

2015

Rhythm Management Product Performance Report

Q3 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 Q3 2015 report includes data through July 10, 2015.

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

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

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

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

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

Medical Review Board

Ronald D. Berger, M.D., PhD

Professor of Medicine
Johns Hopkins University

Stephen R. Shorofsky, M.D., PhD

Professor of Medicine
University of Maryland, School of Medicine

Bruce S. Stambler, M.D.

Director, Cardiac Arrhythmia Research and Education
Piedmont Heart Institute, Atlanta, GA

Boston Scientific Reviewers

Renold Russie

Vice President, Quality Assurance

Arjun Sharma, M.D.

Vice President of Medical Safety

James Broge, PhD

Director, Post-Market Quality Assurance

Jack Litzau, M.S.

Principal Statistician

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. These leads were previously reported as Extrinsic Malfunctions, but are now included in Chronic Lead Complications. Both Malfunctions and Chronic Lead Complications are included in Survival Probability, so this re-categorization has no effect on reported U.S. Survival Probability lead data. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

Supporting Greater Return of Explanted Devices

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

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

Help Us Provide You With More Complete Product Performance Data

Reporting Adverse Events

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

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

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

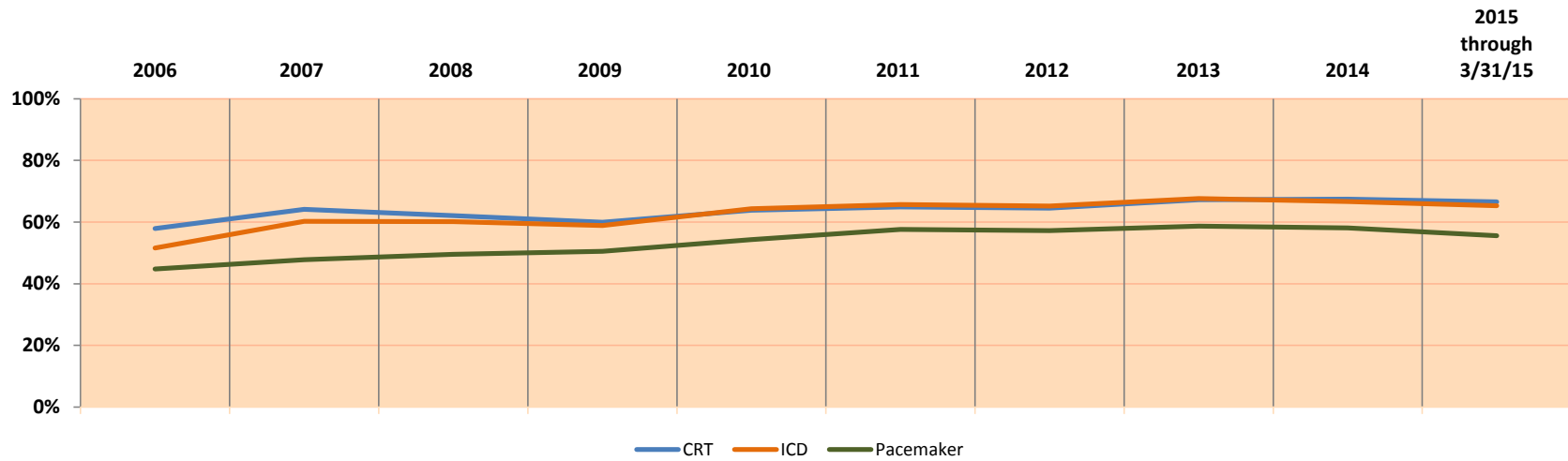
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

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



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




	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015 through 3/31/15
Explants	3346	4241	5663	9242	10428	9264	7981	8212	6742	943
Returns	1936	2718	3517	5541	6655	6017	5150	5520	4547	628
% Returned	58%	64%	62%	60%	64%	65%	65%	67%	67%	67%
Explants	10175	11521	15529	19456	19841	16487	11869	11757	10906	1794
Returns	5252	6942	9333	11449	12768	10828	7737	7948	7270	1172
% Returned	52%	60%	60%	59%	64%	66%	65%	68%	67%	65%
Explants	16921	18348	20377	20930	20997	19865	18523	18516	18823	3039
Returns	7573	8760	10092	10581	11407	11454	10606	10868	10930	1689
% Returned	45%	48%	50%	51%	54%	58%	57%	59%	58%	56%

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

AUTOGEN CRT-D Models G160/G161/G164/G166/G168/ G172/G173/G175/G177/G179 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	1	1	2

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

DYNAGEN/INOGEN/ORIGEN CRT-D

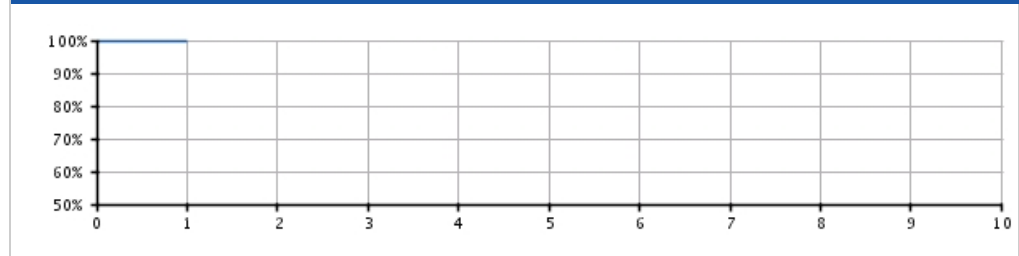
Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

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

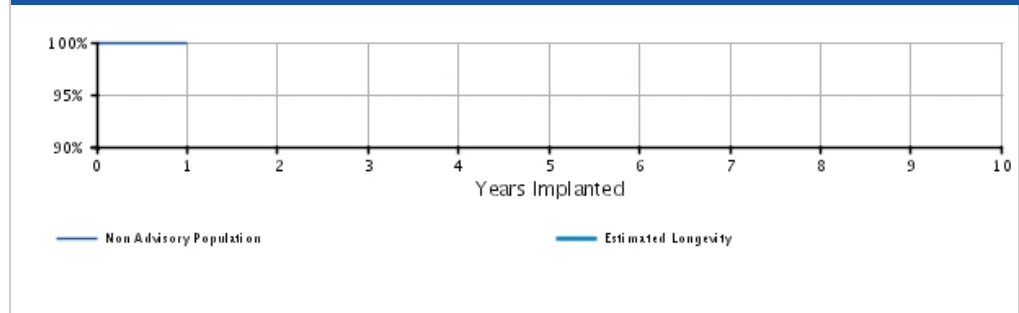
U.S. Summary

U.S. Registered Implants: 8,000	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: 8,000	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 (-0.1/+0.0)	-	-	-	-	-	-	-	-	-
Registered Implants: 8000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	-	-	-	-	-	-	-	-	-
	Effective Sample Size	398	-	-	-	-	-	-	-	-	-

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

DYNAGEN/INOGEN/ORIGEN CRT-D
**Models G050/G051/G056/G058/G140/
 G141/G146/G148/G150/G151/
 G154/G156/G158**



Worldwide Distribution: 13,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁹⁰ High voltage circuit component	1	-	
Mechanical	-	-	0
Software	-	1	1
⁷⁹ Memory errors	-	1	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[References](#) cited in table above

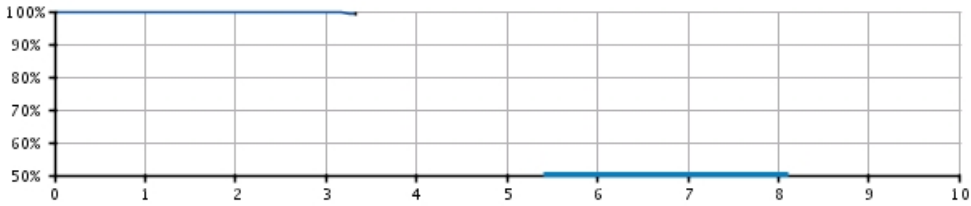
INCEPTA CRT-D 4-Site

Models N160/N162/P162

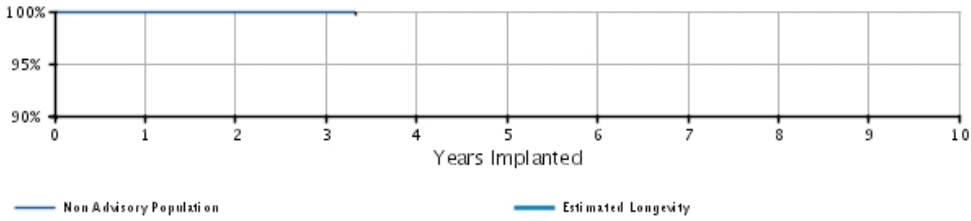
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 9,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 9,000	U.S. Normal Battery Depletions: 6 U.S. Unconfirmed Reports of Premature Battery Depletion : 1 U.S. Malfunctions:5 Without Compromised Therapy:4 With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.61 (-0.5/+0.2)	99.36 @ 40 mo. (-0.9/+0.4)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.88 (-0.2/+0.1)	99.88 @ 40 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Effective Sample Size	6498	3094	852	260	-	-	-	-	-	-	-

INCEPTA CRT-D 4-Site

Models N160/N162/P162

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

INCEPTA CRT-D 4-Site Models N160/N162/P162 			
Worldwide Distribution: 16,000			
Worldwide Confirmed Malfunctions: 7			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁰ Safety Core-electrocautery	1	-	
⁷⁸ Integrated circuit	-	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	5	2	7

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

INCEPTA CRT-D

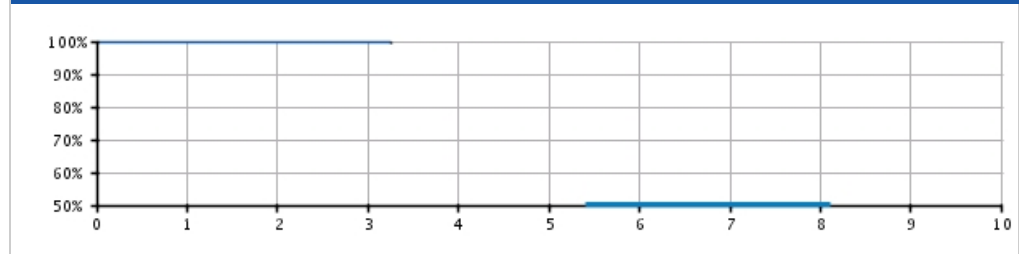
Models N161/N163/N164/N165/P163/
P165

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

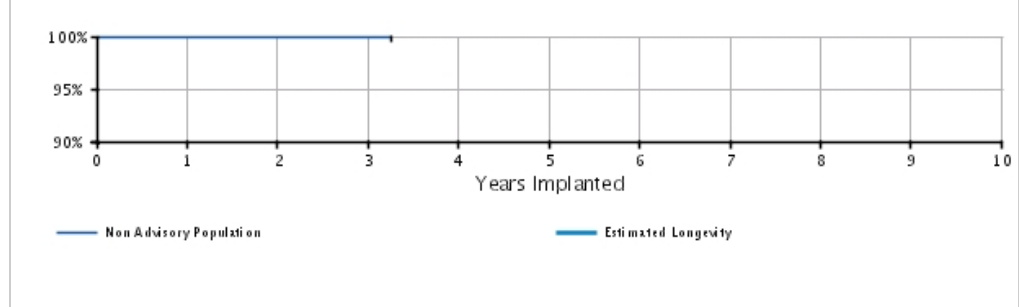
U.S. Summary

U.S. Registered Implants: 12,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 11,000	U.S. Normal Battery Depletions: 11 U.S. Unconfirmed Reports of Premature Battery Depletion : 2 U.S. Malfunctions:3 Without Compromised Therapy:1 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 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.62 (-0.3/+0.2)	99.62 @ 39 mo. (-0.3/+0.2)	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.91 (-0.4/+0.1)	99.91 @ 39 mo. (-0.4/+0.1)	-	-	-	-	-	-
Registered Implants: 12000	Effective Sample Size	8629	4317	939	351	-	-	-	-	-	-

INCEPTA CRT-D

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

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

INCEPTA CRT-D Models N161/N163/N164/N165/P163/ P165 			
Worldwide Distribution: 18,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷¹ High-voltage capacitor	-	1	
⁸² Low-voltage capacitor	1	-	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	2	3

[References](#) cited in table above

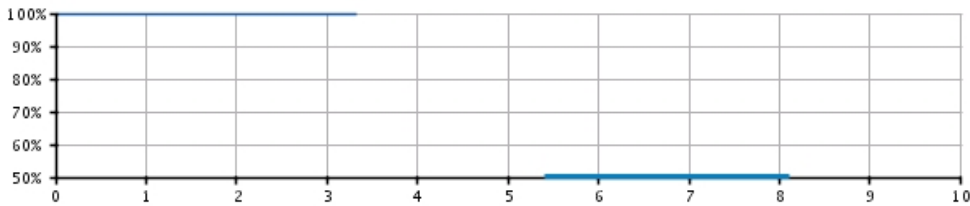
ENERGEN CRT-D 4-Site

Models N140/N142/P142

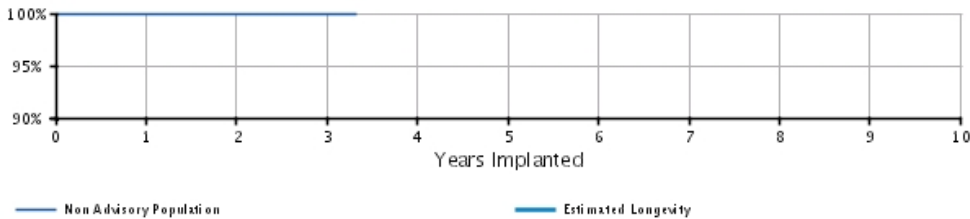
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 14,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 12,000	U.S. Normal Battery Depletions: 4 U.S. Unconfirmed Reports of Premature Battery Depletion : 2 U.S. Malfunctions:3 Without Compromised Therapy:2 With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.85 @ 40 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Registered Implants: 14000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 40 mo. (-0.1/+0.0)	-	-	-	-	-	-
Effective Sample Size		10174	5504	1424	354	-	-	-	-	-	-	-

ENERGEN CRT-D 4-Site

Models N140/N142/P142

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

ENERGEN CRT-D 4-Site Models N140/N142/P142 			
Worldwide Distribution: 20,000 Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁷⁸ Integrated circuit	1	-	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	3	1	4
Non-patterned	3	1	
WW Confirmed Malfunctions	5	1	6

[References](#) cited in table above

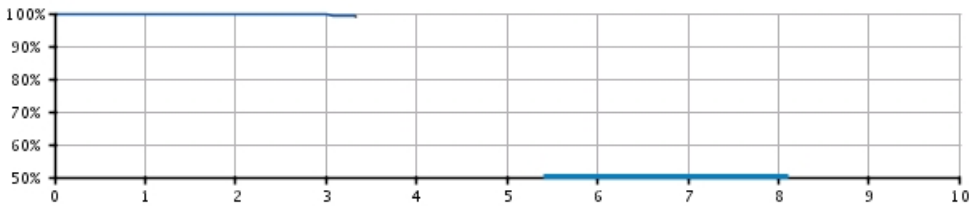
ENERGEN CRT-D

Models N141/N143/P143

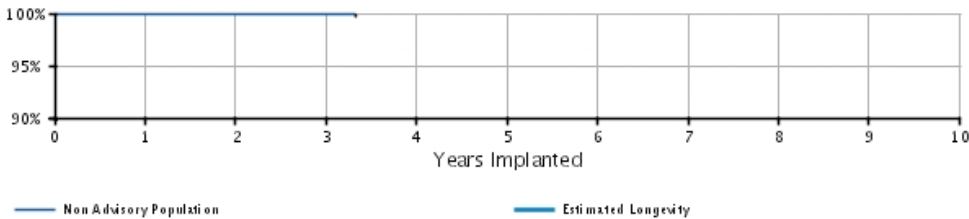
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 13,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 11,000	U.S. Normal Battery Depletions: 11 U.S. Unconfirmed Reports of Premature Battery Depletion : 3 U.S. Malfunctions:10 Without Compromised Therapy:5 With Compromised Therapy:5

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.55 (-0.3/+0.2)	99.29 @ 40 mo. (-0.6/+0.3)	-	-	-	-	-	-	-
	Registered Implants: 13000	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.86 (-0.2/+0.1)	99.86 @ 40 mo. (-0.2/+0.1)	-	-	-	-	-	-
Effective Sample Size		9834	5232	1183	228	-	-	-	-	-	-	-

ENERGEN CRT-D

Models N141/N143/P143

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


ENERGEN CRT-D Models N141/N143/P143 			
Worldwide Distribution: 17,000 Worldwide Confirmed Malfunctions: 12			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁷⁰ Safety Core-electrocautery	1	1	
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	-	2	
⁸² Low-voltage capacitor	1	-	
Mechanical	-	3	3
⁶⁴ Transformer	-	3	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	6	6	12

References cited in table above

PUNCTUA CRT-D 4-Site

Models N050/N052/P052

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

PUNCTUA CRT-D 4-Site Models N050/N052/P052 			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

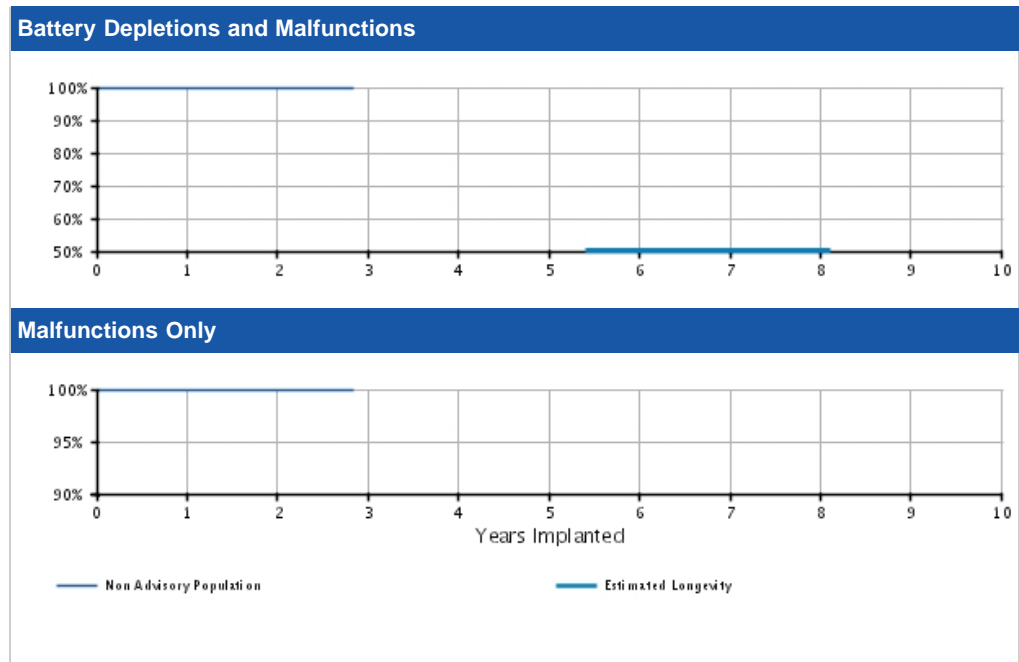
[References](#) cited in table above

PUNCTUA CRT-D

Models N051/N053/P053

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

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




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 34 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Registered Implants: 1000	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 34 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Effective Sample Size		1097	620	204	-	-	-	-	-	-	-	-

PUNCTUA CRT-D

Models N051/N053/P053

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

PUNCTUA CRT-D Models N051/N053/P053 			
Worldwide Distribution: 5,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷⁸ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

COGNIS

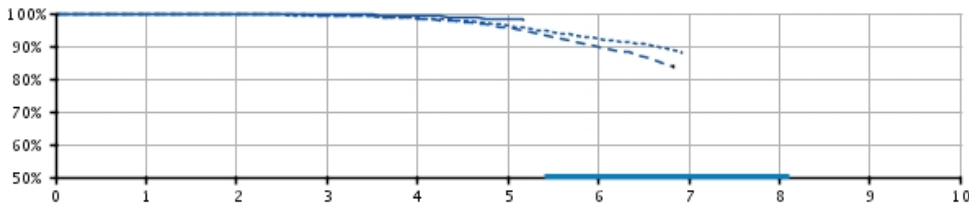
Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

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

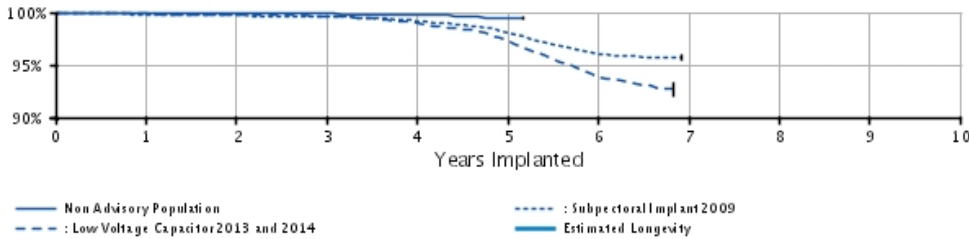
U.S. Summary

U.S. Registered Implants: 75,000	U.S. Normal Battery Depletions: 946
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 60
U.S. Estimated Active Implants: 45,000	U.S. Malfunctions:898
	Without Compromised Therapy:755
	With Compromised Therapy:143

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.14 (-0.4/+0.3)	98.14 @ 62 mo. (-0.4/+0.3)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.79 (-0.1/+0.0)	99.49 (-0.2/+0.1)	99.49 @ 62 mo. (-0.2/+0.1)	-	-	-	-
	Effective Sample Size	31537	28072	24573	14005	1388	255	-	-	-	-
Subjectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.1)	96.38 (-0.3/+0.3)	92.25 (-0.5/+0.5)	88.23 @ 83 mo. (-0.6/+0.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.71 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.12 (-0.2/+0.2)	96.09 (-0.3/+0.3)	95.66 @ 83 mo. (-0.3/+0.3)	-	-	-
	Effective Sample Size	27505	24388	21691	19196	16729	8197	287	-	-	-
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.47 (-0.1/+0.1)	98.41 (-0.2/+0.2)	95.55 (-0.4/+0.3)	89.72 (-1.3/+1.2)	83.74 @ 82 mo. (-1.3/+1.3)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.47 (-0.1/+0.1)	98.41 (-0.2/+0.2)	95.55 (-0.4/+0.3)	89.72 (-1.3/+1.2)	83.74 @ 82 mo. (-1.3/+1.3)	-	-	-
	Effective Sample Size	27505	24388	21691	19196	16729	8197	287	-	-	-


26,000											
	Malfunctions Only (%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.2/+0.1)	97.32 (-0.3/+0.3)	93.90 (-0.7/+0.7)	92.68 @ 82 mo. (-0.8/+0.7)	-	-	-
	Effective Sample Size	22622	20045	17852	15768	12907	3299	248	-	-	-

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

COGNIS

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

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

COGNIS Models N106/N107/N108/N118/N119/ N120/P106/P107/P108 			
Worldwide Distribution: 109,000			
Worldwide Confirmed Malfunctions: 1166			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	893	104	997
¹ Low Voltage Capacitor 2014 (Advisory issued)	743	52	
⁷⁰ Safety Core-electrocautery	47	18	
⁷¹ High-voltage capacitor	1	4	
⁷⁵ Low-voltage capacitors	7	-	
⁷⁸ Integrated circuit	7	19	
⁸⁰ High voltage circuit	-	1	
⁸¹ Battery	24	4	
⁸² Low-voltage capacitor	64	6	
Mechanical	36	84	120
⁵ Subpectoral implant 2009 (Advisory issued)	14	42	
⁶⁴ Transformer	-	9	
⁶⁸ Difficulty securing lead	9	9	
⁷³ Header contacts	7	7	
⁹² Header	6	17	
Software	14	-	14
⁷⁴ Safety Core-programming	1	-	
⁷⁶ Alert messages not displayed post-EOL	2	-	
⁷⁹ Memory errors	11	-	
Other	26	9	35
Non-patterned	26	9	
WW Confirmed Malfunctions	969	197	1166

References cited in table above

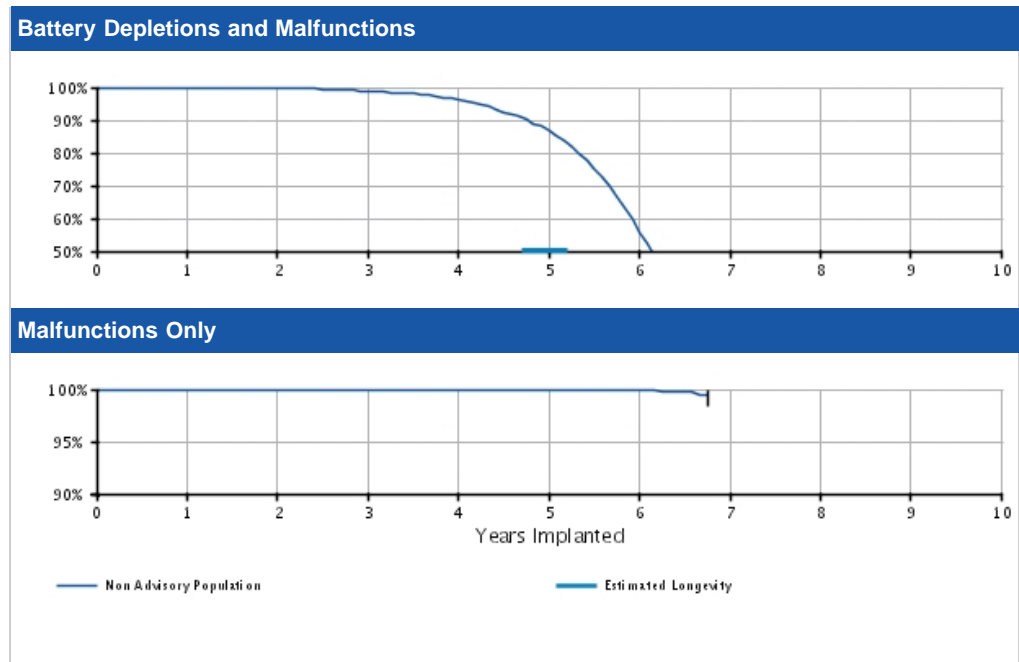
CRM PRODUCT PERFORMANCE REPORT Q3 2015

LIVIAN HE

Models H227/H229/H247/H249

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

U.S. Summary	
U.S. Registered Implants: 6,000 U.S. Approval Date: February 2008 U.S. Estimated Active Implants: 1,000	U.S. Normal Battery Depletions: 1,581 U.S. Unconfirmed Reports of Premature Battery Depletion : 4 U.S. Malfunctions:6 Without Compromised Therapy:3 With Compromised Therapy:3



U.S. Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.74	98.92	96.46	87.14	55.94	24.05	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.4/+0.3)	(-0.7/+0.6)	(-1.2/+1.1)	(-2.0/+2.0)	(-2.2/+2.3)			
Registered Implants: 6000	Malfunctions Only(%)	99.98	99.92	99.92	99.92	99.92	99.92	99.55	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.1/+0.1)	(-1.0/+0.3)			
	Effective Sample Size	4940	4325	3787	3178	2331	1148	210	—	—	—

LIVIAN HE

Models H227/H229/H247/H249

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

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

References cited in table above

CONTAK RENEWAL 4

Models H190/H195

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


CONTAK RENEWAL 4 Models H190/H195			
Worldwide Distribution: 18,000			
Worldwide Confirmed Malfunctions: 355			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	310	11	321
⁸ Shortened replacement window (Advisory issued)	160	5	
¹⁰ Premature battery depletion (Advisory issued)	14	-	
¹⁵ Extended charge time post-mid-life	9	-	
¹⁹ Integrated circuit	2	-	
²³ Capacitor	-	1	
²⁷ Integrated circuit	2	3	
³⁸ Capacitor	-	1	
⁴¹ Capacitor	3	-	
⁴⁸ Mid-life display of replacement indicators	63	-	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	57	-	
Mechanical	8	14	22
⁴ Magnetic reed switch 2010 (Advisory issued)	-	3	
⁷ Subpectoral implant (Advisory issued)	-	7	
¹³ Magnetic switch (Advisory issued)	-	1	
²⁴ Header	2	-	
³¹ Seal plug	4	-	
⁴⁰ Circuit connection	-	1	
⁵⁵ Setscrew	-	1	
⁶² Reed switch	1	1	
⁶³ Cracked solder joint	1	-	
Software	-	-	0
Other	6	6	12
Non-patterned	2	3	
³⁴ Battery depletion	4	3	
WW Confirmed Malfunctions	324	31	355

[References](#) cited in table above

CONTAK RENEWAL 4 HE

Models H197/H199

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


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

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

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

VISIONIST/VALITUDE Models U125/U128/U225/U226/U228 			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[References](#) cited in table above

INTUA

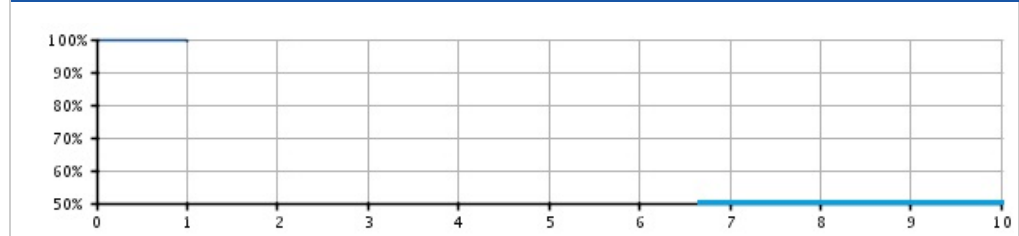
Models V272/V273/V282/V283/W272/
W273

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

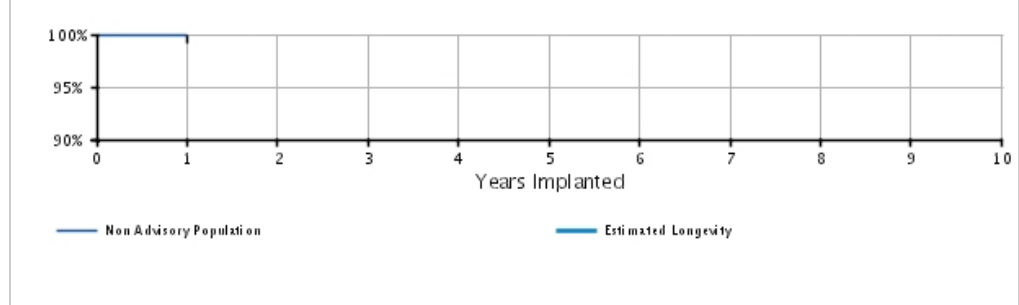
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 2
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)	99.64 (-0.8/+0.3)	-	-	-	-	-	-	-	-	-
Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	99.88 (-0.7/+0.1)	-	-	-	-	-	-	-	-	-
	Effective Sample Size	261	-	-	-	-	-	-	-	-	-

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

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

INVIVE

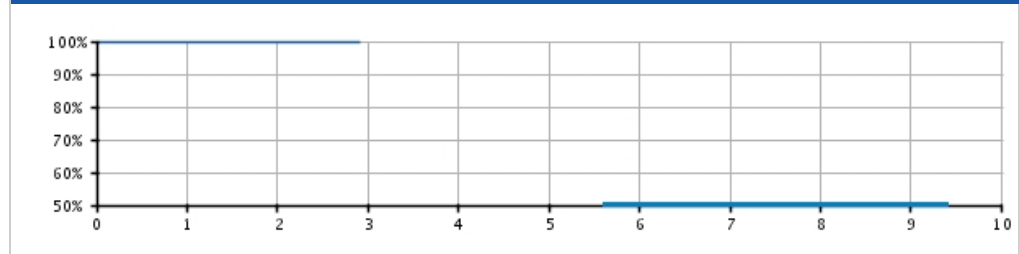
Models V172/V173/V182/V183/W172/
W173

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

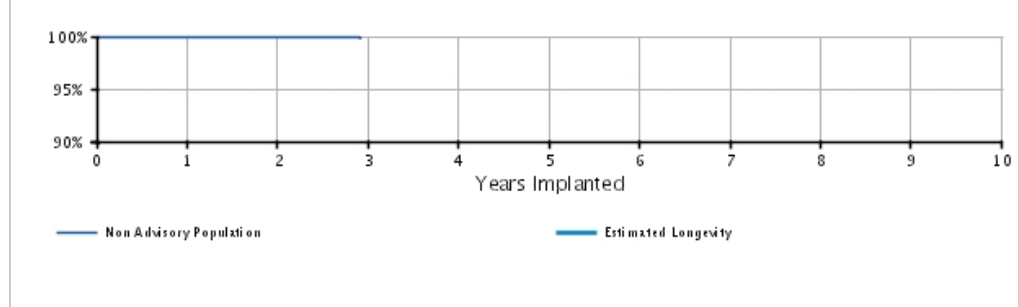
U.S. Summary

U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 6
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)	99.82 (-0.2/+0.1)	99.82 @ 35 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
Registered Implants: 7000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 35 mo. (-0.2/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	5264	2206	272	-	-	-	-	-	-	-

INVIVE

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

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


INVIVE Models V172/V173/V182/V183/W172/ W173 			
Worldwide Distribution: 16,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁷⁵ Low-voltage capacitors	-	1	
Mechanical	-	-	0
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[References](#) cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

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

CONTAK RENEWAL TR 2 Models H140/H145 			
Worldwide Distribution: 31,000			
Worldwide Confirmed Malfunctions: 29			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	4	-	4
³¹ Seal plug	1	-	
⁴⁴ Setscrew block	2	-	
⁵⁶ Seal plug	1	-	
Software	13	-	13
³⁶ Memory error	1	-	
⁴⁶ Stored EGMs	12	-	
Other	10	1	11
Non-patterned	9	1	
⁵⁴ Alert messages	1	-	
WW Confirmed Malfunctions	28	1	29

[References](#) cited in table above

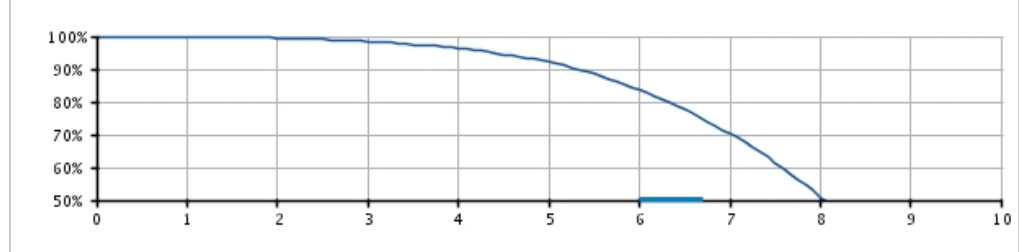
CONTAK RENEWAL TR

Models H120/H125

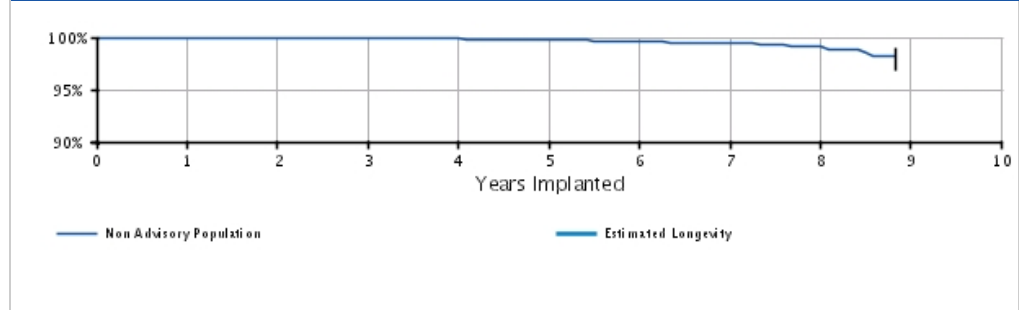
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 19,000	U.S. Normal Battery Depletions: 2,020
U.S. Approval Date: January 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Estimated Active Implants: 7,000	U.S. Malfunctions:46
	Without Compromised Therapy:44
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.37 (-0.4/+0.3)	92.12 (-0.6/+0.6)	83.66 (-1.0/+0.9)	70.41 (-1.5/+1.5)	50.99 (-2.2/+2.2)	33.98 @ 106 mo. (-2.7/+2.8)	-	-
	Registered Implants: 19000	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.75 (-0.1/+0.1)	99.64 (-0.2/+0.1)	99.48 (-0.3/+0.2)	99.11 (-0.5/+0.3)	98.15 @ 106 mo. (-1.4/+0.8)	-
		Effective Sample Size	15602	13625	11685	8673	5516	3213	1607	643	208	-
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: 46			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁹ Low-voltage capacitor (Advisory issued)	1	-	
²³ Capacitor	-	1	
Mechanical	5	-	5
³¹ Seal plug	5	-	
Software	28	-	28
⁴⁶ Stored EGMs	28	-	
Other	10	1	11
Non-patterned	7	1	
⁵⁴ Alert messages	3	-	
WW Confirmed Malfunctions	44	2	46

[References](#) cited in table above

EMBLEM S-ICD

Model A209

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


EMBLEM S-ICD Model A209			
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

[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: 3,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0


[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: 3,000
Worldwide Confirmed Malfunctions: 0

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

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

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: 3,000

Worldwide Confirmed Malfunctions: 0

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


[References](#) cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

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

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



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

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

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

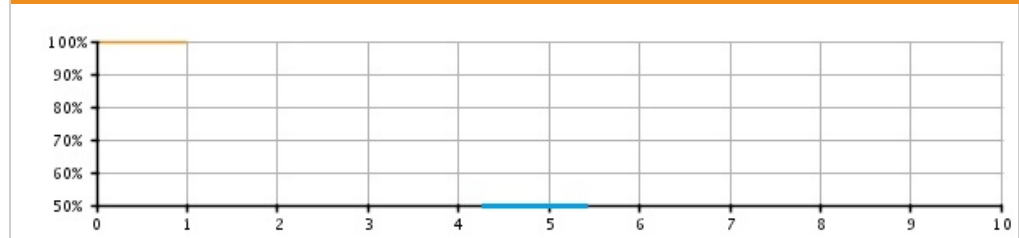
Models D002/D003/D012/D013/D022/
D023

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

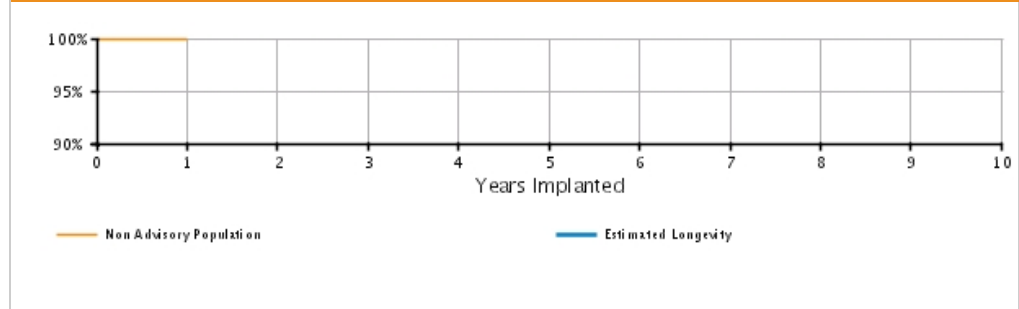
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

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)	-	-	-	-	-	-	-	-	-
Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
	Effective Sample Size	253	-	-	-	-	-	-	-	-	-

CRM PRODUCT PERFORMANCE REPORT Q3 2015

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

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

DYNAGEN/INOGEN/ORIGEN ICD MINI DR 

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

Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

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

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

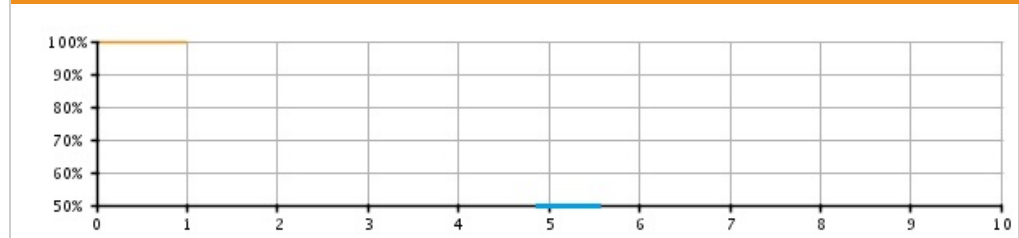
Models D000/D001/D010/D011/D020/
D021

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

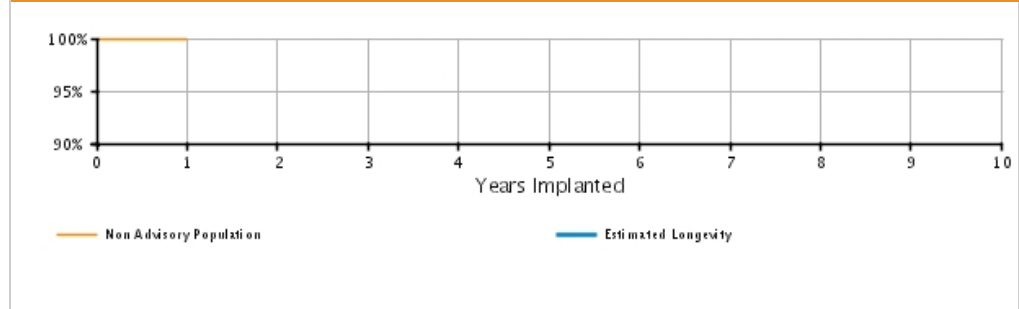
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: April 2014	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

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)	99.88 (-0.7/+0.1)	-	-	-	-	-	-	-	-	-
Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	-	-	-	-	-	-	-	-	-
	Effective Sample Size	210	-	-	-	-	-	-	-	-	-

CRM PRODUCT PERFORMANCE REPORT Q3 2015

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

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

DYNAGEN/INOGEN/ORIGEN ICD MINI VR Models D000/D001/D010/D011/D020/ D021 			
Worldwide Distribution: 4,000 Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

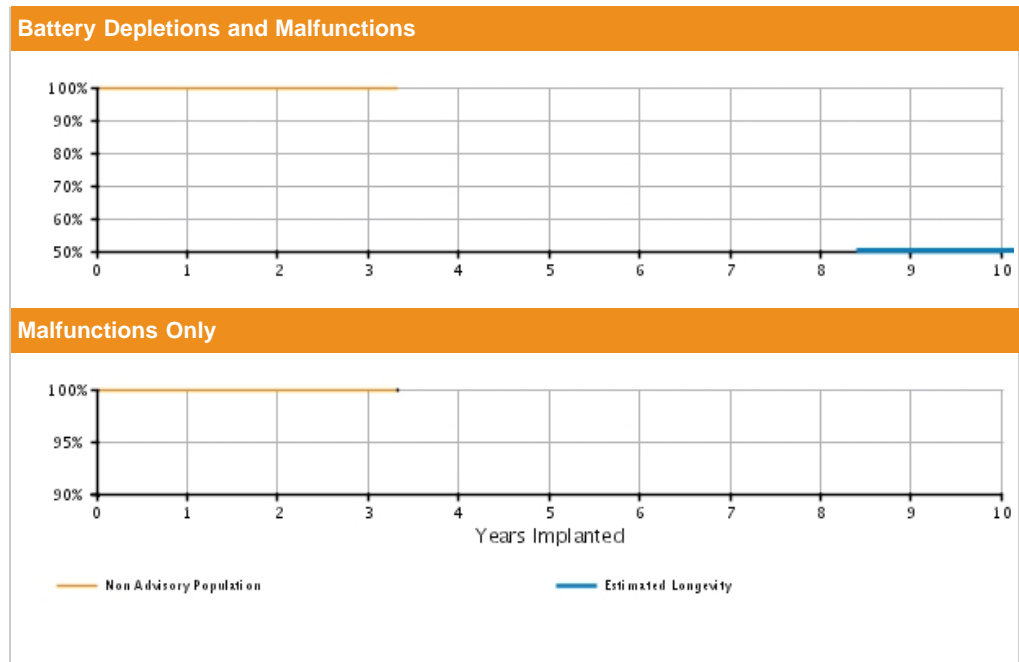
[References](#) cited in table above

INCEPTA ICD DR 4-Site

Models E162/F162

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

U.S. Summary	
U.S. Registered Implants: 12,000	U.S. Normal Battery Depletions: 5
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:4
	Without Compromised Therapy:3
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.96	99.90	99.71	99.71	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.4/+0.2)	@ 40 mo. (-0.4/+0.2)							
Registered Implants: 12000	Malfunctions Only(%)	99.98	99.96	99.92	99.92	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	@ 40 mo. (-0.2/+0.1)							
	Effective Sample Size	7592	3667	915	270	—	—	—	—	—	—	—

