Boston Scientific
Advancing science for life™

2016

Rhythm Management Product Performance Report

Q3 Edition

CRM Quality Pledge

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

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q3 2016 report includes data through July12, 2016.

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

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

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

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

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

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Statistical Methodology

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

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

Boston Scientific estimates survival probability in compliance with the 2014 revision of international standard ISO 5841-2: 2014 (E). Survival probability is calculated at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in the report section entitled U.S. Reason for Out of Service.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Survival Probability — Complications and Malfunctions (Leads)
The 2014 version of ISO 5841-2: 2014(E) outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology for survival probability to all lead families being implanted as of May 2009 and forward. Worldwide malfunctions are not included for older lead families.

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads removed from service with reported complications 30 days or more post-implant, whether returned or not. See the Chronic Lead Complications Table in this report for the observations which are included.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Malfunction Details: Overview

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

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

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

Each pattern description includes:

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

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

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

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

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

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

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

Lead Confirmed Malfunctions
Lead confirmed malfunctions represent leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Boston Scientific Product Performance Report is in compliance with the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. This version categorizes leads with reported complications which are taken out of service and returned, but for which no malfunction can be confirmed, as Chronic Lead Complications. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

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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

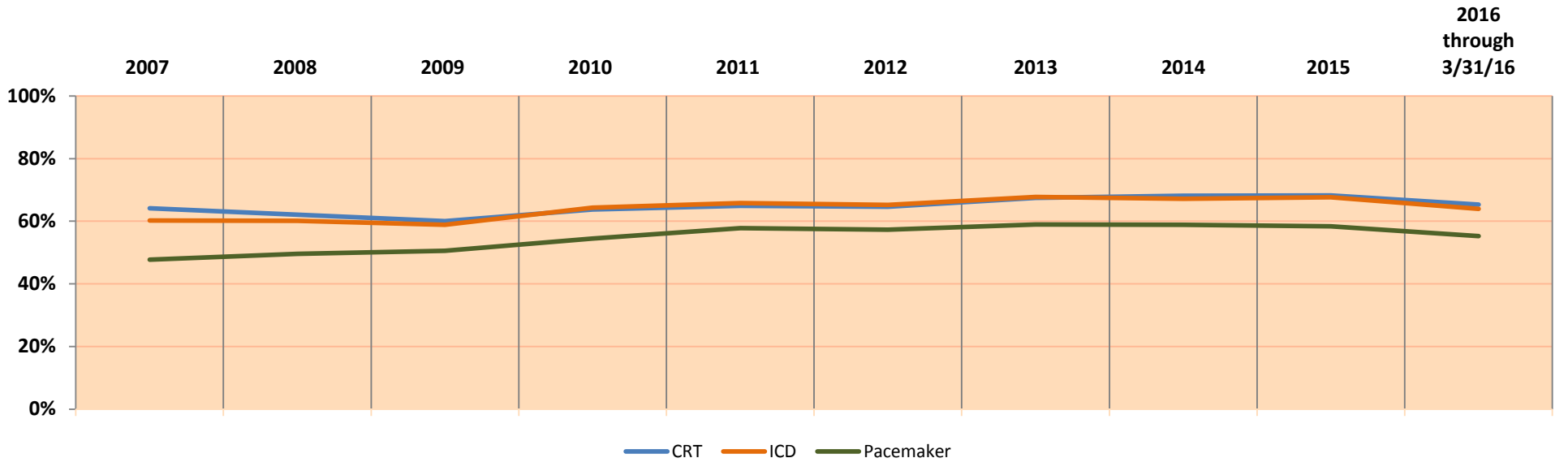
The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department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



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

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

AUTOGEN CRT-D

Models G160/G161/G164/G166/G168/
G172/G173/G175/G177/G179

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

AUTOGEN CRT-D
Models G160/G161/G164/G166/G168/ G172/G173/G175/G177/G179

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 5

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

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN CRT-D

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

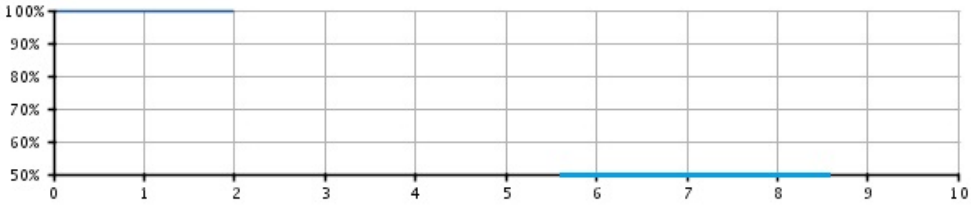
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

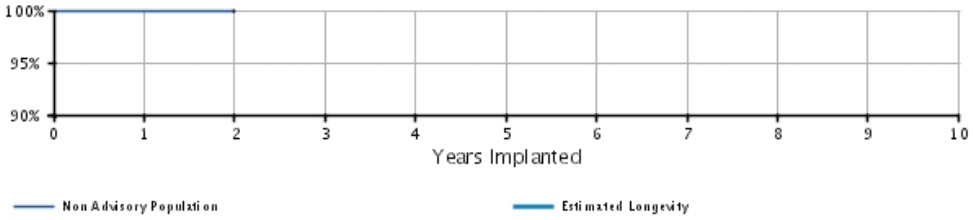
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:6
Without Compromised Therapy:6
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.88 (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.91 (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	7461	337	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN CRT-D

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

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

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

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 11

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**1**	**6**
[80] High voltage circuit component	3	-	
[81] Integrated circuit	2	-	
[82] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**2**	**1**	**3**
[69] Memory errors	2	1	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**9**	**2**	**11**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA CRT-D

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

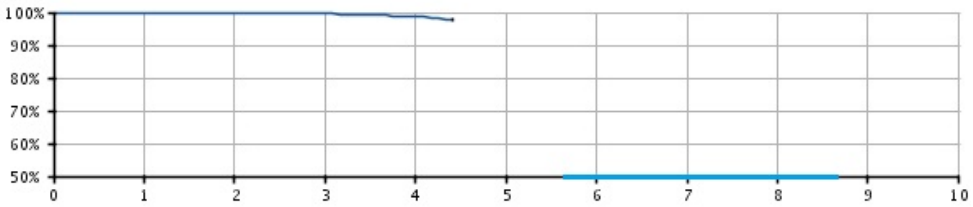
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

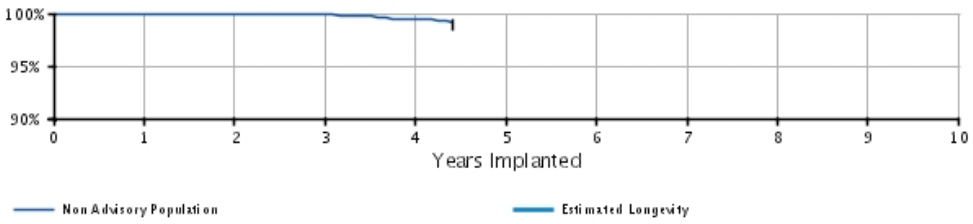
U.S. Registered Implants: 52,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 43,000

U.S. Normal Battery Depletions: 97
U.S. Unconfirmed Reports of Premature Battery Depletion : 23
U.S. Malfunctions:78
Without Compromised Therapy:67
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: 52000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.66 (-0.1/+0.1)	98.73 (-0.2/+0.2)	97.74 @ 53 mo. (-0.8/+0.6)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.41 (-0.2/+0.1)	99.09 @ 53 mo. (-0.7/+0.4)	–	–	–	–	–
	Effective Sample Size	44663	32271	16526	3896	391	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA CRT-D

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

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

INCEPTA/ENERGEN/PUNCTUA CRT-D
Models N050/N051/N052/N053/N140/ N141/N142/N143/N160/N161/ N162/N163/N164/N165/P052/ P053/P142/P143/P162/P163/ P165

Worldwide Distribution: 81,000
Worldwide Confirmed Malfunctions: 108

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**80**	**8**	**88**
[60] Safety Core-electrocautery	5	1	
[61] High-voltage capacitor	-	2	
[65] Low-voltage capacitors	1	-	
[68] Integrated circuit	1	5	
[71] Battery	1	-	
[72] Low-voltage capacitor	72	-	
Mechanical	**-**	**6**	**6**
[54] Transformer	-	6	
Software	**6**	**-**	**6**
[69] Memory errors	6	-	
Other	**7**	**1**	**8**
Non-patterned	7	1	
WW Confirmed Malfunctions	**93**	**15**	**108**

More details about malfunctions

References cited in table above

COGNIS

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

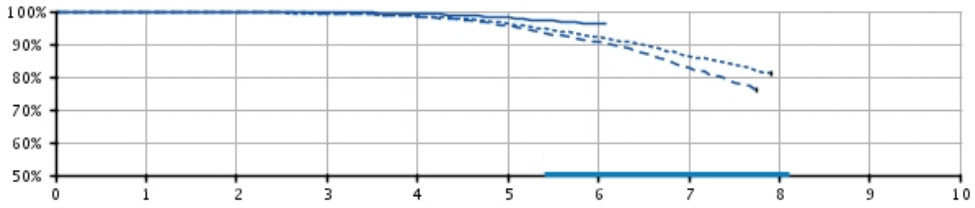
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

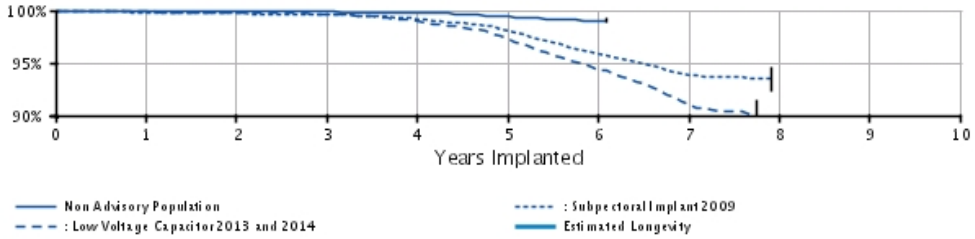
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 40,000

U.S. Normal Battery Depletions: 1,731
U.S. Unconfirmed Reports of Premature Battery Depletion : 99
U.S. Malfunctions:1300
Without Compromised Therapy:1142
With Compromised Therapy:158

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.02 (-0.2/+0.2)	96.28 (-0.5/+0.4)	96.28 @ 73 mo. (-0.5/+0.4)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.40 (-0.1/+0.1)	99.02 (-0.2/+0.2)	99.02 @ 73 mo. (-0.2/+0.2)	–	–	–
	Effective Sample Size	31515	28124	24991	21782	12304	1161	597	–	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.1)	96.37 (-0.3/+0.3)	92.10 (-0.3/+0.2)	86.48 (-0.3/+0.2)	81.18 @ 95 mo. (-1.6/+1.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.0/+0.1)	99.70 (-0.0/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.11 (-0.1/+0.1)	95.84 (-0.2/+0.3)	93.87 (-0.3/+0.3)	93.57 @ 95 mo. (-1.3/+1.0)	–	–
	Effective Sample Size	27497	24370	21674	19184	16723	14197	6834	221	–	–
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.40 (-0.1/+0.2)	95.55 (-0.1/+0.2)	90.55 (-0.3/+0.2)	82.66 (-0.3/+0.3)	75.99 @ 93 mo. (-1.3/+1.3)	–	–

26,000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.37 (-0.2/+0.1)	90.98 (-0.8/+0.7)	90.08 @ 93 mo. (-1.2/+1.4)	–	–
	Effective Sample Size	22617	20029	17835	15757	13658	10825	2642	229	–	–

*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: 1692

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1387**	**121**	**1508**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1110	63	
[60] Safety Core-electrocautery	47	20	
[61] High-voltage capacitor	1	4	
[65] Low-voltage capacitors	7	-	
[68] Integrated circuit	7	20	
[70] High voltage circuit	-	1	
[71] Battery	39	4	
[72] Low-voltage capacitor	176	9	
Mechanical	**39**	**90**	**129**
[4] Subpectoral implant 2009 (Advisory issued)	16	47	
[83] Header	6	17	
[54] Transformer	-	9	
[58] Difficulty securing lead	9	9	
[63] Header contacts	8	8	
Software	**14**	**-**	**14**
[64] Safety Core-programming	1	-	
[66] Alert messages not displayed post-EOL	2	-	
[69] Memory errors	11	-	
Other	**32**	**9**	**41**
Non-patterned	32	9	
WW Confirmed Malfunctions	**1472**	**220**	**1692**

More details about malfunctions

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

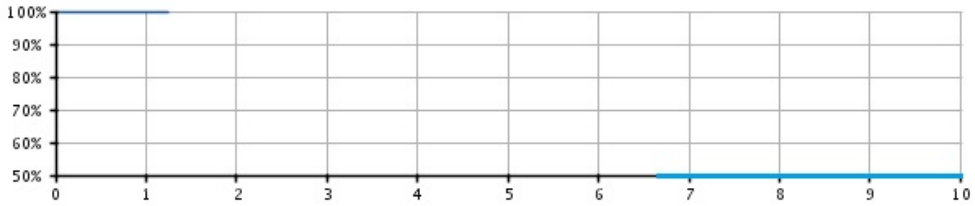
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

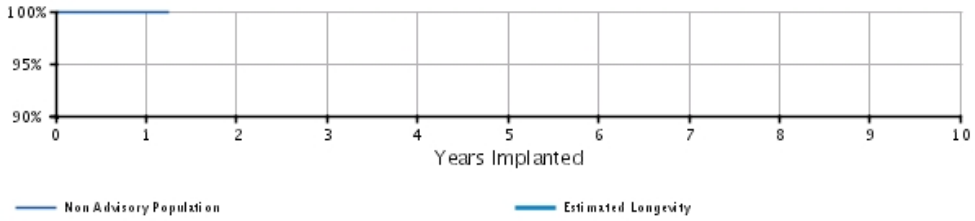
U.S. Registered Implants: 5,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 5,000

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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	794	224	–	–	–	–	–	–	–	–

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

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

VISIONIST/VALITUDE Models U125/U128/U225/U226/U228

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

INTUA

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

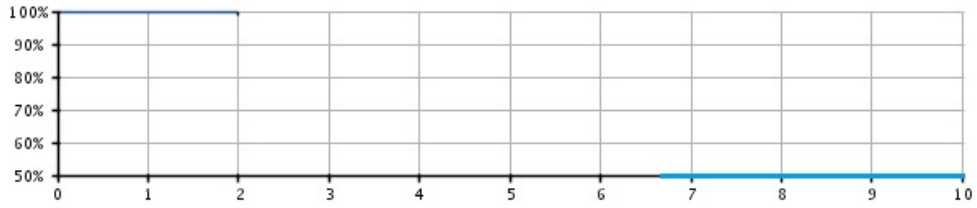
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

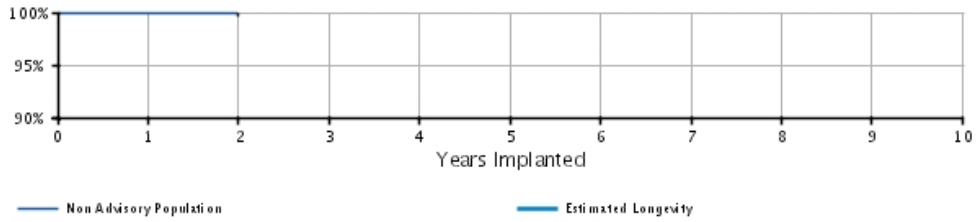
U.S. Registered Implants: 2,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 3
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)	99.86 (-0.3/+0.1)	99.52 (-1.5/+0.4)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1584	221	–	–	–	–	–	–	–	–

INTUA

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

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

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

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

INVIVE

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

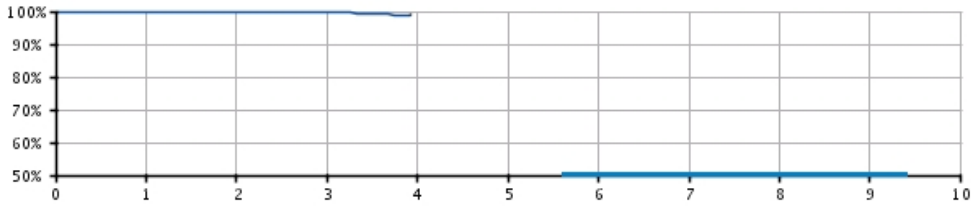
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

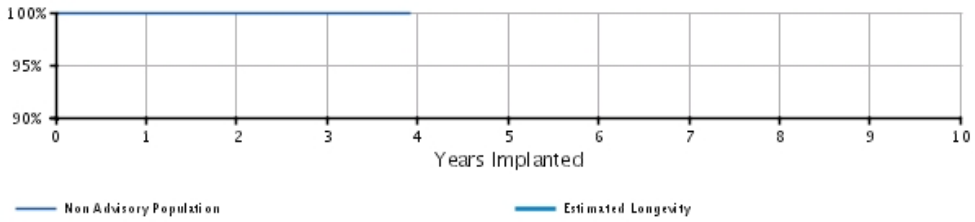
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 20
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)	99.97 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.54 (-0.3/+0.2)	98.98 @ 47 mo. (-0.9/+0.5)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 47 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	6372	4629	1940	234	–	–	–	–	–	–

INVIVE

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

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

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

Worldwide Distribution: 17,000
Worldwide Confirmed Malfunctions: 3

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

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

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

CONTAK RENEWAL TR 2 Models H140/H145

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 31

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[20] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[26] Seal plug	1	-	
[36] Setscrew block	2	-	
[49] Seal plug	1	-	
Software	**14**	**-**	**14**
[30] Memory error	1	-	
[40] Stored EGMs	13	-	
Other	**11**	**1**	**12**
Non-patterned	10	1	
[47] Alert messages	1	-	
WW Confirmed Malfunctions	**30**	**1**	**31**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

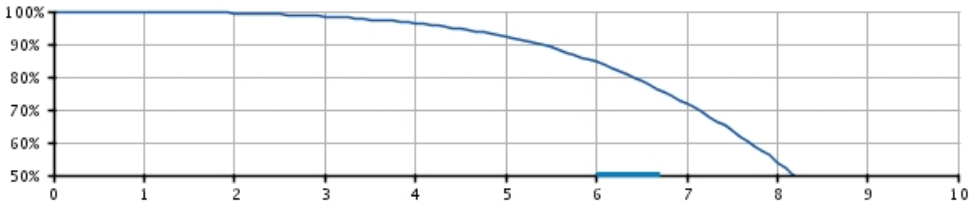
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

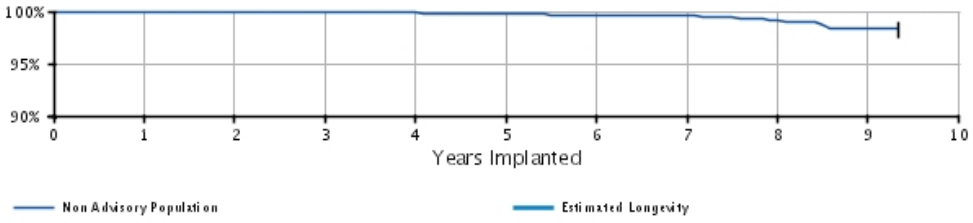
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 2,529
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:50
Without Compromised Therapy:48
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)	99.90 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.34 (-0.4/+0.3)	92.34 (-0.5/+0.5)	84.52 (-0.8/+0.8)	71.82 (-1.3/+1.2)	53.79 (-1.8/+1.8)	35.26 (-2.3/+2.3)	29.94 @ 112 mo. (-2.4/+2.5)
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.66 (-0.1/+0.1)	99.54 (-0.2/+0.1)	99.20 (-0.4/+0.3)	98.43 (-1.0/+0.6)	98.43 @ 112 mo. (-1.0/+0.6)
	Effective Sample Size	15580	13582	11845	10070	7270	4345	2313	996	317	202
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

*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: 50

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[8] Low-voltage capacitor (Advisory issued)	1	-	
[20] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[26] Seal plug	5	-	
Software	**28**	**-**	**28**
[40] Stored EGMs	28	-	
Other	**14**	**1**	**15**
Non-patterned	8	1	
[47] Alert messages	5	-	
[62] Magnet rate	1	-	
WW Confirmed Malfunctions	**48**	**2**	**50**

More details about malfunctions

References cited in table above

EMBLEM S-ICD

Models A209/A219

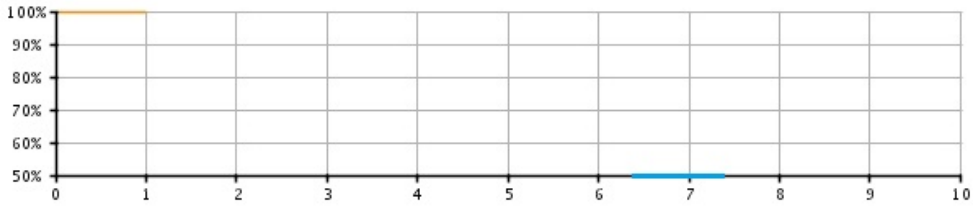
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

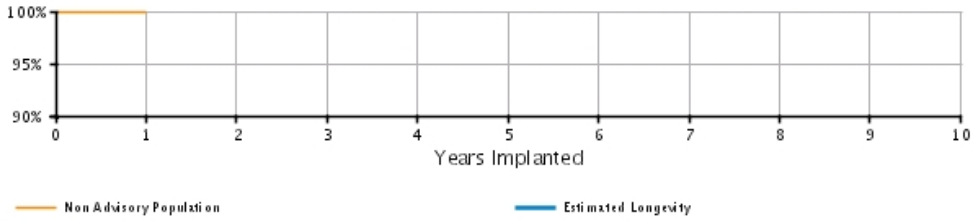
U.S. Registered Implants: 6,000
U.S. Approval Date: March 2015
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions: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: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	375	–	–	–	–	–	–	–	–	–

EMBLEM S-ICD

Models A209/A219

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

EMBLEM S-ICD Models A209/A219

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	4	4
Non-patterned	-	1	
[74] Telemetry	-	3	
WW Confirmed Malfunctions	0	4	4

More details about malfunctions

References cited in table above

AUTOGEN ICD EL DR

Models D162/D163/D176/D177

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

AUTOGEN ICD EL DR
Models D162/D163/D176/D177

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[81] 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

AUTOGEN ICD EL VR

Models D160/D161/D174/D175

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

AUTOGEN ICD EL VR
Models D160/D161/D174/D175

Worldwide Distribution: 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

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

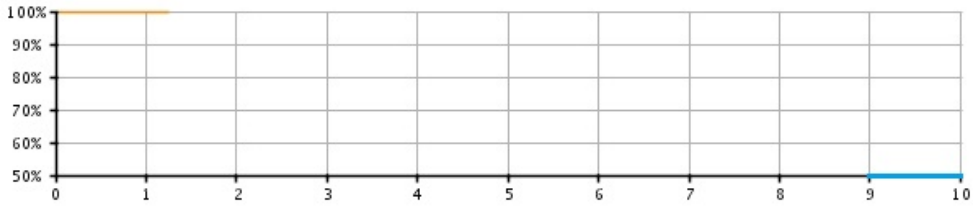
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

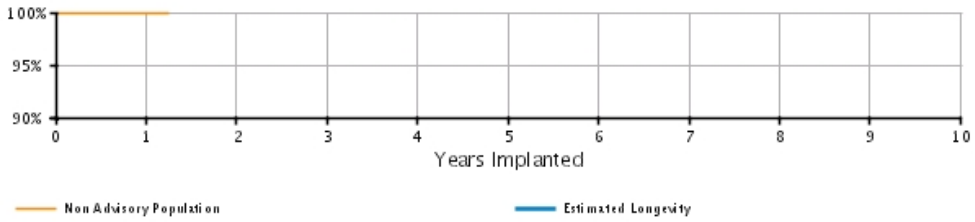
U.S. Registered Implants: 9,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 9,000

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: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 @ 15 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1763	392	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

