

2016

Rhythm Management Product Performance Report

Q4 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 Q4 2016 report includes data through October 10, 2016.

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

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

- ✓ U.S. lead and pulse generator survival probability
- ✓ Worldwide malfunction counts and patterns
- ✓ Worldwide malfunctions during an implant procedure
- ✓ 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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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. See the Chronic Lead Complications Table in this report for the observations which are included.

Further Adjustments for Device and Lead Survival

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

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

Categorization of Malfunctions for Survival Probability Reporting

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

Malfunction With Compromised Therapy —

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

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

Malfunction Without Compromised Therapy —

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

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

Categorization of Normal Battery Depletion for Survival Probability Reporting

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

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

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

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

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

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

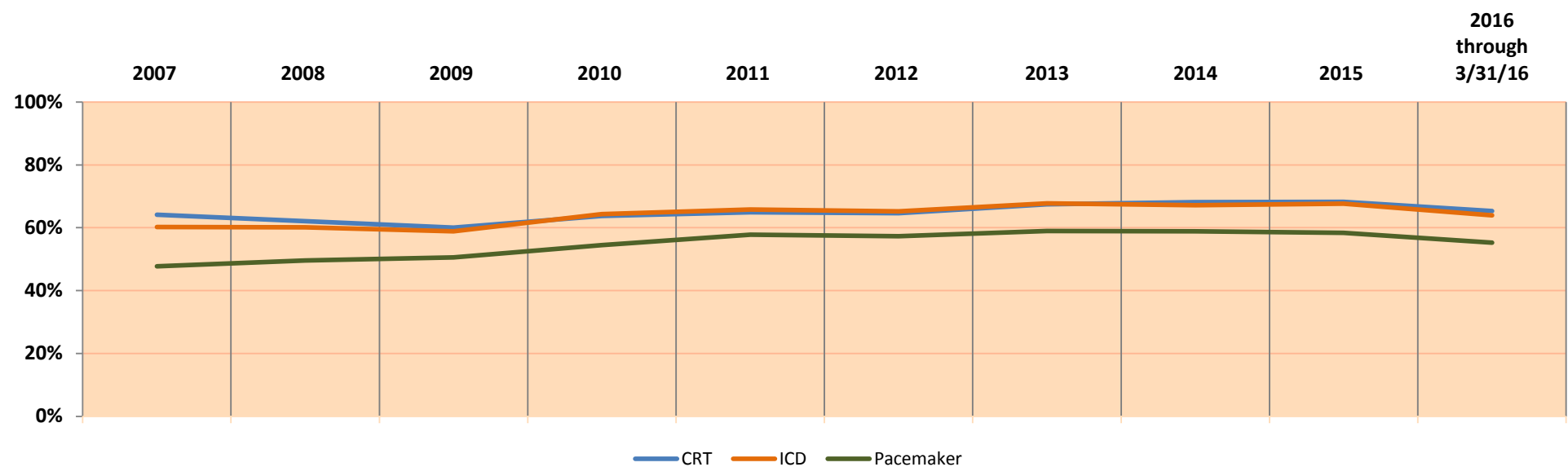
E-mail: crmevent@bsci.com

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.



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016 through 3/31/16
Explants	4245	5676	9258	10456	9297	8016	8277	6856	4943	1152
Returns	2722	3526	5556	6671	6035	5178	5584	4675	3372	752
% Returned	64%	62%	60%	64%	65%	65%	67%	68%	68%	65%
Explants	11530	15548	19480	19892	16539	11929	11854	11215	9906	2254
Returns	6946	9343	11462	12805	10878	7782	8029	7537	6705	1441
% Returned	60%	60%	59%	64%	66%	65%	68%	67%	68%	64%
Explants	18383	20426	20980	21060	19953	18634	18699	19173	19358	4793
Returns	8776	10125	10617	11471	11528	10684	11033	11284	11303	2649
% Returned	48%	50%	51%	54%	58%	57%	59%	59%	58%	55%

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: 16,000

Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	1	4
⁸⁰ High voltage circuit component	3	-	
⁸¹ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	3	2	5

[More details](#) about malfunctions

[References](#) cited in table above

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DYNAGEN/INOGEN/ORIGEN CRT-D

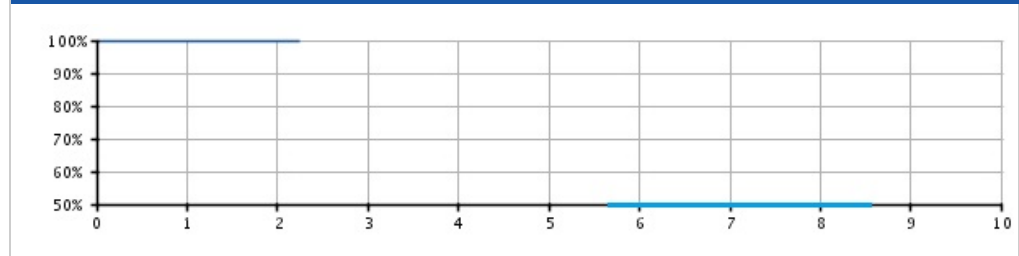
Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

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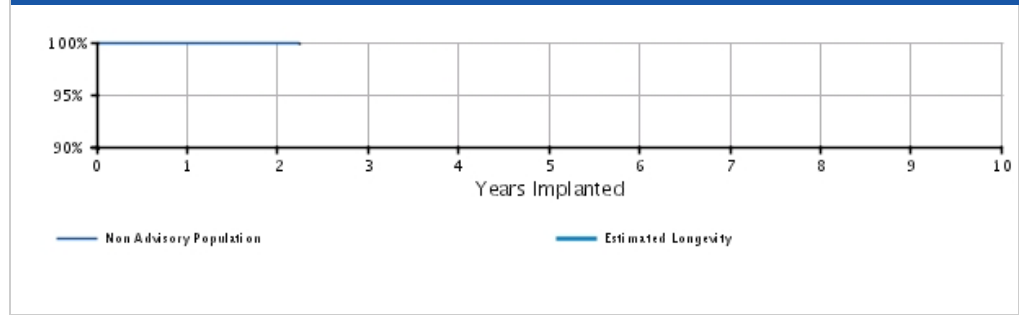
U.S. Summary

U.S. Registered Implants: 26,000	U.S. Normal Battery Depletions: 2
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Estimated Active Implants: 25,000	U.S. Malfunctions:8
	Without Compromised Therapy:8
	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 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.79 @ 27 mo. (-0.4/+0.1)	--	--	--	--	--	--	--
Registered Implants: 26000	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.92 @ 27 mo. (-0.1/+0.0)	--	--	--	--	--	--	--
	Effective Sample Size	10495	1261	319	--	--	--	--	--	--	--

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: 41,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	6	1	7
⁸⁰ High voltage circuit component	3	-	
⁸¹ Integrated circuit	3	-	
⁸² High voltage capacitor	-	1	
Mechanical	-	-	0
Software	2	1	3
⁶⁹ Memory errors	2	1	
Other	3	-	3
Non-patterned	3	-	
WW Confirmed Malfunctions	11	2	13

[More details](#) about malfunctions

[References](#) cited in table above

INCEPTA/ENERGEN/PUNCTUA CRT-D

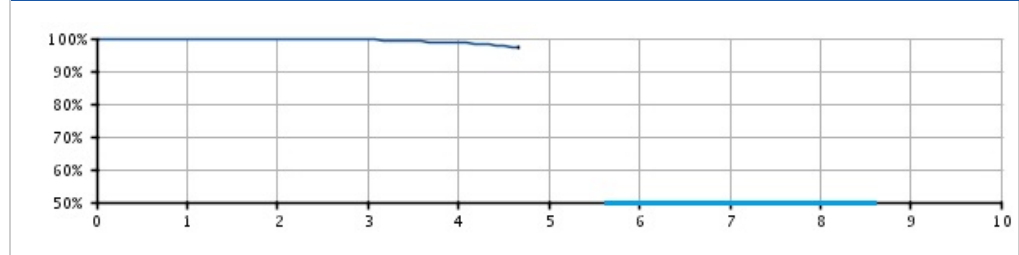
Models N050/N051/N052/N053/N140/
 N141/N142/N143/N160/N161/
 N162/N163/N164/N165/P052/
 P053/P142/P143/P162/P163/
 P165

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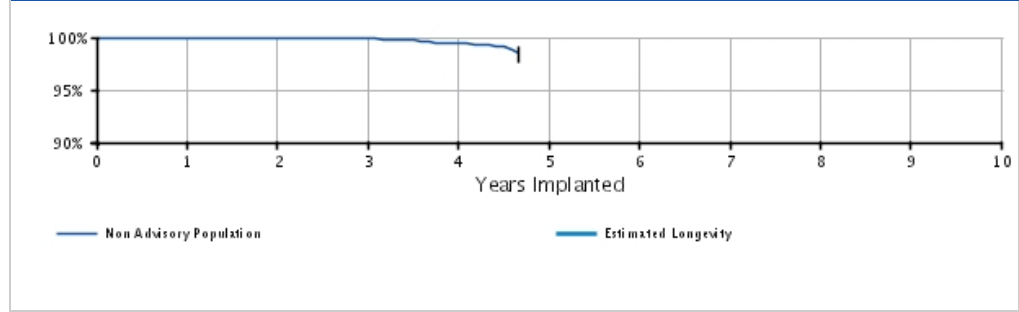
U.S. Summary

U.S. Registered Implants: 52,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 42,000	U.S. Normal Battery Depletions: 127 U.S. Unconfirmed Reports of Premature Battery Depletion : 28 U.S. Malfunctions:105 Without Compromised Therapy:94 With Compromised Therapy:11
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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: 52000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.64 (-0.1/+0.1)	98.68 (-0.2/+0.2)	97.20 @ 56 mo. (-0.9/+0.7)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.40 (-0.2/+0.1)	98.55 @ 56 mo. (-0.9/+0.6)	-	-	-	-	-
	Effective Sample Size	45227	34881	19665	6333	345	-	-	-	-	-

INCEPTA/ENERGEN/PUNCTUA CRT-D

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA/ENERGEN/PUNCTUA CRT-D
 Models N050/N051/N052/N053/N140/
 N141/N142/N143/N160/N161/
 N162/N163/N164/N165/P052/
 P053/P142/P143/P162/P163/
 P165



Worldwide Distribution: 81,000
Worldwide Confirmed Malfunctions: 153

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	122	9	131
⁶⁰ Safety Core-electrocautery	5	1	
⁶¹ High-voltage capacitor	-	2	
⁶⁵ Low-voltage capacitors	1	-	
⁶⁸ Integrated circuit	1	6	
⁷¹ Battery	1	-	
⁷² Low-voltage capacitor	114	-	
Mechanical	-	6	6
⁵⁴ Transformer	-	6	
Software	7	-	7
⁶⁹ Memory errors	7	-	
Other	8	1	9
Non-patterned	8	1	
WW Confirmed Malfunctions	137	16	153

[More details](#) about malfunctions

[References](#) cited in table above

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COGNIS

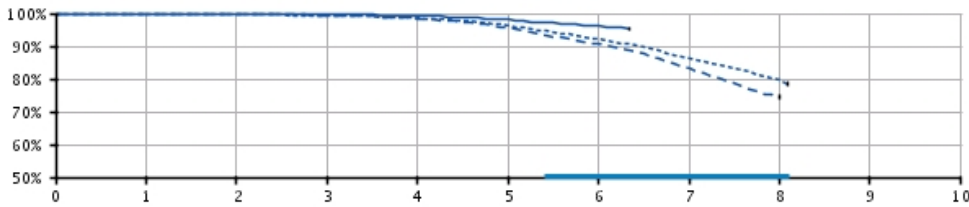
Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

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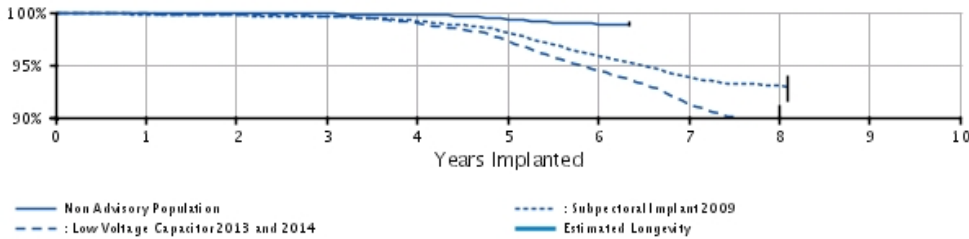
U.S. Summary

U.S. Registered Implants: 75,000	U.S. Normal Battery Depletions: 1,998
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of
U.S. Estimated Active Implants: 39,000	Premature Battery Depletion : 108
	U.S. Malfunctions: 1,395
	Without Compromised Therapy: 1,234
	With Compromised Therapy: 161

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions (%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.01 (-0.2/+0.2)	96.02 (-0.4/+0.4)	95.19 @ 76 mo. (-0.8/+0.7)	-	-	-
	Malfunctions Only (%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.37 (-0.1/+0.1)	98.90 (-0.2/+0.2)	98.90 @ 76 mo. (-0.2/+0.2)	-	-	-
	Effective Sample Size	31512	28120	25055	21959	15023	3237	543	-	-	-
Subjectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions (%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.0)	99.37 (-0.1/+0.0)	98.55 (-0.1/+0.0)	96.37 (-0.1/+0.0)	92.10 (-0.1/+0.1)	86.37 (-0.1/+0.1)	79.61 (-0.4/+0.5)	78.45 @ 97 mo. (-1.6/+1.5)	-
	Malfunctions Only (%) (Confidence Interval)	99.80 (-0.0/+0.1)	99.70 (-0.0/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.11 (-0.1/+0.1)	95.84 (-0.2/+0.3)	93.76 (-0.3/+0.3)	93.10 (-0.4/+0.5)	92.93 @ 97 mo. (-1.4/+1.0)	-
	Effective Sample Size	27495	24366	21670	19180	16719	14192	9024	1014	549	-
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions (%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.40 (-0.1/+0.2)	95.54 (-0.1/+0.2)	90.51 (-0.3/+0.2)	83.16 (-0.3/+0.3)	74.45 (-1.1/+1.3)	-	-
	Effective Sample Size	-	-	-	-	-	-	-	-	-	-


26,000											
	Malfunctions Only (%)	99.85	99.77	99.65	98.96	97.31	94.38	91.25	89.83	-	-
	(Confidence Interval)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.3/+0.1)	(-1.2/+1.4)		
	Effective Sample Size	22616	20025	17831	15753	13655	11275	4078	214	-	-

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

COGNIS

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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COGNIS Models N106/N107/N108/N118/N119/ N120/P106/P107/P108 			
Worldwide Distribution: 109,000			
Worldwide Confirmed Malfunctions: 1824			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1516	123	1639
¹ Low Voltage Capacitor 2014 (Advisory issued)	1183	63	
⁶⁰ Safety Core-electrocautery	48	20	
⁶¹ High-voltage capacitor	1	6	
⁶⁵ Low-voltage capacitors	7	-	
⁶⁸ Integrated circuit	7	20	
⁷⁰ High voltage circuit	-	1	
⁷¹ Battery	40	4	
⁷² Low-voltage capacitor	230	9	
Mechanical	39	90	129
⁴ Subpectoral implant 2009 (Advisory issued)	16	47	
⁵⁴ Transformer	-	9	
⁵⁸ Difficulty securing lead	9	9	
⁶³ Header contacts	8	8	
⁸⁴ Header	6	17	
Software	14	1	15
⁶⁴ Safety Core-programming	1	-	
⁶⁶ Alert messages not displayed post-EOL	2	-	
⁶⁹ Memory errors	11	1	
Other	32	9	41
Non-patterned	32	9	
WW Confirmed Malfunctions	1601	223	1824

[More details](#) about malfunctions

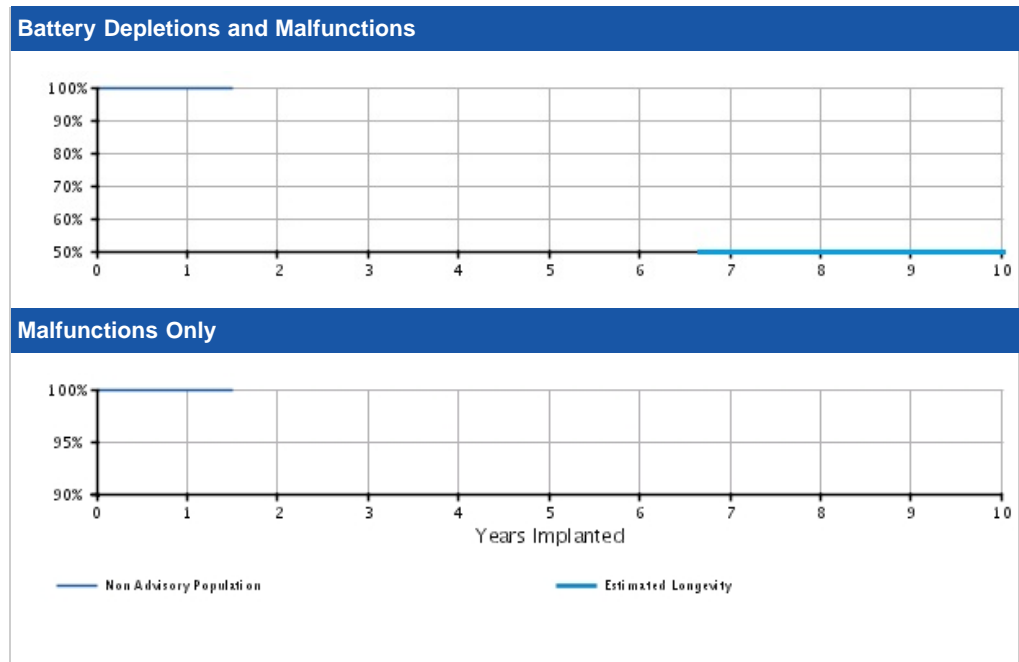
[References](#) cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

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

U.S. Summary	
U.S. Registered Implants: 7,000 U.S. Approval Date: October 2014 U.S. Estimated Active Implants: 7,000	U.S. Normal Battery Depletions: 1 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:0 Without Compromised Therapy:0 With Compromised Therapy:0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.2/+0.0)	99.96 @ 18 mo. (-0.2/+0.0)	-	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 18 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
Registered Implants: 7000	Effective Sample Size	1516	204	-	-	-	-	-	-	-	-	-

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: 15,000			
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 Q4 2016

INTUA

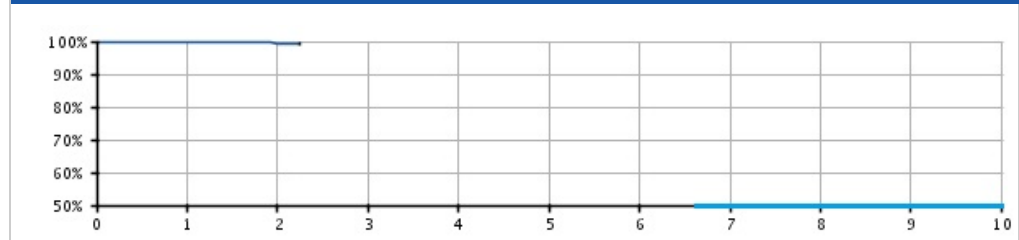
Models V272/V273/V282/V283/W272/
W273

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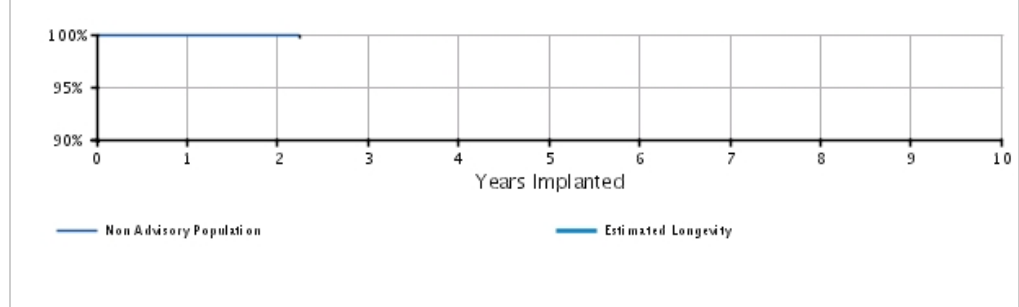
U.S. Summary

U.S. Registered Implants: 3,000	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: 2,000	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)	99.82 (-0.3/+0.1)	99.45 (-0.9/+0.3)	99.45 @ 27 mo. (-0.9/+0.3)	-	-	-	-	-	-	-
Registered Implants: 3000	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 @ 27 mo. (-0.3/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	1825	480	208	-	-	-	-	-	-	-

INTUA

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

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

INTUA Models V272/V273/V282/V283/W272/ W273 			
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	1	0	1

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

INVIVE

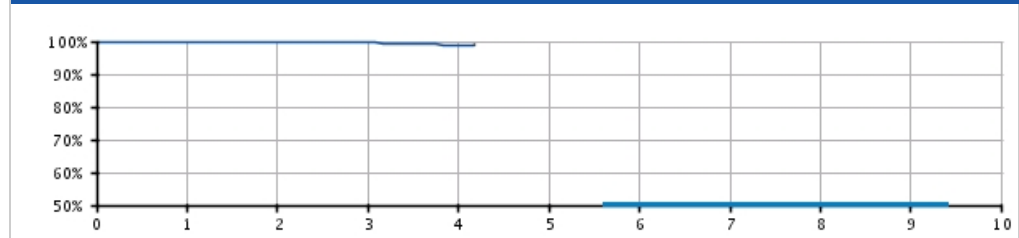
Models V172/V173/V182/V183/W172/
W173

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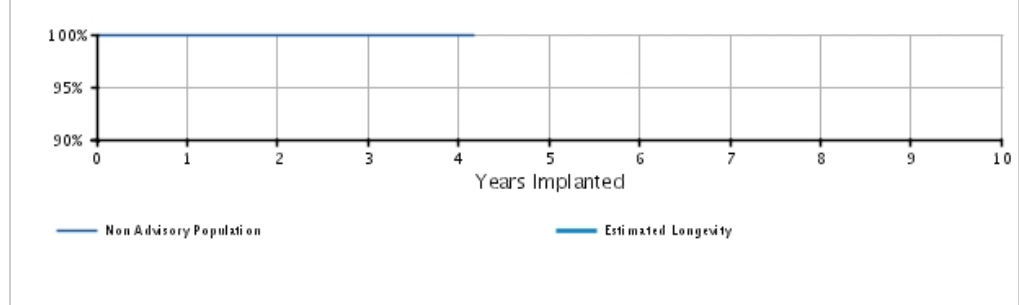
U.S. Summary

U.S. Registered Implants: 8,000	U.S. Normal Battery Depletions: 26
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)	99.97 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.52 (-0.3/+0.2)	98.90 (-0.7/+0.4)	98.90 @ 50 mo. (-0.7/+0.4)	-	-	-	-	-
Registered Implants: 8000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 50 mo. (-0.1/+0.0)	-	-	-	-	-
	Effective Sample Size	6524	4987	2480	432	221	-	-	-	-	-

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: 17,000 Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁶⁵ Low-voltage capacitors	-	1	
Mechanical	-	-	0
Software	2	-	2
⁶⁹ 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
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CONTAK RENEWAL TR 2 Models H140/H145 			
Worldwide Distribution: 31,000			
Worldwide Confirmed Malfunctions: 31			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁰ Capacitor	1	-	
Mechanical	4	-	4
²⁶ Seal plug	1	-	
³⁶ Setscrew block	2	-	
⁴⁹ Seal plug	1	-	
Software	14	-	14
³⁰ Memory error	1	-	
⁴⁰ Stored EGMs	13	-	
Other	11	1	12
Non-patterned	10	1	
⁴⁷ Alert messages	1	-	
WW Confirmed Malfunctions	30	1	31

[More details](#) about malfunctions

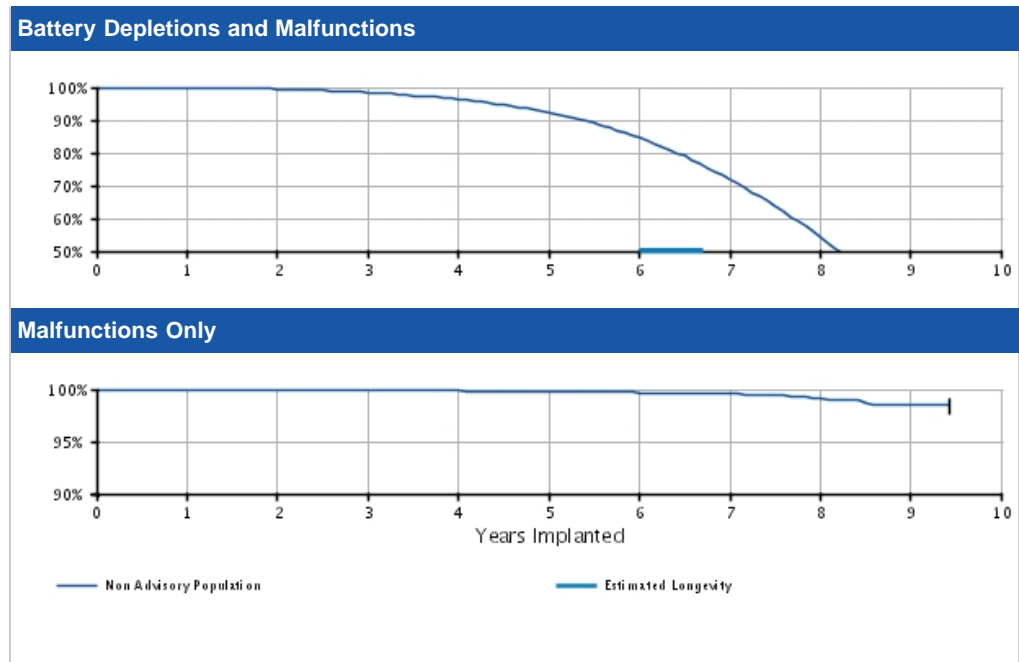
[References](#) cited in table above

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: 2,676
U.S. Approval Date: January 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:51
	Without Compromised Therapy:49
	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)	99.90 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.35 (-0.4/+0.3)	92.33 (-0.5/+0.5)	84.52 (-0.8/+0.8)	71.97 (-1.2/+1.2)	54.14 (-1.7/+1.7)	35.53 (-2.2/+2.2)	27.66 @ 113 mo. (-2.4/+2.5)
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)	99.76 (-0.1/+0.1)	99.67 (-0.1/+0.1)	99.56 (-0.2/+0.1)	99.16 (-0.5/+0.3)	98.47 (-0.9/+0.6)	98.47 @ 113 mo. (-0.9/+0.6)
	Effective Sample Size	15577	13574	11835	10157	7597	4658	2479	1084	340	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

CONTAK RENEWAL TR

Models H120/H125

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

CONTAK RENEWAL TR Models H120/H125 			
Worldwide Distribution: 19,000			
Worldwide Confirmed Malfunctions: 51			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁸ Low-voltage capacitor (Advisory issued)	1	-	
²⁰ Capacitor	-	1	
Mechanical	5	-	5
²⁶ Seal plug	5	-	
Software	28	-	28
⁴⁰ Stored EGMs	28	-	
Other	15	1	16
Non-patterned	9	1	
⁴⁷ Alert messages	5	-	
⁶² Magnet rate	1	-	
WW Confirmed Malfunctions	49	2	51

[More details](#) about malfunctions

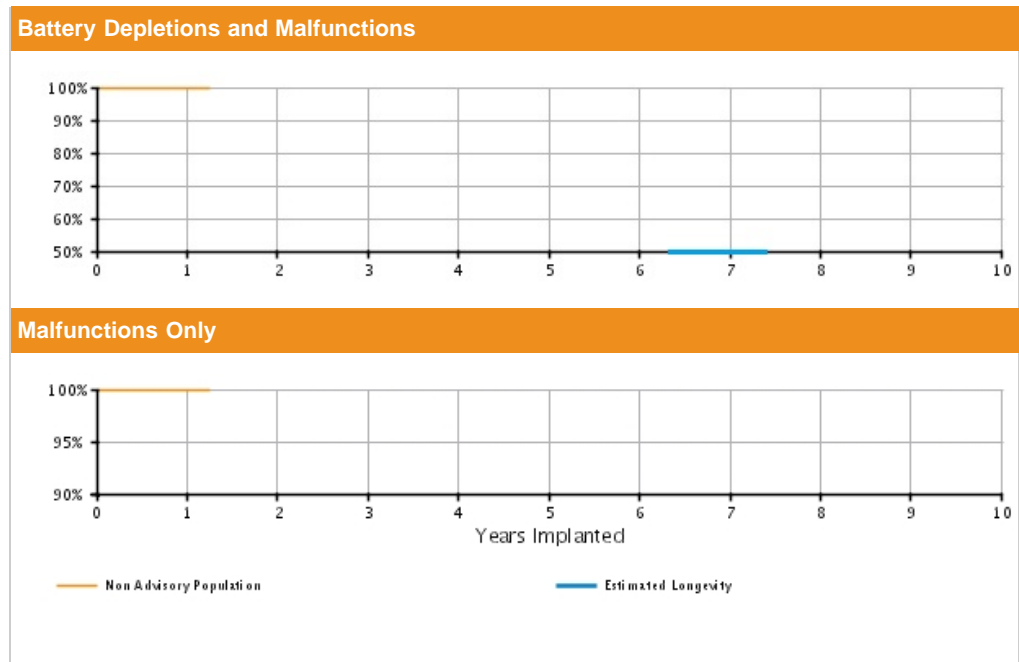
[References](#) cited in table above

EMBLEM S-ICD

Models A209/A219

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: 0
U.S. Approval Date: March 2015	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 8,000	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 (%)	99.96	99.96	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	@ 15 mo. (-0.1/+0.0)									
Registered Implants: 8000	Malfunctions Only (%)	99.96	99.96	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	@ 15 mo. (-0.1/+0.0)									
	Effective Sample Size	1609	353	-	-	-	-	-	-	-	-	-

