table above

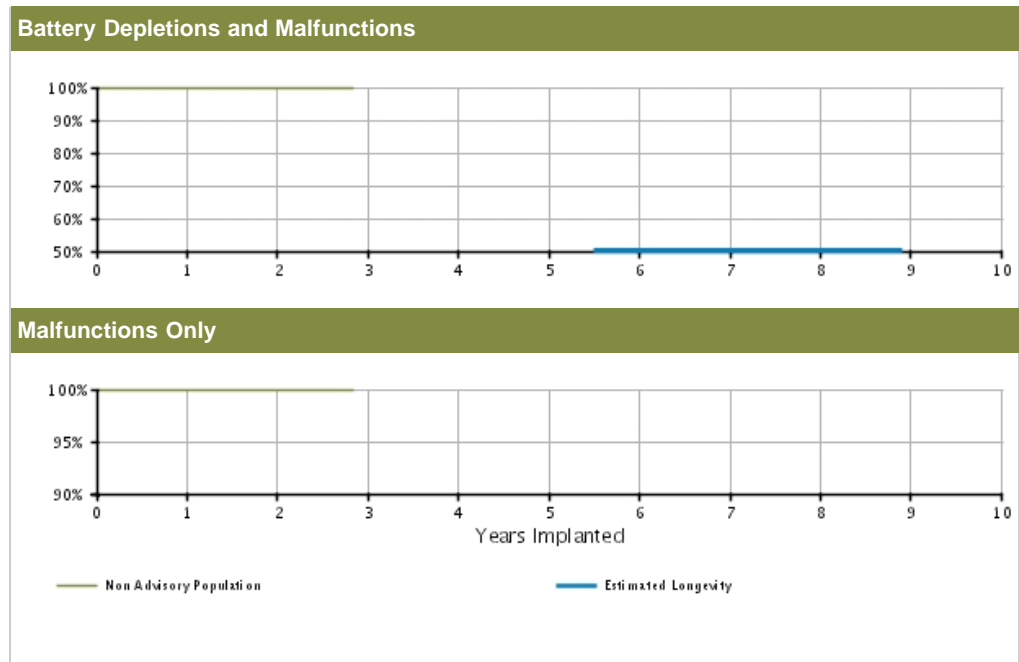
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INGENIO DR

Models J173/J176/K173/K176/K183

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

U.S. Summary	
U.S. Registered Implants: 64,000	U.S. Normal Battery Depletions: 18
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 60,000	U.S. Malfunctions:8
	Without Compromised Therapy:7
	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 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.88 @ 34 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 @ 34 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 64000	Effective Sample Size	35168	11781	435	-	-	-	-	-	-	-	-

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: 102,000			
Worldwide Confirmed Malfunctions: 14			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	1	-	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	4	1	5
⁷⁹ Memory errors	4	1	
Other	6	-	6
Non-patterned	6	-	
WW Confirmed Malfunctions	12	2	14

[More details](#) about malfunctions

[References](#) cited in table above

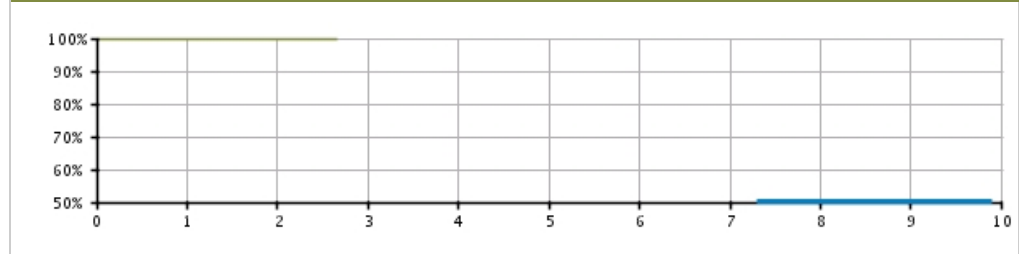
INGENIO SR

Models J172/J175/K172/K175/K182

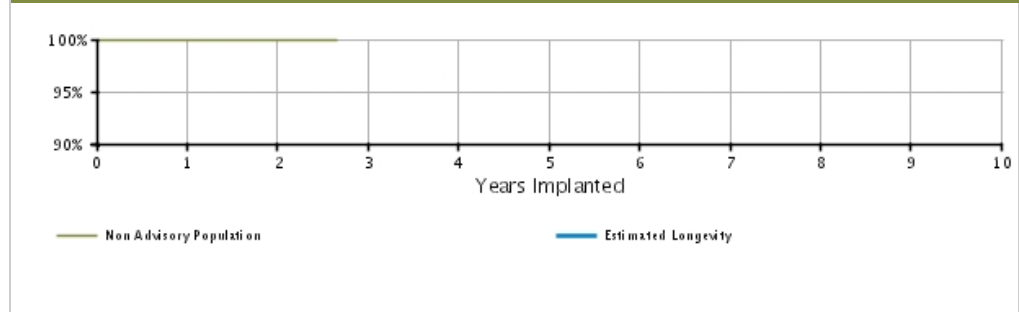
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 12,000	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: 11,000	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 Registered Implants: 12000	Depletions and Malfunctions (%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.99 (-0.1/+0.0)	99.99 @ 32 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Malfunctions Only (%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 32 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	6183	1997	294	-	-	-	-	-	-	-	-

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: 31,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

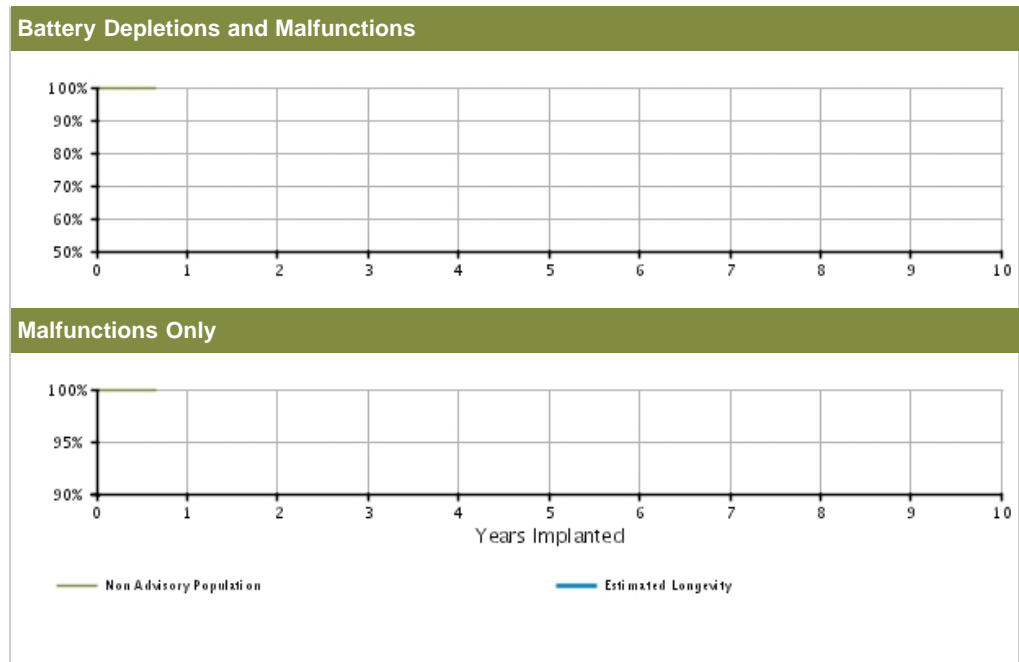
[References](#) cited in table above

VITALIO DR

Models J273/J276/K273/K276

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

U.S. Summary	
U.S. Registered Implants: 2,000	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: 2,000	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 @ 8 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 @ 8 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-	-
Registered Implants: 2000	Effective Sample Size	411	-	-	-	-	-	-	-	-	-	-

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: 8,000
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

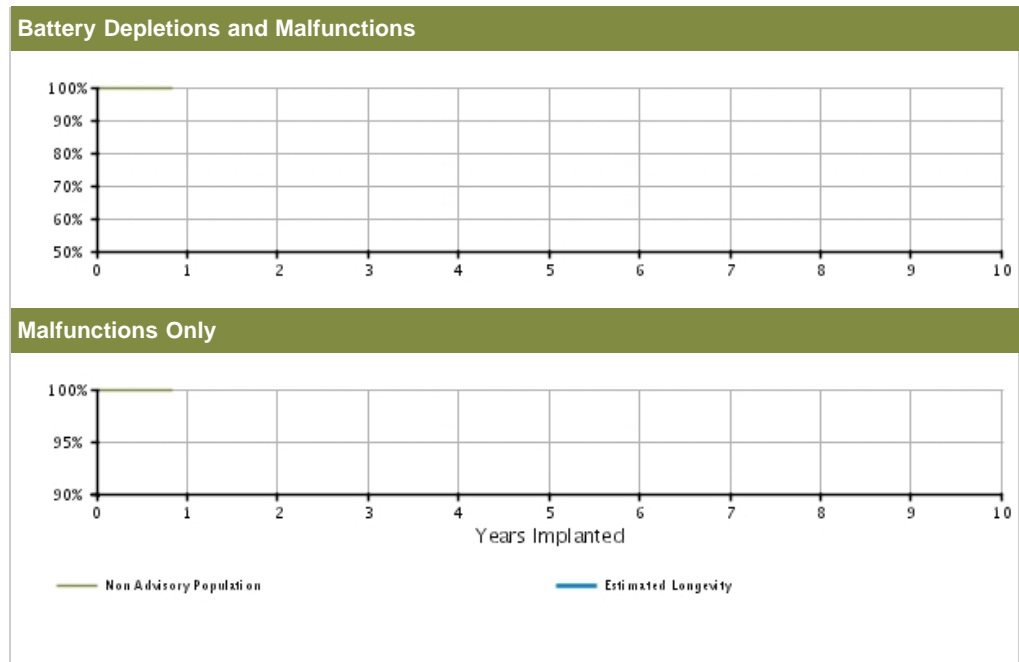
[References](#) cited in table above

VITALIO EL DR

Models J274/J277/K274

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

U.S. Summary	
U.S. Registered Implants: 1,000	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: 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)	100.00 @ 10 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-	-
	Registered Implants: 1000	Malfunctions Only(%) (Confidence Interval)	100.00 @ 10 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
Effective Sample Size		233	-	-	-	-	-	-	-	-	-	-

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: 8,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
^{BB} Titanium case material	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

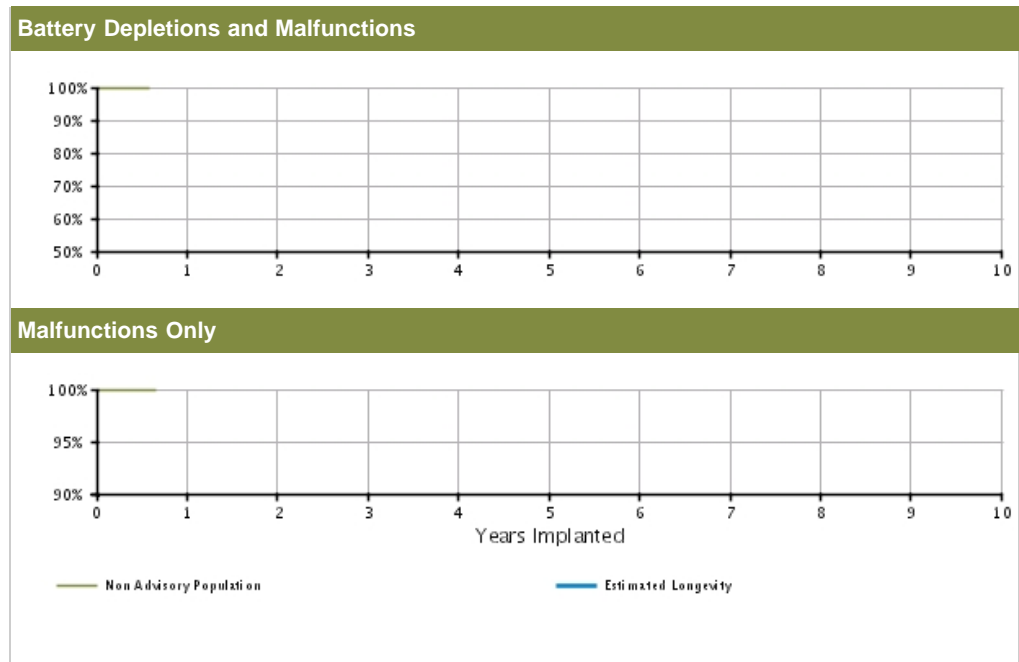
[References](#) cited in table above

VITALIO SR

Models J272/J275/K272/K275

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

U.S. Summary	
U.S. Registered Implants: 1,000	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: 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(%)	100.00	-	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	@ 7 mo. (-0.0/+0.0)										
Registered Implants: 1000	Malfunctions Only(%)	100.00	-	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	@ 7 mo. (-0.0/+0.0)										
	Effective Sample Size	252	-	-	-	-	-	-	-	-	-	-

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: 4,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
^{BB} Titanium case material	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
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: 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

ALTRUA 60 DR

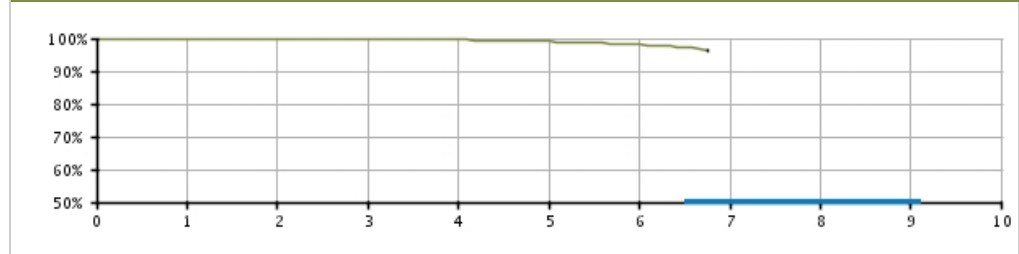
Model S602

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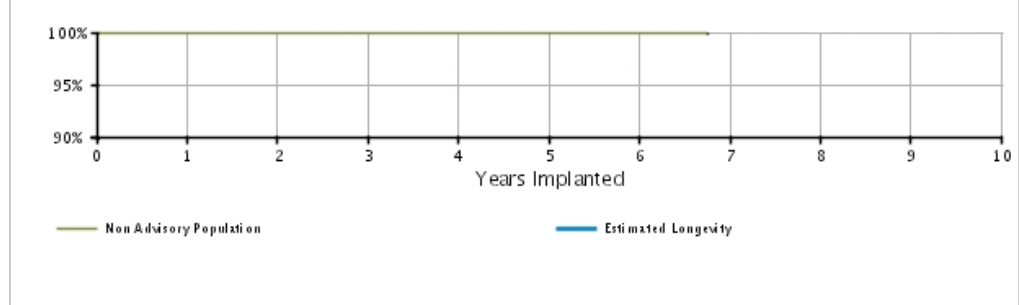
U.S. Summary

U.S. Registered Implants: 22,000	U.S. Normal Battery Depletions: 209
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 15,000	U.S. Malfunctions:5
	Without Compromised Therapy:4
	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)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.02 (-0.2/+0.2)	98.08 (-0.3/+0.3)	96.47 @ 81 mo. (-1.0/+0.8)	-	-	-
Registered Implants: 22000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.94 @ 81 mo. (-0.1/+0.0)	-	-	-
	Effective Sample Size	19312	16920	14552	11752	9111	5083	362	-	-	-

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: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	1	1	2
²⁶ Capacitor array	1	-	
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	4	1	5
Non-patterned	2	1	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	6	2	8

[More details](#) about malfunctions

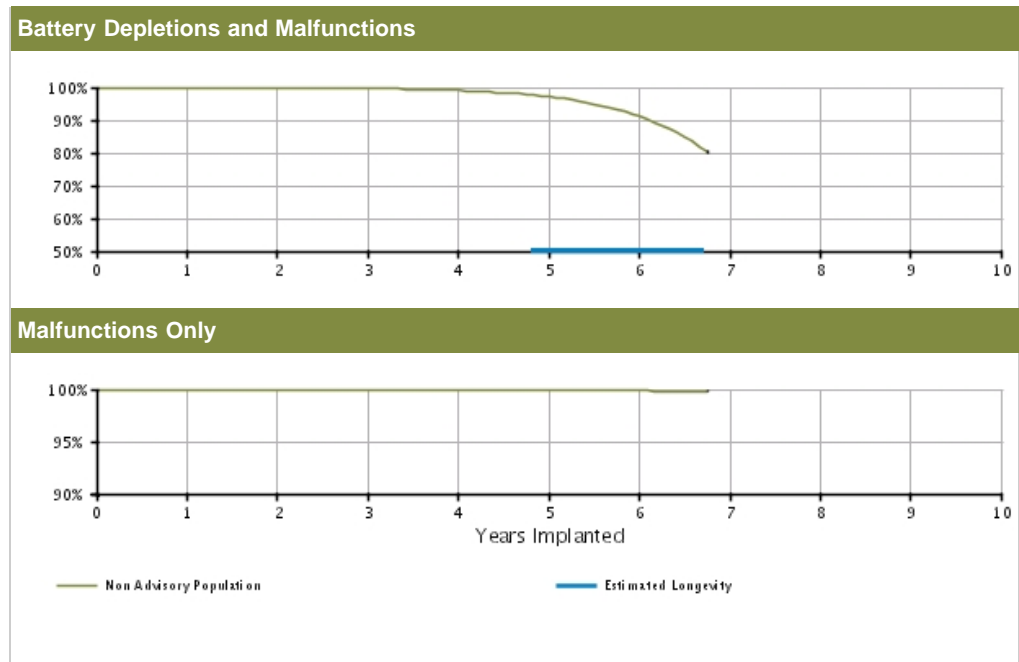
[References](#) cited in table above

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: 2,263
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 32
U.S. Estimated Active Implants: 63,000	U.S. Malfunctions:35
	Without Compromised Therapy:27
	With Compromised Therapy:8




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)	99.66 (-0.0/+0.0)	99.05 (-0.1/+0.1)	97.22 (-0.2/+0.2)	91.27 (-0.4/+0.4)	80.30 @ 81 mo. (-1.5/+1.4)	-	-	-
	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)	99.98 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.82 @ 81 mo. (-0.1/+0.1)	-	-
Effective Sample Size		79375	69989	57385	39171	22854	8385	507	-	-	-	-

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: 38			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	5	6	11
²³ Capacitor	4	5	
⁵³ Integrated circuit	1	1	
Mechanical	2	-	2
⁶⁵ Connector block	1	-	
⁶⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	22	3	25
Non-patterned	-	2	
⁴³ Battery depletion	3	1	
⁷⁷ Battery status	19	-	
WW Confirmed Malfunctions	29	9	38

[More details](#) about malfunctions

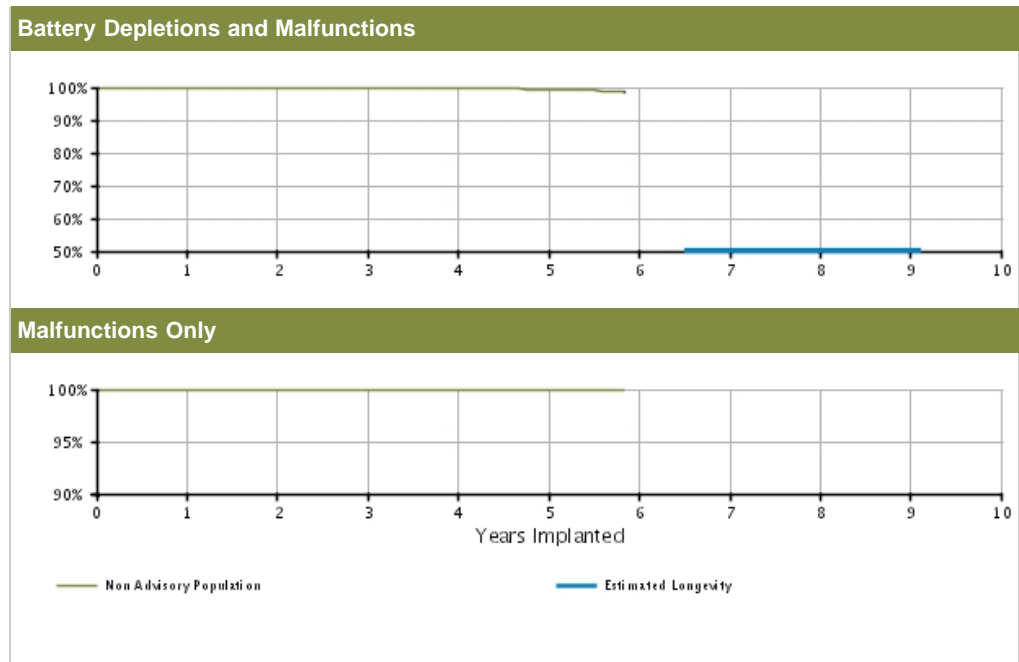
[References](#) cited in table above

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: 148
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 7
U.S. Estimated Active Implants: 47,000	U.S. Malfunctions:7
	Without Compromised Therapy:5
	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)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.71 (-0.1/+0.1)	99.34 (-0.1/+0.1)	98.65 @ 70 mo. (-0.6/+0.4)	-	-	-	-	-
	Registered Implants: 59000	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)	99.98 (-0.0/+0.0)	99.98 @ 70 mo. (-0.0/+0.0)	-	-	-	-
Effective Sample Size		52705	46264	36391	19881	7176	478	-	-	-	-	-

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: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
²³ Capacitor	3	-	
²⁷ Integrated circuit	1	-	
Mechanical	-	1	1
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	2	1	3
Non-patterned	1	-	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	6	2	8

