

2017 **Rhythm Management
Product Performance Report**
Q2 Edition



CRM Quality Pledge

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

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2017 report includes data through April 10, 2017.

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,

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Vice President, Quality Assurance

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Statistical Methodology

What Is Device Survival Probability?

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

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.

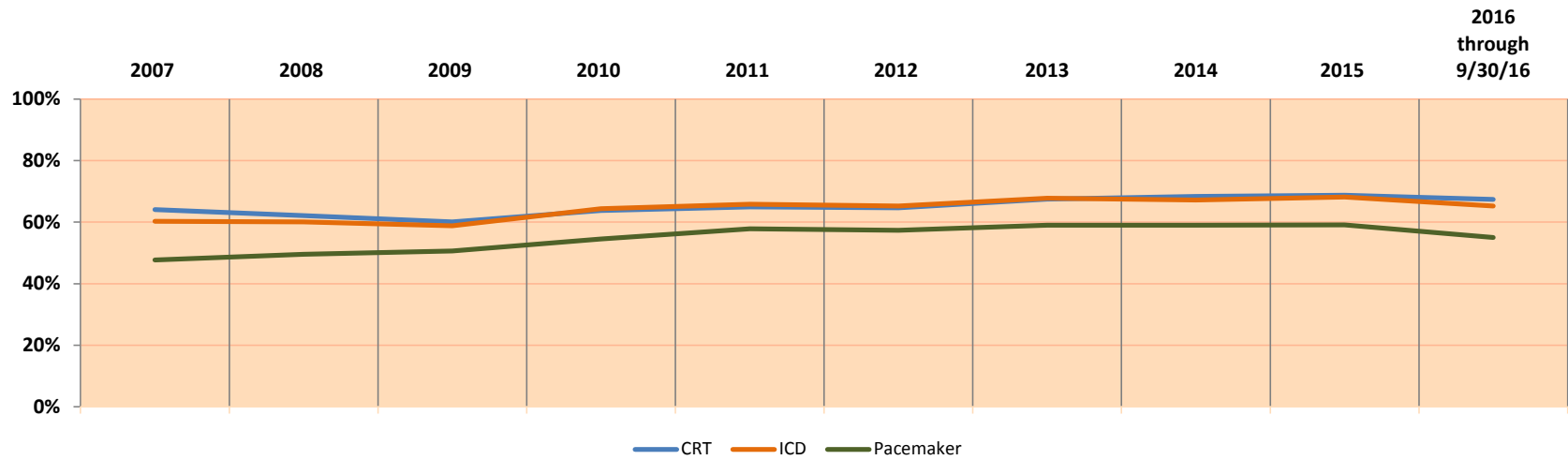
E-mail: crmevent@bsci.com

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 9/30/16
Explants	4247	5678	9264	10472	9311	8033	8296	6885	4988	3366
Returns	2723	3528	5563	6681	6043	5193	5595	4706	3427	2269
% Returned	64%	62%	60%	64%	65%	65%	67%	68%	69%	67%
Explants	11535	15550	19490	19918	16563	11950	11878	11249	9943	6288
Returns	6947	9344	11465	12826	10898	7800	8048	7561	6774	4100
% Returned	60%	60%	59%	64%	66%	65%	68%	67%	68%	65%
Explants	18397	20440	21003	21106	19994	18674	18757	19240	19507	14512
Returns	8780	10133	10633	11509	11567	10713	11075	11352	11528	7988
% Returned	48%	50%	51%	55%	58%	57%	59%	59%	59%	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: 19,000

Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	6	1	7
⁸⁰ High voltage circuit component	4	-	
⁸¹ Integrated circuit	2	1	
Mechanical	-	-	0
Software	-	-	0
Other	2	1	3
Non-patterned	2	1	
WW Confirmed Malfunctions	8	2	10

[More details](#) about malfunctions

[References](#) cited in table above

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DYNAGEN/INOGEN/ORIGEN CRT-D

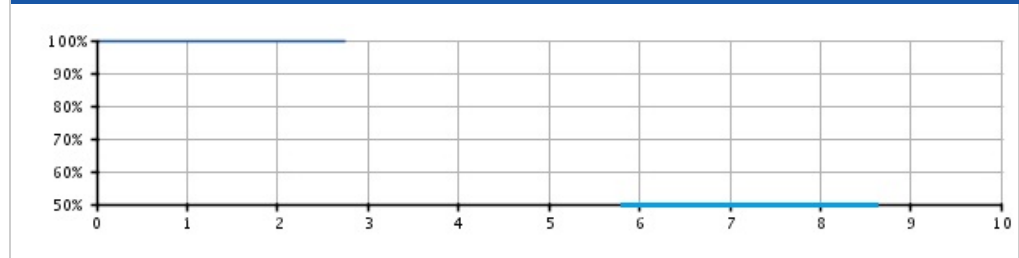
Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

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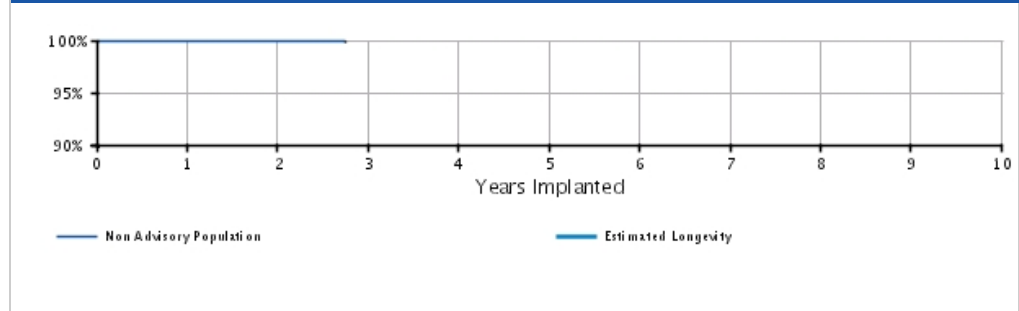
U.S. Summary

U.S. Registered Implants: 34,000	U.S. Normal Battery Depletions: 3
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 32,000	U.S. Malfunctions:12
	Without Compromised Therapy:11
	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)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.86 @ 33 mo. (-0.1/+0.1)	--	--	--	--	--	--	--
Registered Implants: 34000	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 @ 33 mo. (-0.1/+0.1)	--	--	--	--	--	--	--
	Effective Sample Size	16774	4138	299	--	--	--	--	--	--	--

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: 53,000
Worldwide Confirmed Malfunctions: 21

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	13	2	15
⁸⁰ High voltage circuit component	7	-	
⁸¹ Integrated circuit	6	1	
⁸² High voltage capacitor	-	1	
Mechanical	-	-	0
Software	4	1	5
⁶⁹ Memory errors	4	1	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	18	3	21

[More details](#) about malfunctions

[References](#) cited in table above

INCEPTA/ENERGEN/PUNCTUA CRT-D

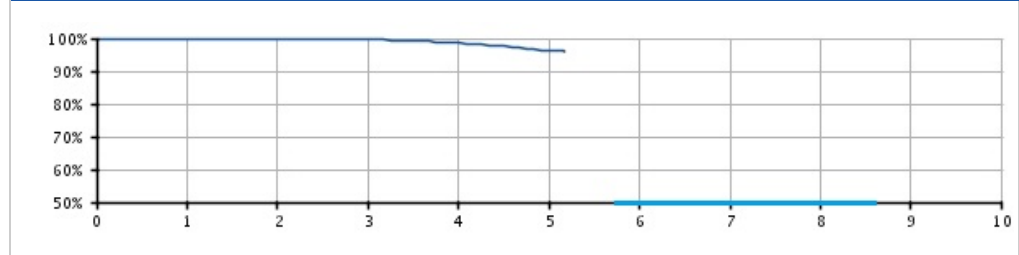
Models N050/N051/N052/N053/N140/
 N141/N142/N143/N160/N161/
 N162/N163/N164/N165/P052/
 P053/P142/P143/P162/P163/
 P165

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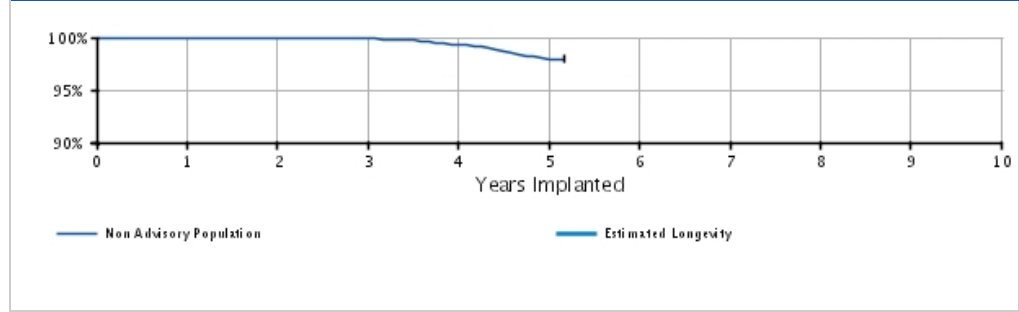
U.S. Summary

U.S. Registered Implants: 52,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 41,000	U.S. Normal Battery Depletions: 195 U.S. Unconfirmed Reports of Premature Battery Depletion : 32 U.S. Malfunctions:209 Without Compromised Therapy:198 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	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.65 (-0.1/+0.1)	98.59 (-0.2/+0.2)	96.15 (-0.6/+0.5)	96.15 @ 62 mo. (-0.6/+0.5)	-	-	-	-
	Registered Implants: 52000										
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.30 (-0.1/+0.1)	97.95 (-0.4/+0.4)	97.95 @ 62 mo. (-0.4/+0.4)	-	-	-	-
	Effective Sample Size	46095	38795	25616	11624	1393	313	-	-	-	-

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: 320

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	288	9	297
⁶⁰ Safety Core-electrocautery	5	1	
⁶¹ High-voltage capacitor	-	2	
⁶⁵ Low-voltage capacitors	1	-	
⁶⁸ Integrated circuit	1	6	
⁷¹ Battery	2	-	
⁷² Low-voltage capacitor	279	-	
Mechanical	-	6	6
⁵⁴ Transformer	-	6	
Software	8	-	8
⁶⁹ Memory errors	8	-	
Other	8	1	9
Non-patterned	8	1	
WW Confirmed Malfunctions	304	16	320

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

COGNIS

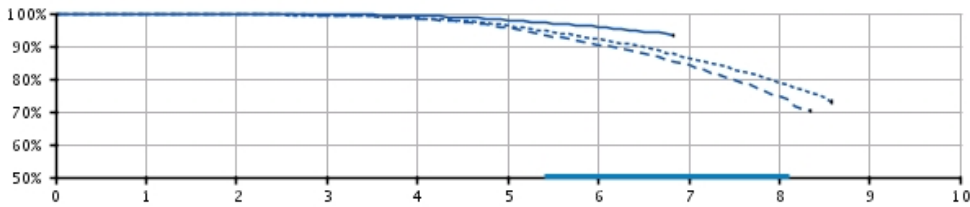
Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

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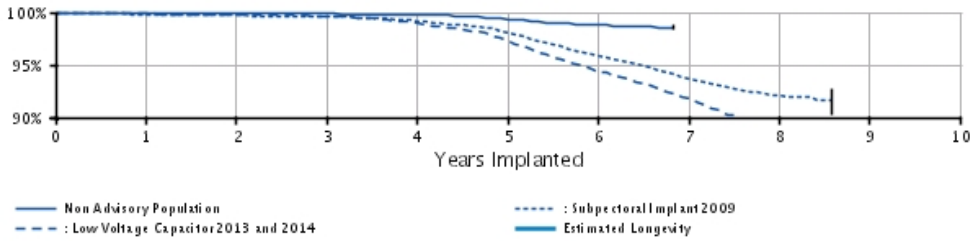
U.S. Summary

U.S. Registered Implants: 75,000	U.S. Normal Battery Depletions: 2,592
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 124
U.S. Estimated Active Implants: 37,000	U.S. Malfunctions:1601
	Without Compromised Therapy:1430
	With Compromised Therapy:171

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)	97.96 (-0.2/+0.2)	95.85 (-0.3/+0.3)	93.15 @ 82 mo. (-0.9/+0.8)	-	-	-
	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)	99.36 (-0.1/+0.1)	98.76 (-0.2/+0.2)	98.57 @ 82 mo. (-0.2/+0.2)	-	-	-
	Effective Sample Size	31503	28110	25050	22100	18828	8207	484	-	-	-
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)	96.36 (-0.1/+0.0)	92.08 (-0.1/+0.1)	86.43 (-0.1/+0.1)	78.88 (-0.4/+0.5)	72.83 @ 103 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)	95.83 (-0.2/+0.3)	93.72 (-0.3/+0.3)	92.14 (-0.4/+0.5)	91.67 @ 103 mo. (-1.4/+1.0)	-
	Effective Sample Size	27493	24362	21666	19176	16714	14186	11828	3836	475	-
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)	98.41 (-0.1/+0.1)	95.53 (-0.1/+0.1)	90.49 (-0.1/+0.1)	84.01 (-0.3/+0.1)	74.70 (-0.3/+0.2)	70.27 @ 100 mo. (-1.4/+1.0)	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.41 (-0.1/+0.1)	95.53 (-0.1/+0.1)	90.49 (-0.1/+0.1)	84.01 (-0.3/+0.1)	74.70 (-0.3/+0.2)	70.27 @ 100 mo. (-1.4/+1.0)	-
	Effective Sample Size	27493	24362	21666	19176	16714	14186	11828	3836	475	-


26,000											
	Malfunctions Only (%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.37 (-0.1/+0.1)	91.73 (-0.3/+0.1)	88.85 (-0.4/+0.2)	88.23 @ 100 mo. (-1.4/+1.0)	-
	Effective Sample Size	22616	20021	17827	15749	13650	11474	7714	1246	210	-

*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: 2105			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1781	134	1915
¹ Low Voltage Capacitor 2014 (Advisory issued)	1338	70	
⁶⁰ Safety Core-electrocautery	48	21	
⁶¹ High-voltage capacitor	1	6	
⁶⁵ Low-voltage capacitors	7	-	
⁶⁸ Integrated circuit	7	20	
⁷⁰ High voltage circuit	-	1	
⁷¹ Battery	41	6	
⁷² Low-voltage capacitor	339	10	
Mechanical	41	92	133
⁴ Subpectoral implant 2009 (Advisory issued)	18	49	
⁵⁴ Transformer	-	9	
⁵⁸ Difficulty securing lead	9	9	
⁶³ Header contacts	8	8	
⁸⁵ Header	6	17	
Software	15	1	16
⁶⁴ Safety Core-programming	1	-	
⁶⁶ Alert messages not displayed post-EOL	2	-	
⁶⁹ Memory errors	12	1	
Other	33	8	41
Non-patterned	33	8	
WW Confirmed Malfunctions	1870	235	2105

[More details](#) about malfunctions

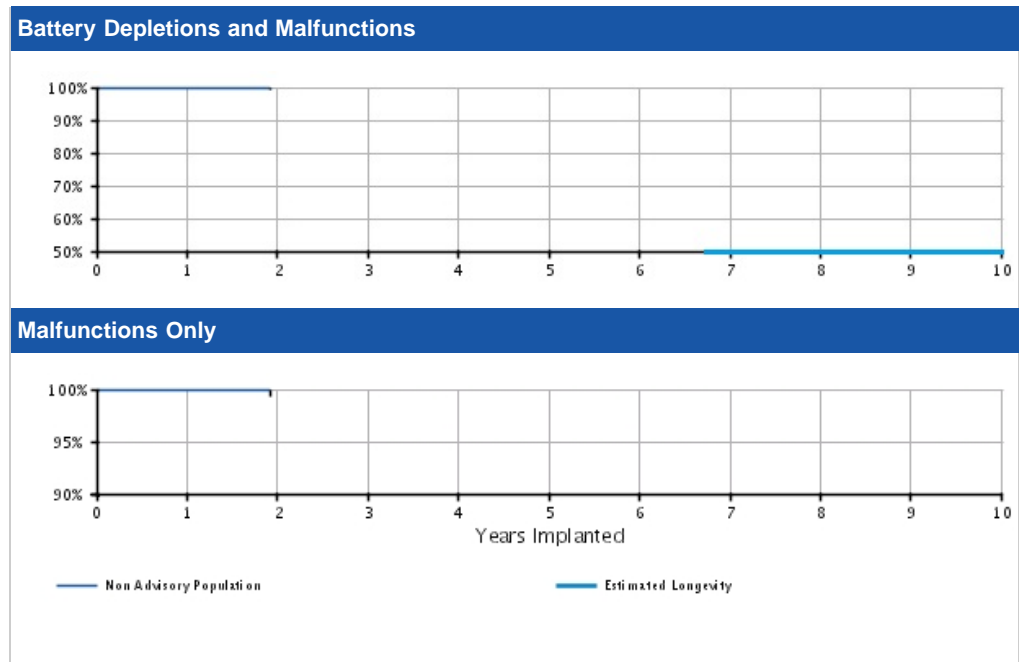
[References](#) cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

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

U.S. Summary	
U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:2
	Without Compromised Therapy:1
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.72 @ 23 mo. (-0.6/+0.2)	-	-	-	-	-	-	-	-	-
	Registered Implants: 11000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.85 @ 23 mo. (-0.5/+0.1)	-	-	-	-	-	-	-	-
Effective Sample Size		3565	338	-	-	-	-	-	-	-	-	-

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: 22,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁸¹ Integrated circuit	-	1	
⁸³ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

INVIVE

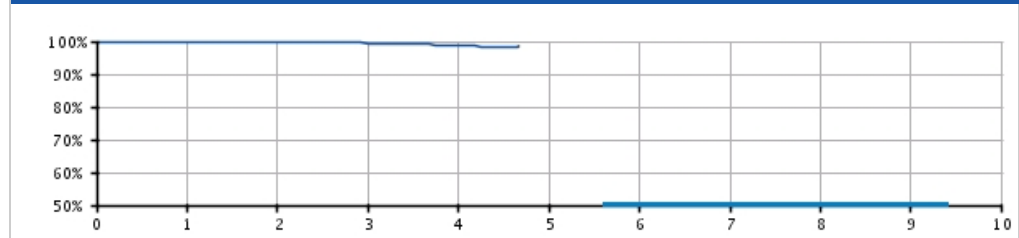
Models V172/V173/V182/V183/W172/
W173

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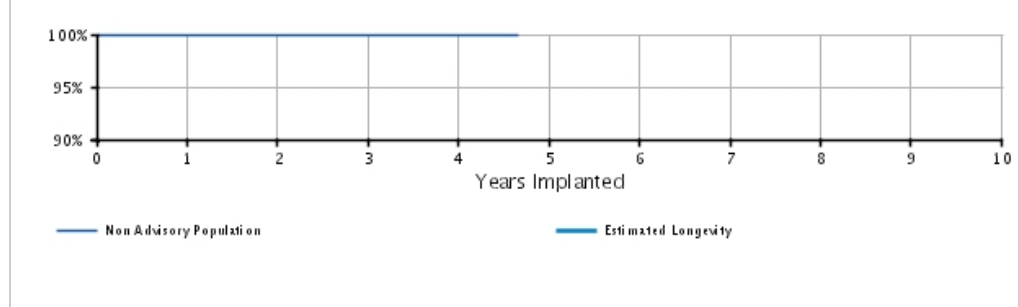
U.S. Summary

U.S. Registered Implants: 8,000	U.S. Normal Battery Depletions: 42
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)	99.86 (-0.1/+0.1)	99.49 (-0.2/+0.2)	98.86 (-0.5/+0.3)	98.40 @ 56 mo. (-0.7/+0.5)	-	-	-	-	-
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 @ 56 mo. (-0.1/+0.0)	-	-	-	-	-
	Effective Sample Size	6703	5470	3589	1191	209	-	-	-	-	-

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: 18,000			
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

CRM PRODUCT PERFORMANCE REPORT Q2 2017

INTUA

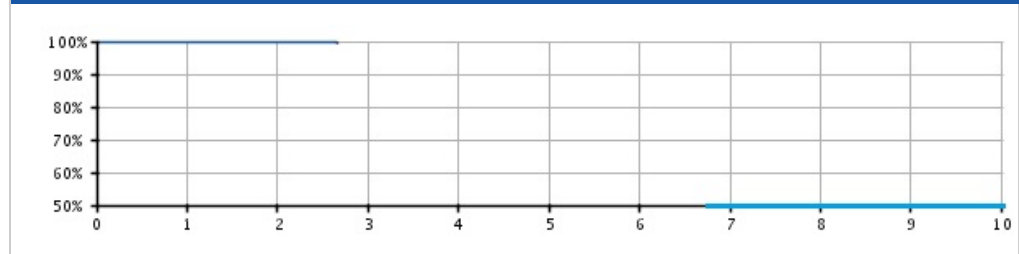
Models V272/V273/V282/V283/W272/
W273

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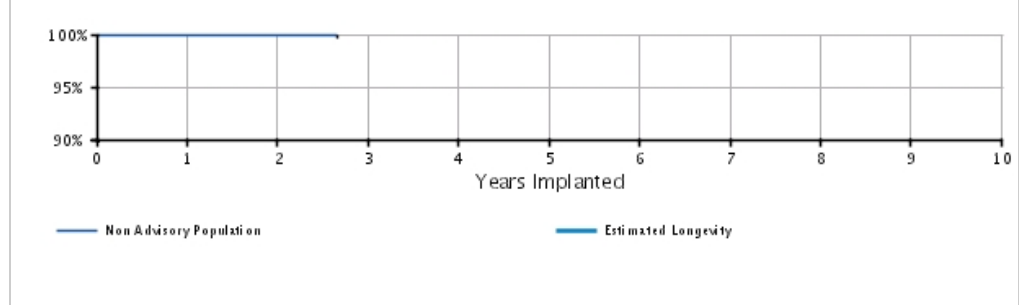
U.S. Summary

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)	99.83 (-0.3/+0.1)	99.66 (-0.5/+0.2)	99.66 @ 32 mo. (-0.5/+0.2)	-	-	-	-	-	-	-
Registered Implants: 3000	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.96 (-0.3/+0.0)	99.96 @ 32 mo. (-0.3/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	2106	1112	262	-	-	-	-	-	-	-

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

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

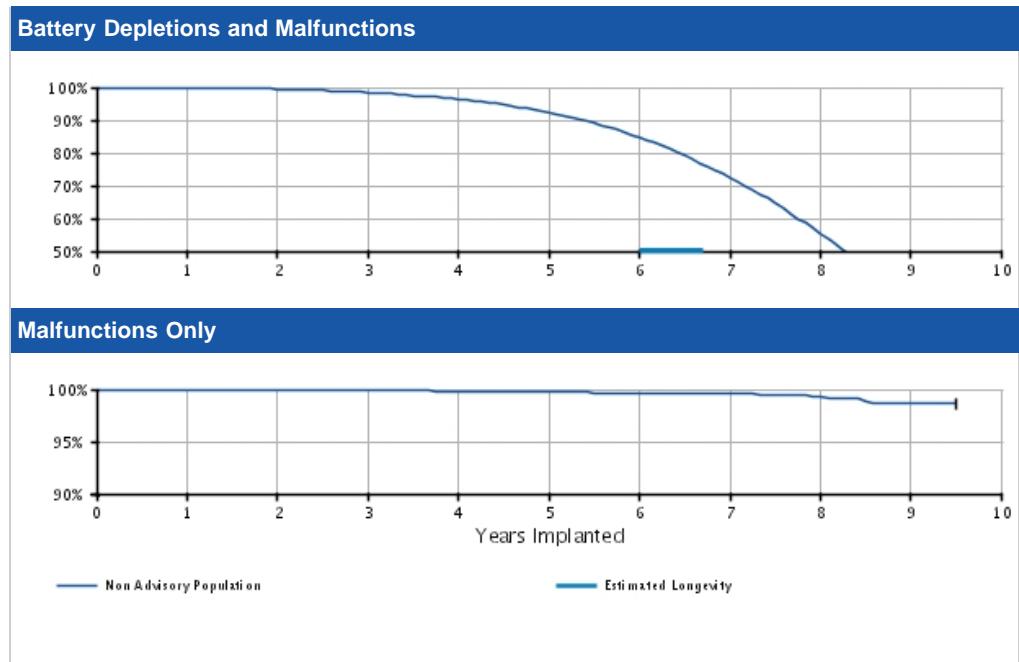
[References](#) cited in table above

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: 2,950
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:52
	Without Compromised Therapy:50
	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)	92.39 (-0.5/+0.5)	84.78 (-0.8/+0.7)	72.47 (-1.1/+1.1)	55.35 (-1.6/+1.6)	37.01 (-2.0/+2.1)	28.03 @ 114 mo. (-2.3/+2.4)
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)	99.84 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.67 (-0.1/+0.1)	99.57 (-0.2/+0.1)	99.24 (-0.4/+0.3)	98.68 (-0.7/+0.5)	98.68 @ 114 mo. (-0.7/+0.5)
	Effective Sample Size	15569	13562	11821	10237	8259	5496	2928	1302	432	203
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: 52			
	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	29	-	29
⁴⁰ Stored EGMs	29	-	
Other	15	1	16
Non-patterned	9	1	
⁴⁷ Alert messages	5	-	
⁶² Magnet rate	1	-	
WW Confirmed Malfunctions	50	2	52

[More details](#) about malfunctions

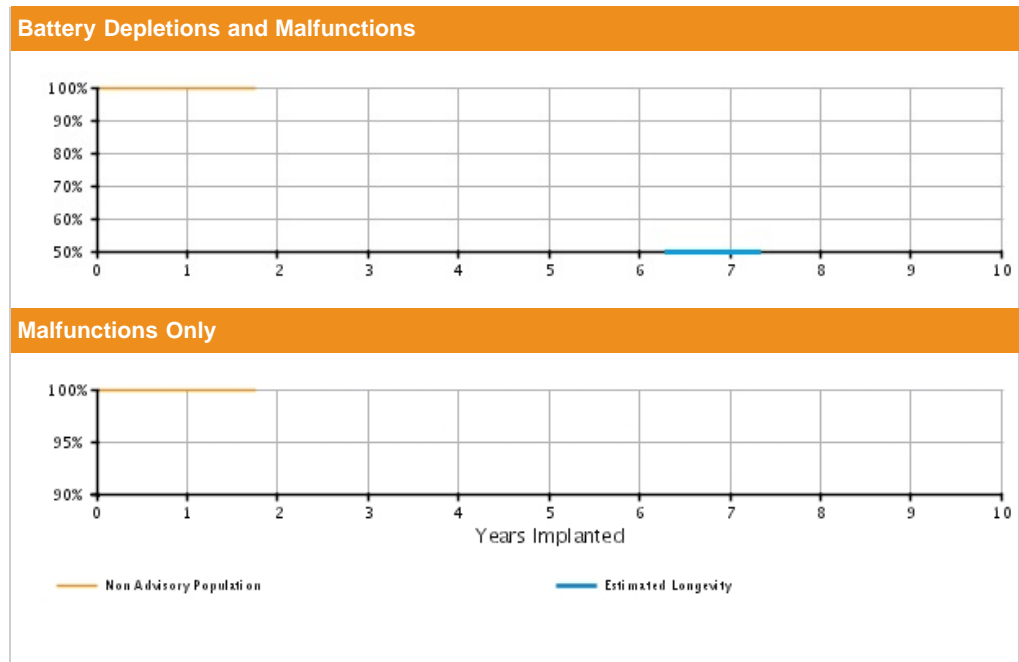
[References](#) cited in table above

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: 11,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: March 2015	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:4
	Without Compromised Therapy:2
	With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 @ 21 mo. (-0.1/+0.0)	—	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 @ 21 mo. (-0.1/+0.0)	—	—	—	—	—	—	—	—	—
Registered Implants: 11000	Effective Sample Size	4310	327	—	—	—	—	—	—	—	—	—