EMBLEM S-ICD

Models A209/A219

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

EMBLEM S-ICD
Models A209/A219



Worldwide Distribution: 15,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	5	7
Non-patterned	2	2	
⁷⁴ Telemetry	-	3	
WW Confirmed Malfunctions	2	5	7

[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: 7,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
^{B1} Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	2	2

[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: 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

CRM PRODUCT PERFORMANCE REPORT Q4 2016

DYNAGEN/INOGEN/ORIGEN ICD EL DR

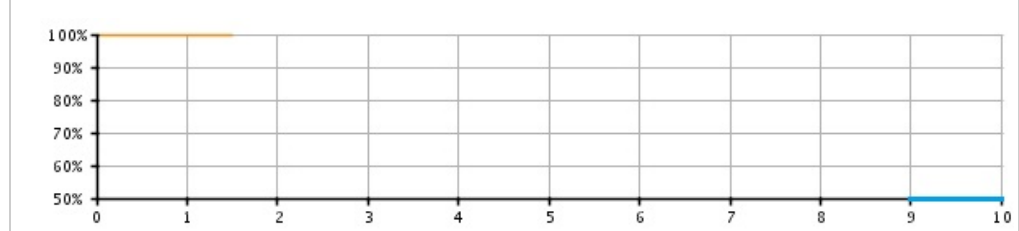
Models D052/D053/D142/D143/D152/
D153

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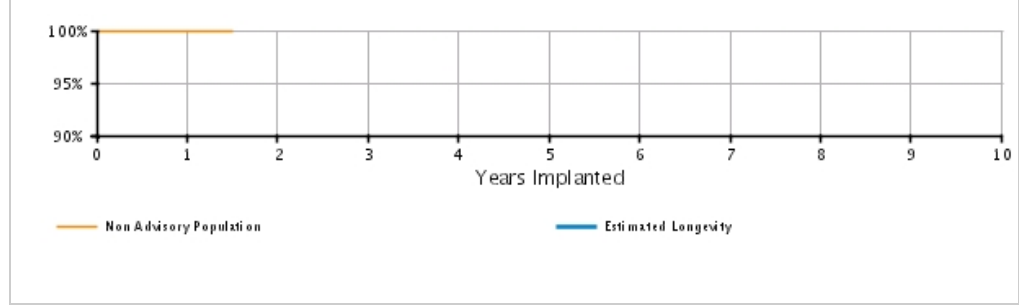
U.S. Summary

U.S. Registered Implants: 12,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: April 2014	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	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 18 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 12000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 18 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	3497	366	-	-	-	-	-	-	-	-

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: 18,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	-	2
⁸⁰ High voltage circuit component	2	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	0	2

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

DYNAGEN/INOGEN/ORIGEN ICD EL VR

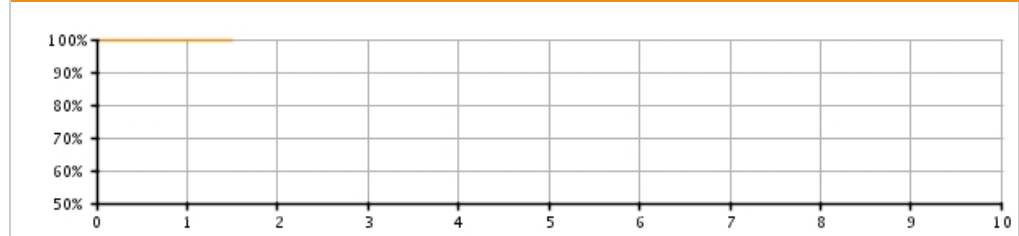
Models D050/D051/D140/D141/D150/
D151

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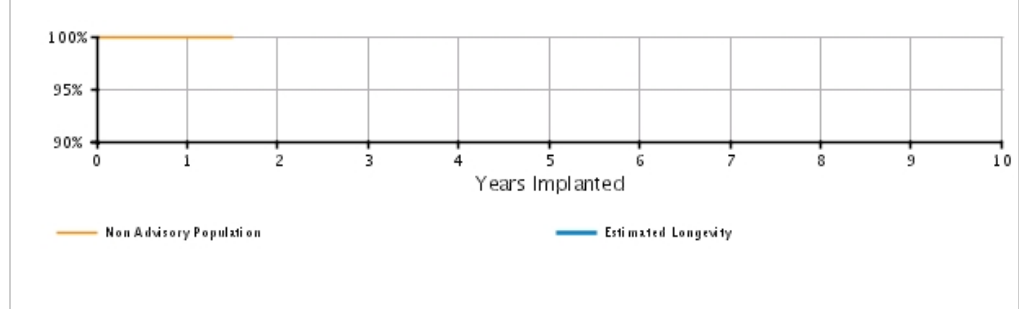
U.S. Summary

U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: May 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:2
	Without Compromised Therapy:2
	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)	99.97 (-0.1/+0.0)	99.97 @ 18 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 11000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 18 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	3427	351	-	-	-	-	-	-	-	-

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: 19,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸⁰ High voltage circuit component	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	3	-	3
Non-patterned	3	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

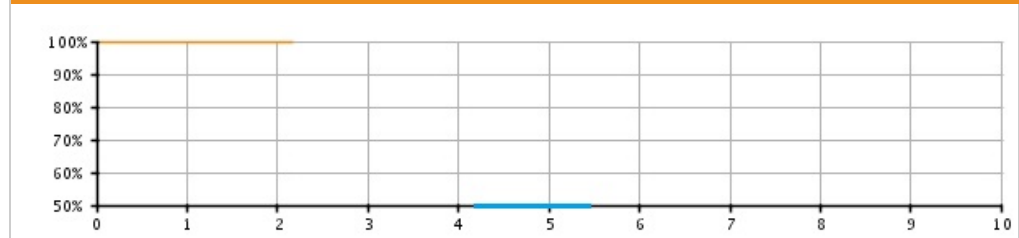
Models D002/D003/D012/D013/D022/
D023

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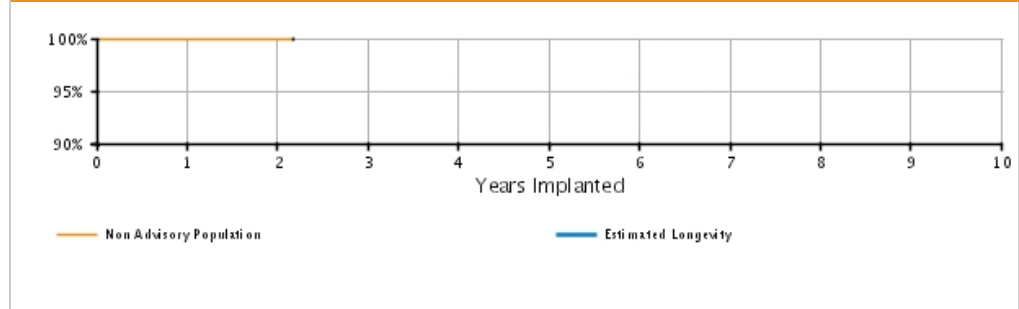
U.S. Summary

U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 1
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:2
	Without Compromised Therapy:2
	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)	99.87 (-0.2/+0.1)	99.87 @ 26 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.92 (-0.2/+0.1)	99.92 @ 26 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Effective Sample Size	2736	614	331	-	-	-	-	-	-	-

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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DYNAGEN/INOGEN/ORIGEN ICD MINI DR
Models D002/D003/D012/D013/D022/
D023 

Worldwide Distribution: 10,000

Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	-	3
⁸⁰ High voltage circuit component	3	-	
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

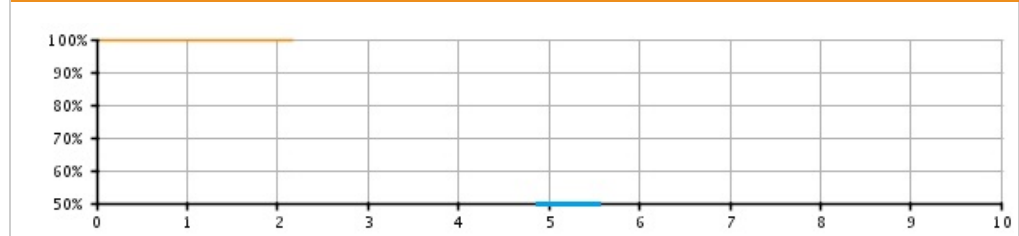
Models D000/D001/D010/D011/D020/
D021

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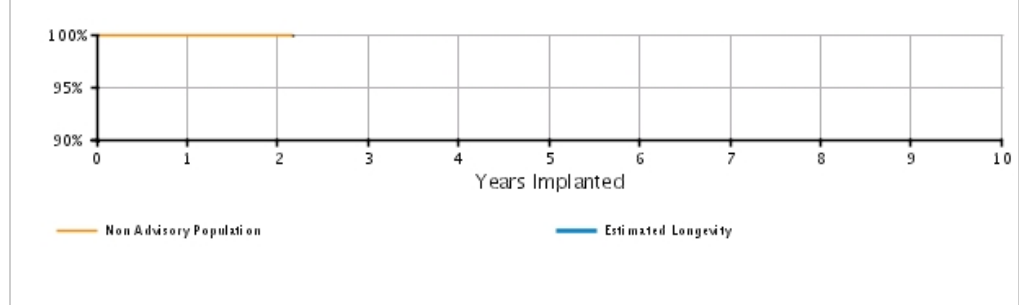
U.S. Summary

U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 2
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:2
	Without Compromised Therapy:2
	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)	99.79 (-0.5/+0.1)	99.79 @ 26 mo. (-0.5/+0.1)	-	-	-	-	-	-	-
Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 26 mo. (-0.2/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	2713	522	254	-	-	-	-	-	-	-

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: 11,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁸⁰ High voltage circuit component	2	-	
⁸² High voltage capacitor	-	1	
Mechanical	-	-	0
Software	1	-	1
⁶⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	1	5

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

INCEPTA/ENERGEN/PUNCTUA ICD DR

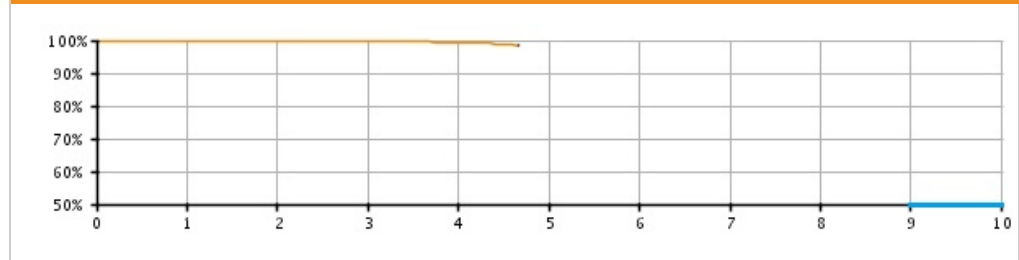
Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

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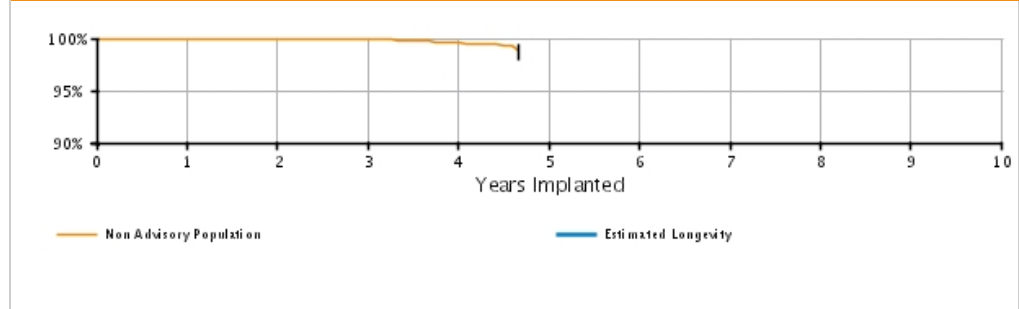
U.S. Summary

U.S. Registered Implants: 47,000	U.S. Normal Battery Depletions: 42
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 40,000	U.S. Malfunctions:68
	Without Compromised Therapy:61
	With Compromised Therapy:7

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.78 (-0.1/+0.1)	99.35 (-0.2/+0.1)	98.48 @ 56 mo. (-0.9/+0.6)	--	--	--	--	--	--
	Registered Implants: 47000											
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.57 (-0.1/+0.1)	98.90 @ 56 mo. (-1.0/+0.6)	--	--	--	--	--	--
	Effective Sample Size	40311	29557	16285	5075	303	--	--	--	--	--	--

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA/ENERGEN/PUNCTUA ICD DR
Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163 

Worldwide Distribution: 72,000
Worldwide Confirmed Malfunctions: 102

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	78	6	84
⁶¹ High-voltage capacitor	1	2	
⁶⁵ Low-voltage capacitors	3	-	
⁶⁸ Integrated circuit	5	3	
⁷¹ Battery	3	1	
⁷² Low-voltage capacitor	65	-	
⁷⁶ High voltage circuit	1	-	
Mechanical	-	2	2
⁵⁴ Transformer	-	2	
Software	2	-	2
⁶⁹ Memory errors	2	-	
Other	10	4	14
Non-patterned	10	4	
WW Confirmed Malfunctions	90	12	102

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

INCEPTA/ENERGEN/PUNCTUA ICD VR

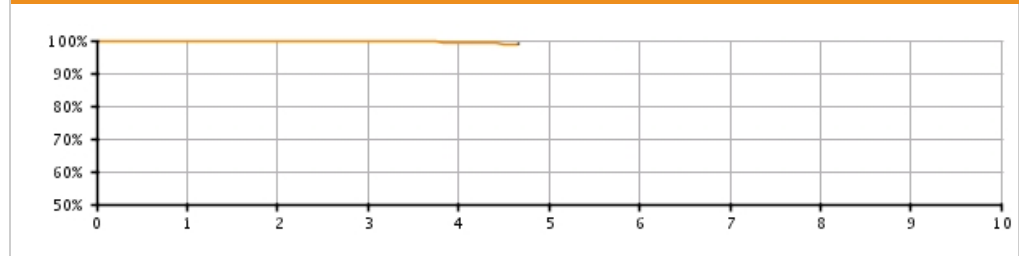
Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

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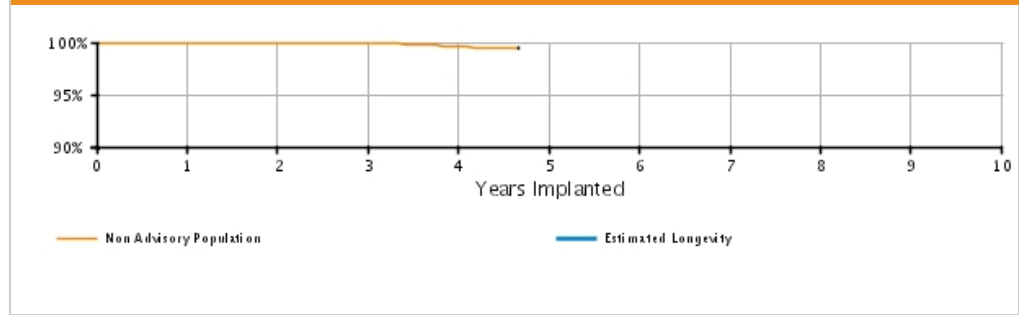
U.S. Summary

U.S. Registered Implants: 39,000	U.S. Normal Battery Depletions: 43
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 6
U.S. Estimated Active Implants: 34,000	U.S. Malfunctions:49
	Without Compromised Therapy:36
	With Compromised Therapy:13

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.33 (-0.2/+0.2)	98.95 @ 56 mo. (-0.4/+0.3)	-	-	-	-	-	-
	Registered Implants: 39000											
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.62 (-0.2/+0.1)	99.48 @ 56 mo. (-0.2/+0.2)	-	-	-	-	-	-
	Effective Sample Size	33919	24632	13275	4237	268	-	-	-	-	-	-

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INCEPTA/ENERGEN/PUNCTUA ICD VR
Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161 

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 72

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	44	7	51
⁶¹ High-voltage capacitor	1	1	
⁶⁸ Integrated circuit	1	4	
⁷¹ Battery	4	1	
⁷² Low-voltage capacitor	38	-	
⁷⁶ High voltage circuit	-	1	
Mechanical	-	5	5
⁵⁴ Transformer	-	5	
Software	5	-	5
⁶⁹ Memory errors	5	-	
Other	6	5	11
Non-patterned	6	5	
WW Confirmed Malfunctions	55	17	72

[More details](#) about malfunctions

[References](#) cited in table above

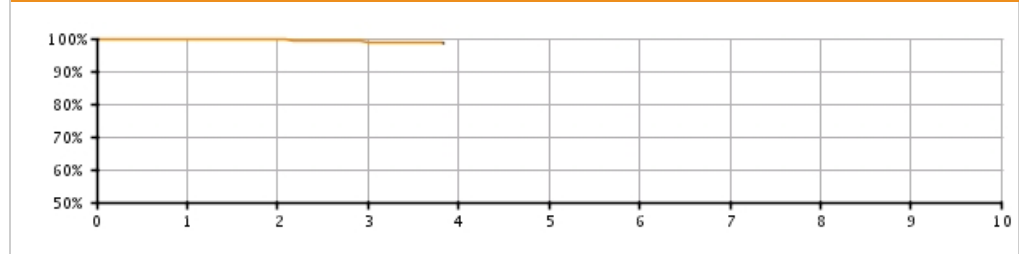
SQ-RX S-ICD

Model 1010

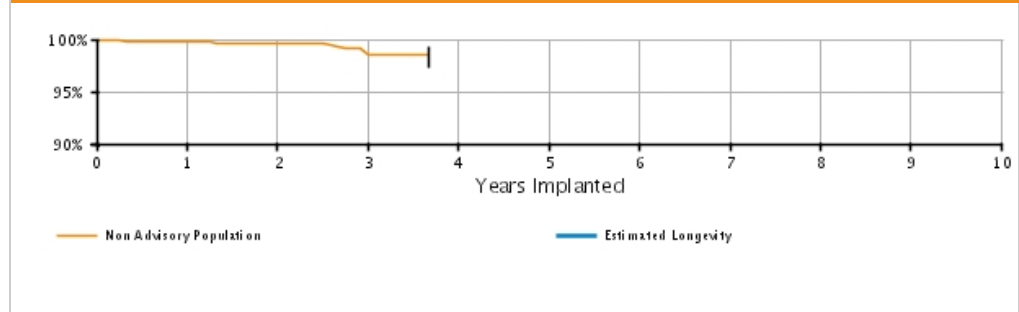
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 8,000	U.S. Normal Battery Depletions: 63
U.S. Approval Date: September 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 7,000	U.S. Malfunctions:36
	Without Compromised Therapy:14
	With Compromised Therapy:22

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(%)	99.75	99.53	98.75	98.75	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.9/+0.5)	@ 46 mo. (-0.9/+0.5)							
Registered Implants: 8000	Malfunctions Only(%)	99.77	99.59	98.85	98.85	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-1.0/+0.5)	@ 46 mo. (-1.0/+0.5)							
	Effective Sample Size	6466	3102	485	235	—	—	—	—	—	—	—

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 Distribution: 11,000			
Worldwide Confirmed Malfunctions: 91			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	8	3	11
² Unintended Fuse Activation 2013	-	3	
⁷⁹ Charge Timeout Alert	8	-	
Mechanical	14	19	33
³ High cathode condition	1	2	
⁷³ Battery depletion	13	17	
Software	2	-	2
⁷⁵ Unintended Battery Depletion Alert	2	-	
Other	15	30	45
Non-patterned	12	21	
⁷⁴ Telemetry	3	9	
WW Confirmed Malfunctions	39	52	91

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

TELIGEN DR

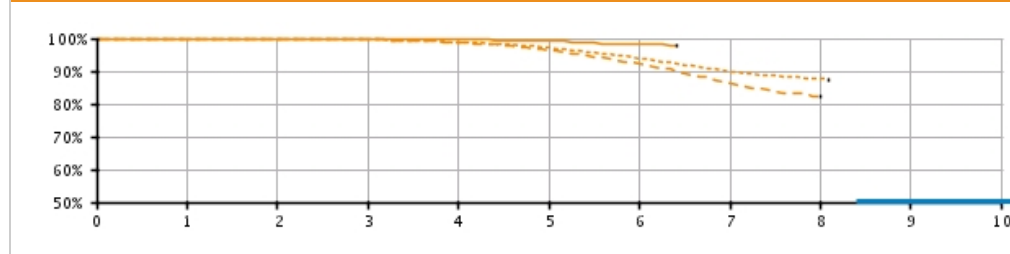
Models E110/E111/F110/F111

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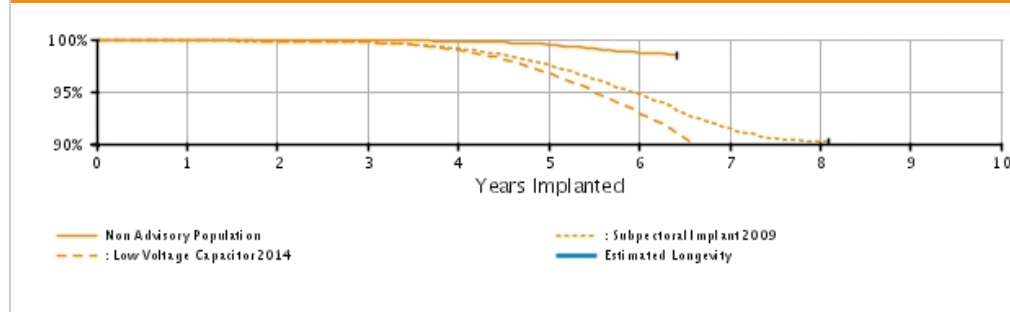
U.S. Summary

U.S. Registered Implants: 66,000	U.S. Normal Battery Depletions: 247
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 136
U.S. Estimated Active Implants: 40,000	U.S. Malfunctions:1620
	Without Compromised Therapy:1,501
	With Compromised Therapy:119

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)	99.78 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.19 (-0.1/+0.1)	98.18 (-0.3/+0.2)	97.76 @ 77 mo. (-0.6/+0.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.49 (-0.1/+0.1)	98.73 (-0.2/+0.2)	98.47 @ 77 mo. (-0.5/+0.4)	-	-	-	-
	Effective Sample Size	26439	23336	20591	18079	12712	3203	218	-	-	-	-
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/+0.1)	98.89 (-0.1/+0.1)	97.19 (-0.1/+0.1)	93.95 (-0.1/+0.1)	89.97 (-0.2/+0.1)	87.69 (-0.2/+0.3)	87.53 @ 97 mo. (-1.2/+0.5)	-	-
	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)	97.56 (-0.1/+0.2)	94.69 (-0.2/+0.3)	91.44 (-0.2/+0.3)	90.24 (-0.4/+0.3)	90.24 @ 97 mo. (-0.4/+0.3)	-	-
	Effective Sample Size	26747	23501	20671	18055	15611	13225	8708	1046	552	-	-
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 (-0.1/+0.1)	96.38 (-0.1/+0.1)	92.14 (-0.1/+0.1)	86.38 (-0.3/+0.2)	82.23 (-1.0/+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 (-0.1/+0.1)	96.76 (-0.2/+0.1)	92.93 (-0.4/+0.3)	88.16 (-0.6/+1.0)	85.70 (-1.2/+1.5)	-	-	-
	Effective Sample Size	23000	20000	17000	14000	11000	8000	5000	3000	1000	-	-


Effective Sample Size	20715	18219	16010	13978	11989	9955	4049	224	-	-
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*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: 91,000			
Worldwide Confirmed Malfunctions: 2126			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1908	88	1996
¹ Low Voltage Capacitor 2014 (Advisory issued)	1524	37	
⁶⁰ Safety Core-electrocautery	3	-	
⁶¹ High-voltage capacitor	1	7	
⁶⁵ Low-voltage capacitors	6	-	
⁶⁸ Integrated circuit	20	20	
⁷¹ Battery	156	23	
⁷² Low-voltage capacitor	198	1	
Mechanical	20	51	71
⁴ Subpectoral implant 2009 (Advisory issued)	3	9	
⁵⁴ Transformer	-	20	
⁵⁷ Seal plug	3	-	
⁵⁸ Difficulty securing lead	9	8	
⁶³ Header contacts	3	11	
⁸⁴ Header	2	3	
Software	16	-	16
⁶⁶ Alert messages not displayed post-EOL	3	-	
⁶⁹ Memory errors	13	-	
Other	32	11	43
Non-patterned	32	11	
WW Confirmed Malfunctions	1976	150	2126

[More details](#) about malfunctions

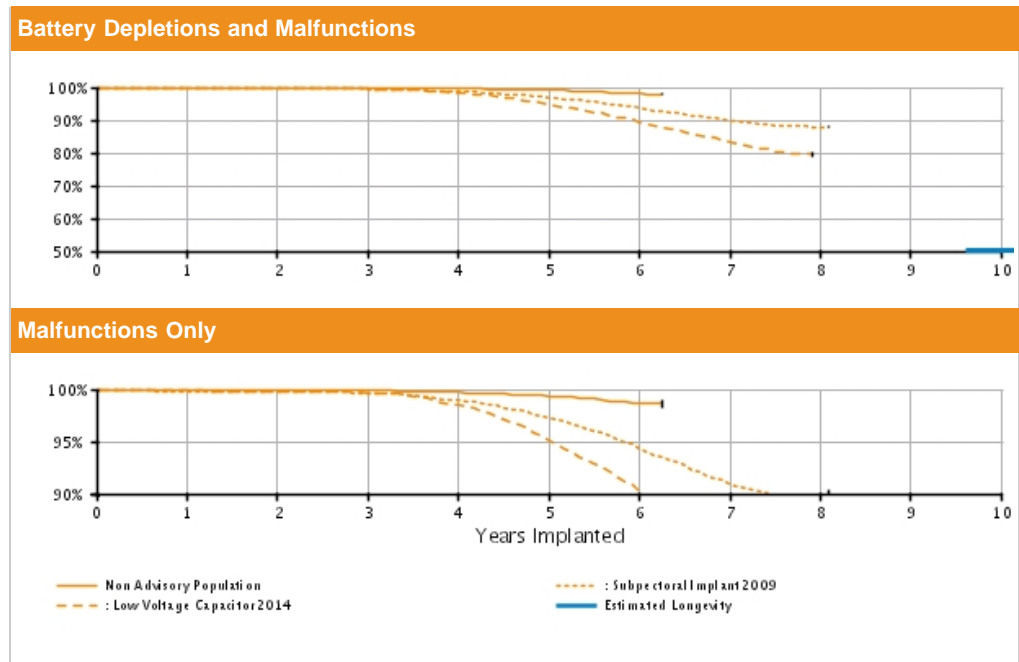
[References](#) cited in table above

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: 87
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 88
U.S. Estimated Active Implants: 23,000	U.S. Malfunctions:1092
	Without Compromised Therapy:1,004
	With Compromised Therapy:88



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.16 (-0.2/+0.2)	98.10 (-0.5/+0.4)	97.89 @ 75 mo. (-0.6/+0.5)	-	-	-	-
	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)	99.37 (-0.2/+0.1)	98.71 (-0.4/+0.3)	98.61 @ 75 mo. (-0.4/+0.3)	-	-	-	-
	Effective Sample Size	16275	14327	12584	11029	7256	1231	369	-	-	-	-
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.0/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.1/+0.1)	96.93 (-0.1/+0.1)	93.70 (-0.1/+0.1)	89.75 (-0.1/+0.5)	87.84 (-0.6/+0.5)	87.84 @ 97 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 (-0.1/+0.1)	97.32 (-0.1/+0.1)	94.37 (-0.1/+0.2)	90.91 (-0.4/+0.3)	89.51 (-0.5/+0.6)	89.51 @ 97 mo. (-0.6/+0.9)	-	-
	Effective Sample Size	13682	11996	10515	9151	7864	6664	4381	561	307	-	-
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/+0.1)	98.23 (-0.1/+0.1)	94.79 (-0.2/+0.1)	89.48 (-0.3/+0.2)	83.17 (-0.4/+0.2)	79.57 @ 95 mo. (-1.5/+1.6)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.45 (-0.1/+0.1)	95.14 (-0.1/+0.1)	90.24 (-0.1/+0.1)	84.73 (-0.3/+0.2)	82.03 @ 95 mo.	-	-	-
	Effective Sample Size	-	-	-	-	-	-	-	-	-	-	-