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

DYNAGEN/INOGEN/ORIGEN ICD EL DR Models D052/D053/D142/D143/D152/ D153

Worldwide Distribution: 15,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

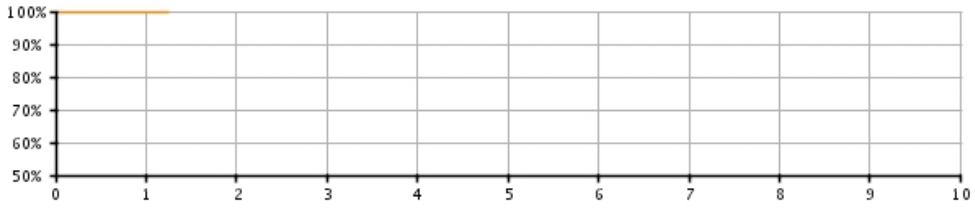
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

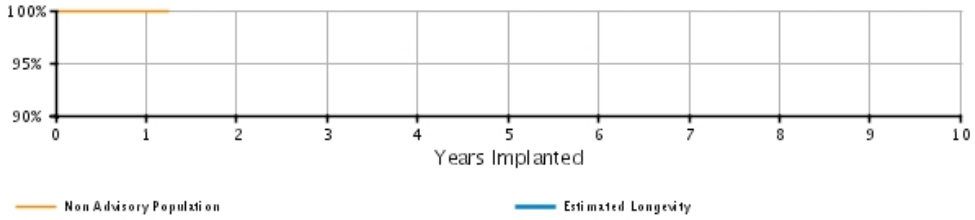
U.S. Registered Implants: 9,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 1
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: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 @ 15 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 15 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1695	379	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

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

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

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

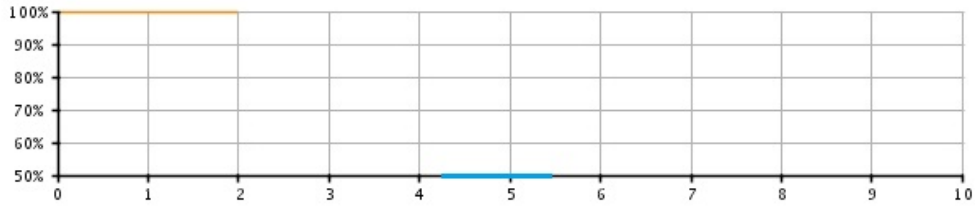
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

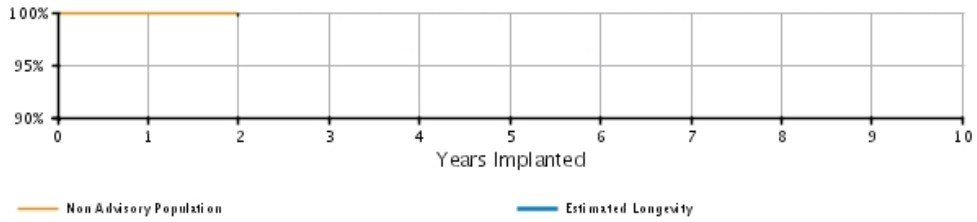
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1
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)	99.96 (-0.2/+0.0)	99.87 (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.95 (-0.3/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2269	212	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

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

DYNAGEN/INOGEN/ORIGEN ICD MINI DR Models D002/D003/D012/D013/D022/ D023

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[80] High voltage circuit component	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

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

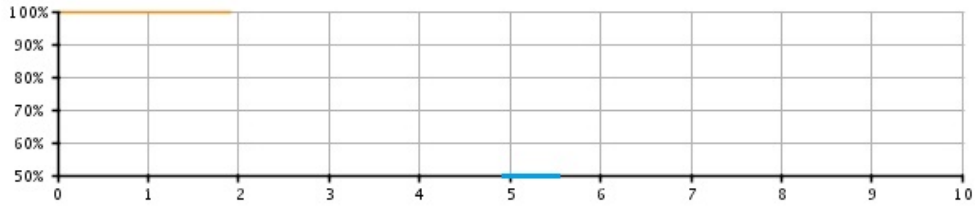
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

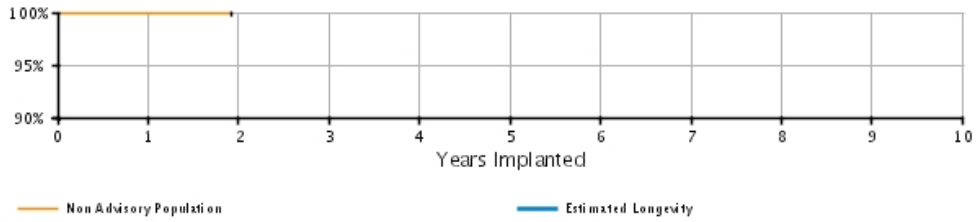
U.S. Registered Implants: 4,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions: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: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.78 @ 23 mo. (-0.5/+0.2)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.93 @ 23 mo. (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	2152	275	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

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

DYNAGEN/INOGEN/ORIGEN ICD MINI VR Models D000/D001/D010/D011/D020/ D021

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 5

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

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

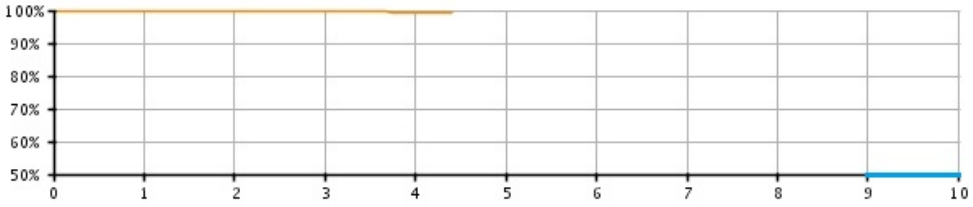
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

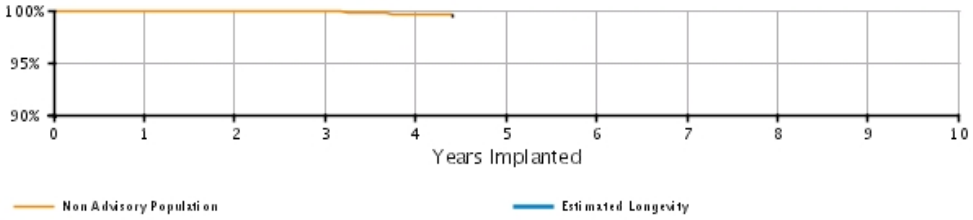
U.S. Registered Implants: 47,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 40,000

U.S. Normal Battery Depletions: 37
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:49
Without Compromised Therapy:43
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: 47000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.1)	99.34 (-0.2/+0.2)	99.34 @ 53 mo. (-0.2/+0.2)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.56 (-0.2/+0.1)	99.56 @ 53 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	39782	26980	13712	3123	337	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

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

INCEPTA/ENERGEN/PUNCTUA ICD DR Models E052/E053/E142/E143/E162/ E163/F052/F053/F142/F143/ F162/F163

Worldwide Distribution: 72,000
Worldwide Confirmed Malfunctions: 75

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**54**	**6**	**60**
[61] High-voltage capacitor	1	2	
[65] Low-voltage capacitors	3	-	
[68] Integrated circuit	5	3	
[71] Battery	2	1	
[72] Low-voltage capacitor	42	-	
[76] High voltage circuit	1	-	
Mechanical	**-**	**2**	**2**
[54] Transformer	-	2	
Software	**2**	**-**	**2**
[69] Memory errors	2	-	
Other	**8**	**3**	**11**
Non-patterned	8	3	
WW Confirmed Malfunctions	**64**	**11**	**75**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

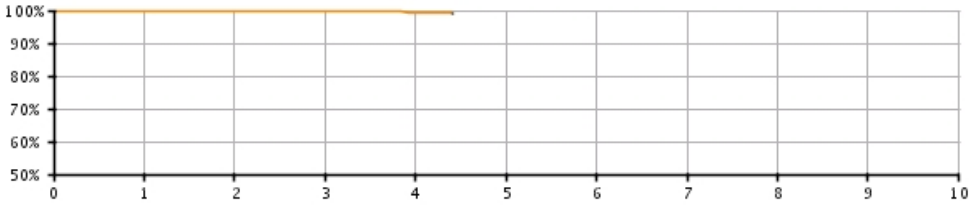
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

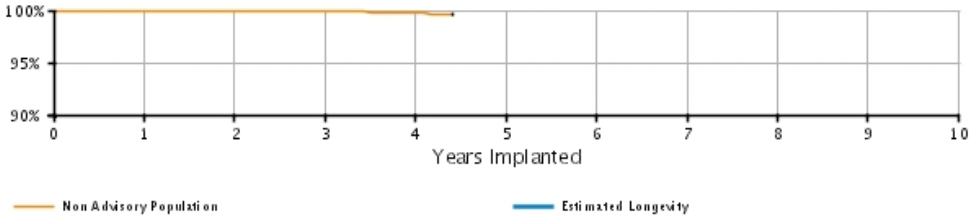
U.S. Registered Implants: 39,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 34,000

U.S. Normal Battery Depletions: 36
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:35
Without Compromised Therapy:23
With Compromised Therapy:12

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: 39000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.78 (-0.1/+0.1)	99.47 (-0.2/+0.1)	99.25 @ 53 mo. (-0.5/+0.3)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.69 (-0.2/+0.1)	99.63 @ 53 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	33423	22457	11109	2604	298	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

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

INCEPTA/ENERGEN/PUNCTUA ICD VR Models E050/E051/E140/E141/E160/ E161/F050/F051/F140/F141/ F160/F161

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 52

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**26**	**7**	**33**
[61] High-voltage capacitor	1	1	
[68] Integrated circuit	1	4	
[71] Battery	1	1	
[72] Low-voltage capacitor	23	-	
[76] High voltage circuit	-	1	
Mechanical	**-**	**5**	**5**
[54] Transformer	-	5	
Software	**5**	**-**	**5**
[69] Memory errors	5	-	
Other	**5**	**4**	**9**
Non-patterned	5	4	
WW Confirmed Malfunctions	**36**	**16**	**52**

More details about malfunctions

References cited in table above

SQ-RX S-ICD

Model 1010

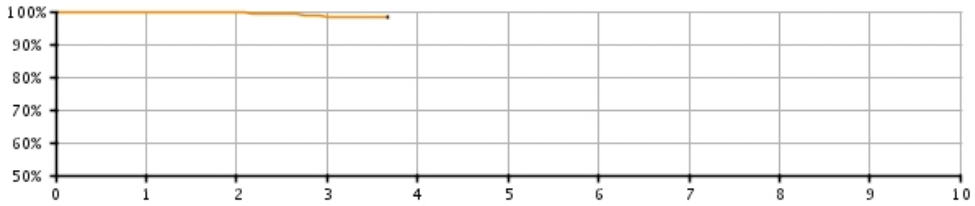
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

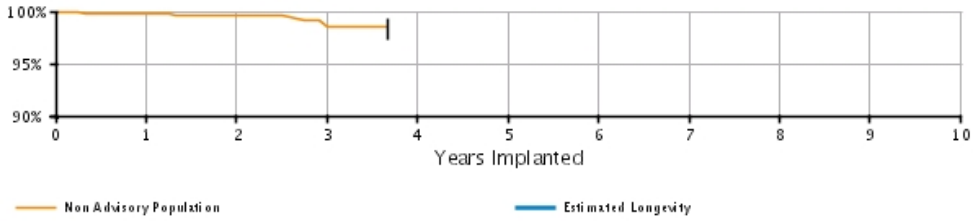
U.S. Registered Implants: 8,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 46
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:32
Without Compromised Therapy:13
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: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.75 (-0.1/+0.1)	99.53 (-0.2/+0.1)	98.43 (-1.3/+0.7)	98.43 @ 44 mo. (-1.3/+0.7)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.77 (-0.1/+0.1)	99.60 (-0.2/+0.1)	98.56 (-1.3/+0.7)	98.56 @ 44 mo. (-1.3/+0.7)	–	–	–	–	–	–
	Effective Sample Size	6315	2315	384	206	–	–	–	–	–	–

SQ-RX S-ICD

Model 1010

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

SQ-RX S-ICD Model 1010

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 86

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**3**	**10**
[2] Unintended Fuse Activation 2013 (Advisory issued)	-	3	
[79] Charge Timeout Alert	7	-	
Mechanical	**14**	**19**	**33**
[3] High cathode condition 2011 (Advisory issued)	1	2	
[73] Battery depletion	13	17	
Software	**2**	**-**	**2**
[75] Unintended Battery Depletion Alert	2	-	
Other	**14**	**27**	**41**
Non-patterned	11	18	
[74] Telemetry	3	9	
WW Confirmed Malfunctions	**37**	**49**	**86**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

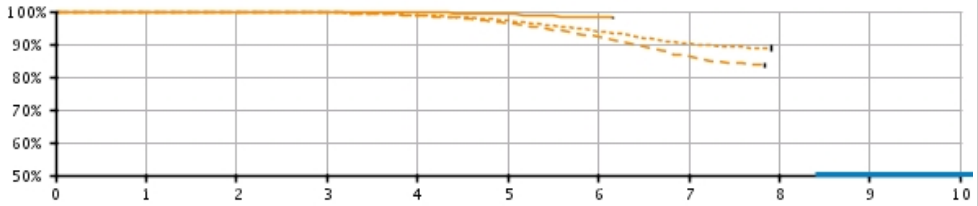
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

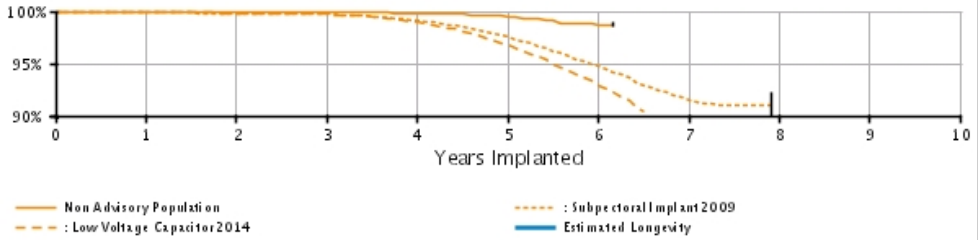
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 41,000

U.S. Normal Battery Depletions: 222
U.S. Unconfirmed Reports of Premature Battery Depletion : 118
U.S. Malfunctions:1505
Without Compromised Therapy:1390
With Compromised Therapy:115

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.18 (-0.2/+0.1)	98.12 (-0.4/+0.3)	98.12 @ 74 mo. (-0.4/+0.3)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.74 (-0.3/+0.3)	98.74 @ 74 mo. (-0.3/+0.3)	–	–	–
	Effective Sample Size	26440	23337	20592	17961	10656	1218	239	–	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.1)	98.89 (-0.1/+0.1)	97.19 (-0.2/+0.1)	93.96 (-0.2/+0.1)	90.12 (-0.3/+0.4)	88.65 @ 95 mo. (-1.8/+1.8)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.56 (-0.2/+0.2)	94.70 (-0.2/+0.3)	91.52 (-0.4/+0.3)	90.99 @ 95 mo. (-1.4/+1.3)	–	–
	Effective Sample Size	26747	23500	20670	18054	15612	13224	6722	218	–	–
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.74 (-0.1/+0.1)	96.38 (-0.1/+0.1)	92.13 (-0.3/+0.3)	86.03 (-0.5/+0.7)	83.68 @ 94 mo. (-1.5/+1.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.95 (-0.1/+0.1)	96.76 (-0.2/+0.1)	92.93 (-0.4/+0.3)	87.78 (-0.6/+1.0)	86.57 @ 94 mo.	–	–

								(-1.2/+1.5)		
	Effective Sample Size	20715	18219	16010	13978	11990	9695	2758	211	–	–

*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: 91,000
Worldwide Confirmed Malfunctions: 1969

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1759**	**86**	**1845**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1422	36	
[60] Safety Core-electrocautery	3	-	
[61] High-voltage capacitor	1	7	
[65] Low-voltage capacitors	6	-	
[68] Integrated circuit	20	20	
[71] Battery	150	22	
[72] Low-voltage capacitor	157	1	
Mechanical	**19**	**51**	**70**
[4] Subpectoral implant 2009 (Advisory issued)	3	9	
[83] Header	2	3	
[54] Transformer	-	20	
[57] Seal plug	3	-	
[58] Difficulty securing lead	9	8	
[63] Header contacts	2	11	
Software	**16**	**-**	**16**
[66] Alert messages not displayed post-EOL	3	-	
[69] Memory errors	13	-	
Other	**29**	**9**	**38**
Non-patterned	29	9	
WW Confirmed Malfunctions	**1823**	**146**	**1969**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

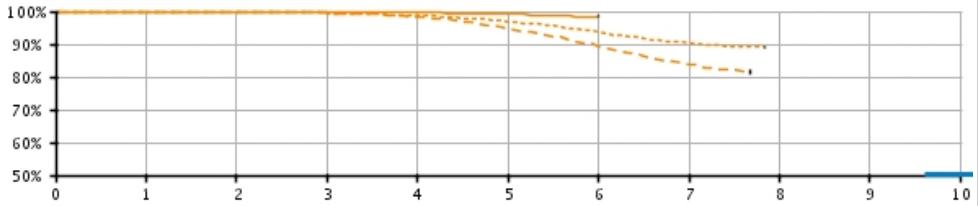
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

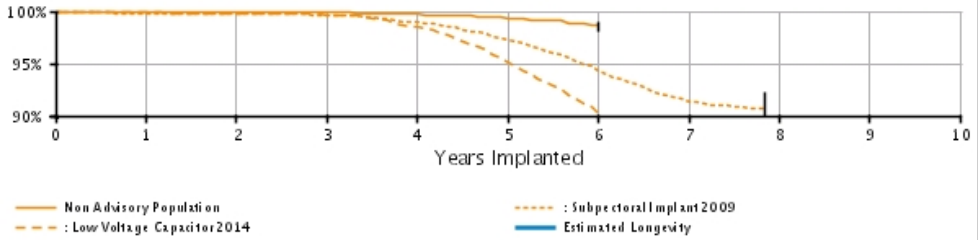
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 24,000

U.S. Normal Battery Depletions: 85
U.S. Unconfirmed Reports of Premature Battery Depletion : 73
U.S. Malfunctions:994
Without Compromised Therapy:913
With Compromised Therapy:81

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: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.17 (-0.2/+0.2)	98.31 (-0.6/+0.4)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.35 (-0.2/+0.1)	98.64 (-0.6/+0.4)	–	–	–	–
	Effective Sample Size	16275	14328	12587	10980	5677	395	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.2)	96.93 (-0.4/+0.3)	93.70 (-0.6/+0.5)	90.22 (-0.6/+0.5)	89.09 @ 94 mo. (-0.6/+0.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.63 (-0.1/+0.1)	98.93 (-0.1/+0.1)	97.32 (-0.1/+0.1)	94.37 (-0.1/+0.2)	91.38 (-0.4/+0.3)	90.69 @ 94 mo. (-1.5/+1.6)	–	–
	Effective Sample Size	13682	11997	10516	9151	7865	6665	3449	331	–	–
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.1)	98.23 (-0.1/+0.1)	94.78 (-0.2/+0.1)	89.44 (-0.3/+0.2)	83.72 (-0.4/+0.2)	81.38 @ 92 mo. (-1.5/+1.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.45 (-0.1/+0.1)	95.14 (-0.1/+0.1)	90.25 (-0.1/+0.1)	85.36 (-0.3/+0.2)	83.84 @ 92 mo. (-1.2/+1.1)	–	–

Effective Sample Size	13682	11997	10516	9151	7865	6665	3449	849	–	–

*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: 66,000
Worldwide Confirmed Malfunctions: 1551

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1373**	**57**	**1430**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1057	24	
[60] Safety Core-electrocautery	1	1	
[61] High-voltage capacitor	-	3	
[65] Low-voltage capacitors	5	-	
[68] Integrated circuit	10	14	
[71] Battery	198	15	
[72] Low-voltage capacitor	102	-	
Mechanical	**21**	**65**	**86**
[4] Subpectoral implant 2009 (Advisory issued)	6	16	
[83] Header	2	8	
[34] Transformer	-	1	
[54] Transformer	-	14	
[57] Seal plug	1	-	
[58] Difficulty securing lead	-	10	
[63] Header contacts	12	16	
Software	**15**	**-**	**15**
[5] Respiratory Sensor Oversensing	1	-	
[66] Alert messages not displayed post-EOL	4	-	
[69] Memory errors	10	-	
Other	**9**	**11**	**20**
Non-patterned	9	11	
WW Confirmed Malfunctions	**1418**	**133**	**1551**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

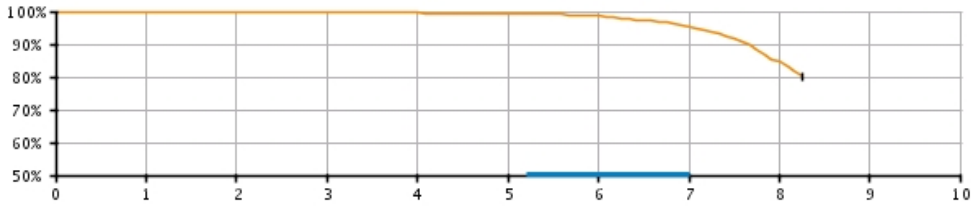
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

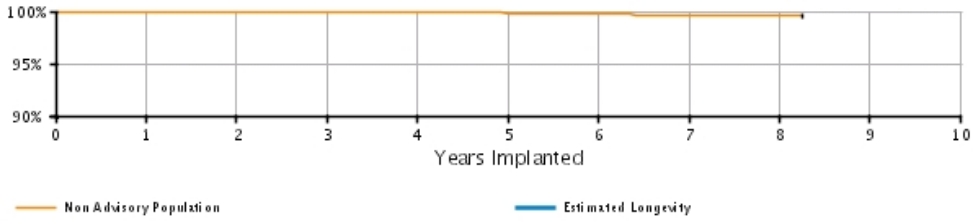
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 321
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:14
Without Compromised Therapy:11
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: 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)	98.51 (-0.4/+0.3)	95.42 (-0.8/+0.7)	84.52 (-1.8/+1.6)	80.26 @ 99 mo. (-2.6/+2.4)	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.84 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.63 (-0.3/+0.2)	99.58 (-0.3/+0.2)	99.58 @ 99 mo. (-0.3/+0.2)	–
	Effective Sample Size	6164	5397	4700	4116	3559	2907	2197	954	221	–

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: 14

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

More details about malfunctions

References cited in table above

VITALITY 2 EL DR

Model T167

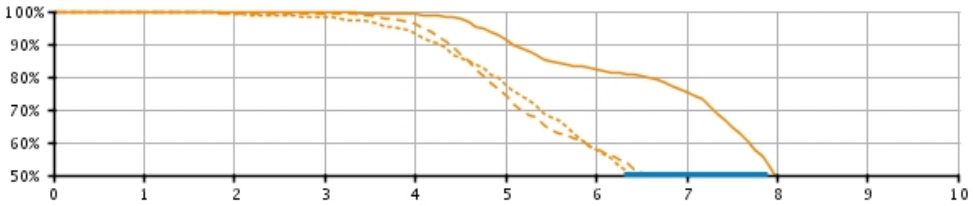
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

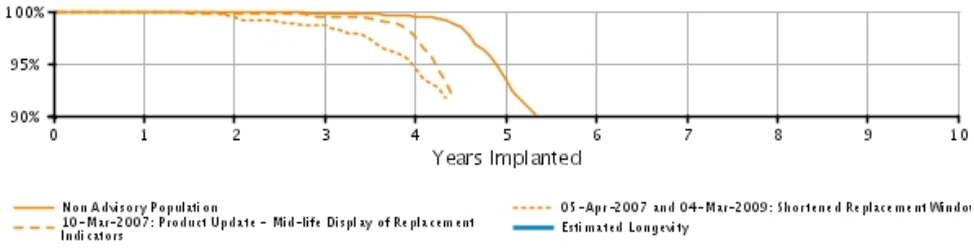
U.S. Registered Implants: 8,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 2,240
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:767
Without Compromised Therapy:753
With Compromised Therapy:14

