Boston Scientific
Advancing science for life™

CRM Product Performance Report 2014

Q3 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 Q3 2014 report includes data through July 21, 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

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Statistical Methodology

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

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

Boston Scientific estimates survival probability in compliance with 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

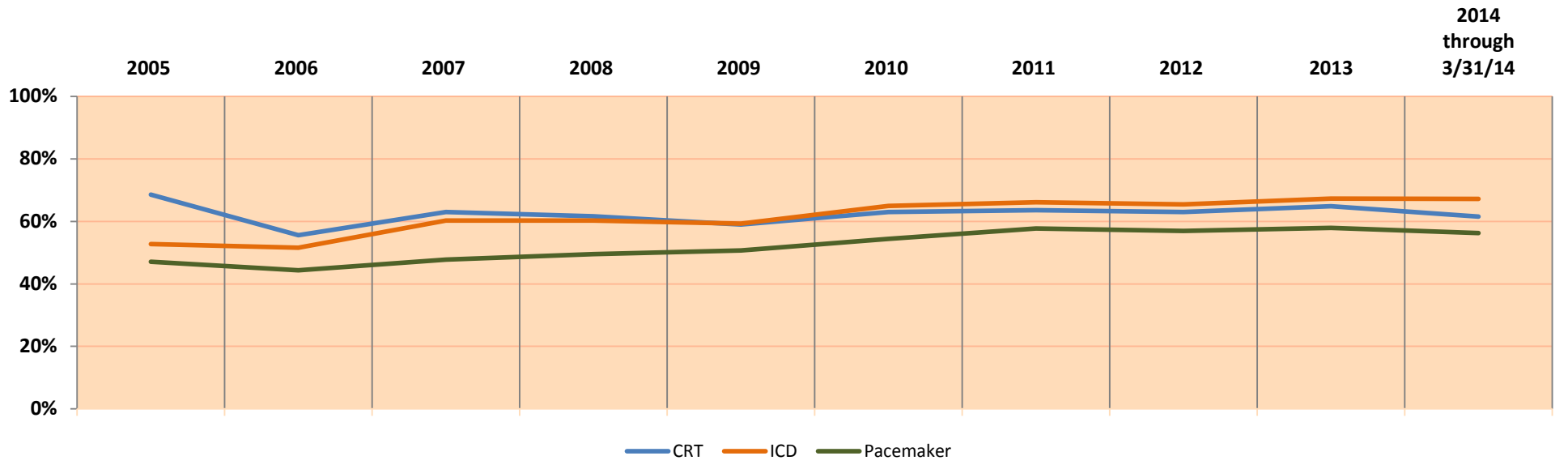
The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department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



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014 through 3/31/14
Explants	4528	4388	4696	5295	8157	9023	7484	5895	5419	949
Returns	3104	2439	2958	3261	4814	5684	4759	3716	3515	584
% Returned	**69%**	**56%**	**63%**	**62%**	**59%**	**63%**	**64%**	**63%**	**65%**	**62%**
Explants	16494	10220	11540	15750	20218	20850	17703	13296	13697	3412
Returns	8697	5267	6952	9495	11981	13541	11710	8696	9214	2294
% Returned	**53%**	**52%**	**60%**	**60%**	**59%**	**65%**	**66%**	**65%**	**67%**	**67%**
Explants	21695	17779	19114	20964	21583	21548	20534	19126	18998	4667
Returns	10218	7877	9130	10383	10936	11714	11851	10896	11001	2627
% Returned	**47%**	**44%**	**48%**	**50%**	**51%**	**54%**	**58%**	**57%**	**58%**	**56%**

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

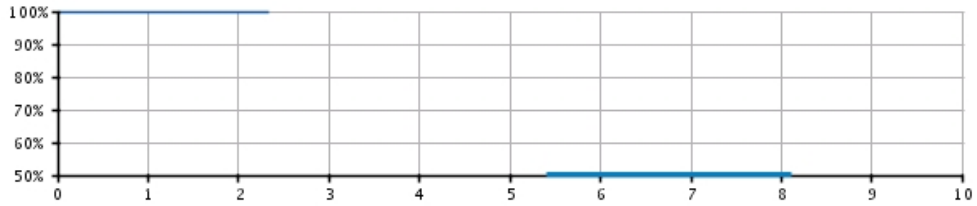
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

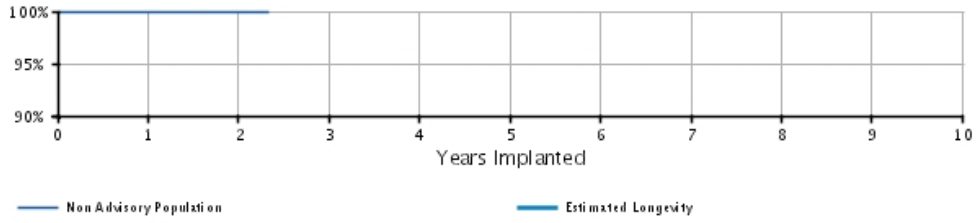
U.S. Registered Implants: 7,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 7,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.3/+0.1)	99.84 @ 28 mo. (-0.3/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	3542	988	302	–	–	–	–	–	–	–

INCEPTA CRT-D 4-Site

Models N160/N162/P162

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

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

Worldwide Distribution: 13,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[79] Safety Core-electrocautery	1	-	
[89] Integrated circuit	-	1	
Mechanical	**-**	**1**	**1**
[73] Transformer	-	1	
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**2**	**2**	**4**

More details about malfunctions

References cited in table above

INCEPTA CRT-D

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

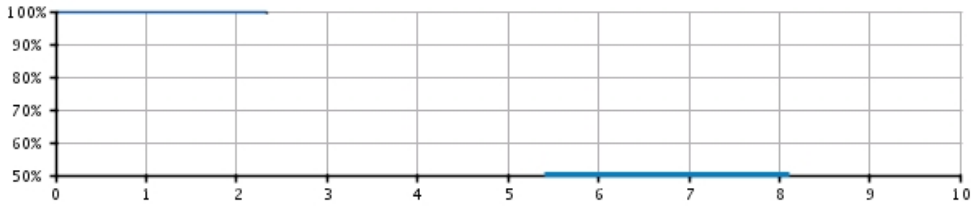
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

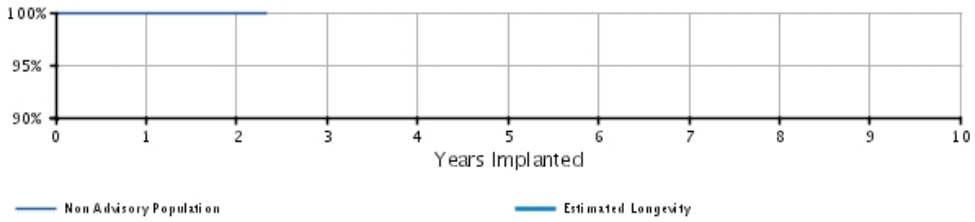
U.S. Registered Implants: 10,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 3
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: 10000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.87 (-0.3/+0.1)	99.72 @ 28 mo. (-0.6/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	4965	1127	235	–	–	–	–	–	–	–

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: 14,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ENERGEN CRT-D 4-Site

Models N140/N142/P142

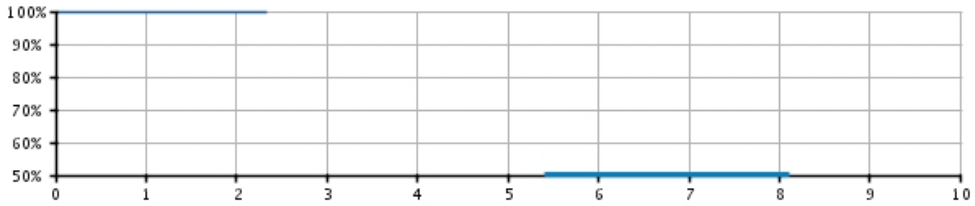
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

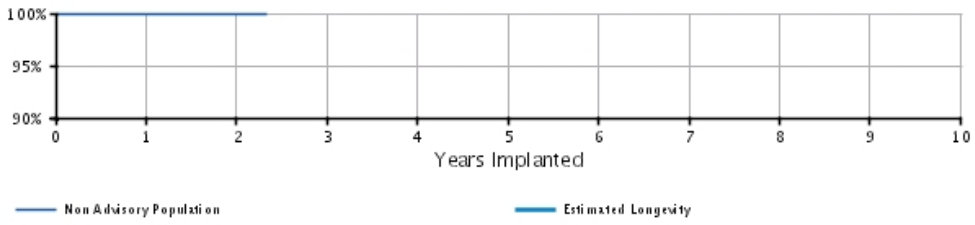
U.S. Registered Implants: 11,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 10,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	6257	1647	418	–	–	–	–	–	–	–

ENERGEN CRT-D 4-Site

Models N140/N142/P142

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

ENERGEN CRT-D 4-Site Models N140/N142/P142

Worldwide Distribution: 17,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[89] Integrated circuit	1	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[90] Memory errors	1	-	
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**3**	**1**	**4**

More details about malfunctions

References cited in table above

ENERGEN CRT-D

Models N141/N143/P143

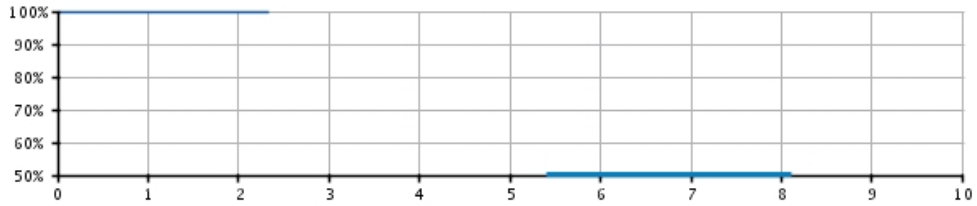
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

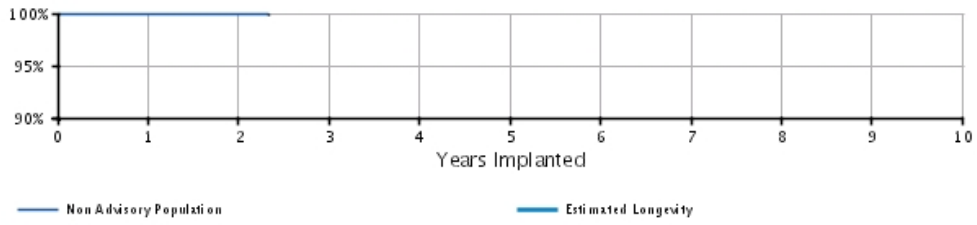
U.S. Registered Implants: 11,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:8
Without Compromised Therapy:4
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: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.71 @ 28 mo. (-0.4/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.90 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	6011	1393	283	–	–	–	–	–	–	–

ENERGEN CRT-D

Models N141/N143/P143

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

ENERGEN CRT-D
Models N141/N143/P143

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**2**	**4**
[79] Safety Core-electrocautery	1	1	
[85] Low-voltage capacitors	1	-	
[89] Integrated circuit	-	1	
Mechanical	**-**	**3**	**3**
[73] Transformer	-	3	
Software	**1**	**-**	**1**
[90] Memory errors	1	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**5**	**5**	**10**

More details about malfunctions

References cited in table above

PUNCTUA CRT-D 4-Site

Models N050/N052/P052

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

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

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

PUNCTUA CRT-D

Models N051/N053/P053

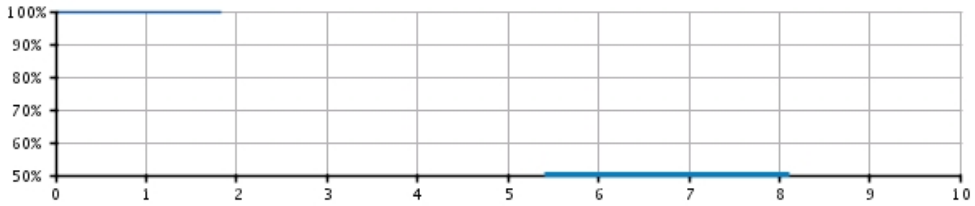
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

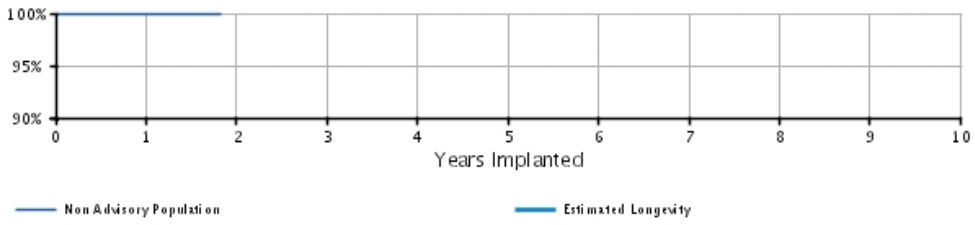
U.S. Registered Implants: 1,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 1,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 22 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 22 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	710	239	–	–	–	–	–	–	–	–

PUNCTUA CRT-D

Models N051/N053/P053

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

PUNCTUA CRT-D
Models N051/N053/P053

Worldwide Distribution: 4,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[89] 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

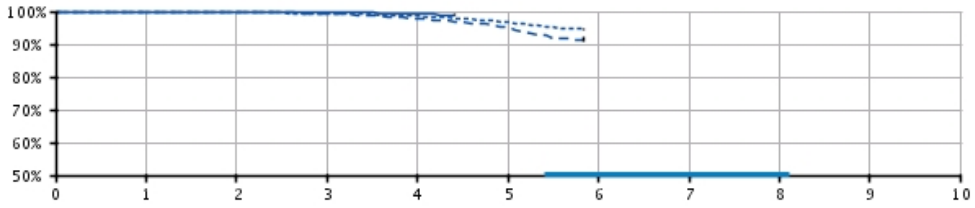
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

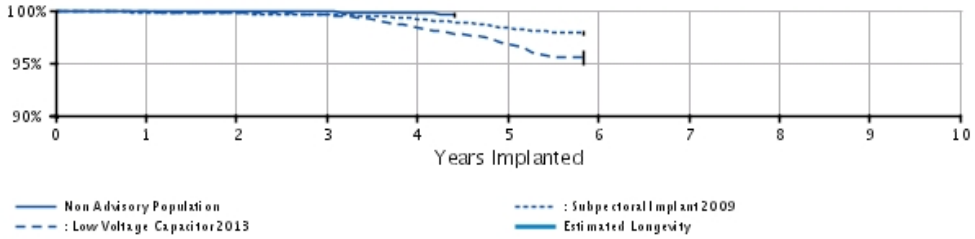
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 50,000

U.S. Normal Battery Depletions: 450
U.S. Unconfirmed Reports of Premature Battery Depletion : 29
U.S. Malfunctions:444
Without Compromised Therapy:328
With Compromised Therapy:116

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)	99.67 (-0.1/+0.1)	99.23 (-0.2/+0.1)	98.95 @ 53 mo. (-0.4/+0.3)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.74 (-0.1/+0.1)	99.60 @ 53 mo. (-0.3/+0.2)	–	–	–	–	–
	Effective Sample Size	35665	31352	19296	3855	258	–	–	–	–	–
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)	96.70 (-0.3/+0.2)	94.60 @ 70 (-0.6/+0.5)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.71 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.36 (-0.2/+0.2)	97.88 @ 70 (-0.3/+0.2)	–	–	–	–
	Effective Sample Size	27517	24404	21705	19215	9699	460	–	–	–	–
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)	97.73 (-0.3/+0.3)	95.03 (-0.6/+0.6)	91.48 @ 70 (-1.3/+1.1)	–	–	–	–

	Malfunctions Only(%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.59 (-0.2/+0.1)	98.36 (-0.3/+0.3)	96.72 (-0.5/+0.5)	95.51 @ 70 (-0.8/+0.7)	–	–	–	–
	Effective Sample Size	10394	9177	8162	6939	2811	320	–	–	–	–

*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: 568

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**339**	**71**	**410**
[1] Low Voltage Capacitor 2013 (Advisory issued)	197	17	
[79] Safety Core-electrocautery	43	18	
[80] High-voltage capacitor	1	4	
[85] Low-voltage capacitors	7	-	
[89] Integrated circuit	7	19	
[91] High voltage circuit	-	1	
[92] Battery	16	2	
[93] Low-voltage capacitor	68	10	
Mechanical	**31**	**77**	**108**
[5] Subpectoral implant 2009 (Advisory issued)	12	37	
[73] Transformer	-	9	
[77] Difficulty securing lead	9	9	
[83] Header contacts	4	7	
[97] Header	6	15	
Software	**11**	**-**	**11**
[84] Safety Core-programming	1	-	
[87] Alert messages not displayed post-EOL	2	-	
[90] Memory errors	8	-	
Other	**30**	**9**	**39**
Non-patterned	30	9	
WW Confirmed Malfunctions	**411**	**157**	**568**

More details about malfunctions

References cited in table above

LIVIAN HE

Models H227/H229/H247/H249

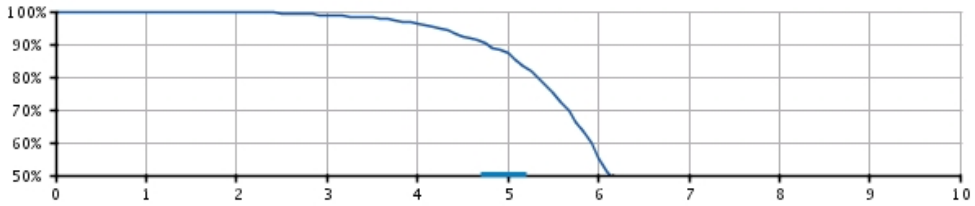
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

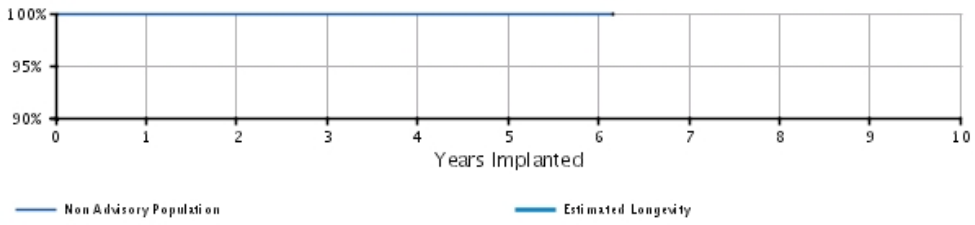
U.S. Registered Implants: 6,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 903
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)	98.91 (-0.4/+0.3)	96.47 (-0.7/+0.6)	87.04 (-1.3/+1.2)	55.38 (-2.5/+2.5)	48.94 @ 74 mo. (-2.9/+2.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 (-0.1/+0.1)	99.92 @ 74 mo. (-0.1/+0.1)	–	–	–
	Effective Sample Size	4941	4329	3699	2934	2002	579	217	–	–	–

LIVIAN HE

Models H227/H229/H247/H249

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

LIVIAN HE
Models H227/H229/H247/H249

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 6

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

More details about malfunctions

References cited in table above

LIVIAN

Models H220/H225/H240/H245

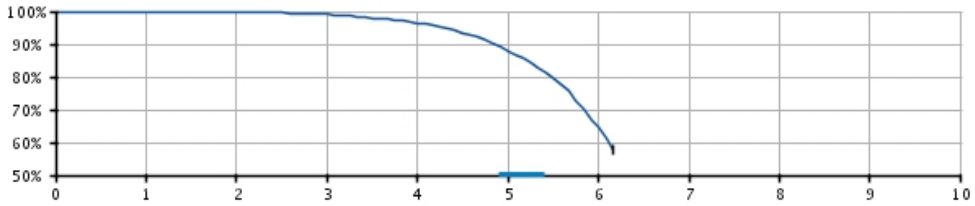
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

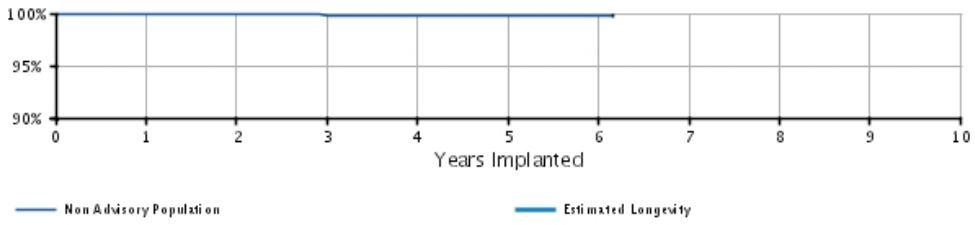
U.S. Registered Implants: 5,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 669
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)	96.45 (-0.7/+0.6)	87.98 (-1.4/+1.3)	64.55 (-2.4/+2.4)	57.97 @ 74 mo. (-3.0/+2.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.80 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.77 @ 74 mo. (-0.2/+0.1)	–	–	–
	Effective Sample Size	3997	3486	3015	2476	1754	670	285	–	–	–

LIVIAN

Models H220/H225/H240/H245

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

LIVIAN
Models H220/H225/H240/H245

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 9

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

More details about malfunctions

References cited in table above

CONTAK RENEWAL 3 RF

Models H210/H215

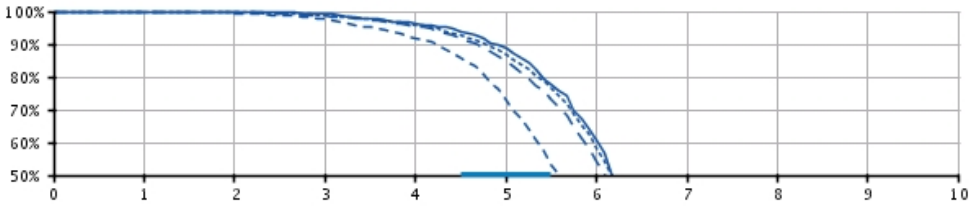
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

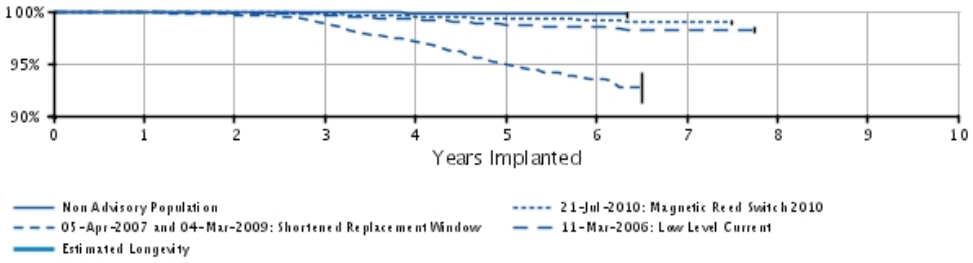
U.S. Registered Implants: 21,000
U.S. Approval Date: February 2005
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 7,224
U.S. Unconfirmed Reports of Premature Battery Depletion : 29
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)	88.55 (-2.0/+1.7)	60.56 (-3.2/+3.2)	41.35 @ 76 mo. (-3.7/+3.8)	–	–	–
	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 @ 76 mo. (-0.5/+0.2)	–	–	–
	Effective Sample Size	1735	1524	1321	1126	901	462	201	–	–	–
21-Jul-10 Magnetic Reed Switch 2010* Registered Implants: 15000	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)	86.60 (-0.7/+0.7)	58.31 (-1.1/+1.1)	20.85 (-1.1/+1.2)	17.67 @ 90 mo. (-1.2/+1.2)	–	–
	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)	98.99 (-0.3/+0.2)	98.99 @ 90 mo. (-0.3/+0.2)	–	–
	Effective Sample Size	12966	11433	9923	8443	6659	3967	666	210	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants:	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)	31.02 (-2.2/+2.2)	14.86 @ 78 mo. (-1.7/+1.9)	–	–	–

4000											
	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	502	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)	84.72 (-0.7/+0.7)	54.01 (-1.0/+1.0)	19.58 (-0.9/+1.0)	15.92 @ 93 mo. (-1.0/+1.1)	–	–
	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)	98.22 (-0.3/+0.3)	98.22 @ 93 mo. (-0.3/+0.3)	–	–
	Effective Sample Size	16379	14428	12468	10562	8187	4613	871	201	–	–

*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

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

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	
[15] Extended charge time post-mid-life	1	-	
[25] Capacitor	2	-	
[30] Integrated circuit	8	3	
[44] Capacitor	1	-	
[47] Capacitor	3	-	
[56] Mid-life display of replacement indicators	13	-	
[57] High-voltage capacitor	2	-	
[78] Low-voltage capacitor	29	-	
Mechanical	**8**	**11**	**19**
[4] Magnetic reed switch 2010 (Advisory issued)	5	6	
[14] Magnetic switch (Advisory issued)	-	1	
[34] Seal plug	2	-	
[63] Setscrew	1	-	
[65] Seal plug	-	1	
[86] Bent flex circuit	-	3	
Software	**3**	**-**	**3**
[19] Parameter errors	1	-	
[55] Memory location	1	-	
[75] Misaligned markers	1	-	
Other	**5**	**3**	**8**
Non-patterned	-	2	
[39] Battery depletion	5	1	
WW Confirmed Malfunctions	**159**	**19**	**178**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 RF HE

