Boston Scientific
Advancing science for life™

CRM Product Performance Report 2014

Q2 Edition

CRM Quality Pledge

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

Advancing Science for Life.

For almost forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2014 report includes data through April 8, 2014.

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

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

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

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

Medical Review Board

Ronald D. Berger, M.D., PhD
Professor of Medicine
Johns Hopkins University

Stepehen R. Shorofsky, M.D., PhD
Professor of Medicine
University of Maryland, School of Medicine

Boston Scientific Reviewers

Renold Russie
Vice President, Quality Assurance

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

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

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

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

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

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

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

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

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

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

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)
Reduction in survival probability for **pulse generators** is due to:

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

Survival Probability – Malfunctions Only (Pulse Generators)
Reduction in survival probability for **pulse generators** is due only to:

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

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

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

Reduction in survival probability is due to:

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

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

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

Categorization of Malfunctions for Survival Probability Reporting
Malfunctions represent pulse generators and leads removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. In addition, leads utilize AdvaMed methodology which includes Extrinsic Factor malfunctions occurring 30 days or more post-implant, where laboratory analysis is inconclusive or unconfirmed. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (such as ionizing therapeutic radiation), are not reported as device malfunctions in survival data. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction. Malfunctions are further classified according to their impact on therapy, as follows:

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

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

Malfunction Without Compromised Therapy —
The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

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

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

a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings and therapeutic use.

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

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

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

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples. Improvement implementation may vary by geography due to various factors including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

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

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

Malfunction Details: Overview

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

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

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

Each pattern description includes:

- ***Clinical Manifestation and Root Cause*** – Malfunctions for each product are characterized according to root cause. Descriptions provide clinical observations and/or analysis findings associated with each malfunction pattern listed in this report. Malfunctions listed within “Other” either do not yet have an identified root cause, or are related to a proprietary product feature, such as connectors or seal rings.

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

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

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

- ***Malfunction With Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

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

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

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

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

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

- ***Conductor:*** Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors), including those associated with clavicle flex fatigue or crush damage.

- ***Insulation:*** Any lead insulation breach. Examples include: 1) proximal abrasions associated with lead-on-lead or lead-on-PG contact in the pocket, 2) mid-lead insulation damage caused by clavicle flex fatigue or crush, suture or suture sleeve, insulation wear in the region of vein insertion, and 3) distal region wear due to lead-on-lead (intracardiac), lead-on-heart valve or lead-on-other anatomy contact.

- ***Crimps/Welds/Bonds:*** Any interruption in the conductor or lead body associated with a point of connection. Typically demonstrated by high or low shocking/pacing impedance, undersensing or oversensing.

- ***Other:*** Includes specific proprietary lead mechanical attributes, such as lead-incorporated sensors, connectors, seal rings or the 4–Site connector, or any malfunction modes not included in the three categories above.

- ***Extrinsic Factors***: Lead complication where the identified lead was removed from service and returned for analysis, where analysis was either inconclusive or the complication was not confirmed. Inconclusive includes leads where only portions of the lead were available for return, or the returned lead was damaged by the explantation process. Unconfirmed includes when lab analysis could not determine an out of specification condition (including complaints of malfunction or complications such as dislodgements, perforations or failure to capture).

The categories of Conductor, Insulation, Crimps/Welds/Bonds and Other represent malfunctions for leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Extrinsic Factors category represents leads with reported complications for which the leads were removed from service and returned, but for which laboratory analysis was inconclusive or the complication was unconfirmed. For the Extrinsic Factors category only, malfunctions are included for leads implanted greater than 30 days.

Supporting Greater Return of Explanted Devices

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

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

Help Us Provide You With More Complete Product Performance Data

Reporting Adverse Events

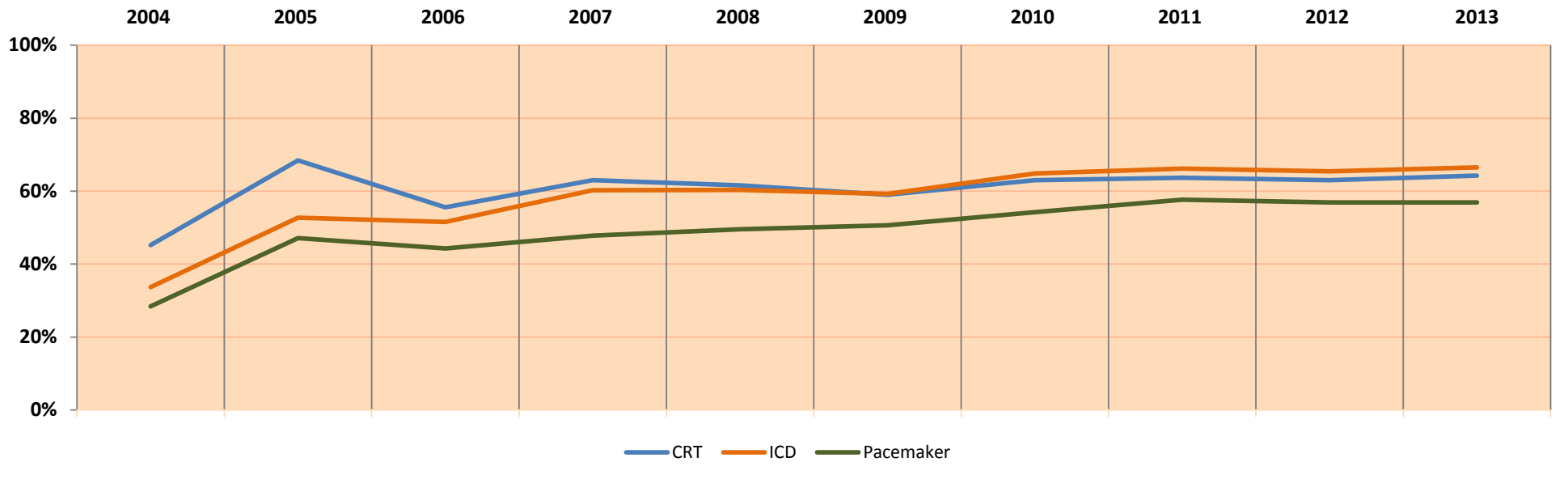
The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department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

United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.
International: Please refer to the Country Offices List for local contact information.
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

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

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



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Explants	1328	4512	4388	4693	5294	8152	9009	7469	5890	5396
Returns	600	3088	2439	2956	3261	4812	5673	4755	3709	3467
% Returned	**45%**	**68%**	**56%**	**63%**	**62%**	**59%**	**63%**	**64%**	**63%**	**64%**
Explants	15305	16491	10218	11536	15743	20202	20816	17665	13286	13607
Returns	5150	8695	5267	6951	9493	11975	13498	11690	8691	9051
% Returned	**34%**	**53%**	**52%**	**60%**	**60%**	**59%**	**65%**	**66%**	**65%**	**67%**
Explants	14485	21691	17771	19113	20951	21560	21499	20470	19074	18860
Returns	4122	10216	7875	9133	10376	10920	11662	11807	10853	10737
% Returned	**28%**	**47%**	**44%**	**48%**	**50%**	**51%**	**54%**	**58%**	**57%**	**57%**

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

INCEPTA CRT-D 4-Site

Models N160/N162/P162

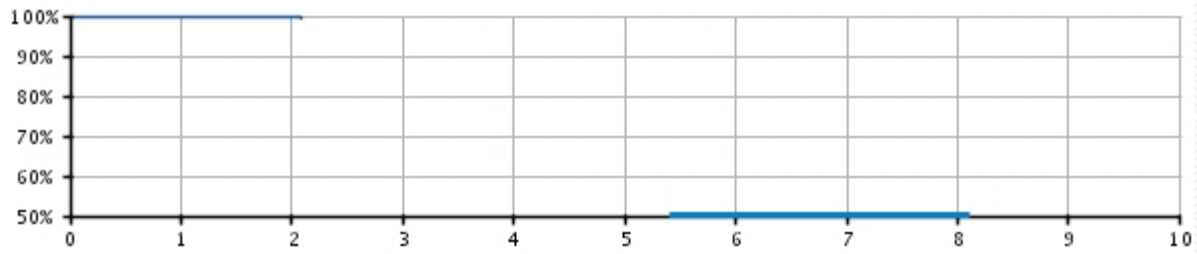
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

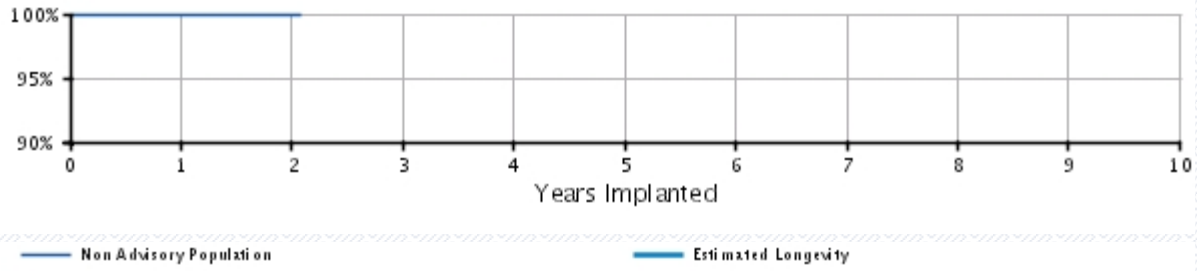
U.S. Registered Implants: 6,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 6,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.80 (-0.8/+0.2)	99.80 @ 25 mo. (-0.8/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 25 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	2824	442	277	–	–	–	–	–	–	–

INCEPTA CRT-D 4-Site

Models N160/N162/P162

INCEPTA CRT-D 4-Site Models N160/N162/P162

Worldwide Distribution: 12,000

Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[89] Safety Core-electrocautery	1	-	
Mechanical	**-**	**1**	**1**
[83] Transformer	-	1	
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

INCEPTA CRT-D

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

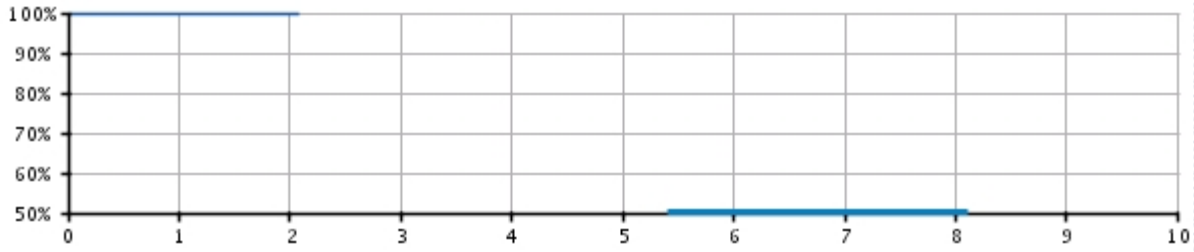
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

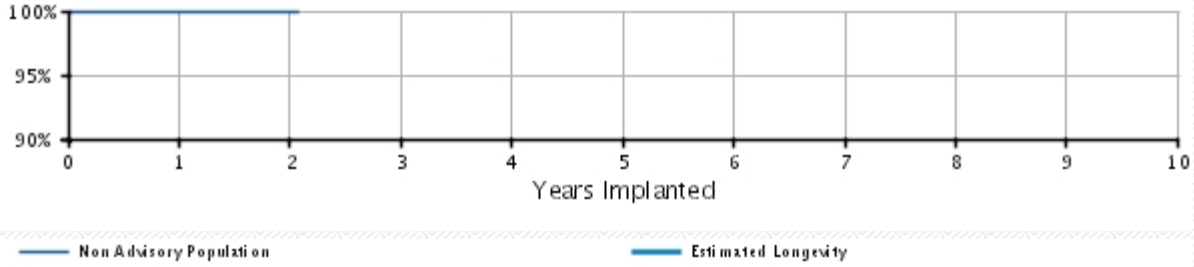
U.S. Registered Implants: 9,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 8,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	3991	414	211	–	–	–	–	–	–	–

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: 13,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[91] High-voltage capacitor	-	1	
Mechanical	**-**	**1**	**1**
[83] Transformer	-	1	
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**2**	**2**

More details about malfunctions

References cited in table above

PUNCTUA CRT-D 4-Site

Models N050/N052/P052

PUNCTUA CRT-D 4-Site Models N050/N052/P052

Worldwide Distribution: 2,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

PUNCTUA CRT-D

Models N051/N053/P053

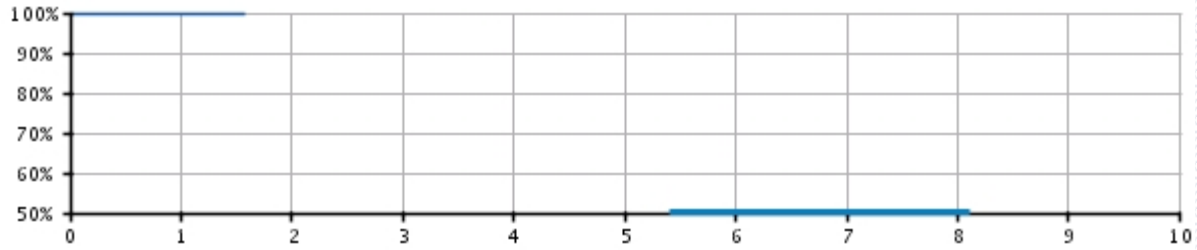
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

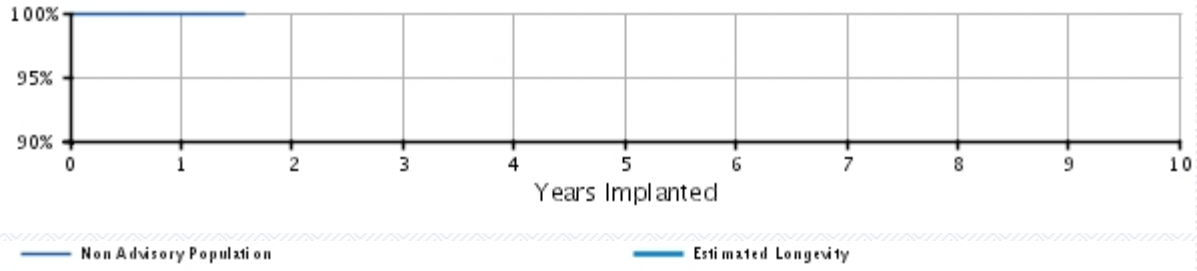
U.S. Registered Implants: 1,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 1,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 19 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 19 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	565	234	–	–	–	–	–	–	–	–

PUNCTUA CRT-D

Models N051/N053/P053

PUNCTUA CRT-D
Models N051/N053/P053

Worldwide Distribution: 4,000

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[100] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

COGNIS

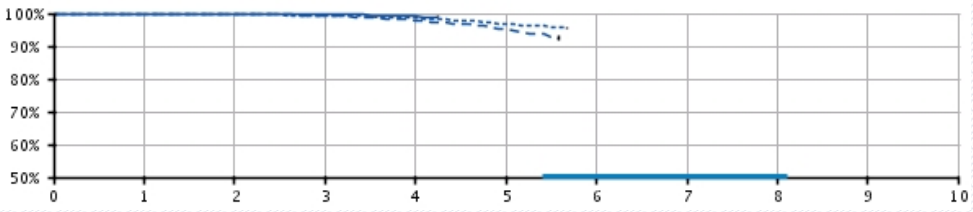
Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

U.S. Summary

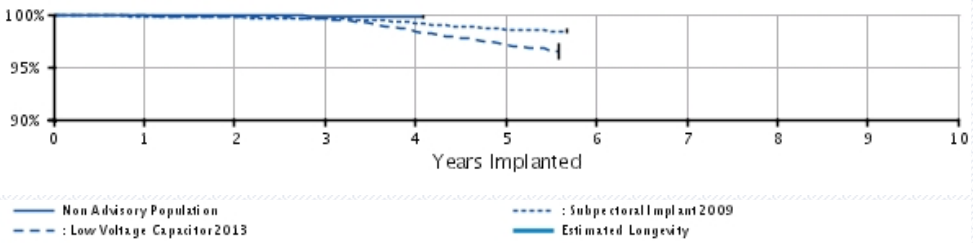
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 51,000

U.S. Normal Battery Depletions: 357
U.S. Unconfirmed Reports of Premature Battery Depletion : 27
U.S. Malfunctions:366
Without Compromised Therapy:257
With Compromised Therapy:108

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 40000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.0/+0.0)	99.84 (-0.0/+0.0)	99.66 (-0.1/+0.1)	99.21 (-0.3/+0.2)	98.99 @ 49 mo. (-0.6/+0.4)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.75 (-0.1/+0.1)	99.75 @ 49 mo. (-0.1/+0.1)	–	–	–	–	–
	Effective Sample Size	35583	30864	15523	857	463	–	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.3)	96.85 (-0.3/+0.3)	95.60 @ 68 mo. (-0.6/+0.6)	–	–	–	–
	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)	98.56 (-0.2/+0.2)	98.43 @ 68 mo. (-0.3/+0.2)	–	–	–	–
	Effective Sample Size	27518	24405	21706	19206	6556	281	–	–	–	–
Low Voltage Capacitor 2013* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.81 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.37 (-0.2/+0.1)	97.78 (-0.4/+0.3)	95.19 (-0.7/+0.6)	92.37 @ 67 mo. (-1.4/+1.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.59 (-0.2/+0.1)	98.41 (-0.3/+0.3)	97.06 (-0.5/+0.4)	96.53 @ 67 mo. (-0.9/+0.7)	–	–	–	–

	Effective Sample Size	10395	9177	8164	6541	2246	321	–	–	–	–

*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: 479

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**262**	**64**	**326**
[1] Low Voltage Capacitor 2013 (Advisory issued)	151	13	
[89] Safety Core-electrocautery	41	18	
[91] High-voltage capacitor	1	4	
[96] Low-voltage capacitors	7	-	
[100] Integrated circuit	7	19	
[102] High voltage circuit	-	1	
[103] Battery	16	2	
[104] Low-voltage capacitor	39	7	
Mechanical	**31**	**77**	**108**
[5] Subpectoral implant 2009 (Advisory issued)	13	37	
[83] Transformer	-	9	
[87] Difficulty securing lead	9	9	
[94] Header contacts	4	7	
[109] Header	5	15	
Software	**11**	**-**	**11**
[95] Safety Core-programming	1	-	
[98] Alert messages not displayed post-EOL	2	-	
[101] Memory errors	8	-	
Other	**26**	**8**	**34**
Non-patterned	26	8	
WW Confirmed Malfunctions	**330**	**149**	**479**

More details about malfunctions

References cited in table above

LIVIAN

Models H220/H225/H240/H245

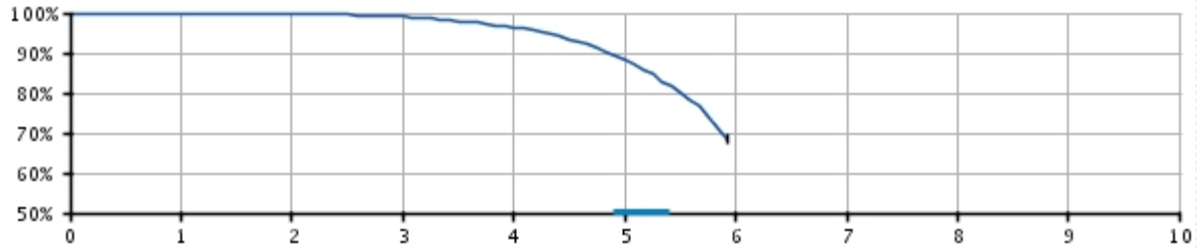
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

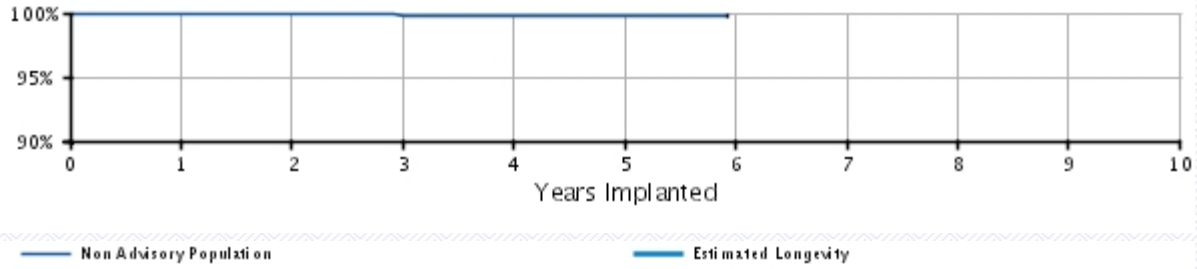
U.S. Registered Implants: 5,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 500
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:8
Without Compromised Therapy:5
With Compromised Therapy:3

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.68 (-0.2/+0.1)	99.06 (-0.4/+0.3)	96.44 (-0.7/+0.6)	88.10 (-1.4/+1.3)	68.47 @ 71 mo. (-2.9/+2.7)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.80 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 @ 71 mo. (-0.2/+0.1)	–	–	–	–
	Effective Sample Size	3997	3486	2999	2423	1637	300	–	–	–	–

LIVIAN

Models H220/H225/H240/H245

LIVIAN
Models H220/H225/H240/H245

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**2**	**3**
[34] Integrated circuit	1	2	
Mechanical	**1**	**-**	**1**
[38] Seal plug	1	-	
Software	**-**	**-**	**0**
Other	**3**	**2**	**5**
Non-patterned	1	2	
[45] Battery depletion	2	-	
WW Confirmed Malfunctions	**5**	**4**	**9**

More details about malfunctions

References cited in table above

LIVIAN HE

Models H227/H229/H247/H249

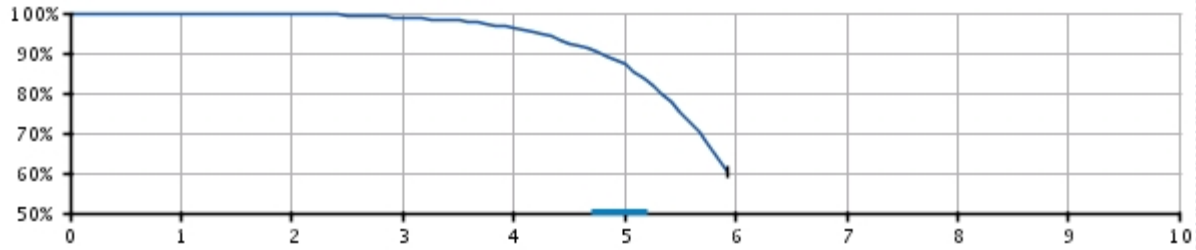
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

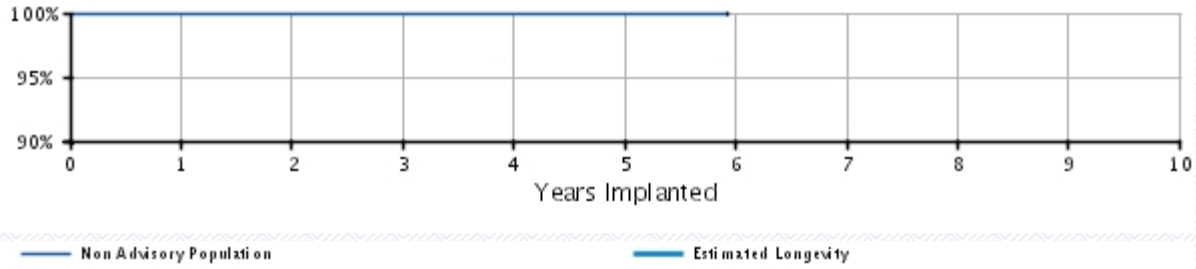
U.S. Registered Implants: 6,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 687
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:4
Without Compromised Therapy:2
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 Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.74 (-0.2/+0.1)	98.90 (-0.4/+0.3)	96.46 (-0.7/+0.6)	87.25 (-1.3/+1.2)	60.09 @ 71 mo. (-3.1/+3.0)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 @ 71 mo. (-0.1/+0.1)	–	–	–	–
	Effective Sample Size	4942	4330	3650	2867	1811	243	–	–	–	–

LIVIAN HE

Models H227/H229/H247/H249

LIVIAN HE
Models H227/H229/H247/H249

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[34] Integrated circuit	1	1	
Mechanical	**-**	**2**	**2**
[87] Difficulty securing lead	-	2	
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	-	
[45] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**4**	**6**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 3 RF

Models H210/H215

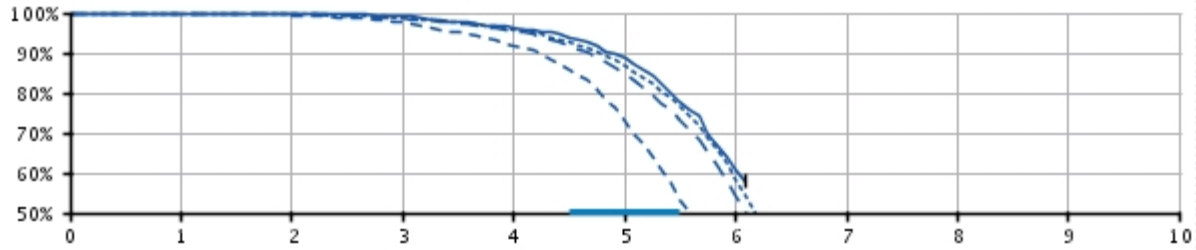
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

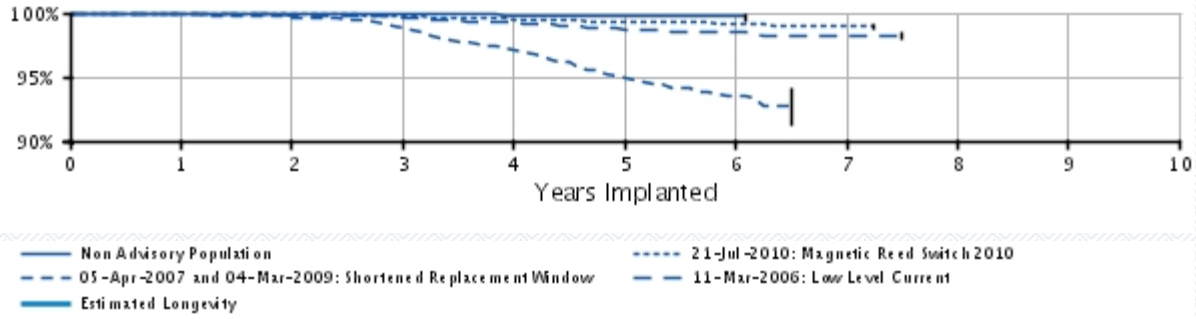
U.S. Registered Implants: 21,000
U.S. Approval Date: February 2005
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 6,760
U.S. Unconfirmed Reports of Premature Battery Depletion : 28
U.S. Malfunctions:176
Without Compromised Therapy:157
With Compromised Therapy:19

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: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.82 (-0.4/+0.1)	99.17 (-0.6/+0.4)	96.26 (-1.2/+0.9)	88.53 (-2.0/+1.7)	60.70 (-3.4/+3.3)	57.96 @ 73 mo. (-3.6/+3.6)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.78 (-0.5/+0.2)	99.78 (-0.5/+0.2)	99.78 (-0.5/+0.2)	99.78 @ 73 mo. (-0.5/+0.2)	–	–	–
	Effective Sample Size	1735	1523	1320	1125	891	346	239	–	–	–
21-Jul-10 Magnetic Reed Switch	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.75 (-0.1/+0.1)	98.81 (-0.2/+0.2)	96.00 (-0.4/+0.4)	86.61 (-0.7/+0.7)	58.42 (-1.1/+1.1)	20.78 (-1.3/+1.3)	18.19 @ 87 mo. (-1.3/+1.4)	–	–

2010* Registered Implants: 15000											
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.53 (-0.2/+0.1)	99.28 (-0.2/+0.2)	99.19 (-0.2/+0.2)	98.97 (-0.3/+0.2)	98.97 @ 87 mo. (-0.3/+0.2)	–	–
	Effective Sample Size	12967	11434	9925	8445	6664	3914	440	220	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.41 (-0.3/+0.2)	97.57 (-0.6/+0.5)	91.86 (-1.2/+1.0)	72.82 (-2.0/+1.9)	30.96 (-2.2/+2.2)	14.80 @ 78 mo. (-1.7/+1.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.2/+0.1)	99.66 (-0.3/+0.2)	98.82 (-0.5/+0.3)	97.09 (-0.7/+0.6)	94.91 (-1.0/+0.9)	93.55 (-1.3/+1.1)	92.74 @ 78 mo. (-1.6/+1.4)	–	–	–
	Effective Sample Size	3377	2941	2484	2036	1398	501	206	–	–	–
11-Mar-06 Low Level Current* Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.67 (-0.1/+0.1)	98.62 (-0.2/+0.2)	95.47 (-0.4/+0.4)	84.73 (-0.7/+0.7)	54.09 (-1.0/+1.0)	19.55 (-1.0/+1.1)	16.71 @ 90 mo. (-1.1/+1.2)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.84 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.23 (-0.2/+0.1)	98.73 (-0.2/+0.2)	98.48 (-0.3/+0.2)	98.20 (-0.3/+0.3)	98.20 @ 90 mo. (-0.3/+0.3)	–	–
	Effective Sample Size	16380	14429	12470	10564	8192	4567	633	216	–	–

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

CONTAK RENEWAL 3 RF

Models H210/H215

CONTAK RENEWAL 3 RF Models H210/H215

Worldwide Distribution: 21,000
Worldwide Confirmed Malfunctions: 178

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**143**	**5**	**148**
[7] Shortened replacement window (Advisory issued)	84	2	
[17] Extended charge time post-mid-life	1	-	
[28] Capacitor	2	-	
[34] Integrated circuit	8	3	
[50] Capacitor	1	-	
[55] Capacitor	3	-	
[65] Mid-life display of replacement indicators	13	-	
[66] High-voltage capacitor	2	-	
[88] Low-voltage capacitor	29	-	
Mechanical	**8**	**11**	**19**
[4] Magnetic reed switch 2010 (Advisory issued)	5	6	
[15] Magnetic switch (Advisory issued)	-	1	
[38] Seal plug	2	-	
[73] Setscrew	1	-	
[75] Seal plug	-	1	
[97] Bent flex circuit	-	3	
Software	**3**	**-**	**3**
[21] Parameter errors	1	-	
[64] Memory location	1	-	
[85] Misaligned markers	1	-	
Other	**5**	**3**	**8**
Non-patterned	-	2	
[45] Battery depletion	5	1	
WW Confirmed Malfunctions	**159**	**19**	**178**

CONTAK RENEWAL 3

Models H170/H175

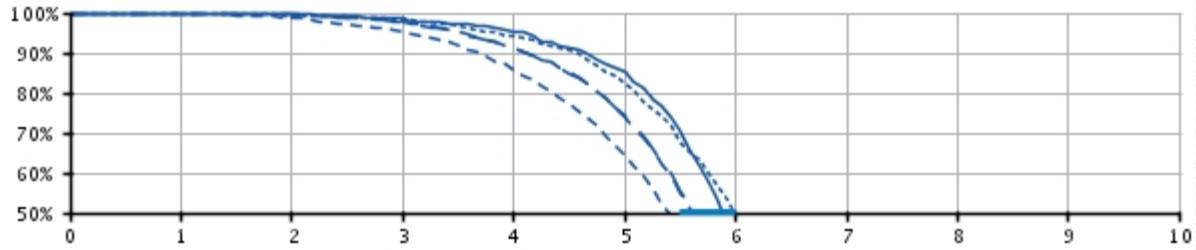
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

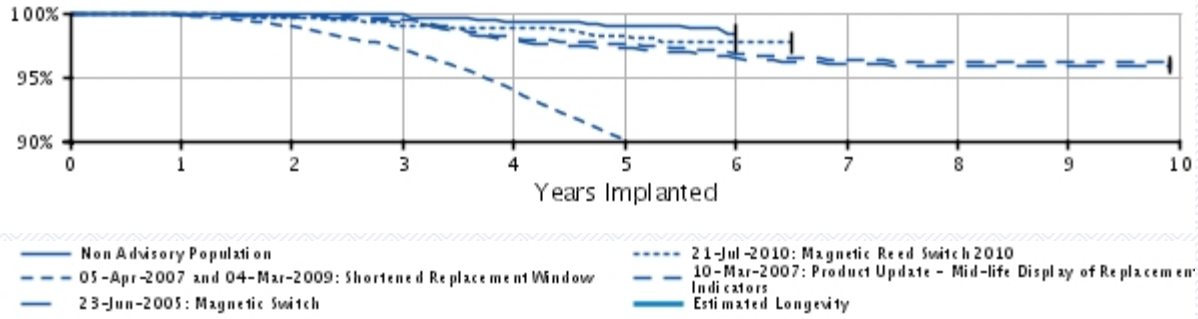
U.S. Registered Implants: 34,000
U.S. Approval Date: June 2003
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 11,943
U.S. Unconfirmed Reports of Premature Battery Depletion : 72
U.S. Malfunctions:973
Without Compromised Therapy:926
With Compromised Therapy:47

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: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.72 (-0.5/+0.2)	98.57 (-0.8/+0.5)	95.43 (-1.4/+1.1)	85.05 (-2.5/+2.2)	43.25 (-4.1/+4.1)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.85 (-0.5/+0.1)	99.28 (-0.7/+0.4)	99.01 (-0.9/+0.5)	98.35 (-1.6/+0.8)	–	–	–	–
	Effective Sample Size	1504	1320	1137	930	655	NaN	–	–	–	–
21-Jul-10 Magnetic Reed Switch 2010*	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.3/+0.1)	99.43 (-0.5/+0.3)	98.14 (-0.8/+0.5)	94.13 (-1.3/+1.1)	82.27 (-2.2/+2.0)	49.12 (-3.0/+3.0)	26.12 @ 78 mo. (-2.7/+2.9)	–	–	–