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)	91.29 (-1.1/+1.0)	82.28 (-1.5/+1.4)	75.35 (-1.8/+1.7)	48.74 (-2.3/+2.3)	24.00 @ 102 mo. (-2.4/+2.6)	–
	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)	93.40 (-1.0/+0.9)	87.35 (-1.4/+1.3)	86.77 (-1.4/+1.3)	86.56 (-1.4/+1.3)	86.56 @ 102 mo. (-1.4/+1.3)	–
	Effective Sample Size	4362	3831	3361	2919	2361	1812	1422	710	&ndash;	–
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)	93.31 (-1.5/+1.3)	77.40 (-2.6/+2.4)	57.68 (-3.2/+3.1)	31.48 (-3.2/+3.4)	28.40 @ 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)	83.49 (-2.4/+2.1)	75.79 (-2.9/+2.6)	73.66 (-3.1/+2.9)	73.66 @ 85 mo. (-3.1/+2.9)	–	–
	Effective Sample Size	1699	1489	1289	1076	782	474	218	&ndash;	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.49 (-0.6/+0.3)	99.17 (-0.8/+0.4)	96.22 (-1.5/+1.1)	74.28 (-3.3/+3.1)	58.03 (-3.8/+3.7)	42.53 @ 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)	80.99 (-3.1/+2.8)	70.76 (-3.7/+3.5)	70.52 @ 82 mo. (-3.7/+3.5)	–	–	–
	Effective Sample Size	1171	1024	898	762	500	317	205	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL DR

Model T167

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

VITALITY 2 EL DR
Model T167

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1067

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1028**	**10**	**1038**
[7] Shortened replacement window (Advisory issued)	143	2	
[12] Extended charge time post-mid-life	15	-	
[20] Capacitor	1	-	
[23] Integrated circuit	-	4	
[32] Capacitor	1	-	
[42] Mid-life display of replacement indicators	826	-	
[43] High-voltage capacitor	-	2	
[46] Integrated circuit	-	1	
[59] Low-voltage capacitor	42	1	
Mechanical	**8**	**3**	**11**
[6] Subpectoral implant (Advisory issued)	1	1	
[19] Header	1	-	
[26] Seal plug	5	1	
[49] Seal plug	1	-	
[54] Transformer	-	1	
Software	**7**	**1**	**8**
[41] Memory location	1	1	
[56] Misaligned markers	6	-	
Other	**3**	**7**	**10**
Non-patterned	2	3	
[15] Firmware error	1	4	
WW Confirmed Malfunctions	**1046**	**21**	**1067**

More details about malfunctions

References cited in table above

VITALITY 2 EL VR

Model T177

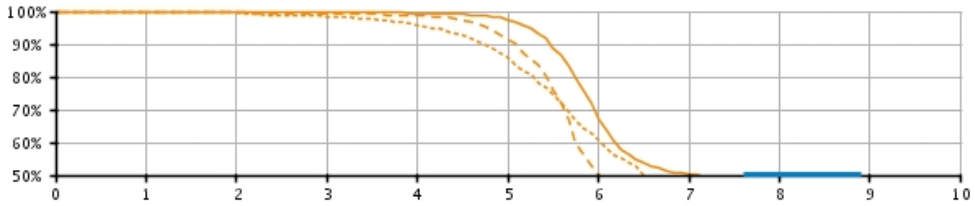
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

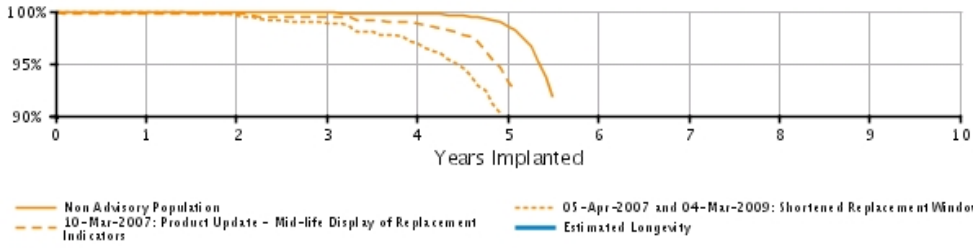
U.S. Registered Implants: 7,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 1,244
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:1277
Without Compromised Therapy:1263
With Compromised Therapy:14

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)	97.37 (-0.7/+0.6)	67.06 (-2.1/+2.1)	50.19 (-2.3/+2.3)	43.64 (-2.4/+2.5)	37.94 @ 100 mo. (-2.6/+2.7)	–
	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)	98.48 (-0.6/+0.4)	73.41 (-2.1/+2.0)	60.00 (-2.4/+2.4)	59.04 (-2.4/+2.4)	58.65 @ 100 mo. (-2.5/+2.4)	–
	Effective Sample Size	3631	3176	2774	2408	2064	1279	740	422	232	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.48 (-0.8/+0.5)	95.88 (-1.2/+1.0)	85.71 (-2.2/+2.0)	60.80 (-3.3/+3.2)	41.29 (-3.4/+3.5)	33.79 @ 88 mo. (-3.4/+3.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.84 (-0.7/+0.4)	97.00 (-1.1/+0.8)	88.93 (-2.1/+1.8)	68.27 (-3.2/+3.1)	60.90 (-3.5/+3.4)	60.37 @ 88 mo. (-3.6/+3.5)	–	–
	Effective Sample Size	1687	1474	1279	1087	820	493	275	206	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	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)	50.22 (-4.4/+4.4)	45.00 @ 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)	59.60 (-4.6/+4.4)	54.40 @ 74 mo. (-4.7/+4.6)	–	–	–
	Effective Sample Size	975	854	747	647	526	237	206	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

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

VITALITY 2 EL VR

Model T177

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

VITALITY 2 EL VR
Model T177

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 1922

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1880**	**8**	**1888**
[7] Shortened replacement window (Advisory issued)	139	1	
[8] Low-voltage capacitor (Advisory issued)	2	1	
[12] Extended charge time post-mid-life	20	2	
[23] Integrated circuit	-	3	
[32] Capacitor	1	-	
[35] Capacitor	2	-	
[42] Mid-life display of replacement indicators	1649	1	
[43] High-voltage capacitor	2	-	
[59] Low-voltage capacitor	65	-	
Mechanical	**3**	**8**	**11**
[6] Subpectoral implant (Advisory issued)	-	5	
[19] Header	-	1	
[26] Seal plug	1	-	
[45] Sensing	2	-	
[54] Transformer	-	2	
Software	**-**	**2**	**2**
[39] Memory location	-	1	
[41] Memory location	-	1	
Other	**12**	**9**	**21**
Non-patterned	12	7	
[21] Battery depletion	-	2	
WW Confirmed Malfunctions	**1895**	**27**	**1922**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

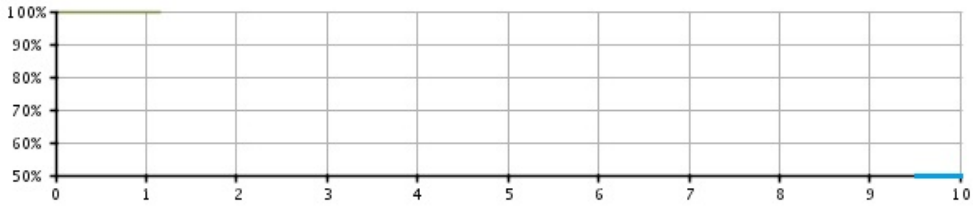
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

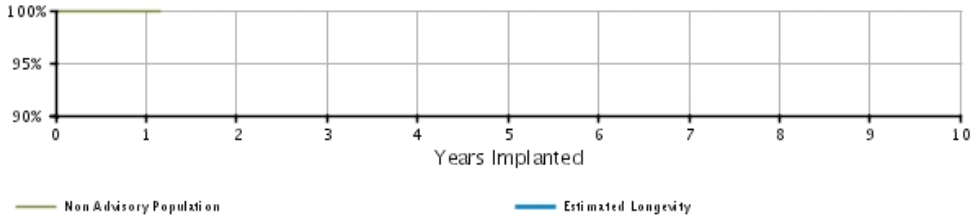
U.S. Registered Implants: 12,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 11,000

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

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 12000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.90 @ 14 mo. (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.99 @ 14 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1507	499	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

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

ACCOLADE/PROPONENT/ESSENTIO DR EL
Models L121/L131/L221/L231/L321/ L331

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR

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

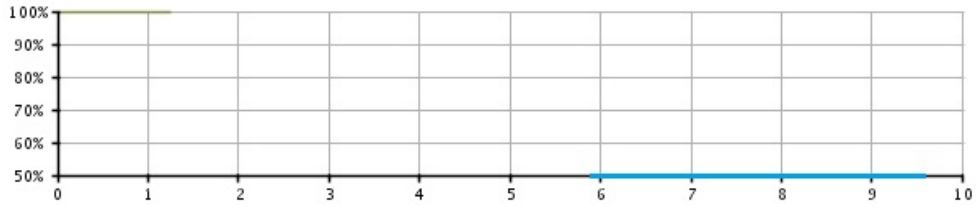
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

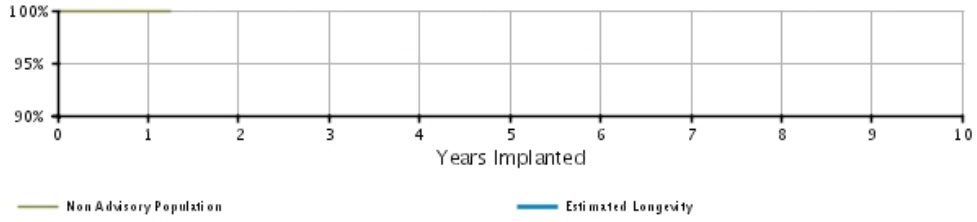
U.S. Registered Implants: 38,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 36,000

U.S. Normal Battery Depletions: 5
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:3
Without Compromised Therapy:1
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 @ 15 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 @ 15 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	4832	594	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR

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

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

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

Worldwide Distribution: 73,000
Worldwide Confirmed Malfunctions: 4

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

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

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

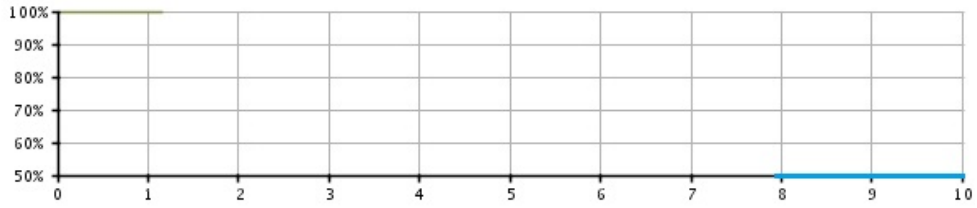
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

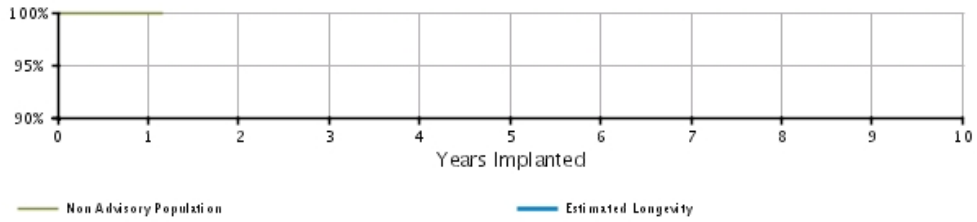
U.S. Registered Implants: 7,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 7,000

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

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 (-0.2/+0.0)	99.97 @ 14 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 14 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	869	274	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO SR

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

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

ACCOLADE/PROPONENT/ESSENTIO SR Models L100/L110/L200/L210/L300/ L310

Worldwide Distribution: 25,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

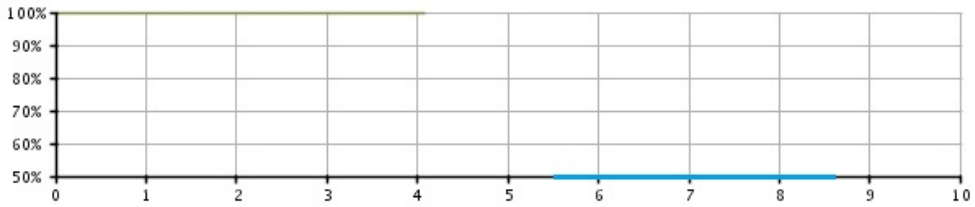
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

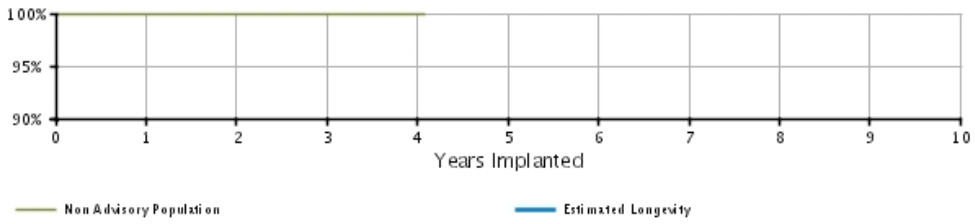
U.S. Registered Implants: 121,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 107,000

U.S. Normal Battery Depletions: 82
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:26
Without Compromised Therapy:19
With Compromised Therapy:7

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 121000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.75 (-0.1/+0.1)	99.75 @ 49 mo. (-0.1/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 49 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	106178	66109	27889	1460	497	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

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

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

Worldwide Distribution: 213,000
Worldwide Confirmed Malfunctions: 44

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**7**	**14**
[65] Low-voltage capacitors	4	-	
[68] Integrated circuit	3	5	
[78] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**10**	**1**	**11**
[69] Memory errors	10	1	
Other	**17**	**2**	**19**
Non-patterned	17	2	
WW Confirmed Malfunctions	**34**	**10**	**44**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO EL DR

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

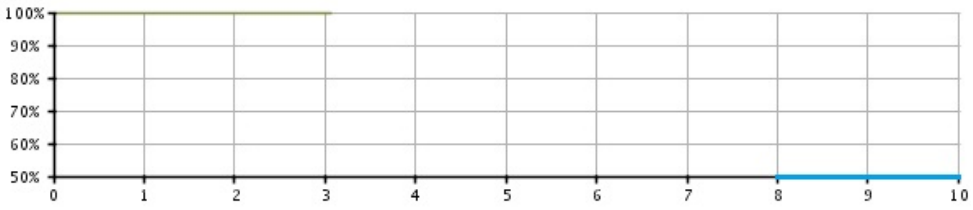
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

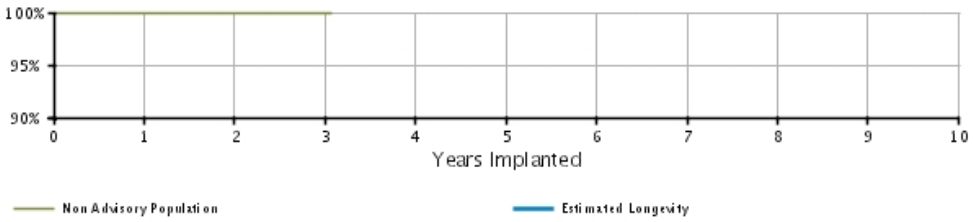
U.S. Registered Implants: 11,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.94 @ 37 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 37 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	9004	3622	354	248	–	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO EL DR

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

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

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

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 18

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**4**	**8**
[65] Low-voltage capacitors	4	1	
[68] Integrated circuit	-	1	
[78] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**4**	**-**	**4**
[69] Memory errors	3	-	
[77] Respiratory sensor	1	-	
Other	**5**	**1**	**6**
Non-patterned	5	1	
WW Confirmed Malfunctions	**13**	**5**	**18**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO SR

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

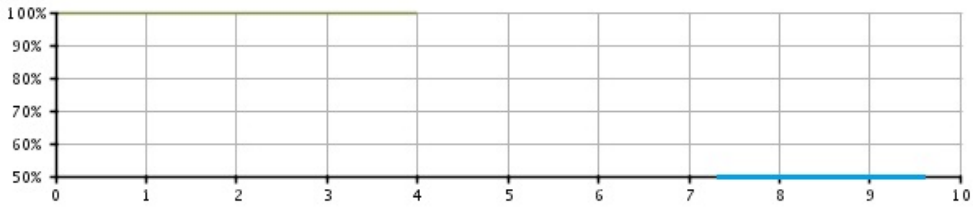
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

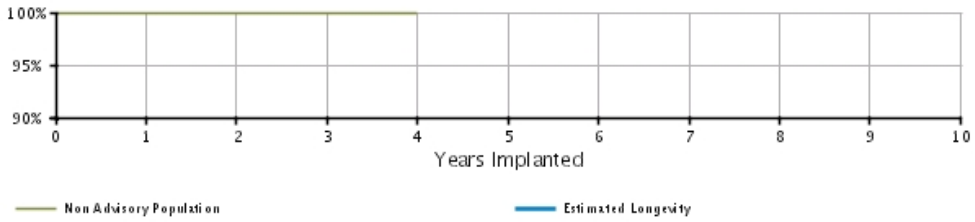
U.S. Registered Implants: 26,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 12
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 26000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.88 (-0.1/+0.0)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	–	–	–	–	–	–
	Effective Sample Size	21752	13024	5188	230	–	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO SR

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

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

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

Worldwide Distribution: 82,000
Worldwide Confirmed Malfunctions: 16

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

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

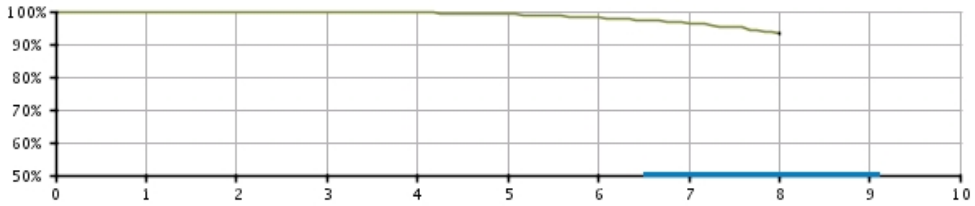
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

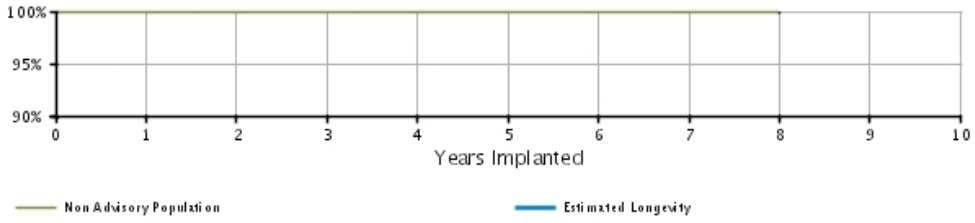
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 398
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:10
Without Compromised Therapy:9
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.54 (-0.1/+0.1)	99.03 (-0.2/+0.2)	98.04 (-0.3/+0.2)	96.44 (-0.4/+0.4)	93.16 (-1.2/+1.0)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.88 (-0.1/+0.1)	–	–
	Effective Sample Size	19483	17221	15077	13036	10587	8323	5512	272	–	–

ALTRUA 60 DR

Model S602

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

ALTRUA 60 DR
Model S602

Worldwide Distribution: 56,000
Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[20] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[22] Capacitor array	1	-	
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**12**	**2**	**14**
Non-patterned	2	1	
[37] Battery depletion	1	1	
[67] Battery status	9	-	
WW Confirmed Malfunctions	**14**	**3**	**17**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

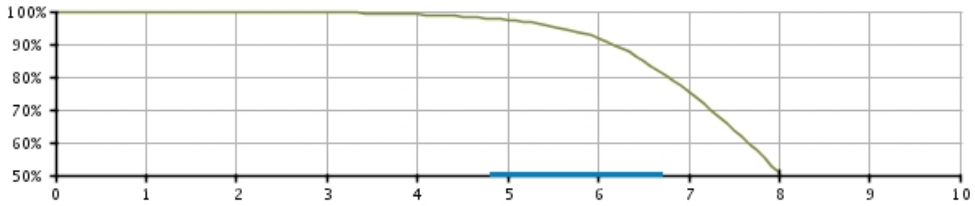
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

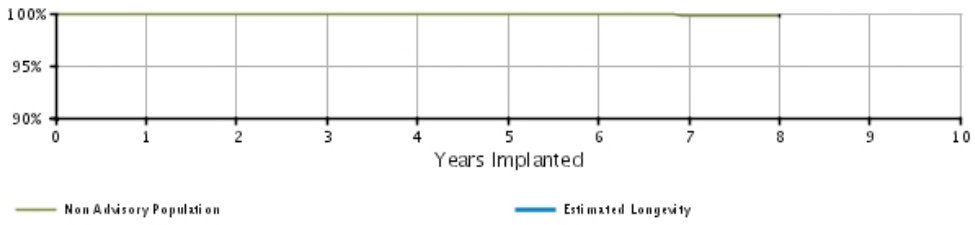
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 53,000

U.S. Normal Battery Depletions: 6,401
U.S. Unconfirmed Reports of Premature Battery Depletion : 44
U.S. Malfunctions:51
Without Compromised Therapy:43
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)	99.67 (-0.0/+0.0)	99.09 (-0.1/+0.1)	97.43 (-0.1/+0.1)	91.82 (-0.3/+0.3)	75.43 (-0.7/+0.6)	50.75 (-2.0/+2.0)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.76 (-0.1/+0.1)	–	–
	Effective Sample Size	79414	70653	62506	53011	36696	21347	8015	232	–	–

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: 63

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**7**	**12**
[20] Capacitor	4	6	
[46] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[55] Connector block	1	-	
[58] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**46**	**3**	**49**
Non-patterned	1	2	
[37] Battery depletion	3	1	
[67] Battery status	42	-	
WW Confirmed Malfunctions	**53**	**10**	**63**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

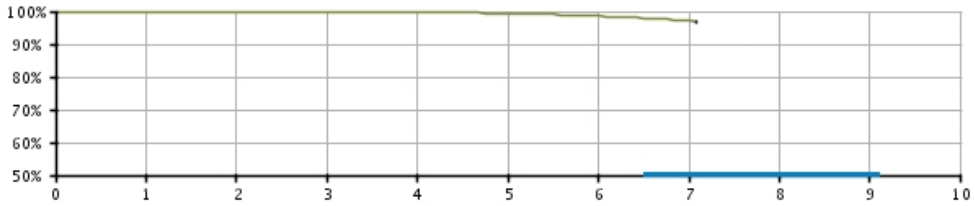
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

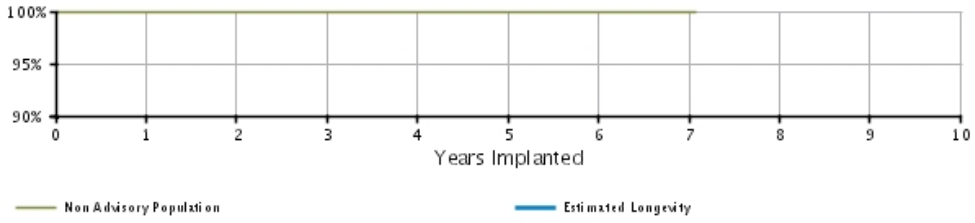
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 43,000

U.S. Normal Battery Depletions: 353
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: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.71 (-0.1/+0.0)	99.37 (-0.1/+0.1)	98.56 (-0.2/+0.2)	97.06 (-0.5/+0.5)	96.79 @ 85 mo. (-0.8/+0.7)	–	–
	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)	99.97 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 85 mo. (-0.1/+0.0)	–	–
	Effective Sample Size	52727	46886	41349	34641	20342	8574	679	355	–	–

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: 11

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[20] Capacitor	3	-	
[23] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**5**	**1**	**6**
Non-patterned	1	-	
[37] Battery depletion	-	1	
[67] Battery status	4	-	
WW Confirmed Malfunctions	**9**	**2**	**11**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

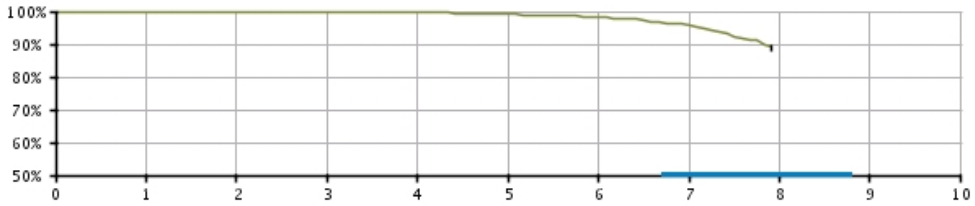
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