[More details](#) about malfunctions

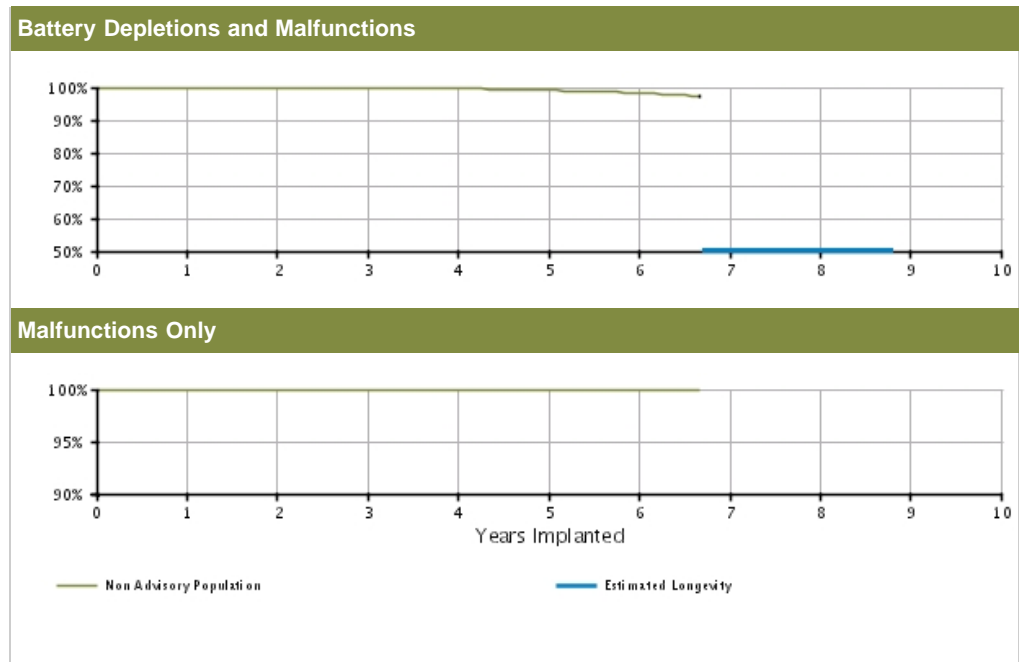
[References](#) cited in table above

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: 161
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 19,000	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)	98.25 (-0.4/+0.3)	97.19 @ 80 mo. (-0.9/+0.7)	-	-	-	-
	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)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 80 mo. (-0.1/+0.0)	-	-	-	-
Registered Implants: 32000	Effective Sample Size	26851	23362	18744	12028	6639	2190	299	-	-	-	-

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
²³ Capacitor	2	1	
⁵³ Integrated circuit	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	2	
⁴³ Battery depletion	-	1	
⁷⁷ 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: 43,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	-	3
²³ Capacitor	2	-	
⁵³ Integrated circuit	1	-	
Mechanical	-	1	1
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁴³ Battery depletion	1	-	
⁷⁷ 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
²³ Capacitor	1	2	
Mechanical	-	-	0
Software	-	-	0
Other	-	3	3
Non-patterned	-	1	
⁴³ 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: 11,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	3	3	6
Non-patterned	-	-	
⁴³ Battery depletion	-	3	
⁷⁷ Battery status	3	-	
WW Confirmed Malfunctions	3	3	6

[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: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	1	0	1


[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	-	-	
⁴³ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

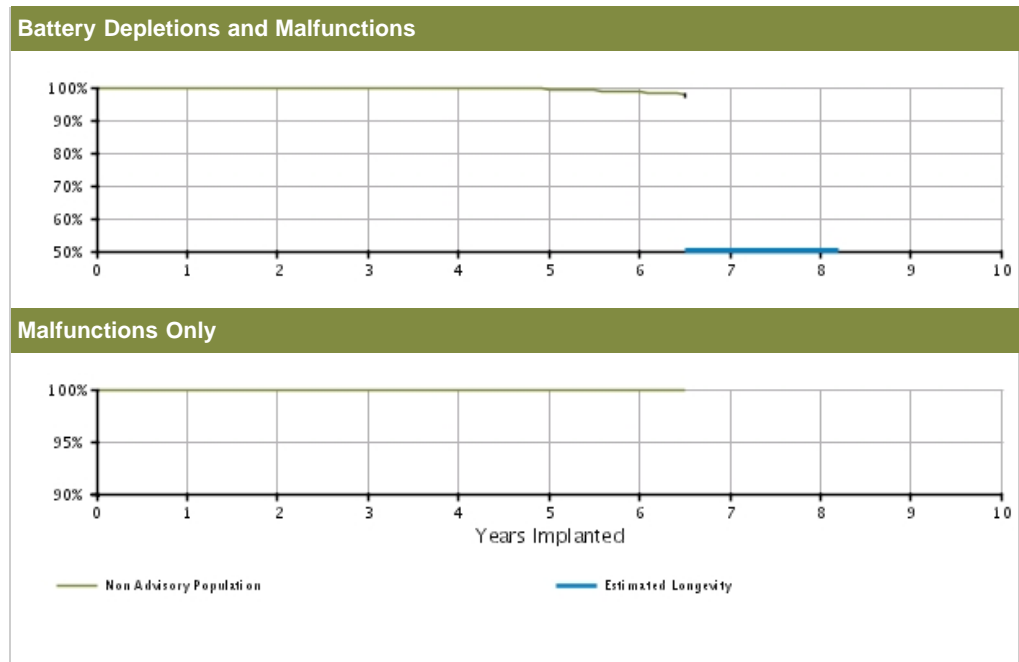
[References](#) cited in table above

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: 16
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)	98.63 (-1.0/+0.6)	97.72 @ 78 mo. (-1.6/+0.9)	-	-	-	-
	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 @ 78 mo. (-0.0/+0.0)	-	-	-
Registered Implants: 2000	Effective Sample Size	1517	1346	1194	1064	943	711	251	-	-	-	-

ALTRUA 40 DR

Model S402

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

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	-	-	
⁴³ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

[References](#) cited in table above

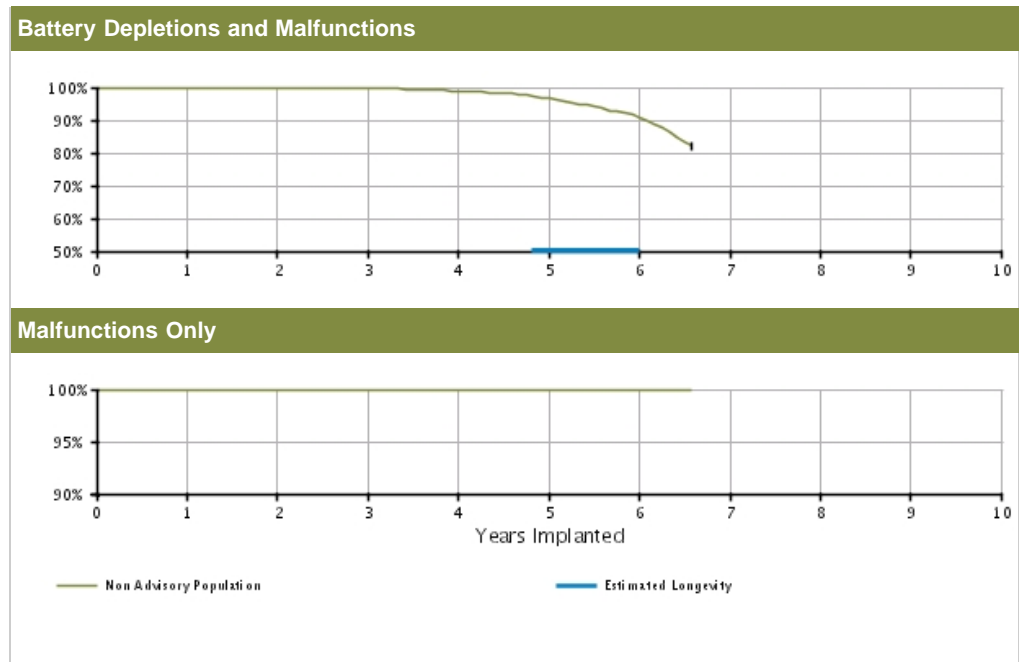
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ALTRUA 40 DR (downsize)

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: 363
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:3
	Without Compromised Therapy:3
	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)	99.98 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.69 (-0.1/+0.1)	98.91 (-0.3/+0.2)	96.53 (-0.5/+0.5)	90.67 (-1.3/+1.1)	82.16 @ 79 mo. (-2.8/+2.5)	-	-	-	-
	Registered Implants: 14000											
	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 @ 79 mo. (-0.1/+0.0)	-	-	-	-
	Effective Sample Size	12516	11149	9437	6252	3339	1035	237	-	-	-	-

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: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	2	-	2
⁶⁷ Seal plug	1	-	
⁶⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁷⁷ Battery status	2	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

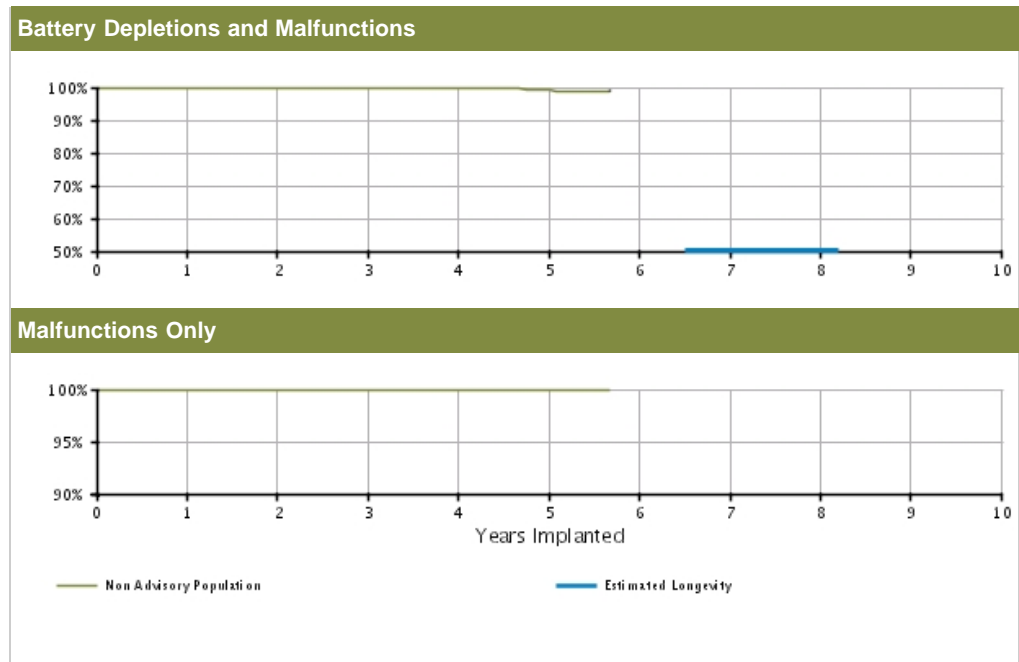
[References](#) cited in table above

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: 16
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)	99.68 (-0.3/+0.2)	99.04 (-0.7/+0.4)	98.92 @ 68 mo. (-0.8/+0.4)	-	-	-	-
	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 @ 68 mo. (-0.0/+0.0)	-	-	-	-
Effective Sample Size		4477	3976	3320	1991	907	202	-	-	-	-	-

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: 10,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

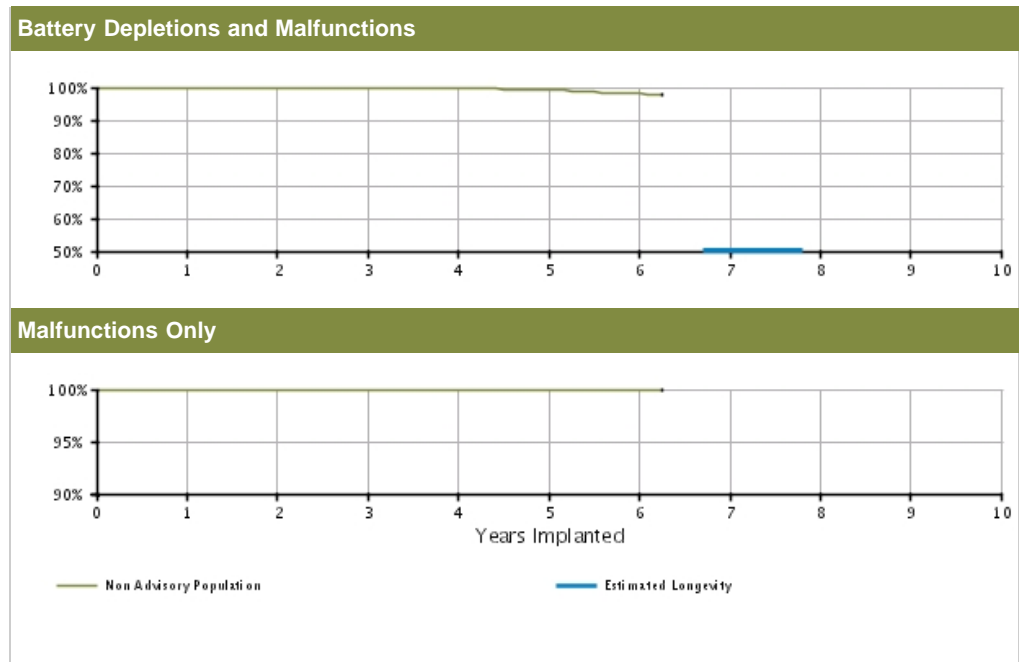
[References](#) cited in table above

ALTRUA 40 SR

Model S401

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

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 22
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)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.70 (-0.3/+0.1)	99.28 (-0.5/+0.3)	98.13 (-1.2/+0.7)	97.79 @ 75 mo. (-1.5/+0.9)	-	-	-	-
	Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.93 (-0.2/+0.1)	99.93 (-0.2/+0.1)	99.93 (-0.2/+0.1)	99.93 @ 75 mo. (-0.2/+0.1)	-	-	-
Effective Sample Size		3964	3476	2882	1885	1010	343	203	-	-	-	-

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
²³ Capacitor	2	-	
⁵³ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

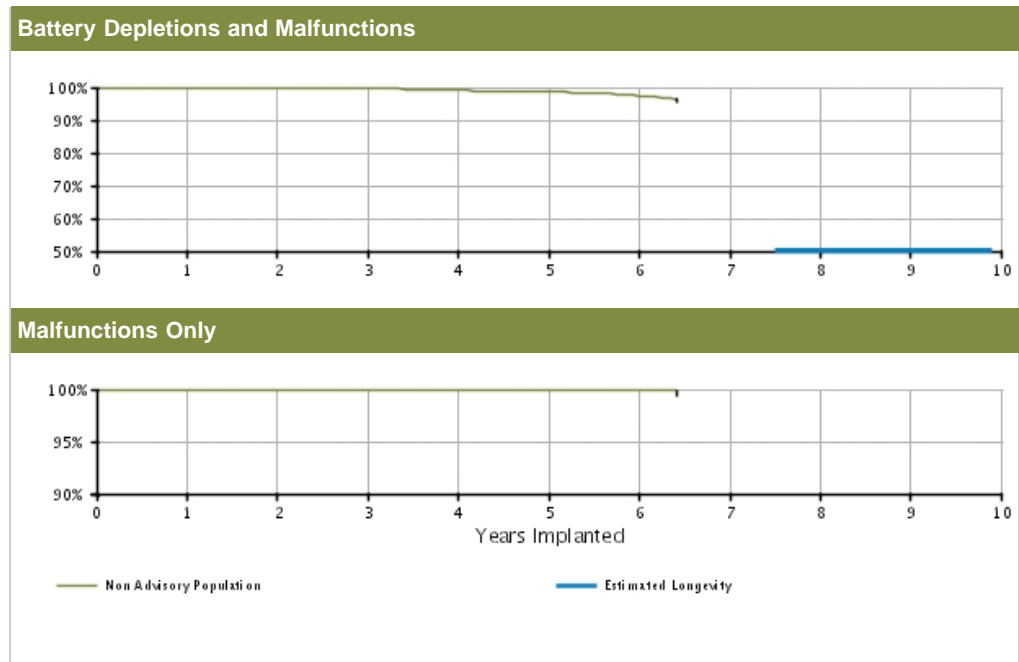
[References](#) cited in table above

ALTRUA 20 DR

Models S202/S205

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

U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 25
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	99.93	99.67	99.28	98.59	97.49	96.11	—	—	—	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.4/+0.1)	(-0.5/+0.2)	(-0.7/+0.4)	(-1.0/+0.6)	(-1.4/+0.9)	@ 77 mo. (-2.2/+1.4)				
Registered Implants: 2000	Malfunctions Only(%)	100.00	100.00	100.00	99.90	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)	(-0.6/+0.1)	@ 77 mo. (-0.6/+0.1)				
	Effective Sample Size	1489	1292	1105	929	765	523	222	—	—	—	—

ALTRUA 20 DR

Models S202/S205

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

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	-	-	
⁷² Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

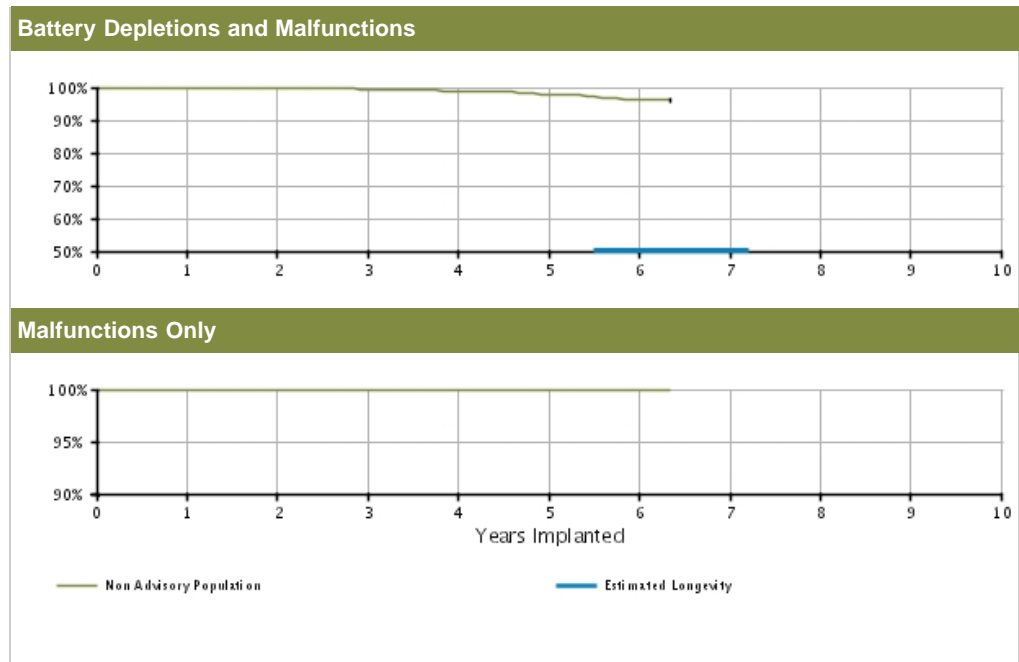
[References](#) cited in table above

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: 65
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
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(%)	99.98	99.83	99.42	98.87	97.97	96.49	96.06	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.3)	(-0.7/+0.5)	(-1.2/+0.9)	@ 76 mo. (-1.5/+1.1)				
Registered Implants: 5000	Malfunctions Only(%)	100.00	100.00	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)	(-0.0/+0.0)	@ 76 mo. (-0.0/+0.0)			
	Effective Sample Size	4416	3913	3304	2248	1279	427	225	-	-	-	-

ALTRUA 20 DR (downsize)

Model S203

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

ALTRUA 20 DR (downsize)
Model S203



Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	-	2
²³ Capacitor	2	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
⁴³ Battery depletion	-	1	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

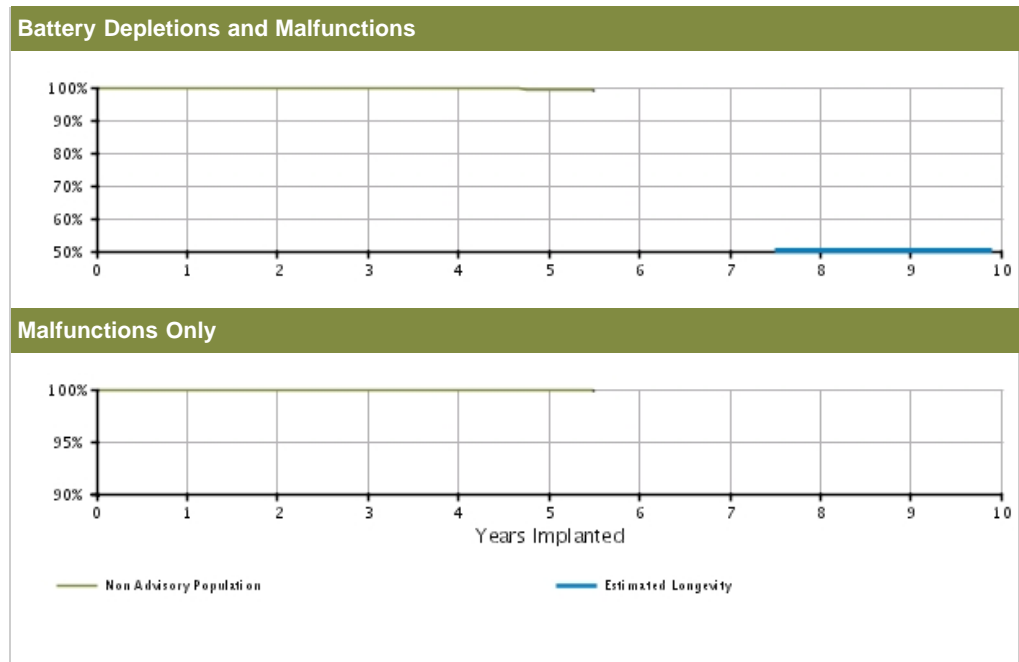
[References](#) cited in table above

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: 11
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(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.86 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.59 (-0.4/+0.2)	99.25 (-0.8/+0.4)	99.25 @ 66 mo. (-0.8/+0.4)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 66 mo. (-0.2/+0.0)	-	-	-	-
Registered Implants: 3000	Effective Sample Size	2774	2468	2008	1209	526	250	-	-	-	-	-