Model H239

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

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	-	
[15] Extended charge time post-mid-life	1	-	
[30] Integrated circuit	2	-	
[78] 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	
[15] Extended charge time post-mid-life	1	-	
[30] Integrated circuit	1	2	
[47] Capacitor	1	-	
[56] Mid-life display of replacement indicators	1	-	
[78] Low-voltage capacitor	2	-	
Mechanical	**-**	**3**	**3**
[4] Magnetic reed switch 2010 (Advisory issued)	-	2	
[26] Header	-	1	
Software	**-**	**-**	**0**
Other	**2**	**3**	**5**
Non-patterned	1	-	
[39] 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

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

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	-	
[15] Extended charge time post-mid-life	10	-	
[25] Capacitor	1	-	
[30] Integrated circuit	1	1	
[44] Capacitor	1	-	
[56] Mid-life display of replacement indicators	26	-	
[57] High-voltage capacitor	1	-	
[78] Low-voltage capacitor	21	-	
Mechanical	**6**	**4**	**10**
[4] Magnetic reed switch 2010 (Advisory issued)	-	1	
[10] Subpectoral implant (Advisory issued)	-	1	
[26] Header	1	1	
[34] Seal plug	2	-	
[63] Setscrew	1	1	
[65] Seal plug	1	-	
[72] Cracked solder joint	1	-	
Software	**-**	**-**	**0**
Other	**3**	**1**	**4**
Non-patterned	1	1	
[39] Battery depletion	2	-	
WW Confirmed Malfunctions	**139**	**7**	**146**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4

Models H190/H195

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

CONTAK RENEWAL 4 Models H190/H195

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 353

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**309**	**11**	**320**
[7] Shortened replacement window (Advisory issued)	160	5	
[9] Premature battery depletion (Advisory issued)	14	-	
[15] Extended charge time post-mid-life	9	-	
[21] Integrated circuit	2	-	
[25] Capacitor	-	1	
[30] Integrated circuit	2	3	
[44] Capacitor	-	1	
[47] Capacitor	3	-	
[56] Mid-life display of replacement indicators	63	-	
[61] Integrated circuit	-	1	
[78] Low-voltage capacitor	56	-	
Mechanical	**7**	**14**	**21**
[4] Magnetic reed switch 2010 (Advisory issued)	-	3	
[10] Subpectoral implant (Advisory issued)	-	7	
[14] Magnetic switch (Advisory issued)	-	1	
[26] Header	2	-	
[34] Seal plug	3	-	
[46] Circuit connection	-	1	
[63] Setscrew	-	1	
[71] Reed switch	1	1	
[72] Cracked solder joint	1	-	
Software	**-**	**-**	**0**
Other	**6**	**6**	**12**
Non-patterned	2	3	
[39] Battery depletion	4	3	
WW Confirmed Malfunctions	**322**	**31**	**353**

More details about malfunctions

References cited in table above

CONTAK RENEWAL 4 AVT HE

Models M177/M179

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

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	-	
[56] Mid-life display of replacement indicators	1	-	
[78] Low-voltage capacitor	5	-	
Mechanical	**-**	**1**	**1**
[10] Subpectoral implant (Advisory issued)	-	1	
Software	**3**	**-**	**3**
[64] Charge time limit	3	-	
Other	**2**	**-**	**2**
Non-patterned	-	-	
[39] 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

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

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	-	
[15] Extended charge time post-mid-life	1	-	
[25] Capacitor	1	-	
[30] Integrated circuit	1	-	
[47] Capacitor	1	-	
[56] Mid-life display of replacement indicators	1	-	
[78] Low-voltage capacitor	2	-	
Mechanical	**2**	**-**	**2**
[34] Seal plug	1	-	
[63] Setscrew	1	-	
Software	**-**	**-**	**0**
Other	**6**	**1**	**7**
Non-patterned	2	-	
[39] 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

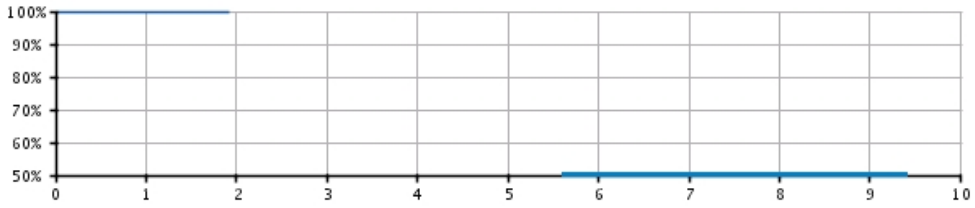
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

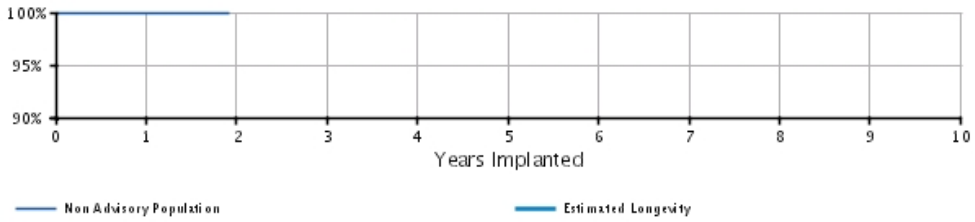
U.S. Registered Implants: 6,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 5,000

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: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 23 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 23 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2537	311	–	–	–	–	–	–	–	–

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: 13,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[85] 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

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**
[25] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[34] Seal plug	1	-	
[52] Setscrew block	2	-	
[65] Seal plug	1	-	
Software	**12**	**-**	**12**
[41] Memory error	1	-	
[54] Stored EGMs	11	-	
Other	**10**	**1**	**11**
Non-patterned	9	1	
[62] Alert messages	1	-	
WW Confirmed Malfunctions	**27**	**1**	**28**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

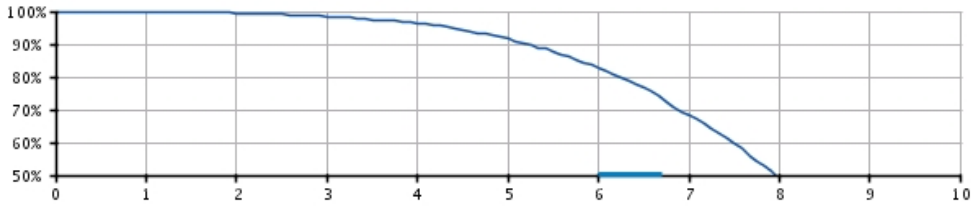
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

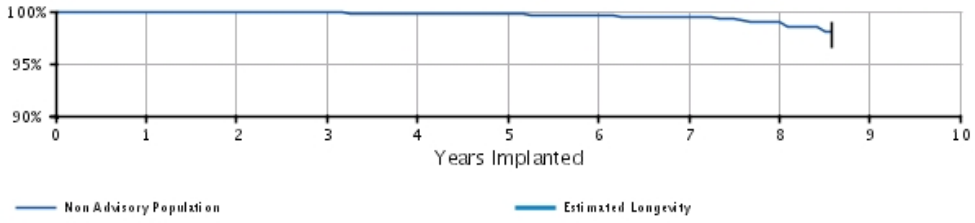
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 1,598
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
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)	99.48 (-0.1/+0.1)	98.50 (-0.2/+0.2)	96.36 (-0.4/+0.4)	91.57 (-0.7/+0.6)	82.77 (-1.2/+1.1)	68.33 (-1.8/+1.7)	48.81 (-2.5/+2.6)	36.15 @ 103 mo. (-2.9/+3.0)	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.56 (-0.2/+0.1)	99.41 (-0.3/+0.2)	98.99 (-0.7/+0.4)	98.06 @ 103 mo. (-1.6/+0.9)	–
	Effective Sample Size	15613	13431	10143	6726	4223	2369	1152	415	218	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

CONTAK RENEWAL TR

Models H120/H125

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

CONTAK RENEWAL TR Models H120/H125

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 43

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[8] Low-voltage capacitor (Advisory issued)	1	-	
[25] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[34] Seal plug	5	-	
Software	**26**	**-**	**26**
[54] Stored EGMs	26	-	
Other	**9**	**1**	**10**
Non-patterned	7	1	
[62] 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

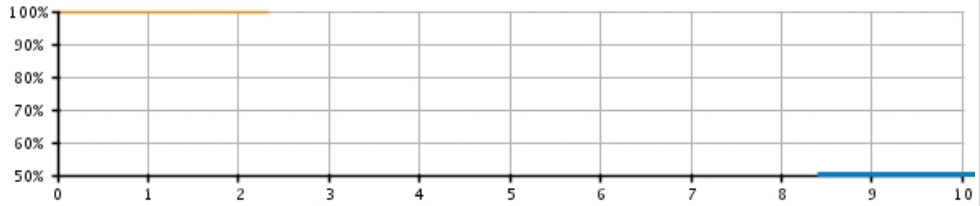
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

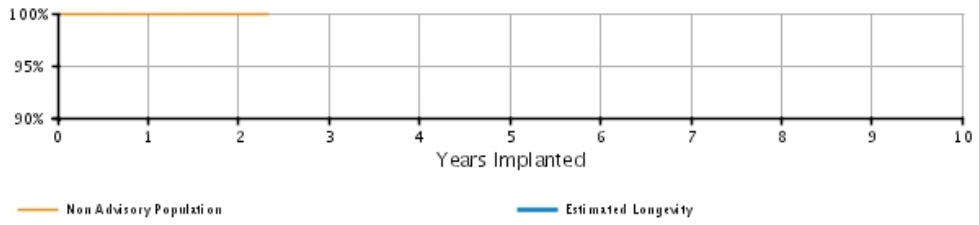
U.S. Registered Implants: 8,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 2
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: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.91 (-0.2/+0.1)	99.91 @ 28 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	4186	1070	316	–	–	–	–	–	–	–

INCEPTA ICD DR 4-Site

Models E162/F162

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

INCEPTA ICD DR 4-Site Models E162/F162

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[89] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[73] Transformer	-	1	
Software	**1**	**-**	**1**
[90] 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

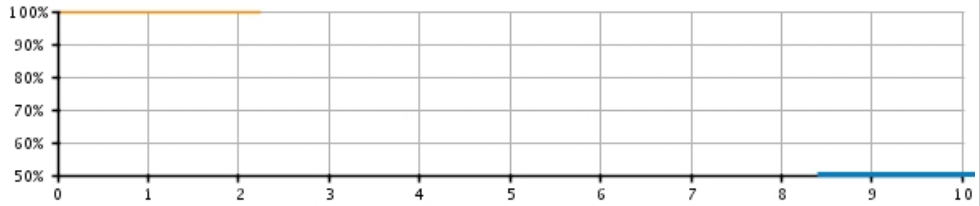
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

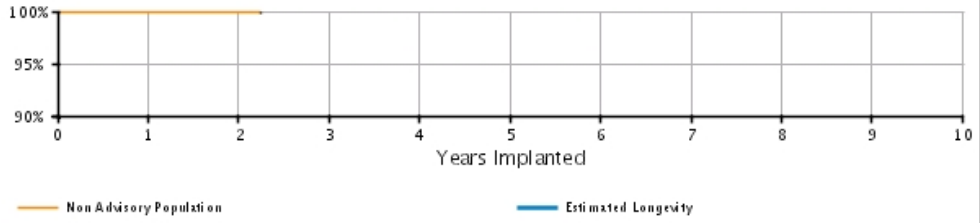
U.S. Registered Implants: 5,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.78 (-0.5/+0.2)	99.78 @ 27 mo. (-0.5/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 27 mo. (-0.2/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	2422	539	216	–	–	–	–	–	–	–

INCEPTA ICD DR

Models E163/F163

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

INCEPTA ICD DR Models E163/F163

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[85] 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

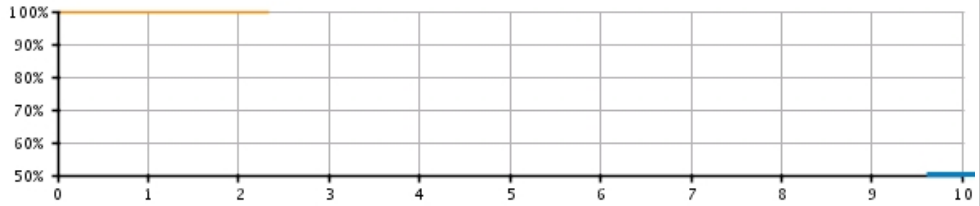
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

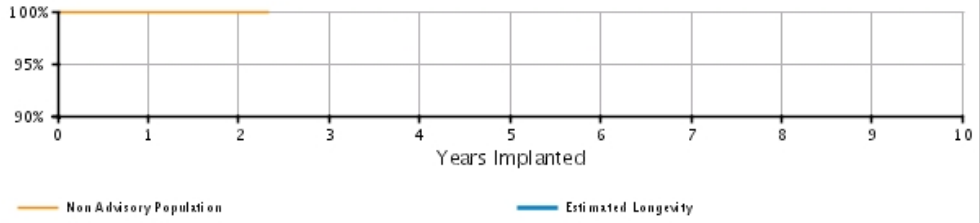
U.S. Registered Implants: 7,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 7,000

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: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 @ 28 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	3440	850	253	–	–	–	–	–	–	–

INCEPTA ICD VR 4-Site

Models E160/F160

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

INCEPTA ICD VR 4-Site Models E160/F160

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**1**	**1**
[73] Transformer	-	1	
Software	**1**	**-**	**1**
[90] 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

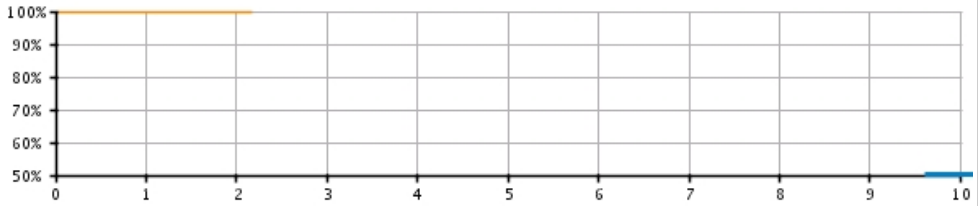
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

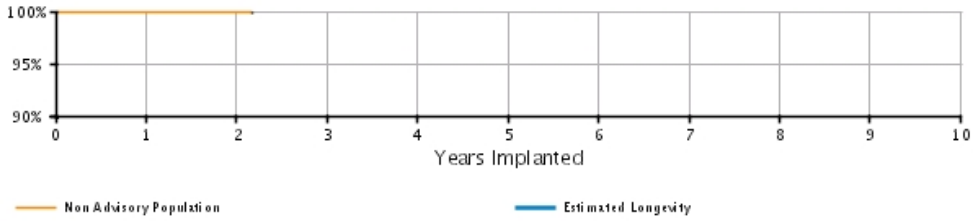
U.S. Registered Implants: 3,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 3,000

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 (-0.2/+0.0)	99.96 @ 26 mo. (-0.2/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.96 @ 26 mo. (-0.2/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	1511	386	236	–	–	–	–	–	–	–

INCEPTA ICD VR

Models E161/F161

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

INCEPTA ICD VR
Models E161/F161

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[80] 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

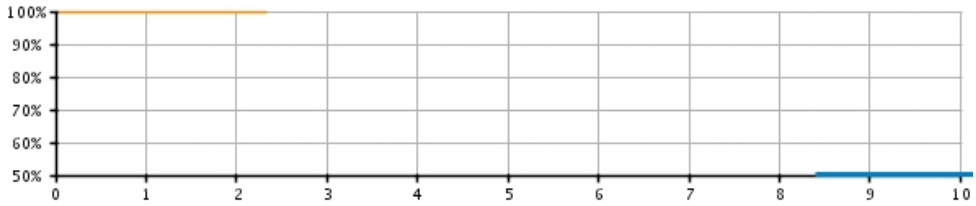
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

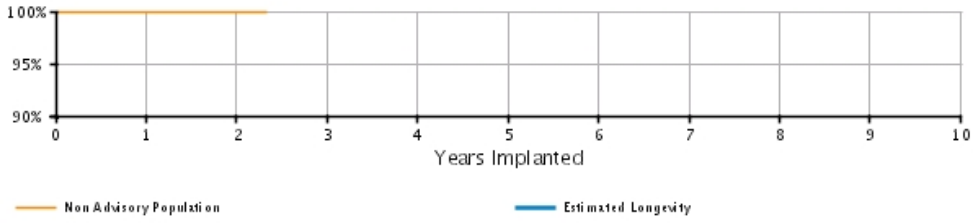
U.S. Registered Implants: 12,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 11,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
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: 12000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.92 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	6483	1680	421	–	–	–	–	–	–	–

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: 16,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**2**	**4**
[85] Low-voltage capacitors	1	-	
[89] 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

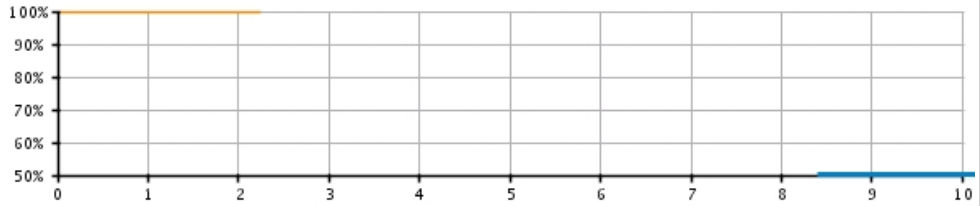
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

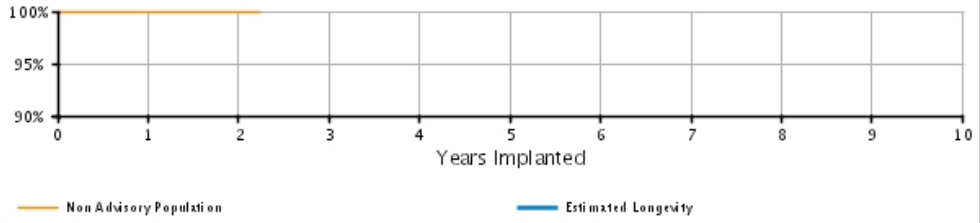
U.S. Registered Implants: 8,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 4
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)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.89 @ 27 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 27 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	4559	947	351	–	–	–	–	–	–	–

ENERGEN ICD DR

Models E143/F143

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

ENERGEN ICD DR Models E143/F143

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[85] 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

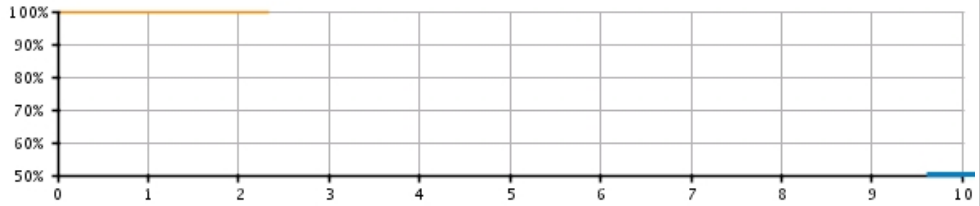
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

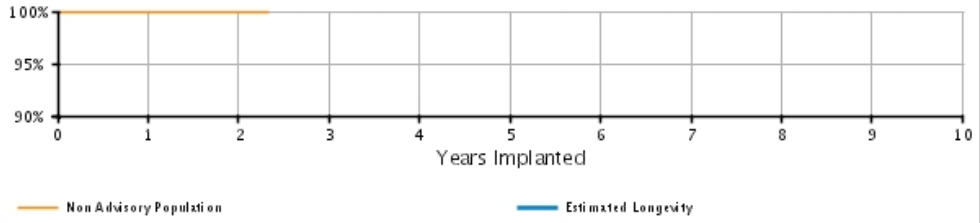
U.S. Registered Implants: 12,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 11,000

U.S. Normal Battery Depletions: 8
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: 12000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.80 (-0.2/+0.1)	99.80 @ 28 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 28 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	6164	1461	378	–	–	–	–	–	–	–

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: 17,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**1**	**1**
[73] Transformer	-	1	
Software	**1**	**-**	**1**
[90] 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

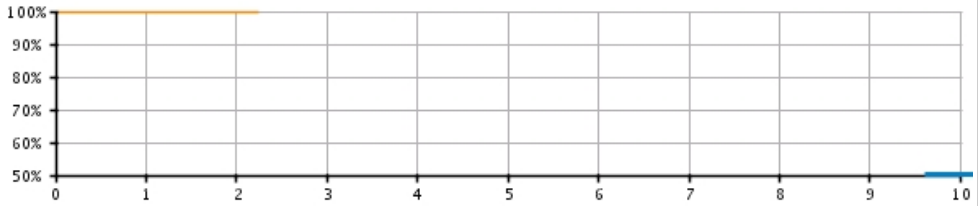
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

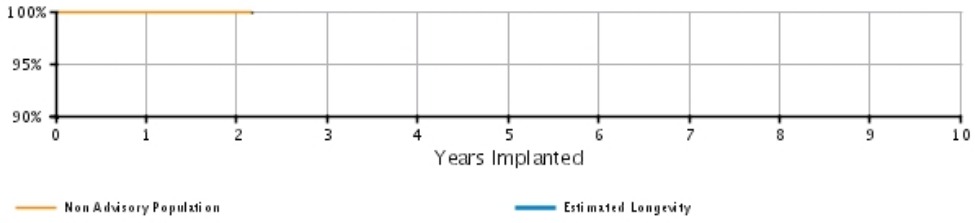
U.S. Registered Implants: 6,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 5,000

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: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.2/+0.1)	99.89 (-0.2/+0.1)	99.89 @ 27 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.95 (-0.2/+0.0)	99.95 @ 27 mo. (-0.2/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	3213	790	326	–	–	–	–	–	–	–

ENERGEN ICD VR

Models E141/F141

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

ENERGEN ICD VR
Models E141/F141

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[89] Integrated circuit	-	3	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[90] 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

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

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

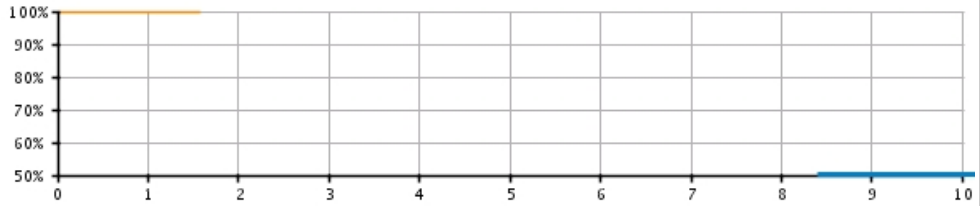
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

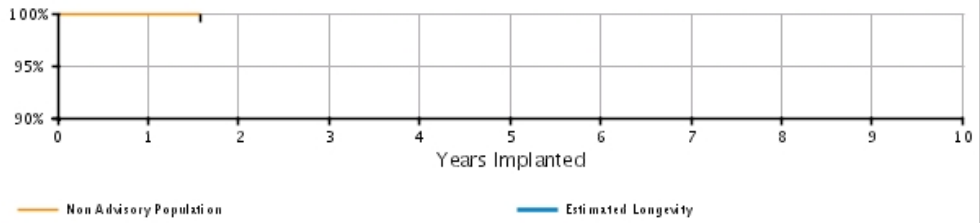
U.S. Registered Implants: 1,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions: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: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.7/+0.1)	99.88 @ 19 mo. (-0.7/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.88 (-0.7/+0.1)	99.88 @ 19 mo. (-0.7/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	479	230	–	–	–	–	–	–	–	–

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: 1

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

More details about malfunctions

References cited in table above

PUNCTUA ICD VR 4-Site

Models E050/F050

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

PUNCTUA ICD VR 4-Site Models E050/F050

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

PUNCTUA ICD VR

Models E051/F051

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

PUNCTUA ICD VR
Models E051/F051

Worldwide Distribution: 5,000
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

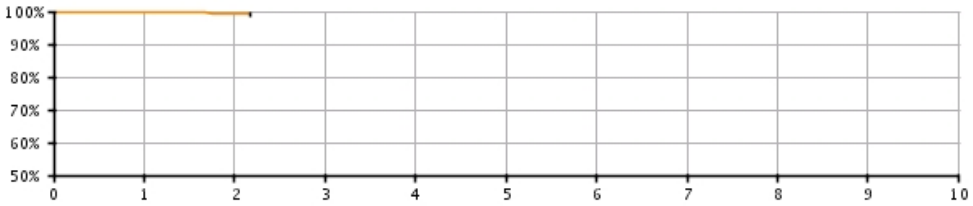
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

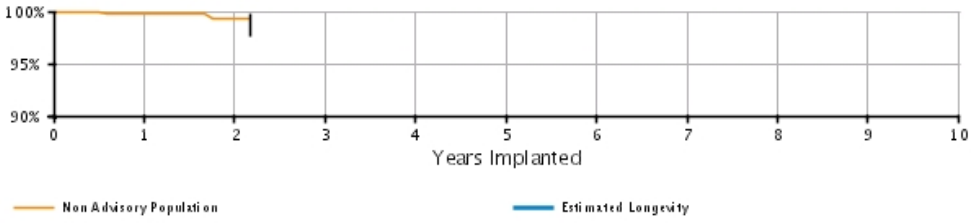
U.S. Approval Date: September 2012

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:7
Without Compromised Therapy:2
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)	99.76 (-0.5/+0.2)	99.34 (-1.8/+0.5)	99.34 @ 26 mo. (-1.8/+0.5)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.76 (-0.5/+0.2)	99.34 (-1.8/+0.5)	99.34 @ 26 mo. (-1.8/+0.5)	–	–	–	–	–	–	–
					–	–	–	–	–	–	–
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.