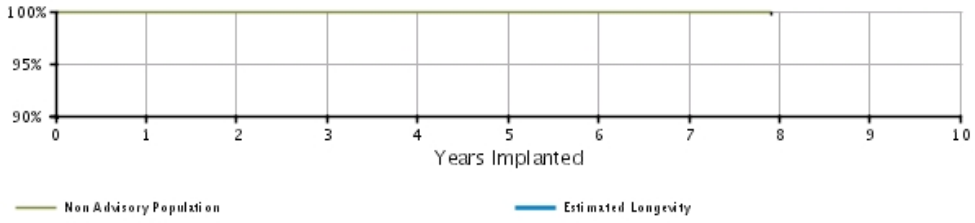
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 406
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
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: 32000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.0)	99.61 (-0.1/+0.1)	99.13 (-0.2/+0.1)	98.21 (-0.3/+0.2)	95.64 (-0.6/+0.5)	89.03 @ 95 mo. (-2.1/+1.8)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.85 @ 95 mo. (-0.3/+0.1)	–	–
	Effective Sample Size	26789	23620	20793	17468	11525	6660	2660	222	–	–

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: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**4**	**6**
[20] Capacitor	2	2	
[46] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**4**	**3**	**7**
Non-patterned	-	2	
[37] Battery depletion	-	1	
[67] Battery status	4	-	
WW Confirmed Malfunctions	**6**	**7**	**13**

More details about malfunctions

References cited in table above

ALTRUA 50 DR (Downsize)

Model S502

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

ALTRUA 50 DR (Downsize) Model S502

Worldwide Distribution: 46,000
Worldwide Confirmed Malfunctions: 15

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**-**	**3**
[20] Capacitor	2	-	
[46] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**11**	**-**	**11**
Non-patterned	-	-	
[37] Battery depletion	2	-	
[67] Battery status	9	-	
WW Confirmed Malfunctions	**14**	**1**	**15**

More details about malfunctions

References cited in table above

ALTRUA 50 SR

Model S501

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

ALTRUA 50 SR
Model S501

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**3**	**4**
[20] Capacitor	1	3	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**3**	**3**
Non-patterned	-	1	
[37] Battery depletion	-	2	
WW Confirmed Malfunctions	**1**	**6**	**7**

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: 11,000
Worldwide Confirmed Malfunctions: 7

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

More details about malfunctions

References cited in table above

ALTRUA 50 VDD (Downsize)

Model S504

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

ALTRUA 50 VDD (Downsize) Model S504

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ALTRUA 50 SSI

Model S508

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

ALTRUA 50 SSI
Model S508

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

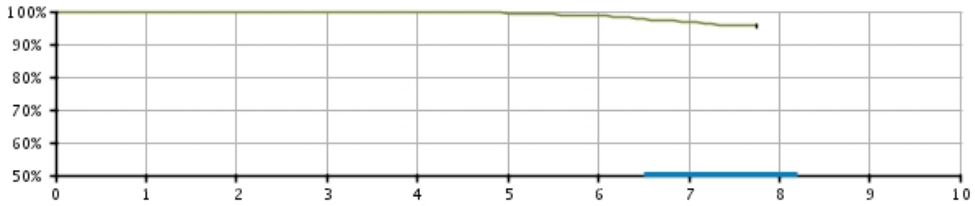
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

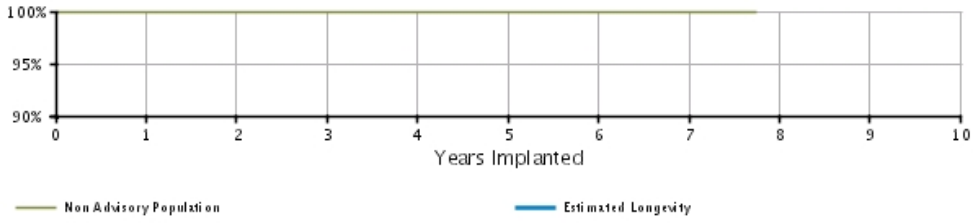
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 33
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)	98.66 (-1.0/+0.6)	96.76 (-1.4/+1.0)	95.71 @ 93 mo. (-1.7/+1.2)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 93 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	1517	1346	1194	1064	945	835	703	212	–	–

ALTRUA 40 DR

Model S402

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

ALTRUA 40 DR
Model S402

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

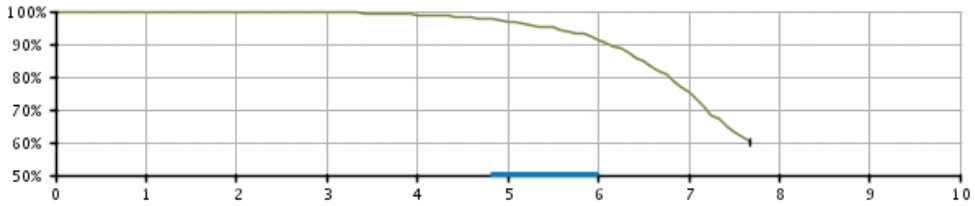
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

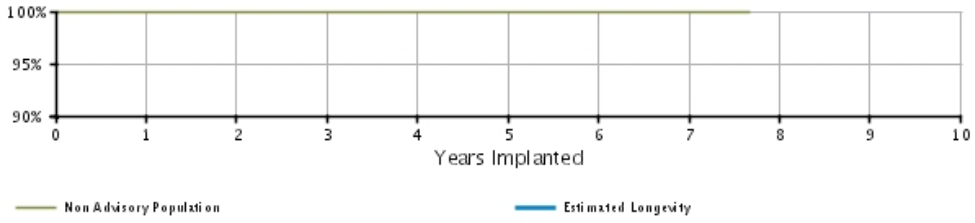
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 989
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
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)	99.69 (-0.1/+0.1)	98.95 (-0.2/+0.2)	96.86 (-0.4/+0.4)	91.46 (-0.8/+0.7)	75.20 (-1.7/+1.7)	60.01 @ 92 mo. (-3.0/+2.9)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 92 mo. (-0.1/+0.0)	–	–
	Effective Sample Size	12514	11155	9909	8675	5932	3242	1103	250	–	–

ALTRUA 40 DR (downsize)

Model S403

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

ALTRUA 40 DR (downsize) Model S403

Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**2**	**-**	**2**
[57] Seal plug	1	-	
[58] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	-	-	
[67] Battery status	2	-	
WW Confirmed Malfunctions	**4**	**0**	**4**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

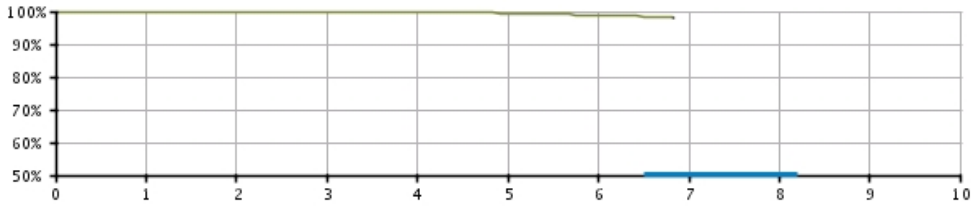
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

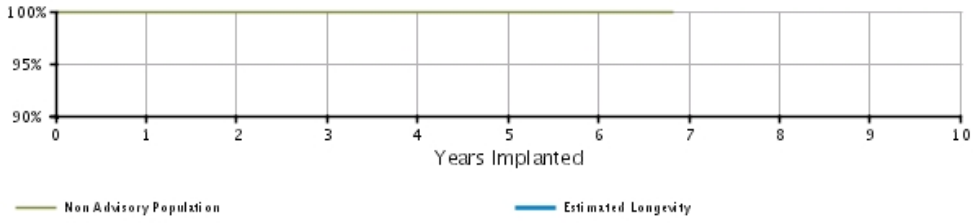
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 29
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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.33 (-0.4/+0.2)	98.76 (-0.6/+0.4)	98.11 @ 82 mo. (-1.1/+0.7)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 82 mo. (-0.0/+0.0)	–	–	–
	Effective Sample Size	4475	3986	3553	3099	1993	1035	224	–	–	–

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ALTRUA 40 SR

Model S401

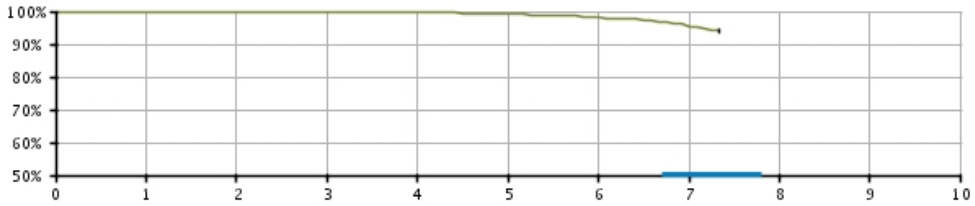
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

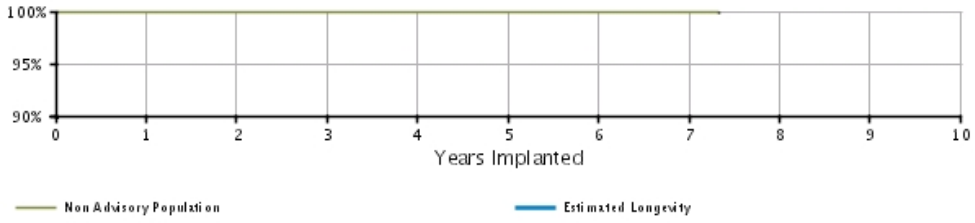
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 58
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)	99.66 (-0.3/+0.2)	99.30 (-0.4/+0.3)	98.12 (-0.8/+0.6)	95.35 (-1.7/+1.3)	94.11 @ 88 mo. (-2.2/+1.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 88 mo. (-0.2/+0.0)	–	–
	Effective Sample Size	3956	3467	3043	2653	1805	1014	422	225	–	–

ALTRUA 40 SR

Model S401

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

ALTRUA 40 SR
Model S401

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**1**	**3**
[20] Capacitor	2	-	
[46] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR

Models S202/S205

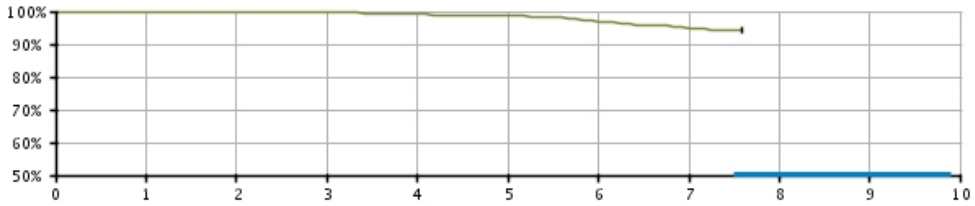
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

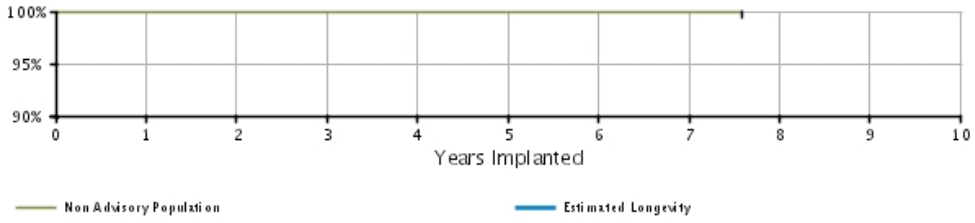
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 41
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)	99.93 (-0.4/+0.1)	99.68 (-0.5/+0.2)	99.30 (-0.7/+0.4)	98.65 (-0.9/+0.6)	96.90 (-1.4/+1.0)	94.75 (-1.9/+1.4)	94.33 @ 91 mo. (-2.0/+1.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 @ 91 mo. (-0.6/+0.1)	–	–
	Effective Sample Size	1523	1330	1134	976	827	671	520	213	–	–

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

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

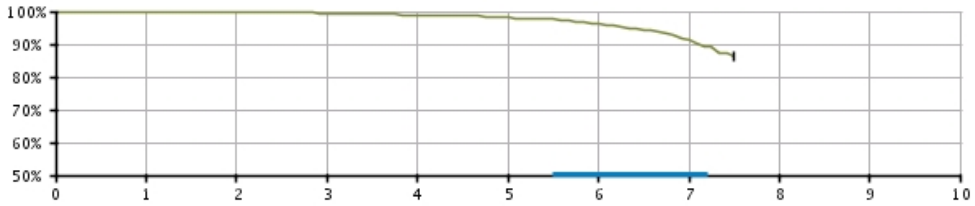
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

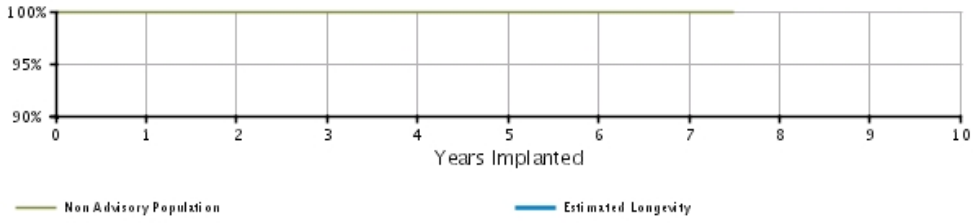
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 153
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
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)	99.43 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.12 (-0.6/+0.4)	96.09 (-0.9/+0.8)	91.33 (-1.9/+1.6)	86.24 @ 90 mo. (-3.1/+2.6)	–	–
	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 @ 90 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	4413	3902	3467	3019	2141	1260	487	205	–	–

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

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

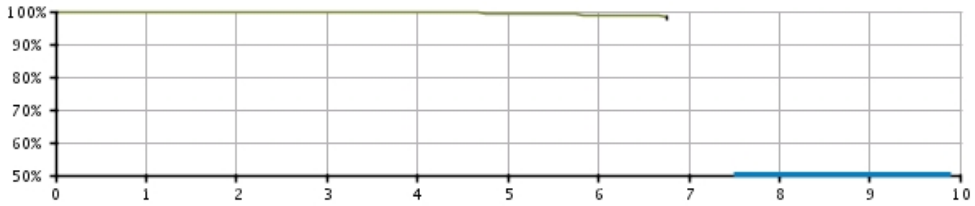
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

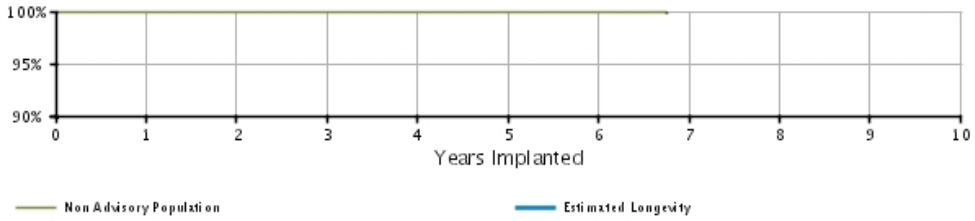
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 17
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)	99.77 (-0.3/+0.1)	99.62 (-0.3/+0.2)	99.42 (-0.5/+0.3)	98.94 (-0.8/+0.4)	98.25 @ 81 mo. (-1.6/+0.9)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 81 mo. (-0.2/+0.0)	–	–	–
	Effective Sample Size	2773	2467	2189	1897	1226	592	211	–	–	–

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: 2

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

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

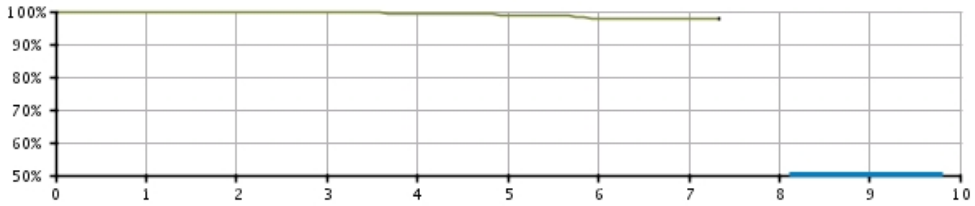
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

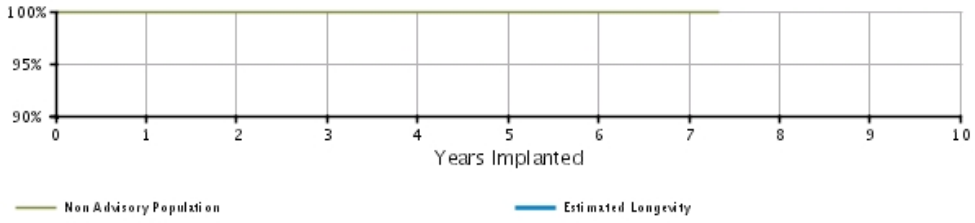
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 38
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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.67 (-0.3/+0.2)	99.37 (-0.4/+0.2)	98.86 (-0.6/+0.4)	97.95 (-0.9/+0.6)	97.78 (-0.9/+0.7)	97.78 @ 88 mo. (-0.9/+0.7)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 88 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	3594	3045	2600	2182	1491	856	350	219	–	–

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**
[20] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

ALTRUA 20 SSI

Model S206

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

ALTRUA 20 SSI Model S206

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ALTRUA 20 DDD

Model S207

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

ALTRUA 20 DDD
Model S207

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR

Model 1291

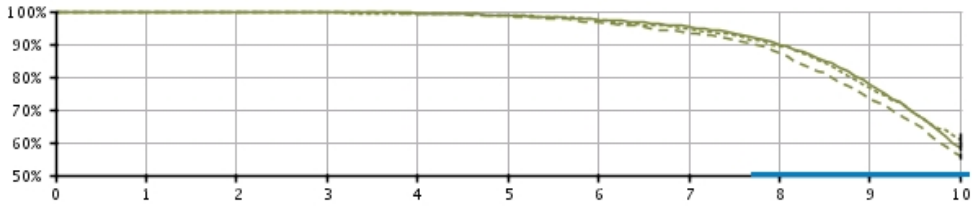
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

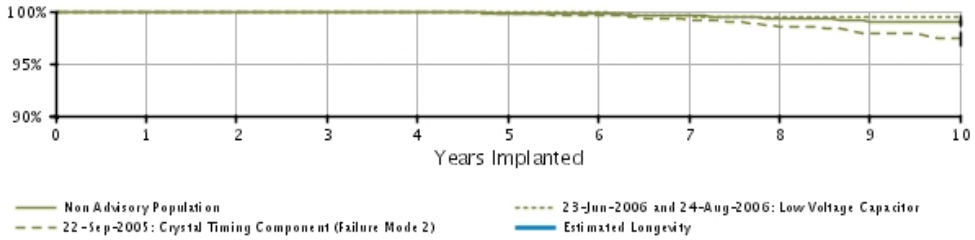
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 12,000

U.S. Normal Battery Depletions: 3,873
U.S. Unconfirmed Reports of Premature Battery Depletion : 21
U.S. Malfunctions:169
Without Compromised Therapy:159
With Compromised Therapy:10

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)	98.71 (-0.2/+0.2)	97.43 (-0.3/+0.3)	95.30 (-0.4/+0.4)	89.77 (-0.6/+0.6)	77.60 (-1.0/+1.0)	58.30 (-2.0/+2.0)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.02 (-0.3/+0.2)	98.93 (-0.3/+0.2)
	Effective Sample Size	21002	18657	16559	14648	12904	11298	9792	7927	2910	569
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.47 (-1.1/+0.8)	94.62 (-1.5/+1.2)	89.38 (-2.2/+1.8)	76.95 (-3.1/+2.8)	60.80 (-3.7/+3.6)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.63 (-0.6/+0.2)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	843	691	520	354
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.58 (-0.7/+0.6)	93.41 (-0.9/+0.8)	87.17 (-1.3/+1.2)	73.45 (-1.8/+1.7)	55.56 (-2.1/+2.1)

	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.96 (-0.7/+0.5)	97.39 (-0.8/+0.6)
	Effective Sample Size	5702	5046	4468	3939	3451	2978	2553	2094	1552	1001

*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: 206

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[17] Capacitor	1	-	
[20] Capacitor	4	2	
[46] Integrated circuit	2	1	
Mechanical	**8**	**5**	**13**
[26] Seal plug	5	4	
[27] Header	2	1	
[48] Setscrew	1	-	
Software	**4**	**-**	**4**
[51] Underestimation of battery status	3	-	
[53] Pacing rate limit	1	-	
Other	**172**	**5**	**177**
Non-patterned	8	4	
[13] Longevity labeling	75	-	
[28] Magnet response	1	-	
[37] Battery depletion	3	1	
[67] Battery status	85	-	
WW Confirmed Malfunctions	**191**	**15**	**206**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

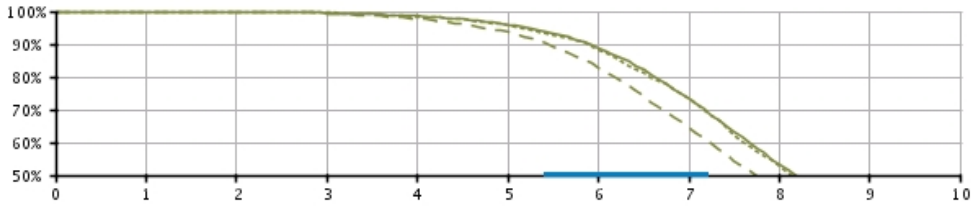
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

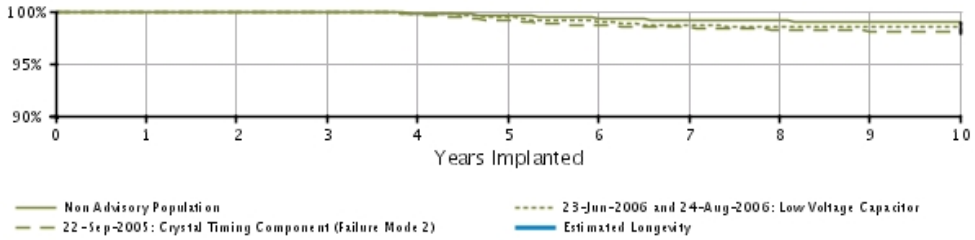
U.S. Registered Implants: 76,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 20,776
U.S. Unconfirmed Reports of Premature Battery Depletion : 115
U.S. Malfunctions:429
Without Compromised Therapy:415
With Compromised Therapy:14

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)	99.95 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.48 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.92 (-0.4/+0.4)	73.23 (-0.5/+0.5)	53.36 (-0.7/+0.7)	35.88 (-0.7/+0.8)	21.80 (-1.0/+1.1)
	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)	99.07 (-0.1/+0.1)	98.93 (-0.2/+0.1)	98.93 (-0.2/+0.1)
	Effective Sample Size	47638	42289	37443	32971	28510	23421	16882	10475	3129	428
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)	88.15 (-1.4/+1.2)	73.14 (-1.9/+1.9)	52.80 (-2.3/+2.3)	34.50 (-2.3/+2.4)	22.62 (-2.1/+2.3)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.38 (-0.4/+0.2)	99.06 (-0.5/+0.3)	98.66 (-0.6/+0.4)	98.48 (-0.6/+0.5)	98.48 (-0.6/+0.5)	98.48 (-0.6/+0.5)
	Effective Sample Size	4024	3553	3142	2732	2337	1903	1369	848	472	264
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.38 (-0.2/+0.1)	97.77 (-0.3/+0.3)	93.65 (-0.5/+0.5)	82.82 (-0.8/+0.8)	64.49 (-1.1/+1.1)	44.50 (-1.2/+1.2)	27.73 (-1.1/+1.2)	17.98 (-1.0/+1.1)

Component (Failure Mode 2)* Registered Implants: 17000											
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.09 (-0.2/+0.2)	98.67 (-0.3/+0.2)	98.45 (-0.3/+0.2)	98.24 (-0.3/+0.3)	98.12 (-0.4/+0.3)	98.12 (-0.4/+0.3)
	Effective Sample Size	14971	13293	11728	10219	8604	6629	4396	2568	1314	701

*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: 580

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**9**	**18**
[8] Low-voltage capacitor (Advisory issued)	1	5	
[20] Capacitor	7	3	
[46] Integrated circuit	1	1	
Mechanical	**6**	**2**	**8**
[11] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[18] Setscrew thread depth	1	-	
[26] Seal plug	4	1	
[33] Circuit connection	1	-	
Software	**12**	**-**	**12**
[30] Memory error	2	-	
[31] Rate fault declaration	1	-	
[51] Underestimation of battery status	8	-	
[53] Pacing rate limit	1	-	
Other	**531**	**11**	**542**
Non-patterned	24	7	
[13] Longevity labeling	402	-	
[37] Battery depletion	6	4	
[67] Battery status	99	-	
WW Confirmed Malfunctions	**558**	**22**	**580**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