							(-1.2/+1.1)		
Effective Sample Size	10906	9580	8403	7291	6171	4951	1862	217	-

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

TELIGEN VR

Models E102/E103/F102/F103

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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TELIGEN VR Models E102/E103/F102/F103 			
Worldwide Distribution: 66,000			
Worldwide Confirmed Malfunctions: 1711			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1522	63	1585
¹ Low Voltage Capacitor 2014 (Advisory issued)	1164	27	
⁶⁰ Safety Core-electrocautery	1	1	
⁶¹ High-voltage capacitor	-	3	
⁶⁵ Low-voltage capacitors	5	-	
⁶⁸ Integrated circuit	10	14	
⁷¹ Battery	217	18	
⁷² Low-voltage capacitor	125	-	
Mechanical	22	68	90
⁴ Subpectoral implant 2009 (Advisory issued)	6	17	
³⁴ Transformer	-	1	
⁵⁴ Transformer	-	14	
⁵⁷ Seal plug	1	-	
⁵⁸ Difficulty securing lead	-	10	
⁶³ Header contacts	13	18	
⁸⁴ Header	2	8	
Software	15	-	15
⁵ Respiratory Sensor Oversensing	1	-	
⁶⁶ Alert messages not displayed post-EOL	4	-	
⁶⁹ Memory errors	10	-	
Other	11	10	21
Non-patterned	11	10	
WW Confirmed Malfunctions	1570	141	1711

[More details](#) about malfunctions

[References](#) cited in table above

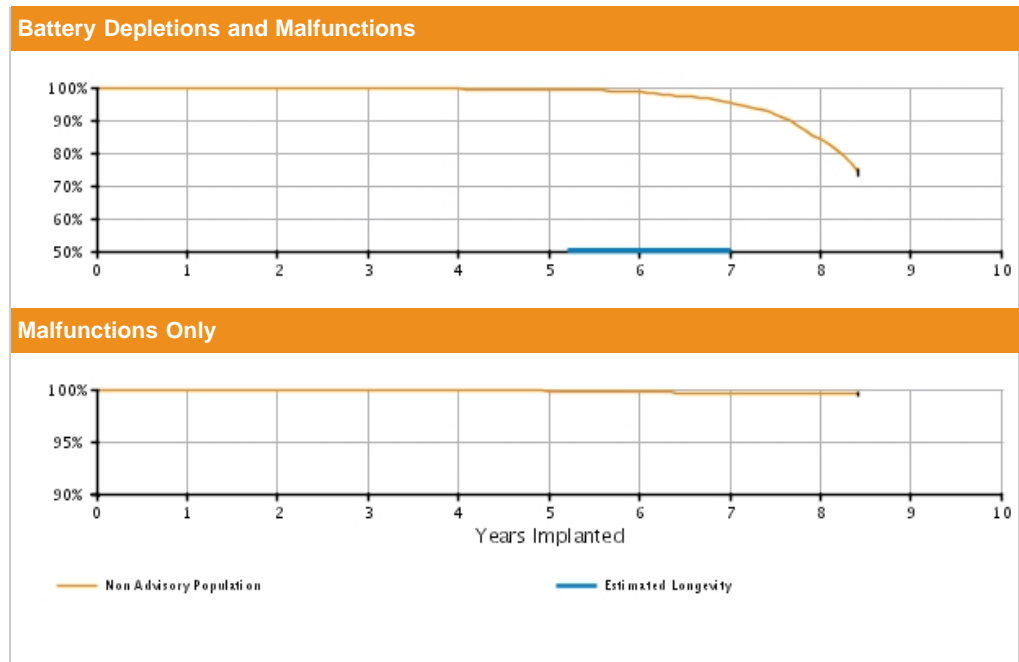
CRM PRODUCT PERFORMANCE REPORT Q4 2016

CONFIENT 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: 420
U.S. Approval Date: February 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:14
	Without Compromised Therapy:11
	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)	99.34 (-0.3/+0.2)	98.53 (-0.4/+0.3)	95.44 (-0.8/+0.7)	84.26 (-1.7/+1.6)	74.05 @ 101 mo. (-2.6/+2.5)	—	—
	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)	99.78 (-0.2/+0.1)	99.63 (-0.3/+0.2)	99.58 (-0.3/+0.2)	99.58 @ 101 mo. (-0.3/+0.2)	—	—
Registered Implants: 7000	Effective Sample Size	6164	5396	4699	4115	3584	2971	2284	1237	385	—	—

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: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	10	-	10
²⁰ Capacitor	1	-	
²³ Integrated circuit	2	-	
⁷² Low-voltage capacitor	7	-	
Mechanical	-	1	1
⁵⁴ Transformer	-	1	
Software	-	-	0
Other	1	2	3
Non-patterned	1	1	
²⁹ Battery depletion	-	1	
WW Confirmed Malfunctions	11	3	14

[More details](#) about malfunctions

[References](#) cited in table above

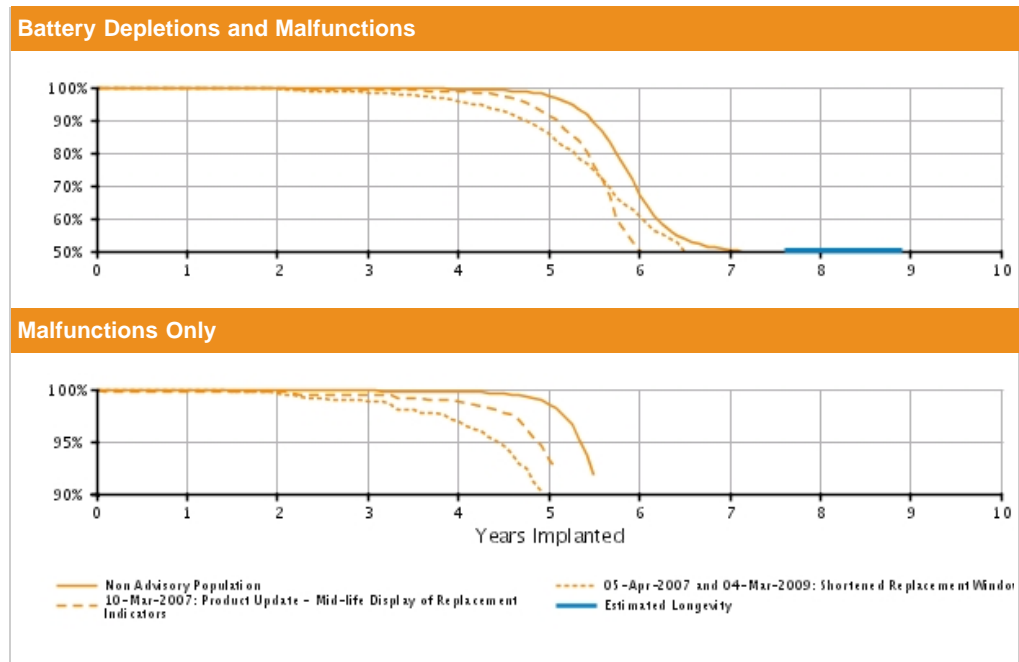
CRM PRODUCT PERFORMANCE REPORT Q4 2016

VITALITY 2 EL VR

Model T177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 1,283
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions:1278
	Without Compromised Therapy:1264
	With Compromised Therapy:14



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.95	99.92	99.78	99.39	97.37	67.10	50.28	44.02	34.98	—	—
	(Confidence Interval)	(-0.2/+0.0)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.4/+0.2)	(-0.7/+0.6)	(-2.1/+2.1)	(-2.3/+2.3)	(-2.4/+2.4)	@ 102 mo. (-2.7/+2.8)	—	—
	Registered Implants: 4000											
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%)	99.95	99.56	98.48	95.88	85.70	60.76	41.23	33.71	—	—	—
	(Confidence Interval)	(-0.3/+0.0)	(-0.5/+0.2)	(-0.8/+0.5)	(-1.2/+1.0)	(-2.2/+2.0)	(-3.3/+3.2)	(-3.4/+3.5)	@ 88 mo. (-3.4/+3.5)	—	—	—
	Registered Implants: 2000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%)	99.61	99.61	99.38	98.80	91.14	50.22	45.00	—	—	—	—
	(Confidence Interval)	(-0.6/+0.2)	(-0.6/+0.2)	(-0.8/+0.3)	(-1.0/+0.6)	(-2.5/+2.0)	(-4.4/+4.4)	@ 74 mo. (-4.4/+4.5)	—	—	—	—
	Registered Implants: 1687											

Registered Implants: 1000	Malfunctions Only (%)	99.72	99.72	99.48	98.90	93.22	59.60	54.40	-	-	-
	(Confidence Interval)	(-0.6/+0.2)	(-0.6/+0.2)	(-0.7/+0.3)	(-1.0/+0.5)	(-2.3/+1.8)	(-4.6/+4.4)	@ 74 mo. (-4.7/+4.6)			
	Effective Sample Size	975	854	747	647	526	237	206	-	-	-
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: 1926			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1885	8	1893
⁷ Shortened replacement window (Advisory issued)	139	1	
⁸ Low-voltage capacitor (Advisory issued)	2	1	
¹² Extended charge time post-mid-life	20	2	
²³ Integrated circuit	-	3	
³² Capacitor	1	-	
³⁵ Capacitor	2	-	
⁴² Mid-life display of replacement indicators	1654	1	
⁴³ High-voltage capacitor	2	-	
⁵⁹ Low-voltage capacitor	65	-	
Mechanical	3	8	11
⁶ Subpectoral implant (Advisory issued)	-	5	
¹⁹ Header	-	1	
²⁶ Seal plug	1	-	
⁴⁵ Sensing	2	-	
⁵⁴ Transformer	-	2	
Software	-	2	2
³⁹ Memory location	-	1	
⁴¹ Memory location	-	1	
Other	11	9	20
Non-patterned	11	7	
²¹ Battery depletion	-	2	
WW Confirmed Malfunctions	1899	27	1926

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

ACCOLADE/PROPONENT/ESSENTIO DR EL

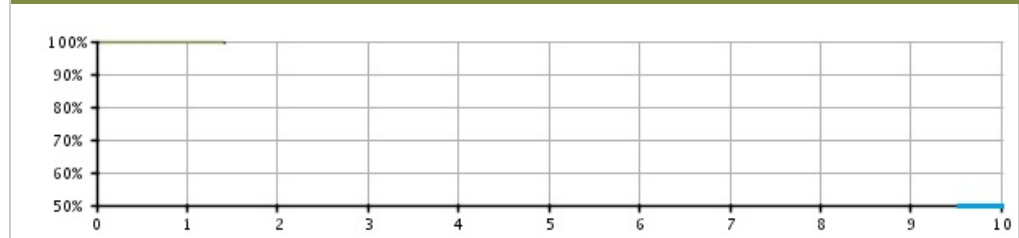
Models L121/L131/L221/L231/L321/
L331

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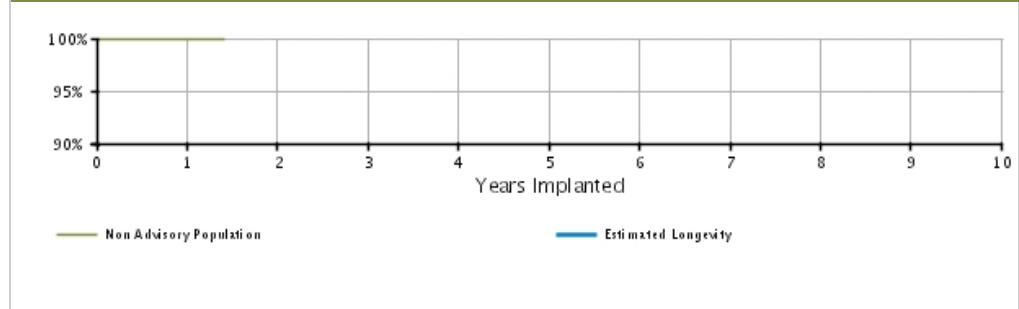
U.S. Summary

U.S. Registered Implants: 16,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: October 2010	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 16,000	U.S. Malfunctions:3
	Without Compromised Therapy:3
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.1)	99.59 @ 17 mo. (-0.9/+0.3)	-	-	-	-	-	-	-	-
Registered Implants: 16000	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 @ 17 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	3545	470	-	-	-	-	-	-	-	-

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: 41,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	6	-	6
⁸³ Capacitor	6	-	
Mechanical	-	-	0
Software	1	-	1
⁶⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	8	0	8

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

ACCOLADE/PROONENT/ESSENTIO DR

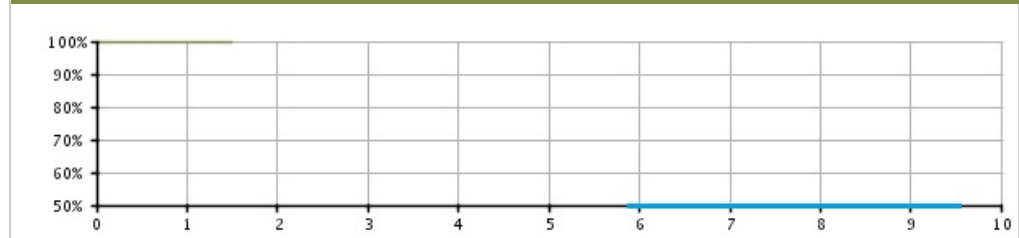
Models L101/L111/L201/L211/L301/
L311

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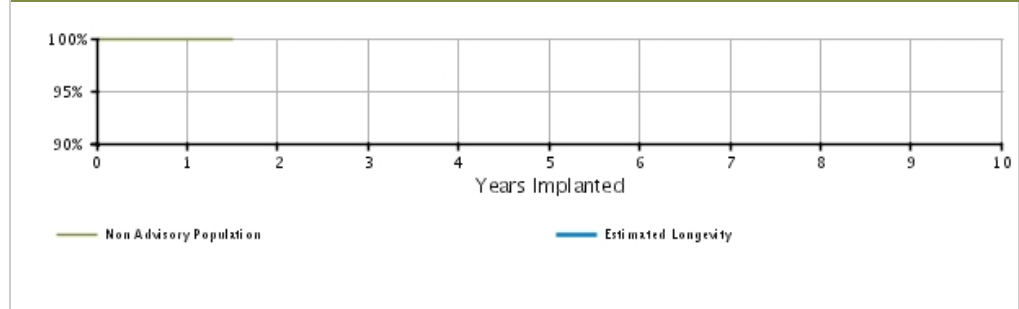
U.S. Summary

U.S. Registered Implants: 48,000	U.S. Normal Battery Depletions: 6
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 47,000	U.S. Malfunctions:6
	Without Compromised Therapy:3
	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 (-0.0/+0.0)	99.95 @ 18 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 48000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 @ 18 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	12141	549	-	-	-	-	-	-	-	-

ACCOLADE/PROPONENT/ESSENTIO DR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ACCOLADE/PROPONENT/ESSENTIO DR
Models L101/L111/L201/L211/L301/
L311 

Worldwide Distribution: 92,000

Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	3	7
⁶⁵ Low-voltage capacitors	1	-	
⁸¹ Integrated circuit	2	3	
⁸³ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	1	2	3
Non-patterned	1	2	
WW Confirmed Malfunctions	5	5	10

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

ACCOLADE/PROONENT/ESSENTIO SR

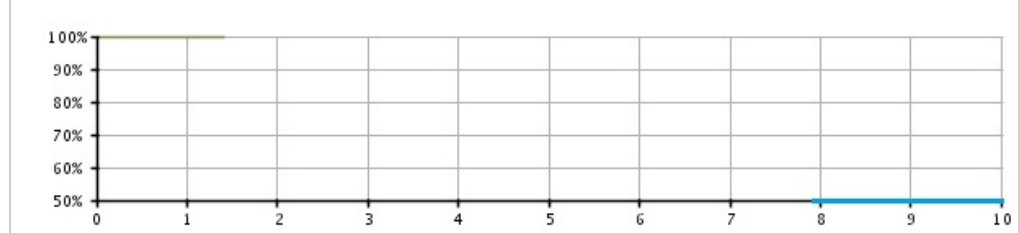
Models L100/L110/L200/L210/L300/
L310

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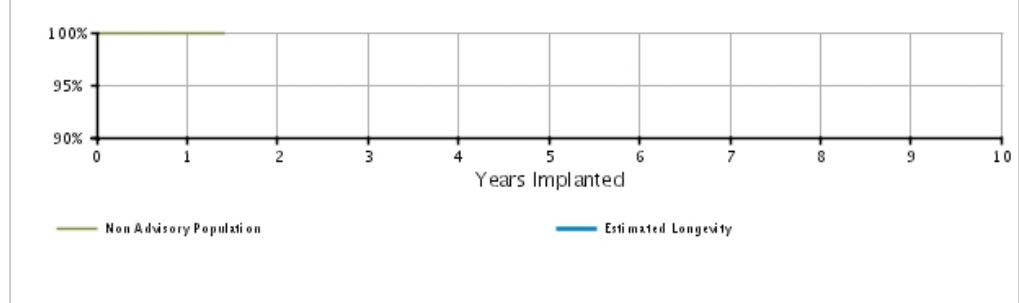
U.S. Summary

U.S. Registered Implants: 10,000	U.S. Normal Battery Depletions: 3
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 9,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

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)	99.97 (-0.1/+0.0)	99.91 @ 17 mo. (-0.3/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 10000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 17 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	2081	252	-	-	-	-	-	-	-	-

ACCOLADE/PROPONENT/ESSENTIO SR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ACCOLADE/PROPONENT/ESSENTIO SR
Models L100/L110/L200/L210/L300/
L310 

Worldwide Distribution: 31,000

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	1	0	1

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO/FORMIO DR

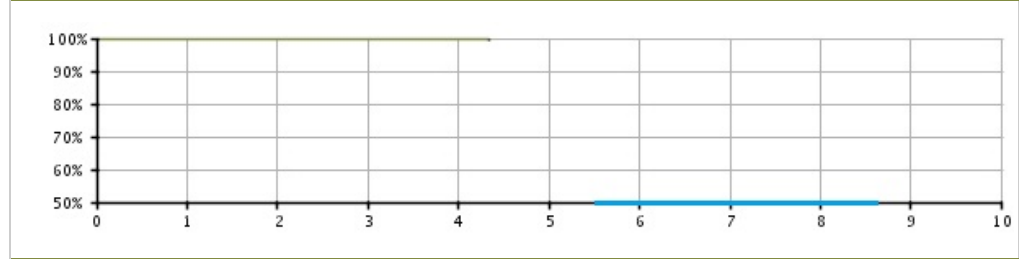
Models J063/J066/J173/J176/J273/
 J276/J278/J279/K063/K066/
 K083/K086/K173/K176/K183/
 K186/K273/K276/K278/K279/
 K283/K286/K288/K289

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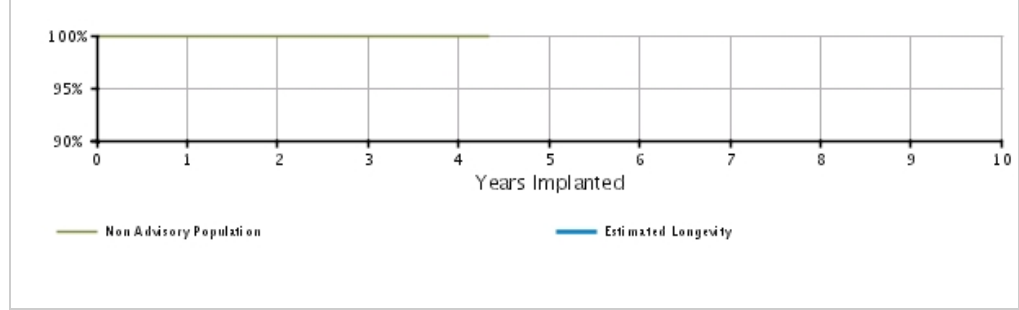
U.S. Summary

U.S. Registered Implants: 121,000	U.S. Normal Battery Depletions: 99
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 105,000	U.S. Malfunctions:32
	Without Compromised Therapy:23
	With Compromised Therapy:9

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)	99.86 (-0.0/+0.0)	99.73 (-0.1/+0.1)	99.52 @ 52 mo. (-0.3/+0.2)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 52 mo. (-0.0/+0.0)	-	-	-	-	-
Registered Implants: 121000	Effective Sample Size	107300	74979	35863	6333	474	-	-	-	-	-

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models J063/J066/J173/J176/J273/
 J276/J278/J279/K063/K066/
 K083/K086/K173/K176/K183/
 K186/K273/K276/K278/K279/
 K283/K286/K288/K289

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ADVANTIO/INGENIO/VITALIO/FORMIO DR 

Models J063/J066/J173/J176/J273/
 J276/J278/J279/K063/K066/
 K083/K086/K173/K176/K183/
 K186/K273/K276/K278/K279/
 K283/K286/K288/K289

Worldwide Distribution: 214,000
Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	8	7	15
⁶⁵ Low-voltage capacitors	5	-	
⁶⁸ Integrated circuit	3	5	
⁷⁸ Titanium case material	-	2	
Mechanical	-	-	0
Software	12	1	13
⁶⁹ Memory errors	12	1	
Other	19	4	23
Non-patterned	19	4	
WW Confirmed Malfunctions	39	12	51

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO EL DR

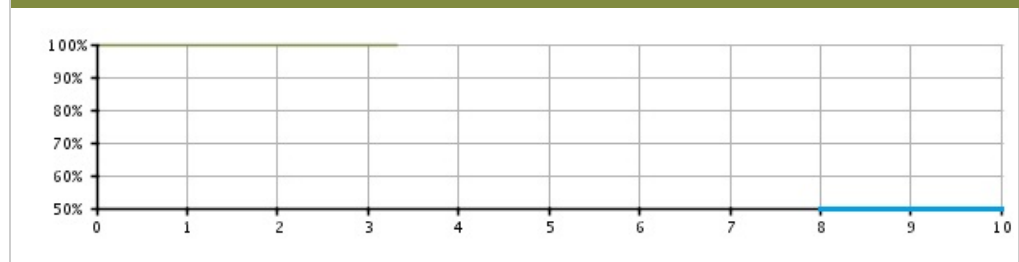
Models J064/J067/J174/J177/J274/
 J277/K064/K067/K084/K087/
 K174/K177/K184/K187/K274/
 K277/K284/K287

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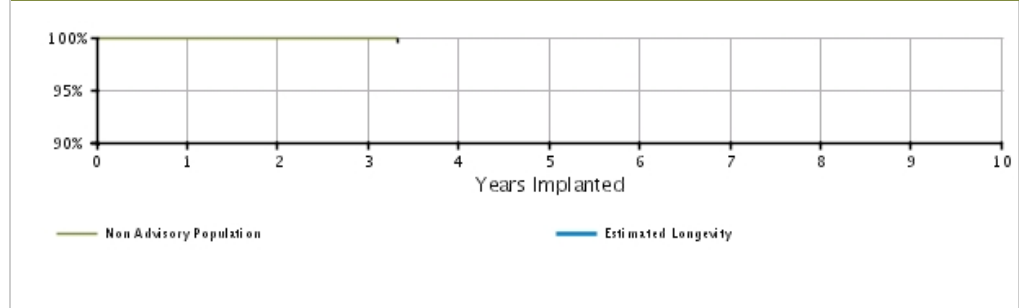
U.S. Summary

U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 3
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:4
	Without Compromised Therapy:3
	With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)		99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.82 (-0.3/+0.1)	99.82 @ 40 mo. (-0.3/+0.1)	-	-	-	-	-	-
	Registered Implants: 11000											
	Malfunctions Only(%) (Confidence Interval)		99.99 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.88 (-0.4/+0.1)	99.88 @ 40 mo. (-0.4/+0.1)	-	-	-	-	-	-
	Effective Sample Size		9298	4886	805	238	-	-	-	-	-	-

ADVANTIO/INGENIO/VITALIO EL DR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ADVANTIO/INGENIO/VITALIO EL DR
 Models J064/J067/J174/J177/J274/
 J277/K064/K067/K084/K087/
 K174/K177/K184/K187/K274/
 K277/K284/K287



Worldwide Distribution: 69,000
Worldwide Confirmed Malfunctions: 20

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁶⁵ Low-voltage capacitors	4	1	
⁶⁸ Integrated circuit	-	2	
⁷⁶ Titanium case material	-	2	
Mechanical	-	-	0
Software	4	-	4
⁶⁹ Memory errors	3	-	
⁷⁷ Respiratory sensor	1	-	
Other	6	1	7
Non-patterned	6	1	
WW Confirmed Malfunctions	14	6	20

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO SR

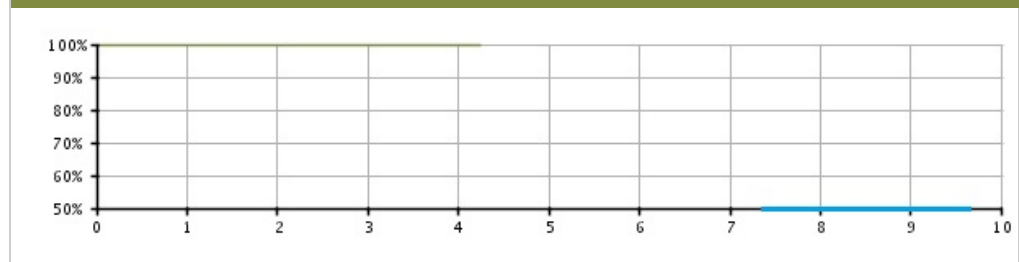
Models J062/J065/J172/J175/J272/
 J275/K062/K065/K082/K085/
 K172/K175/K182/K185/K272/
 K275/K282/K285

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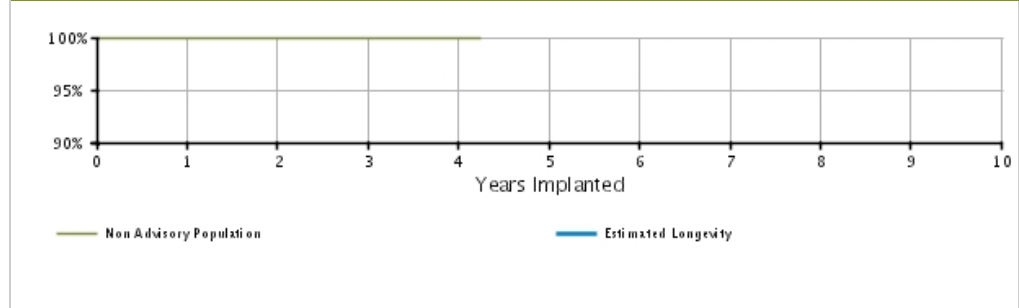
U.S. Summary

U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 11
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 21,000	U.S. Malfunctions:7
	Without Compromised Therapy:6
	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)	99.98 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.89 @ 51 mo. (-0.1/+0.0)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 51 mo. (-0.0/+0.0)	-	-	-	-	-	-
Registered Implants: 27000	Effective Sample Size	22343	14823	6742	1072	214	-	-	-	-	-	-

ADVANTIO/INGENIO/VITALIO SR

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ADVANTIO/INGENIO/VITALIO SR
 Models J062/J065/J172/J175/J272/
 J275/K062/K065/K082/K085/
 K172/K175/K182/K185/K272/
 K275/K282/K285



Worldwide Distribution: 83,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁶⁵ Low-voltage capacitors	3	1	
⁶⁸ Integrated circuit	1	3	
⁷⁶ Titanium case material	-	1	
Mechanical	-	-	0
Software	4	-	4
⁶⁹ Memory errors	4	-	
Other	1	2	3
Non-patterned	1	2	
WW Confirmed Malfunctions	9	7	16

[More details](#) about malfunctions

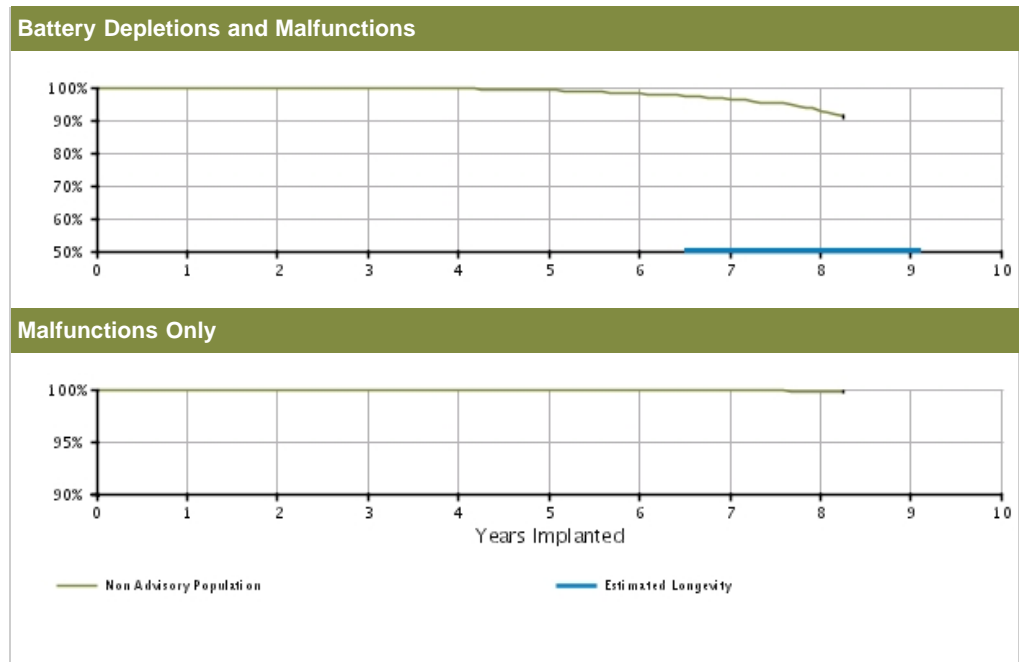
[References](#) cited in table above

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: 453
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 14,000	U.S. Malfunctions:14
	Without Compromised Therapy:13
	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)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.54 (-0.1/+0.1)	99.03 (-0.2/+0.2)	98.04 (-0.3/+0.2)	96.50 (-0.4/+0.4)	92.90 (-0.8/+0.8)	91.25 @ 99 mo. (-1.6/+1.3)	-	-
	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)	99.90 (-0.1/+0.0)	99.75 (-0.2/+0.1)	99.75 @ 99 mo. (-0.2/+0.1)	-	-
Registered Implants: 22000	Effective Sample Size	19510	17257	15146	13158	10886	8609	6182	1326	243	-	-