EMBLEM S-ICD

Models A209/A219

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

EMBLEM S-ICD
Models A209/A219



Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	3	5	8
Non-patterned	3	3	
⁷⁴ Telemetry	-	2	
WW Confirmed Malfunctions	3	5	8

[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: 9,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁸¹ Integrated circuit	-	1	
⁸² High voltage capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	2	2	4

[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: 10,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	1	2
⁶⁹ Memory errors	1	1	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

DYNAGEN/INOGEN/ORIGEN ICD EL DR

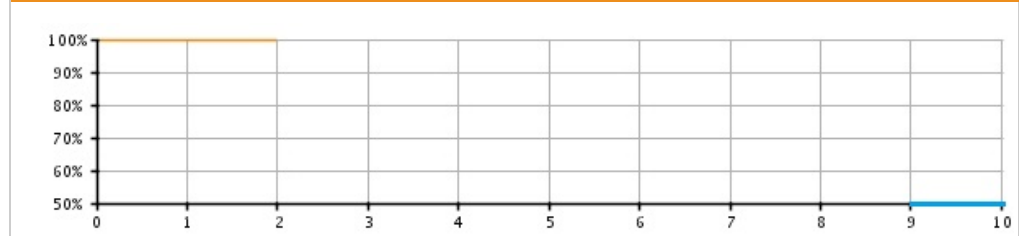
Models D052/D053/D142/D143/D152/
D153

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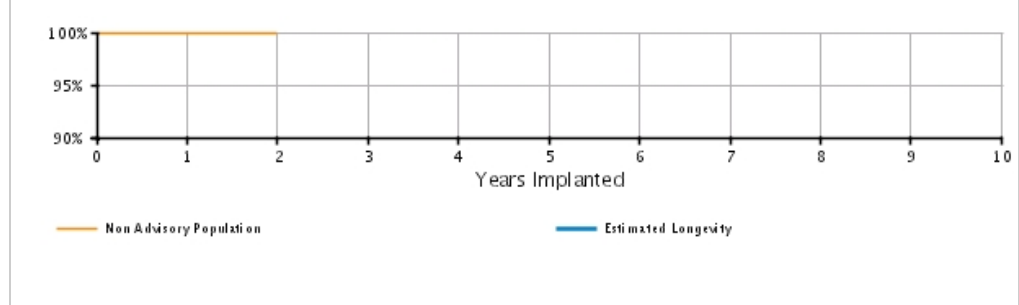
U.S. Summary

U.S. Registered Implants: 17,000	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: 16,000	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)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 17000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	6942	347	-	-	-	-	-	-	-	-

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: 24,000

Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
⁶⁵ Low-voltage capacitors	1	-	
⁸⁰ High voltage circuit component	3	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	4	0	4

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

DYNAGEN/INOGEN/ORIGEN ICD EL VR

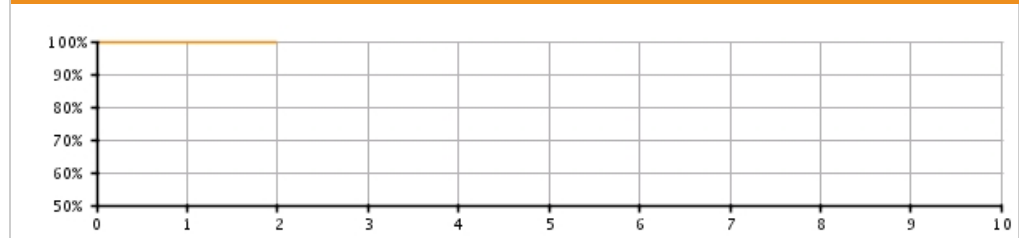
Models D050/D051/D140/D141/D150/
D151

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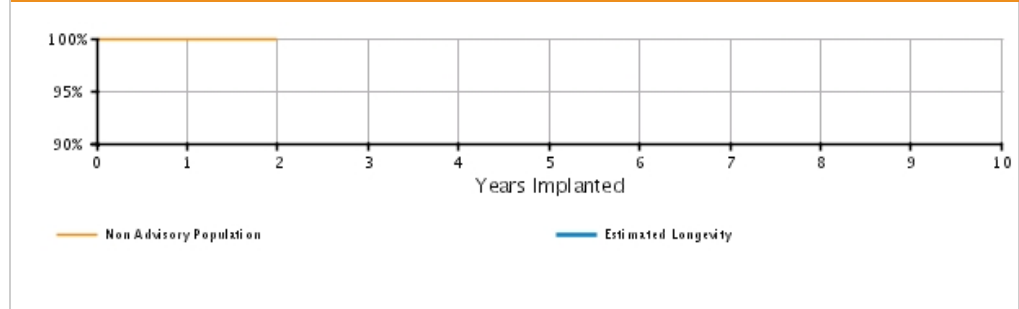
U.S. Summary

U.S. Registered Implants: 16,000	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: 15,000	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)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 16000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.96 (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	6878	328	-	-	-	-	-	-	-	-

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: 26,000

Worldwide Confirmed Malfunctions: 5

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

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

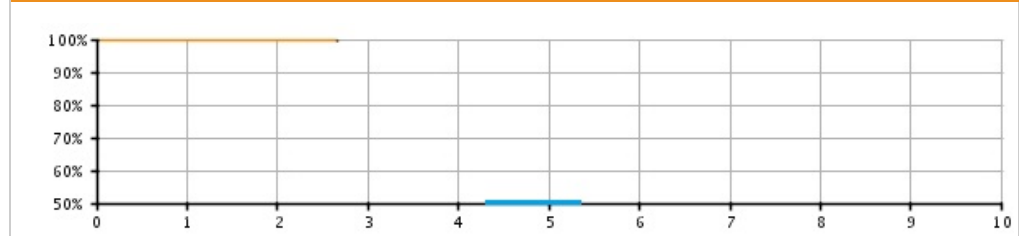
Models D002/D003/D012/D013/D022/
D023

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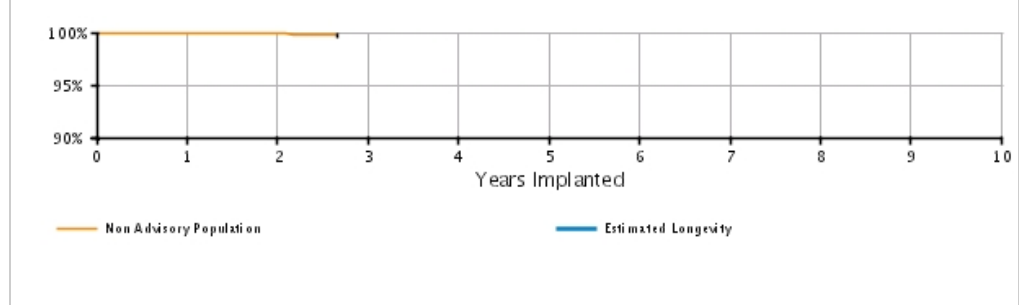
U.S. Summary

U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 2
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:4
	Without Compromised Therapy:4
	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)	99.86 (-0.2/+0.1)	99.70 @ 32 mo. (-0.4/+0.2)	-	-	-	-	-	-	-
Registered Implants: 6000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.94 (-0.2/+0.0)	99.78 @ 32 mo. (-0.4/+0.1)	-	-	-	-	-	-	-
	Effective Sample Size	3609	1522	305	-	-	-	-	-	-	-

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: 12,000

Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
⁸⁰ High voltage circuit component	4	-	
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	6	0	6

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

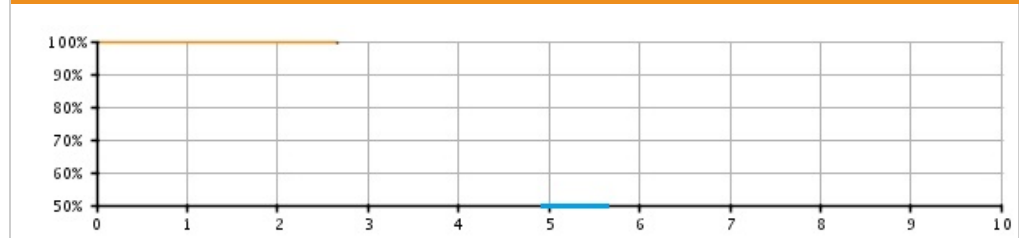
Models D000/D001/D010/D011/D020/
D021

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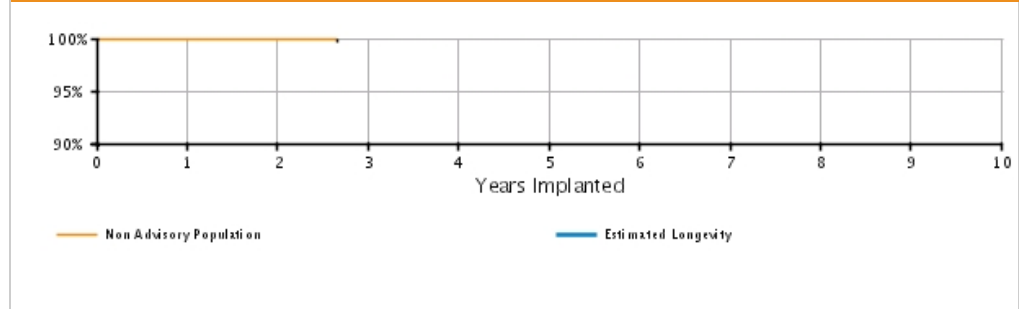
U.S. Summary

U.S. Registered Implants: 6,000	U.S. Normal Battery Depletions: 3
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: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)	99.93 (-0.1/+0.0)	99.84 (-0.2/+0.1)	99.70 @ 32 mo. (-0.5/+0.2)	-	-	-	-	-	-	-
Registered Implants: 6000	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.88 (-0.2/+0.1)	99.88 @ 32 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Effective Sample Size	3597	1386	234	-	-	-	-	-	-	-

CRM PRODUCT PERFORMANCE REPORT Q2 2017

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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DYNAGEN/INOGEN/ORIGEN ICD MINI VR 

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

Worldwide Distribution: 13,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	5	1	6
⁶⁵ Low-voltage capacitors	2	-	
⁸⁰ High voltage circuit component	3	-	
⁸² High voltage capacitor	-	1	
Mechanical	-	-	0
Software	1	1	2
⁶⁹ Memory errors	1	1	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	8	2	10

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

INCEPTA/ENERGEN/PUNCTUA ICD DR

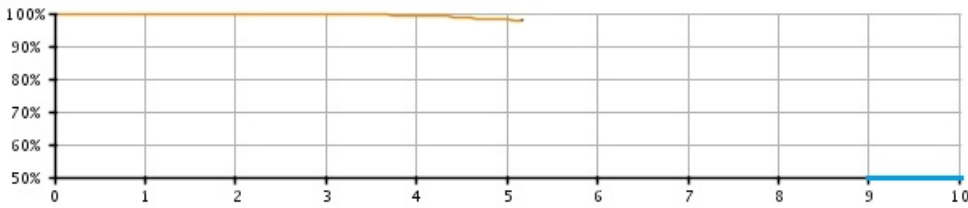
Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

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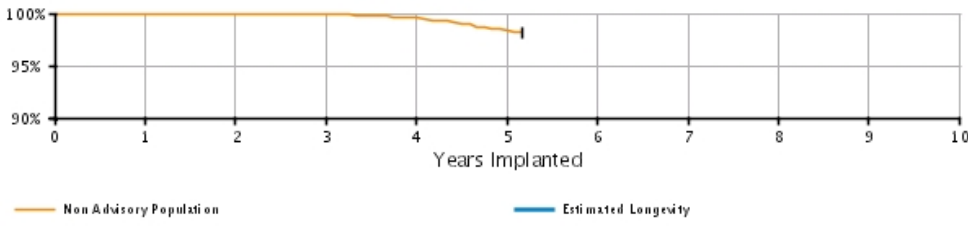
U.S. Summary

U.S. Registered Implants: 47,000	U.S. Normal Battery Depletions: 45
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 39,000	U.S. Malfunctions:132
	Without Compromised Therapy:124
	With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.0)	99.34 (-0.1/+0.1)	98.03 (-0.5/+0.4)	97.88 @ 62 mo. (-0.6/+0.5)	-	-	-	-
Registered Implants: 47000	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.54 (-0.1/+0.1)	98.38 (-0.4/+0.3)	98.23 @ 62 mo. (-0.6/+0.4)	-	-	-	-
	Effective Sample Size	40930	34006	21197	9524	1126	281	-	-	-	-

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: 199

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	173	7	180
⁶¹ High-voltage capacitor	1	2	
⁶⁵ Low-voltage capacitors	3	-	
⁶⁸ Integrated circuit	5	3	
⁷¹ Battery	8	1	
⁷² Low-voltage capacitor	155	1	
⁷⁶ High voltage circuit	1	-	
Mechanical	-	2	2
⁵⁴ Transformer	-	2	
Software	3	-	3
⁶⁹ Memory errors	3	-	
Other	9	5	14
Non-patterned	9	5	
WW Confirmed Malfunctions	185	14	199

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

INCEPTA/ENERGEN/PUNCTUA ICD VR

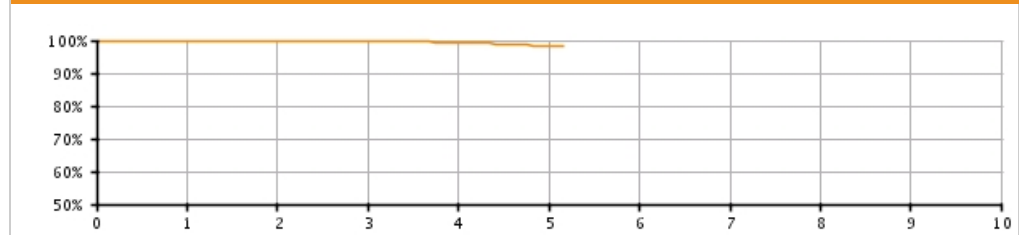
Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

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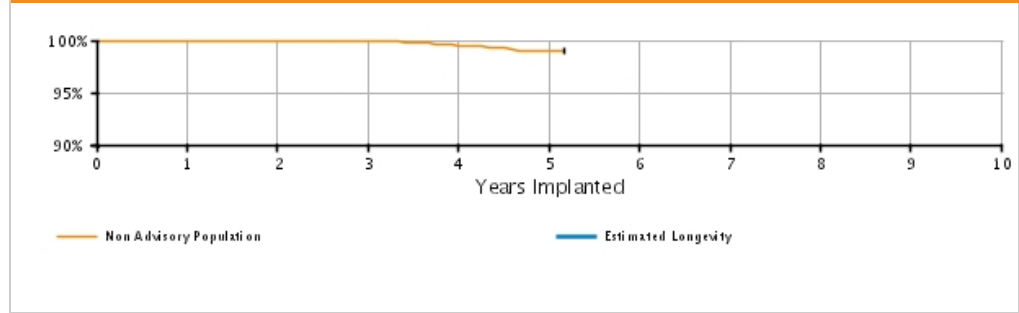
U.S. Summary

U.S. Registered Implants: 39,000	U.S. Normal Battery Depletions: 52
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 33,000	U.S. Malfunctions:90
	Without Compromised Therapy:77
	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)	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.25 (-0.2/+0.1)	98.33 (-0.4/+0.3)	98.33 @ 62 mo. (-0.4/+0.3)	-	-	-	-
Registered Implants: 39000	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.50 (-0.1/+0.1)	98.92 (-0.3/+0.3)	98.92 @ 62 mo. (-0.3/+0.3)	-	-	-	-
	Effective Sample Size	34544	28504	17564	7722	961	244	-	-	-	-

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: 142

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	113	7	120
⁶¹ High-voltage capacitor	1	1	
⁶⁸ Integrated circuit	2	4	
⁷¹ Battery	9	1	
⁷² Low-voltage capacitor	101	-	
⁷⁶ High voltage circuit	-	1	
Mechanical	-	5	5
⁵⁴ Transformer	-	5	
Software	5	-	5
⁶⁹ Memory errors	5	-	
Other	6	6	12
Non-patterned	6	6	
WW Confirmed Malfunctions	124	18	142

[More details](#) about malfunctions

[References](#) cited in table above

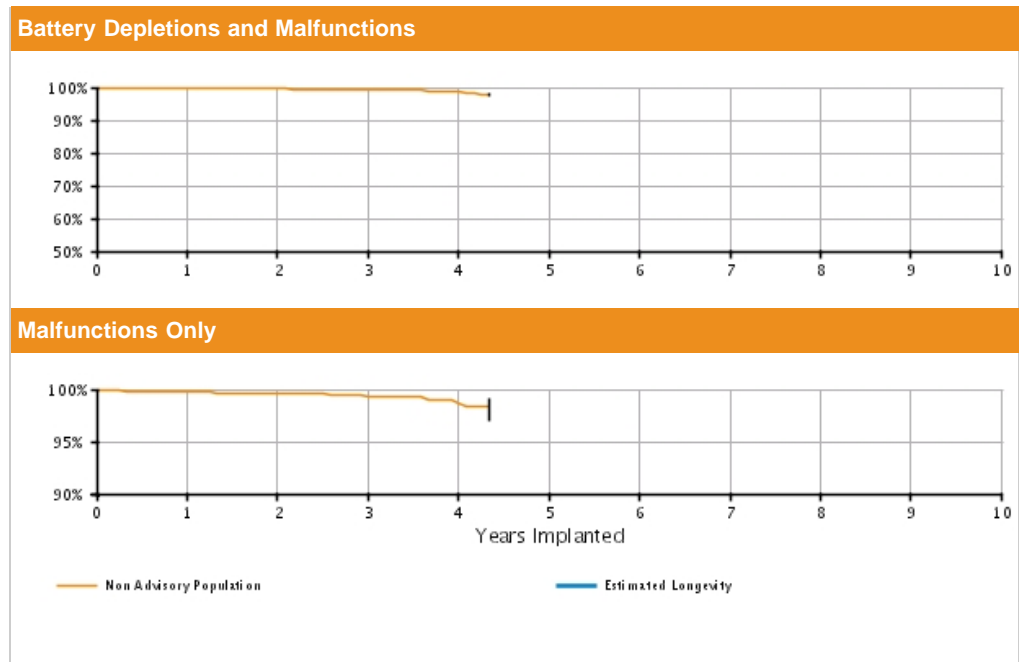
CRM PRODUCT PERFORMANCE REPORT Q2 2017

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: 98
U.S. Approval Date: September 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:43
	Without Compromised Therapy:15
	With Compromised Therapy:28




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.75	99.52	99.19	98.62	97.93	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.4/+0.3)	(-1.2/+0.6)	@ 52 mo. (-1.7/+1.0)						
Registered Implants: 8000	Malfunctions Only(%)	99.77	99.57	99.26	98.69	98.38	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.4/+0.3)	(-1.2/+0.6)	@ 52 mo. (-1.4/+0.8)						
	Effective Sample Size	6540	4823	1293	330	215	—	—	—	—	—	—

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: 100			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	8	3	11
² Unintended Fuse Activation 2013	-	3	
⁷⁹ Charge Timeout Alert	8	-	
Mechanical	14	23	37
³ High cathode condition	1	2	
⁷³ Battery depletion	13	21	
Software	2	-	2
⁷⁵ Unintended Battery Depletion Alert	2	-	
Other	17	33	50
Non-patterned	14	24	
⁷⁴ Telemetry	3	9	
WW Confirmed Malfunctions	41	59	100

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

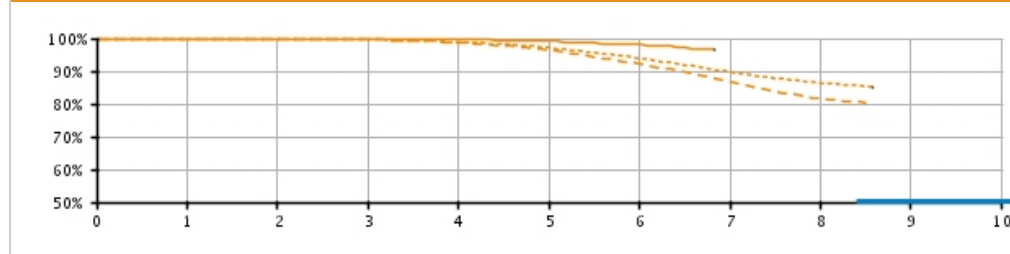
TELIGEN DR

Models E110/E111/F110/F111

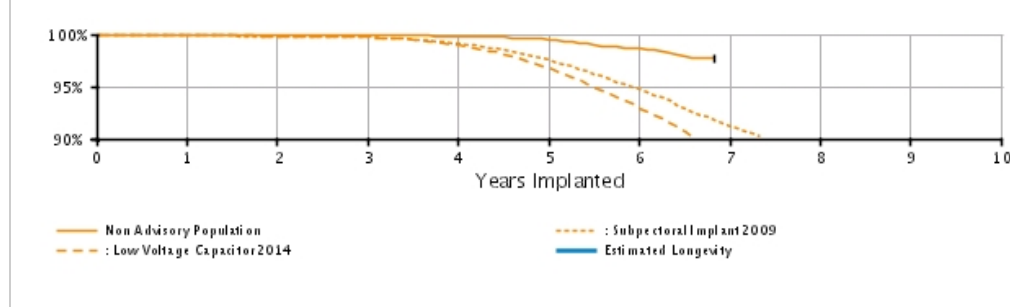
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 66,000	U.S. Normal Battery Depletions: 327
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 161
U.S. Estimated Active Implants: 38,000	U.S. Malfunctions:1896
	Without Compromised Therapy:1768
	With Compromised Therapy:128

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)	99.16 (-0.1/+0.1)	98.07 (-0.2/+0.2)	96.56 @ 82 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)	99.47 (-0.1/+0.1)	98.60 (-0.2/+0.2)	97.70 @ 82 mo. (-0.4/+0.4)	-	-	-
	Effective Sample Size	26439	23336	20591	18093	15500	7308	554	-	-	-
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)	98.88 (-0.1/+0.1)	97.18 (-0.1/+0.1)	93.93 (-0.1/+0.1)	89.77 (-0.2/+0.1)	86.40 (-0.2/+0.3)	85.18 @ 103 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/+0.1)	94.69 (-0.1/+0.1)	91.22 (-0.2/+0.3)	89.07 (-0.2/+0.3)	88.74 @ 103 mo. (-0.4/+0.3)	-
	Effective Sample Size	26747	23500	20670	18052	15609	13223	11043	3979	508	-
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)	98.73 (-0.1/+0.1)	96.37 (-0.1/+0.1)	92.12 (-0.1/+0.1)	86.82 (-0.1/+0.2)	81.52 (-0.3/+0.3)	80.22 @ 102 mo. (-0.4/+0.3)	-
	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 (-0.1/+0.1)	92.93 (-0.1/+0.1)	88.45 (-0.1/+0.1)	84.82 (-0.2/+0.1)	84.33 @ 102 mo.	-
	Effective Sample Size										


									(-0.4/+0.3)	
Effective Sample Size	20715	18218	16009	13974	11985	10031	7118	1388	212	-

*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: 2484			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2262	98	2360
¹ Low Voltage Capacitor 2014 (Advisory issued)	1738	42	
⁶⁰ Safety Core-electrocautery	3	-	
⁶¹ High-voltage capacitor	1	7	
⁶⁵ Low-voltage capacitors	7	-	
⁶⁸ Integrated circuit	20	20	
⁷¹ Battery	176	25	
⁷² Low-voltage capacitor	317	4	
Mechanical	20	53	73
⁴ Subpectoral implant 2009 (Advisory issued)	3	11	
⁵⁴ Transformer	-	20	
⁵⁷ Seal plug	3	-	
⁵⁸ Difficulty securing lead	9	8	
⁶³ Header contacts	3	11	
⁸⁵ Header	2	3	
Software	17	-	17
⁶⁶ Alert messages not displayed post-EOL	3	-	
⁶⁹ Memory errors	14	-	
Other	23	11	34
Non-patterned	23	11	
WW Confirmed Malfunctions	2322	162	2484

[More details](#) about malfunctions

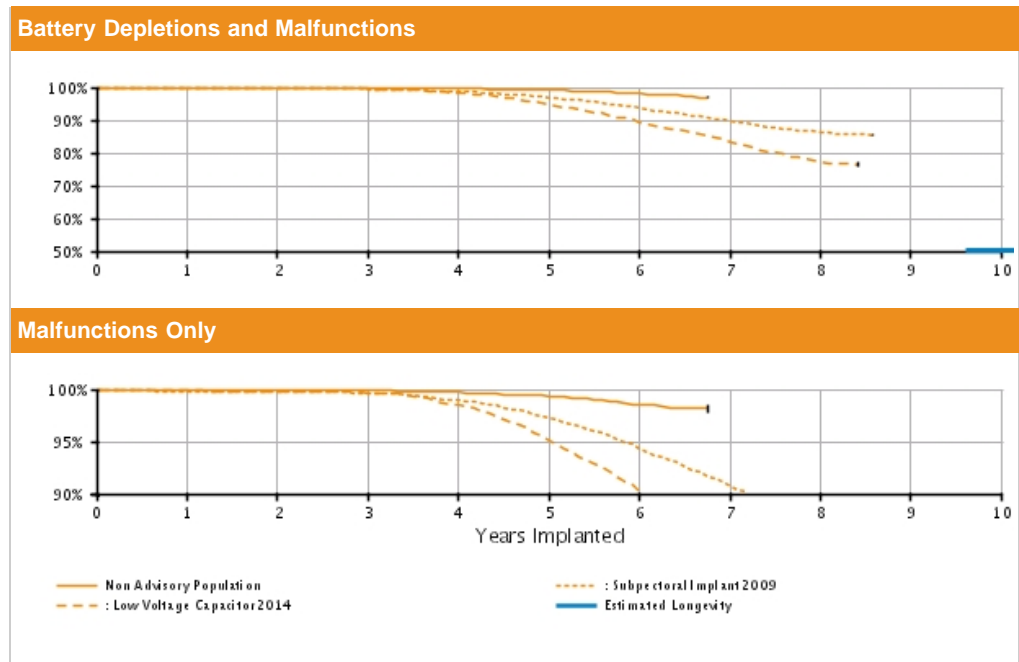
[References](#) cited in table above

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: 96
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 117
U.S. Estimated Active Implants: 22,000	U.S. Malfunctions:1272
	Without Compromised Therapy:1177
	With Compromised Therapy:95