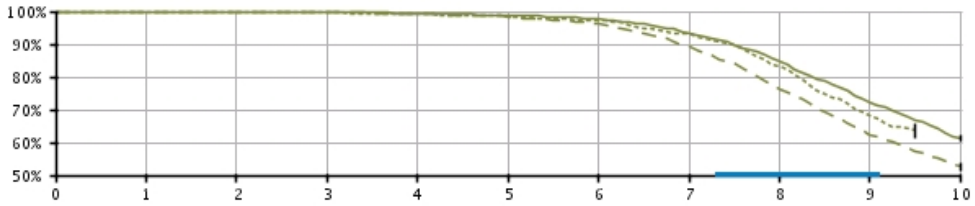
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

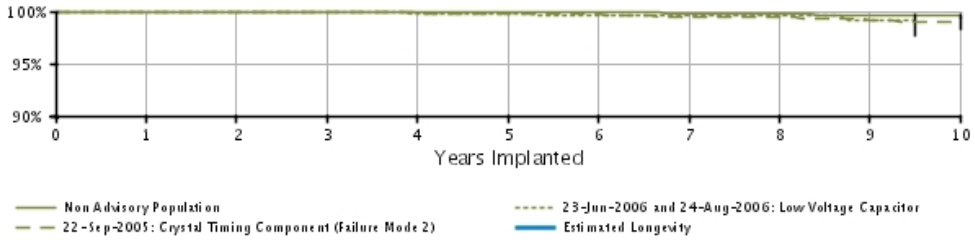
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 2,467
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:40
Without Compromised Therapy:36
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)	99.91 (-0.1/+0.0)	99.70 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.54 (-0.4/+0.3)	93.47 (-0.6/+0.6)	84.58 (-0.9/+0.9)	72.37 (-1.4/+1.3)	61.17 (-2.2/+2.1)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.70 (-0.2/+0.1)	99.67 (-0.2/+0.1)	99.61 (-0.3/+0.2)
	Effective Sample Size	14142	12077	10290	8825	7693	6741	5719	4401	1678	383
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.10 (-0.9/+0.5)	98.46 (-1.2/+0.7)	97.21 (-1.6/+1.0)	93.23 (-2.5/+1.8)	83.13 (-3.7/+3.2)	68.15 (-4.7/+4.4)	63.57 @ 114 mo. (-4.9/+4.7)
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.20 (-1.6/+0.5)	99.20 @ 114 mo. (-1.6/+0.5)
	Effective Sample Size	1147	962	811	698	587	500	418	331	232	200
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.22 (-0.4/+0.3)	98.27 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.33 (-1.5/+1.3)	76.24 (-2.2/+2.1)	62.41 (-2.6/+2.5)	52.60 (-2.8/+2.8)

Component (Failure Mode 2)* Registered Implants: 5000	(Confidence Interval)									
	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)	99.16 (-0.7/+0.4)	99.01 (-0.8/+0.4)
	Effective Sample Size	4142	3555	2997	2525	2108	1765	1414	1030	731	528

*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: 70

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[8] Low-voltage capacitor (Advisory issued)	1	3	
[20] Capacitor	1	-	
[46] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[26] Seal plug	3	-	
[27] Header	-	1	
Software	**1**	**-**	**1**
[30] Memory error	1	-	
Other	**58**	**-**	**58**
Non-patterned	1	-	
[13] Longevity labeling	23	-	
[37] Battery depletion	2	-	
[67] Battery status	32	-	
WW Confirmed Malfunctions	**64**	**6**	**70**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

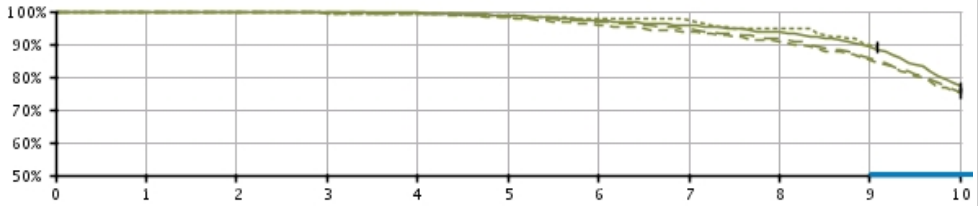
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

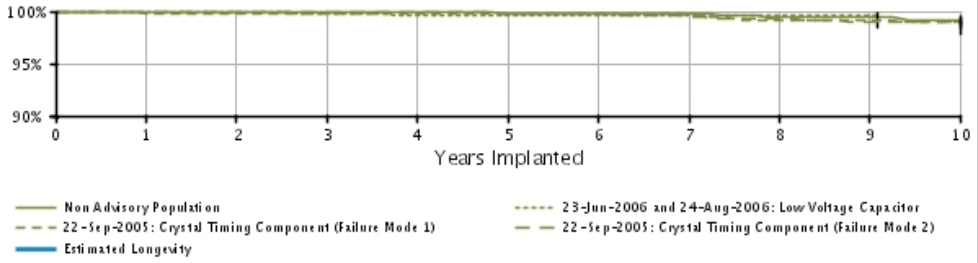
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1,755
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:65
Without Compromised Therapy:58
With Compromised Therapy:7

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.2/+0.2)	98.72 (-0.4/+0.3)	97.05 (-0.6/+0.5)	95.66 (-0.7/+0.6)	93.51 (-0.9/+0.8)	89.39 (-1.3/+1.2)	77.24 (-2.6/+2.4)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.43 (-0.3/+0.2)	99.21 (-0.5/+0.3)
	Effective Sample Size	6261	5548	4914	4354	3806	3311	2888	2414	1301	392
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)	99.23 (-1.3/+0.5)	98.75 (-1.5/+0.7)	97.65 (-2.0/+1.1)	97.31 (-2.2/+1.2)	94.51 (-3.1/+2.0)	89.86 (-4.2/+3.0)	89.41 @ 109 mo. (-4.2/+3.1)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 @ 109 mo. (-1.2/+0.3)
	Effective Sample Size	692	606	527	450	392	335	292	245	203	201
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.69 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.19 (-0.7/+0.4)	98.09 (-1.0/+0.7)	95.93 (-1.4/+1.1)	93.69 (-1.8/+1.4)	90.92 (-2.2/+1.8)	85.21 (-2.9/+2.5)	75.03 (-3.7/+3.4)

	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.19 (-1.0/+0.5)	99.19 (-1.0/+0.5)	98.95 (-1.2/+0.6)
	Effective Sample Size	1676	1454	1213	1063	922	785	662	554	451	333
22-Sep-05 Crystal Timing Component (Failure Mode 2)* 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)	96.91 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.55 (-1.0/+0.9)	85.58 (-1.4/+1.3)	75.45 (-1.8/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.47 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.97 (-0.5/+0.3)	98.91 (-0.5/+0.3)
	Effective Sample Size	6207	5479	4821	4227	3691	3185	2675	2259	1850	1403

*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: 37,000
Worldwide Confirmed Malfunctions: 80

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

More details about malfunctions

References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

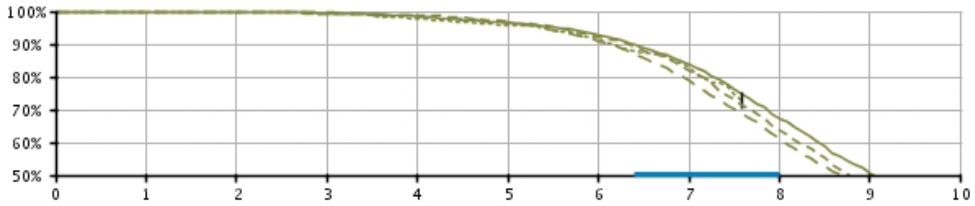
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

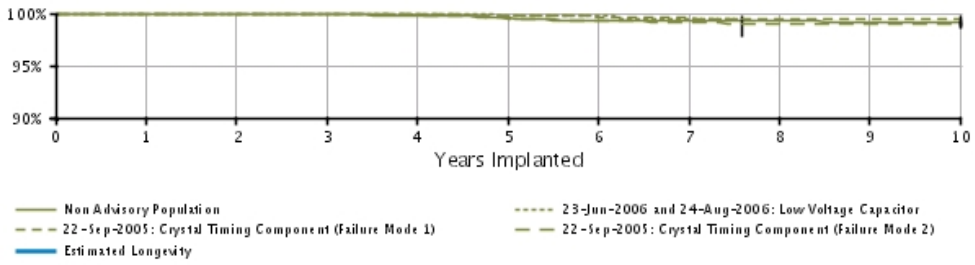
U.S. Registered Implants: 24,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 5,021
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:98
Without Compromised Therapy:92
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)	98.41 (-0.4/+0.3)	96.58 (-0.5/+0.5)	92.98 (-0.8/+0.7)	83.71 (-1.2/+1.1)	67.50 (-1.6/+1.6)	50.76 (-2.0/+2.0)	40.02 (-2.4/+2.4)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.99 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.57 (-0.2/+0.2)	99.37 (-0.3/+0.2)	99.31 (-0.3/+0.2)	99.23 (-0.3/+0.2)	99.15 (-0.4/+0.3)	99.15 (-0.4/+0.3)
	Effective Sample Size	7137	6277	5493	4775	4106	3502	2767	1886	786	226
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)	91.88 (-3.0/+2.2)	82.91 (-4.3/+3.6)	72.97 @ 91 mo. (-5.1/+4.6)	–	–
	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)	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	401	327	248	202	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.02 (-1.5/+1.3)	81.77 (-2.2/+2.0)	63.91 (-2.9/+2.8)	45.62 (-3.2/+3.2)	31.70 (-3.1/+3.3)

	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2735	2404	2070	1812	1514	1226	932	595	356	201
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)	90.84 (-0.8/+0.7)	79.00 (-1.2/+1.1)	61.15 (-1.5/+1.5)	44.76 (-1.6/+1.6)	35.67 (-1.6/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.52 (-0.2/+0.1)	99.26 (-0.3/+0.2)	99.14 (-0.3/+0.2)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)
	Effective Sample Size	9583	8451	7364	6363	5501	4507	3327	2156	1308	889

*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: 120

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	1	
[20] Capacitor	1	-	
[46] Integrated circuit	-	3	
Mechanical	**-**	**3**	**3**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
[14] Solder bond	-	1	
Software	**4**	**-**	**4**
[25] Memory error	1	-	
[51] Underestimation of battery status	1	-	
[52] Interrupted telemetry	2	-	
Other	**106**	**2**	**108**
Non-patterned	5	2	
[13] Longevity labeling	96	-	
[37] Battery depletion	1	-	
[67] Battery status	4	-	
WW Confirmed Malfunctions	**111**	**9**	**120**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

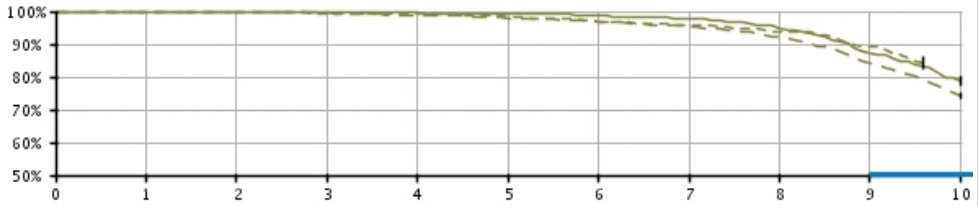
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

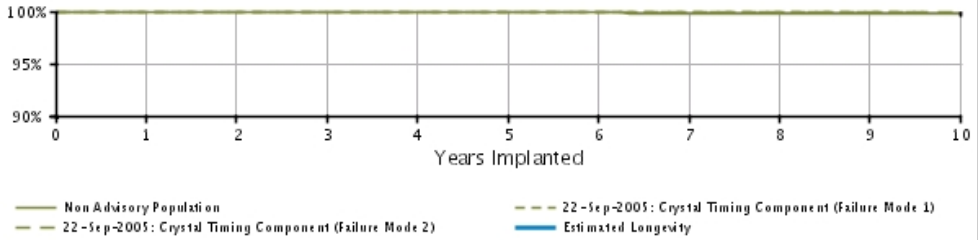
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 905
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)	97.89 (-0.7/+0.5)	94.84 (-1.1/+0.9)	87.22 (-2.0/+1.8)	78.66 (-3.3/+2.9)
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)
	Effective Sample Size	4707	3871	3248	2733	2306	1977	1718	1380	693	238
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.20 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.95 (-1.8/+1.1)	95.71 (-2.1/+1.5)	93.92 (-2.7/+1.9)	89.40 (-3.7/+2.8)	84.28 @ 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	1215	997	805	660	548	445	354	296	243	202
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.94 (-0.8/+0.6)	95.25 (-1.0/+0.8)	92.16 (-1.3/+1.2)	84.02 (-2.0/+1.8)	74.33 (-2.5/+2.3)

Component (Failure Mode 2)* Registered Implants: 6000	(Confidence Interval)										
	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	4575	3824	3171	2631	2174	1818	1529	1274	1010	778

*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: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[20] Capacitor	2	2	
[46] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[11] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[22] Capacitor array	-	2	
[26] Seal plug	-	2	
[49] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**12**	**1**	**13**
Non-patterned	1	1	
[13] Longevity labeling	6	-	
[67] Battery status	5	-	
WW Confirmed Malfunctions	**16**	**11**	**27**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

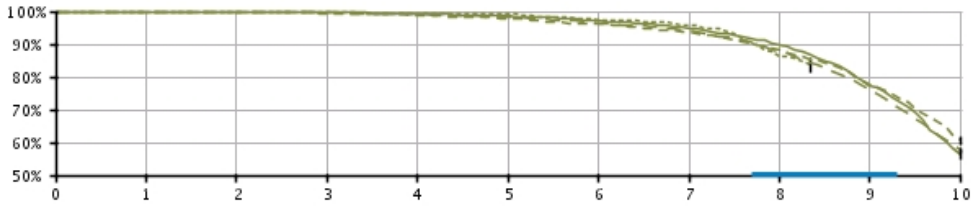
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

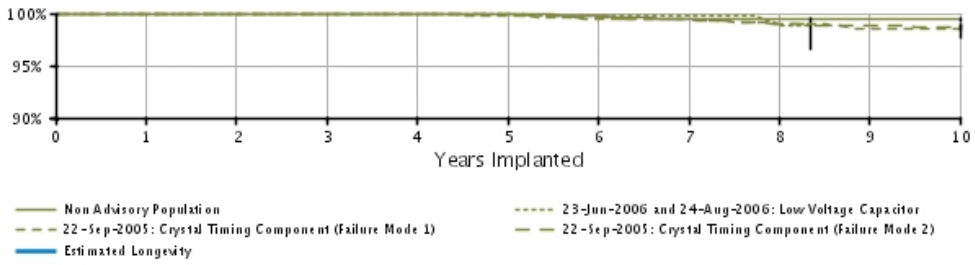
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 5,057
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:127
Without Compromised Therapy:118
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)	97.16 (-0.6/+0.5)	94.98 (-0.7/+0.7)	89.80 (-1.1/+1.0)	77.47 (-1.8/+1.7)	56.43 (-3.0/+3.0)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.49 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)
	Effective Sample Size	6561	5832	5161	4547	3998	3497	3029	2463	1152	321
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.19 (-1.3/+0.5)	99.19 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.95 (-2.6/+1.6)	86.23 (-4.5/+3.5)	83.75 @ 100 mo. (-4.8/+3.9)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.85 (-2.4/+0.8)	98.85 @ 100 mo. (-2.4/+0.8)	–
	Effective Sample Size	664	580	510	442	386	333	285	221	202	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-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)	88.09 (-1.7/+1.5)	77.80 (-2.2/+2.1)	60.58 (-2.8/+2.7)

	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.5/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3514	3072	2597	2280	1971	1704	1456	1208	928	612
22-Sep-05 Crystal Timing Component (Failure Mode 2)* 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)	76.07 (-1.2/+1.1)	57.63 (-1.4/+1.4)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.1)	99.58 (-0.2/+0.1)	99.38 (-0.2/+0.2)	99.05 (-0.3/+0.2)	98.80 (-0.3/+0.3)	98.70 (-0.3/+0.3)
	Effective Sample Size	12755	11251	9911	8722	7618	6594	5628	4611	3471	2253

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

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

INSIGNIA Plus DR

Model 1297

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

INSIGNIA Plus DR Model 1297

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 161

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[8] Low-voltage capacitor (Advisory issued)	1	1	
[20] Capacitor	2	1	
[46] Integrated circuit	-	1	
Mechanical	**16**	**8**	**24**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[11] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[14] Solder bond	1	-	
[22] Capacitor array	1	-	
[26] Seal plug	5	-	
[27] Header	8	5	
Software	**7**	**-**	**7**
[51] Underestimation of battery status	4	-	
[52] Interrupted telemetry	2	-	
[53] Pacing rate limit	1	-	
Other	**120**	**4**	**124**
Non-patterned	7	4	
[13] Longevity labeling	89	-	
[37] Battery depletion	2	-	
[67] Battery status	22	-	
WW Confirmed Malfunctions	**146**	**15**	**161**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

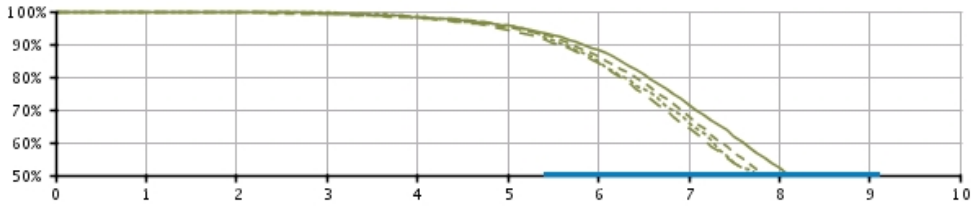
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

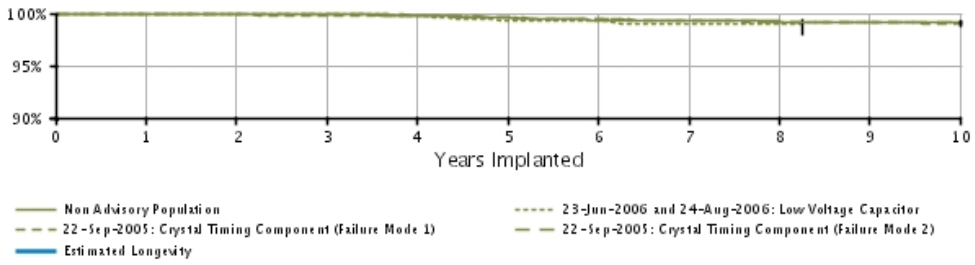
U.S. Registered Implants: 90,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 27,001
U.S. Unconfirmed Reports of Premature Battery Depletion : 114
U.S. Malfunctions:371
Without Compromised Therapy:342
With Compromised Therapy:29

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.41 (-0.1/+0.1)	98.27 (-0.2/+0.2)	95.60 (-0.4/+0.4)	88.23 (-0.6/+0.6)	71.46 (-0.9/+0.9)	52.13 (-1.1/+1.1)	34.68 (-1.2/+1.2)	22.06 (-1.4/+1.5)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.35 (-0.2/+0.1)	99.26 (-0.2/+0.1)	99.17 (-0.2/+0.2)	99.09 (-0.3/+0.2)	99.09 (-0.3/+0.2)
	Effective Sample Size	16866	14982	13239	11651	10059	8185	5792	3570	1239	278
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)	84.84 (-2.6/+2.3)	65.83 (-3.5/+3.4)	45.28 (-3.8/+3.9)	38.68 @ 99 mo. (-3.8/+4.0)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.70 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)	98.91 @ 99 mo. (-1.0/+0.5)	–
	Effective Sample Size	1419	1249	1111	963	824	640	432	250	202	–
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)	67.65 (-1.1/+1.1)	46.92 (-1.3/+1.3)	31.71 (-1.3/+1.3)	21.67 (-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)	99.02 (-0.4/+0.3)
	Effective Sample Size	13681	12071	10372	9051	7723	6109	4087	2332	1282	713
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)	84.12 (-0.4/+0.4)	64.16 (-0.6/+0.6)	44.04 (-0.7/+0.7)	29.64 (-0.7/+0.7)	20.45 (-0.6/+0.6)
	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	47024	41684	36742	32063	27278	21090	13637	7711	4265	2416

*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: 447

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**11**	**10**	**21**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[17] Capacitor	-	1	
[20] Capacitor	6	2	
[23] Integrated circuit	-	1	
[46] Integrated circuit	5	3	
Mechanical	**21**	**22**	**43**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
[11] Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
[14] Solder bond	1	-	
[22] Capacitor array	3	1	
[26] Seal plug	3	1	
[27] Header	5	-	
[49] Seal plug	1	-	
Software	**11**	**-**	**11**
[30] Memory error	1	-	
[50] Interrogation at EOL	2	-	
[51] Underestimation of battery status	6	-	
[52] Interrupted telemetry	1	-	
[53] Pacing rate limit	1	-	
Other	**361**	**11**	**372**
Non-patterned	28	9	
[13] Longevity labeling	310	-	
[24] Battery depletion	2	1	
[28] Magnet response	1	-	
[37] Battery depletion	11	1	
[67] Battery status	9	-	
WW Confirmed Malfunctions	**404**	**43**	**447**

More details about malfunctions

References cited in table above

INSIGNIA Plus SR

Model 1194

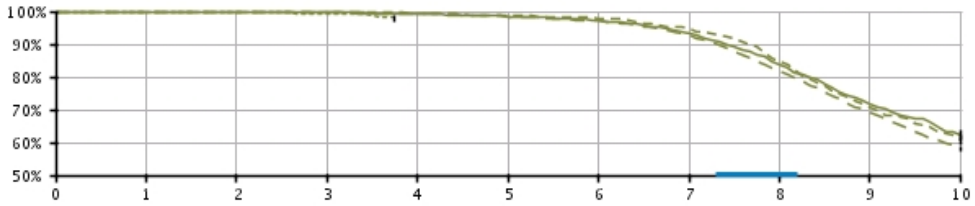
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

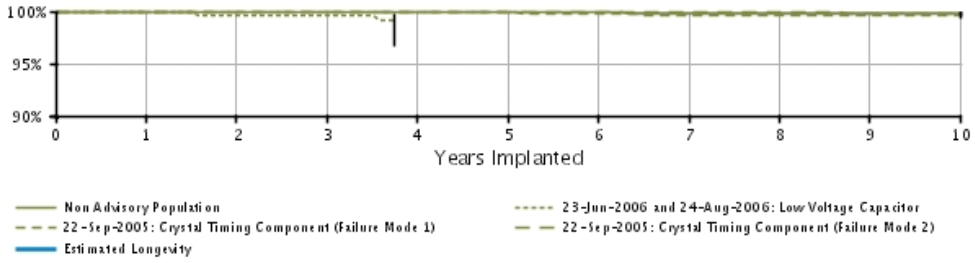
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 3,367
U.S. Unconfirmed Reports of Premature Battery Depletion : 8
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)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.59 (-0.3/+0.2)	99.31 (-0.3/+0.2)	98.44 (-0.5/+0.4)	97.26 (-0.7/+0.6)	93.23 (-1.1/+1.0)	83.51 (-1.7/+1.6)	71.76 (-2.4/+2.3)	62.41 (-3.2/+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)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)
	Effective Sample Size	4724	4028	3445	2881	2464	2119	1779	1349	621	236
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: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.89 (-0.2/+0.1)	99.73 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.74 (-0.6/+0.4)	98.00 (-0.7/+0.5)	94.83 (-1.2/+1.0)	84.81 (-2.2/+1.9)	70.86 (-2.9/+2.7)	60.66 (-3.2/+3.1)

	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.92 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.76 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)
	Effective Sample Size	3452	2916	2416	2063	1737	1431	1165	870	614	452
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)	97.08 (-0.4/+0.4)	92.83 (-0.7/+0.6)	81.74 (-1.1/+1.0)	69.43 (-1.4/+1.3)	58.07 (-1.5/+1.5)
	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	13682	11685	10054	8508	7142	6001	4889	3610	2589	1871

*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: 36

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[8] Low-voltage capacitor (Advisory issued)	1	2	
[20] Capacitor	2	2	
[23] Integrated circuit	-	1	
[46] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[22] Capacitor array	1	-	
[26] Seal plug	-	1	
Software	**1**	**-**	**1**
[53] Pacing rate limit	1	-	
Other	**18**	**1**	**19**
Non-patterned	4	-	
[13] Longevity labeling	10	-	
[24] Battery depletion	-	1	
[37] Battery depletion	1	-	
[67] Battery status	3	-	
WW Confirmed Malfunctions	**24**	**12**	**36**

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: 95

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[20] Capacitor	-	1	
[46] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[26] Seal plug	1	-	
[27] Header	1	-	
Software	**-**	**-**	**0**
Other	**86**	**2**	**88**
Non-patterned	3	1	
[13] Longevity labeling	42	-	
[37] Battery depletion	-	1	
[67] Battery status	41	-	
WW Confirmed Malfunctions	**88**	**7**	**95**

More details about malfunctions

References cited in table above

References

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

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

1. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory.* Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
3. **High cathode condition 2011**— *June 1, 2011 Voluntary Physician Advisory.* Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **Subpectoral implant 2009**— *December 01, 2009 Voluntary Physician Advisory.* Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subpectorally. Weakened bond between header and titanium case. Improvement implemented.
5. **Respiratory Sensor Oversensing**— *March 23, 2009 Voluntary Physician Advisory.* Oversensing, noise, inappropriate shock, pacing inhibition. When Respiratory Sensor is ON, RV lead or system complications may cause oversensing or noise. Improvement implemented.
6. **Subpectoral implant**— *May 12, 2006 and January 04, 2008 Voluntary Physician Advisory.* Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications, loss of pacing (intermittent or permanent) and/or loss of shock therapy. Repetitive mechanical stress-induced component damage, only when implanted subpectorally with the serial number facing the ribs. Improvement implemented.
7. **Shortened replacement window**— *April 05, 2007 and March 04, 2009 Voluntary Physician Advisory.* Accelerated battery depletion may reduce time between elective replacement (ERI) and end of life (EOL) indicators to less than three months. Device replacement indicators continue to function normally. Degradation of low-voltage capacitor. Improvement implemented.
8. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory.* Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
9. **Premature battery depletion**— *May 12, 2006 Voluntary Physician Advisory.* Premature battery depletion, significantly shortened longevity and duration between elective replacement (ERI) and end of life (EOL) indicators. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
10. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
11. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
12. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.
13. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
14. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
15. **Firmware error**— Device beeping unaffected by magnet application, missing EGMs, loss of telemetry, loss of tachy therapy. Multiple resets due to firmware error. Improvement implemented.
16. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
17. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
18. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
19. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.