INCEPTA ICD DR 4-Site

Models E162/F162

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

INCEPTA ICD DR 4-Site
Models E162/F162



Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁷¹ High-voltage capacitor	1	-	
⁷⁸ Integrated circuit	1	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	2	6

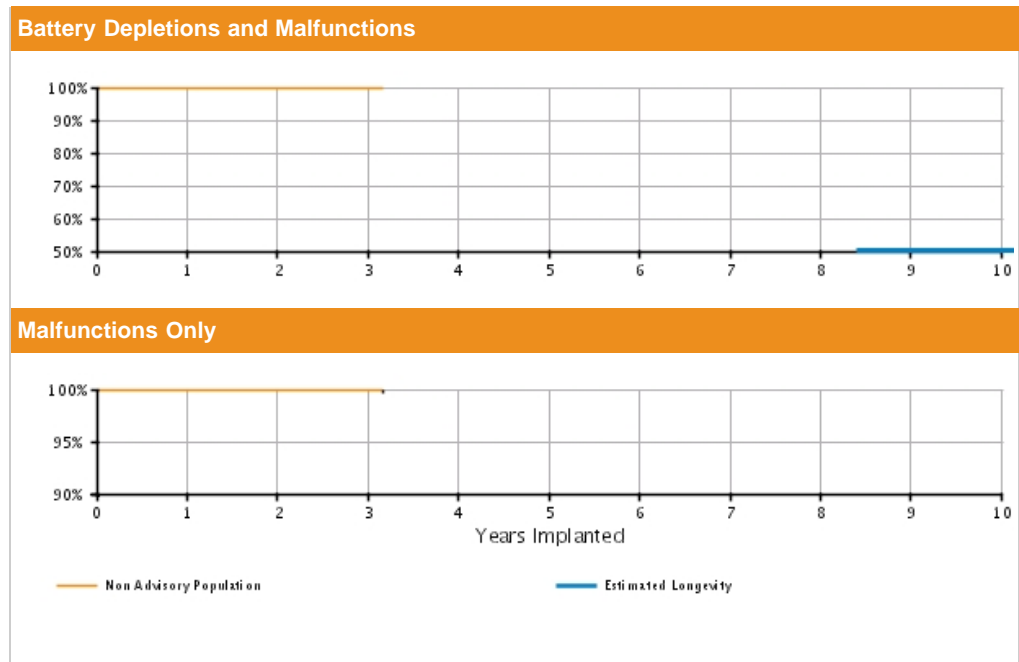
[References](#) cited in table above

INCEPTA ICD DR

Models E163/F163

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

U.S. Summary	
U.S. Registered Implants: 7,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 6,000	U.S. Normal Battery Depletions: 3 U.S. Unconfirmed Reports of Premature Battery Depletion : 2 U.S. Malfunctions:5 Without Compromised Therapy:4 With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.76 (-0.3/+0.1)	99.68 (-0.3/+0.2)	99.68 @ 38 mo. (-0.3/+0.2)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.85 (-0.2/+0.1)	99.85 @ 38 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
Registered Implants: 7000		Effective Sample Size	4492	2084	458	266	-	-	-	-	-	-

INCEPTA ICD DR

Models E163/F163

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

INCEPTA ICD DR Models E163/F163 			
Worldwide Distribution: 11,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	-	
⁸⁶ High voltage circuit	1	-	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	2	1	3
Non-patterned	2	1	
WW Confirmed Malfunctions	7	1	8

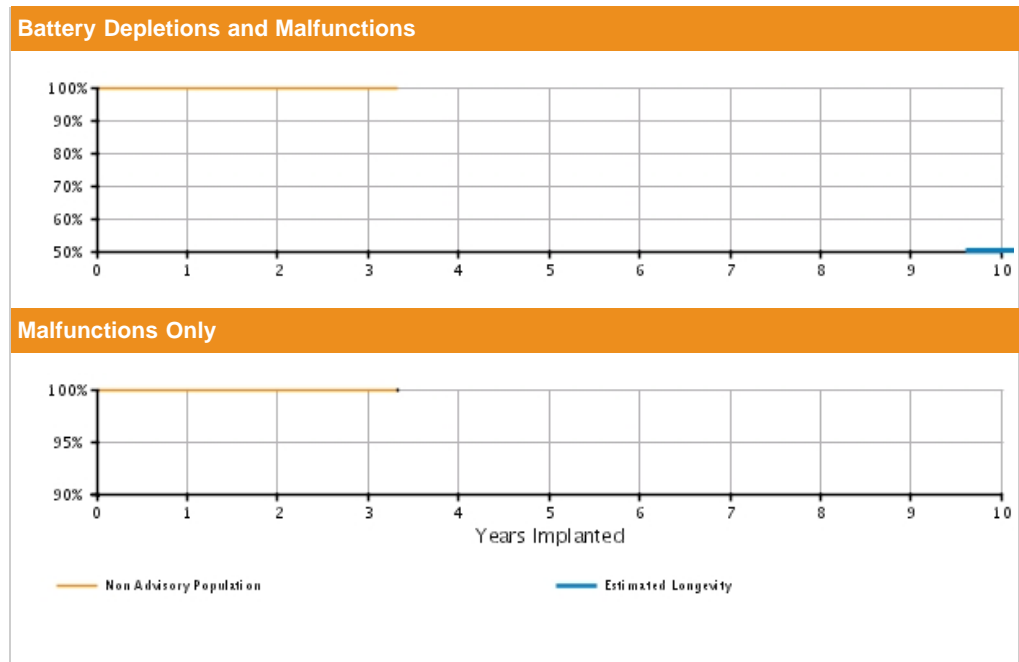
[References](#) cited in table above

INCEPTA ICD VR 4-Site

Models E160/F160

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

U.S. Summary	
U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 3
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:4
	Without Compromised Therapy:3
	With Compromised Therapy:1




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.88 (-0.2/+0.1)	99.88 @ 40 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.92 (-0.2/+0.1)	99.92 @ 40 mo. (-0.2/+0.1)	-	-	-	-	-	-	-
Registered Implants: 11000	Effective Sample Size	6597	3005	730	215	-	-	-	-	-	-	-

INCEPTA ICD VR 4-Site

Models E160/F160

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

INCEPTA ICD VR 4-Site Models E160/F160			
Worldwide Distribution: 17,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	3	1	4

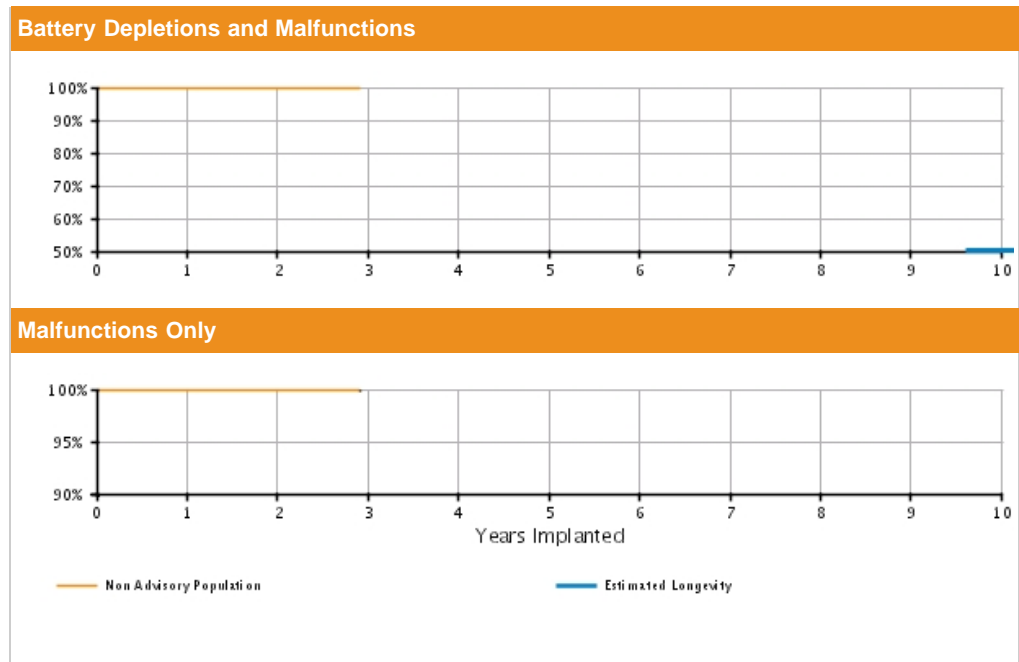
[References](#) cited in table above

INCEPTA ICD VR

Models E161/F161

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

U.S. Summary	
U.S. Registered Implants: 4,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 3,000	U.S. Normal Battery Depletions: 2 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 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 Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.90 @ 35 mo. (-0.2/+0.1)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 35 mo. (-0.2/+0.0)	—	—	—	—	—	—	—	—
	Effective Sample Size	2314	1098	211	—	—	—	—	—	—	—	—

INCEPTA ICD VR

Models E161/F161

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

INCEPTA ICD VR
Models E161/F161



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 1

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

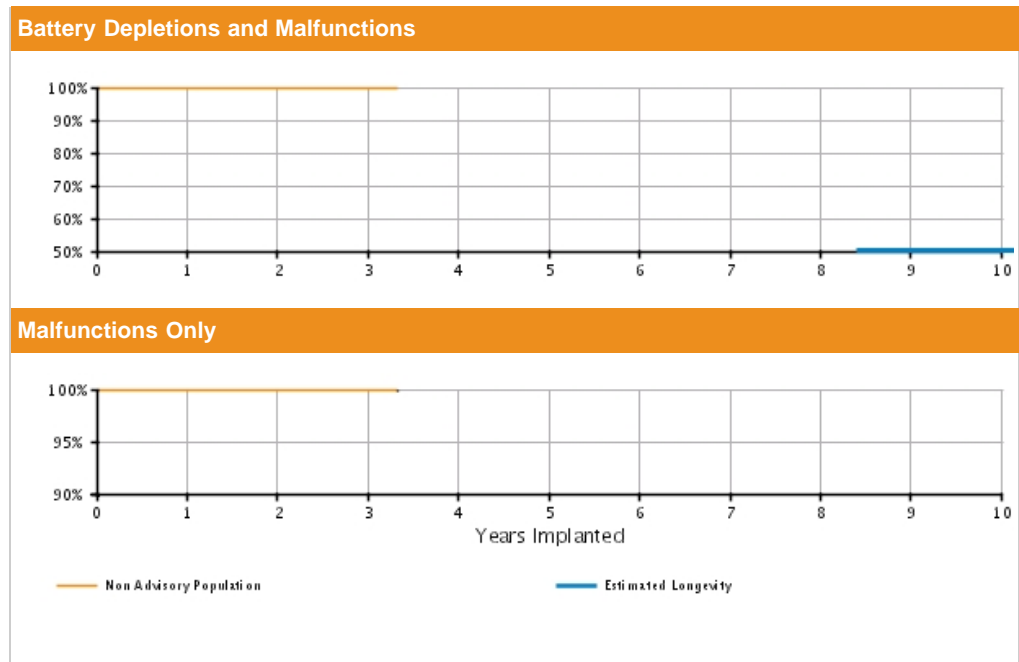
[References](#) cited in table above

ENERGEN ICD DR 4-Site

Models E142/F142

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

U.S. Summary	
U.S. Registered Implants: 14,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 13,000	U.S. Normal Battery Depletions: 6 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:6 Without Compromised Therapy:3 With Compromised Therapy:3



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.79 (-0.2/+0.1)	99.79 @ 40 mo. (-0.2/+0.1)	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.92 @ 40 mo. (-0.1/+0.0)	—	—	—	—	—	—	—
Registered Implants: 14000	Effective Sample Size	10268	5646	1447	354	—	—	—	—	—	—	—

ENERGEN ICD DR 4-Site

Models E142/F142

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

ENERGEN ICD DR 4-Site Models E142/F142			
Worldwide Distribution: 20,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	2	6
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	2	
⁸² Low-voltage capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	1	1	
WW Confirmed Malfunctions	5	3	8

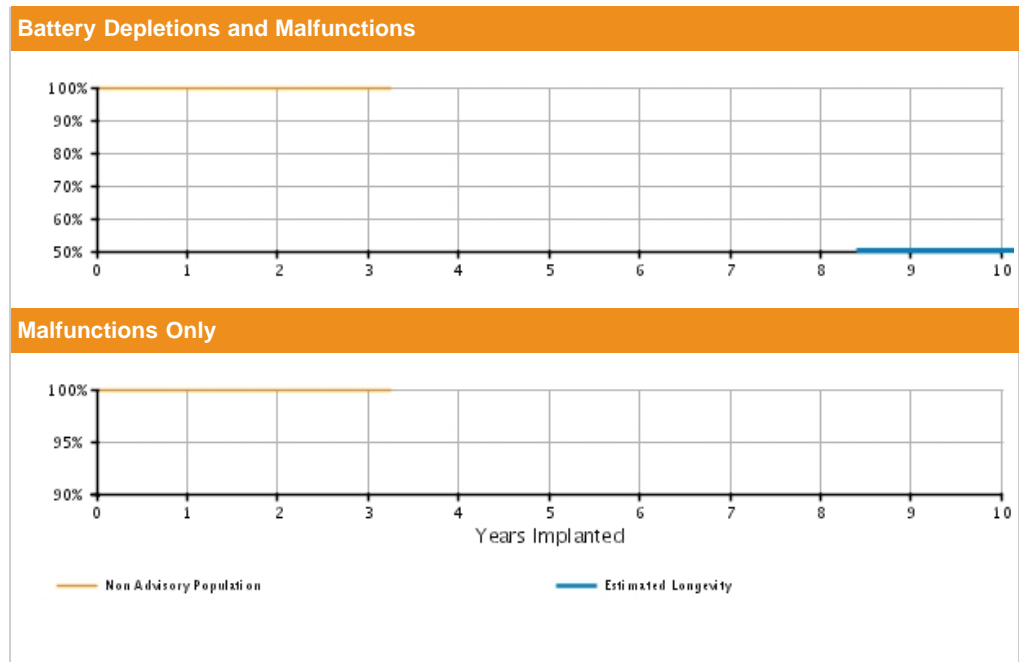
[References](#) cited in table above

ENERGEN ICD DR

Models E143/F143

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

U.S. Summary	
U.S. Registered Implants: 10,000	U.S. Normal Battery Depletions: 4
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 9,000	U.S. Malfunctions:1
	Without Compromised Therapy:1
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.96	99.93	99.93	99.93	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	@ 39 mo. (-0.1/+0.0)							
Registered Implants: 10000	Malfunctions Only(%)	99.99	99.99	99.99	99.99	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	@ 39 mo. (-0.1/+0.0)							
	Effective Sample Size	7459	3957	801	294	—	—	—	—	—	—	—

ENERGEN ICD DR

Models E143/F143

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

ENERGEN ICD DR Models E143/F143 			
Worldwide Distribution: 14,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁵ Low-voltage capacitors	1	-	
⁸¹ Battery	-	1	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	2	3

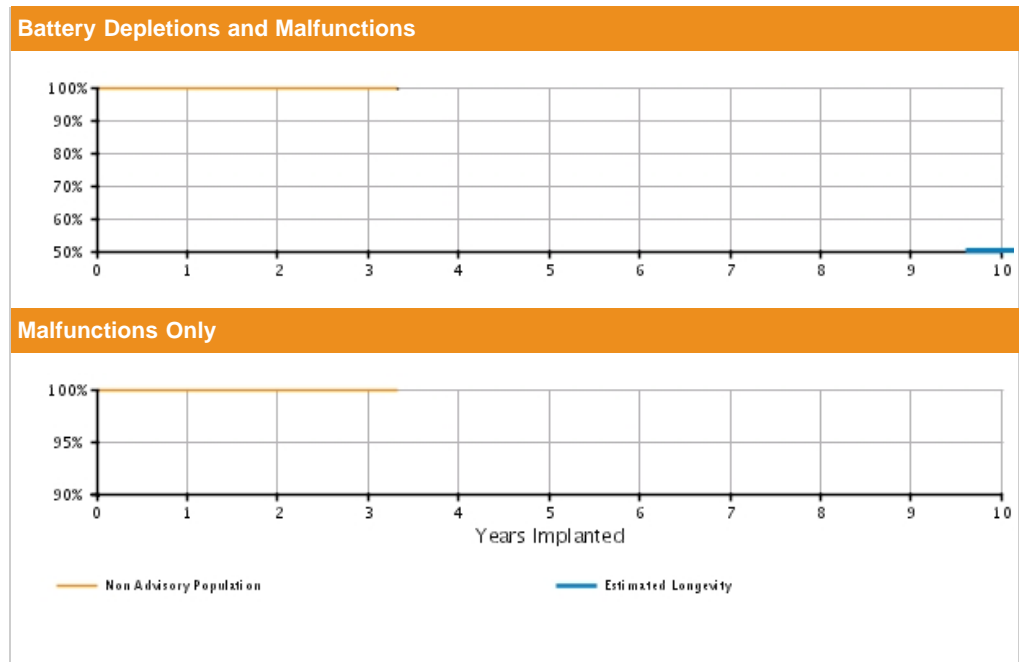
[References](#) cited in table above

ENERGEN ICD VR 4-Site

Models E140/F140

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

U.S. Summary	
U.S. Registered Implants: 15,000	U.S. Normal Battery Depletions: 13
U.S. Approval Date: November 2011	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 14,000	U.S. Malfunctions:4
	Without Compromised Therapy:0
	With Compromised Therapy:4



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.81 (-0.1/+0.1)	99.62 @ 40 mo. (-0.7/+0.2)	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 40 mo. (-0.1/+0.0)	-	-	-	-	-	-	-
Registered Implants: 15000	Effective Sample Size	10485	5380	1253	322	-	-	-	-	-	-	-

ENERGEN ICD VR 4-Site

Models E140/F140

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

ENERGEN ICD VR 4-Site Models E140/F140			
Worldwide Distribution: 21,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
⁸¹ Battery	1	-	
Mechanical	-	2	2
⁶⁴ Transformer	-	2	
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	-	2	2
Non-patterned	-	2	
WW Confirmed Malfunctions	2	4	6

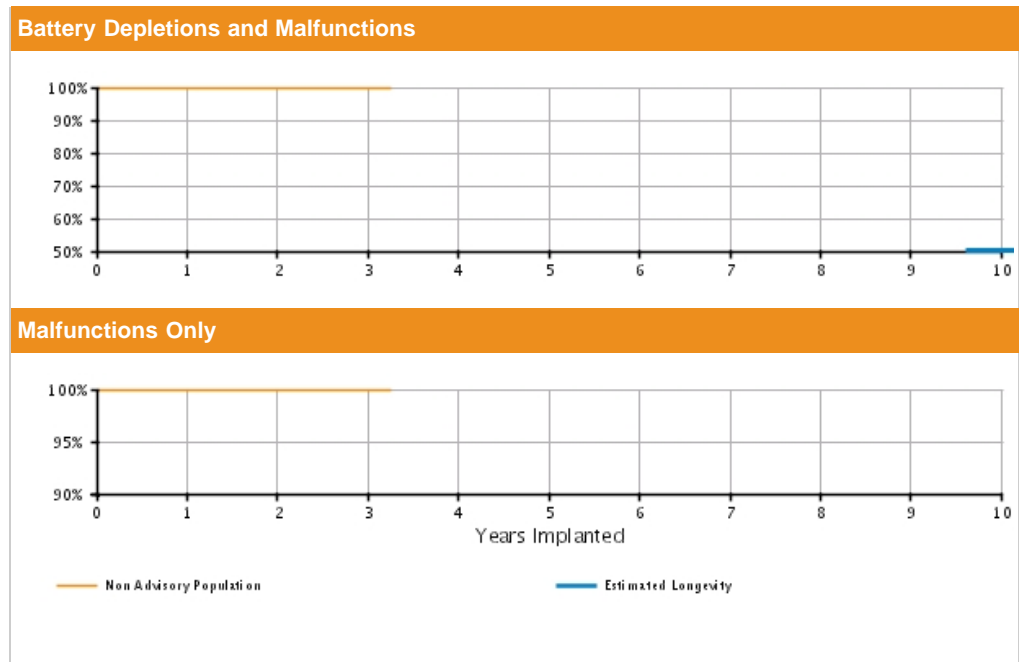
[References](#) cited in table above

ENERGEN ICD VR

Models E141/F141

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

U.S. Summary	
U.S. Registered Implants: 7,000 U.S. Approval Date: November 2011 U.S. Estimated Active Implants: 7,000	U.S. Normal Battery Depletions: 4 U.S. Unconfirmed Reports of Premature Battery Depletion : 0 U.S. Malfunctions:3 Without Compromised Therapy:1 With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.1)	99.86 (-0.2/+0.1)	99.86 (-0.2/+0.1)	99.86 @ 39 mo. (-0.2/+0.1)	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 39 mo. (-0.1/+0.0)	—	—	—	—	—	—	—
Registered Implants: 7000	Effective Sample Size	5223	2790	668	277	—	—	—	—	—	—	—

ENERGEN ICD VR

Models E141/F141

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


ENERGEN ICD VR Models E141/F141			
Worldwide Distribution: 11,000			
Worldwide Confirmed Malfunctions: 6			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	3	4
⁷¹ High-voltage capacitor	1	-	
⁷⁸ Integrated circuit	-	3	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	2	4	6

[References](#) cited in table above

PUNCTUA ICD DR 4-Site

Models E052/F052

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

PUNCTUA ICD DR 4-Site Models E052/F052			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

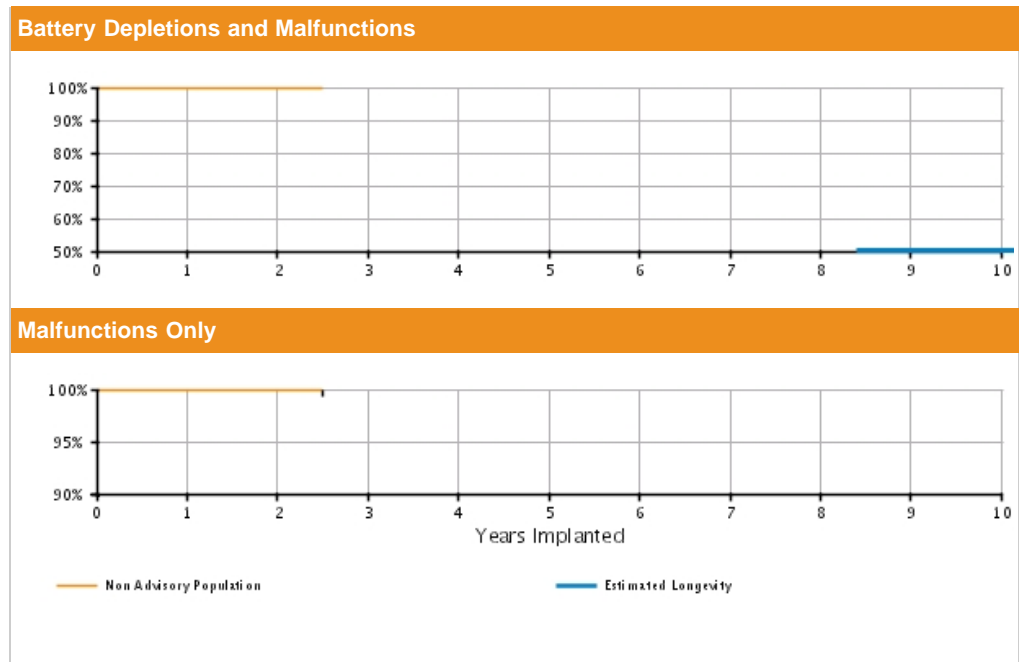
[References](#) cited in table above

PUNCTUA ICD DR

Models E053/F053

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

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




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.6/+0.1)	99.90 (-0.6/+0.1)	99.90 @ 30 mo. (-0.6/+0.1)	—	—	—	—	—	—	—	—
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.6/+0.1)	99.90 (-0.6/+0.1)	99.90 @ 30 mo. (-0.6/+0.1)	—	—	—	—	—	—	—	—
Registered Implants: 1000	Effective Sample Size	769	413	229	—	—	—	—	—	—	—	—

PUNCTUA ICD DR

Models E053/F053

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

PUNCTUA ICD DR Models E053/F053			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	1	1

[References](#) cited in table above

PUNCTUA ICD VR 4-Site

Models E050/F050

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

PUNCTUA ICD VR 4-Site Models E050/F050			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	1	1

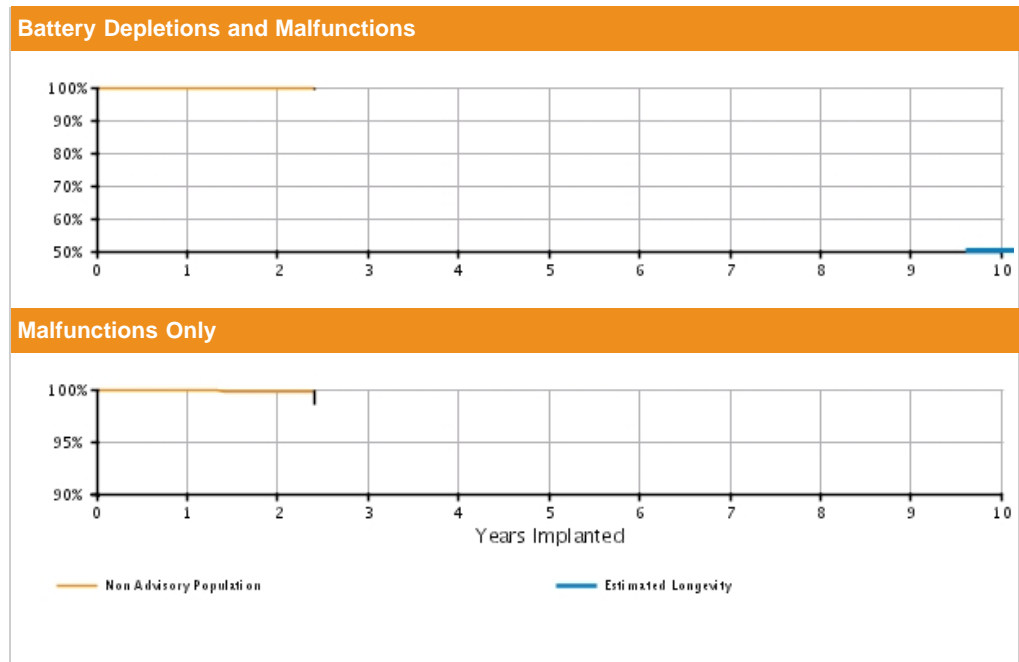
[References](#) cited in table above

PUNCTUA ICD VR

Models E051/F051

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

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




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.79 (-1.3/+0.2)	99.79 @ 29 mo. (-1.3/+0.2)	-	-	-	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.79 (-1.3/+0.2)	99.79 @ 29 mo. (-1.3/+0.2)	-	-	-	-	-	-	-	-
Registered Implants: 1000	Effective Sample Size	566	327	213	-	-	-	-	-	-	-	-

PUNCTUA ICD VR

Models E051/F051

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

PUNCTUA ICD VR Models E051/F051			
Worldwide Distribution: 5,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁸² Low-voltage capacitor	1	-	
⁸⁶ High voltage circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	2	-	
WW Confirmed Malfunctions	3	1	4

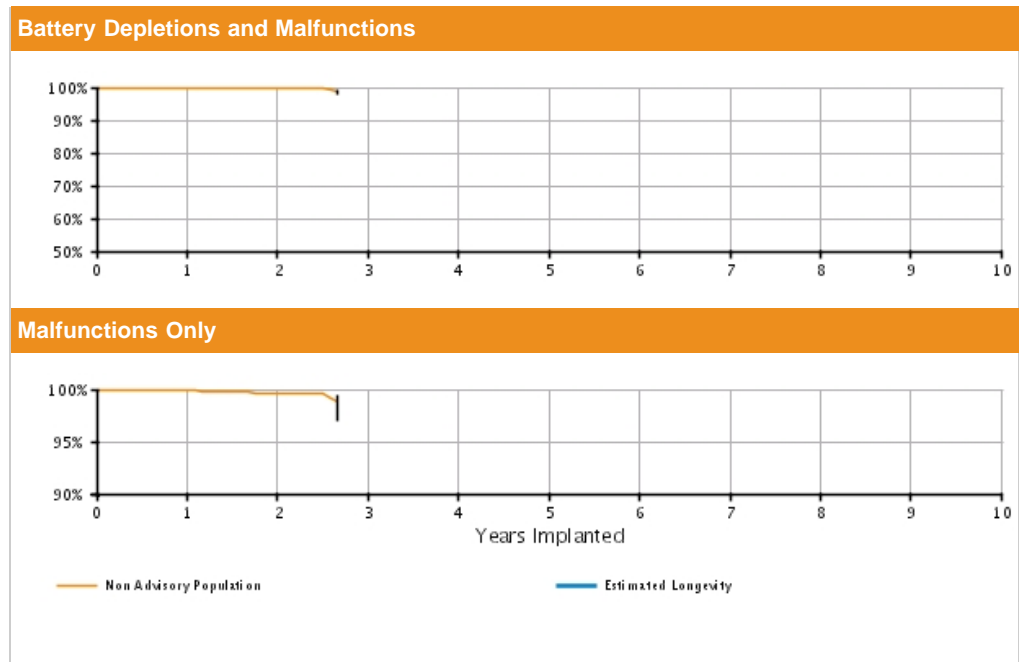
[References](#) cited in table above

SQ-RX S-ICD

Model 1010

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

U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 3
U.S. Approval Date: September 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 7,000	U.S. Malfunctions:17
	Without Compromised Therapy:8
	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(%)	99.84	99.55	98.76	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.6/+0.3)	@ 32 mo. (-1.9/+0.8)								
Registered Implants: 7000	Malfunctions Only(%)	99.86	99.56	98.78	—	—	—	—	—	—	—	—
	(Confidence Interval)	(-0.1/+0.1)	(-0.6/+0.3)	@ 32 mo. (-1.9/+0.7)								
	Effective Sample Size	2672	433	234	—	—	—	—	—	—	—	—


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

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

SQ-RX S-ICD

Model 1010

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

SQ-RX S-ICD Model 1010 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 58			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
² Unintended Fuse Activation 2013	-	3	
⁸⁹ Charge Timeout Alert	3	-	
Mechanical	11	15	26
³ High cathode condition	1	2	
⁸³ Battery depletion	10	13	
Software	2	1	3
⁸⁵ Unintended Battery Depletion Alert	2	1	
Other	10	13	23
Non-patterned	8	7	
⁸⁴ Telemetry	2	6	
WW Confirmed Malfunctions	26	32	58

[References](#) cited in table above

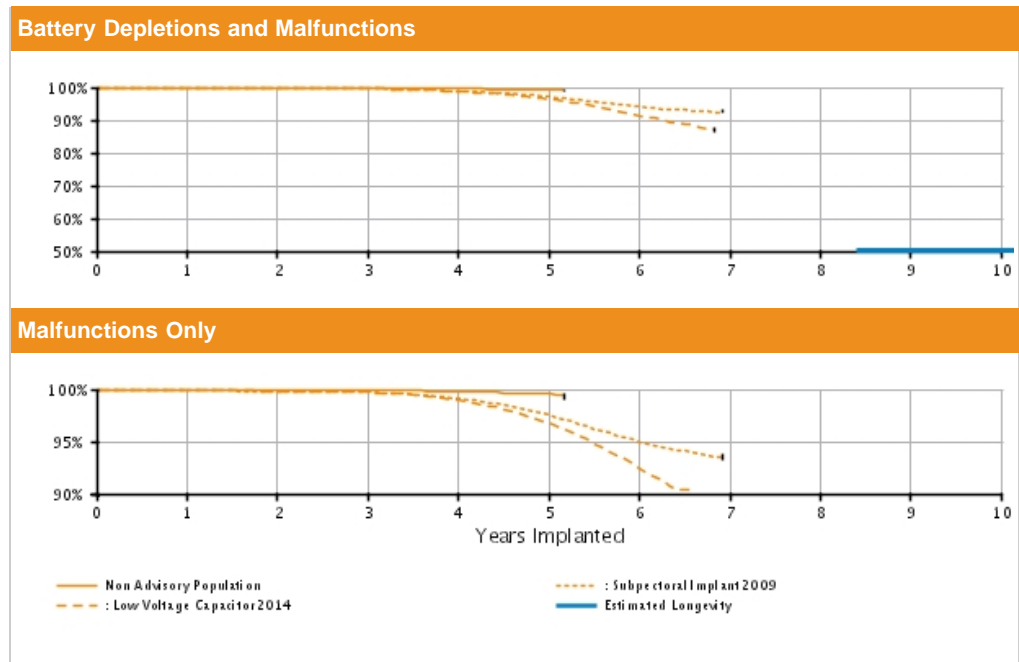
CRM PRODUCT PERFORMANCE REPORT Q3 2015

TELIGEN DR

Models E110/E111/F110/F111

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

U.S. Summary	
U.S. Registered Implants: 66,000	U.S. Normal Battery Depletions: 146
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 61
U.S. Estimated Active Implants: 44,000	U.S. Malfunctions:976
	Without Compromised Therapy:883
	With Compromised Therapy:93



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.79 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.2)	99.14 @ 62 mo. (-0.4/+0.3)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.55 (-0.2/+0.1)	99.43 @ 62 mo. (-0.4/+0.2)	-	-	-	-	-
	Effective Sample Size	26439	23338	20455	12253	1459	311	-	-	-	-	-
Subjectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.2)	98.89 (-0.1/+0.3)	97.19 (-0.2/+0.7)	94.13 (-0.6/+1.3)	92.42 @ 83 mo. (-0.8/+1.8)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.56 (-0.2/+0.2)	94.98 (-0.4/+0.3)	93.53 @ 83 mo. (-0.4/+0.3)	-	-	-	-
	Effective Sample Size	26747	23500	20673	18054	15609	7995	273	-	-	-	-
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.74 (-0.2/+0.2)	96.37 (-0.4/+0.3)	91.49 (-1.5/+1.3)	87.05 @ 82 mo. (-1.5/+1.3)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.95 (-0.2/+0.1)	96.76 (-0.3/+0.3)	92.50 (-1.1/+0.9)	88.40 @ 82 mo.	-	-	-	-
	Effective Sample Size	23000	23000	23000	23000	23000	23000	23000	-	-	-	-


						(-1.2/+1.0)			
Effective Sample Size	20716	18220	16012	13977	11601	3378	244	-	-

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

TELIGEN DR Models E110/E111/F110/F111 			
Worldwide Distribution: 90,000			
Worldwide Confirmed Malfunctions: 1289			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1114	63	1177
¹ Low Voltage Capacitor 2014 (Advisory issued)	926	24	
⁷⁰ Safety Core-electrocautery	3	-	
⁷¹ High-voltage capacitor	1	5	
⁷⁵ Low-voltage capacitors	6	-	
⁷⁸ Integrated circuit	18	18	
⁸¹ Battery	109	15	
⁸² Low-voltage capacitor	51	1	
Mechanical	19	49	68
⁵ Subpectoral implant 2009 (Advisory issued)	3	7	
⁶⁴ Transformer	-	20	
⁶⁷ Seal plug	3	-	
⁶⁸ Difficulty securing lead	9	8	
⁷³ Header contacts	2	11	
⁹² Header	2	3	
Software	16	-	16
⁷⁶ Alert messages not displayed post-EOL	3	-	
⁷⁹ Memory errors	13	-	
Other	20	8	28
Non-patterned	20	8	
WW Confirmed Malfunctions	1169	120	1289

[References](#) cited in table above

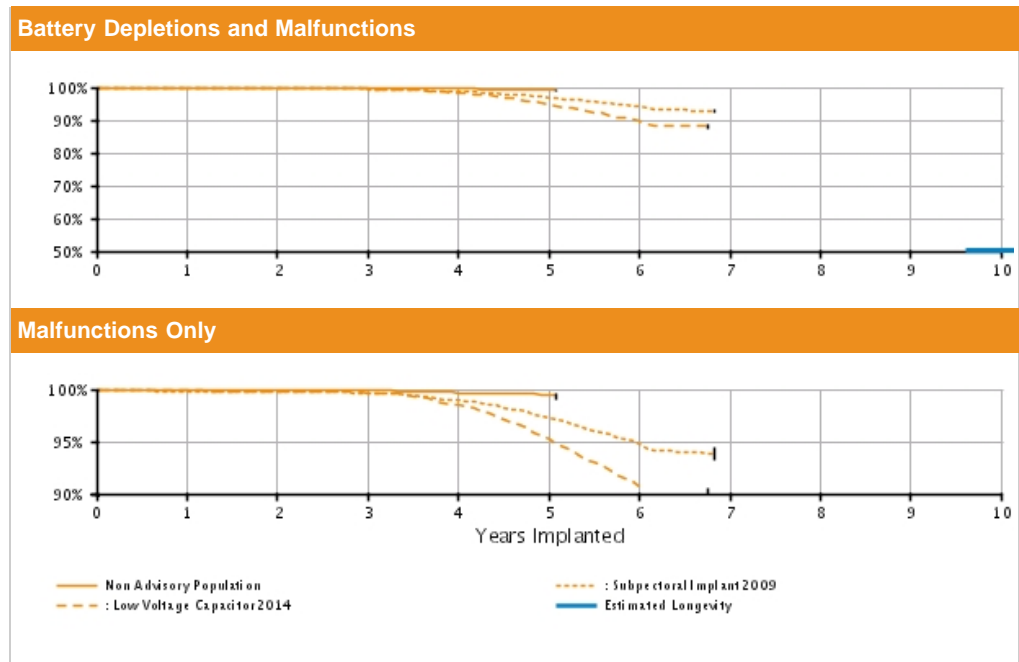
CRM PRODUCT PERFORMANCE REPORT Q3 2015

TELIGEN VR

Models E102/E103/F102/F103

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

U.S. Summary	
U.S. Registered Implants: 38,000	U.S. Normal Battery Depletions: 67
U.S. Approval Date: May 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 38
U.S. Estimated Active Implants: 26,000	U.S. Malfunctions: 647
	Without Compromised Therapy: 576
	With Compromised Therapy: 71



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)	99.52 (-0.2/+0.1)	99.18 (-0.4/+0.3)	99.18 @ 61 mo. (-0.4/+0.3)	-	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.67 (-0.1/+0.1)	99.42 (-0.4/+0.2)	99.42 @ 61 mo. (-0.4/+0.2)	-	-	-	-	-
	Effective Sample Size	16279	14332	12532	6493	456	219	-	-	-	-	-
Subjectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.2)	96.93 (-0.4/+0.3)	94.11 (-0.6/+0.5)	92.80 @ 82 mo. (-0.6/+0.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.63 (-0.1/+0.1)	98.93 (-0.2/+0.2)	97.32 (-0.3/+0.3)	94.81 (-0.6/+0.5)	93.78 @ 82 mo. (-0.5/+0.6)	-	-	-	-
	Effective Sample Size	13682	11998	10516	9150	7864	4074	408	-	-	-	-
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.2)	98.23 (-0.1/+0.5)	94.81 (-0.2/+0.9)	89.72 (-0.6/+1.8)	88.07 @ 81 mo. (-1.4/+1.1)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.45 (-0.3/+0.2)	95.21 (-0.5/+0.5)	90.71 (-1.3/+1.1)	89.34 @ 81 mo.	-	-	-	-
	Effective Sample Size	12000	12000	12000	12000	12000	12000	12000	-	-	-	-


						(-1.5/+1.2)			
Effective Sample Size	10905	9580	8404	7291	5710	1609	224	-	-

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

TELIGEN VR

Models E102/E103/F102/F103

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

TELIGEN VR Models E102/E103/F102/F103 			
Worldwide Distribution: 65,000			
Worldwide Confirmed Malfunctions: 983			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	827	41	868
¹ Low Voltage Capacitor 2014 (Advisory issued)	646	17	
⁷⁰ Safety Core-electrocautery	1	1	
⁷¹ High-voltage capacitor	-	2	
⁷⁵ Low-voltage capacitors	4	-	
⁷⁸ Integrated circuit	8	14	
⁸¹ Battery	137	7	
⁸² Low-voltage capacitor	31	-	
Mechanical	20	62	82
⁵ Subpectoral implant 2009 (Advisory issued)	5	13	
⁵ Header	2	8	
³⁹ Transformer	-	1	
⁶⁴ Transformer	-	14	
⁶⁷ Seal plug	1	-	
⁶⁸ Difficulty securing lead	-	10	
⁷³ Header contacts	12	16	
Software	15	-	15
⁶ Respiratory Sensor Oversensing	1	-	
⁷⁶ Alert messages not displayed post-EOL	4	-	
⁷⁹ Memory errors	10	-	
Other	8	10	18
Non-patterned	8	10	
WW Confirmed Malfunctions	870	113	983

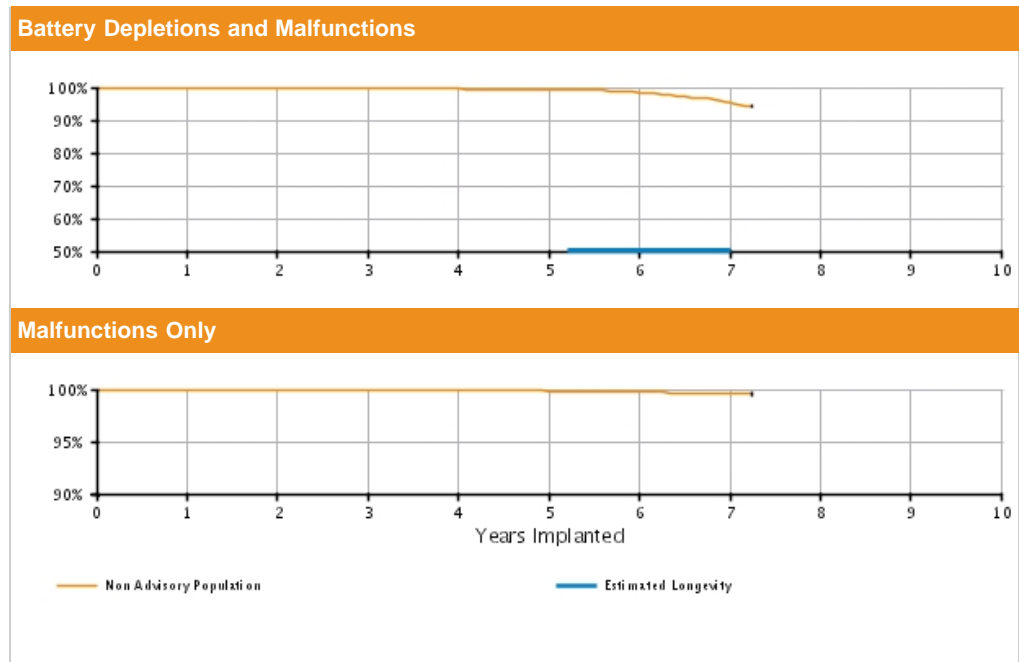
[References](#) cited in table above

CONFIENT DR

Models E030/F030

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

U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 112
U.S. Approval Date: February 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:13
	Without Compromised Therapy:10
	With Compromised Therapy:3




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.54 (-0.2/+0.2)	99.36 (-0.3/+0.2)	98.50 (-0.5/+0.4)	95.02 (-1.0/+0.9)	94.29 @ 87 mo. (-1.2/+1.0)	-	-	-
	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)	99.77 (-0.2/+0.1)	99.58 (-0.3/+0.2)	99.58 @ 87 mo. (-0.3/+0.2)	-	-	-
	Effective Sample Size	6165	5398	4703	4067	3358	2613	1268	316	-	-	-

CONFIENT DR

Models E030/F030

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

CONFIENT DR Models E030/F030			
Worldwide Distribution: 8,000			
Worldwide Confirmed Malfunctions: 13			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	-	9
²³ Capacitor	1	-	
²⁷ Integrated circuit	2	-	
⁸² Low-voltage capacitor	6	-	
Mechanical	-	1	1
⁶⁴ Transformer	-	1	
Software	-	-	0
Other	1	2	3
Non-patterned	1	1	
³⁴ Battery depletion	-	1	
WW Confirmed Malfunctions	10	3	13