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

SQ-RX Pulse Generator

Model 1010

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

SQ-RX Pulse Generator Model 1010

Worldwide Confirmed Malfunctions: 41

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[2] Unintended fuse activation 2013 (Advisory issued)	-	3	
Mechanical	**11**	**10**	**21**
[3] High cathode condition 2011 (Advisory issued)	1	2	
[94] Battery depletion	10	8	
Software	**2**	**-**	**2**
[96] Unintended Battery Depletion Alert	2	-	
Other	**8**	**7**	**15**
Non-patterned	7	6	
[95] Telemetry	1	1	
WW Confirmed Malfunctions	**21**	**20**	**41**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

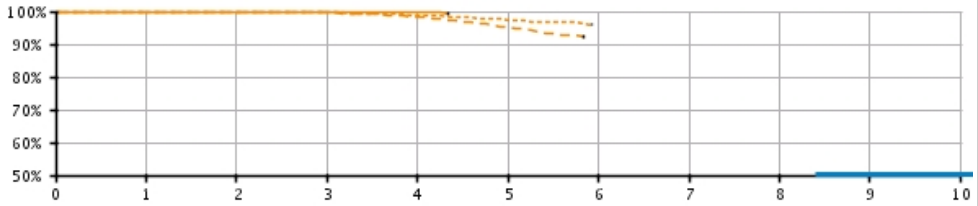
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

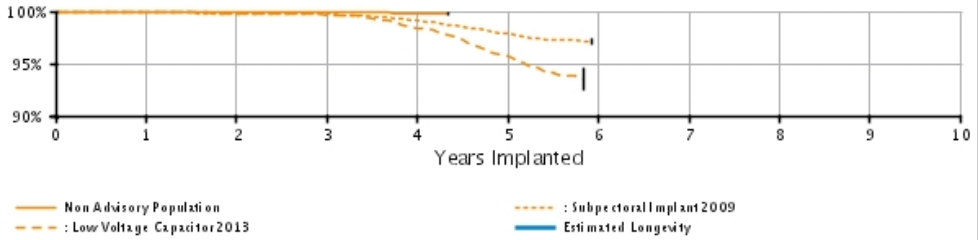
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 48,000

U.S. Normal Battery Depletions: 100
U.S. Unconfirmed Reports of Premature Battery Depletion : 30
U.S. Malfunctions:468
Without Compromised Therapy:392
With Compromised Therapy:76

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)	99.91 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.60 (-0.1/+0.1)	99.35 @ 52 mo. (-0.8/+0.4)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.77 @ 52 mo. (-0.1/+0.1)	–	–	–	–	–
	Effective Sample Size	29279	25673	16269	3269	391	–	–	–	–	–
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)	97.43 (-0.3/+0.2)	95.82 @ 71 (-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)	97.82 (-0.3/+0.2)	97.13 @ 71 (-0.3/+0.3)	–	–	–	–
	Effective Sample Size	26751	23505	20678	18060	9381	354	–	–	–	–
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)	95.18 (-0.7/+0.6)	92.41 @ 70 (-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)	98.41 (-0.3/+0.3)	95.64 (-0.5/+0.5)	93.55 @ 70	–	–	–	–

							(-1.2/+1.0)				
	Effective Sample Size	9986	8789	7721	6588	2792	313	–	–	–	–

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

TELIGEN DR

Models E110/E111/F110/F111

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

TELIGEN DR
Models E110/E111/F110/F111

Worldwide Distribution: 90,000
Worldwide Confirmed Malfunctions: 637

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**489**	**46**	**535**
[1] Low Voltage Capacitor 2013 (Advisory issued)	320	13	
[79] Safety Core-electrocautery	3	-	
[80] High-voltage capacitor	1	5	
[85] Low-voltage capacitors	5	-	
[89] Integrated circuit	13	16	
[92] Battery	63	12	
[93] Low-voltage capacitor	84	-	
Mechanical	**16**	**48**	**64**
[5] Subpectoral implant 2009 (Advisory issued)	3	6	
[73] Transformer	-	20	
[76] Seal plug	3	-	
[77] Difficulty securing lead	8	8	
[83] Header contacts	1	11	
[97] Header	1	3	
Software	**14**	**-**	**14**
[87] Alert messages not displayed post-EOL	3	-	
[90] Memory errors	11	-	
Other	**18**	**6**	**24**
Non-patterned	18	6	
WW Confirmed Malfunctions	**537**	**100**	**637**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

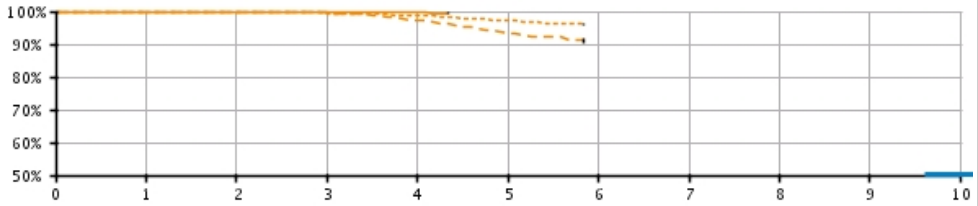
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

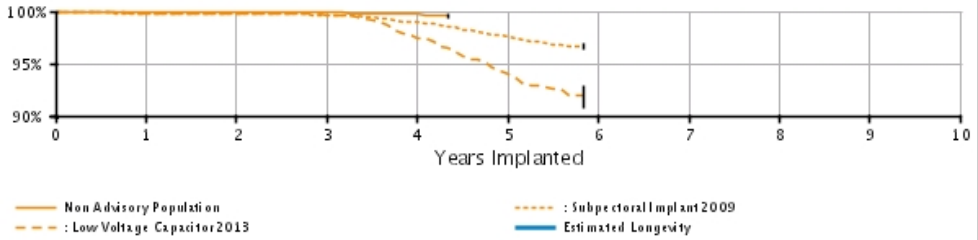
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 28,000

U.S. Normal Battery Depletions: 52
U.S. Unconfirmed Reports of Premature Battery Depletion : 11
U.S. Malfunctions:328
Without Compromised Therapy:270
With Compromised Therapy:58

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)	99.84 (-0.1/+0.0)	99.75 (-0.1/+0.1)	99.60 (-0.2/+0.1)	99.39 @ 52 mo. (-0.4/+0.3)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.63 @ 52 mo. (-0.3/+0.2)	–	–	–	–	–
	Effective Sample Size	18578	16284	9247	1642	251	–	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.1)	97.16 (-0.3/+0.2)	96.06 @ 70 (-0.4/+0.4)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.0)	99.73 (-0.1/+0.0)	99.63 (-0.1/+0.1)	98.93 (-0.1/+0.1)	97.55 (-0.3/+0.2)	96.61 @ 70 (-0.3/+0.3)	–	–	–	–
	Effective Sample Size	13681	11999	10519	9151	4786	461	–	–	–	–
Low Voltage Capacitor 2013* Registered Implants: 11,000	Depletions and Malfunctions(%) (Confidence Interval)	99.56 (-0.1/+0.0)	99.53 (-0.1/+0.1)	97.21 (-0.2/+0.1)	98.19 (-0.4/+0.3)	93.47 (-0.7/+0.6)	91.09 @ 70 (-1.4/+1.1)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.84 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.68 (-0.1/+0.1)	97.50 (-0.3/+0.3)	94.00 (-0.5/+0.5)	91.95 @ 70	–	–	–	–

						(-1.2/+1.0)					
	Effective Sample Size	5225	4584	4024	3341	1440	210	–	–	–	–

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

TELIGEN VR

Models E102/E103/F102/F103

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

TELIGEN VR
Models E102/E103/F102/F103

Worldwide Distribution: 65,000
Worldwide Confirmed Malfunctions: 512

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**378**	**25**	**403**
[1] Low Voltage Capacitor 2013 (Advisory issued)	237	5	
[79] Safety Core-electrocautery	1	1	
[80] High-voltage capacitor	-	2	
[85] Low-voltage capacitors	4	-	
[89] Integrated circuit	6	12	
[92] Battery	74	3	
[93] Low-voltage capacitor	56	2	
Mechanical	**18**	**59**	**77**
[5] Subpectoral implant 2009 (Advisory issued)	5	12	
[45] Transformer	-	1	
[73] Transformer	-	14	
[76] Seal plug	1	-	
[77] Difficulty securing lead	-	10	
[83] Header contacts	11	15	
[97] Header	1	7	
Software	**13**	**-**	**13**
[6] Respiratory Sensor Oversensing	1	-	
[87] Alert messages not displayed post-EOL	4	-	
[90] Memory errors	8	-	
Other	**11**	**8**	**19**
Non-patterned	11	8	
WW Confirmed Malfunctions	**420**	**92**	**512**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

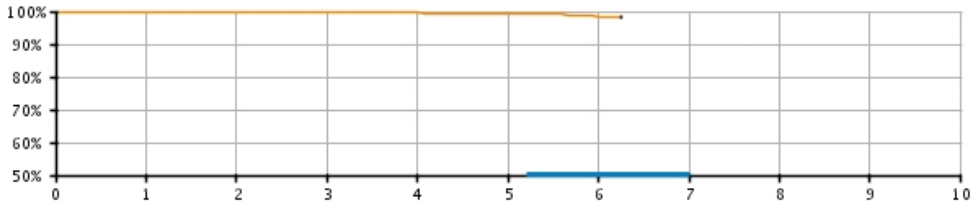
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

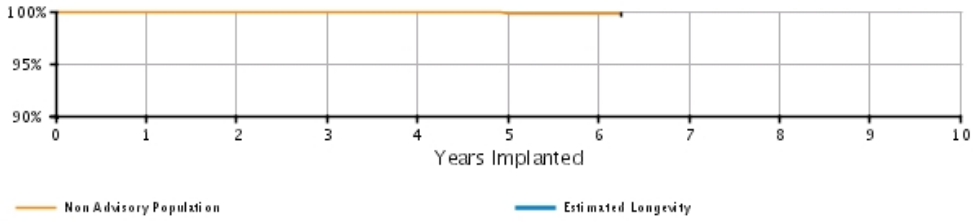
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 39
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:8
Without Compromised Therapy:7
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)	99.54 (-0.2/+0.2)	99.34 (-0.3/+0.2)	98.47 (-0.5/+0.4)	98.22 @ 75 mo. (-0.8/+0.6)	–	–	–
	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)	99.83 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.77 @ 75 mo. (-0.3/+0.1)	–	–	–
	Effective Sample Size	6164	5397	4647	3845	3020	1523	385	–	–	–

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: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**-**	**6**
[25] Capacitor	1	-	
[30] Integrated circuit	2	-	
[93] Low-voltage capacitor	3	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	-	
[39] Battery depletion	-	1	
WW Confirmed Malfunctions	**7**	**1**	**8**

More details about malfunctions

References cited in table above

VITALITY 2 EL DR

Model T167

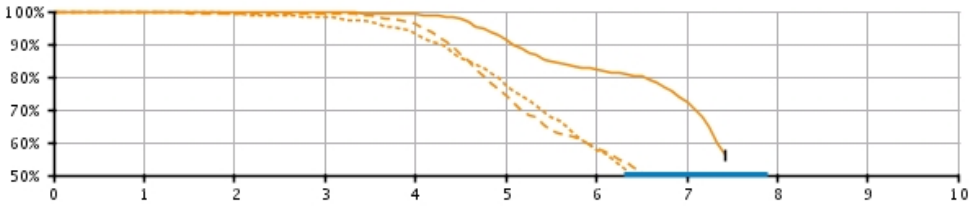
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

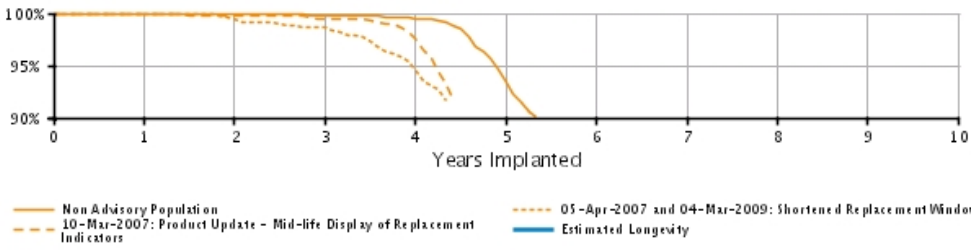
U.S. Registered Implants: 8,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 1,399
U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Malfunctions:759
Without Compromised Therapy:746
With Compromised Therapy:13

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	91.25 (-1.1/+1.0)	82.23 (-1.6/+1.5)	72.06 (-2.3/+2.2)	56.18 @ 89 mo. (-3.6/+3.6)	–	–
	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)	93.37 (-1.0/+0.9)	87.28 (-1.4/+1.3)	86.42 (-1.5/+1.4)	86.42 @ 89 mo. (-1.5/+1.4)	–	–
	Effective Sample Size	4363	3832	3362	2916	2345	1672	566	224	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	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)	57.93 (-3.2/+3.1)	31.78 (-3.2/+3.4)	28.68 @ 85 mo. (-3.1/+3.3)	–	–
	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)	75.89 (-2.8/+2.6)	73.76 (-3.1/+2.9)	73.76 @ 85 mo. (-3.1/+2.9)	–	–
	Effective Sample Size	1699	1489	1289	1076	781	475	219	205	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.40 (-0.7/+0.3)	99.18 (-0.8/+0.4)	96.23 (-1.5/+1.1)	74.33 (-3.3/+3.1)	58.16 (-3.8/+3.7)	42.77 @ 82 mo. (-4.0/+4.1)	–	–	–

Registered Implants: 1000											
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.5/+0.1)	99.74 (-0.6/+0.2)	99.52 (-0.7/+0.3)	97.51 (-1.3/+0.9)	81.03 (-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

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

VITALITY 2 EL DR Model T167

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1044

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1006**	**9**	**1015**
[7] Shortened replacement window (Advisory issued)	143	2	
[15] Extended charge time post-mid-life	15	-	
[25] Capacitor	1	-	
[30] Integrated circuit	-	4	
[44] Capacitor	1	-	
[56] Mid-life display of replacement indicators	805	-	
[57] High-voltage capacitor	-	2	
[61] Integrated circuit	-	1	
[78] Low-voltage capacitor	41	-	
Mechanical	**8**	**3**	**11**
[10] Subpectoral implant (Advisory issued)	1	1	
[26] Header	1	-	
[34] Seal plug	5	1	
[65] Seal plug	1	-	
[73] Transformer	-	1	
Software	**7**	**1**	**8**
[55] Memory location	1	1	
[75] Misaligned markers	6	-	
Other	**3**	**7**	**10**
Non-patterned	2	3	
[20] Firmware error	1	4	
WW Confirmed Malfunctions	**1024**	**20**	**1044**

More details about malfunctions

References cited in table above

VITALITY 2 DR

Model T165

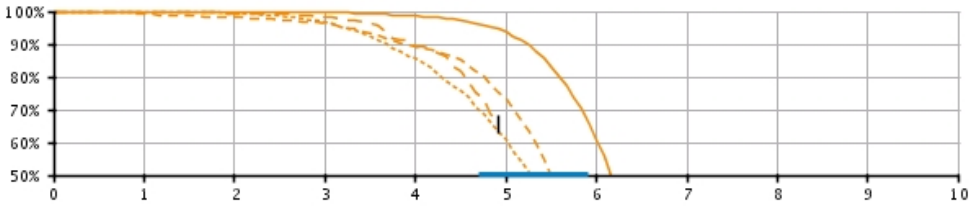
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

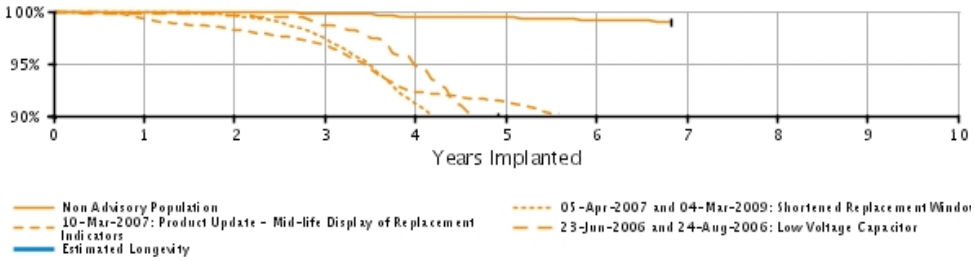
U.S. Registered Implants: 31,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 10,426
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)	93.65 (-0.5/+0.5)	60.62 (-1.1/+1.1)	11.46 @ 82 mo. (-1.1/+1.2)	–	–	–
	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)	99.18 (-0.2/+0.2)	98.94 @ 82 mo. (-0.5/+0.3)	–	–	–
	Effective Sample Size	15245	13387	11709	9973	8053	4144	237	–	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.86 (-0.1/+0.1)	99.39 (-0.2/+0.2)	96.63 (-0.5/+0.4)	85.51 (-0.9/+0.9)	60.66 (-1.4/+1.4)	17.84 (-1.2/+1.2)	6.67 @ 77 mo. (-0.8/+0.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.56 (-0.2/+0.1)	97.36 (-0.4/+0.4)	91.21 (-0.8/+0.7)	86.77 (-1.0/+0.9)	84.75 (-1.2/+1.1)	84.19 @ 77 mo. (-1.4/+1.3)	–	–	–
	Effective Sample Size	7844	6862	5805	4450	2720	683	223	–	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	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)	73.14 (-1.6/+1.5)	22.57 (-1.6/+1.7)	9.02 @ 76 mo. (-1.1/+1.3)	–	–	–

Registered Implants: 6000											
	Malfunctions Only(%) (Confidence Interval)	99.34 (-0.3/+0.2)	98.28 (-0.4/+0.3)	96.80 (-0.6/+0.5)	92.34 (-0.9/+0.8)	91.26 (-1.0/+0.9)	89.29 (-1.3/+1.1)	87.86 @ 76 mo. (-1.8/+1.6)	–	–	–
	Effective Sample Size	4991	4338	3718	2978	2095	543	225	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.42 (-1.2/+0.4)	98.25 (-1.7/+0.9)	89.37 (-3.5/+2.7)	65.57 @ 59 mo. (-5.3/+5.0)	–	–	–	–	–
Registered Implants: 1000											
	Malfunctions Only(%) (Confidence Interval)	99.84 (-1.0/+0.1)	99.63 (-1.1/+0.3)	98.69 (-1.6/+0.7)	94.80 (-2.8/+1.8)	86.94 @ 59 mo. (-4.3/+3.3)	–	–	–	–	–
	Effective Sample Size	555	472	403	321	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

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

VITALITY 2 DR Model T165

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 1370

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1266**	**46**	**1312**
[7] Shortened replacement window (Advisory issued)	477	24	
[8] Low-voltage capacitor (Advisory issued)	1	-	
[9] Premature battery depletion (Advisory issued)	163	1	
[15] Extended charge time post-mid-life	101	1	
[21] Integrated circuit	1	1	
[23] Reconfirmation after charge	1	-	
[25] Capacitor	1	1	
[30] Integrated circuit	7	11	
[44] Capacitor	3	1	
[47] Capacitor	4	-	
[48] Device tones	1	-	
[56] Mid-life display of replacement indicators	267	-	
[57] High-voltage capacitor	4	1	
[61] Integrated circuit	1	-	
[70] Logic errors	-	3	
[78] Low-voltage capacitor	234	2	
Mechanical	**7**	**6**	**13**
[34] Seal plug	4	3	
[45] Transformer	-	1	
[65] Seal plug	2	-	
[98] Solder joint	1	2	
Software	**2**	**2**	**4**
[53] Memory location	-	2	
[55] Memory location	1	-	
[75] Misaligned markers	1	-	
Other	**19**	**22**	**41**
Non-patterned	12	8	
[20] Firmware error	5	8	
[28] Battery depletion	2	5	
[81] Magnet rate	-	1	
WW Confirmed Malfunctions	**1294**	**76**	**1370**

More details about malfunctions

References cited in table above

VITALITY 2 EL VR

Model T177

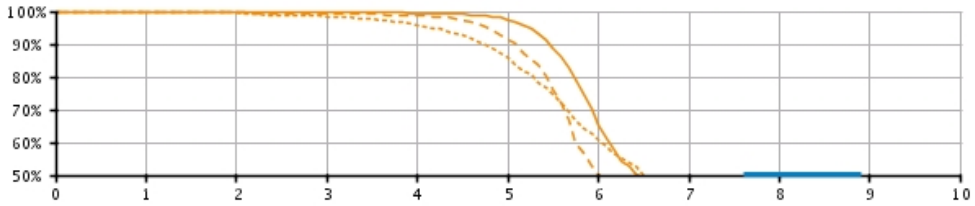
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

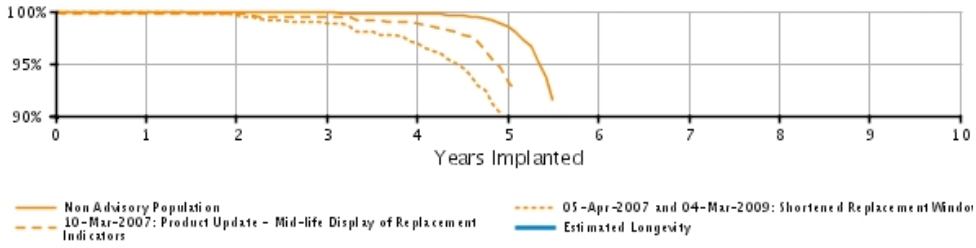
U.S. Registered Implants: 7,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 844
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:1200
Without Compromised Therapy:1187
With Compromised Therapy:13

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	97.33 (-0.8/+0.6)	65.18 (-2.3/+2.2)	43.93 (-2.7/+2.8)	42.48 @ 86 mo. (-2.8/+2.9)	–	–
	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)	98.46 (-0.6/+0.4)	72.41 (-2.2/+2.1)	56.28 (-2.9/+2.8)	56.28 @ 86 mo. (-2.9/+2.8)	–	–
	Effective Sample Size	3631	3176	2770	2392	2025	1093	261	204	–	–
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)	34.08 @ 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)	60.82 @ 88 mo. (-3.6/+3.4)	–	–
	Effective Sample Size	1687	1474	1279	1087	822	496	278	208	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	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)	–	–	–

Registered Implants: 1000											
	Malfunctions Only(%) (Confidence Interval)	99.72 (-0.6/+0.2)	99.72 (-0.6/+0.2)	99.48 (-0.7/+0.3)	98.90 (-1.0/+0.5)	93.22 (-2.3/+1.8)	59.83 (-4.6/+4.4)	54.67 @ 74 mo. (-4.7/+4.6)	–	–	–
	Effective Sample Size	975	854	747	647	527	240	209	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL VR

Model T177

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

VITALITY 2 EL VR
Model T177

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 1767

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1727**	**8**	**1735**
[7] Shortened replacement window (Advisory issued)	138	1	
[8] Low-voltage capacitor (Advisory issued)	2	1	
[15] Extended charge time post-mid-life	15	2	
[30] Integrated circuit	-	3	
[44] Capacitor	1	-	
[47] Capacitor	2	-	
[56] Mid-life display of replacement indicators	1502	1	
[57] High-voltage capacitor	2	-	
[78] Low-voltage capacitor	65	-	
Mechanical	**2**	**8**	**10**
[10] Subpectoral implant (Advisory issued)	-	5	
[26] Header	-	1	
[34] Seal plug	1	-	
[59] Sensing	1	-	
[73] Transformer	-	2	
Software	**-**	**2**	**2**
[53] Memory location	-	1	
[55] Memory location	-	1	
Other	**11**	**9**	**20**
Non-patterned	11	7	
[28] Battery depletion	-	2	
WW Confirmed Malfunctions	**1740**	**27**	**1767**

More details about malfunctions

References cited in table above

VITALITY 2 VR

Model T175

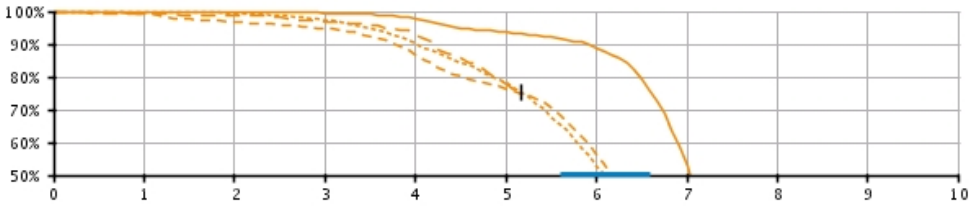
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