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
²³ 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

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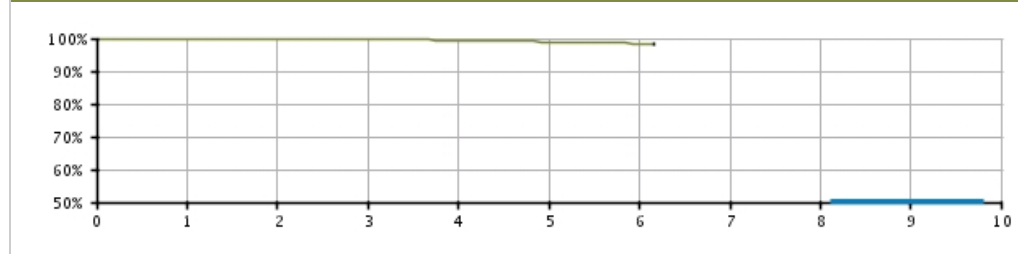
ALTRUA 20 SR

Models S201/S204

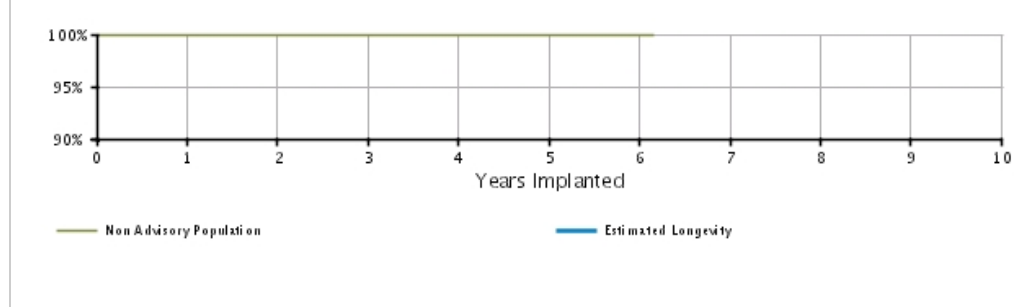
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Normal Battery Depletions: 23
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 2,000	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)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.66 (-0.3/+0.2)	99.40 (-0.4/+0.2)	98.84 (-0.7/+0.4)	98.29 (-1.1/+0.7)	98.29 @ 74 mo. (-1.1/+0.7)	-	-	-	-
	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 (-0.0/+0.0)	100.00 @ 74 mo. (-0.0/+0.0)	-	-	-	-
	Effective Sample Size	3574	3022	2440	1590	856	292	221	-	-	-	-

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
²³ 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
---------------------------	-------------------------------	--------------------

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
---------------------------	-------------------------------	--------------------

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

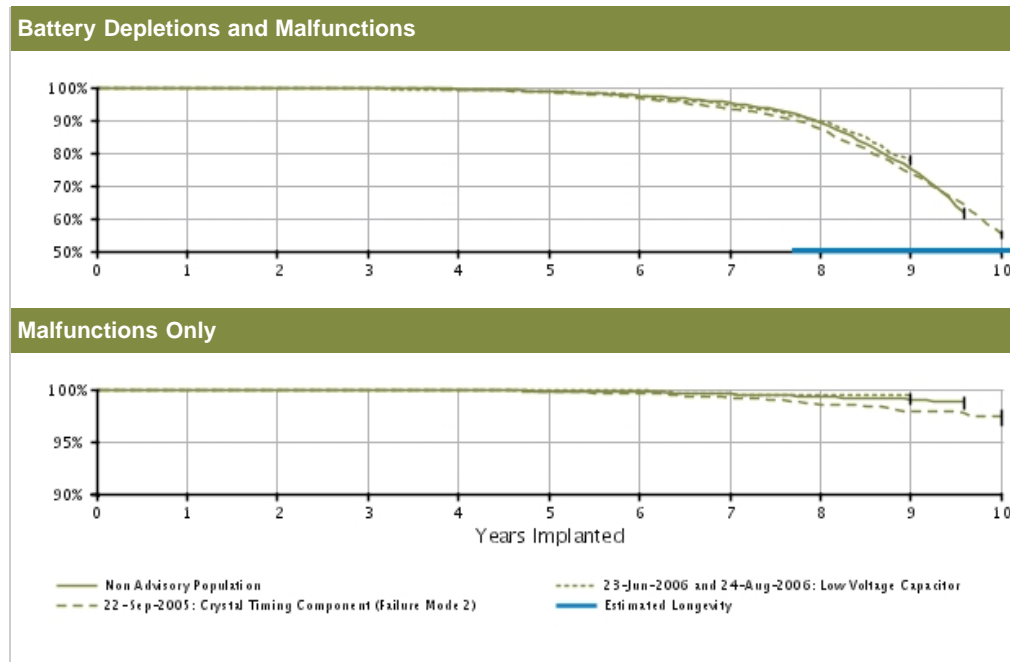
[References](#) cited in table above

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: 2,298
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 19
U.S. Estimated Active Implants: 15,000	U.S. Malfunctions:140
	Without Compromised Therapy:131
	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)	97.45 (-0.3/+0.3)	95.28 (-0.4/+0.4)	89.30 (-0.8/+0.7)	75.32 (-1.9/+1.8)	61.55 @ 115 mo. (-3.4/+3.3)	
	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)	99.55 (-0.1/+0.1)	99.32 (-0.2/+0.2)	99.02 (-0.4/+0.3)	98.82 @ 115 mo. (-0.7/+0.4)	
	Effective Sample Size	21003	18657	16560	14649	12904	11291	8460	3207	726	210	
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)	89.57 (-2.1/+1.8)	77.88 (-3.1/+2.8)	-	
	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)	-	
	Effective Sample Size	1878	1659	1461	1287	1134	987	849	700	292	-	
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	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)	93.42 (-0.9/+0.8)	87.18 (-1.3/+1.2)	73.52 (-1.8/+1.7)	55.20 (-2.4/+2.4)	
	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)	93.42 (-0.9/+0.8)	87.18 (-1.3/+1.2)	73.52 (-1.8/+1.7)	55.20 (-2.4/+2.4)	
	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)	97.36 (-0.9/+0.7)
Effective Sample Size	5704	5047	4468	3940	3453	2980	2555	2096	1556	442

*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
---------------------------	-------------------------------	--------------------

INSIGNIA Ultra DR Model 1291			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 174			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	7	5	12
⁹ Low-voltage capacitor (Advisory issued)	-	2	
²⁰ Capacitor	1	-	
²³ Capacitor	4	2	
⁵³ Integrated circuit	2	1	
Mechanical	7	5	12
³¹ Seal plug	5	4	
³² Header	1	1	
⁵⁵ Setscrew	1	-	
Software	4	-	4
⁵⁸ Underestimation of battery status	3	-	
⁶⁰ Pacing rate limit	1	-	
Other	142	4	146
Non-patterned	7	3	
¹⁶ Longevity labeling	75	-	
³³ Magnet response	1	-	
⁴³ Battery depletion	3	1	
⁷⁷ Battery status	56	-	
WW Confirmed Malfunctions	160	14	174

[More details](#) about malfunctions

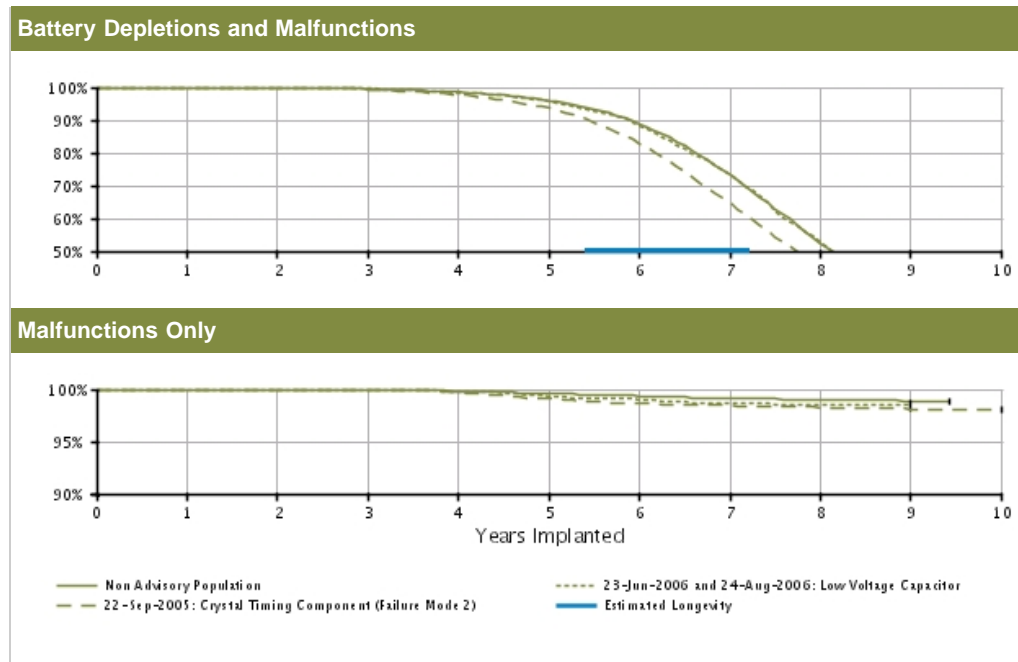
[References](#) cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

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

U.S. Summary	
U.S. Registered Implants: 76,000	U.S. Normal Battery Depletions: 16,826
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 113
U.S. Estimated Active Implants: 19,000	U.S. Malfunctions:415
	Without Compromised Therapy:403
	With Compromised Therapy:12



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)	73.25 (-0.6/+0.5)	52.33 (-0.8/+0.8)	32.94 (-1.2/+1.3)	24.36 @ 113 mo. (-1.6/+1.7)	
	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)	99.06 (-0.1/+0.1)	98.82 (-0.3/+0.3)	98.82 @ 113 mo. (-0.3/+0.3)	
	Effective Sample Size	47637	42290	37445	32967	28503	23421	14906	4528	778	233	
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)	88.16 (-1.4/+1.2)	73.21 (-1.9/+1.8)	53.00 (-2.3/+2.3)	35.41 (-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)	99.05 (-0.5/+0.3)	98.71 (-0.6/+0.4)	98.54 (-0.6/+0.4)	98.54 (-0.6/+0.4)	-	
	Effective Sample Size	4024	3553	3142	2732	2340	1907	1378	858	238	-	
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)	64.56 (-1.1/+1.1)	44.63 (-1.2/+1.2)	28.00 (-1.1/+1.2)	18.26 (-1.2/+1.2)	

Component (Failure Mode 2)*	(Confidence Interval)										
Registered Implants: 17000											
	Malfunctions Only (%)	99.98	99.98	99.95	99.73	99.09	98.67	98.45	98.25	98.12	98.12
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.3/+0.2)	(-0.3/+0.2)	(-0.3/+0.3)	(-0.4/+0.3)	(-0.4/+0.3)
	Effective Sample Size	14977	13298	11732	10223	8609	6640	4412	2589	1342	268


*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 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: 563			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	9	18
⁹ Low-voltage capacitor (Advisory issued)	1	5	
²³ Capacitor	7	3	
⁵³ Integrated circuit	1	1	
Mechanical	6	2	8
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²¹ Setscrew thread depth	1	-	
³¹ Seal plug	4	1	
⁴⁰ Circuit connection	1	-	
Software	12	-	12
³⁶ Memory error	2	-	
³⁷ Rate fault declaration	1	-	
⁵⁸ Underestimation of battery status	8	-	
⁶⁰ Pacing rate limit	1	-	
Other	516	9	525
Non-patterned	23	5	
¹⁶ Longevity labeling	398	-	
⁴³ Battery depletion	6	4	
⁷⁷ Battery status	89	-	
WW Confirmed Malfunctions	543	20	563

[More details](#) about malfunctions

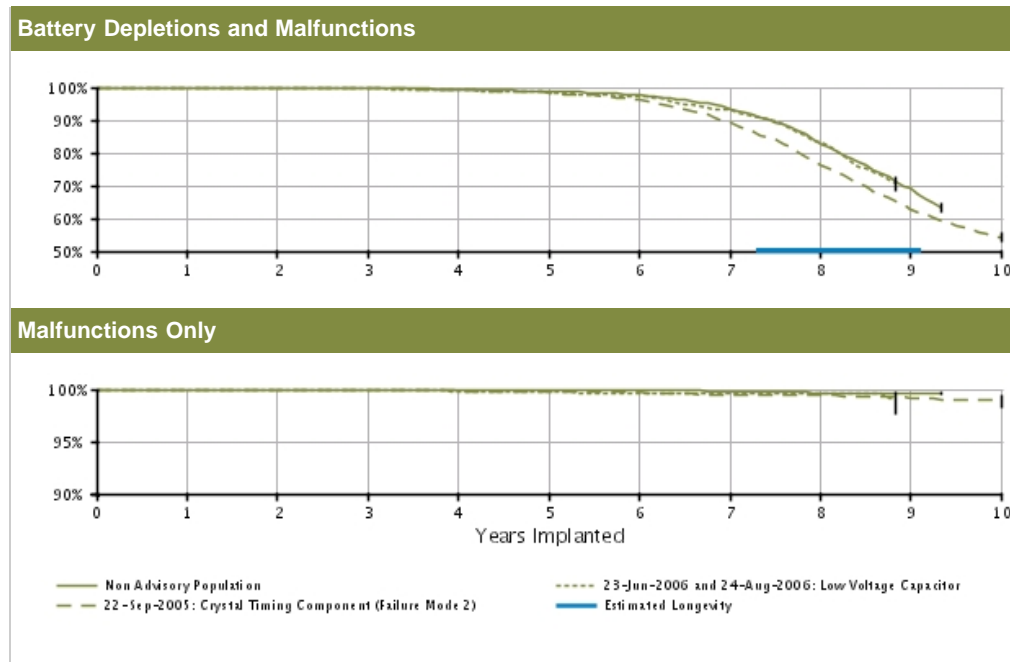
[References](#) cited in table above

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: 1,752
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:36
	Without Compromised Therapy:32
	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(%)	99.97	99.91	99.71	99.40	98.73	97.56	93.48	82.96	69.19	63.20	
	(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.3)	(-0.6/+0.6)	(-1.2/+1.2)	(-2.4/+2.3)	@ 112 mo. (-3.1/+3.0)	
	Registered Implants: 17000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	99.83	99.73	99.51	99.11	98.47	97.21	93.26	83.22	70.62	—	
	(Confidence Interval)	(-0.5/+0.1)	(-0.6/+0.2)	(-0.7/+0.3)	(-0.9/+0.5)	(-1.2/+0.7)	(-1.6/+1.0)	(-2.5/+1.8)	(-3.7/+3.2)	@ 106 mo. (-4.6/+4.2)		
	Registered Implants: 1000											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	99.99	99.99	99.98	99.97	99.94	99.91	99.78	99.67	99.67	99.67	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	@ 112 mo. (-0.2/+0.1)	
	Effective Sample Size	14152	12091	10309	8865	7738	6755	4998	1865	434	208	
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.83	99.73	99.51	99.11	98.47	97.21	93.26	83.22	70.62	—	
	(Confidence Interval)	(-0.5/+0.1)	(-0.6/+0.2)	(-0.7/+0.3)	(-0.9/+0.5)	(-1.2/+0.7)	(-1.6/+1.0)	(-2.5/+1.8)	(-3.7/+3.2)	@ 106 mo. (-4.6/+4.2)		
	Effective Sample Size	1148	963	812	699	588	502	421	333	236	—	
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	99.93	99.81	99.23	98.28	96.25	89.36	76.36	62.67	54.15	
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.4/+0.3)	(-0.6/+0.4)	(-0.9/+0.7)	(-1.5/+1.3)	(-2.2/+2.0)	(-2.6/+2.5)	(-2.9/+2.9)	
	Effective Sample Size	1148	963	812	699	588	502	421	333	236	—	

Component (Failure Mode 2)*	(Confidence Interval)										
Registered Implants: 5000											
Malfunctions Only (%)	100.00	99.98	99.98	99.87	99.83	99.78	99.47	99.40	99.17	99.02	
(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)	(-0.6/+0.4)	(-0.8/+0.4)	
Effective Sample Size	4144	3558	3002	2530	2113	1770	1420	1039	743	236	

*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: 58			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	5	7
⁹ Low-voltage capacitor (Advisory issued)	1	3	
²³ Capacitor	1	-	
⁵³ Integrated circuit	-	2	
Mechanical	3	1	4
³¹ Seal plug	3	-	
³² Header	-	1	
Software	1	-	1
³⁶ Memory error	1	-	
Other	46	-	46
Non-patterned	1	-	
¹⁶ Longevity labeling	23	-	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	21	-	
WW Confirmed Malfunctions	52	6	58

[More details](#) about malfunctions

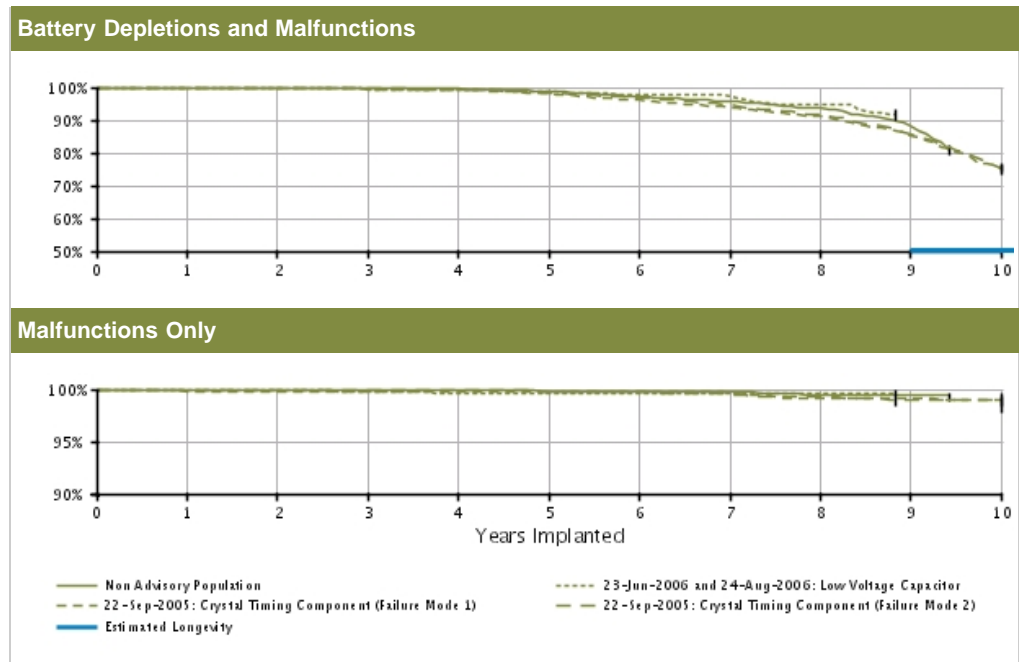
[References](#) cited in table above

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: 1,231
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 11
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:60
	Without Compromised Therapy:53
	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(%)	99.97	99.87	99.75	99.51	98.72	97.05	95.70	93.67	88.49	80.76	
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.2)	(-0.4/+0.3)	(-0.6/+0.5)	(-0.7/+0.6)	(-1.0/+0.8)	(-1.9/+1.7)	@ 113 mo. (-3.5/+3.0)	
	Registered Implants: 7000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	100.00	99.45	99.24	98.76	97.66	97.32	94.53	91.66	—	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-1.1/+0.4)	(-1.3/+0.5)	(-1.5/+0.7)	(-2.0/+1.1)	(-2.1/+1.2)	(-3.0/+2.0)	@ 106 mo. (-3.8/+2.7)		
	Registered Implants: 1000											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	100.00	99.97	99.91	99.91	99.83	99.78	99.71	99.48	99.38	99.38	
	(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.4/+0.2)	(-0.5/+0.3)	@ 113 mo. (-0.5/+0.3)	
	Registered Implants: 6260											
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions(%)	100.00	100.00	99.82	99.61	99.61	99.61	99.61	99.61	99.61	—	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-1.1/+0.2)	(-1.2/+0.3)	(-1.2/+0.3)	(-1.2/+0.3)	(-1.2/+0.3)	(-1.2/+0.3)	(-1.2/+0.3)	@ 106 mo. (-1.2/+0.3)	
	Registered Implants: 693											
Effective Sample Size		6260	5548	4914	4355	3812	3296	2557	1321	448	217	
Effective Sample Size		693	607	529	452	394	337	293	247	208	—	

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	336
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)	96.91 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.56 (-1.0/+0.9)	85.61 (-1.4/+1.3)	75.22 (-1.9/+1.8)
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)	98.92 (-0.5/+0.3)
	Effective Sample Size	6210	5482	4823	4229	3693	3187	2679	2267	1860	1000

*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: 70			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
¹⁹ Integrated circuit	-	1	
²³ Capacitor	-	1	
⁵³ Integrated circuit	-	1	
Mechanical	3	7	10
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
³¹ Seal plug	3	-	
³² Header	-	2	
Software	-	-	0
Other	55	2	57
Non-patterned	4	2	
¹⁶ Longevity labeling	49	-	
⁷⁷ Battery status	2	-	
WW Confirmed Malfunctions	58	12	70