References cited in table above

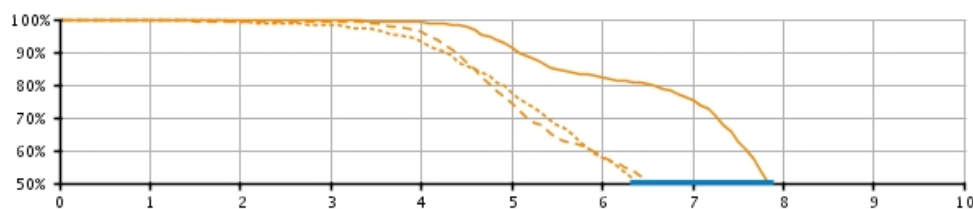
VITALITY 2 EL DR

Model T167

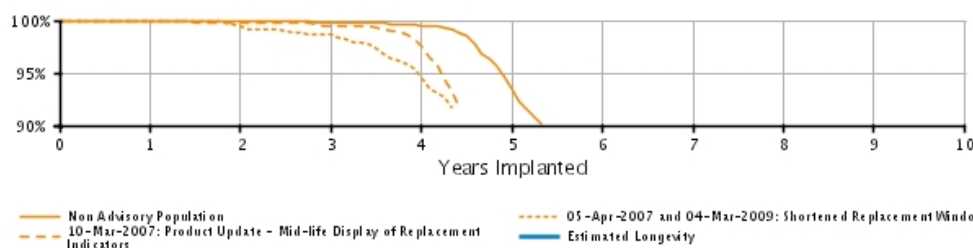
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 8,000	U.S. Normal Battery Depletions: 1,808
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions: 767

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	99.85	99.66	99.01	91.28	82.25	75.15	39.57	--	--	--
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.4/+0.3)	(-1.1/+1.0)	(-1.5/+1.4)	(-1.8/+1.7)	(-3.3/+3.3)			
	Registered Implants: 5000											
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions (%)	99.94	99.22	98.37	93.31	77.40	57.88	31.65	28.57	--	--	--
	(Confidence Interval)	(-0.4/+0.1)	(-0.6/+0.3)	(-0.8/+0.5)	(-1.5/+1.3)	(-2.6/+2.4)	(-3.2/+3.1)	(-3.2/+3.4)	@ 85 mo. (-3.1/+3.3)			
	Registered Implants: 2000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions (%)	99.94	99.41	98.63	94.61	83.49	75.79	73.66	73.66	--	--	--
	(Confidence Interval)	(-0.4/+0.1)	(-0.5/+0.3)	(-0.7/+0.5)	(-1.4/+1.1)	(-2.4/+2.1)	(-2.9/+2.6)	(-3.1/+2.9)	@ 85 mo. (-3.1/+2.9)			
	Registered Implants: 1000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions (%)	99.68	99.40	99.18	96.23	74.32	58.09	42.62	--	--	--	--
	(Confidence Interval)	(-0.5/+0.2)	(-0.7/+0.3)	(-0.8/+0.4)	(-1.5/+1.1)	(-3.3/+3.1)	(-3.8/+3.7)	@ 82 mo. (-4.0/+4.1)				
	Registered Implants: 1000											

	Malfunctions Only (%) (Confidence Interval)	99.92 (-0.5/+0.1)	99.74 (-0.6/+0.2)	99.52 (-0.7/+0.3)	97.51 (-1.3/+0.9)	81.02 (-3.1/+2.8)	70.80 (-3.7/+3.5)	70.56 @ 82 mo. (-3.7/+3.5)	-	-	-
	Effective Sample Size	1171	1024	899	763	500	318	205	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL DR

Model T167

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

VITALITY 2 EL DR Model T167			
Worldwide Distribution: 14,000			
Worldwide Confirmed Malfunctions: 1061			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1022	10	1032
⁸ Shortened replacement window (Advisory issued)	143	2	
¹⁵ Extended charge time post-mid-life	15	-	
²³ Capacitor	1	-	
²⁷ Integrated circuit	-	4	
³⁸ Capacitor	1	-	
⁴⁸ Mid-life display of replacement indicators	820	-	
⁴⁹ High-voltage capacitor	-	2	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	42	1	
Mechanical	8	3	11
⁷ Subpectoral implant (Advisory issued)	1	1	
²⁴ Header	1	-	
³¹ Seal plug	5	1	
⁵⁶ Seal plug	1	-	
⁶⁴ Transformer	-	1	
Software	7	1	8
⁴⁷ Memory location	1	1	
⁶⁶ Misaligned markers	6	-	
Other	3	7	10
Non-patterned	2	3	
¹⁸ Firmware error	1	4	
WW Confirmed Malfunctions	1040	21	1061

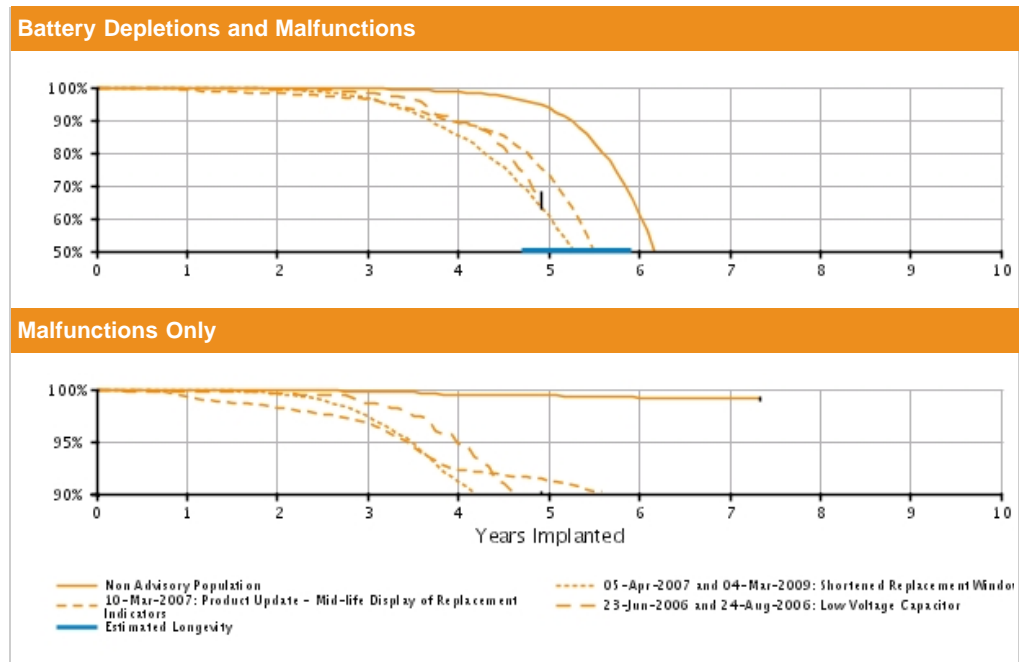
References cited in table above

VITALITY 2 DR

Model T165

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

U.S. Summary	
U.S. Registered Implants: 31,000	U.S. Normal Battery Depletions: 11,839
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 79
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:1140
	Without Compromised Therapy:1075
	With Compromised Therapy:65



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.59 (-0.1/+0.1)	98.58 (-0.2/+0.2)	93.66 (-0.5/+0.5)	61.09 (-1.1/+1.1)	10.40 (-0.8/+0.8)	6.52 @ 88 mo. (-0.7/+0.7)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.40 (-0.2/+0.1)	99.20 (-0.2/+0.2)	99.09 (-0.3/+0.2)	99.09 @ 88 mo. (-0.3/+0.2)	-	-	-
	Effective Sample Size	15245	13387	11744	10124	8280	4623	570	211	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.39 (-0.2/+0.2)	96.62 (-0.5/+0.4)	85.49 (-0.9/+0.9)	60.64 (-1.4/+1.4)	17.72 (-1.2/+1.2)	6.48 @ 77 mo. (-0.8/+0.9)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.56 (-0.2/+0.1)	97.36 (-0.4/+0.4)	91.21 (-0.8/+0.7)	86.77 (-1.0/+0.9)	84.74 (-1.2/+1.1)	84.16 @ 77 mo. (-1.5/+1.4)	-	-	-	-
	Effective Sample Size	7844	6862	5804	4449	2717	677	215	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.30 (-0.3/+0.2)	98.16 (-0.4/+0.3)	96.34 (-0.6/+0.5)	89.37 (-1.0/+0.9)	73.17 (-1.6/+1.5)	22.40 (-1.6/+1.7)	8.78 @ 76 mo. (-1.1/+1.3)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.40 (-0.2/+0.1)	99.20 (-0.2/+0.2)	99.09 (-0.3/+0.2)	99.09 @ 88 mo. (-0.3/+0.2)	-	-	-
	Effective Sample Size	3000	3000	3000	3000	3000	3000	3000	3000	-	-	-

Registered Implants: 6000											
	Malfunctions Only (%) (Confidence Interval)	99.34 (-0.3/+0.2)	98.28 (-0.4/+0.3)	96.80 (-0.6/+0.5)	92.34 (-0.9/+0.8)	91.25 (-1.0/+0.9)	89.28 (-1.3/+1.1)	87.83 @ 76 mo. (-1.9/+1.6)	-	-	-
	Effective Sample Size	4991	4338	3718	2977	2092	537	205	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions (%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.42 (-1.2/+0.4)	98.25 (-1.7/+0.9)	89.37 (-3.5/+2.7)	65.57 @ 59 mo. (-5.3/+5.0)	-	-	-	-	-
Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.63 (-1.1/+0.3)	98.69 (-1.6/+0.7)	94.80 (-2.8/+1.8)	86.94 @ 59 mo. (-4.3/+3.3)	-	-	-	-	-
	Effective Sample Size	555	472	403	321	201	-	-	-	-	-
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 DR

Model T165

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

VITALITY 2 DR Model T165			
Worldwide Distribution: 43,000			
Worldwide Confirmed Malfunctions: 1372			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1267	46	1313
⁸ Shortened replacement window (Advisory issued)	477	24	
⁹ Low-voltage capacitor (Advisory issued)	1	-	
¹⁰ Premature battery depletion (Advisory issued)	163	1	
¹⁵ Extended charge time post-mid-life	101	1	
¹⁹ Integrated circuit	1	1	
²² Reconfirmation after charge	1	-	
²³ Capacitor	1	1	
²⁷ Integrated circuit	7	11	
³⁸ Capacitor	3	1	
⁴¹ Capacitor	4	-	
⁴² Device tones	1	-	
⁴⁸ Mid-life display of replacement indicators	268	-	
⁴⁹ High-voltage capacitor	4	1	
⁵³ Integrated circuit	1	-	
⁶¹ Logic errors	-	3	
⁶⁹ Low-voltage capacitor	234	2	
Mechanical	7	6	13
³¹ Seal plug	4	3	
³⁹ Transformer	-	1	
⁵⁶ Seal plug	2	-	
⁹¹ Solder joint	1	2	
Software	2	2	4
⁴⁵ Memory location	-	2	
⁴⁷ Memory location	1	-	
⁶⁶ Misaligned markers	1	-	
Other	19	23	42
Non-patterned	12	8	
¹⁸ Firmware error	5	8	
²⁵ Battery depletion	2	6	
⁷² Magnet rate	-	1	
WW Confirmed Malfunctions	1295	77	1372

References cited in table above

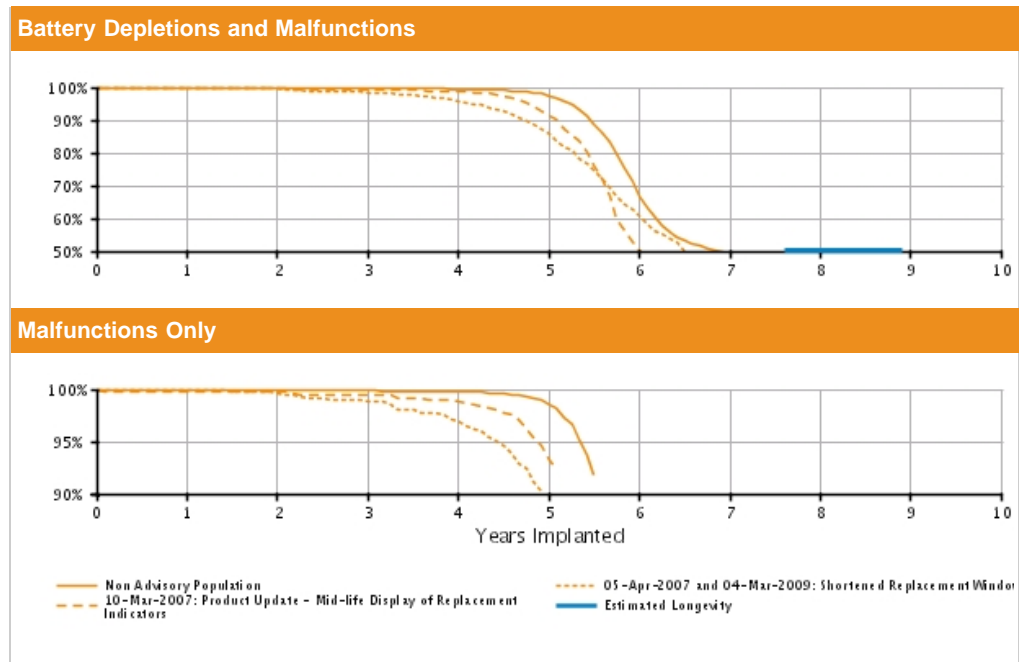
CRM PRODUCT PERFORMANCE REPORT Q3 2015

VITALITY 2 EL VR

Model T177

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

U.S. Summary	
U.S. Registered Implants: 7,000	U.S. Normal Battery Depletions: 1,054
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1259
	Without Compromised Therapy:1246
	With Compromised Therapy:13



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.39 (-0.4/+0.2)	97.36 (-0.7/+0.6)	66.76 (-2.2/+2.1)	49.34 (-2.4/+2.4)	41.46 @ 94 mo. (-2.8/+2.8)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.85 (-0.2/+0.1)	99.73 (-0.3/+0.1)	98.47 (-0.6/+0.4)	73.27 (-2.1/+2.0)	59.55 (-2.4/+2.4)	58.48 @ 94 mo. (-2.5/+2.5)	-	-	-
	Effective Sample Size	3631	3176	2774	2406	2052	1256	612	205	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.48 (-0.8/+0.5)	95.88 (-1.2/+1.0)	85.71 (-2.2/+2.0)	60.80 (-3.3/+3.2)	41.29 (-3.4/+3.5)	33.79 @ 88 mo. (-3.4/+3.5)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.84 (-0.7/+0.4)	97.00 (-1.1/+0.8)	88.93 (-2.1/+1.8)	68.27 (-3.2/+3.1)	60.90 (-3.5/+3.4)	60.37 @ 88 mo. (-3.6/+3.5)	-	-	-
	Effective Sample Size	1687	1474	1279	1087	820	493	275	206	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.39 (-4.4/+4.4)	45.20 @ 74 mo. (-4.4/+4.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.39 (-4.4/+4.4)	45.20 @ 74 mo. (-4.4/+4.5)	-	-	-	-
	Effective Sample Size	1687	1474	1279	1087	820	493	275	206	-	-	-

Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.72 (-0.6/+0.2)	99.72 (-0.6/+0.2)	99.48 (-0.7/+0.3)	98.90 (-1.0/+0.5)	93.22 (-2.3/+1.8)	59.75 (-4.6/+4.4)	54.58 @ 74 mo. (-4.7/+4.6)	-	-	-
	Effective Sample Size	975	854	747	647	526	239	208	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL VR

Model T177

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

VITALITY 2 EL VR Model T177			
Worldwide Distribution: 16,000			
Worldwide Confirmed Malfunctions: 1879			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1838	8	1846
⁸ Shortened replacement window (Advisory issued)	139	1	
⁹ Low-voltage capacitor (Advisory issued)	2	1	
¹⁵ Extended charge time post-mid-life	15	2	
²⁷ Integrated circuit	-	3	
³⁸ Capacitor	1	-	
⁴¹ Capacitor	2	-	
⁴⁸ Mid-life display of replacement indicators	1612	1	
⁴⁹ High-voltage capacitor	2	-	
⁶⁹ Low-voltage capacitor	65	-	
Mechanical	3	8	11
⁷ Subpectoral implant (Advisory issued)	-	5	
²⁴ Header	-	1	
³¹ Seal plug	1	-	
⁵¹ Sensing	2	-	
⁶⁴ Transformer	-	2	
Software	-	2	2
⁴⁵ Memory location	-	1	
⁴⁷ Memory location	-	1	
Other	11	9	20
Non-patterned	11	7	
²⁵ Battery depletion	-	2	
WW Confirmed Malfunctions	1852	27	1879

[References](#) cited in table above

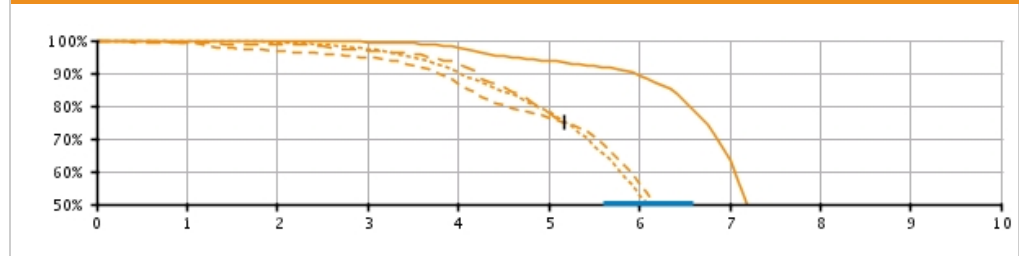
VITALITY 2 VR

Model T175

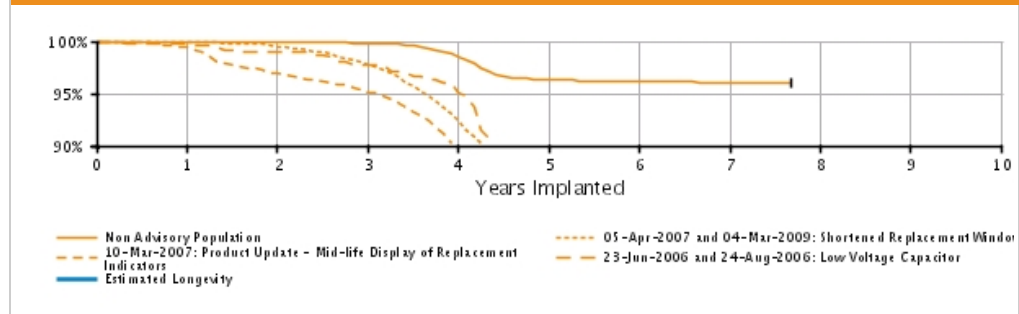
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 21,000	U.S. Normal Battery Depletions: 5,755
U.S. Approval Date: March 2004	U.S. Unconfirmed Reports of Premature Battery Depletion : 35
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:1240
	Without Compromised Therapy:1215
	With Compromised Therapy:25

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.49 (-0.2/+0.1)	97.63 (-0.4/+0.3)	93.79 (-0.6/+0.6)	89.17 (-0.9/+0.8)	63.11 (-1.5/+1.5)	11.51 @ 92 mo. (-1.5/+1.7)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	98.47 (-0.3/+0.3)	96.32 (-0.5/+0.4)	96.14 (-0.5/+0.5)	96.00 (-0.5/+0.5)	96.00 @ 92 mo. (-0.5/+0.5)	-	-
	Effective Sample Size	9497	8337	7262	6199	5015	4033	2237	231	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.43 (-0.3/+0.2)	97.47 (-0.5/+0.4)	90.30 (-1.0/+0.9)	78.07 (-1.4/+1.3)	52.55 (-1.8/+1.8)	16.95 (-1.5/+1.6)	9.13 @ 87 mo. (-1.2/+1.3)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.39 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.19 (-1.5/+1.4)	83.19 @ 87 mo. (-1.5/+1.4)	-	-
	Effective Sample Size	5391	4691	4022	3236	2376	1374	364	202	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.34 (-0.3/+0.2)	96.85 (-0.6/+0.5)	94.72 (-0.8/+0.7)	86.62 (-1.3/+1.2)	76.42 (-1.7/+1.6)	56.28 (-2.1/+2.1)	15.94 (-1.7/+1.9)	13.62 @ 85 mo. (-1.6/+1.8)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.39 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.19 (-1.5/+1.4)	83.19 @ 87 mo. (-1.5/+1.4)	-	-
	Effective Sample Size	4000	3500	3000	2500	2000	1500	1000	500	-	-

Registered Implants: 4000											
	Malfunctions Only (%) (Confidence Interval)	99.39 (-0.3/+0.2)	96.95 (-0.6/+0.5)	95.13 (-0.8/+0.7)	89.21 (-1.2/+1.1)	84.05 (-1.4/+1.3)	83.37 (-1.5/+1.4)	81.60 (-1.8/+1.7)	81.60 @ 85 mo. (-1.8/+1.7)	-	-
	Effective Sample Size	3907	3331	2852	2262	1679	1058	245	204	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions (%) (Confidence Interval)	99.47 (-1.1/+0.4)	98.64 (-1.5/+0.7)	96.87 (-2.1/+1.3)	92.76 (-3.1/+2.2)	77.80 (-5.0/+4.3)	75.17 @ 62 mo. (-5.2/+4.5)	-	-	-	-
Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.82 (-1.1/+0.2)	98.99 (-1.4/+0.6)	97.72 (-1.9/+1.1)	95.06 (-2.7/+1.8)	84.87 (-4.5/+3.6)	84.87 @ 62 mo. (-4.5/+3.6)	-	-	-	-
	Effective Sample Size	503	430	364	305	214	NaN	-	-	-	-
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 VR

Model T175

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

VITALITY 2 VR Model T175			
Worldwide Distribution: 37,000			
Worldwide Confirmed Malfunctions: 1583			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1530	26	1556
⁸ Shortened replacement window (Advisory issued)	347	9	
⁹ Low-voltage capacitor (Advisory issued)	-	1	
¹⁰ Premature battery depletion (Advisory issued)	219	6	
¹⁵ Extended charge time post-mid-life	63	-	
¹⁹ Integrated circuit	-	1	
²³ Capacitor	1	-	
²⁷ Integrated circuit	4	7	
³⁸ Capacitor	1	-	
⁴¹ Capacitor	4	-	
⁴⁸ Mid-life display of replacement indicators	771	-	
⁴⁹ High-voltage capacitor	-	1	
⁶⁹ Low-voltage capacitor	120	1	
Mechanical	2	1	3
³¹ Seal plug	2	1	
Software	-	1	1
⁴⁷ Memory location	-	1	
Other	17	6	23
Non-patterned	15	6	
²⁵ Battery depletion	2	-	
WW Confirmed Malfunctions	1549	34	1583

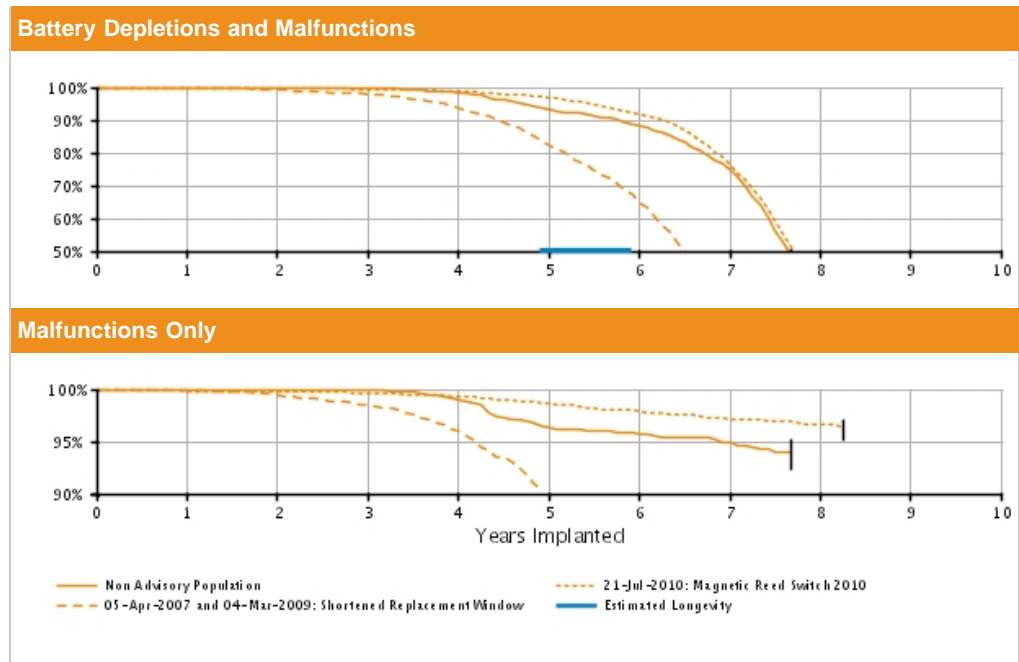
[References](#) cited in table above

VITALITY DR HE

Model T180

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

U.S. Summary	
U.S. Registered Implants: 13,000	U.S. Normal Battery Depletions: 2,983
U.S. Approval Date: May 2005	U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:420
	Without Compromised Therapy:389
	With Compromised Therapy:31



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.86 (-0.3/+0.1)	99.76 (-0.3/+0.1)	98.27 (-0.8/+0.5)	93.29 (-1.4/+1.2)	88.36 (-1.9/+1.6)	74.80 (-2.7/+2.5)	48.57 @ 92 mo. (-3.9/+3.9)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.91 (-0.3/+0.1)	99.86 (-0.3/+0.1)	99.01 (-0.6/+0.4)	96.29 (-1.1/+0.9)	95.67 (-1.2/+1.0)	94.96 (-1.4/+1.1)	93.96 @ 92 mo. (-1.7/+1.3)	-	-	-
	Effective Sample Size	2235	1950	1699	1464	1202	978	681	201	-	-	-
21-Jul-10 Magnetic Reed Switch 2010* Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.42 (-0.2/+0.2)	98.78 (-0.3/+0.3)	96.77 (-0.6/+0.5)	91.87 (-0.9/+0.8)	76.43 (-1.5/+1.4)	35.43 (-2.1/+2.2)	25.30 @ 99 mo. (-2.2/+2.4)	-	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.81 (-0.1/+0.1)	99.63 (-0.2/+0.1)	99.28 (-0.3/+0.2)	98.60 (-0.4/+0.3)	97.85 (-0.5/+0.4)	97.09 (-0.6/+0.5)	96.68 (-0.7/+0.6)	96.26 @ 99 mo. (-1.2/+0.9)	-	-
	Effective Sample Size	6979	6087	5304	4598	3914	3205	2312	483	227	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.86 (-0.2/+0.1)	99.21 (-0.4/+0.3)	97.96 (-0.7/+0.5)	93.65 (-1.2/+1.0)	82.31 (-1.9/+1.8)	64.76 (-2.5/+2.4)	34.39 (-2.7/+2.8)	21.63 @ 90 mo. (-2.4/+2.6)	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.86 (-0.2/+0.1)	99.21 (-0.4/+0.3)	97.96 (-0.7/+0.5)	93.65 (-1.2/+1.0)	82.31 (-1.9/+1.8)	64.76 (-2.5/+2.4)	34.39 (-2.7/+2.8)	21.63 @ 90 mo. (-2.4/+2.6)	-	-	-
	Effective Sample Size	3000	2500	2000	1500	1000	500	200	100	50	-	-


3000											
	Malfunctions Only (%) (Confidence Interval)	99.93 (-0.2/+0.1)	99.44 (-0.4/+0.2)	98.51 (-0.6/+0.4)	95.95 (-1.0/+0.8)	89.76 (-1.6/+1.4)	84.81 (-2.0/+1.8)	79.82 (-2.5/+2.3)	78.94 @ 90 mo. (-2.7/+2.5)	-	-
	Effective Sample Size	2672	2313	1994	1652	1237	826	368	207	-	-

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

VITALITY DR HE

Model T180

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

VITALITY DR HE Model T180			
Worldwide Distribution: 13,000			
Worldwide Confirmed Malfunctions: 420			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	372	5	377
⁸ Shortened replacement window (Advisory issued)	88	1	
¹⁵ Extended charge time post-mid-life	26	-	
²³ Capacitor	2	1	
²⁷ Integrated circuit	3	1	
³⁸ Capacitor	1	1	
⁴⁸ Mid-life display of replacement indicators	171	-	
⁵³ Integrated circuit	-	1	
⁶⁹ Low-voltage capacitor	81	-	
Mechanical	6	20	26
⁴ Magnetic reed switch 2010 (Advisory issued)	2	10	
⁷ Subpectoral implant (Advisory issued)	-	1	
²⁴ Header	3	8	
⁵⁵ Setscrew	1	-	
⁶² Reed switch	-	1	
Software	1	2	3
⁴⁵ Memory location	-	1	
⁴⁷ Memory location	-	1	
⁶⁶ Misaligned markers	1	-	
Other	10	4	14
Non-patterned	8	3	
²⁵ Battery depletion	1	1	
³⁴ Battery depletion	1	-	
WW Confirmed Malfunctions	389	31	420

References cited in table above

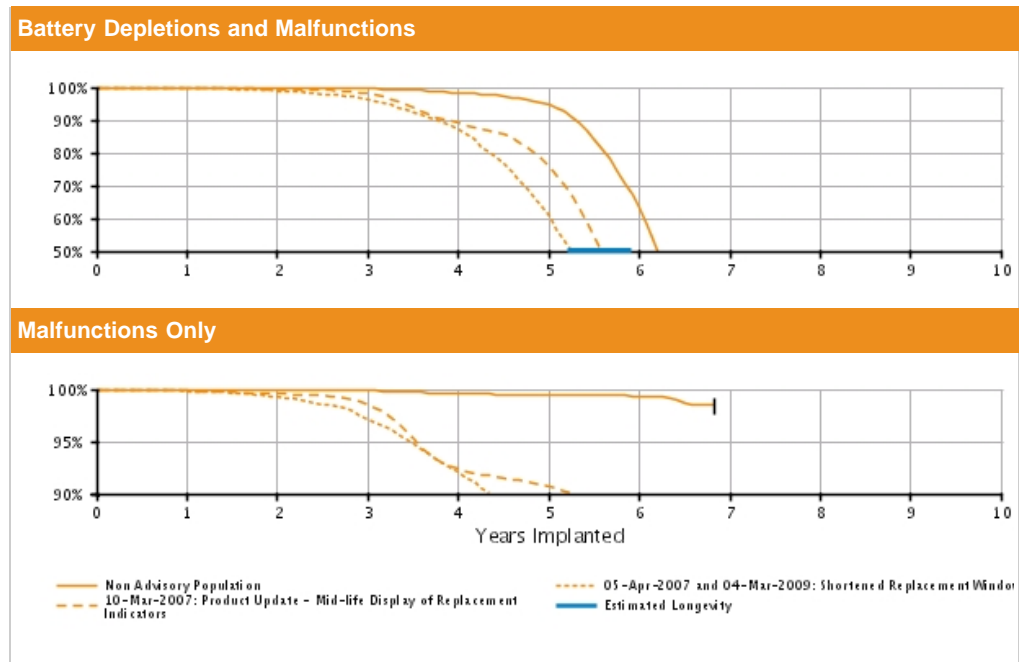
CRM PRODUCT PERFORMANCE REPORT Q3 2015

VITALITY DS DR

Model T125

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

U.S. Summary	
U.S. Registered Implants: 22,000	U.S. Normal Battery Depletions: 8,358
U.S. Approval Date: July 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 67
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1187
	Without Compromised Therapy:1148
	With Compromised Therapy:39



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.84 (-0.2/+0.1)	99.54 (-0.2/+0.2)	98.39 (-0.4/+0.3)	94.54 (-0.8/+0.7)	63.04 (-1.9/+1.8)	11.74 @ 82 mo. (-1.4/+1.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.86 (-0.2/+0.1)	99.60 (-0.3/+0.2)	99.44 (-0.3/+0.2)	99.29 (-0.4/+0.2)	98.49 @ 82 mo. (-0.9/+0.6)	-	-	-	-
	Effective Sample Size	5265	4644	4050	3474	2843	1562	228	-	-	-	-
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.2/+0.1)	98.97 (-0.4/+0.3)	96.16 (-0.7/+0.6)	87.05 (-1.2/+1.1)	60.74 (-1.9/+1.8)	17.52 (-1.6/+1.7)	10.24 @ 75 mo. (-1.3/+1.5)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.82 (-0.2/+0.1)	99.24 (-0.3/+0.2)	97.09 (-0.6/+0.5)	92.09 (-1.0/+0.9)	87.89 (-1.3/+1.2)	84.92 (-1.7/+1.6)	84.01 @ 75 mo. (-2.2/+2.0)	-	-	-	-
	Effective Sample Size	4302	3766	3202	2519	1484	343	202	-	-	-	-
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.45 (-0.2/+0.1)	98.01 (-0.3/+0.3)	89.10 (-0.7/+0.7)	75.98 (-1.0/+1.0)	29.29 (-1.2/+1.2)	5.85 @ 79 mo. (-0.7/+0.8)	-	-	-	-
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.45 (-0.2/+0.1)	98.01 (-0.3/+0.3)	89.10 (-0.7/+0.7)	75.98 (-1.0/+1.0)	29.29 (-1.2/+1.2)	5.85 @ 79 mo. (-0.7/+0.8)	-	-	-	-
	Effective Sample Size	2000	2000	2000	2000	2000	2000	2000	-	-	-	-


Registered Implants: 12000											
	Malfunctions Only (%) (Confidence Interval)	99.87 (-0.1/+0.1)	99.56 (-0.1/+0.1)	98.52 (-0.3/+0.2)	92.35 (-0.6/+0.6)	90.69 (-0.7/+0.6)	88.47 (-0.9/+0.8)	86.68 @ 79 mo. (-1.5/+1.4)	-	-	-
	Effective Sample Size	10839	9499	8204	6405	4721	1508	247	-	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY DS DR

Model T125

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

VITALITY DS DR Model T125 			
Worldwide Distribution: 22,000			
Worldwide Confirmed Malfunctions: 1188			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1114	23	1137
⁸ Shortened replacement window (Advisory issued)	207	8	
¹⁰ Premature battery depletion (Advisory issued)	68	2	
¹⁵ Extended charge time post-mid-life	146	2	
¹⁹ Integrated circuit	1	-	
²⁷ Integrated circuit	2	8	
⁴¹ Capacitor	3	-	
⁴⁸ Mid-life display of replacement indicators	589	-	
⁴⁹ High-voltage capacitor	2	1	
⁶¹ Logic errors	-	1	
⁶⁹ Low-voltage capacitor	96	1	
Mechanical	11	5	16
³¹ Seal plug	11	3	
³⁹ Transformer	-	1	
⁹¹ Solder joint	-	1	
Software	6	-	6
²⁸ Impedance measurements	2	-	
⁴⁷ Memory location	1	-	
⁶⁶ Misaligned markers	3	-	
Other	18	11	29
Non-patterned	8	3	
¹⁸ Firmware error	5	8	
²⁵ Battery depletion	5	-	
WW Confirmed Malfunctions	1149	39	1188

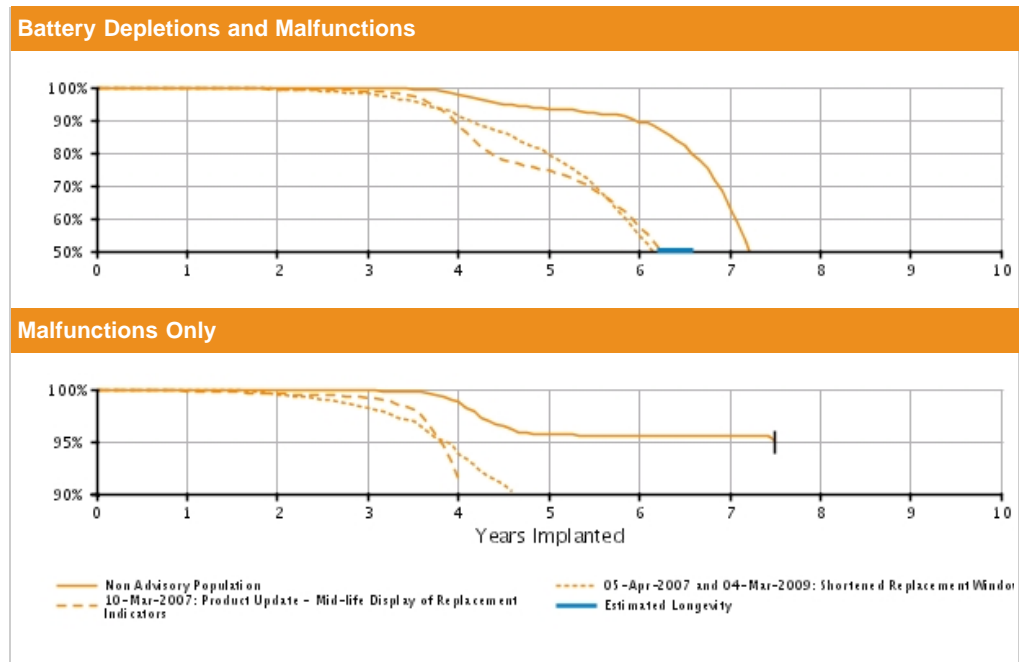
[References](#) cited in table above

VITALITY DS VR

Model T135

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

U.S. Summary	
U.S. Registered Implants: 19,000	U.S. Normal Battery Depletions: 5,620
U.S. Approval Date: July 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 39
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1555
	Without Compromised Therapy:1539
	With Compromised Therapy:16



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.92	99.72	97.96	93.34	89.50	62.83	27.34	-	-	-
	(Confidence Interval)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.6/+0.5)	(-1.1/+0.9)	(-1.3/+1.2)	(-2.4/+2.4)	@ 90 mo. (-2.7/+2.8)	-	-	-
	Registered Implants: 4000											
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%)	99.94	99.40	98.02	91.28	79.23	54.56	19.09	16.08	-	-	-
	(Confidence Interval)	(-0.2/+0.0)	(-0.4/+0.2)	(-0.6/+0.5)	(-1.2/+1.1)	(-1.8/+1.7)	(-2.3/+2.3)	(-2.0/+2.1)	@ 85 mo. (-1.9/+2.1)	-	-	-
	Registered Implants: 4000											
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%)	99.76	99.49	98.88	88.44	74.53	57.39	20.92	5.43	-	-	-
	(Confidence Interval)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.2)	(-0.8/+0.7)	(-1.1/+1.0)	(-1.3/+1.3)	(-1.2/+1.2)	@ 90 mo. (-0.7/+0.8)	-	-	-
	Registered Implants: 4000											
		Effective Sample Size	3863	3373	2952	2539	2045	1633	863	254	-	-
		Effective Sample Size	3237	2836	2447	1979	1475	866	254	211	-	-


Registered Implants: 12000											
	Malfunctions Only (%) (Confidence Interval)	99.84 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.16 (-0.2/+0.2)	91.52 (-0.7/+0.6)	83.12 (-0.9/+0.9)	81.67 (-1.0/+1.0)	80.37 (-1.1/+1.1)	79.11 @ 90 mo. (-1.6/+1.5)	-	-
	Effective Sample Size	10129	8847	7670	6031	4224	2792	849	204	-	-
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY DS VR

Model T135

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


VITALITY DS VR Model T135 			
Worldwide Distribution: 19,000			
Worldwide Confirmed Malfunctions: 1556			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1525	11	1536
⁸ Shortened replacement window (Advisory issued)	122	1	
⁹ Low-voltage capacitor (Advisory issued)	2	-	
¹⁰ Premature battery depletion (Advisory issued)	61	4	
¹⁵ Extended charge time post-mid-life	70	-	
²³ Capacitor	2	1	
²⁷ Integrated circuit	-	1	
³⁸ Capacitor	3	1	
⁴¹ Capacitor	2	1	
⁴⁸ Mid-life display of replacement indicators	1211	-	
⁴⁹ High-voltage capacitor	3	1	
⁶⁹ Low-voltage capacitor	49	1	
Mechanical	4	2	6
³¹ Seal plug	3	1	
⁵⁶ Seal plug	-	1	
⁶³ Cracked solder joint	1	-	
Software	2	-	2
²⁸ Impedance measurements	2	-	
Other	9	3	12
Non-patterned	7	1	
²⁵ Battery depletion	2	2	
WW Confirmed Malfunctions	1540	16	1556

[References](#) cited in table above

VITALITY DR

Model 1871

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

VITALITY DR Model 1871 			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 734			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	711	2	713
¹⁵ Extended charge time post-mid-life	168	1	
²³ Capacitor	6	-	
²⁷ Integrated circuit	-	1	
⁴⁸ Mid-life display of replacement indicators	536	-	
⁵³ Integrated circuit	1	-	
Mechanical	9	2	11
²⁴ Header	2	1	
³¹ Seal plug	7	-	
¹⁰⁰ Solder joint (Advisory issued)	-	1	
Software	3	-	3
³⁵ Reset during charge	1	-	
⁵² Software download	2	-	
Other	3	4	7
Non-patterned	3	3	
²⁵ Battery depletion	-	1	
WW Confirmed Malfunctions	726	8	734

[References](#) cited in table above

VITALITY VR

Model 1870

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

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

[References](#) cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

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

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

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


[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

ACCOLADE/PROPONENT/ESSENTIO DR

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

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


ACCOLADE/PROPONENT/ESSENTIO DR Models L101/L111/L201/L211/L301/ L311 			
Worldwide Distribution: 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

[References](#) cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

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

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

ACCOLADE/PROPONENT/ESSENTIO SR Models L100/L110/L200/L210/L300/ L310 			
Worldwide Distribution: 2,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[References](#) cited in table above

ADVANTIO EL DR

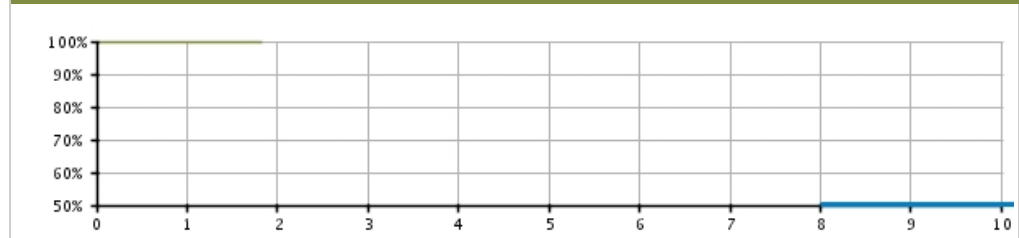
Models J064/J067/K064/K067/K084/
K087

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

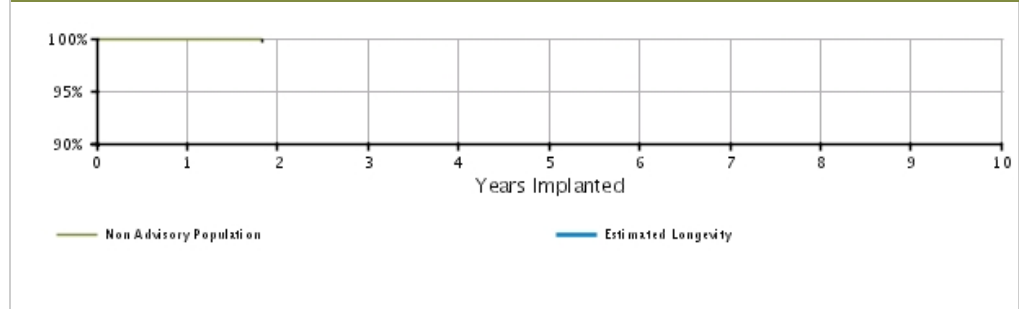
U.S. Summary

U.S. Registered Implants: 3,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: 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)	99.94 (-0.3/+0.0)	99.85 @ 22 mo. (-0.5/+0.1)	-	-	-	-	-	-	-	-
Registered Implants: 3000	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.94 @ 22 mo. (-0.3/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	1141	243	-	-	-	-	-	-	-	-

ADVANTIO EL DR

Models J064/J067/K064/K067/K084/
K087

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

ADVANTIO EL DR Models J064/J067/K064/K067/K084/ K087 			
Worldwide Distribution: 12,000 Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	1	2
⁷⁵ Low-voltage capacitors	1	1	
Mechanical	-	-	0
Software	1	-	1
⁸⁷ Respiratory sensor	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