Registered Implants: 2000											
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.3/+0.1)	99.54 (-0.4/+0.2)	99.04 (-0.6/+0.4)	98.77 (-0.7/+0.4)	98.13 (-0.9/+0.6)	97.78 (-1.0/+0.7)	97.78 @ 78 mo. (-1.0/+0.7)	–	–	–
	Effective Sample Size	2059	1777	1529	1263	951	504	207	–	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window*	Depletions and Malfunctions(%) (Confidence Interval)	99.76 (-0.1/+0.1)	98.67 (-0.3/+0.2)	95.23 (-0.5/+0.5)	86.00 (-0.9/+0.8)	64.33 (-1.3/+1.2)	26.41 (-1.3/+1.3)	14.06 (-1.0/+1.1)	12.80 (-1.0/+1.1)	12.80 @ 100 mo. (-1.0/+1.1)	–
Registered Implants: 10000											
	Malfunctions Only(%) (Confidence Interval)	99.78 (-0.1/+0.1)	98.95 (-0.2/+0.2)	97.13 (-0.4/+0.4)	94.05 (-0.6/+0.5)	90.05 (-0.8/+0.8)	88.12 (-1.0/+0.9)	87.78 (-1.1/+1.0)	87.57 (-1.2/+1.1)	87.57 @ 100 mo. (-1.2/+1.1)	–
	Effective Sample Size	8903	7753	6531	5103	3282	1126	483	302	213	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.84 (-0.1/+0.0)	99.62 (-0.1/+0.1)	97.83 (-0.3/+0.2)	91.12 (-0.5/+0.5)	73.94 (-0.8/+0.8)	33.27 (-1.0/+1.0)	16.38 (-0.8/+0.9)	15.14 (-0.8/+0.8)	15.01 (-0.8/+0.8)	14.90 @ 119 mo. (-0.8/+0.8)
Registered Implants: 21000											
	Malfunctions Only(%) (Confidence Interval)	99.87 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.11 (-0.3/+0.2)	97.56 (-0.3/+0.3)	96.86 (-0.4/+0.4)	96.36 (-0.5/+0.5)	96.15 (-0.6/+0.5)	96.15 (-0.6/+0.5)	96.15 @ 119 mo. (-0.6/+0.5)
	Effective Sample Size	17334	15154	13017	10427	7260	2730	1028	826	664	202
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.										
23-Jun-05 Magnetic Switch*	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.0)	99.51 (-0.1/+0.1)	97.65 (-0.2/+0.2)	91.01 (-0.5/+0.5)	74.13 (-0.8/+0.8)	33.79 (-0.9/+0.9)	16.29 (-0.8/+0.8)	14.94 (-0.8/+0.8)	14.78 (-0.8/+0.8)	14.68 @ 119 mo. (-0.8/+0.8)
Registered Implants: 23000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.0)	99.70 (-0.1/+0.1)	99.30 (-0.1/+0.1)	97.88 (-0.3/+0.2)	97.21 (-0.3/+0.3)	96.54 (-0.4/+0.3)	96.07 (-0.5/+0.4)	95.89 (-0.6/+0.5)	95.89 (-0.6/+0.5)	95.89 @ 119 mo. (-0.6/+0.5)
	Effective Sample Size	19269	16832	14470	11629	8154	3107	1160	927	685	202

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

CONTAK RENEWAL 3

Models H170/H175

CONTAK RENEWAL 3
Models H170/H175

Worldwide Distribution: 34,000
Worldwide Confirmed Malfunctions: 975

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**859**	**26**	**885**
[7] Shortened replacement window (Advisory issued)	320	13	
[9] Premature battery depletion (Advisory issued)	18	-	
[17] Extended charge time post-mid-life	46	-	
[23] Integrated circuit	1	1	
[28] Capacitor	3	1	
[34] Integrated circuit	2	5	
[50] Capacitor	9	3	
[55] Capacitor	12	-	
[56] Device tones	1	-	
[65] Mid-life display of replacement indicators	203	-	
[70] Integrated circuit	1	1	
[88] Low-voltage capacitor	243	2	
Mechanical	**37**	**16**	**53**
[4] Magnetic reed switch 2010 (Advisory issued)	-	1	
[10] Subpectoral implant (Advisory issued)	-	5	
[15] Magnetic switch (Advisory issued)	-	2	
[29] Header	5	2	
[38] Seal plug	26	4	
[48] Adhesive consistency	-	1	
[73] Setscrew	4	1	
[75] Seal plug	1	-	
[82] Cracked solder joint	1	-	
Software	**3**	**-**	**3**
[64] Memory location	1	-	
[85] Misaligned markers	2	-	
Other	**29**	**5**	**34**
Non-patterned	18	4	
[22] Firmware error	1	-	

[45] Battery depletion	10	1	
WW Confirmed Malfunctions	**928**	**47**	**975**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 RF HE

Model H239

CONTAK RENEWAL 4 RF HE Model H239

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**-**	**6**
[7] Shortened replacement window (Advisory issued)	2	-	
[17] Extended charge time post-mid-life	1	-	
[34] Integrated circuit	2	-	
[88] Low-voltage capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**6**	**0**	**6**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 RF

Models H230/H235

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

CONTAK RENEWAL 4 RF Models H230/H235

Worldwide Distribution: 8,000

Worldwide Confirmed Malfunctions: 25

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**14**	**3**	**17**
[7] Shortened replacement window (Advisory issued)	8	1	
[17] Extended charge time post-mid-life	1	-	
[34] Integrated circuit	1	2	
[55] Capacitor	1	-	
[65] Mid-life display of replacement indicators	1	-	
[88] Low-voltage capacitor	2	-	
Mechanical	**-**	**3**	**3**
[4] Magnetic reed switch 2010 (Advisory issued)	-	2	
[29] Header	-	1	
Software	**-**	**-**	**0**
Other	**2**	**3**	**5**
Non-patterned	1	-	
[45] Battery depletion	1	3	
WW Confirmed Malfunctions	**16**	**9**	**25**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 HE

Models H197/H199

CONTAK RENEWAL 4 HE Models H197/H199

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 146

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**130**	**2**	**132**
[7] Shortened replacement window (Advisory issued)	67	1	
[9] Premature battery depletion (Advisory issued)	2	-	
[17] Extended charge time post-mid-life	10	-	
[28] Capacitor	1	-	
[34] Integrated circuit	1	1	
[50] Capacitor	1	-	
[65] Mid-life display of replacement indicators	26	-	
[66] High-voltage capacitor	1	-	
[88] Low-voltage capacitor	21	-	
Mechanical	**6**	**4**	**10**
[4] Magnetic reed switch 2010 (Advisory issued)	-	1	
[10] Subpectoral implant (Advisory issued)	-	1	
[29] Header	1	1	
[38] Seal plug	2	-	
[73] Setscrew	1	1	
[75] Seal plug	1	-	
[82] Cracked solder joint	1	-	
Software	**-**	**-**	**0**
Other	**3**	**1**	**4**
Non-patterned	1	1	
[45] Battery depletion	2	-	
WW Confirmed Malfunctions	**139**	**7**	**146**

CONTAK RENEWAL 4

Models H190/H195

CONTAK RENEWAL 4
Models H190/H195

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 353

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**309**	**11**	**320**
7 Shortened replacement window (Advisory issued)	159	5	
9 Premature battery depletion (Advisory issued)	14	-	
17 Extended charge time post-mid-life	9	-	
23 Integrated circuit	2	-	
28 Capacitor	-	1	
34 Integrated circuit	3	3	
50 Capacitor	-	1	
55 Capacitor	3	-	
65 Mid-life display of replacement indicators	63	-	
70 Integrated circuit	-	1	
88 Low-voltage capacitor	56	-	
Mechanical	**7**	**14**	**21**
4 Magnetic reed switch 2010 (Advisory issued)	-	3	
10 Subpectoral implant (Advisory issued)	-	7	
15 Magnetic switch (Advisory issued)	-	1	
29 Header	2	-	
38 Seal plug	3	-	
52 Circuit connection	-	1	
73 Setscrew	-	1	
81 Reed switch	1	1	
82 Cracked solder joint	1	-	
Software	**-**	**-**	**0**
Other	**6**	**6**	**12**
Non-patterned	2	3	
45 Battery depletion	4	3	
WW Confirmed Malfunctions	**322**	**31**	**353**

CONTAK RENEWAL 4 AVT HE

Models M177/M179

CONTAK RENEWAL 4 AVT HE Models M177/M179

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 32

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**26**	**-**	**26**
[7] Shortened replacement window (Advisory issued)	17	-	
[9] Premature battery depletion (Advisory issued)	3	-	
[65] Mid-life display of replacement indicators	1	-	
[88] Low-voltage capacitor	5	-	
Mechanical	**-**	**1**	**1**
[10] Subpectoral implant (Advisory issued)	-	1	
Software	**3**	**-**	**3**
[74] Charge time limit	3	-	
Other	**2**	**-**	**2**
Non-patterned	-	-	
[45] Battery depletion	2	-	
WW Confirmed Malfunctions	**31**	**1**	**32**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 AVT

Models M170/M175

CONTAK RENEWAL 4 AVT Models M170/M175

Worldwide Distribution: 2,000

Worldwide Confirmed Malfunctions: 24

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**15**	**-**	**15**
[7] Shortened replacement window (Advisory issued)	8	-	
[17] Extended charge time post-mid-life	1	-	
[28] Capacitor	1	-	
[34] Integrated circuit	1	-	
[55] Capacitor	1	-	
[65] Mid-life display of replacement indicators	1	-	
[88] Low-voltage capacitor	2	-	
Mechanical	**2**	**-**	**2**
[38] Seal plug	1	-	
[73] Setscrew	1	-	
Software	**-**	**-**	**0**
Other	**6**	**1**	**7**
Non-patterned	2	-	
[45] Battery depletion	4	1	
WW Confirmed Malfunctions	**23**	**1**	**24**

More details about malfunctions

References cited in table above

INVIVE

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

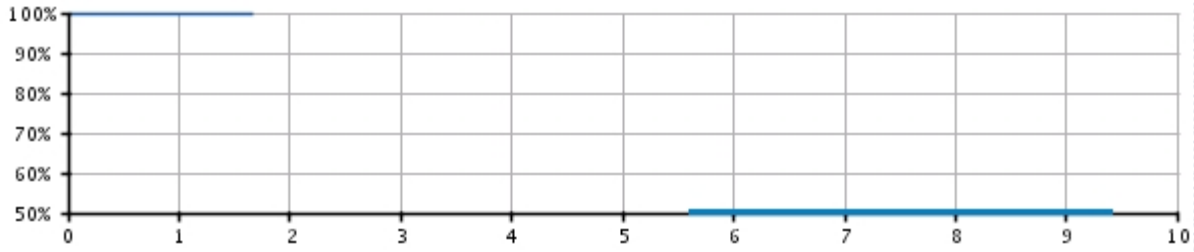
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

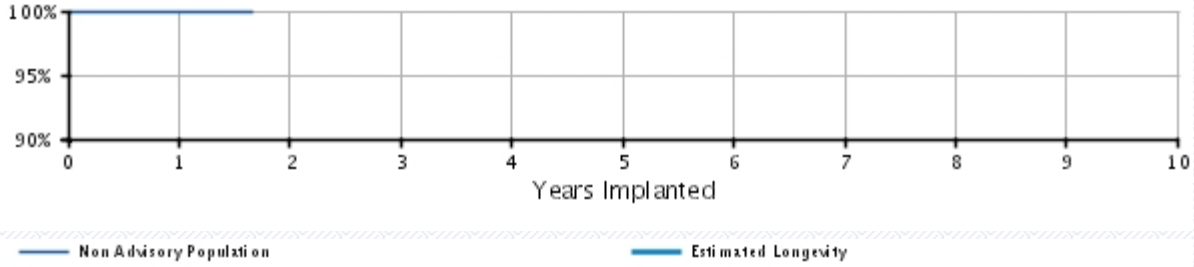
U.S. Registered Implants: 5,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 5,000

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

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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 20 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 20 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1771	285	–	–	–	–	–	–	–	–

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: 12,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

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

CONTAK RENEWAL TR 2 Models H140/H145

Worldwide Distribution: 31,000

Worldwide Confirmed Malfunctions: 28

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[28] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[38] Seal plug	1	-	
[60] Setscrew block	2	-	
[75] Seal plug	1	-	
Software	**12**	**-**	**12**
[47] Memory error	1	-	
[63] Stored EGMs	11	-	
Other	**10**	**1**	**11**
Non-patterned	9	1	
[71] Alert messages	1	-	
WW Confirmed Malfunctions	**27**	**1**	**28**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

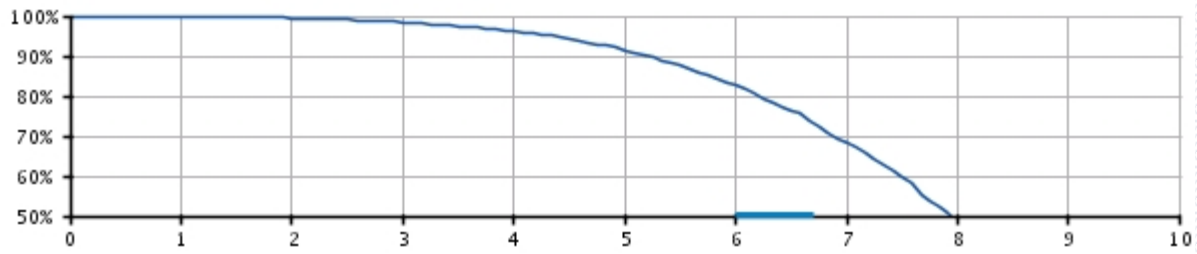
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

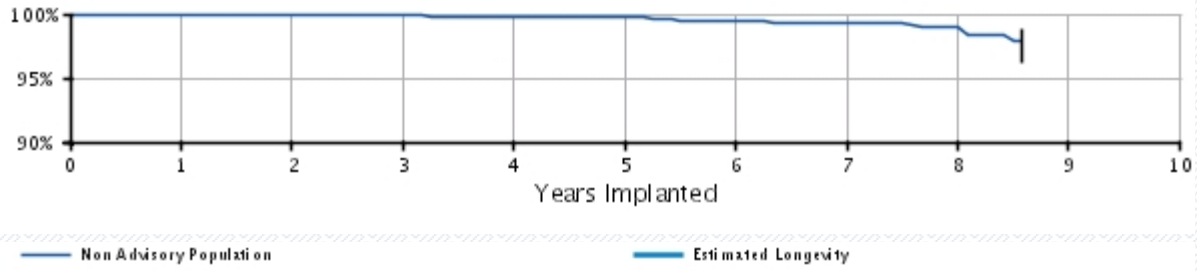
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 1,503
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:43
Without Compromised Therapy:41
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 Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.29 (-0.4/+0.4)	91.41 (-0.7/+0.7)	82.56 (-1.2/+1.1)	68.18 (-1.9/+1.8)	48.45 (-2.6/+2.7)	36.19 @ 103 mo. (-3.0/+3.1)	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.69 (-0.2/+0.1)	99.53 (-0.2/+0.2)	99.37 (-0.3/+0.2)	98.91 (-0.8/+0.5)	97.95 @ 103 mo. (-1.7/+0.9)	–
	Effective Sample Size	15612	13114	9685	6287	3879	2194	1061	404	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

CONTAK RENEWAL TR Models H120/H125

Worldwide Distribution: 19,000

Worldwide Confirmed Malfunctions: 43

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[8] Low-voltage capacitor (Advisory issued)	1	-	
[28] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[38] Seal plug	5	-	
Software	**26**	**-**	**26**
[63] Stored EGMs	26	-	
Other	**9**	**1**	**10**
Non-patterned	7	1	
[71] Alert messages	2	-	
WW Confirmed Malfunctions	**41**	**2**	**43**

More details about malfunctions

References cited in table above

INCEPTA ICD DR 4-Site

Models E162/F162

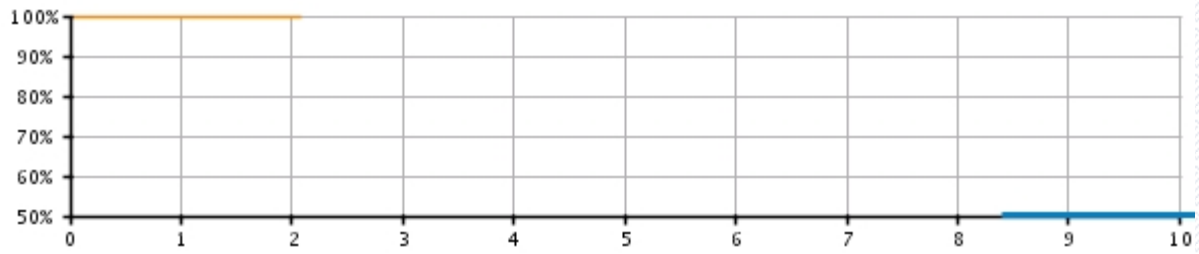
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

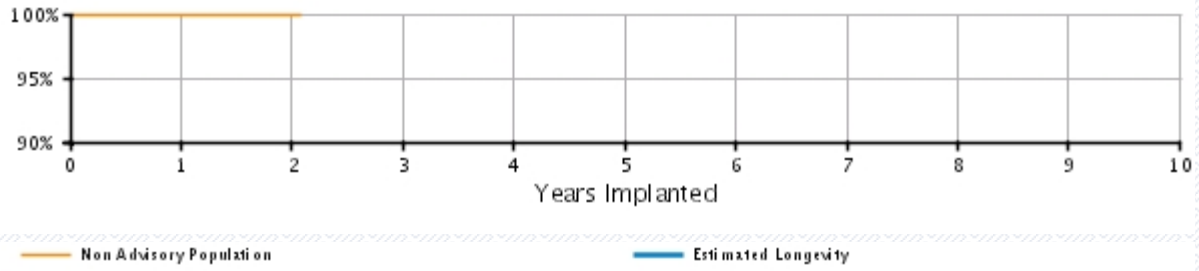
U.S. Registered Implants: 7,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 7,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.92 (-0.2/+0.1)	99.92 @ 25 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	3335	492	298	–	–	–	–	–	–	–

INCEPTA ICD DR 4-Site

Models E162/F162

INCEPTA ICD DR 4-Site Models E162/F162

Worldwide Distribution: 13,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[100] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[83] Transformer	-	1	
Software	**1**	**-**	**1**
[101] Memory errors	1	-	
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

INCEPTA ICD DR

Models E163/F163

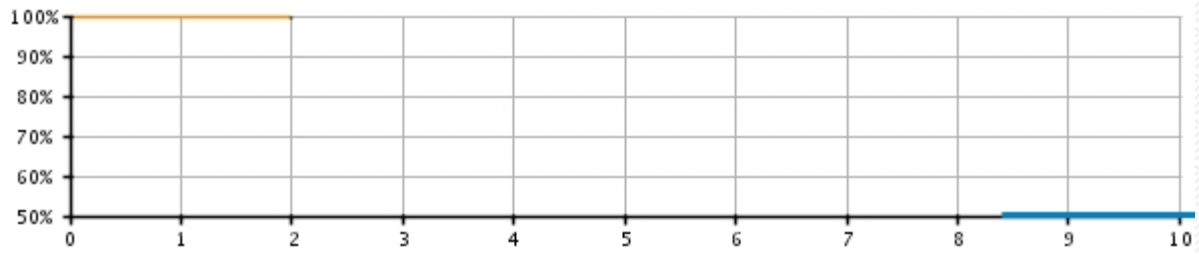
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

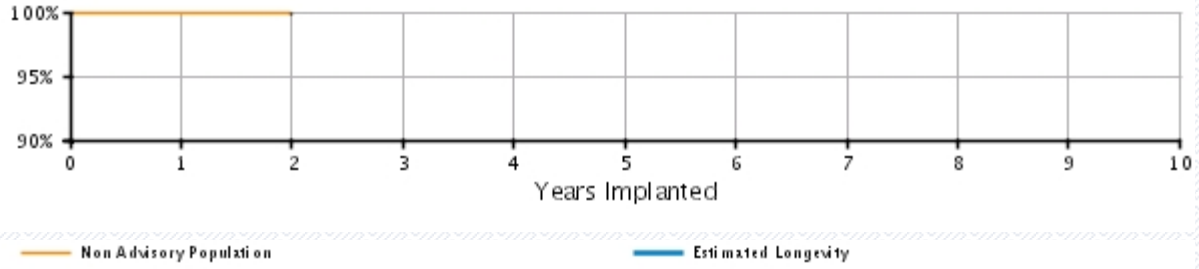
U.S. Registered Implants: 4,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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 Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.1)	99.69 (-1.1/+0.2)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1906	205	–	–	–	–	–	–	–	–

INCEPTA ICD DR

Models E163/F163

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

INCEPTA ICD DR Models E163/F163

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[96] Low-voltage capacitors	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**2**	**0**	**2**

More details about malfunctions

References cited in table above

INCEPTA ICD VR 4-Site

Models E160/F160

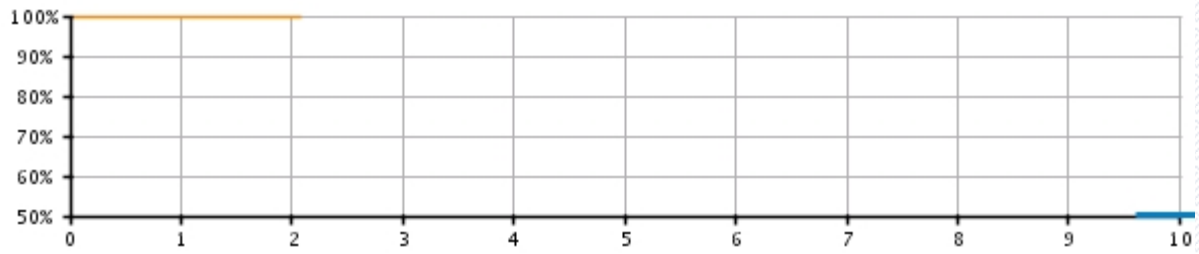
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

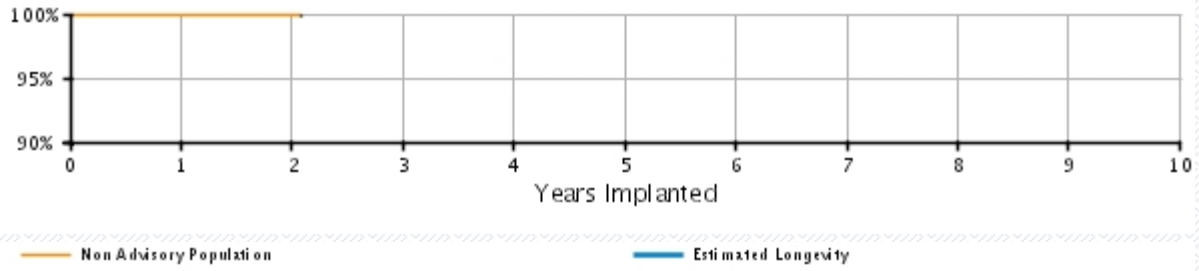
U.S. Registered Implants: 6,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:1
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.85 (-0.2/+0.1)	99.85 (-0.2/+0.1)	99.85 @ 25 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 25 mo. (-0.2/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	2719	382	229	–	–	–	–	–	–	–

INCEPTA ICD VR 4-Site

Models E160/F160

INCEPTA ICD VR 4-Site Models E160/F160

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**1**	**1**
[83] Transformer	-	1	
Software	**1**	**-**	**1**
[101] Memory errors	1	-	
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

INCEPTA ICD VR

Models E161/F161

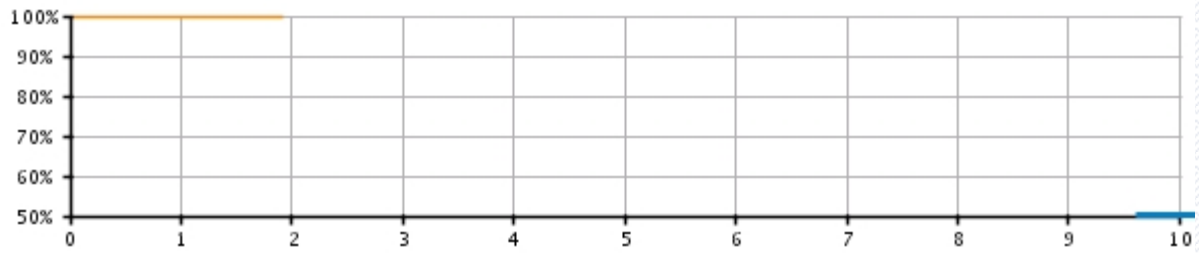
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

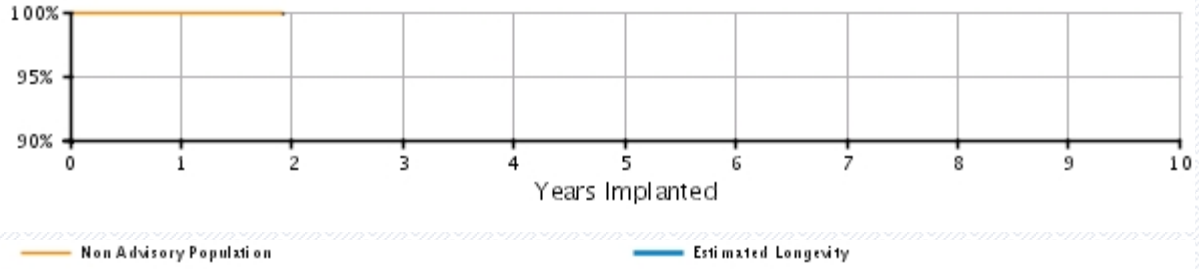
U.S. Registered Implants: 3,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:0
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: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.2/+0.0)	99.96 @ 23 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.2/+0.0)	99.96 @ 23 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1241	232	–	–	–	–	–	–	–	–

INCEPTA ICD VR

Models E161/F161

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

INCEPTA ICD VR
Models E161/F161

Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ENERGEN ICD DR 4-Site

Models E142/F142

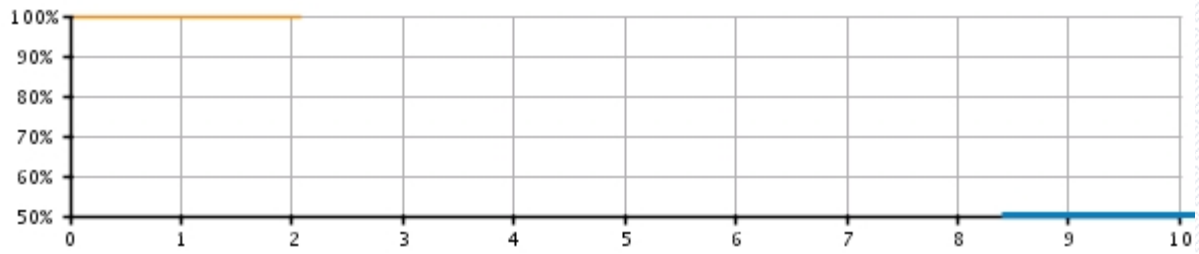
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

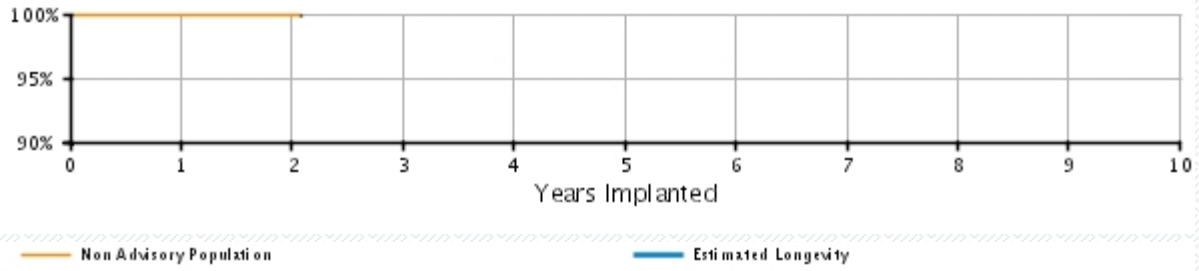
U.S. Registered Implants: 10,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:4
Without Compromised Therapy:2
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 Registered Implants: 10000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.93 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.94 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	5264	692	383	–	–	–	–	–	–	–

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: 15,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**2**	**4**
[96] Low-voltage capacitors	1	-	
[100] Integrated circuit	1	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**3**	**2**	**5**

More details about malfunctions

References cited in table above

ENERGEN ICD DR

Models E143/F143

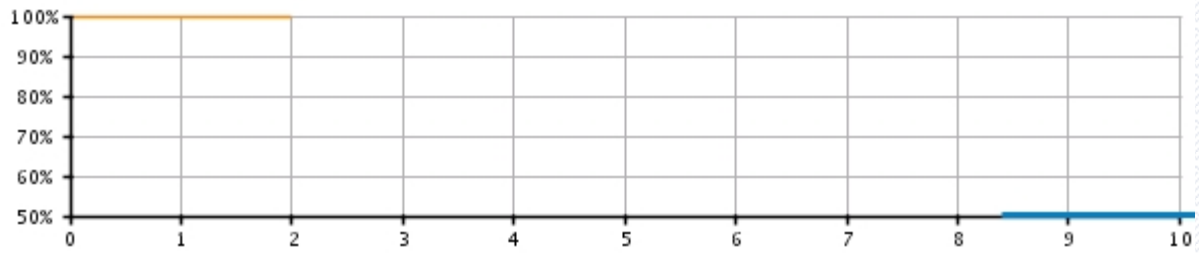
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

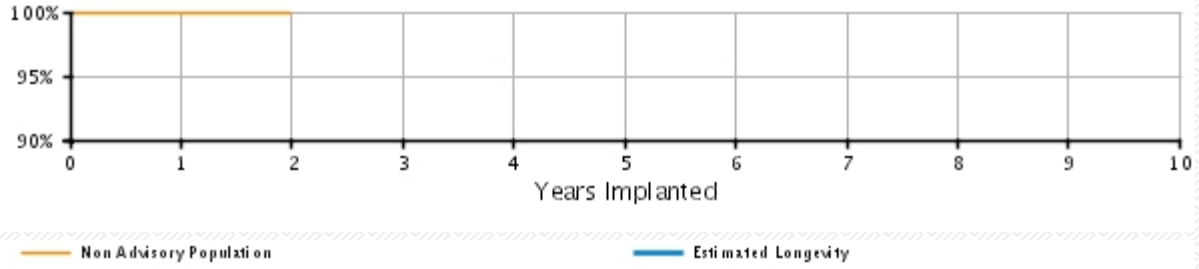
U.S. Registered Implants: 8,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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 Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	3618	331	–	–	–	–	–	–	–	–

ENERGEN ICD DR

Models E143/F143

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

ENERGEN ICD DR Models E143/F143

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[96] Low-voltage capacitors	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**0**	**1**

More details about malfunctions

References cited in table above

ENERGEN ICD VR 4-Site

Models E140/F140

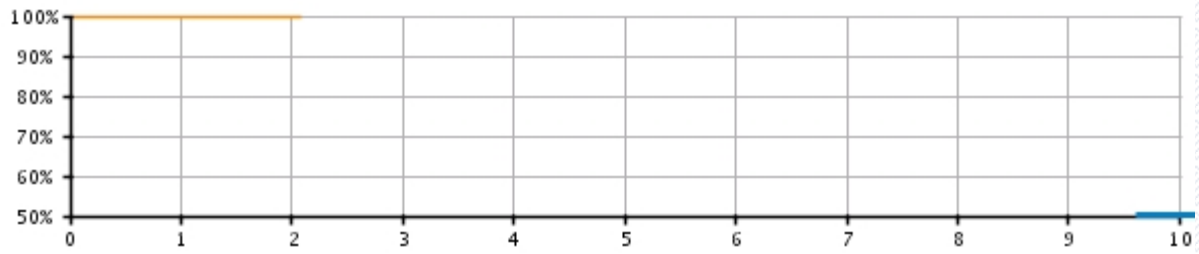
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

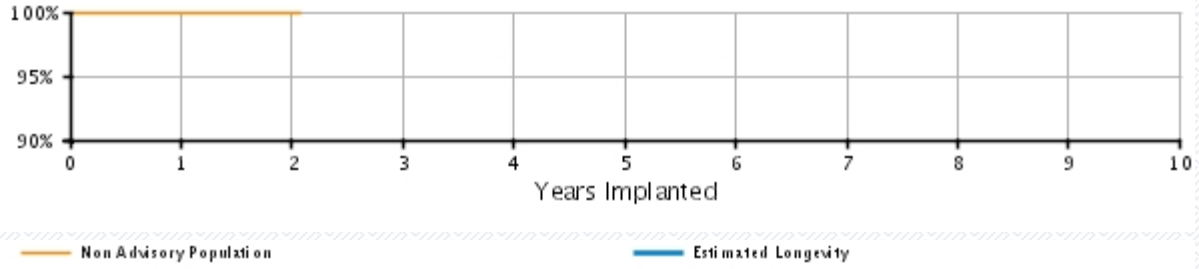
U.S. Registered Implants: 11,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:0
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.88 (-0.2/+0.1)	99.88 @ 25 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	4838	597	338	–	–	–	–	–	–	–

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: 15,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**1**	**1**
[83] Transformer	-	1	
Software	**1**	**-**	**1**
[101] Memory errors	1	-	
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**1**	**2**	**3**

More details about malfunctions

References cited in table above

ENERGEN ICD VR

Models E141/F141

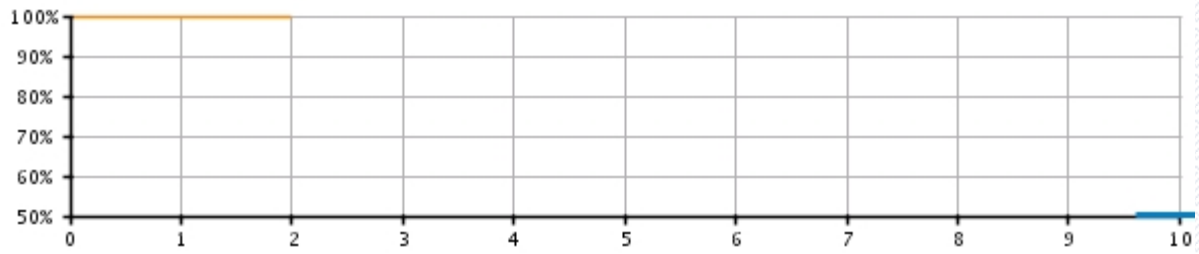
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

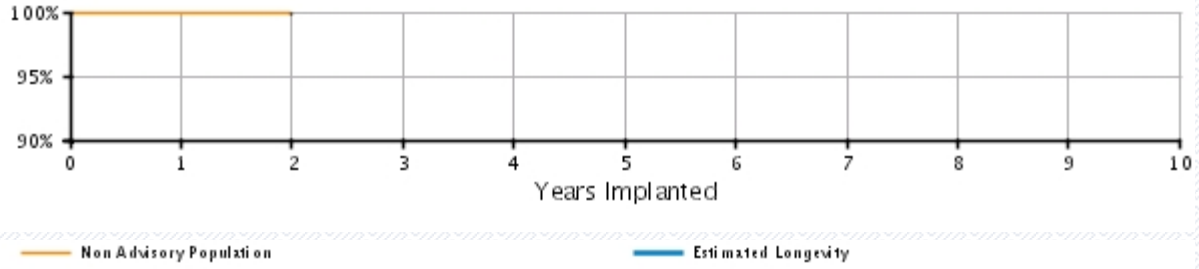
U.S. Registered Implants: 5,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 5,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.87 (-0.2/+0.1)	99.87 (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2621	315	–	–	–	–	–	–	–	–