ALTRUA 60 DR

Model S602

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

ALTRUA 60 DR Model S602 			
Worldwide Distribution: 56,000			
Worldwide Confirmed Malfunctions: 21			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁰ Capacitor	1	-	
Mechanical	1	1	2
²² Capacitor array	1	-	
⁵⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	16	2	18
Non-patterned	2	1	
³⁷ Battery depletion	1	1	
⁶⁷ Battery status	13	-	
WW Confirmed Malfunctions	18	3	21

[More details](#) about malfunctions

[References](#) cited in table above

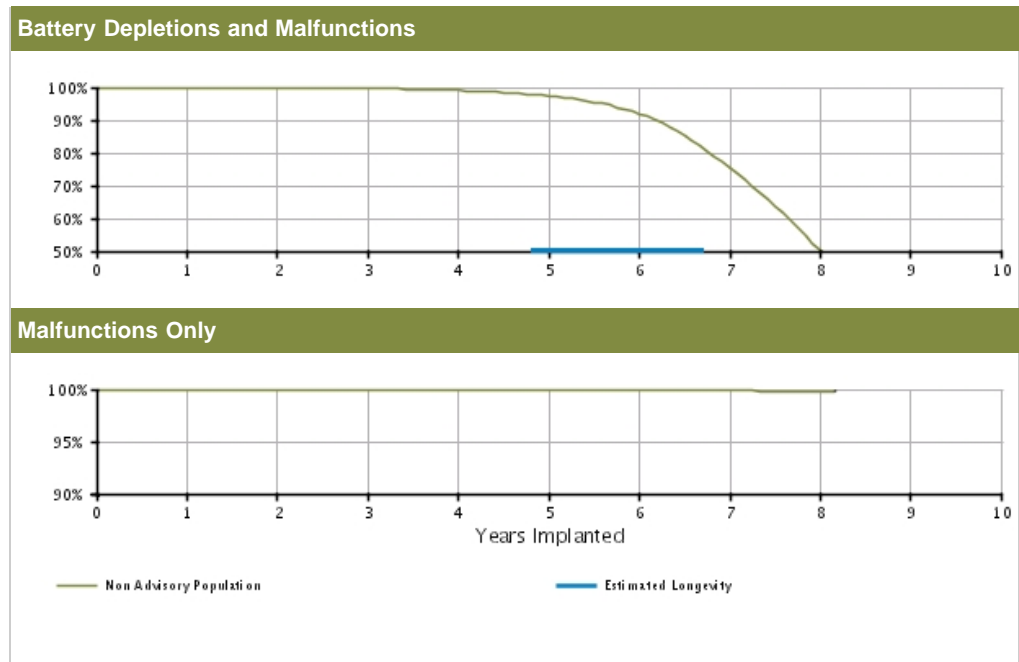
CRM PRODUCT PERFORMANCE REPORT Q4 2016

ALTRUA 60 DR (Downsize)

Model S603

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: 7,581
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 44
U.S. Estimated Active Implants: 51,000	U.S. Malfunctions:52
	Without Compromised Therapy:44
	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(%)	99.98	99.91	99.67	99.09	97.42	91.94	75.46	50.26	45.60	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.3/+0.3)	(-0.6/+0.6)	(-1.3/+1.3)	@ 98 mo. (-1.7/+1.7)	
Registered Implants: 90000	Malfunctions Only(%)	99.99	99.99	99.98	99.98	99.96	99.90	99.85	99.80	99.80	—
	(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)	(-0.1/+0.0)	(-0.1/+0.1)	@ 98 mo. (-0.1/+0.1)	
	Effective Sample Size	79411	70666	62667	54114	39349	23871	9880	1184	401	—

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: 64

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	5	7	12
²⁰ Capacitor	4	6	
⁴⁶ Integrated circuit	1	1	
Mechanical	2	-	2
⁵⁵ Connector block	1	-	
⁵⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	47	3	50
Non-patterned	1	2	
³⁷ Battery depletion	3	1	
⁶⁷ Battery status	43	-	
WW Confirmed Malfunctions	54	10	64

[More details](#) about malfunctions

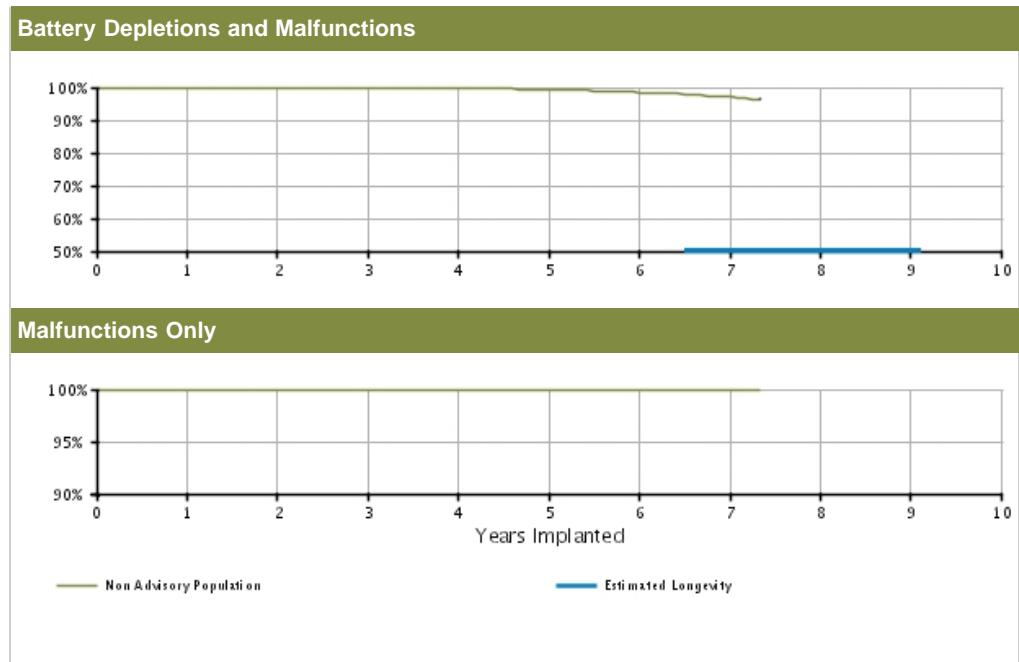
[References](#) cited in table above

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: 421
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 43,000	U.S. Malfunctions:10
	Without Compromised Therapy:8
	With Compromised Therapy:2



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.71 (-0.1/+0.0)	99.33 (-0.1/+0.1)	98.50 (-0.2/+0.2)	97.21 (-0.4/+0.3)	96.48 @ 88 mo. (-0.7/+0.6)	-	-	-
	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)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 88 mo. (-0.0/+0.0)	-	-	-
	Effective Sample Size	52726	46892	41513	35670	23172	10899	1993	318	-	-	-

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: 12			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
²⁰ Capacitor	3	-	
²³ Integrated circuit	1	-	
Mechanical	-	1	1
⁵⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	6	1	7
Non-patterned	1	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	5	-	
WW Confirmed Malfunctions	10	2	12

[More details](#) about malfunctions

[References](#) cited in table above

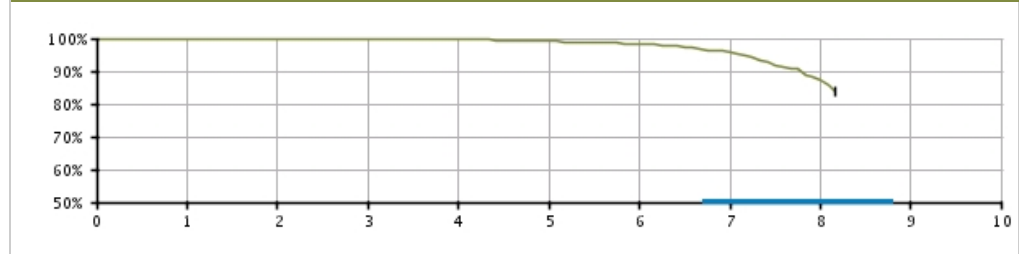
ALTRUA 60 SR

Model S601

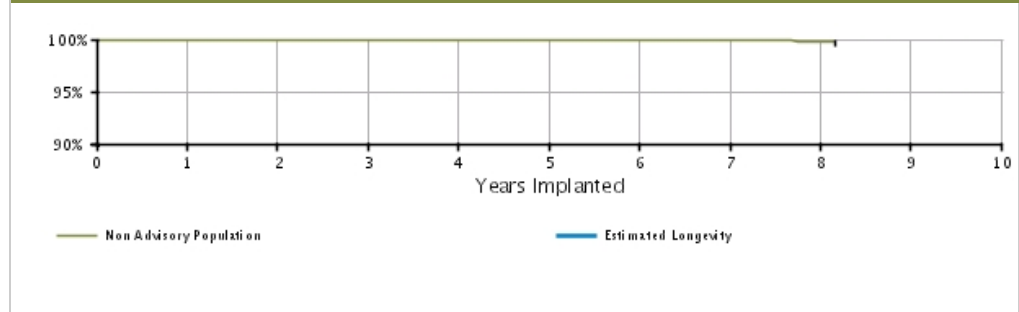
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
----------------------------------	--------------------------------------	---------------------------

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 504
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Estimated Active Implants: 17,000	U.S. Malfunctions:9
	Without Compromised Therapy:7
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.0)	99.61 (-0.1/+0.1)	99.13 (-0.2/+0.1)	98.26 (-0.2/+0.2)	95.70 (-0.5/+0.5)	87.33 (-1.7/+1.5)	83.85 @ 98 mo. (-2.8/+2.4)	—
Registered Implants: 32000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.93 (-0.1/+0.0)	99.76 (-0.4/+0.1)	99.76 @ 98 mo. (-0.4/+0.1)	—
	Effective Sample Size	26771	23606	20854	17871	12532	7543	3409	520	–	—

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: 17			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	4	6
²⁰ Capacitor	2	2	
⁴⁶ Integrated circuit	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	8	3	11
Non-patterned	-	2	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	8	-	
WW Confirmed Malfunctions	10	7	17


[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: 46,000			
Worldwide Confirmed Malfunctions: 18			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	1	4
²⁰ Capacitor	2	1	
⁴⁶ Integrated circuit	1	-	
Mechanical	-	1	1
⁵⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	13	-	13
Non-patterned	-	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	11	-	
WW Confirmed Malfunctions	16	2	18


[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: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
²⁰ Capacitor	1	4	
Mechanical	-	-	0
Software	-	-	0
Other	-	3	3
Non-patterned	-	1	
³⁷ Battery depletion	-	2	
WW Confirmed Malfunctions	1	7	8


[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: 12,000			
Worldwide Confirmed Malfunctions: 7			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	4	3	7
Non-patterned	-	-	
³⁷ Battery depletion	-	3	
⁶⁷ Battery status	4	-	
WW Confirmed Malfunctions	4	3	7

[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: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁶⁷ Battery status	2	-	
WW Confirmed Malfunctions	2	0	2


[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: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	-	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	1	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 40 DR

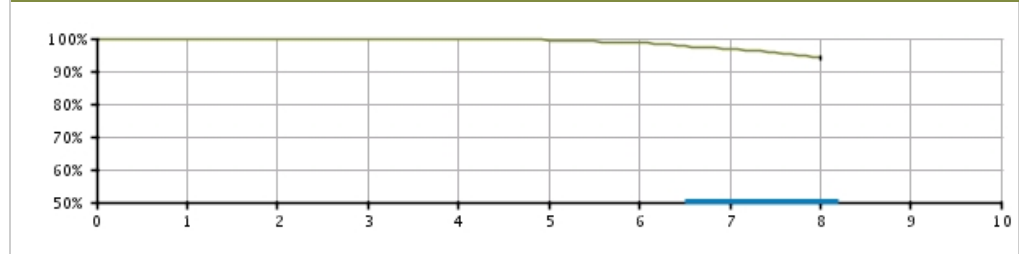
Model S402

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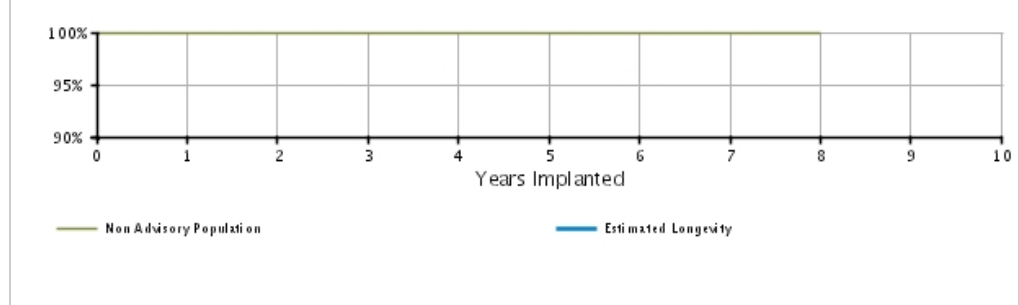
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 41
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

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)	99.93 (-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)	98.66 (-1.0/+0.6)	96.77 (-1.4/+1.0)	94.14 (-2.2/+1.6)	-	-
	Registered Implants: 2000										
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	-	-
	Effective Sample Size	1517	1346	1194	1064	945	835	714	204	-	-

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	-	-	
³⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[More details](#) about malfunctions

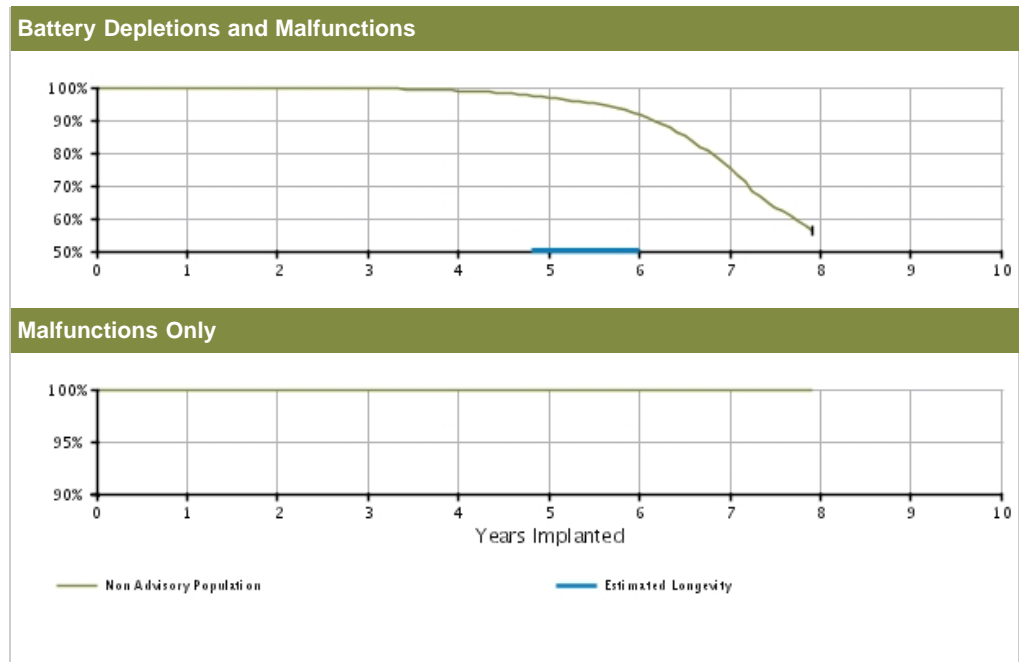
[References](#) cited in table above

ALTRUA 40 DR (downsize)

Model S403

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

U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 1,144
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 8,000	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)	99.91 (-0.1/+0.0)	99.69 (-0.1/+0.1)	98.95 (-0.2/+0.2)	96.86 (-0.4/+0.4)	91.56 (-0.8/+0.7)	75.44 (-1.6/+1.5)	56.12 @ 95 mo. (-2.9/+2.9)	-	-
	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)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 95 mo. (-0.1/+0.0)	-	-
	Effective Sample Size	12513	11155	9910	8754	6412	3697	1432	219	-	-

ALTRUA 40 DR (downsize)

Model S403

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

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
⁵⁷ Seal plug	1	-	
⁵⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁶⁷ Battery status	2	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

[References](#) cited in table above

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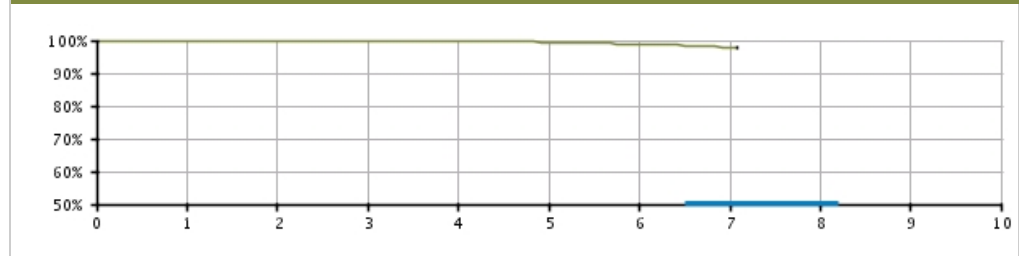
ALTRUA 40 DR EL

Model S404

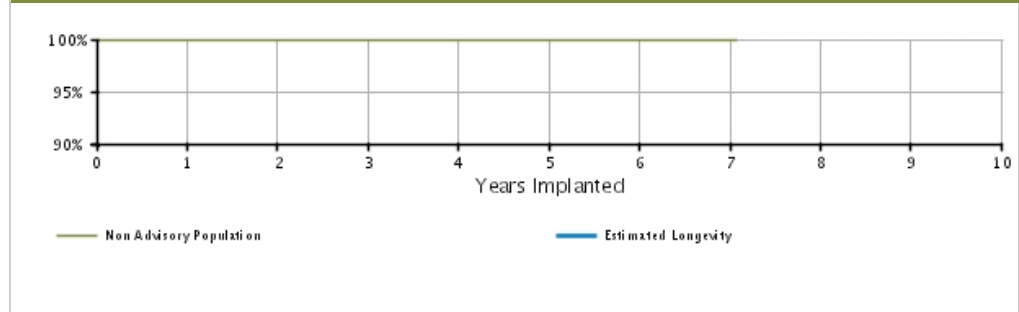
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 34
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

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)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.36 (-0.4/+0.2)	98.67 (-0.6/+0.4)	97.85 (-1.1/+0.7)	97.85 @ 85 mo. (-1.1/+0.7)	-	-
	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 @ 85 mo. (-0.0/+0.0)	-
Registered Implants: 5000	Effective Sample Size	4475	3986	3555	3131	2238	1229	281	215	-	-

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL Model S404 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁰ 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

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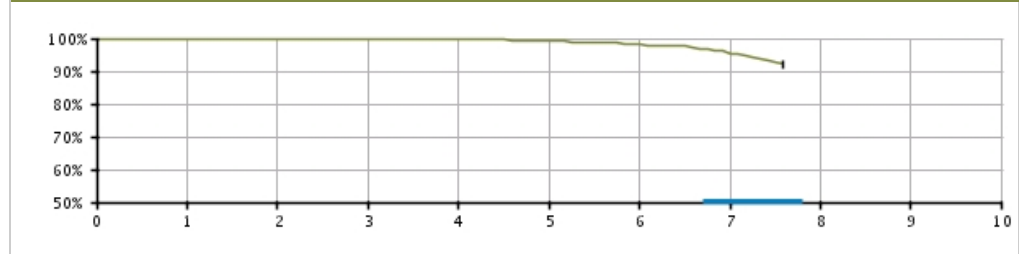
ALTRUA 40 SR

Model S401

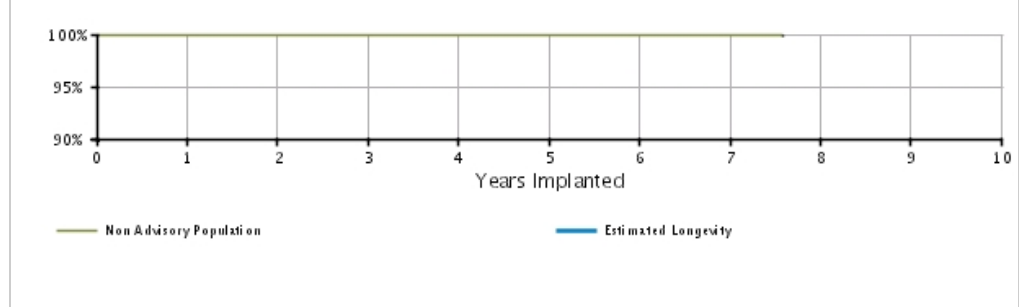
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 71
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:2
	Without Compromised Therapy:2
	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)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.66 (-0.3/+0.2)	99.32 (-0.4/+0.3)	98.12 (-0.8/+0.5)	95.31 (-1.6/+1.2)	92.12 @ 91 mo. (-2.7/+2.1)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 91 mo. (-0.2/+0.0)	-	-
Registered Implants: 5000	Effective Sample Size	3955	3463	3038	2685	1968	1158	532	210	-	-	-

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
²⁰ Capacitor	2	-	
⁴⁶ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

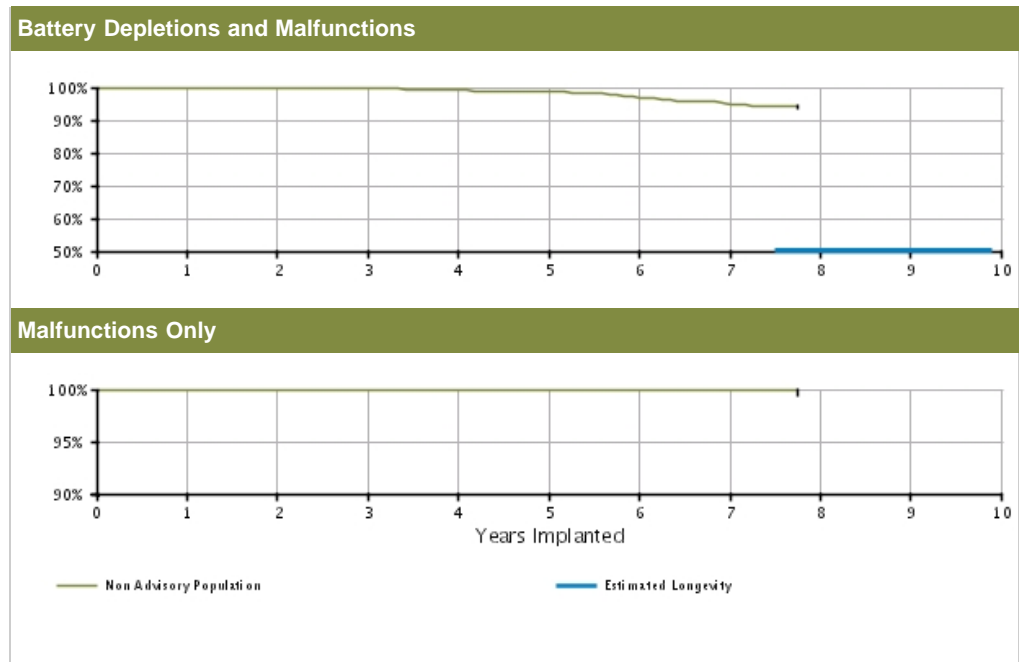
[References](#) cited in table above

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: 46
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(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 (-0.4/+0.1)	99.68 (-0.5/+0.2)	99.30 (-0.7/+0.4)	98.66 (-0.9/+0.5)	96.92 (-1.4/+1.0)	94.80 (-1.9/+1.4)	94.02 @ 93 mo. (-2.0/+1.5)	-	-	-
	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)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 @ 93 mo. (-0.6/+0.1)	-	-	-
	Effective Sample Size	1526	1332	1138	977	829	677	531	246	-	-	-

ALTRUA 20 DR

Models S202/S205

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



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
⁶² Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

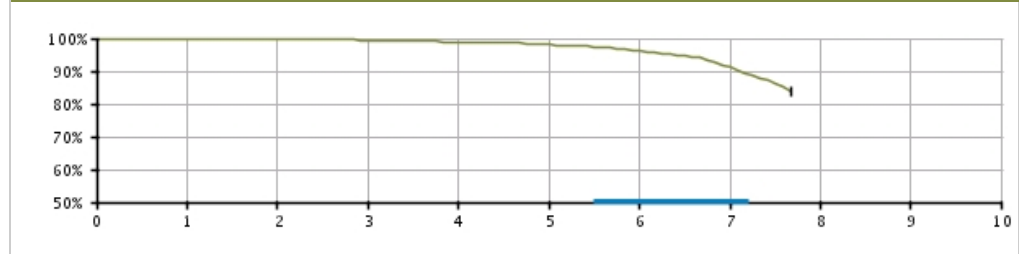
ALTRUA 20 DR (downsize)

Model S203

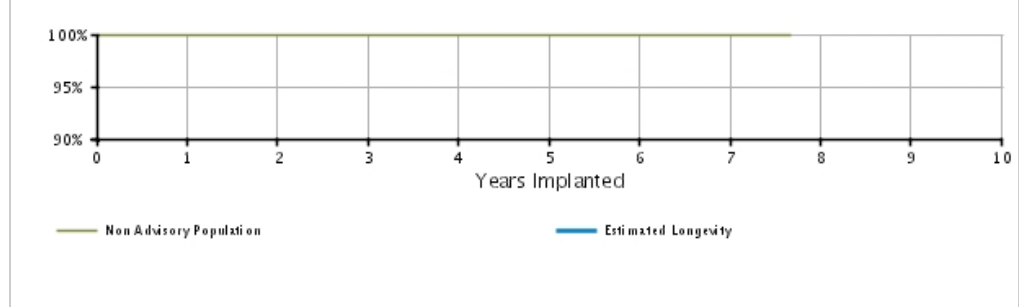
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 180
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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.42 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.12 (-0.5/+0.4)	96.10 (-0.9/+0.7)	91.27 (-1.7/+1.5)	83.73 @ 92 mo. (-3.2/+2.8)	-	-
	Registered Implants: 5000										
	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 @ 92 mo. (-0.0/+0.0)	-	-
	Effective Sample Size	4408	3894	3460	3043	2307	1417	650	224	-	-

ALTRUA 20 DR (downsize)

Model S203

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



Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	-	2
²⁰ Capacitor	2	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
³⁷ Battery depletion	-	1	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

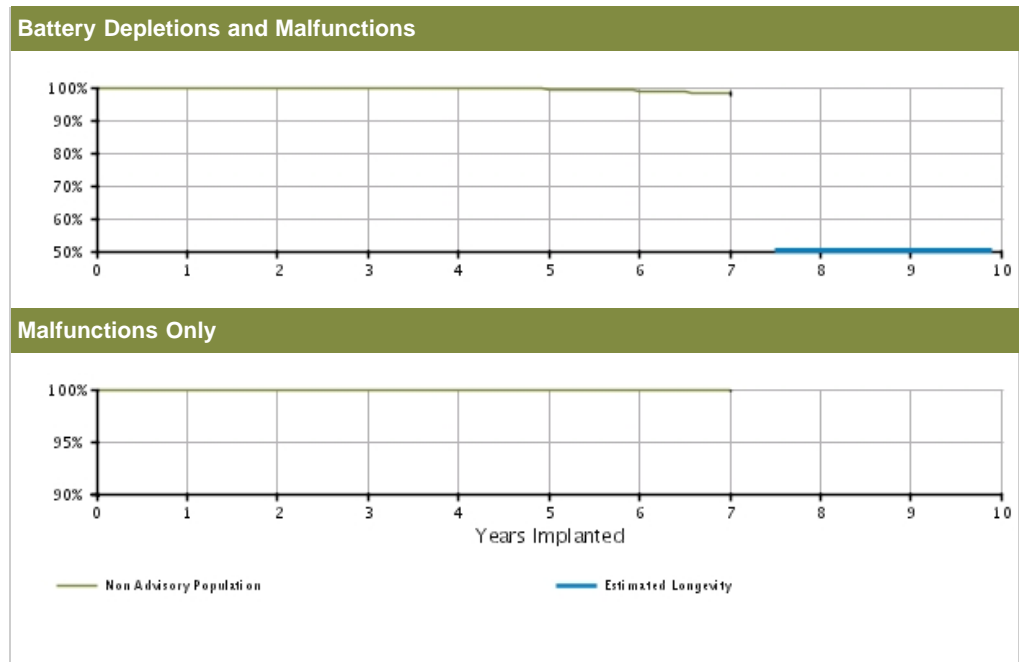
[References](#) cited in table above

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: 20
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.93	99.86	99.77	99.62	99.43	98.88	98.14	-	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.3/+0.2)	(-0.4/+0.2)	(-0.8/+0.5)	(-1.4/+0.8)				
Registered Implants: 3000	Malfunctions Only(%)	99.97	99.97	99.97	99.97	99.97	99.97	99.97	99.97	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)		
	Effective Sample Size	2773	2467	2190	1934	1362	711	202	-	-	-	-

ALTRUA 20 DR EL

Model S208

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

ALTRUA 20 DR EL Model S208 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	2	2
²⁰ Capacitor	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	3	3