ADVANTIO DR

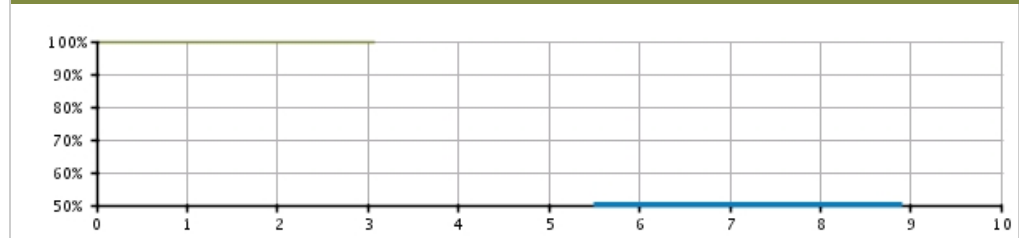
Models J063/J066/K063/K066/K083/
K086

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

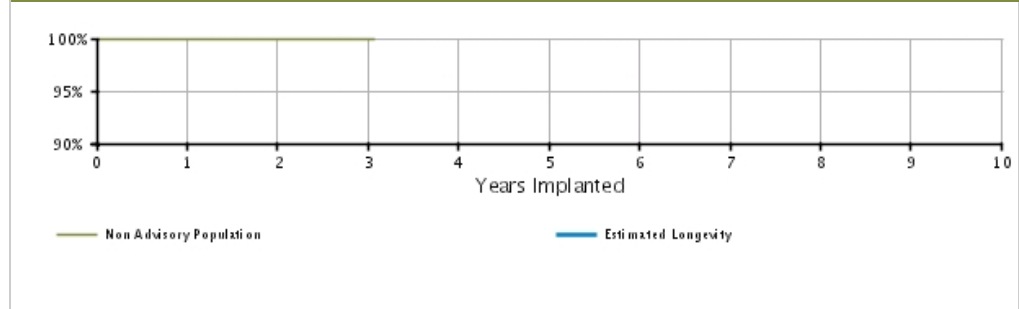
U.S. Summary

U.S. Registered Implants: 47,000	U.S. Normal Battery Depletions: 22
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 44,000	U.S. Malfunctions:12
	Without Compromised Therapy:9
	With Compromised Therapy:3

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.82 @ 37 mo. (-0.1/+0.1)	-	-	-	-	-	-
Registered Implants: 47000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.95 @ 37 mo. (-0.0/+0.0)	-	-	-	-	-	-
	Effective Sample Size	32805	15502	722	212	-	-	-	-	-	-

ADVANTIO DR

Models J063/J066/K063/K066/K083/
K086

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

ADVANTIO DR Models J063/J066/K063/K066/K083/ K086 			
Worldwide Distribution: 74,000			
Worldwide Confirmed Malfunctions: 17			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁷⁵ Low-voltage capacitors	1	-	
⁷⁸ Integrated circuit	2	2	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	5	-	5
⁷⁹ Memory errors	5	-	
Other	5	1	6
Non-patterned	5	1	
WW Confirmed Malfunctions	13	4	17

References cited in table above

ADVANTIO SR

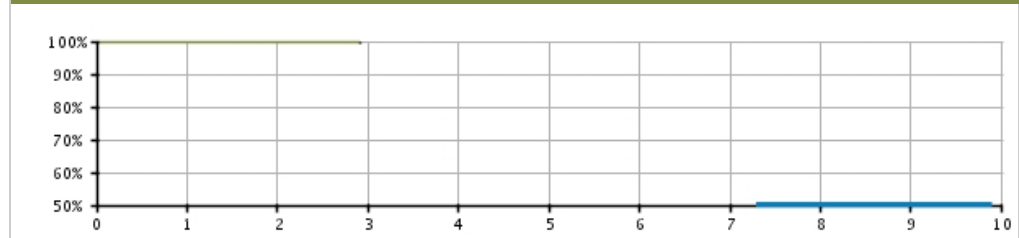
Models J062/J065/K062/K065/K082/
K085

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

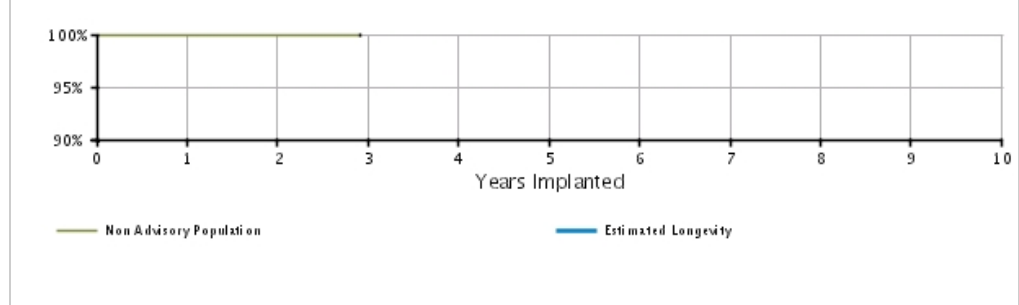
U.S. Summary

U.S. Registered Implants: 11,000	U.S. Normal Battery Depletions: 6
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:5
	Without Compromised Therapy:4
	With Compromised Therapy:1

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)	99.88 (-0.1/+0.1)	99.71 @ 35 mo. (-0.5/+0.2)	-	-	-	-	-	-	-
Registered Implants: 11000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 @ 35 mo. (-0.1/+0.1)	-	-	-	-	-	-	-
	Effective Sample Size	7403	3183	288	-	-	-	-	-	-	-

ADVANTIO SR

Models J062/J065/K062/K065/K082/
K085

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

ADVANTIO SR Models J062/J065/K062/K065/K082/ K085 			
Worldwide Distribution: 31,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁷⁵ Low-voltage capacitors	3	-	
⁷⁸ Integrated circuit	-	3	
Mechanical	-	-	0
Software	2	-	2
⁷⁹ Memory errors	2	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	5	3	8

[References](#) cited in table above

INGENIO EL DR

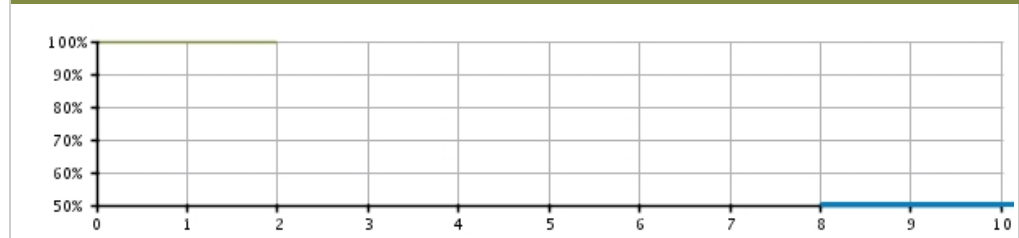
Models J174/J177/K174/K177/K184/
K187

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

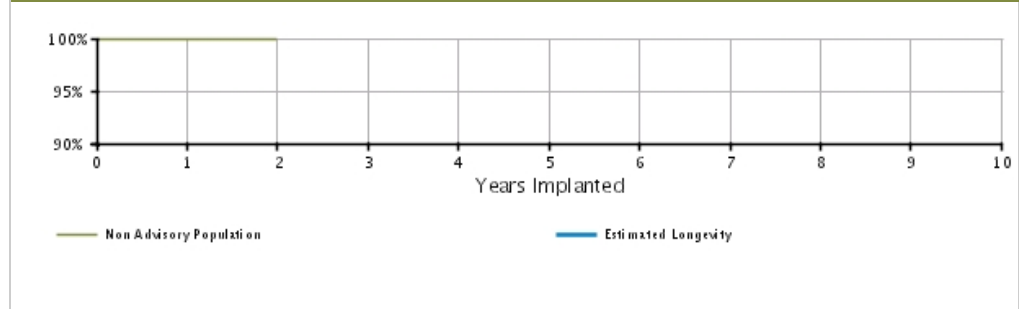
U.S. Summary

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 6000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	2521	267	-	-	-	-	-	-	-	-

INGENIO EL DR

Models J174/J177/K174/K177/K184/
K187

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

INGENIO EL DR Models J174/J177/K174/K177/K184/ K187			
Worldwide Distribution: 33,000			
Worldwide Confirmed Malfunctions: 5			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
⁷⁵ Low-voltage capacitors	2	-	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	1	-	1
⁷⁹ Memory errors	1	-	
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	4	1	5

[References](#) cited in table above

INGENIO DR

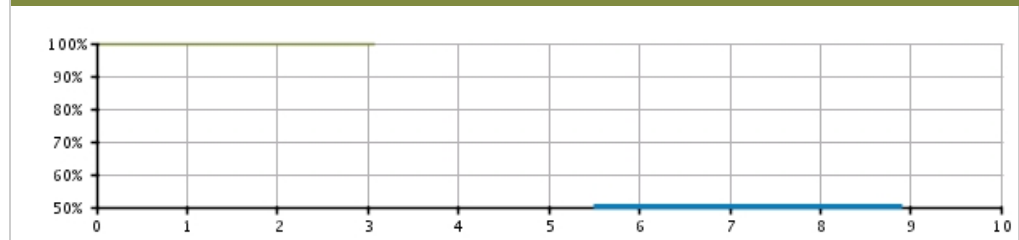
Models J173/J176/K173/K176/K183/
K186

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

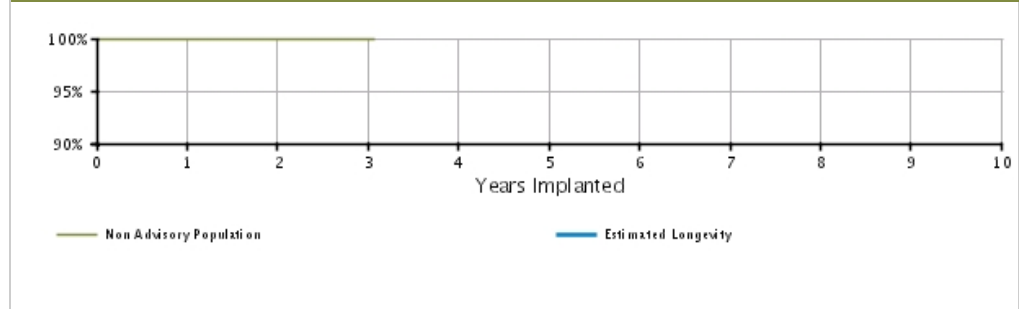
U.S. Summary

U.S. Registered Implants: 68,000	U.S. Normal Battery Depletions: 20
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 64,000	U.S. Malfunctions:10
	Without Compromised Therapy:8
	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)	99.97 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.88 (-0.1/+0.1)	99.88 @ 37 mo. (-0.1/+0.1)	-	-	-	-	-	-
Registered Implants: 68000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 @ 37 mo. (-0.0/+0.0)	-	-	-	-	-	-
	Effective Sample Size	41322	16305	1076	404	-	-	-	-	-	-

INGENIO DR

Models J173/J176/K173/K176/K183/
K186

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

INGENIO DR Models J173/J176/K173/K176/K183/ K186 			
Worldwide Distribution: 111,000			
Worldwide Confirmed Malfunctions: 16			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	1	4
⁷⁵ Low-voltage capacitors	2	-	
⁷⁸ Integrated circuit	1	-	
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	4	1	5
⁷⁹ Memory errors	4	1	
Other	6	1	7
Non-patterned	6	1	
WW Confirmed Malfunctions	13	3	16

References cited in table above

INGENIO SR

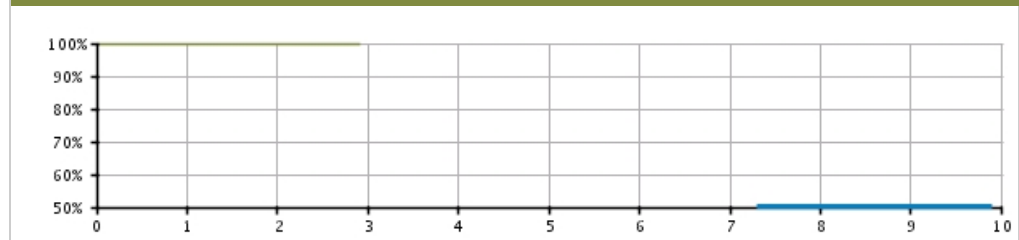
Models J172/J175/K172/K175/K182/
K185

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

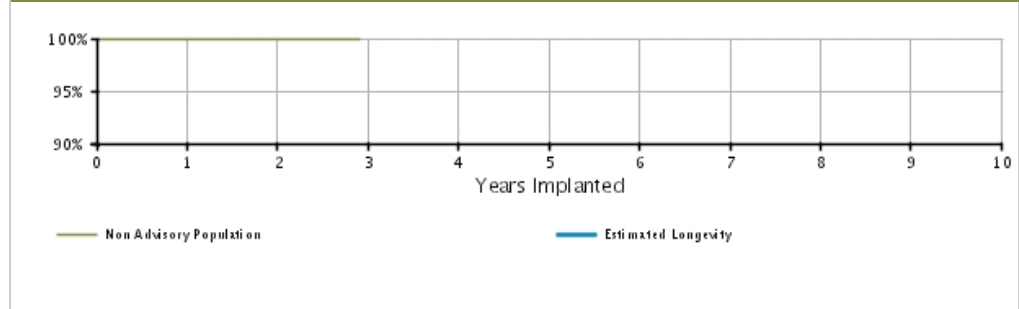
U.S. Summary

U.S. Registered Implants: 13,000	U.S. Normal Battery Depletions: 1
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability


	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 @ 35 mo. (-0.0/+0.0)	-	-	-	-	-	-	-
Registered Implants: 13000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 35 mo. (-0.0/+0.0)	-	-	-	-	-	-	-
	Effective Sample Size	7364	2786	278	-	-	-	-	-	-	-

INGENIO SR

Models J172/J175/K172/K175/K182/
K185

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

INGENIO SR
Models J172/J175/K172/K175/K182/
K185



Worldwide Distribution: 34,000
Worldwide Confirmed Malfunctions: 2

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

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

VITALIO EL DR

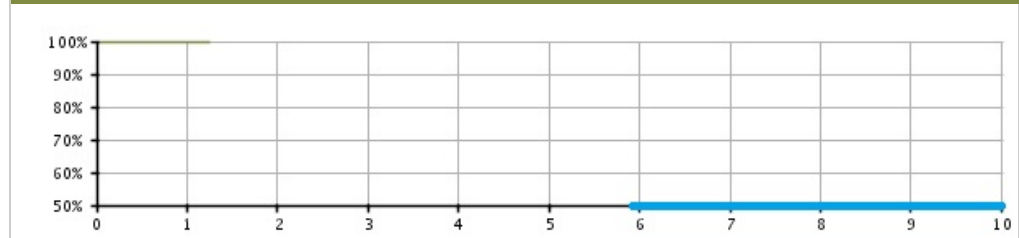
Models J274/J277/K274/K277/K284/
K287

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

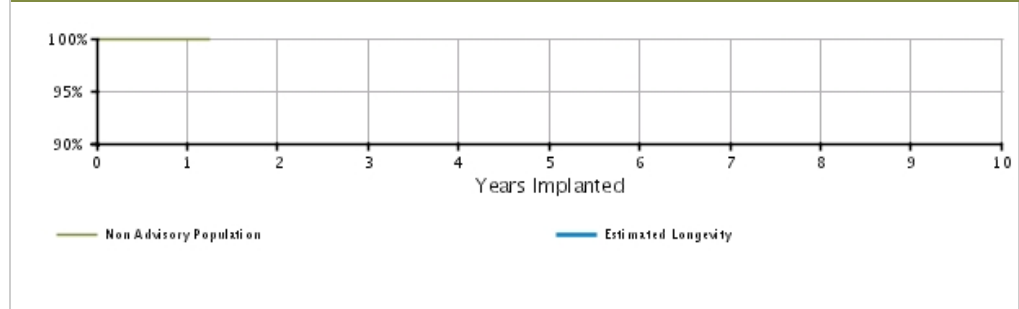
U.S. Summary

U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
Registered Implants: 2000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	-	-	-	-	-	-	-	-
	Effective Sample Size	485	260	-	-	-	-	-	-	-	-

VITALIO EL DR

Models J274/J277/K274/K277/K284/
K287

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

VITALIO EL DR Models J274/J277/K274/K277/K284/ K287			
Worldwide Distribution: 11,000 Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	1	2

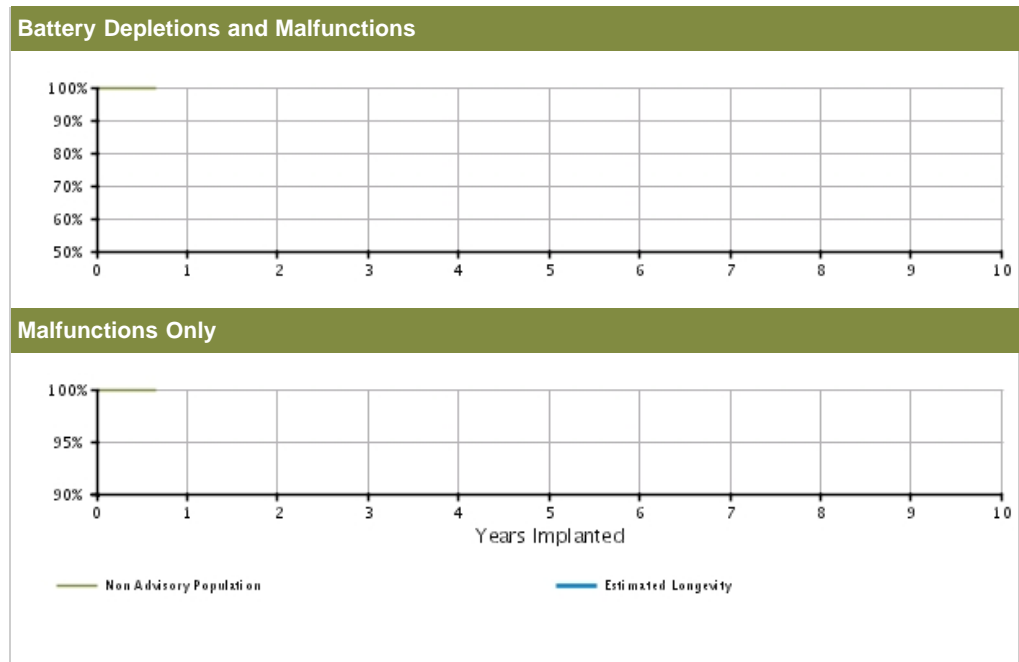
[References](#) cited in table above

VITALIO DR

Models J273/J276/K273/K276

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

U.S. Summary	
U.S. Registered Implants: 3,000	U.S. Normal Battery Depletions: 0
U.S. Approval Date: May 2012	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%)	100.00	-	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)										
Registered Implants: 3000	Malfunctions Only (%)	100.00	-	-	-	-	-	-	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)										
	Effective Sample Size	275	-	-	-	-	-	-	-	-	-	-

VITALIO DR

Models J273/J276/K273/K276

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


VITALIO DR Models J273/J276/K273/K276 			
Worldwide Distribution: 11,000 Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[References](#) cited in table above

VITALIO SR

Models J272/J275/K272/K275/K282/
K285

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


VITALIO SR Models J272/J275/K272/K275/K282/ K285 			
Worldwide Distribution: 6,000 Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
⁸⁸ Titanium case material	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	0	2	2

[References](#) cited in table above

FORMIO DR

Models J278/J279/K278/K279/K288/
K289

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

FORMIO DR Models J278/J279/K278/K279/K288/ K289 			
Worldwide Distribution: 3,000 Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

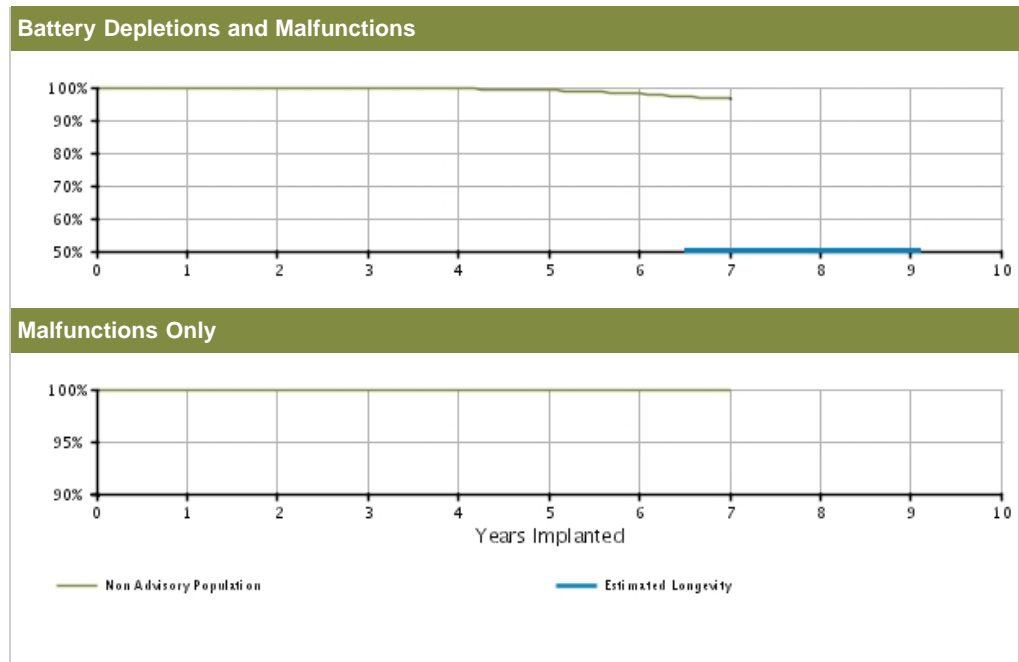
[References](#) cited in table above

ALTRUA 60 DR

Model S602

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

U.S. Summary	
U.S. Registered Implants: 22,000	U.S. Normal Battery Depletions: 238
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 15,000	U.S. Malfunctions:5
	Without Compromised Therapy:4
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.54 (-0.1/+0.1)	99.05 (-0.2/+0.2)	98.01 (-0.3/+0.3)	96.62 (-0.8/+0.7)	-	-	-	-
	Registered Implants: 22000											
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.95 (-0.1/+0.0)	-	-	-	-
	Effective Sample Size	19369	17000	14748	12018	9505	6348	337	-	-	-	-

ALTRUA 60 DR

Model S602

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

ALTRUA 60 DR Model S602			
Worldwide Distribution: 55,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	1	1	2
²⁶ Capacitor array	1	-	
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	4	1	5
Non-patterned	2	1	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	6	2	8

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

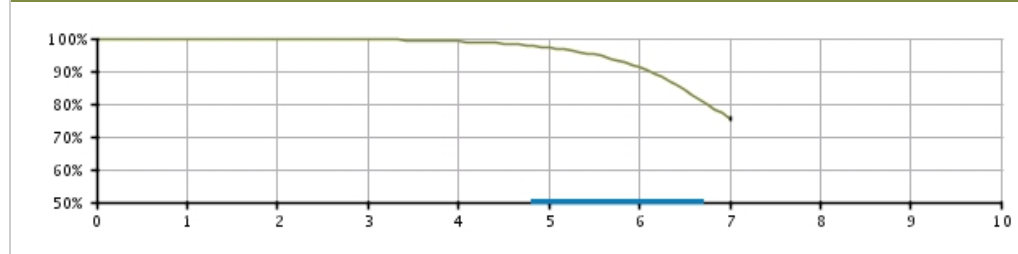
ALTRUA 60 DR (Downsize)

Model S603

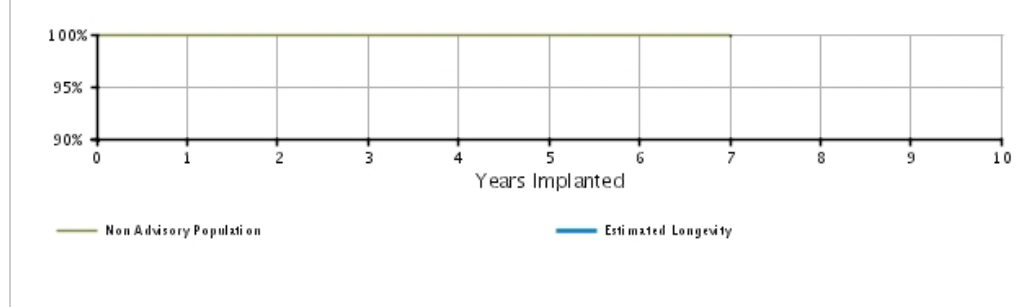
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 90,000	U.S. Normal Battery Depletions: 2,872
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 40
U.S. Estimated Active Implants: 61,000	U.S. Malfunctions:35
	Without Compromised Therapy:27
	With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only




U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.67 (-0.0/+0.0)	99.06 (-0.1/+0.1)	97.27 (-0.2/+0.2)	91.27 (-0.4/+0.4)	75.34 (-1.6/+1.5)	-	-	-
Registered Implants: 90000	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.86 (-0.1/+0.0)	-	-	-
	Effective Sample Size	79400	70350	59980	42097	25730	11156	442	-	-	-

ALTRUA 60 DR (Downsize)

Model S603

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

ALTRUA 60 DR (Downsize) Model S603 			
Worldwide Distribution: 132,000			
Worldwide Confirmed Malfunctions: 39			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	5	6	11
²³ Capacitor	4	5	
⁵³ Integrated circuit	1	1	
Mechanical	2	-	2
⁶⁵ Connector block	1	-	
⁶⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	23	3	26
Non-patterned	-	2	
⁴³ Battery depletion	3	1	
⁷⁷ Battery status	20	-	
WW Confirmed Malfunctions	30	9	39

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

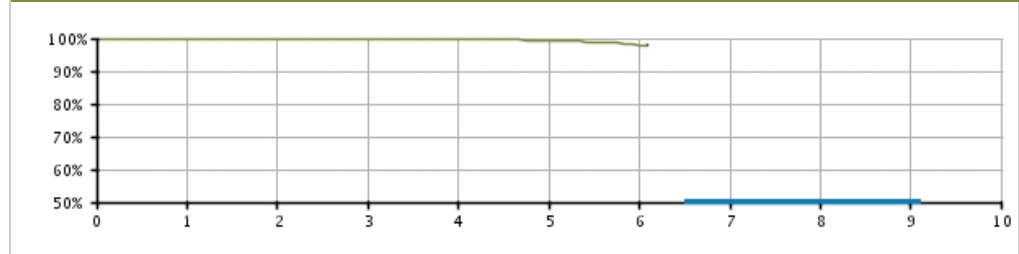
ALTRUA 60 DR EL

Model S606

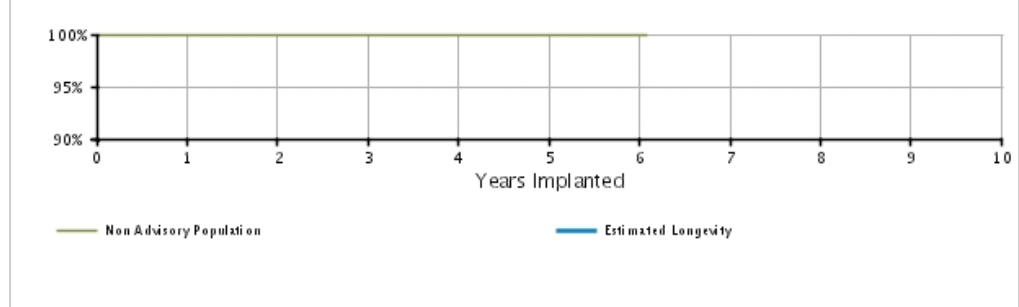
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 59,000	U.S. Normal Battery Depletions: 185
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 11
U.S. Estimated Active Implants: 47,000	U.S. Malfunctions:7
	Without Compromised Therapy:5
	With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.70 (-0.1/+0.1)	99.34 (-0.1/+0.1)	98.00 (-0.6/+0.5)	98.00 @ 73 mo. (-0.6/+0.5)	-	-	-
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)	99.98 @ 73 mo. (-0.0/+0.0)	-	-	-
	Effective Sample Size	52724	46578	39098	22962	9739	805	447	-	-	-

ALTRUA 60 DR EL

Model S606

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

ALTRUA 60 DR EL Model S606			
Worldwide Distribution: 90,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	-	4
²³ Capacitor	3	-	
²⁷ Integrated circuit	1	-	
Mechanical	-	1	1
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	2	1	3
Non-patterned	1	-	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	6	2	8

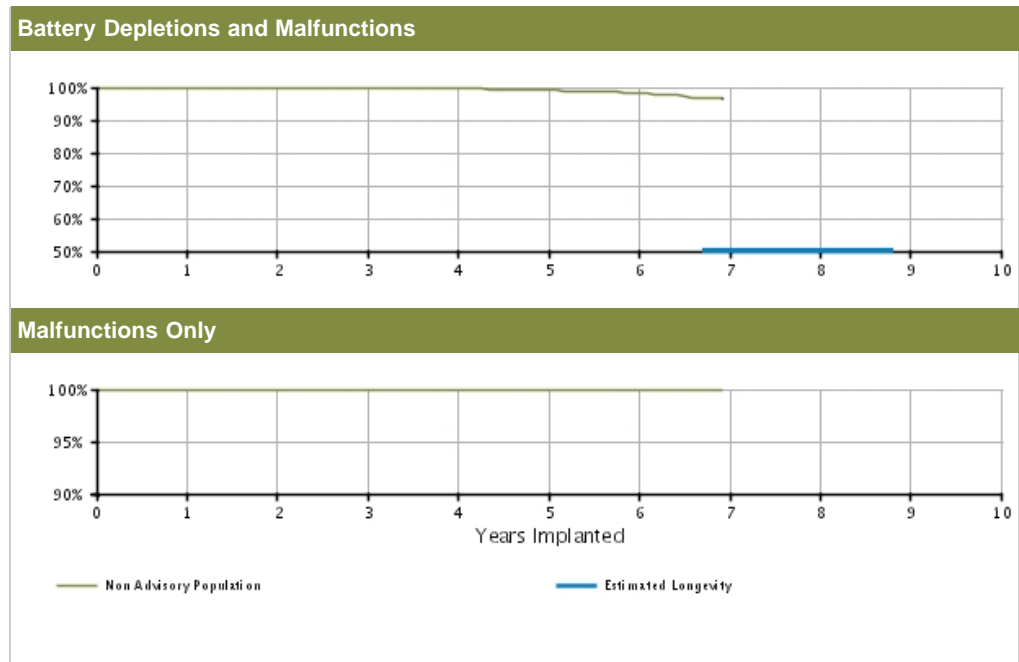
References cited in table above

ALTRUA 60 SR

Model S601

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

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 192
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 19,000	U.S. Malfunctions:3
	Without Compromised Therapy:1
	With Compromised Therapy:2




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.11 (-0.2/+0.2)	98.20 (-0.4/+0.3)	96.63 @ 83 mo. (-0.8/+0.7)	-	-	-	-
	Registered Implants: 32000	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 83 mo. (-0.1/+0.0)	-	-	-	-
Effective Sample Size		26871	23540	19806	13132	7643	3082	278	-	-	-	-

ALTRUA 60 SR

Model S601

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


ALTRUA 60 SR Model S601 			
Worldwide Distribution: 68,000			
Worldwide Confirmed Malfunctions: 9			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	3	5
²³ Capacitor	2	1	
⁵³ Integrated circuit	-	2	
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	2	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	3	6	9

[References](#) cited in table above

ALTRUA 50 DR (Downsize)

Model S502

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

ALTRUA 50 DR (Downsize) Model S502 			
Worldwide Distribution: 44,000			
Worldwide Confirmed Malfunctions: 8			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	-	3
²³ Capacitor	2	-	
⁵³ Integrated circuit	1	-	
Mechanical	-	1	1
⁶⁸ Difficulty securing lead	-	1	
Software	-	-	0
Other	4	-	4
Non-patterned	1	-	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	2	-	
WW Confirmed Malfunctions	7	1	8

[References](#) cited in table above

ALTRUA 50 SR

Model S501

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

ALTRUA 50 SR
Model S501

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	2	3
²³ Capacitor	1	2	
Mechanical	-	-	0
Software	-	-	0
Other	-	3	3
Non-patterned	-	1	
⁴³ Battery depletion	-	2	
WW Confirmed Malfunctions	1	5	6

[References](#) cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

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

ALTRUA 50 DDD (Downsize)
Model S503

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	3	3	6
Non-patterned	-	-	
⁴³ Battery depletion	-	3	
⁷⁷ Battery status	3	-	
WW Confirmed Malfunctions	3	3	6

[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	-	-	
⁷⁷ Battery status	2	-	
WW Confirmed Malfunctions	2	0	2

[References](#) cited in table above

ALTRUA 50 SSI

Model S508

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

ALTRUA 50 SSI Model S508			
Worldwide Distribution: 6,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	-	-	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	1	-	
WW Confirmed Malfunctions	1	1	2

[References](#) cited in table above

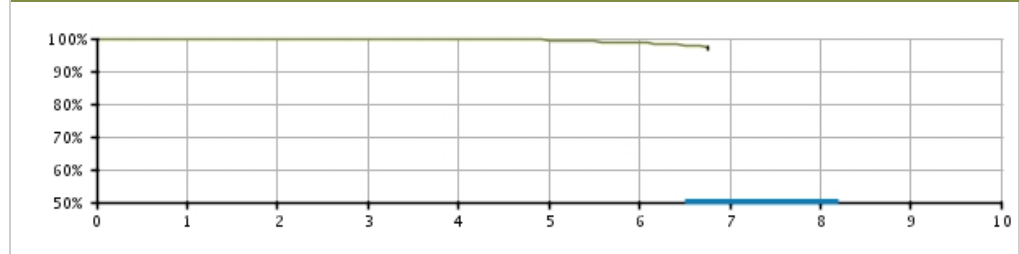
ALTRUA 40 DR

Model S402

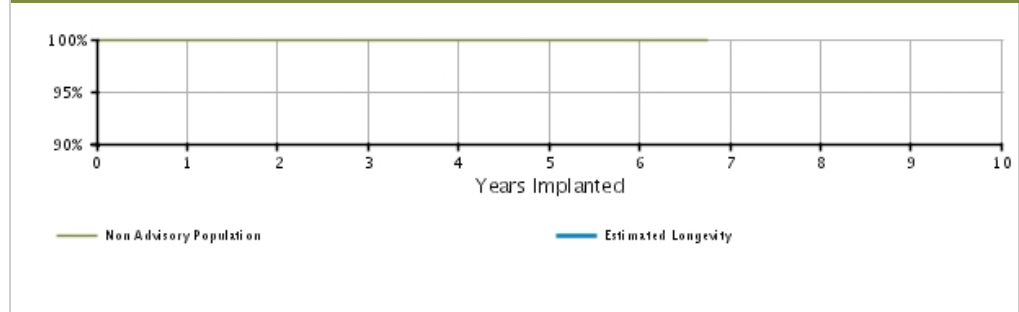
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories
---------------------------	-------------------------------	--------------------

U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 20
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)	98.65 (-1.0/+0.6)	97.23 @ 81 mo. (-1.7/+1.1)	-	-	-
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 @ 81 mo. (-0.0/+0.0)	-	-	-
	Effective Sample Size	1517	1346	1194	1064	945	807	243	-	-	-

ALTRUA 40 DR

Model S402

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

ALTRUA 40 DR Model S402			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
⁴³ Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

[References](#) cited in table above

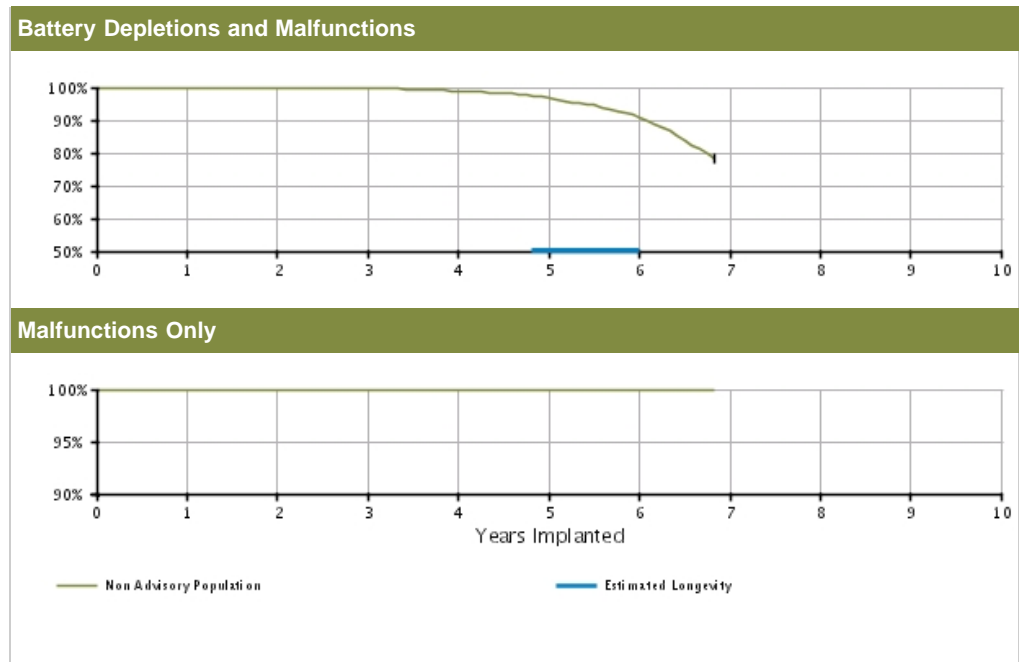
CRM PRODUCT PERFORMANCE REPORT Q3 2015

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: 451
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Estimated Active Implants: 10,000	U.S. Malfunctions:3
	Without Compromised Therapy:3
	With Compromised Therapy:0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%)	99.98	99.92	99.69	98.90	96.63	90.89	78.26	—	—	—	—
	(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.2/+0.2)	(-0.5/+0.4)	(-1.1/+1.0)	@ 82 mo. (-3.0/+2.8)				
Registered Implants: 14000	Malfunctions Only(%)	99.99	99.99	99.99	99.98	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)	@ 82 mo. (-0.1/+0.0)				
	Effective Sample Size	12516	11152	9803	6821	3911	1511	210	—	—	—	—

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
⁶⁷ Seal plug	1	-	
⁶⁸ Difficulty securing lead	1	-	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
⁷⁷ Battery status	2	-	
WW Confirmed Malfunctions	4	0	4

[References](#) cited in table above

ALTRUA 40 DR EL

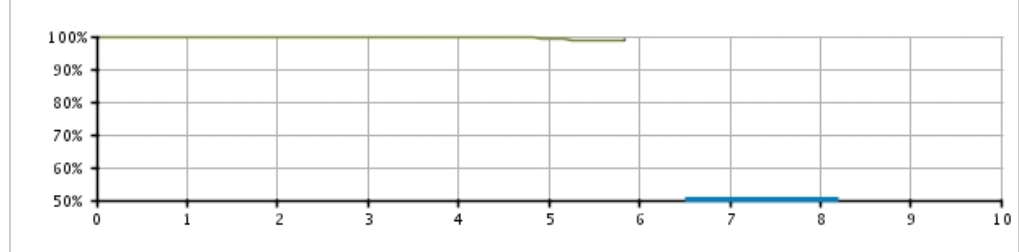
Model S404

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

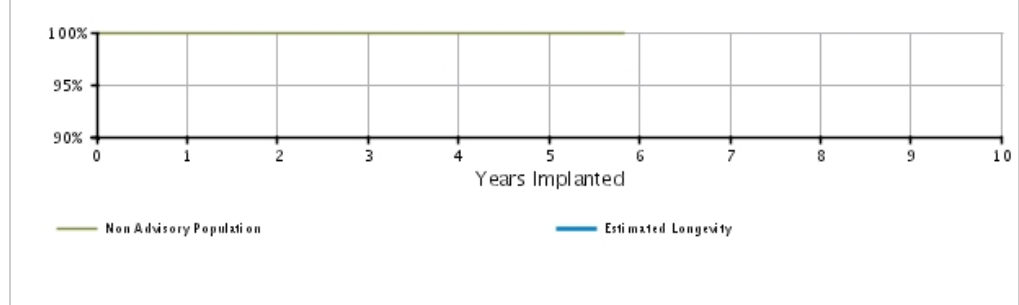
U.S. Summary

U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 17
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 4,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

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)	99.71 (-0.3/+0.1)	99.18 (-0.6/+0.3)	98.97 @ 70 mo. (-0.7/+0.4)	-	-	-	-
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 @ 70 mo. (-0.0/+0.0)	-	-	-	-
	Effective Sample Size	4477	3979	3491	2228	1157	259	-	-	-	-

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL Model S404			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	0	1

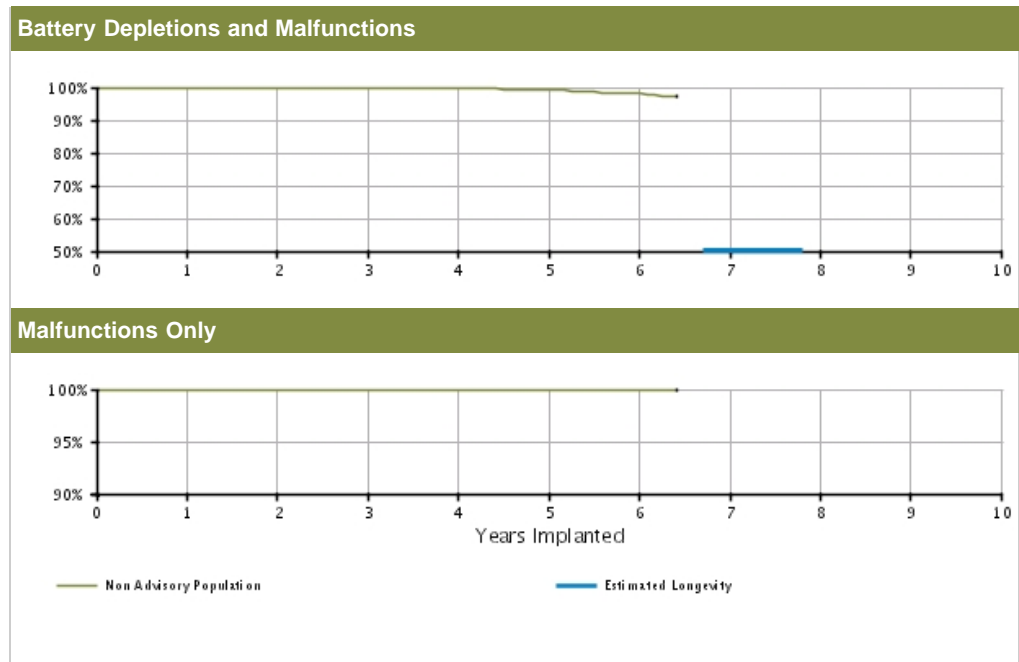
[References](#) cited in table above

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: 27
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions: 2
	Without Compromised Therapy: 2
	With Compromised Therapy: 0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.71 (-0.3/+0.1)	99.25 (-0.5/+0.3)	98.06 (-1.1/+0.7)	97.32 @ 77 mo. (-1.5/+1.0)	-	-	-	-
	Registered Implants: 5000	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.93 (-0.2/+0.1)	99.93 (-0.2/+0.1)	99.93 (-0.2/+0.1)	99.93 @ 77 mo. (-0.2/+0.1)	-	-	-
		Effective Sample Size	3963	3475	3008	2056	1179	499	228	-	-	-

ALTRUA 40 SR

Model S401

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

ALTRUA 40 SR Model S401			
Worldwide Distribution: 9,000			
Worldwide Confirmed Malfunctions: 3			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	1	3
²³ Capacitor	2	-	
⁵³ Integrated circuit	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	2	1	3