ENERGEN ICD VR

Models E141/F141

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

ENERGEN ICD VR
Models E141/F141

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[100] Integrated circuit	-	3	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[101] Memory errors	1	-	
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**2**	**3**	**5**

More details about malfunctions

References cited in table above

PUNCTUA ICD DR 4-Site

Models E052/F052

PUNCTUA ICD DR 4-Site Models E052/F052

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

PUNCTUA ICD DR

Models E053/F053

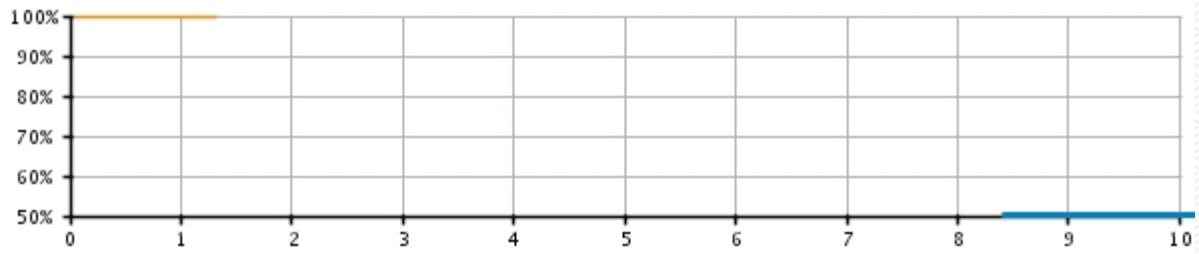
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

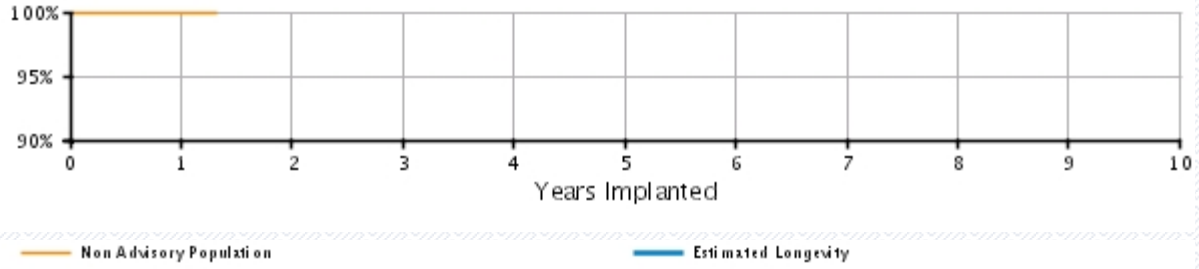
U.S. Registered Implants: 1,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 1,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 16 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 16 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	380	232	–	–	–	–	–	–	–	–

PUNCTUA ICD DR

Models E053/F053

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

PUNCTUA ICD DR Models E053/F053

Worldwide Distribution: 3,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

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: 2,000

Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

PUNCTUA ICD VR

Models E051/F051

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

PUNCTUA ICD VR Models E051/F051

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	**1**	**0**	**1**

More details about malfunctions

References cited in table above

SQ-RX Pulse Generator

Model 1010

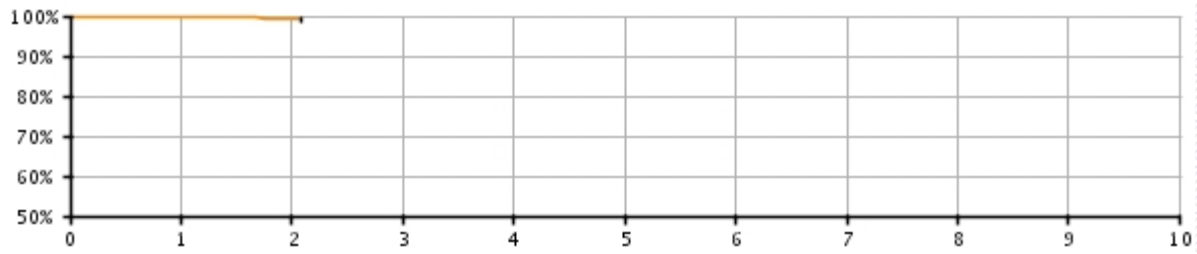
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

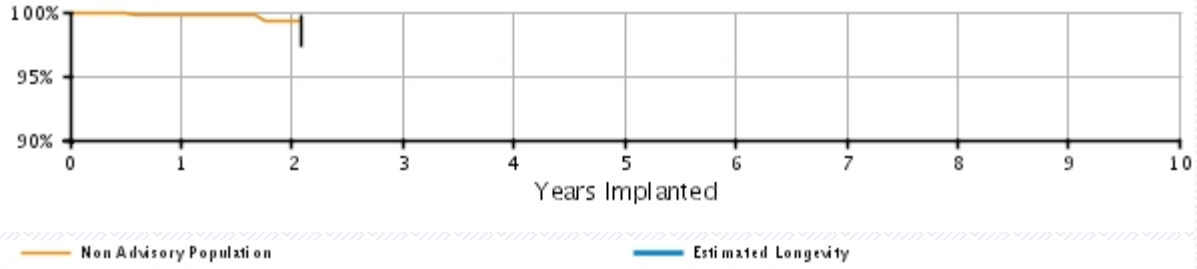
U.S. Approval Date: September 2012

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:8
Without Compromised Therapy:3
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)	99.71 (-0.7/+0.2)	99.24 (-2.0/+0.6)	99.24 @ 25 mo. (-2.0/+0.6)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.71 (-0.7/+0.2)	99.24 (-2.0/+0.6)	99.24 @ 25 mo. (-2.0/+0.6)	–	–	–	–	–	–	–
		–	–	–	–	–	–	–	–	–	–
1-Mar-13 Unintended Fuse	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.										

Activation*	
1-Jun-11 High Cathode Condition *	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.

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

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

SQ-RX Pulse Generator

Model 1010

SQ-RX Pulse Generator Model 1010

Worldwide Confirmed Malfunctions: 37

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[2] Unintended fuse activation 2013 (Advisory issued)	-	3	
Mechanical	**10**	**9**	**19**
[3] High cathode condition 2011 (Advisory issued)	1	2	
[105] Battery depletion	9	7	
Software	**2**	**-**	**2**
[107] Unintended Battery Depletion Alert	2	-	
Other	**8**	**5**	**13**
Non-patterned	7	4	
[106] Telemetry	1	1	
WW Confirmed Malfunctions	**20**	**17**	**37**

More details about malfunctions

References cited in table above

TELIGEN DR

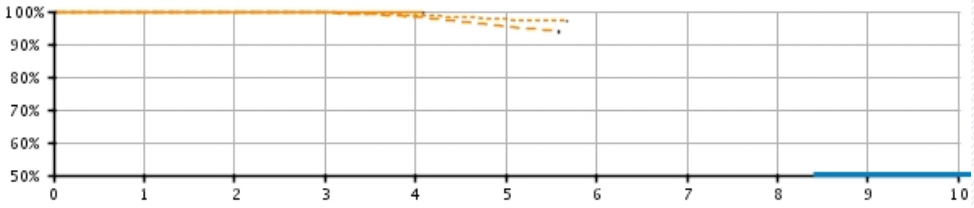
Models E110/E111/F110/F111

U.S. Summary

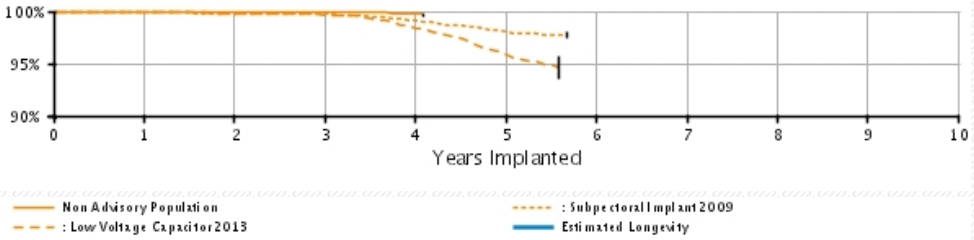
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 49,000

U.S. Normal Battery Depletions: 89
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:373
Without Compromised Therapy:302
With Compromised Therapy:71

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: 33000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.54 (-0.3/+0.2)	99.54 @ 49 mo. (-0.3/+0.2)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.74 (-0.3/+0.1)	99.74 @ 49 mo. (-0.3/+0.1)	–	–	–	–	–
	Effective Sample Size	29281	25380	13262	651	339	–	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.1)	98.89 (-0.2/+0.1)	97.62 (-0.3/+0.2)	97.13 @ 68 mo. (-0.4/+0.4)	–	–	–	–
	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)	98.04 (-0.3/+0.2)	97.68 @ 68 mo. (-0.3/+0.3)	–	–	–	–
	Effective Sample Size	26751	23506	20679	18053	6433	264	–	–	–	–
Low Voltage Capacitor 2013* Registered Implants: 11,000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.56 (-0.2/+0.1)	98.19 (-0.4/+0.3)	95.35 (-0.7/+0.6)	93.75 @ 67 mo. (-1.4/+1.1)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.67 (-0.1/+0.1)	98.43 (-0.3/+0.3)	95.88 (-0.5/+0.5)	94.67 @ 67 mo. (-1.2/+1.0)	–	–	–	–
	Effective Sample Size	9986	8790	7723	6136	2300	315	–	–	–	–

*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

TELIGEN DR
Models E110/E111/F110/F111

Worldwide Distribution: 90,000
Worldwide Confirmed Malfunctions: 509

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**370**	**41**	**411**
[1] Low Voltage Capacitor 2013 (Advisory issued)	252	10	
[89] Safety Core-electrocautery	3	-	
[91] High-voltage capacitor	1	5	
[96] Low-voltage capacitors	5	-	
[100] Integrated circuit	13	16	
[103] Battery	56	10	
[104] Low-voltage capacitor	40	-	
Mechanical	**15**	**47**	**62**
[5] Subpectoral implant 2009 (Advisory issued)	3	5	
[83] Transformer	-	20	
[86] Seal plug	2	-	
[87] Difficulty securing lead	8	8	
[94] Header contacts	1	11	
[109] Header	1	3	
Software	**14**	**-**	**14**
[98] Alert messages not displayed post-EOL	3	-	
[101] Memory errors	11	-	
Other	**16**	**6**	**22**
Non-patterned	16	6	
WW Confirmed Malfunctions	**415**	**94**	**509**

More details about malfunctions

References cited in table above

TELIGEN VR

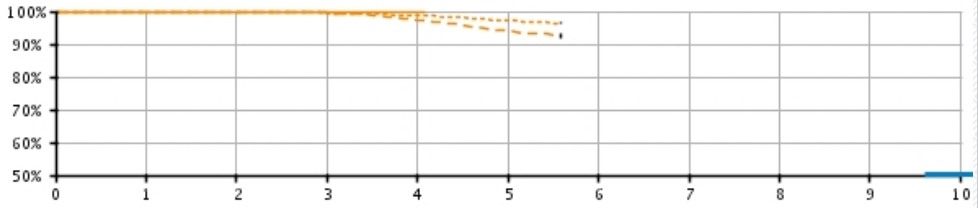
Models E102/E103/F102/F103

U.S. Summary

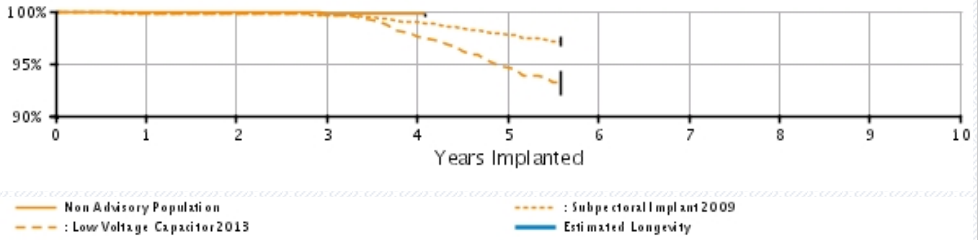
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 28,000

U.S. Normal Battery Depletions: 45
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:261
Without Compromised Therapy:205
With Compromised Therapy:56

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: 21000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.85 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.2/+0.1)	99.63 @ 49 mo. (-0.2/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.72 (-0.2/+0.1)	99.72 @ 49 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	18578	16074	7126	374	223	–	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 16000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.1)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.2)	97.24 (-0.5/+0.4)	96.50 @ 67 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)	98.94 (-0.2/+0.2)	97.73 (-0.4/+0.4)	97.08 @ 67 mo. (-0.5/+0.5)	–	–	–	–
	Effective Sample Size	13682	12001	10520	9149	3351	432	–	–	–	–
Low Voltage Capacitor 2013* Registered Implants: 6,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.2/+0.1)	99.74 (-0.2/+0.1)	99.53 (-0.2/+0.1)	97.26 (-0.6/+0.5)	94.10 (-1.0/+0.8)	92.72 @ 67 mo. (-1.6/+1.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.84 (-0.1/+0.1)	99.82 (-0.2/+0.1)	99.68 (-0.2/+0.1)	97.61 (-0.6/+0.5)	94.64 (-1.3/+1.0)	93.26 @ 67 mo. (-1.3/+1.0)	–	–	–	–
	Effective Sample Size	5226	4585	4025	3126	1093	209	–	–	–	–

*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

TELIGEN VR
Models E102/E103/F102/F103

Worldwide Distribution: 65,000
Worldwide Confirmed Malfunctions: 414

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**292**	**23**	**315**
[1] Low Voltage Capacitor 2013 (Advisory issued)	181	3	
[89] Safety Core-electrocautery	1	1	
[91] High-voltage capacitor	-	2	
[96] Low-voltage capacitors	4	-	
[100] Integrated circuit	6	12	
[103] Battery	64	3	
[104] Low-voltage capacitor	36	2	
Mechanical	**15**	**58**	**73**
[5] Subpectoral implant 2009 (Advisory issued)	4	12	
[51] Transformer	-	1	
[83] Transformer	-	14	
[86] Seal plug	1	-	
[87] Difficulty securing lead	-	10	
[94] Header contacts	9	15	
[109] Header	1	6	
Software	**12**	**-**	**12**
[6] Respiratory Sensor Oversensing (Advisory issued)	1	-	
[98] Alert messages not displayed post-EOL	4	-	
[101] Memory errors	7	-	
Other	**7**	**7**	**14**
Non-patterned	7	7	
WW Confirmed Malfunctions	**326**	**88**	**414**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

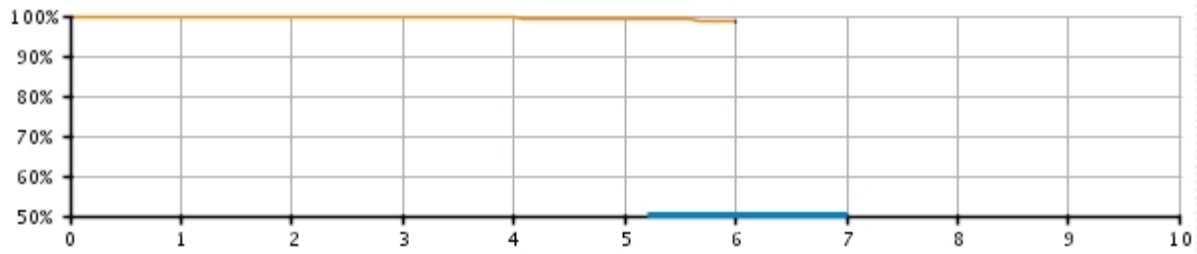
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

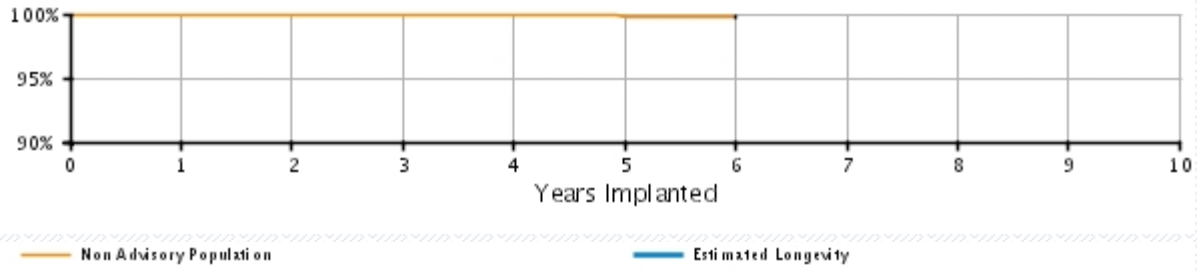
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 32
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.53 (-0.2/+0.2)	99.36 (-0.3/+0.2)	98.68 (-0.6/+0.4)	–	–	–	–
	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)	99.82 (-0.2/+0.1)	99.82 (-0.2/+0.1)	–	–	–	–
	Effective Sample Size	6164	5397	4616	3785	2796	324	–	–	–	–

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: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**-**	**5**
[28] Capacitor	1	-	
[34] Integrated circuit	2	-	
[104] Low-voltage capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	-	
[45] Battery depletion	-	1	
WW Confirmed Malfunctions	**6**	**1**	**7**

More details about malfunctions

References cited in table above

VITALITY 2 EL DR

Model T167

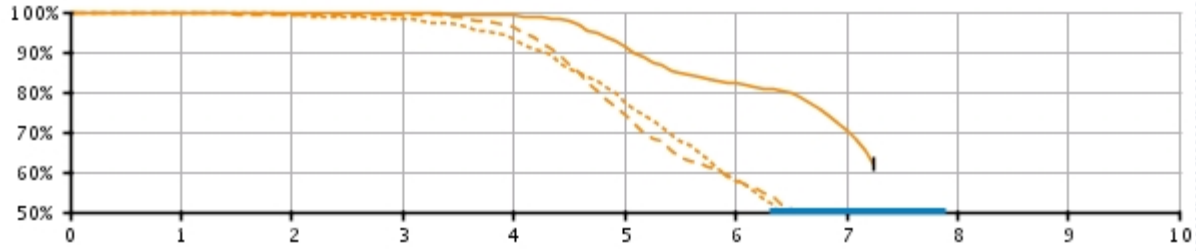
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

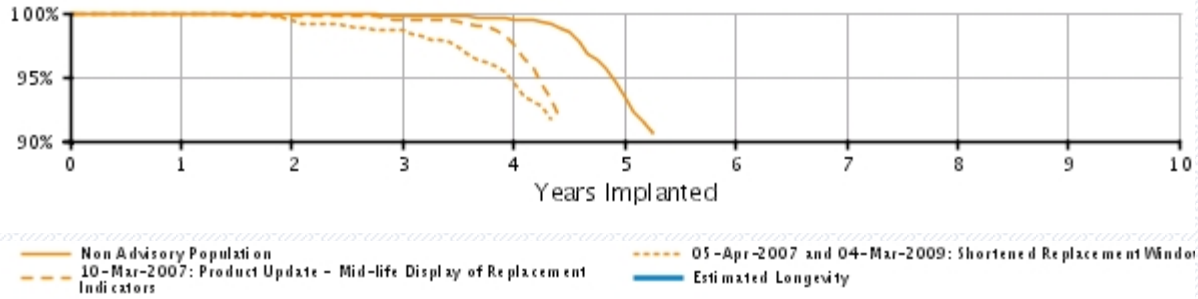
U.S. Registered Implants: 8,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 1,286
U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Malfunctions:754

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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.66 (-0.2/+0.1)	99.01 (-0.4/+0.3)	91.23 (-1.1/+1.0)	82.22 (-1.6/+1.5)	70.15 (-2.7/+2.5)	61.97 @ 87 mo. (-3.5/+3.4)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.90 (-0.2/+0.1)	99.82 (-0.2/+0.1)	99.50 (-0.3/+0.2)	93.36 (-1.0/+0.9)	87.30 (-1.4/+1.3)	86.45 (-1.5/+1.4)	86.45 @ 87 mo. (-1.5/+1.4)	–	–
	Effective Sample Size	4363	3832	3362	2913	2340	1459	407	229	–	–
05-Apr-07 and 04-Mar-09	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.22 (-0.6/+0.3)	98.37 (-0.8/+0.5)	93.39 (-1.5/+1.2)	77.47 (-2.6/+2.4)	57.97 (-3.2/+3.1)	31.95 (-3.2/+3.4)	28.87 @ 85 mo. (-3.1/+3.3)	–	–

Shortened Replacement Window* Registered Implants: 2000											
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.41 (-0.5/+0.3)	98.63 (-0.7/+0.5)	94.61 (-1.4/+1.1)	83.60 (-2.4/+2.1)	75.90 (-2.8/+2.6)	73.79 (-3.1/+2.9)	73.79 @ 85 mo. (-3.1/+2.9)	–	–
	Effective Sample Size	1699	1489	1289	1076	781	477	222	207	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.40 (-0.7/+0.3)	99.18 (-0.8/+0.4)	96.23 (-1.5/+1.1)	74.33 (-3.3/+3.1)	58.01 (-3.8/+3.7)	42.66 @ 82 mo. (-4.0/+4.1)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.5/+0.1)	99.74 (-0.6/+0.2)	99.52 (-0.7/+0.3)	97.51 (-1.3/+0.9)	81.03 (-3.1/+2.8)	71.00 (-3.7/+3.4)	70.76 @ 82 mo. (-3.7/+3.5)	–	–	–
	Effective Sample Size	1171	1024	899	763	501	320	207	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL DR

Model T167

VITALITY 2 EL DR
Model T167

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1028

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**991**	**9**	**1000**
[7] Shortened replacement window (Advisory issued)	143	2	
[17] Extended charge time post-mid-life	13	-	
[28] Capacitor	1	-	
[34] Integrated circuit	-	4	
[50] Capacitor	1	-	
[65] Mid-life display of replacement indicators	792	-	
[66] High-voltage capacitor	-	2	
[70] Integrated circuit	-	1	
[88] Low-voltage capacitor	41	-	
Mechanical	**7**	**3**	**10**
[10] Subpectoral implant (Advisory issued)	1	1	
[29] Header	1	-	
[38] Seal plug	5	1	
[83] Transformer	-	1	
Software	**7**	**1**	**8**
[64] Memory location	1	1	
[85] Misaligned markers	6	-	
Other	**3**	**7**	**10**
Non-patterned	2	3	
[22] Firmware error	1	4	
WW Confirmed Malfunctions	**1008**	**20**	**1028**

More details about malfunctions

References cited in table above

VITALITY 2 DR

Model T165

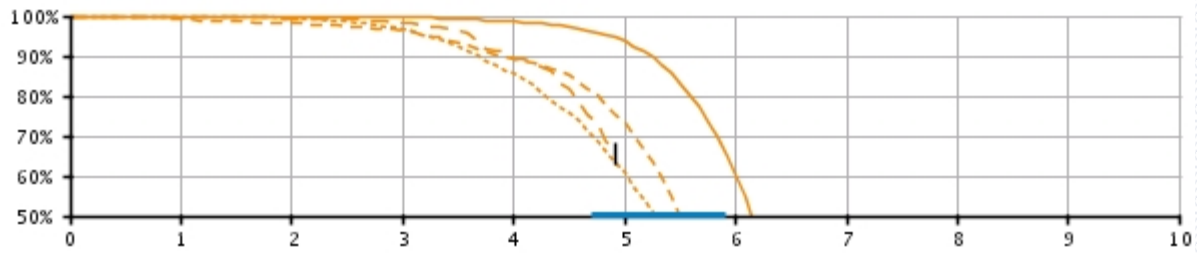
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

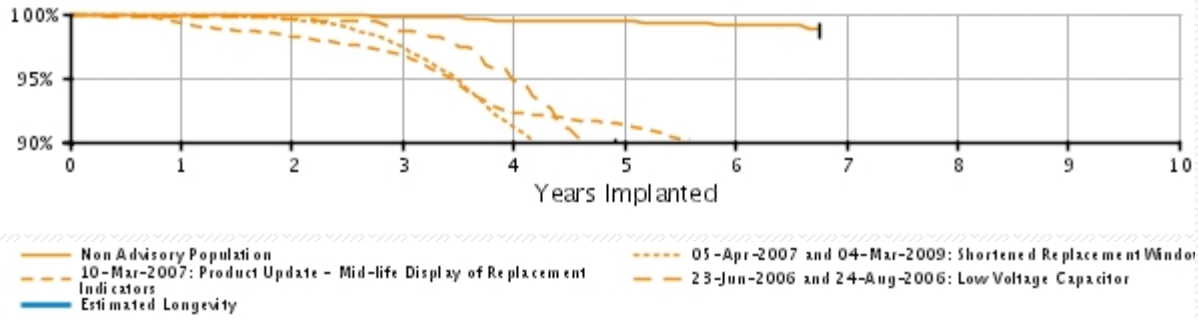
U.S. Registered Implants: 31,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 9,851
U.S. Unconfirmed Reports of Premature Battery Depletion : 78
U.S. Malfunctions:1139
Without Compromised Therapy:1075
With Compromised Therapy:64

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: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.79 (-0.1/+0.1)	99.60 (-0.1/+0.1)	98.58 (-0.2/+0.2)	93.63 (-0.5/+0.5)	60.03 (-1.2/+1.2)	12.63 @ 81 mo. (-1.2/+1.4)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.17 (-0.2/+0.2)	98.79 @ 81 mo. (-0.8/+0.5)	–	–	–
	Effective Sample Size	15245	13386	11679	9923	7960	3509	244	–	–	–

05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.39 (-0.2/+0.2)	96.63 (-0.5/+0.4)	85.51 (-0.9/+0.9)	60.68 (-1.4/+1.4)	17.95 (-1.2/+1.2)	6.86 @ 77 mo. (-0.8/+0.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.56 (-0.2/+0.1)	97.37 (-0.4/+0.4)	91.21 (-0.8/+0.7)	86.78 (-1.0/+0.9)	84.76 (-1.2/+1.1)	84.21 @ 77 mo. (-1.4/+1.3)	–	–	–
	Effective Sample Size	7845	6863	5806	4452	2723	689	231	–	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.30 (-0.3/+0.2)	98.16 (-0.4/+0.3)	96.34 (-0.6/+0.5)	89.38 (-1.0/+0.9)	73.15 (-1.6/+1.5)	22.63 (-1.6/+1.7)	9.13 @ 76 mo. (-1.1/+1.3)	–	–	–
	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)	91.26 (-1.0/+0.9)	89.30 (-1.2/+1.1)	87.88 @ 76 mo. (-1.8/+1.6)	–	–	–
	Effective Sample Size	4991	4338	3718	2978	2096	546	203	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	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)	–	–	–	–	–
	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	203	–	–	–	–	–
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

VITALITY 2 DR
Model T165

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 1369

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1265**	**46**	**1311**
[7] Shortened replacement window (Advisory issued)	477	24	
[8] Low-voltage capacitor (Advisory issued)	1	-	
[9] Premature battery depletion (Advisory issued)	163	1	
[17] Extended charge time post-mid-life	100	1	
[23] Integrated circuit	1	1	
[25] Reconfirmation after charge	1	-	
[28] Capacitor	1	1	
[34] Integrated circuit	7	11	
[50] Capacitor	3	1	
[55] Capacitor	4	-	
[56] Device tones	1	-	
[65] Mid-life display of replacement indicators	267	-	
[66] High-voltage capacitor	4	1	
[70] Integrated circuit	1	-	
[80] Logic errors	-	3	
[88] Low-voltage capacitor	234	2	
Mechanical	**7**	**6**	**13**
[38] Seal plug	4	3	
[51] Transformer	-	1	
[75] Seal plug	2	-	
[108] Solder joint	1	2	
Software	**2**	**2**	**4**
[62] Memory location	-	2	
[64] Memory location	1	-	
[85] Misaligned markers	1	-	
Other	**19**	**22**	**41**
Non-patterned	12	8	
[22] Firmware error	5	8	
[31] Battery depletion	2	5	
[92]			

Magnet rate	-	1	
WW Confirmed Malfunctions	**1293**	**76**	**1369**

More details about malfunctions

References cited in table above

VITALITY 2 EL VR

Model T177

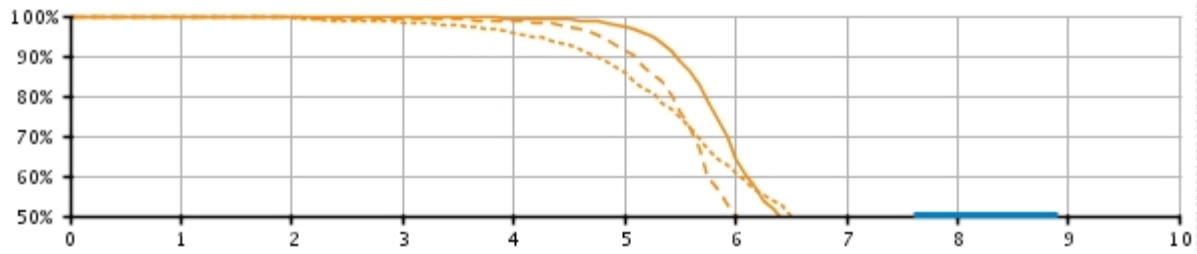
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

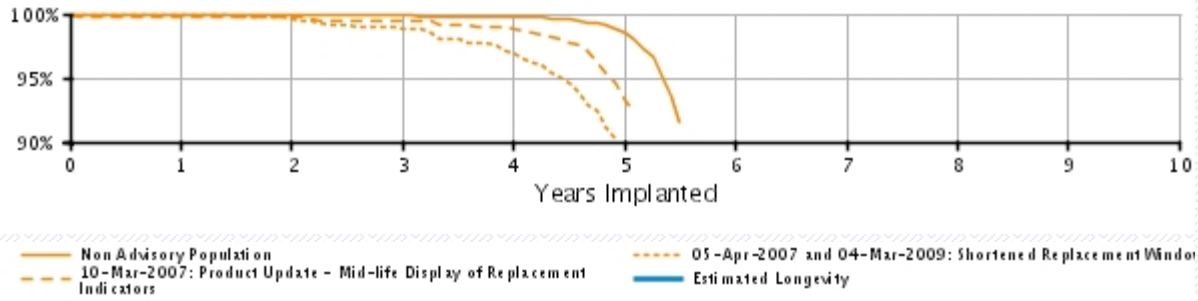
U.S. Registered Implants: 7,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 774
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:1143
Without Compromised Therapy:1132
With Compromised Therapy:11

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 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)	97.32 (-0.8/+0.6)	64.32 (-2.4/+2.3)	44.38 @ 83 mo. (-2.9/+3.0)	–	–	–
	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)	98.45 (-0.6/+0.4)	72.05 (-2.3/+2.2)	56.42 @ 83 mo. (-3.1/+3.0)	–	–	–
	Effective Sample Size	3631	3176	2766	2389	2003	934	230	–	–	–

05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.48 (-0.8/+0.5)	95.88 (-1.2/+1.0)	85.72 (-2.2/+2.0)	60.99 (-3.2/+3.2)	41.55 (-3.4/+3.5)	33.98 @ 88 mo. (-3.4/+3.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.84 (-0.7/+0.4)	97.00 (-1.1/+0.8)	88.94 (-2.1/+1.8)	68.72 (-3.2/+3.0)	61.34 (-3.5/+3.4)	60.81 @ 88 mo. (-3.6/+3.4)	–	–
	Effective Sample Size	1687	1474	1279	1087	822	496	278	202	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.48 (-4.4/+4.4)	45.30 @ 74 mo. (-4.4/+4.5)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.72 (-0.6/+0.2)	99.72 (-0.6/+0.2)	99.48 (-0.7/+0.3)	98.90 (-1.0/+0.5)	93.22 (-2.3/+1.8)	59.83 (-4.6/+4.4)	54.67 @ 74 mo. (-4.7/+4.6)	–	–	–
	Effective Sample Size	975	854	747	647	527	240	209	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL VR

Model T177

VITALITY 2 EL VR
Model T177

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 1682

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1643**	**6**	**1649**
[7] Shortened replacement window (Advisory issued)	138	1	
[8] Low-voltage capacitor (Advisory issued)	2	1	
[17] Extended charge time post-mid-life	11	1	
[34] Integrated circuit	-	3	
[50] Capacitor	1	-	
[55] Capacitor	2	-	
[65] Mid-life display of replacement indicators	1422	-	
[66] High-voltage capacitor	2	-	
[88] Low-voltage capacitor	65	-	
Mechanical	**2**	**8**	**10**
[10] Subpectoral implant (Advisory issued)	-	5	
[29] Header	-	1	
[38] Seal plug	1	-	
[68] Sensing	1	-	
[83] Transformer	-	2	
Software	**-**	**2**	**2**
[62] Memory location	-	1	
[64] Memory location	-	1	
Other	**12**	**9**	**21**
Non-patterned	12	7	
[31] Battery depletion	-	2	
WW Confirmed Malfunctions	**1657**	**25**	**1682**

More details about malfunctions

VITALITY 2 VR

Model T175

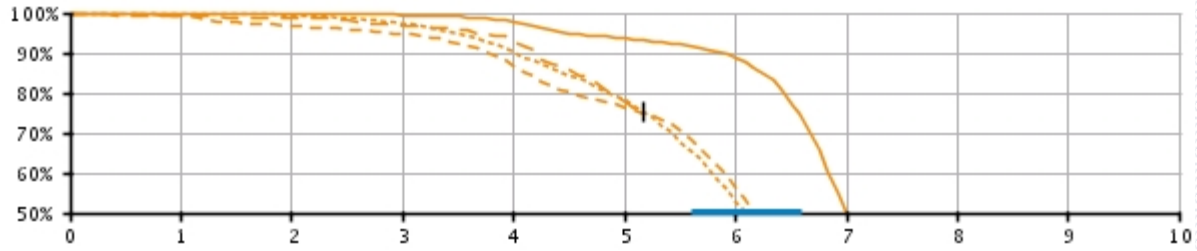
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

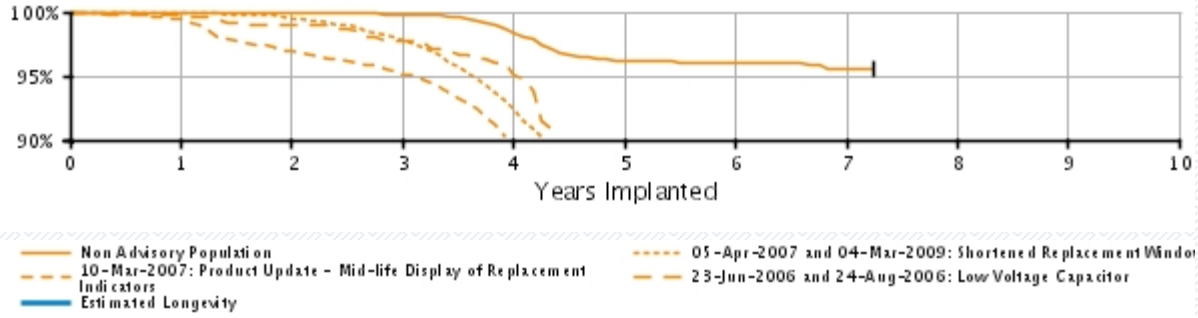
U.S. Registered Implants: 21,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 4,368
U.S. Unconfirmed Reports of Premature Battery Depletion : 33
U.S. Malfunctions:1239
Without Compromised Therapy:1214
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)	97.57 (-0.4/+0.3)	93.63 (-0.6/+0.6)	88.61 (-0.9/+0.9)	49.11 (-2.6/+2.6)	27.54 @ 87 mo. (-2.9/+3.1)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	98.43 (-0.3/+0.3)	96.22 (-0.5/+0.5)	96.02 (-0.5/+0.5)	95.62 (-0.7/+0.6)	95.62 @ 87 mo. (-0.7/+0.6)	–	–
	Effective Sample Size	9497	8337	7160	6014	4831	3078	492	206	–	–