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)	99.15 (-0.2/+0.2)	98.14 (-0.3/+0.3)	96.96 @ 81 mo. (-0.8/+0.6)	-	-	-	-
	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)	99.35 (-0.2/+0.1)	98.54 (-0.3/+0.3)	98.14 @ 81 mo. (-0.4/+0.4)	-	-	-	-
	Effective Sample Size	16275	14325	12583	11032	9459	3562	338	-	-	-	-
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)	89.66 (-0.1/+0.1)	86.32 (-0.2/+0.1)	85.47 @ 103 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)	90.67 (-0.4/+0.3)	88.12 (-0.5/+0.6)	87.92 @ 103 mo. (-0.6/+0.9)	-	-
	Effective Sample Size	13680	11994	10512	9148	7861	6660	5551	2084	289	-	-
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)	94.78 (-0.2/+0.1)	89.46 (-0.3/+0.2)	83.35 (-0.4/+0.2)	74.40 (-0.5/+0.6)	76.34 @ 101 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)	90.26 (-0.1/+0.1)	84.78 (-0.3/+0.2)	79.94 (-0.5/+0.6)	79.46 @ 101 mo.	-	-
	Effective Sample Size	12000	11000	10000	9000	8000	7000	6000	5000	4000	3000	2000

								(-1.5/+1.6)	
Effective Sample Size	10903	9576	8399	7287	6165	5087	3242	674	202
									-

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

TELIGEN VR

Models E102/E103/F102/F103

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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TELIGEN VR Models E102/E103/F102/F103			
Worldwide Distribution: 66,000			
Worldwide Confirmed Malfunctions: 2020			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1814	75	1889
¹ Low Voltage Capacitor 2014 (Advisory issued)	1357	32	
⁶⁰ Safety Core-electrocautery	1	1	
⁶¹ High-voltage capacitor	-	3	
⁶⁵ Low-voltage capacitors	5	-	
⁶⁸ Integrated circuit	10	15	
⁷¹ Battery	249	24	
⁷² Low-voltage capacitor	192	-	
Mechanical	24	70	94
⁴ Subpectoral implant 2009 (Advisory issued)	7	17	
³⁴ Transformer	-	2	
⁵⁴ Transformer	-	14	
⁵⁷ Seal plug	1	-	
⁵⁸ Difficulty securing lead	-	10	
⁶³ Header contacts	14	19	
⁸⁵ Header	2	8	
Software	16	-	16
⁵ Respiratory Sensor Oversensing	1	-	
⁶⁶ Alert messages not displayed post-EOL	4	-	
⁶⁹ Memory errors	11	-	
Other	9	12	21
Non-patterned	9	12	
WW Confirmed Malfunctions	1863	157	2020

[More details](#) about malfunctions

[References](#) cited in table above

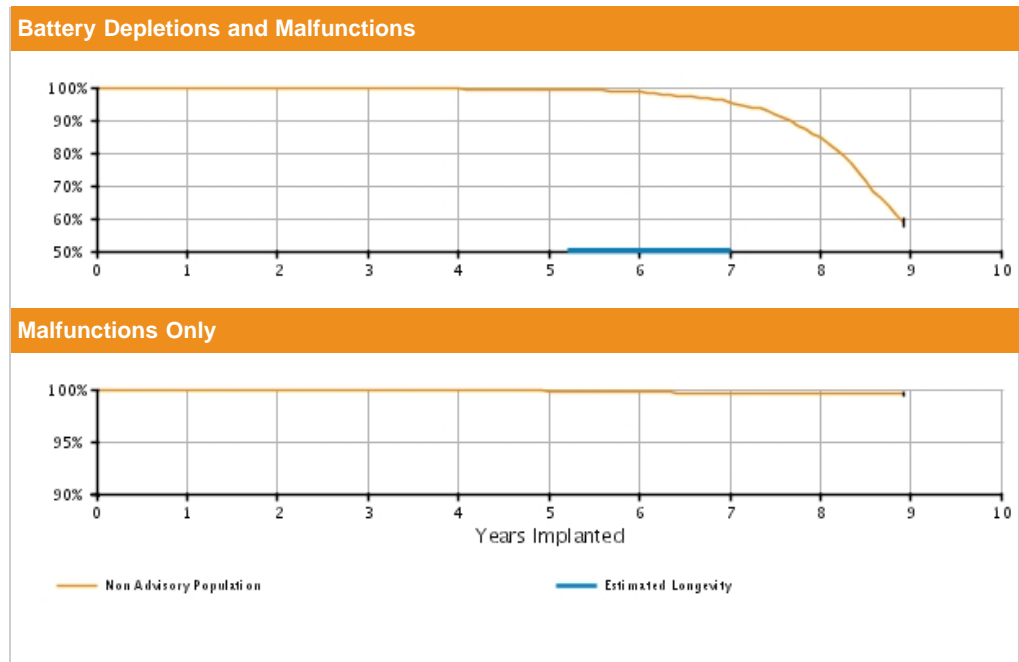
CRM PRODUCT PERFORMANCE REPORT Q2 2017

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: 668
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)	98.54 (-0.4/+0.3)	95.50 (-0.8/+0.7)	84.51 (-1.6/+1.4)	58.78 @ 107 mo. (-2.9/+2.9)	-
	Registered Implants: 7000										
	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)	99.64 (-0.3/+0.2)	99.59 (-0.3/+0.2)	99.59 @ 107 mo. (-0.3/+0.2)	-
	Effective Sample Size	6163	5395	4698	4115	3605	3057	2413	1526	273	-

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

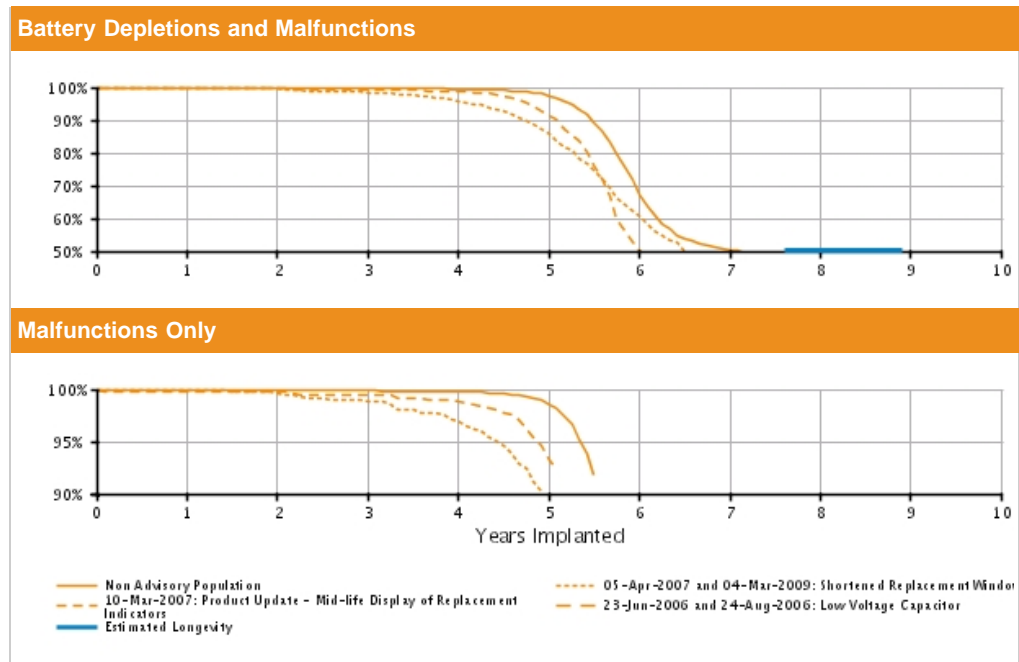
[References](#) cited in table above

VITALITY 2 EL VR

Model T177

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary U.S. Registered Implants: 7,000 U.S. Approval Date: March 2004 U.S. Estimated Active Implants: 1,000	U.S. Normal Battery Depletions: 1,375 U.S. Unconfirmed Reports of Premature Battery Depletion : 9 U.S. Malfunctions:1277 Without Compromised Therapy:1264 With Compromised Therapy:13
-----------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------




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	67.18	50.34	44.34	30.59	—	—
	(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)	@ 106 mo. (-2.6/+2.7)	—	—
	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	60.73	41.15	33.59	—	—	—
	(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(%)	99.95	99.56	98.84	97.00	88.93	68.22	60.82	60.28	—	—	—
	(Confidence Interval)	(-0.3/+0.0)	(-0.5/+0.2)	(-0.7/+0.4)	(-1.1/+0.8)	(-2.1/+1.8)	(-3.2/+3.1)	(-3.5/+3.4)	@ 88 mo. (-3.6/+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: 2000											
Effective Sample Size		3631	3177	2775	2408	2065	1286	757	530	203	—	—

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.										

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: 1930			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1889	8	1897
⁷ Shortened replacement window (Advisory issued)	139	1	
⁸ Low-voltage capacitor (Advisory issued)	2	1	
¹² Extended charge time post-mid-life	21	2	
²³ Integrated circuit	-	3	
³² Capacitor	1	-	
³⁵ Capacitor	2	-	
⁴² Mid-life display of replacement indicators	1657	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	1903	27	1930

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

ACCOLADE/PROONENT/ESSENTIO DR

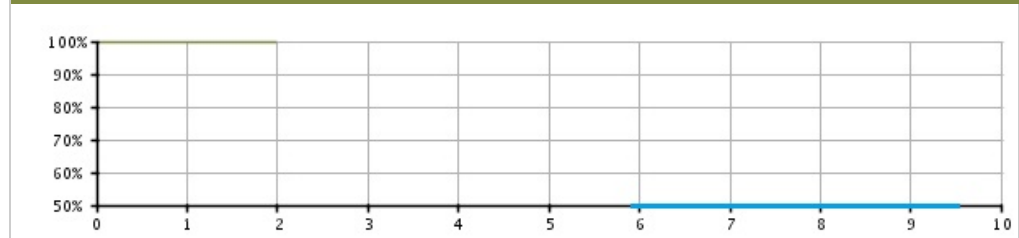
Models L101/L111/L201/L211/L301/
L311

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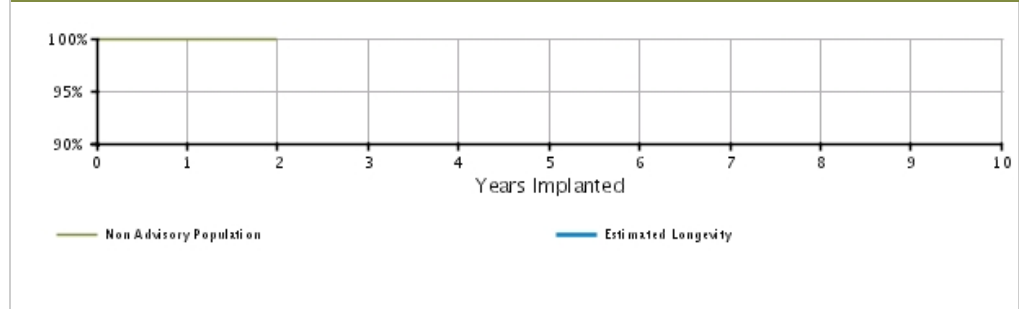
U.S. Summary

U.S. Registered Implants: 69,000	U.S. Normal Battery Depletions: 12
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 5
U.S. Estimated Active Implants: 66,000	U.S. Malfunctions:12
	Without Compromised Therapy:8
	With Compromised Therapy:4

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.90 (-0.1/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 69000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	26326	508	-	-	-	-	-	-	-	-

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: 130,000

Worldwide Confirmed Malfunctions: 19

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	8	4	12
⁶⁵ Low-voltage capacitors	1	-	
⁸¹ Integrated circuit	3	3	
⁸³ Capacitor	3	-	
⁸⁴ Telemetry	1	1	
Mechanical	-	-	0
Software	-	-	0
Other	5	2	7
Non-patterned	5	2	
WW Confirmed Malfunctions	13	6	19

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

ACCOLADE/PROPONENT/ESSENTIO DR EL

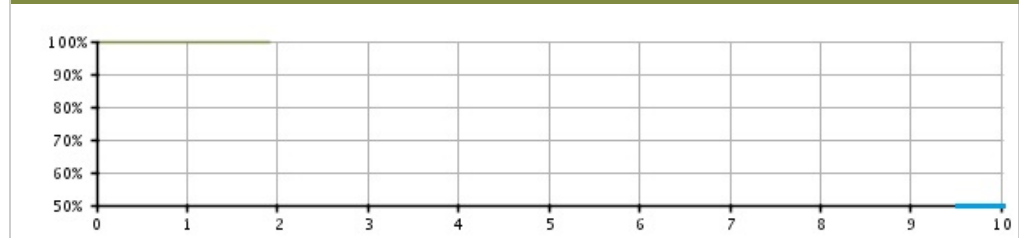
Models L121/L131/L221/L231/L321/
L331

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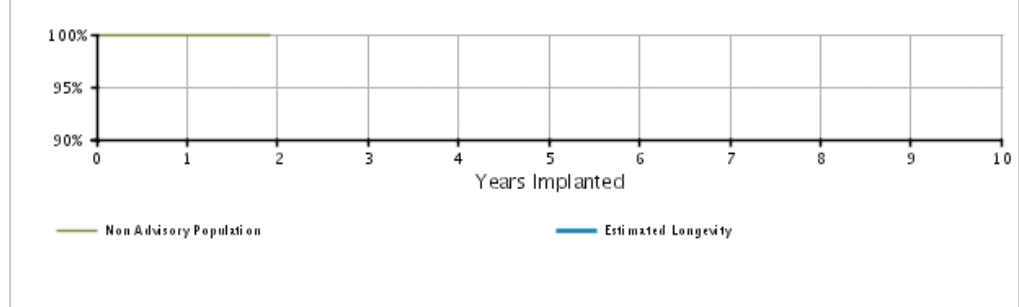
U.S. Summary

U.S. Registered Implants: 24,000	U.S. Normal Battery Depletions: 5
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 24,000	U.S. Malfunctions:6
	Without Compromised Therapy:6
	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 (-0.1/+0.0)	99.87 @ 23 mo. (-0.1/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 24000	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 @ 23 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	7908	434	-	-	-	-	-	-	-	-

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: 60,000

Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	12	-	12
⁶⁵ Low-voltage capacitors	1	-	
⁸¹ Integrated circuit	3	-	
⁸³ Capacitor	8	-	
Mechanical	-	-	0
Software	3	-	3
⁶⁹ Memory errors	3	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	17	0	17

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

ACCOLADE/PROONENT/ESSENTIO SR

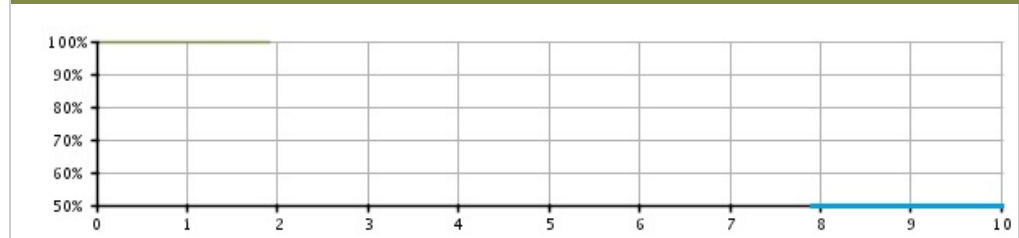
Models L100/L110/L200/L210/L300/
L310

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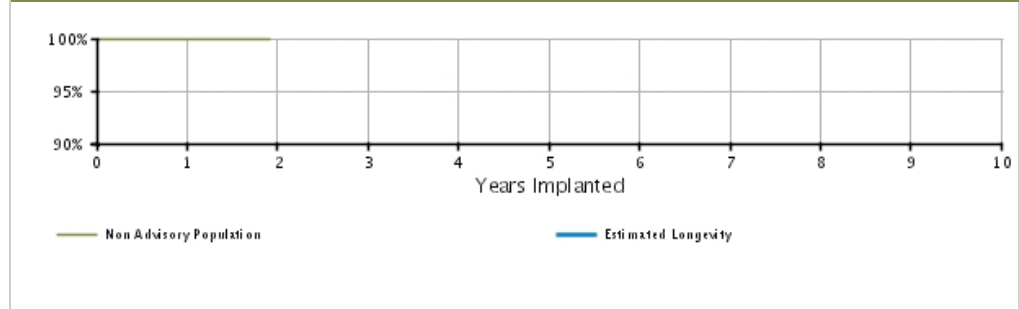
U.S. Summary

U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: October 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 13,000	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)	99.96 (-0.1/+0.0)	99.88 @ 23 mo. (-0.2/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 14000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.95 @ 23 mo. (-0.1/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	4857	235	-	-	-	-	-	-	-	-

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: 45,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	2	5
⁶⁵ Low-voltage capacitors	2	-	
⁸¹ Integrated circuit	-	2	
⁸⁴ Telemetry	1	-	
Mechanical	-	-	0
Software	1	-	1
⁶⁹ Memory errors	1	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	6	2	8

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO/FORMIO DR

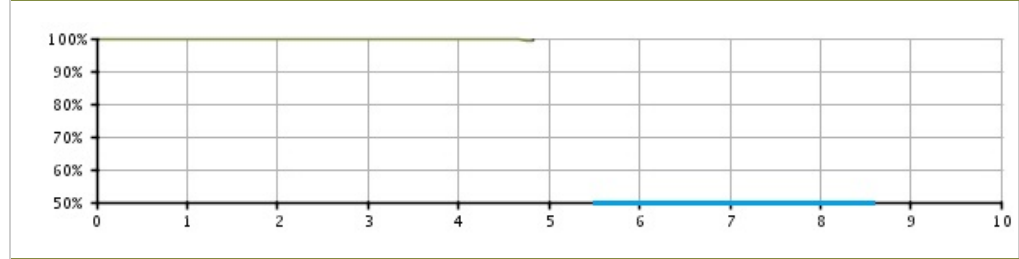
Models J063/J066/J173/J176/J273/
 J276/J278/J279/K063/K066/
 K083/K086/K173/K176/K183/
 K186/K273/K276/K278/K279/
 K283/K286/K288/K289

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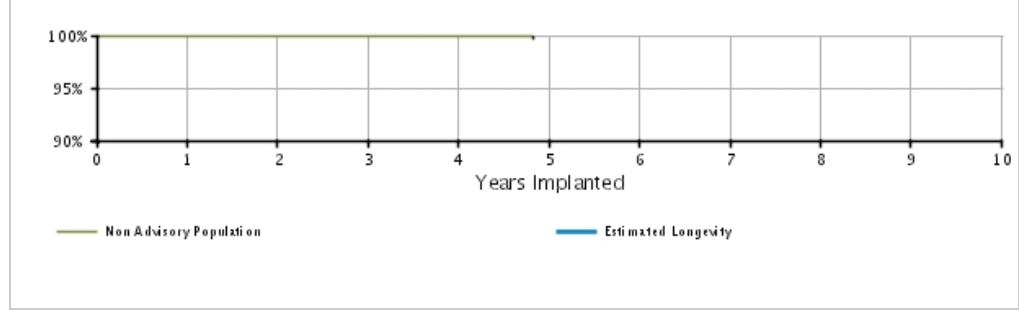
U.S. Summary

U.S. Registered Implants: 121,000	U.S. Normal Battery Depletions: 130
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 12
U.S. Estimated Active Implants: 103,000	U.S. Malfunctions:40
	Without Compromised Therapy:29
	With Compromised Therapy:11

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: 121000	Depletions and Malfunctions(%) (Confidence Interval)		99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.73 (-0.1/+0.0)	99.48 @ 58 mo. (-0.2/+0.2)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)		99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.87 @ 58 mo. (-0.3/+0.1)	-	-	-	-	-
	Effective Sample Size		107659	89914	50260	17604	426	-	-	-	-	-

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: 216,000
Worldwide Confirmed Malfunctions: 58

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	8	17
⁶⁵ Low-voltage capacitors	6	-	
⁶⁸ Integrated circuit	3	6	
⁷⁸ Titanium case material	-	2	
Mechanical	-	-	0
Software	14	1	15
⁶⁹ Memory errors	14	1	
Other	22	4	26
Non-patterned	22	4	
WW Confirmed Malfunctions	45	13	58

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO EL DR

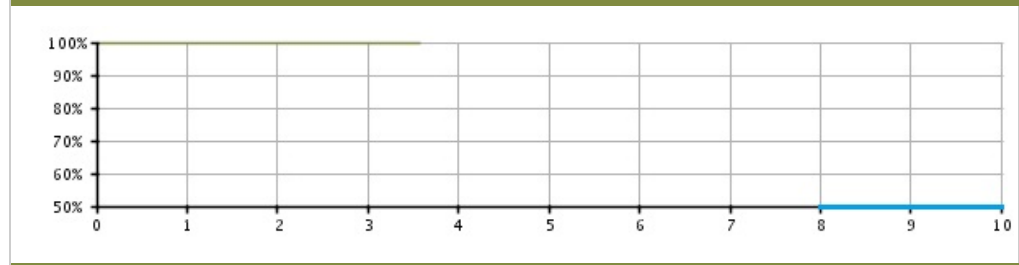
Models J064/J067/J174/J177/J274/
 J277/K064/K067/K084/K087/
 K174/K177/K184/K187/K274/
 K277/K284/K287

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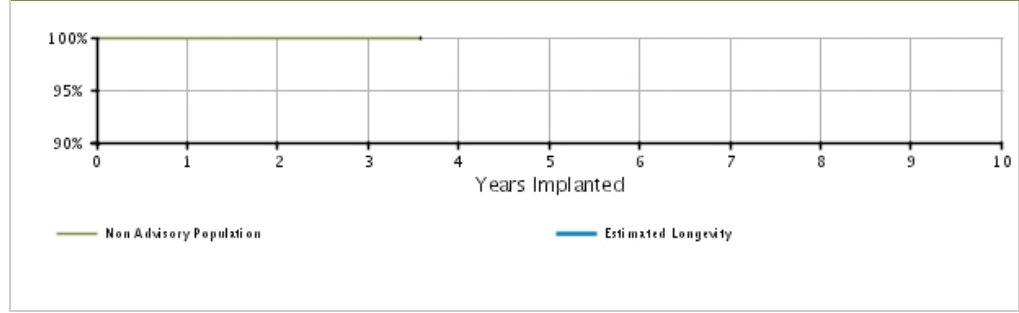
U.S. Summary

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)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 @ 46 mo. (-0.1/+0.1)	-	-	-	-	-	-
Registered Implants: 11000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 46 mo. (-0.1/+0.0)	-	-	-	-	-	-
	Effective Sample Size	9573	7341	2137	219	-	-	-	-	-	-

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: 71,000
Worldwide Confirmed Malfunctions: 23

	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	5	-	5
⁶⁹ Memory errors	4	-	
⁷⁷ Respiratory sensor	1	-	
Other	7	2	9
Non-patterned	7	2	
WW Confirmed Malfunctions	16	7	23

[More details](#) about malfunctions

[References](#) cited in table above

ADVANTIO/INGENIO/VITALIO SR

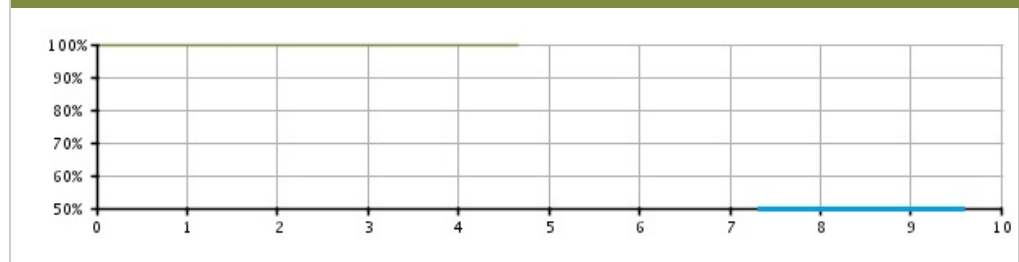
Models J062/J065/J172/J175/J272/
 J275/K062/K065/K082/K085/
 K172/K175/K182/K185/K272/
 K275/K282/K285

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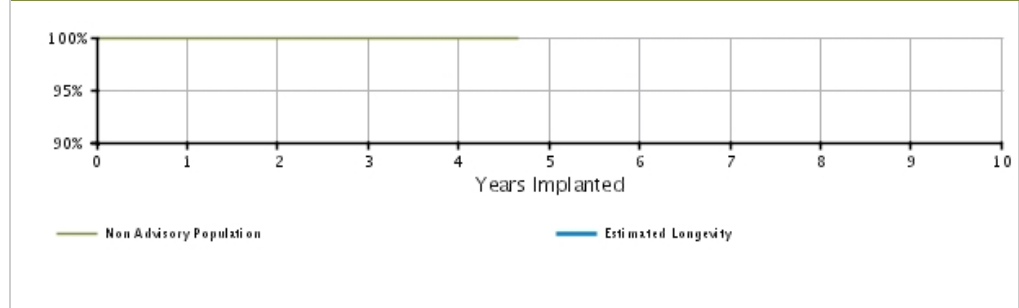
U.S. Summary

U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 17
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 20,000	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)	99.94 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.86 @ 56 mo. (-0.1/+0.1)	-	-	-	-	-	-
	Registered Implants: 27000											
	Malfunctions Only (%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 56 mo. (-0.0/+0.0)	-	-	-	-	-	-
	Effective Sample Size	22841	18079	9696	3209	409	-	-	-	-	-	-

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: 84,000
Worldwide Confirmed Malfunctions: 18

	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	5	-	5
⁶⁹ Memory errors	5	-	
Other	1	3	4
Non-patterned	1	3	
WW Confirmed Malfunctions	10	8	18

[More details](#) about malfunctions

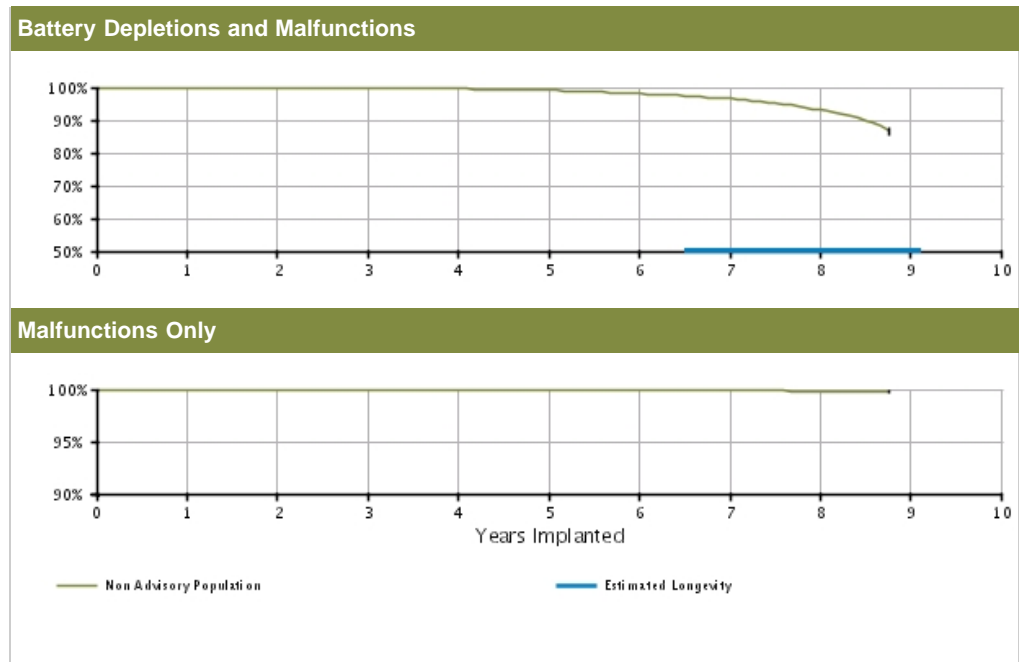
[References](#) cited in table above

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: 607
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Estimated Active Implants: 13,000	U.S. Malfunctions:16
	Without Compromised Therapy:15
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.99	99.94	99.85	99.53	99.03	98.06	96.53	93.08	86.64	—	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.3/+0.2)	(-0.4/+0.3)	(-0.6/+0.6)	@ 105 mo. (-2.3/+2.0)		
Registered Implants: 22000	Malfunctions Only(%)	99.99	99.98	99.98	99.98	99.98	99.97	99.91	99.80	99.76	—	—
	(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)	@ 105 mo. (-0.2/+0.1)		
	Effective Sample Size	19554	17310	15238	13275	11329	9067	6927	3662	201	—	—