[More details](#) about malfunctions

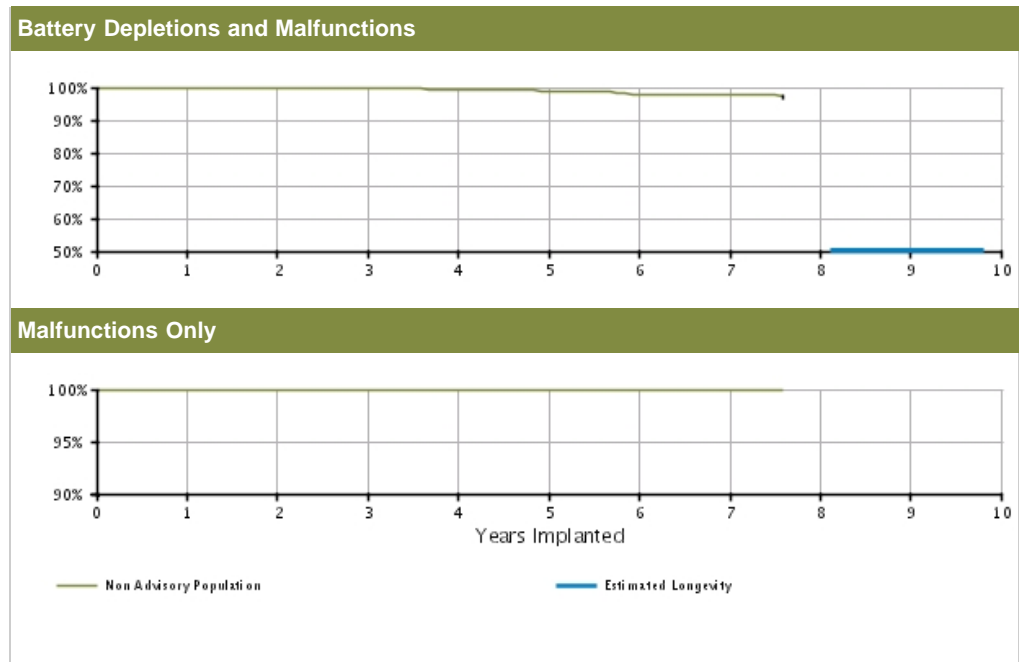
[References](#) cited in table above

ALTRUA 20 SR

Models S201/S204

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 42
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



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)	99.67 (-0.3/+0.2)	99.33 (-0.4/+0.2)	98.80 (-0.5/+0.4)	97.97 (-0.8/+0.6)	97.65 (-1.0/+0.7)	97.19 @ 91 mo. (-1.5/+1.0)	-	-	
	Registered Implants: 5000											
	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 @ 91 mo. (-0.0/+0.0)	-	-
	Effective Sample Size	3598	3047	2606	2219	1638	988	437	211	-	-	

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
²⁰ 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 SSI

Model S206

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

ALTRUA 20 SSI Model S206 			
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

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

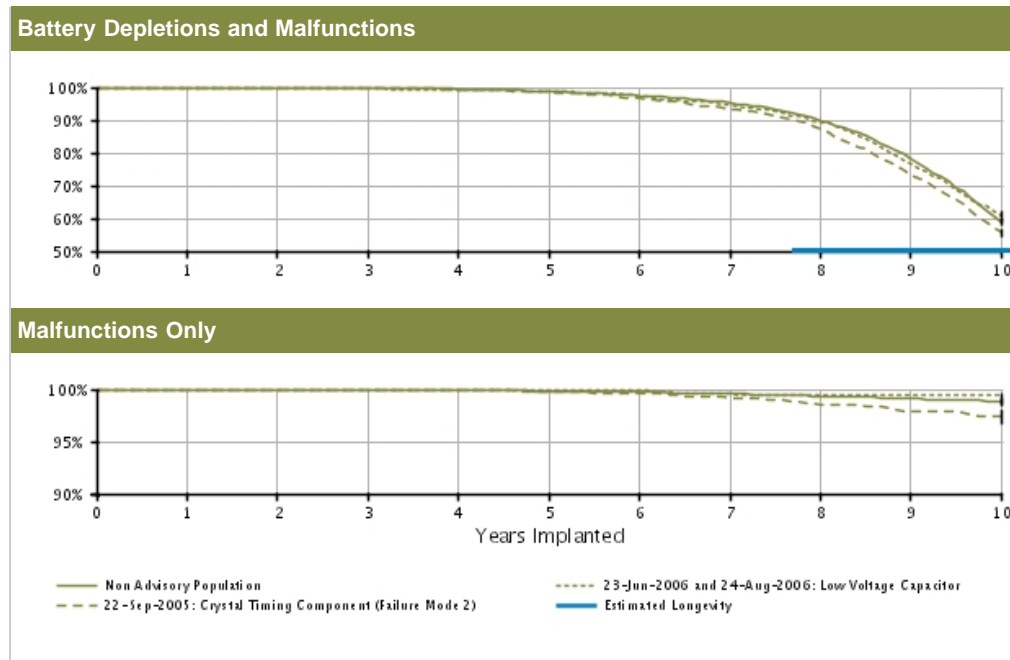
[References](#) cited in table above

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 4,227
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 21
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:173
	Without Compromised Therapy:163
	With Compromised Therapy:10



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)	97.43 (-0.3/+0.3)	95.30 (-0.4/+0.4)	89.77 (-0.6/+0.6)	78.15 (-1.0/+0.9)	58.87 (-1.8/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.07 (-0.2/+0.2)	98.82 (-0.4/+0.3)
	Effective Sample Size	21001	18656	16558	14648	12904	11297	9793	8116	3660	843
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)	97.47 (-1.1/+0.8)	94.62 (-1.5/+1.2)	89.38 (-2.2/+1.8)	76.94 (-3.1/+2.8)	60.60 (-3.7/+3.6)
	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)	99.38 (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	843	691	519	352
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)	96.58 (-0.7/+0.6)	93.41 (-0.9/+0.8)	87.17 (-1.3/+1.2)	73.44 (-1.8/+1.7)	55.55 (-2.1/+2.1)
	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)	96.58 (-0.7/+0.6)	93.41 (-0.9/+0.8)	87.17 (-1.3/+1.2)	73.44 (-1.8/+1.7)	55.55 (-2.1/+2.1)
	Effective Sample Size	6000	6000	6000	6000	6000	6000	6000	6000	6000	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)	97.95 (-0.7/+0.5)	97.39 (-0.8/+0.6)
Effective Sample Size	5702	5046	4467	3938	3451	2978	2553	2094	1552	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 Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Ultra DR Model 1291			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 211			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	7	5	12
⁸ Low-voltage capacitor (Advisory issued)	-	2	
¹⁷ Capacitor	1	-	
²⁰ Capacitor	4	2	
⁴⁶ Integrated circuit	2	1	
Mechanical	8	5	13
²⁶ Seal plug	5	4	
²⁷ Header	2	1	
⁴⁸ Setscrew	1	-	
Software	4	-	4
⁵¹ Underestimation of battery status	3	-	
⁵³ Pacing rate limit	1	-	
Other	177	5	182
Non-patterned	8	4	
¹³ Longevity labeling	74	-	
²⁸ Magnet response	1	-	
³⁷ Battery depletion	3	1	
⁶⁷ Battery status	91	-	
WW Confirmed Malfunctions	196	15	211

[More details](#) about malfunctions

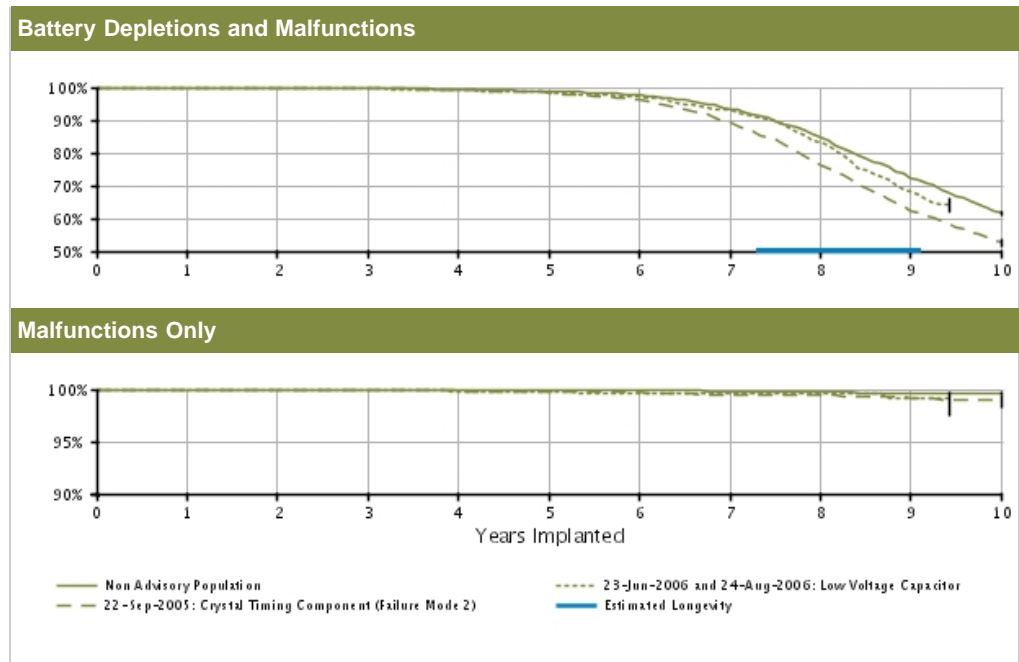
[References](#) cited in table above

INSIGNIA Ultra SR

Model 1190

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

U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Normal Battery Depletions: 2,610
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:42
	Without Compromised Therapy:38
	With Compromised Therapy:4



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.70 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.54 (-0.4/+0.3)	93.47 (-0.6/+0.6)	84.62 (-0.9/+0.9)	72.49 (-1.3/+1.3)	61.52 (-1.9/+1.9)	
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.70 (-0.2/+0.1)	99.68 (-0.2/+0.1)	99.62 (-0.2/+0.1)	
	Effective Sample Size	14142	12077	10290	8824	7691	6738	5728	4512	2094	578	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.10 (-0.9/+0.5)	98.46 (-1.2/+0.7)	97.20 (-1.6/+1.0)	93.22 (-2.5/+1.9)	83.09 (-3.8/+3.2)	68.03 (-4.8/+4.4)	64.06 (-4.9/+4.7)	@ 113 mo. (-1.7/+0.5)
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.20 (-1.7/+0.5)	99.20 (-1.7/+0.5)	@ 113 mo. (-1.7/+0.5)
	Effective Sample Size	1147	962	811	697	586	499	417	329	231	202	
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.											
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.22 (-0.4/+0.3)	98.27 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.33 (-1.5/+1.3)	76.24 (-2.2/+2.1)	62.41 (-2.6/+2.5)	52.60 (-2.8/+2.8)	

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	99.16	99.01	
(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.5/+0.3)	(-0.7/+0.4)	(-0.8/+0.4)	
Effective Sample Size	4142	3555	2997	2525	2108	1765	1414	1030	731	529	

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

INSIGNIA Ultra SR Model 1190			
Worldwide Distribution: 48,000			
Worldwide Confirmed Malfunctions: 71			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	5	7
⁸ Low-voltage capacitor (Advisory issued)	1	3	
²⁰ Capacitor	1	-	
⁴⁶ Integrated circuit	-	2	
Mechanical	3	1	4
²⁶ Seal plug	3	-	
²⁷ Header	-	1	
Software	1	-	1
³⁰ Memory error	1	-	
Other	59	-	59
Non-patterned	1	-	
¹³ Longevity labeling	23	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	33	-	
WW Confirmed Malfunctions	65	6	71

[More details](#) about malfunctions

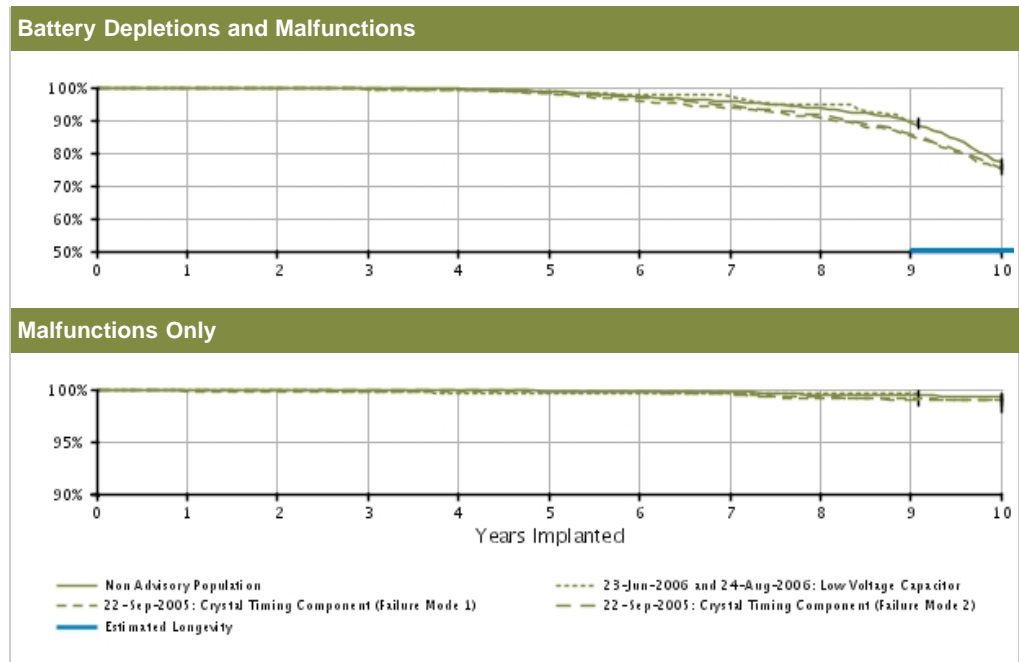
[References](#) cited in table above

INSIGNIA Entra DR

Models 1294/1295

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

U.S. Summary	
U.S. Registered Implants: 17,000	U.S. Normal Battery Depletions: 1,868
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:65
	Without Compromised Therapy:58
	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	95.66	93.53	89.44	77.39	
	(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)	(-0.9/+0.8)	(-1.2/+1.1)	(-2.3/+2.2)	
	Registered Implants: 7000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	100.00	99.45	99.23	98.75	97.65	97.31	94.51	89.84	89.40	
	(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)	(-2.2/+1.2)	(-3.1/+2.0)	(-4.2/+3.1)	(-4.3/+3.1)	
	Registered Implants: 1000											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	100.00	100.00	99.82	99.60	99.60	99.60	99.60	99.60	99.60	99.60	99.60
	(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)	(-1.2/+0.3)	(-1.2/+0.3)
	Registered Implants: 2000											
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions(%)	100.00	100.00	99.82	99.60	99.60	99.60	99.60	99.60	99.60	99.60	99.60
	(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)	(-1.2/+0.3)	(-1.2/+0.3)
	Registered Implants: 2000											
		Effective Sample Size	6262	5549	4915	4355	3806	3312	2896	2470	1496	540
		Effective Sample Size	692	606	527	450	392	335	292	245	202	200

	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	1676	1454	1213	1063	922	785	662	554	451	333
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)	98.37 (-0.4/+0.3)	96.89 (-0.6/+0.5)	94.56 (-0.8/+0.7)	91.52 (-1.0/+0.9)	85.55 (-1.4/+1.3)	75.41 (-1.8/+1.7)
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)	98.97 (-0.5/+0.3)	98.91 (-0.5/+0.3)
	Effective Sample Size	6207	5479	4821	4227	3690	3184	2674	2259	1848	1401

*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: 37,000			
Worldwide Confirmed Malfunctions: 80			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
¹⁶ Integrated circuit	-	1	
²⁰ Capacitor	-	1	
⁴⁶ Integrated circuit	-	1	
Mechanical	3	7	10
¹⁰ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
²⁶ Seal plug	3	-	
²⁷ Header	-	2	
Software	-	-	0
Other	63	4	67
Non-patterned	4	4	
¹³ Longevity labeling	49	-	
⁶⁷ Battery status	10	-	
WW Confirmed Malfunctions	66	14	80

[More details](#) about malfunctions

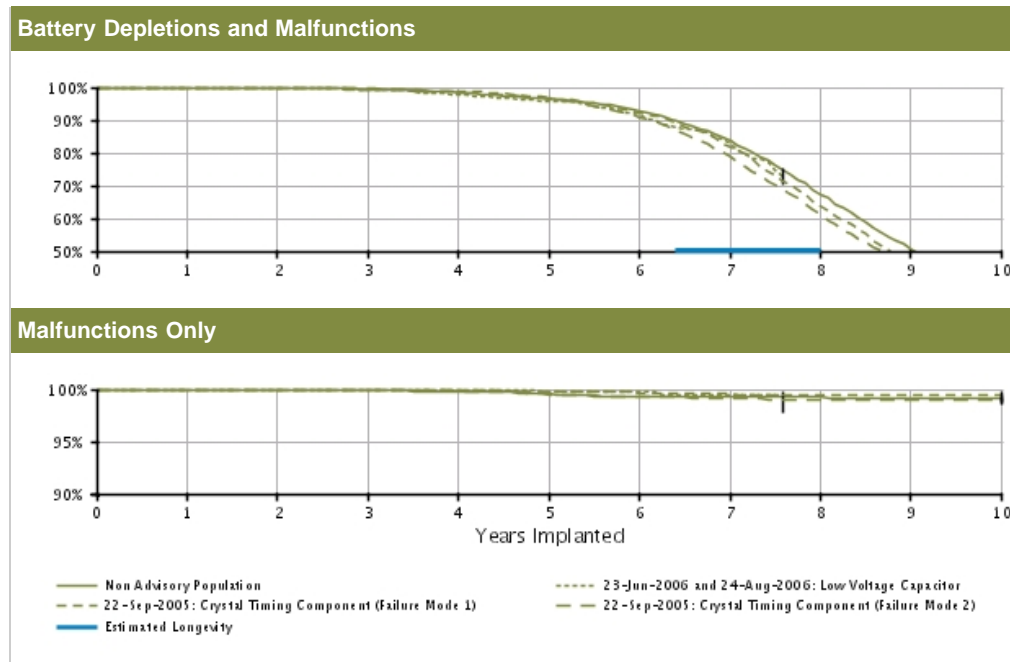
[References](#) cited in table above

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: 5,098
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:100
	Without Compromised Therapy:94
	With Compromised Therapy:6



U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.96	99.85	99.43	98.41	96.58	92.98	83.67	67.44	50.56	40.04
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.4/+0.3)	(-0.5/+0.5)	(-0.8/+0.7)	(-1.2/+1.1)	(-1.6/+1.6)	(-1.9/+1.9)	(-2.2/+2.3)
	Registered Implants: 8000										
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	99.70	99.20	97.84	95.61	91.88	82.91	72.97	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.9/+0.2)	(-1.1/+0.5)	(-1.6/+0.9)	(-2.2/+1.5)	(-3.0/+2.2)	(-4.3/+3.6)	@ 91 mo. (-5.1/+4.6)		
	Registered Implants: 1000										
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	99.83	99.79	99.34	98.82	96.71	92.02	81.76	63.88	45.56	31.63
	(Confidence Interval)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.3)	(-0.6/+0.4)	(-0.9/+0.7)	(-1.5/+1.3)	(-2.2/+2.0)	(-2.9/+2.8)	(-3.2/+3.2)	(-3.1/+3.3)
	Registered Implants: 3000										
	Effective Sample Size	7136	6276	5492	4773	4102	3498	2768	1922	899	313
	Effective Sample Size	763	657	563	476	401	327	248	–	-	-

	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	2735	2404	2070	1812	1513	1225	932	594	356	200
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)	90.84 (-0.8/+0.7)	79.00 (-1.2/+1.1)	61.11 (-1.5/+1.5)	44.70 (-1.6/+1.6)	35.59 (-1.6/+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	9583	8451	7364	6363	5500	4506	3326	2153	1304	885

*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: 122			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
⁸ Low-voltage capacitor (Advisory issued)	-	1	
²⁰ Capacitor	1	-	
⁴⁶ Integrated circuit	-	3	
Mechanical	-	3	3
¹⁰ Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
¹⁴ Solder bond	-	1	
Software	4	-	4
²⁵ Memory error	1	-	
⁵¹ Underestimation of battery status	1	-	
⁵² Interrupted telemetry	2	-	
Other	108	2	110
Non-patterned	5	2	
¹³ Longevity labeling	96	-	
³⁷ Battery depletion	1	-	
⁶⁷ Battery status	6	-	
WW Confirmed Malfunctions	113	9	122

[More details](#) about malfunctions

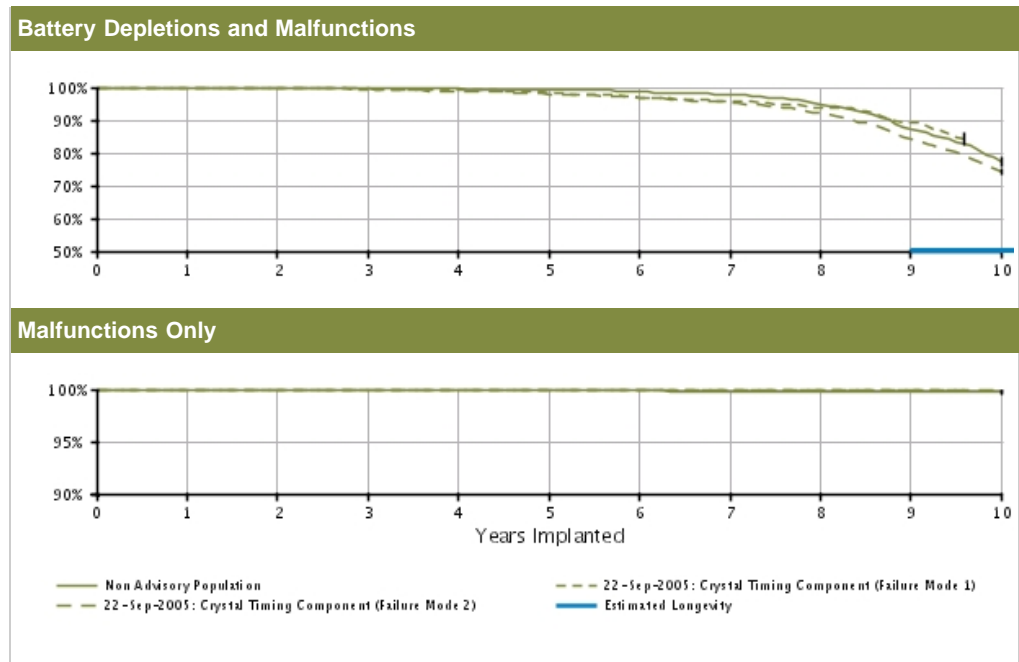
[References](#) cited in table above

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: 946
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 2,000	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	Depletions and Malfunctions(%)	99.90	99.85	99.77	99.52	99.36	98.74	97.89	94.82	87.38	77.26	
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.2)	(-0.5/+0.4)	(-0.7/+0.5)	(-1.1/+0.9)	(-1.9/+1.7)	(-3.2/+2.9)	
	Registered Implants: 6000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Malfunctions Only(%)	99.94	99.94	99.91	99.91	99.91	99.91	99.81	99.81	99.81	99.81	
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	
	Effective Sample Size	4708	3872	3249	2734	2306	1977	1723	1430	797	306	
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 Component (Failure Mode 1)*	Depletions and Malfunctions(%)	99.93	99.84	99.50	99.20	98.19	96.95	95.71	93.92	89.40	84.28	
	(Confidence Interval)	(-0.4/+0.1)	(-0.5/+0.1)	(-0.7/+0.3)	(-0.9/+0.4)	(-1.3/+0.8)	(-1.8/+1.1)	(-2.1/+1.5)	(-2.7/+1.9)	(-3.7/+2.8)	(-4.5/+3.6)	
	Registered Implants: 2000											
22-Sep-05 Crystal Timing	Malfunctions Only(%)	100.00	100.00	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)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	@ 115 mo. (-0.0/+0.0)
	Effective Sample Size	1215	997	805	660	548	445	354	296	243	202	
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96	99.87	99.58	98.79	97.94	96.94	95.25	92.16	84.02	74.31	
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.3)	(-0.6/+0.5)	(-0.8/+0.6)	(-1.0/+0.8)	(-1.3/+1.2)	(-2.0/+1.8)	(-2.5/+2.3)	

Component (Failure Mode 2)*	(Confidence Interval)										
Registered Implants: 6000											
Malfunctions Only (%)	100.00	100.00	100.00	100.00	99.96	99.96	99.90	99.90	99.90	99.90	99.90
(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)
Effective Sample Size	4575	3824	3171	2631	2174	1818	1529	1274	1010	776	


*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: 28			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	4	7
⁸ Low-voltage capacitor (Advisory issued)	-	2	
²⁰ Capacitor	2	2	
⁴⁶ Integrated circuit	1	-	
Mechanical	1	6	7
¹⁰ Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
¹¹ Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²² Capacitor array	-	2	
²⁶ Seal plug	-	2	
⁴⁹ Seal plug	-	1	
Software	-	-	0
Other	12	2	14
Non-patterned	1	2	
¹³ Longevity labeling	6	-	
⁶⁷ Battery status	5	-	
WW Confirmed Malfunctions	16	12	28

[More details](#) about malfunctions

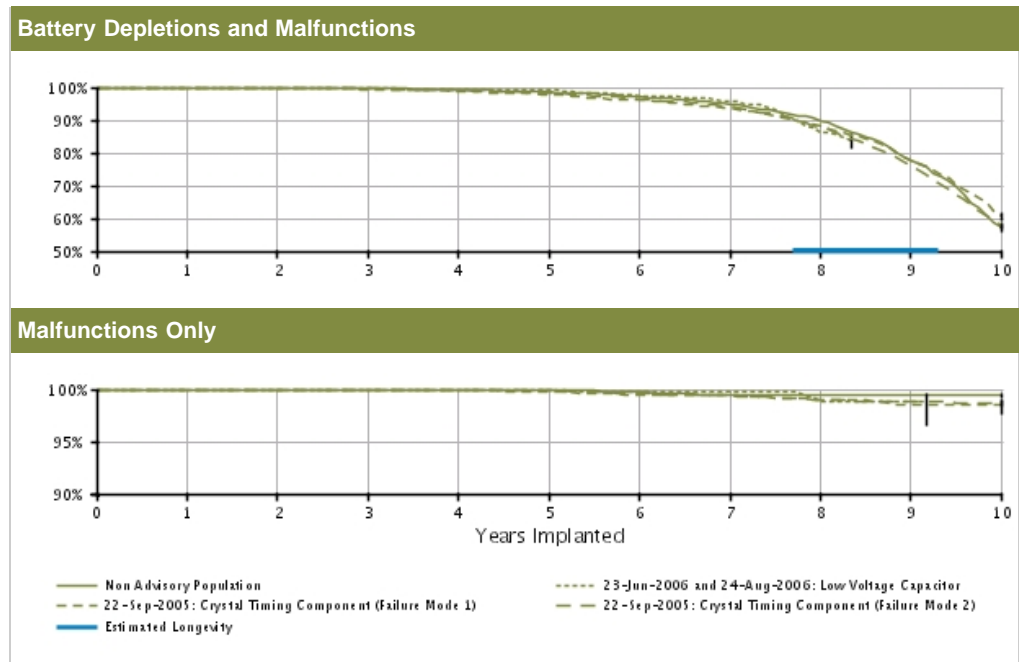
[References](#) cited in table above

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: 5,257
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:129
	Without Compromised Therapy:120
	With Compromised Therapy:9



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.95	99.75	99.26	98.51	97.16	94.98	89.79	77.74	57.18	
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.3)	(-0.6/+0.5)	(-0.7/+0.7)	(-1.1/+1.0)	(-1.7/+1.6)	(-2.8/+2.7)	
	Registered Implants: 7000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	100.00	100.00	99.19	99.19	97.24	95.95	86.23	83.75	-	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-1.3/+0.5)	(-1.3/+0.5)	(-2.2/+1.2)	(-2.6/+1.6)	(-4.5/+3.5)	(-4.8/+3.9)	@ 100 mo. (-2.4/+0.8)	
	Registered Implants: 1000											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	99.92	99.83	99.43	98.89	97.87	96.19	93.52	88.09	77.80	60.58	
	(Confidence Interval)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.5/+0.3)	(-0.7/+0.5)	(-0.9/+0.7)	(-1.2/+1.0)	(-1.7/+1.5)	(-2.2/+2.1)	(-2.8/+2.7)	
	Registered Implants: 4000											
		Effective Sample Size	6560	5831	5160	4545	3996	3496	3029	2516	1341	403
		Effective Sample Size	664	580	510	442	386	333	285	221	202	-

	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 (-0.5/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3514	3072	2597	2280	1971	1704	1456	1208	928	612
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)	76.07 (-1.2/+1.1)	57.63 (-1.4/+1.4)
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)	98.70 (-0.3/+0.3)
	Effective Sample Size	12755	11251	9911	8722	7618	6594	5628	4611	3471	2253


*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: 162			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁸ Low-voltage capacitor (Advisory issued)	1	1	
²⁰ Capacitor	2	1	
⁴⁶ Integrated circuit	-	1	
Mechanical	16	8	24
¹⁰ Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
¹¹ Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
¹⁴ Solder bond	1	-	
²² Capacitor array	1	-	
²⁶ Seal plug	5	-	
²⁷ Header	8	5	
Software	7	-	7
⁵¹ Underestimation of battery status	4	-	
⁵² Interrupted telemetry	2	-	
⁵³ Pacing rate limit	1	-	
Other	121	4	125
Non-patterned	7	4	
¹³ Longevity labeling	88	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	24	-	
WW Confirmed Malfunctions	147	15	162