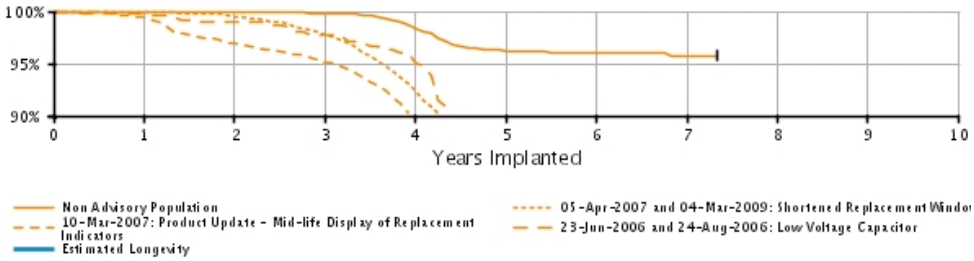
U.S. Registered Implants: 21,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 4,673
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)	97.59 (-0.4/+0.3)	93.65 (-0.6/+0.6)	88.79 (-0.9/+0.8)	52.64 (-2.3/+2.3)	22.72 @ 88 mo. (-2.5/+2.8)	–	–
	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)	96.24 (-0.5/+0.5)	96.05 (-0.5/+0.5)	95.76 (-0.6/+0.5)	95.76 @ 88 mo. (-0.6/+0.5)	–	–
	Effective Sample Size	9496	8337	7207	6047	4878	3622	702	205	–	–
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)	52.60 (-1.8/+1.8)	17.05 (-1.5/+1.6)	9.29 @ 87 mo. (-1.2/+1.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.40 (-1.2/+1.1)	84.87 (-1.3/+1.2)	83.20 (-1.5/+1.4)	83.20 @ 87 mo. (-1.5/+1.4)	–	–
	Effective Sample Size	5392	4692	4023	3237	2376	1375	365	210	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	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)	16.18 (-1.7/+1.9)	13.86 @ 85 mo. (-1.6/+1.8)	–	–

Registered Implants: 4000											
	Malfunctions Only(%) (Confidence Interval)	99.39 (-0.3/+0.2)	96.95 (-0.6/+0.5)	95.13 (-0.8/+0.7)	89.21 (-1.2/+1.1)	84.05 (-1.4/+1.3)	83.38 (-1.5/+1.4)	81.62 (-1.8/+1.7)	81.62 @ 85 mo. (-1.8/+1.7)	–	–
	Effective Sample Size	3907	3331	2852	2263	1681	1061	249	207	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Depletions and Malfunctions(%) (Confidence Interval)	99.47 (-1.1/+0.4)	98.64 (-1.5/+0.7)	96.88 (-2.1/+1.3)	92.79 (-3.1/+2.2)	77.91 (-4.9/+4.3)	75.29 @ 62 mo. (-5.2/+4.5)	–	–	–	–
Registered Implants: 1000											
	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

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

VITALITY 2 VR Model T175

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 1579

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1527**	**26**	**1553**
[7] Shortened replacement window (Advisory issued)	347	9	
[8] Low-voltage capacitor (Advisory issued)	-	1	
[9] Premature battery depletion (Advisory issued)	219	6	
[15] Extended charge time post-mid-life	61	-	
[21] Integrated circuit	-	1	
[25] Capacitor	1	-	
[30] Integrated circuit	4	7	
[44] Capacitor	1	-	
[47] Capacitor	4	-	
[56] Mid-life display of replacement indicators	770	-	
[57] High-voltage capacitor	-	1	
[78] Low-voltage capacitor	120	1	
Mechanical	**2**	**1**	**3**
[34] Seal plug	2	1	
Software	**-**	**1**	**1**
[55] Memory location	-	1	
Other	**16**	**6**	**22**
Non-patterned	14	6	
[28] Battery depletion	2	-	
WW Confirmed Malfunctions	**1545**	**34**	**1579**

More details about malfunctions

References cited in table above

ADVANTIO DR

Models J063/J066/K063/K066/K083

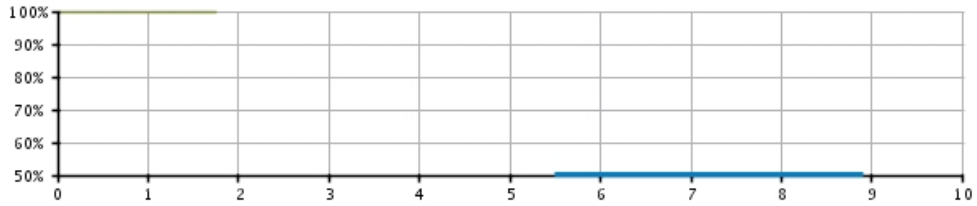
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

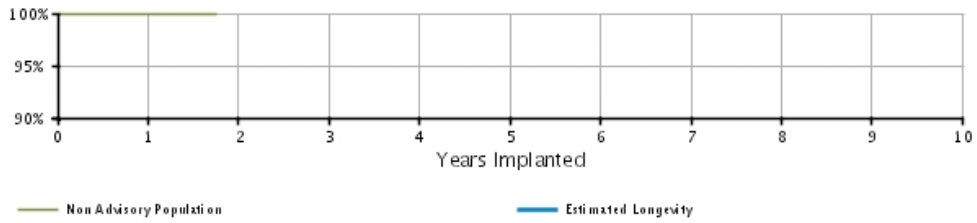
U.S. Registered Implants: 36,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 35,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:7
Without Compromised Therapy:7
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: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.91 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	17655	828	259	–	–	–	–	–	–	–

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: 50,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**-**	**3**
[85] Low-voltage capacitors	1	-	
[89] Integrated circuit	2	-	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[90] Memory errors	3	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**8**	**0**	**8**

More details about malfunctions

References cited in table above

ADVANTIO EL DR

Models J064/K064/K067/K084

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

ADVANTIO EL DR
Models J064/K064/K067/K084

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[85] Low-voltage capacitors	-	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

ADVANTIO SR

Models J062/J065/K062/K065/K082

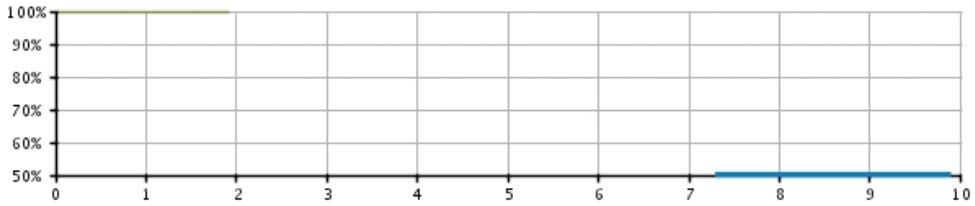
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

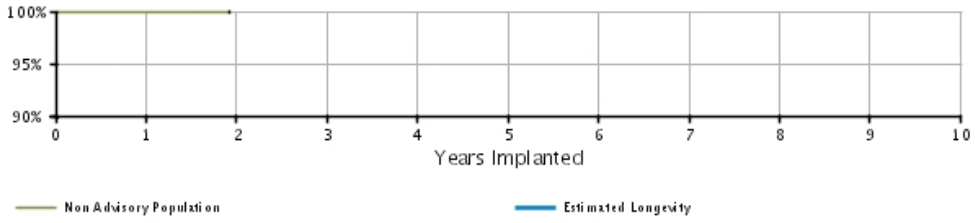
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.90 @ 23 mo. (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.92 @ 23 mo. (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	3710	349	–	–	–	–	–	–	–	–

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: 19,000
Worldwide Confirmed Malfunctions: 5

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

More details about malfunctions

References cited in table above

INGENIO DR

Models J173/J176/K173/K176/K183

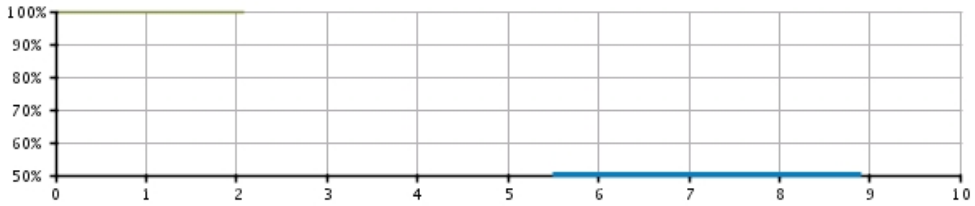
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

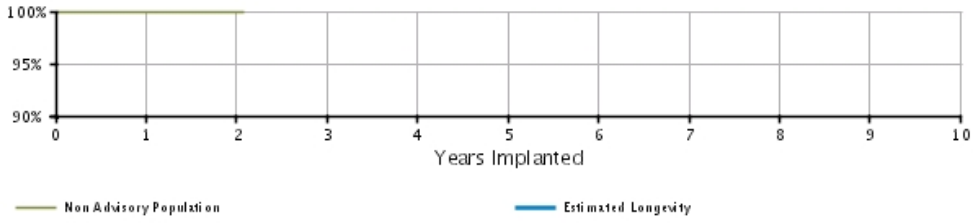
U.S. Registered Implants: 45,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 43,000

U.S. Normal Battery Depletions: 7
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: 45000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 25 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 @ 25 mo. (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	18606	1240	493	–	–	–	–	–	–	–

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: 72,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[85] Low-voltage capacitors	1	-	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[90] Memory errors	3	-	
Other	**4**	**-**	**4**
Non-patterned	4	-	
WW Confirmed Malfunctions	**8**	**0**	**8**

More details about malfunctions

References cited in table above

INGENIO EL DR

Models J174/J177/K174/K177/K184

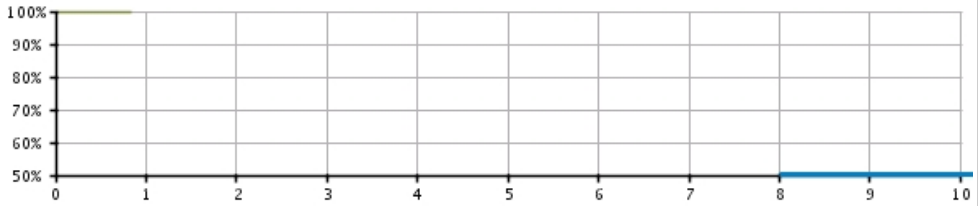
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

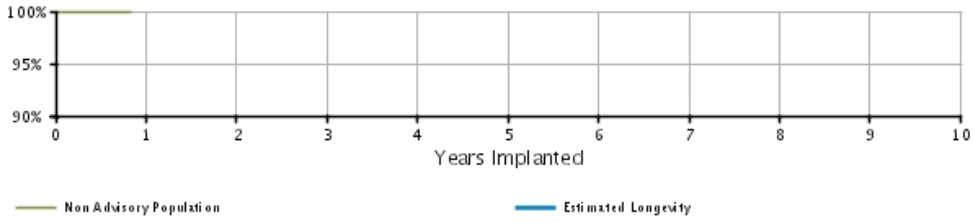
U.S. Registered Implants: 3,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 3,000

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: 3000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 13 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 13 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	309	227	–	–	–	–	–	–	–	–

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: 19,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[85] 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

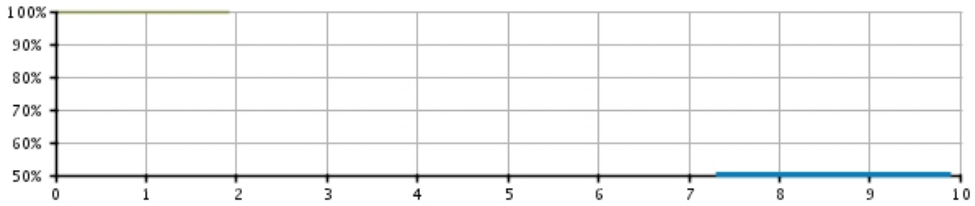
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

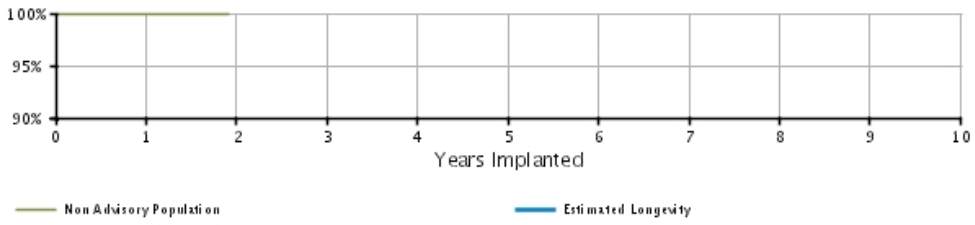
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 8,000

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: 8000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 23 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 23 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	3256	334	–	–	–	–	–	–	–	–

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: 22,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	-	1
[90] Memory errors	1	-	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

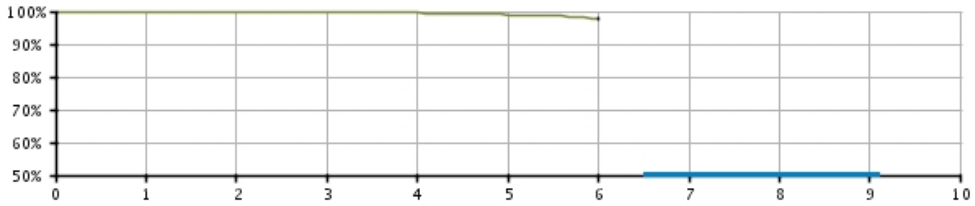
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

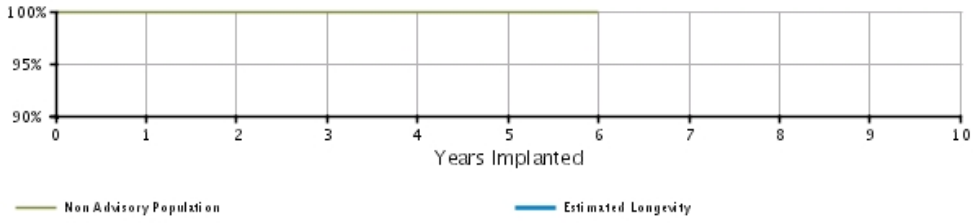
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 139
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)	99.84 (-0.1/+0.1)	99.51 (-0.1/+0.1)	99.00 (-0.2/+0.2)	97.78 (-0.6/+0.5)	–	–	–	–
	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 (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	19117	16618	13616	10799	7264	397	–	–	–	–

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: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[25] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[29] Capacitor array	1	-	
[77] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**2**	**1**	**3**
Non-patterned	1	1	
[49] Battery depletion	1	-	
WW Confirmed Malfunctions	**4**	**2**	**6**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

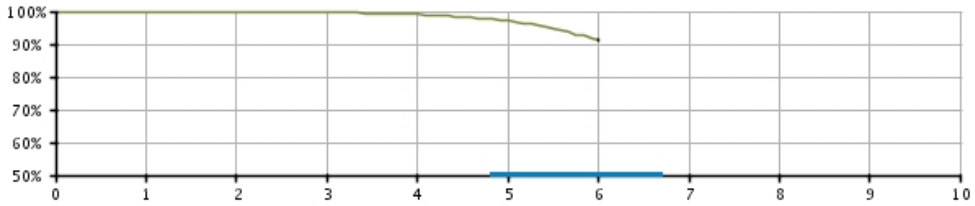
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

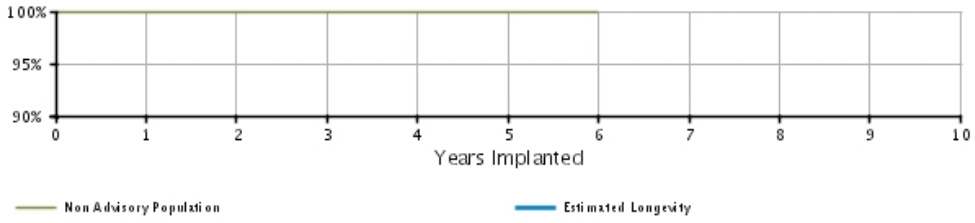
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 67,000

U.S. Normal Battery Depletions: 1,111
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:19
Without Compromised Therapy:11
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)	99.01 (-0.1/+0.1)	97.11 (-0.2/+0.2)	91.14 (-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)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	79071	67609	47949	29883	13719	632	–	–	–	–

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: 21

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**6**	**11**
[25] Capacitor	4	5	
[61] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[74] Connector block	1	-	
[77] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**5**	**3**	**8**
Non-patterned	-	2	
[49] Battery depletion	3	1	
[88] Battery status	2	-	
WW Confirmed Malfunctions	**12**	**9**	**21**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

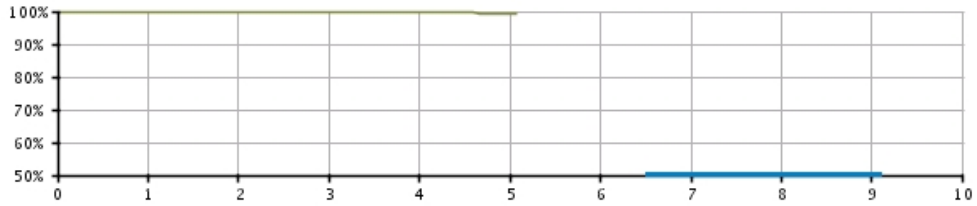
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

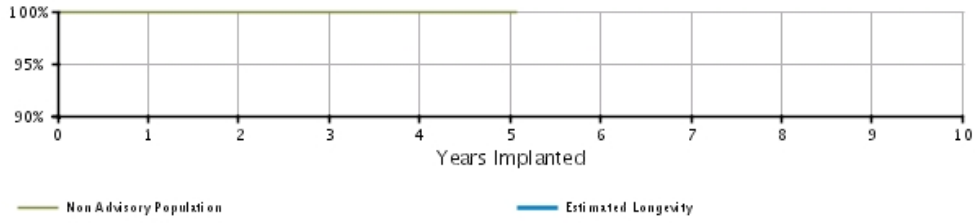
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 49,000

U.S. Normal Battery Depletions: 83
U.S. Unconfirmed Reports of Premature Battery Depletion : 6
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)	99.86 (-0.0/+0.0)	99.71 (-0.1/+0.1)	99.39 (-0.2/+0.2)	99.39 @ 61 mo. (-0.2/+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 (-0.0/+0.0)	99.99 @ 61 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	52382	44103	26085	11144	927	495	–	–	–	–

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**
[25] Capacitor	3	-	
[30] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[77] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	-	
[49] Battery depletion	-	1	
WW Confirmed Malfunctions	**5**	**2**	**7**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

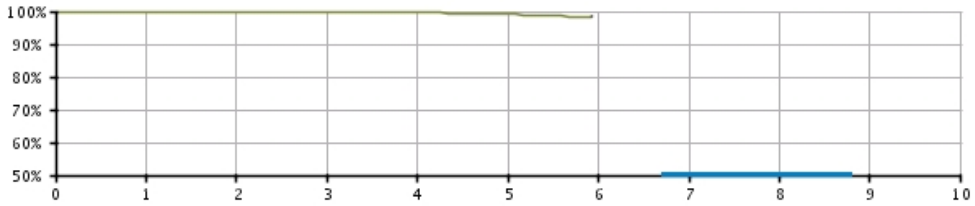
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

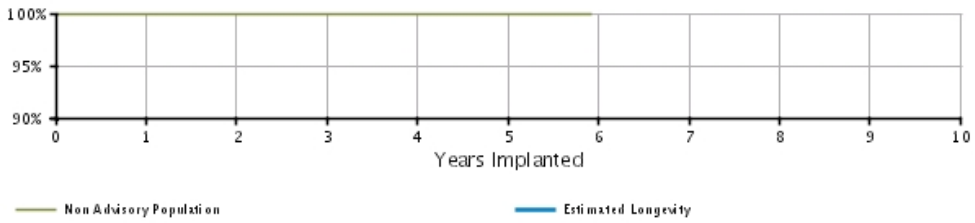
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 107
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)	99.89 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.08 (-0.2/+0.2)	98.47 @ 71 mo. (-0.5/+0.4)	–	–	–	–
	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 @ 71 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	26656	22381	14974	8833	3615	340	–	–	–	–

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**
[25] Capacitor	2	1	
[61] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**3**	**3**
Non-patterned	-	2	
[49] 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**
[25] Capacitor	2	-	
[61] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[77] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	-	-	
[49] 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: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**2**	**3**
[25] Capacitor	1	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**3**	**3**
Non-patterned	-	1	
[49] Battery depletion	-	2	
WW Confirmed Malfunctions	**1**	**5**	**6**

More details about malfunctions

References cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

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

ALTRUA 50 DDD (Downsize) Model S503

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	3	4
Non-patterned	-	-	
[49] Battery depletion	-	3	
[88] Battery status	1	-	
WW Confirmed Malfunctions	1	3	4

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

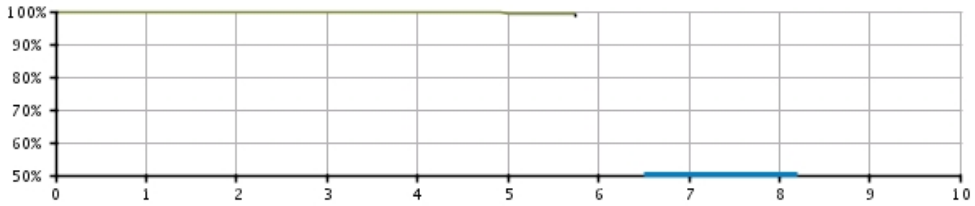
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

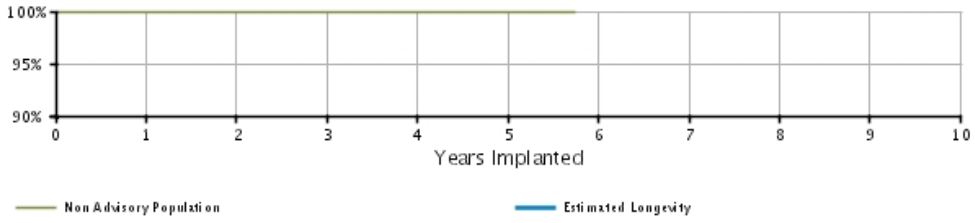
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 8
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)	99.45 (-0.7/+0.3)	99.01 @ 69 mo. (-1.1/+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 @ 69 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	1517	1346	1194	1064	911	272	–	–	–	–

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

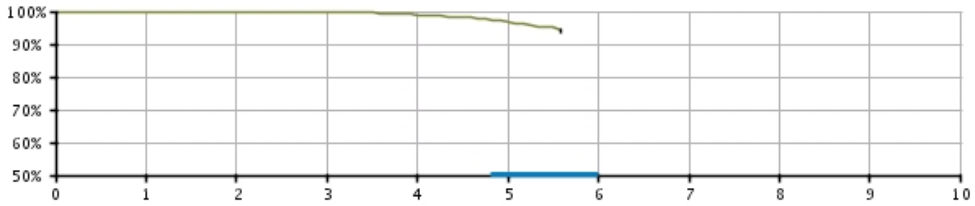
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

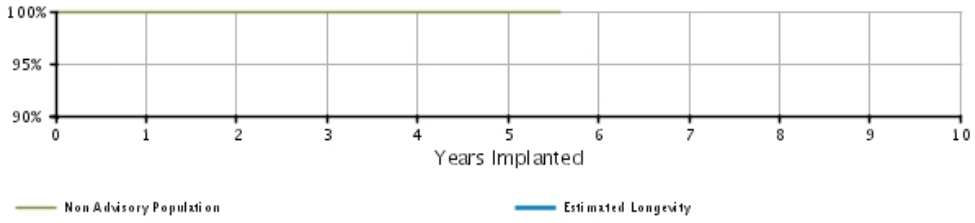
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 180
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)	99.91 (-0.1/+0.0)	99.67 (-0.1/+0.1)	98.91 (-0.3/+0.2)	96.48 (-0.7/+0.6)	91.59 @ 70 mo. (-2.0/+1.6)	–	–	–	–
	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 @ 70 mo. (-0.1/+0.0)	–	–	–	–
	Effective Sample Size	12510	11026	7753	4557	1842	280	–	–	–	–

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**
[76] Seal plug	1	-	
[77] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	-	-	
[88] Battery status	1	-	
WW Confirmed Malfunctions	**3**	**0**	**3**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

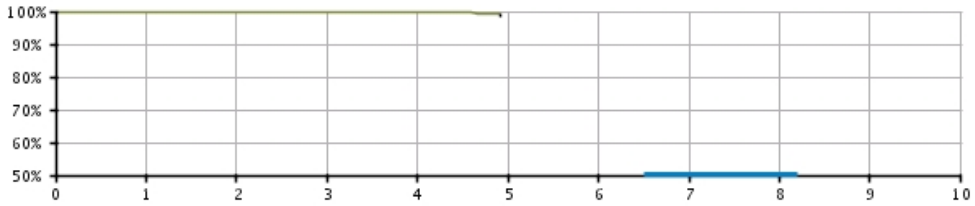
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

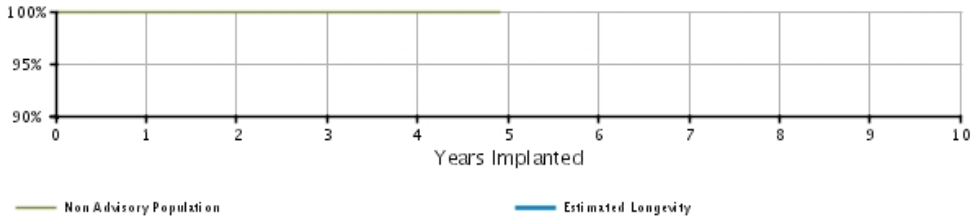
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 8
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)	99.94 (-0.2/+0.0)	99.70 (-0.4/+0.2)	99.04 @ 59 mo. (-1.7/+0.6)	–	–	–	–	–
	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 @ 59 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	4470	3911	2528	1327	223	–	–	–	–	–

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**
[25] 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