20. **Capacitor**— No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.
21. **Battery depletion**— Premature battery depletion.
22. **Capacitor array**— Loss of device output, loss of capture, inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.
23. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
24. **Battery depletion**— Premature battery depletion and loss of capture.
25. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
26. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
27. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
28. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
29. **Battery depletion**— Premature battery depletion.
30. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
31. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
32. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
33. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
34. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
35. **Capacitor**— Premature battery depletion, significantly shortened ERI to EOL time. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
36. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
37. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
38. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
39. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
40. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
41. **Memory location**— Loss of pacing and/or shock therapy, premature battery depletion, inability to perform diagnostic testing, loss of telemetry, and/or incorrect diagnostic information. Incorrect data within a specific memory location.
42. **Mid-life display of replacement indicators**— Extended charge time resulting in early occurrence of ERI or EOL, or shortened ERI to EOL time. Please reference the ERI Charge Time Limit Extended During Mid-Life Product Update for more details. Improvement implemented.
43. **High-voltage capacitor**— In most cases, temporary long capform charge time; in some cases delayed therapy or loss of tachy therapy. Extended charge time could prompt EOL declaration. High-voltage capacitor issue.
44. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
45. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
46. **Integrated circuit**— Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing, loss of shock therapy. Damage to integrated circuit. Improvement implemented.
47. **Alert messages**— During programmer interactions, alert messages appear which are able to be cleared. In one case, an alert message occurred with two memory errors after multiple device resets.
48. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
49. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
50. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
51. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
52. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
53. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
54. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
55. **Connector block**— Connector block can be moved out of alignment or displaced from header. Prolonged implant procedure, high impedance, no pacing, no sensing. Improvement implemented.
56. **Misaligned markers**— Stored episode markers do not match recorded EGM. Software error when ventricular episode begins during ATR episode. New software was released in 2006 which prevents misaligned markers. Improvement implemented.
57. **Seal plug**— Non-cardiac signals on electrograms may result in loss of pacing or inappropriate shocks. Seal plug allows air in lead port to escape.

58. **Difficulty securing lead**— Noise, high impedance, inappropriate shocks or loss of therapy due to crossthreaded setscrews, intermittent or lack of contact between lead and header. Improvement implemented.
59. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
60. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
61. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
62. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
63. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
64. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
65. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
66. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
67. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
68. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
69. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
70. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
71. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
72. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
73. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
74. **Telemetry**— Inability to interrogate, premature battery depletion.
75. **Unintended Battery Depletion Alert**— Beeping tones, Battery Depletion alert during followup despite normal battery depletion. Alert may be cleared without impact to battery status or therapy availability. Improvement implemented.
76. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
77. **Respiratory sensor**— Temporary increase or decrease in pacing rate as a result of respiratory sensor response to non-respiratory signals. No loss of pacing output.
78. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.
79. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
80. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
81. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor
82. **High voltage capacitor**— Charge time alert message, end of life (EOL) indicator displayed, beeping tones. Loss of tachy therapy without loss of brady therapy. Internal high-voltage capacitor issue. Improvement implemented.
83. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement Implemented.

Before/During Implant Procedure - Worldwide Malfunctions: Pulse Generators

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling (e.g. radiation) is not reported as device malfunction here.
The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.

CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN CRT-D G160/G161/G164/G166/G172/G173/G175/ G177/G179	14,000	2	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	36,000	2	1	0	5	0	0
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/ N143/N160/N161/N162/N163/N164/N165/ P052/P053/P142/P143/P162/P163/P165	81,000	10	0	0	10	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	24	50	4	26	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE V172/V173/V182/V183/W172/W173	12,000	0	0	0	1	0	0
INTUA V272/V273/V282/V283/W272/W273	3,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	17,000	0	0	1	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN ICD EL VR D160/D161/D174/D175	7,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	7,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	16,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	15,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	9,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	9,000	1	0	0	2	0	0

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

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	12,000	0	0	0	12	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	23	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	31,000	0	0	0	1	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	73,000	0	0	0	4	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	25,000	0	0	0	2	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	68,000	1	1	0	3	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	213,000	4	1	1	13	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	82,000	0	0	1	3	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	56,000	1	11	0	2	0	0
ALTRUA 50 SR S501	24,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	46,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	11,000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0

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

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INSIGNIA Entra SR 1195/1198*	52,000	1	0	3	5	0	0
INSIGNIA Entra DR (Downsize) 1296*	47,000	1	7	6	3	0	0
INSIGNIA Entra DR 1294/1295*	37,000	0	6	3	9	0	0
INSIGNIA Plus SR 1194*	51,000	1	5	13	5	0	0
INSIGNIA Plus DR (Downsize) 1298*	140,000	3	16	30	7	0	1
INSIGNIA Plus DR 1297*	47,000	0	7	8	6	0	1
INSIGNIA AVT 0482/0882/0982/1192/1292*	51,000	1	1	0	3	0	0

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

U.S. Reason for Out of Service

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

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

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	22000	2	3	11	6	186	785
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	52000	97	23	55	78	824	8232
COGNIS N118/N119/N120/P106/P107/P108	75000	1731	99	58	1305	1689	29396

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
VISIONIST/VALITUDE U125/U128/U225/U226/U228	5000	0	0	34	0	22	152
INTUA V272/V273/V282/V283/W272/W273	2000	3	0	16	1	15	196
INVIVE V172/V173/V182/V183/W172/W173	8000	20	0	38	1	53	1323
CONTAK RENEWAL TR H120/H125	19000	2529	16	151	50	255	9763

S-ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
EMBLEM S-ICD A209, A219	6000	0	0	2	2	96	125
SQ-RX S-ICD 1010	8000	46	1	16	35	246	598

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	9000	1	0	41	0	63	175
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	9000	1	1	42	0	49	148
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	5000	1	1	21	1	47	234
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	4000	2	0	29	2	42	222
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	36	4	262	35	434	4377
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	37	4	339	49	534	5534

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	85	73	566	994	630	11858
TELIGEN DR E110/E111/F110/F111	66000	222	118	787	1515	1125	21487
CONFIENT DR E030/F030	7000	321	2	133	14	155	3013
VITALITY 2 EL VR T177	7000	1244	9	159	1274	114	2755
VITALITY 2 EL DR T167	8000	2240	14	159	769	133	3405

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	12000	2	0	39	1	32	162
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	38000	5	3	125	3	141	757

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	7000	1	0	37	0	30	285
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	2	0	81	3	48	610
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	121000	82	9	603	27	658	12965
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	26000	12	0	140	7	134	4734
ALTRUA 60 SR S601	32000	406	3	225	6	168	13880
ALTRUA 60 DR (Downsize) S603	90000	6401	44	532	51	557	28756
ALTRUA 60 DR S602	22000	398	3	174	10	192	7044
ALTRUA 60 DR EL S606	59000	353	10	370	9	412	14623
ALTRUA 40 SR S401	5000	58	0	24	2	22	2259
ALTRUA 40 DR (downsize) S403	14000	989	2	56	3	78	4791
ALTRUA 40 DR S402	2000	33	1	15	0	8	706
ALTRUA 40 DR EL S404	5000	29	1	32	0	43	1647
ALTRUA 20 SR S201/S204	5000	38	1	18	0	36	2386
ALTRUA 20 DR (downsize) S203	5000	153	3	26	0	36	2119

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 20 DR S202/S205	2000	41	0	7	1	13	790
ALTRUA 20 DR EL S208	3000	17	0	21	1	10	1160
INSIGNIA Ultra SR 1190 [4]	24000	2467	9	213	42	146	16348
INSIGNIA Ultra DR (Downsize) 1290 [4]	76000	20776	115	568	438	601	39814
INSIGNIA Ultra DR 1291 [4]	32000	3873	21	329	169	308	15544
INSIGNIA Entra SR 1195/1198 [4]	14000	905	10	88	9	75	10561
INSIGNIA Entra DR (Downsize) 1296 [4]	24000	5021	25	128	98	152	15520
INSIGNIA Entra DR 1294/1295 [4]	17000	1755	14	129	65	183	10894
INSIGNIA Plus SR 1194 [4]	27000	3367	8	225	27	155	20669
INSIGNIA Plus DR (Downsize) 1298 [4]	90000	27001	114	541	374	699	52445
INSIGNIA Plus DR 1297 [4]	27000	5057	20	264	131	261	15152

[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 X4 Spiral L

Models 4677/4678

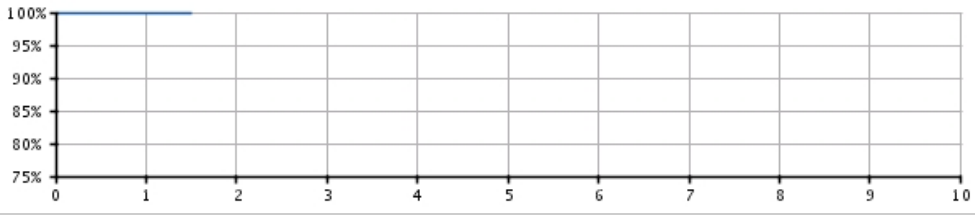
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 2,000

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 Registered Implants: 2000	100.00 (-0.0/+0.0)	100.00 @ 18 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	399	218	–	–	–	–	–	–	–	–

ACUITY X4 Spiral L

Models 4677/4678

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

ACUITY X4 Spiral L
Models 4677/4678

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ACUITY X4 Spiral S

Models 4674/4675

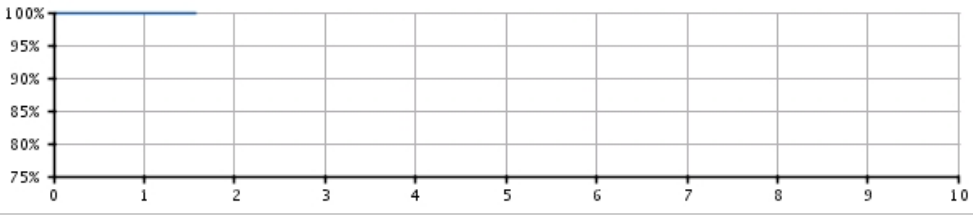
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 3,000

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 Registered Implants: 3000	100.00 (-0.0/+0.0)	100.00 @ 19 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	531	222	–	–	–	–	–	–	–	–

ACUITY X4 Spiral S

Models 4674/4675

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

ACUITY X4 Spiral S Models 4674/4675

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ACUITY X4 Straight

Models 4671/4672

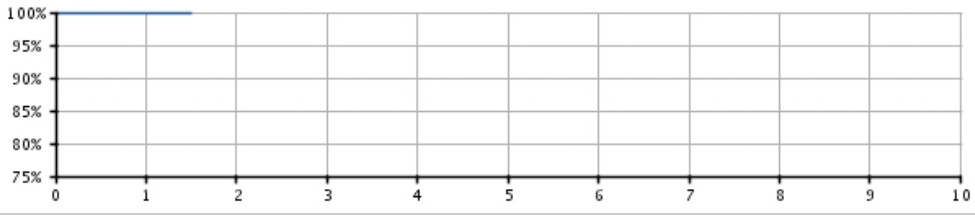
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 2,000

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 Registered Implants: 2000	100.00 (-0.0/+0.0)	100.00 @ 18 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	408	216	–	–	–	–	–	–	–	–

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ACUITY Spiral

Models 4591/4592/4593

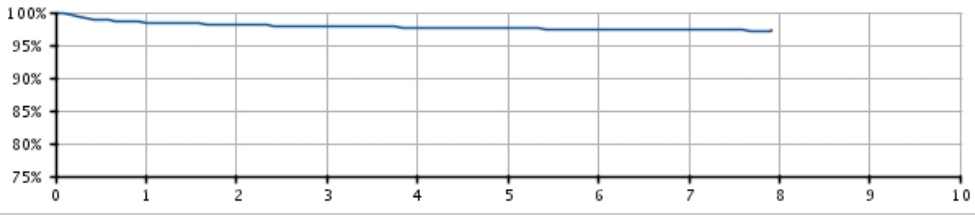
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 23,000
U.S. Approval Date: May 2006
U.S. Estimated Active Implants: 15,000

U.S. Chronic Lead Complications: 435
U.S. Malfunctions:8
Without Compromised Therapy:4
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 Registered Implants: 21000	98.50 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.88 (-0.2/+0.2)	97.70 (-0.2/+0.2)	97.54 (-0.3/+0.2)	97.42 (-0.3/+0.2)	97.38 (-0.3/+0.3)	97.18 @ 95 mo. (-0.5/+0.4)	–	–
Effective Sample Size	18389	14972	11504	8381	5794	3349	1512	228	–	–

ACUITY Spiral

Models 4591/4592/4593

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

ACUITY Spiral Models 4591/4592/4593

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 8

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

More details about malfunctions

References cited in table above

ACUITY Spiral Longitude*

Models 4591/4592/4593

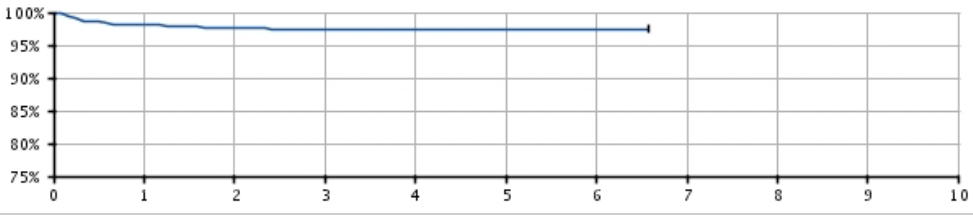
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1379
Leads Active: 905
Cumulative Followup Months : 43,899

Chronic Lead Complications: 33
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: 1379	98.01 (-1.6/+1.6)	97.64 (-1.7/+1.7)	97.30 (-1.9/+1.9)	97.30 (-1.9/+1.9)	97.30 (-1.9/+1.9)	97.30 (-1.9/+3.8)	97.30 @ 79 mo. (-1.9/+3.8)	–	–	–
Effective Sample Size	1130	964	741	580	380	168	63	–	–	–

ACUITY Steerable

Models 4554/4555/4556

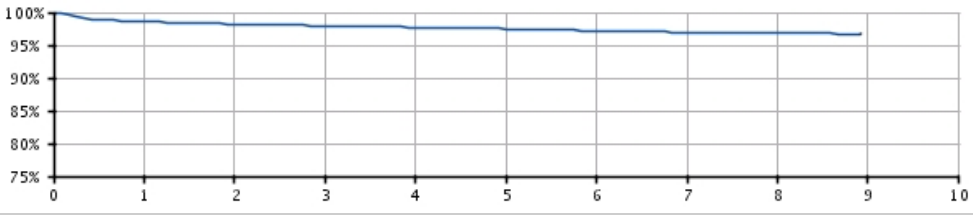
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 17,000

U.S. Chronic Lead Complications: 577
U.S. Malfunctions:32
Without Compromised Therapy:11
With Compromised Therapy:21

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 29000	98.58 (-0.1/+0.1)	98.22 (-0.2/+0.2)	97.95 (-0.2/+0.2)	97.73 (-0.2/+0.2)	97.47 (-0.2/+0.2)	97.21 (-0.3/+0.2)	96.97 (-0.3/+0.3)	96.94 (-0.3/+0.3)	96.75 @ 107 mo. (-0.4/+0.4)	–
Effective Sample Size	23883	20118	16163	12827	9802	6939	4323	2021	296	–

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 63,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**36**	**46**
[25] Conductor fracture	1	-	
[27] Non-patterned, Conductor	6	9	
[34] Extracardiac fracture	3	27	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**6**	**1**	**7**
[26] Non-patterned, Other	6	1	
WW Confirmed Malfunctions	**16**	**38**	**54**

More details about malfunctions

References cited in table above

EASYTRAK 3

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

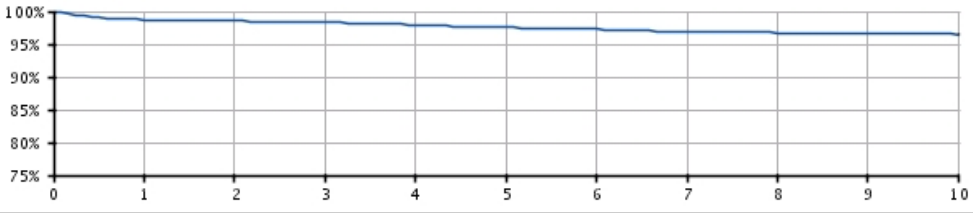
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 22,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 10,000

U.S. Chronic Lead Complications: 435
U.S. Malfunctions:30
Without Compromised Therapy:7
With Compromised Therapy:23

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	98.71 (-0.2/+0.1)	98.53 (-0.2/+0.2)	98.30 (-0.2/+0.2)	97.97 (-0.2/+0.2)	97.57 (-0.3/+0.2)	97.28 (-0.3/+0.3)	96.88 (-0.3/+0.3)	96.73 (-0.3/+0.3)	96.57 (-0.4/+0.3)	96.48 (-0.4/+0.4)
Effective Sample Size	18162	15556	12899	10515	8543	6880	5409	4084	2984	1747

EASYTRAK 3

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

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

EASYTRAK 3
Models 4522/4524/4525/4527/4548/ 4549/4550

Worldwide Distribution: 42,000
Worldwide Confirmed Malfunctions: 48

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

More details about malfunctions

References cited in table above

EASYTRAK 2

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

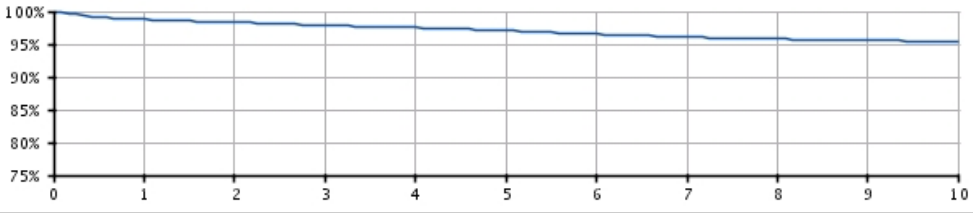
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 96,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 44,000

U.S. Chronic Lead Complications: 2,186
U.S. Malfunctions:345
Without Compromised Therapy:90
With Compromised Therapy:255

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 96000	98.78 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.89 (-0.1/+0.1)	97.52 (-0.1/+0.1)	97.06 (-0.1/+0.1)	96.52 (-0.2/+0.1)	96.08 (-0.2/+0.2)	95.78 (-0.2/+0.2)	95.60 (-0.2/+0.2)	95.34 (-0.2/+0.2)
Effective Sample Size	80194	68474	57061	47042	38307	30055	22798	16587	11472	6676

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: 176,000
Worldwide Confirmed Malfunctions: 481

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**98**	**357**	**455**
[25] Conductor fracture	94	310	
[27] Non-patterned, Conductor	4	47	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**11**	**2**	**13**
[28] Non-patterned, Insulation	11	2	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**117**	**364**	**481**

More details about malfunctions

References cited in table above

EASYTRAK

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

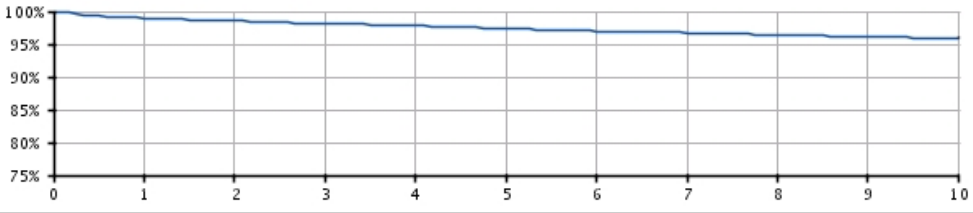
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 906
U.S. Malfunctions:24
Without Compromised Therapy:10
With Compromised Therapy:14

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population 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)	96.75 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.93 (-0.3/+0.3)
Effective Sample Size	30533	26246	22511	19338	16504	14110	12108	10497	8984	7644

EASYTRAK

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

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

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

Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 26

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

More details about malfunctions

References cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

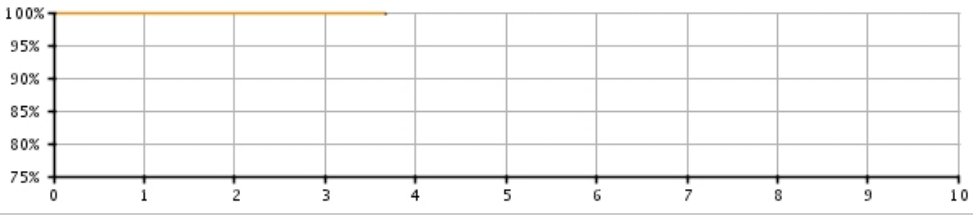
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 13,000

U.S. Chronic Lead Complications: 9
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 Registered Implants: 14000	99.87 (-0.1/+0.1)	99.78 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.78 @ 44 mo. (-0.2/+0.1)	–	–	–	–	–	–
Effective Sample Size	6658	2307	387	212	–	–	–	–	–	–

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

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

EMBLEM/Q-TRAK S-ICD Electrode Models 3010/3401

Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**-**	**0**
Crimp/Weld/Bond	**-**	**1**	**1**
[37] Weld fracture	-	1	
Insulation	**-**	**-**	**0**
Other	**-**	**2**	**2**
[27] Non-patterned, other	-	2	
WW Confirmed Malfunctions	**0**	**3**	**3**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

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

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

Worldwide Distribution: 9,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation

Models 0657/0692/0693

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

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

Worldwide Distribution: 29,000

Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**4**	**4**
[27] Non-patterned, Conductor	-	1	
[38] Conductor cable fracture	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**-**	**-**	**0**
[26] Non-patterned, Other	-	-	
WW Confirmed Malfunctions	**0**	**5**	**5**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation