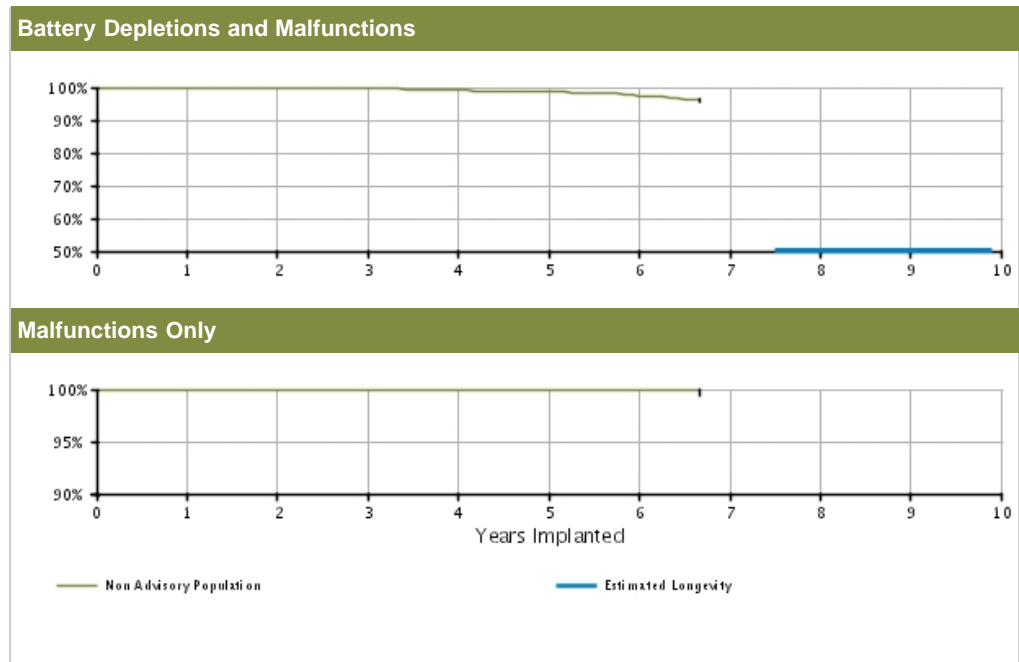
[References](#) cited in table above

ALTRUA 20 DR

Models S202/S205

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

U.S. Summary	
U.S. Registered Implants: 2,000	U.S. Normal Battery Depletions: 26
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 1,000	U.S. Malfunctions: 1
	Without Compromised Therapy: 1
	With Compromised Therapy: 0




U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions (%)	100.00	99.93	99.67	99.28	98.61	97.42	96.24	-	-	-	-
	(Confidence Interval)	(-0.0/+0.0)	(-0.4/+0.1)	(-0.5/+0.2)	(-0.7/+0.4)	(-1.0/+0.6)	(-1.4/+0.9)	@ 80 mo. (-1.8/+1.2)				
Registered Implants: 2000	Malfunctions Only (%)	100.00	100.00	100.00	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)	@ 80 mo. (-0.6/+0.1)				
	Effective Sample Size	1503	1301	1111	940	778	614	208	-	-	-	-

ALTRUA 20 DR

Models S202/S205

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

ALTRUA 20 DR
Models S202/S205



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
⁷² Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

[References](#) cited in table above

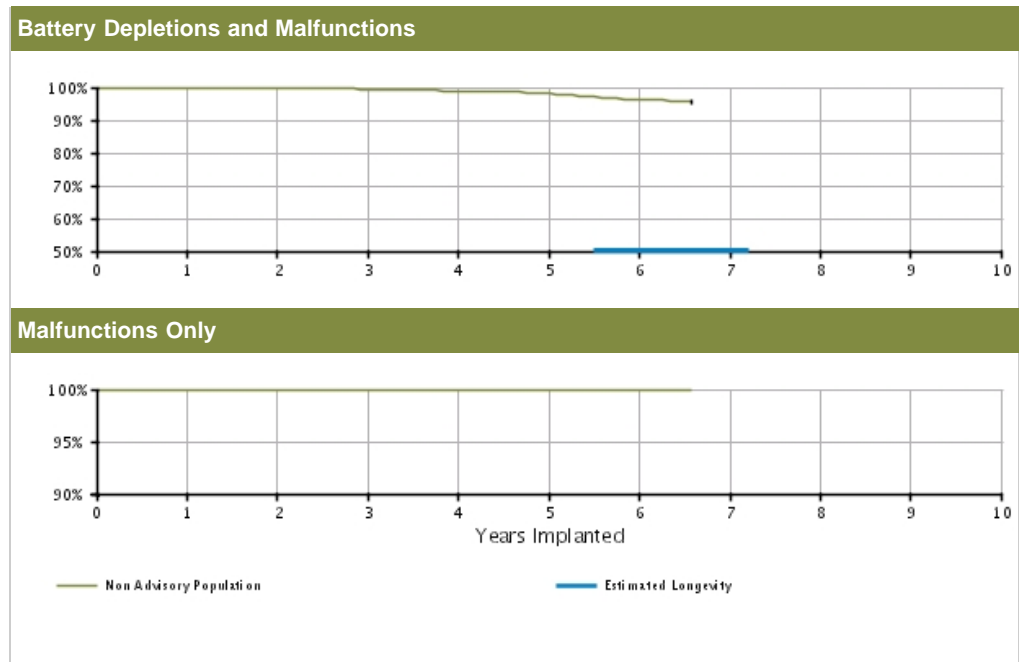
CRM PRODUCT PERFORMANCE REPORT Q3 2015

ALTRUA 20 DR (downsize)

Model S203

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

U.S. Summary	
U.S. Registered Implants: 5,000	U.S. Normal Battery Depletions: 75
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.90 (-0.4/+0.3)	98.03 (-0.6/+0.5)	96.18 (-1.1/+0.9)	95.59 @ 79 mo. (-1.5/+1.1)	-	-	-	-
	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 @ 79 mo. (-0.0/+0.0)	-	-	-	-
	Effective Sample Size	4418	3916	3421	2436	1469	580	210	-	-	-	-

ALTRUA 20 DR (downsize)

Model S203

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

ALTRUA 20 DR (downsize)
Model S203

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

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

[References](#) cited in table above

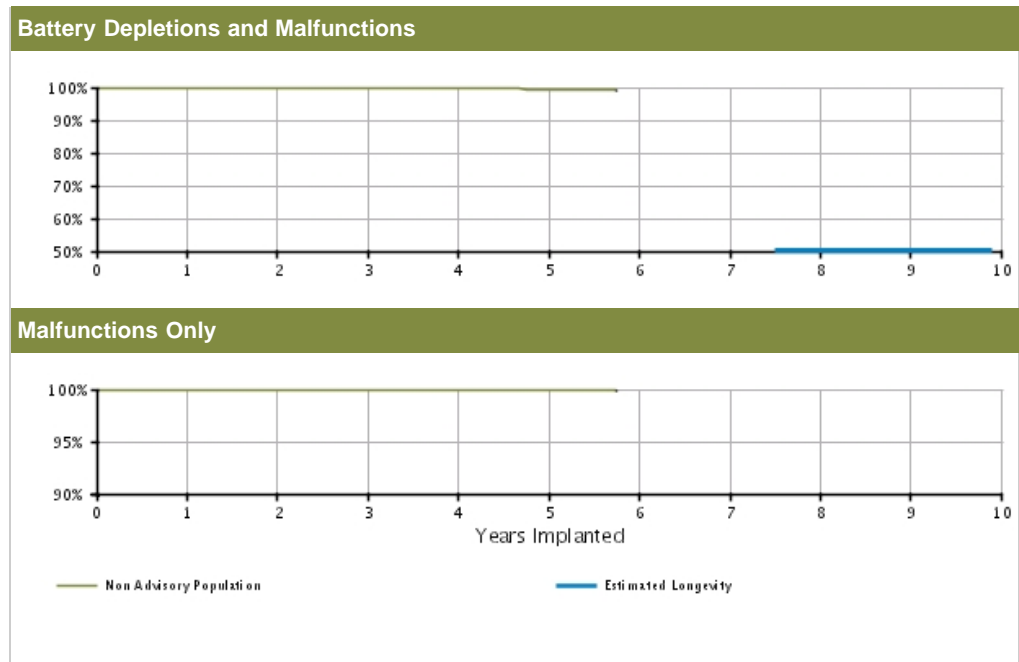
CRM PRODUCT PERFORMANCE REPORT Q3 2015

ALTRUA 20 DR EL

Model S208

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

U.S. Summary	
U.S. Registered Implants: 3,000	U.S. Normal Battery Depletions: 11
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:1
	Without Compromised Therapy:0
	With Compromised Therapy:1



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.86 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.60 (-0.4/+0.2)	99.33 (-0.7/+0.3)	99.33 @ 69 mo. (-0.7/+0.3)	-	-	-	-	-
	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 @ 69 mo. (-0.2/+0.0)	-	-	-	-	-
	Effective Sample Size	2774	2468	2125	1368	663	239	-	-	-	-	-

ALTRUA 20 DR EL

Model S208

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

ALTRUA 20 DR EL Model S208			
Worldwide Distribution: 10,000			
Worldwide Confirmed Malfunctions: 1			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	1	1
²³ Capacitor	-	1	
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	1	1

[References](#) cited in table above

ALTRUA 20 SR

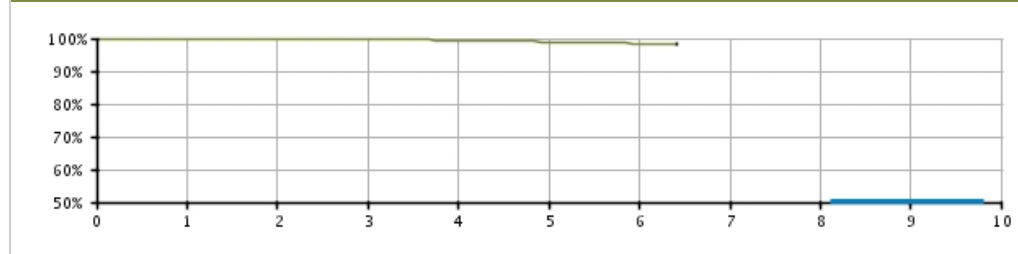
Models S201/S204

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

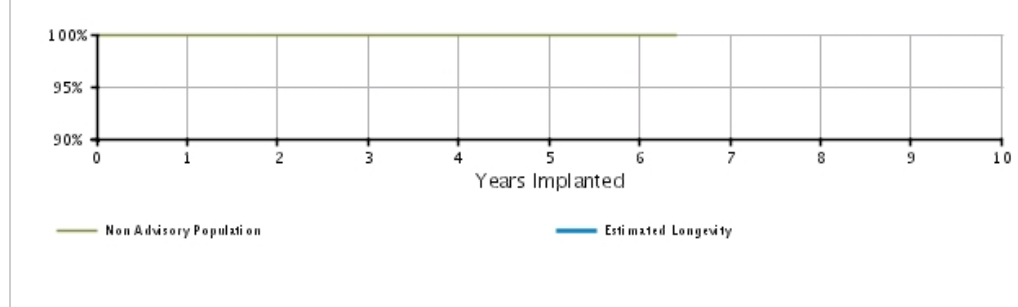
U.S. Summary

U.S. Registered Implants: 4,000	U.S. Normal Battery Depletions: 25
U.S. Approval Date: April 2008	U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Estimated Active Implants: 2,000	U.S. Malfunctions:0
	Without Compromised Therapy:0
	With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.67 (-0.3/+0.2)	99.43 (-0.4/+0.2)	98.77 (-0.7/+0.4)	98.34 (-1.0/+0.6)	98.34 @ 77 mo. (-1.0/+0.6)	-	-	-
Registered Implants: 4000	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 77 mo. (-0.0/+0.0)	-	-	-
	Effective Sample Size	3579	3043	2528	1733	1005	397	210	-	-	-

ALTRUA 20 SR

Models S201/S204

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


ALTRUA 20 SR Models S201/S204			
Worldwide Distribution: 24,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	-	1
²³ Capacitor	1	-	
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	1	
WW Confirmed Malfunctions	1	1	2

[References](#) cited in table above

ALTRUA 20 SSI

Model S206

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

ALTRUA 20 SSI Model S206 			
Worldwide Distribution: 7,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[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

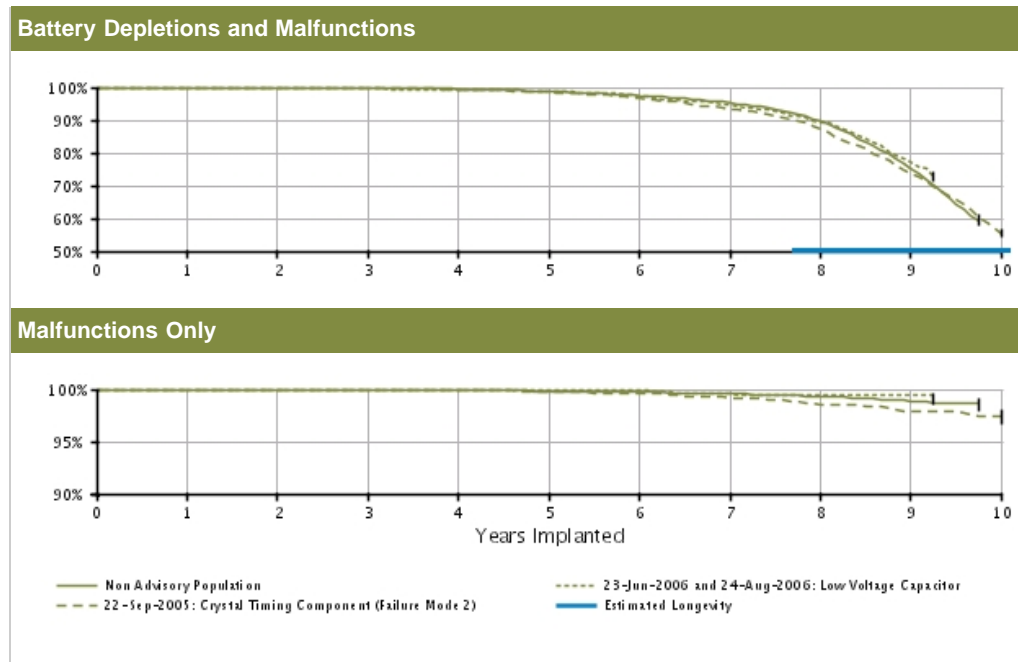
[References](#) cited in table above

INSIGNIA Ultra DR

Model 1291

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

U.S. Summary	
U.S. Registered Implants: 32,000	U.S. Normal Battery Depletions: 2,578
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Estimated Active Implants: 14,000	U.S. Malfunctions:148
	Without Compromised Therapy:138
	With Compromised Therapy:10



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.50 (-0.1/+0.1)	98.71 (-0.2/+0.2)	97.44 (-0.3/+0.3)	95.32 (-0.4/+0.4)	89.55 (-0.7/+0.7)	75.13 (-1.7/+1.6)	59.46 @ 117 mo. (-3.1/+3.1)	
	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)	99.34 (-0.2/+0.1)	98.90 (-0.4/+0.3)	98.60 @ 117 mo. (-0.7/+0.5)	
	Effective Sample Size	21003	18657	16560	14649	12905	11295	9531	3947	896	207	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.48 (-1.1/+0.8)	94.64 (-1.5/+1.2)	89.44 (-2.2/+1.8)	77.31 (-3.1/+2.8)	72.88 @ 111 mo. (-3.5/+3.2)	
	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 @ 111 mo. (-0.8/+0.3)	
	Effective Sample Size	1878	1659	1460	1287	1133	986	848	699	531	263	
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.58 (-0.7/+0.6)	93.42 (-0.9/+0.8)	87.18 (-1.3/+1.2)	73.51 (-1.8/+1.7)	55.44 (-2.2/+2.2)	
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.58 (-0.7/+0.6)	93.42 (-0.9/+0.8)	87.18 (-1.3/+1.2)	73.51 (-1.8/+1.7)	55.44 (-2.2/+2.2)	
	Effective Sample Size	1878	1659	1460	1287	1133	986	848	699	531	263	

6000


Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.96 (-0.7/+0.5)	97.47 (-0.8/+0.6)
Effective Sample Size	5704	5047	4468	3939	3452	2979	2554	2096	1556	645

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

INSIGNIA Ultra DR

Model 1291

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

INSIGNIA Ultra DR Model 1291 			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 183			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	7	5	12
⁹ Low-voltage capacitor (Advisory issued)	-	2	
²⁰ Capacitor	1	-	
²³ Capacitor	4	2	
⁵³ Integrated circuit	2	1	
Mechanical	7	5	12
³¹ Seal plug	5	4	
³² Header	1	1	
⁵⁵ Setscrew	1	-	
Software	4	-	4
⁵⁸ Underestimation of battery status	3	-	
⁶⁰ Pacing rate limit	1	-	
Other	150	5	155
Non-patterned	8	4	
¹⁶ Longevity labeling	74	-	
³³ Magnet response	1	-	
⁴³ Battery depletion	3	1	
⁷⁷ Battery status	64	-	
WW Confirmed Malfunctions	168	15	183

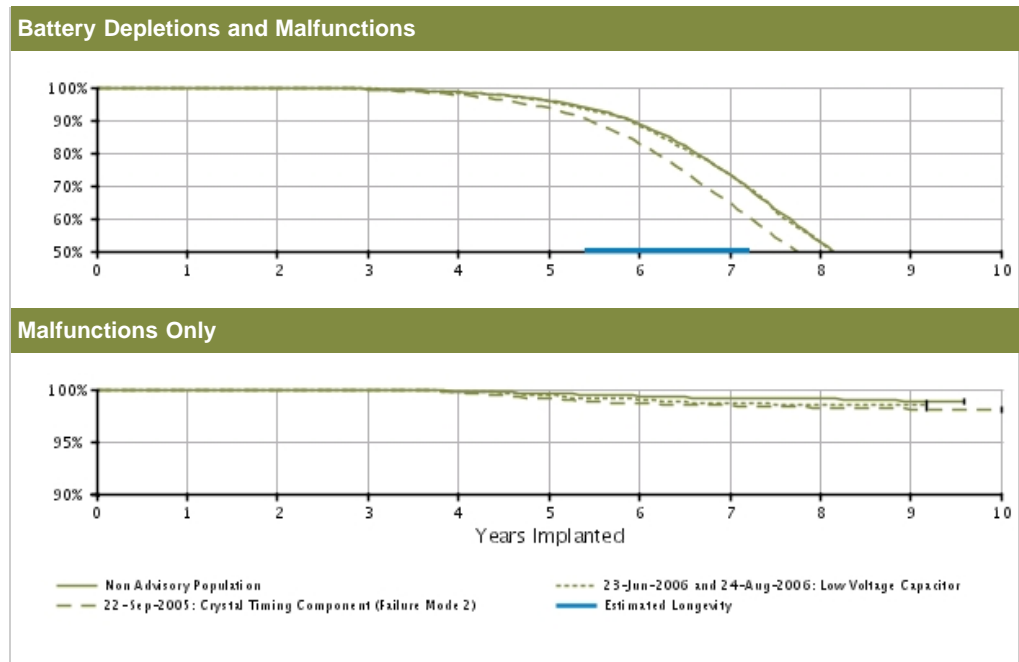
[References](#) cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

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

U.S. Summary	
U.S. Registered Implants: 76,000	U.S. Normal Battery Depletions: 17,840
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 114
U.S. Estimated Active Implants: 18,000	U.S. Malfunctions:418
	Without Compromised Therapy:405
	With Compromised Therapy:13



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.48 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.92 (-0.4/+0.4)	73.24 (-0.5/+0.5)	52.62 (-0.7/+0.7)	33.26 (-1.1/+1.1)	21.88 (-1.5/+1.6)	21.88 (-1.5/+1.6)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.17 (-0.1/+0.1)	99.07 (-0.1/+0.1)	98.89 (-0.3/+0.2)	98.89 (-0.3/+0.2)	98.89 (-0.3/+0.2)
	Effective Sample Size	47638	42291	37445	32974	28503	23421	16599	5601	951	221	221
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.2/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.3/+0.2)	98.41 (-0.5/+0.4)	95.67 (-0.8/+0.7)	88.16 (-1.4/+1.2)	73.20 (-1.9/+1.8)	52.96 (-2.3/+2.3)	34.94 (-2.3/+2.4)	31.88 (-2.3/+2.4)	31.88 (-2.3/+2.4)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.38 (-0.4/+0.2)	99.06 (-0.5/+0.3)	98.72 (-0.6/+0.4)	98.54 (-0.6/+0.4)	98.54 (-0.6/+0.4)	98.54 (-0.6/+0.4)	98.54 (-0.6/+0.4)
	Effective Sample Size	4024	3553	3142	2732	2340	1907	1376	856	487	331	331
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.											
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.38 (-0.2/+0.1)	97.77 (-0.3/+0.3)	93.65 (-0.5/+0.5)	82.84 (-0.8/+0.8)	64.55 (-1.1/+1.1)	44.61 (-1.2/+1.2)	27.95 (-1.1/+1.2)	18.01 (-1.1/+1.1)	18.01 (-1.1/+1.1)

Component (Failure Mode 2)*	(Confidence Interval)										
Registered Implants: 17000											
Malfunctions Only (%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.09 (-0.2/+0.2)	98.67 (-0.3/+0.2)	98.45 (-0.3/+0.2)	98.25 (-0.3/+0.3)	98.12 (-0.4/+0.3)	98.12 (-0.4/+0.3)	
Effective Sample Size	14977	13298	11732	10223	8609	6639	4409	2585	1337	405	

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

INSIGNIA Ultra DR (downsize)

Model 1290

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

INSIGNIA Ultra DR (downsize) Model 1290			
Worldwide Distribution: 124,000			
Worldwide Confirmed Malfunctions: 572			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	9	9	18
⁹ Low-voltage capacitor (Advisory issued)	1	5	
²³ Capacitor	7	3	
⁵³ Integrated circuit	1	1	
Mechanical	6	2	8
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²¹ Setscrew thread depth	1	-	
³¹ Seal plug	4	1	
⁴⁰ Circuit connection	1	-	
Software	12	-	12
³⁶ Memory error	2	-	
³⁷ Rate fault declaration	1	-	
⁵⁸ Underestimation of battery status	8	-	
⁶⁰ Pacing rate limit	1	-	
Other	524	10	534
Non-patterned	23	6	
¹⁶ Longevity labeling	398	-	
⁴³ Battery depletion	6	4	
⁷⁷ Battery status	97	-	
WW Confirmed Malfunctions	551	21	572

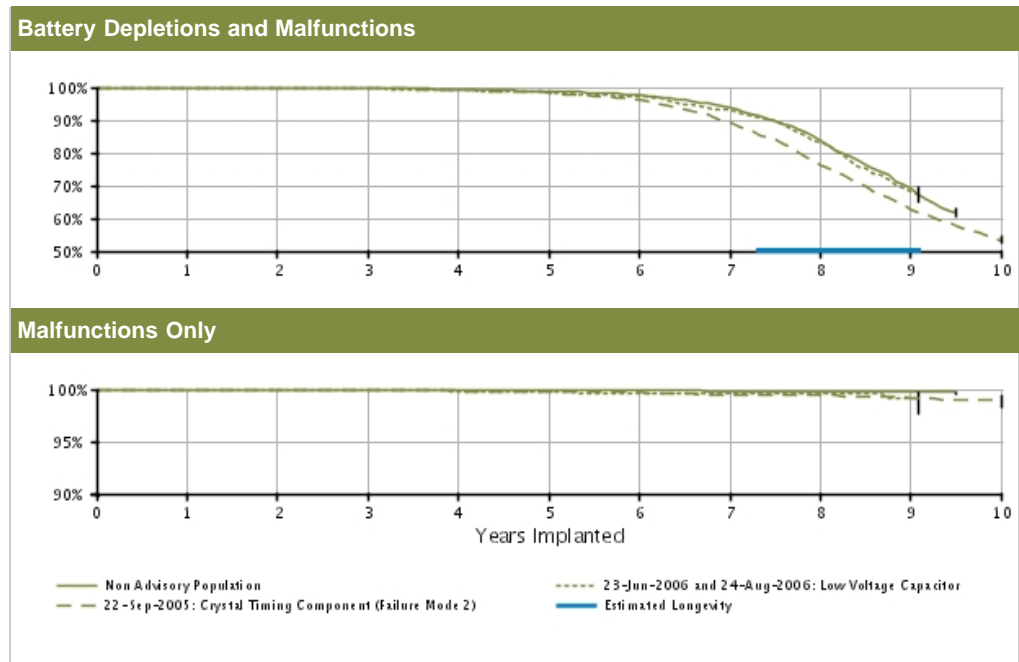
[References](#) cited in table above

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: 1,910
U.S. Approval Date: November 2003	U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Estimated Active Implants: 6,000	U.S. Malfunctions:37
	Without Compromised Therapy:33
	With Compromised Therapy:4



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.71 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.55 (-0.4/+0.3)	93.51 (-0.6/+0.6)	83.53 (-1.1/+1.1)	69.21 (-2.1/+2.0)	61.91 @ 114 mo. (-2.9/+2.8)	
	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)	99.69 (-0.2/+0.1)	99.69 (-0.2/+0.1)	99.69 @ 114 mo. (-0.2/+0.1)	
	Effective Sample Size	14152	12090	10308	8860	7733	6763	5564	2308	543	234	
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)	97.21 (-1.6/+1.0)	93.24 (-2.5/+1.8)	83.19 (-3.7/+3.2)	68.33 (-4.7/+4.4)	67.38 @ 109 mo. (-4.8/+4.4)	
	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)	99.21 (-1.6/+0.5)	99.21 @ 109 mo. (-1.6/+0.5)	
	Effective Sample Size	1147	962	811	698	587	501	420	333	236	215	
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.											
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.23 (-0.4/+0.3)	98.28 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.35 (-1.5/+1.3)	76.34 (-2.2/+2.0)	62.64 (-2.6/+2.5)	53.44 (-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	99.17	99.02	
(Confidence Interval)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.2/+0.1)	(-0.2/+0.1)	(-0.3/+0.1)	(-0.4/+0.2)	(-0.5/+0.3)	(-0.6/+0.4)	(-0.8/+0.4)	
Effective Sample Size	4143	3557	3001	2529	2112	1769	1419	1038	741	329	

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

INSIGNIA Ultra SR

Model 1190

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

INSIGNIA Ultra SR Model 1190			
Worldwide Distribution: 48,000			
Worldwide Confirmed Malfunctions: 60			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	2	5	7
⁹ Low-voltage capacitor (Advisory issued)	1	3	
²³ Capacitor	1	-	
⁵³ Integrated circuit	-	2	
Mechanical	3	1	4
³¹ Seal plug	3	-	
³² Header	-	1	
Software	1	-	1
³⁶ Memory error	1	-	
Other	48	-	48
Non-patterned	1	-	
¹⁶ Longevity labeling	23	-	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	23	-	
WW Confirmed Malfunctions	54	6	60

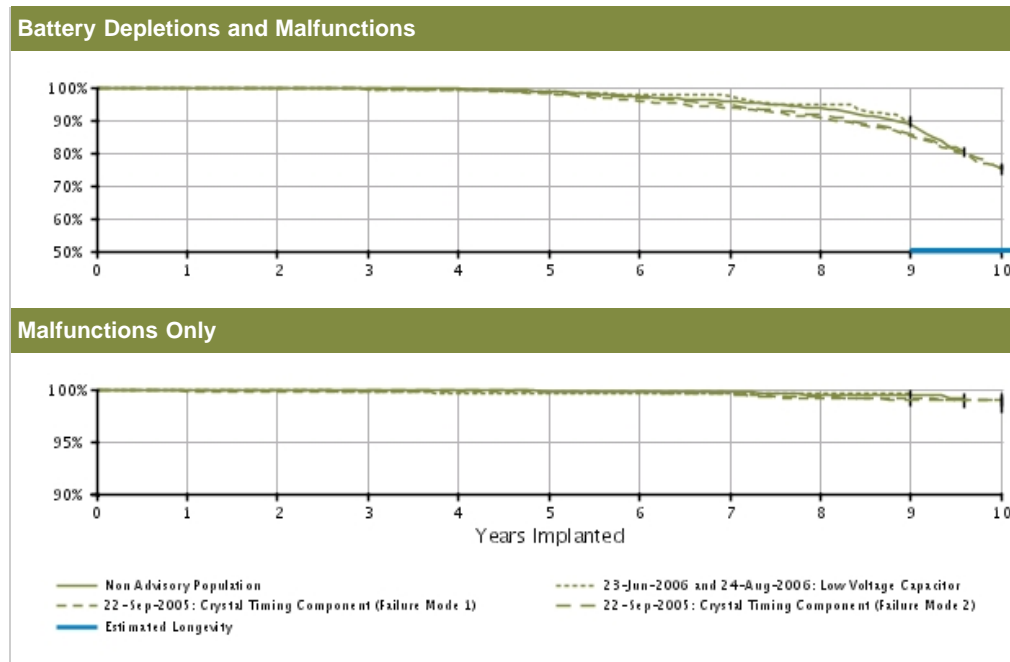
[References](#) cited in table above

INSIGNIA Entra DR

Models 1294/1295

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

U.S. Summary	
U.S. Registered Implants: 17,000	U.S. Normal Battery Depletions: 1,335
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 12
U.S. Estimated Active Implants: 5,000	U.S. Malfunctions:61
	Without Compromised Therapy:54
	With Compromised Therapy:7



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.2/+0.2)	98.72 (-0.4/+0.3)	97.05 (-0.6/+0.5)	95.70 (-0.7/+0.6)	93.62 (-0.9/+0.8)	88.74 (-1.7/+1.5)	80.24 @ 115 mo. (-3.2/+2.8)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.51 (-0.3/+0.2)	99.42 (-0.4/+0.2)	99.15 @ 115 mo. (-0.9/+0.4)	
	Effective Sample Size	6260	5548	4913	4354	3810	3304	2791	1549	545	237	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.45 (-1.1/+0.4)	99.24 (-1.3/+0.5)	98.76 (-1.5/+0.7)	97.66 (-2.0/+1.1)	97.32 (-2.1/+1.2)	94.53 (-3.0/+2.0)	89.94 (-4.1/+3.0)	-	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	-	
	Effective Sample Size	693	607	529	452	394	337	293	247	208	-	
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.69 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.19 (-0.7/+0.4)	98.09 (-1.0/+0.7)	95.94 (-1.4/+1.1)	93.70 (-1.8/+1.4)	90.92 (-2.2/+1.8)	85.22 (-2.9/+2.5)	75.11 (-3.7/+3.4)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	
	Effective Sample Size	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	


	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.19 (-1.0/+0.5)	99.19 (-1.0/+0.5)	98.95 (-1.2/+0.6)
	Effective Sample Size	1676	1454	1214	1064	923	785	662	554	452	336
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.31 (-0.3/+0.2)	98.40 (-0.4/+0.3)	96.91 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.56 (-1.0/+0.9)	85.61 (-1.4/+1.3)	75.50 (-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)	98.98 (-0.5/+0.3)	98.92 (-0.5/+0.3)
	Effective Sample Size	6210	5482	4823	4229	3693	3187	2679	2267	1859	1188

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

INSIGNIA Entra DR

Models 1294/1295

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

INSIGNIA Entra DR Models 1294/1295 			
Worldwide Distribution: 36,000			
Worldwide Confirmed Malfunctions: 72			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	3	3
¹⁹ Integrated circuit	-	1	
²³ Capacitor	-	1	
⁵³ Integrated circuit	-	1	
Mechanical	3	7	10
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
³¹ Seal plug	3	-	
³² Header	-	2	
Software	-	-	0
Other	56	3	59
Non-patterned	4	3	
¹⁶ Longevity labeling	49	-	
⁷⁷ Battery status	3	-	
WW Confirmed Malfunctions	59	13	72

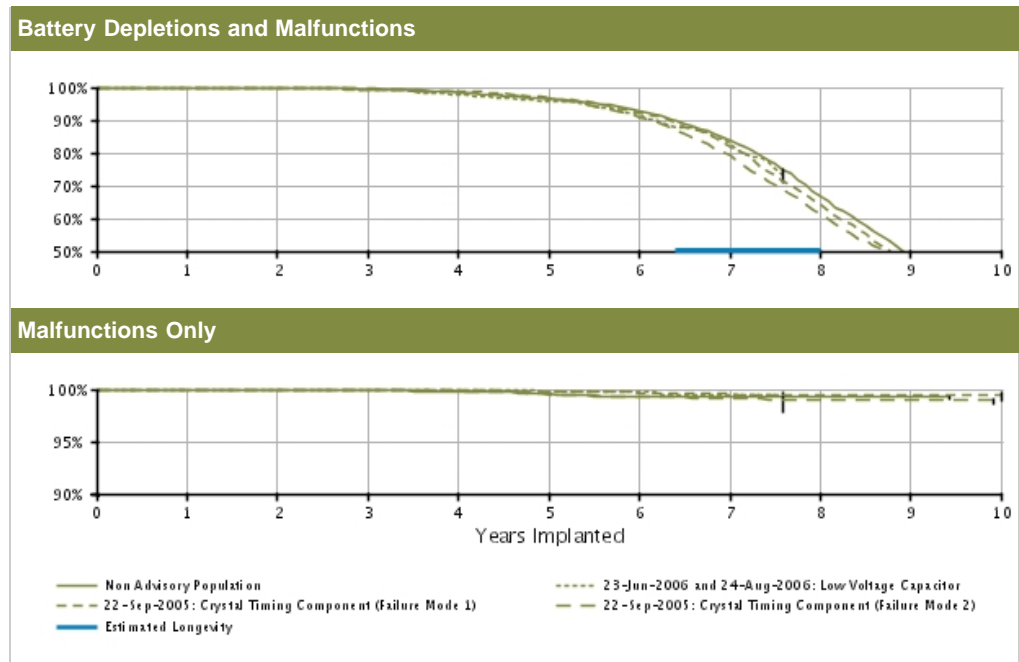
References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

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

U.S. Summary	
U.S. Registered Implants: 24,000	U.S. Normal Battery Depletions: 4,616
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Estimated Active Implants: 3,000	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 Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.43 (-0.2/+0.2)	98.43 (-0.4/+0.3)	96.58 (-0.5/+0.5)	93.00 (-0.8/+0.7)	83.83 (-1.2/+1.1)	66.75 (-1.8/+1.8)	48.82 (-2.5/+2.5)	43.00 @ 113 mo. (-2.9/+3.0)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.99 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.57 (-0.2/+0.2)	99.37 (-0.3/+0.2)	99.31 (-0.3/+0.2)	99.22 (-0.3/+0.2)	99.22 (-0.3/+0.2)	99.22 @ 113 mo. (-0.3/+0.2)	
	Effective Sample Size	7139	6280	5496	4779	4121	3507	2707	1222	336	205	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.70 (-0.9/+0.2)	99.20 (-1.1/+0.5)	97.84 (-1.6/+0.9)	95.61 (-2.2/+1.5)	91.90 (-3.0/+2.2)	82.99 (-4.2/+3.5)	73.19 @ 91 mo. (-5.1/+4.5)	--	--	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.75 (-1.5/+0.2)	99.75 (-1.5/+0.2)	99.43 (-1.7/+0.4)	99.43 @ 91 mo. (-1.7/+0.4)	--	--	
	Effective Sample Size	763	657	563	476	402	329	251	203	--	--	
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.03 (-1.5/+1.3)	81.78 (-2.2/+2.0)	64.03 (-2.9/+2.8)	45.79 (-3.2/+3.2)	31.97 (-3.1/+3.3)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	
	Effective Sample Size											

3000	Malfunctions Only (%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2736	2405	2071	1813	1515	1227	933	597	360	205
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.56 (-0.2/+0.1)	98.52 (-0.3/+0.3)	96.46 (-0.5/+0.4)	90.85 (-0.8/+0.7)	79.03 (-1.2/+1.1)	61.25 (-1.5/+1.5)	45.03 (-1.6/+1.6)	36.25 (-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	8452	7365	6366	5505	4512	3338	2171	1334	753

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

INSIGNIA Entra DR (downsize)

Model 1296

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

INSIGNIA Entra DR (downsize) Model 1296			
Worldwide Distribution: 47,000			
Worldwide Confirmed Malfunctions: 119			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	1	4	5
⁹ Low-voltage capacitor (Advisory issued)	-	1	
²³ Capacitor	1	-	
⁵³ Integrated circuit	-	3	
Mechanical	-	3	3
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
¹⁷ Solder bond	-	1	
Software	4	-	4
³⁰ Memory error	1	-	
⁵⁸ Underestimation of battery status	1	-	
⁵⁹ Interrupted telemetry	2	-	
Other	105	2	107
Non-patterned	4	2	
¹⁶ Longevity labeling	96	-	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	4	-	
WW Confirmed Malfunctions	110	9	119

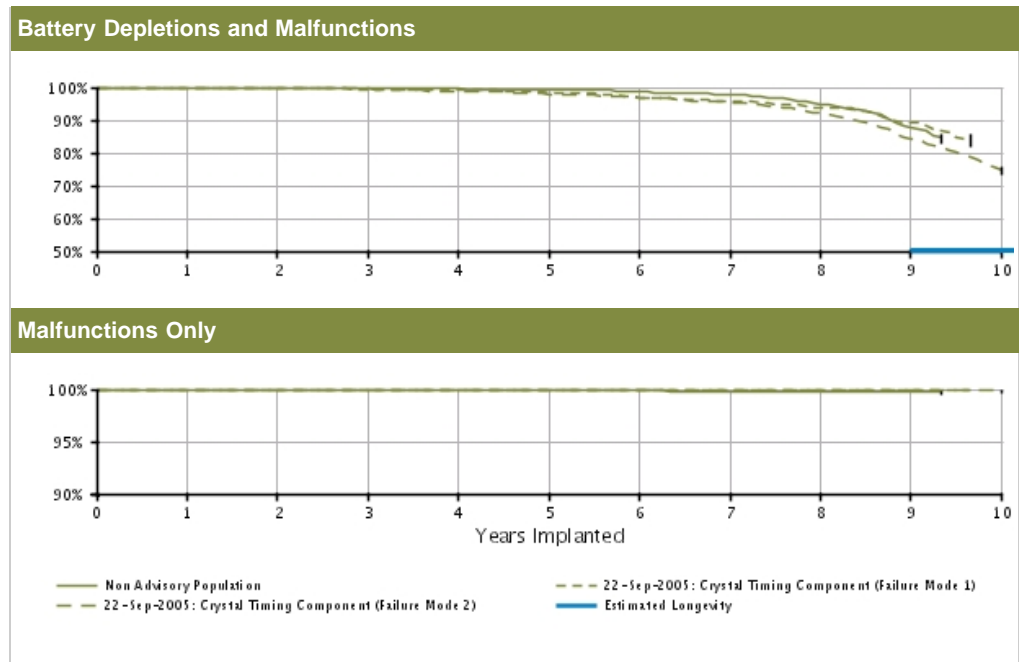
[References](#) cited in table above

INSIGNIA Entra SR

Models 1195/1198

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

U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Normal Battery Depletions: 707
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 Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.85 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.75 (-0.5/+0.4)	97.90 (-0.7/+0.5)	94.92 (-1.3/+1.0)	87.73 (-2.7/+2.3)	84.52 @ 112 mo. (-3.5/+2.9)	
	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 @ 112 mo. (-0.3/+0.1)	
	Effective Sample Size	4708	3872	3251	2742	2324	2002	1651	881	300	213	
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)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.21 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.96 (-1.8/+1.1)	95.73 (-2.1/+1.4)	93.95 (-2.6/+1.9)	89.47 (-3.6/+2.8)	83.99 @ 116 mo. (-4.5/+3.7)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 116 mo. (-0.0/+0.0)	
	Effective Sample Size	1216	999	807	662	550	447	356	299	245	201	
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.95 (-0.8/+0.6)	95.27 (-1.0/+0.8)	92.21 (-1.3/+1.2)	84.17 (-2.0/+1.8)	74.74 (-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	4579	3828	3177	2641	2183	1829	1540	1287	1026	647	

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

INSIGNIA Entra SR

Models 1195/1198

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

INSIGNIA Entra SR Models 1195/1198 			
Worldwide Distribution: 52,000			
Worldwide Confirmed Malfunctions: 27			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	4	7
⁹ Low-voltage capacitor (Advisory issued)	-	2	
²³ Capacitor	2	2	
⁵³ Integrated circuit	1	-	
Mechanical	1	6	7
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
²⁶ Capacitor array	-	2	
³¹ Seal plug	-	2	
⁵⁶ Seal plug	-	1	
Software	-	-	0
Other	12	1	13
Non-patterned	1	1	
¹⁶ Longevity labeling	6	-	
⁷⁷ Battery status	5	-	
WW Confirmed Malfunctions	16	11	27

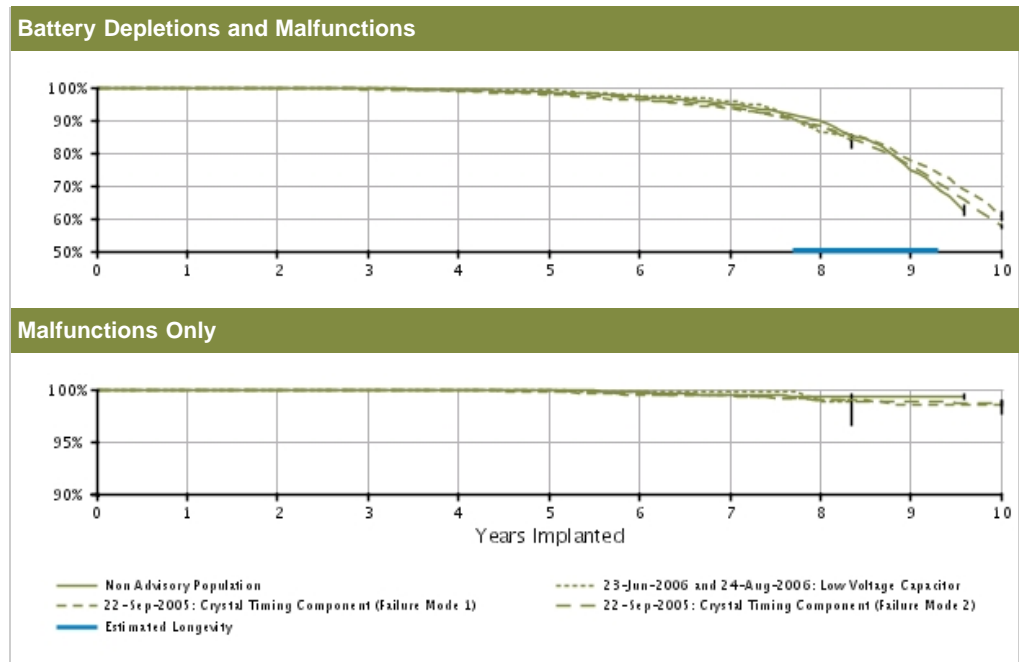
[References](#) cited in table above

INSIGNIA Plus DR

Model 1297

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

U.S. Summary	
U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 4,250
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 19
U.S. Estimated Active Implants: 7,000	U.S. Malfunctions:126
	Without Compromised Therapy:117
	With Compromised Therapy:9



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.75 (-0.2/+0.1)	99.26 (-0.3/+0.2)	98.51 (-0.4/+0.3)	97.16 (-0.6/+0.5)	94.99 (-0.7/+0.7)	89.53 (-1.2/+1.1)	74.72 (-2.6/+2.4)	62.34 @ 115 mo. (-3.6/+3.5)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.49 (-0.3/+0.2)	99.35 (-0.4/+0.2)	99.35 (-0.4/+0.2)	99.35 @ 115 mo. (-0.4/+0.2)	
	Effective Sample Size	6560	5831	5161	4546	3997	3495	2952	1527	506	229	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.19 (-1.3/+0.5)	99.19 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.95 (-2.6/+1.6)	86.27 (-4.5/+3.5)	83.82 @ 100 mo. (-4.8/+3.9)		-
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.86 (-2.4/+0.8)	98.86 @ 100 mo. (-2.4/+0.8)		-
	Effective Sample Size	664	580	510	442	386	333	285	223	204		-
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.10 (-1.7/+1.5)	77.82 (-2.2/+2.1)	60.66 (-2.8/+2.7)	
	Malfunctions Only(%) (Confidence Interval)											
	Effective Sample Size											

4000	Malfunctions Only (%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.4/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3514	3072	2597	2280	1972	1705	1458	1210	929	615
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.55 (-0.1/+0.1)	99.10 (-0.2/+0.2)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.78 (-0.8/+0.8)	76.09 (-1.2/+1.1)	57.70 (-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	12754	11251	9911	8722	7618	6596	5630	4614	3483	2078

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

INSIGNIA Plus DR

Model 1297

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

INSIGNIA Plus DR Model 1297			
Worldwide Distribution: 47,000			
Worldwide Confirmed Malfunctions: 156			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	3	3	6
⁹ Low-voltage capacitor (Advisory issued)	1	1	
²³ Capacitor	2	1	
⁵³ Integrated circuit	-	1	
Mechanical	15	8	23
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
¹⁷ Solder bond	1	-	
²⁶ Capacitor array	1	-	
³¹ Seal plug	5	-	
³² Header	7	5	
Software	7	-	7
⁵⁸ Underestimation of battery status	4	-	
⁵⁹ Interrupted telemetry	2	-	
⁶⁰ Pacing rate limit	1	-	
Other	117	3	120
Non-patterned	6	3	
¹⁶ Longevity labeling	89	-	
⁴³ Battery depletion	2	-	
⁷⁷ Battery status	20	-	
WW Confirmed Malfunctions	142	14	156