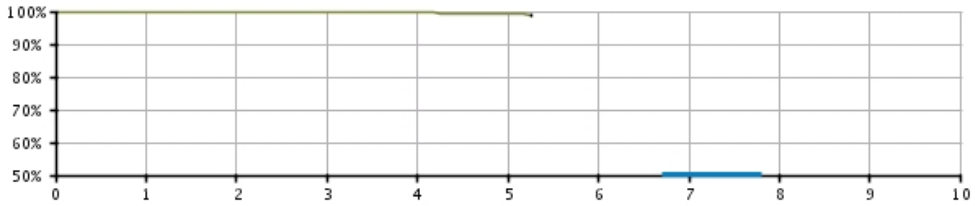
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

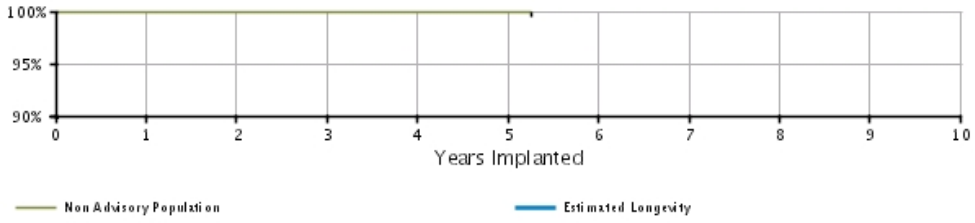
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 14
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)	99.88 (-0.2/+0.1)	99.71 (-0.3/+0.2)	99.43 (-0.6/+0.3)	98.25 @ 66 mo. (-1.7/+0.9)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.91 (-0.3/+0.1)	99.91 (-0.3/+0.1)	99.91 @ 66 mo. (-0.3/+0.1)	–	–	–	–
	Effective Sample Size	3960	3416	2340	1364	582	227	–	–	–	–

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**
[25] Capacitor	2	-	
[61] 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

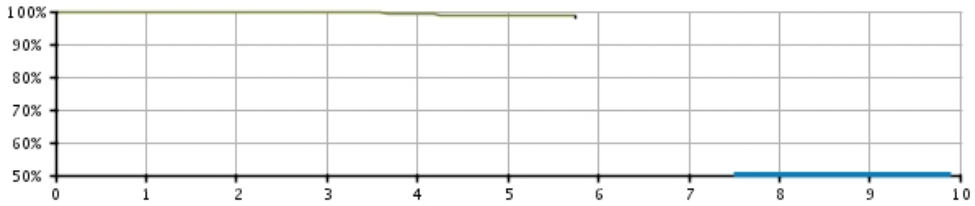
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

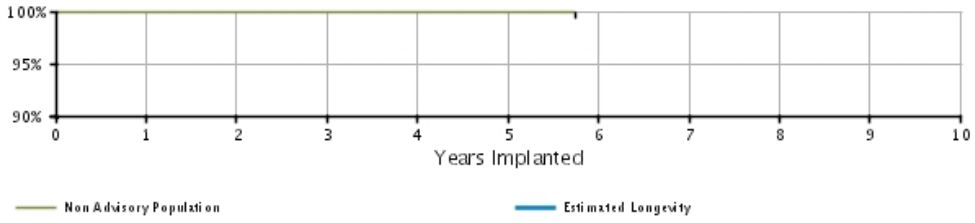
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 12
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)	99.42 (-0.7/+0.3)	98.70 (-1.0/+0.6)	98.53 @ 69 mo. (-1.1/+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 @ 69 mo. (-0.6/+0.1)	–	–	–	–
	Effective Sample Size	1466	1273	1072	888	710	201	–	–	–	–

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

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

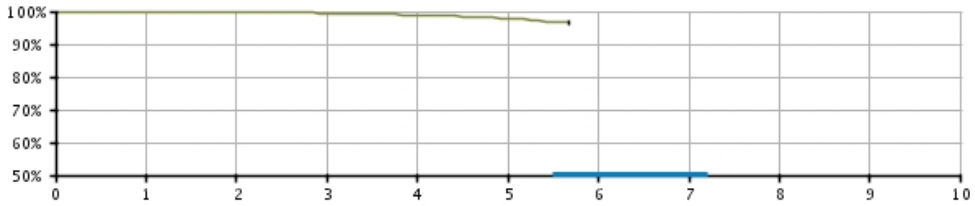
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

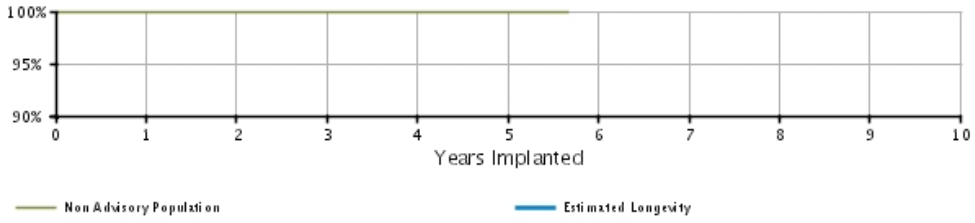
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 46
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)	98.81 (-0.5/+0.4)	97.99 (-0.8/+0.6)	96.64 @ 68 mo. (-1.5/+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 @ 68 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	4418	3854	2771	1691	689	203	–	–	–	–

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

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

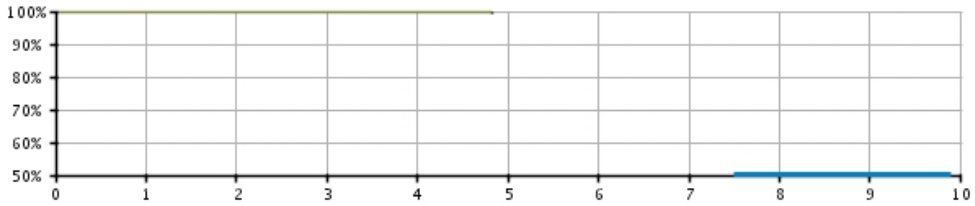
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

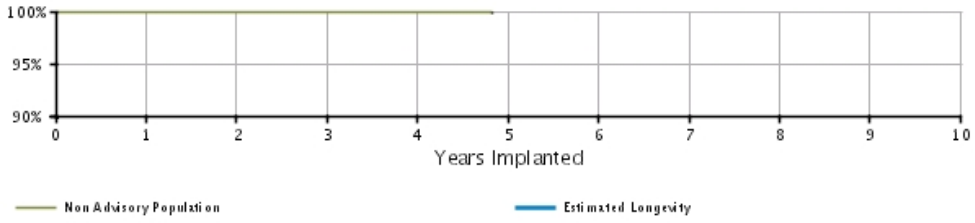
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 6
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)	99.86 (-0.2/+0.1)	99.74 (-0.3/+0.1)	99.66 (-0.4/+0.2)	99.66 @ 58 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 @ 58 mo. (-0.2/+0.0)	–	–	–	–	–
	Effective Sample Size	2774	2395	1527	751	214	–	–	–	–	–

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**
[25] 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

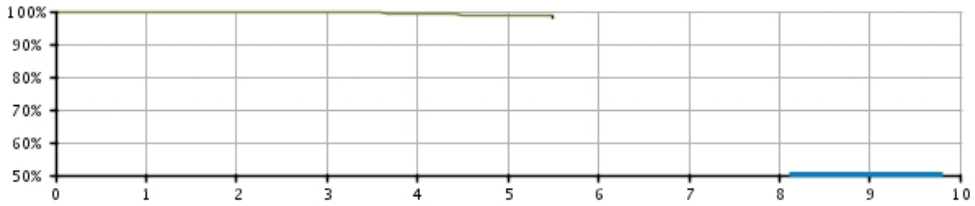
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

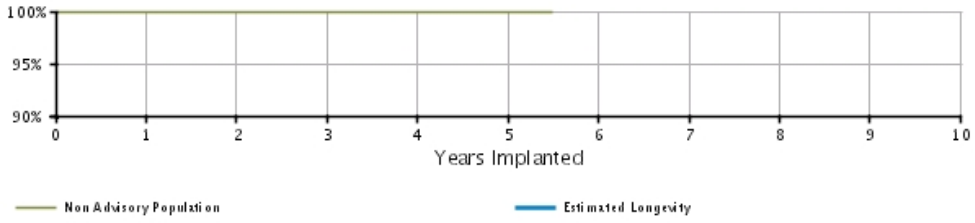
U.S. Registered Implants: 4,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 19
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)	99.63 (-0.3/+0.2)	99.30 (-0.5/+0.3)	98.75 (-0.9/+0.5)	98.51 @ 66 mo. (-1.1/+0.6)	–	–	–	–
	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 @ 66 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	3549	2928	1993	1177	465	204	–	–	–	–

ALTRUA 20 SR

Models S201/S204

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

ALTRUA 20 SR Models S201/S204

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[25] 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

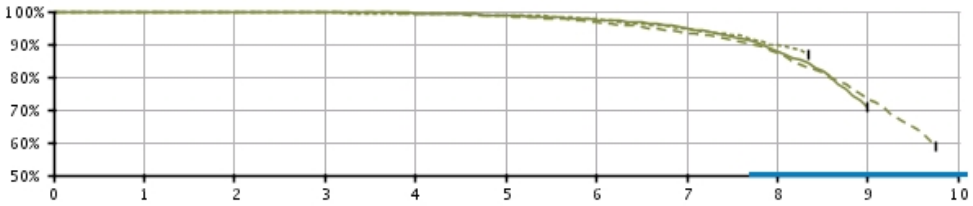
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

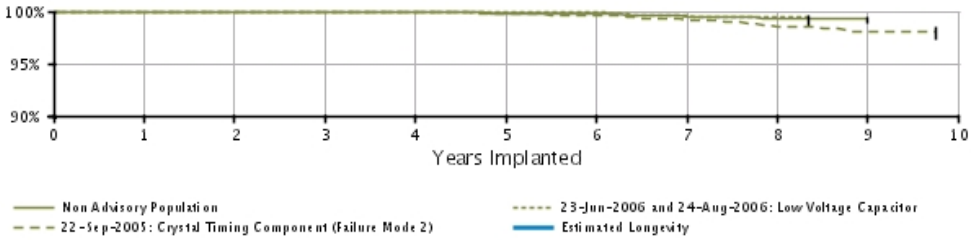
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 1,612
U.S. Unconfirmed Reports of Premature Battery Depletion : 15
U.S. Malfunctions:114
Without Compromised Therapy:105
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)	97.45 (-0.3/+0.3)	94.96 (-0.5/+0.4)	87.73 (-1.2/+1.1)	70.78 (-3.4/+3.2)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.53 (-0.2/+0.1)	99.35 (-0.3/+0.2)	99.24 (-0.4/+0.2)	–
	Effective Sample Size	21005	18659	16561	14650	12901	10999	4858	1271	232	–
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)	89.66 (-2.1/+1.8)	86.88 @ 100 mo. (-2.8/+2.3)	–
	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 @ 100 mo. (-0.8/+0.3)	–
	Effective Sample Size	1878	1659	1461	1287	1134	988	850	700	226	–
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.59 (-0.7/+0.6)	93.45 (-0.9/+0.8)	87.21 (-1.3/+1.2)	73.31 (-1.9/+1.8)	58.87 @ 117 mo. (-3.0/+3.0)

	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)	97.97 (-0.7/+0.5)	97.97 @ 117 mo. (-0.7/+0.5)
	Effective Sample Size	5702	5045	4467	3940	3453	2980	2556	2098	1025	271

*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: 143

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[22] Capacitor	1	-	
[25] Capacitor	4	2	
[61] Integrated circuit	2	1	
Mechanical	**7**	**5**	**12**
[34] Seal plug	5	4	
[35] Header	1	1	
[63] Setscrew	1	-	
Software	**4**	**-**	**4**
[67] Underestimation of battery status	3	-	
[69] Pacing rate limit	1	-	
Other	**111**	**4**	**115**
Non-patterned	6	3	
[16] Longevity labeling	68	-	
[37] Magnet response	1	-	
[49] Battery depletion	2	1	
[88] Battery status	34	-	
WW Confirmed Malfunctions	**129**	**14**	**143**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

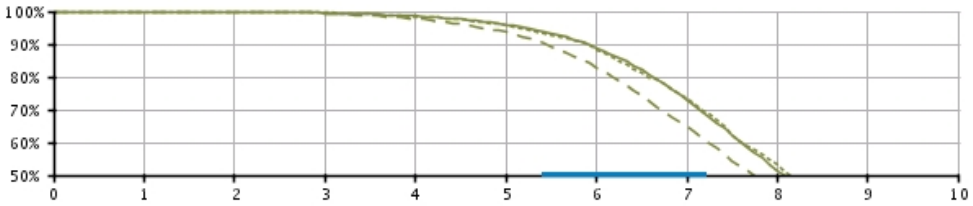
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

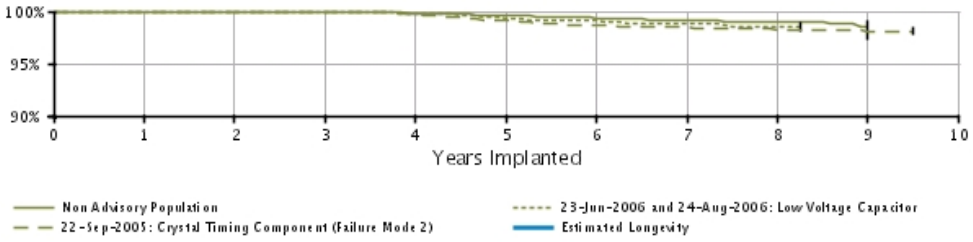
U.S. Registered Implants: 76,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 24,000

U.S. Normal Battery Depletions: 13,658
U.S. Unconfirmed Reports of Premature Battery Depletion : 106
U.S. Malfunctions:399
Without Compromised Therapy:388
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: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.48 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.94 (-0.4/+0.4)	72.90 (-0.6/+0.6)	51.08 (-1.1/+1.1)	29.01 (-2.1/+2.1)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.17 (-0.1/+0.1)	99.06 (-0.2/+0.1)	98.49 (-1.2/+0.7)	–
	Effective Sample Size	47637	42290	37445	32963	28494	23037	9168	1880	202	–
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)	73.28 (-1.9/+1.8)	53.13 (-2.3/+2.3)	47.92 @ 99 mo. (-2.4/+2.5)	–
	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)	98.59 @ 99 mo. (-0.6/+0.4)	–
	Effective Sample Size	4025	3553	3142	2733	2340	1910	1382	865	353	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.38 (-0.2/+0.1)	97.77 (-0.3/+0.3)	93.65 (-0.5/+0.5)	82.84 (-0.8/+0.8)	64.59 (-1.1/+1.1)	44.72 (-1.2/+1.2)	27.92 (-1.2/+1.2)	21.20 @ 114 mo. (-1.4/+1.5)

Component (Failure Mode 2)* Registered Implants: 17000	(Confidence Interval)										
	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)	98.08 (-0.4/+0.4)	98.08 @ 114 mo. (-0.4/+0.4)
	Effective Sample Size	14977	13298	11732	10224	8613	6644	4424	2604	818	247

*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: 543

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**9**	**18**
[8] Low-voltage capacitor (Advisory issued)	1	5	
[25] Capacitor	7	3	
[61] Integrated circuit	1	1	
Mechanical	**6**	**2**	**8**
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[24] Setscrew thread depth	1	-	
[34] Seal plug	4	1	
[46] Circuit connection	1	-	
Software	**12**	**-**	**12**
[40] Rate fault declaration	1	-	
[41] Memory error	2	-	
[67] Underestimation of battery status	8	-	
[69] Pacing rate limit	1	-	
Other	**498**	**7**	**505**
Non-patterned	21	5	
[16] Longevity labeling	397	-	
[49] Battery depletion	6	2	
[88] Battery status	74	-	
WW Confirmed Malfunctions	**525**	**18**	**543**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

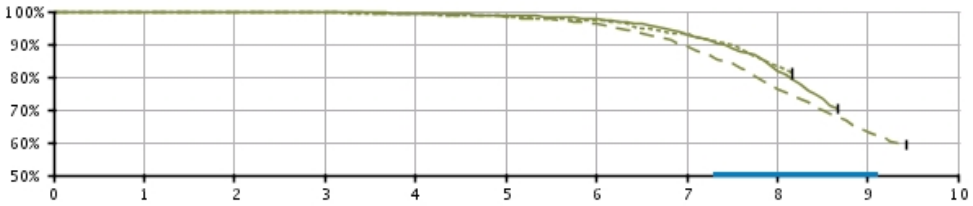
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

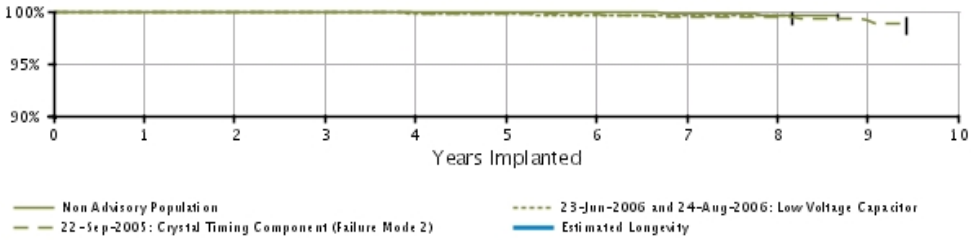
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 1,297
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:35
Without Compromised Therapy:31
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)	97.58 (-0.4/+0.3)	92.97 (-0.7/+0.7)	81.70 (-1.8/+1.7)	70.47 @ 104 mo. (-3.1/+2.9)	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.54 (-0.4/+0.2)	99.54 @ 104 mo. (-0.4/+0.2)	–
	Effective Sample Size	14153	12093	10317	8878	7721	6560	3015	804	226	–
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)	97.21 (-1.6/+1.0)	93.27 (-2.5/+1.8)	83.26 (-3.7/+3.2)	81.13 @ 98 mo. (-4.0/+3.4)	–
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 @ 98 mo. (-0.9/+0.3)	–
	Effective Sample Size	1148	963	812	700	589	503	422	335	235	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.95 (-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)	89.38 (-1.5/+1.3)	76.39 (-2.2/+2.0)	63.16 (-2.7/+2.6)	59.20 @ 113 mo.

Component (Failure Mode 2)* Registered Implants: 5000	(Confidence Interval)										(-3.0/+3.0)
	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)	99.47 (-0.4/+0.2)	99.40 (-0.5/+0.3)	99.08 (-0.8/+0.4)	98.83 @ 113 mo. (-1.1/+0.6)
	Effective Sample Size	4144	3558	3002	2530	2113	1770	1421	1040	461	223

*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: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[8] Low-voltage capacitor (Advisory issued)	1	3	
[25] Capacitor	1	-	
[61] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[34] Seal plug	3	-	
[35] Header	-	1	
Software	**1**	**-**	**1**
[41] Memory error	1	-	
Other	**42**	**-**	**42**
Non-patterned	1	-	
[16] Longevity labeling	23	-	
[49] Battery depletion	1	-	
[88] Battery status	17	-	
WW Confirmed Malfunctions	**48**	**6**	**54**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

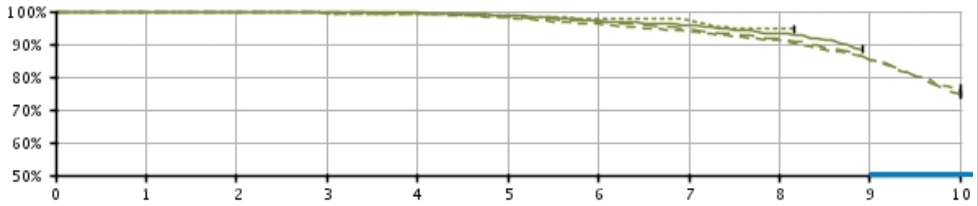
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

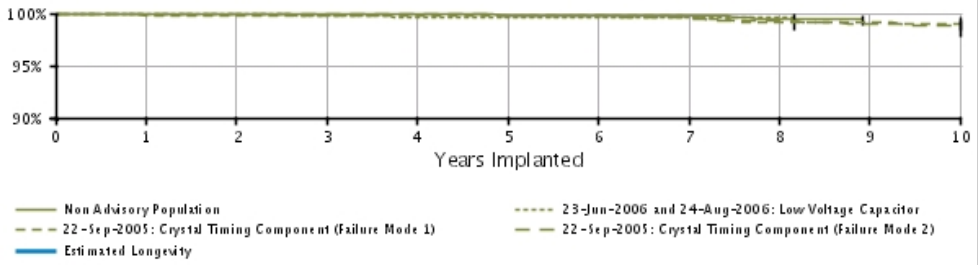
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 931
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:57
Without Compromised Therapy:51
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)	97.02 (-0.6/+0.5)	95.63 (-0.8/+0.7)	93.15 (-1.2/+1.1)	88.50 @ 107 mo. (-2.8/+2.3)	–
	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)	99.74 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.40 (-0.6/+0.3)	99.40 @ 107 mo. (-0.6/+0.3)	–
	Effective Sample Size	6258	5546	4914	4356	3797	3192	1799	672	202	–
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)	94.56 (-3.0/+2.0)	94.56 @ 98 mo. (-3.0/+2.0)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 @ 98 mo. (-1.2/+0.3)	–
	Effective Sample Size	693	607	529	452	394	338	294	251	204	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	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)	85.33 (-2.9/+2.5)	75.84 (-3.7/+3.4)

2000											
	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.19 (-1.0/+0.5)	99.19 (-1.0/+0.5)	98.94 (-1.2/+0.6)
	Effective Sample Size	1675	1453	1213	1063	923	785	662	554	451	320
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)	91.56 (-1.0/+0.9)	85.49 (-1.4/+1.3)	74.53 (-2.2/+2.1)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.47 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.97 (-0.5/+0.3)	98.88 (-0.5/+0.4)
	Effective Sample Size	6210	5482	4824	4230	3694	3188	2681	2269	1576	531

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

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

INSIGNIA Entra DR

Models 1294/1295

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

INSIGNIA Entra DR Models 1294/1295

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 67

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[21] Integrated circuit	-	1	
[25] Capacitor	-	1	
[61] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[34] Seal plug	3	-	
[35] Header	-	2	
Software	**-**	**-**	**0**
Other	**53**	**1**	**54**
Non-patterned	5	1	
[16] Longevity labeling	46	-	
[88] Battery status	2	-	
WW Confirmed Malfunctions	**56**	**11**	**67**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

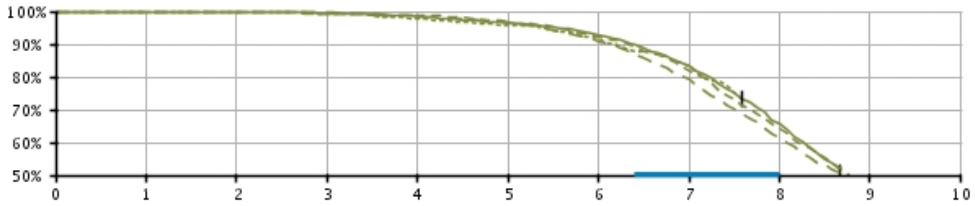
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

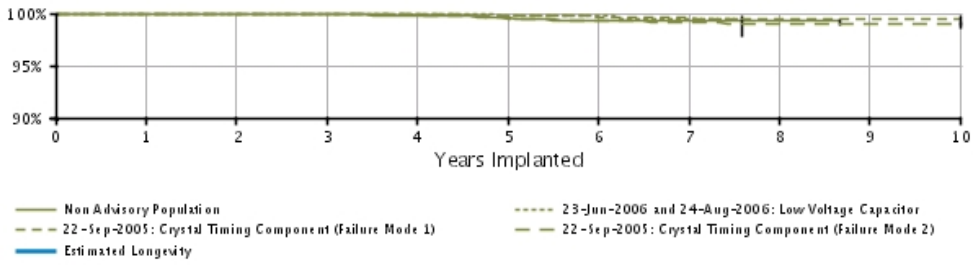
U.S. Registered Implants: 24,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 4,073
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)	96.58 (-0.5/+0.5)	92.98 (-0.8/+0.7)	83.15 (-1.4/+1.3)	65.60 (-2.3/+2.3)	51.58 @ 104 mo. (-3.3/+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)	99.30 (-0.3/+0.2)	99.23 (-0.4/+0.2)	99.23 @ 104 mo. (-0.4/+0.2)	–
	Effective Sample Size	7138	6280	5498	4782	4112	3420	1800	568	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)	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)	83.01 (-4.2/+3.5)	73.28 @ 91 mo. (-5.1/+4.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.75 (-1.5/+0.2)	99.75 (-1.5/+0.2)	99.43 (-1.7/+0.4)	99.43 @ 91 mo. (-1.7/+0.4)	–	–
	Effective Sample Size	763	657	563	476	402	329	253	205	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.03 (-1.5/+1.3)	81.79 (-2.2/+2.0)	64.06 (-2.9/+2.8)	45.84 (-3.2/+3.2)	32.02 (-3.1/+3.3)

3000											
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2736	2405	2071	1813	1515	1227	934	597	361	202
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)	61.29 (-1.5/+1.5)	45.12 (-1.6/+1.6)	35.82 (-1.8/+1.9)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.52 (-0.2/+0.1)	99.26 (-0.3/+0.2)	99.14 (-0.3/+0.2)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)
	Effective Sample Size	9584	8452	7365	6366	5505	4512	3340	2179	1130	406

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

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

INSIGNIA Entra DR (downsize)