05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.43 (-0.3/+0.2)	97.47 (-0.5/+0.4)	90.30 (-1.0/+0.9)	78.08 (-1.4/+1.3)	52.63 (-1.8/+1.8)	17.19 (-1.5/+1.6)	9.40 @ 87 mo. (-1.2/+1.4)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.40 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.21 (-1.5/+1.4)	83.21 @ 87 mo. (-1.5/+1.4)	–	–
	Effective Sample Size	5391	4691	4023	3238	2377	1378	369	204	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.34 (-0.3/+0.2)	96.85 (-0.6/+0.5)	94.72 (-0.8/+0.7)	86.62 (-1.3/+1.2)	76.43 (-1.7/+1.6)	56.33 (-2.1/+2.1)	16.19 (-1.7/+1.9)	13.87 @ 85 mo. (-1.6/+1.8)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.39 (-0.3/+0.2)	96.95 (-0.6/+0.5)	95.13 (-0.8/+0.7)	89.20 (-1.2/+1.1)	84.05 (-1.4/+1.3)	83.38 (-1.5/+1.4)	81.62 (-1.8/+1.7)	81.62 @ 85 mo. (-1.8/+1.7)	–	–
	Effective Sample Size	3906	3330	2851	2263	1681	1062	249	207	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.47 (-1.1/+0.4)	98.64 (-1.5/+0.7)	96.88 (-2.1/+1.3)	92.79 (-3.1/+2.2)	77.91 (-4.9/+4.3)	75.29 @ 62 mo. (-5.2/+4.5)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.82 (-1.1/+0.2)	98.99 (-1.4/+0.6)	97.73 (-1.9/+1.0)	95.08 (-2.7/+1.8)	84.94 (-4.5/+3.6)	84.94 @ 62 mo. (-4.5/+3.6)	–	–	–	–
	Effective Sample Size	504	432	366	307	215	201	–	–	–	–
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 VR

Model T175

VITALITY 2 VR
Model T175

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 1578

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1526**	**26**	**1552**
[7] Shortened replacement window (Advisory issued)	347	9	
[8] Low-voltage capacitor (Advisory issued)	-	1	
[9] Premature battery depletion (Advisory issued)	219	6	
[17] Extended charge time post-mid-life	61	-	
[23] Integrated circuit	-	1	
[28] Capacitor	1	-	
[34] Integrated circuit	4	7	
[50] Capacitor	1	-	
[55] Capacitor	4	-	
[65] Mid-life display of replacement indicators	769	-	
[66] High-voltage capacitor	-	1	
[88] Low-voltage capacitor	120	1	
Mechanical	**2**	**1**	**3**
[38] Seal plug	2	1	
Software	**-**	**1**	**1**
[64] Memory location	-	1	
Other	**16**	**6**	**22**
Non-patterned	14	6	
[31] Battery depletion	2	-	
WW Confirmed Malfunctions	**1544**	**34**	**1578**

More details about malfunctions

References cited in table above

ADVANTIO DR

Models J063/J066/K063/K066/K083

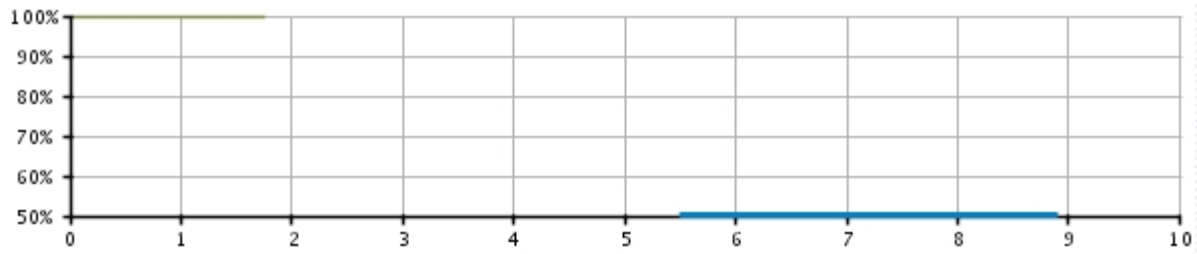
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

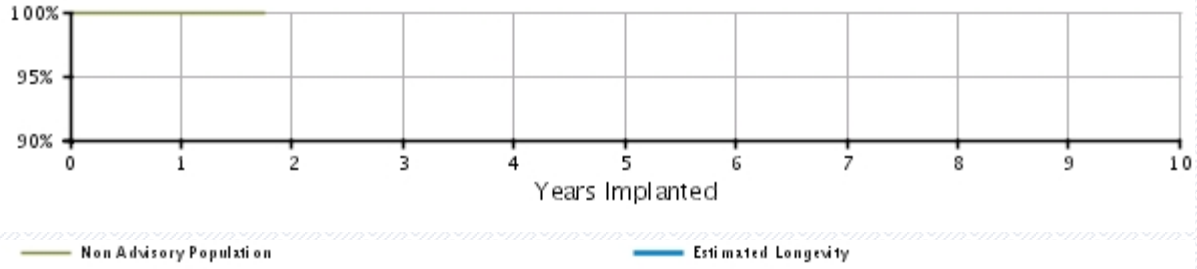
U.S. Registered Implants: 32,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 31,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:5
Without Compromised Therapy:5
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.95 @ 21 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.97 @ 21 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	12717	698	–	–	–	–	–	–	–	–

ADVANTIO DR

Models J063/J066/K063/K066/K083

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

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

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[96] Low-voltage capacitors	1	-	
[100] Integrated circuit	1	-	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[101] Memory errors	2	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**6**	**0**	**6**

More details about malfunctions

References cited in table above

ADVANTIO EL DR

Models J064/K064/K067/K084

ADVANTIO EL DR
Models J064/K064/K067/K084

Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[96] Low-voltage capacitors	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ADVANTIO SR

Models J062/J065/K062/K065/K082

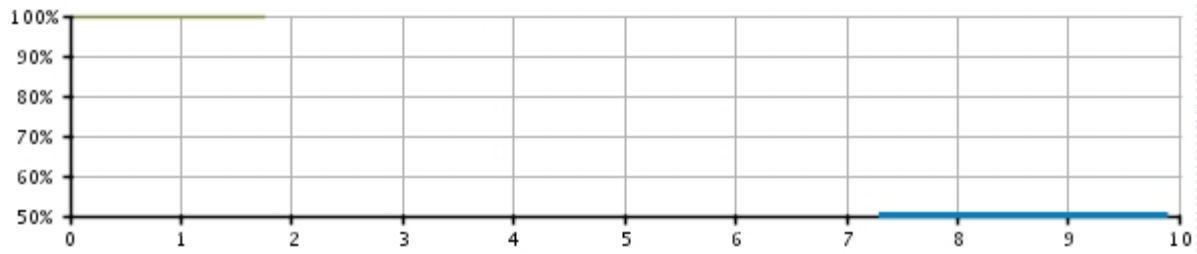
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

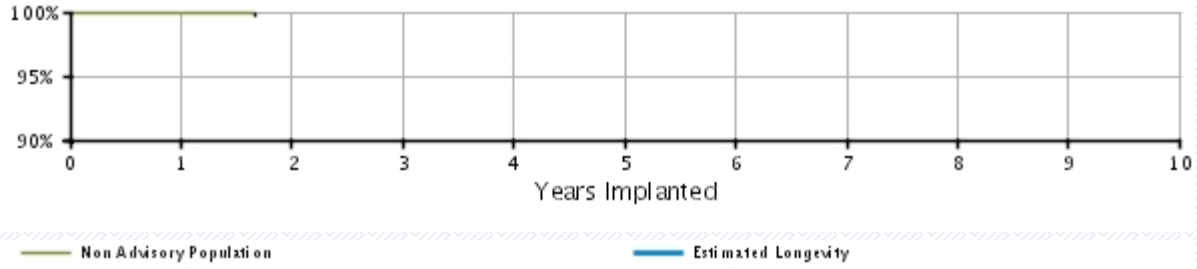
U.S. Registered Implants: 7,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions: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 Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.94 @ 20 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.96 @ 20 mo. (-0.3/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2617	309	–	–	–	–	–	–	–	–

ADVANTIO SR

Models J062/J065/K062/K065/K082

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

ADVANTIO SR
Models J062/J065/K062/K065/K082

Worldwide Distribution: 15,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[96] Low-voltage capacitors	1	-	
[100] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

INGENIO DR

Models J173/J176/K173/K176/K183

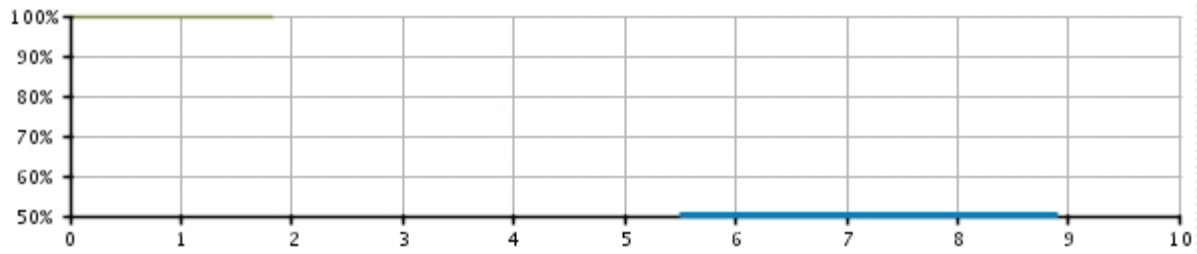
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

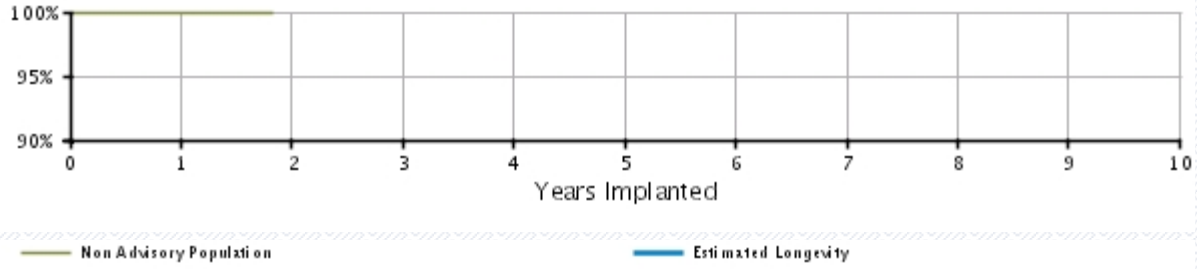
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 36,000

U.S. Normal Battery Depletions: 6
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:4
Without Compromised Therapy:4
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.94 @ 22 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 @ 22 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	13116	380	–	–	–	–	–	–	–	–

INGENIO DR

Models J173/J176/K173/K176/K183

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

INGENIO DR
Models J173/J176/K173/K176/K183

Worldwide Distribution: 61,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[96] Low-voltage capacitors	1	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[101] Memory errors	1	-	
Other	**3**	**-**	**3**
Non-patterned	3	-	
WW Confirmed Malfunctions	**5**	**0**	**5**

More details about malfunctions

References cited in table above

INGENIO EL DR

Models J174/J177/K174/K177/K184

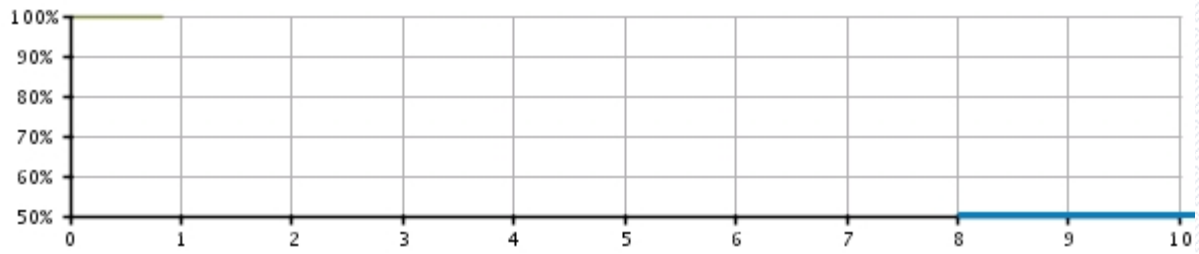
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

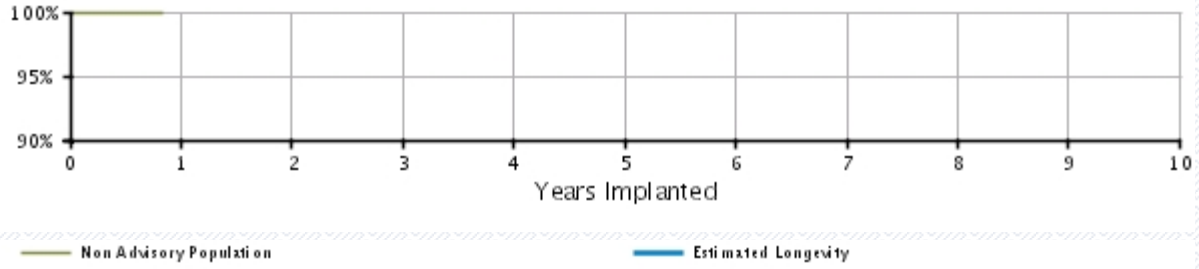
U.S. Registered Implants: 2,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 @ 10 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 @ 10 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	220	–	–	–	–	–	–	–	–	–

INGENIO EL DR

Models J174/J177/K174/K177/K184

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

INGENIO EL DR
Models J174/J177/K174/K177/K184

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[96] Low-voltage capacitors	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**3**	**0**	**3**

More details about malfunctions

References cited in table above

INGENIO SR

Models J172/J175/K172/K175/K182

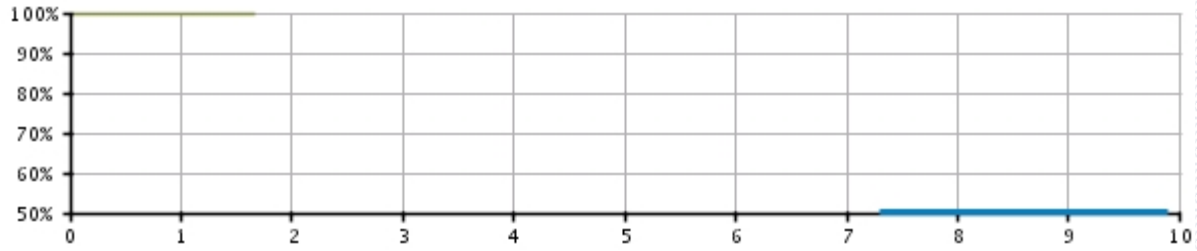
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

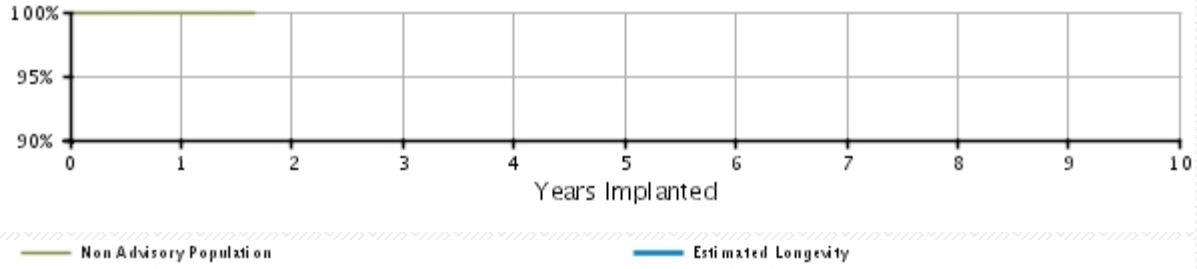
U.S. Registered Implants: 7,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 20 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 20 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2256	307	–	–	–	–	–	–	–	–

INGENIO SR

Models J172/J175/K172/K175/K182

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

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

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

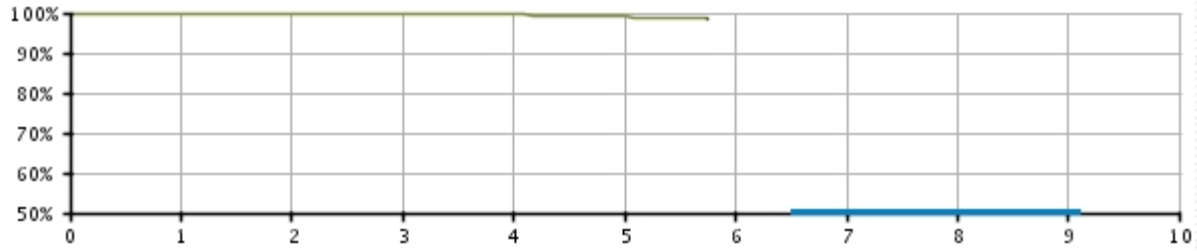
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

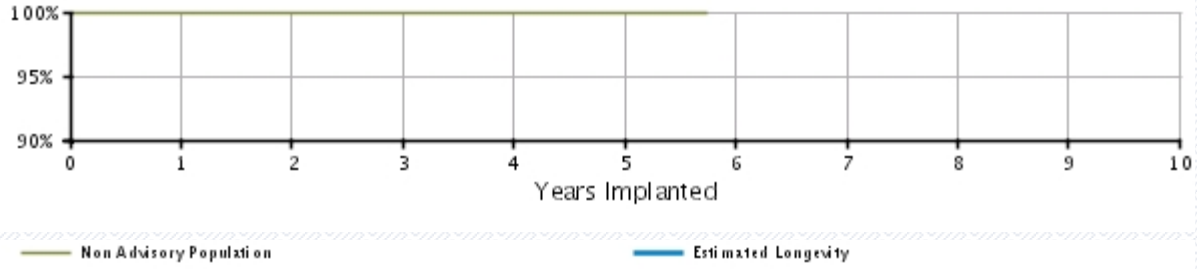
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 108
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 Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.01 (-0.2/+0.2)	98.61 @ 69 mo. (-0.4/+0.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 @ 69 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	19014	16388	13291	10332	5714	346	–	–	–	–

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: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[28] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[32] Capacitor array	1	-	
[87] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**3**	**2**	**5**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

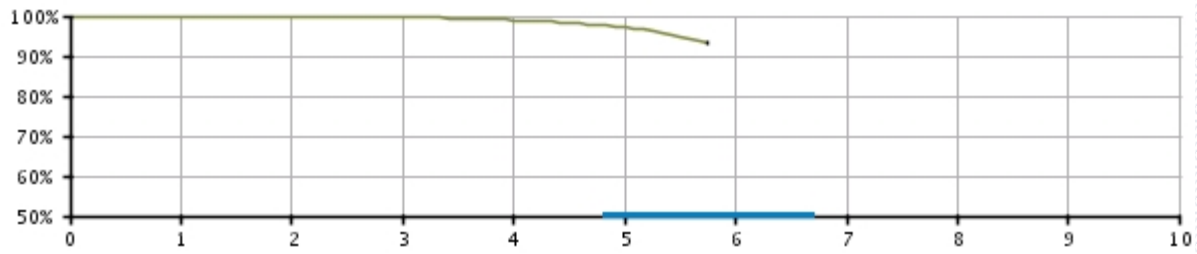
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

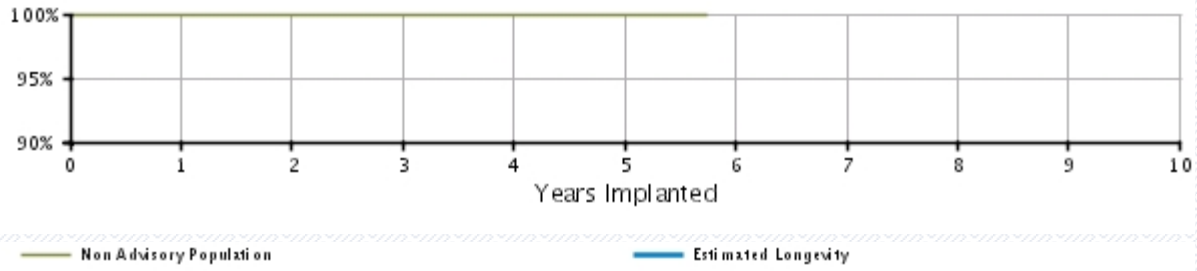
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 68,000

U.S. Normal Battery Depletions: 841
U.S. Unconfirmed Reports of Premature Battery Depletion : 24
U.S. Malfunctions:17
Without Compromised Therapy:9
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 Registered Implants: 90000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.66 (-0.1/+0.0)	98.98 (-0.1/+0.1)	97.15 (-0.2/+0.2)	93.08 @ 69 mo. (-1.0/+0.9)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 69 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	78654	64507	44411	26330	10054	554	–	–	–	–

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: 19

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**6**	**11**
[28] Capacitor	4	5	
[70] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[84] Connector block	1	-	
[87] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**3**	**3**	**6**
Non-patterned	-	2	
[57] Battery depletion	2	1	
[99] Battery status	1	-	
WW Confirmed Malfunctions	**10**	**9**	**19**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

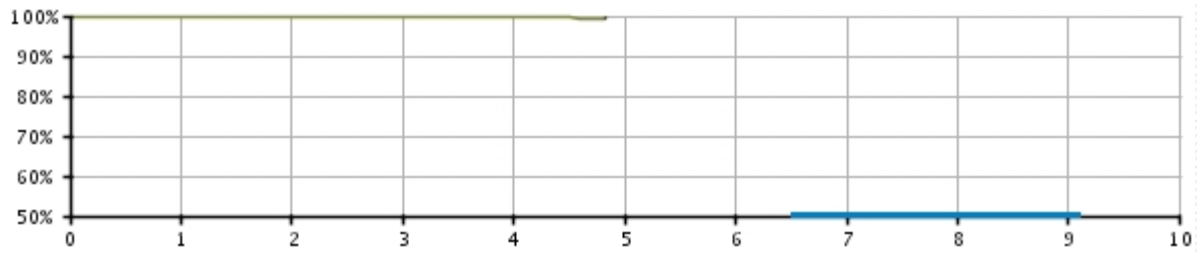
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

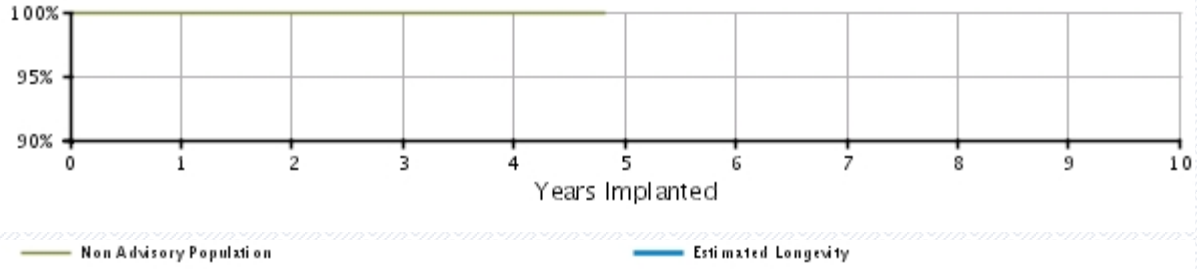
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 50,000

U.S. Normal Battery Depletions: 71
U.S. Unconfirmed Reports of Premature Battery Depletion : 5
U.S. Malfunctions:6
Without Compromised Therapy:4
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.70 (-0.1/+0.1)	99.43 @ 58 mo. (-0.3/+0.2)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 @ 58 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	52002	40852	22337	7965	455	–	–	–	–	–

ALTRUA 60 DR EL

Model S606

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

ALTRUA 60 DR EL
Model S606

Worldwide Distribution: 90,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[28] Capacitor	3	-	
[34] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[87] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	-	
[57] Battery depletion	-	1	
WW Confirmed Malfunctions	**5**	**2**	**7**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

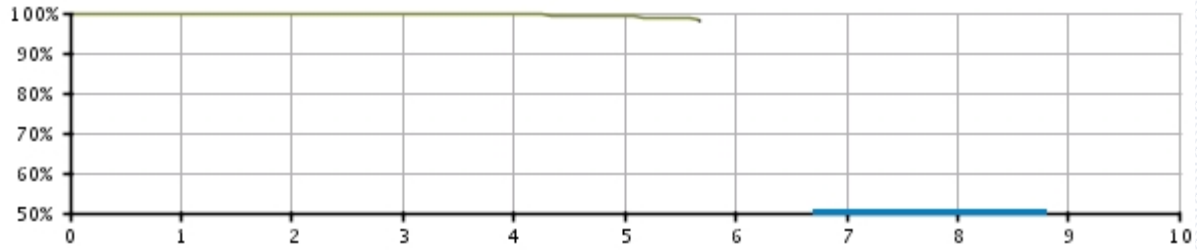
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

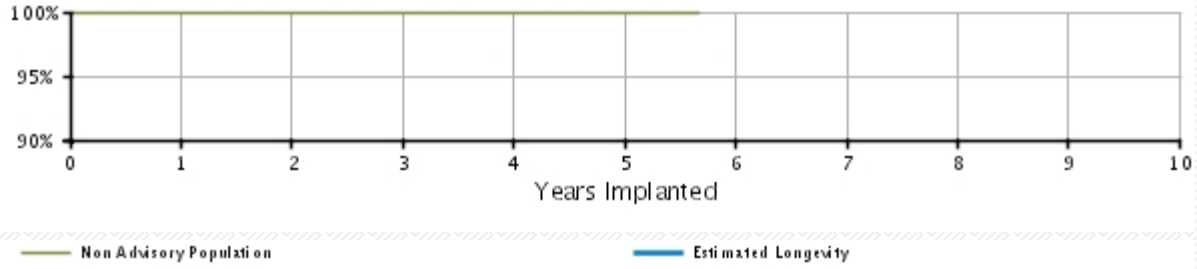
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 93
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:2
Without Compromised Therapy:0
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.12 (-0.3/+0.2)	98.20 @ 68 mo. (-0.9/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 @ 68 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	26459	21139	13642	7598	2517	316	–	–	–	–

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: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**3**	**5**
[28] Capacitor	2	1	
[70] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**3**	**3**
Non-patterned	-	2	
[57] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**6**	**8**

More details about malfunctions

References cited in table above

ALTRUA 50 DR (Downsize)

Model S502

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

ALTRUA 50 DR (Downsize) Model S502

Worldwide Distribution: 42,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**-**	**3**
[28] Capacitor	2	-	
[70] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[87] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	-	-	
[57] Battery depletion	1	-	
WW Confirmed Malfunctions	**4**	**1**	**5**

More details about malfunctions

References cited in table above

ALTRUA 50 SR

Model S501

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

ALTRUA 50 SR
Model S501

Worldwide Distribution: 23,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**2**	**3**
[28] Capacitor	1	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**2**	**2**
Non-patterned	-	1	
[57] Battery depletion	-	1	
WW Confirmed Malfunctions	**1**	**4**	**5**

More details about malfunctions

References cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

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

ALTRUA 50 DDD (Downsize) Model S503

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	2	3
Non-patterned	-	-	
[57] Battery depletion	-	2	
[99] Battery status	1	-	
WW Confirmed Malfunctions	1	2	3

More details about malfunctions

References cited in table above

ALTRUA 50 VDD (Downsize)

Model S504

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

ALTRUA 50 VDD (Downsize) Model S504

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ALTRUA 50 SSI

Model S508

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

ALTRUA 50 SSI Model S508

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

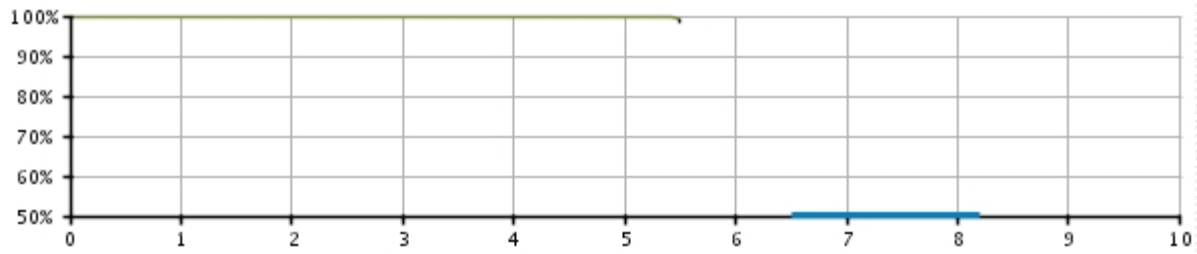
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

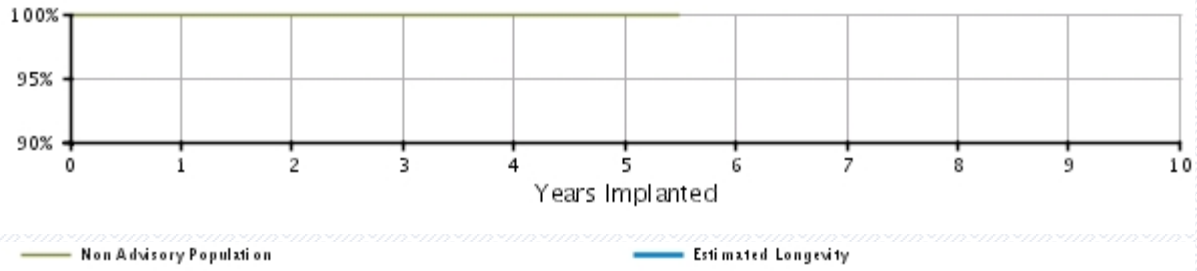
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 6
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	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)	99.53 (-0.7/+0.3)	99.16 @ 66 mo. (-1.4/+0.5)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 66 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	1517	1346	1195	1060	788	266	–	–	–	–

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	-	-	
[57] Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

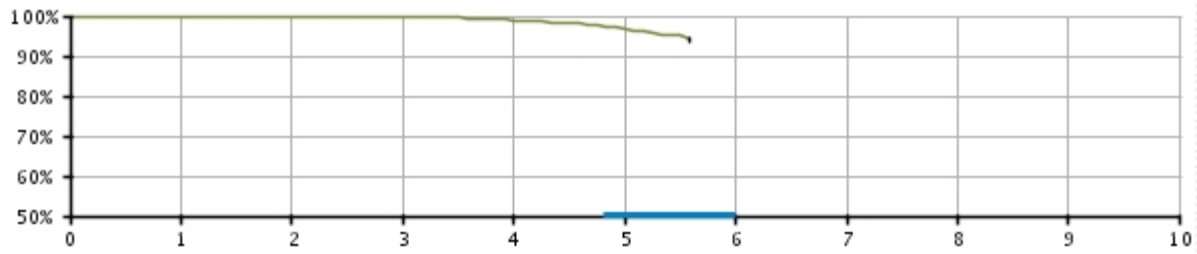
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

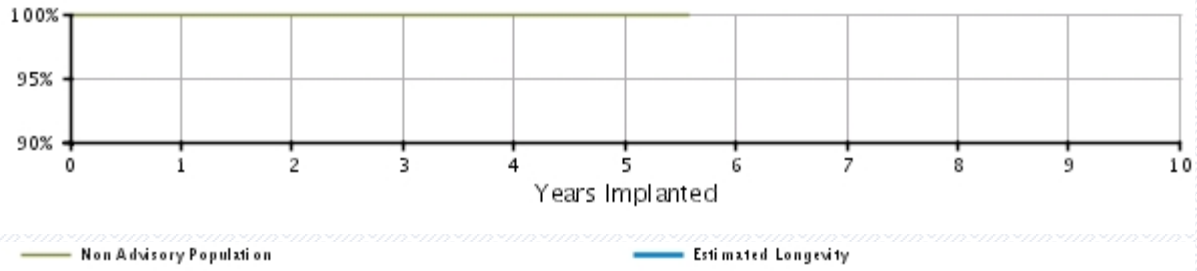
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 11,000

U.S. Normal Battery Depletions: 126
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:3
Without Compromised Therapy:3
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.70 (-0.1/+0.1)	98.94 (-0.3/+0.2)	96.79 (-0.8/+0.6)	94.17 @ 67 mo. (-1.8/+1.4)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 67 mo. (-0.1/+0.0)	–	–	–	–
	Effective Sample Size	12508	10593	7088	3867	1236	272	–	–	–	–

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: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**2**	**-**	**2**
[86] Seal plug	1	-	
[87] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	-	-	
[99] Battery status	1	-	
WW Confirmed Malfunctions	**3**	**0**	**3**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

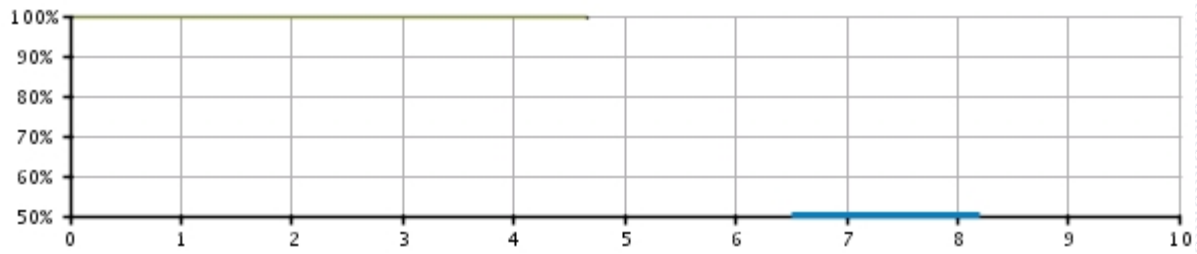
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