[More details](#) about malfunctions

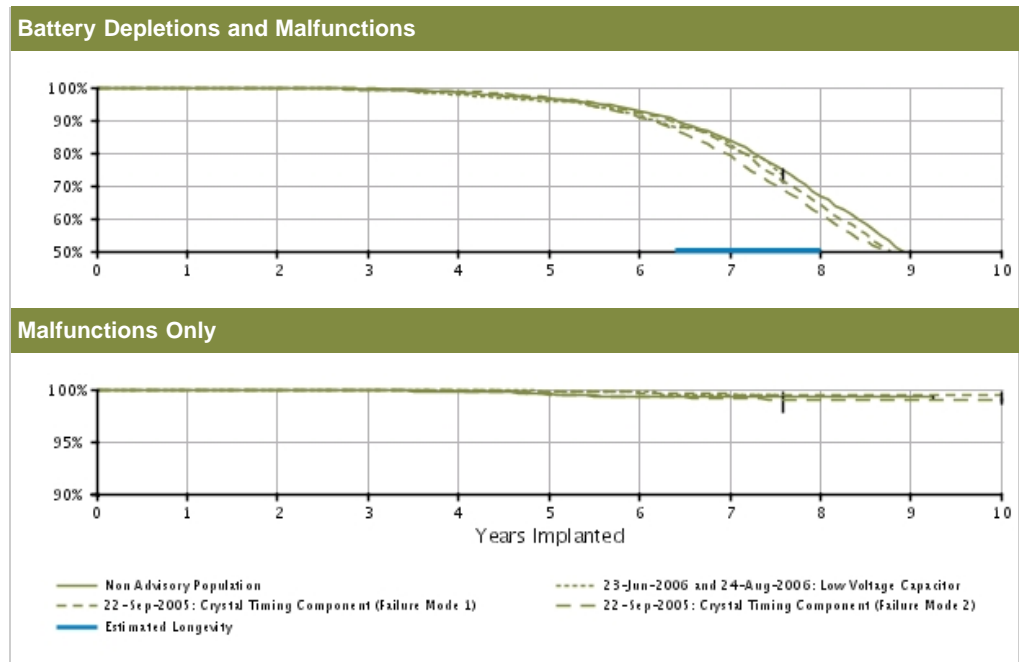
[References](#) cited in table above

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: 4,482
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:96
	Without Compromised Therapy:90
	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)	92.99 (-0.8/+0.7)	83.77 (-1.2/+1.2)	67.00 (-1.9/+1.8)	48.50 (-2.8/+2.8)	44.37 @ 111 mo. (-3.1/+3.1)	
	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)	99.22 (-0.3/+0.2)	99.22 (-0.3/+0.2)	99.22 @ 111 mo. (-0.3/+0.2)	
	Effective Sample Size	7139	6280	5496	4780	4123	3496	2494	1057	288	201	
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)	82.99 (-4.2/+3.5)	73.19 @ 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	251	203	--	--	
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)	81.78 (-2.2/+2.0)	64.03 (-2.9/+2.8)	45.79 (-3.2/+3.2)	31.97 (-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)	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)	99.22 @ 111 mo. (-0.3/+0.2)	
	Effective Sample Size	7139	6280	5496	4780	4123	3496	2494	1057	288	201	

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	933	597	360	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)	61.25 (-1.5/+1.5)	45.09 (-1.6/+1.6)	36.23 (-1.7/+1.7)
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	3338	2173	1339	664

*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: 118			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
⁹ Low-voltage capacitor (Advisory issued)	-	1	
²³ Capacitor	1	-	
⁵³ Integrated circuit	-	3	
Mechanical	-	3	3
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
¹⁷ Solder bond	-	1	
Software	4	-	4
³⁰ Memory error	1	-	
⁵⁸ Underestimation of battery status	1	-	
⁵⁹ Interrupted telemetry	2	-	
Other	104	2	106
Non-patterned	4	2	
¹⁶ Longevity labeling	95	-	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	4	-	
WW Confirmed Malfunctions	109	9	118

[More details](#) about malfunctions

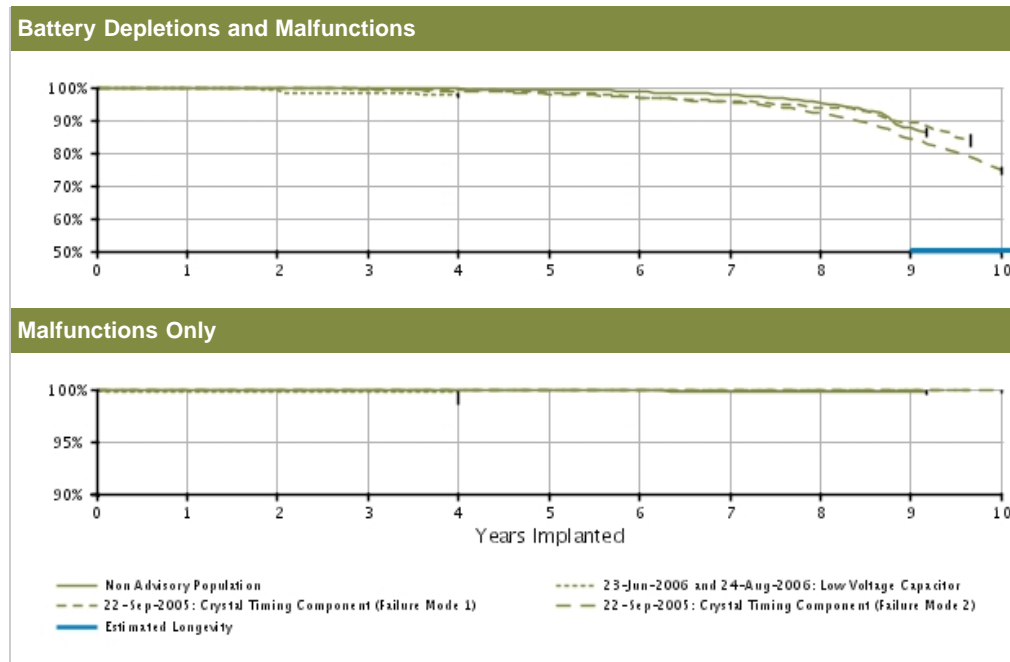
[References](#) cited in table above

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: 655
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)	98.75 (-0.5/+0.4)	97.88 (-0.7/+0.5)	95.29 (-1.3/+1.0)	87.64 (-3.1/+2.6)	86.48 @ 110 mo. (-3.4/+2.8)	
	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)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 @ 110 mo. (-0.3/+0.1)	
	Effective Sample Size	4708	3872	3252	2746	2328	1992	1497	747	260	208	
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)	89.47 (-3.6/+2.8)	83.99 @ 116 mo. (-4.5/+3.7)	
	Malfunctions Only(%) (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)	89.47 (-3.6/+2.8)	83.99 @ 116 mo. (-4.5/+3.7)	
	Effective Sample Size	2000	2000	2000	2000	2000	2000	2000	2000	2000	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)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 116 mo. (-0.0/+0.0)
	Effective Sample Size	1216	999	807	662	550	447	356	299	245	201
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)	97.94 (-0.6/+0.5)	96.95 (-0.8/+0.6)	95.27 (-1.0/+0.8)	92.21 (-1.3/+1.2)	84.17 (-2.0/+1.8)	74.72 (-2.5/+2.4)
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	3828	3177	2641	2183	1829	1540	1287	1027	581

*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	
²³ Capacitor	2	2	
⁵³ Integrated circuit	1	-	
Mechanical	1	6	7
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²⁶ Capacitor array	-	2	
³¹ Seal plug	-	2	
⁵⁶ Seal plug	-	1	
Software	-	-	0
Other	11	1	12
Non-patterned	1	1	
¹⁶ Longevity labeling	6	-	
⁷⁷ Battery status	4	-	
WW Confirmed Malfunctions	15	11	26

[More details](#) about malfunctions

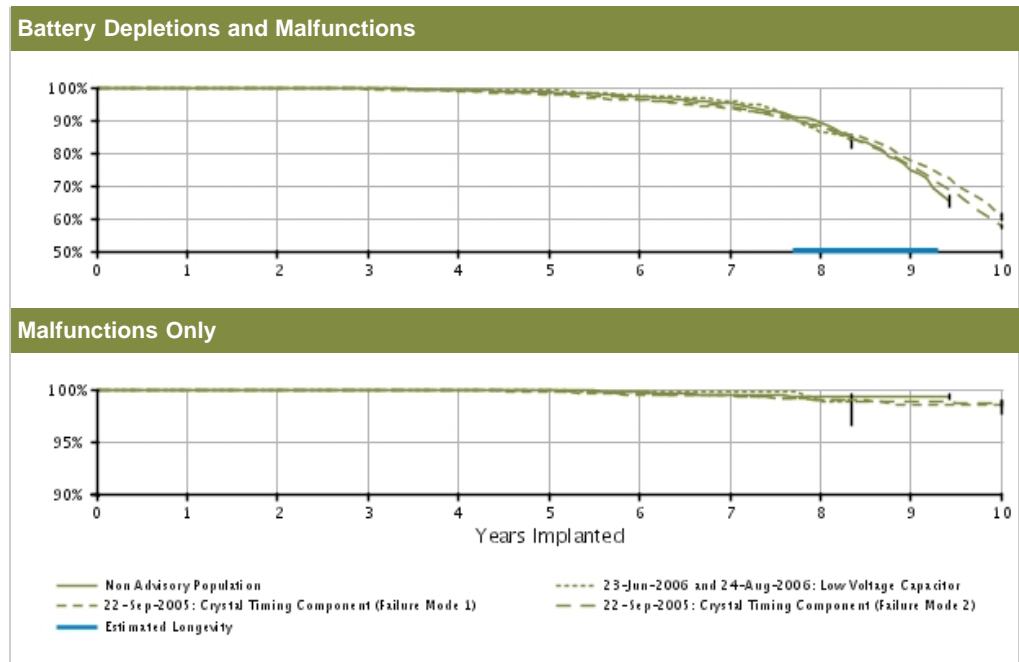
[References](#) cited in table above

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: 3,966
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 19
U.S. Estimated Active Implants: 7,000	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)	95.04 (-0.7/+0.7)	89.10 (-1.3/+1.2)	74.81 (-2.7/+2.5)	65.35 (-3.7/+3.5)	@ 113 mo. (-0.4/+0.2)
	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)	99.48 (-0.3/+0.2)	99.37 (-0.4/+0.2)	99.37 (-0.4/+0.2)	99.37 (-0.4/+0.2)	@ 113 mo. (-0.4/+0.2)
	Effective Sample Size	6560	5831	5161	4546	3997	3490	2722	1274	449	225	
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)	95.95 (-2.6/+1.6)	86.27 (-4.5/+3.5)	83.82 (-4.8/+3.9)	—	@ 100 mo. (-2.4/+0.8)
	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 (-2.4/+0.8)	—	@ 100 mo. (-2.4/+0.8)
	Effective Sample Size	664	580	510	442	386	333	285	223	204	—	
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)	77.83 (-2.2/+2.1)	60.63 (-2.8/+2.7)	
	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)	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	664	580	510	442	386	333	285	223	204	—	

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	930	611
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)	87.78 (-0.8/+0.8)	76.10 (-1.2/+1.1)	57.55 (-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)	98.69 (-0.3/+0.3)
	Effective Sample Size	12754	11251	9911	8722	7618	6597	5631	4615	3485	1928


*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: 153			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁹ Low-voltage capacitor (Advisory issued)	1	1	
²³ Capacitor	2	1	
⁵³ Integrated circuit	-	1	
Mechanical	14	7	21
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
¹⁷ Solder bond	1	-	
²⁶ Capacitor array	1	-	
³¹ Seal plug	5	-	
³² Header	6	4	
Software	7	-	7
⁵⁸ Underestimation of battery status	4	-	
⁵⁹ Interrupted telemetry	2	-	
⁶⁰ Pacing rate limit	1	-	
Other	116	3	119
Non-patterned	6	3	
¹⁶ Longevity labeling	89	-	
⁴³ Battery depletion	2	-	
⁷⁷ Battery status	19	-	
WW Confirmed Malfunctions	140	13	153

[More details](#) about malfunctions

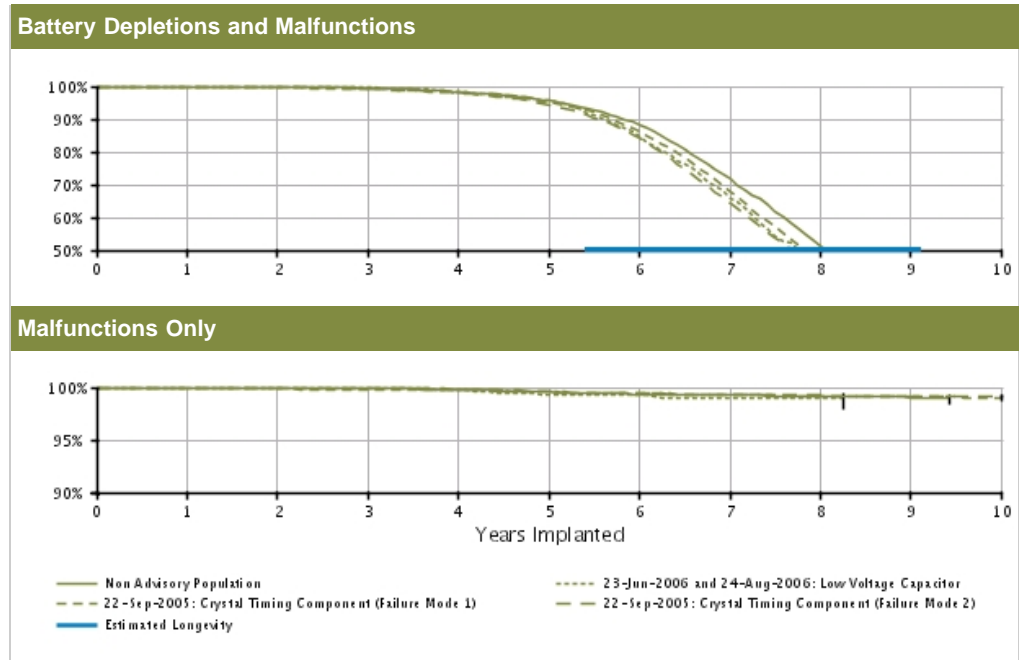
[References](#) cited in table above

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: 25,671
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 114
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions: 370



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)	88.24 (-0.6/+0.6)	71.53 (-0.9/+0.9)	51.29 (-1.3/+1.3)	32.36 (-1.7/+1.7)	25.77 (-1.9/+2.0)	25.77 (-1.9/+2.0)
	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)	99.26 (-0.2/+0.1)	99.12 (-0.2/+0.2)	98.91 (-0.6/+0.4)	98.91 (-0.6/+0.4)	98.91 (-0.6/+0.4)
	Effective Sample Size	16865	14981	13240	11653	10065	8195	5277	1942	475	NaN	NaN
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)	45.66 (-3.8/+3.9)	39.19 (-3.8/+3.9)	39.19 (-3.8/+3.9)	39.19 (-3.8/+3.9)
	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)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)
	Effective Sample Size	1420	1250	1112	964	825	642	435	256	209	209	209
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)	67.69 (-1.1/+1.1)	47.01 (-1.3/+1.3)	31.90 (-1.3/+1.3)	21.98 (-1.2/+1.3)	21.98 (-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 (-0.2/+0.2)	99.13 (-0.2/+0.2)	99.03 (-0.4/+0.3)

	Effective Sample Size	13683	12074	10375	9055	7729	6115	4096	2346	1300	733
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)	64.20 (-0.6/+0.6)	44.16 (-0.7/+0.7)	29.91 (-0.7/+0.7)	20.77 (-0.6/+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	27286	21110	13679	7780	4349	2125


*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	
²⁰ Capacitor	-	1	
²³ Capacitor	6	2	
²⁷ Integrated circuit	-	1	
⁵³ Integrated circuit	5	3	
Mechanical	21	22	43
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
¹⁷ Solder bond	1	-	
²⁶ Capacitor array	3	1	
³¹ Seal plug	3	1	
³² Header	5	-	
⁵⁶ Seal plug	1	-	
Software	11	-	11
³⁶ Memory error	1	-	
⁵⁷ Interrogation at EOL	2	-	
⁵⁸ Underestimation of battery status	6	-	
⁵⁹ Interrupted telemetry	1	-	
⁶⁰ Pacing rate limit	1	-	
Other	360	11	371
Non-patterned	28	9	
¹⁶ Longevity labeling	311	-	
²⁹ Battery depletion	2	1	
³³ Magnet response	1	-	
⁴³ Battery depletion	11	1	
⁷⁷ Battery status	7	-	
WW Confirmed Malfunctions	403	43	446

[More details](#) about malfunctions

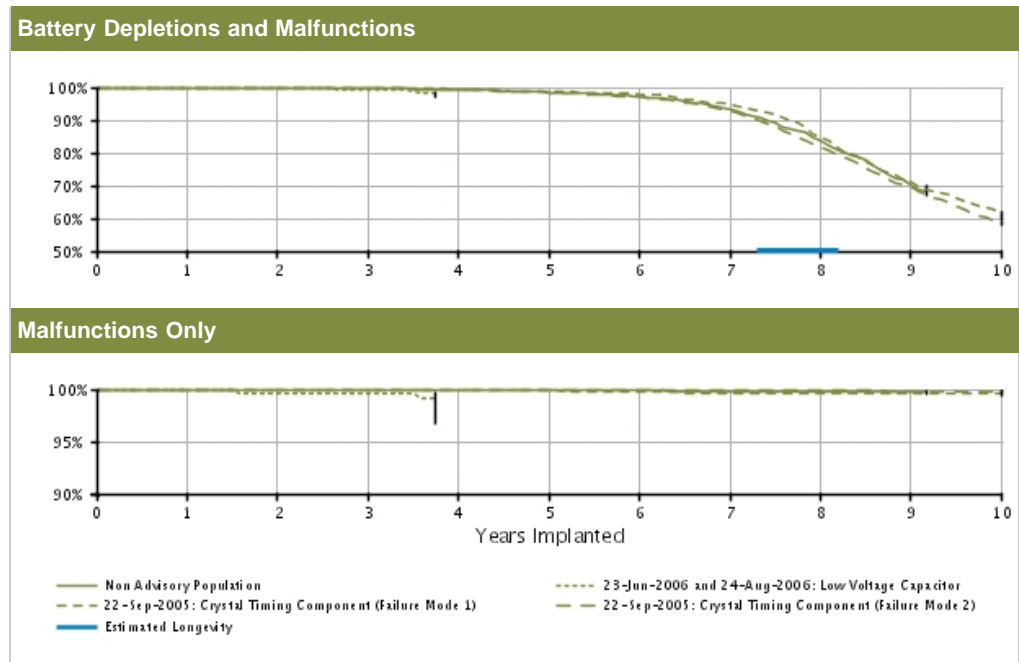
[References](#) cited in table above

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: 3,008
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 8
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	Depletions and Malfunctions(%)	99.96	99.92	99.61	99.33	98.47	97.29	93.25	83.69	70.40	68.32	
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.3/+0.2)	(-0.3/+0.2)	(-0.5/+0.4)	(-0.7/+0.6)	(-1.1/+1.0)	(-2.0/+1.8)	(-3.4/+3.2)	@ 110 mo. (-3.6/+3.4)	
	Registered Implants: 6000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	99.66	99.27	98.33	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-2.0/+0.3)	(-2.2/+0.6)	@ 45 mo. (-2.7/+1.0)							
	Registered Implants: 400											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	100.00	99.66	99.66	99.18	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-2.0/+0.3)	(-2.0/+0.3)	@ 45 mo. (-2.5/+0.6)							
	Registered Implants:											
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions(%)	99.92	99.89	99.74	99.37	98.74	98.00	94.86	84.90	71.08	60.85	
	(Confidence Interval)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.6/+0.4)	(-0.7/+0.5)	(-1.2/+1.0)	(-2.2/+1.9)	(-2.8/+2.7)	(-3.2/+3.1)	
	Registered Implants:											

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	461
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)	92.86 (-0.7/+0.6)	81.82 (-1.1/+1.0)	69.64 (-1.4/+1.3)	58.32 (-1.5/+1.5)
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	11696	10065	8521	7162	6021	4911	3642	2626	1655


*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: 36			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁹ Low-voltage capacitor (Advisory issued)	1	2	
²³ Capacitor	2	2	
²⁷ Integrated circuit	-	1	
⁵³ Integrated circuit	1	-	
Mechanical	1	6	7
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
²⁶ Capacitor array	1	-	
³¹ Seal plug	-	1	
Software	1	-	1
⁶⁰ Pacing rate limit	1	-	
Other	18	1	19
Non-patterned	4	-	
¹⁶ Longevity labeling	10	-	
²⁹ Battery depletion	-	1	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	3	-	
WW Confirmed Malfunctions	24	12	36


[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: 82			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	5	5
⁹ Low-voltage capacitor (Advisory issued)	-	3	
²³ Capacitor	-	1	
⁵³ Integrated circuit	-	1	
Mechanical	2	-	2
³¹ Seal plug	1	-	
³² Header	1	-	
Software	-	-	0
Other	73	2	75
Non-patterned	2	1	
¹⁶ Longevity labeling	42	-	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	29	-	
WW Confirmed Malfunctions	75	7	82

[More details](#) about malfunctions

[References](#) cited in table above

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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. **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.
12. **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.
13. **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.
14. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
15. **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.
16. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
17. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
18. **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.

19. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
20. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
21. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
22. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.
23. **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.
24. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.
25. **Battery depletion**— Premature battery depletion.
26. **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.
27. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
28. **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.
29. **Battery depletion**— Premature battery depletion and loss of capture.
30. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
31. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
32. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
33. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
34. **Battery depletion**— Premature battery depletion.
35. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.
36. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
37. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
38. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
39. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
40. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
41. **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.
42. **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.
43. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
44. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
45. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
46. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
47. **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.
48. **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.
49. **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.
50. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
51. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
52. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.
53. **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.
54. **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.
55. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process

variability. Improvement implemented.

56. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
57. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
58. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
59. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
60. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
61. **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.
62. **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.
63. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.
64. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
65. **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.
66. **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.
67. **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.
68. **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.
69. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
70. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
71. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
72. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
73. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
74. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
75. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
76. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
77. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
78. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
79. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
80. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
81. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
82. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
83. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
84. **Telemetry**— Inability to interrogate, premature battery depletion.
85. **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.
86. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
87. **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.
88. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition.
89. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
90. **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.

91. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement implemented.

Before/During Implant Procedure - Worldwide Malfunctions: Pulse Generators

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

The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.

CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN CRT-D G160/G161/G164/G166/G172/G173/G175/ G177/G179	5,000	0	0	0	4	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	9,000	0	1	0	4	0	0
INCEPTA CRT-D 4-Site N160/N162/P162	16,000	0	0	0	1	0	0
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	17,000	2	0	0	1	0	0
ENERGEN CRT-D 4-Site N140/N142/P142	19,000	2	0	0	3	0	0
ENERGEN CRT-D N141/N143/P143	17,000	3	0	0	4	0	0
PUNCTUA CRT-D 4-Site N050/N052/P052	2,000	0	0	0	0	0	0
PUNCTUA CRT-D N051/N053/P053	5,000	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
CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INVIVE V172/V173/V182/V183/W172/W173	16,000	0	0	1	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	2,000	0	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	2,000	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	3,000	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	3,000	0	0	0	0	0	0

ICD/Model, continued...	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA ICD VR 4-Site E160/F160	16,000	0	1	0	2	0	0
INCEPTA ICD DR 4-Site E162/F162	19,000	0	0	0	0	0	0
INCEPTA ICD VR E161/F161	7,000	0	0	0	1	0	0
INCEPTA ICD DR E163/F163	10,000	0	0	0	0	0	0
ENERGEN ICD VR 4-Site E140/F140	21,000	1	0	0	4	0	0
ENERGEN ICD DR 4-Site E142/F142	20,000	1	0	0	1	0	0
ENERGEN ICD VR E141/F141	11,000	2	0	0	1	0	0
ENERGEN ICD DR E143/F143	14,000	2	1	0	2	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	23	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	9,000	0	0	0	0	0	0
ADVANTIO SR J062/J065/K062/K065/K082	28,000	0	0	0	2	0	0
ADVANTIO DR J063/J066/K063/K066/K083	69,000	4	1	0	3	0	0
INGENIO EL DR J174/J177/K174/K177/K184	28,000	1	0	0	1	0	0
INGENIO SR J172/J175/K172/K175/K182	31,000	0	0	0	1	0	0
INGENIO DR J173/J176/K173/K176/K183	102,000	0	1	0	5	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	0	0
FORMIO DR J278/J279/K278/K279	2,000	0	0	0	0	0	0
VITALIO DR J273/J276/K273/K276	9,000	0	0	0	1	0	0
VITALIO EL DR J274/J277/K274	8,000	0	0	0	0	0	0
VITALIO SR J272/J275/K272/K275	4,000	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	43,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	11,000	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	10,000	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
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	5000	0	1	0	1	20	78
INCEPTA CRT-D 4-Site N160/N162/P162	9000	5	2	0	4	108	679
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	12000	8	2	0	2	144	1221
ENERGEN CRT-D 4-Site N140/N142/P142	13000	4	1	2	2	156	1201
ENERGEN CRT-D N141/N143/P143	13000	6	3	1	9	177	1502
COGNIS N118/N119/N120/P106/P107/P108	75000	803	59	8	798	1547	25227
LIVIAN HE H227/H229/H247/H249	6000	1447	4	2	6	176	2568
LIVIAN H220/H225/H240/H245	5000	1158	0	3	8	120	2130

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	7000	5	0	2	1	43	747
CONTAK RENEWAL TR H120/H125	19000	1897	16	133	44	252	9035
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 S-ICD 1010		2	1	1	17	128	256
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	10000	3	0	4	3	76	571
INCEPTA ICD DR 4-Site E162/F162	11000	2	0	7	4	90	693
INCEPTA ICD VR E161/F161	4000	2	0	1	1	39	284
INCEPTA ICD DR E163/F163	7000	3	1	1	5	52	450
ENERGEN ICD VR 4-Site E140/F140	14000	11	1	7	4	130	990
ENERGEN ICD DR 4-Site E142/F142	14000	5	0	7	5	144	1083
ENERGEN ICD VR E141/F141	7000	4	0	2	3	52	622
ENERGEN ICD DR E143/F143	10000	4	1	4	1	79	878
PUNCTUA ICD VR E051/F051	1000	0	0	0	1	2	60

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	63	33	322	559	589	10031
TELIGEN DR E110/E111/F110/F111	66000	135	47	444	839	1037	18211
CONFIENT DR E030/F030	7000	85	2	91	13	142	2670
VITALITY 2 EL VR T177	7000	990	9	148	1255	109	2596
VITALITY 2 EL DR T167	8000	1707	14	141	765	131	3196
VITALITY 2 VR T175	21000	5452	35	378	1240	300	9169
VITALITY 2 DR T165	31000	11647	79	526	1139	454	13359
VITALITY DR HE T180	13000	2715	13	230	416	306	6419
VITALITY DS DR T125	22000	8273	67	361	1187	305	10236
VITALITY DS VR T135	19000	5506	39	320	1555	255	8809
VITALITY EL T127	4000	928	9	60	618	69	1554

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	11000	4	0	9	5	46	1174
ADVANTIO DR J063/J066/K063/K066/K083	45000	12	2	11	11	234	2998
ADVANTIO EL DR J064/K064/K067/K084	2000	1	0	1	1	5	64
INGENIO SR J172/J175/K172/K175/K182	12000	1	0	4	0	50	1145
INGENIO DR J173/J176/K173/K176/K183	64000	18	3	17	8	266	3281

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
VITALIO DR J273/J276/K273/K276	3000	0	0	0	0	6	67
ALTRUA 60 SR S601	32000	161	2	159	3	157	11672
ALTRUA 60 DR (Downsize) S603	90000	2263	32	339	35	540	23596
ALTRUA 60 DR S602	22000	209	2	122	5	174	5948
ALTRUA 60 DR EL S606	59000	148	7	185	7	390	11351
ALTRUA 40 SR S401	5000	22	0	14	2	21	1910
ALTRUA 40 DR (downsize) S403	14000	363	2	34	3	77	3888
ALTRUA 40 DR S402	2000	16	1	14	0	6	616
ALTRUA 40 DR EL S404	5000	16	1	21	0	40	1286
ALTRUA 20 SR S201/S204	4000	23	1	15	0	35	2029
ALTRUA 20 DR (downsize) S203	5000	65	3	18	0	36	1758
ALTRUA 20 DR S202/S205	2000	25	0	5	1	12	651
ALTRUA 20 DR EL S208	3000	11	0	12	1	10	936
INSIGNIA Ultra SR 1190 ⁴	24000	1752	9	192	38	140	15599
INSIGNIA Ultra DR (Downsize) 1290 ⁴	76000	16826	113	531	429	590	37755
INSIGNIA Ultra DR 1291 ⁴	32000	2298	19	284	140	299	14280

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	655	10	81	9	72	10206
INSIGNIA Entra DR (Downsize) 1296 ⁴	24000	4482	25	128	97	150	15024
INSIGNIA Entra DR 1294/1295 ⁴	17000	1231	11	114	60	178	10261
INSIGNIA Plus SR 1194 ⁴	27000	3008	8	222	27	156	20211
INSIGNIA Plus DR (Downsize) 1298 ⁴	90000	25671	114	530	374	694	51281
INSIGNIA Plus DR 1297 ⁴	27000	3966	19	247	127	259	14425

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
---------------------------	-------------------------------	--------------------

ACUITY X4 Spiral L Models 4677/4678			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	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: 3,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	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
---------------------------	-------------------------------	--------------------

ACUITY X4 Straight Models 4671/4672			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[More details](#) about malfunctions

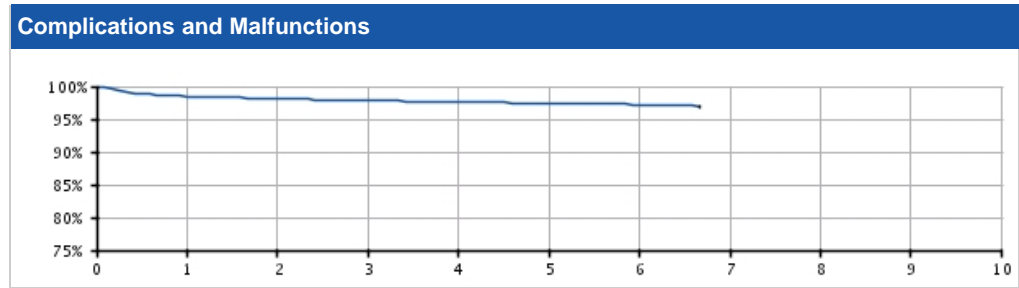
[References](#) cited in table above

ACUITY Spiral

Models 4591/4592/4593

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

U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Chronic Lead Complications: 399
U.S. Approval Date: May 2008	U.S. Malfunctions: 7
U.S. Estimated Active Implants: 15,000	Without Compromised Therapy: 3
	With Compromised Therapy: 4




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.50 (-0.2/+0.2)	98.10 (-0.2/+0.2)	97.82 (-0.2/+0.2)	97.58 (-0.3/+0.2)	97.45 (-0.3/+0.3)	97.21 (-0.4/+0.3)	96.88 @ 80 mo. (-0.8/+0.7)	—	—	—
Registered Implants: 20000										
Effective Sample Size	16410	12506	9112	6111	3444	1348	290	—	—	—

ACUITY Spiral

Models 4591/4592/4593

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

ACUITY Spiral Models 4591/4592/4593			
Worldwide Distribution: 40,000			
Worldwide Confirmed Malfunctions: 7			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	3	4
²⁸ Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	2	-	2
²⁷ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	3	4	7

[More details](#) about malfunctions

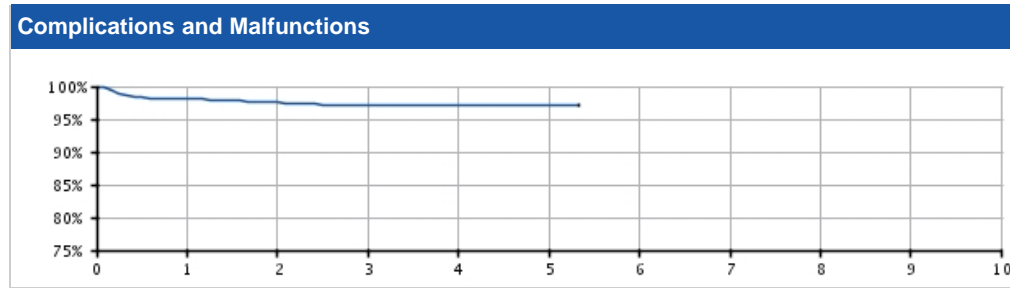
[References](#) cited in table above

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: 1347	Chronic Lead Complications: 31
Leads Active: 1009	Malfunctions:0
Cumulative Followup Months : 37,392	Without Compromised Therapy:0
	With Compromised Therapy:0



Longitude Registry Survival Probability

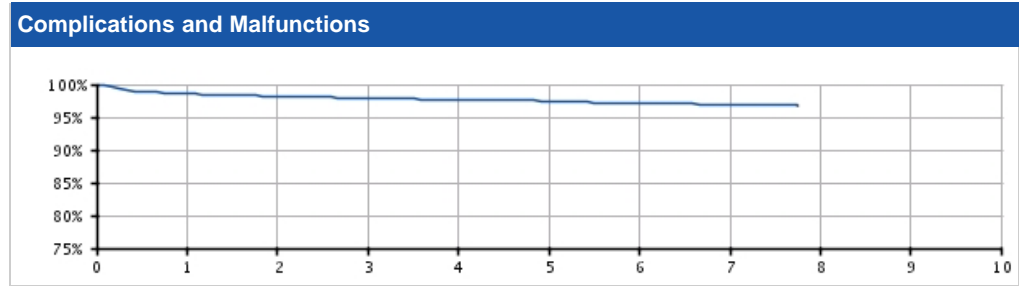
Year	1	2	3	4	5	6	7	8	9	10
Longitude	98.05 (-0.9/+0.6)	97.62 (-1.1/+0.7)	97.24 (-1.2/+0.8)	97.24 (-1.2/+0.8)	97.24 (-1.2/+0.8)	97.24 @ 64 mo. (-1.2/+0.8)	—	—	—	—
Registered Implants: 1347										
Effective Sample Size	1050	821	624	395	131	69	—	—	—	—

ACUITY Steerable

Models 4554/4555/4556

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

U.S. Summary	
U.S. Registered Implants: 28,000	U.S. Chronic Lead Complications: 534
U.S. Approval Date: May 2008	U.S. Malfunctions:31
U.S. Estimated Active Implants: 18,000	Without Compromised Therapy:10
	With Compromised Therapy:21




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>	98.18 <small>(-0.2/+0.2)</small>	97.91 <small>(-0.2/+0.2)</small>	97.69 <small>(-0.2/+0.2)</small>	97.40 <small>(-0.2/+0.2)</small>	97.11 <small>(-0.3/+0.3)</small>	96.85 <small>(-0.4/+0.3)</small>	96.85 @ 93 mo. <small>(-0.4/+0.3)</small>	--	--
Registered Implants: 28000										
Effective Sample Size	22255	17778	14057	10669	7430	4467	1833	219	--	--

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556 			
Worldwide Distribution: 61,000			
Worldwide Confirmed Malfunctions: 52			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	9	35	44
²⁸ Non-patterned, Conductor	6	9	
³⁵ Extracardiac fracture	3	26	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	6	1	7
²⁷ Non-patterned, Other	6	1	
WW Confirmed Malfunctions	15	37	52

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 3

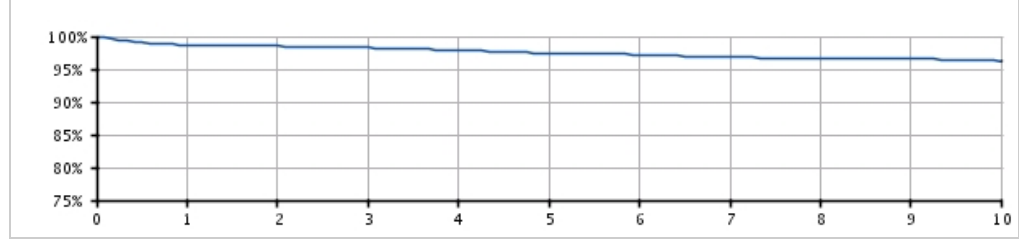
Models 4522/4524/4525/4527/4548/
4549/4550

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

U.S. Summary

U.S. Registered Implants: 21,000	U.S. Chronic Lead Complications: 415
U.S. Approval Date: August 2004	U.S. Malfunctions:30
U.S. Estimated Active Implants: 11,000	Without Compromised Therapy:7
	With Compromised Therapy:23

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.69 (-0.2/+0.2)	98.51 (-0.2/+0.2)	98.27 (-0.2/+0.2)	97.92 (-0.2/+0.2)	97.49 (-0.3/+0.2)	97.19 (-0.3/+0.3)	96.82 (-0.3/+0.3)	96.66 (-0.4/+0.3)	96.52 (-0.4/+0.4)	96.19 (-0.6/+0.5)
Registered Implants: 21000										
Effective Sample Size	17302	14316	11770	9646	7736	6019	4527	3217	1758	611

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: 41,000			
Worldwide Confirmed Malfunctions: 47			
	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
Insulation	3	1	4
²⁹ Non-patterned, Insulation	3	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	12	35	47

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 2

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

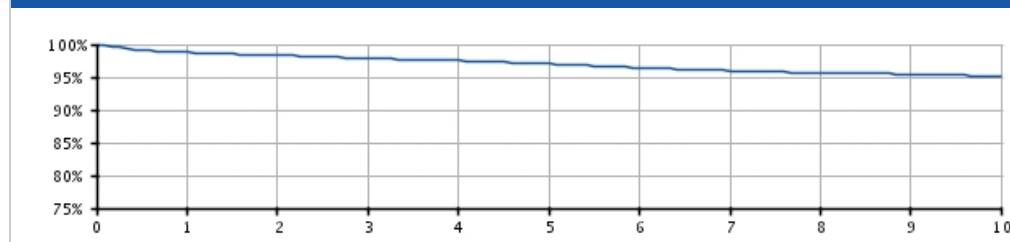
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary

U.S. Registered Implants: 94,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 47,000

U.S. Chronic Lead Complications: 2,049
U.S. Malfunctions:308
Without Compromised Therapy:54
With Compromised Therapy:254

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)	98.32 (-0.1/+0.1)	97.89 (-0.1/+0.1)	97.52 (-0.1/+0.1)	97.03 (-0.1/+0.1)	96.45 (-0.2/+0.2)	95.99 (-0.2/+0.2)	95.66 (-0.2/+0.2)	95.46 (-0.2/+0.2)	95.11 (-0.3/+0.3)
Registered Implants: 94000										
Effective Sample Size	76528	63683	52698	42974	33748	25368	18414	12485	7044	2684

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: 171,000
Worldwide Confirmed Malfunctions: 438

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	60	354	414
²⁶ Conductor fracture	56	307	
²⁸ Non-patterned, Conductor	4	47	
Crimp/Weld/Bond	-	-	0
Insulation	9	2	11
²⁹ Non-patterned, Insulation	9	2	
Other	8	5	13
²⁷ Non-patterned, Other	8	5	
WW Confirmed Malfunctions	77	361	438

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK

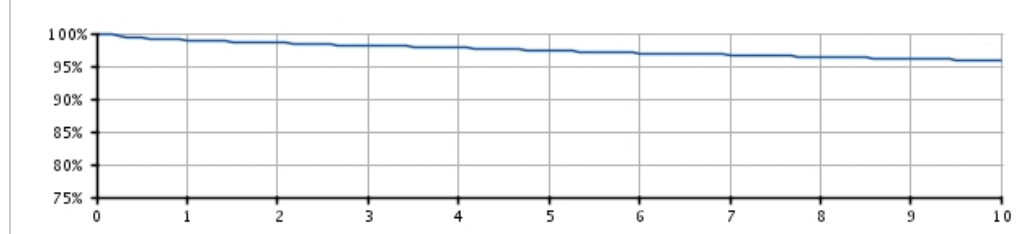
Models 4510/4511/4512/4513/4535/
4536/4537/4538

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

U.S. Summary

U.S. Registered Implants: 38,000	U.S. Chronic Lead Complications: 889
U.S. Approval Date: May 2002	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy: 10
	With Compromised Therapy: 15

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)	96.35 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.92 (-0.3/+0.3)
Registered Implants: 38000										
Effective Sample Size	30543	26257	22527	19361	16533	14141	12035	10144	8576	7240

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: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	13	13
²⁸ Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	-	-	0
Insulation	3	3	6
²⁹ Non-patterned, Insulation	3	3	
Other	7	1	8
²⁷ Non-patterned, Other	7	1	
WW Confirmed Malfunctions	10	17	27

[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: 5,000
Worldwide Confirmed Malfunctions: 0

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

[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: 13,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	4	4
³⁸ Conductor cable fracture	-	4	
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
²⁷ Non-patterned, Other	-	-	
WW Confirmed Malfunctions	0	4	4

[More details](#) about malfunctions

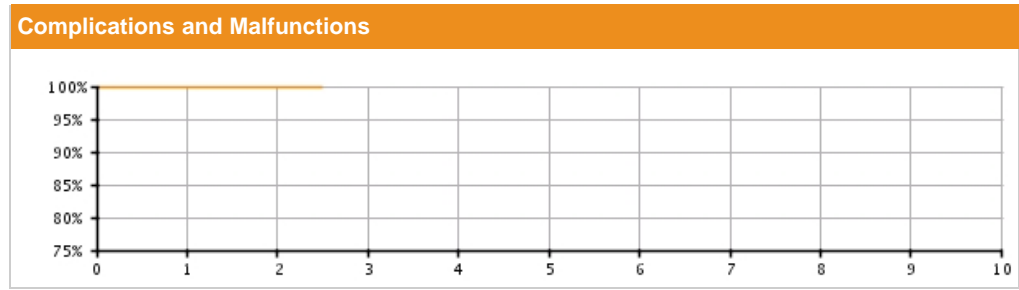
[References](#) cited in table above

Q-TRAK SQ Electrode

Model 3010

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

U.S. Summary	
U.S. Approval Date: September 2012	U.S. Chronic Lead Complications: 4 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	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.91 @ 30 mo. (-0.2/+0.1)	--	--	--	--	--	--	--	

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
³⁷ Weld fracture	-	1	
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**

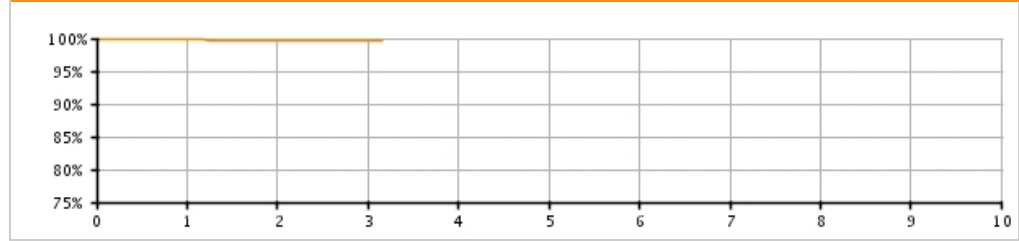
Models 0295/0296

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

U.S. Summary

U.S. Registered Implants: 40,000	U.S. Chronic Lead Complications: 92
U.S. Approval Date: November 2010	U.S. Malfunctions:5
U.S. Estimated Active Implants: 37,000	Without Compromised Therapy:0
	With Compromised Therapy:5

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.63 @ 38 mo. (-0.1/+0.1)	—	—	—	—	—	—
Registered Implants: 40000										
Effective Sample Size	26859	13807	2068	590	—	—	—	—	—	—

**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: 70,000

Worldwide Confirmed Malfunctions: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁸ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	7	12	19
²⁹ Non-patterned, Insulation	7	12	
Other	2	2	4
²⁷ Non-patterned, Other	2	2	
WW Confirmed Malfunctions	9	17	26