ALTRUA 60 DR

Model S602

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 60 DR Model S602 			
Worldwide Distribution: 56,000			
Worldwide Confirmed Malfunctions: 25			
	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	20	2	22
Non-patterned	2	1	
³⁷ Battery depletion	1	1	
⁶⁷ Battery status	17	-	
WW Confirmed Malfunctions	22	3	25

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

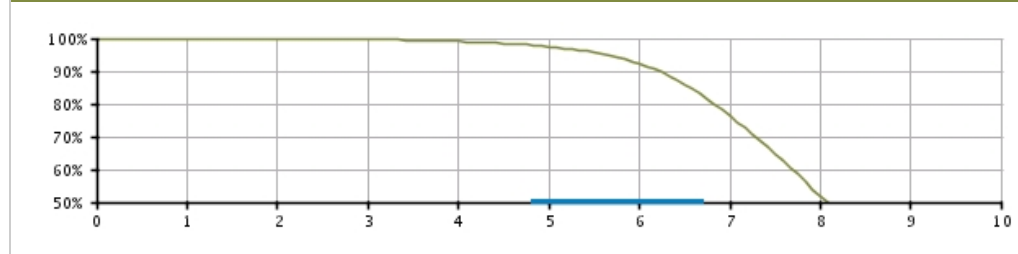
ALTRUA 60 DR (Downsize)

Model S603

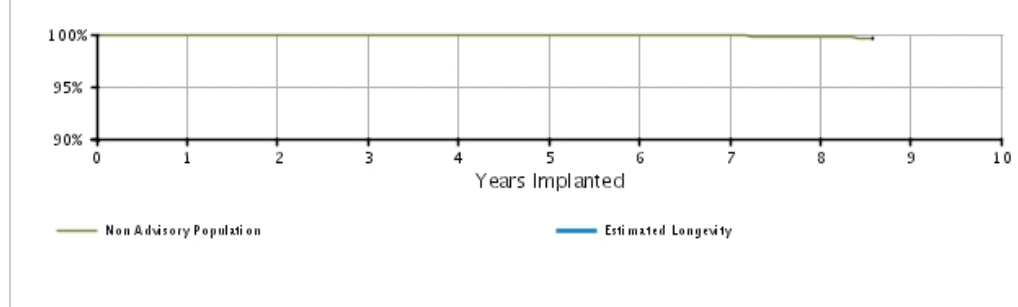
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 90,000	U.S. Normal Battery Depletions: 9,869
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 46
U.S. Estimated Active Implants: 47,000	U.S. Malfunctions:63
	Without Compromised Therapy:55
	With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.91	99.66	99.09	97.47	92.23	76.30	51.89	36.73	—
	(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)	(-0.5/+0.5)	(-0.9/+0.9)	@ 104 mo. (-1.7/+1.7)	
Registered Implants: 90000	Malfunctions Only(%)	99.99	99.99	99.98	99.98	99.96	99.90	99.85	99.77	99.68	—
	(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)	@ 104 mo. (-0.3/+0.1)	
	Effective Sample Size	79405	70670	62764	55012	44189	28313	13316	3273	221	—

ALTRUA 60 DR (Downsize)

Model S603

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 60 DR (Downsize) Model S603 			
Worldwide Distribution: 132,000			
Worldwide Confirmed Malfunctions: 80			
	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	63	3	66
Non-patterned	3	2	
²⁸ Magnet response	1	-	
³⁷ Battery depletion	3	1	
⁶⁷ Battery status	56	-	
WW Confirmed Malfunctions	70	10	80

[More details](#) about malfunctions

[References](#) cited in table above

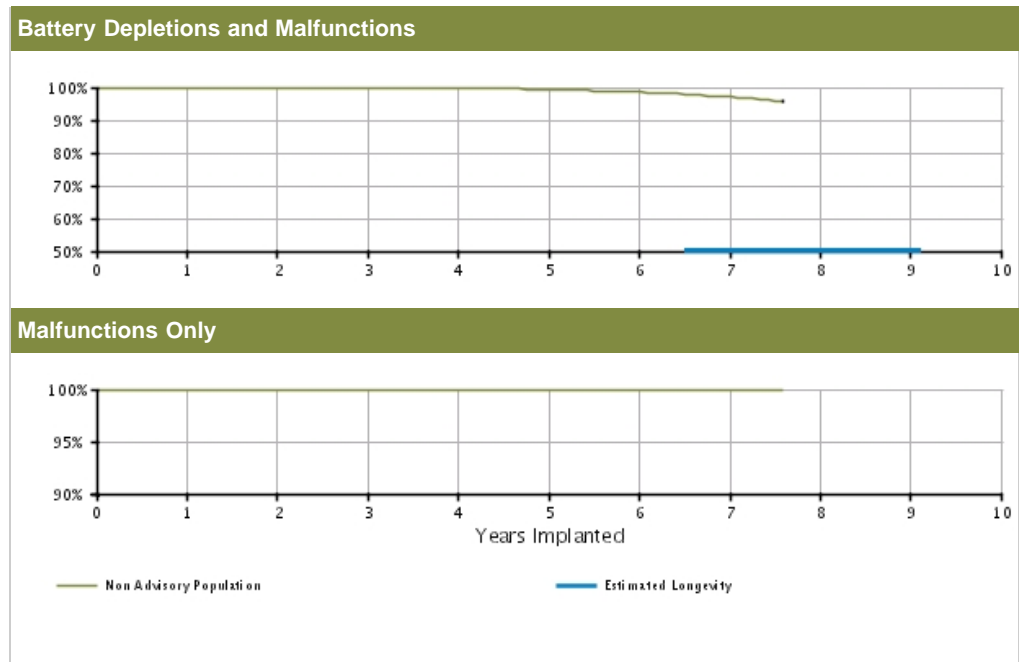
CRM PRODUCT PERFORMANCE REPORT Q2 2017

ALTRUA 60 DR EL

Model S606

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 59,000	U.S. Normal Battery Depletions: 568
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Estimated Active Implants: 41,000	U.S. Malfunctions:10
	Without Compromised Therapy:8
	With Compromised Therapy:2




U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.34 (-0.1/+0.1)	98.55 (-0.2/+0.1)	97.20 (-0.3/+0.3)	94.72 @ 94 mo. (-1.1/+0.9)	-	-
	Registered Implants: 59000										
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 94 mo. (-0.0/+0.0)	-	-
	Effective Sample Size	52722	46896	41610	36426	28443	15336	5391	293	-	-

ALTRUA 60 DR EL

Model S606

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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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

CRM PRODUCT PERFORMANCE REPORT Q2 2017

ALTRUA 60 SR

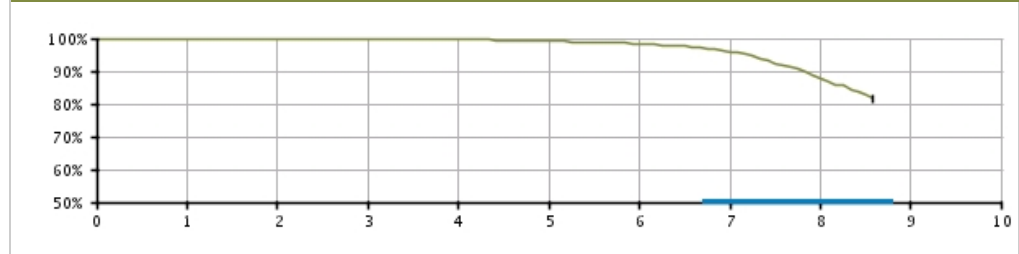
Model S601

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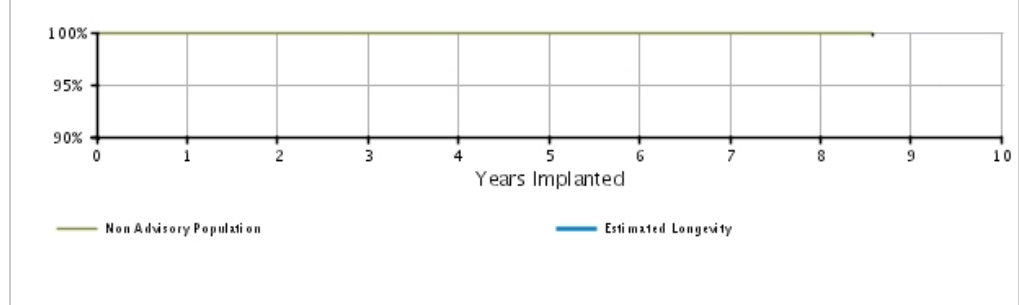
U.S. Summary

U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 694
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Estimated Active Implants: 16,000	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)	99.14 (-0.1/+0.1)	98.31 (-0.2/+0.2)	95.98 (-0.4/+0.4)	87.97 (-1.2/+1.1)	81.58 @ 103 mo. (-2.2/+2.0)	-
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)	99.94 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.85 @ 103 mo. (-0.2/+0.1)	-
	Effective Sample Size	26744	23563	20907	18241	14493	9134	4896	1456	289	-

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: 18			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
²⁰ Capacitor	1	2	
⁴⁶ Integrated circuit	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	10	3	13
Non-patterned	1	2	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	9	-	
WW Confirmed Malfunctions	11	7	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: 25,000			
Worldwide Confirmed Malfunctions: 9			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
²⁰ Capacitor	1	4	
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	1	
³⁷ Battery depletion	-	2	
⁶⁷ Battery status	1	-	
WW Confirmed Malfunctions	2	7	9


[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 50 DR (Downsize)

Model S502

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 50 DR (Downsize) Model S502 			
Worldwide Distribution: 48,000			
Worldwide Confirmed Malfunctions: 23			
	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	18	-	18
Non-patterned	1	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	15	-	
WW Confirmed Malfunctions	21	2	23


[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: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	5	3	8
Non-patterned	-	-	
³⁷ Battery depletion	-	3	
⁶⁷ Battery status	5	-	
WW Confirmed Malfunctions	5	3	8

[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: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	1	3
Non-patterned	-	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	2	-	
WW Confirmed Malfunctions	2	1	3


[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: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	1	3
Non-patterned	-	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	2	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 40 DR

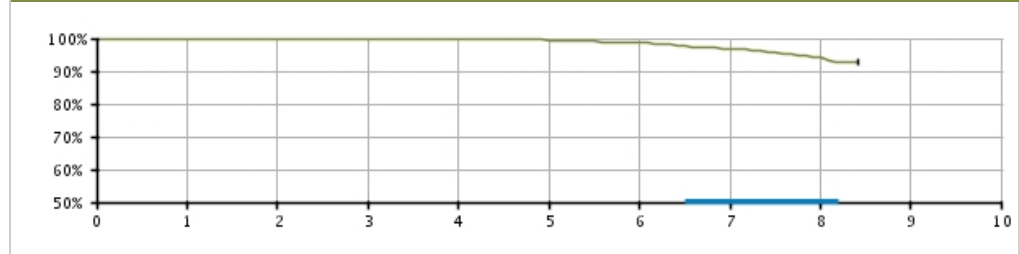
Model S402

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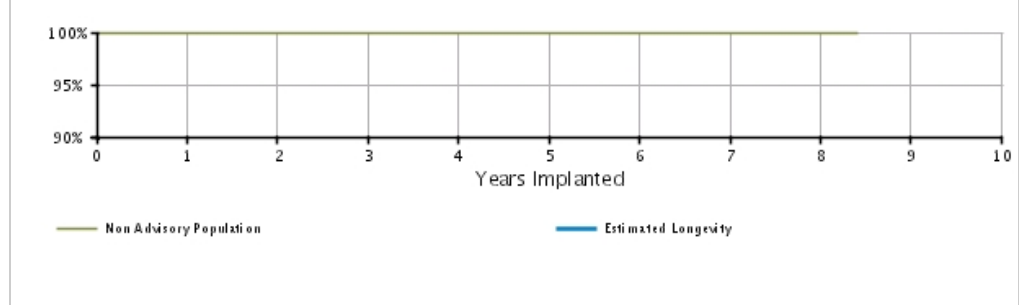
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 58
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)	96.78 (-1.4/+1.0)	94.12 (-1.9/+1.5)	92.81 @ 101 mo. (-2.2/+1.7)	-
Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 101 mo. (-0.0/+0.0)	-
	Effective Sample Size	1517	1346	1194	1064	945	835	724	524	244	-

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

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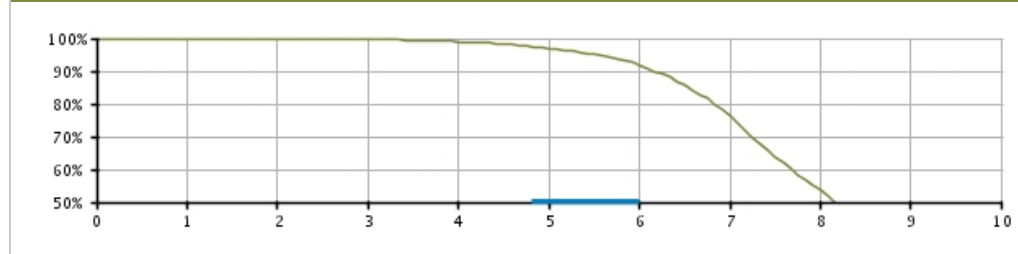
ALTRUA 40 DR (downsize)

Model S403

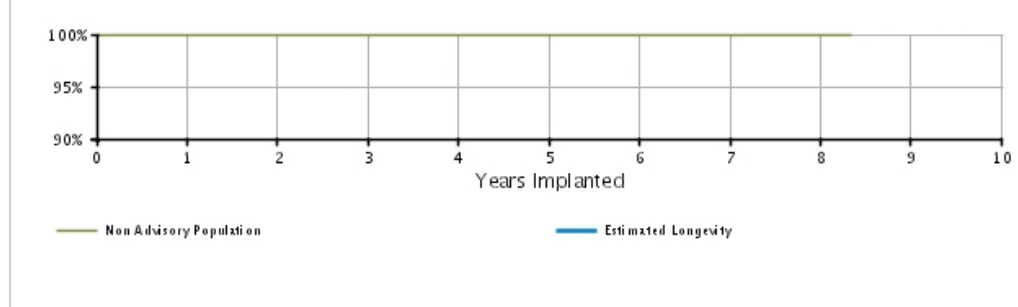
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 1,522
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 7,000	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(%)	99.98	99.91	99.69	98.95	96.93	91.78	76.31	53.72	46.32	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.4/+0.3)	(-0.7/+0.6)	(-1.4/+1.3)	(-2.3/+2.3)	@ 100 mo. (-2.9/+2.9)	
Registered Implants: 14000	Malfunctions Only(%)	99.99	99.99	99.99	99.98	99.97	99.97	99.97	99.97	99.97	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	@ 100 mo. (-0.1/+0.0)	
	Effective Sample Size	12513	11156	9912	8771	7260	4516	1953	454	206	—

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

CRM PRODUCT PERFORMANCE REPORT Q2 2017

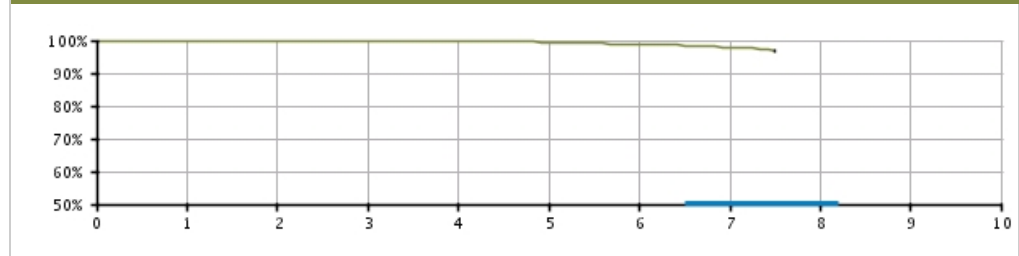
ALTRUA 40 DR EL

Model S404

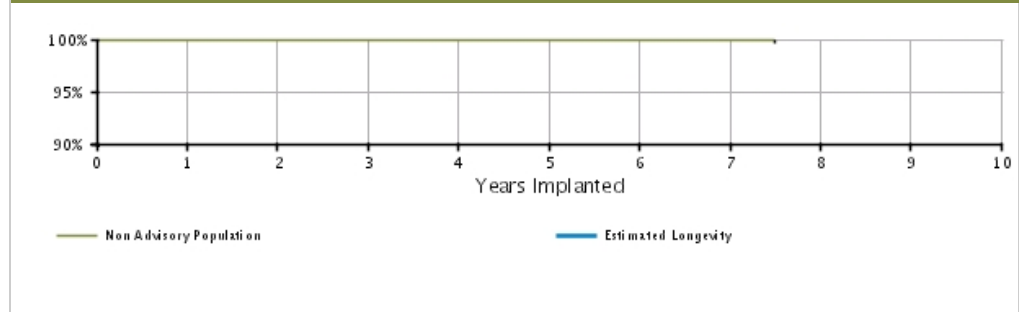
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 45
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions: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)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.40 (-0.3/+0.2)	98.60 (-0.6/+0.4)	97.90 (-0.8/+0.6)	96.93 @ 90 mo. (-1.5/+1.0)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 @ 90 mo. (-0.3/+0.0)	-	-	-
Registered Implants: 5000	Effective Sample Size	4474	3985	3561	3154	2617	1551	710	253	-	-	-

ALTRUA 40 DR EL

Model S404

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

Worldwide Distribution: 11,000
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	-	-	
⁶⁷ Battery status	1	-	
WW Confirmed Malfunctions	2	0	2

[More details](#) about malfunctions

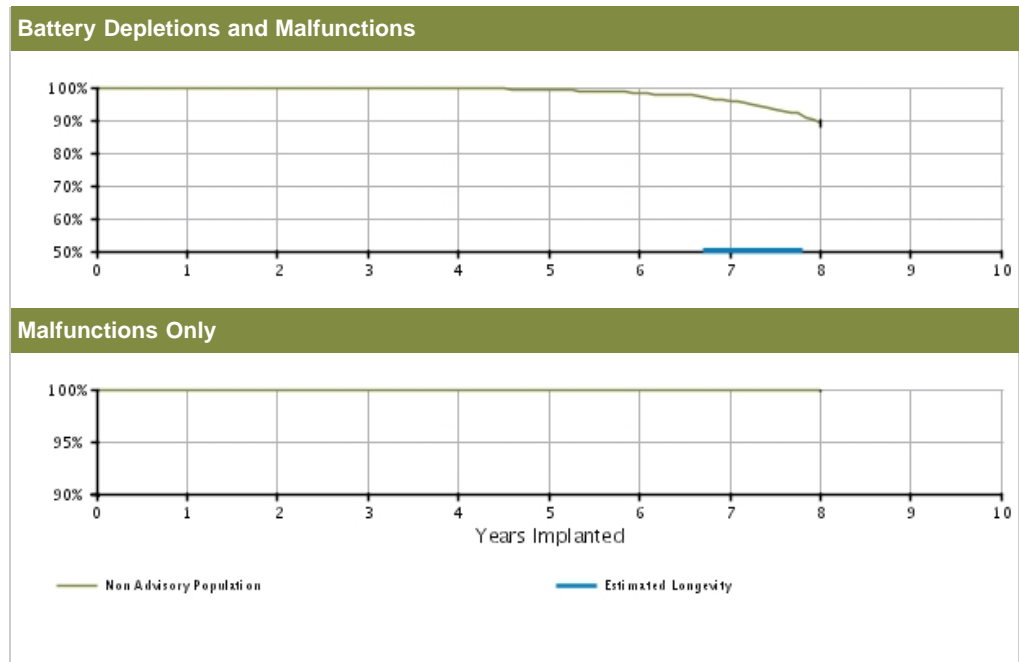
[References](#) cited in table above

ALTRUA 40 SR

Model S401

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

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 95
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




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.91	99.91	99.88	99.66	99.34	98.29	95.80	89.19	—	—	—
	(Confidence Interval)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.2)	(-0.4/+0.2)	(-0.7/+0.5)	(-1.3/+1.0)	(-3.0/+2.4)			
Registered Implants: 5000	Malfunctions Only(%)	99.98	99.98	99.98	99.94	99.94	99.94	99.94	99.94	99.94	—	—
	(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)	(-0.2/+0.0)	(-0.2/+0.0)
Effective Sample Size		3953	3460	3038	2697	2227	1429	725	227	—	—	—

ALTRUA 40 SR

Model S401

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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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

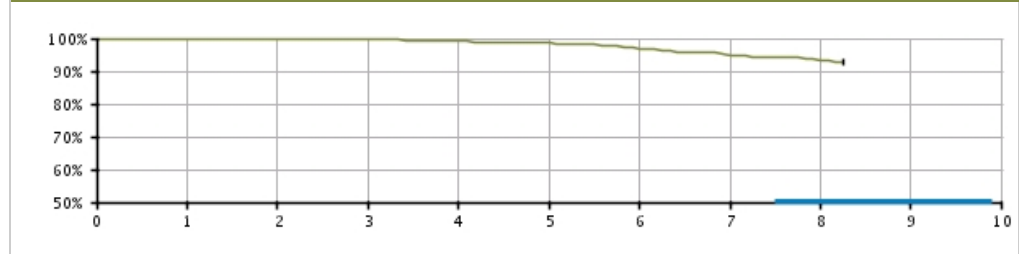
Models S202/S205

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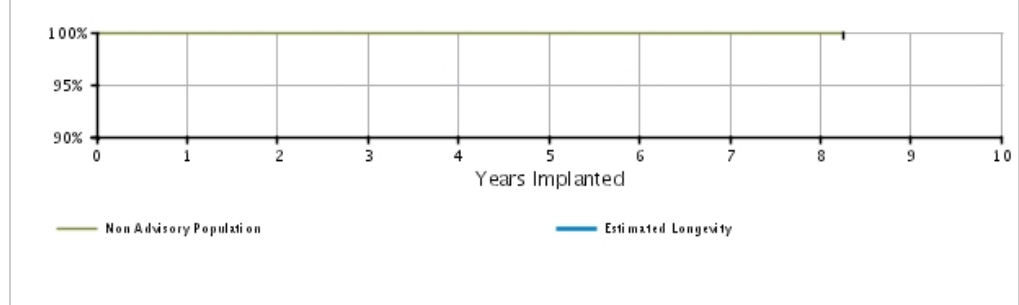
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 51
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

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(%)	100.00	99.93	99.68	99.21	98.58	96.88	94.83	93.40	92.74	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.4/+0.1)	(-0.5/+0.2)	(-0.7/+0.4)	(-0.9/+0.6)	(-1.4/+1.0)	(-1.8/+1.4)	(-2.2/+1.7)	@ 99 mo. (-2.4/+1.8)	
Registered Implants: 2000	Malfunctions Only(%)	100.00	100.00	100.00	99.91	99.91	99.91	99.91	99.91	99.91	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.6/+0.1)	(-0.6/+0.1)	(-0.6/+0.1)	(-0.6/+0.1)	(-0.6/+0.1)	(-0.6/+0.1)	@ 99 mo. (-0.6/+0.1)
	Effective Sample Size	1536	1342	1150	990	851	697	551	368	220	—

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

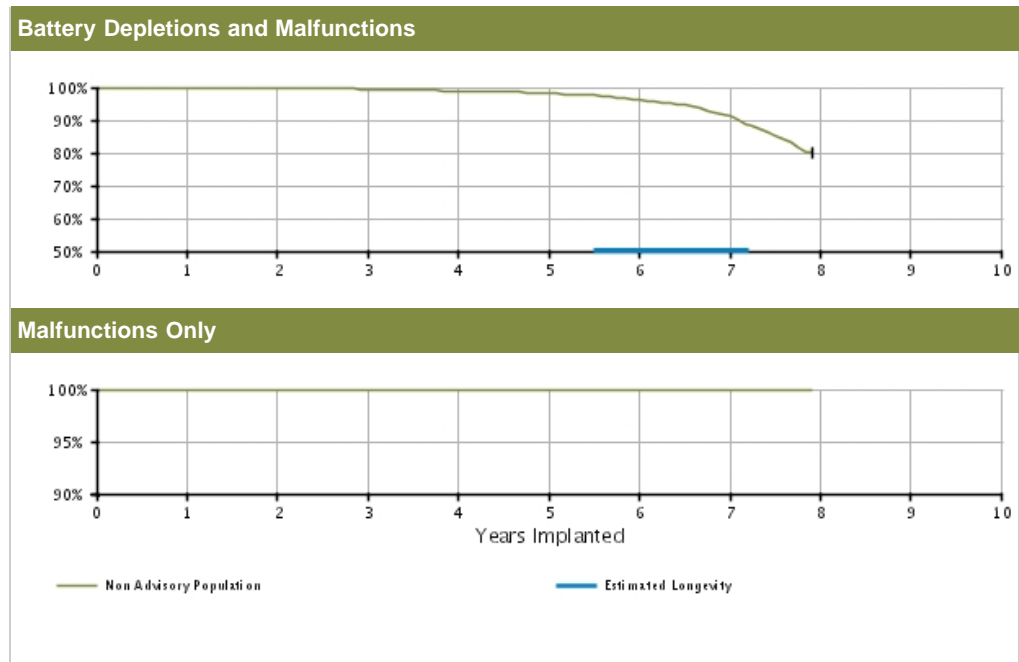
CRM PRODUCT PERFORMANCE REPORT Q2 2017

ALTRUA 20 DR (downsize)

Model S203

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: 268
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
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)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.42 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.16 (-0.5/+0.4)	96.25 (-0.8/+0.7)	90.66 (-1.6/+1.4)	75.20 (-3.5/+3.2)	74.51 @ 97 mo. (-3.7/+3.3)	-
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 @ 97 mo. (-0.0/+0.0)	-
	Effective Sample Size	4405	3891	3458	3064	2573	1708	891	257	215	-