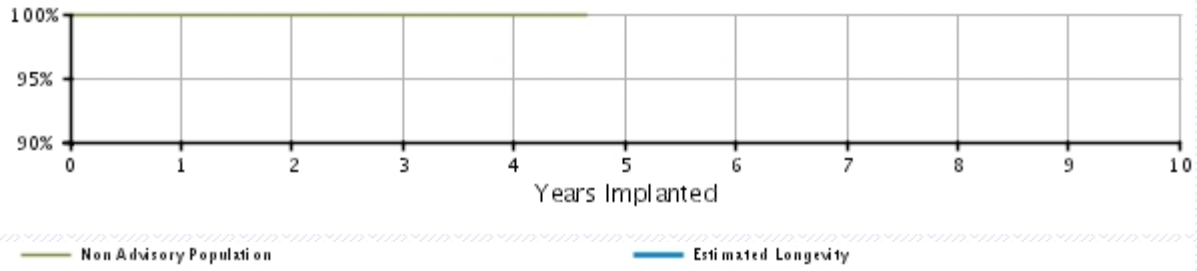
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 6
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.93 (-0.2/+0.0)	99.64 (-0.5/+0.2)	99.64 @ 56 mo. (-0.5/+0.2)	–	–	–	–	–
	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 @ 56 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	4466	3714	2251	1021	210	–	–	–	–	–

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[28] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**0**	**1**

More details about malfunctions

References cited in table above

ALTRUA 40 SR

Model S401

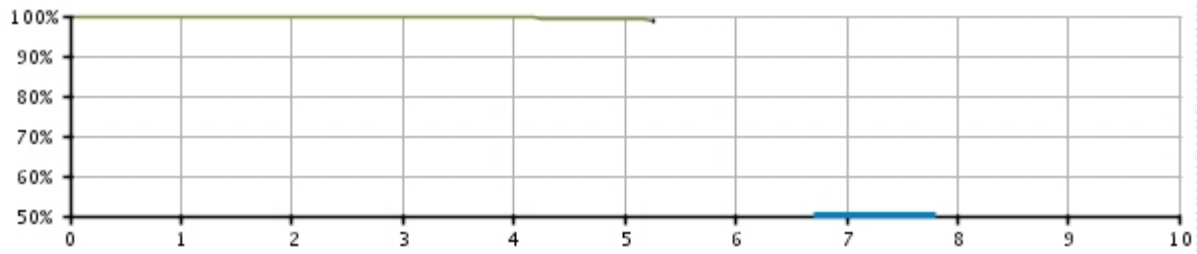
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

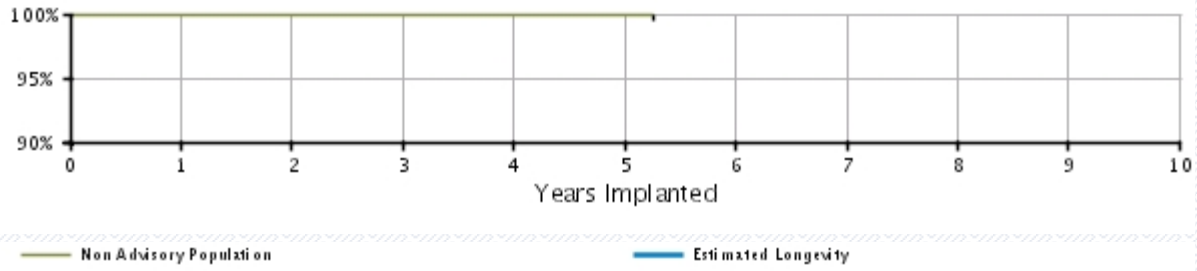
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 12
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.87 (-0.2/+0.1)	99.68 (-0.4/+0.2)	99.36 (-0.6/+0.3)	98.93 @ 63 mo. (-1.5/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.90 (-0.4/+0.1)	99.90 (-0.4/+0.1)	99.90 @ 63 mo. (-0.4/+0.1)	–	–	–	–
	Effective Sample Size	3961	3270	2137	1169	388	231	–	–	–	–

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**
[28] Capacitor	2	-	
[70] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR

Models S202/S205

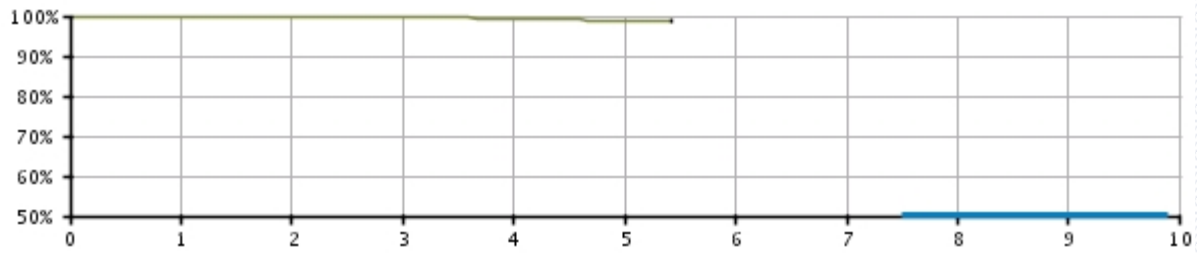
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

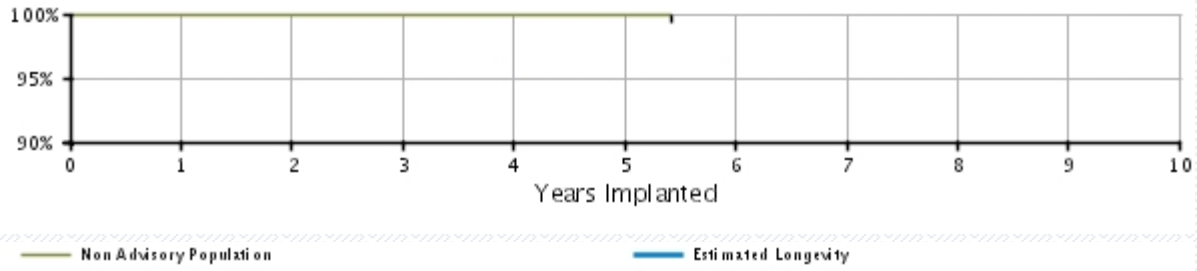
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 10
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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 Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.83 (-0.5/+0.1)	99.41 (-0.7/+0.3)	98.77 (-1.0/+0.6)	98.77 @ 65 mo. (-1.0/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.90 (-0.6/+0.1)	99.90 (-0.6/+0.1)	99.90 @ 65 mo. (-0.6/+0.1)	–	–	–	–
	Effective Sample Size	1456	1265	1060	870	593	258	–	–	–	–

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	-	-	
[92] Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

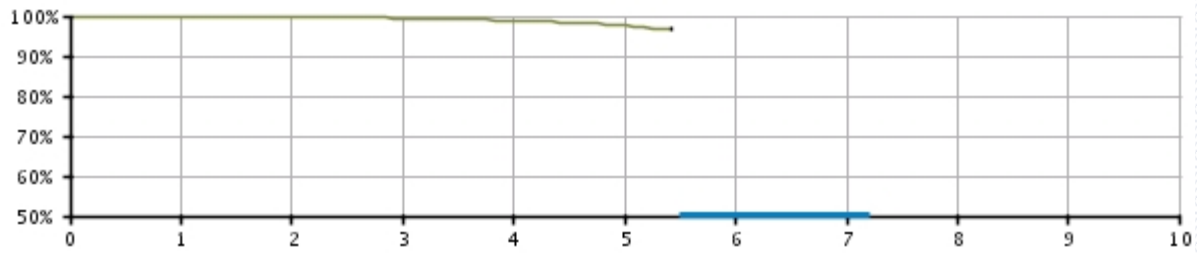
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

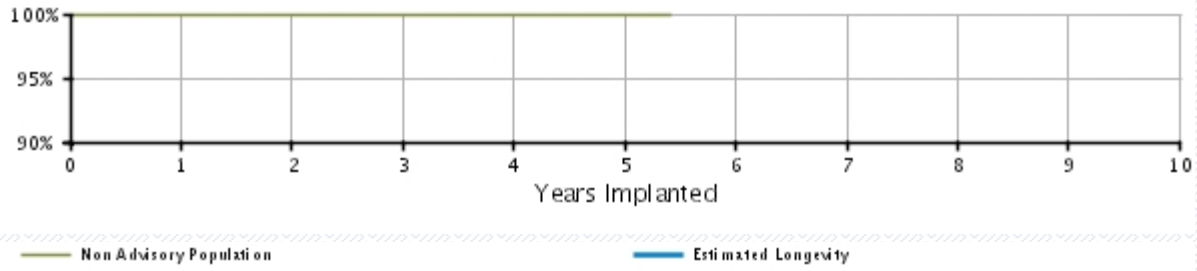
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 41
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.48 (-0.3/+0.2)	98.80 (-0.5/+0.4)	97.73 (-1.0/+0.7)	96.86 @ 65 mo. (-1.6/+1.1)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 65 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	4421	3726	2551	1459	489	202	–	–	–	–

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**
[28] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	-	
[57] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

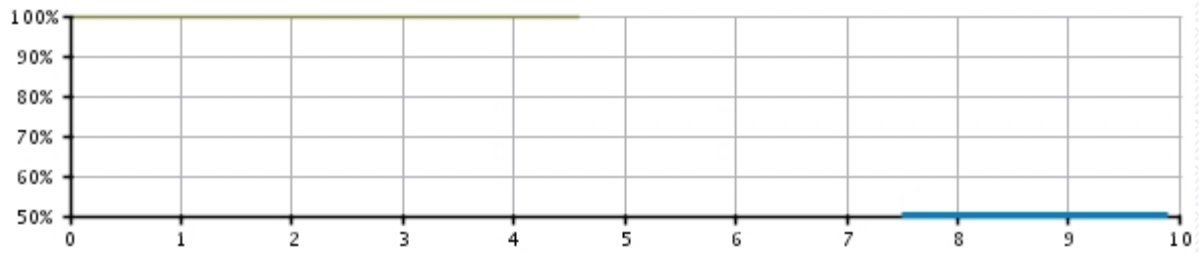
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

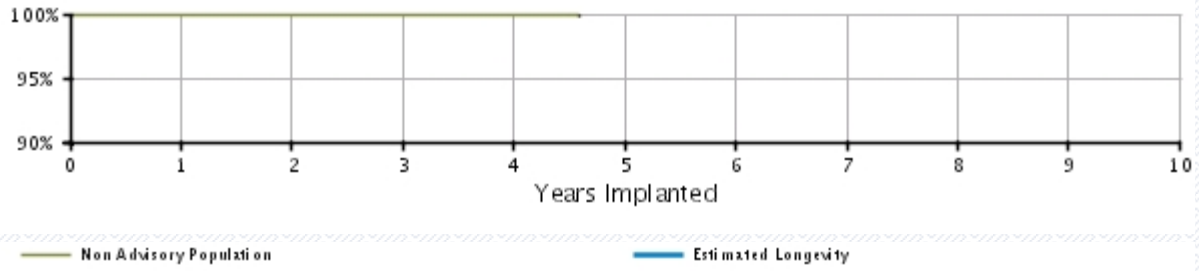
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 5
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:0
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: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.85 (-0.2/+0.1)	99.73 (-0.4/+0.2)	99.73 (-0.4/+0.2)	99.73 @ 55 mo. (-0.4/+0.2)	–	–	–	–	–
	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 @ 55 mo. (-0.2/+0.0)	–	–	–	–	–
	Effective Sample Size	2772	2253	1342	586	213	–	–	–	–	–

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**
[28] Capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

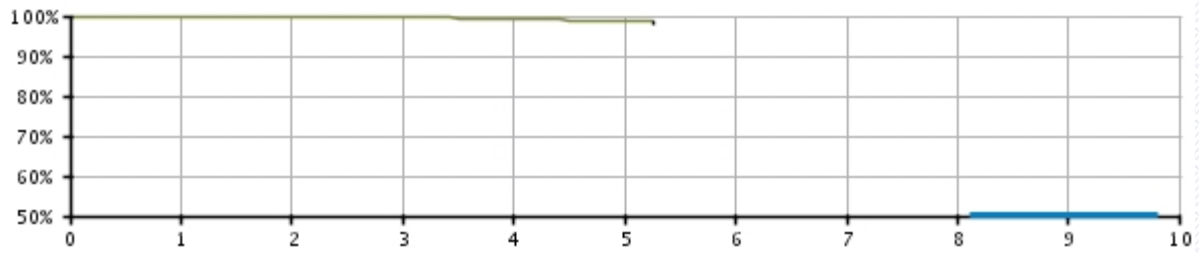
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

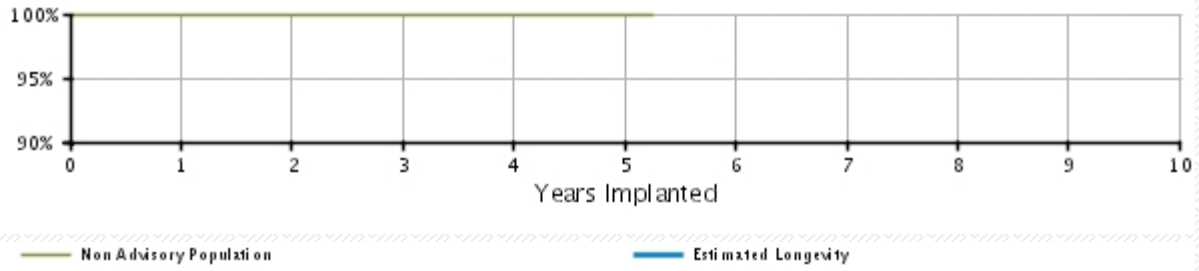
U.S. Registered Implants: 4,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 17
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.61 (-0.3/+0.2)	99.23 (-0.6/+0.3)	98.92 (-0.8/+0.5)	98.59 @ 63 mo. (-1.2/+0.7)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 63 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	3527	2822	1817	987	337	204	–	–	–	–

ALTRUA 20 SR

Models S201/S204

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

ALTRUA 20 SR
Models S201/S204

Worldwide Distribution: 23,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[28] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

ALTRUA 20 DDD

Model S207

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

ALTRUA 20 DDD
Model S207

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ALTRUA 20 SSI

Model S206

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

ALTRUA 20 SSI Model S206

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR

Model 1291

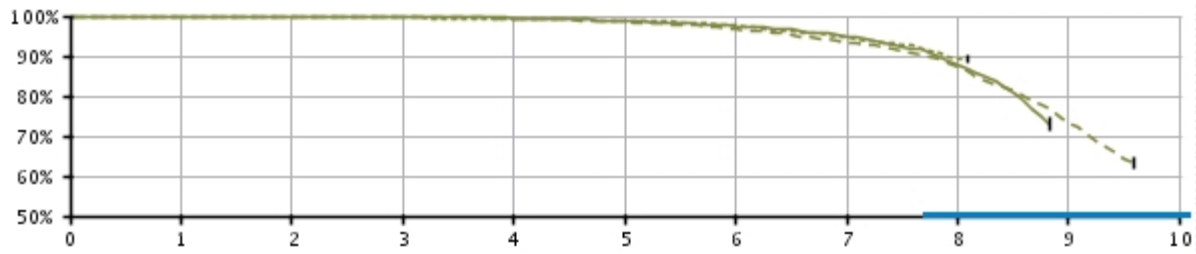
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

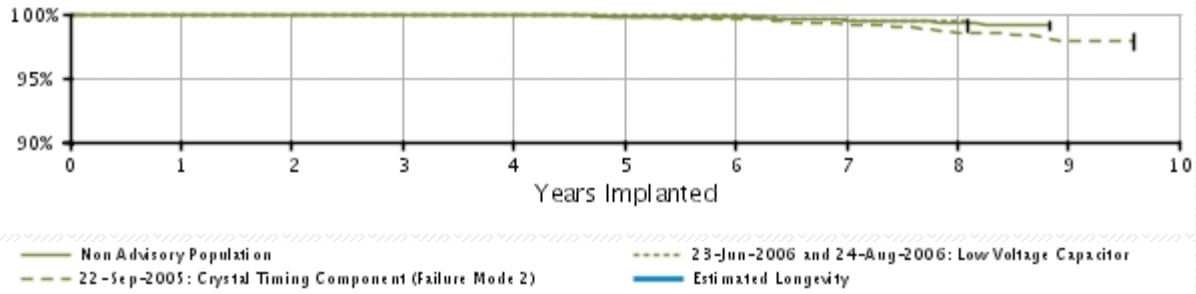
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 1,369
U.S. Unconfirmed Reports of Premature Battery Depletion : 15
U.S. Malfunctions:111
Without Compromised Therapy:102
With Compromised Therapy:9

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	98.72 (-0.2/+0.2)	97.41 (-0.3/+0.3)	94.95 (-0.5/+0.5)	87.62 (-1.4/+1.3)	72.88 @ 106 mo. (-3.6/+3.4)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.72 (-0.1/+0.1)	99.51 (-0.2/+0.1)	99.31 (-0.3/+0.2)	99.16 @ 106 mo. (-0.5/+0.3)	–
	Effective Sample Size	21005	18659	16561	14649	12896	9676	3902	1003	212	–

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)	97.57 (-1.0/+0.7)	94.73 (-1.5/+1.2)	89.49 (-2.2/+1.9)	89.49 @ 97 mo. (-2.2/+1.9)	–
	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 @ 97 mo. (-0.8/+0.3)	–
	Effective Sample Size	1878	1659	1461	1287	1134	988	850	356	220	–
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.62 (-0.7/+0.6)	93.48 (-0.9/+0.8)	87.24 (-1.3/+1.2)	73.46 (-2.0/+2.0)	63.23 @ 115 mo. (-3.0/+2.9)
	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)	97.86 (-0.8/+0.6)	97.86 @ 115 mo. (-0.8/+0.6)
	Effective Sample Size	5702	5045	4467	3940	3453	2980	2556	2097	719	214

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

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

INSIGNIA Ultra DR

Model 1291

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

INSIGNIA Ultra DR Model 1291

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 139

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[24] Capacitor	1	-	
[28] Capacitor	4	2	
[70] Integrated circuit	2	1	
Mechanical	**7**	**5**	**12**
[38] Seal plug	5	4	
[39] Header	1	1	
[73] Setscrew	1	-	
Software	**4**	**-**	**4**
[77] Underestimation of battery status	3	-	
[79] Pacing rate limit	1	-	
Other	**107**	**4**	**111**
Non-patterned	6	3	
[18] Longevity labeling	68	-	
[41] Magnet response	1	-	
[57] Battery depletion	2	1	
[99] Battery status	30	-	
WW Confirmed Malfunctions	**125**	**14**	**139**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

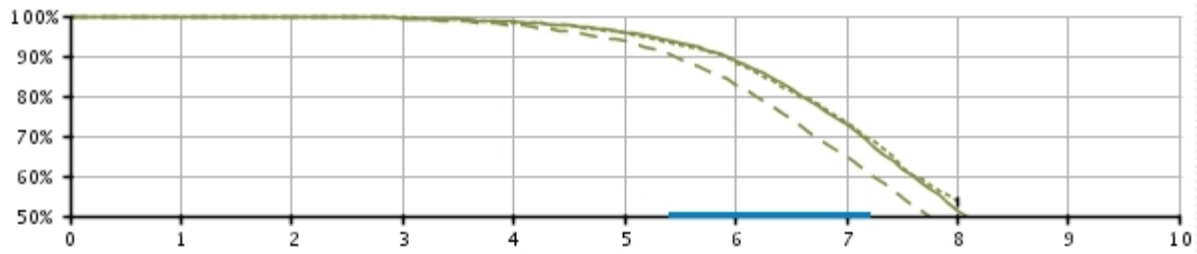
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

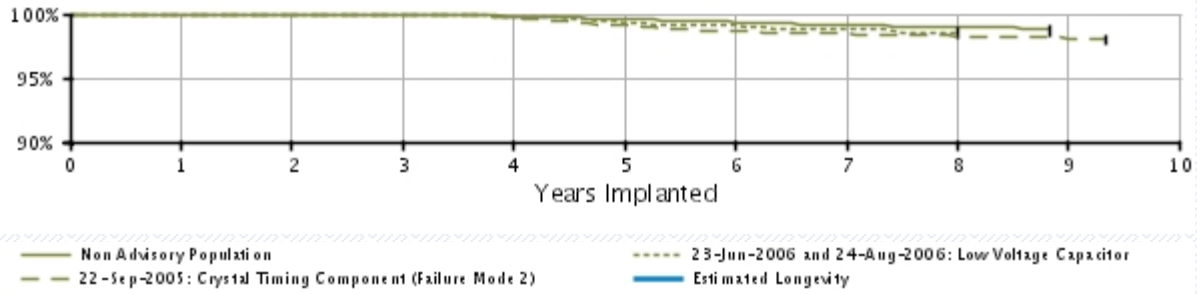
U.S. Registered Implants: 76,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 26,000

U.S. Normal Battery Depletions: 12,444
U.S. Unconfirmed Reports of Premature Battery Depletion : 105
U.S. Malfunctions:396
Without Compromised Therapy:11
With Compromised Therapy:385

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: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.49 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.88 (-0.4/+0.4)	72.68 (-0.7/+0.7)	51.27 (-1.2/+1.2)	32.72 @ 106 mo. (-2.2/+2.3)	–
	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)	99.37 (-0.1/+0.1)	99.16 (-0.1/+0.1)	99.04 (-0.2/+0.1)	98.79 @ 106 mo. (-0.6/+0.4)	–
	Effective Sample Size	47641	42293	37439	32966	28491	20540	7425	1527	212	–

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)	88.21 (-1.4/+1.2)	73.29 (-1.9/+1.8)	53.68 (-2.4/+2.4)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.37 (-0.4/+0.2)	99.10 (-0.5/+0.3)	98.76 (-0.6/+0.4)	98.59 (-0.6/+0.4)	–	–
	Effective Sample Size	4025	3553	3142	2733	2340	1910	1385	369	–	–
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 Component (Failure Mode 2)* Registered Implants: 17000	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)	82.85 (-0.8/+0.8)	64.60 (-1.1/+1.1)	44.76 (-1.2/+1.2)	27.55 (-1.3/+1.4)	22.10 @ 112 mo. (-1.6/+1.6)
	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)	98.02 (-0.5/+0.4)	98.02 @ 112 mo. (-0.5/+0.4)
	Effective Sample Size	14977	13298	11733	10225	8614	6646	4428	2608	564	214

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

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

INSIGNIA Ultra DR (downsize)

Model 1290

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

INSIGNIA Ultra DR (downsize) Model 1290

Worldwide Distribution: 124,000
Worldwide Confirmed Malfunctions: 536

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**9**	**18**
[8] Low-voltage capacitor (Advisory issued)	1	5	
[28] Capacitor	7	3	
[70] Integrated circuit	1	1	
Mechanical	**4**	**2**	**6**
[13] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[27] Setscrew thread depth	1	-	
[38] Seal plug	2	1	
[52] Circuit connection	1	-	
Software	**12**	**-**	**12**
[46] Rate fault declaration	1	-	
[47] Memory error	2	-	
[77] Underestimation of battery status	8	-	
[79] Pacing rate limit	1	-	
Other	**493**	**7**	**500**
Non-patterned	21	5	
[18] Longevity labeling	393	-	
[57] Battery depletion	6	2	
[99] Battery status	73	-	
WW Confirmed Malfunctions	**518**	**18**	**536**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

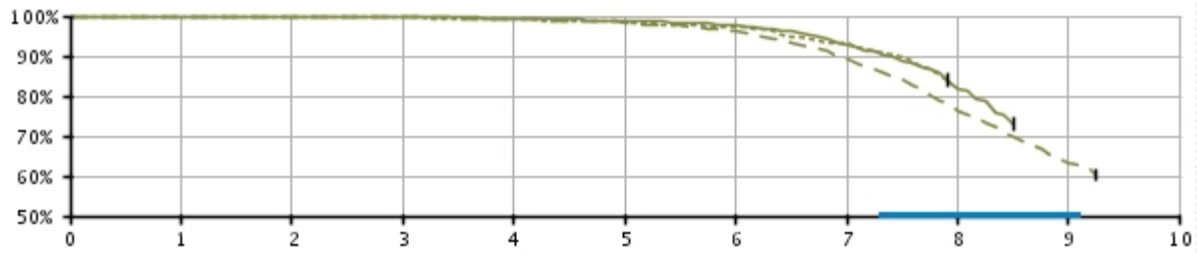
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

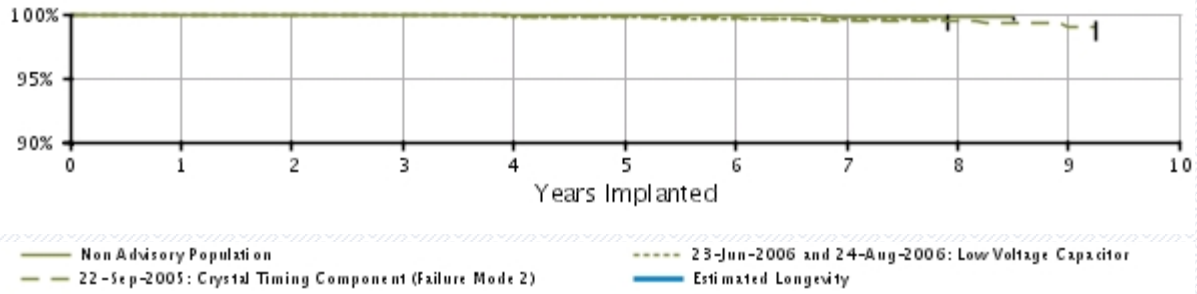
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 1,135
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:30
Without Compromised Therapy:26
With Compromised Therapy:4

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.71 (-0.1/+0.1)	99.41 (-0.2/+0.1)	98.73 (-0.3/+0.2)	97.57 (-0.4/+0.3)	92.68 (-0.8/+0.8)	81.81 (-2.1/+1.9)	72.92 @ 102 mo. (-3.5/+3.2)	–
	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 (-0.2/+0.1)	99.73 (-0.2/+0.1)	99.73 @ 102 mo. (-0.2/+0.1)	–
	Effective Sample Size	14155	12095	10318	8882	7716	5833	2421	628	208	–

23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.11 (-0.9/+0.5)	98.47 (-1.2/+0.7)	97.22 (-1.6/+1.0)	93.28 (-2.5/+1.8)	83.96 @ 95 mo. (-3.8/+3.2)	–	–
	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 @ 95 mo. (-0.9/+0.3)	–	–
	Effective Sample Size	1148	964	813	701	590	504	423	237	–	–
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 Component (Failure Mode 2)* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.25 (-0.4/+0.3)	98.30 (-0.6/+0.4)	96.27 (-0.9/+0.7)	89.40 (-1.5/+1.3)	76.46 (-2.2/+2.0)	63.29 (-2.9/+2.8)	60.18 @ 111 mo. (-3.3/+3.2)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.78 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.40 (-0.5/+0.3)	98.99 (-1.1/+0.5)	98.99 @ 111 mo. (-1.1/+0.5)
	Effective Sample Size	4144	3558	3004	2532	2115	1772	1425	1047	319	201

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

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

INSIGNIA Ultra SR

Model 1190

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

INSIGNIA Ultra SR Model 1190

Worldwide Distribution: 48,000
Worldwide Confirmed Malfunctions: 49

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[8] Low-voltage capacitor (Advisory issued)	1	3	
[28] Capacitor	1	-	
[70] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[38] Seal plug	3	-	
[39] Header	-	1	
Software	**1**	**-**	**1**
[47] Memory error	1	-	
Other	**37**	**-**	**37**
Non-patterned	1	-	
[18] Longevity labeling	23	-	
[57] Battery depletion	1	-	
[99] Battery status	12	-	
WW Confirmed Malfunctions	**43**	**6**	**49**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

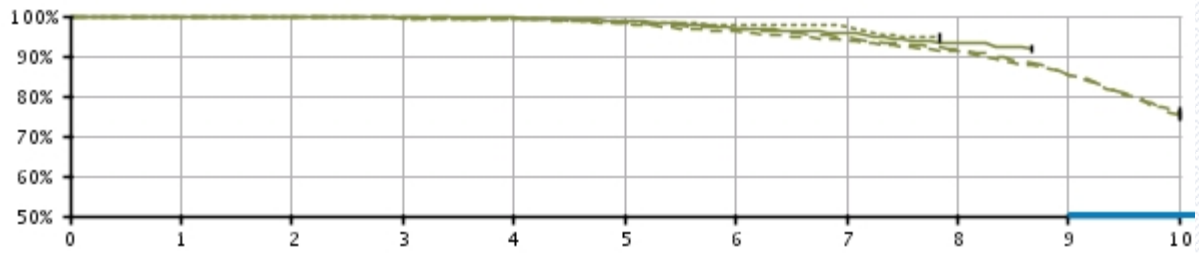
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

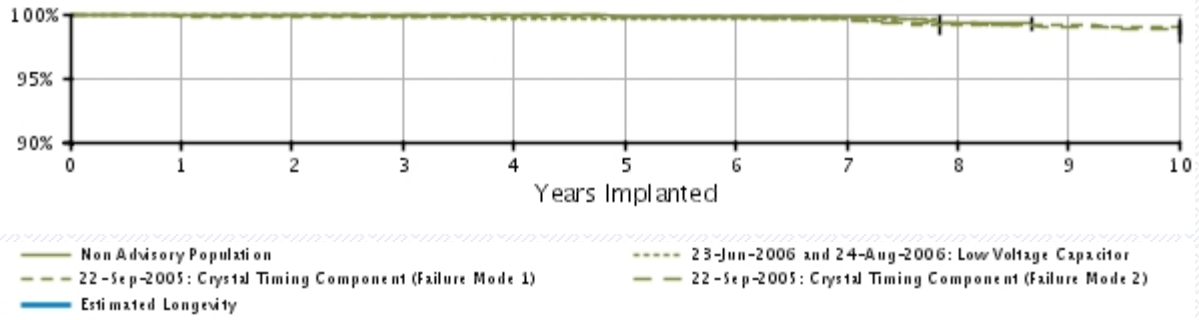
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 825
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:55
Without Compromised Therapy:49
With Compromised Therapy:6

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: 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)	97.00 (-0.6/+0.5)	95.58 (-0.8/+0.7)	93.19 (-1.3/+1.1)	91.91 @ 104 mo. (-1.9/+1.6)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.73 (-0.2/+0.1)	99.32 (-0.7/+0.4)	99.32 @ 104 mo. (-0.7/+0.4)	–
	Effective Sample Size	6258	5546	4914	4357	3792	2910	1529	545	209	–

23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.45 (-1.1/+0.4)	99.24 (-1.3/+0.5)	98.76 (-1.5/+0.7)	97.66 (-2.0/+1.1)	97.33 (-2.1/+1.2)	94.93 @ 94 mo. (-2.9/+1.9)	–	–
	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 @ 94 mo. (-1.2/+0.3)	–	–
	Effective Sample Size	693	607	529	452	394	338	294	242	–	–
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)	96.06 (-1.4/+1.1)	93.81 (-1.8/+1.4)	91.04 (-2.2/+1.8)	85.50 (-2.9/+2.5)	75.79 (-3.8/+3.4)
	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)	98.94 (-1.2/+0.6)
	Effective Sample Size	1675	1453	1213	1063	923	785	662	554	447	304
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.31 (-0.3/+0.2)	98.40 (-0.4/+0.3)	96.92 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.57 (-1.0/+0.9)	85.44 (-1.5/+1.3)	75.35 (-2.5/+2.3)
	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)	99.00 (-0.5/+0.3)	98.89 (-0.5/+0.4)
	Effective Sample Size	6210	5482	4824	4230	3695	3189	2682	2271	1327	335

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

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

INSIGNIA Entra DR

Models 1294/1295

INSIGNIA Entra DR Models 1294/1295

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 65

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[23] Integrated circuit	-	1	
[28] Capacitor	-	1	
[70] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[38] Seal plug	3	-	
[39] Header	-	2	
Software	**-**	**-**	**0**
Other	**51**	**1**	**52**
Non-patterned	4	1	
[18] Longevity labeling	45	-	
[99] Battery status	2	-	
WW Confirmed Malfunctions	**54**	**11**	**65**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

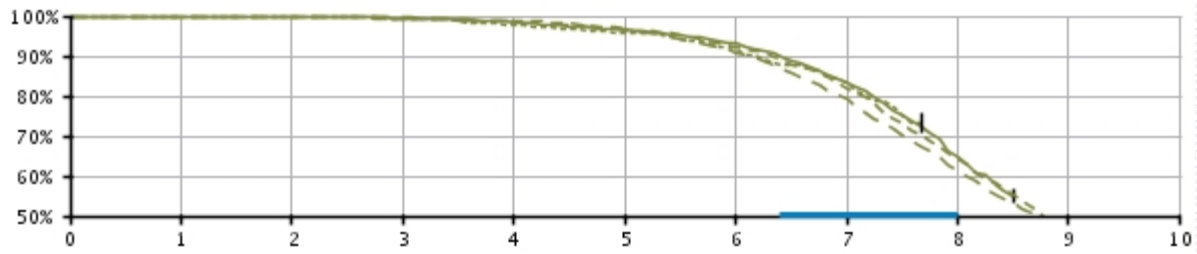
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

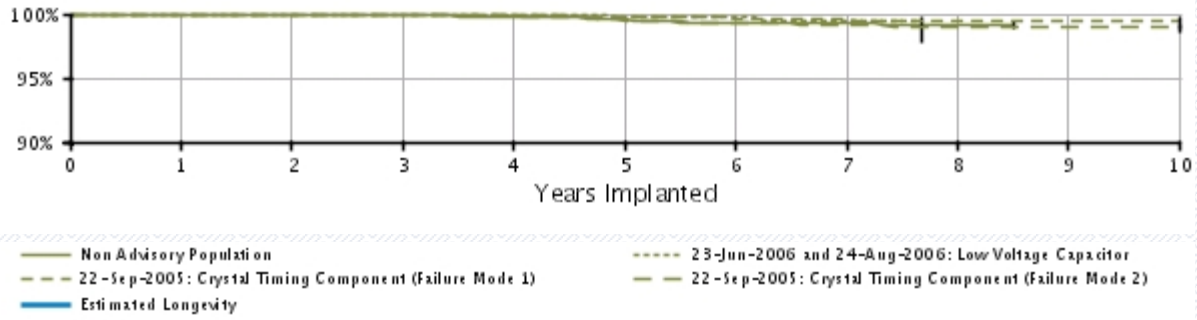
U.S. Registered Implants: 24,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 3,890
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:96
Without Compromised Therapy:90
With Compromised Therapy:6

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: 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)	96.60 (-0.5/+0.5)	93.02 (-0.8/+0.7)	83.24 (-1.4/+1.3)	64.72 (-2.7/+2.6)	54.96 @ 102 mo. (-3.4/+3.3)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.99 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.57 (-0.2/+0.2)	99.37 (-0.3/+0.2)	99.29 (-0.3/+0.2)	99.20 (-0.4/+0.3)	99.20 @ 102 mo. (-0.4/+0.3)	–
	Effective Sample Size	7138	6281	5500	4785	4104	3150	1537	471	211	–