[More details](#) about malfunctions

[References](#) cited in table above

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

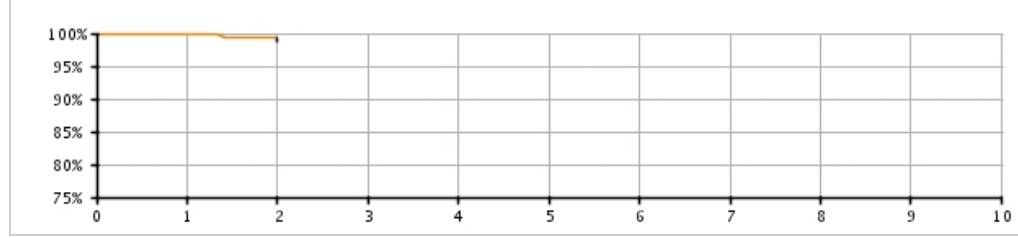
Models 0295/0296

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

Longitude Registry Summary Data

Leads Enrolled: 750	Chronic Lead Complications: 2
Leads Active: 695	Malfunctions: 0
Cumulative Followup Months : 9,069	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	99.86 (-0.8/+0.1)	99.26 (-3.0/+0.6)	-	-	-	-	-	-	-	-
Registered Implants: 750										
Effective Sample Size	369	51	-	-	-	-	-	-	-	-

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

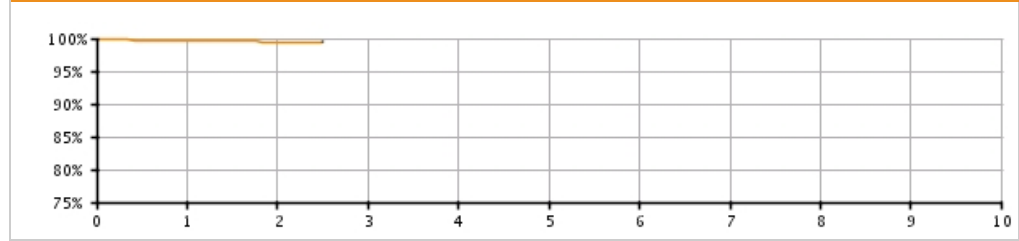
Models 0285/0286

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

U.S. Summary

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 5
U.S. Approval Date: November 2010	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	99.70 (-0.5/+0.2)	99.50 (-0.8/+0.3)	99.50 @ 30 mo. (-0.8/+0.3)	--	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	895	415	220	--	--	--	--	--	--	--

**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: 0

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

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation

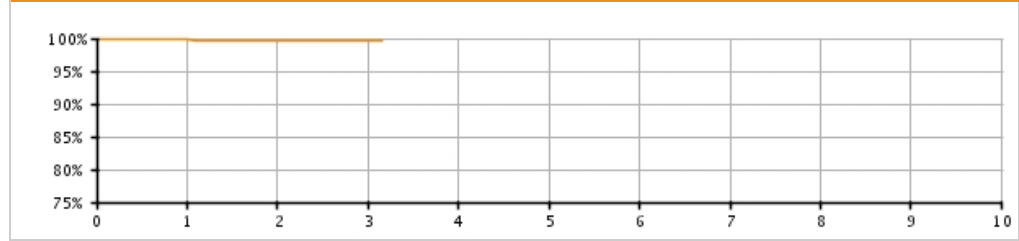
Models 0292/0293

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

U.S. Registered Implants: 36,000	U.S. Chronic Lead Complications: 76
U.S. Approval Date: November 2010	U.S. Malfunctions: 2
U.S. Estimated Active Implants: 34,000	Without Compromised Therapy: 1
	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	99.76 (-0.1/+0.1)	99.69 (-0.1/+0.1)	99.69 (-0.1/+0.1)	99.69 @ 38 mo. (-0.1/+0.1)	—	—	—	—	—	—
Registered Implants: 36000										
Effective Sample Size	19285	7550	933	286	—	—	—	—	—	—

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

Models 0292/0293

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability
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**ENDOTAK RELIANCE SG 4-Site
Single Coil, Active Fixation
Models 0292/0293**



Worldwide Distribution: 65,000
Worldwide Confirmed Malfunctions: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁵ Conductor fracture	-	1	
²⁸ Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	-	-	0
Insulation	2	8	10
²⁹ Non-patterned, Insulation	2	8	
Other	-	2	2
²⁷ Non-patterned, Other	-	2	
WW Confirmed Malfunctions	2	12	14

[More details](#) about malfunctions

[References](#) cited in table above

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

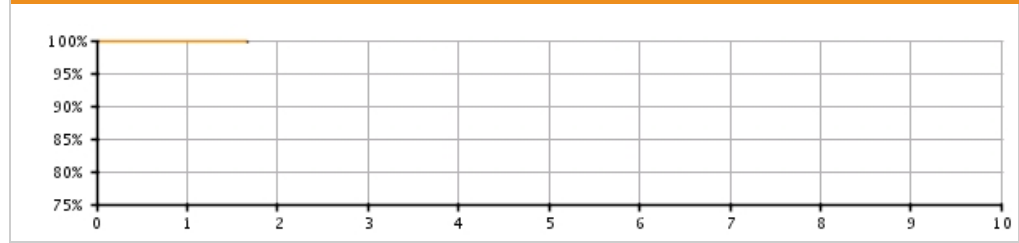
Models 0292/0293

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

Leads Enrolled: 1099	Chronic Lead Complications: 2
Leads Active: 1004	Malfunctions: 0
Cumulative Followup Months : 12,299	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	99.89 (-0.6/+0.1)	99.89 @ 20 mo. (-0.7/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 1099										
Effective Sample Size	456	68	-	-	-	-	-	-	-	-

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

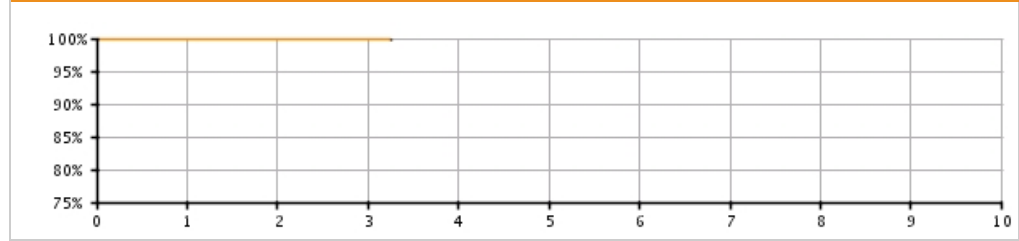
Models 0282/0283

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: 1
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions: 0
	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 (-1.1/+0.2)	99.82 @ 17 mo. (-1.1/+0.2)	--	--	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	288	201	--	--	--	--	--	--	--	--

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

Models 0282/0283

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE SG 4-Site Single Coil, Passive Fixation Models 0282/0283 			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁶ Non-patterned, Insulation	-	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

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

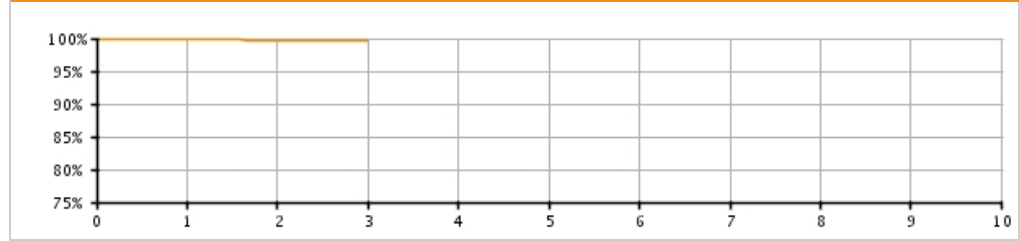
Models 0275/0276

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

U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 8
U.S. Approval Date: November 2010	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 3,000	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	99.85 (-0.2/+0.1)	99.68 (-0.3/+0.2)	99.68 (-0.3/+0.2)	--	--	--	--	--	--	--
Registered Implants: 4000										
Effective Sample Size	2468	1389	225	--	--	--	--	--	--	--

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

Models 0275/0276

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation
Models 0275/0276**



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

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

[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
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**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
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

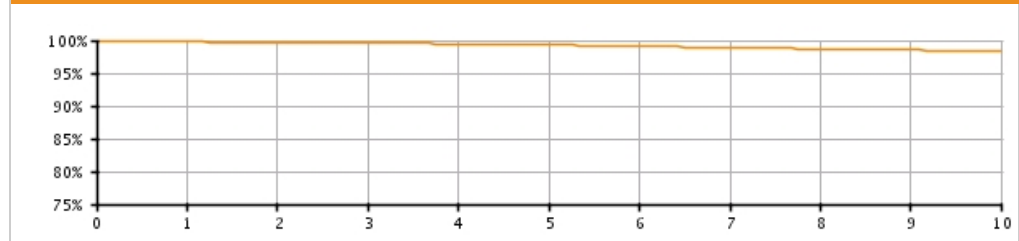
Models 0164/0165/0166/0167/0184/
0185/0186/0187

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

U.S. Registered Implants: 188,000	U.S. Chronic Lead Complications: 1,112
U.S. Approval Date: May 2004	U.S. Malfunctions: 186
U.S. Estimated Active Implants: 111,000	Without Compromised Therapy: 80
	With Compromised Therapy: 106

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)	99.58 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.30 (-0.0/+0.0)	99.10 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.71 (-0.1/+0.1)	98.55 (-0.1/+0.1)	98.32 (-0.1/+0.1)
Registered Implants: 188000										
Effective Sample Size	164670	145334	127402	102903	79482	58094	38929	24600	14214	5769

**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: 254,000
Worldwide Confirmed Malfunctions: 321

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	92	94
²⁵ Conductor fracture	-	57	
²⁸ Non-patterned, Conductor	2	35	
Crimp/Weld/Bond	2	-	2
³² Non-patterned, Crimp, Weld, Bond	2	-	
Insulation	115	73	188
²⁹ Non-patterned, Insulation	115	73	
Other	22	15	37
²⁷ Non-patterned, Other	22	15	
WW Confirmed Malfunctions	141	180	321

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE G
Dual Coil, Active Fixation Longitude

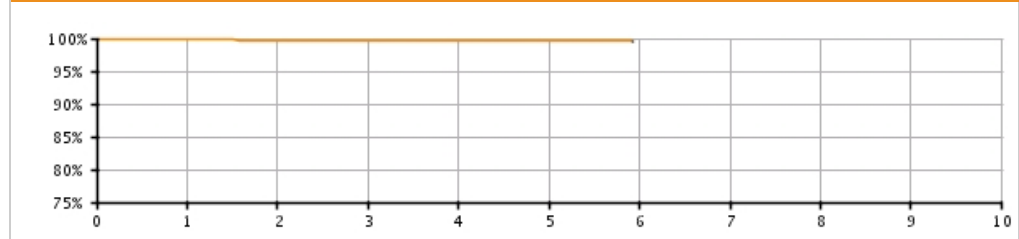
Models 0164/0165/0166/0167/0184/
 0185/0186/0187

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

Longitude Registry Summary Data

Leads Enrolled: 629	Chronic Lead Complications: 1
Leads Active: 440	Malfunctions:1
Cumulative Followup Months : 20,379	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 @ 71 mo. (-1.2/+0.3)	—	—	—	—
Registered Implants: 629										
Effective Sample Size	546	476	404	299	140	51	—	—	—	—

ENDOTAK RELIANCE G Dual Coil, Passive Fixation

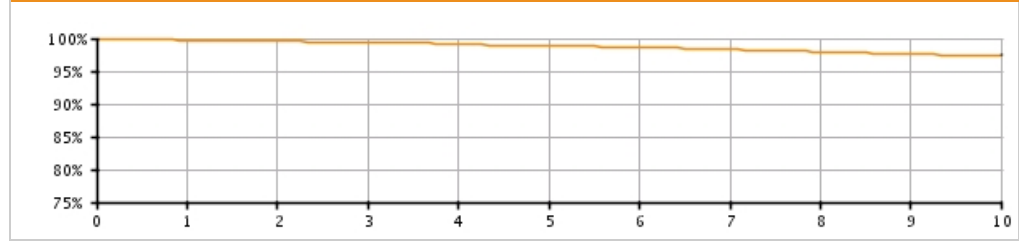
Models 0174/0175/0176/0177

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

U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 136
U.S. Approval Date: May 2004	U.S. Malfunctions: 14
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy: 5
	With Compromised Therapy: 9

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)	99.40 (-0.2/+0.1)	99.15 (-0.2/+0.2)	98.88 (-0.2/+0.2)	98.64 (-0.3/+0.2)	98.27 (-0.3/+0.3)	98.00 (-0.4/+0.3)	97.54 (-0.5/+0.4)	97.46 (-0.6/+0.5)
Registered Implants: 14000										
Effective Sample Size	11918	10471	9008	7416	5866	4503	3250	2194	1383	645

ENDOTAK RELIANCE G
Dual Coil, Passive Fixation

Models 0174/0175/0176/0177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE G
Dual Coil, Passive Fixation
Models 0174/0175/0176/0177



Worldwide Distribution: 39,000
Worldwide Confirmed Malfunctions: 54

	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	
Insulation	16	14	30
²⁹ Non-patterned, Insulation	16	14	
Other	7	-	7
²⁷ Non-patterned, Other	7	-	
WW Confirmed Malfunctions	23	31	54

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

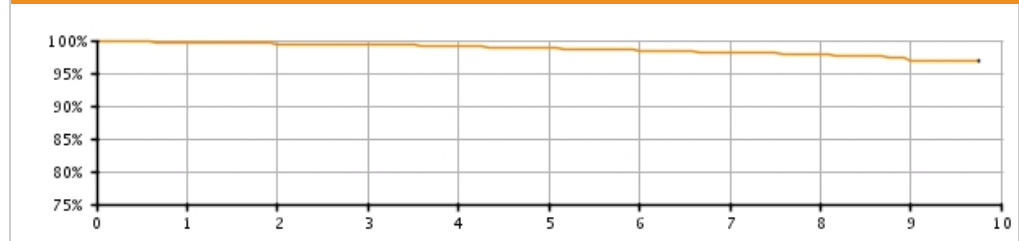
Models 0160/0161/0162/0180/0181/
 0182

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

U.S. Registered Implants: 27,000	U.S. Chronic Lead Complications: 170
U.S. Approval Date: May 2004	U.S. Malfunctions:49
U.S. Estimated Active Implants: 21,000	Without Compromised Therapy:18
	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	99.68 (-0.1/+0.1)	99.48 (-0.1/+0.1)	99.35 (-0.1/+0.1)	99.11 (-0.2/+0.1)	98.84 (-0.2/+0.2)	98.47 (-0.3/+0.2)	98.11 (-0.4/+0.3)	97.82 (-0.5/+0.4)	96.81 (-1.2/+0.9)	96.81 @ 117 mo. (-1.2/+0.9)
Registered Implants: 27000										
Effective Sample Size	22266	18117	14593	9383	5664	3284	1654	780	412	207

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE SG
Single Coil, Active Fixation
 Models 0160/0161/0162/0180/0181/
 0182



Worldwide Distribution: 58,000
Worldwide Confirmed Malfunctions: 130

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	49	50
²⁵ Conductor fracture	1	42	
²⁸ Non-patterned, Conductor	-	7	
Crimp/Weld/Bond	-	-	0
Insulation	43	24	67
²⁹ Non-patterned, Insulation	43	24	
Other	7	6	13
²⁷ Non-patterned, Other	7	6	
WW Confirmed Malfunctions	51	79	130

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE SG Single Coil, Passive Fixation

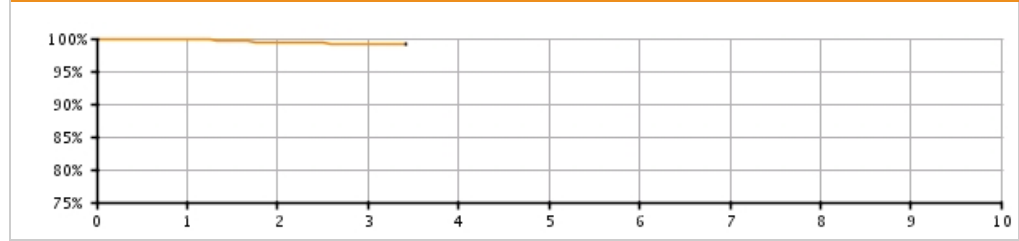
Models 0170/0171/0172/0173

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

U.S. Summary

<p>U.S. Registered Implants: 1,000 U.S. Approval Date: May 2004 U.S. Estimated Active Implants: 1,000</p>	<p>U.S. Chronic Lead Complications: 4 U.S. Malfunctions: 0 Without Compromised Therapy: 0 With Compromised Therapy: 0</p>
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Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.88 <small>(-0.7/+0.1)</small>	99.49 <small>(-1.1/+0.3)</small>	99.18 <small>(-1.5/+0.5)</small>	99.18 @ 41 mo. <small>(-1.5/+0.5)</small>	—	—	—	—	—	—
Registered Implants: 1000										
Effective Sample Size	619	423	256	206	—	—	—	—	—	—

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE SG
Single Coil, Passive Fixation
Models 0170/0171/0172/0173



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	2	3
²⁵ Conductor fracture	1	2	
Crimp/Weld/Bond	-	-	0
Insulation	3	-	3
²⁹ Non-patterned, Insulation	3	-	
Other	-	-	0
WW Confirmed Malfunctions	4	2	6

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

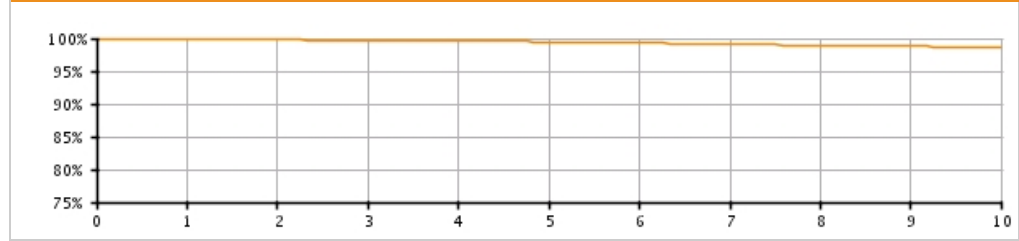
Models 0157/0158/0159

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: 608
U.S. Approval Date: July 2002	U.S. Malfunctions: 75
U.S. Estimated Active Implants: 39,000	Without Compromised Therapy: 30
	With Compromised Therapy: 45

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)	99.10 (-0.1/+0.1)	98.95 (-0.1/+0.1)	98.79 (-0.1/+0.1)	98.65 (-0.1/+0.1)
Registered Implants: 97000										
Effective Sample Size	85051	75698	67124	58148	49646	41541	34366	28047	22595	17257

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

Models 0157/0158/0159

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159



Worldwide Distribution: 114,000
Worldwide Confirmed Malfunctions: 93

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	20	20
²⁵ Conductor fracture	-	13	
²⁸ Non-patterned, Conductor	-	7	
Crimp/Weld/Bond	3	1	4
³ Seal rings	2	1	
³² Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	30	27	57
²⁹ Non-patterned, Insulation	30	27	
Other	8	4	12
²⁷ Non-patterned, Other	8	4	
WW Confirmed Malfunctions	41	52	93

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

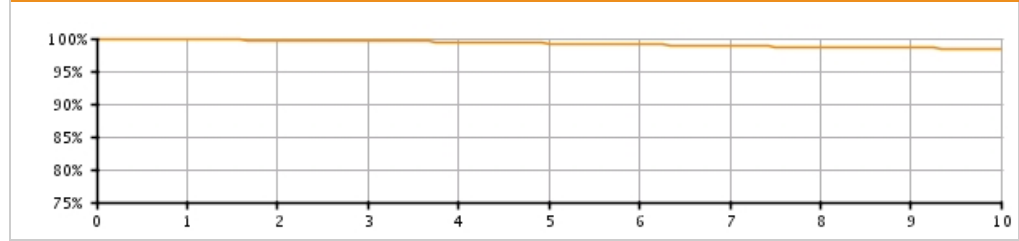
Models 0147/0148/0149

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

U.S. Registered Implants: 33,000	U.S. Chronic Lead Complications: 317
U.S. Approval Date: October 2000	U.S. Malfunctions:19
U.S. Estimated Active Implants: 11,000	Without Compromised Therapy:5
	With Compromised Therapy:14

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)	99.25 (-0.1/+0.1)	99.06 (-0.1/+0.1)	98.86 (-0.2/+0.1)	98.64 (-0.2/+0.2)	98.53 (-0.2/+0.2)	98.36 (-0.2/+0.2)
Registered Implants: 33000										
Effective Sample Size	28520	25430	22635	20013	17612	15450	13463	11654	10020	8504

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE
Dual Coil, Passive Fixation
Models 0147/0148/0149



Worldwide Distribution: 67,000
Worldwide Confirmed Malfunctions: 65

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	12	12
²⁵ Conductor fracture	-	3	
²⁸ Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	-	2	2
³⁶ Conductor connection	-	2	
Insulation	21	24	45
²⁹ Non-patterned, Insulation	21	24	
Other	2	4	6
⁴ Manufacturing material	-	1	
²⁷ Non-patterned, Other	2	3	
WW Confirmed Malfunctions	23	42	65

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE S

Single Coil, Active Fixation

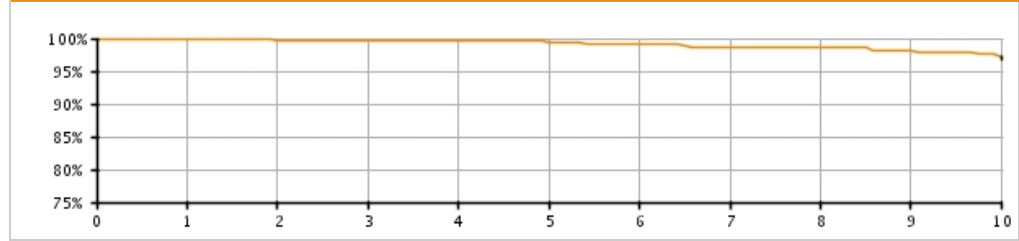
Models 0137/0138

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

<p>U.S. Registered Implants: 3,000</p> <p>U.S. Approval Date: July 2002</p> <p>U.S. Estimated Active Implants: 1,000</p>	<p>U.S. Chronic Lead Complications: 15</p> <p>U.S. Malfunctions: 3</p> <p>Without Compromised Therapy: 2</p> <p>With Compromised Therapy: 1</p>
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Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.83 (-0.3/+0.1)	99.72 (-0.3/+0.2)	99.65 (-0.4/+0.2)	99.57 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.22 (-0.7/+0.4)	98.73 (-1.0/+0.6)	98.53 (-1.1/+0.6)	98.25 (-1.3/+0.8)	97.20 (-2.0/+1.2)
Registered Implants: 3000										
Effective Sample Size	2143	1814	1470	1153	895	683	514	398	325	252