Model 1296

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

INSIGNIA Entra DR (downsize) Model 1296

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 118

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	1	
[25] Capacitor	1	-	
[61] Integrated circuit	-	3	
Mechanical	**-**	**3**	**3**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
[17] Solder bond	-	1	
Software	**4**	**-**	**4**
[32] Memory error	1	-	
[67] Underestimation of battery status	1	-	
[68] Interrupted telemetry	2	-	
Other	**104**	**2**	**106**
Non-patterned	4	2	
[16] Longevity labeling	96	-	
[49] Battery depletion	1	-	
[88] Battery status	3	-	
WW Confirmed Malfunctions	**109**	**9**	**118**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

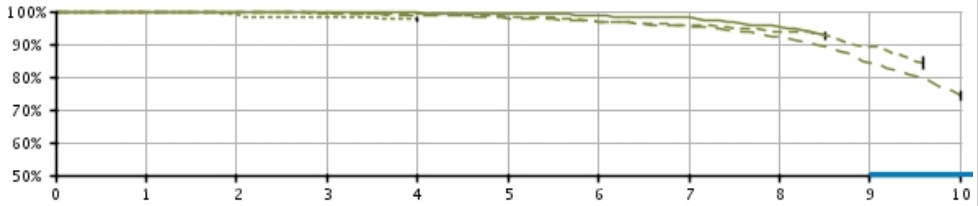
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

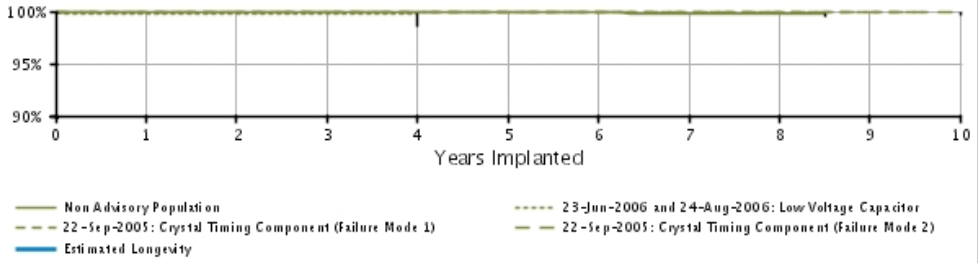
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 503
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)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.74 (-0.5/+0.4)	98.07 (-0.7/+0.5)	95.35 (-1.6/+1.2)	92.62 @ 102 mo. (-2.7/+2.0)	–
	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)	99.79 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.79 @ 102 mo. (-0.3/+0.1)	–
	Effective Sample Size	4710	3874	3254	2748	2329	1905	1047	375	219	–
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)	89.46 (-3.6/+2.8)	84.32 @ 115 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 @ 115 mo. (-0.0/+0.0)
	Effective Sample Size	1216	999	807	662	550	447	356	298	245	201
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)	84.15 (-2.0/+1.8)	74.43 (-2.9/+2.7)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	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	844	346

*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: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[25] Capacitor	2	2	
[61] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[29] Capacitor array	-	2	
[34] Seal plug	-	2	
[65] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**11**	**1**	**12**
Non-patterned	1	1	
[16] Longevity labeling	6	-	
[88] Battery status	4	-	
WW Confirmed Malfunctions	**15**	**11**	**26**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

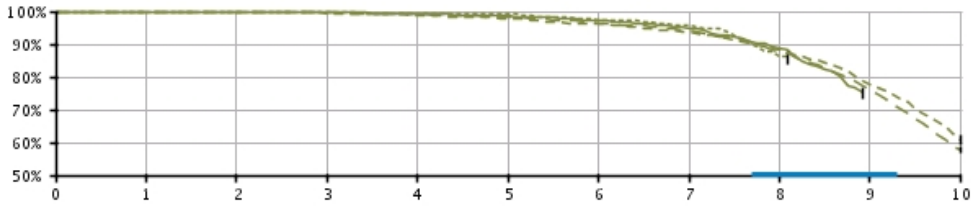
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

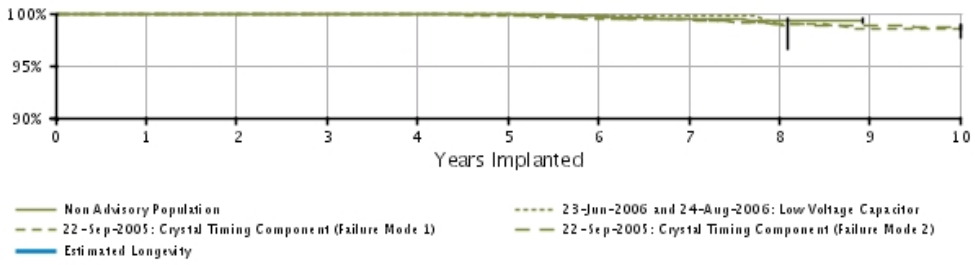
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 3,243
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 (-0.5/+0.5)	94.89 (-0.8/+0.7)	88.57 (-1.7/+1.5)	75.01 @ 107 mo. (-3.7/+3.4)	–
	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)	99.42 (-0.3/+0.2)	99.32 (-0.4/+0.3)	99.32 @ 107 mo. (-0.4/+0.3)	–
	Effective Sample Size	6560	5831	5161	4546	3995	3408	1855	703	213	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.19 (-1.3/+0.5)	99.19 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.64 (-2.7/+1.7)	86.01 (-4.5/+3.5)	86.01 @ 97 mo. (-4.5/+3.5)	–
	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)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.86 (-2.4/+0.8)	98.86 @ 97 mo. (-2.4/+0.8)	–
	Effective Sample Size	664	580	510	442	386	333	285	224	208	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.10 (-1.7/+1.5)	77.84 (-2.2/+2.1)	60.68 (-2.8/+2.7)

4000											
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.4/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3515	3073	2598	2281	1973	1705	1459	1211	931	600
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)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.78 (-0.8/+0.8)	76.16 (-1.2/+1.1)	57.78 (-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)	98.72 (-0.3/+0.3)
	Effective Sample Size	12752	11249	9910	8721	7617	6597	5631	4616	3214	1471

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

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

INSIGNIA Plus DR

Model 1297

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

INSIGNIA Plus DR Model 1297

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 139

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[8] Low-voltage capacitor (Advisory issued)	1	1	
[25] Capacitor	2	1	
[61] Integrated circuit	-	1	
Mechanical	**12**	**7**	**19**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[17] Solder bond	1	-	
[29] Capacitor array	1	-	
[34] Seal plug	5	-	
[35] Header	4	4	
Software	**7**	**-**	**7**
[67] Underestimation of battery status	4	-	
[68] Interrupted telemetry	2	-	
[69] Pacing rate limit	1	-	
Other	**105**	**2**	**107**
Non-patterned	5	2	
[16] Longevity labeling	85	-	
[49] Battery depletion	2	-	
[88] Battery status	13	-	
WW Confirmed Malfunctions	**127**	**12**	**139**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

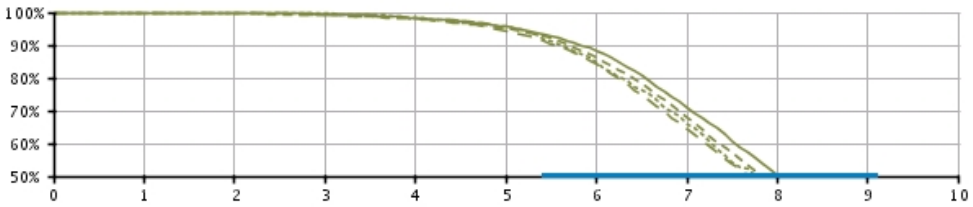
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

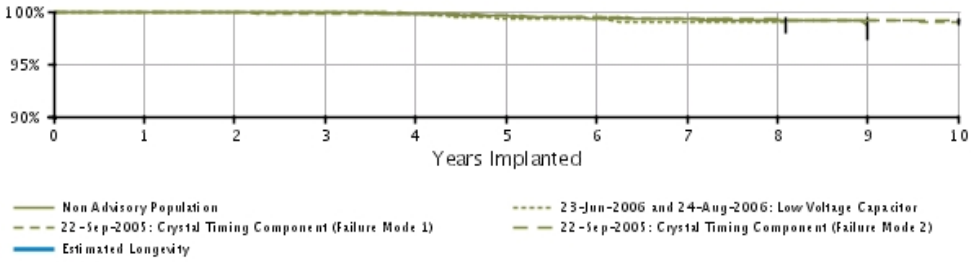
U.S. Registered Implants: 90,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 24,443
U.S. Unconfirmed Reports of Premature Battery Depletion : 113
U.S. Malfunctions:369

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)	95.61 (-0.4/+0.4)	88.27 (-0.6/+0.6)	70.97 (-1.0/+1.0)	50.07 (-1.5/+1.5)	29.03 (-2.2/+2.3)	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.35 (-0.2/+0.1)	99.25 (-0.2/+0.2)	99.17 (-0.2/+0.2)	98.70 (-1.4/+0.7)	–
	Effective Sample Size	16864	14980	13240	11653	10062	8075	3780	1106	209	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.86 (-0.4/+0.1)	99.77 (-0.5/+0.2)	98.12 (-1.0/+0.7)	95.80 (-1.5/+1.1)	84.87 (-2.6/+2.3)	65.93 (-3.5/+3.4)	45.70 (-3.8/+3.9)	43.98 @ 97 mo. (-3.8/+3.9)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.70 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)	98.91 @ 97 mo. (-1.0/+0.5)	–
	Effective Sample Size	1420	1250	1112	964	825	642	435	258	234	–
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)	47.03 (-1.3/+1.3)	31.96 (-1.3/+1.3)	22.17 (-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	12074	10375	9055	7730	6116	4098	2350	1308	742
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)	44.21 (-0.7/+0.7)	30.01 (-0.7/+0.7)	20.57 (-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	47026	41685	36743	32066	27289	21116	13692	7805	4057	1673

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

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

INSIGNIA Plus DR (downsize)

Model 1298

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

INSIGNIA Plus DR (downsize) Model 1298

Worldwide Distribution: 140,000
Worldwide Confirmed Malfunctions: 443

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**11**	**10**	**21**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[22] Capacitor	-	1	
[25] Capacitor	6	2	
[30] Integrated circuit	-	1	
[61] Integrated circuit	5	3	
Mechanical	**21**	**22**	**43**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
[17] Solder bond	1	-	
[29] Capacitor array	3	1	
[34] Seal plug	3	1	
[35] Header	5	-	
[65] Seal plug	1	-	
Software	**11**	**-**	**11**
[41] Memory error	1	-	
[66] Interrogation at EOL	2	-	
[67] Underestimation of battery status	6	-	
[68] Interrupted telemetry	1	-	
[69] Pacing rate limit	1	-	
Other	**357**	**11**	**368**
Non-patterned	27	9	
[16] Longevity labeling	309	-	
[33] Battery depletion	2	1	
[37] Magnet response	1	-	
[49] Battery depletion	11	1	
[88] Battery status	7	-	
WW Confirmed Malfunctions	**400**	**43**	**443**

More details about malfunctions

References cited in table above

INSIGNIA Plus SR

Model 1194

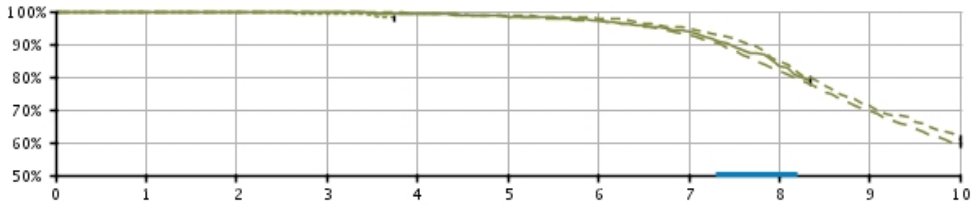
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

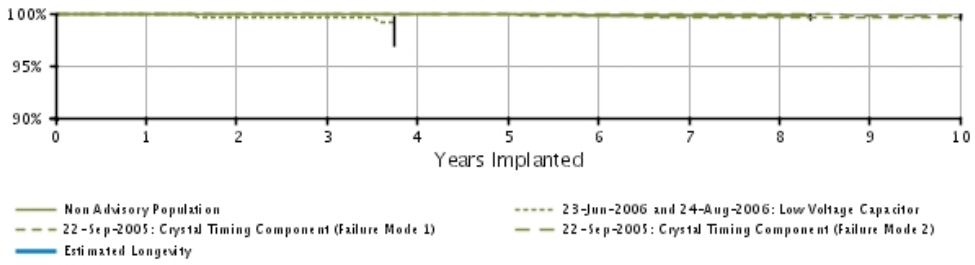
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2,673
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)	97.28 (-0.7/+0.6)	93.74 (-1.2/+1.0)	83.25 (-2.6/+2.3)	77.53 @ 102 mo. (-3.4/+3.1)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.85 (-0.3/+0.1)	99.73 (-0.3/+0.2)	99.73 (-0.3/+0.2)	99.73 @ 102 mo. (-0.3/+0.2)	–
	Effective Sample Size	4727	4035	3452	2890	2468	2066	1106	433	232	–
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/+0.6)	98.33 @ 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)	99.18 @ 45 mo. (-2.5/+0.6)	–	–	–	–	–	–
	Effective Sample Size	326	277	240	201	–	–	–	–	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	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)	84.90 (-2.2/+1.9)	71.07 (-2.8/+2.7)	60.89 (-3.2/+3.1)

4000											
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.92 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.76 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)
	Effective Sample Size	3454	2919	2422	2071	1744	1437	1173	878	620	453
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)	92.86 (-0.7/+0.6)	81.86 (-1.1/+1.0)	69.76 (-1.4/+1.3)	58.63 (-1.6/+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	10066	8522	7166	6027	4919	3656	2423	1321

*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	
[25] Capacitor	2	2	
[30] Integrated circuit	-	1	
[61] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[29] Capacitor array	1	-	
[34] Seal plug	-	1	
Software	**1**	**-**	**1**
[69] Pacing rate limit	1	-	
Other	**17**	**1**	**18**
Non-patterned	4	-	
[16] Longevity labeling	10	-	
[33] Battery depletion	-	1	
[49] Battery depletion	1	-	
[88] 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

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

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

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 73

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[25] Capacitor	-	1	
[61] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[34] Seal plug	1	-	
[35] Header	1	-	
Software	**-**	**-**	**0**
Other	**64**	**2**	**66**
Non-patterned	2	1	
[16] Longevity labeling	39	-	
[49] Battery depletion	-	1	
[88] Battery status	23	-	
WW Confirmed Malfunctions	**66**	**7**	**73**

More details about malfunctions

References cited in table above

DISCOVERY II DR

Models 1284/1286

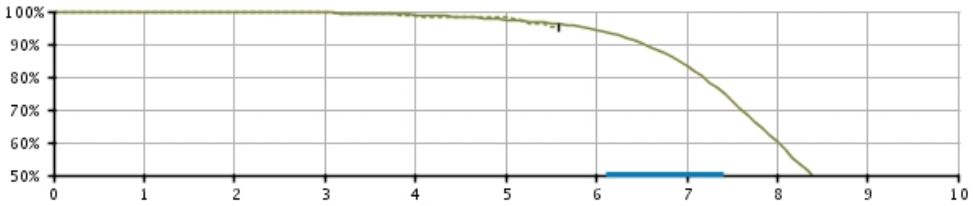
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

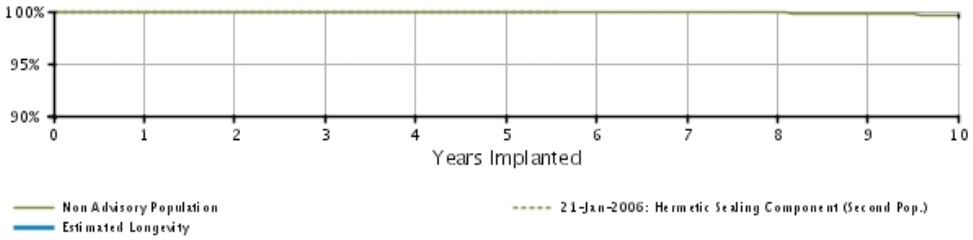
U.S. Registered Implants: 23,000
U.S. Approval Date: March 2000
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 5,847
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:21
Without Compromised Therapy:15
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: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.60 (-0.1/+0.1)	98.94 (-0.2/+0.2)	97.50 (-0.3/+0.3)	94.45 (-0.4/+0.4)	83.35 (-0.7/+0.7)	60.08 (-1.0/+1.0)	37.01 (-1.1/+1.1)	26.07 (-1.1/+1.1)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.70 (-0.2/+0.1)	99.63 (-0.3/+0.2)
	Effective Sample Size	19377	17254	15236	13364	11590	9849	7537	4469	2065	1034
21-Jan-06 Hermetic Sealing Component (Second Pop.)* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.72 (-1.7/+0.2)	98.77 (-2.0/+0.8)	98.04 (-2.4/+1.1)	95.44 @ 67 mo. (-3.4/+2.0)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 67 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	442	386	340	283	240	202	–	–	–	–
21-Jan-06 and 18-Jul-05 Hermetic Sealing Component (Original Pop.)*	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.

Data are representative of Boston Scientific DISCOVERY II and Intermedics INTELIS II device performance.

DISCOVERY II DR

Models 1284/1286

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

DISCOVERY II DR Models 1284/1286

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 32

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[61] Integrated circuit	-	1	
Mechanical	**7**	**4**	**11**
[13] Hermetic sealing component Original Population (Advisory issued)	5	2	
[27] Feedthrough wires	-	1	
[36] Telemetry or atrial noise	1	-	
[51] Internal device connection	1	-	
[52] Setscrew block	-	1	
Software	**3**	**1**	**4**
[38] Overestimation of battery status (Advisory issued)	-	1	
[41] Memory error	1	-	
[82] Battery status	2	-	
Other	**13**	**3**	**16**
Non-patterned	4	3	
[18] Longevity Remaining error	6	-	
[49] Battery depletion	3	-	
WW Confirmed Malfunctions	**23**	**9**	**32**

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. 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.

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. Improvement implemented.
2. **Unintended fuse activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning.
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. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
12. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
13. **Hermetic sealing component Original Population**— *July 18, 2005 and January 21, 2006 Voluntary Physician.* 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.
14. **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.
15. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.
16. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.

17. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
18. **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.
19. **Parameter errors**— During RF interrogation, parameter errors occur, requiring manual parameter correction. Corruption in telemetry logic. Improvement implemented.
20. **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.
21. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
22. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
23. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.
24. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
25. **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.
26. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.
27. **Feedthrough wires**— High impedance and/or loss of pacing therapy. Broken wire connecting header to internal circuitry. Improvement implemented.
28. **Battery depletion**— Premature battery depletion.
29. **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.
30. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
31. **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.
32. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
33. **Battery depletion**— Premature battery depletion and loss of capture.
34. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
35. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
36. **Telemetry or atrial noise**— Noise during telemetry and/or atrial sensing. Inappropriate contact between telemetry coil and device case. Improvement implemented.
37. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
38. **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.
39. **Battery depletion**— Premature battery depletion.
40. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
41. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
42. **Adhesive consistency**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Bubbles or voids in adhesive. Improvement implemented.
43. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.
44. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
45. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
46. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
47. **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.
48. **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.
49. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
50. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
51. **Internal device connection**— Intermittent or no telemetry. Telemetry coil connection. Improvement implemented.
52. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect

setscrew block. Improvement implemented.

53. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
54. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
55. **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.
56. **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.
57. **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.
58. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
59. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
60. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.
61. **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.
62. **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.
63. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
64. **Charge time limit**— Early appearance of elective replacement indicator (ERI). Incorrect extended charge time limit. Improvement implemented.
65. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
66. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
67. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
68. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
69. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
70. **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.
71. **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.
72. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.
73. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
74. **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.
75. **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.
76. **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.
77. **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.
78. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
79. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
80. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
81. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
82. **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.
83. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
84. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
85. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
86. **Bent flex circuit**— Charge time-out and/or EOL declaration, due to bent flex circuit. Improvement implemented.
87. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.

88. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
89. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
90. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
91. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
92. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
93. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
94. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
95. **Telemetry**— Inability to interrogate, premature battery depletion.
96. **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.
97. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement implemented.
98. **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.

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	13,000	0	0	0	1	0	0
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	14,000	2	0	0	0	0	0
ENERGEN CRT-D 4-Site N140/N142/P142	17,000	2	0	0	3	0	0
ENERGEN CRT-D N141/N143/P143	14,000	3	0	0	3	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	1	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	23	50	4	26	0	0
LIVIAN HE H227/H229/H247/H249	7,000	3	1	0	2	0	0
LIVIAN H220/H225/H240/H245	6,000	0	1	0	2	0	0

CRT-D/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
CONTAK RENEWAL 4 RF HE H239	1,000	14	0	0	0	0	0
CONTAK RENEWAL 4 RF H230/H235	8,000	45	2	0	1	0	0
CONTAK RENEWAL 4 HE H197/H199	7,000	7	7	0	0	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0
CONTAK RENEWAL 4 AVT HE M177/M179	1,000	0	2	0	1	0	0
CONTAK RENEWAL 4 AVT M170/M175	2,000	1	0	0	1	0	0
CONTAK RENEWAL 3 RF H210/H215	21,000	493	9	1	7	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INVIVE V172/V173/V182/V183/W172/W173	13,000	0	0	0	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA ICD VR 4-Site E160/F160	12,000	0	0	0	3	0	0
INCEPTA ICD DR 4-Site E162/F162	14,000	0	0	0	0	0	0
INCEPTA ICD VR E161/F161	6,000	0	0	0	1	0	0
INCEPTA ICD DR E163/F163	8,000	0	0	0	0	0	0
ENERGEN ICD VR 4-Site E140/F140	17,000	1	0	0	3	0	0
ENERGEN ICD DR 4-Site E142/F142	16,000	1	0	0	1	0	0
ENERGEN ICD VR E141/F141	9,000	2	0	0	1	0	0
ENERGEN ICD DR E143/F143	11,000	2	1	0	1	0	0
PUNCTUA ICD VR 4-Site E050/F050	3,000	0	0	0	0	0	0
PUNCTUA ICD DR 4-Site E052/F052	1,000	1	0	0	0	0	0
PUNCTUA ICD VR E051/F051	5,000	0	0	0	1	0	0
PUNCTUA ICD DR E053/F053	3,000	1	0	0	0	0	0
TELIGEN VR E102/E103/F102/F103	65,000	7	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	90,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO EL DR J064/K064/K067/K084	6,000	0	0	0	0	0	0
ADVANTIO SR J062/J065/K062/K065/K082	19,000	0	0	0	0	0	0
ADVANTIO DR J063/J066/K063/K066/K083	50,000	4	0	0	2	0	0
INGENIO EL DR J174/J177/K174/K177/K184	19,000	1	0	0	0	0	0
INGENIO SR J172/J175/K172/K175/K182	22,000	0	0	0	1	0	0
INGENIO DR J173/J176/K173/K176/K183	72,000	0	0	0	3	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	55,000	1	11	0	2	0	0
ALTRUA 50 SR S501	23,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	42,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	10,000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0
ALTRUA 50 SSI S508	6,000	0	0	0	1	0	0
ALTRUA 40 SR S401	9,000	0	2	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 40 DR (Downsize) S403	22,000	0	4	0	2	0	0
ALTRUA 40 DR S402	3,000	1	3	0	0	0	0
ALTRUA 40 DR EL S404	9,000	0	0	0	0	0	0
ALTRUA 20 SR S201/S204	24,000	0	2	0	0	0	0
ALTRUA 20 DR (Downsize) S203	16,000	0	1	0	0	0	0
ALTRUA 20 DR S202/S205	3,000	1	0	0	1	0	0
ALTRUA 20 DR EL S208	10,000	0	0	0	0	0	0
ALTRUA 20 DDD S207	1,000	0	0	0	0	0	0
ALTRUA 20 SSI S206	7,000	0	0	0	0	0	0
INSIGNIA Ultra SR 1190*	48,000	3	3	1	4	0	0
INSIGNIA Ultra DR (Downsize) 1290*	124,000	3	3	1	6	0	0
INSIGNIA Ultra DR 1291*	51,000	1	8	1	4	0	0
INSIGNIA Entra SR 1195/1198*	52,000	1	0	3	5	0	0
INSIGNIA Entra DR (Downsize) 1296*	47,000	1	7	6	3	0	0
INSIGNIA Entra DR 1294/1295*	36,000	0	6	3	9	0	0

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

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

U.S. Reason for Out of Service

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

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

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
INCEPTA CRT-D 4-Site N160/N162/P162	7000	2	1	0	2	68	436
INCEPTA CRT-D N161/N163/N164/N165/P163/P165	10000	3	1	0	2	105	755
ENERGEN CRT-D 4-Site N140/N142/P142	11000	1	1	2	2	118	800
ENERGEN CRT-D N141/N143/P143	11000	2	1	1	8	116	973
COGNIS N118/N119/N120/P106/P107/P108	75000	450	29	7	444	1454	22554
LIVIAN HE H227/H229/H247/H249	6000	903	4	1	4	174	2386
LIVIAN H220/H225/H240/H245	5000	669	0	3	8	118	1996
CONTAK RENEWAL 3 RF H210/H215	21000	7224	29	13	176	526	10913

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	6000	1	0	1	0	27	431
CONTAK RENEWAL TR H120/H125	19000	1598	14	132	43	248	8562