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

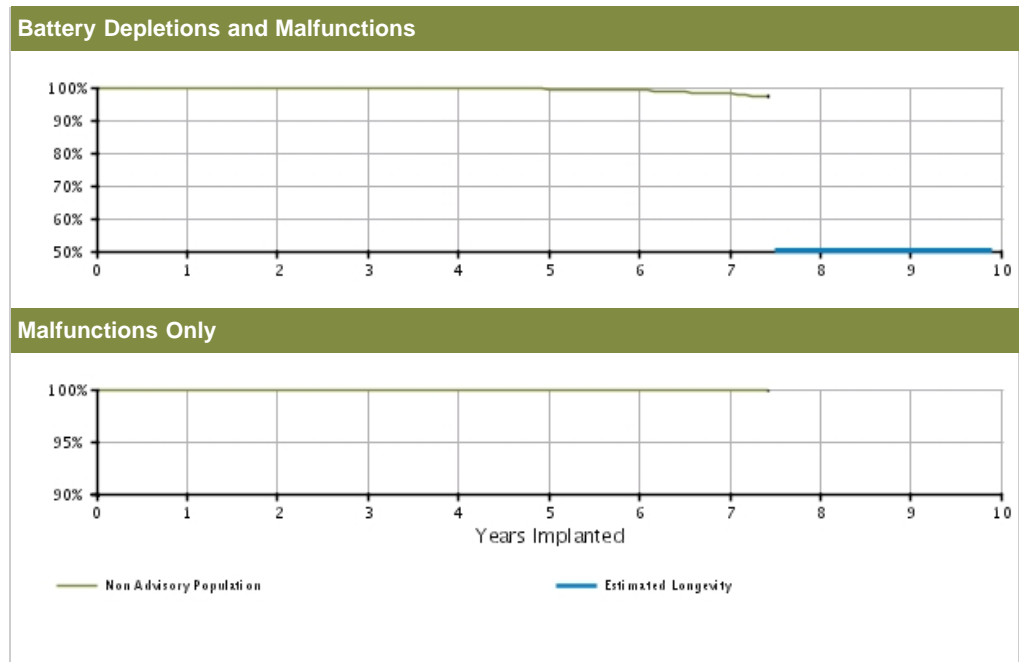
CRM PRODUCT PERFORMANCE REPORT Q2 2017

ALTRUA 20 DR EL

Model S208

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: 24
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.86 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.62 (-0.3/+0.2)	99.45 (-0.4/+0.2)	99.02 (-0.6/+0.4)	98.05 (-1.2/+0.7)	97.43 @ 89 mo. (-1.6/+1.0)	-	-	-
	Registered Implants: 3000											
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 89 mo. (-0.2/+0.0)	-	-
	Effective Sample Size	2771	2466	2189	1954	1591	947	400	214	-	-	-

ALTRUA 20 DR EL

Model S208

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



Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 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

CRM PRODUCT PERFORMANCE REPORT Q2 2017

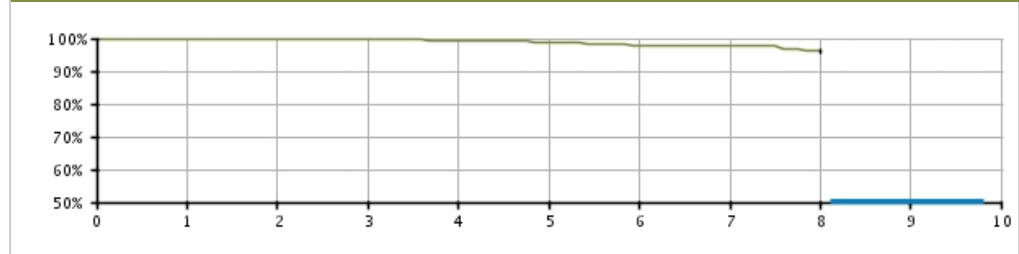
ALTRUA 20 SR

Models S201/S204

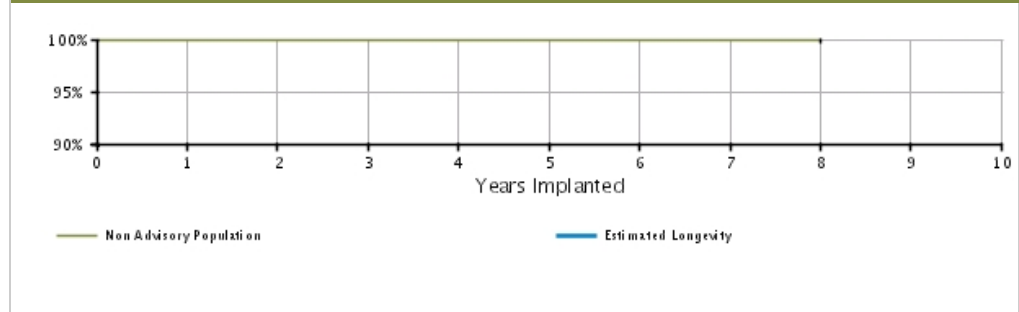
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 50
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: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)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.67 (-0.3/+0.2)	99.34 (-0.4/+0.2)	98.74 (-0.6/+0.4)	97.88 (-0.8/+0.6)	97.53 (-0.9/+0.7)	96.30 (-1.7/+1.2)	-	-
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)	99.94 (-0.4/+0.1)	99.94 (-0.4/+0.1)	99.94 (-0.4/+0.1)	-	-
	Effective Sample Size	3608	3062	2611	2252	1830	1160	616	215	-	-

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: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²⁰ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	-	1	
⁶⁷ Battery status	1	-	
WW Confirmed Malfunctions	2	1	3

[More details](#) about malfunctions

[References](#) cited in table above

ALTRUA 20 SSI

Model S206

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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ALTRUA 20 SSI Model S206			
Worldwide Distribution: 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

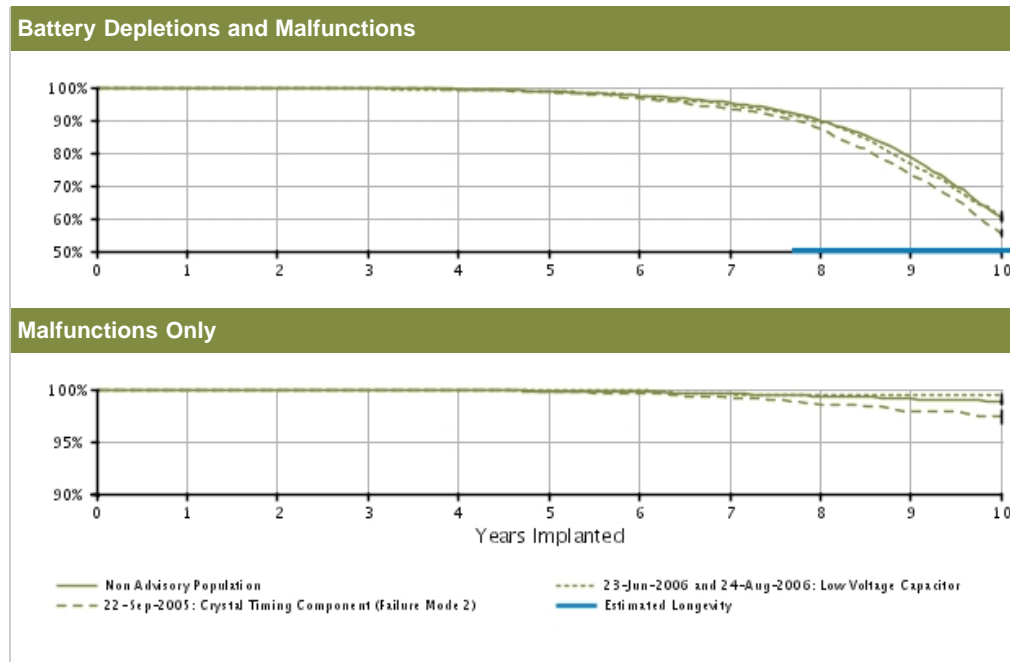
[References](#) cited in table above

INSIGNIA Ultra DR

Model 1291

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

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 4,934
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 21
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:183
	Without Compromised Therapy:170
	With Compromised Therapy:13



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)	89.76 (-0.6/+0.6)	78.56 (-0.9/+0.8)	60.10 (-1.4/+1.4)	
	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)	98.86 (-0.3/+0.2)	
	Effective Sample Size	21001	18656	16557	14647	12903	11295	9792	8147	5290	1499	
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)	89.39 (-2.2/+1.8)	76.96 (-3.1/+2.8)	60.41 (-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	692	519	350	
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)	55.50 (-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)	55.50 (-2.1/+2.1)	
	Effective Sample Size	6000										

Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.95 (-0.7/+0.5)	97.39 (-0.8/+0.6)
Effective Sample Size	5702	5046	4467	3938	3451	2978	2553	2094	1551	996


*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: 227			
	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	190	8	198
Non-patterned	9	7	
¹³ Longevity labeling	75	-	
²⁸ Magnet response	1	-	
³⁷ Battery depletion	3	1	
⁶⁷ Battery status	102	-	
WW Confirmed Malfunctions	209	18	227

[More details](#) about malfunctions

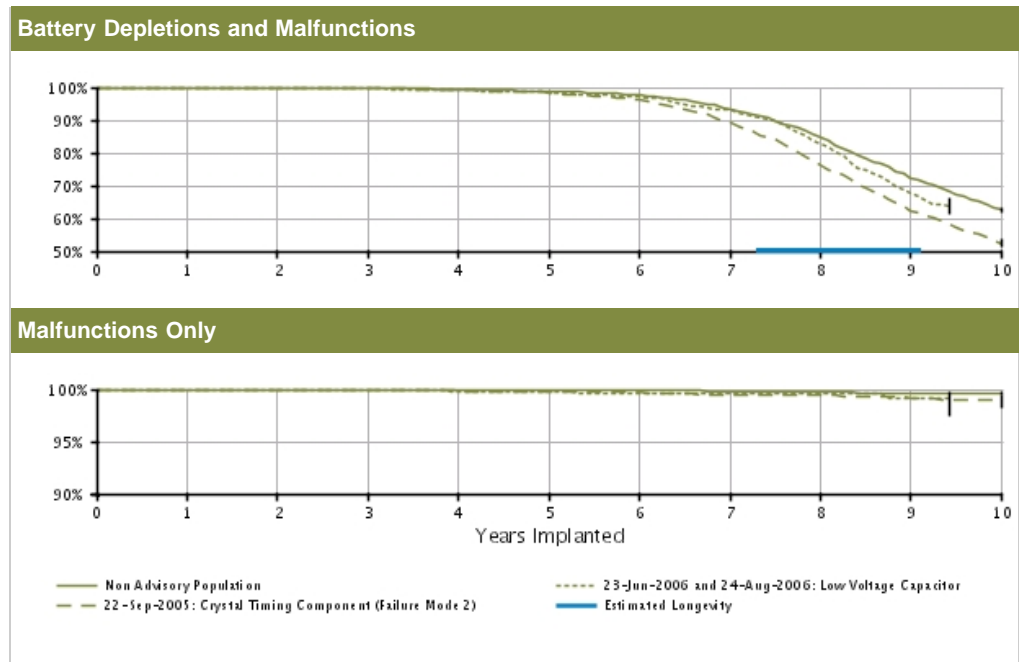
[References](#) cited in table above

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: 2,830
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:41
	Without Compromised Therapy:37
	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)	97.53 (-0.4/+0.3)	93.45 (-0.6/+0.6)	84.58 (-0.9/+0.9)	72.40 (-1.2/+1.2)	62.65 (-1.6/+1.6)	
	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)	99.65 (-0.2/+0.1)	99.61 (-0.2/+0.1)	
	Effective Sample Size	14137	12070	10282	8814	7674	6713	5715	4536	2920	977	
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)	93.19 (-2.5/+1.9)	82.99 (-3.8/+3.2)	67.80 (-4.8/+4.4)	63.81 (-5.0/+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)	99.19 (-1.7/+0.5)	99.19 (-1.7/+0.5)	@ 113 mo. (-1.7/+0.5)
	Effective Sample Size	1146	961	810	696	585	497	415	326	228	NaN	
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)	89.32 (-1.5/+1.3)	76.21 (-2.2/+2.1)	62.32 (-2.6/+2.5)	52.47 (-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	4143	3554	2996	2524	2107	1764	1413	1026	727	525	

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

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

INSIGNIA Ultra SR

Model 1190

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
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INSIGNIA Ultra SR Model 1190			
Worldwide Distribution: 48,000			
Worldwide Confirmed Malfunctions: 72			
	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	60	-	60
Non-patterned	1	-	
¹³ Longevity labeling	23	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	34	-	
WW Confirmed Malfunctions	66	6	72

[More details](#) about malfunctions

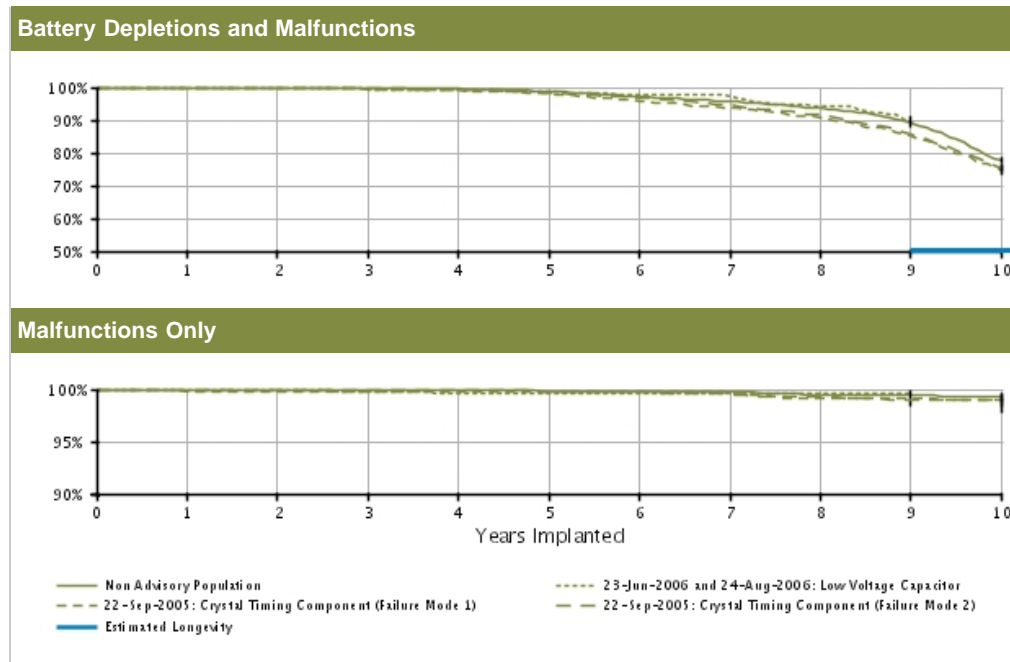
[References](#) cited in table above

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: 2,065
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Estimated Active Implants: 3,000	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	93.54	89.35	77.77	
	(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)	(-2.0/+1.9)	
	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	94.50	89.84	-	
	(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)		
	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	-	
	(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)	
	Registered Implants: 2000											
		Effective Sample Size	6262	5548	4914	4354	3804	3308	2897	2507	1858	830
		Effective Sample Size	692	606	527	450	392	335	292	245	202	-

	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)	99.18 (-1.0/+0.5)	99.18 (-1.0/+0.5)	98.94 (-1.2/+0.6)
	Effective Sample Size	1676	1453	1212	1062	922	783	659	552	449	331
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)	85.54 (-1.4/+1.3)	75.38 (-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	2258	1845	1395

*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: 81			
	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	64	4	68
Non-patterned	4	4	
¹³ Longevity labeling	49	-	
⁶⁷ Battery status	11	-	
WW Confirmed Malfunctions	67	14	81

[More details](#) about malfunctions

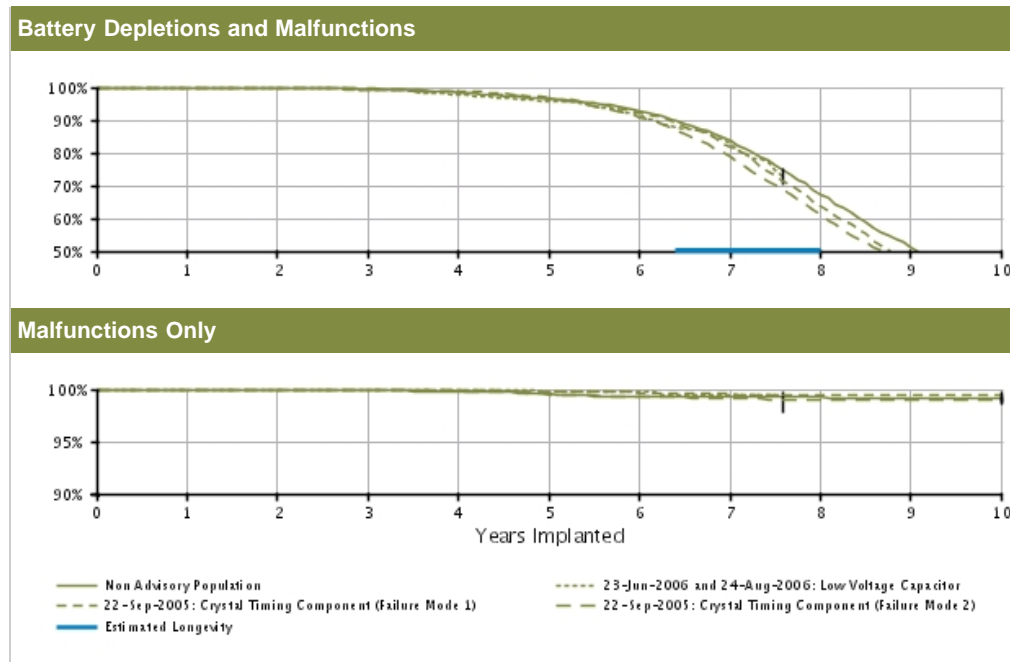
[References](#) cited in table above

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: 5,211
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:97
	Without Compromised Therapy:91
	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	83.66	67.42	51.06	40.24	
	(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)	(-1.8/+1.8)	(-2.0/+2.1)	
	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(%)	100.00	100.00	100.00	100.00	99.75	99.75	99.43	99.43	-	-	
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.0/+0.0)	(-1.5/+0.2)	(-1.5/+0.2)	(-1.7/+0.4)	@ 91 mo. (-1.7/+0.4)			
	Registered Implants: 3000											
		Effective Sample Size	7137	6277	5493	4773	4101	3497	2769	1933	1118	450
		Depletions and Malfunctions(%)	99.83	99.79	99.34	98.82	96.71	92.02	81.76	63.88	45.56	31.59
		(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)

	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	–
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)	90.82 (-0.8/+0.7)	78.97 (-1.2/+1.1)	61.07 (-1.5/+1.5)	44.64 (-1.6/+1.6)	35.51 (-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	9584	8451	7364	6363	5500	4505	3323	2149	1300	882

*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: 120			
	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	106	2	108
Non-patterned	5	2	
¹³ Longevity labeling	95	-	
³⁷ Battery depletion	1	-	
⁶⁷ Battery status	5	-	
WW Confirmed Malfunctions	111	9	120

[More details](#) about malfunctions

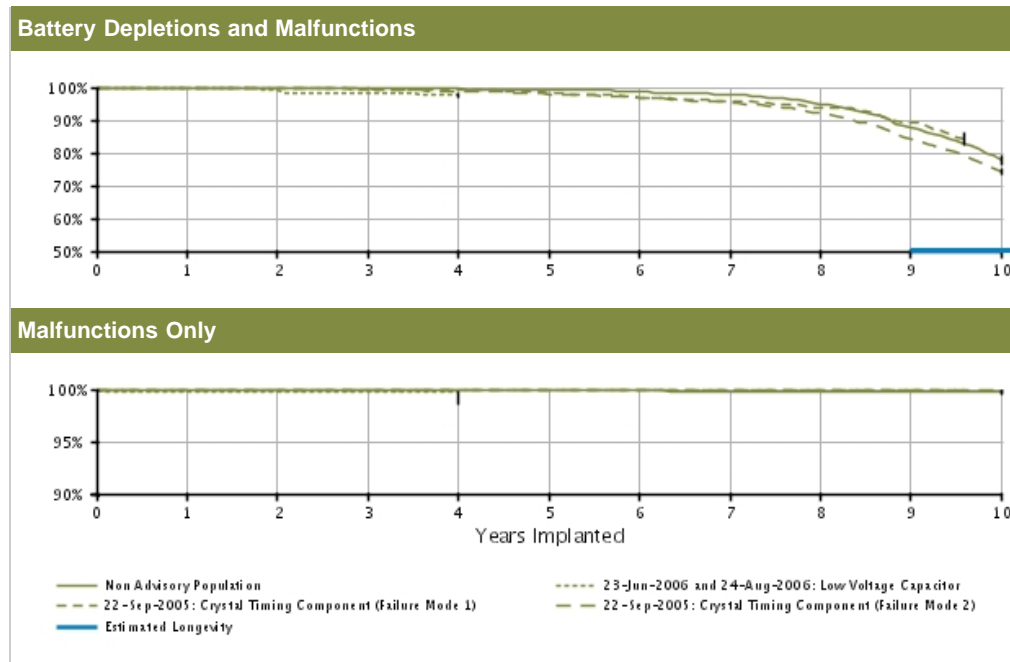
[References](#) cited in table above

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: 1,019
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(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.85 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.74 (-0.5/+0.4)	97.89 (-0.7/+0.5)	94.85 (-1.1/+0.9)	87.91 (-1.8/+1.6)	78.72 (-2.7/+2.4)	
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	
	Effective Sample Size	4707	3871	3248	2732	2304	1974	1722	1455	987	461	
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.											
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.20 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.95 (-1.8/+1.1)	95.71 (-2.1/+1.5)	93.92 (-2.7/+1.9)	89.40 (-3.7/+2.8)	84.27 (-4.5/+3.6)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 115 mo. (-0.0/+0.0)	
	Effective Sample Size	1215	997	805	660	548	445	354	296	242	202	
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.94 (-0.8/+0.6)	95.25 (-1.0/+0.8)	92.15 (-1.3/+1.2)	84.02 (-2.0/+1.8)	74.29 (-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	1528	1273	1009	774	


*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

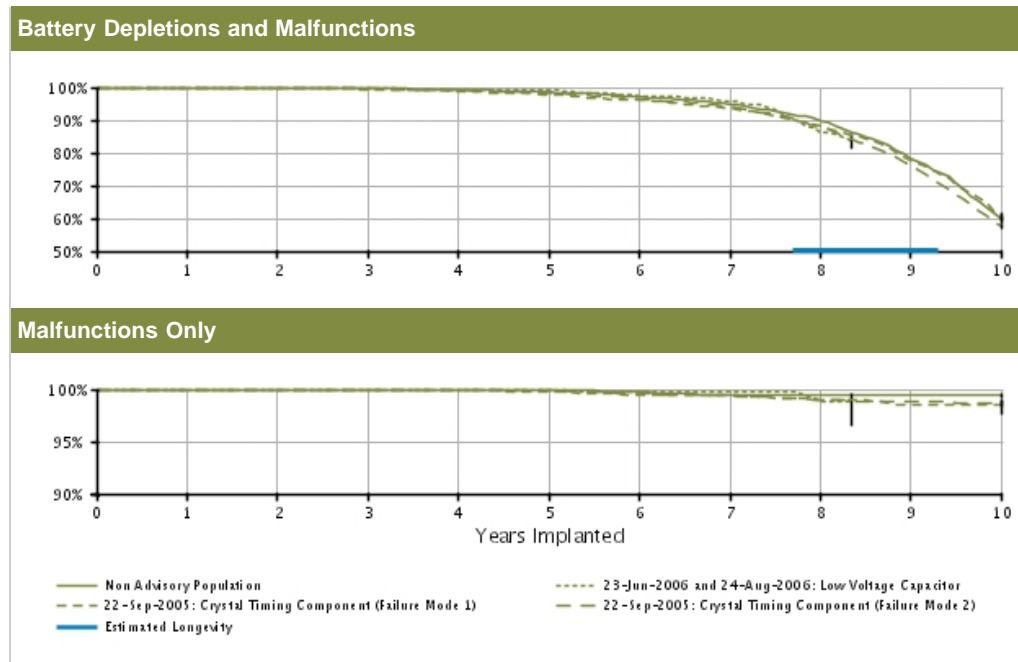
[References](#) cited in table above

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: 5,601
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:128
	Without Compromised Therapy:119
	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	89.80	78.50	59.63	
	(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)	(-1.6/+1.5)	(-2.4/+2.3)	
	Registered Implants: 7000											
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%)	100.00	100.00	100.00	99.18	99.18	97.24	95.94	86.19	83.71	-	
	(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	60.57	
	(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	3495	3029	2525	1731	607
		Effective Sample Size	664	580	510	441	385	333	284	220	201	-

	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	1209	928	611
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.55 (-0.1/+0.1)	99.10 (-0.2/+0.2)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.77 (-0.8/+0.8)	76.06 (-1.2/+1.1)	57.58 (-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	6593	5626	4609	3468	2248


*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: 165			
	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	9	25
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	6	
Software	7	-	7
⁵¹ Underestimation of battery status	4	-	
⁵² Interrupted telemetry	2	-	
⁵³ Pacing rate limit	1	-	
Other	122	5	127
Non-patterned	7	5	
¹³ Longevity labeling	88	-	
³⁷ Battery depletion	2	-	
⁶⁷ Battery status	25	-	
WW Confirmed Malfunctions	148	17	165

[More details](#) about malfunctions

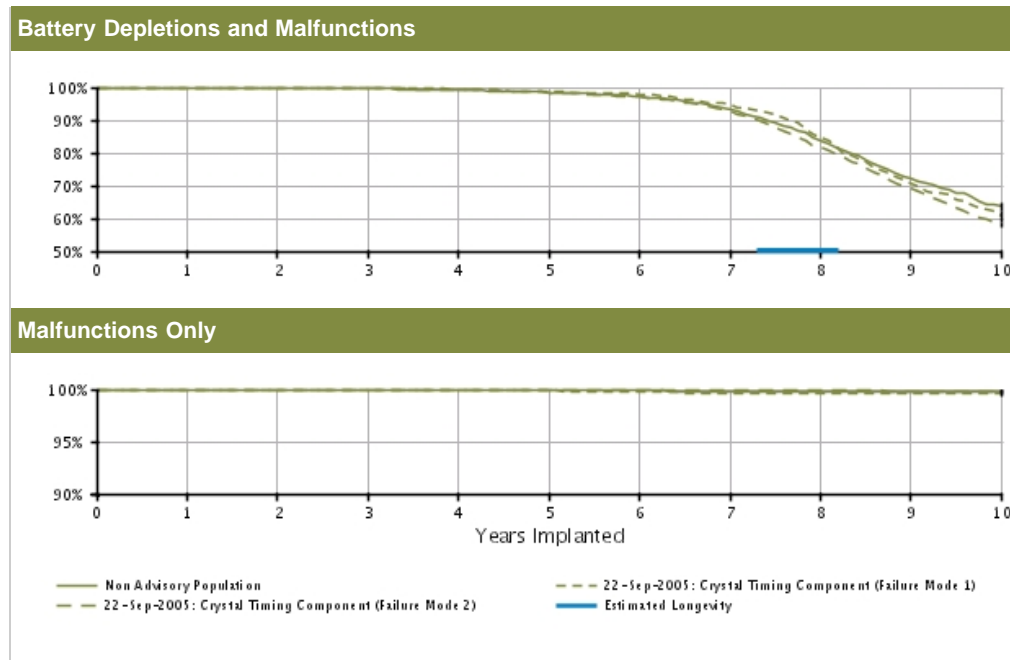
[References](#) cited in table above

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: 3,523
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Estimated Active Implants: 2,000	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	83.52	72.27	63.56
	(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)	(-2.2/+2.1)	(-2.7/+2.6)
	Registered Implants: 6000										
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Malfunctions Only(%)	100.00	100.00	99.97	99.97	99.89	99.85	99.75	99.75	99.75	99.75
	(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.2/+0.0)	(-0.2/+0.0)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)	(-0.3/+0.1)
	Effective Sample Size	4723	4027	3443	2879	2461	2113	1782	1394	917	411
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(%)	99.92	99.89	99.73	99.37	98.74	98.00	94.83	84.78	70.81	60.58
	(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										
22-Sep-05 Crystal Timing	Malfunctions Only(%)	99.92	99.92	99.88	99.88	99.88	99.76	99.68	99.68	99.68	99.68
	(Confidence Interval)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.4/+0.2)	(-0.4/+0.2)	(-0.4/+0.2)
	Effective Sample Size	3451	2915	2414	2061	1736	1429	1163	868	612	450
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.94	99.87	99.65	99.24	98.49	97.08	92.83	81.72	69.39	58.00
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.3/+0.2)	(-0.4/+0.4)	(-0.7/+0.6)	(-1.1/+1.0)	(-1.4/+1.3)	(-1.5/+1.5)