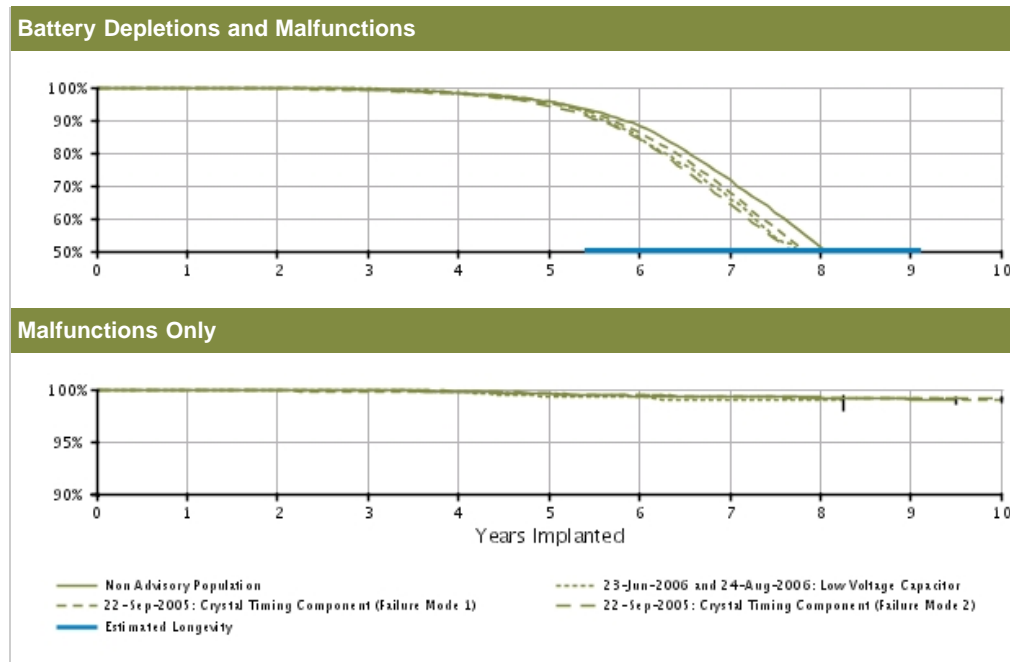
[References](#) cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

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

U.S. Summary	
U.S. Registered Implants: 90,000	U.S. Normal Battery Depletions: 26,034
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 114
U.S. Estimated Active Implants: 11,000	U.S. Malfunctions:370
	Without Compromised Therapy:341
	With Compromised Therapy:29



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.41 (-0.1/+0.1)	98.27 (-0.2/+0.2)	95.60 (-0.4/+0.4)	88.24 (-0.6/+0.6)	71.52 (-0.9/+0.9)	51.41 (-1.2/+1.2)	32.25 (-1.5/+1.6)	24.82 @ 114 mo. (-1.8/+1.8)	
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.35 (-0.2/+0.1)	99.26 (-0.2/+0.1)	99.14 (-0.2/+0.2)	98.96 (-0.5/+0.3)	98.96 @ 114 mo. (-0.5/+0.3)	
	Effective Sample Size	16865	14981	13239	11653	10064	8195	5710	2264	546	242	
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.86 (-0.4/+0.1)	99.77 (-0.5/+0.2)	98.12 (-1.0/+0.7)	95.80 (-1.5/+1.1)	84.87 (-2.6/+2.3)	65.93 (-3.5/+3.4)	45.66 (-3.8/+3.9)	39.19 @ 99 mo. (-3.8/+3.9)		
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.70 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)	98.91 @ 99 mo. (-1.0/+0.5)		
	Effective Sample Size	1420	1250	1112	964	825	642	435	256	209		
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.13 (-0.2/+0.2)	98.03 (-0.3/+0.2)	95.06 (-0.5/+0.4)	86.20 (-0.8/+0.7)	67.68 (-1.1/+1.1)	46.99 (-1.3/+1.3)	31.85 (-1.3/+1.3)	21.91 (-1.2/+1.3)	
	Malfunctions Only(%) (Confidence Interval)											
	Effective Sample Size											


16000	Malfunctions Only (%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.57 (-0.2/+0.1)	99.38 (-0.2/+0.1)	99.32 (-0.2/+0.2)	99.19 (-0.2/+0.2)	99.13 (-0.3/+0.2)	99.03 (-0.4/+0.3)
	Effective Sample Size	13682	12074	10374	9053	7728	6115	4094	2342	1295	729
22-Sep-05 Crystal Timing Component (Failure Mode 2)*	Depletions and Malfunctions (%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.80 (-0.0/+0.0)	99.26 (-0.1/+0.1)	97.91 (-0.2/+0.1)	94.47 (-0.3/+0.2)	84.13 (-0.4/+0.4)	64.20 (-0.6/+0.6)	44.15 (-0.7/+0.7)	29.89 (-0.7/+0.7)	20.80 (-0.6/+0.6)
Registered Implants: 54000	Malfunctions Only (%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.30 (-0.1/+0.1)	99.22 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.14 (-0.1/+0.1)
	Effective Sample Size	47026	41685	36742	32065	27285	21108	13674	7774	4341	2287

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

INSIGNIA Plus DR (downsize)

Model 1298

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

INSIGNIA Plus DR (downsize) Model 1298 			
Worldwide Distribution: 140,000			
Worldwide Confirmed Malfunctions: 447			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	11	10	21
⁹ Low-voltage capacitor (Advisory issued)	-	3	
²⁰ Capacitor	-	1	
²³ Capacitor	6	2	
²⁷ Integrated circuit	-	1	
⁵³ Integrated circuit	5	3	
Mechanical	21	22	43
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
¹² Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
¹⁷ Solder bond	1	-	
²⁶ Capacitor array	3	1	
³¹ Seal plug	3	1	
³² Header	5	-	
⁵⁶ Seal plug	1	-	
Software	11	-	11
³⁶ Memory error	1	-	
⁵⁷ Interrogation at EOL	2	-	
⁵⁸ Underestimation of battery status	6	-	
⁵⁹ Interrupted telemetry	1	-	
⁶⁰ Pacing rate limit	1	-	
Other	361	11	372
Non-patterned	28	9	
¹⁶ Longevity labeling	309	-	
²⁹ Battery depletion	2	1	
³³ Magnet response	1	-	
⁴³ Battery depletion	11	1	
⁷⁷ Battery status	10	-	
WW Confirmed Malfunctions	404	43	447

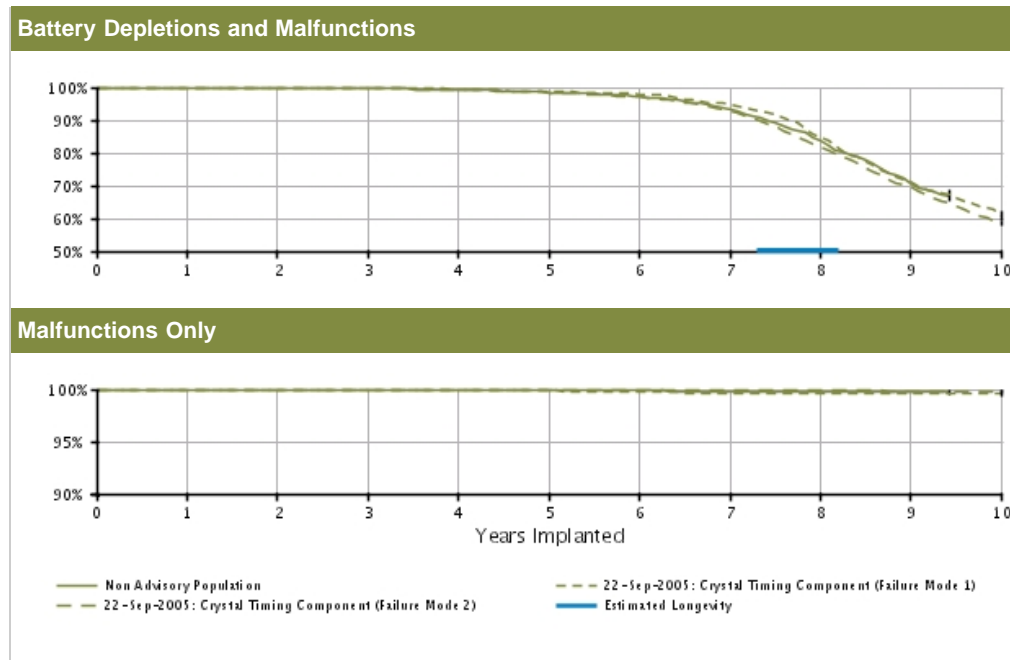
[References](#) cited in table above

INSIGNIA Plus SR

Model 1194

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

U.S. Summary	
U.S. Registered Implants: 27,000	U.S. Normal Battery Depletions: 3,094
U.S. Approval Date: March 2002	U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Estimated Active Implants: 3,000	U.S. Malfunctions:27
	Without Compromised Therapy:19
	With Compromised Therapy:8



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.61 (-0.3/+0.2)	99.33 (-0.3/+0.2)	98.47 (-0.5/+0.4)	97.29 (-0.7/+0.6)	93.30 (-1.1/+1.0)	83.65 (-1.9/+1.8)	70.82 (-3.1/+2.9)	66.98 @ 113 mo. (-3.6/+3.4)	
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.85 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 @ 113 mo. (-0.3/+0.1)	
	Effective Sample Size	4726	4034	3451	2888	2477	2128	1738	858	311	202	
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)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.89 (-0.2/+0.1)	99.73 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.74 (-0.6/+0.4)	98.00 (-0.7/+0.5)	94.85 (-1.2/+1.0)	84.88 (-2.2/+1.9)	71.02 (-2.8/+2.7)	60.90 (-3.2/+3.1)	
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.92 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.76 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	
	Effective Sample Size	3454	2919	2420	2068	1742	1436	1171	876	619	458	
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.24 (-0.2/+0.2)	98.49 (-0.3/+0.2)	97.09 (-0.4/+0.4)	92.86 (-0.7/+0.6)	81.82 (-1.1/+1.0)	69.62 (-1.4/+1.3)	58.35 (-1.5/+1.5)	


Component (Failure Mode 2)*	(Confidence Interval)										
Registered Implants: 17000											
Malfunctions Only (%)	99.99	99.99	99.96	99.95	99.94	99.91	99.89	99.89	99.82	99.82	
(Confidence Interval)	(-0.0/+0.0)	(-0.0/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.0)	(-0.1/+0.1)	(-0.1/+0.1)	(-0.2/+0.1)	(-0.2/+0.1)	
Effective Sample Size	13687	11696	10065	8521	7161	6020	4910	3640	2624	1754	

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

INSIGNIA Plus SR

Model 1194

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


INSIGNIA Plus SR Model 1194 			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 36			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	4	5	9
⁹ Low-voltage capacitor (Advisory issued)	1	2	
²³ Capacitor	2	2	
²⁷ Integrated circuit	-	1	
⁵³ Integrated circuit	1	-	
Mechanical	1	6	7
¹¹ Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
²⁶ Capacitor array	1	-	
³¹ Seal plug	-	1	
Software	1	-	1
⁶⁰ Pacing rate limit	1	-	
Other	18	1	19
Non-patterned	4	-	
¹⁶ Longevity labeling	10	-	
²⁹ Battery depletion	-	1	
⁴³ Battery depletion	1	-	
⁷⁷ Battery status	3	-	
WW Confirmed Malfunctions	24	12	36

[References](#) cited in table above

INSIGNIA AVT

Models 0482/0882/0982/1192/1292

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

INSIGNIA AVT Models 0482/0882/0982/1192/1292 			
Worldwide Distribution: 51,000			
Worldwide Confirmed Malfunctions: 83			
	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	5	5
⁹ Low-voltage capacitor (Advisory issued)	-	3	
²³ Capacitor	-	1	
⁵³ Integrated circuit	-	1	
Mechanical	2	-	2
³¹ Seal plug	1	-	
³² Header	1	-	
Software	-	-	0
Other	74	2	76
Non-patterned	2	1	
¹⁶ Longevity labeling	39	-	
⁴³ Battery depletion	-	1	
⁷⁷ Battery status	33	-	
WW Confirmed Malfunctions	76	7	83

[References](#) cited in table above

CRM PRODUCT PERFORMANCE REPORT Q3 2015

Confirmed Malfunction Details: Pulse Generators

References

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

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

1. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory*. Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory*. Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
3. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory*. Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **Magnetic reed switch 2010**— *July 21, 2010 Voluntary Physician Advisory*. Upon magnet removal, magnetic reed switch remains closed and device tones do not cease. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON.
5. **Subpectoral implant 2009**— *December 01, 2009 Voluntary Physician Advisory*. Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subpectorally. Weakened bond between header and titanium case. Improvement implemented.
6. **Respiratory Sensor Oversensing**— *March 23, 2009 Voluntary Physician Advisory*. Oversensing, noise, inappropriate shock, pacing inhibition. When Respiratory Sensor is ON, RV lead or system complications may cause oversensing or noise. Improvement implemented.
7. **Subpectoral implant**— *May 12, 2006 and January 04, 2008 Voluntary Physician Advisory*. Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications, loss of pacing (intermittent or permanent) and/or loss of shock therapy. Repetitive mechanical stress-induced component damage, only when implanted subpectorally with the serial number facing the ribs. Improvement implemented.
8. **Shortened replacement window**— *April 05, 2007 and March 04, 2009 Voluntary Physician Advisory*. Accelerated battery depletion may reduce time between elective replacement (ERI) and end of life (EOL) indicators to less than three months. Device replacement indicators continue to function normally. Degradation of low-voltage capacitor. Improvement implemented.
9. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory*. Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
10. **Premature battery depletion**— *May 12, 2006 Voluntary Physician Advisory*. Premature battery depletion, significantly shortened longevity and duration between elective replacement (ERI) and end of life (EOL) indicators. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
11. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory*. Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
12. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory*. At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
13. **Magnetic switch**— *June 23, 2005 Voluntary Physician Advisory*. Inhibition of tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. Magnetic switch stuck in closed position. Improvement implemented.
14. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
15. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.
16. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
17. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
18. **Firmware error**— Device beeping unaffected by magnet application, missing EGMs, loss of telemetry, loss of tachy therapy. Multiple resets due to firmware error. Improvement implemented.

19. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
20. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
21. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
22. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.
23. **Capacitor**— No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.
24. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.
25. **Battery depletion**— Premature battery depletion.
26. **Capacitor array**— Loss of device output, loss of capture, inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.
27. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
28. **Impedance measurements**— High impedance value (generally >3000 ohms) recorded and displayed as weekly average impedance. Low daily impedance recordings cause error in calculating weekly average impedance due to memory storage limitations. Device fully capable of therapy delivery as programmed. Improvement implemented.
29. **Battery depletion**— Premature battery depletion and loss of capture.
30. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
31. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
32. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
33. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
34. **Battery depletion**— Premature battery depletion.
35. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.
36. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
37. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
38. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
39. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
40. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
41. **Capacitor**— Premature battery depletion, significantly shortened ERI to EOL time. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
42. **Device tones**— Inappropriately sustained device tone. Magnet removal or initialization of programming event during specific timing window. Device fully capable of therapy delivery as programmed. Improvement implemented.
43. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
44. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
45. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
46. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
47. **Memory location**— Loss of pacing and/or shock therapy, premature battery depletion, inability to perform diagnostic testing, loss of telemetry, and/or incorrect diagnostic information. Incorrect data within a specific memory location.
48. **Mid-life display of replacement indicators**— Extended charge time resulting in early occurrence of ERI or EOL, or shortened ERI to EOL time. Please reference the ERI Charge Time Limit Extended During Mid-Life Product Update for more details. Improvement implemented.
49. **High-voltage capacitor**— In most cases, temporary long capform charge time; in some cases delayed therapy or loss of tachy therapy. Extended charge time could prompt EOL declaration. High-voltage capacitor issue.
50. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
51. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
52. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.
53. **Integrated circuit**— Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing, loss of shock therapy. Damage to integrated circuit. Improvement implemented.
54. **Alert messages**— During programmer interactions, alert messages appear which are able to be cleared. In one case, an alert message occurred with two memory errors after multiple device resets.
55. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process

variability. Improvement implemented.

56. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
57. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
58. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
59. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
60. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
61. **Logic errors**— Unable to complete diagnostic, cap reform or daily shock lead measurement processes; loss of pacing output, loss of shock therapy. Logic errors when device is performing capacitor reforms or shock impedance measurements.
62. **Reed switch**— While implanted, continuous device tone or beeping occurs. During interrogation, magnet presence dialog box appears. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON. Reed switch stuck in closed position. Improvement implemented.
63. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.
64. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
65. **Connector block**— Connector block can be moved out of alignment or displaced from header. Prolonged implant procedure, high impedance, no pacing, no sensing. Improvement implemented.
66. **Misaligned markers**— Stored episode markers do not match recorded EGM. Software error when ventricular episode begins during ATR episode. New software was released in 2006 which prevents misaligned markers. Improvement implemented.
67. **Seal plug**— Non-cardiac signals on electrograms may result in loss of pacing or inappropriate shocks. Seal plug allows air in lead port to escape.
68. **Difficulty securing lead**— Noise, high impedance, inappropriate shocks or loss of therapy due to crossthreaded setscrews, intermittent or lack of contact between lead and header. Improvement implemented.
69. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
70. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
71. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
72. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
73. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
74. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
75. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
76. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
77. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
78. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
79. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
80. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
81. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
82. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
83. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
84. **Telemetry**— Inability to interrogate, premature battery depletion.
85. **Unintended Battery Depletion Alert**— Beeping tones, Battery Depletion alert during followup despite normal battery depletion. Alert may be cleared without impact to battery status or therapy availability. Improvement implemented.
86. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
87. **Respiratory sensor**— Temporary increase or decrease in pacing rate as a result of respiratory sensor response to non-respiratory signals. No loss of pacing output.
88. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.
89. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
90. **High voltage circuit component**— Charge time alert message and/or end of life (EOL) indicator displayed, beeping tones. High voltage circuit component.

91. **Solder joint**— Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications. Cracked solder joint due to repetitive mechanical stress-induced component damage when implanted subpectorally with the serial number facing the ribs.
92. **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	7,000	1	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	13,000	2	1	0	4	0	0
INCEPTA CRT-D 4-Site N160/N162/P162	16,000	0	0	0	1	0	0
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	18,000	2	0	0	1	0	0
ENERGEN CRT-D 4-Site N140/N142/P142	20,000	2	0	0	3	0	0
ENERGEN CRT-D N141/N143/P143	17,000	3	0	0	4	0	0
PUNCTUA CRT-D 4-Site N050/N052/P052	2,000	0	0	0	0	0	0
PUNCTUA CRT-D N051/N053/P053	5,000	1	0	0	1	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	23	50	4	26	0	0
LIVIAN HE H227/H229/H247/H249	7,000	3	1	0	2	0	0

CRT-D/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL 4 HE H197/H199	7,000	7	7	0	0	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0
CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE V172/V173/V182/V183/W172/W173	2,000	0	0	0	0	0	0
INTUA V272/V273/V282/V283/W272/W273	2,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	16,000	0	0	1	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0
ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN ICD EL VR D160/D161/D174/D175	3,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	3,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	4,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	3,000	0	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	4,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	4,000	0	0	0	1	0	0

ICD/Model, continued...	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA ICD VR 4-Site E160/F160	17,000	0	1	0	2	0	0
INCEPTA ICD DR 4-Site E162/F162	19,000	0	0	0	0	0	0
INCEPTA ICD VR E161/F161	7,000	0	0	0	1	0	0
INCEPTA ICD DR E163/F163	11,000	0	0	0	0	0	0
ENERGEN ICD VR 4-Site E140/F140	21,000	1	0	0	4	0	0
ENERGEN ICD DR 4-Site E142/F142	20,000	1	0	0	1	0	0
ENERGEN ICD VR E141/F141	11,000	2	0	0	1	0	0
ENERGEN ICD DR E143/F143	14,000	2	1	0	2	0	0
PUNCTUA ICD VR 4-Site E050/F050	3,000	0	0	0	0	0	0
PUNCTUA ICD DR 4-Site E052/F052	2,000	1	0	0	0	0	0
PUNCTUA ICD VR E051/F051	5,000	0	0	0	1	0	0
PUNCTUA ICD DR E053/F053	4,000	1	0	0	0	0	0
TELIGEN VR E102/E103/F102/F103	65,000	7	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	90,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	4,000	0	0	0	0	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	8,000	0	0	0	0	0	0
ADVANTIO EL DR J064/K064/K067/K084	12,000	0	0	0	0	0	0
ADVANTIO SR J062/J065/K062/K065/K082	31,000	0	0	1	2	0	0
ADVANTIO DR J063/J066/K063/K066/K083	74,000	4	1	0	4	0	0
INGENIO EL DR J174/J177/K174/K177/K184	33,000	1	0	0	2	0	0
INGENIO SR J172/J175/K172/K175/K182	34,000	0	0	0	1	0	0
INGENIO DR J173/J176/K173/K176/K183	111,000	0	1	1	5	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	0	0
FORMIO DR J278/J279/K278/K279	3,000	0	0	0	0	0	0
VITALIO DR J273/J276/K273/K276	11,000	0	0	0	1	0	0
VITALIO EL DR J274/J277/K274	11,000	0	0	0	0	0	0
VITALIO SR J272/J275/K272/K275	6,000	0	0	0	0	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	55,000	1	11	0	2	0	0

ALTRUA 50 SR S501	24,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	44,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	11,000	1	1	0	0	0	0

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

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

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

U.S. Reason for Out of Service

As requested by the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Boston Scientific provides reasons for device explant or out of service, if known. The reasons consist of normal battery depletion, unconfirmed premature battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical condition, (such as infection), or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.

The counts for normal battery depletion, unconfirmed premature battery depletion, and device malfunction are reflected in the U.S. survival probability data. Reason for device explant or out of service may either be confirmed through laboratory analysis (as in the case of device malfunction) or it may be reported to Boston Scientific with no associated device return or laboratory analysis. Although a device may be indicated by the health care provider to have been taken out of service for more than one reason, the table below indicates only one reason per device in category counts.

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	8000	1	1	0	1	39	121
INCEPTA CRT-D 4-Site N160/N162/P162	9000	6	1	1	5	121	755
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	12000	11	2	0	3	153	1337
ENERGEN CRT-D 4-Site N140/N142/P142	14000	4	2	2	3	170	1312
ENERGEN CRT-D N141/N143/P143	13000	11	3	1	10	189	1612
COGNIS N118/N119/N120/P106/P107/P108	75000	946	60	10	898	1578	25755
LIVIAN HE H227/H229/H247/H249	6000	1581	4	2	6	178	2592

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
INTUA V272/V273/V282/V283/W272/W273	2000	2	0	0	1	8	56
INVIVE V172/V173/V182/V183/W172/W173	7000	6	0	2	1	46	819
CONTAK RENEWAL TR H120/H125	19000	2020	16	133	46	252	9112
S-ICD/Model		Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
SQ-RX S-ICD 1010		3	0	2	19	170	311
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 MINI DR D002/D003/D012/D013/D022/D023	2000	0	0	0	0	18	72
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	2000	1	0	1	0	17	65
INCEPTA ICD VR 4-Site E160/F160	11000	3	0	4	4	88	663
INCEPTA ICD DR 4-Site E162/F162	12000	5	2	10	4	98	807
INCEPTA ICD VR E161/F161	4000	4	0	2	1	41	326
INCEPTA ICD DR E163/F163	7000	3	2	1	5	60	507
ENERGEN ICD VR 4-Site E140/F140	15000	13	0	7	4	144	1114
ENERGEN ICD DR 4-Site E142/F142	14000	6	0	8	6	156	1206

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
ENERGEN ICD VR E141/F141	7000	4	0	2	3	54	668
ENERGEN ICD DR E143/F143	10000	4	1	4	1	87	970
PUNCTUA ICD VR E051/F051	1000	0	0	0	1	2	62
TELIGEN VR E102/E103/F102/F103	38000	67	38	324	647	604	10297
TELIGEN DR E110/E111/F110/F111	66000	146	61	451	976	1048	18694
CONFIENT DR E030/F030	7000	112	2	92	13	144	2735
VITALITY 2 EL VR T177	7000	1054	9	148	1259	110	2622
VITALITY 2 EL DR T167	8000	1808	13	142	767	131	3225
VITALITY 2 VR T175	21000	5755	35	379	1240	301	9217
VITALITY 2 DR T165	31000	11839	79	527	1140	455	13417
VITALITY DR HE T180	13000	2983	13	230	420	306	6480
VITALITY DS DR T125	22000	8358	67	362	1187	305	10261
VITALITY DS VR T135	19000	5620	39	320	1555	255	8843
VITALITY EL T127	4000	947	9	60	619	70	1558

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
ADVANTIO SR J062/J065/K062/K065/K082	11000	6	0	9	5	50	1327
ADVANTIO DR J063/J066/K063/K066/K083	47000	22	2	11	12	258	3356
ADVANTIO EL DR J064/K064/K067/K084	3000	1	0	2	1	5	86

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
INGENIO SR J172/J175/K172/K175/K182	13000	1	0	6	0	55	1312
INGENIO DR J173/J176/K173/K176/K183	68000	20	3	22	10	296	3867
VITALIO EL DR J274/J277/K274/K277/K284/K287	2000	0	0	0	0	6	31
VITALIO DR J273/J276/K273/K276	4000	0	0	0	0	8	100
ALTRUA 60 SR S601	32000	192	2	161	3	159	11944
ALTRUA 60 DR (Downsize) S603	90000	2872	40	344	35	543	24217
ALTRUA 60 DR S602	22000	238	2	122	5	176	6105
ALTRUA 60 DR EL S606	59000	185	11	187	7	397	11728
ALTRUA 40 SR S401	5000	27	0	14	2	21	1966
ALTRUA 40 DR (downsize) S403	14000	451	2	34	3	77	4038
ALTRUA 40 DR S402	2000	20	1	14	0	6	629
ALTRUA 40 DR EL S404	5000	17	1	21	0	40	1323
ALTRUA 20 SR S201/S204	4000	25	1	15	0	35	2076
ALTRUA 20 DR (downsize) S203	5000	75	3	18	0	36	1788
ALTRUA 20 DR S202/S205	2000	26	0	5	1	12	667
ALTRUA 20 DR EL S208	3000	11	0	12	1	10	953
INSIGNIA Ultra SR 1190 ⁴	24000	1910	9	192	38	141	15693

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction ¹	Complication related to another system component or clinical condition ²	Other ³
INSIGNIA Ultra DR (Downsize) 1290 ⁴	76000	17840	114	532	431	595	38022
INSIGNIA Ultra DR 1291 ⁴	32000	2578	20	285	149	300	14416
INSIGNIA Entra SR 1195/1198 ⁴	14000	707	10	82	9	72	10252
INSIGNIA Entra DR (Downsize) 1296 ⁴	24000	4616	25	128	97	152	15096
INSIGNIA Entra DR 1294/1295 ⁴	17000	1335	12	114	61	179	10318
INSIGNIA Plus SR 1194 ⁴	27000	3094	8	222	27	156	20274
INSIGNIA Plus DR (Downsize) 1298 ⁴	90000	26034	114	531	374	694	51409
INSIGNIA Plus DR 1297 ⁴	27000	4250	19	247	129	259	14521

¹ Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned.. U.S. confirmed malfunction counts are reflected in U.S. survival probability.

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


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

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

ACUITY X4 Spiral L

Models 4677/4678

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


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

[References](#) cited in table above

ACUITY X4 Spiral S

Models 4674/4675

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


ACUITY X4 Spiral S Models 4674/4675			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	0	0	0

[References](#) cited in table above

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

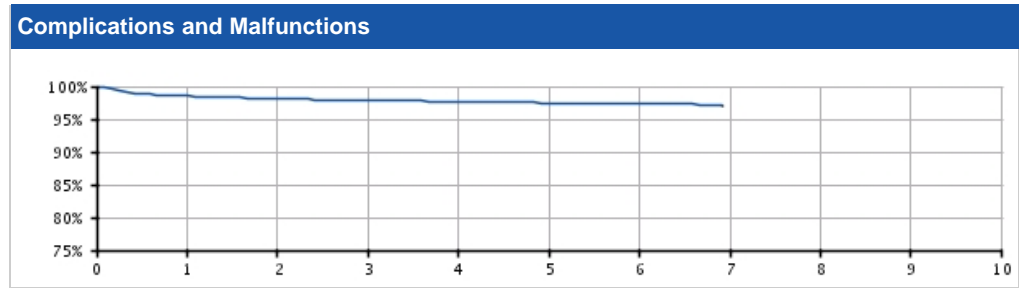
[References](#) cited in table above

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: 22,000	U.S. Chronic Lead Complications: 406
U.S. Approval Date: May 2008	U.S. Malfunctions: 7
U.S. Estimated Active Implants: 15,000	Without Compromised Therapy: 3
	With Compromised Therapy: 4




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.52 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.86 (-0.2/+0.2)	97.63 (-0.3/+0.2)	97.47 (-0.3/+0.3)	97.28 (-0.3/+0.3)	97.11 @ 83 mo. (-0.5/+0.4)	-	-	-
Registered Implants: 20000										
Effective Sample Size	16956	13043	9541	6612	3854	1746	269	-	-	-

ACUITY Spiral

Models 4591/4592/4593

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

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

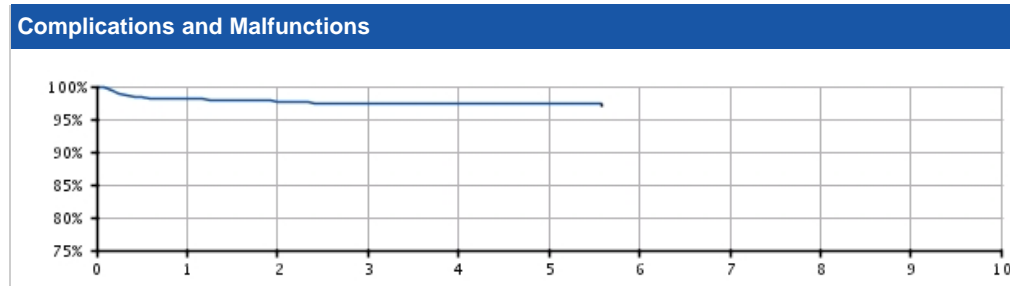
[References](#) cited in table above

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: 1354	Chronic Lead Complications: 30
Leads Active: 1052	Malfunctions:0
Cumulative Followup Months : 39,020	Without Compromised Therapy:0
	With Compromised Therapy:0



Longitude Registry Survival Probability

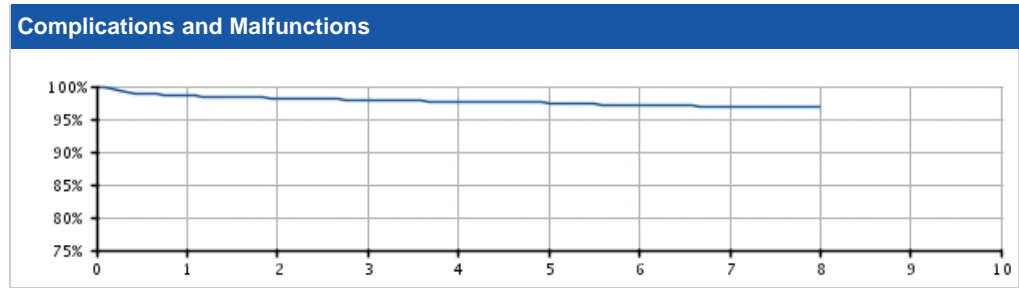
Year	1	2	3	4	5	6	7	8	9	10
Longitude	98.06 (-0.9/+0.6)	97.65 (-1.0/+0.7)	97.27 (-1.1/+0.8)	97.27 (-1.1/+0.8)	97.27 (-1.1/+0.8)	97.27 @ 67 mo. (-1.1/+0.8)	—	—	—	—
Registered Implants: 1354										
Effective Sample Size	1093	840	653	442	190	69	—	—	—	—

ACUITY Steerable

Models 4554/4555/4556

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

U.S. Summary	
U.S. Registered Implants: 28,000	U.S. Chronic Lead Complications: 543
U.S. Approval Date: May 2008	U.S. Malfunctions:31
U.S. Estimated Active Implants: 18,000	Without Compromised Therapy:10
	With Compromised Therapy:21




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.56 <small>(-0.2/+0.1)</small>	98.20 <small>(-0.2/+0.2)</small>	97.92 <small>(-0.2/+0.2)</small>	97.70 <small>(-0.2/+0.2)</small>	97.43 <small>(-0.2/+0.2)</small>	97.13 <small>(-0.3/+0.3)</small>	96.88 <small>(-0.3/+0.3)</small>	96.88 <small>(-0.3/+0.3)</small>	-	-
Registered Implants: 28000										
Effective Sample Size	22719	18248	14494	11112	7917	4969	2315	204	-	-

ACUITY Steerable

Models 4554/4555/4556

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

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

[References](#) cited in table above

EASYTRAK 3

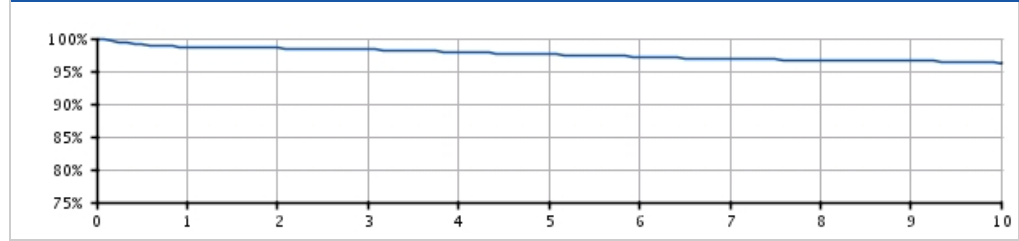
Models 4522/4524/4525/4527/4548/
4549/4550

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

U.S. Summary

U.S. Registered Implants: 21,000 U.S. Approval Date: August 2004 U.S. Estimated Active Implants: 11,000	U.S. Chronic Lead Complications: 420 U.S. Malfunctions: 30 Without Compromised Therapy: 7 With Compromised Therapy: 23
--	---

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.70 (-0.2/+0.1)	98.51 (-0.2/+0.2)	98.28 (-0.2/+0.2)	97.94 (-0.2/+0.2)	97.52 (-0.3/+0.2)	97.22 (-0.3/+0.3)	96.84 (-0.3/+0.3)	96.66 (-0.4/+0.3)	96.53 (-0.4/+0.4)	96.25 (-0.5/+0.5)
Registered Implants: 21000										
Effective Sample Size	17546	14592	11954	9775	7901	6210	4672	3434	2012	843

EASYTRAK 3

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

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

EASYTRAK 3 Models 4522/4524/4525/4527/4548/ 4549/4550			
Worldwide Distribution: 41,000 Worldwide Confirmed Malfunctions: 47			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	8	34	42
²⁸ Non-patterned, Conductor	5	5	
³⁵ Extracardiac fracture	3	29	
Crimp/Weld/Bond	-	-	0
Insulation	3	1	4
²⁹ Non-patterned, Insulation	3	1	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	12	35	47

[References](#) cited in table above

EASYTRAK 2

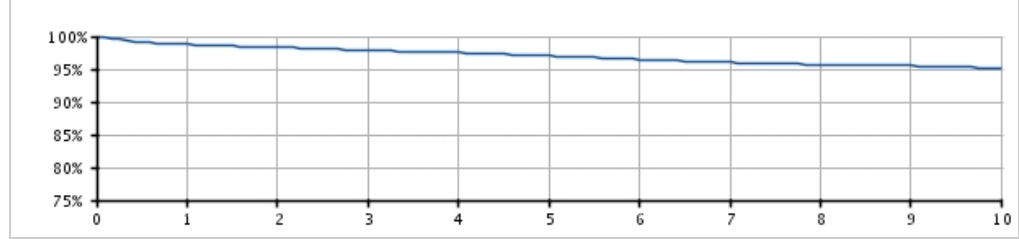
Models 4515/4517/4518/4520/4542/
4543/4544

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

U.S. Summary

U.S. Registered Implants: 95,000	U.S. Chronic Lead Complications: 2,079
U.S. Approval Date: August 2004	U.S. Malfunctions: 316
U.S. Estimated Active Implants: 47,000	Without Compromised Therapy: 59
	With Compromised Therapy: 257

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.78 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.89 (-0.1/+0.1)	97.53 (-0.1/+0.1)	97.04 (-0.1/+0.1)	96.46 (-0.2/+0.2)	96.01 (-0.2/+0.2)	95.70 (-0.2/+0.2)	95.51 (-0.2/+0.2)	95.17 (-0.3/+0.3)
Registered Implants: 95000										
Effective Sample Size	77548	64708	53508	43790	34653	26354	19218	13348	7836	3546

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: 173,000 Worldwide Confirmed Malfunctions: 446			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	66	357	423
²⁶ Conductor fracture	61	310	
²⁸ Non-patterned, Conductor	5	47	
Crimp/Weld/Bond	-	-	0
Insulation	9	2	11
²⁹ Non-patterned, Insulation	9	2	
Other	7	5	12
²⁷ Non-patterned, Other	7	5	
WW Confirmed Malfunctions	82	364	446

[References](#) cited in table above

EASYTRAK

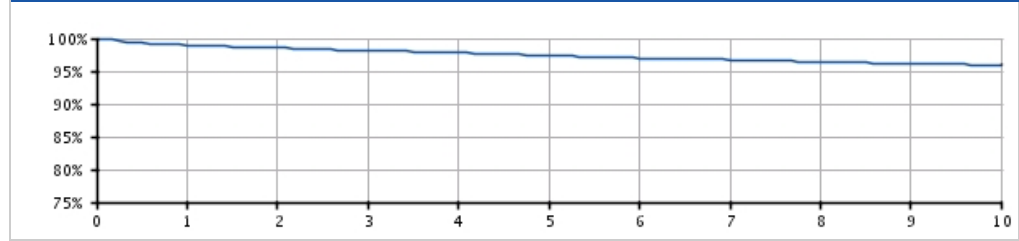
Models 4510/4511/4512/4513/4535/
4536/4537/4538

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

U.S. Summary

U.S. Registered Implants: 38,000	U.S. Chronic Lead Complications: 890
U.S. Approval Date: May 2002	U.S. Malfunctions: 24
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy: 10
	With Compromised Therapy: 14

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.75 (-0.2/+0.2)	96.35 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.93 (-0.3/+0.3)
Registered Implants: 38000										
Effective Sample Size	30544	26258	22527	19360	16531	14143	12096	10239	8662	7330

EASYTRAK

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

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

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



Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 26


	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	12	12
²⁸ Non-patterned, Conductor	-	12	
Crimp/Weld/Bond	-	-	0
Insulation	3	3	6
²⁹ Non-patterned, Insulation	3	3	
Other	7	1	8
²⁷ Non-patterned, Other	7	1	
WW Confirmed Malfunctions	10	16	26

[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: 6,000			
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

[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: 16,000			
Worldwide Confirmed Malfunctions: 4			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	4	4
³⁸ Conductor cable fracture	-	4	
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
²⁷ Non-patterned, Other	-	-	
WW Confirmed Malfunctions	0	4	4

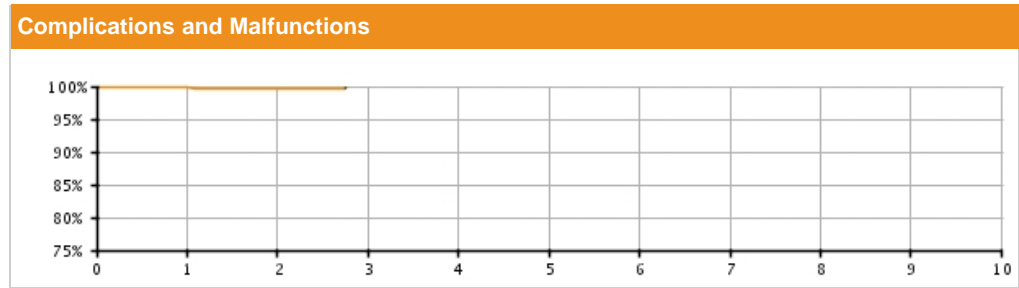
[References](#) cited in table above

Q-TRAK SQ Electrode

Model 3010

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

U.S. Summary	
U.S. Registered Implants: 8,000	U.S. Chronic Lead Complications: 4
U.S. Approval Date: September 2012	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 7,000	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	99.83 (-0.2/+0.1)	99.74 (-0.2/+0.1)	99.74 @ 33 mo. (-0.2/+0.1)	--	--	--	--	--	--	--	
Registered Implants: 8000											
Effective Sample Size	2672	432	202	--	--	--	--	--	--	--	

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

Q-TRAK SQ Electrode

Model 3010

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

Q-TRAK SQ Electrode Model 3010			
Worldwide Distribution: 11,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	1	1
³⁷ Weld fracture	-	1	
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	-	-	0
WW Confirmed Malfunctions	0	2	2

[References](#) cited in table above

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

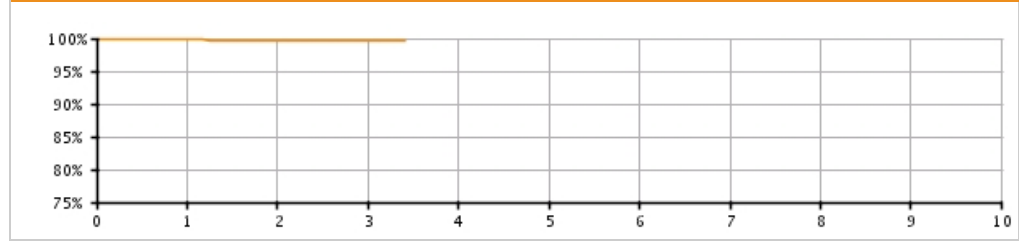
Models 0295/0296

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

U.S. Summary

U.S. Registered Implants: 43,000	U.S. Chronic Lead Complications: 99
U.S. Approval Date: November 2010	U.S. Malfunctions: 6
U.S. Estimated Active Implants: 39,000	Without Compromised Therapy: 0
	With Compromised Therapy: 6

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.65 (-0.1/+0.1)	99.65 @ 41 mo. (-0.1/+0.1)	—	—	—	—	—	—
Registered Implants: 42000										
Effective Sample Size	29343	16583	4532	556	—	—	—	—	—	—

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

Models 0295/0296

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

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Active Fixation
Models 0295/0296**



Worldwide Distribution: 73,000

Worldwide Confirmed Malfunctions: 29

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	3	3
²⁸ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	-	0
Insulation	7	17	24
²⁹ Non-patterned, Insulation	7	17	
Other	2	-	2
²⁷ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	9	20	29

[References](#) cited in table above

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

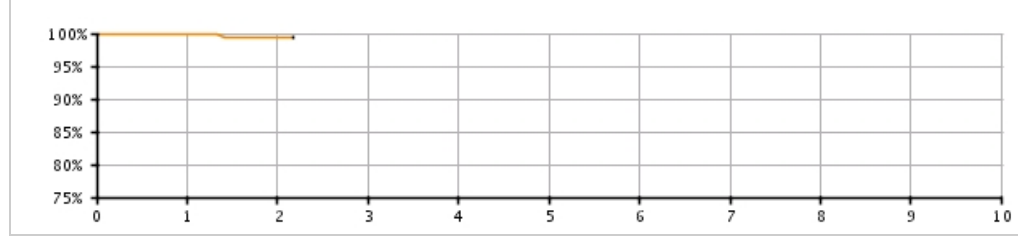
Models 0295/0296

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

Longitude Registry Summary Data

Leads Enrolled: 753	Chronic Lead Complications: 1
Leads Active: 687	Malfunctions: 0
Cumulative Followup Months : 10,981	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	99.86 (-0.8/+0.1)	99.49 (-1.8/+0.4)	99.49 @ 26 mo. (-1.8/+0.4)	--	--	--	--	--	--	--
Registered Implants: 753										
Effective Sample Size	499	71	54	--	--	--	--	--	--	--