[More details](#) about malfunctions

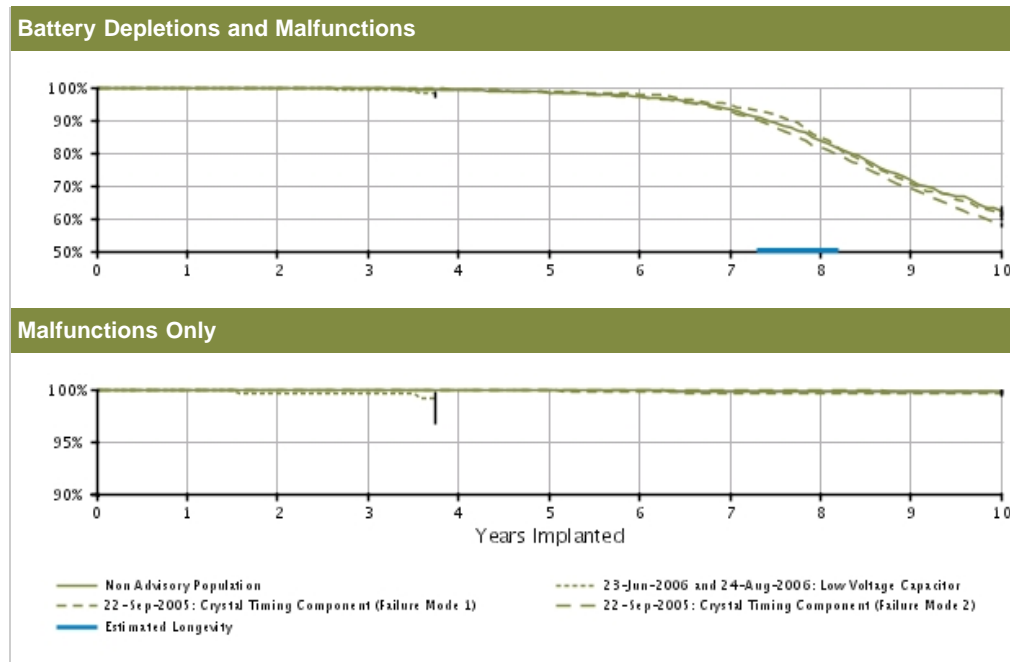
[References](#) cited in table above

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: 3,430
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Estimated Active Implants: 3,000	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(%)	99.94	99.90	99.59	99.30	98.44	97.26	93.23	83.57	71.60	62.49	
	(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)	(-1.7/+1.6)	(-2.3/+2.2)	(-3.0/+2.9)	
	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)	(-2.7/+1.0)							
	Registered Implants: 400											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%)	99.92	99.89	99.73	99.37	98.74	98.00	94.83	84.81	70.86	60.66	
	(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)	(-2.9/+2.7)	(-3.2/+3.1)	
	Registered Implants: 4000											
Effective Sample Size		4724	4028	3444	2880	2463	2116	1780	1378	710	286	

	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	3452	2916	2416	2063	1737	1431	1165	870	614	452
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)	97.08 (-0.4/+0.4)	92.83 (-0.7/+0.6)	81.73 (-1.1/+1.0)	69.41 (-1.4/+1.3)	58.03 (-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	13681	11683	10052	8506	7140	5999	4887	3607	2585	1868

*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: 37			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁸ Low-voltage capacitor (Advisory issued)	1	2	
²⁰ Capacitor	2	2	
²³ Integrated circuit	-	1	
⁴⁶ Integrated circuit	1	-	
Mechanical	1	6	7
¹⁰ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
²² Capacitor array	1	-	
²⁶ Seal plug	-	1	
Software	1	-	1
⁵³ Pacing rate limit	1	-	
Other	19	1	20
Non-patterned	4	-	
¹³ Longevity labeling	10	-	
²⁴ Battery depletion	-	1	
³⁷ Battery depletion	1	-	
⁶⁷ Battery status	4	-	
WW Confirmed Malfunctions	25	12	37


[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: 101			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	5	5
⁸ Low-voltage capacitor (Advisory issued)	-	3	
²⁰ Capacitor	-	1	
⁴⁶ Integrated circuit	-	1	
Mechanical	2	-	2
²⁶ Seal plug	1	-	
²⁷ Header	1	-	
Software	-	-	0
Other	92	2	94
Non-patterned	3	1	
¹³ Longevity labeling	42	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	47	-	
WW Confirmed Malfunctions	94	7	101

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

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 2011**— *June 1, 2011 Voluntary Physician Advisory*. Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **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.
5. **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.
6. **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.
7. **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.
8. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory*. Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
9. **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.
10. **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.
11. **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.
12. **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.
13. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
14. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
15. **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.
16. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
17. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
18. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
19. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.

20. **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.
21. **Battery depletion**— Premature battery depletion.
22. **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.
23. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
24. **Battery depletion**— Premature battery depletion and loss of capture.
25. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
26. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
27. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
28. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
29. **Battery depletion**— Premature battery depletion.
30. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
31. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
32. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
33. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
34. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
35. **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.
36. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
37. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
38. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
39. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
40. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
41. **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.
42. **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.
43. **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.
44. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
45. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
46. **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.
47. **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.
48. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
49. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented.
50. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
51. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
52. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
53. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
54. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
55. **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.
56. **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.
57. **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.

58. **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.
59. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
60. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
61. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
62. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
63. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
64. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
65. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
66. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
67. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
68. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
69. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
70. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
71. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
72. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
73. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
74. **Telemetry**— Inability to interrogate, premature battery depletion.
75. **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.
76. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
77. **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.
78. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.
79. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
80. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
81. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented.
82. **High voltage capacitor**— Charge time alert message, end of life (EOL) indicator displayed, beeping tones. Loss of tachy therapy without loss of brady therapy. Internal high-voltage capacitor issue. Improvement implemented.
83. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.
84. **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	16,000	2	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	41,000	2	1	0	5	0	0
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/ N143/N160/N161/N162/N163/N164/N165/ P052/P053/P142/P143/P162/P163/P165	81,000	10	0	0	10	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	24	50	4	26	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
VISIONIST/VALITUDE V172/V173/V182/V183/W172/W173	15,000	0	0	0	1	0	0
INTUA V272/V273/V282/V283/W272/W273	3,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	17,000	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	8,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	7,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	19,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	18,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	11,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	10,000	1	0	0	2	0	0

ICD/Model, continued...	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	68,000	3	1	0	9	0	0
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	72,000	5	1	0	4	0	0
TELIGEN VR E102/E103/F102/F103	66,000	8	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	91,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	15,000	0	0	0	16	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	23	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROONENT/ESSENTIO DR EL J064/K064/K067/K084	41,000	0	0	0	1	0	0
ACCOLADE/PROONENT/ESSENTIO DR J064/K064/K067/K084	92,000	0	0	0	4	0	0
ACCOLADE/PROONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	31,000	0	0	0	2	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	69,000	1	1	0	3	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	214,000	4	0	1	15	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	83,000	0	0	1	4	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	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	56,000	1	11	0	2	0	0
ALTRUA 50 SR S501	24,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	46,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	12,000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
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	8,000	0	0	0	0	0	0
INSIGNIA Ultra SR 1190*	48,000	3	3	1	4	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*	37,000	0	6	3	9	0	0
INSIGNIA Plus SR 1194*	51,000	1	5	13	5	0	0
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	26000	2	4	16	8	237	1006
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/N1 61/N162/N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	52000	127	28	69	107	856	8787
COGNIS N118/N119/N120/P106/P107/P108	75000	1998	108	71	1402	1711	30016
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
VISIONIST/VALITUDE U125/U128/U225/U226/U228	7000	1	0	55	0	35	232
INTUA V272/V273/V282/V283/W272/W273	3000	5	0	21	1	18	224
INVIVE V172/V173/V182/V183/W172/W173	8000	26	0	42	1	56	1417
CONTAK RENEWAL TR H120/H125	19000	2676	16	160	51	256	9845

S-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
EMBLEM S-ICD A209, A219	8000	0	0	4	3	125	174
SQ-RX S-ICD 1010	8000	63	1	26	36	251	650

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
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	12000	1	0	64	0	80	244
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	11000	1	0	77	2	64	205
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	5000	1	1	33	2	53	274
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	5000	2	0	38	2	50	258
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	43	6	337	49	460	4631
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	42	9	445	68	562	5851

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	87	88	653	1094	639	12080
TELIGEN DR E110/E111/F110/F111	66000	247	136	909	1629	1146	21903
CONFIENT DR E030/F030	7000	420	2	145	14	155	3051
VITALITY 2 EL VR T177	7000	1283	9	163	1275	114	2773

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
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	16000	4	0	68	3	53	226
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	48000	6	2	203	6	175	1106

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
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	10000	3	0	60	0	42	423
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	3	0	101	4	50	673
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	121000	99	9	788	33	678	14084
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	11	0	193	7	136	5087
ALTRUA 60 SR S601	32000	504	4	248	9	169	14168
ALTRUA 60 DR (Downsize) S603	90000	7581	44	596	52	560	29457
ALTRUA 60 DR S602	22000	453	3	189	14	195	7184
ALTRUA 60 DR EL S606	59000	421	10	444	10	415	15179
ALTRUA 40 SR S401	5000	71	0	25	2	23	2305
ALTRUA 40 DR (downsize) S403	14000	1144	2	61	3	78	4886
ALTRUA 40 DR S402	2000	41	1	16	0	8	717
ALTRUA 40 DR EL S404	5000	34	1	32	0	43	1709
ALTRUA 20 SR S201/S204	5000	42	1	21	0	36	2434
ALTRUA 20 DR (downsize) S203	5000	180	3	27	0	36	2191

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
ALTRUA 20 DR S202/S205	2000	46	0	9	1	15	805
ALTRUA 20 DR EL S208	3000	20	0	23	1	10	1193
INSIGNIA Ultra SR 1190 ⁴	24000	2610	9	220	42	146	16444
INSIGNIA Ultra DR 1291 ⁴	32000	4227	21	342	175	311	15698
INSIGNIA Entra SR 1195/1198 ⁴	14000	946	10	90	9	75	10607
INSIGNIA Entra DR (Downsize) 1296 ⁴	24000	5098	25	130	99	152	15568
INSIGNIA Entra DR 1294/1295 ⁴	17000	1868	14	134	65	183	10962
INSIGNIA Plus SR 1194 ⁴	27000	3430	8	226	27	155	20707
INSIGNIA Plus DR 1297 ⁴	27000	5257	20	267	131	261	15241

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.

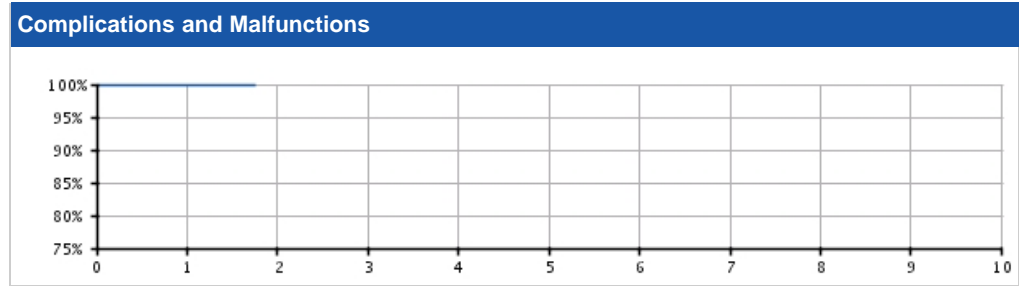
⁴ Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

ACUITY X4 Spiral L

Models 4677/4678

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

U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Chronic Lead Complications: 0
U.S. Approval Date: February 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 2,000	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	100.00 <small>(-0.0/+0.0)</small>	100.00 @ 21 mo. <small>(-0.0/+0.0)</small>	-	-	-	-	-	-	-	-
Registered Implants: 2000										
Effective Sample Size	451	251	-	-	-	-	-	-	-	-

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: 8,000			
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

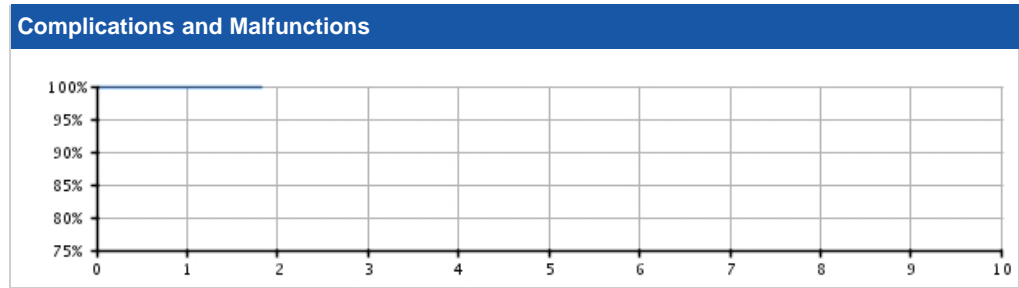
[References](#) cited in table above

ACUITY X4 Spiral S

Models 4674/4675

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

U.S. Summary	
U.S. Registered Implants: 5,000 U.S. Approval Date: February 2016 U.S. Estimated Active Implants: 5,000	U.S. Chronic Lead Complications: 1 U.S. Malfunctions: 0 Without Compromised Therapy: 0 With Compromised Therapy: 0




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.98 <small>(-0.1/+0.0)</small>	99.98 @ 22 mo. <small>(-0.1/+0.0)</small>	-	-	-	-	-	-	-	-
Registered Implants: 5000										
Effective Sample Size	638	212	-	-	-	-	-	-	-	-

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: 16,000			
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

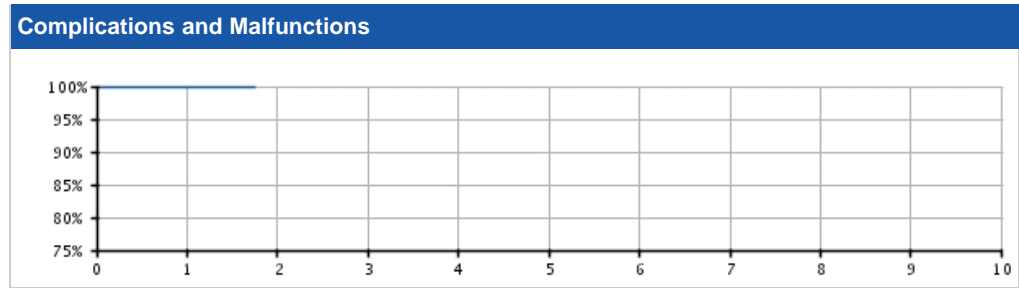
[References](#) cited in table above

ACUITY X4 Straight

Models 4671/4672

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

U.S. Summary	
U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 2
U.S. Approval Date: February 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 3,000	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 (-0.3/+0.1)	99.91 @ 21 mo. (-0.3/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 3000										
Effective Sample Size	499	210	-	-	-	-	-	-	-	-

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672			
Worldwide Distribution: 14,000			
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

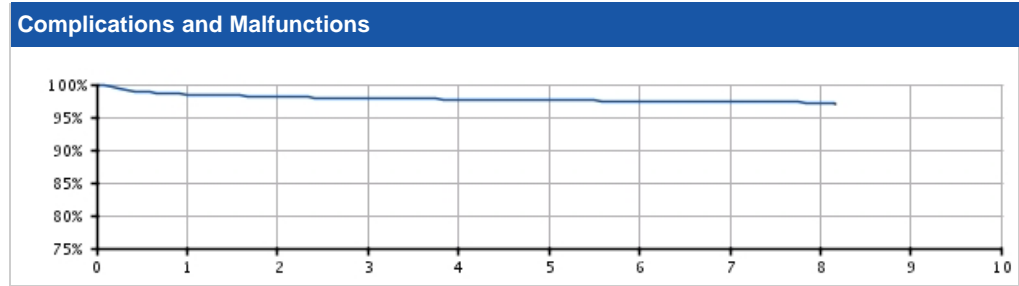
[References](#) cited in table above

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: 23,000	U.S. Chronic Lead Complications: 445
U.S. Approval Date: May 2008	U.S. Malfunctions: 8
U.S. Estimated Active Implants: 15,000	Without Compromised Therapy: 4
	With Compromised Therapy: 4




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.49 <small>(-0.2/+0.2)</small>	98.13 <small>(-0.2/+0.2)</small>	97.88 <small>(-0.2/+0.2)</small>	97.71 <small>(-0.2/+0.2)</small>	97.55 <small>(-0.2/+0.2)</small>	97.45 <small>(-0.3/+0.2)</small>	97.41 <small>(-0.3/+0.3)</small>	97.12 <small>(-0.5/+0.4)</small>	97.12 @ 98 mo. <small>(-0.5/+0.4)</small>	-
Registered Implants: 21000										
Effective Sample Size	18663	15397	11967	8812	6211	3756	1849	391	212	-

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: 43,000				
Worldwide Confirmed Malfunctions: 8				
	Without Compromised Therapy	With Compromised Therapy	Total	
Conductor	1	3	4	
²⁷ Non-patterned, Conductor	1	3		
Crimp/Weld/Bond	-	-	0	
Insulation	1	1	2	
²⁸ Non-patterned, Insulation	1	1		
Other	2	-	2	
²⁶ Non-patterned, Other	2	-		
WW Confirmed Malfunctions	4	4	8	

[More details](#) about malfunctions

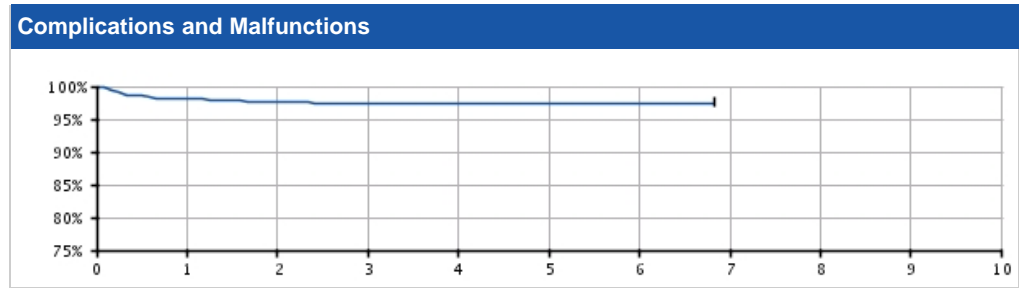
[References](#) cited in table above

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: 1381	Chronic Lead Complications: 33
Leads Active: 895	Malfunctions:0
Cumulative Followup Months : 44,850	Without Compromised Therapy:0
	With Compromised Therapy:0



Longitude Registry Survival Probability

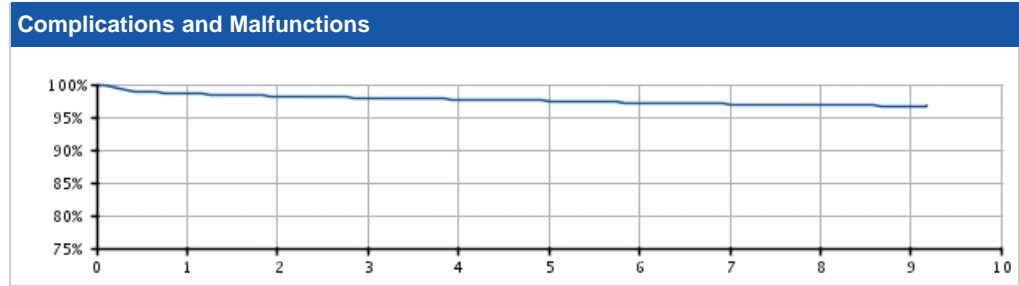
Year	1	2	3	4	5	6	7	8	9	10
Longitude	98.01 (-1.6/+1.6)	97.64 (-1.7/+1.7)	97.32 (-1.9/+1.9)	97.32 (-1.9/+1.9)	97.32 (-1.9/+1.9)	97.32 (-1.9/+3.8)	97.32 @ 82 mo. (-1.9/+3.8)	--	--	--
Registered Implants: 1379										
Effective Sample Size	1134	978	768	603	417	217	62	--	--	--

ACUITY Steerable

Models 4554/4555/4556

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

U.S. Summary	
U.S. Registered Implants: 29,000	U.S. Chronic Lead Complications: 586
U.S. Approval Date: May 2008	U.S. Malfunctions:32
U.S. Estimated Active Implants: 17,000	Without Compromised Therapy:11
	With Compromised Therapy:21




U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.58 <small>(-0.1/+0.1)</small>	98.21 <small>(-0.2/+0.2)</small>	97.95 <small>(-0.2/+0.2)</small>	97.74 <small>(-0.2/+0.2)</small>	97.48 <small>(-0.2/+0.2)</small>	97.21 <small>(-0.2/+0.2)</small>	96.99 <small>(-0.3/+0.3)</small>	96.91 <small>(-0.3/+0.3)</small>	96.72 <small>(-0.4/+0.3)</small>	96.72 @ 110 mo. <small>(-0.4/+0.3)</small>
Registered Implants: 29000										
Effective Sample Size	24066	20462	16584	13165	10156	7315	4801	2450	542	279

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556 			
Worldwide Distribution: 63,000			
Worldwide Confirmed Malfunctions: 54			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	11	35	46
²⁵ Conductor fracture	1	-	
²⁷ Non-patterned, Conductor	7	9	
³⁴ Extracardiac fracture	3	26	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁸ Non-patterned, Insulation	-	1	
Other	6	1	7
²⁶ Non-patterned, Other	6	1	
WW Confirmed Malfunctions	17	37	54

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 3

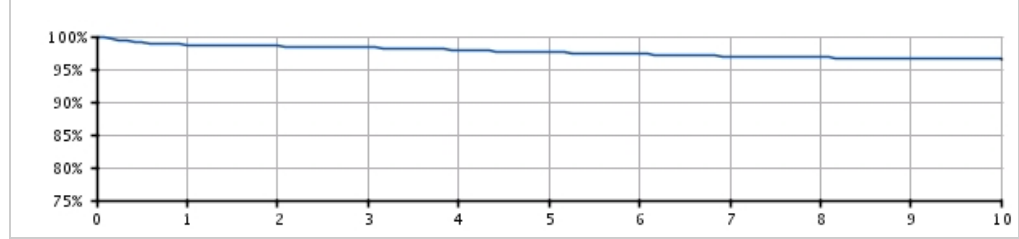
Models 4522/4524/4525/4527/4548/
4549/4550

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

U.S. Summary

U.S. Registered Implants: 22,000	U.S. Chronic Lead Complications: 438
U.S. Approval Date: August 2004	U.S. Malfunctions:30
U.S. Estimated Active Implants: 10,000	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	98.70 (-0.2/+0.1)	98.51 (-0.2/+0.2)	98.29 (-0.2/+0.2)	97.96 (-0.2/+0.2)	97.58 (-0.3/+0.2)	97.29 (-0.3/+0.3)	96.90 (-0.3/+0.3)	96.76 (-0.3/+0.3)	96.60 (-0.4/+0.3)	96.52 (-0.4/+0.3)
Registered Implants: 22000										
Effective Sample Size	18249	15737	13124	10703	8698	7032	5586	4241	3152	1951

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: 42,000
Worldwide Confirmed Malfunctions: 48

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	9	34	43
²⁷ Non-patterned, Conductor	6	5	
³⁴ Extracardiac fracture	3	29	
Crimp/Weld/Bond	-	-	0
Insulation	3	1	4
²⁸ Non-patterned, Insulation	3	1	
Other	1	-	1
²⁶ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	13	35	48

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 2

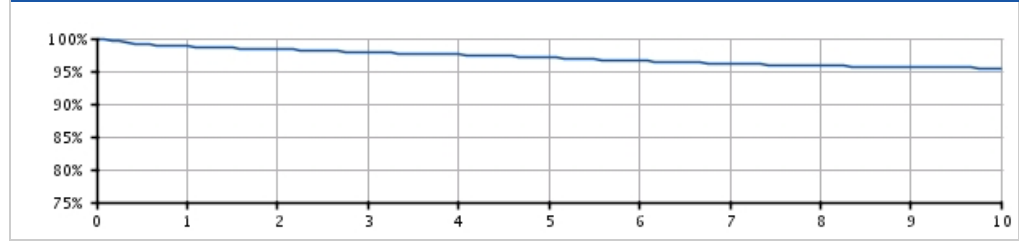
Models 4515/4517/4518/4520/4542/
4543/4544

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

U.S. Summary

U.S. Registered Implants: 97,000	U.S. Chronic Lead Complications: 2,201
U.S. Approval Date: August 2004	U.S. Malfunctions:347
U.S. Estimated Active Implants: 44,000	Without Compromised Therapy:92
	With Compromised Therapy:255

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)	97.90 (-0.1/+0.1)	97.53 (-0.1/+0.1)	97.08 (-0.1/+0.1)	96.55 (-0.2/+0.1)	96.12 (-0.2/+0.2)	95.83 (-0.2/+0.2)	95.64 (-0.2/+0.2)	95.40 (-0.2/+0.2)
Registered Implants: 97000										
Effective Sample Size	80638	69252	57963	47844	39038	30945	23693	17298	12150	7433

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: 177,000
Worldwide Confirmed Malfunctions: 482

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	100	355	455
²⁵ Conductor fracture	96	308	
²⁷ Non-patterned, Conductor	4	47	
Crimp/Weld/Bond	-	-	0
Insulation	11	2	13
²⁸ Non-patterned, Insulation	11	2	
Other	9	5	14
²⁶ Non-patterned, Other	9	5	
WW Confirmed Malfunctions	120	362	482

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK

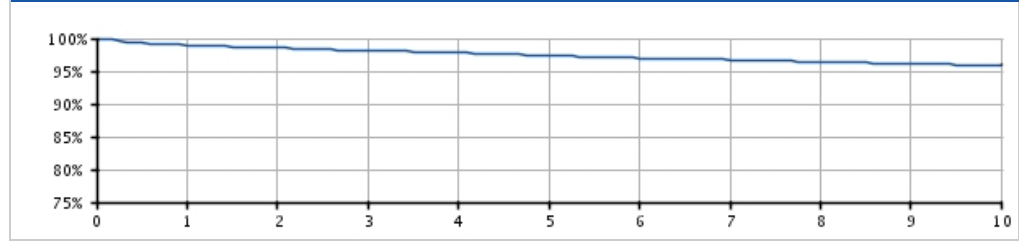
Models 4510/4511/4512/4513/4535/
4536/4537/4538

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

U.S. Summary

U.S. Registered Implants: 38,000	U.S. Chronic Lead Complications: 906
U.S. Approval Date: May 2002	U.S. Malfunctions: 24
U.S. Estimated Active Implants: 7,000	Without Compromised Therapy: 10
	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	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.75 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.12 (-0.3/+0.3)	95.93 (-0.3/+0.3)
Registered Implants: 38000										
Effective Sample Size	30532	26245	22511	19338	16503	14106	12103	10513	9061	7710

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: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	12	12
²⁷ Non-patterned, Conductor	-	12	
Crimp/Weld/Bond	-	-	0
Insulation	3	3	6
²⁸ Non-patterned, Insulation	3	3	
Other	7	1	8
²⁶ Non-patterned, Other	7	1	
WW Confirmed Malfunctions	10	16	26

[More details](#) about malfunctions

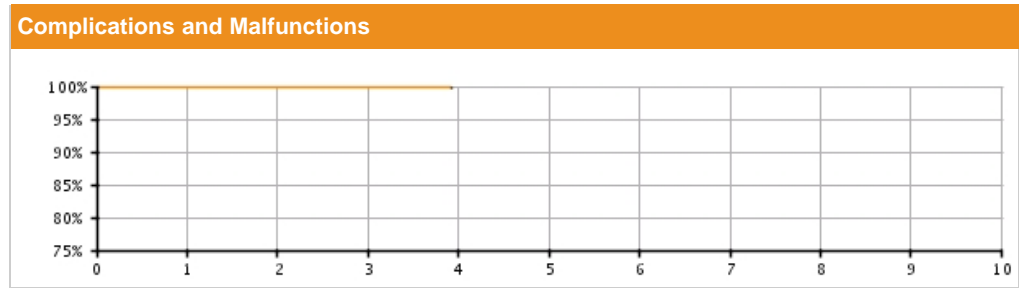
[References](#) cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

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

U.S. Summary	
U.S. Registered Implants: 15,000	U.S. Chronic Lead Complications: 10
U.S. Approval Date: September 2012	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 14,000	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	99.87 (-0.1/+0.1)	99.80 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.76 @ 47 mo. (-0.2/+0.1)	—	—	—	—	—	—
Registered Implants: 15000										
Effective Sample Size	8033	3087	484	203	—	—	—	—	—	—

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

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

EMBLEM/Q-TRAK S-ICD Electrode Models 3010/3401			
Worldwide Distribution: 25,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	1	1
³⁷ Weld fracture	-	1	
Insulation	-	-	0
Other	-	2	2
WW Confirmed Malfunctions	0	3	3


[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: 9,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
²⁸ Non-patterned, Insulation	-	-	
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: 32,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	6	6
²⁷ Non-patterned, Conductor	-	1	
³⁸ Conductor cable fracture	-	5	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁸ Non-patterned, Insulation	-	1	
Other	-	1	1
²⁶ Non-patterned, Other	-	1	
WW Confirmed Malfunctions	0	8	8