Models 0655/0685/0686

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

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

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation

Models 0654/0682/0683

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

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

Worldwide Distribution: 2,000

Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276/0295/0296

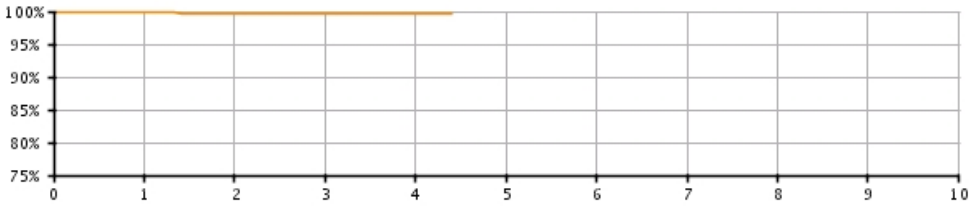
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 55,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 48,000

U.S. Chronic Lead Complications: 141
U.S. Malfunctions:9
Without Compromised Therapy:0
With Compromised Therapy:9

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 54000	99.79 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.60 (-0.1/+0.1)	99.57 @ 53 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	41447	28364	16040	4314	525	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models 0275/0276/0295/0296

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

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation Models 0275/0276/0295/0296

Worldwide Distribution: 90,000

Worldwide Confirmed Malfunctions: 36

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

More details about malfunctions

References cited in table above

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

Models 0275/0276/0295/0296

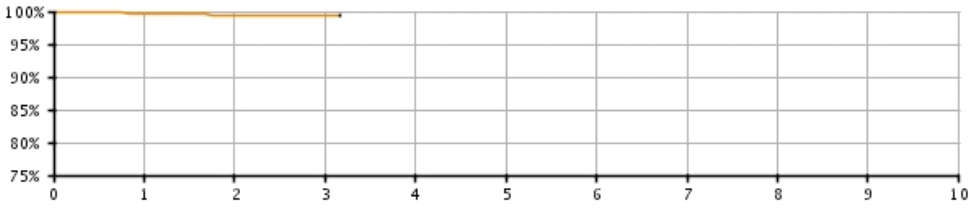
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 849
Leads Active: 654
Cumulative Followup Months : 19,862

U.S. Chronic Lead Complications: 2
U.S. 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: 849	99.74 (-0.8/+0.1)	99.45 (-1.3/+0.3)	99.45 (-1.3/+0.3)	99.45 @ 38 mo. (-1.3/+0.3)	–	–	–	–	–	–
Effective Sample Size	736	492	51	50	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

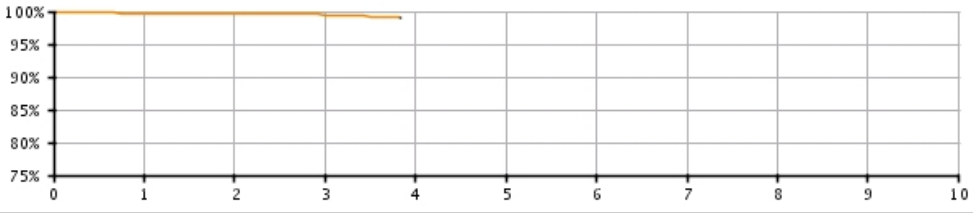
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 10
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 Registered Implants: 2000	99.72 (-0.3/+0.2)	99.56 (-0.5/+0.2)	99.38 (-0.7/+0.3)	99.09 @ 46 mo. (-1.1/+0.5)	–	–	–	–	–	–
Effective Sample Size	1772	1115	561	208	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

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

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation Models 0265/0266/0285/0286

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation

Models 0292/0293

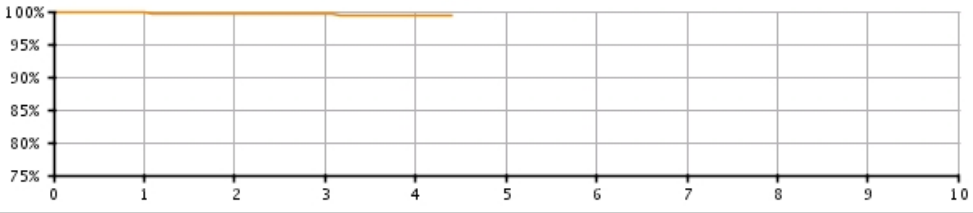
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 54,000

U.S. Chronic Lead Complications: 152
U.S. Malfunctions:9
Without Compromised Therapy:1
With Compromised Therapy:8

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 57000	99.77 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.55 (-0.1/+0.1)	99.47 (-0.1/+0.1)	99.47 @ 53 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	36750	19872	8574	1770	230	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation

Models 0292/0293

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

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

Worldwide Distribution: 97,000

Worldwide Confirmed Malfunctions: 28

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[24] Conductor fracture	-	1	
[27] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**21**	**23**
[28] Non-patterned, Insulation	2	21	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**26**	**28**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation Longitude

Models 0292/0293

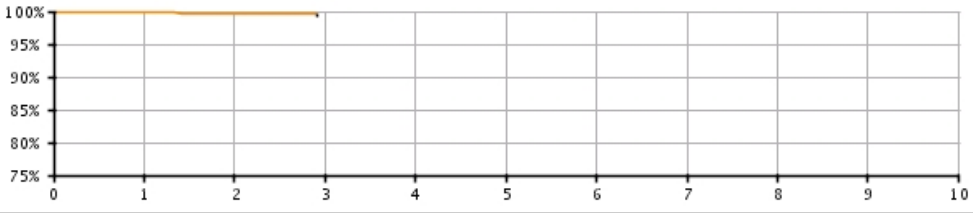
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1103
Leads Active: 940
Cumulative Followup Months : 25,383

Chronic Lead Complications: 4
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: 1103	99.89 (-0.6/+0.1)	99.52 (-1.7/+0.6)	99.52 @ 35 mo. (-1.7/+0.6)	–	–	–	–	–	–	–
Effective Sample Size	854	585	57	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

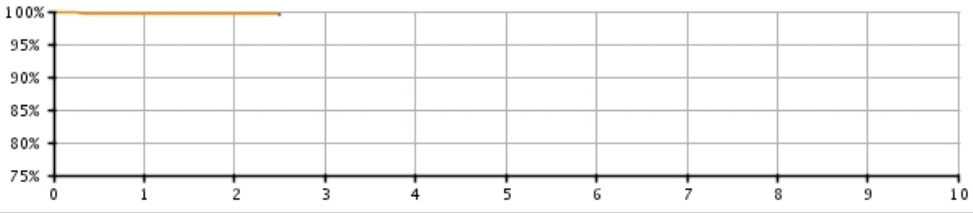
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

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

U.S. Chronic Lead Complications: 4
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 Registered Implants: 1000	99.57 (-0.7/+0.3)	99.57 (-0.7/+0.3)	99.57 @ 30 mo. (-0.7/+0.3)	–	–	–	–	–	–	–
Effective Sample Size	613	297	201	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

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

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

Worldwide Distribution: 4,000

Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
[28] Non-patterned, Insulation	-	1	
Other	1	-	1
[27] Non-patterned, other	1	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation

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

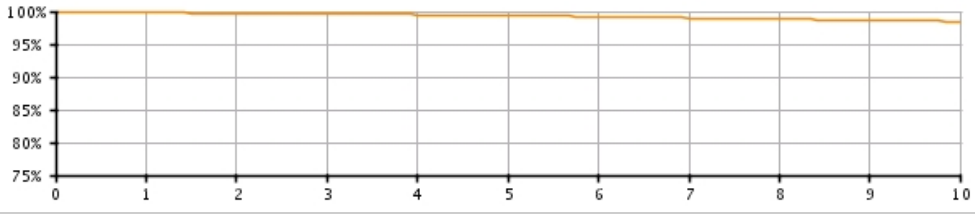
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 286,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 139,000

U.S. Chronic Lead Complications: 1,902
U.S. Malfunctions:285
Without Compromised Therapy:109
With Compromised Therapy:176

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 285000	99.80 (-0.0/+0.0)	99.70 (-0.0/+0.0)	99.61 (-0.0/+0.0)	99.50 (-0.0/+0.0)	99.37 (-0.0/+0.0)	99.20 (-0.0/+0.0)	99.00 (-0.0/+0.0)	98.84 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.47 (-0.1/+0.1)
Effective Sample Size	251245	223337	198044	174324	146280	116986	90568	66130	46467	32196

ENDOTAK RELIANCE
Dual Coil, Active Fixation

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

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

ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159/0164/0165/ 0166/0167/0184/0185/0186/ 0187

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 448

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**125**	**127**
[24] Conductor fracture	-	82	
[27] Non-patterned, Conductor	2	43	
Crimp/Weld/Bond	**5**	**1**	**6**
[5] Seal rings	2	1	
[31] Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	**145**	**121**	**266**
[28] Non-patterned, Insulation	145	121	
Other	**29**	**20**	**49**
[26] Non-patterned, Other	29	20	
WW Confirmed Malfunctions	**181**	**267**	**448**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation Longitude

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

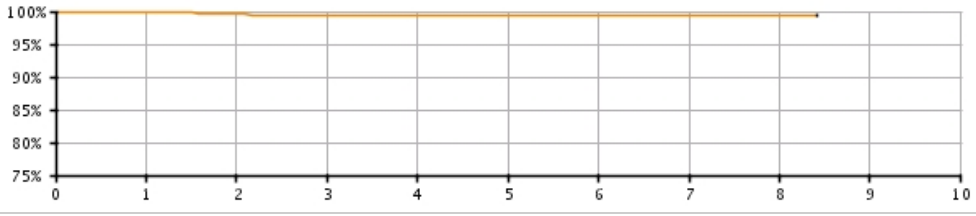
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 742
Leads Active: 402
Cumulative Followup Months : 25,993

U.S. Chronic Lead Complications: 2
U.S. 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: 741	100.00 (-0.0/+0.0)	99.67 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 @ 101 mo. (-1.2/+0.3)	–
Effective Sample Size	645	569	502	430	336	157	70	56	50	–

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

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

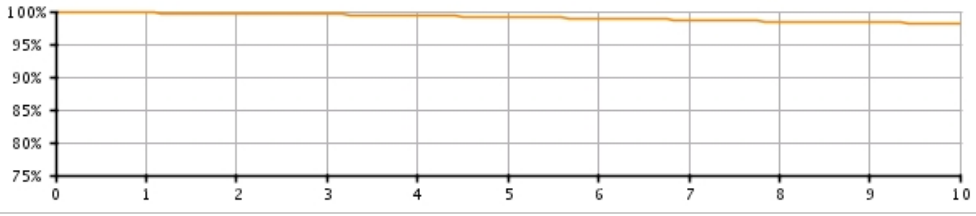
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 46,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 17,000

U.S. Chronic Lead Complications: 487
U.S. Malfunctions:38
Without Compromised Therapy:10
With Compromised Therapy:28

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.0/+0.0)	99.69 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.47 (-0.2/+0.1)	98.31 (-0.2/+0.2)	98.12 (-0.2/+0.2)
Registered Implants: 46000										
Effective Sample Size	40550	36090	32048	28206	24485	20941	17807	14923	12330	10168

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

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

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

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

Worldwide Distribution: 108,000

Worldwide Confirmed Malfunctions: 126

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**31**	**31**
[24] Conductor fracture	-	17	
[27] Non-patterned, Conductor	-	14	
Crimp/Weld/Bond	**-**	**3**	**3**
[36] Conductor connection	-	3	
Insulation	**37**	**44**	**81**
[28] Non-patterned, Insulation	37	44	
Other	**7**	**4**	**11**
[6] Manufacturing material	-	1	
[26] Non-patterned, Other	7	3	
WW Confirmed Malfunctions	**44**	**82**	**126**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

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

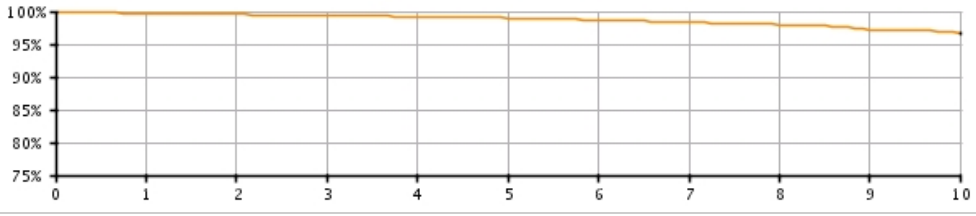
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 31,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 22,000

U.S. Chronic Lead Complications: 212
U.S. Malfunctions:56
Without Compromised Therapy:20
With Compromised Therapy:36

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 31000	99.69 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.01 (-0.2/+0.1)	98.72 (-0.2/+0.2)	98.37 (-0.3/+0.2)	97.95 (-0.4/+0.3)	97.21 (-0.7/+0.5)	96.79 (-0.9/+0.7)
Effective Sample Size	26462	22059	18088	14534	10042	6105	3708	1981	978	580

ENDOTAK RELIANCE
Single Coil, Active Fixation

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

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

ENDOTAK RELIANCE
Single Coil, Active Fixation
Models 0137/0138/0160/0161/0162/ 0180/0181/0182

Worldwide Distribution: 67,000

Worldwide Confirmed Malfunctions: 151

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**59**	**60**
[24] Conductor fracture	1	50	
[27] Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**48**	**30**	**78**
[28] Non-patterned, Insulation	48	30	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**57**	**94**	**151**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

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

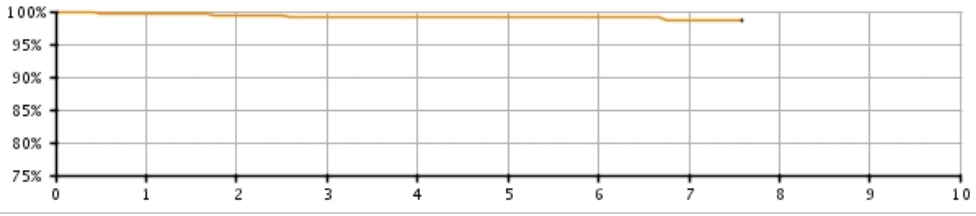
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 17
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.74 (-0.4/+0.2)	99.41 (-0.6/+0.3)	99.21 (-0.7/+0.4)	99.08 (-0.8/+0.4)	99.08 (-0.8/+0.4)	99.08 (-0.8/+0.4)	98.70 (-1.4/+0.7)	98.70 @ 91 mo. (-1.4/+0.7)	–	–
Effective Sample Size	1352	1082	846	609	458	315	234	202	–	–

ENDOTAK RELIANCE
Single Coil, Passive Fixation

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

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

ENDOTAK RELIANCE
Single Coil, Passive Fixation
Models 0127/0128/0170/0171/0172/ 0173

Worldwide Distribution: 7,000

Worldwide Confirmed Malfunctions: 16

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

More details about malfunctions

References cited in table above

ENDOTAK ENDURANCE
Passive Fixation

Models 0134/0135/0136

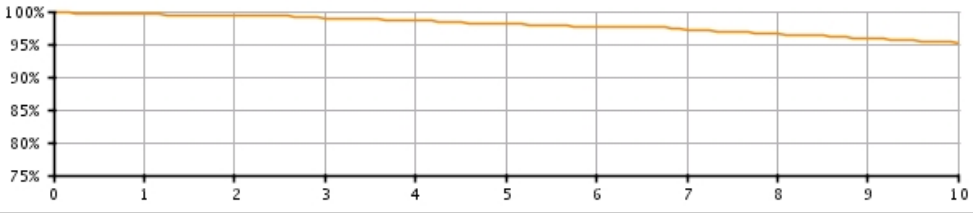
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: August 1998
U.S. Estimated Active Implants: 500

U.S. Chronic Lead Complications: 112
U.S. Malfunctions:3
Without Compromised Therapy:2
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.53 (-0.4/+0.2)	99.35 (-0.4/+0.3)	98.98 (-0.5/+0.3)	98.57 (-0.6/+0.4)	98.12 (-0.7/+0.5)	97.68 (-0.8/+0.6)	97.17 (-0.9/+0.7)	96.60 (-1.1/+0.8)	95.95 (-1.2/+0.9)	95.08 (-1.4/+1.1)
Registered Implants: 3000										
Effective Sample Size	2332	2067	1830	1609	1426	1251	1103	961	831	728

ENDOTAK ENDURANCE EZ
Active Fixation

Models 0154/0155/0156

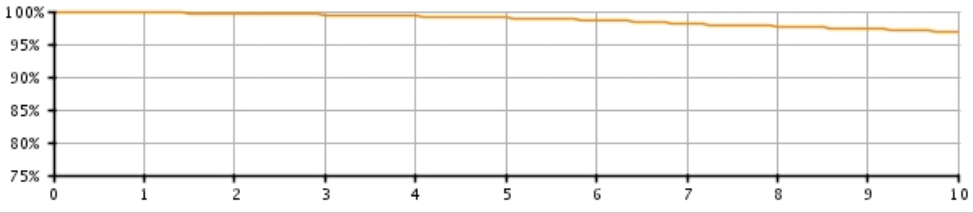
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 577
U.S. Malfunctions:24
Without Compromised Therapy:11
With Compromised Therapy:13

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.73 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.96 (-0.3/+0.3)
Registered Implants: 29000										
Effective Sample Size	24453	21794	19399	17263	15330	13600	12053	10713	9492	8402

ENDOTAK ENDURANCE Rx
Passive Fixation Steroid Eluting

Models 0144/0145/0146

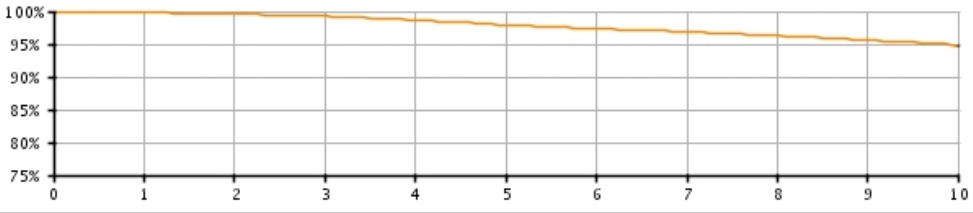
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 18,000
U.S. Approval Date: January 1999
U.S. Estimated Active Implants: 4,000

U.S. Chronic Lead Complications: 686
U.S. Malfunctions:24
Without Compromised Therapy:6
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	99.81 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.85 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15628	13937	12418	10989	9679	8564	7597	6723	5920	5202

INGEVITY Positive Fixation

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

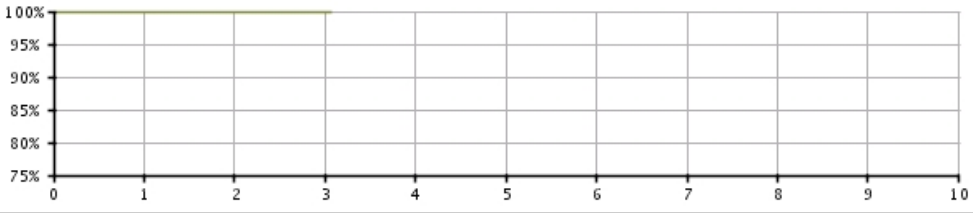
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 9,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 9,000

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 Registered Implants: 9000	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 37 mo. (-0.0/+0.0)	–	–	–	–	–	–
Effective Sample Size	1055	925	362	274	–	–	–	–	–	–

INGEVITY Positive Fixation

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

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

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

Worldwide Distribution: 135,000
Worldwide Confirmed Malfunctions: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**4**	**10**
[27] Non-patterned, Conductor	4	2	
[39] Inner conductor break	2	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**-**	**1**	**1**
[26] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**6**	**6**	**12**

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: 19,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

INGEVITY 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: 16,000
Worldwide Confirmed Malfunctions: 0

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

More details about malfunctions

References cited in table above

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: 180,000
Worldwide Confirmed Malfunctions: 112

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**5**	**32**	**37**
[7] Lead conductor	2	18	
[32] Conductor damage	3	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**52**	**10**	**62**
[2] Inner insulation abrasion	3	1	
[28] Non-patterned, Insulation	4	-	
[33] Insulation damage	45	9	
Other	**13**	**-**	**13**
[26] Non-patterned, Other	13	-	
WW Confirmed Malfunctions	**70**	**42**	**112**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

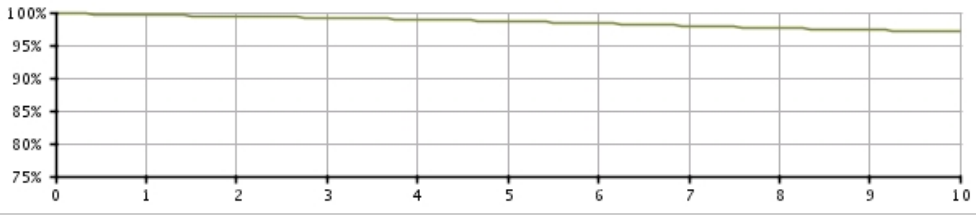
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 234,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 100,000

U.S. Chronic Lead Complications: 3,272
U.S. Malfunctions:313
Without Compromised Therapy:125
With Compromised Therapy:188

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 234000	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.93 (-0.0/+0.0)	98.65 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.97 (-0.1/+0.1)	97.62 (-0.1/+0.1)	97.30 (-0.1/+0.1)	97.06 (-0.1/+0.1)
Effective Sample Size	198332	172637	149485	128459	109720	92184	76179	62313	50279	35484

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: 288,000
Worldwide Confirmed Malfunctions: 337

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**13**	**174**	**187**
[7] Lead conductor	7	83	
[27] Non-patterned, Conductor	-	7	
[32] Conductor damage	6	84	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**104**	**26**	**130**
[2] Inner insulation abrasion	19	6	
[28] Non-patterned, Insulation	9	-	
[33] Insulation damage	76	20	
Other	**17**	**3**	**20**
[26] Non-patterned, Other	17	3	
WW Confirmed Malfunctions	**134**	**203**	**337**

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

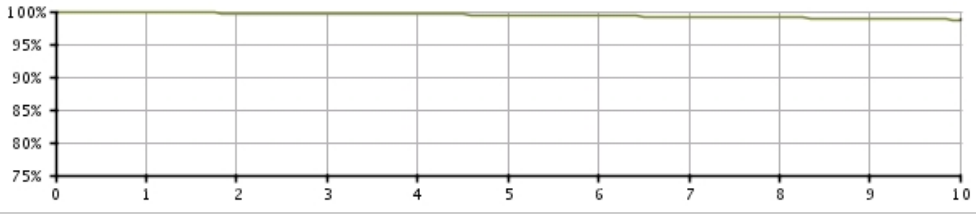
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 447,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 254,000

U.S. Chronic Lead Complications: 2,382
U.S. Malfunctions:132
Without Compromised Therapy:26
With Compromised Therapy:106

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.56 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.32 (-0.0/+0.0)	99.17 (-0.0/+0.0)	99.04 (-0.0/+0.0)	98.88 (-0.1/+0.1)	98.74 (-0.1/+0.1)
Registered Implants: 446000										
Effective Sample Size	377962	318695	266419	220195	179633	143024	110318	83174	62234	44744

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: 685,000

Worldwide Confirmed Malfunctions: 159

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**118**	**129**
[7] Lead conductor	6	55	
[27] Non-patterned, Conductor	-	5	
[32] Conductor damage	5	58	
Crimp/Weld/Bond	**1**	**2**	**3**
[23] Terminal weld	-	1	
[31] Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	**12**	**6**	**18**
[33] Insulation damage	12	6	
Other	**7**	**2**	**9**
[26] Non-patterned, Other	7	2	
WW Confirmed Malfunctions	**31**	**128**	**159**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

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

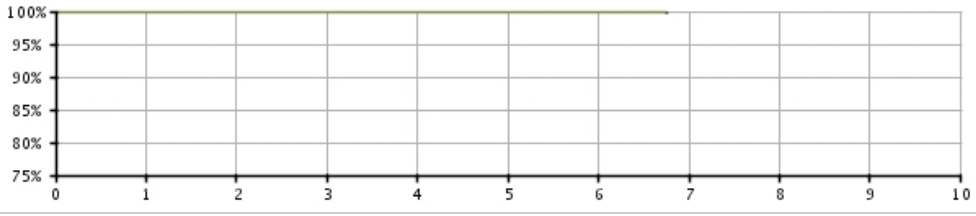
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 922
Leads Active: 693
Cumulative Followup Months : 25,866