23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.70 (-0.9/+0.2)	99.20 (-1.1/+0.5)	97.84 (-1.6/+0.9)	95.61 (-2.2/+1.5)	91.90 (-3.0/+2.2)	83.05 (-4.2/+3.5)	73.37 @ 92 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 @ 92 mo. (-1.7/+0.4)	–	–
	Effective Sample Size	763	657	563	476	402	330	254	200	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.03 (-1.5/+1.3)	81.79 (-2.2/+2.0)	64.06 (-2.9/+2.8)	45.84 (-3.2/+3.2)	31.92 (-3.1/+3.3)
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2736	2405	2071	1813	1515	1227	934	597	361	205
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 11000	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)	61.32 (-1.5/+1.5)	45.10 (-1.7/+1.7)	35.91 (-1.9/+2.0)
	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	4513	3343	2185	996	295

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

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

INSIGNIA Entra DR (downsize)

Model 1296

INSIGNIA Entra DR (downsize) Model 1296

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 117

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	1	
[28] Capacitor	1	-	
[70] Integrated circuit	-	3	
Mechanical	**-**	**3**	**3**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
[19] Solder bond	-	1	
Software	**4**	**-**	**4**
[36] Memory error	1	-	
[77] Underestimation of battery status	1	-	
[78] Interrupted telemetry	2	-	
Other	**103**	**2**	**105**
Non-patterned	4	2	
[18] Longevity labeling	96	-	
[57] Battery depletion	1	-	
[99] Battery status	2	-	
WW Confirmed Malfunctions	**108**	**9**	**117**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

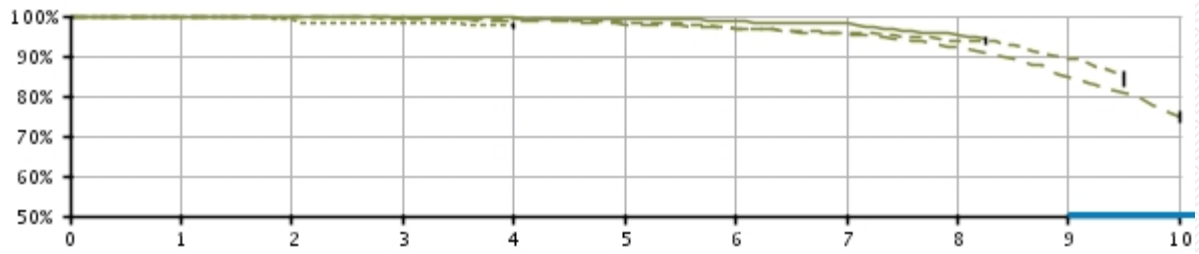
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

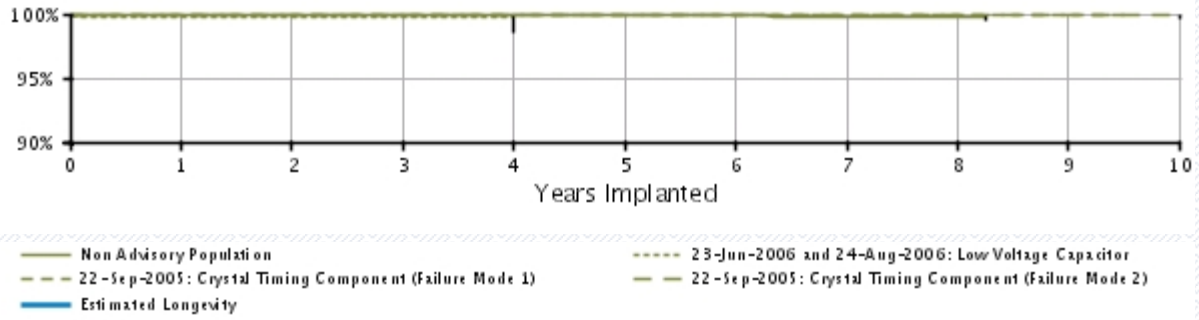
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 451
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:9
Without Compromised Therapy:7
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	99.53 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.76 (-0.5/+0.4)	98.16 (-0.7/+0.5)	95.49 (-1.7/+1.3)	94.02 @ 99 mo. (-2.4/+1.7)	–
	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)	99.78 (-0.3/+0.1)	99.78 (-0.3/+0.1)	99.78 @ 99 mo. (-0.3/+0.1)	–
	Effective Sample Size	4710	3876	3257	2753	2320	1716	884	322	231	–

23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 500	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.10 (-1.9/+0.6)	98.39 (-2.2/+0.9)	97.94 (-2.5/+1.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	–	–	–	–	–	–
	Effective Sample Size	348	284	237	204	–	–	–	–	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.21 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.96 (-1.8/+1.1)	95.73 (-2.1/+1.4)	93.95 (-2.6/+1.9)	89.44 (-3.6/+2.8)	84.66 @ 114 mo. (-4.5/+3.6)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 114 mo. (-0.0/+0.0)
	Effective Sample Size	1216	999	807	662	550	447	356	298	243	204
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.95 (-0.6/+0.5)	96.96 (-0.8/+0.6)	95.27 (-1.0/+0.8)	92.22 (-1.3/+1.2)	84.58 (-2.0/+1.8)	74.75 (-3.2/+3.0)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)
	Effective Sample Size	4579	3830	3179	2644	2186	1832	1543	1290	759	258

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

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

INSIGNIA Entra SR

Models 1195/1198

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

INSIGNIA Entra SR Models 1195/1198

Worldwide Distribution: 52,000
Worldwide Confirmed Malfunctions: 25

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[28] Capacitor	2	2	
[70] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[13] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[32] Capacitor array	-	2	
[38] Seal plug	-	2	
[75] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**10**	**1**	**11**
Non-patterned	1	1	
[18] Longevity labeling	6	-	
[99] Battery status	3	-	
WW Confirmed Malfunctions	**14**	**11**	**25**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

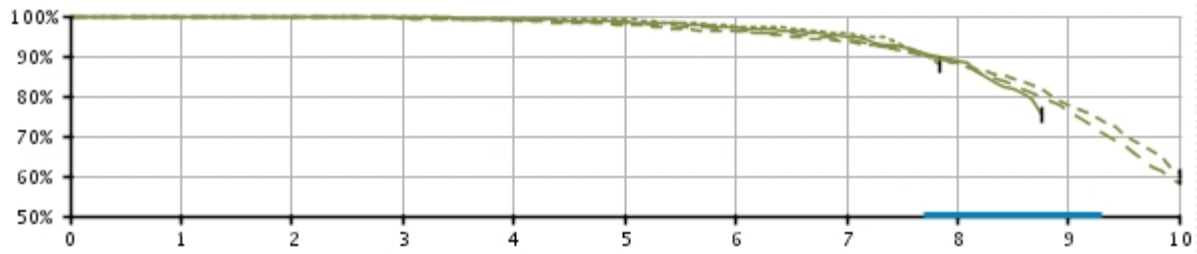
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

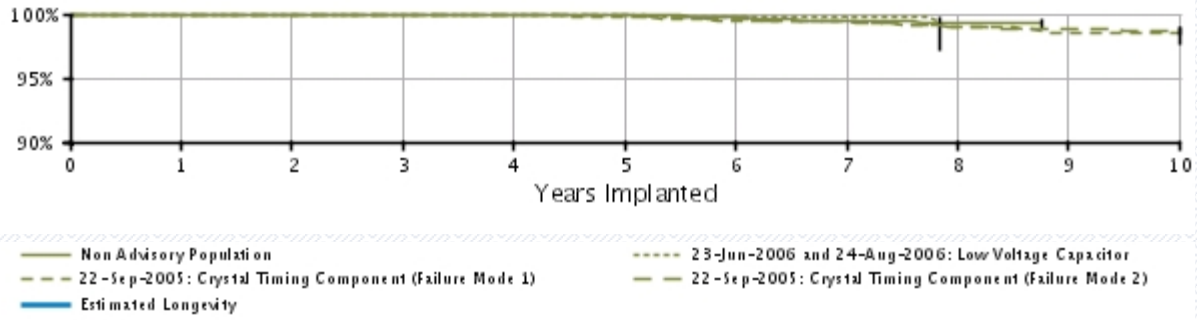
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 2,941
U.S. Unconfirmed Reports of Premature Battery Depletion : 18
U.S. Malfunctions:119
Without Compromised Therapy:110
With Compromised Therapy:9

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	97.17 (-0.6/+0.5)	94.77 (-0.9/+0.8)	88.57 (-1.8/+1.6)	75.42 @ 105 mo. (-4.0/+3.6)	–
	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)	99.43 (-0.4/+0.2)	99.31 (-0.5/+0.3)	99.31 @ 105 mo. (-0.5/+0.3)	–
	Effective Sample Size	6559	5830	5160	4545	3991	3111	1545	603	208	–

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)	97.25 (-2.2/+1.2)	95.65 (-2.7/+1.7)	87.93 @ 94 mo. (-4.2/+3.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	99.28 @ 94 mo. (-2.2/+0.5)	–	–
	Effective Sample Size	664	580	510	442	387	334	287	222	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.10 (-1.7/+1.5)	77.83 (-2.2/+2.1)	60.52 (-2.8/+2.8)
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.4/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3515	3073	2598	2281	1973	1705	1459	1211	927	586
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 14000	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)	98.17 (-0.3/+0.3)	96.50 (-0.4/+0.4)	94.06 (-0.6/+0.5)	87.80 (-0.8/+0.8)	76.28 (-1.2/+1.1)	58.37 (-1.6/+1.6)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.94 (-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)	98.71 (-0.3/+0.3)
	Effective Sample Size	12751	11249	9910	8721	7618	6597	5632	4621	2995	1249

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

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

INSIGNIA Plus DR

Model 1297

INSIGNIA Plus DR Model 1297

Worldwide Distribution: 47,000

Worldwide Confirmed Malfunctions: 140

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[8] Low-voltage capacitor (Advisory issued)	1	1	
[28] Capacitor	2	1	
[70] Integrated circuit	-	1	
Mechanical	**12**	**7**	**19**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[13] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[19] Solder bond	1	-	
[32] Capacitor array	1	-	
[38] Seal plug	5	-	
[39] Header	4	4	
Software	**7**	**-**	**7**
[77] Underestimation of battery status	4	-	
[78] Interrupted telemetry	2	-	
[79] Pacing rate limit	1	-	
Other	**106**	**2**	**108**
Non-patterned	5	2	
[18] Longevity labeling	85	-	
[57] Battery depletion	2	-	
[99] Battery status	14	-	
WW Confirmed Malfunctions	**128**	**12**	**140**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

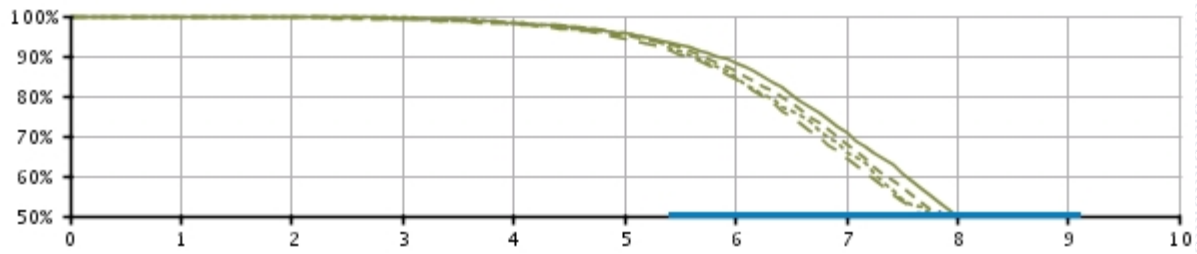
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

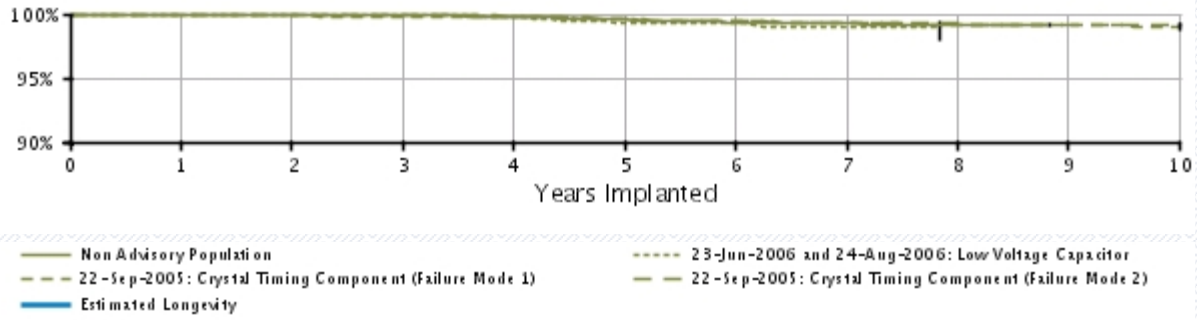
U.S. Registered Implants: 90,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 23,881
U.S. Unconfirmed Reports of Premature Battery Depletion : 113
U.S. Malfunctions:367
Without Compromised Therapy:338
With Compromised Therapy:29

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: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.41 (-0.1/+0.1)	98.27 (-0.2/+0.2)	95.60 (-0.4/+0.4)	88.21 (-0.6/+0.6)	70.54 (-1.1/+1.1)	49.52 (-1.7/+1.7)	30.31 @ 106 mo. (-2.4/+2.5)	–
	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)	99.34 (-0.2/+0.1)	99.23 (-0.2/+0.2)	99.15 (-0.2/+0.2)	99.15 @ 106 mo. (-0.2/+0.2)	–
	Effective Sample Size	16863	14980	13240	11653	10060	7467	3243	952	202	–

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)	84.88 (-2.6/+2.3)	65.99 (-3.5/+3.3)	49.57 @ 94 mo. (-3.8/+3.8)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.71 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 @ 94 mo. (-1.0/+0.5)	–	–
	Effective Sample Size	1421	1251	1113	965	826	643	437	261	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 16000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.13 (-0.2/+0.2)	98.03 (-0.3/+0.2)	95.05 (-0.5/+0.4)	86.19 (-0.8/+0.7)	67.68 (-1.1/+1.1)	47.04 (-1.3/+1.3)	31.99 (-1.3/+1.3)	22.23 (-1.2/+1.3)
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.57 (-0.2/+0.1)	99.38 (-0.2/+0.1)	99.32 (-0.2/+0.2)	99.19 (-0.2/+0.2)	99.13 (-0.3/+0.2)	99.03 (-0.4/+0.3)
	Effective Sample Size	13683	12073	10374	9054	7729	6117	4098	2353	1308	740
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 54000	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)	84.14 (-0.4/+0.4)	64.22 (-0.6/+0.6)	44.23 (-0.7/+0.7)	30.03 (-0.7/+0.7)	20.41 (-0.7/+0.7)
	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	47027	41686	36744	32067	27291	21120	13698	7816	3778	1457

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

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

INSIGNIA Plus DR (downsize)

Model 1298

INSIGNIA Plus DR (downsize) Model 1298

Worldwide Distribution: 140,000
Worldwide Confirmed Malfunctions: 442

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**11**	**10**	**21**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[24] Capacitor	-	1	
[28] Capacitor	6	2	
[34] Integrated circuit	-	1	
[70] Integrated circuit	5	3	
Mechanical	**21**	**22**	**43**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
[13] Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
[19] Solder bond	1	-	
[32] Capacitor array	3	1	
[38] Seal plug	3	1	
[39] Header	5	-	
[75] Seal plug	1	-	
Software	**12**	**-**	**12**
[47] Memory error	1	-	
[76] Interrogation at EOL	2	-	
[77] Underestimation of battery status	7	-	
[78] Interrupted telemetry	1	-	
[79] Pacing rate limit	1	-	
Other	**355**	**11**	**366**
Non-patterned	27	9	
[18] Longevity labeling	309	-	
[37] Battery depletion	2	1	
[41] Magnet response	1	-	
[57] Battery depletion	11	1	
[99] Battery status	5	-	
WW Confirmed Malfunctions	**399**	**43**	**442**

INSIGNIA Plus SR

Model 1194

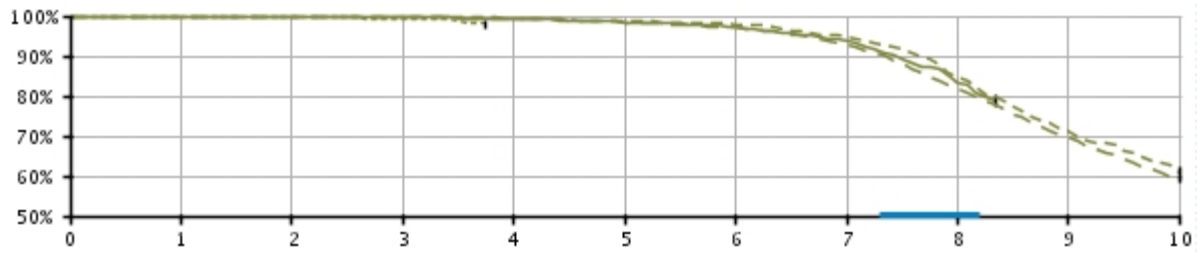
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

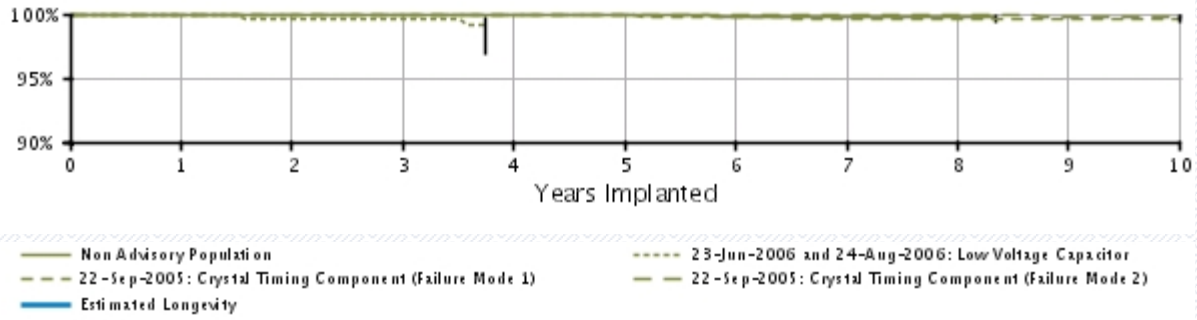
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2,527
U.S. Unconfirmed Reports of Premature Battery Depletion : 7
U.S. Malfunctions:27
Without Compromised Therapy:19
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 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)	97.25 (-0.7/+0.6)	93.87 (-1.2/+1.0)	83.44 (-2.8/+2.5)	78.89 @ 100 mo. (-3.6/+3.2)	–
	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)	99.84 (-0.3/+0.1)	99.71 (-0.4/+0.2)	99.71 (-0.4/+0.2)	99.71 @ 100 mo. (-0.4/+0.2)	–
	Effective Sample Size	4728	4038	3455	2896	2474	1900	966	367	203	–

23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 400	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.27 (-2.2/+0.5)	98.34 @ 45 mo. (-2.7/+1.0)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.66 (-2.0/+0.3)	99.19 @ 45 mo. (-2.4/+0.6)	–	–	–	–	–	–
	Effective Sample Size	326	278	241	202	–	–	–	–	–	–
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)	99.74 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.74 (-0.6/+0.4)	98.00 (-0.7/+0.5)	94.86 (-1.2/+1.0)	84.91 (-2.1/+1.9)	71.09 (-2.8/+2.7)	60.81 (-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	2422	2071	1744	1437	1173	879	621	438
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.24 (-0.2/+0.2)	98.49 (-0.3/+0.2)	97.09 (-0.4/+0.4)	92.87 (-0.7/+0.6)	81.88 (-1.1/+1.0)	69.73 (-1.4/+1.3)	58.99 (-1.7/+1.6)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 (-0.1/+0.1)	99.82 (-0.2/+0.1)	99.82 (-0.2/+0.1)
	Effective Sample Size	13687	11697	10067	8523	7167	6028	4925	3665	2283	1139

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

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

INSIGNIA Plus SR

Model 1194

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

INSIGNIA Plus SR Model 1194

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 35

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[8] Low-voltage capacitor (Advisory issued)	1	2	
[28] Capacitor	2	2	
[34] Integrated circuit	-	1	
[70] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[12] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[32] Capacitor array	1	-	
[38] Seal plug	-	1	
Software	**1**	**-**	**1**
[79] Pacing rate limit	1	-	
Other	**17**	**1**	**18**
Non-patterned	4	-	
[18] Longevity labeling	10	-	
[37] Battery depletion	-	1	
[57] Battery depletion	1	-	
[99] Battery status	2	-	
WW Confirmed Malfunctions	**23**	**12**	**35**

More details about malfunctions

References cited in table above

INSIGNIA AVT

Models 0482/0882/0982/1192/1292

INSIGNIA AVT
Models 0482/0882/0982/1192/1292

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 66

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[28] Capacitor	-	1	
[70] Integrated circuit	-	1	
Mechanical	**1**	**-**	**1**
[38] Seal plug	1	-	
Software	**-**	**-**	**0**
Other	**58**	**2**	**60**
Non-patterned	1	1	
[18] Longevity labeling	37	-	
[57] Battery depletion	-	1	
[99] Battery status	20	-	
WW Confirmed Malfunctions	**59**	**7**	**66**

More details about malfunctions

References cited in table above

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 2013**— *August 29, 2013 Voluntary Physician Advisory.* Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning
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. **Shortened replacement window**— *April 05, 2007 and March 04, 2009 Voluntary Physician Advisory.* Accelerated battery depletion may reduce time between elective replacement (ERI) and end of life (EOL) indicators to less than three months. Device replacement indicators continue to function normally. Degradation of low-voltage capacitor. Improvement implemented.
8. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory.* Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
9. **Premature battery depletion**— *May 12, 2006 Voluntary Physician Advisory.* Premature battery depletion, significantly shortened longevity and duration between elective replacement (ERI) and end of life (EOL) indicators. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
10. **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.
11. **Hermetic sealing component Second Population**— *January 21, 2006 Voluntary Physician Advisory.* Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate, or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.
12. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.

13. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.

14. **Hermetic sealing component Original Population**— *July 18, 2005 and January 21, 2006 Voluntary Physician Advisory.* Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.

15. **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.

16. **Integrated circuit chips**— *March 29, 1999 Voluntary Physician Advisory.* Loss of pacing, premature replacement indicators, backup mode operation, disruption of diagnostic measurements. High current drain resulting from a short circuit between two integrated circuit chips. Improvement implemented.

17. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.

18. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.

19. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.

20. **Longevity Remaining error**— When near ERT, Longevity Remaining Estimate is incorrect when amplitude is reprogrammed to a higher value. Gas gauge display is not affected.

21. **Parameter errors**— During RF interrogation, parameter errors occur, requiring manual parameter correction. Corruption in telemetry logic. Improvement implemented.

22. **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.

23. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.

24. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.

25. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.

26. **Pacing wire weld**— Loss of telemetry, loss of pacing. Weld failure between header and internal circuitry.

27. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.

28. **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.

29. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.

30. **Feedthrough wires**— High impedance and/or loss of pacing therapy. Broken wire connecting header to internal circuitry. Improvement implemented.

31. **Battery depletion**— Premature battery depletion.

32. **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.

33. **High current drain**— Loss of pacing, premature replacement indicators, backup mode operation, disruption of diagnostic measurements. High current drain resulting from a short circuit between two integrated circuit chips. Improvement implemented.

34. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.

35. **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.

36. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.

37. **Battery depletion**— Premature battery depletion and loss of capture.

38. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.

39. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.

40. **Telemetry or atrial noise**— Noise during telemetry and/or atrial sensing. Inappropriate contact between telemetry coil and device case. Improvement implemented.

41. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.

42. **Overestimation of battery status**— *May 06, 2003 Voluntary Physician Advisory.* Improvement in battery status between follow-up visits and/or overestimation of remaining longevity. Very specific conditions involving the use of an atrial tachycardia response feature. Software upgrade distributed late November 2003 eliminated the possibility of battery status overestimation. Improvement implemented.

43. **Impedance**— Atrial and/or ventricular pacing impedances >2500 ohms in unipolar and bipolar modes.

44. **Battery weld**— No pacing output and/or inability to interrogate. Battery weld. Improvement implemented.

45. **Battery depletion**— Premature battery depletion.

46. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.

47. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.

48. **Adhesive consistency**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Bubbles or voids in adhesive. Improvement implemented.

49. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.

50. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.

51. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.

52. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.

53. **Memory address**— Inability to interrogate. Memory address error. Improvement implemented.

54. **Telemetry coil**— No pacing output and/or an inability to interrogate. Short circuit between pulse generator feedthrough wires and telemetry coil. Improvement implemented.

55. **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.

56. **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.

57. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.

58. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.

59. **Internal device connection**— Intermittent or no telemetry. Telemetry coil connection. Improvement implemented.

60. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.

61. **Memory location**— Inappropriate early display of elective replacement indicator (ERI). Incorrect data within a specific memory location.

62. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.

63. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.

64. **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.

65. **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.

66. **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.

67. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.

68. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.

69. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.

70. **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.

71. **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.

72. **Diagnostic data error**— Potential inability to view daily measurements and/or inappropriate indication of BOL. Rate fault reset. Improvement implemented.

73. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.

74. **Charge time limit**— Early appearance of elective replacement indicator (ERI). Incorrect extended charge time limit. Improvement implemented.

75. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented

76. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.

77. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.

78. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.

79. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.

80. **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.

81. **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.

82. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.

83. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.

84. **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.

85. **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.

86. **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.

87. **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.

88. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.

89. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.

90. **Resistor**— Alert messages upon interrogation, beeping tones or premature battery depletion. Resistor material oxidation. Improvement implemented.

91. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.

92. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.

93. **Battery status**— Battery status readings below BOL at or soon after implant caused by exposure to below room temperatures before implant. Actual battery status and longevity are not affected. Improvement implemented.

94. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.

95. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.

96. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor

failure.

97. **Bent flex circuit**— Charge time-out and/or EOL declaration, due to bent flex circuit. Improvement implemented.
98. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
99. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
100. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
101. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
102. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
103. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
104. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance.
105. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
106. **Telemetry**— Inability to interrogate, premature battery depletion.
107. **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.
108. **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.
109. **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 isssues. 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
INCEPTA CRT-D 4-Site N160/N162/P162	12,000	0	0	0	1	0	0
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	13,000	0	0	0	1	0	0
ENERGEN CRT-D 4-Site N140/N142/P142	15,000	1	0	0	2	0	0
ENERGEN CRT-D N141/N143/P143	13,000	3	0	0	2	0	0
PUNCTUA CRT-D 4-Site N050/N052/P052	2,000	0	0	0	0	0	0
PUNCTUA CRT-D N051/N053/P053	4,000	1	0	0	0	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	23	50	3	26	0	0
LIVIAN HE H227/H229/H247/H249	7,000	3	1	0	0	0	0
LIVIAN H220/H225/H240/H245	6,000	0	1	0	2	0	0

CRT-D/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL 4 RF HE H239	1,000	14	0	0	0	0	0
CONTAK RENEWAL 4 RF H230/H235	8,000	45	2	0	0	0	0
CONTAK RENEWAL 4 HE H197/H199	7,000	7	7	0	0	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	12	1	1	0	0
CONTAK RENEWAL 4 AVT HE M177/M179	1,000	0	1	0	1	0	0
CONTAK RENEWAL 4 AVT M170/M175	2,000	1	0	0	0	0	0
CONTAK RENEWAL 3 RF H210/H215	21,000	486	9	1	7	0	0
CONTAK RENEWAL 3 H170/H175	34,000	45	61	0	9	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INVIVE V172/V173/V182/V183/W172/W173	12000	0	0	0	0	0	0
CONTAK RENEWAL TR 2 H140/H145	31000	0	6	0	3	0	0
CONTAK RENEWAL TR H120/H125	19000	0	9	0	3	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA ICD VR 4-Site E160/F160	11000	0	1	0	0	0	0
INCEPTA ICD DR 4-Site E162/F162	13000	0	0	0	0	0	0
INCEPTA ICD VR E161/F161	5000	0	0	0	0	0	0
INCEPTA ICD DR E163/F163	7000	0	0	0	0	0	0
ENERGEN ICD VR 4-Site E140/F140	15000	1	0	0	1	0	0
ENERGEN ICD DR 4-Site E142/F142	15000	1	1	0	0	0	0
ENERGEN ICD VR E141/F141	8000	2	0	0	0	0	0
ENERGEN ICD DR E143/F143	10000	2	0	0	1	0	0
PUNCTUA ICD VR 4-Site E050/F050	2000	0	1	0	0	0	0
PUNCTUA ICD DR 4-Site E052/F052	1000	1	0	0	0	0	0
PUNCTUA ICD VR E051/F051	4000	0	0	0	0	0	0
PUNCTUA ICD DR E053/F053	3000	1	0	0	0	0	0
TELIGEN VR E102/E103/F102/F103	65000	5	27	2	17	0	0
TELIGEN DR E110/E111/F110/F111	90000	5	38	1	17	0	0
CONFIENT DR E030/F030	8000	0	1	0	3	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO EL DR J064/K064/K067/K084	4000	0	0	0	0	0	0
ADVANTIO SR J062/J065/K062/K065/K082	15000	0	0	0	0	0	0
ADVANTIO DR J063/J066/K063/K066/K083	43000	3	0	0	2	0	0
INGENIO EL DR J174/J177/K174/K177/K184	16000	1	1	0	0	0	0
INGENIO SR J172/J175/K172/K175/K182	18000	0	0	0	0	0	0
INGENIO DR J173/J176/K173/K176/K183	61000	0	0	0	0	0	0
ALTRUA 60 SR S601	68000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132000	1	22	0	4	0	0
ALTRUA 60 DR S602	55000	1	11	0	2	0	0
ALTRUA 50 SR S501	23000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	42000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	10000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6000	0	0	0	0	0	0
ALTRUA 50 SSI S508	6000	0	0	0	0	0	0
ALTRUA 40 SR S401	9000	0	2	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 40 DR (Downsize) S403	22000	0	4	0	2	0	0
ALTRUA 40 DR S402	3000	1	3	0	0	0	0
ALTRUA 40 DR EL S404	9000	0	0	0	0	0	0
ALTRUA 20 SR S201/S204	23000	0	2	0	0	0	0
ALTRUA 20 DR (Downsize) S203	16000	0	1	0	0	0	0
ALTRUA 20 DR S202/S205	3000	1	0	0	1	0	0
ALTRUA 20 DR EL S208	10000	0	0	0	0	0	0
ALTRUA 20 DDD S207	1000	0	0	0	0	0	0
ALTRUA 20 SSI S206	7000	0	0	0	0	0	0
INSIGNIA Ultra SR 1190*	48000	3	3	0	1	0	0
INSIGNIA Ultra DR (Downsize) 1290*	124000	1	1	1	7	0	0
INSIGNIA Ultra DR 1291*	51000	1	7	1	3	0	0
INSIGNIA Entra SR 1195/1198*	52000	1	0	3	0	0	0
INSIGNIA Entra DR (Downsize) 1296*	47000	1	6	5	3	0	0
INSIGNIA Entra DR 1294/1295*	36000	0	6	2	4	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INSIGNIA Plus SR 1194*	51000	1	5	11	2	0	0
INSIGNIA Plus DR (Downsize) 1298*	140000	3	15	27	6	0	1
INSIGNIA Plus DR 1297*	47000	0	6	8	1	0	1
INSIGNIA AVT 0482/0882/0982/1192/1292*	51000	1	1	0	2	0	0

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

U.S. Reason for Out of Service

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

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

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
INCEPTA CRT-D 4-Site N160/N162/P162	6000	2	1	0	0	60	341
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	9000	0	1	0	2	89	617
ENERGEN CRT-D 4-Site N140/N142/P142	10000	1	1	2	2	106	649
ENERGEN CRT-D N141/N143/P143	10000	2	0	1	7	97	777
COGNIS N118/N119/N120/P106/P107/P108	75000	357	27	6	366	1424	21560
LIVIAN HE H227/H229/H247/H249	6000	687	4	1	4	173	2338
LIVIAN H220/H225/H240/H245	5000	500	0	3	8	118	1948
CONTAK RENEWAL 3 RF H210/H215	21000	6760	28	13	176	524	10817
CONTAK RENEWAL 3 H170/H175	34000	11943	72	29	973	776	18245

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
INVIVE V172/V173/V182/V183/W172/W173	5000	1	0	0	0	18	319
CONTAK RENEWAL TR H120/H125	19000	1503	10	131	43	242	8410

S-ICD/Model		Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
SQ-RX Pulse Generator 1010		0	0	0	8	17	83

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
INCEPTA ICD VR 4-Site E160/F160	6000	3	0	3	2	40	250
INCEPTA ICD DR 4-Site E162/F162	7000	1	0	6	2	55	323
INCEPTA ICD VR E161/F161	3000	0	0	1	1	28	127
INCEPTA ICD DR E163/F163	4000	2	0	1	1	28	189
ENERGEN ICD VR 4-Site E140/F140	11000	4	0	4	2	86	474
ENERGEN ICD DR 4-Site E142/F142	10000	1	0	5	4	95	546
ENERGEN ICD VR E141/F141	5000	2	0	1	2	32	284
ENERGEN ICD DR E143/F143	8000	0	0	3	1	43	416

ICD/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
TELIGEN VR E102/E103/F102/F103	38000	45	16	306	261	540	8299
TELIGEN DR E110/E111/F110/F111	66000	89	25	439	373	971	15304
CONFIENT DR E030/F030	7000	32	2	91	7	137	2350
VITALITY 2 EL VR T177	7000	774	9	146	1143	107	2426
VITALITY 2 EL DR T167	8000	1286	13	141	754	129	2995
VITALITY 2 VR T175	21000	4368	33	377	1239	293	8794
VITALITY 2 DR T165	31000	9851	78	526	1139	451	12916
VITALITY DR HE T180	13000	1642	14	229	408	299	6121
VITALITY DS DR T125	22000	7708	67	361	1182	303	10031
VITALITY DS VR T135	19000	5058	39	317	1553	252	8598
VITALITY EL T127	4000	832	9	60	617	69	1507

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	7000	1	0	4	1	31	533
ADVANTIO DR J063/J066/K063/K066/K083	32000	3	1	6	5	135	1235
INGENIO SR J172/J175/K172/K175/K182	7000	0	0	4	0	26	443
INGENIO DR J173/J176/K173/K176/K183	38000	6	2	6	4	132	1222