Component (Failure Mode 2)*											
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	13680	11682	10051	8505	7139	5998	4886	3604	2581	1863	


*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: 110			
	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	101	2	103
Non-patterned	3	1	
¹³ Longevity labeling	43	-	
³⁷ Battery depletion	-	1	
⁶⁷ Battery status	55	-	
WW Confirmed Malfunctions	103	7	110

[More details](#) about malfunctions

[References](#) cited in table above

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Confirmed Malfunction Details: Pulse Generators

References

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

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

1. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory.* Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
3. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory.* Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **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. **Telemetry**— Alert message during followup, inability to interrogate, premature battery depletion, loss of pacing therapy. Telemetry component.
85. **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	19,000	3	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	53,000	3	1	0	7	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	22,000	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	18,000	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	10,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	9,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	26,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	24,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	13,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	12,000	2	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	5	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	22,000	0	0	2	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	60,000	1	0	0	1	0	0
ACCOLADE/PROONENT/ESSENTIO DR J064/K064/K067/K084	130,000	1	0	0	6	0	0
ACCOLADE/PROONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	45,000	0	0	0	5	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	71,000	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	216,000	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	84,000	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	25,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	48,000	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	11,000	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	1	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	34000	3	3	40	12	354	1596
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	195	32	100	209	922	9892
COGNIS N118/N119/N120/P106/P107/P108	75000	2592	124	110	1601	1756	31128

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	11000	1	1	90	2	72	412
INTUA V272/V273/V282/V283/W272/W273	3000	5	0	25	1	21	281
INVIVE V172/V173/V182/V183/W172/W173	8000	42	0	63	1	61	1597
CONTAK RENEWAL TR H120/H125	19000	2950	16	169	52	260	10013

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	11000	1	0	23	4	208	338
SQ-RX S-ICD 1010	8000	98	0	43	43	262	766

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	17000	2	0	144	1	116	442
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	16000	1	1	146	3	98	365
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	6000	2	1	55	4	70	361
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	6000	3	0	73	4	64	350
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	52	13	545	90	496	5240
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	45	10	660	132	607	6529

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	96	117	778	1272	662	12562
TELIGEN DR E110/E111/F110/F111	66000	327	161	1139	1896	1163	22761
CONFIENT DR E030/F030	7000	668	2	176	14	158	3155
VITALITY 2 EL VR T177	7000	1375	9	169	1277	114	2823
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	24000	5	1	177	6	94	467
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	69000	12	5	422	12	280	2060

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	14000	4	0	126	4	60	785
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	147	4	52	811
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	130	12	1112	40	711	16302
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	17	0	253	7	146	5860
ALTRUA 60 SR S601	32000	694	4	282	9	176	14769
ALTRUA 60 DR (Downsize) S603	90000	9869	46	714	63	569	30894
ALTRUA 60 DR S602	22000	607	4	232	16	198	7540
ALTRUA 60 DR EL S606	59000	568	10	552	10	421	16178
ALTRUA 40 SR S401	5000	95	0	29	2	23	2388
ALTRUA 40 DR (downsize) S403	14000	1522	3	80	3	79	5111
ALTRUA 40 DR S402	2000	58	1	18	0	8	744
ALTRUA 40 DR EL S404	5000	45	1	41	1	43	1809
ALTRUA 20 SR S201/S204	5000	50	1	22	1	36	2514
ALTRUA 20 DR (downsize) S203	5000	268	3	30	0	39	2291

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	51	0	11	1	15	828
ALTRUA 20 DR EL S208	3000	24	0	24	1	11	1248
INSIGNIA Ultra SR 1190 ⁴	24000	2830	9	224	43	146	16634
INSIGNIA Ultra DR 1291 ⁴	32000	4934	21	365	183	316	16041
INSIGNIA Entra SR 1195/1198 ⁴	14000	1019	10	93	9	75	10676
INSIGNIA Entra DR (Downsize) 1296 ⁴	24000	5211	25	130	99	152	15648
INSIGNIA Entra DR 1294/1295 ⁴	17000	2065	14	147	65	183	11135
INSIGNIA Plus SR 1194 ⁴	27000	3523	8	228	27	155	20791
INSIGNIA Plus DR 1297 ⁴	27000	5601	20	271	131	261	15430

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.

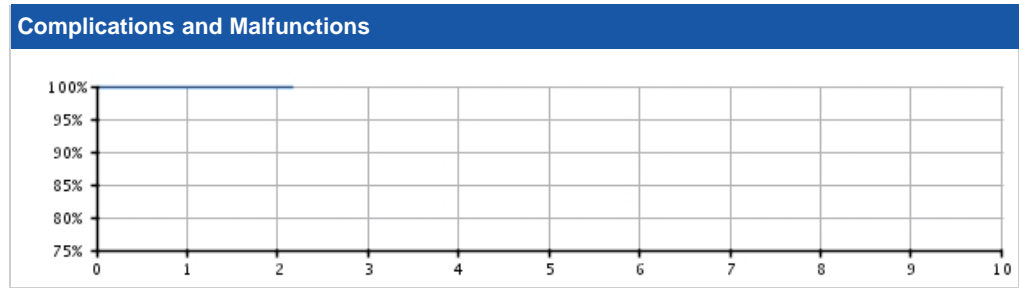
⁴ Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

ACUITY X4 Spiral L

Models 4677/4678

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

U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 0
U.S. Approval Date: February 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 4,000	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 <small>(-0.0/+0.0)</small>	100.00 @ <small>26 mo. (-0.0/+0.0)</small>	-	-	-	-	-	-	-
Registered Implants: 4000										
Effective Sample Size	837	278	229	-	-	-	-	-	-	-

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: 11,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	1	-	1
WW Confirmed Malfunctions	1	0	1

[More details](#) about malfunctions

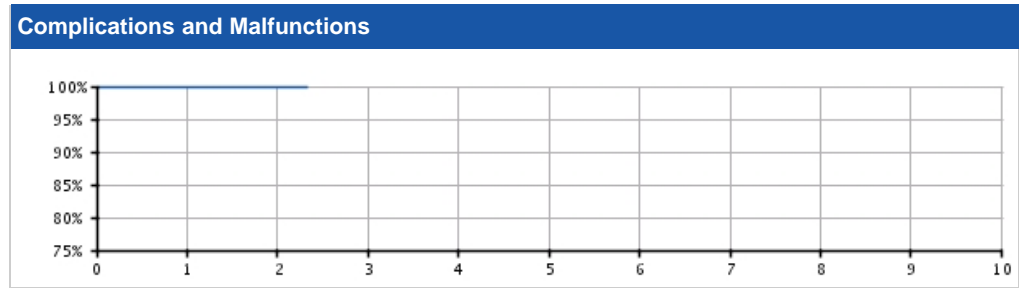
[References](#) cited in table above

ACUITY X4 Spiral S

Models 4674/4675

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

U.S. Summary	
U.S. Registered Implants: 9,000	U.S. Chronic Lead Complications: 6
U.S. Approval Date: February 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 9,000	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	99.90 <small>(-0.1/+0.1)</small>	99.90 <small>(-0.1/+0.1)</small>	99.90 @ 28 mo. <small>(-0.1/+0.1)</small>	--	--	--	--	--	--	--
Registered Implants: 9000										
Effective Sample Size	1477	372	202	--	--	--	--	--	--	--

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: 23,000			
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

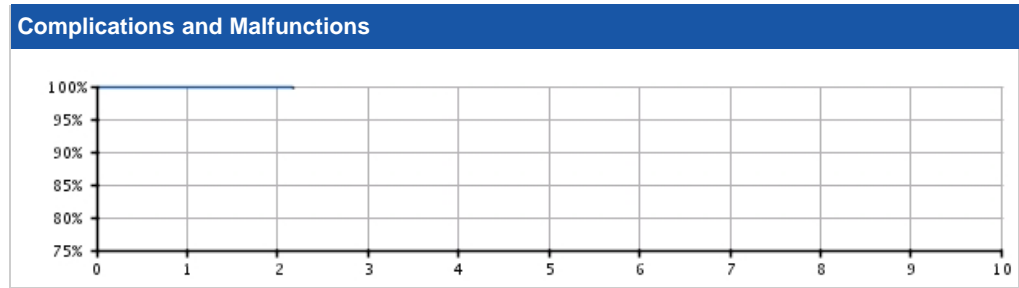
[References](#) cited in table above

ACUITY X4 Straight

Models 4671/4672

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

U.S. Summary	
U.S. Registered Implants: 6,000	U.S. Chronic Lead Complications: 10
U.S. Approval Date: February 2016	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 6,000	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	99.76 <small>(-0.2/+0.1)</small>	99.76 <small>(-0.2/+0.1)</small>	99.76 @ 26 mo. <small>(-0.2/+0.1)</small>	--	--	--	--	--	--	--
Registered Implants: 6000										
Effective Sample Size	927	284	228	--	--	--	--	--	--	--

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672			
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

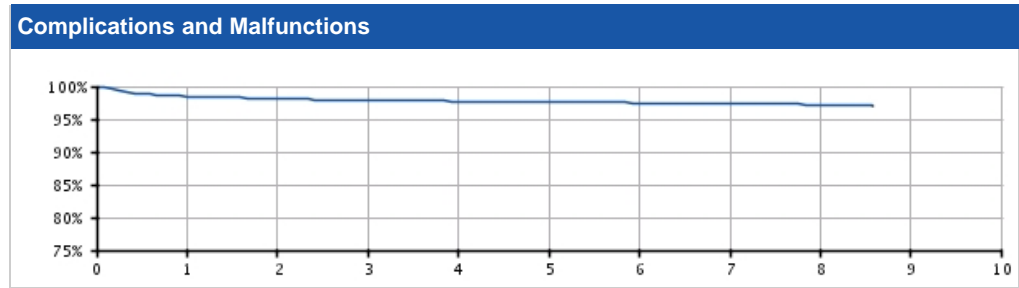
[References](#) cited in table above

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: 452
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	98.48 (-0.2/+0.2)	98.13 (-0.2/+0.2)	97.89 (-0.2/+0.2)	97.72 (-0.2/+0.2)	97.59 (-0.2/+0.2)	97.49 (-0.3/+0.2)	97.46 (-0.3/+0.2)	97.18 (-0.4/+0.3)	97.03 @ 103 mo. (-0.5/+0.4)	—
Registered Implants: 22000										
Effective Sample Size	19057	16025	12800	9680	6977	4595	2554	965	263	—

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: 44,000			
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

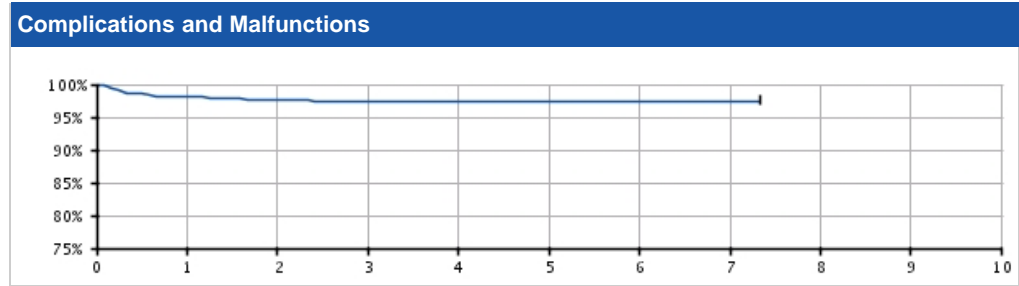
[References](#) cited in table above

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: 1383	Chronic Lead Complications: 33
Leads Active: 881	Malfunctions:0
Cumulative Followup Months : 46,704	Without Compromised Therapy:0
	With Compromised Therapy:0



Longitude Registry Survival Probability

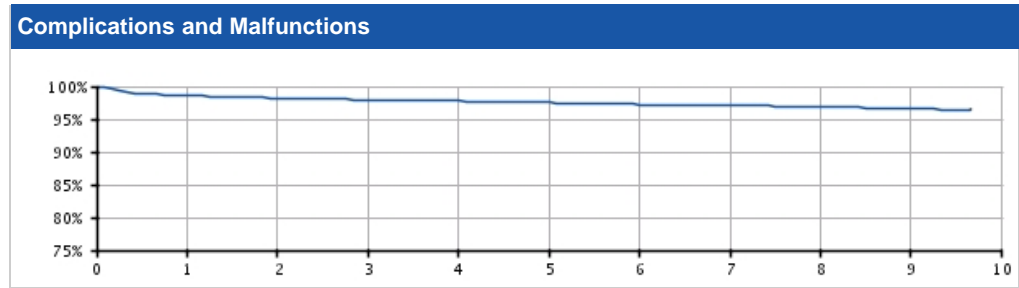
Year	1	2	3	4	5	6	7	8	9	10
Longitude	98.03 (-1.6/+1.6)	97.64 (-1.7/+1.7)	97.34 (-1.9/+1.9)	97.34 (-1.9/+1.9)	97.34 (-1.9/+1.9)	97.34 (-1.9/+1.9)	97.34 (-1.9/+3.8)	97.34 @ 88 mo. (-1.9/+3.8)	--	--
Registered Implants: 1383										
Effective Sample Size	1146	989	816	640	481	293	105	59	--	--

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: 601
U.S. Approval Date: May 2008	U.S. Malfunctions:32
U.S. Estimated Active Implants: 16,000	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	98.59 <small>(-0.1/+0.1)</small>	98.22 <small>(-0.2/+0.2)</small>	97.97 <small>(-0.2/+0.2)</small>	97.76 <small>(-0.2/+0.2)</small>	97.51 <small>(-0.2/+0.2)</small>	97.25 <small>(-0.2/+0.2)</small>	97.04 <small>(-0.3/+0.2)</small>	96.92 <small>(-0.3/+0.3)</small>	96.63 <small>(-0.4/+0.3)</small>	96.50 @ <small>116 mo. (-0.5/+0.4)</small>
Registered Implants: 29000										
Effective Sample Size	24276	20994	17455	13895	10890	8162	5587	3280	1329	252

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556 			
Worldwide Distribution: 64,000			
Worldwide Confirmed Malfunctions: 55			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	12	35	47
²⁷ Non-patterned, Conductor	7	9	
³⁴ Extracardiac fracture	5	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	18	37	55

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 3

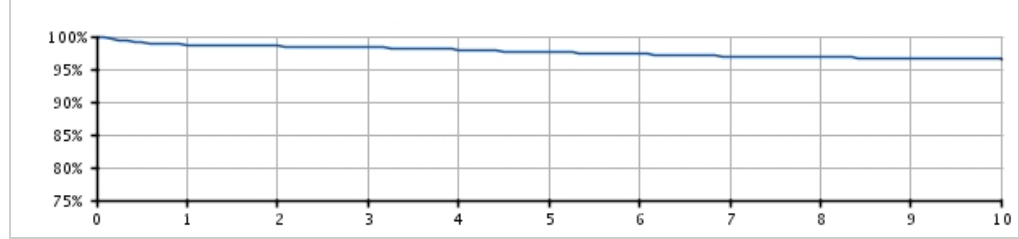
Models 4522/4524/4525/4527/4548/
4549/4550

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

U.S. Summary

U.S. Registered Implants: 22,000	U.S. Chronic Lead Complications: 441
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)	98.52 (-0.2/+0.2)	98.30 (-0.2/+0.2)	97.99 (-0.2/+0.2)	97.61 (-0.3/+0.2)	97.33 (-0.3/+0.3)	96.95 (-0.3/+0.3)	96.82 (-0.3/+0.3)	96.67 (-0.4/+0.3)	96.60 (-0.4/+0.3)
Registered Implants: 22000										
Effective Sample Size	18371	16019	13579	11152	9043	7335	5860	4558	3410	2392

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: 43,000 Worldwide Confirmed Malfunctions: 49			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	10	34	44
²⁷ Non-patterned, Conductor	6	5	
³⁴ Extracardiac fracture	4	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	14	35	49

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK 2

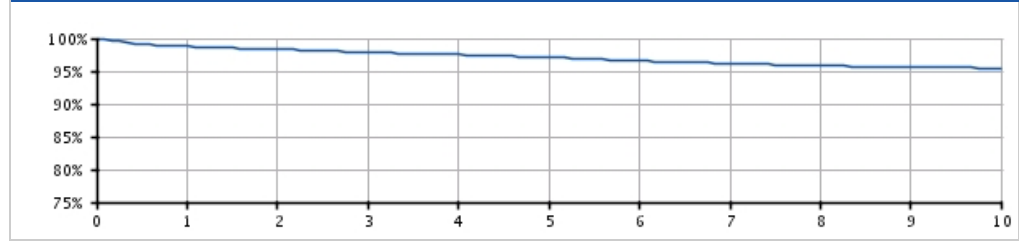
Models 4515/4517/4518/4520/4542/
4543/4544

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

U.S. Summary

U.S. Registered Implants: 97,000	U.S. Chronic Lead Complications: 2,239
U.S. Approval Date: August 2004	U.S. Malfunctions: 359
U.S. Estimated Active Implants: 43,000	Without Compromised Therapy: 104
	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	98.77 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.90 (-0.1/+0.1)	97.54 (-0.1/+0.1)	97.09 (-0.1/+0.1)	96.57 (-0.1/+0.1)	96.14 (-0.2/+0.2)	95.84 (-0.2/+0.2)	95.65 (-0.2/+0.2)	95.43 (-0.2/+0.2)
Registered Implants: 97000										
Effective Sample Size	81314	70447	59662	49416	40543	32600	25273	18820	13497	8979

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: 178,000			
Worldwide Confirmed Malfunctions: 496			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	114	356	470
²⁴ Conductor fracture	1	-	
²⁵ Conductor fracture	106	309	
²⁷ Non-patterned, Conductor	7	47	
Crimp/Weld/Bond	-	-	0
Insulation	11	2	13
²⁸ Non-patterned, Insulation	11	2	
Other	8	5	13
²⁶ Non-patterned, Other	8	5	
WW Confirmed Malfunctions	133	363	496

[More details](#) about malfunctions

[References](#) cited in table above

EASYTRAK

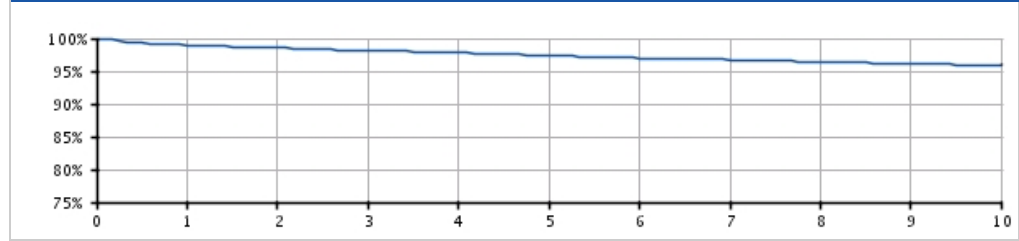
Models 4510/4511/4512/4513/4535/
4536/4537/4538

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

U.S. Summary

U.S. Registered Implants: 38,000	U.S. Chronic Lead Complications: 908
U.S. Approval Date: May 2002	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 7,000	Without Compromised Therapy: 10
	With Compromised Therapy: 15

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.75 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.94 (-0.3/+0.3)
Registered Implants: 38000										
Effective Sample Size	30531	26244	22510	19337	16500	14100	12093	10521	9189	7879

EASYTRAK

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

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

EASYTRAK Models 4510/4511/4512/4513/4535/ 4536/4537/4538			
Worldwide Distribution: 53,000 Worldwide Confirmed Malfunctions: 27			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	13	13
²⁷ Non-patterned, Conductor	-	13	
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	17	27

[More details](#) about malfunctions

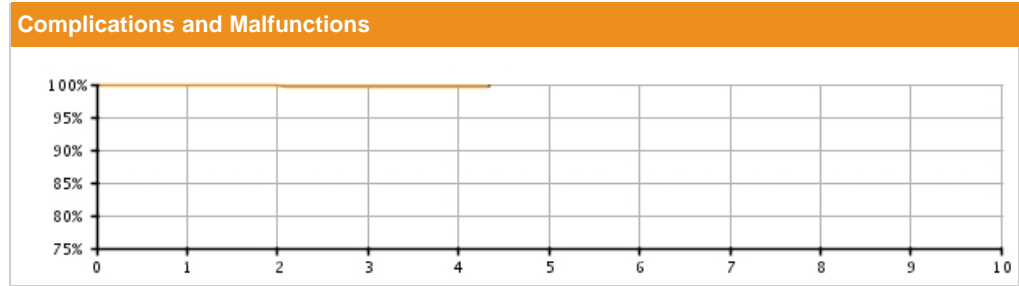
[References](#) cited in table above

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: 19,000	U.S. Chronic Lead Complications: 12
U.S. Approval Date: September 2012	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 17,000	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 <small>(-0.1/+0.0)</small>	99.77 <small>(-0.1/+0.1)</small>	99.75 <small>(-0.1/+0.1)</small>	99.75 <small>(-0.1/+0.1)</small>	99.75 @ 52 mo. <small>(-0.1/+0.1)</small>	—	—	—	—	—
Registered Implants: 19000										
Effective Sample Size	10772	4781	1289	333	220	—	—	—	—	—

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: 32,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	3	3
³⁷ Weld fracture	-	3	
Insulation	-	-	0
Other	-	2	2
WW Confirmed Malfunctions	0	5	5

[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: 10,000
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: 38,000
Worldwide Confirmed Malfunctions: 15

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	11	11
²⁷ Non-patterned, Conductor	-	4	
³⁸ Conductor cable fracture	-	7	
Crimp/Weld/Bond	-	-	0
Insulation	-	3	3
²⁸ Non-patterned, Insulation	-	3	
Other	-	1	1
²⁶ Non-patterned, Other	-	1	
WW Confirmed Malfunctions	0	15	15

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



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

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

[More details](#) about malfunctions

[References](#) cited in table above

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

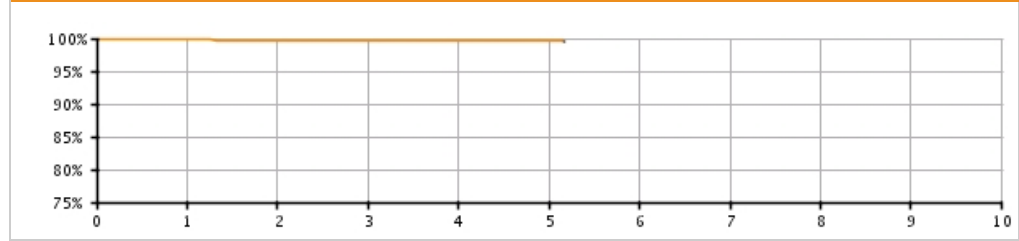
Models 0275/0276/0295/0296

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

U.S. Registered Implants: 60,000	U.S. Chronic Lead Complications: 169
U.S. Approval Date: November 2010	U.S. Malfunctions: 12
U.S. Estimated Active Implants: 52,000	Without Compromised Therapy: 0
	With Compromised Therapy: 12

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.78 (-0.0/+0.0)	99.69 (-0.1/+0.0)	99.64 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.52 @ 62 mo. (-0.1/+0.1)	—	—	—	—
Registered Implants: 59000										
Effective Sample Size	46941	34805	22998	11725	1659	439	—	—	—	—

**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: 97,000
Worldwide Confirmed Malfunctions: 39

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁷ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	7	27	34
²⁸ Non-patterned, Insulation	7	27	
Other	2	-	2
²⁶ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	9	30	39

[More details](#) about malfunctions

[References](#) cited in table above

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

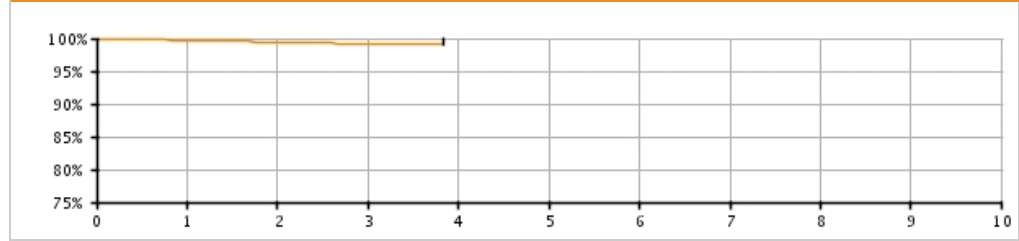
Models 0275/0276/0295/0296

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: 629	Malfunctions: 0
Cumulative Followup Months : 25,002	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)	99.46 (-1.7/+1.7)	99.25 (-1.9/+1.9)	99.25 @ 46 mo. (-1.9/+3.8)	—	—	—	—	—	—
Registered Implants: 851										
Effective Sample Size	742	653	312	–	—	—	—	—	—	—

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

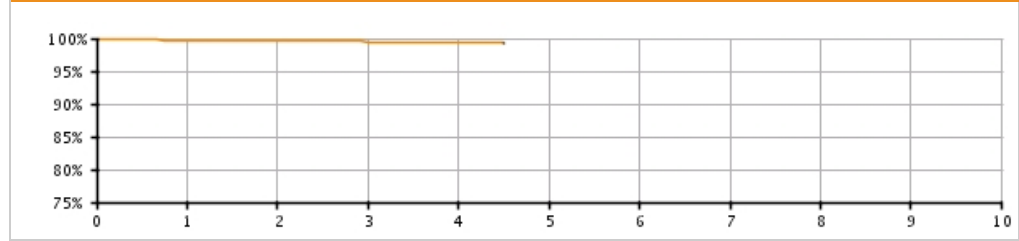
Models 0265/0266/0285/0286

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

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 11
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	99.75 (-0.3/+0.1)	99.62 (-0.4/+0.2)	99.43 (-0.5/+0.3)	99.27 (-0.7/+0.4)	99.27 @ 54 mo. (-0.7/+0.4)	--	--	--	--	--
Registered Implants: 3000										
Effective Sample Size	2008	1464	878	412	218	--	--	--	--	--

**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

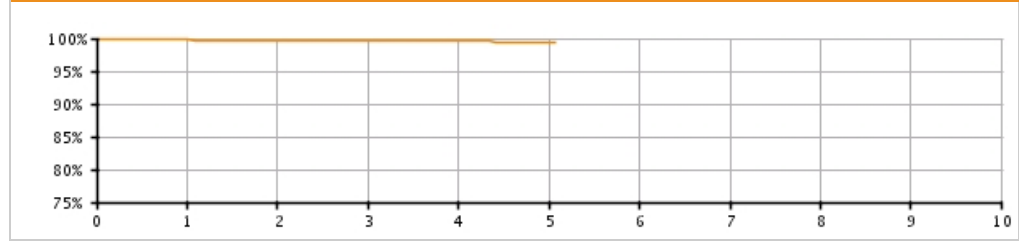
Models 0292/0293

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

U.S. Registered Implants: 72,000	U.S. Chronic Lead Complications: 199
U.S. Estimated Active Implants: 66,000	U.S. Malfunctions: 11
	Without Compromised Therapy: 1
	With Compromised Therapy: 10