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE S Single Coil, Active Fixation Models 0137/0138 			
Worldwide Distribution: 5,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁵ Conductor fracture	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	5	1	6
²⁹ Non-patterned, Insulation	5	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	6	4	10

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE S

Single Coil, Passive Fixation

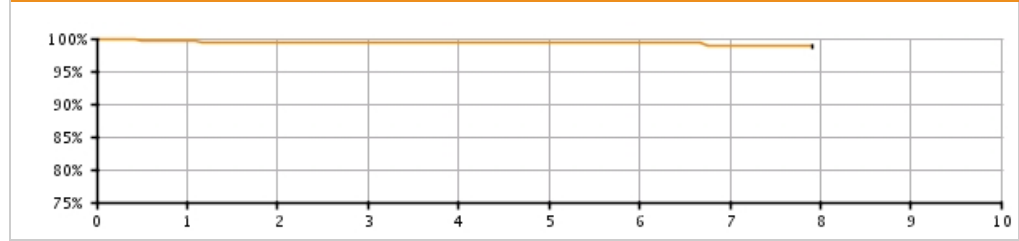
Models 0127/0128

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

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 9
U.S. Approval Date: October 2000	U.S. Malfunctions: 1
U.S. Estimated Active Implants: 200	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	99.67 (-1.0/+0.2)	99.49 (-1.1/+0.3)	99.49 (-1.1/+0.3)	99.26 (-1.2/+0.5)	99.26 (-1.2/+0.5)	99.26 (-1.2/+0.5)	98.86 (-1.8/+0.7)	98.86 @ 95 mo. (-1.8/+0.7)	-	-
Registered Implants: 1000										
Effective Sample Size	571	491	431	378	330	277	235	201	-	-

ENDOTAK RELIANCE S
Single Coil, Passive Fixation

Models 0127/0128

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE S Single Coil, Passive Fixation Models 0127/0128 			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 10			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁸ Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	-	-	0
Insulation	3	4	7
²⁹ Non-patterned, Insulation	3	4	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	4	6	10

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK DSP
Passive Fixation**

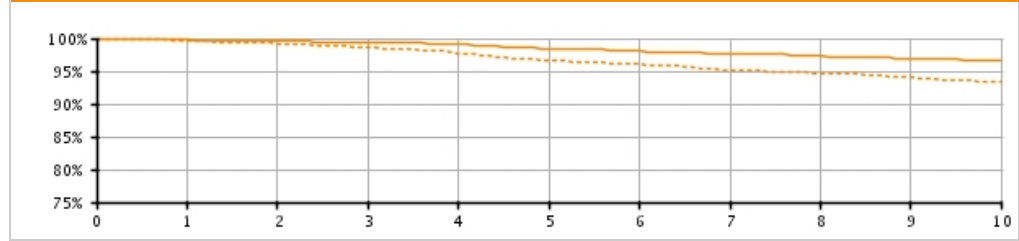
Models 0094/0095/0125

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

U.S. Registered Implants: 36,000	U.S. Chronic Lead Complications: 1,340
U.S. Approval Date: November 1995	U.S. Malfunctions: 173
U.S. Estimated Active Implants: 6,000	Without Compromised Therapy: 52
	With Compromised Therapy: 121

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	13505	12010	10701	9499	8337	7385	6519	5765	5075	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	11014	9642	8419	7362	6436	5638

ENDOTAK ENDURANCE
Passive Fixation

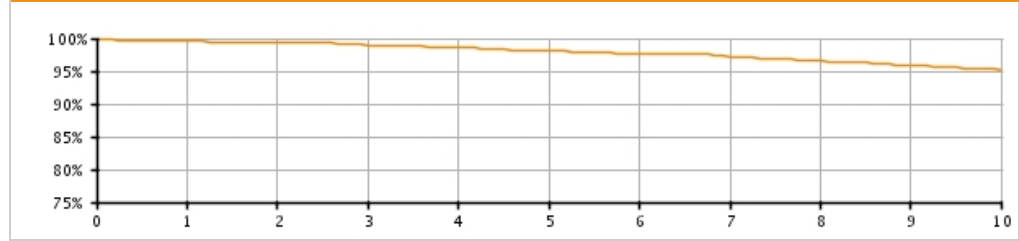
Models 0134/0135/0136

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

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 108
U.S. Approval Date: August 1998	U.S. Malfunctions: 3
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy: 2
	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	99.53 (-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

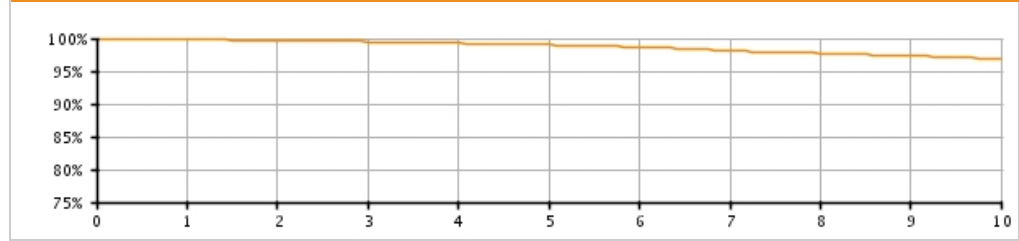
Models 0154/0155/0156

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

U.S. Registered Implants: 29,000	U.S. Chronic Lead Complications: 550
U.S. Approval Date: June 1999	U.S. Malfunctions: 22
U.S. Estimated Active Implants: 7,000	Without Compromised Therapy: 10
	With Compromised Therapy: 12

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	9498	8410

ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting

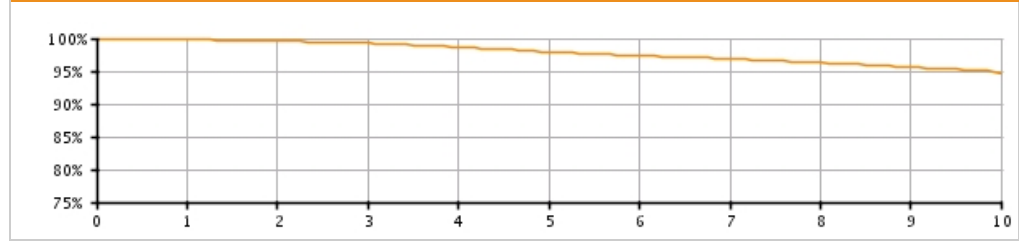
Models 0144/0145/0146

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

U.S. Registered Implants: 18,000	U.S. Chronic Lead Complications: 663
U.S. Approval Date: January 1999	U.S. Malfunctions: 24
U.S. Estimated Active Implants: 4,000	Without Compromised Therapy: 6
	With Compromised Therapy: 18

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/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.86 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15631	13940	12420	10991	9683	8568	7602	6727	5923	5206

**ENDOTAK SQ
Array and SQ Array XP**

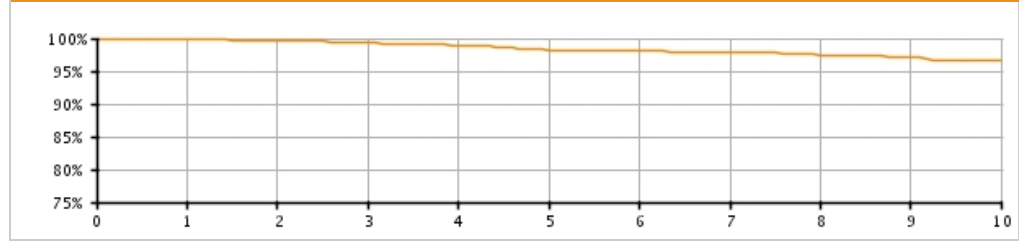
Models 0048/0049/0085

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

U.S. Summary

U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 69
U.S. Approval Date: April 2000	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)	98.86 (-0.5/+0.3)	98.17 (-0.6/+0.5)	98.11 (-0.7/+0.5)	97.88 (-0.7/+0.5)	97.49 (-0.8/+0.6)	97.02 (-1.0/+0.7)	96.59 (-1.1/+0.9)
Registered Implants: 4000										
Effective Sample Size	3125	2745	2415	2075	1762	1451	1178	930	754	582

INGEVITY Positive Fixation

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INGEVITY Positive Fixation Models 7640/7641/7642/7740/7741/ 7742			
Worldwide Distribution: 35,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	1	1
³⁹ Inner conductor fracture	-	1	
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
²⁷ Non-patterned, Other	-	-	
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: 5,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	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
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INGEVITY Atrial J Passive Fixation
Models 7635/7636/7735/7736



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	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: 169,000			
Worldwide Confirmed Malfunctions: 101			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	4	32	36
⁷ Lead conductor	2	18	
³³ Conductor damage	2	14	
Crimp/Weld/Bond	-	-	0
Insulation	48	6	54
² Inner insulation abrasion	3	-	
²⁹ Non-patterned, Insulation	4	-	
³⁴ Insulation damage	41	6	
Other	11	-	11
²⁷ Non-patterned, Other	11	-	
WW Confirmed Malfunctions	63	38	101

[More details](#) about malfunctions

[References](#) cited in table above

FLEXTEND Active Fixation

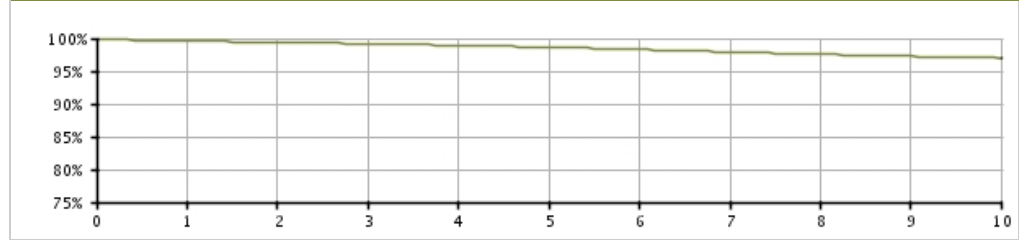
Models 4086/4087/4088

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

<p>U.S. Registered Implants: 230,000 U.S. Approval Date: February 2002 U.S. Estimated Active Implants: 104,000</p>	<p>U.S. Chronic Lead Complications: 3,078 U.S. Malfunctions: 299 Without Compromised Therapy: 119 With Compromised Therapy: 180</p>
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Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 <small>(-0.0/+0.0)</small>	99.40 <small>(-0.0/+0.0)</small>	99.19 <small>(-0.0/+0.0)</small>	98.92 <small>(-0.1/+0.0)</small>	98.64 <small>(-0.1/+0.1)</small>	98.30 <small>(-0.1/+0.1)</small>	97.94 <small>(-0.1/+0.1)</small>	97.59 <small>(-0.1/+0.1)</small>	97.26 <small>(-0.1/+0.1)</small>	97.00 <small>(-0.1/+0.1)</small>
Registered Implants: 230000										
Effective Sample Size	193341	167422	144333	123248	103716	85954	70535	55616	38894	25421

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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FLEXTEND Active Fixation Models 4086/4087/4088 			
Worldwide Distribution: 280,000			
Worldwide Confirmed Malfunctions: 322			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	12	169	181
⁷ Lead conductor	6	78	
²⁸ Non-patterned, Conductor	-	8	
³³ Conductor damage	6	83	
Crimp/Weld/Bond	-	-	0
Insulation	102	23	125
² Inner insulation abrasion	19	4	
²⁹ Non-patterned, Insulation	8	-	
³⁴ Insulation damage	75	19	
Other	14	2	16
²⁷ Non-patterned, Other	14	2	
WW Confirmed Malfunctions	128	194	322

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2015

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

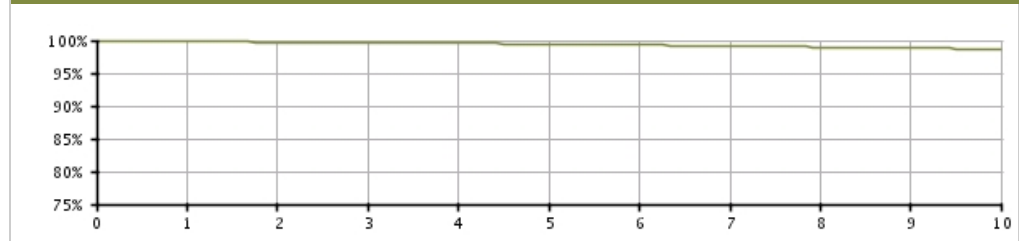
Models 4463/4464/4465/4469/4470/
4471

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

U.S. Registered Implants: 422,000	U.S. Chronic Lead Complications: 2,179
U.S. Approval Date: January 2000	U.S. Malfunctions:126
U.S. Estimated Active Implants: 247,000	Without Compromised Therapy:23
	With Compromised Therapy:103

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)	99.45 (-0.0/+0.0)	99.30 (-0.0/+0.0)	99.13 (-0.0/+0.0)	98.99 (-0.1/+0.0)	98.83 (-0.1/+0.1)	98.68 (-0.1/+0.1)
Registered Implants: 422000										
Effective Sample Size	352693	294998	244367	199334	159072	122735	93456	69945	49920	33838


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: 637,000
Worldwide Confirmed Malfunctions: 152

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	9	114	123
⁷ Lead conductor	5	54	
²⁸ Non-patterned, Conductor	-	5	
³³ Conductor damage	4	55	
Crimp/Weld/Bond	1	2	3
²³ Terminal weld	-	1	
³² Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	11	6	17
³⁴ Insulation damage	11	6	
Other	7	2	9
²⁷ Non-patterned, Other	7	2	
WW Confirmed Malfunctions	28	124	152

[More details](#) about malfunctions

[References](#) cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

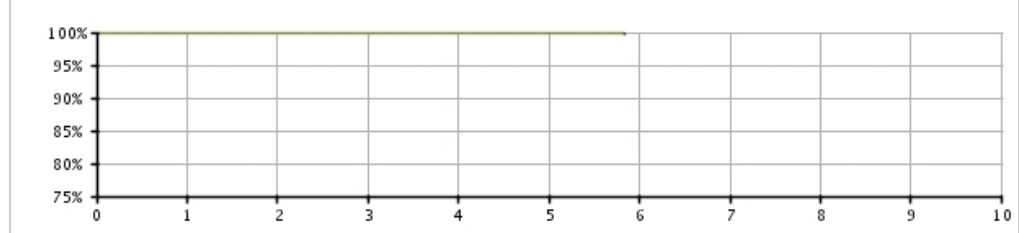
Models 4463/4464/4465/4469/4470/
 4471

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

Leads Enrolled: 910	Chronic Lead Complications: 1
Leads Active: 745	Malfunctions:0
Cumulative Followup Months : 18,609	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	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 @ 70 mo. (-0.7/+0.1)	—	—	—	—
Registered Implants: 910										
Effective Sample Size	605	354	284	199	101	50	—	—	—	—

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

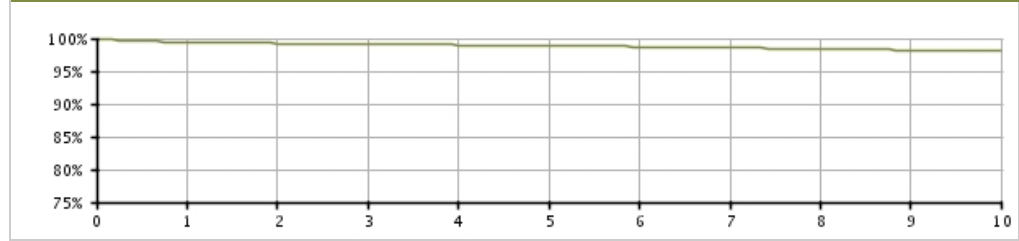
Models 4477/4478/4479/4480

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

U.S. Registered Implants: 58,000	U.S. Chronic Lead Complications: 595
U.S. Approval Date: January 2000	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 31,000	Without Compromised Therapy: 18
	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	99.41 (-0.1/+0.1)	99.25 (-0.1/+0.1)	99.12 (-0.1/+0.1)	99.00 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.73 (-0.1/+0.1)	98.56 (-0.1/+0.1)	98.40 (-0.2/+0.1)	98.16 (-0.2/+0.2)	98.08 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	48041	40470	33900	28121	22964	18248	14331	11073	8368	6098

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: 270,000			
Worldwide Confirmed Malfunctions: 50			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	3	10	13
⁷ Lead conductor	-	3	
³³ Conductor damage	3	7	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
³⁴ Insulation damage	-	1	
Other	32	4	36
²² J-shape	30	4	
²⁷ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	35	15	50

[More details](#) about malfunctions

[References](#) cited in table above

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

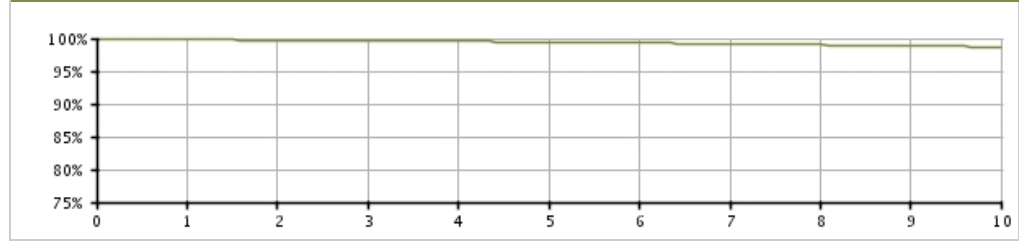
Models 4452/4453/4456/4457

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

U.S. Registered Implants: 178,000	U.S. Chronic Lead Complications: 987
U.S. Approval Date: January 2000	U.S. Malfunctions: 40
U.S. Estimated Active Implants: 89,000	Without Compromised Therapy: 5
	With Compromised Therapy: 35

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-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)	99.32 (-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: 178000										
Effective Sample Size	148031	124919	104657	86841	70966	56544	44432	34655	26364	19391


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: 486,000
Worldwide Confirmed Malfunctions: 58

	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
Insulation	2	7	9
³⁴ Insulation damage	2	7	
Other	4	1	5
²⁷ Non-patterned, Other	4	1	
WW Confirmed Malfunctions	7	51	58

[More details](#) about malfunctions

[References](#) cited in table above

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

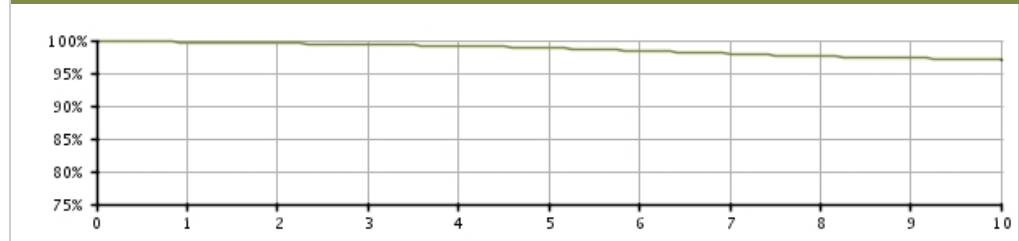
Models 4466/4467/4468/4472/4473/
4474

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

U.S. Registered Implants: 50,000	U.S. Chronic Lead Complications: 550
U.S. Approval Date: January 2000	U.S. Malfunctions:115
U.S. Estimated Active Implants: 25,000	Without Compromised Therapy:16
	With Compromised Therapy:99

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)	98.85 (-0.1/+0.1)	98.42 (-0.2/+0.1)	97.99 (-0.2/+0.2)	97.58 (-0.2/+0.2)	97.35 (-0.2/+0.2)	97.05 (-0.3/+0.2)
Registered Implants: 50000										
Effective Sample Size	42687	36595	31144	26249	21701	17664	14168	11241	8582	6149


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
---------------------------	-------------------------------	--------------------

**FINELINE II EZ/FINELINE II Sterox EZ
Positive Fixation (Silicone)**
Models 4466/4467/4468/4472/4473/
4474



Worldwide Distribution: 134,000
Worldwide Confirmed Malfunctions: 152

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	5	120	125
⁷ Lead conductor	1	74	
²⁸ Non-patterned, Conductor	-	2	
³³ Conductor damage	4	44	
Crimp/Weld/Bond	1	-	1
³² Non-patterned, Crimp, Weld, Bond	1	-	
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	19	133	152

[More details](#) about malfunctions

[References](#) cited in table above

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

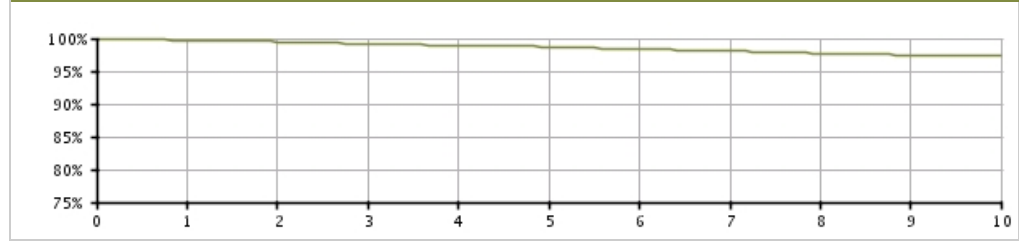
Models 4454/4455/4458/4459

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: 178
U.S. Approval Date: January 2000	U.S. Malfunctions: 21
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy: 0
	With Compromised Therapy: 21