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 60 SR S601	32000	93	1	158	2	151	9912
ALTRUA 60 DR (Downsize) S603	90000	841	24	339	17	511	19716
ALTRUA 60 DR S602	22000	108	2	121	3	164	5101
ALTRUA 60 DR EL S606	59000	71	5	175	6	349	8804
ALTRUA 40 SR S401	5000	12	0	14	2	20	1671
ALTRUA 40 DR (downsize) S403	14000	126	1	34	3	72	3321
ALTRUA 40 DR S402	2000	6	1	14	0	6	550
ALTRUA 40 DR EL S404	5000	6	0	20	0	39	1046
ALTRUA 20 SR S201/S204	4000	17	1	15	0	33	1758
ALTRUA 20 DR (downsize) S203	5000	41	2	18	0	35	1500
ALTRUA 20 DR S202/S205	2000	10	0	5	1	11	568
ALTRUA 20 DR EL S208	3000	5	0	12	1	7	747
INSIGNIA Ultra SR 1190 [4]	24000	1135	9	193	31	138	14923
INSIGNIA Ultra DR (Downsize) 1290 [4]	76000	12444	105	525	405	581	35780
INSIGNIA Ultra DR 1291 [4]	32000	1369	15	281	112	290	13266

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
INSIGNIA Entra SR 1195/1198 [4]	14000	451	10	80	9	72	9863
INSIGNIA Entra DR (Downsize) 1296 [4]	24000	3890	25	128	96	146	14574
INSIGNIA Entra DR 1294/1295 [4]	17000	825	10	114	55	176	9756
INSIGNIA Plus SR 1194 [4]	27000	2527	7	221	27	156	19783
INSIGNIA Plus DR (Downsize) 1298 [4]	90000	23881	113	528	372	692	50217
INSIGNIA Plus DR 1297 [4]	27000	2941	18	246	121	252	13781
DISCOVERY II DR 1284/1286 [4]	23000	5807	9	123	21	168	14961

[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, electrive replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

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

ACUITY Spiral

Models 4591/4592/4593

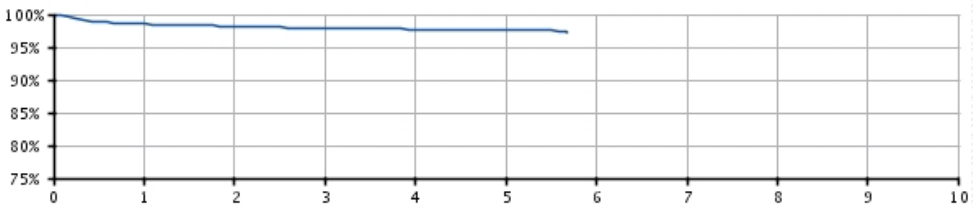
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 19,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 14,000

U.S. Chronic Lead Complications: 246
U.S. Malfunctions:89
Without Compromised Therapy:3
With Compromised Therapy:86

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	98.54 (-0.2/+0.2)	98.20 (-0.2/+0.2)	97.91 (-0.2/+0.2)	97.69 (-0.3/+0.3)	97.54 (-0.3/+0.3)	97.32 @ 68 mo. (-0.6/+0.5)	–	–	–	–
Effective Sample Size	14161	10363	6991	3943	1562	312	–	–	–	–

ACUITY Spiral

Models 4591/4592/4593

ACUITY Spiral Models 4591/4592/4593

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 99

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**3**	**4**
[28] Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**92**	**92**
[30] Unconfirmed Extrinsic	-	92	
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**2**	**-**	**2**
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**3**	**96**	**99**

More details about malfunctions

References cited in table above

ACUITY Spiral Longitude*

Models 4591/4592/4593

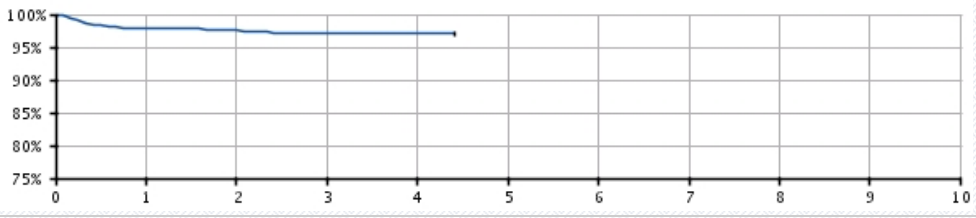
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1220
Leads Active: 939
Cumulative Followup Months : 42,144

Chronic Lead Complications: 19
Malfunctions:10
Without Compromised Therapy:0
With Compromised Therapy:10

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 1220	98.00 (-1.0/+0.7)	97.51 (-1.2/+0.8)	97.03 (-1.3/+0.9)	97.03 (-1.3/+0.9)	97.03 @ 50 mo. (-1.3/+0.9)	–	–	–	–	–
Effective Sample Size	924	698	440	147	121	–	–	–	–	–

ACUITY Steerable

Models 4554/4555/4556

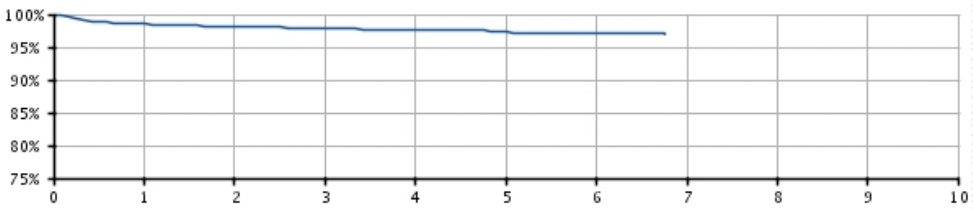
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 26,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 17,000

U.S. Chronic Lead Complications: 330
U.S. Malfunctions:180
Without Compromised Therapy:7
With Compromised Therapy:173

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 26000	98.51 (-0.2/+0.1)	98.14 (-0.2/+0.2)	97.85 (-0.2/+0.2)	97.63 (-0.2/+0.2)	97.27 (-0.3/+0.3)	97.03 (-0.3/+0.3)	97.03 @ 81 mo. (-0.3/+0.3)	–	–	–
Effective Sample Size	20128	15947	12134	8525	5150	2131	240	–	–	–

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 57,000
Worldwide Confirmed Malfunctions: 235

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**3**	**36**	**39**
[28] Non-patterned, Conductor	1	9	
[35] Extracardiac fracture	2	27	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**2**	**187**	**189**
[30] Unconfirmed Extrinsic	-	187	
[31] Inconclusive Extrinsic	2	-	
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**5**	**1**	**6**
[27] Non-patterned, Other	5	1	
WW Confirmed Malfunctions	**10**	**225**	**235**

More details about malfunctions

References cited in table above

EASYTRAK 3

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

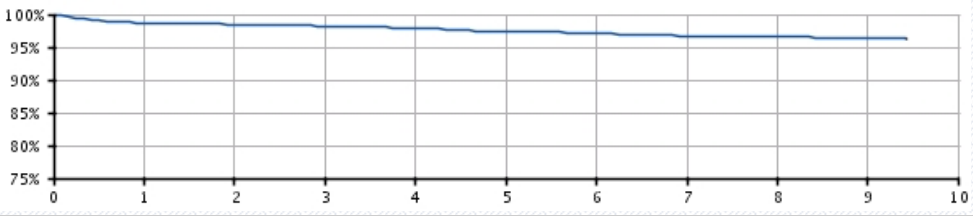
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 20,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 317
U.S. Malfunctions:102
Without Compromised Therapy:5
With Compromised Therapy:97

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 20000	98.68 (-0.2/+0.2)	98.49 (-0.2/+0.2)	98.25 (-0.2/+0.2)	97.91 (-0.2/+0.2)	97.46 (-0.3/+0.3)	97.12 (-0.3/+0.3)	96.68 (-0.4/+0.3)	96.60 (-0.4/+0.4)	96.31 (-0.5/+0.4)	96.31 @ 113 mo. (-0.5/+0.4)
Effective Sample Size	16173	13338	10994	8915	6954	5239	3716	2037	718	230

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: 39,000
Worldwide Confirmed Malfunctions: 129

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**34**	**40**
[28] Non-patterned, Conductor	4	5	
[35] Extracardiac fracture	2	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**84**	**84**
[30] Unconfirmed Extrinsic	-	84	
Insulation	**3**	**1**	**4**
[29] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**10**	**119**	**129**

More details about malfunctions

References cited in table above

EASYTRAK 2

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

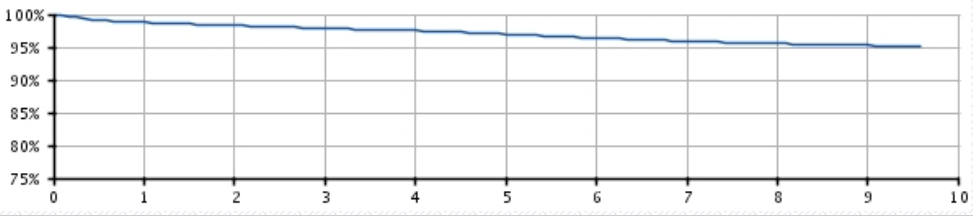
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 90,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 47,000

U.S. Chronic Lead Complications: 1,555
U.S. Malfunctions:624
Without Compromised Therapy:27
With Compromised Therapy:597

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 90000	98.77 (-0.1/+0.1)	98.30 (-0.1/+0.1)	97.88 (-0.1/+0.1)	97.52 (-0.1/+0.1)	97.00 (-0.1/+0.1)	96.40 (-0.2/+0.2)	95.90 (-0.2/+0.2)	95.58 (-0.2/+0.2)	95.32 (-0.3/+0.3)	95.17 @ 115 mo. (-0.3/+0.3)
Effective Sample Size	72141	59780	48964	38739	29377	21339	14518	8236	3155	390

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: 164,000
Worldwide Confirmed Malfunctions: 804

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**19**	**357**	**376**
[26] Conductor fracture	16	311	
[28] Non-patterned, Conductor	3	46	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**4**	**402**	**406**
[30] Unconfirmed Extrinsic	-	394	
[31] Inconclusive Extrinsic	4	8	
Insulation	**9**	**2**	**11**
[29] Non-patterned, Insulation	9	2	
Other	**6**	**5**	**11**
[27] Non-patterned, Other	6	5	
WW Confirmed Malfunctions	**38**	**766**	**804**

More details about malfunctions

References cited in table above

EASYTRAK

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

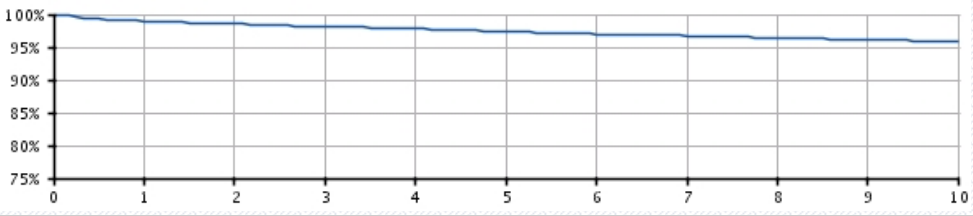
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 9,000

U.S. Chronic Lead Complications: 715
U.S. Malfunctions:186
Without Compromised Therapy:10
With Compromised Therapy:176

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	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)	96.74 (-0.2/+0.2)	96.35 (-0.3/+0.3)	96.09 (-0.3/+0.3)	95.92 (-0.3/+0.3)
Effective Sample Size	30542	26258	22530	19364	16533	14026	11668	9755	8168	5297

EASYTRAK

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

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

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

Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 203

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**13**	**13**
[28] Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**176**	**176**
[30] Unconfirmed Extrinsic	-	176	
[31] Inconclusive Extrinsic	-	-	
Insulation	**3**	**3**	**6**
[29] Non-patterned, Insulation	3	3	
Other	**7**	**1**	**8**
[27] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**193**	**203**

More details about malfunctions

References cited in table above

Q-TRAK SQ Electrode

Model 3010

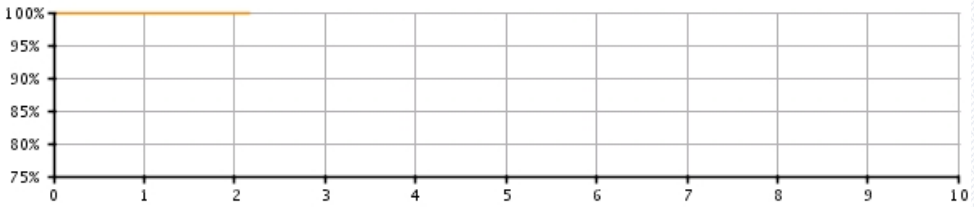
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Approval Date: September 2012

U.S. Chronic Lead Complications: 0
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	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 26 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	–	–	–	–	–	–	–	–	–	–

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

Q-TRAK SQ Electrode

Model 3010

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

Q-TRAK SQ Electrode Model 3010

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**-**	**0**
Crimp/Weld/Bond	**-**	**1**	**1**
[37] Weld fracture	-	1	
Extrinsic	**-**	**-**	**0**
Insulation	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

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

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	-	4	4
[30] Unconfirmed Extrinsic	-	4	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	4	4

More details about malfunctions

References cited in table above

RELIANCE SG 4-FRONT Single Coil Active Fixation

Models 0657/0692/0693

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

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

Worldwide Distribution: 5,000

Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-Site
Dual Coil, Active Fixation

Models 0295/0296

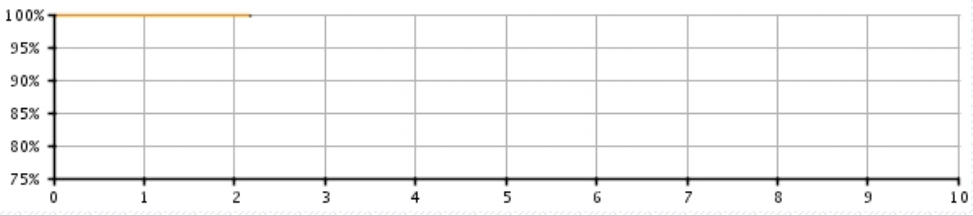
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 30,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 28,000

U.S. Chronic Lead Complications: 35
U.S. Malfunctions:20
Without Compromised Therapy:0
With Compromised Therapy:20

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 29000	99.77 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.76 @ 26 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	15421	2178	527	–	–	–	–	–	–	–

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: 55,000

Worldwide Confirmed Malfunctions: 79

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[28] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**57**	**57**
[30] Unconfirmed Extrinsic	-	57	
Insulation	**7**	**9**	**16**
[29] Non-patterned, Insulation	7	9	
Other	**2**	**1**	**3**
[27] Non-patterned, Other	2	1	
WW Confirmed Malfunctions	**9**	**70**	**79**

More details about malfunctions

References cited in table above

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

Models 0295/0296

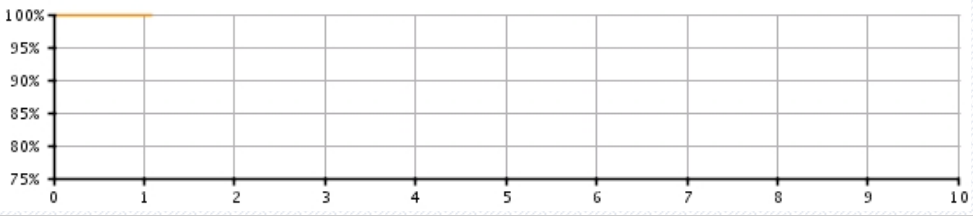
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 359
Leads Active: 338
Cumulative Followup Months : 2,315

Chronic Lead Complications: 1
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
Longitude Registered Implants: 359	100.00 (-0.0/+0.0)	100.00 @ 13 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	56	52	–	–	–	–	–	–	–	–

ENDOTAK RELIANCE G 4-Site
Dual Coil, Passive Fixation

Models 0285/0286

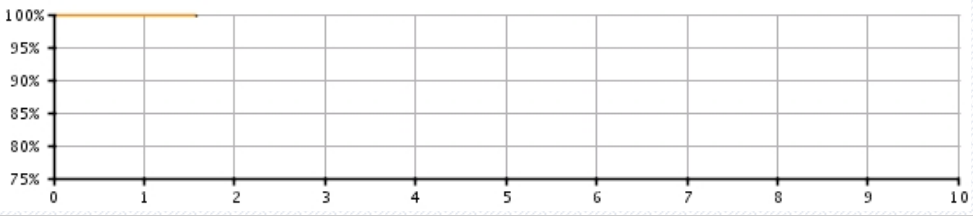
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 1,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 2
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	99.76 (-0.7/+0.2)	99.76 @ 19 mo. (-0.7/+0.2)	–	–	–	–	–	–	–	–
Effective Sample Size	476	217	–	–	–	–	–	–	–	–

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: 6,000

Worldwide Confirmed Malfunctions: 3

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation

Models 0292/0293

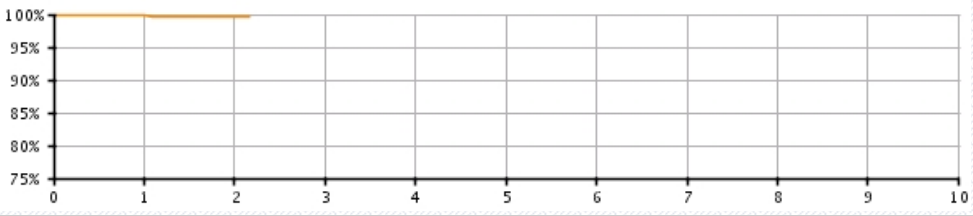
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 21,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 20,000

U.S. Chronic Lead Complications: 29
U.S. Malfunctions:12
Without Compromised Therapy:1
With Compromised Therapy:11

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 20000	99.76 (-0.1/+0.1)	99.64 (-0.2/+0.1)	99.64 @ 26 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	8418	1008	263	–	–	–	–	–	–	–

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: 42,000

Worldwide Confirmed Malfunctions: 32

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**1**	**1**
[28] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**24**	**24**
[30] Unconfirmed Extrinsic	-	24	
Insulation	**2**	**4**	**6**
[29] Non-patterned, Insulation	2	4	
Other	**-**	**1**	**1**
[27] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**2**	**30**	**32**

More details about malfunctions

References cited in table above

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

Models 0292/0293

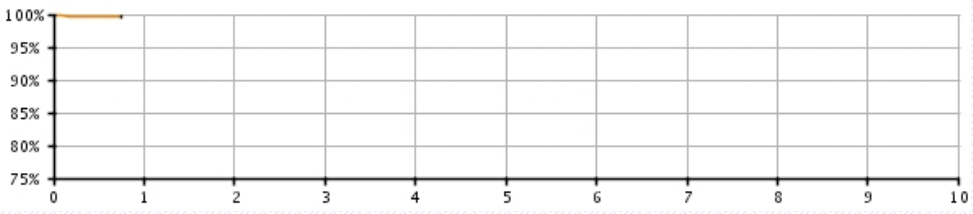
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 495
Leads Active: 474
Cumulative Followup Months : 2,340

Chronic Lead Complications: 0
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
Longitude Registered Implants: 495	99.71 @ 9 mo. (-1.7/+0.3)	–	–	–	–	–	–	–	–	–
Effective Sample Size	50	–	–	–	–	–	–	–	–	–

ENDOTAK RELIANCE SG 4-Site Single Coil, Passive Fixation

Models 0282/0283

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

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

Worldwide Distribution: 2,000

Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Extrinsic	2	1	3
[30] Unconfirmed Extrinsic	-	1	
[31] Inconclusive Extrinsic	2	-	
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	2	1	3

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276

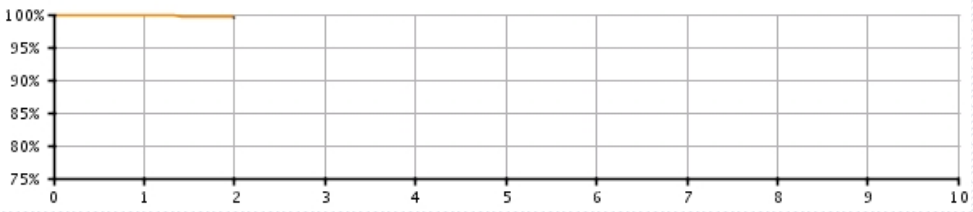
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 3,000

U.S. Chronic Lead Complications: 4
U.S. Malfunctions:3
Without Compromised Therapy:0
With Compromised Therapy:3

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.80 (-0.3/+0.1)	99.53 (-0.7/+0.3)	–	–	–	–	–	–	–	–
Registered Implants: 3000										
Effective Sample Size	1556	233	–	–	–	–	–	–	–	–

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: 3,000

Worldwide Confirmed Malfunctions: 3

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models 0265/0266

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

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

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G
Dual Coil, Active Fixation

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

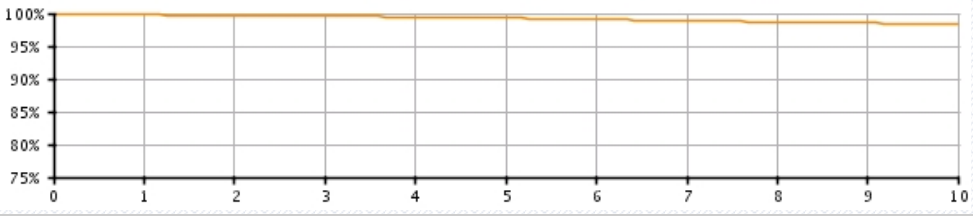
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 187,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 116,000

U.S. Chronic Lead Complications: 572
U.S. Malfunctions:594
Without Compromised Therapy:85
With Compromised Therapy:509

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.29 (-0.0/+0.0)	99.09 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.68 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.38 (-0.2/+0.2)
Registered Implants: 186000										
Effective Sample Size	162859	142643	115568	89891	66169	44777	28571	16613	6738	231

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: 251,000

Worldwide Confirmed Malfunctions: 862

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**80**	**82**
[25] Conductor fracture	-	51	
[28] Non-patterned, Conductor	2	29	
Crimp/Weld/Bond	**2**	**-**	**2**
[32] Non-patterned, Crimp, Weld, Bond	2	-	
Extrinsic	**10**	**568**	**578**
[30] Unconfirmed Extrinsic	-	566	
[31] Inconclusive Extrinsic	10	2	
Insulation	**113**	**53**	**166**
[29] Non-patterned, Insulation	113	53	
Other	**21**	**13**	**34**
[27] Non-patterned, Other	21	13	
WW Confirmed Malfunctions	**148**	**714**	**862**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G
Dual Coil, Active Fixation Longitude

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

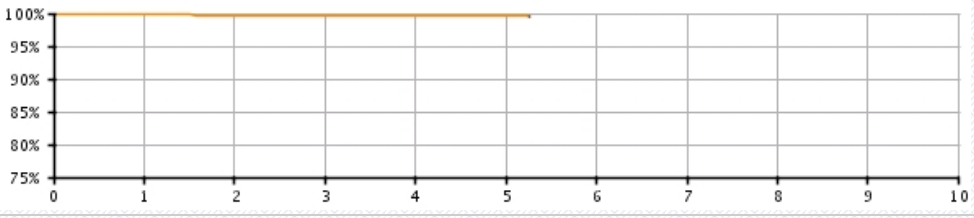
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 620
Leads Active: 470
Cumulative Followup Months : 25,002

Chronic Lead Complications: 1
Malfunctions:1
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 Registered Implants: 620	100.00 (-0.0/+0.0)	99.59 (-1.2/+0.3)	99.59 (-1.2/+0.3)	99.59 (-1.2/+0.3)	99.59 (-1.2/+0.3)	99.59 @ 63 mo. (-1.2/+0.3)	–	–	–	–
Effective Sample Size	535	452	334	156	54	51	–	–	–	–

ENDOTAK RELIANCE G
Dual Coil, Passive Fixation

Models 0174/0175/0176/0177

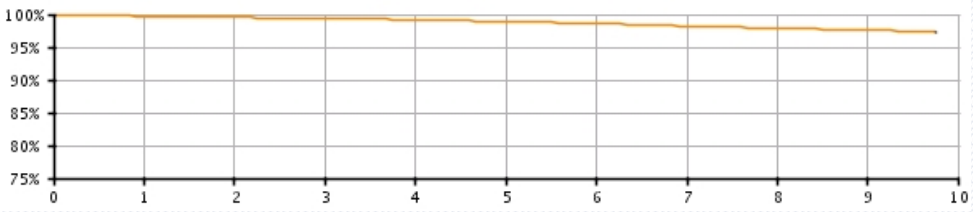
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 8,000

U.S. Chronic Lead Complications: 81
U.S. Malfunctions:53
Without Compromised Therapy:8
With Compromised Therapy:45

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	99.72 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.38 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.91 (-0.2/+0.2)	98.64 (-0.3/+0.2)	98.22 (-0.4/+0.3)	97.87 (-0.5/+0.4)	97.53 (-0.6/+0.5)	97.32 @ 117 mo. (-0.8/+0.6)
Effective Sample Size	11732	10128	8378	6690	5154	3743	2548	1602	745	218

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: 145

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**16**	**16**
[25] Conductor fracture	-	13	
[28] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**1**	**1**
[36] Conductor connection	-	1	
Extrinsic	**9**	**90**	**99**
[30] Unconfirmed Extrinsic	-	86	
[31] Inconclusive Extrinsic	9	4	
Insulation	**15**	**9**	**24**
[29] Non-patterned, Insulation	15	9	
Other	**5**	**-**	**5**
[27] Non-patterned, Other	5	-	
WW Confirmed Malfunctions	**29**	**116**	**145**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

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

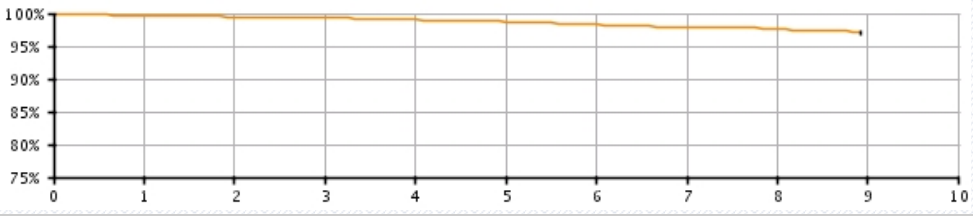
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 25,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 20,000

U.S. Chronic Lead Complications: 72
U.S. Malfunctions:118
Without Compromised Therapy:18
With Compromised Therapy:100

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 25000	99.67 (-0.1/+0.1)	99.46 (-0.1/+0.1)	99.32 (-0.1/+0.1)	99.01 (-0.2/+0.2)	98.74 (-0.2/+0.2)	98.35 (-0.4/+0.3)	97.95 (-0.5/+0.4)	97.67 (-0.7/+0.5)	97.03 @ 107 mo. (-1.3/+0.9)	–
Effective Sample Size	20367	16451	10623	6481	3811	1960	958	509	211	–

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: 53,000

Worldwide Confirmed Malfunctions: 256

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**42**	**43**
[25] Conductor fracture	1	36	
[28] Non-patterned, Conductor	-	6	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**143**	**144**
[30] Unconfirmed Extrinsic	-	142	
[31] Inconclusive Extrinsic	1	1	
Insulation	**42**	**17**	**59**
[29] Non-patterned, Insulation	42	17	
Other	**6**	**4**	**10**
[27] Non-patterned, Other	6	4	
WW Confirmed Malfunctions	**50**	**206**	**256**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

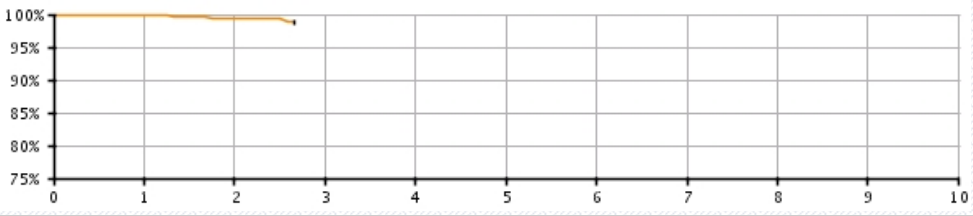
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 1,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 1
U.S. Malfunctions:3
Without Compromised Therapy:1
With Compromised Therapy:2

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	99.85 (-0.9/+0.1)	99.30 (-1.5/+0.5)	98.83 @ 32 mo. (-2.2/+0.8)	–	–	–	–	–	–	–
Effective Sample Size	480	295	202	–	–	–	–	–	–	–

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

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

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

Worldwide Distribution: 3,000

Worldwide Confirmed Malfunctions: 20

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159

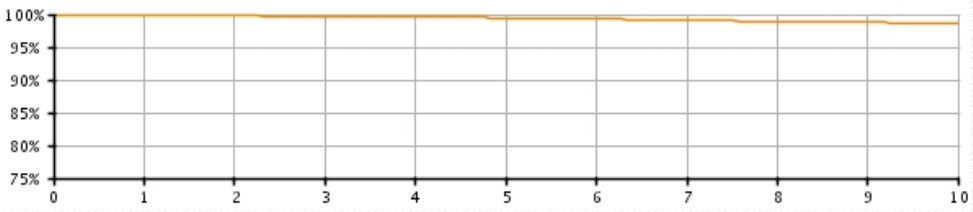
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 97,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 42,000

U.S. Chronic Lead Complications: 383
U.S. Malfunctions:247
Without Compromised Therapy:31
With Compromised Therapy:216

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.84 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.57 (-0.0/+0.0)	99.47 (-0.1/+0.1)	99.33 (-0.1/+0.1)	99.11 (-0.1/+0.1)	98.95 (-0.1/+0.1)	98.79 (-0.1/+0.1)	98.66 (-0.1/+0.1)
Registered Implants: 97000										
Effective Sample Size	84750	75171	65277	55826	46967	38920	31820	25626	19538	12081

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159

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

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

Worldwide Distribution: 113,000

Worldwide Confirmed Malfunctions: 280

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**18**	**18**
[25] Conductor fracture	-	13	
[28] Non-patterned, Conductor	-	5	
Crimp/Weld/Bond	**3**	**1**	**4**
[4] Seal rings	2	1	
[32] Non-patterned, Crimp, Weld, Bond	1	-	
Extrinsic	**1**	**196**	**197**
[30] Unconfirmed Extrinsic	-	195	
[31] Inconclusive Extrinsic	1	1	
Insulation	**30**	**20**	**50**
[29] Non-patterned, Insulation	30	20	
Other	**8**	**3**	**11**
[27] Non-patterned, Other	8	3	
WW Confirmed Malfunctions	**42**	**238**	**280**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149

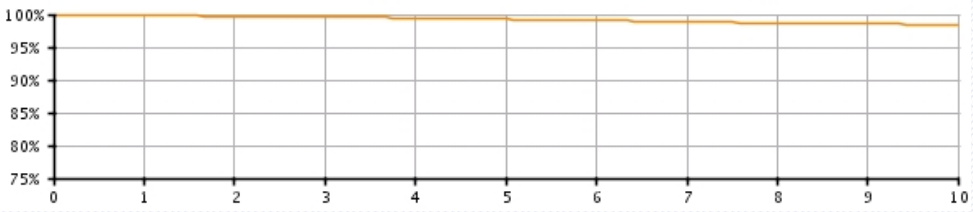
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 33,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 12,000

U.S. Chronic Lead Complications: 222
U.S. Malfunctions:89
Without Compromised Therapy:7
With Compromised Therapy:82

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.79 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.60 (-0.1/+0.1)	99.44 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.07 (-0.1/+0.1)	98.87 (-0.2/+0.1)	98.66 (-0.2/+0.2)	98.54 (-0.2/+0.2)	98.39 (-0.2/+0.2)
Registered Implants: 33000										
Effective Sample Size	28511	25388	22501	19841	17413	15215	13170	11328	9589	7718

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: 191

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**11**	**11**
[25] Conductor fracture	-	3	
[28] Non-patterned, Conductor	-	8	
Crimp/Weld/Bond	**-**	**2**	**2**
[36] Conductor connection	-	2	
Extrinsic	**7**	**119**	**126**
[30] Unconfirmed Extrinsic	-	118	
[31] Inconclusive Extrinsic	7	1	
Insulation	**22**	**24**	**46**
[29] Non-patterned, Insulation	22	24	
Other	**2**	**4**	**6**
[5] Manufacturing material	-	1	
[27] Non-patterned, Other	2	3	
WW Confirmed Malfunctions	**31**	**160**	**191**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

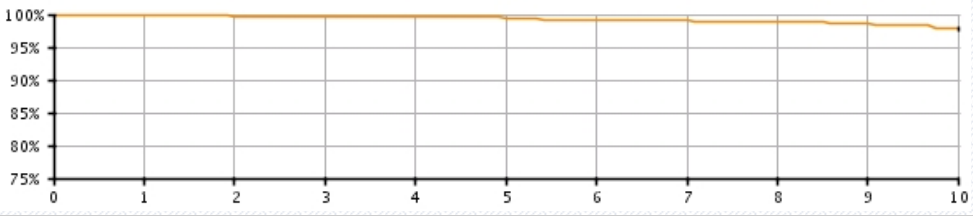
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 7
U.S. Malfunctions:8
Without Compromised Therapy:2
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	99.82 (-0.3/+0.1)	99.70 (-0.4/+0.2)	99.63 (-0.4/+0.2)	99.54 (-0.5/+0.2)	99.41 (-0.6/+0.3)	99.13 (-0.8/+0.4)	99.13 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.61 (-1.3/+0.7)	97.84 (-2.0/+1.0)
Registered Implants: 2000										
Effective Sample Size	2035	1655	1318	1032	794	607	471	378	294	208

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

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

ENDOTAK RELIANCE S
Single Coil, Active Fixation
Models 0137/0138

Worldwide Distribution: 5,000

Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[25] Conductor fracture	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**8**	**8**
[30] Unconfirmed Extrinsic	-	8	
Insulation	**5**	**1**	**6**
[29] Non-patterned, Insulation	5	1	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**6**	**11**	**17**

More details about malfunctions

References cited in table above

INGEVITY Positive Fixation

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

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

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

INGEVITY 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: 1,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

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: 1,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

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: 152,000
Worldwide Confirmed Malfunctions: 196

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**3**	**32**	**35**
[7] Lead conductor	2	18	
[33] Conductor damage	1	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**101**	**102**
[30] Unconfirmed Extrinsic	-	101	
[31] Inconclusive Extrinsic	1	-	
Insulation	**40**	**9**	**49**
[2] Inner insulation abrasion	3	-	
[29] Non-patterned, Insulation	4	-	
[34] Insulation damage	33	9	
Other	**10**	**-**	**10**
[27] Non-patterned, Other	10	-	
WW Confirmed Malfunctions	**54**	**142**	**196**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

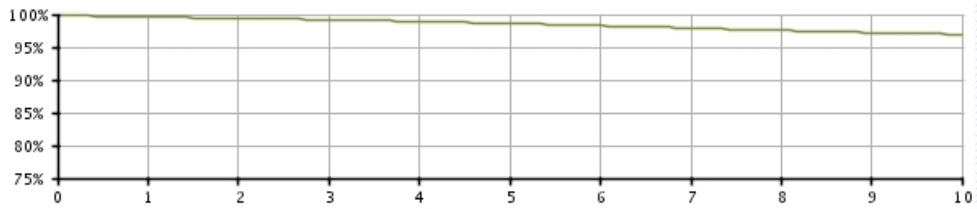
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 225,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 106,000