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	10	34	116

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	7000	3	0	3	2	50	322
INCEPTA ICD DR 4-Site E162/F162	8000	2	0	6	2	65	409
INCEPTA ICD VR E161/F161	3000	0	0	1	1	32	169
INCEPTA ICD DR E163/F163	5000	2	1	1	1	35	250
ENERGEN ICD VR 4-Site E140/F140	12000	8	0	5	2	102	587
ENERGEN ICD DR 4-Site E142/F142	12000	1	1	5	4	112	693
ENERGEN ICD VR E141/F141	6000	2	0	2	2	38	356
ENERGEN ICD DR E143/F143	8000	4	0	3	1	52	531

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	52	11	312	328	552	8745
TELIGEN DR E110/E111/F110/F111	66000	100	30	439	468	992	16070
CONFIENT DR E030/F030	7000	39	2	91	8	139	2422
VITALITY 2 EL VR T177	7000	844	9	147	1201	107	2467
VITALITY 2 EL DR T167	8000	1399	13	141	760	130	3045
VITALITY 2 VR T175	21000	4673	33	378	1239	295	8898
VITALITY 2 DR T165	31000	10426	78	526	1139	452	13039
VITALITY DR HE T180	13000	1897	13	229	411	301	6202
VITALITY DS DR T125	22000	7895	67	361	1182	304	10095
VITALITY DS VR T135	19000	5165	39	318	1553	252	8647
VITALITY EL T127	4000	851	9	60	617	69	1519

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	8000	2	0	7	3	32	665
ADVANTIO DR J063/J066/K063/K066/K083	36000	3	3	9	7	170	1577
INGENIO SR J172/J175/K172/K175/K182	8000	0	0	4	0	32	589
INGENIO DR J173/J176/K173/K176/K183	45000	7	1	8	5	171	1626

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	107	1	158	2	151	10303
ALTRUA 60 DR (Downsize) S603	90000	1111	25	338	19	518	20565
ALTRUA 60 DR S602	22000	139	2	121	3	167	5279
ALTRUA 60 DR EL S606	59000	83	6	179	6	356	9352
ALTRUA 40 SR S401	5000	14	0	14	2	21	1734
ALTRUA 40 DR (downsize) S403	14000	180	1	34	3	73	3443
ALTRUA 40 DR S402	2000	8	1	14	0	6	566
ALTRUA 40 DR EL S404	5000	8	0	20	0	39	1101
ALTRUA 20 SR S201/S204	4000	19	1	15	0	33	1826
ALTRUA 20 DR (downsize) S203	5000	46	2	18	0	35	1569
ALTRUA 20 DR S202/S205	2000	12	0	5	1	12	593
ALTRUA 20 DR EL S208	3000	6	0	12	1	7	775
INSIGNIA Ultra SR 1190 [4]	24000	1297	9	193	35	138	15065
INSIGNIA Ultra DR (Downsize) 1290 [4]	76000	13658	106	527	413	584	36222
INSIGNIA Ultra DR 1291 [4]	32000	1612	15	282	115	293	13460

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	503	10	81	9	72	9915
INSIGNIA Entra DR (Downsize) 1296 [4]	24000	4073	25	128	96	147	14705
INSIGNIA Entra DR 1294/1295 [4]	17000	931	10	115	57	177	9850
INSIGNIA Plus SR 1194 [4]	27000	2673	7	222	27	156	19899
INSIGNIA Plus DR (Downsize) 1298 [4]	90000	24443	113	529	372	693	50500
INSIGNIA Plus DR 1297 [4]	27000	3243	18	246	122	252	13931
DISCOVERY II DR 1284/1286 [4]	23000	5847	9	123	21	168	15014

[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

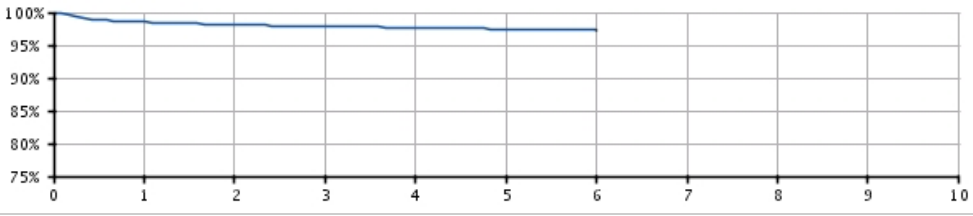
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 20,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 14,000

U.S. Chronic Lead Complications: 271
U.S. Malfunctions:87
Without Compromised Therapy:3
With Compromised Therapy:84

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	98.53 (-0.2/+0.2)	98.16 (-0.2/+0.2)	97.84 (-0.2/+0.2)	97.62 (-0.3/+0.3)	97.45 (-0.3/+0.3)	97.29 (-0.4/+0.4)	–	–	–	–
Effective Sample Size	14829	10890	7620	4464	2058	205	–	–	–	–

ACUITY Spiral

Models 4591/4592/4593

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

ACUITY Spiral Models 4591/4592/4593

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 97

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**3**	**4**
[28] Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**90**	**90**
[30] Unconfirmed Extrinsic	-	90	
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**2**	**-**	**2**
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**3**	**94**	**97**

More details about malfunctions

References cited in table above

ACUITY Spiral Longitude

Models 4591/4592/4593

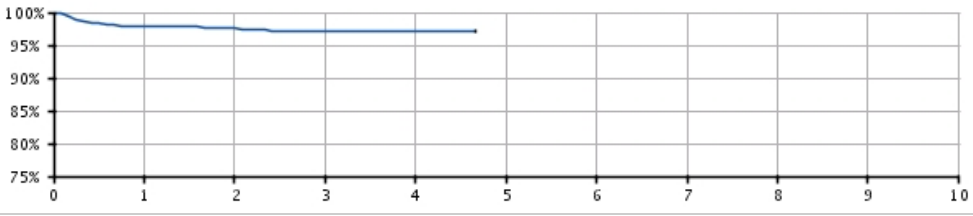
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1283
Leads Active: 981
Cumulative Followup Months : 45,954

Chronic Lead Complications: 20
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: 1283	98.00 (-1.0/+0.7)	97.53 (-1.1/+0.8)	97.08 (-1.3/+0.9)	97.08 (-1.3/+0.9)	97.08 @ 56 mo. (-1.3/+0.9)	–	–	–	–	–
Effective Sample Size	947	731	493	216	51	–	–	–	–	–

ACUITY Steerable

Models 4554/4555/4556

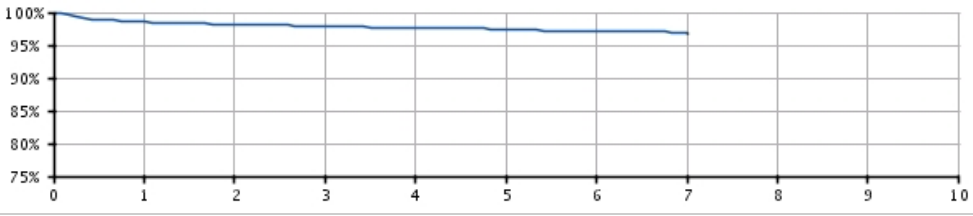
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 27,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 18,000

U.S. Chronic Lead Complications: 339
U.S. Malfunctions:185
Without Compromised Therapy:10
With Compromised Therapy:175

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 27000	98.53 (-0.2/+0.1)	98.16 (-0.2/+0.2)	97.88 (-0.2/+0.2)	97.66 (-0.2/+0.2)	97.33 (-0.3/+0.2)	97.03 (-0.3/+0.3)	96.87 (-0.5/+0.4)	–	–	–
Effective Sample Size	20687	16473	12680	9114	5798	2765	252	–	–	–

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 58,000
Worldwide Confirmed Malfunctions: 243

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**7**	**36**	**43**
[28] Non-patterned, Conductor	4	9	
[35] Extracardiac fracture	3	27	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**2**	**190**	**192**
[30] Unconfirmed Extrinsic	-	190	
[31] Inconclusive Extrinsic	2	-	
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**6**	**1**	**7**
[27] Non-patterned, Other	6	1	
WW Confirmed Malfunctions	**15**	**228**	**243**

More details about malfunctions

References cited in table above

EASYTRAK 3

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

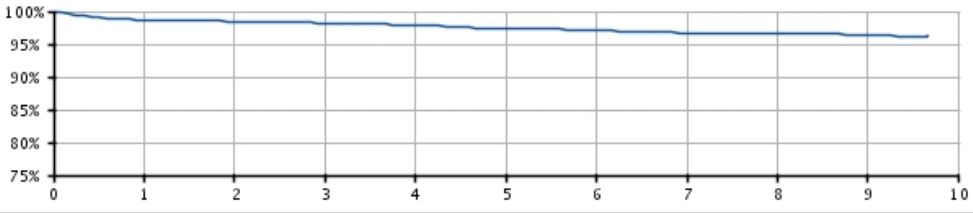
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 21,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 325
U.S. Malfunctions:105
Without Compromised Therapy:6
With Compromised Therapy:99

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 21000	98.68 (-0.2/+0.2)	98.49 (-0.2/+0.2)	98.25 (-0.2/+0.2)	97.89 (-0.2/+0.2)	97.45 (-0.3/+0.3)	97.12 (-0.3/+0.3)	96.70 (-0.4/+0.3)	96.62 (-0.4/+0.3)	96.36 (-0.5/+0.4)	96.20 @ 116 mo. (-0.6/+0.5)
Effective Sample Size	16493	13579	11164	9113	7194	5434	4006	2378	1012	229

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: 40,000
Worldwide Confirmed Malfunctions: 132

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**7**	**34**	**41**
[28] Non-patterned, Conductor	5	5	
[35] Extracardiac fracture	2	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**86**	**86**
[30] Unconfirmed Extrinsic	-	86	
Insulation	**3**	**1**	**4**
[29] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**11**	**121**	**132**

More details about malfunctions

References cited in table above

EASYTRAK 2

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

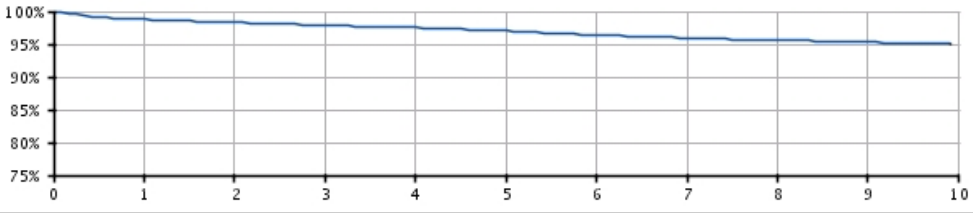
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 92,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 47,000

U.S. Chronic Lead Complications: 1,592
U.S. Malfunctions:639
Without Compromised Therapy:33
With Compromised Therapy:606

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 92000	98.77 (-0.1/+0.1)	98.30 (-0.1/+0.1)	97.88 (-0.1/+0.1)	97.52 (-0.1/+0.1)	97.01 (-0.1/+0.1)	96.41 (-0.2/+0.2)	95.92 (-0.2/+0.2)	95.60 (-0.2/+0.2)	95.33 (-0.3/+0.2)	95.08 @ 119 mo. (-0.4/+0.4)
Effective Sample Size	73356	60808	50006	39875	30644	22424	15665	9319	4292	206

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: 166,000
Worldwide Confirmed Malfunctions: 827

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**29**	**356**	**385**
[26] Conductor fracture	25	310	
[28] Non-patterned, Conductor	4	46	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**5**	**414**	**419**
[30] Unconfirmed Extrinsic	-	404	
[31] Inconclusive Extrinsic	5	10	
Insulation	**9**	**2**	**11**
[29] Non-patterned, Insulation	9	2	
Other	**7**	**5**	**12**
[27] Non-patterned, Other	7	5	
WW Confirmed Malfunctions	**50**	**777**	**827**

More details about malfunctions

References cited in table above

EASYTRAK

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

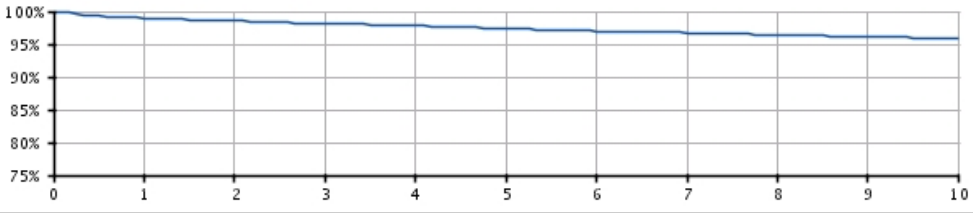
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 8,000

U.S. Chronic Lead Complications: 716
U.S. Malfunctions:187
Without Compromised Therapy:10
With Compromised Therapy:177

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)	96.10 (-0.3/+0.3)	95.92 (-0.3/+0.3)
Effective Sample Size	30542	26257	22527	19360	16533	14097	11776	9863	8276	6512

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: 204

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**12**	**12**
[28] Non-patterned, Conductor	-	12	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**178**	**178**
[30] Unconfirmed Extrinsic	-	177	
[31] Inconclusive Extrinsic	-	1	
Insulation	**3**	**3**	**6**
[29] Non-patterned, Insulation	3	3	
Other	**7**	**1**	**8**
[27] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**194**	**204**

More details about malfunctions

References cited in table above

RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

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

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: 6,000

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**1**	**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

Q-TRAK SQ Electrode

Model 3010

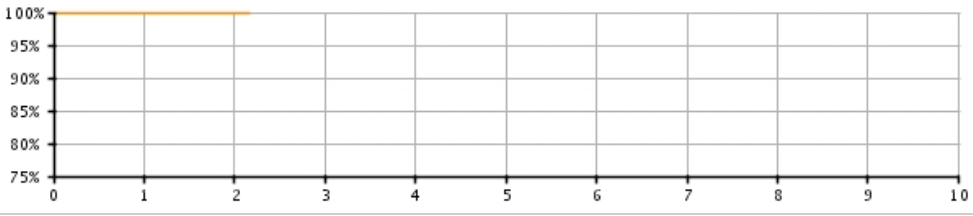
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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
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

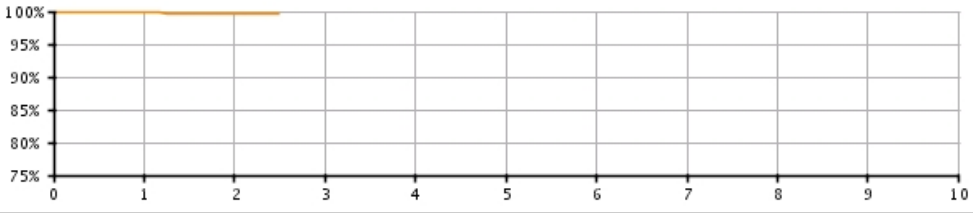
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 33,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 30,000

U.S. Chronic Lead Complications: 45
U.S. Malfunctions:22
Without Compromised Therapy:0
With Compromised Therapy:22

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	99.77 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.70 @ 30 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	18745	5188	207	–	–	–	–	–	–	–

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: 59,000

Worldwide Confirmed Malfunctions: 84

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[28] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**61**	**61**
[30] Unconfirmed Extrinsic	-	61	
Insulation	**7**	**10**	**17**
[29] Non-patterned, Insulation	7	10	
Other	**2**	**1**	**3**
[27] Non-patterned, Other	2	1	
WW Confirmed Malfunctions	**9**	**75**	**84**

More details about malfunctions

References cited in table above

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

Models 0295/0296

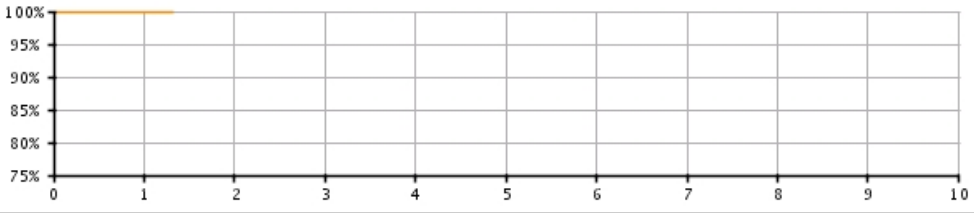
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 528
Leads Active: 501
Cumulative Followup Months : 3,750

Chronic Lead Complications: 1
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 528	100.00 (-0.0/+0.0)	100.00 @ 16 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	78	52	–	–	–	–	–	–	–	–

ENDOTAK RELIANCE G 4-Site
Dual Coil, Passive Fixation

Models 0285/0286

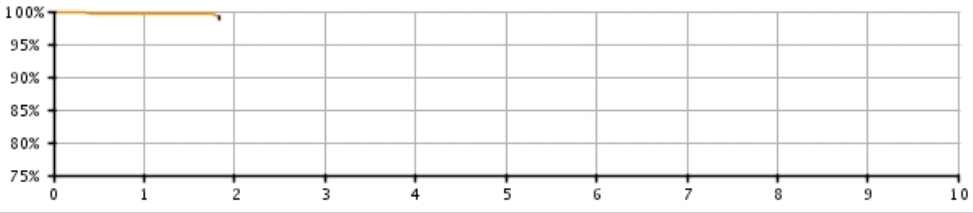
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 3
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	99.69 (-0.7/+0.2)	99.22 @ 22 mo. (-1.9/+0.6)	–	–	–	–	–	–	–	–
Effective Sample Size	565	212	–	–	–	–	–	–	–	–

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

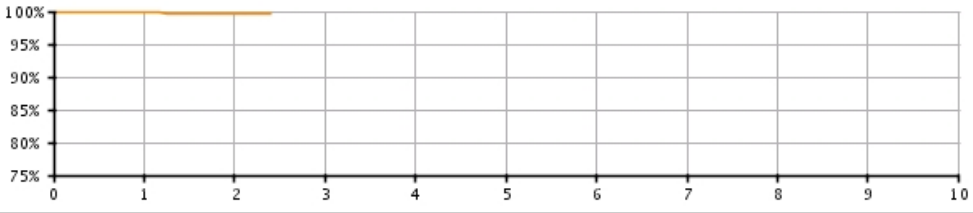
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 25,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 24,000

U.S. Chronic Lead Complications: 28
U.S. Malfunctions:19
Without Compromised Therapy:1
With Compromised Therapy:18

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	99.78 (-0.1/+0.1)	99.69 (-0.1/+0.1)	99.69 @ 29 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
Effective Sample Size	11072	2345	308	–	–	–	–	–	–	–

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: 48,000

Worldwide Confirmed Malfunctions: 41

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**1**	**1**
[28] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**32**	**32**
[30] Unconfirmed Extrinsic	-	32	
Insulation	**2**	**4**	**6**
[29] Non-patterned, Insulation	2	4	
Other	**-**	**2**	**2**
[27] Non-patterned, Other	-	2	
WW Confirmed Malfunctions	**2**	**39**	**41**

More details about malfunctions

References cited in table above

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

Models 0292/0293

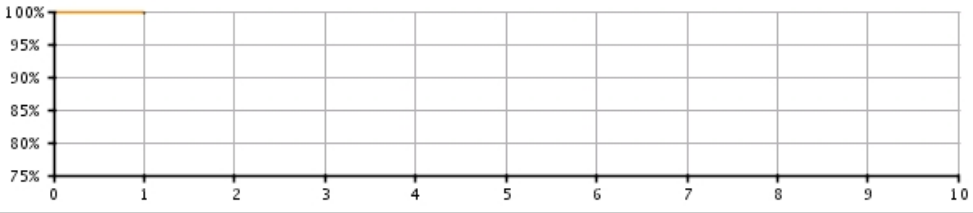
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 748
Leads Active: 709
Cumulative Followup Months : 4,304

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: 748	99.83 (-1.1/+0.2)	–	–	–	–	–	–	–	–	–
Effective Sample Size	53	–	–	–	–	–	–	–	–	–

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	1	1	2
[30] Unconfirmed Extrinsic	-	1	
[31] Inconclusive Extrinsic	1	-	
Insulation	-	-	0
Other	1	-	1
[27] Non-patterned, Other	1	-	
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

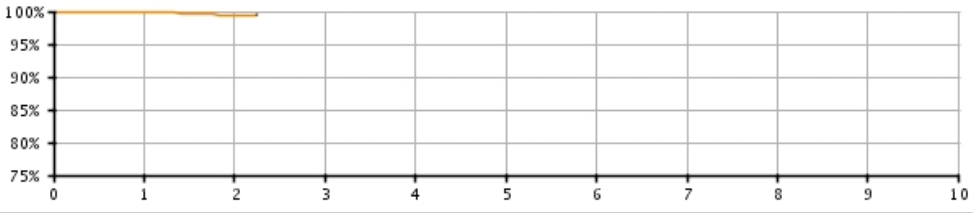
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 6
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 Registered Implants: 3000	99.77 (-0.3/+0.1)	99.46 (-0.6/+0.3)	99.46 @ 27 mo. (-0.6/+0.3)	–	–	–	–	–	–	–
Effective Sample Size	1820	504	245	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276

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

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

Worldwide Distribution: 4,000

Worldwide Confirmed Malfunctions: 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 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**
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

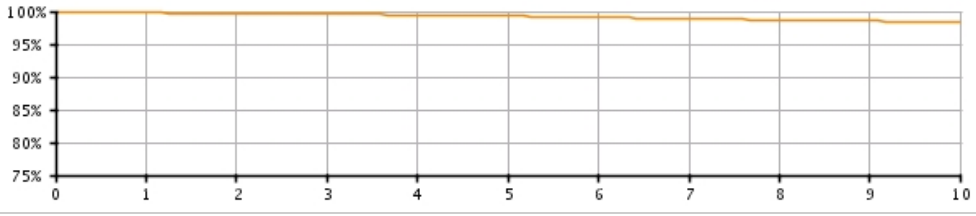
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 187,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 115,000

U.S. Chronic Lead Complications: 585
U.S. Malfunctions:616
Without Compromised Therapy:86
With Compromised Therapy:530

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)	99.30 (-0.0/+0.0)	99.09 (-0.1/+0.1)	98.90 (-0.1/+0.1)	98.69 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.33 (-0.2/+0.2)
Registered Implants: 186000										
Effective Sample Size	163480	143526	119164	93325	69963	48102	30809	18676	8979	1075

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: 252,000

Worldwide Confirmed Malfunctions: 891

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**83**	**85**
[25] Conductor fracture	-	54	
[28] Non-patterned, Conductor	2	29	
Crimp/Weld/Bond	**2**	**-**	**2**
[32] Non-patterned, Crimp, Weld, Bond	2	-	
Extrinsic	**11**	**582**	**593**
[30] Unconfirmed Extrinsic	-	580	
[31] Inconclusive Extrinsic	11	2	
Insulation	**113**	**63**	**176**
[29] Non-patterned, Insulation	113	63	
Other	**22**	**13**	**35**
[27] Non-patterned, Other	22	13	
WW Confirmed Malfunctions	**150**	**741**	**891**

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

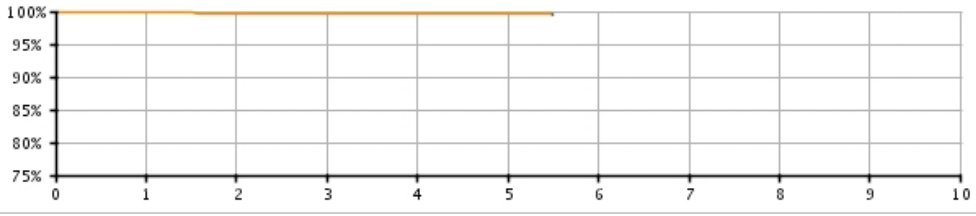
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 625
Leads Active: 470
Cumulative Followup Months : 26,907

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: 625	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 @ 66 mo. (-1.2/+0.3)	–	–	–	–
Effective Sample Size	541	461	363	206	57	50	–	–	–	–

ENDOTAK RELIANCE G
Dual Coil, Passive Fixation

Models 0174/0175/0176/0177

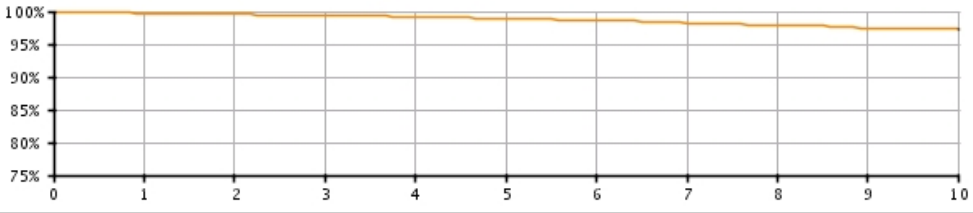
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 82
U.S. Malfunctions:56
Without Compromised Therapy:8
With Compromised Therapy:48

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.73 (-0.1/+0.1)	99.58 (-0.1/+0.1)	99.39 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.91 (-0.2/+0.2)	98.66 (-0.3/+0.2)	98.22 (-0.4/+0.3)	97.90 (-0.5/+0.4)	97.50 (-0.6/+0.5)	97.35 (-0.7/+0.6)
Registered Implants: 14000										
Effective Sample Size	11805	10222	8560	6845	5360	3961	2708	1778	962	216

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: 150

	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	**8**	**93**	**101**
[30] Unconfirmed Extrinsic	-	88	
[31] Inconclusive Extrinsic	8	5	
Insulation	**15**	**11**	**26**
[29] Non-patterned, Insulation	15	11	
Other	**6**	**-**	**6**
[27] Non-patterned, Other	6	-	
WW Confirmed Malfunctions	**29**	**121**	**150**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG
Single Coil, Active Fixation