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)	98.91 (-0.2/+0.2)	98.74 (-0.2/+0.2)	98.42 (-0.3/+0.2)	98.05 (-0.3/+0.3)	97.73 (-0.4/+0.3)	97.50 (-0.4/+0.4)	97.36 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12002	10426	8995	7609	6411	5341	4418	3686	3003	2345


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: 101,000
Worldwide Confirmed Malfunctions: 49

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	40	40
⁷ Lead conductor	-	15	
³³ Conductor damage	-	25	
Crimp/Weld/Bond	-	-	0
Insulation	2	4	6
³⁴ Insulation damage	2	4	
Other	-	3	3
²⁷ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	47	49

[More details](#) about malfunctions

[References](#) cited in table above

FINELINE EZ Positive Fixation

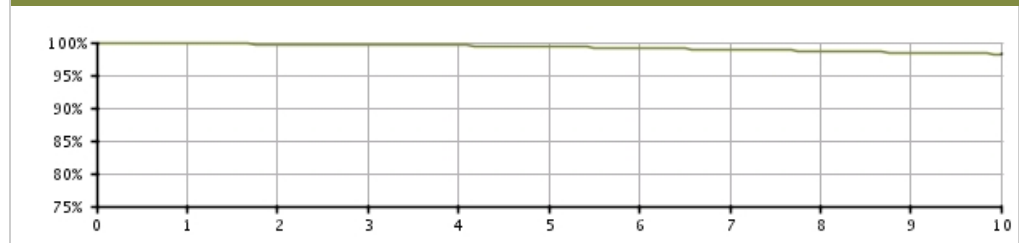
Models 4460/4461/4462

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: 281
U.S. Approval Date: July 1999	U.S. Malfunctions: 10
U.S. Estimated Active Implants: 5,000	

Complications and Malfunctions



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)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.70 (-0.2/+0.2)	98.45 (-0.2/+0.2)	98.23 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20913	18710	16691	14867	13216	11630	10249	9038	7932	7000

Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

FINELINE Passive Fixation

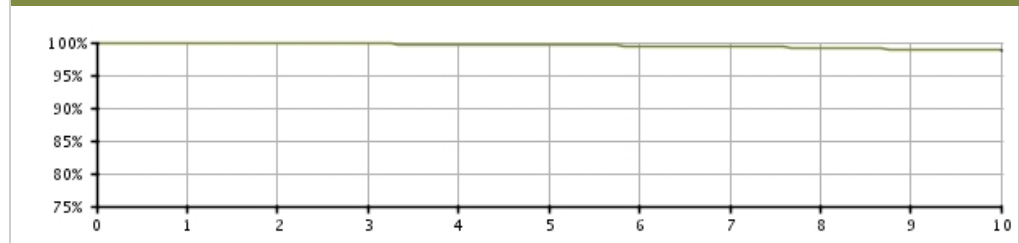
Models 4450/4451

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: 318
U.S. Approval Date: November 1996	U.S. Malfunctions: 10
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	99.91 (-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)	99.35 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.97 (-0.1/+0.1)	98.79 (-0.2/+0.1)
Registered Implants: 42000										
Effective Sample Size	35811	32053	28642	25424	22479	19781	17346	15311	13491	11897

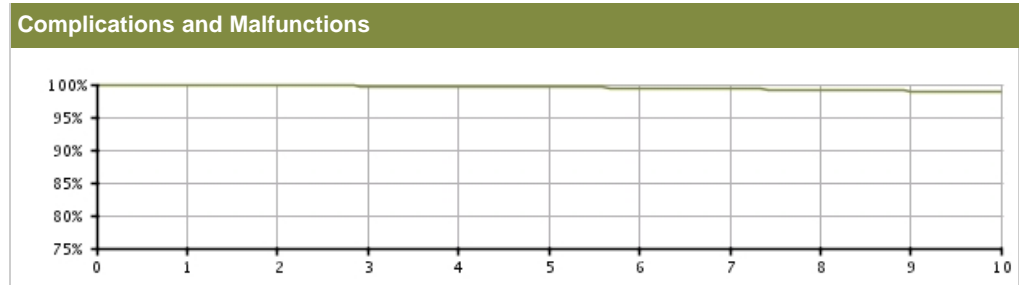
Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

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: 102
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 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.75 (-0.1/+0.1)	99.68 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.45 (-0.2/+0.1)	99.31 (-0.2/+0.2)	99.16 (-0.2/+0.2)	98.98 (-0.3/+0.2)	98.89 (-0.3/+0.2)
Registered Implants: 14000										
Effective Sample Size	12441	11148	9968	8891	7907	6971	6147	5430	4757	4161

Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

SELUTE
Passive Fixation

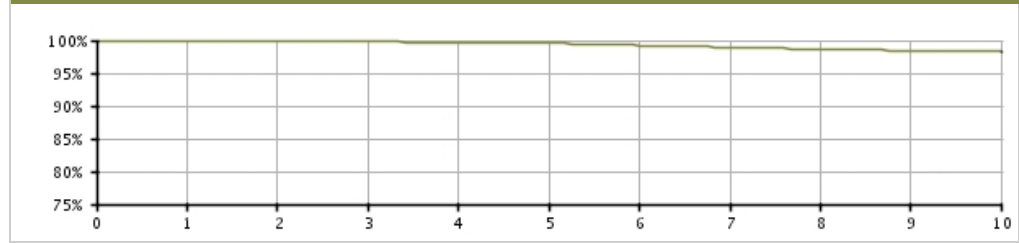
Models 4185/4285

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: 461
U.S. Approval Date: May 1996	U.S. Malfunctions: 26
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)	98.29 (-0.2/+0.2)
Registered Implants: 48000										
Effective Sample Size	40978	36614	32655	28944	25598	22395	19618	17131	14923	12976

SELUTE PICOTIP
Passive Fixation

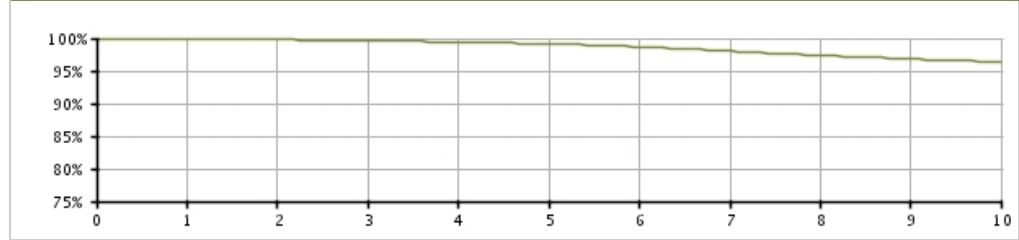
Models 4030/4031/4032/4033/4034/
 4035

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: 1,079
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)	98.05 (-0.2/+0.1)	97.37 (-0.2/+0.2)	96.79 (-0.2/+0.2)	96.38 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49285	43972	39183	34815	30816	27064	23540	20329	17365	14802

SELUTE PICOTIP Atrial J

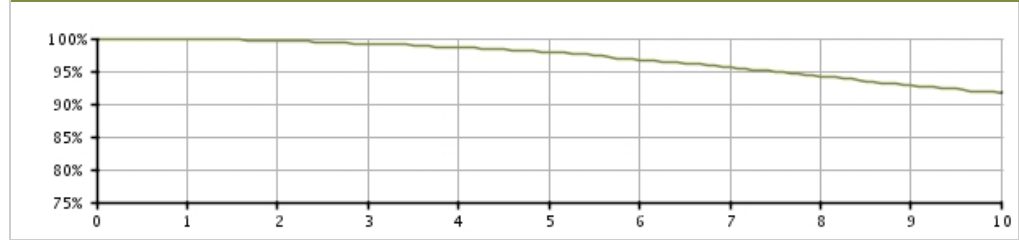
Models 4040/4041/4042/4043/4044/
4045/4063/4064

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: 413
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions: 21

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)	92.85 (-0.8/+0.7)	91.73 (-0.9/+0.8)
Registered Implants: 10000										
Effective Sample Size	8579	7645	6794	6024	5320	4666	3987	3381	2825	2319

SWEET PICOTIP Rx
Positive Fixation

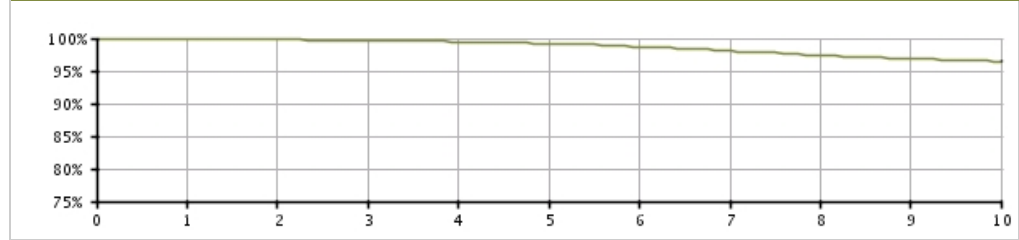
Models 4050/4051/4052/4053/4054/
 4055

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: 669
U.S. Approval Date: April 1999	U.S. Malfunctions: 55
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 (-0.1/+0.1)	98.05 (-0.2/+0.2)	97.41 (-0.2/+0.2)	96.87 (-0.3/+0.2)	96.49 (-0.3/+0.3)
Registered Implants: 41000										
Effective Sample Size	35767	31935	28498	25358	22471	19670	16666	13808	11369	9152

SWEET TIP
Positive Fixation

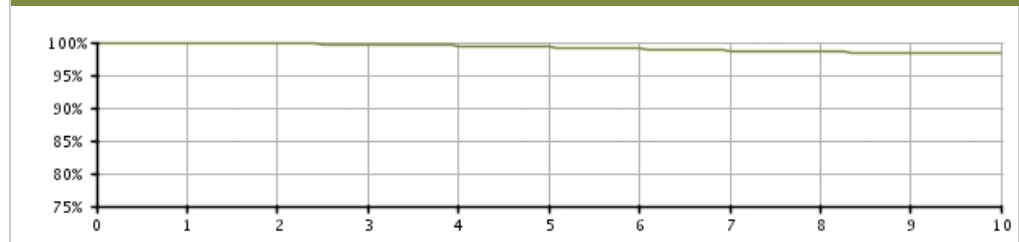
Models 4165/4168/4169/4268/4269

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: 949
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	77718	69456	62067	55311	49107	43277	38073	33562	29654	26158

SWEET TIP RX
Positive Fixation

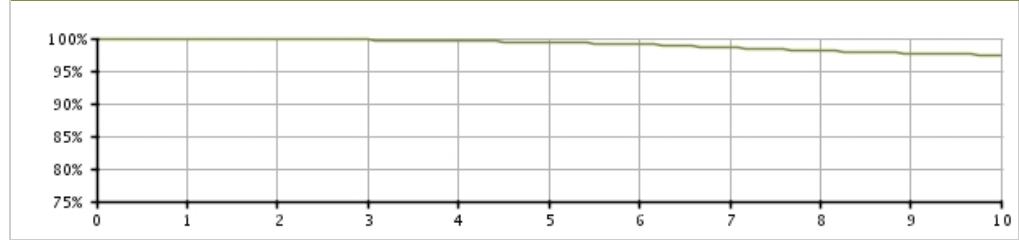
Models 4143/4144/4145/4243/4244/
4245

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: 469
U.S. Approval Date: October 1998	U.S. Malfunctions: 27
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	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.10 (-0.1/+0.1)	98.58 (-0.2/+0.2)	98.09 (-0.2/+0.2)	97.73 (-0.2/+0.2)	97.42 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26539	23706	21103	18667	16391	14244	12152	10385	8812

CRM PRODUCT PERFORMANCE REPORT Q2 2015

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. **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.
4. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
5. **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.
6. **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.
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. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
13. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. 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. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
18. **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.
19. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **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. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **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.
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. **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. U.S. Chronic Lead Complications are reported in compliance with the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations occurring after the first month of implant, and have been removed from service surgically or electronically. The lead either was not returned for analysis, or was returned but had no confirmation of a malfunction. Leads previously reported as having Extrinsic Malfunctions, are now included in Chronic Lead Complications. Both Malfunctions and Chronic Lead Complications are included in Survival Probability so re-categorization has no effect on reported U.S. Lead Survival Probability data. While multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	229000	70	710	817	641	219	79	148	332	0	62
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	178000	3	288	182	159	25	17	143	150	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	422000	21	458	595	288	56	72	380	278	0	31
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	58000	1	88	292	99	5	15	56	33	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	82	19	34	10	2	13	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	50000	0	201	72	70	42	15	66	80	0	4
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	28000	2	18	373	31	2	1	6	18	0	83
ACUITY Spiral 4591/4592/4593	21000	0	10	230	25	1	1	2	5	0	125

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	2	26	243	37	2	1	9	10	0	85
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	94000	1	237	1031	217	5	5	55	72	0	426
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	62	395	99	2	0	47	30	0	253

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	40000	5	7	50	9	8	5	2	2	3	1
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	0	0	4	0	1	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	36000	8	8	33	10	5	4	1	3	3	1
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	4000	1	1	1	3	0	0	0	1	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	188000	21	223	268	80	230	36	49	90	97	18
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	0	17	29	18	17	2	8	35	8	2
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	27000	6	31	40	17	30	1	7	19	18	1
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	0	0	0	0	2	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	6	128	70	36	173	24	38	91	36	6
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	3	64	35	27	52	5	23	86	18	4

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	3000	0	8	0	1	1	0	0	2	1	2
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	2	3	1	2	0	1	0	0	0

S-ICD Electrodes/Model	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3010	0	0	0	0	4	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	1347	0	0	21	2	0	0	0	0	0	8
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	629	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	750	0	0	0	1	1	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	1099	0	0	0	1	1	0	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	910	0	1	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	229000	232	191	1330	417	75	87	54	213	0	49
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	178000	15	13	432	162	7	27	24	36	0	19
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	422000	77	78	659	234	102	92	57	233	0	43
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	58000	1	18	439	90	7	29	17	20	0	10
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	50000	3	16	98	26	9	9	21	13	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	28000	1	2	322	44	25	2	7	134	0	235
ACUITY Spiral 4591/4592/4593	21000	5	5	197	64	8	1	10	36	0	237

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	269	38	12	2	8	45	0	183
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	94000	13	7	912	126	46	9	26	194	0	706
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	40000	34	27	121	64	40	10	7	62	15	8
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	2	0	4	1	2	0	0	14	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	36000	33	37	94	36	46	13	5	63	59	16
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	4000	3	2	4	2	6	1	0	9	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	188000	119	123	479	125	250	34	45	256	191	61
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	4	2	48	27	15	3	0	103	15	1
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	27000	27	15	74	25	28	12	3	52	110	9
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	1	0	1	0	10	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	31	63	164	43	116	20	24	102	43	18
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	34	27	121	64	40	10	7	62	15	8

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	3000	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	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3010	1	0	7	0	69	4	1	12	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	1347	0	0	10	12	1	0	0	3	0	47
RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	750	0	2	10	0	0	0	1	3	0	2
RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	1099	6	1	10	4	5	3	0	1	0	2
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	629	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	910	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	2,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	3,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	3,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	61,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	40,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	41,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	171,000	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	5,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	13,000	2	0	0	2	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil Active Fixation 0295/0296	70,000	0	0	0	48	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	65,000	0	0	0	14	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Passive Fixation 0282/0283	3,000	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	254,000	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	58,000	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	114,000	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	5,000	0	0	0	0	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	35,000	65	0	0	81	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	3,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	169,000	0	0	10	114	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	280,000	0	0	55	587	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	486,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	637,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	270,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	101,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	101,000	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
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
AUTOGEN CRT-D Models G172/G173/G175/ G177/G179	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.
AUTOGEN ICD MINI DR Models D046/D047	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.
AUTOGEN ICD EL DR Models D176/D177	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.
AUTOGEN RVAT November 2014 Physician Letter, Nov 17, 2014	CURRENT STATUS 10-Apr-15
AUTOGEN RVAT November 2014 Patient Letter, Nov 17, 2014	<i>Reported events (worldwide)</i> Four (4) reports have been received worldwide of ineffective pacing support during an RVAT test.
	There have been no reported patient deaths associated with this advisory.
	CURRENT RECOMMENDATION 10-Apr-15
	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:
	1. 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.
	2. 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).
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT

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

[Device Lookup Tool](#)

COGNIS

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

TELIGEN VR

Models E102/E103/F102/F103

TELIGEN DR

Models E110/E111/F110/F111

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

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.

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

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

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

Advisory population

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

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

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

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

CURRENT STATUS 10-Apr-15

Advisory devices have not been available for implant for more than three years.

Confirmed Malfunctions (worldwide)

2,053 malfunctions have been confirmed from the advisory population. Approximately 45,000 devices from the advisory population remain in service.

There has been one reported patient death associated with this advisory.

Projected Rate of Occurrence

The projected rate of occurrence for advisory population devices is approximately 7.6% at 72 months.

CURRENT RECOMMENDATION 10-Apr-15

Updated Software

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.

LATITUDE Patient Management System

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

Additional Recommendations

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

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

PRODUCT

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

[Device Lookup Tool](#)

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-Apr-15

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-Apr-15

– 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>one in one million for a 60-month device service life.</p>
<p>CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179</p>	<p>CURRENT STATUS 10-Apr-15</p>
<p>CONTAK RENEWAL 4 RF Models H230/H235/H239</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 the advisory device population is 0.0029 at 60 months.</p>
<p>VITALITY DR HE Model T180</p>	<p>CURRENT RECOMMENDATION 10-Apr-15</p>
<p>Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010 Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010</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> <ol style="list-style-type: none"> 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. 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.]

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

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](#)

ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant 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-Apr-15

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)

Ninety (90) 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-Apr-15

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.

PRODUCT	ORIGINAL COMMUNICATION 05-Apr-07 and 04-Mar-09— Shortened Replacement Window
<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>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.</p>
<p>CONTAK RENEWAL 4 RF HE Model H239</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 RF Models H230/H235</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 HE Models H197/H199</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 Models H190/H195</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p>CURRENT STATUS 10-Apr-15 <i>Confirmed Malfunctions (worldwide)</i></p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>April 2007 Population 2,566 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices.</p>
<p>CONTAK RENEWAL 3 RF Models H210/H215</p>	<p>115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	<p>March 2009 Population 117 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).</p>
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p>There have been no reported patient deaths associated with either advisory population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	<p>No devices currently being distributed are susceptible to this malfunction mode.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p><i>Rate of Occurrence</i> 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.</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p>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.</p>
<p>VITALITY DR HE Model T180</p>	<p>Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.</p>
<p>VITALITY DS VR/DR Model T135/T125</p>	<p>Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.</p>

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

CURRENT RECOMMENDATION 10-Apr-15

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

VITALITY EL

Model T127

VITALITY AVT A155

Model A155

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
<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>FDA Classification: Devices in Table 1, Column 1 of this <i>Product Update</i> were classified as Class II (27-November-07)</p>
<p>CONTAK RENEWAL 4 RF HE Model H239</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 RF / HE Models H230/H235/H197/H199</p>	<p>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.</p>
<p>CONTAK RENEWAL 4 and 4 AVT / AVT HE Models H190/H195/M170/M175/M177/M179</p>	<p><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:</p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>– 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%)</p>
<p>CONTAK RENEWAL 3 RF / HE Models H210/H215/H177/H179</p>	<p>– 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%)</p>
<p>CONTAK RENEWAL 3 and 3 AVT / AVT HE Models H170/H175/M155/M159</p>	<p>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.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>CURRENT STATUS 10-Apr-15</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p><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.”</p>
<p>VITALITY DR HE and EL Model T180 and Model T127</p>	<p><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.”</p>
<p>VITALITY DS VR/DR Model T135/T125</p>	
<p>VITALITY AVT A135 / A155 Models A135/A155</p>	
<p>VITALITY VR/DR and DR+ Models 1871/1870/1872</p>	<p>CURRENT RECOMMENDATION 10-Apr-15</p>
<p>ASSURE Model B301</p>	<p><u>Patient management recommendations from the March 10, 2007 Product Update remain unchanged.</u></p>
<p>Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007</p>	<p><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.</p>
<p>Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007</p>	<p>– 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.</p>
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

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-Apr-15</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-Apr-15</p>
<p>INSIGNIA AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492</p>	<p>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</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 whenmaking 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 – 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 DR HE Model T180</p>	
<p>VITALITY DS VR/DR Models T135/T125</p>	
<p>VITALITY VR/DR and EL Models 1870/1871/T127</p>	

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](#)

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

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>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>CURRENT STATUS 10-Apr-15</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>There have been no reported patient deaths associated with this advisory.</p>
<p>VITALITY DR+ Model 1872</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>Subpectoral Implant, Physician Letter, Jan 04, 2008</p>	<p>CURRENT RECOMMENDATION 10-Apr-15</p> <p><u>Patient management recommendations for both populations remain unchanged from the 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. - 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-Apr-15
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 1192/12921392/1428/1432/1492	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 5,000 is projected to range between 0.027% and 0.038%.
Crystal Timing Component, Patient Letter, Oct 03, 2005	CURRENT RECOMMENDATION 10-Apr-15
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	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 Models 1284/1286/1484/1485	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 SSI (downsize) Models 0481/1349	Original Population— <u>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 DDD Models 0981/1285/1499	Original Population— <u>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).
PULSAR MAX II SR (downsize) Models 1180/1380	Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.
PULSAR MAX II SR / DR Models 1181/1290/1480	<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.
DISCOVERY SR/SR (downsize) Models 1174/1175	<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.
DISCOVERY DR/DR (downsize) Models 1274/1275/1273	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 SR (downsize) Model 1170	CURRENT STATUS 10-Apr-15
PULSAR MAX SR / DR Model 1171/1270	<i>Reported Events (worldwide)</i> Refined Original Population— 342 malfunctions have been confirmed out of the 77,500 advisory population devices.
PULSAR Models 1272/0470/0870/0970/ 0972/1172	Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices.
MERIDIAN SSI / DDD Models 0476/0976	<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.
MERIDIAN SR / DR Models 1176/1276	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.

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

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

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

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

CURRENT RECOMMENDATION 10-Apr-15

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.

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

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

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

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