U.S. Chronic Lead Complications: 2,370
U.S. Malfunctions:795
Without Compromised Therapy:114
With Compromised Therapy:681

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 225000	99.60 (-0.0/+0.0)	99.39 (-0.0/+0.0)	99.19 (-0.0/+0.0)	98.92 (-0.1/+0.0)	98.63 (-0.1/+0.1)	98.28 (-0.1/+0.1)	97.92 (-0.1/+0.1)	97.56 (-0.1/+0.1)	97.22 (-0.1/+0.1)	96.94 (-0.1/+0.1)
Effective Sample Size	188542	162765	139471	117773	98162	81013	64083	45205	29656	16138

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: 273,000
Worldwide Confirmed Malfunctions: 880

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**7**	**169**	**176**
[7] Lead conductor	3	79	
[28] Non-patterned, Conductor	-	7	
[33] Conductor damage	4	83	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**2**	**566**	**568**
[30] Unconfirmed Extrinsic	-	564	
[31] Inconclusive Extrinsic	2	2	
Insulation	**97**	**22**	**119**
[2] Inner insulation abrasion	19	4	
[29] Non-patterned, Insulation	8	-	
[34] Insulation damage	70	18	
Other	**15**	**2**	**17**
[27] Non-patterned, Other	15	2	
WW Confirmed Malfunctions	**121**	**759**	**880**

More details about malfunctions

References cited in table above

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

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

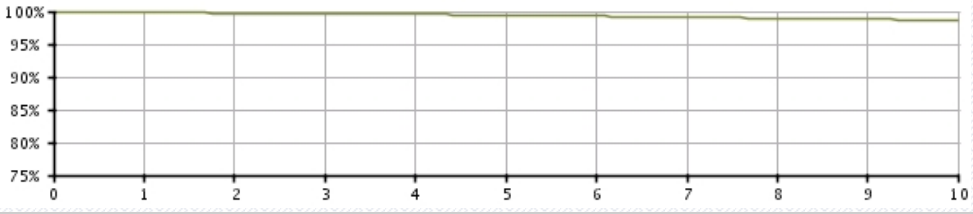
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 399,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 236,000

U.S. Chronic Lead Complications: 1,691
U.S. Malfunctions:421
Without Compromised Therapy:17
With Compromised Therapy:404

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 398000	99.82 (-0.0/+0.0)	99.73 (-0.0/+0.0)	99.65 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.43 (-0.0/+0.0)	99.28 (-0.0/+0.0)	99.10 (-0.0/+0.0)	98.96 (-0.1/+0.1)	98.80 (-0.1/+0.1)	98.65 (-0.1/+0.1)
Effective Sample Size	331214	275189	225553	181059	140899	108330	81803	58811	40165	24470

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: 593,000

Worldwide Confirmed Malfunctions: 471

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**5**	**109**	**114**
[7] Lead conductor	3	51	
[28] Non-patterned, Conductor	-	6	
[33] Conductor damage	2	52	
Crimp/Weld/Bond	**-**	**2**	**2**
[24] Terminal weld	-	1	
[32] Non-patterned, Crimp, Weld, Bond	-	1	
Extrinsic	**-**	**331**	**331**
[30] Unconfirmed Extrinsic	-	325	
[31] Inconclusive Extrinsic	-	6	
Insulation	**9**	**6**	**15**
[34] Insulation damage	9	6	
Other	**7**	**2**	**9**
[27] Non-patterned, Other	7	2	
WW Confirmed Malfunctions	**21**	**450**	**471**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude

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

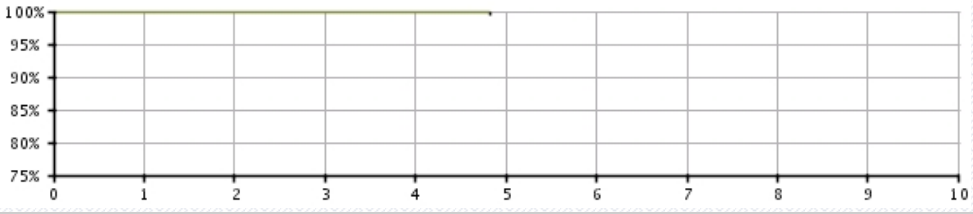
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 620
Leads Active: 515
Cumulative Followup Months : 17,531

Chronic Lead Complications: 0
Malfunctions:1
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 Registered Implants: 620	99.80 (-1.2/+0.2)	99.80 (-1.2/+0.2)	99.80 (-1.2/+0.2)	99.80 (-1.2/+0.2)	99.80 @ 58 mo. (-1.2/+0.2)	–	–	–	–	–
Effective Sample Size	381	311	213	112	51	–	–	–	–	–

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

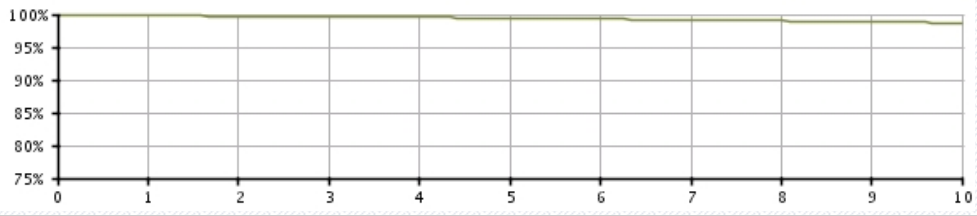
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 170,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 86,000

U.S. Chronic Lead Complications: 831
U.S. Malfunctions:113
Without Compromised Therapy:5
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	99.81 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.63 (-0.0/+0.0)	99.54 (-0.0/+0.0)	99.44 (-0.0/+0.0)	99.32 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.83 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 170000										
Effective Sample Size	140476	118091	98292	80566	64621	51137	40042	30532	22522	15337

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: 457,000

Worldwide Confirmed Malfunctions: 150

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**41**	**42**
[7] Lead conductor	-	13	
[28] Non-patterned, Conductor	-	3	
[33] Conductor damage	1	25	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**93**	**94**
[30] Unconfirmed Extrinsic	-	91	
[31] Inconclusive Extrinsic	1	2	
Insulation	**2**	**7**	**9**
[34] Insulation damage	2	7	
Other	**4**	**-**	**4**
[27] Non-patterned, Other	4	-	
WW Confirmed Malfunctions	**8**	**142**	**150**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

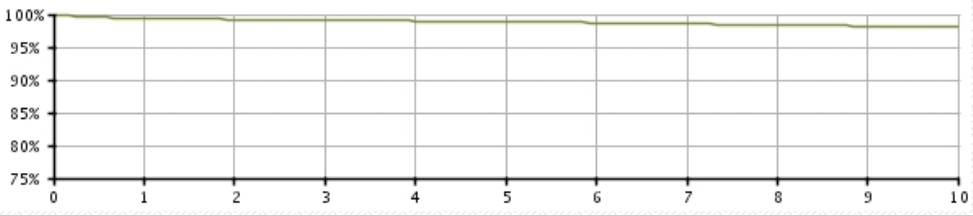
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 55,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 30,000

U.S. Chronic Lead Complications: 493
U.S. Malfunctions:88
Without Compromised Therapy:18
With Compromised Therapy:70

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 55000	99.41 (-0.1/+0.1)	99.24 (-0.1/+0.1)	99.11 (-0.1/+0.1)	98.99 (-0.1/+0.1)	98.88 (-0.1/+0.1)	98.71 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.39 (-0.2/+0.1)	98.15 (-0.2/+0.2)	98.06 (-0.2/+0.2)
Effective Sample Size	45446	38136	31765	26030	20856	16529	12853	9753	7143	4626

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: 249,000

Worldwide Confirmed Malfunctions: 146

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**10**	**12**
[7] Lead conductor	-	3	
[33] Conductor damage	2	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**97**	**97**
[30] Unconfirmed Extrinsic	-	96	
[31] Inconclusive Extrinsic	-	1	
Insulation	**-**	**1**	**1**
[34] Insulation damage	-	1	
Other	**32**	**4**	**36**
[23] J-shape	30	4	
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**34**	**112**	**146**

More details about malfunctions

References cited in table above

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

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

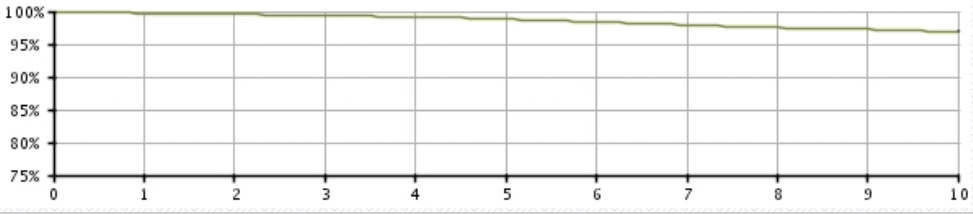
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 48,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 24,000

U.S. Chronic Lead Complications: 456
U.S. Malfunctions:169
Without Compromised Therapy:15
With Compromised Therapy:154

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 48000	99.74 (-0.1/+0.0)	99.57 (-0.1/+0.1)	99.38 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.82 (-0.1/+0.1)	98.37 (-0.2/+0.1)	97.93 (-0.2/+0.2)	97.51 (-0.2/+0.2)	97.28 (-0.3/+0.2)	96.98 (-0.3/+0.3)
Effective Sample Size	41074	35078	29686	24671	20242	16342	13033	9991	7202	4747

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: 129,000

Worldwide Confirmed Malfunctions: 215

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**121**	**123**
[7] Lead conductor	1	74	
[28] Non-patterned, Conductor	-	2	
[33] Conductor damage	1	45	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**66**	**66**
[30] Unconfirmed Extrinsic	-	65	
[31] Inconclusive Extrinsic	-	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	**15**	**200**	**215**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

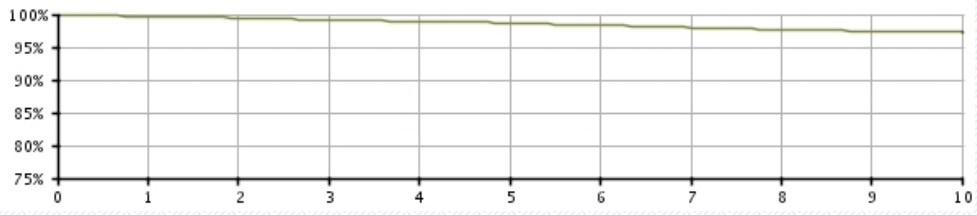
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 162
U.S. Malfunctions:30
Without Compromised Therapy:0
With Compromised Therapy:30

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	99.67 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.17 (-0.2/+0.2)	98.89 (-0.2/+0.2)	98.71 (-0.3/+0.2)	98.37 (-0.3/+0.3)	97.99 (-0.4/+0.3)	97.65 (-0.4/+0.3)	97.43 (-0.4/+0.4)	97.27 (-0.5/+0.4)
Effective Sample Size	11742	10170	8665	7267	6127	5091	4229	3444	2681	1930

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: 98,000

Worldwide Confirmed Malfunctions: 67

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**38**	**38**
[7] Lead conductor	-	15	
[33] Conductor damage	-	23	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**20**	**20**
[30] Unconfirmed Extrinsic	-	20	
[31] Inconclusive Extrinsic	-	-	
Insulation	**2**	**4**	**6**
[34] Insulation damage	2	4	
Other	**-**	**3**	**3**
[27] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**65**	**67**

More details about malfunctions

References cited in table above

Confirmed Malfunction Details: Leads

References

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

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

1. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
4. **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.
5. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
6. **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.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
11. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
12. **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. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
18. **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. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
21. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
22. **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.
23. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
24. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
25. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.

26. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
27. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
28. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
29. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.
30. **Unconfirmed Extrinsic**— Lead complication after 30 days of implant time with lead return, where analysis could not identify an out of specification condition. Includes complications such as dislodgement, perforation or failure to capture.
31. **Inconclusive Extrinsic**— Lead complication after 30 days of implant time with lead return, where analysis was inconclusive. Includes partial lead returns and leads damaged by the explantation process.
32. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.
33. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
34. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
35. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.
36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
37. **Weld fracture**— Noise, loss of sensing. Fractured weld.
38. **Conductor Cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable.

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	225000	49	563	604	488	161	60	121	272	0	52
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	170000	0	244	146	136	18	16	130	121	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	399000	12	362	449	221	26	56	311	230	0	24
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	55000	0	67	244	90	4	8	46	28	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	76	15	33	8	2	12	14	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	48000	0	171	56	58	26	9	59	75	0	2

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	26000	1	10	218	14	1	1	3	8	0	74
ACUITY Spiral 4591/4592/4593	19000	0	7	122	13	0	1	0	4	0	100

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	20000	1	23	181	28	0	1	5	5	0	73
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	90000	0	174	787	142	1	2	34	49	0	366
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	45	308	76	1	0	30	20	0	234

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	30000	0	3	22	3	4	3	0	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	400	5	0	14	4	2	2	0	1	0	1
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	1	1	0	1	0	0	0	0	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	11	110	150	46	89	21	33	52	45	15
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	0	13	20	9	4	2	4	20	7	2
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	25000	3	14	18	8	14	0	4	8	3	0
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	4	90	52	23	89	15	30	56	19	5
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	3	45	27	19	31	3	18	62	12	2

Defibrillation Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	2000	0	4	0	0	0	0	0	2	0	1
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	0	2	1	1	0	0	0	0	0

S-ICD Electrodes/Model		Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3400		0	0	0	0	0	0	0	0	0	0

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1220	0	0	11	1	0	0	0	0	0	7
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	620	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	359	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	495	0	0	0	0	0	0	0	0	0	1
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	620	0	0	0	0	0	0	0	0	0	0

U.S. Acute Lead Observations

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

Because acute implant time contributes to overall clinical experience. Boston Scientific provides specific information regarding acute llead 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	225000	224	187	1315	410	69	86	54	207	0	49
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	170000	14	12	409	156	6	25	23	37	0	19
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	399000	70	77	619	227	94	85	57	222	0	36
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	55000	1	18	424	87	5	27	17	18	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	33	16	1	2	6	5	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	48000	2	16	95	25	9	8	21	12	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	26000	1	2	304	42	25	2	7	132	0	223
ACUITY Spiral 4591/4592/4593	19000	5	4	183	58	8	2	9	36	0	213

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	20000	4	2	259	37	10	2	7	45	0	176
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	90000	13	7	867	120	47	10	24	193	0	672
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	17	34	0	185

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	30000	24	23	87	55	36	7	4	46	9	3
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	1	0	3	0	2	0	0	11	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	30000	18	31	60	19	31	7	4	37	44	7
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	2	2	2	1	3	1	1	8	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	117	124	479	122	248	33	45	255	190	60
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	4	2	48	27	15	3	0	102	15	1
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	25000	25	16	71	25	29	12	3	47	109	7
ENDOTAK RELIANCE SG Single Coil, Passive Fixation 0170/0171/0172/0173	1000	0	0	1	1	0	1	0	9	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159	97000	30	64	162	43	116	20	23	102	43	18
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	24	23	87	55	36	7	4	46	9	3

Defibrillation Leads/Model continued…	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE S Single Coil, Active Fixation 0137/0138	2000	0	1	2	2	2	1	0	5	7	0
ENDOTAK RELIANCE S Single Coil, Passive Fixation 0127/0128	1000	0	0	1	0	1	1	0	1	0	0

S-ICD Electrodes/Model		Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
Q-TRAK SQ Electrode 3400		0	0	1	0	11	3	0	1	2	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	1220	0	0	10	8	1	0	0	2	0	41
RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	359	0	0	2	0	0	0	0	0	0	0
RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	495	0	0	0	0	1	0	0	0	0	0
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	620	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	620	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 Steerable 4554/4555/4556	57,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	36,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	39,000	0	0	0	9	0	0	1
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	164,000	0	2	0	7	0	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	3	0	0	2

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
RELIANCE G 4-FRONT Dual Coil Active Fixation 0658/0695/0696	3,000	0	0	0	0	0	0	0
RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	5,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil Active Fixation 0295/0296	55,000	0	0	0	40	0	1	0
ENDOTAK RELIANCE G 4-Site Dual Coil Passive Fixation 0285/0286	6,000	0	0	0	3	0	1	0

Defibrillation Leads/Model (cont.)	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE SG 4-Site Single Coil Active Fixation 0292/0293	42,000	0	0	0	3	0	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil Passive Fixation 0282/0283	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276	3,000	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	251,000	0	0	24	283	0	3	14
ENDOTAK RELIANCE G Dual Coil Passive Fixation 0174/0175/0176/0177	39,000	0	0	3	48	0	1	0
ENDOTAK RELIANCE SG Single Coil Active Fixation 0160/0161/0162/0180/0181/0182	53,000	0	0	5	45	0	0	2
ENDOTAK RELIANCE SG Single Coil Passive Fixation 0170/0171/0172/0173	3,000	0	0	0	2	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	113,000	0	0	15	107	0	0	0
ENDOTAK RELIANCE Dual Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	67,000	0	1	0	21	0	1	0
ENDOTAK RELIANCE S Single Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	5,000	0	0	1	3	0	0	0
ENDOTAK RELIANCE S Single Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	4,000	0	0	0	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Passive Fixation 7631/7632/7731/7732	1,000	0	0	0	0	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	3,000	0	0	0	0	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	1,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	152,000	0	0	6	82	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	273,000	0	0	52	510	0	0	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	457,000	1	0	2	6	2	22	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	593,000	0	0	7	42	1	43	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	249,000	0	0	7	42	1	43	2
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	98,000	0	0	2	2	0	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	98,000	0	0	2	2	0	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 **29-Aug-13 — Low Voltage Capacitor 2013**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.	Voluntary Physician Advisory FDA Classification: Class II Boston Scientific has identified a low voltage (LV) capacitor component that, in some devices, may experience diminished performance after two or more years of implant time. This can increase battery use and eventually trigger one or more Safety Architecture alerts, accompanied by patient-audible beeping. Safety Architecture alerts have proven effective in identifying instances of unexpected battery use before therapy becomes unavailable. The most common alert is a yellow screen displayed on the programmer upon initial interrogation which states: "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". In other instances, diminished LV capacitor performance can result in an unanticipated "Explant" ("ERI") battery status alert and a replacement window that may be less than 3 months. All devices that experience diminished LV capacitor performance require replacement. If not replaced, increased current drain could deplete the battery and compromise therapy or telemetry. If device beeping or a Safety Architecture alert is observed, call Technical Services for an analysis of "save-to-disk" information, which will clarify how much time is available to replace the device. *Rate of Occurrence* A total of approximately 264,000 COGNIS and TELIGEN defibrillators have been distributed and implanted since May of 2008. However, a subset of ~38,500 devices (15% of the total) that were manufactured prior to December 2009 has experienced a higher number of LV capacitor malfunctions (approximately 0.67% or 1 in 150). Devices from this subset have not been available for implant since November of 2010. In contrast to the subset population, the rate of diminished LV capacitor performance for other COGNIS/TELIGEN devices (225,500) is approximately 0.0093% or 1 in 10,700. Please refer to Appendix A of the physician letter for US Survival Probability for the Low Voltage Capacitor 2013 subset and devices not in the subset.
COGNIS Models N106/N107/N118/N119/ P106/P107	
TELIGEN VR Models E102/F102	
TELIGEN DR Models E110/F110	
Physician and patient letters are available at www.bostonscientific.com.	
	CURRENT STATUS **07-Apr-14** No devices in the advisory population remain available for implant. *Confirmed Malfunctions (worldwide)* 610 malfunctions have been confirmed from the advisory population. Approximately 24,000 devices from the advisory population remain in service. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* The rate of occurrence for advisory population devices is approximately 1.5% at 48 months. *Projected Rate of Occurrence* The projected rate of occurrence for advisory population devices is approximately 3.8% at 60 months.

29-Aug-13 — Low Voltage Capacitor 2013, continued…

CURRENT RECOMMENDATION **07-Apr-14**

There are no additional clinical recommendations beyond the current standard of patient care and normal device monitoring, which are described in device labeling.

– As always, instruct patients to contact your clinic if beeping is heard from their device. Note that “Beep When Explant is Indicated” is nominally programmed “On” when shipped from the factory.
– Physicians should promptly investigate alerts and unanticipated replacement indicator messages.
– Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer alert screens. Technical Services can facilitate an evaluation of “save-to-disk” information (while still implanted) to help clarify available replacement time. Note that “Approximate time to Explant” and “Time Remaining” estimates displayed on the programmer are not accurate following a Safety Architecture low voltage alert.
– Boston Scientific’s LATITUDE® Patient Management System (remote monitoring) can improve detection time for battery performance messages by conveying Safety Architecture alerts and/or notifying when scheduled check-ups have not occurred. Note that weekly voltage alerts are nominally configured “On” in LATITUDE.

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

PRODUCT	ORIGINAL COMMUNICATION **01-Jun-11 — High Cathode Condition**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. **SQ-RX S-ICD** Model1010 *Physician letter is available at www.bostonscientific.com.*	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 **07-Apr-14**
	No devices in the advisory population remain available for implant. *Confirmed Malfunctions (worldwide)* Three (3) malfunctions have been confirmed worldwide of devices experiencing High Cathode Condition. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* – Population I – Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. – Population II - Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity.
	CURRENT RECOMMENDATION **07-Apr-14**
	– If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible. – Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone. For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **July 2010— Magnetic Reed Switch 2010**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.	Voluntary Physician Advisory FDA Classification: Class II
CONTAK RENEWAL 3 Models H170/H175 **CONTAK RENEWAL 3 HE** Models H177/H179	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. 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. 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
CONTAK RENEWAL 3 RF Models H210/H215 **CONTAK RENEWAL 3 RF HE** Models H217/H219 **CONTAK RENEWAL 4** Models H190/H195/H197/H199	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). 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.
CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179 **CONTAK RENEWAL 4 RF** Models H230/H235/H239 **VITALITY DR HE** Model T180	CURRENT STATUS **07-Apr-14** There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for the advisory device population is 0.0029 at 60 months. CURRENT RECOMMENDATION **07-Apr-14** 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: 1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care. 2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]
Physician and patient letters are available at www.bostonscientific.com.	

July 2010— Magnetic Reed Switch 2010, continued…

CURRENT RECOMMENDATION, continued…

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

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

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

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

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

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant 2009**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.	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.
This advisory is limited to those models listed below implanted subpectorally.	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.
COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108 **TELIGEN VR** Models E102/F102 **TELIGEN DR** Models E110/E111/F110/F111	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.
Physician and patient letters are available at www.bostonscientific.com.	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
	CURRENT STATUS **07-Apr-14**
	COGNIS and TELIGEN devices are available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired. *Reported events (worldwide)* Eighty-two (82) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 105,000 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 **07-Apr-14**

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

For affected devices implanted in a subpectoral location:
– Follow patient at least once every three months as recommended in device instructions for use.

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

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

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

PRODUCT	ORIGINAL COMMUNICATION **05-Apr-07 and 04-Mar-09— Shortened Replacement Window**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.	Voluntary Physician Advisory FDA Classification: Class II Low-voltage capacitors may be subject to degradation. These capacitors may cause accelerated battery depletion and may reduce the time between Elective Replacement Indicator (ERI) and End Of Life (EOL) to less than three months. Device replacement indicators continue to function normally.
CONTAK RENEWAL 4 RF HE Model H239 **CONTAK RENEWAL 4 RF** Models H230/H235 **CONTAK RENEWAL 4 HE** Models H197/H199 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 AVT / AVT HE** Models M170/M175/M177/M179 **CONTAK RENEWAL 3 RF HE** Models H217/H219 **CONTAK RENEWAL 3 RF** Models H210/H215 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 AVT / AVT HE** Models M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE** Model T180 **VITALITY DS VR/DR** Model T135/T125	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. 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. CURRENT STATUS **07-Apr-14** *Confirmed Malfunctions (worldwide)* **April 2007 Population** 2,563 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices. 115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days). **March 2009 Population** 116 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days). There have been no reported patient deaths associated with either advisory population. No devices currently being distributed are susceptible to this malfunction mode. *Rate of Occurrence* **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. **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. Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.

VITALITY EL
Model T127

VITALITY AVT A155
Model A155

Physician and patient letters are available at
www.bostonscientific.com.

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

CURRENT RECOMMENDATION **07-Apr-14**

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

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

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

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

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

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

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

PRODUCT	ORIGINAL COMMUNICATION **10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. **CONTAK RENEWAL 4 RF HE** Model H239 **CONTAK RENEWAL 4 RF / HE** Models H230/H235/H197/H199 **CONTAK RENEWAL 4 and 4 AVT / AVT HE** Models H190/H195/M170/M175/ M177/M179 **CONTAK RENEWAL 3 RF HE** Models H217/H219 **CONTAK RENEWAL 3 RF / HE** Models H210/H215/H177/H179 **CONTAK RENEWAL 3 and 3 AVT / AVT HE** Models H170/H175/M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE and EL** Model T180 and Model T127 **VITALITY DS VR/DR** Model T135/T125 **VITALITY AVT A135 / A155** Models A135/A155 **VITALITY VR/DR and DR+** Models 1871/1870/1872 **ASSURE** Model B301 *The Product Update and patient letter are available at* *www.bostonscientific.com.*	FDA Classification: Devices in Table 1, Column 1 of this *Product Update* were classified as Class II (27-November-07) 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. 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. *Rate Projection* 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: – 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%**) – 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%**) 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. CURRENT STATUS **07-Apr-14** *Confirmed Malfunctions (worldwide)* 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.” *Projected Rate of Occurrence* 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.” CURRENT RECOMMENDATION **07-Apr-14** Patient management recommendations from the March 10, 2007 Product Update remain unchanged. *Patient Management Considerations* – 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 amanual capacitor reform may be helpful in characterizing the current charge time. Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **23-Jun-06 and 24-Aug-06— Low Voltage Capacitor**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492 **CONTAK RENEWAL TR / TR2** Models H120/H125/H140/H145 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE** Model T180 **VITALITY DS VR/DR** Models T135/T125	Voluntary Physician Advisory FDA Classification: Class II 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. *Reported Events (worldwide)* 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. *Projected Rate of Occurrence* 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. CURRENT STATUS **07-Apr-14** *Confirmed Malfunctions (worldwide)* 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. There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* The rate of occurrence is projected to range between 0.10% and 0.22%. CURRENT RECOMMENDATION **07-Apr-14** Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged. – 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. **Device Behavior** **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

VITALITY VR/DR and EL
Models 1870/1871/T127

VENTAK PRIZM 2 VR/DR
Models 1860/1861

Physician and patient letters are available at www.bostonscientific.com.

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**
A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. *This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..* **CONTAK RENEWAL 4 HE** Models H197/H199 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 AVT / AVT HE** Models M170/M175/M177/M179 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 AVT / AVT HE** Models M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY DR HE** Model T180 **VITALITY EL** Model T127 **VITALITY DR+** Model 1872 *Physician and patient letters are available at* *www.bostonscientific.com.*	Voluntary Physician Advisory FDA Classification: Class II 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. This failure mechanism can result in one or more of the following device behaviors: – 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 *Reported Events* 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. *Rate of Occurrence* 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. CURRENT STATUS **07-Apr-14** *Confirmed Malfunctions (worldwide)* May 12, 2006 Population Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation. January 4, 2008 Population Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months. CURRENT RECOMMENDATION **07-Apr-14** Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication. – 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. - 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. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492 *Physician and patient letters are available at www.bostonscientific.com.*	Voluntary Physician Advisory FDA Classification: Class II 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. *Reported Events* 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. 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. *Rate Projection* 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. CURRENT STATUS **07-Apr-14** *Confirmed Malfunctions (worldwide)* 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. 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. None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 6,000 is projected to range between 0.027% and 0.038%. CURRENT RECOMMENDATION **07-Apr-14** Failure Mode 1— Patient management recommendations from the September 22, 2005 physician communication remain unchanged. Failure Mode 2— Patient management recommendations supersede those originally communicated on September 22, 2005. – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com. **CONTAK TR** Model 1241 **DISCOVERY II SR (downsize)** Models 1184/1384 **DISCOVERY II SR** Models 1186/1187/1385 **DISCOVERY II DR (downsize)** Models 1283/1483 **DISCOVERY II DR** Models 1284/1286/1484/1485 **DISCOVERY II SSI (downsize)** Models 0481/1349 **DISCOVERY II DDD** Models 0981/1285/1499 **PULSAR MAX II SR (downsize)** Models 1180/1380 **PULSAR MAX II SR / DR** Models 1181/1290/1480 **DISCOVERY SR/SR (downsize)** Models 1174/1175 **DISCOVERY DR/DR (downsize)** Models 1274/1275/1273 **PULSAR MAX SR (downsize)** Model 1170 **PULSAR MAX SR / DR** Model 1171/1270 **PULSAR** Models 1272/0470/0870/0970/ 0972/1172 **MERIDIAN SSI / DDD** Models 0476/0976 **MERIDIAN SR / DR** Models 1176/1276	Voluntary Physician Advisory (18-Jul-05) FDA Classification: Class I Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I 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. 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. 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. 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. Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below). Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence. *Rate Projection* 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. 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%. CURRENT STATUS **07-Apr-14** *Reported Events (worldwide)* Refined Original Population— 342 malfunctions have been confirmed out of the 77,500 advisory population devices. Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices. *Projected Rate of Occurrence* 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. 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.

Physician and patient letters are available at www.bostonscientific.com.

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

CURRENT RECOMMENDATION **07-Apr-14**

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
ACUITY X4
ADVANTIO
ALTRUA
AUTOGEN
AVT
CHFD
COGNIS
CONFIENT
CONTAK
CONTAK RENEWAL
CONTAK RENEWAL TR
CONTAK TR
DISCOVERY
DYNAGEN
EASYTRAK
ENDOTAK
EQUIO
ENDOTAK DSP
ENDOTAK ENDURANCE
ENDOTAK ENDURANCE EZ
ENDOTAK ENDURANCE RX
ENDOTAK RELIANCE
ENERGEN
FINELINE
FLEXTEND
FORMIO
INSIGNIA
INGENIO
INGEVITY
INCEPTA
INLIVEN
INOGEN
INTUA
INVIVE
LIVIAN
MERIDIAN
ORIGEN
PULSAR
PUNCTUA
RELIANCE 4-FRONT
SELUTE
SWEET PICOTIP
SWEET TIP
TELIGEN
ULTRA 1
VENTAK
VENTAK PRIZM
VITALIO
VITALITY
4-SITE

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
S-ICD
SQ-RX
UNIPASS
VIRTUS

OTHER

GORE and associated logos are trademarks of W.L. Gore & Associates.

Country Offices Contact Information

Argentina
Boston Scientific Argentina S.A.
Av. Cabildo 2677 — Piso 6
C1428AAI Buenos Aires
Argentina
Tel: 54 11 4896 8500
Fax: 54 11 4896 8550

Australia & New Zealand
Boston Scientific ANZ
Level 5, 247 Coward Street
MASCOT NSW 202 0
Australia
Tel: 61-2-8063 8100
Fax: 61-2-9330 1404

Austria
Boston Scientific
Vienna Twin Tower
Turm A/ 190G
Wienerbergstrasse 11
1100 Vienna
Austria
Tel: +43 1 60 810

Belgium
Boston Scientific Company
Green Square, Lambroekstraat 5D
1831 Diegem
Belgium
Tel: +32-2-4167011

Canada
Boston Scientific
5060 Spectrum Way. Suite 500A
Mississauga, Ontario L4W 5N5
Canada

China
BSC International Medical Trading (Shanghai) Co. Ltd.
#68, Rijing Road
Waigaoqiao Free Trade Zone
Shanghai, 200131, China
Telephone: 021-61415959
Fax: 021-614159000

Czech Republic
Guidant CR s.r.o.
Karla Englise 3219/4
150 00 Praha 5
Tel: +420 296 331 900
Fax: +420 296 331 902

Denmark
Boston Scientific A/S
Standvejen 70
DK-2900 Hellerup
Denmark

France
Boston Scientific Headquarters
Le Capitole
55, avenue des Champs Pierreux
92729 Nanterre
France

Germany
Boston Scientific Medizintechnik GmbH
Daniel-Goldbach Strasse 17–27
40880 Ratingen
Germany
Tel: 49 (0) 2102 489 3
Fax: +49 (0) 2102 489 439

Hong Kong
Boston Scientific Hong Kong Ltd.
22/F., Bank of East Harbour View Centre
56 Gloucester Road
Wanchai,Hong Kong135 984
Tel: 852-2960 7100
Fax: 852-2563 5276
Ireland
Boston Scientific — Clonmel
Cashel Rd.
Clonmel
Co Tipperary
Ireland
Tel:353.52.6181000

Italy
Boston Scientific SpA
Viale Enrico Forlanini, 23
20134 Milan
Italy
Tel:39.02.269831

Japan
Boston Scientific Japan KK
Headquarters
Nikko Bldg.
1-14-11 Nishi Shinjuke
Shinjuku-ku, Tokyo160-0023
Japan

Netherlands
Boston Scientific B.V.
Kuifmees 56
3435 RG Nieuwegein
Netherlands
Tel: + 31 – 30 - 6025555

Singapore
Boston Scientific Asia Pacific Pte Ltd
No. 1 Pickering Street
#07–02, Great Eastern Centre
Singapore048659
Tel: 65-6418 8888
Fax: 65-6418 8899

Portugal
Boston Scientific
Amoreiras Plaza
R. Prof. Carlos Alberto Mota Pinto N° 9 — ° 4 C
1070–374 Lisboa
Portugal

Spain
Boston Scientific Iberica S.A.
Parque Empresarial Puerta de las Naciones
C/ ribera del Loira, 38. Edificio 4–1° planta
28042 Madrid
Spain
Tel: 34-91 657 25 45

Sweden
Boston Scientific Sweden AB
Berga Alle 1
254 52 Helsingborg
Sweden
Tel: 46 42 25 69 00

Switzerland
Boston Scientific AG
Dornacherplatz 7
CH-4500 Solothurn
Switzerland
Tel: 0041 32 626 57 00

United Kingdom
Boston Scientific
Breakspear Park
Breakspear Way
Hemel Hempstead
Hertz,HP2 4TZ
United Kingdom
Tel:01442 411600
Fax:01442 411601

United States
Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798
USA
Tel:651.582.4000
Fax:651.582.4166
Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268
171

Boston Scientific

Advancing science for life™

Cardiac Rhythm Management
One Boston Scientific Place
Natick, MA 01760-1537 USA
www.bostonscientific.com

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

CRM-209101-AA Q2 2014

Data as of April 8th, 2014