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

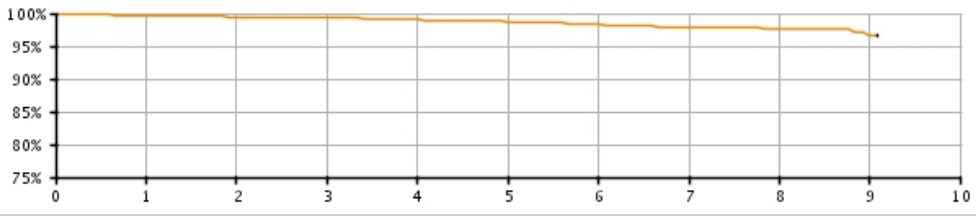
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 26,000
U.S. Approval Date: May 2004
U.S. Estimated Active Implants: 20,000

U.S. Chronic Lead Complications: 75
U.S. Malfunctions:123
Without Compromised Therapy:18
With Compromised Therapy:105

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 26000	99.68 (-0.1/+0.1)	99.47 (-0.1/+0.1)	99.33 (-0.1/+0.1)	99.04 (-0.2/+0.1)	98.74 (-0.2/+0.2)	98.29 (-0.4/+0.3)	97.96 (-0.5/+0.4)	97.70 (-0.6/+0.5)	96.75 (-1.5/+1.0)	96.75 @ 109 mo. (-1.5/+1.0)
Effective Sample Size	20890	16934	11733	7085	4308	2267	1058	580	241	223

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: 55,000
Worldwide Confirmed Malfunctions: 263

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**43**	**44**
[25] Conductor fracture	1	37	
[28] Non-patterned, Conductor	-	6	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**145**	**146**
[30] Unconfirmed Extrinsic	-	145	
[31] Inconclusive Extrinsic	1	-	
Insulation	**42**	**18**	**60**
[29] Non-patterned, Insulation	42	18	
Other	**7**	**6**	**13**
[27] Non-patterned, Other	7	6	
WW Confirmed Malfunctions	**51**	**212**	**263**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG
Single Coil, Passive Fixation

Models 0170/0171/0172/0173

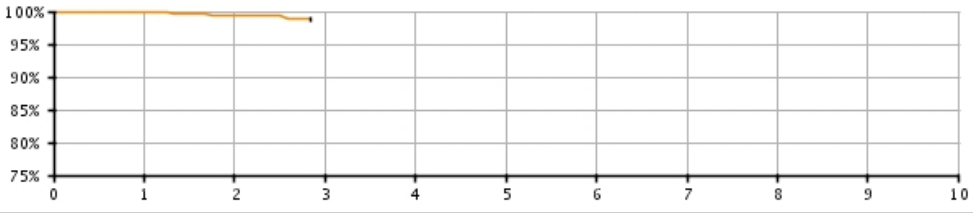
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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	99.86 (-0.8/+0.1)	99.37 (-1.4/+0.4)	98.95 @ 34 mo. (-1.9/+0.7)	–	–	–	–	–	–	–
Effective Sample Size	527	317	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

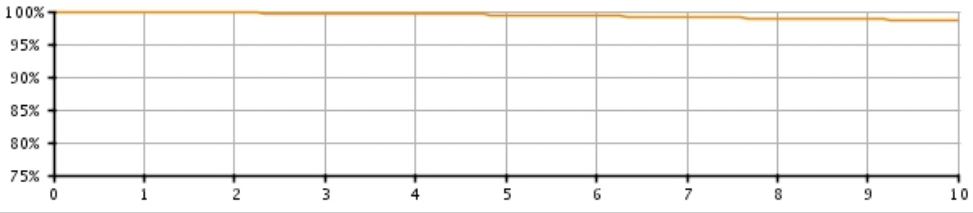
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 388
U.S. Malfunctions:252
Without Compromised Therapy:31
With Compromised Therapy:221

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)	98.96 (-0.1/+0.1)	98.80 (-0.1/+0.1)	98.66 (-0.1/+0.1)
Registered Implants: 97000										
Effective Sample Size	84852	75337	65780	56454	47784	39587	32420	26325	20450	13815

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: 284

	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**
[3] Seal rings	2	1	
[32] Non-patterned, Crimp, Weld, Bond	1	-	
Extrinsic	**1**	**198**	**199**
[30] Unconfirmed Extrinsic	-	197	
[31] Inconclusive Extrinsic	1	1	
Insulation	**30**	**21**	**51**
[29] Non-patterned, Insulation	30	21	
Other	**8**	**4**	**12**
[27] Non-patterned, Other	8	4	
WW Confirmed Malfunctions	**42**	**242**	**284**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149

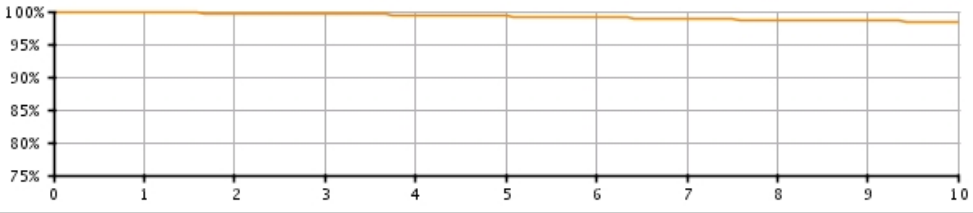
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 226
U.S. Malfunctions:94
Without Compromised Therapy:7
With Compromised Therapy:87

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)	98.65 (-0.2/+0.2)	98.54 (-0.2/+0.2)	98.38 (-0.2/+0.2)
Registered Implants: 33000										
Effective Sample Size	28516	25400	22542	19901	17465	15289	13254	11441	9718	8025

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: 198

	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**	**126**	**133**
[30] Unconfirmed Extrinsic	-	124	
[31] Inconclusive Extrinsic	7	2	
Insulation	**22**	**24**	**46**
[29] Non-patterned, Insulation	22	24	
Other	**2**	**4**	**6**
[4] Manufacturing material	-	1	
[27] Non-patterned, Other	2	3	
WW Confirmed Malfunctions	**31**	**167**	**198**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE S
Single Coil, Active Fixation

Models 0137/0138

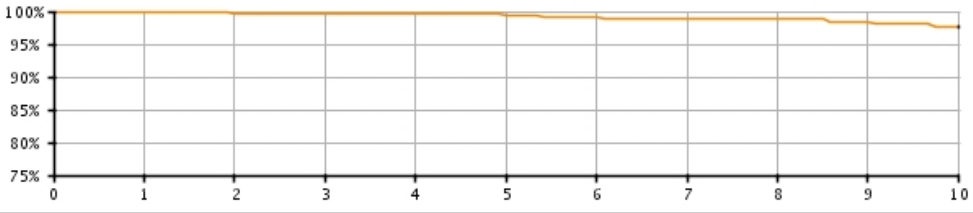
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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:9
Without Compromised Therapy:2
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.3/+0.1)	99.71 (-0.4/+0.2)	99.63 (-0.4/+0.2)	99.55 (-0.5/+0.2)	99.43 (-0.6/+0.3)	99.15 (-0.8/+0.4)	98.99 (-0.9/+0.5)	98.78 (-1.0/+0.6)	98.48 (-1.3/+0.7)	97.74 (-1.9/+1.0)
Registered Implants: 2000										
Effective Sample Size	2065	1690	1352	1060	824	626	477	379	301	217

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: 18

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[25] Conductor fracture	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**-**	**9**	**9**
[30] Unconfirmed Extrinsic	-	9	
Insulation	**5**	**1**	**6**
[29] Non-patterned, Insulation	5	1	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**6**	**12**	**18**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE S
Single Coil, Passive Fixation

Models 0127/0128

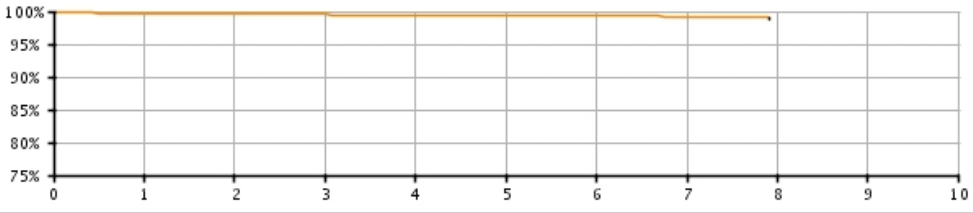
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 1,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 200

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

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-1.0/+0.2)	99.67 (-1.0/+0.2)	99.67 (-1.0/+0.2)	99.44 (-1.2/+0.4)	99.44 (-1.2/+0.4)	99.44 (-1.2/+0.4)	99.04 (-1.8/+0.6)	99.04 @ 95 mo. (-1.8/+0.6)	–	–
Registered Implants: 1000										
Effective Sample Size	563	488	430	372	328	277	236	202	–	–

ENDOTAK RELIANCE S
Single Coil, Passive Fixation

Models 0127/0128

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

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

Worldwide Distribution: 4,000

Worldwide Confirmed Malfunctions: 22

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[28] Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**1**	**12**	**13**
[30] Unconfirmed Extrinsic	-	12	
[31] Inconclusive Extrinsic	1	-	
Insulation	**3**	**3**	**6**
[29] Non-patterned, Insulation	3	3	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**5**	**17**	**22**

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: 8,000
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: 157,000
Worldwide Confirmed Malfunctions: 200

	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**	**103**	**104**
[30] Unconfirmed Extrinsic	-	103	
[31] Inconclusive Extrinsic	1	-	
Insulation	**45**	**6**	**51**
[2] Inner insulation abrasion	3	-	
[29] Non-patterned, Insulation	4	-	
[34] Insulation damage	38	6	
Other	**10**	**-**	**10**
[27] Non-patterned, Other	10	-	
WW Confirmed Malfunctions	**59**	**141**	**200**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

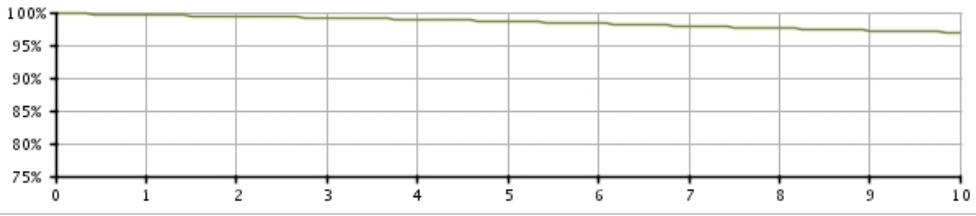
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 226,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 106,000

U.S. Chronic Lead Complications: 2,426
U.S. Malfunctions:807
Without Compromised Therapy:116
With Compromised Therapy:691

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 226000	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)	98.29 (-0.1/+0.1)	97.92 (-0.1/+0.1)	97.57 (-0.1/+0.1)	97.23 (-0.1/+0.1)	96.93 (-0.1/+0.1)
Effective Sample Size	189906	163986	140865	119322	99661	82304	66912	47749	32405	18392

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: 275,000
Worldwide Confirmed Malfunctions: 891

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**169**	**179**
[7] Lead conductor	4	79	
[28] Non-patterned, Conductor	1	7	
[33] Conductor damage	5	83	
Crimp/Weld/Bond	**-**	**-**	**0**
Extrinsic	**2**	**574**	**576**
[30] Unconfirmed Extrinsic	-	572	
[31] Inconclusive Extrinsic	2	2	
Insulation	**98**	**22**	**120**
[2] Inner insulation abrasion	19	4	
[29] Non-patterned, Insulation	8	-	
[34] Insulation damage	71	18	
Other	**14**	**2**	**16**
[27] Non-patterned, Other	14	2	
WW Confirmed Malfunctions	**124**	**767**	**891**

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

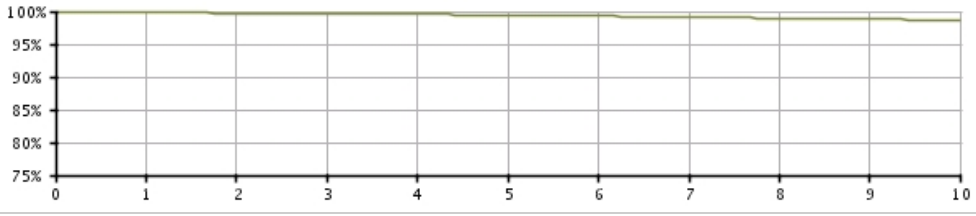
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 405,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 240,000

U.S. Chronic Lead Complications: 1,730
U.S. Malfunctions:435
Without Compromised Therapy:19
With Compromised Therapy:416

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 404000	99.82 (-0.0/+0.0)	99.73 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.44 (-0.0/+0.0)	99.28 (-0.0/+0.0)	99.11 (-0.0/+0.0)	98.97 (-0.1/+0.1)	98.81 (-0.1/+0.1)	98.67 (-0.1/+0.1)
Effective Sample Size	337158	280524	230857	186037	145902	111885	85027	61843	42823	26764

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: 605,000

Worldwide Confirmed Malfunctions: 487

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**7**	**111**	**118**
[7] Lead conductor	5	53	
[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	**-**	**343**	**343**
[30] Unconfirmed Extrinsic	-	337	
[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	**23**	**464**	**487**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude

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

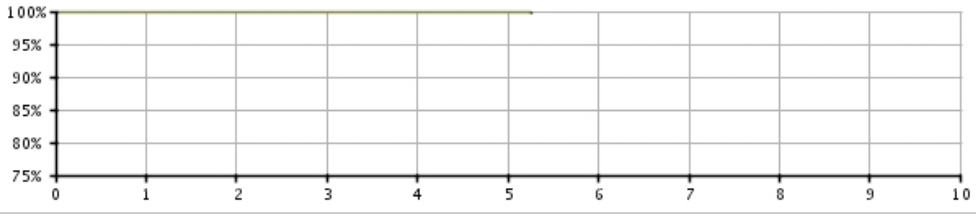
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 766
Leads Active: 640
Cumulative Followup Months : 19,928

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: 766	99.83 (-1.0/+0.2)	99.83 (-1.0/+0.2)	99.83 (-1.0/+0.2)	99.83 (-1.0/+0.2)	99.83 (-1.0/+0.2)	99.83 @ 63 mo. (-1.0/+0.2)	–	–	–	–
Effective Sample Size	396	324	236	142	51	50	–	–	–	–

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

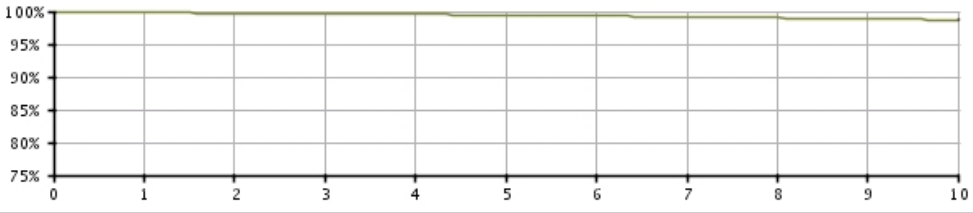
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 173,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 87,000

U.S. Chronic Lead Complications: 849
U.S. Malfunctions:114
Without Compromised Therapy:5
With Compromised Therapy:109

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)	99.15 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.83 (-0.1/+0.1)	98.73 (-0.1/+0.1)
Registered Implants: 173000										
Effective Sample Size	142618	119983	100130	82355	66434	52534	41178	31700	23604	16445

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: 466,000

Worldwide Confirmed Malfunctions: 152

	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**	**95**	**96**
[30] Unconfirmed Extrinsic	-	93	
[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**	**144**	**152**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

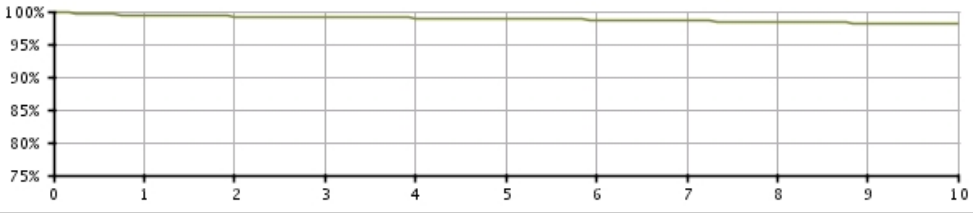
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 56,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 30,000

U.S. Chronic Lead Complications: 505
U.S. Malfunctions:89
Without Compromised Therapy:18
With Compromised Therapy:71

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.41 (-0.1/+0.1)	99.24 (-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)	98.38 (-0.2/+0.1)	98.15 (-0.2/+0.2)	98.07 (-0.2/+0.2)
Registered Implants: 56000										
Effective Sample Size	46224	38817	32365	26674	21469	16978	13230	10118	7520	5066

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: 256,000

Worldwide Confirmed Malfunctions: 148

	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	**-**	**99**	**99**
[30] Unconfirmed Extrinsic	-	98	
[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**	**114**	**148**

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

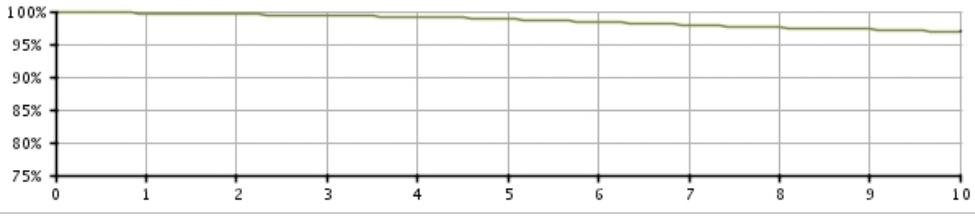
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 49,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 25,000

U.S. Chronic Lead Complications: 465
U.S. Malfunctions:174
Without Compromised Therapy:16
With Compromised Therapy:158

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 49000	99.73 (-0.1/+0.0)	99.56 (-0.1/+0.1)	99.38 (-0.1/+0.1)	99.16 (-0.1/+0.1)	98.83 (-0.1/+0.1)	98.39 (-0.2/+0.1)	97.94 (-0.2/+0.2)	97.51 (-0.2/+0.2)	97.29 (-0.2/+0.2)	96.98 (-0.3/+0.3)
Effective Sample Size	41541	35497	30106	25115	20661	16668	13399	10355	7597	5157

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: 131,000

Worldwide Confirmed Malfunctions: 222

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**3**	**120**	**123**
[7] Lead conductor	1	73	
[28] Non-patterned, Conductor	-	2	
[33] Conductor damage	2	45	
Crimp/Weld/Bond	**1**	**-**	**1**
[32] Non-patterned, Crimp, Weld, Bond	1	-	
Extrinsic	**-**	**72**	**72**
[30] Unconfirmed Extrinsic	-	70	
[31] Inconclusive Extrinsic	-	2	
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	**17**	**205**	**222**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

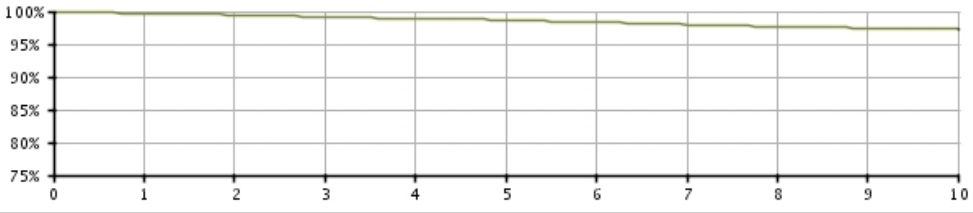
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 164
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	99.67 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.17 (-0.2/+0.2)	98.89 (-0.2/+0.2)	98.71 (-0.3/+0.2)	98.38 (-0.3/+0.3)	98.00 (-0.3/+0.3)	97.67 (-0.4/+0.3)	97.45 (-0.4/+0.4)	97.29 (-0.5/+0.4)
Registered Implants: 14000										
Effective Sample Size	11818	10251	8755	7390	6215	5147	4276	3519	2795	2054

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: 99,000

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. 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.

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

26. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
27. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.
28. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
29. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.
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	576	613	496	173	63	126	278	0	52
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	170000	0	249	152	138	20	15	130	125	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	399000	12	369	458	227	31	58	315	236	0	24
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	55000	0	71	246	92	5	9	48	28	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	76	15	33	9	2	12	15	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	48000	0	174	58	60	27	9	60	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	27000	1	12	222	14	1	1	4	9	0	75
ACUITY Spiral 4591/4592/4593	20000	0	7	142	14	0	1	0	4	0	104

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	1	23	186	28	0	1	5	5	0	76
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	92000	0	178	804	143	1	2	35	51	0	378
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	45	308	76	1	0	30	20	0	235

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	33000	0	3	26	3	4	4	1	0	3	1
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	25000	5	0	14	4	2	2	0	1	0	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	1	2	1	1	0	0	0	0	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	11	113	150	47	94	23	34	51	46	16
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	0	13	20	9	5	2	4	20	7	2
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	26000	3	13	19	7	16	0	4	9	4	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	24	90	17	31	56	19	5
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	3	47	27	20	31	3	18	63	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	1283	0	0	11	1	0	0	0	0	0	7
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	528	0	0	0	0	0	0	0	1	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	748	0	0	0	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	625	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	766	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	226000	226	189	1321	411	72	86	54	209	0	48
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	173000	14	13	420	162	6	25	22	36	0	19
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	405000	72	77	642	227	94	87	57	225	0	38
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	56000	1	18	428	88	7	27	17	18	0	8
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	33	15	1	3	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	49000	2	16	96	26	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	27000	1	2	310	44	25	2	7	133	0	228
ACUITY Spiral 4591/4592/4593	20000	5	4	187	61	8	2	10	38	0	216

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	21000	4	2	261	38	10	2	7	45	0	177
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	92000	13	7	883	122	46	9	25	194	0	680
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	33000	27	22	98	59	38	7	5	50	11	4
ENDOTAK RELIANCE G 4-Site Dual Coil, Passive Fixation 0285/0286	1000	2	0	3	1	2	0	0	12	1	0
ENDOTAK RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	21000	22	33	66	27	35	10	2	46	47	11
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276	3000	3	2	4	2	3	1	0	8	0	1
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	187000	117	125	479	124	249	34	45	254	190	60
ENDOTAK RELIANCE G Dual Coil, Passive Fixation 0174/0175/0176/0177	14000	4	2	46	28	15	3	0	103	15	1
ENDOTAK RELIANCE SG Single Coil, Active Fixation 0160/0161/0162/0180/0181/0182	26000	27	15	70	26	29	12	3	48	110	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	62	163	44	116	20	24	102	43	18
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149	33000	27	22	98	59	38	7	5	50	11	4

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	2	0	35	3	0	1	5	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	1283	0	0	10	12	1	0	0	3	0	43
RELIANCE G 4-Site Dual Coil, Active Fixation 0295/0296	528	0	1	8	0	0	0	1	2	0	0
RELIANCE SG 4-Site Single Coil, Active Fixation 0292/0293	748	4	1	6	1	4	1	0	0	0	2
ENDOTAK RELIANCE G Dual Coil, Active Fixation 0164/0165/0167/0184/0185/0186/0187	625	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	766	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	58,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	37,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	40,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	166,000	0	5	0	7	1	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	4	0	0	3

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
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	6,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G 4-Site Dual Coil Active Fixation 0295/0296	59,000	0	0	0	44	0	1	0
ENDOTAK RELIANCE G 4-Site Dual Coil Passive Fixation 0285/0286	6,000	0	0	0	4	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	48,000	0	0	0	8	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	4,000	0	0	0	6	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE G Dual Coil Active Fixation 0164/0165/0166/0167/0184/0185/0186/0187	252,000	0	0	29	353	0	3	14
ENDOTAK RELIANCE G Dual Coil Passive Fixation 0174/0175/0176/0177	39,000	0	0	3	56	0	2	0
ENDOTAK RELIANCE SG Single Coil Active Fixation 0160/0161/0162/0180/0181/0182	55,000	0	0	7	57	0	1	3
ENDOTAK RELIANCE SG Single Coil Passive Fixation 0170/0171/0172/0173	3,000	0	0	0	2	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 4515/4517/4518/4520/4542/4543/4544	113,000	0	0	17	129	0	0	0
ENDOTAK RELIANCE Dual Coil Passive Fixation 4510/4511/4512/4513/4535/4536/4537/4538	67,000	0	1	1	29	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	8,000	9	0	0	12	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	157,000	1	0	9	106	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	275,000	1	0	55	576	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	466,000	1	0	3	6	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	605,000	2	0	7	53	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	256,000	2	0	7	53	1	44	2
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	99,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	99,000	0	0	2	1	1	1	0

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

Product Advisories

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

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

PRODUCT	ORIGINAL COMMUNICATION **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 **15-Jul-14**
	No devices in the advisory population remain available for implant. *Confirmed Malfunctions (worldwide)* 789 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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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-three (83) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.6% at 60 months.

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

CURRENT RECOMMENDATION **15-Jul-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 **15-Jul-14** *Confirmed Malfunctions (worldwide)* **April 2007 Population** 2,565 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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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.](http://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..*	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.
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.*	CURRENT STATUS **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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 **15-Jul-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.](http://www.bostonscientific.com)

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

CURRENT RECOMMENDATION **15-Jul-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.

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