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)	99.67 (-0.1/+0.0)	99.58 (-0.1/+0.1)	99.51 (-0.1/+0.1)	99.41 (-0.2/+0.1)	99.41 @ 61 mo. (-0.2/+0.1)	-	-	-	-
Registered Implants: 71000										
Effective Sample Size	48102	29152	14977	5797	676	411	-	-	-	-

**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: 116,000
Worldwide Confirmed Malfunctions: 30

	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	23	25
²⁸ Non-patterned, Insulation	2	23	
Other	-	3	3
²⁶ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	28	30

[More details](#) about malfunctions

[References](#) cited in table above

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

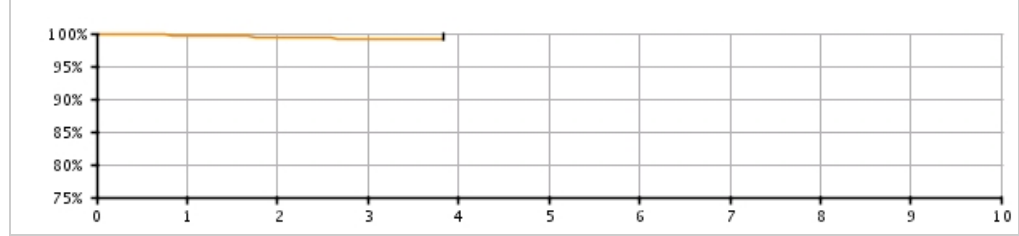
Models 0292/0293

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

Longitude Registry Summary Data

Leads Enrolled: 1104 Leads Active: 897 Cumulative Followup Months : 32,473	Chronic Lead Complications: 5 Malfunctions:0 Without Compromised Therapy:0 With Compromised Therapy:0
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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)	99.39 (-1.9/+1.9)	99.39 @ 44 mo. (-1.9/+3.8)	--	--	--	--	--	--
Registered Implants: 1104										
Effective Sample Size	854	757	354	51	--	--	--	--	--	--

**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: 116,000
Worldwide Confirmed Malfunctions: 30

	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	23	25
²⁸ Non-patterned, Insulation	2	23	
Other	-	3	3
²⁶ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	28	30

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

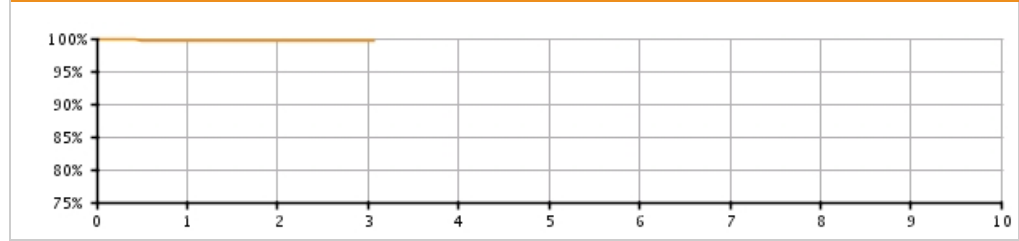
Models 0282/0283

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	99.67 (-0.6/+0.2)	99.67 (-0.6/+0.2)	99.67 (-0.6/+0.2)	99.67 @ 37 mo. (-0.6/+0.2)	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	866	460	221	211	--	--	--	--	--	--

**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
Non-patterned, Other	-	1	
WW Confirmed Malfunctions	0	2	2

[More details](#) about malfunctions

[References](#) cited in table above

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

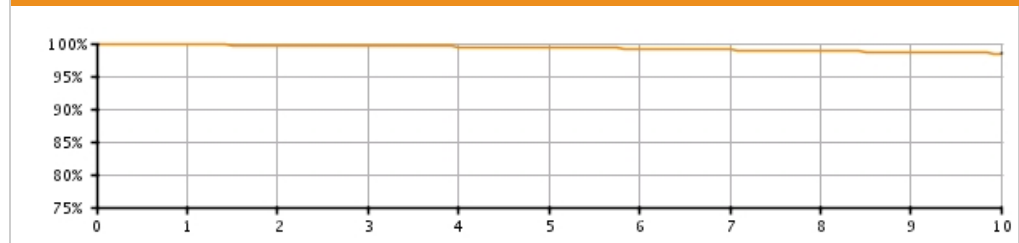
Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

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: 134,000	U.S. Chronic Lead Complications: 1,987 U.S. Malfunctions: 298 Without Compromised Therapy:110 With Compromised Therapy:188
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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	99.80 (-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)	99.02 (-0.0/+0.0)	98.86 (-0.1/+0.1)	98.68 (-0.1/+0.1)	98.49 (-0.1/+0.1)
Registered Implants: 286000										
Effective Sample Size	251750	224085	199215	176150	154578	126605	100112	75902	54429	37898

**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: 374,000
Worldwide Confirmed Malfunctions: 466

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	131	133
²⁴ Conductor fracture	-	87	
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	146	129	275
²⁸ Non-patterned, Insulation	146	129	
Other	29	22	51
²⁶ Non-patterned, Other	29	22	
WW Confirmed Malfunctions	183	283	466

[More details](#) about malfunctions

[References](#) cited in table above

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

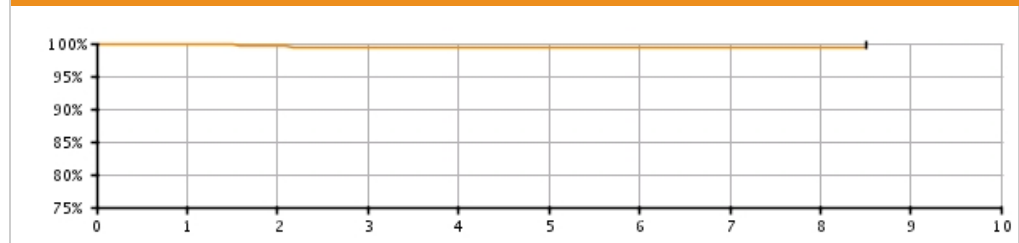
Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

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

Longitude Registry Summary Data

Leads Enrolled: 743	Chronic Lead Complications: 2
Leads Active: 390	Malfunctions:1
Cumulative Followup Months : 26,718	Without Compromised Therapy:0
	With Compromised Therapy:1

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	100 (-1.6/+1.6)	99.67 (-1.7/+1.7)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 @ 102 mo. (-1.9/+3.8)	–
Registered Implants: 743										
Effective Sample Size	645	572	505	440	371	273	141	62	51	–

**ENDOTAK RELIANCE
Dual Coil, Passive Fixation**

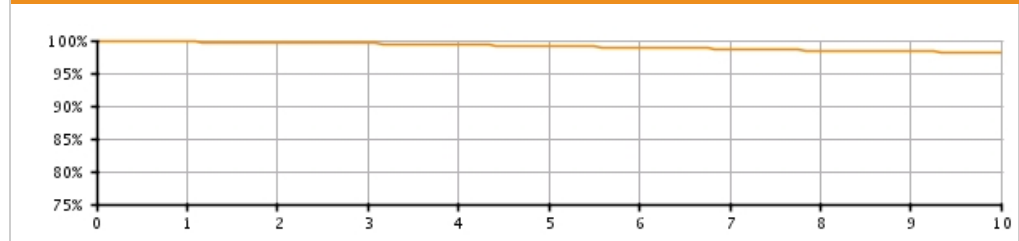
Models 0147/0148/0149/0174/0175/
0176/0177

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: 509
U.S. Approval Date: October 2000	U.S. Malfunctions:38
U.S. Estimated Active Implants: 17,000	Without Compromised Therapy:9
	With Compromised Therapy:29

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)	99.68 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.46 (-0.2/+0.1)	98.30 (-0.2/+0.2)	98.09 (-0.2/+0.2)
Registered Implants: 46000										
Effective Sample Size	40581	36151	32150	28451	24943	21518	18353	15503	12918	10650

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



Worldwide Distribution: 108,000
Worldwide Confirmed Malfunctions: 128

	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	45	83
²⁸ Non-patterned, Insulation	38	45	
Other	7	4	11
⁶ Manufacturing material	-	1	
²⁶ Non-patterned, Other	7	3	
WW Confirmed Malfunctions	45	83	128

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

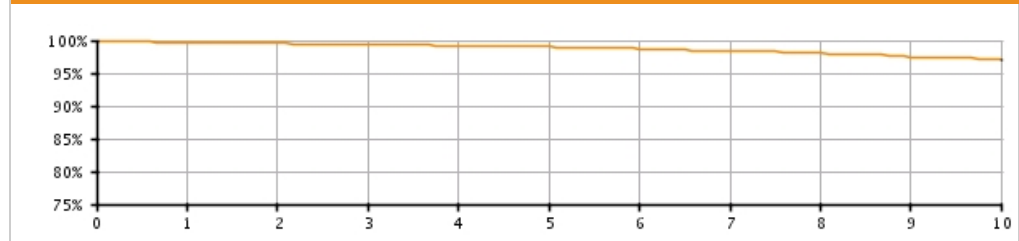
Models 0137/0138/0160/0161/0162/
 0180/0181/0182

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

U.S. Registered Implants: 32,000	U.S. Chronic Lead Complications: 233
U.S. Approval Date: July 2002	U.S. Malfunctions:61
U.S. Estimated Active Implants: 22,000	Without Compromised Therapy:20
	With Compromised Therapy:41

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)	99.53 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.75 (-0.2/+0.2)	98.39 (-0.2/+0.2)	98.03 (-0.3/+0.3)	97.43 (-0.5/+0.4)	97.10 (-0.7/+0.5)
Registered Implants: 32000										
Effective Sample Size	27300	23212	19261	15606	12464	7981	4842	2791	1410	707

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: 69,000
Worldwide Confirmed Malfunctions: 158

	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	34	82
²⁸ Non-patterned, Insulation	48	34	
Other	8	6	14
²⁶ Non-patterned, Other	8	6	
WW Confirmed Malfunctions	57	101	158

[More details](#) about malfunctions

[References](#) cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

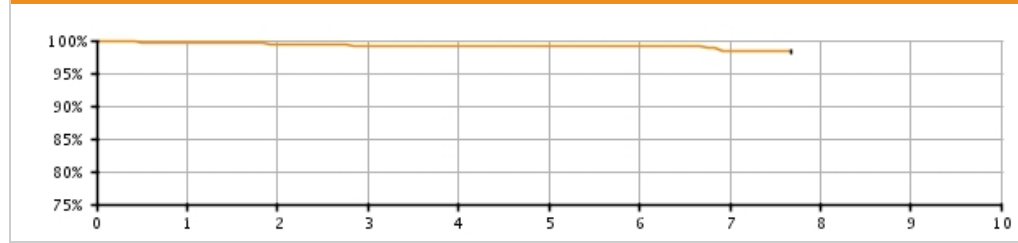
Models 0127/0128/0170/0171/0172/
 0173

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

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: 18 U.S. Malfunctions: 1 Without Compromised Therapy: 0 With Compromised Therapy: 1
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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	99.75 (-0.4/+0.2)	99.44 (-0.6/+0.3)	99.24 (-0.7/+0.4)	99.13 (-0.7/+0.4)	99.13 (-0.7/+0.4)	99.13 (-0.7/+0.4)	98.38 (-1.7/+0.8)	98.38 @ 92 mo. (-1.7/+0.8)	-	-
Registered Implants: 2000										
Effective Sample Size	1442	1172	925	700	513	359	247	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 EZ
Active Fixation

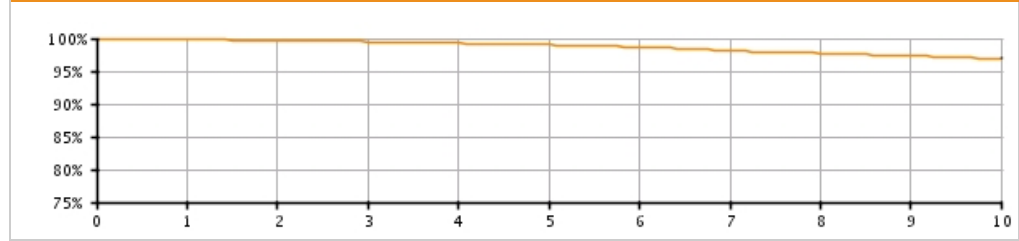
Models 0154/0155/0156

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: 591
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	21792	19398	17262	15329	13598	12052	10712	9490	8401

ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting

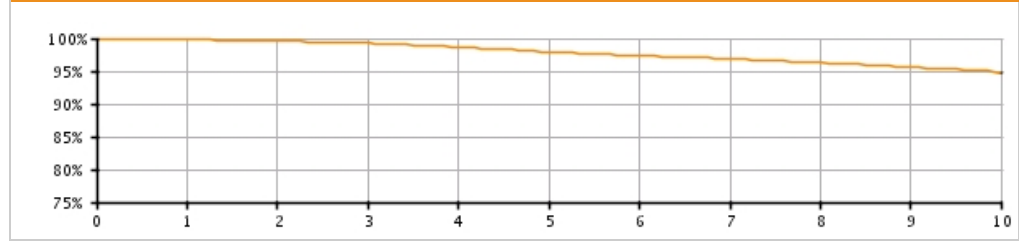
Models 0144/0145/0146

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

U.S. Summary

U.S. Registered Implants: 18,000	U.S. Chronic Lead Complications: 697
U.S. Approval Date: January 1999	U.S. Malfunctions: 27
U.S. Estimated Active Implants: 4,000	Without Compromised Therapy: 6
	With Compromised Therapy: 21

Complications and Malfunctions



U.S. Survival Probability

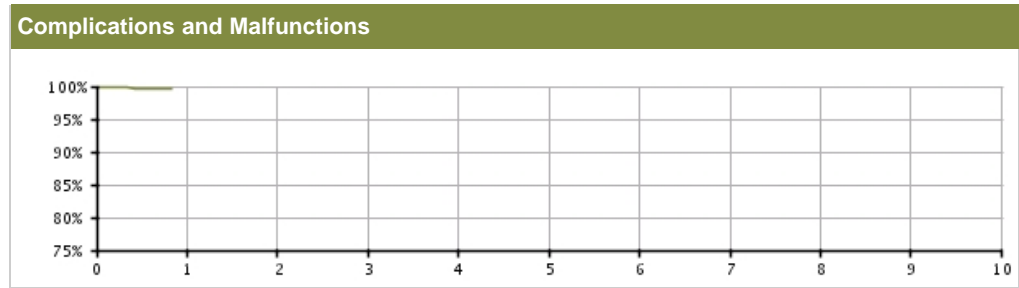
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.85 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15628	13937	12418	10989	9679	8564	7597	6723	5920	5203

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

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: 0
U.S. Approval Date: April 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	99.64 @ 10 mo. (-0.5/+0.2)	-	-	-	-	-	-	-	-	-
Registered Implants: 2000										
Effective Sample Size	204	-	-	-	-	-	-	-	-	-

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

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

INGEVITY Atrial J Passive Fixation
Models 7635/7636/7735/7736


Worldwide Distribution: 28,000
Worldwide Confirmed Malfunctions: 0

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

[More details](#) about malfunctions

[References](#) cited in table above

INGEVITY Positive Fixation

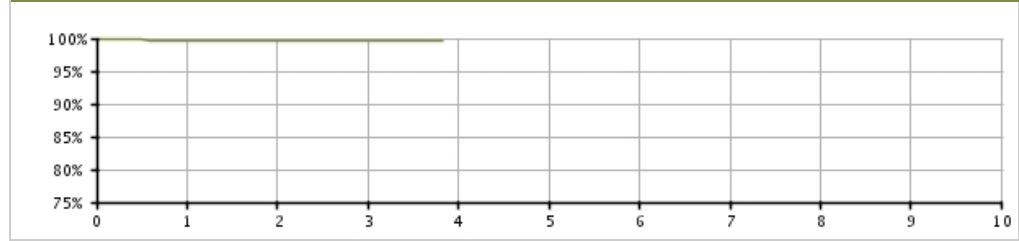
Models 7640/7641/7642/7740/7741/
7742

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

U.S. Summary

U.S. Registered Implants: 78,000	U.S. Chronic Lead Complications: 123
U.S. Approval Date: April 2016	U.S. Malfunctions: 8
U.S. Estimated Active Implants: 76,000	Without Compromised Therapy: 5
	With Compromised Therapy: 3

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.72 (-0.1/+0.1)	99.72 (-0.1/+0.1)	99.72 (-0.1/+0.1)	99.72 @ 46 mo. (-0.1/+0.1)	—	—	—	—	—	—
Registered Implants: 78000										
Effective Sample Size	1141	930	721	246	—	—	—	—	—	—

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: 269,000
Worldwide Confirmed Malfunctions: 25

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	13	9	22
²⁷ Non-patterned, Conductor	9	7	
³⁹ Inner conductor break	4	2	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
²⁸ Non-patterned, Insulation	-	1	
Other	1	1	2
²⁶ Non-patterned, Other	1	1	
WW Confirmed Malfunctions	14	11	25

[More details](#) about malfunctions

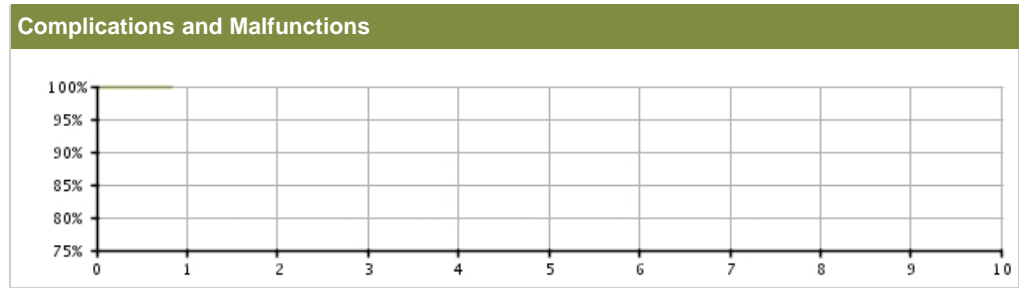
[References](#) cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

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

U.S. Summary	
U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 0
U.S. Approval Date: April 2016	U.S. Malfunctions: 1
U.S. Estimated Active Implants: 4,000	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	99.91 @ 10 mo. (-0.3/+0.1)	-	-	-	-	-	-	-	-	-
Registered Implants: 4000										
Effective Sample Size	394	-	-	-	-	-	-	-	-	-

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: 33,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁷ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	3	3


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

FLEXTEND 2 Active Fixation Models 4095/4096/4097 			
Worldwide Distribution: 183,000			
Worldwide Confirmed Malfunctions: 117			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	7	32	39
⁷ Lead conductor	3	18	
³² Conductor damage	4	14	
Crimp/Weld/Bond	-	-	0
Insulation	54	10	64
² Inner insulation abrasion	4	1	
²⁸ Non-patterned, Insulation	3	-	
³³ Insulation damage	47	9	
Other	14	-	14
²⁶ Non-patterned, Other	14	-	
WW Confirmed Malfunctions	75	42	117

[More details](#) about malfunctions

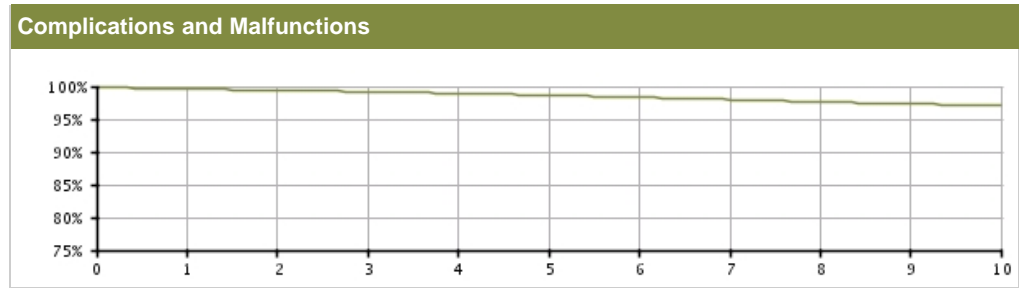
[References](#) cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

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

U.S. Summary	
U.S. Registered Implants: 235,000	U.S. Chronic Lead Complications: 3,387
U.S. Approval Date: February 2002	U.S. Malfunctions: 329
U.S. Estimated Active Implants: 96,000	Without Compromised Therapy: 133
	With Compromised Therapy: 196




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 <small>(-0.0/+0.0)</small>	99.40 <small>(-0.0/+0.0)</small>	99.20 <small>(-0.0/+0.0)</small>	98.94 <small>(-0.0/+0.0)</small>	98.66 <small>(-0.1/+0.1)</small>	98.33 <small>(-0.1/+0.1)</small>	97.99 <small>(-0.1/+0.1)</small>	97.64 <small>(-0.1/+0.1)</small>	97.32 <small>(-0.1/+0.1)</small>	97.09 <small>(-0.1/+0.1)</small>
Registered Implants: 235000										
Effective Sample Size	200956	175222	152230	131320	112527	95443	79479	65160	53060	41504

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: 290,000			
Worldwide Confirmed Malfunctions: 353			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	17	174	191
⁷ Lead conductor	10	83	
²⁷ Non-patterned, Conductor	-	7	
³² Conductor damage	7	84	
Crimp/Weld/Bond	-	-	0
Insulation	108	33	141
² Inner insulation abrasion	19	8	
²⁸ Non-patterned, Insulation	9	1	
³³ Insulation damage	80	24	
Other	17	4	21
²⁶ Non-patterned, Other	17	4	
WW Confirmed Malfunctions	142	211	353

[More details](#) about malfunctions

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q2 2017

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

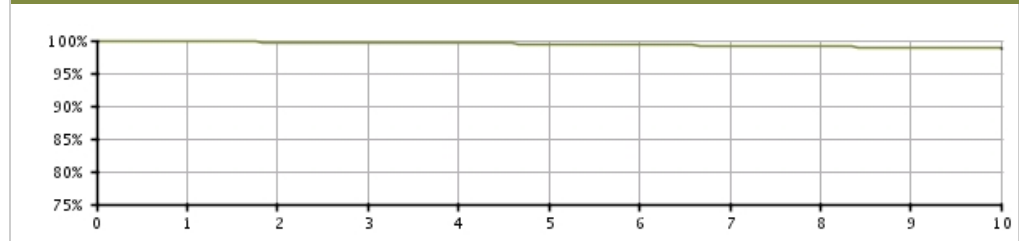
Models 4463/4464/4465/4469/4470/
4471

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

U.S. Summary

U.S. Registered Implants: 455,000	U.S. Chronic Lead Complications: 2,492
U.S. Approval Date: January 2000	U.S. Malfunctions:138
U.S. Estimated Active Implants: 253,000	Without Compromised Therapy:30
	With Compromised Therapy:108

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)	99.67 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.47 (-0.0/+0.0)	99.34 (-0.0/+0.0)	99.19 (-0.0/+0.0)	99.06 (-0.0/+0.0)	98.90 (-0.1/+0.1)	98.76 (-0.1/+0.1)
Registered Implants: 454000										
Effective Sample Size	391762	332023	278848	231783	190475	153718	120937	91547	68523	50443

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

**FINELINE II EZ/FINELINE II Sterox EZ
Positive Fixation (Polyurethane)
Models 4463/4464/4465/4469/4470/
4471**



Worldwide Distribution: 701,000
Worldwide Confirmed Malfunctions: 166

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	14	121	135
⁷ Lead conductor	6	56	
²⁷ Non-patterned, Conductor	1	6	
³² Conductor damage	7	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	8	2	10
²⁶ Non-patterned, Other	8	2	
WW Confirmed Malfunctions	35	131	166

[More details](#) about malfunctions

[References](#) cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

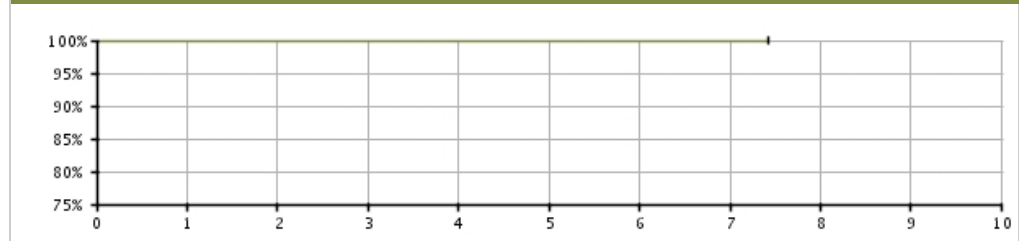
Models 4463/4464/4465/4469/4470/
 4471

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

Longitude Registry Summary Data

Leads Enrolled: 924	Chronic Lead Complications: 2
Leads Active: 667	Malfunctions:0
Cumulative Followup Months : 29,599	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	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.1)	99.77 (-0.7/+0.5)	99.77 @ 89 mo. (-1.9/+3.4)	-	-
Registered Implants: 924										
Effective Sample Size	777	685	473	278	219	151	84	59	-	-

CRM PRODUCT PERFORMANCE REPORT Q2 2017

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

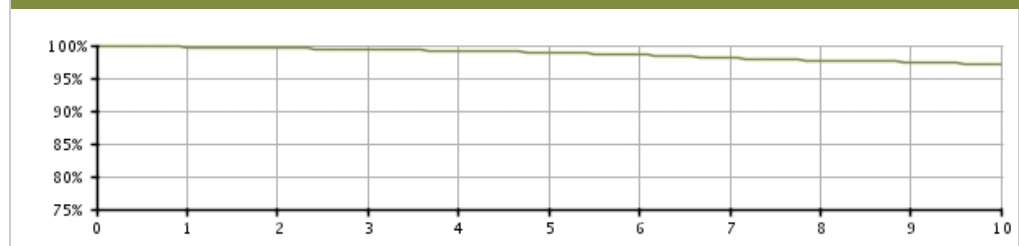
Models 4466/4467/4468/4472/4473/
4474

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

U.S. Summary

U.S. Registered Implants: 52,000	U.S. Chronic Lead Complications: 618
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)	99.58 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.19 (-0.1/+0.1)	98.91 (-0.1/+0.1)	98.52 (-0.1/+0.1)	98.07 (-0.2/+0.2)	97.67 (-0.2/+0.2)	97.44 (-0.2/+0.2)	97.15 (-0.2/+0.2)
Registered Implants: 52000										
Effective Sample Size	45338	39289	33789	28762	24263	20209	16418	13186	10430	8167

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

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

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

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



Worldwide Distribution: 140,000
Worldwide Confirmed Malfunctions: 165

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	11	126	137
⁷ Lead conductor	4	75	
²⁷ Non-patterned, Conductor	-	2	
³² Conductor damage	7	46	
³⁵ Lead conductor	-	3	
Crimp/Weld/Bond	1	-	1
³¹ Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	9	9	18
²⁸ Non-patterned, Insulation	2	-	
³³ Insulation damage	7	9	
Other	5	4	9
²⁶ Non-patterned, Other	5	4	
WW Confirmed Malfunctions	26	139	165