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

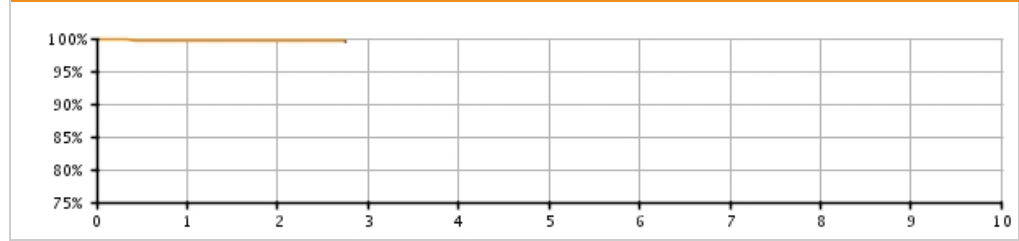
Models 0285/0286

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

U.S. Summary

U.S. Registered Implants: 2,000	U.S. Chronic Lead Complications: 5
U.S. Approval Date: November 2010	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 1,000	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.72 (-0.5/+0.2)	99.55 (-0.7/+0.3)	99.55 @ 33 mo. (-0.7/+0.3)	--	--	--	--	--	--	--
Registered Implants: 2000										
Effective Sample Size	1009	496	213	--	--	--	--	--	--	--

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

Models 0285/0286

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

**ENDOTAK RELIANCE G 4-Site
Dual Coil, Passive Fixation
Models 0285/0286**



Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 0

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

[References](#) cited in table above

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

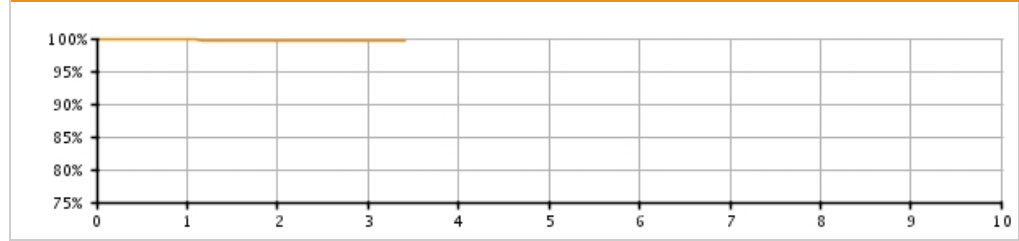
Models 0292/0293

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

U.S. Summary

U.S. Registered Implants: 41,000	U.S. Chronic Lead Complications: 87
U.S. Approval Date: November 2010	U.S. Malfunctions:4
U.S. Estimated Active Implants: 38,000	Without Compromised Therapy:1
	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	99.77 (-0.1/+0.0)	99.68 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.62 @ 41 mo. (-0.1/+0.1)	--	--	--	--	--	--
Registered Implants: 41000										
Effective Sample Size	22506	9750	2039	271	--	--	--	--	--	--

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

Models 0292/0293

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

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



Worldwide Distribution: 71,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁵ Conductor fracture	-	1	
²⁸ Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	-	-	0
Insulation	2	11	13
²⁹ Non-patterned, Insulation	2	11	
Other	-	1	1
²⁷ Non-patterned, Other	-	1	
WW Confirmed Malfunctions	2	14	16

[References](#) cited in table above

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

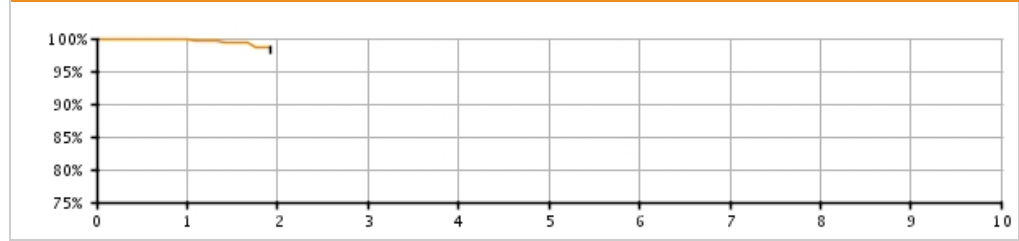
Models 0292/0293

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

Longitude Registry Summary Data

Leads Enrolled: 1102	Chronic Lead Complications: 4
Leads Active: 989	Malfunctions: 0
Cumulative Followup Months : 15,067	Without Compromised Therapy: 0
	With Compromised Therapy: 0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	99.89 (-0.6/+0.1)	98.58 @ 23 mo. (-3.4/+1.0)	--	--	--	--	--	--	--	--
Registered Implants: 1102										
Effective Sample Size	660	66	--	--	--	--	--	--	--	--

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

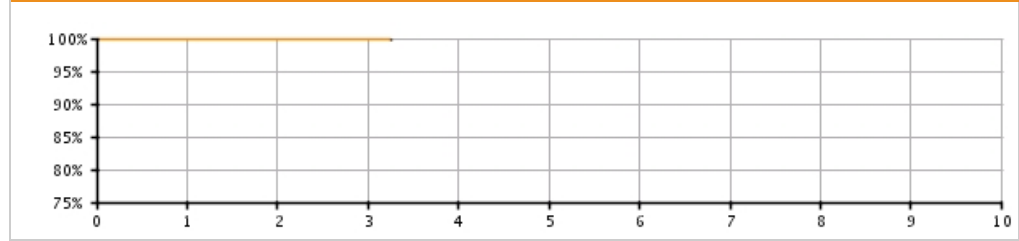
Models 0282/0283

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

U.S. Summary

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

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.85 (-0.9/+0.1)	99.85 @ 19 mo. (-0.9/+0.1)	--	--	--	--	--	--	--	--
Registered Implants: 1000										
Effective Sample Size	339	214	--	--	--	--	--	--	--	--

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

Models 0282/0283

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

ENDOTAK RELIANCE SG 4-Site Single Coil, Passive Fixation Models 0282/0283 			
Worldwide Distribution: 3,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	1	1	2
³⁰ Unconfirmed Extrinsic	-	1	
³¹ Inconclusive Extrinsic	1	-	
Insulation	-	1	1
²⁹ Non-patterned, Insulation	-	1	
Other	-	-	-1
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

[References](#) cited in table above

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

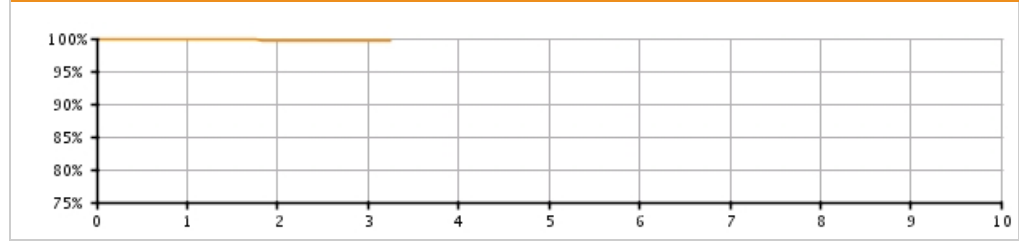
Models 0275/0276

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

U.S. Summary

U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 8
U.S. Approval Date: November 2010	U.S. Malfunctions:0
U.S. Estimated Active Implants: 3,000	Without Compromised Therapy:0
	With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.86 (-0.2/+0.1)	99.70 (-0.3/+0.2)	99.70 (-0.3/+0.2)	99.70 @ 39 mo. (-0.3/+0.2)	—	—	—	—	—	—
Registered Implants: 4000										
Effective Sample Size	2667	1602	439	216	—	—	—	—	—	—

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

Models 0275/0276

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

**ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation
Models 0275/0276**



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 0

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


[References](#) cited in table above

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

Models 0265/0266

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

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



Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

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

[References](#) cited in table above

ENDOTAK RELIANCE G Dual Coil, Active Fixation

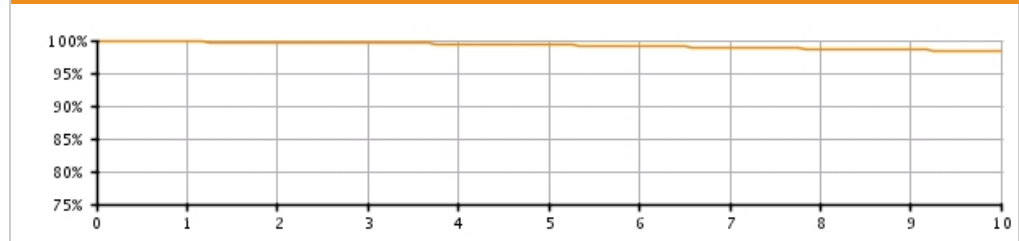
Models 0164/0165/0166/0167/0184/
0185/0186/0187

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

U.S. Summary

U.S. Registered Implants: 188,000	U.S. Chronic Lead Complications: 1,138
U.S. Approval Date: May 2004	U.S. Malfunctions: 187
U.S. Estimated Active Implants: 110,000	Without Compromised Therapy: 79
	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	99.78 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.58 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.31 (-0.0/+0.0)	99.11 (-0.1/+0.1)	98.91 (-0.1/+0.1)	98.73 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.33 (-0.1/+0.1)
Registered Implants: 187000										
Effective Sample Size	164982	145849	128120	105917	82370	61182	41534	26273	15759	7468

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

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

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

ENDOTAK RELIANCE G
Dual Coil, Active Fixation
Models 0164/0165/0166/0167/0184/
0185/0186/0187



Worldwide Distribution: 255,000
Worldwide Confirmed Malfunctions: 320

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	2	93	95
²⁵ Conductor fracture	-	58	
²⁸ Non-patterned, Conductor	2	35	
Crimp/Weld/Bond	2	-	2
³² Non-patterned, Crimp, Weld, Bond	2	-	
Insulation	115	76	191
²⁹ Non-patterned, Insulation	115	76	
Other	19	13	32
²⁷ Non-patterned, Other	19	13	
WW Confirmed Malfunctions	138	182	320

[References](#) cited in table above

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

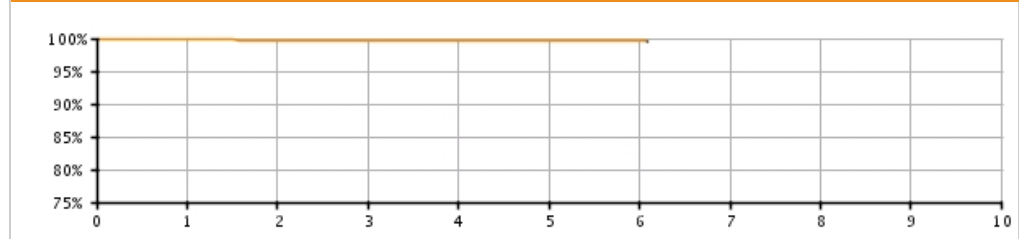
Models 0164/0165/0166/0167/0184/
0185/0186/0187

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

Longitude Registry Summary Data

Leads Enrolled: 629	Chronic Lead Complications: 1
Leads Active: 430	Malfunctions:1
Cumulative Followup Months : 20,906	Without Compromised Therapy:0
	With Compromised Therapy:1

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	100.00 (-0.0/+0.0)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 @ 73 mo. (-1.2/+0.3)	—	—	—	—
Registered Implants: 629										
Effective Sample Size	545	476	408	321	177	52	51	—	—	—

ENDOTAK RELIANCE G Dual Coil, Passive Fixation

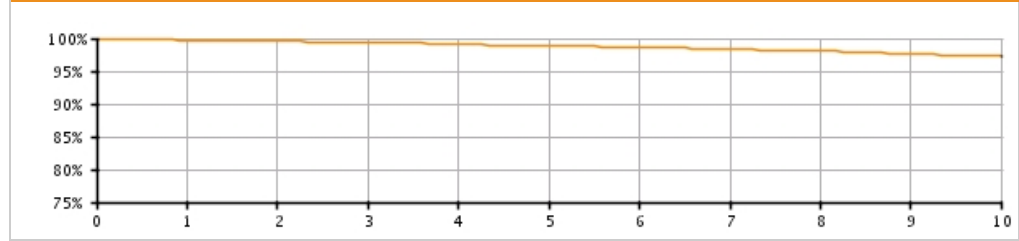
Models 0174/0175/0176/0177

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

U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 138
U.S. Approval Date: May 2004	U.S. Malfunctions: 13
U.S. Estimated Active Implants: 8,000	Without Compromised Therapy: 4
	With Compromised Therapy: 9

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.73 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.40 (-0.2/+0.1)	99.15 (-0.2/+0.2)	98.89 (-0.2/+0.2)	98.65 (-0.3/+0.2)	98.29 (-0.3/+0.3)	98.01 (-0.4/+0.3)	97.58 (-0.5/+0.4)	97.33 (-0.6/+0.5)
Registered Implants: 14000										
Effective Sample Size	11946	10534	9095	7575	6001	4673	3424	2335	1528	817

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

Models 0174/0175/0176/0177

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

ENDOTAK RELIANCE G Dual Coil, Passive Fixation Models 0174/0175/0176/0177 			
Worldwide Distribution: 39,000			
Worldwide Confirmed Malfunctions: 52			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	16	16
²⁵ Conductor fracture	-	13	
²⁸ Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	-	1	1
³⁶ Conductor connection	-	1	
Insulation	16	14	30
²⁹ Non-patterned, Insulation	16	14	
Other	5	-	5
²⁷ Non-patterned, Other	5	-	
WW Confirmed Malfunctions	21	31	52

References cited in table above

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

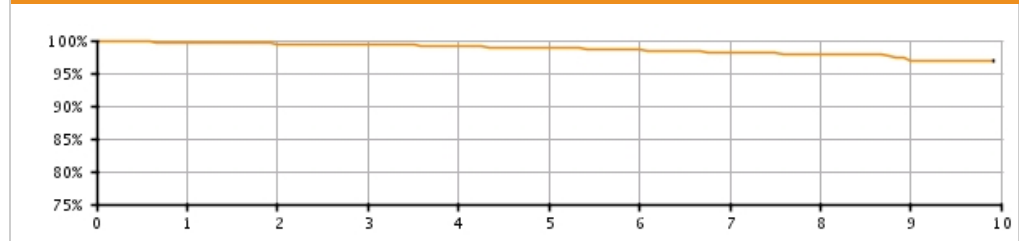
Models 0160/0161/0162/0180/0181/
 0182

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

U.S. Summary

U.S. Registered Implants: 27,000	U.S. Chronic Lead Complications: 173
U.S. Approval Date: May 2004	U.S. Malfunctions: 49
U.S. Estimated Active Implants: 21,000	Without Compromised Therapy: 18
	With Compromised Therapy: 31

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.68 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.12 (-0.1/+0.1)	98.87 (-0.2/+0.2)	98.53 (-0.3/+0.2)	98.20 (-0.4/+0.3)	97.89 (-0.5/+0.4)	96.97 (-1.1/+0.8)	96.97 @ 119 mo. (-1.1/+0.8)
Registered Implants: 27000										
Effective Sample Size	22625	18543	14982	10284	6145	3671	1887	857	458	203

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

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

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

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



Worldwide Distribution: 59,000
Worldwide Confirmed Malfunctions: 132

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	50	51
²⁵ Conductor fracture	1	42	
²⁸ Non-patterned, Conductor	-	8	
Crimp/Weld/Bond	-	-	0
Insulation	43	26	69
²⁹ Non-patterned, Insulation	43	26	
Other	7	5	12
²⁷ Non-patterned, Other	7	5	
WW Confirmed Malfunctions	51	81	132

[References](#) cited in table above

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

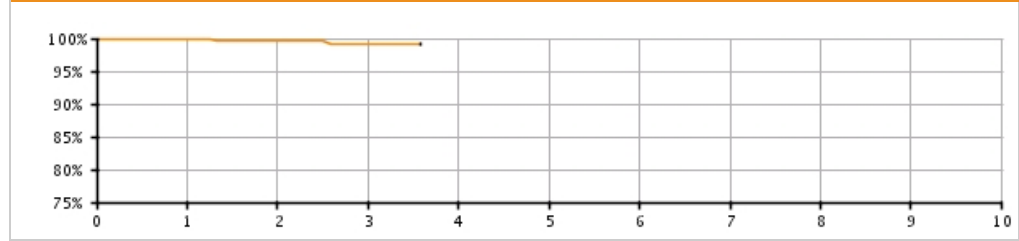
Models 0170/0171/0172/0173

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

U.S. Summary

U.S. Registered Implants: 1,000	U.S. Chronic Lead Complications: 4
U.S. Approval Date: May 2004	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	99.88 (-0.7/+0.1)	99.52 (-1.0/+0.3)	99.23 (-1.4/+0.5)	99.23 @ 43 mo. (-1.4/+0.5)	-	-	-	-	-	-
Registered Implants: 1000										
Effective Sample Size	648	465	273	205	-	-	-	-	-	-

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

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

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



Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 6

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

[References](#) cited in table above

ENDOTAK RELIANCE Dual Coil, Active Fixation

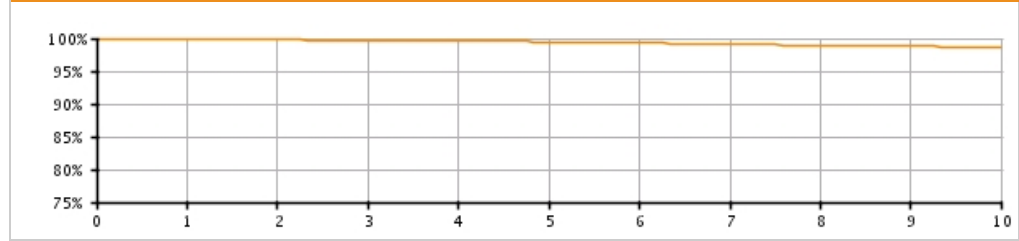
Models 0157/0158/0159

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

U.S. Summary

<p>U.S. Registered Implants: 97,000 U.S. Approval Date: July 2002 U.S. Estimated Active Implants: 39,000</p>	<p>U.S. Chronic Lead Complications: 608 U.S. Malfunctions: 76 Without Compromised Therapy: 30 With Compromised Therapy: 46</p>
--	---

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.84 <small>(-0.0/+0.0)</small>	99.78 <small>(-0.0/+0.0)</small>	99.68 <small>(-0.0/+0.0)</small>	99.57 <small>(-0.0/+0.0)</small>	99.47 <small>(-0.1/+0.1)</small>	99.32 <small>(-0.1/+0.1)</small>	99.11 <small>(-0.1/+0.1)</small>	98.96 <small>(-0.1/+0.1)</small>	98.79 <small>(-0.1/+0.1)</small>	98.66 <small>(-0.1/+0.1)</small>
Registered Implants: 97000										
Effective Sample Size	85083	75787	67259	58576	50189	42236	34906	28528	23125	17943

**ENDOTAK RELIANCE
Dual Coil, Active Fixation**

Models 0157/0158/0159

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

ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159



Worldwide Distribution: 114,000
Worldwide Confirmed Malfunctions: 94

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	20	20
²⁵ Conductor fracture	-	13	
²⁸ Non-patterned, Conductor	-	7	
Crimp/Weld/Bond	3	1	4
⁵ Seal rings	2	1	
³² Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	30	27	57
²⁹ Non-patterned, Insulation	30	27	
Other	8	5	13
²⁷ Non-patterned, Other	8	5	
WW Confirmed Malfunctions	41	53	94

[References](#) cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

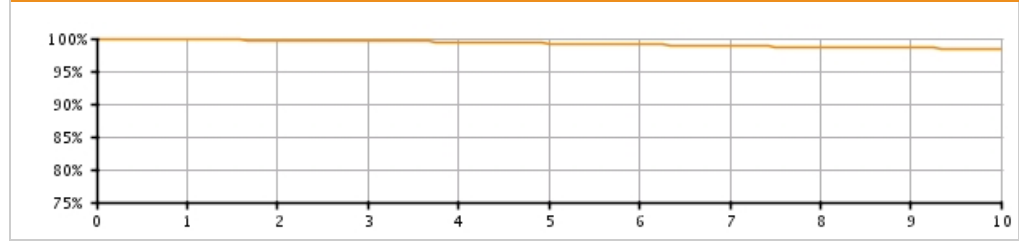
Models 0147/0148/0149

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

U.S. Summary

U.S. Registered Implants: 33,000	U.S. Chronic Lead Complications: 320
U.S. Approval Date: October 2000	U.S. Malfunctions: 20
U.S. Estimated Active Implants: 11,000	Without Compromised Therapy: 5
	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	99.79 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.44 (-0.1/+0.1)	99.25 (-0.1/+0.1)	99.06 (-0.1/+0.1)	98.85 (-0.2/+0.1)	98.63 (-0.2/+0.2)	98.52 (-0.2/+0.2)	98.35 (-0.2/+0.2)
Registered Implants: 33000										
Effective Sample Size	28520	25433	22646	20052	17667	15495	13527	11725	10114	8617

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149

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

ENDOTAK RELIANCE Dual Coil, Passive Fixation Models 0147/0148/0149 			
Worldwide Distribution: 67,000			
Worldwide Confirmed Malfunctions: 66			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	12	12
²⁵ Conductor fracture	-	3	
²⁸ Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	-	2	2
³⁶ Conductor connection	-	2	
Insulation	22	25	47
²⁹ Non-patterned, Insulation	22	25	
Other	1	4	5
⁶ Manufacturing material	-	1	
²⁷ Non-patterned, Other	1	3	
WW Confirmed Malfunctions	23	43	66

[References](#) cited in table above

ENDOTAK RELIANCE S

Single Coil, Active Fixation

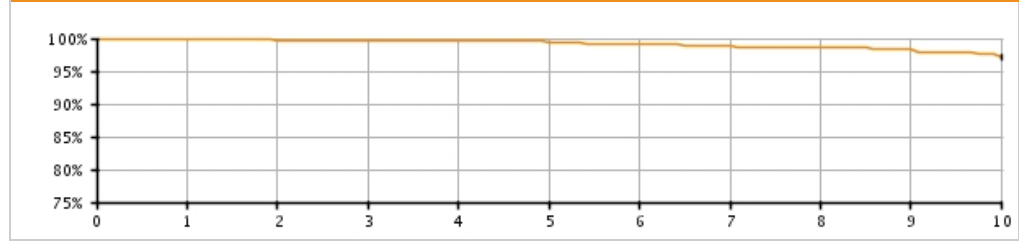
Models 0137/0138

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

U.S. Summary

<p>U.S. Registered Implants: 3,000 U.S. Approval Date: July 2002 U.S. Estimated Active Implants: 1,000</p>	<p>U.S. Chronic Lead Complications: 320 U.S. Malfunctions: 3 Without Compromised Therapy: 2 With Compromised Therapy: 1</p>
--	--

Complications and Malfunctions




U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.83 <small>(-0.3/+0.1)</small>	99.72 <small>(-0.3/+0.2)</small>	99.66 <small>(-0.4/+0.2)</small>	99.58 <small>(-0.4/+0.2)</small>	99.47 <small>(-0.5/+0.3)</small>	99.23 <small>(-0.7/+0.4)</small>	98.76 <small>(-1.0/+0.6)</small>	98.57 <small>(-1.1/+0.6)</small>	98.29 <small>(-1.3/+0.7)</small>	97.24 <small>(-2.0/+1.2)</small>
Registered Implants: 3000										
Effective Sample Size	2176	1838	1499	1183	919	707	526	401	327	256

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

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

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

[References](#) cited in table above

ENDOTAK RELIANCE S

Single Coil, Passive Fixation

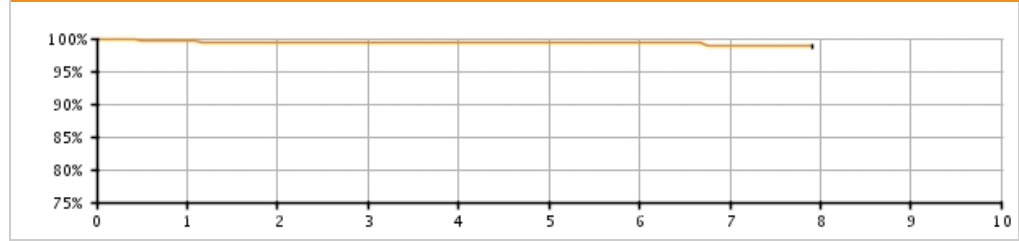
Models 0127/0128

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

U.S. Summary

<p>U.S. Registered Implants: 1,000 U.S. Approval Date: October 2000 U.S. Estimated Active Implants: 200</p>	<p>U.S. Chronic Lead Complications: 9 U.S. Malfunctions: 1 Without Compromised Therapy: 0 With Compromised Therapy: 1</p>
---	--

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 <small>(-1.0/+0.2)</small>	99.49 <small>(-1.1/+0.3)</small>	99.49 <small>(-1.1/+0.3)</small>	99.26 <small>(-1.2/+0.5)</small>	99.26 <small>(-1.2/+0.5)</small>	99.26 <small>(-1.2/+0.5)</small>	98.86 <small>(-1.8/+0.7)</small>	98.86 @ 95 mo. <small>(-1.8/+0.7)</small>	--	--
Registered Implants: 1000										
Effective Sample Size	571	493	431	379	331	276	235	201	--	--

ENDOTAK RELIANCE S
Single Coil, Passive Fixation

Models 0127/0128

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

ENDOTAK RELIANCE S
Single Coil, Passive Fixation
Models 0127/0128



Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	2	2
²⁸ Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	-	-	0
Insulation	3	4	7
²⁹ Non-patterned, Insulation	3	4	
Other	1	-	1
²⁷ Non-patterned, Other	1	-	
WW Confirmed Malfunctions	4	6	10

[References](#) cited in table above

ENDOTAK DSP
Passive Fixation

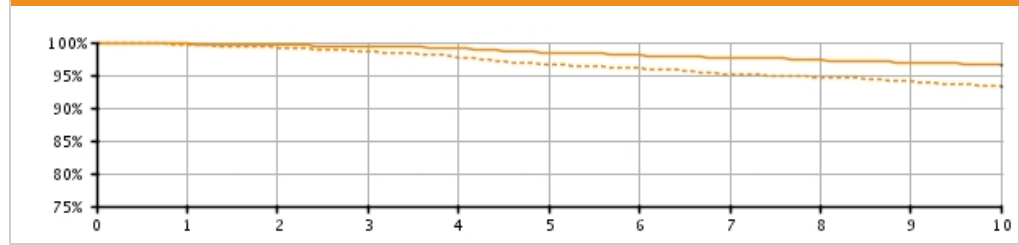
Models 0094/0095/0125

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

U.S. Summary

U.S. Registered Implants: 36,000	U.S. Chronic Lead Complications: 1,349
U.S. Approval Date: November 1995	U.S. Malfunctions: 174
U.S. Estimated Active Implants: 6,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.10 (-0.2/+0.2)	98.47 (-0.3/+0.2)	98.05 (-0.3/+0.3)	97.70 (-0.3/+0.3)	97.33 (-0.4/+0.3)	96.95 (-0.4/+0.4)	96.60 (-0.4/+0.4)
Registered Implants: 16000										
Effective Sample Size	13505	12010	10701	9499	8337	7385	6519	5765	5075	4439
19-Jul-99	99.66 (-0.1/+0.1)	99.22 (-0.1/+0.1)	98.60 (-0.2/+0.2)	97.74 (-0.2/+0.2)	96.62 (-0.3/+0.3)	96.01 (-0.3/+0.3)	95.19 (-0.4/+0.4)	94.70 (-0.4/+0.4)	94.05 (-0.5/+0.4)	93.36 (-0.5/+0.5)
"Long" IS-1 Terminal Pin*										
Registered Implants: 21000										
Effective Sample Size	18130	16101	14289	12617	11014	9642	8419	7361	6435	5637

*Devices subject to an advisory.

**ENDOTAK ENDURANCE
Passive Fixation**

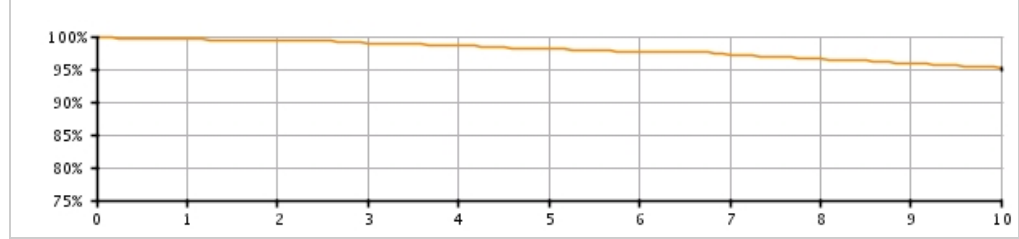
Models 0134/0135/0136

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

U.S. Summary

U.S. Registered Implants: 3,000	U.S. Chronic Lead Complications: 108
U.S. Approval Date: August 1998	U.S. Malfunctions: 3
U.S. Estimated Active Implants: 1,000	

Complications and Malfunctions



U.S. Survival Probability

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

ENDOTAK ENDURANCE EZ Active Fixation

Models 0154/0155/0156

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

U.S. Summary

U.S. Registered Implants: 29,000	U.S. Chronic Lead Complications: 554
U.S. Approval Date: June 1999	U.S. Malfunctions: 22
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	99.81 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.73 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.96 (-0.3/+0.3)
Registered Implants: 29000										
Effective Sample Size	24454	21795	19402	17267	15334	13604	12057	10719	9499	8411

ENDOTAK ENDURANCE Rx Passive Fixation Steroid Eluting

Models 0144/0145/0146

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

U.S. Summary

U.S. Registered Implants: 18,000 U.S. Approval Date: January 1999 U.S. Estimated Active Implants: 4,000	U.S. Chronic Lead Complications: 671 U.S. Malfunctions: 24
---	---

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 <small>(-0.1/+0.1)</small>	99.61 <small>(-0.1/+0.1)</small>	99.26 <small>(-0.2/+0.1)</small>	98.65 <small>(-0.2/+0.2)</small>	97.92 <small>(-0.3/+0.2)</small>	97.39 <small>(-0.3/+0.3)</small>	96.85 <small>(-0.3/+0.3)</small>	96.26 <small>(-0.4/+0.4)</small>	95.65 <small>(-0.4/+0.4)</small>	94.69 <small>(-0.5/+0.5)</small>
Registered Implants: 18000										
Effective Sample Size	15630	13939	12419	10990	9682	8567	7601	6726	5922	5205

**ENDOTAK SQ
Array and SQ Array XP**

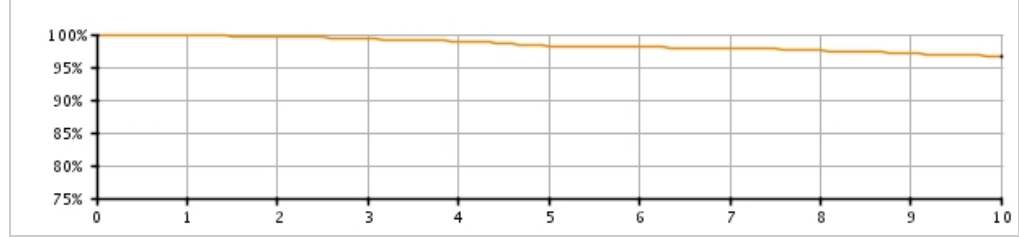
Models 0048/0049/0085

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

U.S. Summary

U.S. Registered Implants: 4,000	U.S. Chronic Lead Complications: 69
U.S. Approval Date: April 1995	U.S. Malfunctions: 0
U.S. Estimated Active Implants: 1,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.2/+0.1)	99.51 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.86 (-0.5/+0.3)	98.18 (-0.6/+0.5)	98.12 (-0.7/+0.5)	97.89 (-0.7/+0.5)	97.51 (-0.8/+0.6)	97.04 (-1.0/+0.7)	96.62 (-1.1/+0.8)
Registered Implants: 4000										
Effective Sample Size	3125	2745	2415	2085	1775	1468	1191	946	763	597

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: 47,000			
Worldwide Confirmed Malfunctions: 2			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	1	2
²⁸ Non-patterned, Conductor	1	-	
³⁹ Inner conductor break	-	1	
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	1	1	2

[More details](#) about malfunctions

[References](#) cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

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

INGEVITY Passive Fixation Models 7631/7632/7731/7732			
Worldwide Distribution: 6,000			
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

[References](#) cited in table above

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

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

INGEVITY Atrial J Passive Fixation Models 7635/7636/7735/7736			
Worldwide Distribution: 4,000			
Worldwide Confirmed Malfunctions: 0			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

[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: 172,000			
Worldwide Confirmed Malfunctions: 102			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	5	32	37
⁷ Lead conductor	2	18	
³³ Conductor damage	3	14	
Crimp/Weld/Bond	-	-	0
Insulation	49	6	55
² Inner insulation abrasion	3	-	
²⁹ Non-patterned, Insulation	4	-	
³⁴ Insulation damage	42	6	
Other	10	-	10
²⁷ Non-patterned, Other	10	-	
WW Confirmed Malfunctions	64	38	102

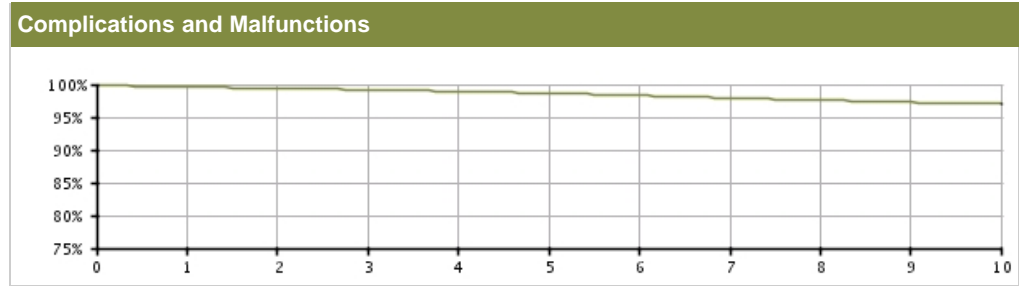
[References](#) cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

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

U.S. Summary	
U.S. Registered Implants: 231,000	U.S. Chronic Lead Complications: 3,101
U.S. Approval Date: February 2002	U.S. Malfunctions: 303
U.S. Estimated Active Implants: 104,000	Without Compromised Therapy: 121
	With Compromised Therapy: 182



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 <small>(-0.0/+0.0)</small>	99.40 <small>(-0.0/+0.0)</small>	99.19 <small>(-0.0/+0.0)</small>	98.93 <small>(-0.0/+0.0)</small>	98.64 <small>(-0.1/+0.1)</small>	98.31 <small>(-0.1/+0.1)</small>	97.95 <small>(-0.1/+0.1)</small>	97.60 <small>(-0.1/+0.1)</small>	97.27 <small>(-0.1/+0.1)</small>	97.01 <small>(-0.1/+0.1)</small>
Registered Implants: 231000										
Effective Sample Size	194522	168556	145336	124403	105019	87236	71605	57946	40986	27646

FLEXTEND Active Fixation

Models 4086/4087/4088

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

FLEXTEND Active Fixation Models 4086/4087/4088			
Worldwide Distribution: 282,000			
Worldwide Confirmed Malfunctions: 325			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	13	171	184
⁷ Lead conductor	7	80	
²⁸ Non-patterned, Conductor	-	7	
³³ Conductor damage	6	84	
Crimp/Weld/Bond	-	-	0
Insulation	103	23	126
² Inner insulation abrasion	19	4	
²⁹ Non-patterned, Insulation	8	-	
³⁴ Insulation damage	76	19	
Other	14	1	15
²⁷ Non-patterned, Other	14	1	
WW Confirmed Malfunctions	130	195	325

[References](#) cited in table above

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

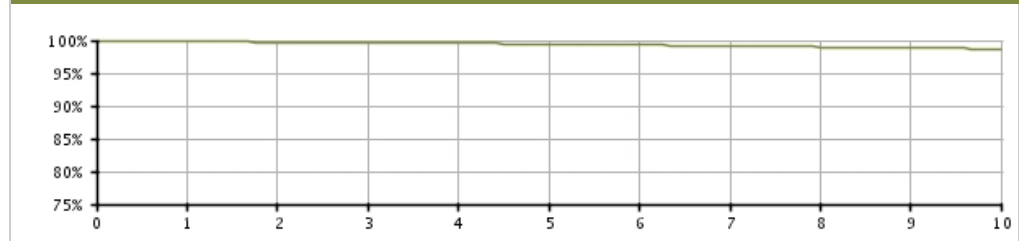
Models 4463/4464/4465/4469/4470/
4471

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

U.S. Summary

U.S. Registered Implants: 427,000	U.S. Chronic Lead Complications: 2,219
U.S. Approval Date: January 2000	U.S. Malfunctions:131
U.S. Estimated Active Implants: 250,000	Without Compromised Therapy:26
	With Compromised Therapy:105

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.0/+0.0)	99.73 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.30 (-0.0/+0.0)	99.13 (-0.0/+0.0)	99.00 (-0.1/+0.0)	98.84 (-0.1/+0.1)	98.69 (-0.1/+0.1)
Registered Implants: 427000										
Effective Sample Size	358105	299960	248810	203642	163108	126785	96161	72416	52146	35754


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

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

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

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

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



Worldwide Distribution: 647,000
Worldwide Confirmed Malfunctions: 157

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	11	117	128
⁷ Lead conductor	6	54	
²⁸ Non-patterned, Conductor	-	5	
³³ Conductor damage	5	58	
Crimp/Weld/Bond	1	2	3
²⁴ Terminal weld	-	1	
³² Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	12	6	18
³⁴ Insulation damage	12	6	
Other	6	2	8
²⁷ Non-patterned, Other	6	2	
WW Confirmed Malfunctions	30	127	157

[References](#) cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

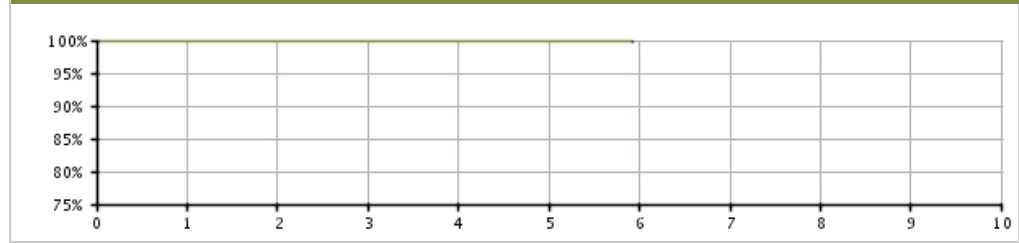
Models 4463/4464/4465/4469/4470/
 4471

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

Longitude Registry Summary Data

Leads Enrolled: 911	Chronic Lead Complications: 1
Leads Active: 733	Malfunctions:0
Cumulative Followup Months : 20,218	Without Compromised Therapy:0
	With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 @ 71 mo. (-0.7/+0.1)	—	—	—	—
Registered Implants: 911										
Effective Sample Size	685	362	291	216	123	51	—	—	—	—

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

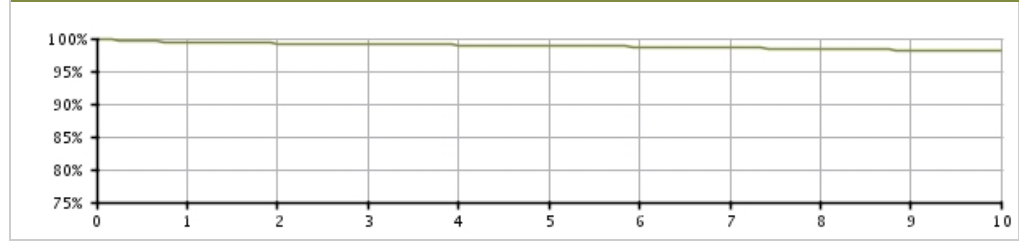
Models 4477/4478/4479/4480

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

U.S. Summary

U.S. Registered Implants: 59,000	U.S. Chronic Lead Complications: 605
U.S. Approval Date: January 2000	U.S. Malfunctions: 25
U.S. Estimated Active Implants: 31,000	Without Compromised Therapy: 18
	With Compromised Therapy: 7

Complications and Malfunctions



U.S. Survival Probability


Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.42 (-0.1/+0.1)	99.25 (-0.1/+0.1)	99.12 (-0.1/+0.1)	99.00 (-0.1/+0.1)	98.89 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.55 (-0.1/+0.1)	98.40 (-0.2/+0.1)	98.16 (-0.2/+0.2)	98.07 (-0.2/+0.2)
Registered Implants: 59000										
Effective Sample Size	48694	41129	34433	28595	23464	18729	14655	11363	8634	6388

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

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

Models 4477/4478/4479/4480

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

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) Models 4477/4478/4479/4480 			
Worldwide Distribution: 275,000			
Worldwide Confirmed Malfunctions: 50			
	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	3	10	13
⁷ Lead conductor	-	3	
³³ Conductor damage	3	7	
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
³⁴ Insulation damage	-	1	
Other	32	4	36
²³ J-shape	30	4	
²⁷ Non-patterned, Other	2	-	
WW Confirmed Malfunctions	35	15	50

References cited in table above

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

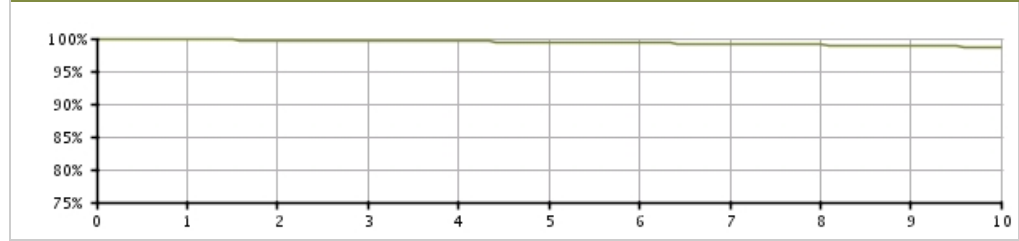
Models 4452/4453/4456/4457

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

U.S. Summary

U.S. Registered Implants: 180,000	U.S. Chronic Lead Complications: 1,011
U.S. Approval Date: January 2000	U.S. Malfunctions: 42
U.S. Estimated Active Implants: 90,000	Without Compromised Therapy: 5
	With Compromised Therapy: 37

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.80 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.63 (-0.0/+0.0)	99.54 (-0.0/+0.0)	99.44 (-0.0/+0.0)	99.33 (-0.1/+0.0)	99.15 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.83 (-0.1/+0.1)	98.70 (-0.1/+0.1)
Registered Implants: 180000										
Effective Sample Size	149980	126699	106198	88338	72380	58005	45487	35530	27226	20194


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

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

Models 4452/4453/4456/4457

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

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



Worldwide Distribution: 493,000

Worldwide Confirmed Malfunctions: 59

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	1	45	46
⁷ Lead conductor	-	15	
²⁸ Non-patterned, Conductor	-	2	
³³ Conductor damage	1	28	
Crimp/Weld/Bond	-	-	0
Insulation	2	7	9
³⁴ Insulation damage	2	7	
Other	4	-	4
²⁷ Non-patterned, Other	4	-	
WW Confirmed Malfunctions	7	52	59

References cited in table above

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

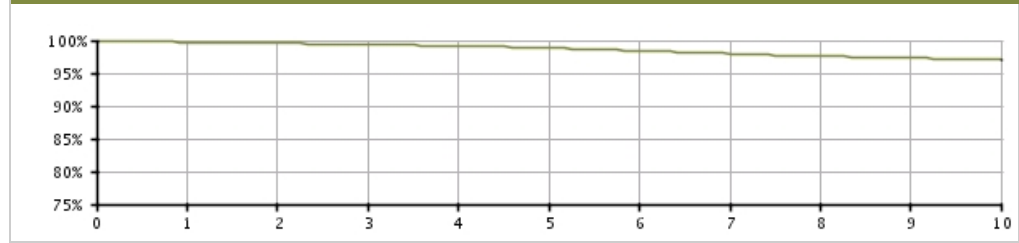
Models 4466/4467/4468/4472/4473/
4474

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

U.S. Summary

U.S. Registered Implants: 50,000	U.S. Chronic Lead Complications: 557
U.S. Approval Date: January 2000	U.S. Malfunctions:116
U.S. Estimated Active Implants: 25,000	Without Compromised Therapy:17
	With Compromised Therapy:99

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.73 (-0.1/+0.0)	99.56 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.16 (-0.1/+0.1)	98.85 (-0.1/+0.1)	98.43 (-0.2/+0.1)	98.00 (-0.2/+0.2)	97.59 (-0.2/+0.2)	97.37 (-0.2/+0.2)	97.07 (-0.3/+0.2)
Registered Implants: 50000										
Effective Sample Size	43074	36968	31493	26581	22054	17991	14409	11523	8842	6431