[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation

Models 0655/0685/0686

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

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation Models 0655/0685/0686 			
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 SG 4-FRONT Single Coil Passive Fixation

Models 0654/0682/0683

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

ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation
Models 0654/0682/0683



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

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

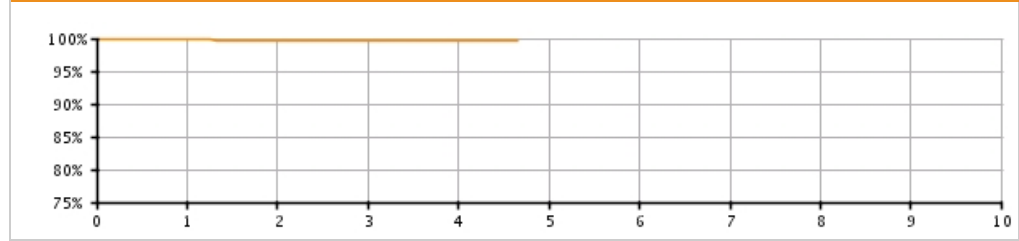
Models 0275/0276/0295/0296

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

U.S. Registered Implants: 57,000	U.S. Chronic Lead Complications: 150
U.S. Approval Date: November 2010	U.S. Malfunctions: 9
U.S. Estimated Active Implants: 50,000	Without Compromised Therapy: 0
	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	99.79 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.60 (-0.1/+0.1)	99.58 @ 56 mo. (-0.1/+0.1)	--	--	--	--	--
Registered Implants: 56000										
Effective Sample Size	43414	30658	18557	6781	471	--	--	--	--	--

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

Models 0275/0276/0295/0296

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation
Models 0275/0276/0295/0296**



Worldwide Distribution: 93,000
Worldwide Confirmed Malfunctions: 36

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁷ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	7	24	31
²⁸ Non-patterned, Insulation	7	24	
Other	2	-	2
²⁶ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	9	27	36

[More details](#) about malfunctions

[References](#) cited in table above

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

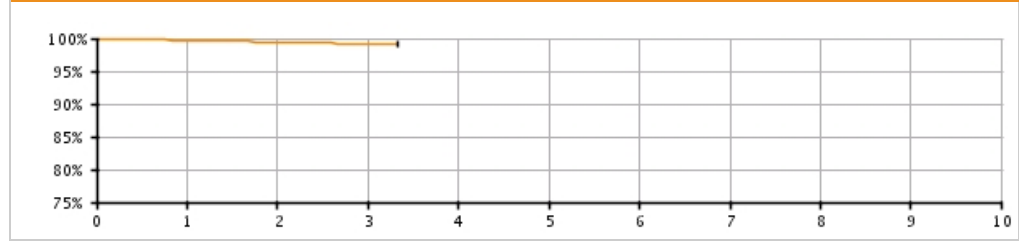
Models 0275/0276/0295/0296

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

Leads Enrolled: 851	Chronic Lead Complications: 3
Leads Active: 646	U.S. Malfunctions: 0
Cumulative Followup Months: 21,552	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	99.75 (-1.6/+1.6)	99.45 (-1.7/+1.7)	99.05 (-1.9/+1.9)	99.05 @ 40 mo. (-1.9/+1.9)	—	—	—	—	—	—
Registered Implants: 851										
Effective Sample Size	737	618	114	56	—	—	—	—	—	—

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

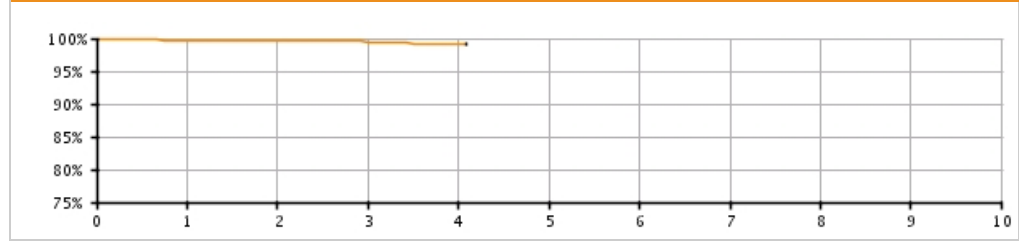
Models 0265/0266/0285/0286

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

U.S. Registered Implants: 2,000	U.S. Chronic Lead Complications: 10
U.S. Approval Date: November 2010	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 2,000	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	99.73 (-0.3/+0.1)	99.58 (-0.4/+0.2)	99.43 (-0.6/+0.3)	99.21 (-0.9/+0.4)	99.21 @ 49 mo. (-0.9/+0.4)	--	--	--	--	--
Registered Implants: 2000										
Effective Sample Size	1847	1238	666	236	202	--	--	--	--	--

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

Models 0265/0266/0285/0286

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation
Models 0265/0266/0285/0286**



Worldwide Distribution: 9,000
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
Single Coil, Active Fixation**

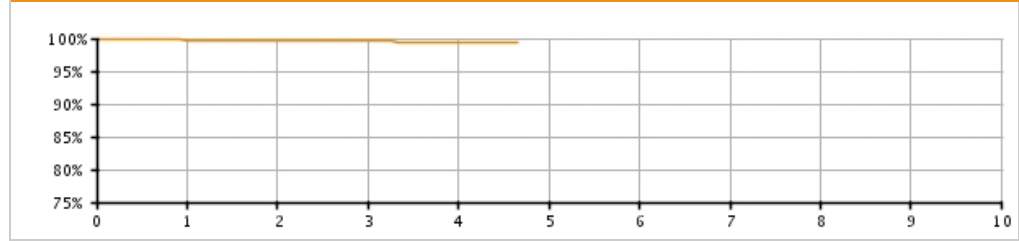
Models 0292/0293

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

U.S. Registered Implants: 63,000	U.S. Chronic Lead Complications: 174
U.S. Approval Date: November 2010	U.S. Malfunctions: 10
U.S. Estimated Active Implants: 58,000	Without Compromised Therapy: 1
	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	99.75 (-0.0/+0.0)	99.63 (-0.1/+0.1)	99.55 (-0.1/+0.1)	99.47 (-0.1/+0.1)	99.47 @ 56 mo. (-0.1/+0.1)	--	--	--	--	--
Registered Implants: 62000										
Effective Sample Size	40595	22886	10602	2913	209	--	--	--	--	--

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

Models 0292/0293

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



Worldwide Distribution: 104,000
Worldwide Confirmed Malfunctions: 29

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁴ Conductor fracture	-	1	
²⁷ Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	-	-	0
Insulation	2	22	24
²⁸ Non-patterned, Insulation	2	22	
Other	-	3	3
²⁶ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	27	29

[More details](#) about malfunctions

[References](#) cited in table above

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

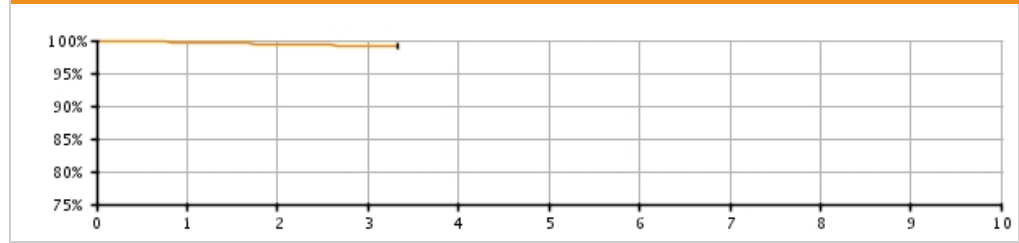
Models 0292/0293

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

Leads Enrolled: 1,103	Chronic Lead Complications: 4
Leads Active: 929	U.S. Malfunctions: 0
Cumulative Followup Months: 27,710	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 (-1.6/+1.6)	99.53 (-1.7/+1.7)	99.53 (-1.9/+1.9)	99.53 @ 38 mo. (-1.9/+1.9)	—	—	—	—	—	—
Registered Implants: 1,103										
Effective Sample Size	854	724	100	55	—	—	—	—	—	—

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

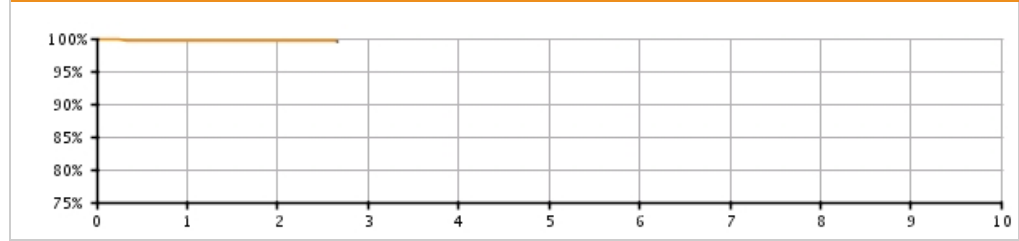
Models 0282/0283

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: 4
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	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.61 @ 32 mo. (-0.6/+0.2)	--	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	689	333	208	--	--	--	--	--	--	--

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

Models 0282/0283

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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**ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation
Models 0282/0283**



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁸ 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
Dual Coil, Active Fixation**

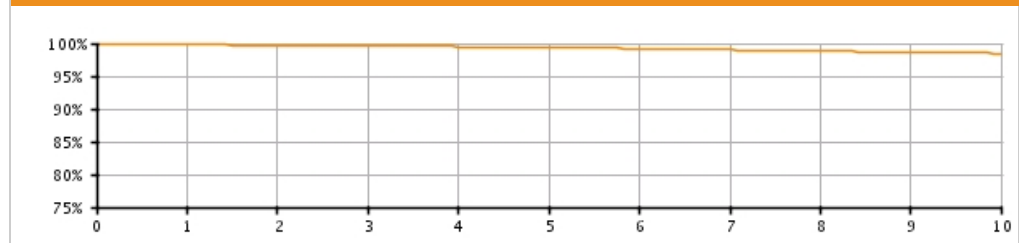
Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

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

U.S. Registered Implants: 286,000 U.S. Approval Date: July 2002 U.S. Estimated Active Implants: 138,000	U.S. Chronic Lead Complications: 1,924 U.S. Malfunctions: 290 Without Compromised Therapy:110 With Compromised Therapy:180
--	---

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.80 (-0.0/+0.0)	99.70 (-0.0/+0.0)	99.61 (-0.0/+0.0)	99.50 (-0.0/+0.0)	99.37 (-0.0/+0.0)	99.21 (-0.0/+0.0)	99.01 (-0.0/+0.0)	98.85 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.47 (-0.1/+0.1)
Registered Implants: 285000										
Effective Sample Size	251460	223614	198522	174959	149600	120285	94174	69357	48885	33976

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187



Worldwide Distribution: 373,000
Worldwide Confirmed Malfunctions: 456

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	127	129
²⁴ Conductor fracture	-	83	
²⁷ Non-patterned, Conductor	2	44	
Crimp/Weld/Bond	6	1	7
⁵ Seal rings	3	1	
³¹ Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	145	124	269
²⁸ Non-patterned, Insulation	145	124	
Other	30	21	51
²⁶ Non-patterned, Other	30	21	
WW Confirmed Malfunctions	183	273	456

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation Longitude

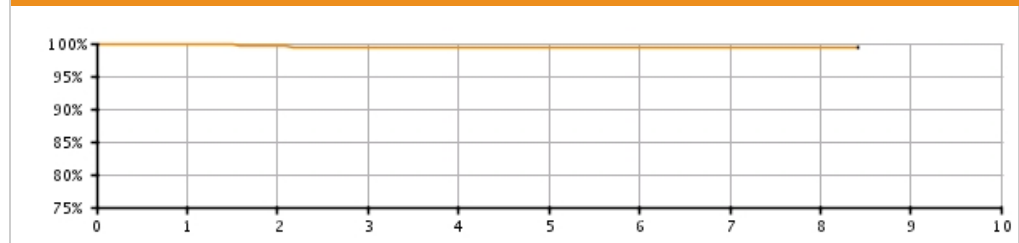
Models 0157/0158/0159/0164/0165/
 0166/0167/0184/0185/0186/
 0187

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

Leads Enrolled: 743	Chronic Lead Complications: 2
Leads Active: 397	U.S. Malfunctions: 0
Cumulative Followup Months: 26,309	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	100.00 (-0.0/+0.0)	99.67 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 @ 102 mo. (-1.2/+0.3)	–
Registered Implants: 743										
Effective Sample Size	645	569	502	430	336	229	88	57	55	–

CRM PRODUCT PERFORMANCE REPORT Q4 2016

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

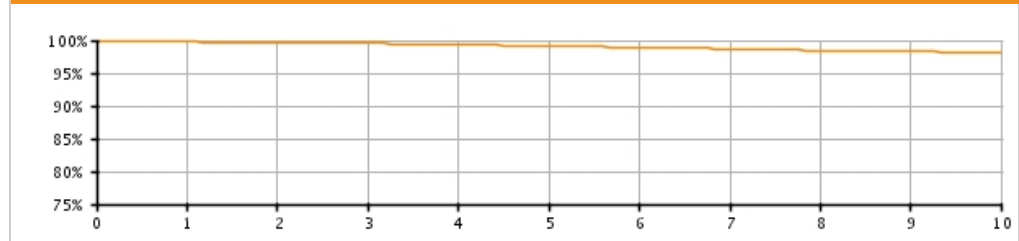
Models 0147/0148/0149/0174/0175/
0176/0177

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

U.S. Registered Implants: 46,000	U.S. Chronic Lead Complications: 499
U.S. Approval Date: October 2000	U.S. Malfunctions:37
U.S. Estimated Active Implants: 17,000	Without Compromised Therapy:9
	With Compromised Therapy:28

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)	99.69 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.94 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.46 (-0.2/+0.1)	98.30 (-0.2/+0.2)	98.10 (-0.2/+0.2)
Registered Implants: 46000										
Effective Sample Size	40565	36112	32093	28293	24659	21153	18002	15108	12501	10317

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

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

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

ENDOTAK RELIANCE
Dual Coil, Passive Fixation
 Models 0147/0148/0149/0174/0175/
 0176/0177



Worldwide Distribution: 108,000
Worldwide Confirmed Malfunctions: 126

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	31	31
²⁴ Conductor fracture	-	17	
²⁷ Non-patterned, Conductor	-	14	
Crimp/Weld/Bond	-	3	3
³⁶ Conductor connection	-	3	
Insulation	38	44	82
²⁸ Non-patterned, Insulation	38	44	
Other	7	3	10
⁶ Manufacturing material	-	1	
²⁶ Non-patterned, Other	7	3	
WW Confirmed Malfunctions	45	81	126

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

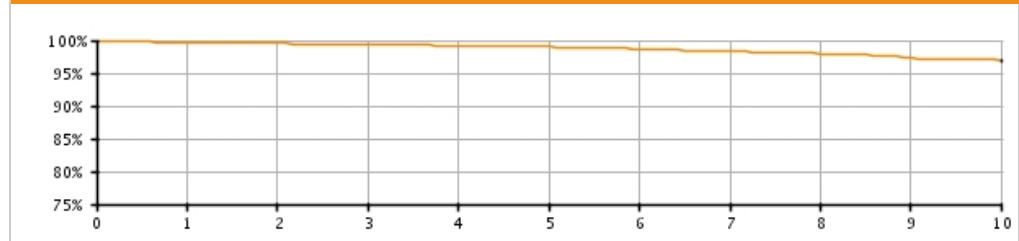
Models 0137/0138/0160/0161/0162/
 0180/0181/0182

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

U.S. Registered Implants: 31,000	U.S. Chronic Lead Complications: 219
U.S. Approval Date: July 2002	U.S. Malfunctions:59
U.S. Estimated Active Implants: 22,000	Without Compromised Therapy:20
	With Compromised Therapy:39

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.69 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.72 (-0.2/+0.2)	98.35 (-0.3/+0.2)	97.98 (-0.4/+0.3)	97.31 (-0.6/+0.5)	96.92 (-0.8/+0.6)
Registered Implants: 31000										
Effective Sample Size	26784	22470	18517	14891	10927	6632	4092	2217	1051	608

ENDOTAK RELIANCE
Single Coil, Active Fixation

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE
Single Coil, Active Fixation
 Models 0137/0138/0160/0161/0162/
 0180/0181/0182



Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 156

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	61	62
²⁴ Conductor fracture	1	52	
²⁷ Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	-	-	0
Insulation	48	33	81
²⁸ Non-patterned, Insulation	48	33	
Other	8	5	13
²⁶ Non-patterned, Other	8	5	
WW Confirmed Malfunctions	57	99	156

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

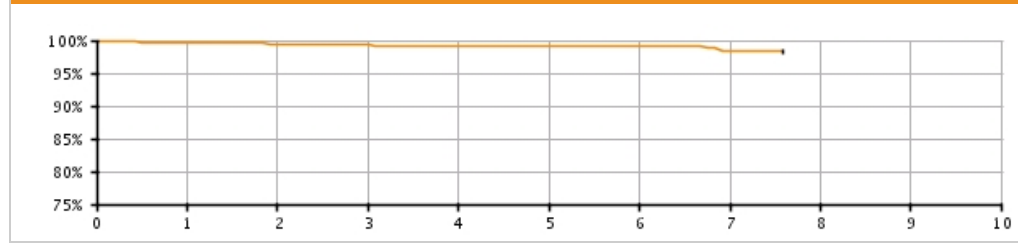
Models 0127/0128/0170/0171/0172/
 0173

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

U.S. Registered Implants: 2,000 U.S. Approval Date: October 2000 U.S. Estimated Active Implants: 1,000	U.S. Chronic Lead Complications: 17 U.S. Malfunctions:1 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	99.75 (-0.4/+0.2)	99.42 (-0.6/+0.3)	99.32 (-0.6/+0.3)	99.20 (-0.7/+0.4)	99.20 (-0.7/+0.4)	99.20 (-0.7/+0.4)	98.41 (-1.8/+0.8)	98.41 @ 91 mo. (-1.8/+0.8)	-	-
Registered Implants: 2000										
Effective Sample Size	1394	1101	875	643	473	326	238	201	-	-

ENDOTAK RELIANCE
Single Coil, Passive Fixation

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

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ENDOTAK RELIANCE
Single Coil, Passive Fixation
 Models 0127/0128/0170/0171/0172/
 0173



Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	4	5
²⁴ Conductor fracture	1	2	
²⁷ Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	-	-	0
Insulation	6	4	10
²⁸ Non-patterned, Insulation	6	4	
Other	1	-	1
²⁶ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	8	8	16

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK ENDURANCE
Passive Fixation

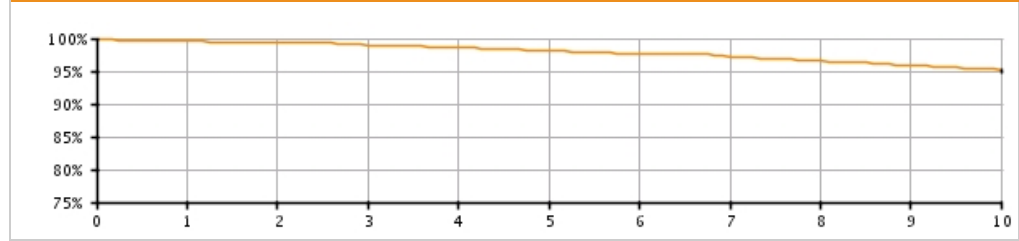
Models 0134/0135/0136

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

U.S. Registered Implants: 3,000 U.S. Approval Date: August 1998 U.S. Estimated Active Implants: 500	U.S. Chronic Lead Complications: 112 U.S. Malfunctions: 3 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)	95.96 (-1.2/+0.9)	95.09 (-1.4/+1.1)
Registered Implants: 3000										
Effective Sample Size	2333	2068	1831	1610	1426	1252	1103	961	831	728

ENDOTAK ENDURANCE EZ Active Fixation

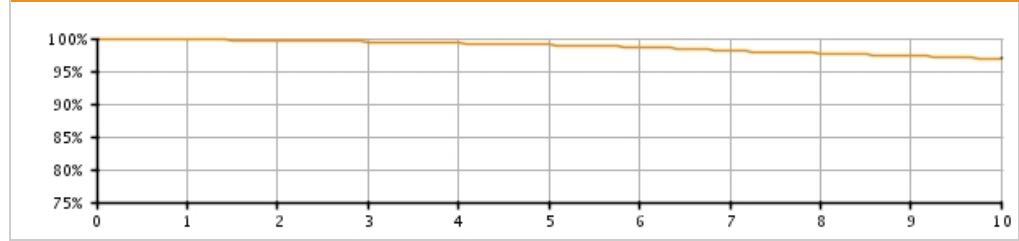
Models 0154/0155/0156

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: 582
U.S. Approval Date: June 1999	U.S. Malfunctions: 24
U.S. Estimated Active Implants: 7,000	Without Compromised Therapy: 11
	With Compromised Therapy: 13

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	24452	21793	19399	17262	15330	13599	12052	10712	9491	8401

ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting

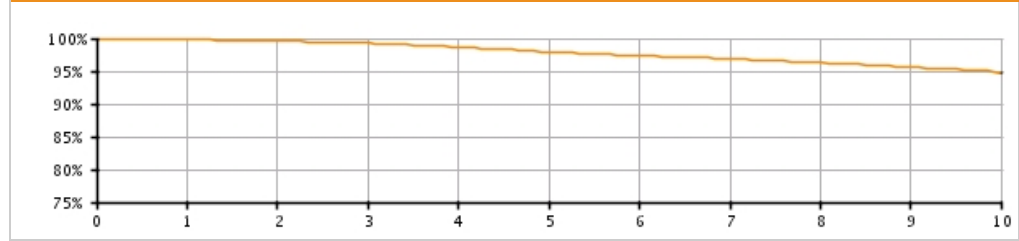
Models 0144/0145/0146

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: 690
U.S. Approval Date: January 1999	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 4,000	Without Compromised Therapy: 6
	With Compromised Therapy: 19

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-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)	96.85 (-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	15628	13937	12418	10989	9679	8564	7597	6723	5920	5203

INGEVITY Positive Fixation

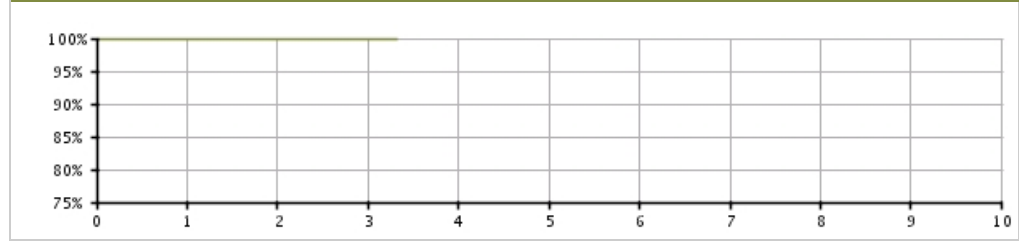
Models 7640/7641/7642/7740/7741/
7742

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

U.S. Registered Implants: 31,000	U.S. Chronic Lead Complications: 18
U.S. Approval Date: April 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 31,000	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	99.90 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.90 @ 40 mo. (-0.1/+0.0)	—	—	—	—	—	—
Registered Implants: 31000										
Effective Sample Size	1057	931	565	261	—	—	—	—	—	—

INGEVITY Positive Fixation

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

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

INGEVITY Positive Fixation
Models 7640/7641/7642/7740/7741/
7742



Worldwide Distribution: 179,000
Worldwide Confirmed Malfunctions: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	8	4	12
²⁷ Non-patterned, Conductor	6	2	
³⁹ Inner conductor break	2	2	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁸ Non-patterned, Insulation	-	1	
Other	-	1	1
²⁶ Non-patterned, Other	-	1	
WW Confirmed Malfunctions	8	6	14

[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: 24,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	1	1
²⁶ Non-patterned, Other	-	1	
WW Confirmed Malfunctions	0	1	1


[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: 20,000			
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: 181,000			
Worldwide Confirmed Malfunctions: 114			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	6	32	38
⁷ Lead conductor	3	18	
³² Conductor damage	3	14	
Crimp/Weld/Bond	-	-	0
Insulation	53	10	63
² Inner insulation abrasion	3	1	
²⁸ Non-patterned, Insulation	4	-	
³³ Insulation damage	46	9	
Other	13	-	13
²⁶ Non-patterned, Other	13	-	
WW Confirmed Malfunctions	72	42	114

[More details](#) about malfunctions

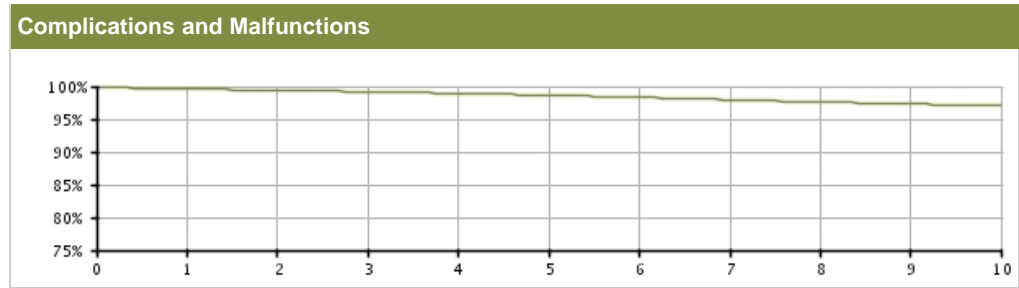
[References](#) cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 234,000	U.S. Chronic Lead Complications: 3,350
U.S. Approval Date: February 2002	U.S. Malfunctions: 318
U.S. Estimated Active Implants: 99,000	Without Compromised Therapy: 129
	With Compromised Therapy: 189




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.93 (-0.0/+0.0)	98.66 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.98 (-0.1/+0.1)	97.62 (-0.1/+0.1)	97.31 (-0.1/+0.1)	97.06 (-0.1/+0.1)
Registered Implants: 234000										
Effective Sample Size	199288	173574	150418	129479	110719	93443	77413	63350	51471	37551

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: 289,000			
Worldwide Confirmed Malfunctions: 342			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	15	172	187
⁷ Lead conductor	9	81	
²⁷ Non-patterned, Conductor	-	7	
³² Conductor damage	6	84	
Crimp/Weld/Bond	-	-	0
Insulation	105	28	133
² Inner insulation abrasion	19	6	
²⁸ Non-patterned, Insulation	8	2	
³³ Insulation damage	78	20	
Other	18	4	22
²⁶ Non-patterned, Other	18	4	
WW Confirmed Malfunctions	138	204	342

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

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

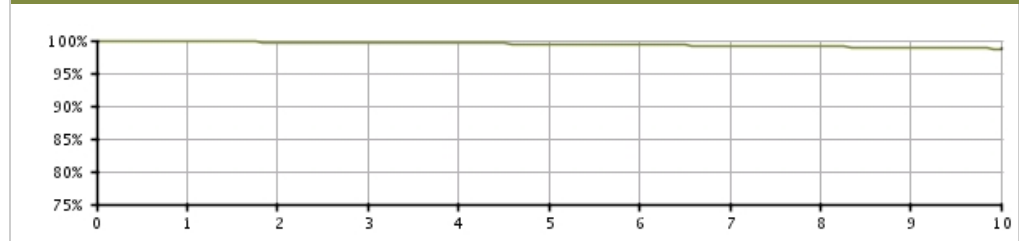
Models 4463/4464/4465/4469/4470/
4471

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

U.S. Registered Implants: 450,000	U.S. Chronic Lead Complications: 2,438
U.S. Approval Date: January 2000	U.S. Malfunctions:133
U.S. Estimated Active Implants: 254,000	Without Compromised Therapy:27
	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	99.82 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.56 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.33 (-0.0/+0.0)	99.18 (-0.0/+0.0)	99.04 (-0.0/+0.0)	98.88 (-0.1/+0.1)	98.74 (-0.1/+0.1)
Registered Implants: 449000										
Effective Sample Size	382762	323315	270718	224218	183297	146781	114037	85871	64303	46530

**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: 691,000
Worldwide Confirmed Malfunctions: 160

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	12	118	130
⁷ Lead conductor	6	54	
²⁷ Non-patterned, Conductor	1	5	
³² Conductor damage	5	59	
Crimp/Weld/Bond	1	2	3
²³ Terminal weld	-	1	
³¹ Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	12	6	18
³³ Insulation damage	12	6	
Other	7	2	9
²⁶ Non-patterned, Other	7	2	
WW Confirmed Malfunctions	32	128	160

[More details](#) about malfunctions

[References](#) cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

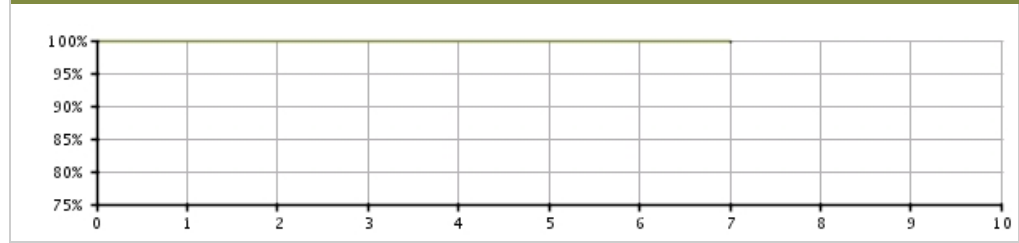
Models 4463/4464/4465/4469/4470/
 4471

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

Longitude Registry Summary Data

Leads Enrolled: 923	Chronic Lead Complications: 2
Leads Active: 686	Malfunctions: 0
Cumulative Followup Months : 27,121	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	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.5)	-	-	-
Registered Implants: 922										
Effective Sample Size	776	665	344	267	197	125	53	-	-	-