[More details](#) about malfunctions

[References](#) cited in table above

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

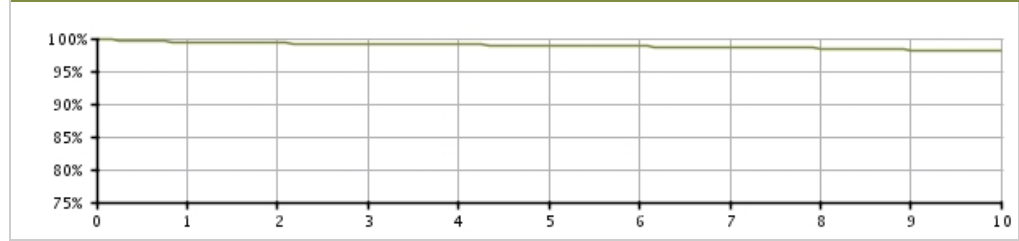
Models 4477/4478/4479/4480

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

U.S. Summary

U.S. Registered Implants: 61,000	U.S. Chronic Lead Complications: 646
U.S. Approval Date: January 2000	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 30,000	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	99.44 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.15 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.78 (-0.1/+0.1)	98.63 (-0.1/+0.1)	98.50 (-0.1/+0.1)	98.24 (-0.2/+0.2)	98.16 (-0.2/+0.2)
Registered Implants: 61000										
Effective Sample Size	52521	44886	38021	31852	26467	21718	17458	13647	10590	8072

**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: 296,000
Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	4	10	14
⁷ Lead conductor	1	3	
³² Conductor damage	3	7	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
³³ Insulation damage	-	1	
Other	32	4	36
²² J-shape	30	4	
²⁶ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	36	15	51

[More details](#) about malfunctions

[References](#) cited in table above

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

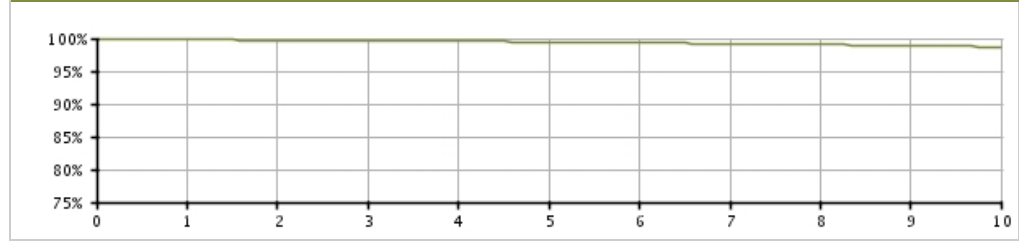
Models 4452/4453/4456/4457

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

U.S. Summary

U.S. Registered Implants: 188,000	U.S. Chronic Lead Complications: 1,124
U.S. Approval Date: January 2000	U.S. Malfunctions:43
U.S. Estimated Active Implants: 87,000	Without Compromised Therapy:5
	With Compromised Therapy:38

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)	99.46 (-0.0/+0.0)	99.35 (-0.0/+0.0)	99.18 (-0.1/+0.1)	99.04 (-0.1/+0.1)	98.85 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 188000										
Effective Sample Size	160950	137740	116595	97838	81534	67138	54239	42670	33291	25802

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

Models 4452/4453/4456/4457

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

**FINELINE II/FINELINE II Sterox
Passive Fixation (Polyurethane)
Models 4452/4453/4456/4457**



Worldwide Distribution: 523,000
Worldwide Confirmed Malfunctions: 61

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	46	47
⁷ Lead conductor	-	15	
²⁷ Non-patterned, Conductor	-	3	
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	54	61

[More details](#) about malfunctions

[References](#) cited in table above

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

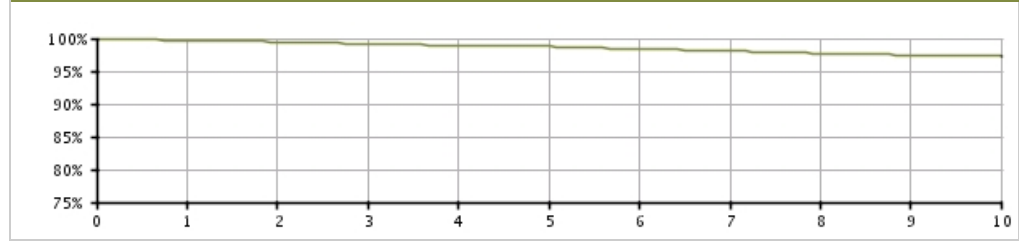
Models 4454/4455/4458/4459

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

U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 192
U.S. Approval Date: January 2000	U.S. Malfunctions: 24
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy: 0
	With Compromised Therapy: 24

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)	98.44 (-0.3/+0.2)	98.05 (-0.3/+0.3)	97.72 (-0.4/+0.3)	97.47 (-0.4/+0.4)	97.35 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12434	10865	9435	8124	6982	5862	4866	4046	3354	2797

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

Models 4454/4455/4458/4459

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

**FINELINE II/FINELINE II Sterox
Passive Fixation (Silicone)
Models 4454/4455/4458/4459**



Worldwide Distribution: 104,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	45	45
⁷ Lead conductor	-	17	
³² Conductor damage	-	28	
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	52	54

[More details](#) about malfunctions

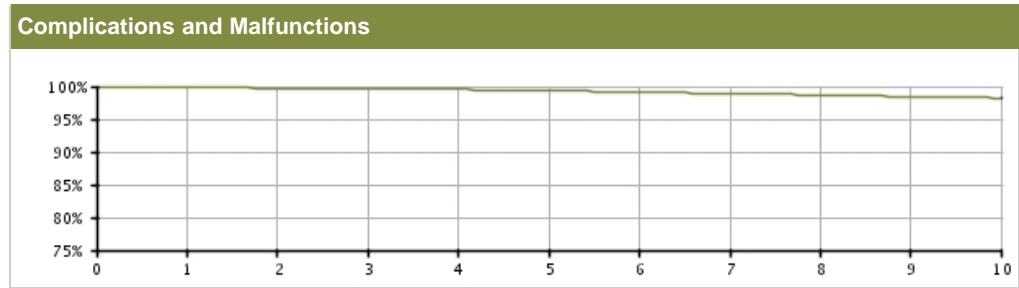
[References](#) cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

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

U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Chronic Lead Complications: 298
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



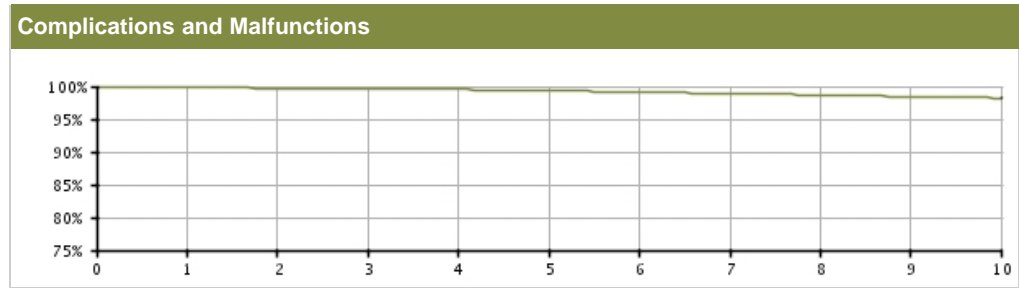
U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.70 (-0.2/+0.2)	98.45 (-0.2/+0.2)	98.23 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20914	18711	16691	14868	13217	11627	10246	9034	7925	6991

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: 298
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	20914	18711	16691	14868	13217	11627	10246	9034	7925	6991

SELUTE PICOTIP
Passive Fixation

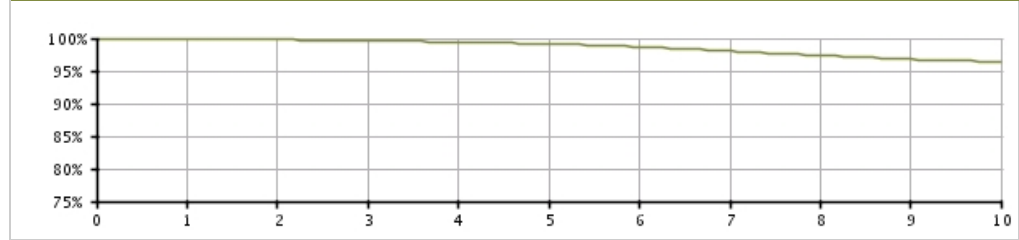
Models 4030/4031/4032/4033/4034/
 4035

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: 1,122
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)	97.37 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.39 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49276	43964	39175	34802	30800	27094	23781	20868	18143	15751

SELUTE PICOTIP Atrial J

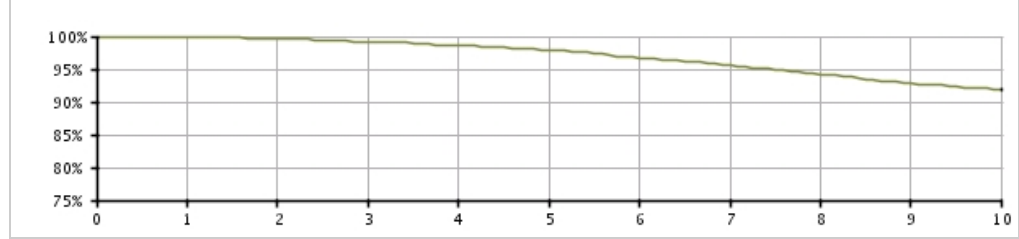
Models 4040/4041/4042/4043/4044/
4045/4063/4064

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: 441
U.S. Approval Date: May 2000	U.S. Malfunctions: 23
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)	92.87 (-0.8/+0.7)	91.81 (-0.9/+0.8)
Registered Implants: 10000										
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3477	2950	2521

SWEET PICOTIP Rx
Positive Fixation

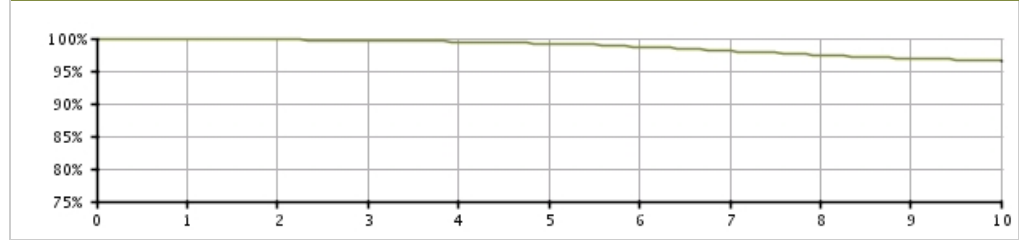
Models 4050/4051/4052/4053/4054/
 4055

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: 697
U.S. Approval Date: April 1999	U.S. Malfunctions: 58
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)	97.43 (-0.2/+0.2)	96.91 (-0.3/+0.2)	96.56 (-0.3/+0.3)
Registered Implants: 41000										
Effective Sample Size	35767	31935	28498	25356	22465	19811	17401	15162	12821	10625

SWEET TIP
Positive Fixation

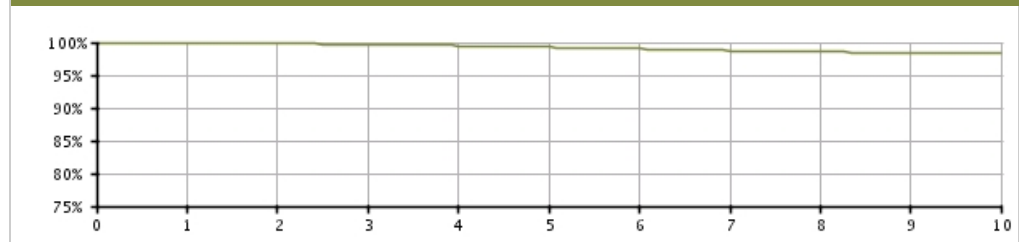
Models 4165/4168/4169/4268/4269

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: 970
U.S. Estimated Active Implants: 15,000	U.S. Malfunctions: 161

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	33559	29652	26154

SWEET TIP RX
Positive Fixation

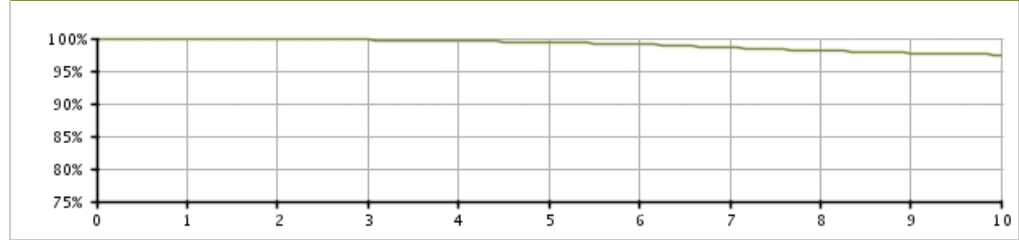
Models 4143/4144/4145/4243/4244/
 4245

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: 503
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)	98.57 (-0.2/+0.2)	98.09 (-0.2/+0.2)	97.74 (-0.2/+0.2)	97.44 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26538	23707	21103	18667	16401	14405	12636	11027	9413

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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 conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
9. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
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. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
22. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.

26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
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	78000	15	46	48	6	1	0	2	1	0	4
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	2000	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	4000	0	0	0	0	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	73	769	841	704	297	90	160	388	0	65
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	188000	4	329	204	178	37	20	158	174	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	455000	21	528	661	341	81	85	407	327	0	41
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	95	308	110	10	19	59	36	0	8
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	89	19	37	12	3	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	221	74	80	58	15	72	94	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	4000	0	0	0	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	9000	0	0	5	0	0	0	0	0	0	1

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	6000	0	0	7	1	0	0	0	1	0	1
ACUIITY Steerable 4554/4555/4556	29000	2	26	401	41	4	2	7	23	0	95
ACUIITY Spiral 4591/4592/4593	23000	0	15	251	28	1	1	3	6	0	147
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	27	252	42	4	2	10	11	0	91
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	2	278	1090	244	8	6	62	80	0	469
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	64	397	101	3	1	47	32	0	262

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	60000	14	22	72	15	13	8	5	8	8	4
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	0	1	5	0	2	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	72000	16	21	82	25	17	8	4	8	12	6
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	1000	28	412	348	125	491	65	98	216	175	29
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	91	64	47	82	7	34	142	32	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	32000	10	48	43	21	41	2	7	28	30	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	2	5	1	4	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	19000	0	0	2	0	7	0	3	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	1383	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	1104	0	1	1	1	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	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	78000	99	151	207	86	20	17	7	63	0	13
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	2000	0	0	6	4	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	4000	1	1	8	3	1	2	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	236	195	1361	433	74	90	57	215	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	188000	15	13	448	177	9	26	25	40	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	455000	83	84	709	257	112	99	63	249	0	44
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	18	452	91	8	29	17	22	0	11
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	11	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	4000	1	0	9	6	2	0	0	3	0	11
ACUITY X4 Spiral S 4674/4675	9000	1	0	15	7	1	0	0	18	0	21

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	5000	1	0	14	4	0	0	0	14	0	11
ACUITY Steerable 4554/4555/4556	29000	1	3	328	47	25	2	7	133	0	242
ACUITY Spiral 4591/4592/4593	23000	5	4	211	73	8	1	9	39	0	242
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	275	38	12	2	8	47	0	187
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	13	9	932	137	46	9	27	201	0	730
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	19	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	60000	54	31	180	85	69	12	7	81	22	12
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	2	0	9	1	3	0	0	17	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	72000	63	40	184	71	82	20	7	88	75	25
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	1	1	3	2	1	1	0	18	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	150	187	651	169	365	55	70	361	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	32000	29	16	77	33	32	13	3	57	121	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	3	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	19000	1	0	15	0	194	15	1	62	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	1383	0	0	11	11	1	0	0	3	0	48
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
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	1104	6	1	11	6	5	3	0	1	1	2
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	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	11,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	23,000	0	0	0	2	0	0	0
ACUITY X4 Straight 4671/4672	20,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	64,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	44,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	43,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	178,000	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	10,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	38,000	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	3,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	97,000	0	0	0	65	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	116,000	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	374,000	0	0	44	488	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	69,000	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	32,000	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	269,000	671	0	0	1261	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	28,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	33,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	183,000	0	0	10	122	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	290,000	0	0	55	604	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	523,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	701,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	296,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	104,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	140,000	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).

This report section includes summaries of Product Advisories for which significant, active U.S. device populations exist. In general, this includes advisories for which the estimated active U.S. advisory population is at least 200. Physician and patient letters, as well as Advisory Updates, are available at www.bostonscientific.com. With respect to the number of reported events listed in the summaries below, Boston Scientific recognizes that the actual number of clinical malfunctions may be greater than the number reported. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION January 2017 — S-ICD Programmer Commands
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here:</p> <p>Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification: Unclassified</p> <p>This advisory discusses the potential for radio frequency (RF) interference to alter wireless communication from a Model 3200 S-ICD programmer, which in rare instances may cause an S-ICD to perform an unintended command. This behavior can only occur during an active, in-clinic interrogation/programming session with the Model 3200 S-ICD programmer. There is no risk of this behavior occurring when the LATITUDE Patient Management System communicates with an S-ICD in an ambulatory setting.</p>
<p>S-ICD Programmer Model 3200</p> <p>S-ICD Programmer Commands, Physician Letter, Jan 12, 2017</p> <p>S-ICD Programmer Commands, Patient Letter, Jan 12, 2017</p>	<p>Both the programmer and the S-ICD check the validity of telemetry commands using an algorithm intended to detect whether these commands have been altered. In nearly all instances, invalid commands are rejected. In rare instances, interference may go undetected and alter communications from the programmer. This can potentially result in the S-ICD performing an induction, utilizing temporary parameters that impair the S-ICD from detecting or treating a tachyarrhythmia during the active telemetry session, or disabling therapy in the permanent programming mode such that therapy will be unavailable after the telemetry session is ended.</p> <p>Because the programmer display may not match device programming when this behavior occurs, ending the session and re-interrogating the S-ICD is an effective means to check the permanently programmed device parameters. The potential for this behavior to occur during this brief re-interrogation is extremely remote.</p> <p>All communications between the programmer and S-ICD remain secure. This behavior is not related to a cybersecurity vulnerability. The LATITUDE Patient Management System (remote monitoring) is not subject to this behavior and is a reliable way to check S-ICD settings and performance.</p> <p><i>Estimated Rate of Occurrence</i></p> <p>For the EMBLEM S-ICD, the probability of serious adverse consequences is estimated to be 1 in 25,000 at 5 years.</p> <p>For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.</p>
	<p>CURRENT STATUS 10-Apr-17</p> <p>Ten observations of unintended programming commands or data changes have been observed within the population of approximately 20,300 EMBLEM and EMBLEM MRI S-ICDs. Three observations of unintended programming commands or data changes have occurred with the SQ-RX™ S-ICD.</p> <p>There have been no reported patient deaths associated with this advisory.</p> <p><i>Estimated Rate of Occurrence</i></p> <p>For the EMBLEM S-ICD, the probability of serious adverse consequences is estimated to be 1 in 25,000 at 5 years.</p> <p>For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.</p>

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Boston Scientific is developing software to mitigate this behavior. Until updated software is available, the recommendations below mitigate the risks associated with this behavior:

- Using the LATITUDE Patient Management System for routine S-ICD assessments will minimize the number of programmer interactions with an S-ICD.
- If the LATITUDE Patient Management System is not available, consider reducing the frequency of in-clinic checks while following medical society guidelines.
- When performing any S-ICD programming or check using a Model 3200 S-ICD Programmer:
 - Ensure external defibrillation equipment and medical personnel skilled in CPR are available during implant and in-office follow-up testing and do not leave the patient unattended.
 - Place the telemetry wand directly over the S-ICD at all times and increase the distance between any source of interference and the programmer and S-ICD as much as possible.
 - Minimize the duration of programmer communications and end the programmer telemetry session promptly after completion.
- When the programmer is communicating with an S-ICD, it is possible that this behavior may alter temporary parameters without the user's knowledge. Altering of temporary parameters may result in an inability for the S-ICD to detect a tachyarrhythmia or an inappropriate detection of a heart rhythm.
 - To initiate a defibrillation therapy, press the Rescue Shock icon and follow screen prompts.
 - To abort an inappropriate shock, press the Abort button while the S-ICD is charging.
- When the S-ICD programming or check is complete, confirm S-ICD settings by performing the following steps:
 1. End the original telemetry session
 2. Initiate a new telemetry session
 3. Print a device Summary Report (see Appendix A)
 4. End the telemetry session
 5. Confirm device settings: if any settings have been altered from intended programming, contact Technical Services
 6. Instruct the patient to contact their physician if the device emits beeping tones

PRODUCT	ORIGINAL COMMUNICATION Aug 2013 and Sep 2014 — Low Voltage Capacitor
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II
COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108	In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. It also informed physicians how to identify and respond to a Safety Architecture low voltage alert. In September 2014, a second subset of devices was identified that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset. The second communication also discussed improvements to Safety Architecture's low voltage alert, which were released through a programmer software update.
TELIGEN VR Models E102/E103/F102/F103	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.
TELIGEN DR Models E110/E111/F110/F111	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><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>
Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014	CURRENT STATUS 10-Apr-17 Advisory devices have not been available for implant for more than seven years.
Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014	<i>Confirmed Malfunctions (worldwide)</i> 4,569 malfunctions have been confirmed from the advisory population. Approximately 36,000 devices from the advisory populations remain in service.
Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013	There has been one reported patient death due to complications with the replacement of an advisory device.
	<p><i>Projected Rate of Occurrence</i></p> <ul style="list-style-type: none"> • COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.9% at 60 months and 6.0% at 72 months. The projected rate of occurrence is 8.5% at 84 months. The potential for life-threatening harm from loss of therapy is approximately 1 in 200,000 (0.0005%) at 60 months. • COGNIS CRT-D and TELIGEN ICD populations (advisory and non-advisory) - The overall rate of occurrence is approximately 1% at 60 months. Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy has decreased to approximately 2%. The potential for life-threatening harm from loss of therapy is approximately 1 in 500,000 (0.0002%) at 60 months. • INCEPTA, ENERGEN and PUNCTUA CRT-Ds and ICDs (non-advisory) - The projected rate is approximately 1% at 60 months. The portion of malfunctions with compromised therapy is approximately 0.2%. The potential for life-threatening harm from loss of therapy is approximately 1 in 5,000,000 (0.00002%) at 60 months.
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	<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.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p>
<p><i>This advisory is limited to those models listed below implanted subpectorally.</i></p>	<p>This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.</p> <p>Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.</p>
<p>COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108</p>	<p>A weakened header bond can result in one or more of the following device behaviors:</p> <ul style="list-style-type: none"> – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy
<p>TELIGEN VR Models E102/F102</p>	<p>No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.</p>
<p>TELIGEN DR Models E110/E111/F110/F111</p>	<p><i>Rate of Occurrence</i> The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.</p> <p>The following factors may also impact the risk of failure if implanted in a subpectoral location:</p> <ul style="list-style-type: none"> – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
<p>Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009</p>	<p>CURRENT STATUS 10-Apr-17</p>
	<p><i>Reported events (worldwide)</i> 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.</p> <p>There have been no reported patient deaths associated with this advisory.</p> <p><i>Rate of Occurrence</i> 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.</p>
	<p>CURRENT RECOMMENDATION 10-Apr-17</p> <p>If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended.</p> <p>For affected devices implanted in a subpectoral location:</p> <ul style="list-style-type: none"> – Follow patient at least once every three months as recommended in device instructions for use. – Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation. – Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

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></p>
<p>INSIGNIA Entra DR Models 1294/1295/1494/1495</p>	<p>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 SSI Models 0484/0485/1325/1326</p>	<p>CURRENT STATUS 10-Apr-17</p>
<p>INSIGNIA Entra DDD Models 0985/0986/1426</p>	<p><i>Confirmed Malfunctions (worldwide)</i></p>
<p>INSIGNIA Plus SR Models 1194/1394</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 DR and Plus DR Downsize Models 1297/1467/1298/1468</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 AVT Models 0482/0882/0982 1192/1292/1392/1428/1432/1492</p>	<p><i>Projected Rate of Occurrence</i> The rate of occurrence is projected to range between 0.10% and 0.22%.</p>
<p>CONTAK RENEWAL TR / TR2 Models H120/H125/H140/H145</p>	<p>CURRENT RECOMMENDATION 10-Apr-17 Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</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. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation.</p>
<p>VITALITY DR HE Model T180</p>	<p>Device Behavior</p>
<p>VITALITY DS VR/DR Models T135/T125</p>	<p>Pacemakers: INSIGNIA – Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant</p>
<p>VITALITY VR/DR and EL Models 1870/1871/T127</p>	
<p>VENTAK PRIZM 2 VR/DR Models 1860/1861</p>	
<p>Low Voltage Capacitor, Physician</p>	
<p>Low Voltage Capacitor, Patient Letter</p>	
<p>Low Voltage Capacitor, Physician Letter, Jun 23, 2006</p>	
<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>	

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>Voluntary Physician Advisory FDA Classification: Class II</p>
<p><i>This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..</i></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>
<p>CONTAK RENEWAL 4 Models H190/H195</p>	<ul style="list-style-type: none"> - Loss of shock therapy - Loss of pacing therapy (intermittent or permanent) - Loss of telemetry communications - Beeping (16 tones every six hours), and a programmer warning screen upon interrogation
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p><i>Reported Events</i> Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p><i>Rate of Occurrence</i> The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	<p>CURRENT STATUS 10-Apr-17</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u> Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation.</p>
<p>VITALITY DR HE Model T180</p>	<p><u>January 4, 2008 Population</u> Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation.</p>
<p>VITALITY EL Model T127</p>	<p>There have been no reported patient deaths associated with this advisory.</p>
<p>VITALITY DR+ Model 1872</p>	<p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.</p>
<p>Subpectoral Implant, Physician Letter, Jan 04, 2008</p>	<p>CURRENT RECOMMENDATION 10-Apr-17 <u>Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.</u></p>
<p>Subpectoral Implant, Patient Letter, Jan 04, 2008</p>	<p>- 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.</p>
<p></p>	<p>- For subpectoral implants, use an AP radiograph to determine specific device orientation. - 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.</p>
<p></p>	<p>If the device is in a susceptible orientation (serial number facing the ribs):</p> <ul style="list-style-type: none"> - 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.
<p></p>	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

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 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	
INSIGNIA Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490	<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 Entra SR Models 1195/1198/1395/1398	
INSIGNIA Entra DR (downsize) Models 1296/1466	Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths.
INSIGNIA Entra DR Models 1294/1295/1494/1495	<i>Rate Projection</i> Failure Mode 1—As of the September 22, 2005 communication, Modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
INSIGNIA Entra SSI Models 0484/0485/1325/1326	
INSIGNIA Entra DDD Models 0985/0986/1426	CURRENT STATUS 10-Apr-17 <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 Plus SR Models 1194/1394	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 Plus DR and Plus DR Downsize Models 1297/1467/1298/1468	
INSIGNIA AVT Models 0482/0882/0982 1192/1292/1392/1428/1432/1492	<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%.
Crystal Timing Component, Physician Letter, Dec 12, 2005	Failure Mode 1— <u>Patient management recommendations from the September 22, 2005 physician communication remain unchanged.</u>
Crystal Timing Component, Patient Letter, Oct 03, 2005	Failure Mode 2— <u>Patient management recommendations supersede those originally communicated on September 22, 2005.</u>
Crystal Timing Component, Physician Letter, Sep 22, 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.
	Standard Warranty program available, please contact your local representative for terms and conditions.

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