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

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

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

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

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



Worldwide Distribution: 135,000
Worldwide Confirmed Malfunctions: 154

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	6	121	127
⁷ Lead conductor	2	75	
²⁸ Non-patterned, Conductor	-	2	
³³ Conductor damage	4	44	
Crimp/Weld/Bond	1	-	1
³² Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	8	8	16
²⁹ Non-patterned, Insulation	2	-	
³⁴ Insulation damage	6	8	
Other	5	2	7
²⁷ Non-patterned, Other	5	2	
WW Confirmed Malfunctions	20	134	154

[References](#) cited in table above

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

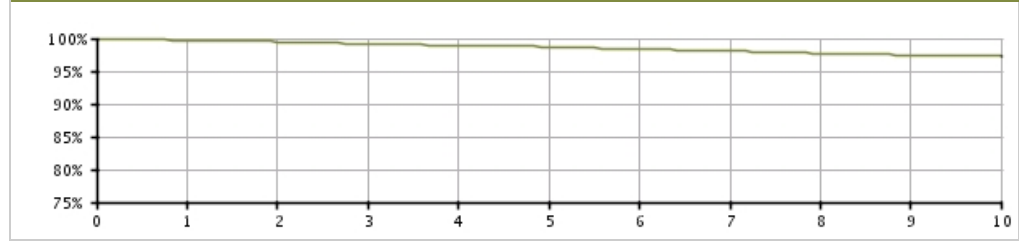
Models 4454/4455/4458/4459

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

U.S. Summary

U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 182
U.S. Approval Date: January 2000	U.S. Malfunctions: 21
U.S. Estimated Active Implants: 5,000	Without Compromised Therapy: 0
	With Compromised Therapy: 21

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.68 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.18 (-0.2/+0.2)	98.91 (-0.2/+0.2)	98.74 (-0.2/+0.2)	98.42 (-0.3/+0.2)	98.06 (-0.3/+0.3)	97.72 (-0.4/+0.3)	97.49 (-0.4/+0.4)	97.35 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12087	10488	9060	7688	6510	5415	4464	3726	3066	2443


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

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

Models 4454/4455/4458/4459

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

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



Worldwide Distribution: 101,000
Worldwide Confirmed Malfunctions: 50

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	41	41
⁷ Lead conductor	-	16	
³³ Conductor damage	-	25	
Crimp/Weld/Bond	-	-	0
Insulation	2	4	6
³⁴ Insulation damage	2	4	
Other	-	3	3
²⁷ Non-patterned, Other	-	3	
WW Confirmed Malfunctions	2	48	50

[References](#) cited in table above

FINELINE EZ Positive Fixation

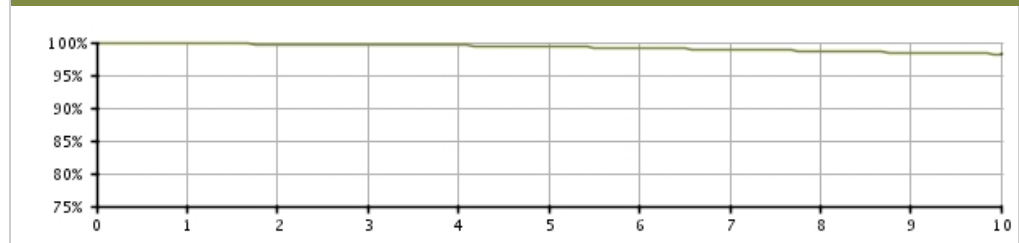
Models 4460/4461/4462

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

U.S. Summary

U.S. Registered Implants: 24,000	U.S. Chronic Lead Complications: 285
U.S. Approval Date: August 1997	U.S. Malfunctions: 10
U.S. Estimated Active Implants: 5,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.70 (-0.2/+0.2)	98.45 (-0.2/+0.2)	98.23 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20913	18710	16691	14867	13216	11630	10249	9038	7932	7000

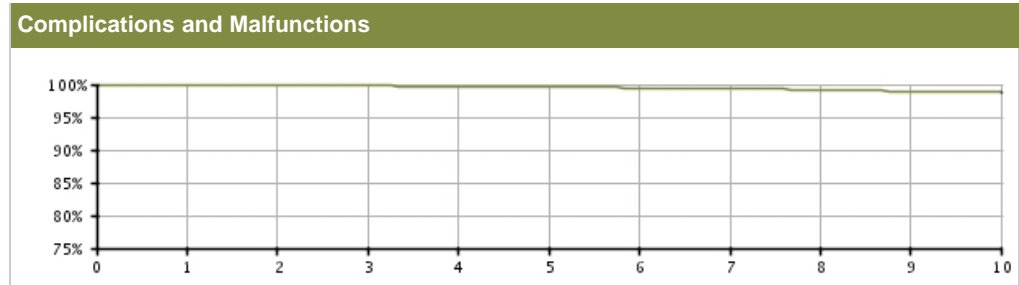
Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

FINELINE Passive Fixation

Models 4450/4451

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

U.S. Summary	
U.S. Registered Implants: 42,000	U.S. Chronic Lead Complications: 320
U.S. Approval Date: November 1996	U.S. Malfunctions: 11
U.S. Estimated Active Implants: 7,000	



U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.91 <small>(-0.0/+0.0)</small>	99.84 <small>(-0.0/+0.0)</small>	99.79 <small>(-0.1/+0.0)</small>	99.72 <small>(-0.1/+0.1)</small>	99.62 <small>(-0.1/+0.1)</small>	99.49 <small>(-0.1/+0.1)</small>	99.35 <small>(-0.1/+0.1)</small>	99.18 <small>(-0.1/+0.1)</small>	98.97 <small>(-0.1/+0.1)</small>	98.79 <small>(-0.2/+0.1)</small>
Registered Implants: 42000										
Effective Sample Size	35811	32053	28642	25424	22479	19781	17345	15309	13488	11893

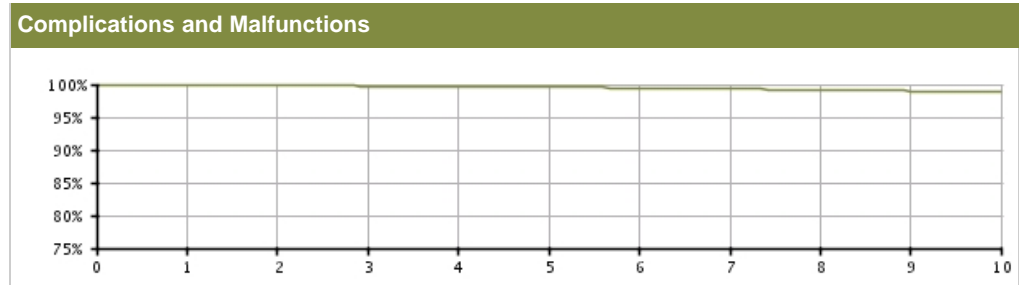
Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

FINELINE Atrial J

Models 4475/4476

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

U.S. Summary	
U.S. Registered Implants: 14,000	U.S. Chronic Lead Complications: 102
U.S. Approval Date: November 1996	U.S. Malfunctions: 6
U.S. Estimated Active Implants: 3,000	



U.S. Survival Probability										
Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.87 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.75 (-0.1/+0.1)	99.68 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.45 (-0.2/+0.1)	99.31 (-0.2/+0.2)	99.16 (-0.2/+0.2)	98.98 (-0.3/+0.2)	98.89 (-0.3/+0.2)
Registered Implants: 14000										
Effective Sample Size	12441	11148	9968	8891	7907	6971	6147	5430	4757	4161

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

SELUTE
Passive Fixation

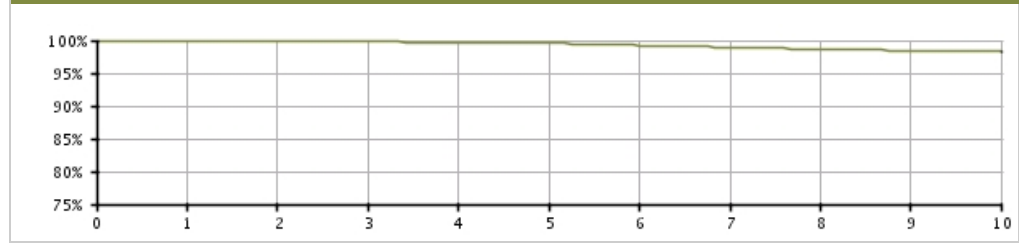
Models 4185/4285

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

U.S. Summary

U.S. Registered Implants: 48,000	U.S. Chronic Lead Complications: 465
U.S. Approval Date: May 1996	U.S. Malfunctions: 26
U.S. Estimated Active Implants: 8,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.68 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.25 (-0.1/+0.1)	98.94 (-0.1/+0.1)	98.66 (-0.2/+0.1)	98.43 (-0.2/+0.2)	98.29 (-0.2/+0.2)
Registered Implants: 48000										
Effective Sample Size	40979	36615	32657	28945	25598	22402	19635	17148	14950	13017

SELUTE PICOTIP
Passive Fixation

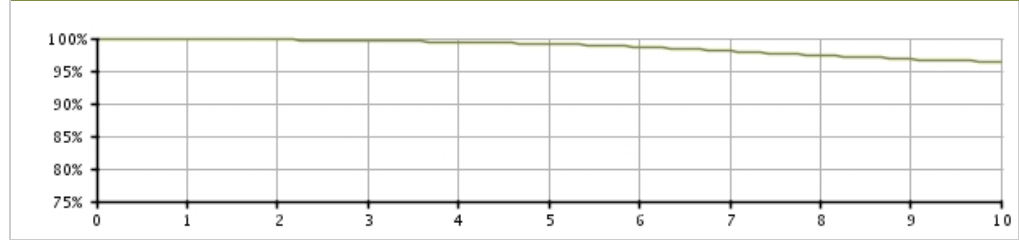
Models 4030/4031/4032/4033/4034/
 4035

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

U.S. Summary

U.S. Registered Implants: 58,000	U.S. Chronic Lead Complications: 1,086
U.S. Approval Date: April 1998	U.S. Malfunctions: 34
U.S. Estimated Active Implants: 14,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.86 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.05 (-0.2/+0.1)	97.38 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.38 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49285	43972	39183	34815	30816	27084	23621	20417	17510	14936

SELUTE PICOTIP Atrial J

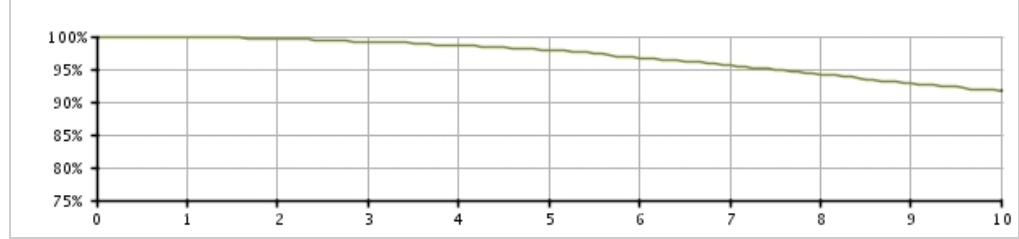
Models 4040/4041/4042/4043/4044/
4045/4063/4064

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

U.S. Summary

U.S. Registered Implants: 10,000	U.S. Chronic Lead Complications: 416
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)	98.62 (-0.3/+0.2)	97.90 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.57 (-0.6/+0.5)	94.19 (-0.7/+0.6)	92.83 (-0.8/+0.7)	91.73 (-0.9/+0.8)
Registered Implants: 10000										
Effective Sample Size	8579	7646	6795	6024	5320	4667	3999	3392	2843	2360

SWEET PICOTIP Rx
Positive Fixation

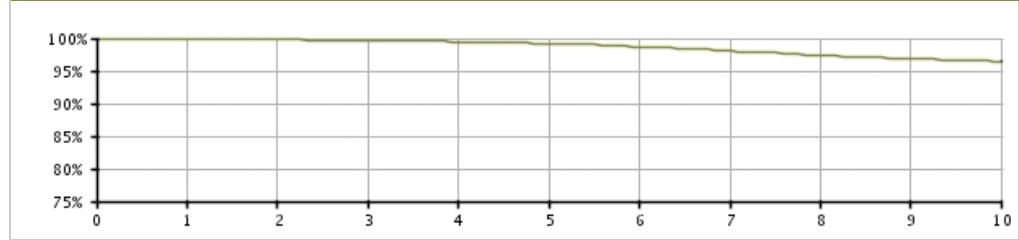
Models 4050/4051/4052/4053/4054/
 4055

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

U.S. Summary

U.S. Registered Implants: 41,000	U.S. Chronic Lead Complications: 675
U.S. Approval Date: April 1999	U.S. Malfunctions: 55
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	99.91 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.69 (-0.1/+0.1)	98.06 (-0.2/+0.2)	97.42 (-0.2/+0.2)	96.88 (-0.3/+0.2)	96.50 (-0.3/+0.3)
Registered Implants: 41000										
Effective Sample Size	35767	31935	28498	25358	22471	19729	16880	14036	11538	9356

SWEET TIP
Positive Fixation

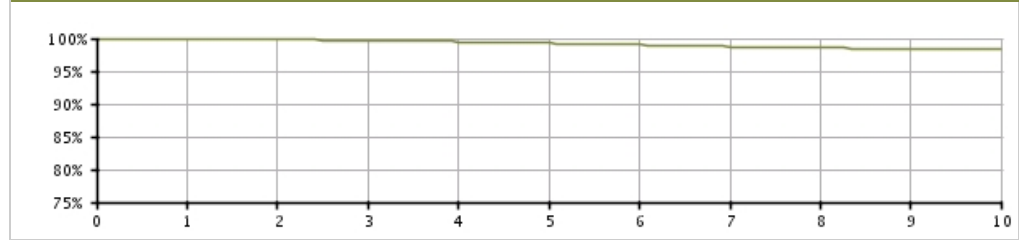
Models 4165/4168/4169/4268/4269

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

U.S. Summary

U.S. Registered Implants: 89,000	U.S. Chronic Lead Complications: 951
U.S. Estimated Active Implants: 16,000	U.S. Malfunctions: 159

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.88 (-0.0/+0.0)	99.79 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.50 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.41 (-0.1/+0.1)	98.28 (-0.1/+0.1)
Registered Implants: 89000										
Effective Sample Size	77721	69458	62069	55313	49109	43279	38075	33564	29657	26160

SWEET TIP RX
Positive Fixation

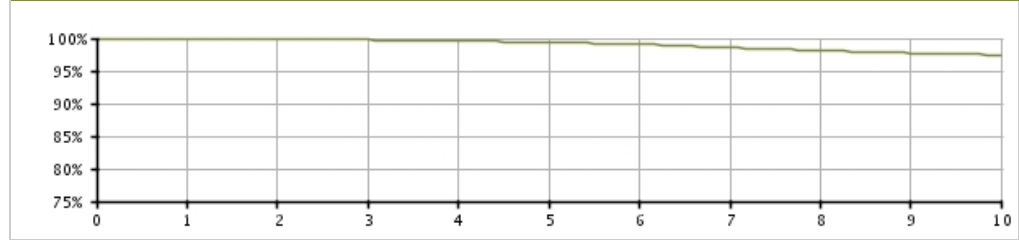
Models 4143/4144/4145/4243/4244/
4245

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

U.S. Summary

U.S. Registered Implants: 34,000	U.S. Chronic Lead Complications: 471
U.S. Approval Date: October 1998	U.S. Malfunctions: 27
U.S. Estimated Active Implants: 8,000	

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.10 (-0.1/+0.1)	98.58 (-0.2/+0.2)	98.10 (-0.2/+0.2)	97.74 (-0.2/+0.2)	97.43 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26539	23707	21104	18670	16407	14308	12235	10469	8894

CRM PRODUCT PERFORMANCE REPORT Q3 2015

Confirmed Malfunction Details: Leads

References

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

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

1. **IS-1 terminal pin**— July 19, 1999 *Voluntary Physician Advisory*. Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
4. **Lead body**— Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
5. **Seal rings**— Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.
6. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
11. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
12. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
13. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
14. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.
15. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
16. **Electrode tip**— Separation between electrode tip and lead body.
17. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
18. **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.
19. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
20. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
21. **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.
22. **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.
23. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
24. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
25. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.

26. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
27. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
28. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
29. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.
32. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.
33. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
34. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
35. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.
36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
37. **Weld fracture**— Noise, loss of sensing. Fractured weld.
38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable.
39. **Inner conductor 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 the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations (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. Leads previously reported as having Extrinsic Malfunctions are now included in Chronic Lead Complications. Both Malfunctions and Chronic Lead Complications are included in Survival Probability so re-categorization has no effect on reported U.S. Lead Survival Probability data. While multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	231000	70	715	814	643	225	81	149	342	0	62
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	180000	3	296	184	166	26	18	145	153	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	427000	20	466	606	296	57	72	382	287	0	33
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	59000	1	89	296	101	6	15	57	34	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	83	19	35	11	3	13	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	50000	0	203	73	72	43	15	66	81	0	4
CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	28000	2	19	378	32	2	1	7	18	0	84
ACUITY Spiral 4591/4592/4593	22000	0	11	232	25	1	1	2	5	0	129

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	2	27	246	38	3	1	9	10	0	84
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	95000	1	241	1042	221	6	5	58	74	0	431
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	62	396	100	2	0	46	30	0	253

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	43000	6	10	52	9	8	5	2	2	4	1
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	2000	0	0	4	0	1	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	41000	10	9	37	11	6	5	2	3	3	1
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	4000	1	1	1	3	0	0	0	1	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	188000	21	229	268	81	241	38	50	92	100	18
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	0	18	28	18	17	2	8	37	8	2
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	27000	7	32	41	15	30	1	7	21	18	1
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	0	0	0	0	2	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	6	128	69	36	173	24	38	91	37	6
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	3	64	35	27	52	5	24	88	18	4

Defibrillation Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	3000	0	8	0	1	1	0	0	2	1	2
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	2	3	1	2	0	1	0	0	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3010	8000	0	0	2	0	7	0	1	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	1354	0	0	20	2	0	0	0	0	0	8
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	629	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	753	0	0	0	0	1	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	1102	0	0	0	1	1	1	1	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	911	0	1	0	0	0	0	0	0	0	0

U.S. Acute Lead Observations

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	231000	233	191	1341	418	75	85	54	213	0	49
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	180000	15	13	433	164	9	26	24	37	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	427000	77	78	674	239	106	92	57	236	0	42
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	59000	1	18	439	93	7	28	17	20	0	10
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	33	16	1	2	7	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	50000	3	17	100	26	9	9	21	13	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	28000	1	2	322	47	25	2	7	134	0	234
ACUITY Spiral 4591/4592/4593	22000	5	4	205	64	8	1	9	37	0	237

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	4	2	268	40	12	2	8	46	0	183
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	95000	13	7	914	129	46	9	26	198	0	713
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	18	34	0	186

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	43000	36	27	131	66	41	10	7	66	15	9
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	2000	2	0	6	1	2	0	0	14	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	41000	45	37	100	36	50	14	5	68	62	15
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	4000	3	2	5	2	5	1	0	10	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	188000	118	126	479	126	248	35	45	256	191	60
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	5	2	47	28	15	3	0	103	15	1
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	27000	27	16	73	27	29	13	3	49	110	9
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	1	0	1	0	10	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	31	62	163	44	116	20	24	102	44	19
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	36	27	131	66	41	10	7	66	15	9

Defibrillation Leads/Model continued...	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	3000	0	1	2	2	2	1	0	5	7	0
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	0	1	0	1	1	0	1	0	0

S-ICD Electrodes/Model	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3010	1	0	8	0	86	5	1	17	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	1354	0	0	10	12	1	0	0	3	0	48
RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	753	0	2	10	0	0	0	1	3	0	2
RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	1102	6	1	10	3	5	3	0	2	0	2
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	629	0	0	1	0	1	0	1	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	911	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	3,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	4,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	4,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	61,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	40,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	41,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	173,000	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	6,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	16,000	2	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil Active Fixation 0295/0296	73,000	0	0	0	49	0	1	0
ENDOTAK RELIANCE G 4-Site Dual Coil Passive Fixation 0285/0286	7,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Active Fixation 0292/0293	71,000	0	0	0	15	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Passive Fixation 0282/0283	3,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276	4,000	0	0	0	6	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G Dual Coil Active Fixation 0164/0165/0166/0167/0184/0185/0186/0187	255,000	0	0	27	355	0	3	14
ENDOTAK RELIANCE G Dual Coil Passive Fixation 0174/0175/0176/0177	39,000	0	0	3	56	0	2	0
ENDOTAK RELIANCE SG Single Coil Active Fixation 0160/0161/0162/0180/0181/0182	59,000	0	0	6	58	0	1	3
ENDOTAK RELIANCE SG Single Coil Passive Fixation 0170/0171/0172/0173	3,000	0	0	0	2	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	114,000	0	0	16	130	0	0	0
ENDOTAK RELIANCE Dual Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	67,000	0	1	0	31	0	1	0

Defibrillation Leads/Model, continued...

	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE S Single Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	6,000	0	0	1	3	0	0	0
ENDOTAK RELIANCE S Single Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	4,000	0	0	0	0	0	0	0

Pacing Leads/Model

	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Passive Fixation 7631/7632/7731/7732	6,000	0	0	0	0	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	47,000	124	0	0	114	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	4,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	172,000	0	0	10	118	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	282,000	0	0	55	588	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	493,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	647,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	275,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	101,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	101,000	0	0	2	1	1	1	0

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

Product Advisories

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

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

PRODUCT	ORIGINAL COMMUNICATION 17-Nov-2014 - AUTOGEN RVAT November 2014
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory
AUTOGEN CRT-D Models G172/G173/G175/ G177/G179	AUTOGEN DR ICD and CRT-D devices include the option of enabling a Right Ventricular Automatic Threshold (RVAT) test to determine the RV pacing threshold and adjust amplitude in an ambulatory setting. If the RVAT test feature is enabled and noise signals are continuously sensed within a brief RV noise window following an Atrial pace, a patient may not receive effective pacing support until the RVAT test ends (i.e., up to 20 cardiac cycles). Although no patients have been harmed in the cases reported to date, brief periods of dizziness were reported in one case. Note that there is no additional risk for patients in whom the RVAT feature is disabled.
AUTOGEN ICD MINI DR Models D046/D047	Single-chamber AUTOGEN ICDs (VR models) have not demonstrated this behavior. The Left Ventricular Auto Threshold (LVAT) test (for AUTOGEN CRT-Ds) and the Right Atrial Auto Threshold (RAAT) test (for AUTOGEN CRT-Ds and dual-chamber ICDs) are not subject to this device behavior and are performing as intended. In addition, Boston Scientific pacemaker and CRT-P models with similar automatic pacing threshold test features are performing as intended and thus are not subject to this device behavior.
AUTOGEN ICD EL DR Models D176/D177	Boston Scientific is developing a software solution that will prevent this device behavior from occurring when the RVAT test feature is enabled. Following geography-specific regulatory approval, this software solution will be implemented via a non-invasive download from the programmer.
AUTOGEN RVAT November 2014 Physician Letter, Nov 17, 2014	CURRENT STATUS 10-Jul-15
AUTOGEN RVAT November 2014 Patient Letter, Nov 17, 2014	<i>Reported events (worldwide)</i> Four (4) reports have been received worldwide of ineffective pacing support during an RVAT test.
	There have been no reported patient deaths associated with this advisory.
	CURRENT RECOMMENDATION 10-Jul-15
	The RVAT test can be used in-clinic to run an automatic threshold test (nominally enabled) or it can be enabled for ambulatory use (nominally not enabled). Until a software solution can be implemented, Boston Scientific recommends the following:
	1. For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use:
	<ul style="list-style-type: none"> • Select the SETTINGS tab • Select the SETTINGS SUMMARY tab • In the BRADY section, select the NORMAL SETTINGS details icon • In the PACING and SENSING section, select the desired pacing RV Amplitude (do not select Auto) • Ensure that DAILY TREND is not selected • Press PROGRAM to implement the selected fixed amplitude pacing output.
	2. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilizing the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude).
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p> <p>COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108</p> <p>TELIGEN VR Models E102/E103/F102/F103</p> <p>TELIGEN DR Models E110/E111/F110/F111</p>	<p>Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II</p> <p>In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.</p> <p>The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.</p> <p>The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.</p> <p><u>Advisory population</u> Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.</p>
<p>Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014</p> <p>Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014</p> <p>Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013</p>	<p>CURRENT STATUS 10-Jul-15</p> <p>Advisory devices have not been available for implant for more than three years.</p> <p><i>Confirmed Malfunctions (worldwide)</i> 2,401 malfunctions have been confirmed from the advisory population. Approximately 45,000 devices from the advisory population remain in service.</p> <p>There has been one reported patient death associated with this advisory.</p> <p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for advisory population devices is approximately 7.6% at 72 months.</p>
	<p>CURRENT RECOMMENDATION 10-Jul-15</p> <p><u>Updated Software</u> Boston Scientific introduced updated programmer software (Model 2868, version 3.04) that enhances the effectiveness of the Safety Architecture tools later in device life. Patients with a device in the advisory population should be scheduled for an in-clinic follow-up at first opportunity, but within 3 months, using a programmer with the new software. In-clinic interrogation with an updated programmer will automatically download Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.</p> <p><u>LATITUDE Patient Management System</u> Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity" is configured "On".</p> <p><u>Additional Recommendations</u></p> <ul style="list-style-type: none"> - After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling. - Device replacement is not recommended for advisory devices displaying normal behavior. - Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages. - Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that "Approximate time to Explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a low voltage alert. <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT

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

[Device Lookup Tool](#)

SQ-RX S-ICD

Model1010

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

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

ORIGINAL COMMUNICATION 01-Jun-11 — High Cathode Condition

Voluntary Physician Advisory
FDA Classification: Pending

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

Rate of Occurrence

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

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

– Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date.

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

CURRENT STATUS 10-Jul-15

No devices in the advisory population remain available for implant.

Confirmed Malfunctions (worldwide)

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

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

Projected Rate of Occurrence

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

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

CURRENT RECOMMENDATION 10-Jul-15

– If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible.

– Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone.

For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.

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

PRODUCT	ORIGINAL COMMUNICATION July 2010— Magnetic Reed Switch 2010
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Some Boston Scientific defibrillators include a component referred to as a “magnetic reed switch,” designed to sense the presence of a magnet. If Enable Magnet Use is programmed to On (nominally On) and a magnet is applied in emergent situations or during a medical/surgical procedure, the switch is designed to close and temporarily prevent delivery of undesired tachy therapy. When the magnet is removed, the magnetic switch is designed to open and thereby restore ability to deliver programmed tachy therapy.</p>
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p>Magnetic reed switch technology has historically demonstrated a very low but non-zero rate of failing to open upon magnet removal. However, certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007 have exhibited a somewhat higher rate of magnetic reed switch failure.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	<p>Approximately 34,000 of these devices remain actively implanted; no devices in this population are available for implant. Devices manufactured after November of 2007 have returned to historic performance rates and are not included in this advisory</p>
<p>CONTAK RENEWAL 3 RF Models H210/H215</p>	<p>No patient deaths or injuries have been reported as a result of this issue, although some devices have been replaced. Most devices with a magnetic reed switch confirmed to be stuck in a closed position have remained implanted after “Enable Magnet Use” was programmed to Off (see Recommendations).</p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>Rate of Occurrence A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.</p>
<p>CONTAK RENEWAL 4 Models H190/H195/H197/H199</p>	<p>Rate of Occurrence A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.</p>
<p>CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179</p>	<p>CURRENT STATUS 10-Jul-15</p> <p>There have been no reported patient deaths associated with this advisory.</p> <p><i>Projected Rate of Occurrence</i></p>
<p>CONTAK RENEWAL 4 RF Models H230/H235/H239</p>	<p>The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.</p>
<p>VITALITY DR HE Model T180</p>	<p>CURRENT RECOMMENDATION 10-Jul-15</p> <p>Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device. In addition, Boston Scientific recommends:</p>
<p>Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010</p>	<p>1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.</p>
<p>Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010</p>	<p>2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]</p>

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

CURRENT RECOMMENDATION, continued...

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

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

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

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

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

PRODUCT

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

[Device Lookup Tool](#)

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

COGNIS

Models

N106/N107/N108/N118/N119

P106/P107/P108

TELIGEN VR

Models E102/F102

TELIGEN DR

Models E110/E111/F110/F111

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

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

ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant 2009

Voluntary Physician Advisory
FDA Classification: Class II

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

Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.

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

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

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

Rate of Occurrence

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

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

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

CURRENT STATUS 10-Jul-15

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

Reported events (worldwide)

Ninety (90) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

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

Rate of Occurrence

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

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

CURRENT RECOMMENDATION 10-Jul-15

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

For affected devices implanted in a subpectoral location:

- Follow patient at least once every three months as recommended in device instructions for use.

- Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.
- Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

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

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

PRODUCT	ORIGINAL COMMUNICATION 05-Apr-07 and 04-Mar-09— Shortened Replacement Window
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Low-voltage capacitors may be subject to degradation. These capacitors may cause accelerated battery depletion and may reduce the time between Elective Replacement Indicator (ERI) and End Of Life (EOL) to less than three months. Device replacement indicators continue to function normally.</p>
<p>CONTAK RENEWAL 4 RF HE Model H239</p>	<p>In April 2007, Boston Scientific CRM communicated with physicians regarding a population of devices subject to this failure mechanism. As of March 2009, the April 2007 advisory population has not experienced any clinically significant changes to either the rate of occurrence or patient management recommendations.</p>
<p>CONTAK RENEWAL 4 RF Models H230/H235</p>	<p>In March 2009, a second population was identified of 856 active ICDs and CRT-Ds manufactured with capacitors from the same supplier that may be subject to the same failure mechanism. The cumulative failure rate for accelerated depletion within this population is approximately 6% at 42 months and is projected to increase. Recommendations described in April 2007 have been 99.9% successful in identifying susceptible devices and ensuring replacement at ERI in the original population, and will minimize patient risk associated with a shortened replacement window when applied to this second population. No devices from this population have been registered as implanted after April 2007. No devices in this subset remain available for implant.</p>
<p>CONTAK RENEWAL 4 HE Models H197/H199</p>	
<p>CONTAK RENEWAL 4 Models H190/H195</p>	
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p>CURRENT STATUS 10-Jul-15 <i>Confirmed Malfunctions (worldwide)</i></p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>April 2007 Population 2,566 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices.</p>
<p>CONTAK RENEWAL 3 RF Models H210/H215</p>	<p>115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	<p>March 2009 Population 117 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).</p>
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p>There have been no reported patient deaths associated with either advisory population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	<p>No devices currently being distributed are susceptible to this malfunction mode.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p><i>Rate of Occurrence</i> April 2007 Population The cumulative rate of occurrence for accelerated battery depletion for the April 2007 advisory population is approximately 5.0% at 60 months.</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p>March 2009 Population The cumulative rate of occurrence for accelerated battery depletion for the March 2009 advisory population is approximately 15.8% at 60 months.</p>
<p>VITALITY DR HE Model T180</p>	<p>Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.</p>
<p>VITALITY DS VR/DR Model T135/T125</p>	

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

CURRENT RECOMMENDATION 10-Jul-15

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

VITALITY EL

Model T127

VITALITY AVT A155

Model A155

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

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

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

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

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

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

PRODUCT	ORIGINAL COMMUNICATION 10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p>	<p>FDA Classification: Devices in Table 1, Column 1 of this <i>Product Update</i> were classified as Class II (27-November-07)</p> <p>Certain devices may display ERI or EOL during mid-life (typically 24–48 months), even though battery voltage (typically greater than or equal to 2.65 volts) and capacity remain available. This behavior is caused by high battery impedance rather than low battery voltage.</p>
<p>CONTAK RENEWAL 4 RF HE Model H239</p>	<p>Devices that have triggered charge time-based ERI or EOL during mid-life have several months, and in most cases more than one year of remaining battery voltage and capacity, which allows the devices to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled.</p>
<p>CONTAK RENEWAL 4 RF / HE Models H230/H235/H197/H199</p>	<p><i>Rate Projection</i> Certain devices, typically implanted prior to July 2005 (Table 1, Column 1 of the Product Update) are projected to exhibit Mid-Life Display of Replacement Indicators as indicated below:</p>
<p>CONTAK RENEWAL 4 and 4 AVT / AVT HE Models H190/H195/M170/M175/M177/M179</p>	<p>– VITALITY AVT (Model A135), VITALITY VR/DR, VITALITY DR+ (Projected rate: 8–10%) – VITALITY AVT (Model A155), VITALITY DS VR/DR, VITALITY 2 VR/DR, ASSURE (Projected rate: 4–7%)</p>
<p>CONTAK RENEWAL 3 RF HE Models H217/H219</p>	<p>– VITALITY EL; VITALITY 2 EL DR/VR; VITALITY DR HE; CONTAK RENEWAL 3/4/3HE/4HE; CONTAK RENEWAL 3 RF/4RF/3RF HE/4RF HE; CONTAK RENEWAL 3 AVT/4AVT/3AVT HE/4AVT HE (Projected rate: 1–2%)</p>
<p>CONTAK RENEWAL 3 and 3 AVT / AVT HE Models H170/H175/M155/M159</p>	<p>Continuous manufacturing improvements intended to reduce variability in battery performance have been implemented by our battery supplier, which mitigate the occurrence of mid-life display of replacement indicators.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>CURRENT STATUS 10-Jul-15 <i>Confirmed Malfunctions (worldwide)</i> For confirmed malfunction counts related to a specific product family, refer to the Confirmed Malfunction Details section of the Product Performance Report and see pattern titled “Mid-life display of replacement indicators.”</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p><i>Projected Rate of Occurrence</i> For projected rates of occurrence see device-specific ranges listed above. Some performance differences have been observed between product families. For example, dual chamber devices have generally performed better than single chamber devices within the same product family. For current performance of a specific product family, refer to the U.S. Survival Probability section of the Product Performance Report and see population titled “10–Mar-07 Product Update — Mid-Life Display of Replacement Indicators.”</p>
<p>VITALITY DR HE and EL Model T180 and Model T127</p>	<p>CURRENT RECOMMENDATION 10-Jul-15 <u>Patient management recommendations from the March 10, 2007 Product Update remain unchanged.</u></p>
<p>VITALITY DS VR/DR Model T135/T125</p>	<p><i>Patient Management Considerations</i> – Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled. – Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL. – Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI. – Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding a manual capacitor reform may be helpful in characterizing the current charge time.</p>
<p>VITALITY AVT A135 / A155 Models A135/A155</p>	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>
<p>VITALITY VR/DR and DR+ Models 1871/1870/1872</p>	<p>ASSURE Model B301</p>
<p>Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007 Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007</p>	

PRODUCT	ORIGINAL COMMUNICATION 23-Jun-06 and 24-Aug-06— Low Voltage Capacitor
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p>
<p>INSIGNIA Ultra SR Models 1190/1390</p>	<p>Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue.</p>
<p>INSIGNIA Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490</p>	<p><i>Reported Events (worldwide)</i></p>
<p>INSIGNIA Entra SR Models 1195/1198/1395/1398</p>	<p>At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing.</p>
<p>INSIGNIA Entra DR (downsize) Models 1296/1466</p>	<p><i>Projected Rate of Occurrence</i> While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future.</p>
<p>INSIGNIA Entra DR Models 1294/1295/1494/1495</p>	<p>CURRENT STATUS 10-Jul-15</p>
<p>INSIGNIA Entra SSI Models 0484/0485/1325/1326</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation.</p>
<p>INSIGNIA Entra DDD Models 0985/0986/1426</p>	<p>There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode.</p>
<p>INSIGNIA Plus SR Models 1194/1394</p>	<p><i>Projected Rate of Occurrence</i> The rate of occurrence is projected to range between 0.10% and 0.22%.</p>
<p>INSIGNIA Plus DR and Plus DR Downsize Models 1297/1467/1298/1468</p>	<p>CURRENT RECOMMENDATION 10-Jul-15</p>
<p>INSIGNIA AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492</p>	<p>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</p>
<p>CONTAK RENEWAL TR / TR2 Models H120/H125/H140/H145</p>	<p>– Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients whenmaking medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation.</p>
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>Device Behavior</p>
<p>VITALITY 2 VR/DR Models T175/T165</p>	<p>Pacemakers: INSIGNIA/NEXUS – Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant</p>
<p>VITALITY DR HE Model T180</p>	
<p>VITALITY DS VR/DR Models T135/T125</p>	
<p>VITALITY VR/DR and EL Models 1870/1871/T127</p>	

VENTAK PRIZM 2 VR/DR
Models 1860/1861

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

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

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

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

CURRENT RECOMMENDATION, continued...

CRT-Ps: RENEWAL TR/TR2

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

ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2

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

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

PRODUCT	ORIGINAL COMMUNICATION 12-May-06 and 04-Jan-08 Subpectoral Implant
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</p> <p><i>This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..</i></p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up.</p>
<p>CONTAK RENEWAL 4 HE Models H197/H199</p>	<p>This failure mechanism can result in one or more of the following device behaviors:</p> <ul style="list-style-type: none"> - Loss of shock therapy - Loss of pacing therapy (intermittent or permanent) - Loss of telemetry communications - Beeping (16 tones every six hours), and a programmer warning screen upon interrogation
<p>CONTAK RENEWAL 4 Models H190/H195</p>	
<p>CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179</p>	<p><i>Reported Events</i> Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p>	
<p>CONTAK RENEWAL 3 Models H170/H175</p>	<p><i>Rate of Occurrence</i> The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.</p>
<p>CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159</p>	
<p>VITALITY 2 EL VR/DR Models T177/T167</p>	<p>CURRENT STATUS 10-Jul-15</p> <p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u> Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation.</p>
<p>VITALITY DR HE Model T180</p>	<p><u>January 4, 2008 Population</u> Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation.</p>
<p>VITALITY EL Model T127</p>	<p>There have been no reported patient deaths associated with this advisory.</p>
<p>VITALITY DR+ Model 1872</p>	<p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.</p>
<p>Subpectoral Implant, Physician Letter, Jan 04, 2008</p> <p>Subpectoral Implant, Patient Letter, Jan 04, 2008</p>	<p>CURRENT RECOMMENDATION 10-Jul-15</p> <p><u>Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.</u></p> <ul style="list-style-type: none"> - For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. - For subpectoral implants, use an AP radiograph to determine specific device orientation. <ul style="list-style-type: none"> - If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary.

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

CURRENT RECOMMENDATION, continued...

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

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

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

PRODUCT	ORIGINAL COMMUNICATION 22-Sep-05 — Crystal Timing Component
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory FDA Classification: Class II
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of September 22, 2005, the root cause of the second failure mode had not yet been determined and analysis was ongoing. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component.
INSIGNIA Ultra SR Models 1190/1390	<i>Reported Events</i>
INSIGNIA Ultra DR and Ultra DR Downsize Models 1291/1491/1290/1490	Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004.
INSIGNIA Entra SR Models 1195/1198/1395/1398	Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths.
INSIGNIA Entra DR (downsize) Models 1296/1466	<i>Rate Projection</i>
INSIGNIA Entra DR Models 1294/1295/1494/1495	Failure Mode 1—As of the September 22, 2005 communication, Guidant's modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
INSIGNIA Entra SSI Models 0484/0485/1325/1326	CURRENT STATUS 10-Jul-15
INSIGNIA Entra DDD Models 0985/0986/1426	<i>Confirmed Malfunctions (worldwide)</i>
INSIGNIA Plus SR Models 1194/1394	Failure Mode 1— 62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory.
INSIGNIA Plus DR and Plus DR Downsize Models 1297/1467/1298/1468	Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory.
INSIGNIA AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492	None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode.
Crystal Timing Component, Physician Letter, Dec 12, 2005	<i>Projected Rate of Occurrence</i> Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 5,000 is projected to range between 0.027% and 0.038%.
Crystal Timing Component, Patient Letter, Oct 03, 2005	CURRENT RECOMMENDATION 10-Jul-15
Crystal Timing Component, Physician Letter, Sep 22, 2005	Failure Mode 1— <u>Patient management recommendations from the September 22, 2005 physician communication remain unchanged.</u>
	Failure Mode 2— <u>Patient management recommendations supersede those originally communicated on September 22, 2005.</u>
	<ul style="list-style-type: none"> – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component
Identifiable by serial number. Not all serial numbers are affected.	Voluntary Physician Advisory (18-Jul-05) FDA Classification: Class I
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I
CONTAK TR Model 1241	A hermetic sealing component utilized in a subset of pacemakers may experience a gradual degradation, resulting in higher than normal moisture content within the pacemaker case late in the device's service life; this could lead to a variety of inappropriate clinical behaviors.
DISCOVERY II SR (downsize) Models 1184/1384	The original July 18, 2005 physician communication bounded the population to approximately 78,000 devices manufactured between November 25, 1997 and October 26, 2000; this number was further refined to 77,500 devices manufactured between October 27, 1997 and October 26, 2000.
DISCOVERY II SR Models 1186/1187/1385	The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated at that time to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis.
DISCOVERY II DR (downsize) Models 1283/1483	The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated at that time to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis.
DISCOVERY II DR Models 1284/1286/1484/1485	A Second Population of 54,000 devices was subsequently identified to be at risk of hermetic seal degradation (but at a much lower rate than the original population). This was communicated in the January 21, 2006 letter.
DISCOVERY II SSI (downsize) Models 0481/1349	Original Population— <u>Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u> ; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).
DISCOVERY II DDD Models 0981/1285/1499	Original Population— <u>Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u> ; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).
PULSAR MAX II SR (downsize) Models 1180/1380	Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.
PULSAR MAX II SR / DR Models 1181/1290/1480	<i>Rate Projection</i> Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 had increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and was projected to range between 0.31% and 0.88% over the remaining device lifetime.
DISCOVERY SR/SR (downsize) Models 1174/1175	Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 had increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and was projected to range between 0.31% and 0.88% over the remaining device lifetime.
DISCOVERY DR/DR (downsize) Models 1274/1275/1273	Second Population—For the remaining lifetime of the estimated worldwide 19,300 active devices, the projected rate of occurrence for reported events was estimated to be between 0.02% and 0.06%.
PULSAR MAX SR (downsize) Model 1170	CURRENT STATUS 10-Jul-15
PULSAR MAX SR / DR Model 1171/1270	<i>Reported Events (worldwide)</i> Refined Original Population— 342 malfunctions have been confirmed out of the 77,500 advisory population devices.
PULSAR Models 1272/0470/0870/0970/ 0972/1172	Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices.
MERIDIAN SSI / DDD Models 0476/0976	<i>Projected Rate of Occurrence</i> Refined Original Population—The rate of occurrence for the estimated worldwide active device population of 3,000 is projected to range between 0.31% and 0.88% over the remaining device lifetime, as communicated in the January 21, 2006 Advisory Update letter.
MERIDIAN SR / DR Models 1176/1276	Second Population—The rate of occurrence for the estimated worldwide active device population of 2,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.

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

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

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

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

CURRENT RECOMMENDATION 10-Jul-15

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

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

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

OR

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

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

Trademarks

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

ACUITY	ENDOTAK DSP	INVIVE
ACUITY X4	ENDOTAK ENDURANCE	LIVIAN
ADVANTIO	ENDOTAK ENDURANCE EZ	ORIGEN
ALTRUA	ENDOTAK ENDURANCE RX	PUNCTUA
AUTOGEN	ENDOTAK RELIANCE	RELIANCE 4-FRONT
AVT	ENERGEN	SELUTE
CHFD	FINELINE	SWEET PICOTIP
COGNIS	FLEXTEND	SWEET TIP
CONFIENT	FORMIO	TELIGEN
CONTAK	INSIGNIA	ULTRA 1
CONTAK RENEWAL	INGENIO	VITALIO
CONTAK RENEWAL TR	INGEVITY	VITALITY
DYNAGEN	INCEPTA	4-SITE
EASYTRAK	INLIVEN	
EMBLEM	INOGEN	
ENDOTAK	INTUA	
EQUIO		

The following marks are registered trademarks for Intermedics, Inc and Cameron Health, Inc. (doing business as Cardiac Pacemakers, Inc., a Boston Scientific Company) used in connection with the goods or services indicated:

Q-TRAK	SQ-RX	VIRTUS
S-ICD	UNIPASS	

OTHER

GORE and associated logos are trademarks of W.L. Gore & Associates.



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

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

© 2015 Boston Scientific Corporation
or its affiliates. All rights reserved.
CRM-294808-AA FEB2015