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

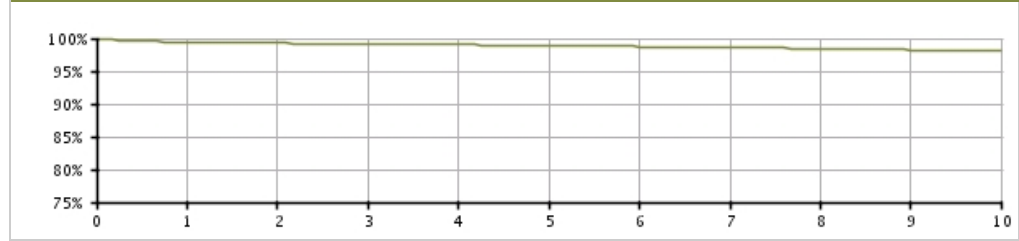
Models 4477/4478/4479/4480

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

U.S. Registered Implants: 61,000	U.S. Chronic Lead Complications: 639
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	99.43 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.92 (-0.1/+0.1)	98.75 (-0.1/+0.1)	98.60 (-0.1/+0.1)	98.46 (-0.1/+0.1)	98.22 (-0.2/+0.2)	98.14 (-0.2/+0.2)
Registered Implants: 61000										
Effective Sample Size	51524	43904	37128	31010	25718	20979	16748	13039	10113	7694

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

Models 4477/4478/4479/4480

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

**FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)
Models 4477/4478/4479/4480**



Worldwide Distribution: 291,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	3	10	13
⁷ Lead conductor	-	3	
³² Conductor damage	3	7	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
³³ Insulation damage	-	1	
Other	2	-	2
²² J-shape	30	4	
²⁶ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	5	11	16

[More details](#) about malfunctions

[References](#) cited in table above

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

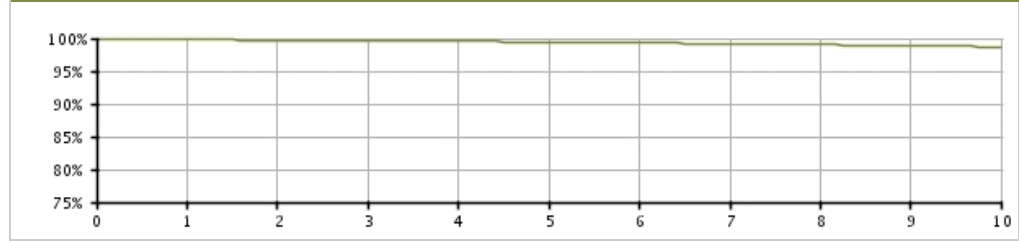
Models 4452/4453/4456/4457

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

U.S. Registered Implants: 187,000	U.S. Chronic Lead Complications: 1,092
U.S. Approval Date: January 2000	U.S. Malfunctions:42
U.S. Estimated Active Implants: 88,000	Without Compromised Therapy:5
	With Compromised Therapy:37

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)	99.64 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.34 (-0.0/+0.0)	99.18 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.85 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 187000										
Effective Sample Size	158245	134870	113867	95333	79290	64941	52027	40683	31803	24458

**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: 517,000
Worldwide Confirmed Malfunctions: 60

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	45	46
⁷ Lead conductor	-	15	
²⁷ Non-patterned, Conductor	-	2	
³² Conductor damage	1	28	
Crimp/Weld/Bond	-	-	0
Insulation	2	7	9
³³ Insulation damage	2	7	
Other	4	-	4
²⁶ Non-patterned, Other	4	-	
WW Confirmed Malfunctions	7	53	60

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q4 2016

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

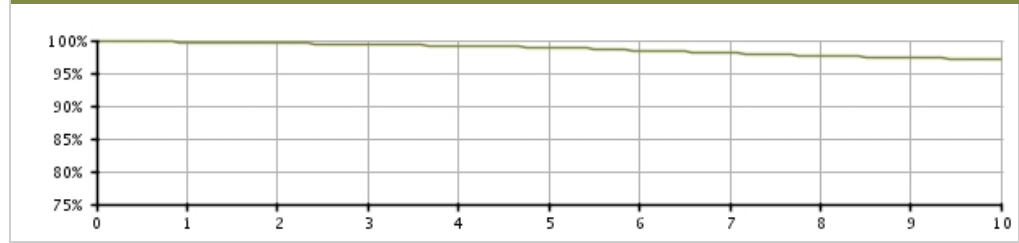
Models 4466/4467/4468/4472/4473/
4474

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

U.S. Registered Implants: 52,000	U.S. Chronic Lead Complications: 602
U.S. Approval Date: January 2000	U.S. Malfunctions:125
U.S. Estimated Active Implants: 24,000	Without Compromised Therapy:22
	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	99.74 (-0.0/+0.0)	99.57 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.19 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.49 (-0.1/+0.1)	98.05 (-0.2/+0.2)	97.63 (-0.2/+0.2)	97.40 (-0.2/+0.2)	97.10 (-0.3/+0.2)
Registered Implants: 52000										
Effective Sample Size	44774	38688	33211	28197	23736	19598	15877	12698	10095	7784

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

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

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



Worldwide Distribution: 139,000
Worldwide Confirmed Malfunctions: 164

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	9	125	134
⁷ Lead conductor	3	74	
²⁷ Non-patterned, Conductor	-	2	
³² Conductor damage	6	46	
³⁵ Lead conductor	-	3	
Crimp/Weld/Bond	1	-	1
³¹ Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	10	9	19
²⁸ Non-patterned, Insulation	3	-	
³³ Insulation damage	7	9	
Other	6	4	10
²⁶ Non-patterned, Other	6	4	
WW Confirmed Malfunctions	26	138	164

[More details](#) about malfunctions

[References](#) cited in table above

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

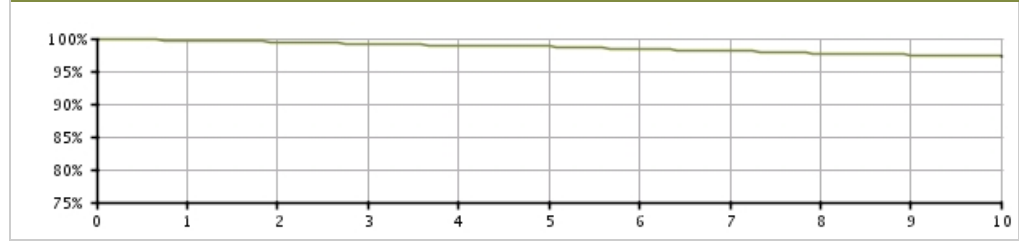
Models 4454/4455/4458/4459

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: 188
U.S. Approval Date: January 2000	U.S. Malfunctions: 23
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy: 0
	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	99.67 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.18 (-0.2/+0.1)	98.92 (-0.2/+0.2)	98.76 (-0.2/+0.2)	98.43 (-0.3/+0.2)	98.07 (-0.3/+0.3)	97.73 (-0.4/+0.3)	97.48 (-0.4/+0.4)	97.35 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12342	10781	9335	8040	6853	5759	4762	3939	3292	2725

**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: 103,000
Worldwide Confirmed Malfunctions: 52

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	43	43
⁷ Lead conductor	-	16	
³² Conductor damage	-	27	
Crimp/Weld/Bond	-	-	0
Insulation	2	4	6
³³ Insulation damage	2	4	
Other	-	3	3
²⁶ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	50	52

[More details](#) about malfunctions

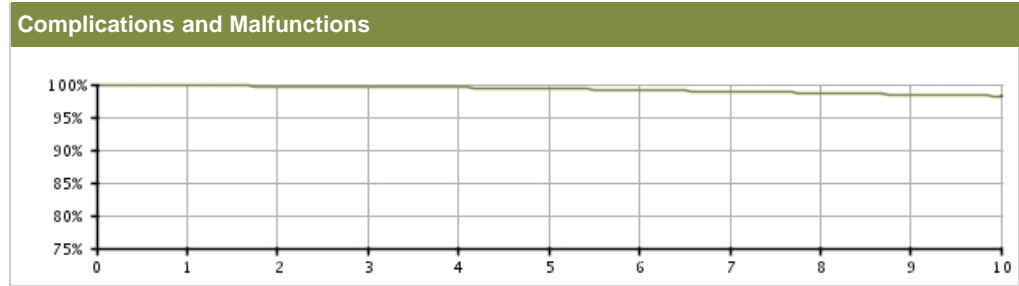
[References](#) cited in table above

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: 294
U.S. Approval Date: July 1999	U.S. Malfunctions:10
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy:1
	With Compromised Therapy:9



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	13217	11629	10247	9036	7928	6995

FINELINE Passive Fixation

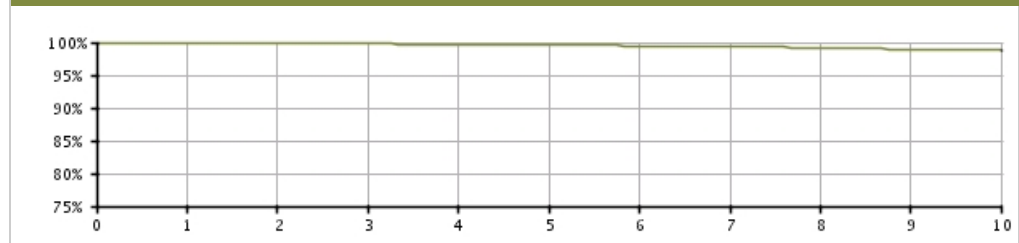
Models 4450/4451

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

<p>U.S. Registered Implants: 42,000 U.S. Approval Date: November 1996 U.S. Estimated Active Implants: 7,000</p>	<p>U.S. Chronic Lead Complications: 330 U.S. Malfunctions: 11</p>
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Complications and Malfunctions



U.S. Survival Probability

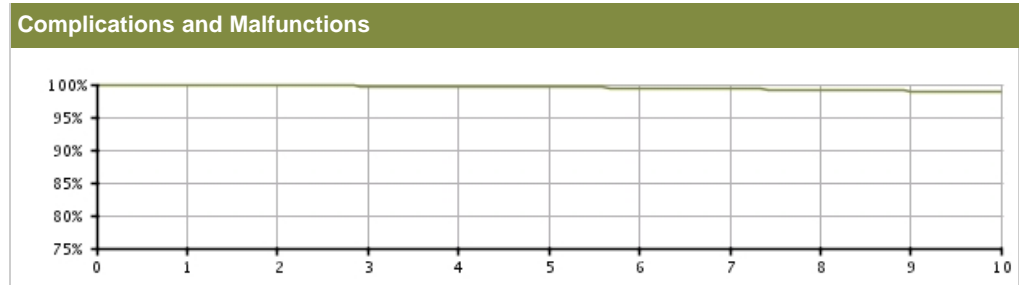
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.91 <small>(-0.0/+0.0)</small>	99.84 <small>(-0.0/+0.0)</small>	99.79 <small>(-0.1/+0.0)</small>	99.72 <small>(-0.1/+0.1)</small>	99.62 <small>(-0.1/+0.1)</small>	99.49 <small>(-0.1/+0.1)</small>	99.35 <small>(-0.1/+0.1)</small>	99.17 <small>(-0.1/+0.1)</small>	98.97 <small>(-0.1/+0.1)</small>	98.79 <small>(-0.2/+0.1)</small>
Registered Implants: 42000										
Effective Sample Size	35802	32044	28627	25410	22459	19757	17317	15282	13456	11860

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: 105
U.S. Approval Date: November 1996	U.S. Malfunctions: 6
U.S. Estimated Active Implants: 3,000	



U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 <small>(-0.1/+0.0)</small>	99.83 <small>(-0.1/+0.1)</small>	99.75 <small>(-0.1/+0.1)</small>	99.68 <small>(-0.1/+0.1)</small>	99.61 <small>(-0.1/+0.1)</small>	99.45 <small>(-0.2/+0.1)</small>	99.31 <small>(-0.2/+0.2)</small>	99.16 <small>(-0.2/+0.2)</small>	98.98 <small>(-0.3/+0.2)</small>	98.89 <small>(-0.3/+0.2)</small>
Registered Implants: 14000										
Effective Sample Size	12441	11148	9968	8891	7907	6971	6147	5430	4755	4157

SELUTE PICOTIP
Passive Fixation

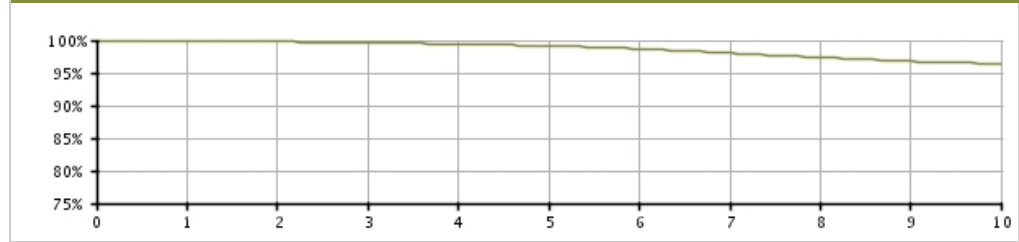
Models 4030/4031/4032/4033/4034/
 4035

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: 1,109
U.S. Approval Date: April 1998	U.S. Malfunctions: 36
U.S. Estimated Active Implants: 12,000	

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)	97.38 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.39 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49277	43965	39177	34805	30802	27098	23777	20802	17977	15571

SELUTE PICOTIP Atrial J

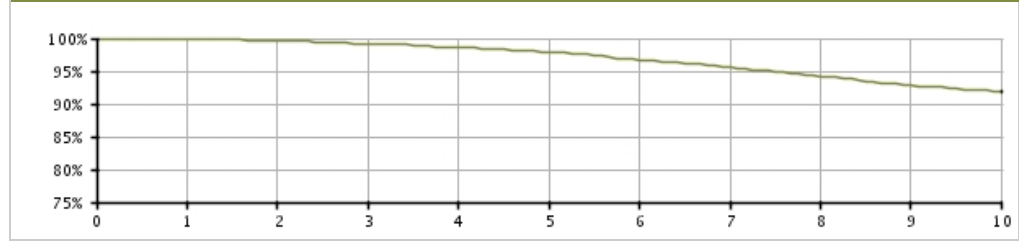
Models 4040/4041/4042/4043/4044/
4045/4063/4064

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: 432
U.S. Approval Date: May 2000	U.S. Malfunctions: 22
U.S. Estimated Active Implants: 3,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 (-0.1/+0.1)	99.65 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.61 (-0.3/+0.2)	97.89 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.57 (-0.6/+0.5)	94.22 (-0.7/+0.6)	92.88 (-0.8/+0.7)	91.82 (-0.9/+0.8)
Registered Implants: 10000										
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3464	2924	2487

SWEET PICOTIP Rx
Positive Fixation

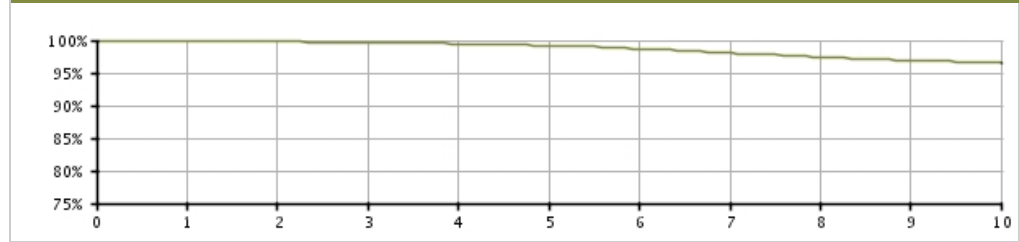
Models 4050/4051/4052/4053/4054/
 4055

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: 694
U.S. Approval Date: April 1999	U.S. Malfunctions: 57
U.S. Estimated Active Implants: 11,000	

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)	98.68 (-0.2/+0.1)	98.05 (-0.2/+0.2)	97.44 (-0.2/+0.2)	96.91 (-0.3/+0.2)	96.56 (-0.3/+0.3)
Registered Implants: 41000										
Effective Sample Size	35765	31934	28498	25355	22465	19813	17375	14992	12474	10325

SWEET TIP
Positive Fixation

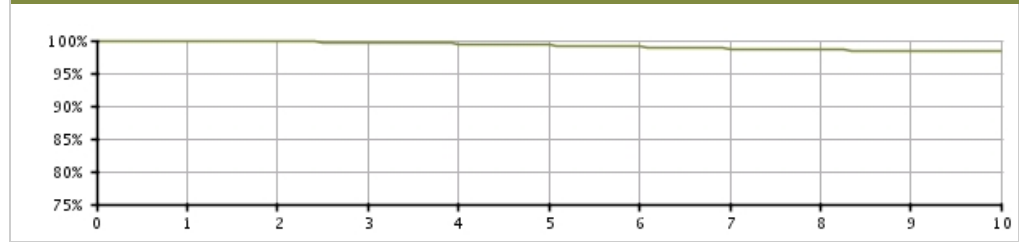
Models 4165/4168/4169/4268/4269

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: 963
U.S. Estimated Active Implants: 15,000	U.S. Malfunctions: 162

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	77716	69454	62065	55311	49106	43279	38075	33560	29652	26155

SWEET TIP RX
Positive Fixation

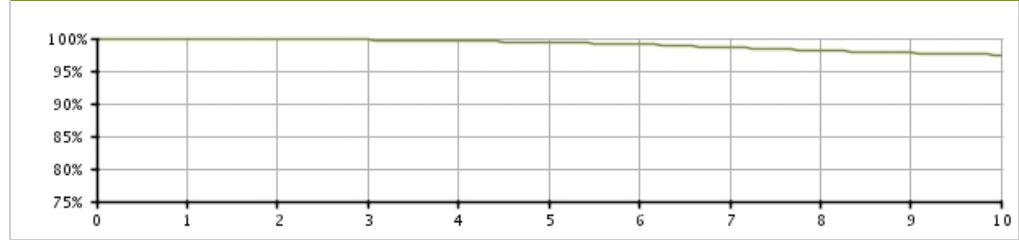
Models 4143/4144/4145/4243/4244/
 4245

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: 495
U.S. Approval Date: October 1998	U.S. Malfunctions: 28
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	99.90 (-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)	98.11 (-0.2/+0.2)	97.76 (-0.2/+0.2)	97.44 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26538	23707	21102	18667	16404	14411	12593	10872	9287

CRM PRODUCT PERFORMANCE REPORT Q4 2016

Confirmed Malfunction Details: Leads

References

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

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

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

26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
27. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
28. **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.
31. **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.
32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
34. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.
35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.
36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
37. **Weld fracture**— Noise, loss of sensing. Fractured weld.
38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable. Improvement implemented.
39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.

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

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	31000	2	7	8	1	0	0	0	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	1000	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	2000	0	0	0	0	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	234000	72	760	851	693	283	87	160	379	0	65
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	187000	4	315	201	174	35	19	153	171	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	450000	22	518	653	329	78	81	404	317	0	36
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	95	307	108	8	19	59	35	0	7
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	85	19	36	12	4	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	221	73	75	53	15	70	91	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 X4 Spiral L 4677/4678	2000	0	0	0	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	5000	0	0	1	0	0	0	0	0	0	0

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
ACUIITY X4 Straight 4671/4672	3000	0	0	2	0	0	0	0	0	0	0
ACUIITY Steerable 4554/4555/4556	29000	2	22	395	38	3	1	7	23	0	95
ACUIITY Spiral 4591/4592/4593	23000	0	14	250	28	1	1	2	5	0	144
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	27	253	41	3	2	9	10	0	91
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	2	265	1084	235	8	6	61	77	0	463
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	63	397	103	3	1	47	31	0	260

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	57000	14	18	66	14	11	7	4	5	7	4
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	0	1	4	0	2	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	63000	16	17	75	23	14	7	2	6	10	4
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	0	0	2	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	28	403	347	121	467	64	95	210	161	28
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	89	63	48	81	7	34	137	30	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	8	46	43	20	40	1	7	26	25	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	2	5	1	3	0	1	3	2	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	15000	0	0	2	0	6	0	2	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	1381	0	0	22	2	0	0	0	0	0	9
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	743	0	0	0	0	0	0	0	1	1	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	851	0	0	1	1	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	0	1	0	1	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	923	0	1	1	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
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	31000	38	66	67	28	7	4	3	32	0	7
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	1000	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	2000	0	1	2	2	0	1	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	234000	237	192	1363	430	76	90	57	215	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	187000	15	14	450	177	7	25	24	38	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	450000	82	85	701	255	111	97	61	248	0	43
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	18	451	92	7	29	17	22	0	10
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	34	16	1	3	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/4473/4474	52000	3	18	105	28	9	10	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 X4 Spiral L 4677/4678	2000	1	0	4	2	1	0	0	2	0	6
ACUITY X4 Spiral S 4674/4675	3000	0	1	11	2	0	0	0	7	0	14

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	2000	0	0	4	3	0	0	0	6	0	2
ACUITY Steerable 4554/4555/4556	29000	1	3	327	48	25	2	7	133	0	242
ACUITY Spiral 4591/4592/4593	23000	5	4	215	68	8	1	9	38	0	240
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	274	38	12	2	8	47	0	187
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	13	9	932	134	46	9	27	199	0	731
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 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	57000	48	31	162	80	56	11	7	81	19	10
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	2	0	9	1	3	0	0	17	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	63000	58	38	160	57	69	19	7	81	70	24
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	1	1	2	2	1	1	0	15	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	149	190	648	170	364	54	69	362	234	81
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	8	2	106	46	57	8	5	178	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	29	16	77	30	31	14	3	57	120	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	2	1	1	2	0	11	1	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401	15000	1	0	16	0	159	12	1	49	1

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	1381	0	0	12	10	1	0	0	3	0	48
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	851	0	2	12	0	0	0	1	2	0	3
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	6	1	10	5	5	3	0	2	1	2
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	743	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	923	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	8,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	16,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	14,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	63,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	43,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	42,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	177,000	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	9,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	32,000	3	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	93,000	0	0	0	64	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	9,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	104,000	0	0	0	22	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Passive Fixation 0282/0283	4,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	373,000	0	0	44	487	0	3	14
ENDOTAK RELIANCE Dual Coil Passive Fixation 0147/0148/0149/0174/0175/0176/0177	108,000	0	1	3	87	0	3	0
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	68,000	0	0	7	63	0	1	3
ENDOTAK RELIANCE Single Coil Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	0	0	0	2	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	25,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	179,000	452	0	0	754	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	20,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	24,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	181,000	0	0	10	122	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	289,000	0	0	55	601	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	517,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	691,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	291,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	103,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	139,000	0	1	1	25	1	6	0

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

Product Advisories

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

<p>PRODUCT</p> <p>A serialized search tool to determine if a specific device is affected by this product advisory is available here:</p>	<p>ORIGINAL COMMUNICATION Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014</p>
<p>Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II</p>
<p>COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108</p>	<p>In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.</p>
<p>TELIGEN VR Models E102/E103/F102/F103</p>	<p>The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.</p>
<p>TELIGEN DR Models E110/E111/F110/F111</p>	<p>The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.</p>
	<p><u>Advisory population</u> Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.</p>
<p>Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014</p>	<p>CURRENT STATUS 07-Oct-16</p>
<p>Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014</p>	<p>Advisory devices have not been available for implant for more than three years.</p>
<p>Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 3,997 malfunctions have been confirmed from the advisory population. Approximately 39,000 devices from the advisory population remain in service.</p>
	<p>There has been one reported patient death associated with this advisory.</p> <p><i>Projected Rate of Occurrence</i> The rate of occurrence for advisory population devices is 5.9% at 72 months. The projected rate of occurrence at 84 months is approximately 9.1%.</p>
	<p>CURRENT RECOMMENDATION 07-Oct-16</p>
	<p><u>Updated Software</u> In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.</p>
	<p><u>LATITUDE Patient Management System</u> Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity" is configured "On".</p>
	<p><u>Additional Recommendations</u></p> <ul style="list-style-type: none"> - After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling. - Device replacement is not recommended for advisory devices displaying normal behavior. - Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages. - Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that "Approximate time to Explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a low voltage alert.
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT

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

[Device Lookup Tool](#)

SQ-RX S-ICD

Model1010

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

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

ORIGINAL COMMUNICATION 01-Jun-11 — High Cathode Condition

Voluntary Physician Advisory

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 07-Oct-16

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 07-Oct-16

- 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 07-Oct-16</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>VITALITY DR HE Model T180</p>	<p><i>Projected Rate of Occurrence</i></p>
<p>Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010</p>	<p>The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.</p>
<p>Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010</p>	<p>CURRENT RECOMMENDATION 07-Oct-16</p>
	<p>Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device. In addition, Boston Scientific recommends:</p>
	<p>1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.</p>
	<p>2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]</p>

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

CURRENT RECOMMENDATION, continued...

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

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

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

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

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

PRODUCT

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 07-Oct-16

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-five (95) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

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

Rate of Occurrence

An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.

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

CURRENT RECOMMENDATION 07-Oct-16

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>CONTAK RENEWAL 4 RF HE Model H239</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 Models H230/H235</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 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>CURRENT STATUS 07-Oct-16</p>
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p><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>	

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

CURRENT RECOMMENDATION 07-Oct-16

VITALITY EL

Model T127

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

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.

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

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:

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

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.

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

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**.

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

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 07-Oct-16</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 07-Oct-16 Patient management recommendations from the March 10, 2007 Product Update remain unchanged.</p>
<p>ASSURE Model B301</p>	<p><i>Patient Management Considerations</i></p> <ul style="list-style-type: none"> – Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled. – Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL. – Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI. – Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding a manual capacitor reform may be helpful in characterizing the current charge time.
<p>Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007</p>	
<p>Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007</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 07-Oct-16</p>
<p>INSIGNIA Entra SSI Models 0484/0485/1325/1326</p>	<p><i>Confirmed Malfunctions (worldwide)</i></p>
<p>INSIGNIA Entra DDD Models 0985/0986/1426</p>	<p>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 Plus SR Models 1194/1394</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 DR and Plus DR Downsize Models 1297/1467/1298/1468</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 AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492</p>	<p>CURRENT RECOMMENDATION 07-Oct-16</p>
<p>CONTAK RENEWAL TR / TR2 Models H120/H125/H140/H145</p>	<p><u>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</u></p>
<p>VITALITY 2 EL VR/DR Models T177/T167</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.</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p>As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.</p>
<p>VITALITY DR HE Model T180</p>	<p>– Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation.</p>
<p>VITALITY DS VR/DR Models T135/T125</p>	<p>Device Behavior Pacemakers: INSIGNIA/NEXUS</p>
<p>VITALITY VR/DR and EL Models 1870/1871/T127</p>	<p>– Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant</p>

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
<p>CONTAK RENEWAL 4 Models H190/H195</p>	<ul style="list-style-type: none"> - 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 AVT / AVT HE Models M170/M175/M177/M179</p>	<p><i>Reported Events</i></p> <p>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></p> <p>The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	<p>CURRENT STATUS 07-Oct-16</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u></p> <p>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></p> <p>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></p> <p>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>Subpectoral Implant, Patient Letter, Jan 04, 2008</p>	<p>CURRENT RECOMMENDATION 07-Oct-16</p> <p><u>Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.</u></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> 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 Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490	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 SR Models 1195/1198/1395/1398	<i>Rate Projection</i> 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 DR (downsize) Models 1296/1466	CURRENT STATUS 07-Oct-16
INSIGNIA Entra DR Models 1294/1295/1494/1495	<i>Confirmed Malfunctions (worldwide)</i> 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 Entra SSI Models 0484/0485/1325/1326	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 Entra DDD Models 0985/0986/1426	None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode.
INSIGNIA Plus SR Models 1194/1394	<i>Projected Rate of Occurrence</i> Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 4,000 is projected to range between 0.027% and 0.038%.
INSIGNIA Plus DR and Plus DR Downsize Models 1297/1467/1298/1468	CURRENT RECOMMENDATION 07-Oct-16
INSIGNIA AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492	Failure Mode 1— <u>Patient management recommendations from the September 22, 2005 physician communication remain unchanged.</u>
Crystal Timing Component, Physician Letter, Dec 12, 2005	Failure Mode 2— <u>Patient management recommendations supersede those originally communicated on September 22, 2005.</u>
Crystal Timing Component, Patient Letter, Oct 03, 2005	– Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
Crystal Timing Component, Physician Letter, Sep 22, 2005	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	<u>Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u> ; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).
DISCOVERY II DDD Models 0981/1285/1499	<u>Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u> ; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).
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 07-Oct-16
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...

CURRENT RECOMMENDATION 07-Oct-16

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

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

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

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

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

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

OR

- Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR.
- Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a malfunction that has already occurred, but does not guarantee that the device will not exhibit this malfunction mode in the future. At each patient follow-up:
 - Evaluate for the clinical behaviors described in the July 18, 2005 letter.
 - Evaluate battery status for signs of early or rapid depletion between sequential follow-up visits.
 - Evaluate the accelerometer rate response (for devices with this feature).
 - Accelerometer ON:
 - Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit (LRL) while the patient is at rest.
 - Look for lack of rate response with activity (i.e., isometrics, short hall walk).
 - Accelerometer OFF:
 - *Temporarily* program the accelerometer ON and evaluate as described above
- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.
- If any of these device behaviors are observed, contact your local representative or Technical Services for troubleshooting and recommendations.

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

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