Chronic Lead Complications: 0
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: 922	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 @ 81 mo. (-0.7/+0.5)	–	–	–
Effective Sample Size	774	609	319	260	185	111	55	–	–	–

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

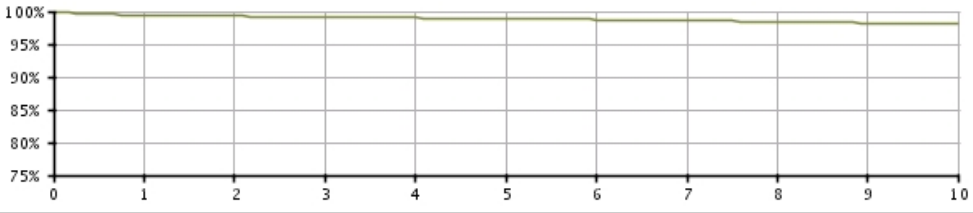
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 61,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 31,000

U.S. Chronic Lead Complications: 633
U.S. Malfunctions:25
Without Compromised Therapy:7
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	99.43 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.92 (-0.1/+0.1)	98.75 (-0.1/+0.1)	98.59 (-0.1/+0.1)	98.46 (-0.1/+0.1)	98.22 (-0.2/+0.2)	98.13 (-0.2/+0.2)
Registered Implants: 61000										
Effective Sample Size	50919	43352	36556	30515	25274	20613	16324	12737	9833	7453

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: 289,000

Worldwide Confirmed Malfunctions: 50

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**3**	**10**	**13**
[7] Lead conductor	-	3	
[32] Conductor damage	3	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[33] Insulation damage	-	1	
Other	**32**	**4**	**36**
[22] J-shape	30	4	
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**35**	**15**	**50**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

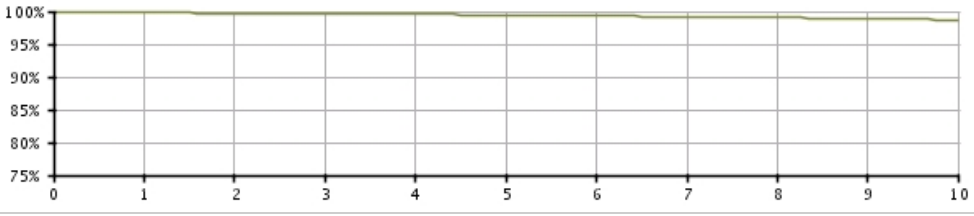
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 187,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 88,000

U.S. Chronic Lead Complications: 1,071
U.S. Malfunctions:42
Without Compromised Therapy:5
With Compromised Therapy:37

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 187000	99.81 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.34 (-0.0/+0.0)	99.18 (-0.1/+0.1)	99.04 (-0.1/+0.1)	98.86 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Effective Sample Size	156604	133263	112305	93916	78023	63636	50713	39714	30965	23746

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: 514,000

Worldwide Confirmed Malfunctions: 60

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

More details about malfunctions

References cited in table above

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

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

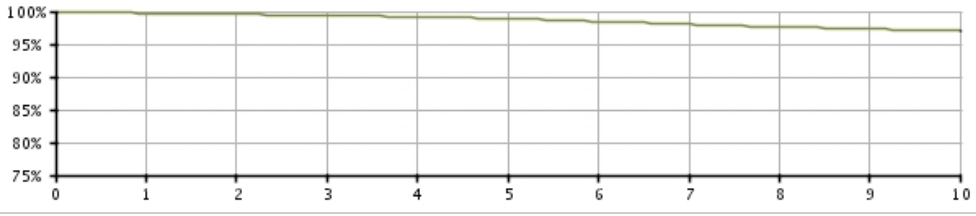
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 52,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 24,000

U.S. Chronic Lead Complications: 595
U.S. Malfunctions:122
Without Compromised Therapy:20
With Compromised Therapy:102

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	99.74 (-0.0/+0.0)	99.57 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.89 (-0.1/+0.1)	98.48 (-0.1/+0.1)	98.04 (-0.2/+0.2)	97.61 (-0.2/+0.2)	97.38 (-0.2/+0.2)	97.07 (-0.3/+0.2)
Effective Sample Size	44434	38347	32824	27843	23398	19258	15613	12420	9876	7544

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: 138,000

Worldwide Confirmed Malfunctions: 162

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**9**	**125**	**134**
[7] Lead conductor	3	75	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	6	45	
[35] Lead conductor	-	3	
Crimp/Weld/Bond	**1**	**-**	**1**
[31] Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	**9**	**9**	**18**
[28] Non-patterned, Insulation	2	-	
[33] Insulation damage	7	9	
Other	**5**	**4**	**9**
[26] Non-patterned, Other	5	4	
WW Confirmed Malfunctions	**24**	**138**	**162**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

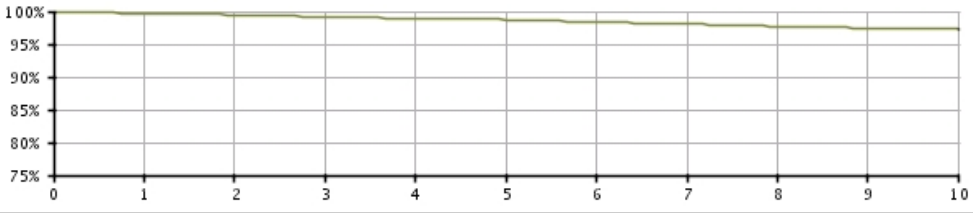
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 187
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	99.67 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.18 (-0.2/+0.1)	98.92 (-0.2/+0.2)	98.75 (-0.2/+0.2)	98.42 (-0.3/+0.2)	98.06 (-0.3/+0.3)	97.71 (-0.4/+0.3)	97.46 (-0.4/+0.4)	97.33 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12287	10734	9281	7975	6776	5679	4715	3892	3257	2672

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: 103,000

Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**42**	**42**
[7] Lead conductor	-	16	
[32] Conductor damage	-	26	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**4**	**6**
[33] Insulation damage	2	4	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**49**	**51**

More details about malfunctions

References cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

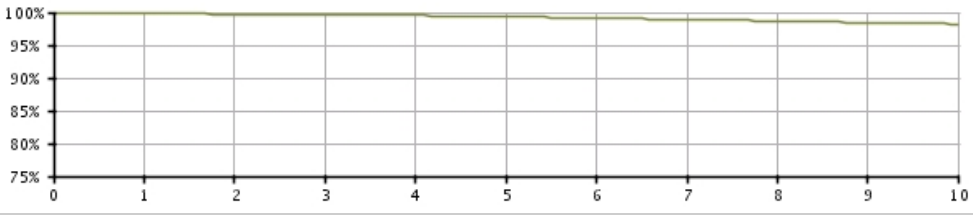
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 24,000
U.S. Approval Date: July 1999
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 292
U.S. Malfunctions:10
Without Compromised Therapy:1
With Compromised Therapy:9

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.70 (-0.2/+0.2)	98.45 (-0.2/+0.2)	98.23 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20913	18710	16691	14867	13217	11628	10247	9036	7928	6995

FINELINE Passive Fixation

Models 4450/4451

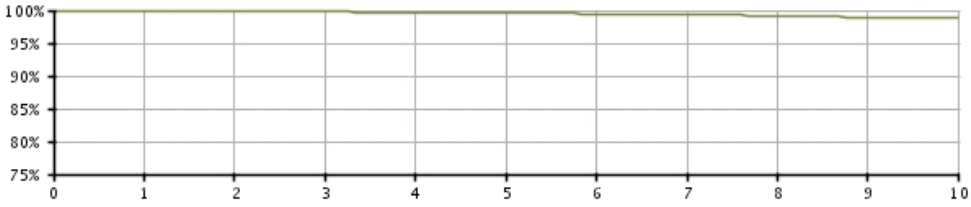
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 42,000
U.S. Approval Date: November 1996
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 328
U.S. Malfunctions:11

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 42000	99.91 (-0.0/+0.0)	99.84 (-0.0/+0.0)	99.79 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.35 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.97 (-0.1/+0.1)	98.79 (-0.2/+0.1)
Effective Sample Size	35801	32043	28627	25410	22459	19759	17322	15286	13461	11865

FINELINE Atrial J

Models 4475/4476

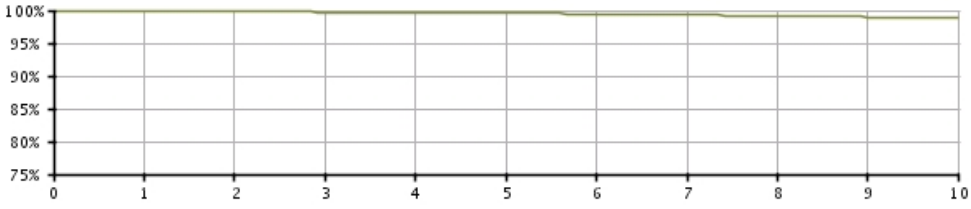
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: November 1996
U.S. Estimated Active Implants: 3,000

U.S. Chronic Lead Complications: 105
U.S. Malfunctions:6

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	99.87 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.75 (-0.1/+0.1)	99.68 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.45 (-0.2/+0.1)	99.31 (-0.2/+0.2)	99.16 (-0.2/+0.2)	98.98 (-0.3/+0.2)	98.89 (-0.3/+0.2)
Effective Sample Size	12441	11148	9968	8891	7907	6971	6147	5430	4756	4160

SELUTE PICOTIP
Passive Fixation

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

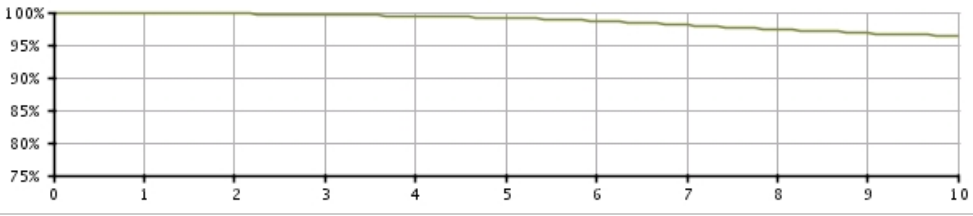
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 13,000

U.S. Chronic Lead Complications: 1,103
U.S. Malfunctions:35

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 58000	99.86 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.05 (-0.2/+0.1)	97.38 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.39 (-0.2/+0.2)
Effective Sample Size	49277	43965	39177	34805	30802	27099	23752	20738	17893	15450

SELUTE PICOTIP Atrial J

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

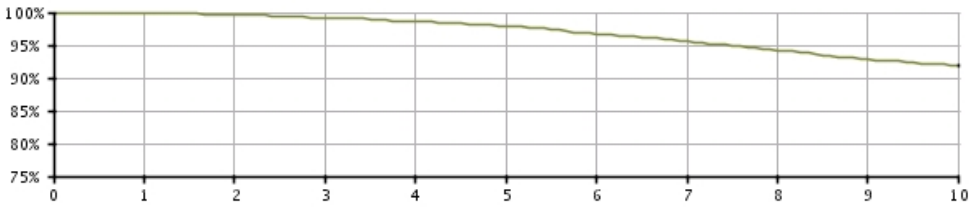
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 10,000
U.S. Approval Date: May 2000
U.S. Estimated Active Implants: 3,000

U.S. Chronic Lead Complications: 428
U.S. Malfunctions:23

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 10000	99.87 (-0.1/+0.1)	99.65 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.61 (-0.3/+0.2)	97.89 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.57 (-0.6/+0.5)	94.21 (-0.7/+0.6)	92.88 (-0.8/+0.7)	91.81 (-0.9/+0.8)
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3448	2914	2467

SWEET PICOTIP Rx
Positive Fixation

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

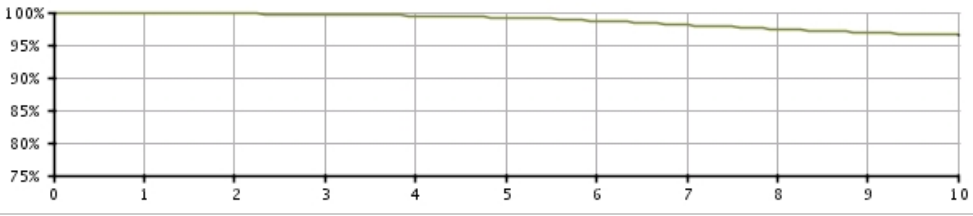
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 41,000
U.S. Approval Date: April 1999
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 688
U.S. Malfunctions:56

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 41000	99.91 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.68 (-0.2/+0.1)	98.05 (-0.2/+0.2)	97.44 (-0.2/+0.2)	96.91 (-0.3/+0.2)	96.55 (-0.3/+0.3)
Effective Sample Size	35764	31933	28497	25355	22465	19813	17329	14812	12309	10152

SWEET TIP
Positive Fixation

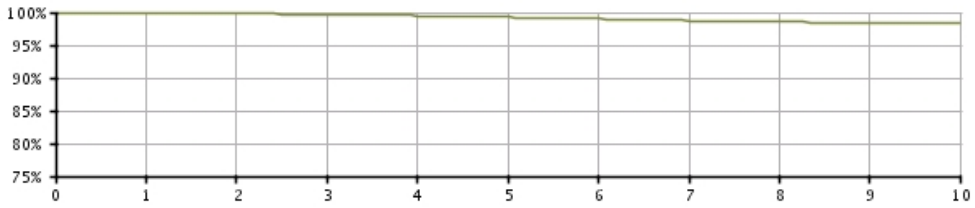
Models 4165/4168/4169/4268/4269

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

U.S. Summary

U.S. Registered Implants: 89,000
U.S. Estimated Active Implants: 15,000
U.S. Chronic Lead Complications: 960
U.S. Malfunctions:161

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 89000	99.88 (-0.0/+0.0)	99.79 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.50 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.41 (-0.1/+0.1)	98.28 (-0.1/+0.1)
Effective Sample Size	77716	69454	62065	55311	49106	43278	38074	33560	29652	26154

SWEET TIP RX
Positive Fixation

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

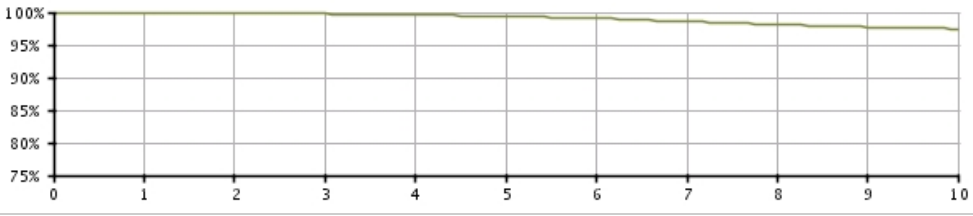
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 34,000
U.S. Approval Date: October 1998
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 488
U.S. Malfunctions:28

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.10 (-0.1/+0.1)	98.58 (-0.2/+0.2)	98.11 (-0.2/+0.2)	97.75 (-0.2/+0.2)	97.44 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26538	23707	21102	18667	16404	14412	12554	10796	9195

Confirmed Malfunction Details: Leads

References

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

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

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

26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.

27. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.

28. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.

31. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.

32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.

33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.

34. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.

35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.

36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.

37. **Weld fracture**— Noise, loss of sensing. Fractured weld.

38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable. Improvement implemented.

39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.

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

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	9000	0	0	0	0	0	0	0	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	300	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	1000	0	0	0	0	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	234000	72	747	831	677	267	86	156	372	0	64
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	187000	4	308	197	172	31	19	149	171	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	447000	21	503	640	325	73	76	396	313	0	35
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	91	305	108	8	18	60	35	0	7
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	85	19	36	11	4	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	218	74	75	51	15	69	89	0	4

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	2000	0	0	0	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	3000	0	0	0	0	0	0	0	0	0	0

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	2000	0	0	0	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	29000	2	21	393	38	3	1	6	19	0	94
ACUITY Spiral 4591/4592/4593	23000	0	14	245	26	1	1	2	5	0	141
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	27	250	41	4	2	9	10	0	90
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	96000	1	261	1079	231	8	6	60	77	0	463
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	63	397	103	3	1	47	31	0	260

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	55000	11	16	65	14	10	7	4	5	6	3
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	0	1	4	0	2	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	58000	13	15	62	21	13	7	2	6	9	4
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	0	0	2	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	28	394	346	121	462	64	95	207	159	26
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	86	64	47	78	7	34	130	31	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	8	44	41	17	39	1	7	27	25	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	3	5	1	3	0	1	2	2	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	14000	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	1379	0	0	22	2	0	0	0	0	0	9
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	742	0	0	0	0	0	0	0	1	1	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	849	0	0	1	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	0	1	0	1	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	922	0	1	1	0	0	0	0	0	0	0

U.S. Acute Lead Observations

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

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

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	9000	3	20	17	11	3	3	1	9	0	1
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	300	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	1000	0	0	2	0	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	234000	236	195	1356	432	75	90	57	215	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	187000	15	13	446	175	7	27	25	38	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	447000	81	83	701	251	110	95	61	244	0	42
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	18	452	91	7	30	17	21	0	10
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	34	16	1	3	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/4473/4474	52000	3	18	106	27	9	10	21	13	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	2000	1	0	3	2	1	0	0	1	0	4
ACUITY X4 Spiral S 4674/4675	3000	0	0	4	1	0	0	0	4	0	9

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Straight 4671/4672	2000	0	0	2	1	0	0	0	4	0	1
ACUITY Steerable 4554/4555/4556	29000	1	3	328	47	24	2	7	134	0	242
ACUITY Spiral 4591/4592/4593	23000	5	4	211	69	9	1	9	38	0	241
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	273	38	12	2	8	47	0	188
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	96000	13	9	927	134	46	9	27	199	0	732
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	18	34	0	186

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	55000	42	29	161	77	53	11	7	80	19	10
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	2	0	8	1	3	0	0	17	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	58000	53	40	148	54	68	18	6	78	68	21
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	1	1	2	2	1	1	0	15	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	149	190	648	169	366	54	69	360	234	80
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	8	2	107	46	57	8	5	177	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	29	16	77	29	31	14	3	57	120	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	2	1	1	2	0	11	1	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010/3011	14000	1	0	16	0	143	11	1	42	1

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1379	0	0	12	10	1	0	0	3	0	48
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	849	0	2	12	0	0	0	1	2	0	3
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	6	1	10	5	5	3	0	2	1	2
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	742	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	922	0	0	1	1	0	0	0	0	0	0

Before/During Implant Procedure - Worldwide Malfunctions: Leads

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling is not reported as device malfunction here.
The Conductor category includes any conductor break or damage with complete or intermittent loss of continuity that could interrupt current flow, including clavicle fatigue or crush damage. The Insulation category includes any lead insulation breach, such as damage due to lead-on-lead or lead-on-anatomy contact, or clavicle fatigue or crush. The Crimp/Weld/Bond category includes any interruption in the conductor or lead body associated with a point of connection. The Other category includes malfunctions for which the root cause does not fit within other categories or has not yet been determined. The Labeling and Packaging categories include product identification issues and damage to sterile packaging, respectively. The Implant Accessory category includes lead malfunctions due to catheter, guidewire or sheath issues.

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	7,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	12,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	12,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	63,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	43,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	42,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	176,000	0	5	0	7	1	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	4	0	0	3

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation 0658/0695/0696	9,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	29,000	3	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	90,000	0	0	0	62	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	9,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	97,000	0	0	0	22	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Passive Fixation 0282/0283	4,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	372,000	0	0	44	486	0	3	14
ENDOTAK RELIANCE Dual Coil Passive Fixation 0147/0148/0149/0174/0175/0176/0177	108,000	0	1	3	87	0	3	0
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	67,000	0	0	7	62	0	1	3
ENDOTAK RELIANCE Single Coil Passive Fixation 0127/0128/0170/0171/0172/0173	7,000	0	0	0	2	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	22,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	135,000	310	0	0	510	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	16,000	0	0	0	1	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	19,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	180,000	0	0	10	122	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	288,000	0	0	55	599	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	514,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	685,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	289,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	103,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	138,000	0	1	1	25	1	6	0

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

Product Advisories

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

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

PRODUCT	ORIGINAL COMMUNICATION **17-Nov-2014** - **AUTOGEN RVAT November 2014**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **AUTOGEN CRT-D** Models G172/G173/G175/ G177/G179 **AUTOGEN ICD MINI DR** Models D046/D047 **AUTOGEN ICD EL DR** Models D176/D177 AUTOGEN RVAT November 2014 Physician Letter, Nov 17, 2014 AUTOGEN RVAT November 2014 Patient Letter, Nov 17, 2014	Voluntary Physician Advisory AUTOGEN DR ICD and CRT-D devices include the option of enabling a Right Ventricular Automatic Threshold (RVAT) test to determine the RV pacing threshold and adjust amplitude in an ambulatory setting. If the RVAT test feature is enabled and noise signals are continuously sensed within a brief RV noise window following an Atrial pace, a patient may not receive effective pacing support until the RVAT test ends (i.e., up to 20 cardiac cycles). Although no patients have been harmed in the cases reported to date, brief periods of dizziness were reported in one case. Note that there is no additional risk for patients in whom the RVAT feature is disabled. Single-chamber AUTOGEN ICDs (VR models) have not demonstrated this behavior. The Left Ventricular Auto Threshold (LVAT) test (for AUTOGEN CRT-Ds) and the Right Atrial Auto Threshold (RAAT) test (for AUTOGEN CRT-Ds and dual-chamber ICDs) are not subject to this device behavior and are performing as intended. In addition, Boston Scientific pacemaker and CRT-P models with similar automatic pacing threshold test features are performing as intended and thus are not subject to this device behavior. Boston Scientific is developing a software solution that will prevent this device behavior from occurring when the RVAT test feature is enabled. Following geography-specific regulatory approval, this software solution will be implemented via a non-invasive download from the programmer. CURRENT STATUS **08-Jul-16** *Reported events (worldwide)* Four (4) reports have been received worldwide of ineffective pacing support during an RVAT test. There have been no reported patient deaths associated with this advisory. CURRENT RECOMMENDATION **08-Jul-16** Updated software is available in the U.S. and most geographies which provides effective pacing support with the RVAT test feature enabled for ambulatory use. If the software update has not been performed, Boston Scientific recommends the following: 1. For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use: • Select the SETTINGS tab • Select the SETTINGS SUMMARY tab • In the BRADY section, select the NORMAL SETTINGS details icon • In the PACING and SENSING section, select the desired pacing RV Amplitude (do not select Auto) • Ensure that DAILY TREND is not selected • Press PROGRAM to implement the selected fixed amplitude pacing output. 2. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilizing the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude). Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.
COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108	The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.
TELIGEN VR Models E102/E103/F102/F103	The most common alert is a yellow programmer screen that states, “Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003”. LATITUDE issues a corresponding yellow alert (nominally configured “On”). In other instances, diminished LV capacitor performance can result in an early “Explant” battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.
TELIGEN DR Models E110/E111/F110/F111	
	Advisory population Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.
Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014 Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014 Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013	CURRENT STATUS **08-Jul-16** Advisory devices have not been available for implant for more than three years. *Confirmed Malfunctions (worldwide)* 3,705 malfunctions have been confirmed from the advisory population. Approximately 39,000 devices from the advisory population remain in service. There has been one reported patient death associated with this advisory. *Projected Rate of Occurrence* The rate of occurrence for advisory population devices is 5.9% at 72 months. The projected rate of occurrence at 84 months is approximately 9.1%.
	CURRENT RECOMMENDATION **08-Jul-16** Updated Software In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted. LATITUDE Patient Management System Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert “Voltage was too low for projected remaining capacity” is configured “On”. Additional Recommendations - After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling. - Device replacement is not recommended for advisory devices displaying normal behavior. - Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages. - Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that “Approximate time to Explant” and “Time Remaining” estimates displayed on the programmer are not accurate following a low voltage alert.
	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 here: Device Lookup Tool **SQ-RX S-ICD** Model1010 High Cathode Condition Physician Letter, Jun 01, 2011 High Cathode Condition Patient Letter, Jun 01, 2011	Voluntary Physician Advisory Boston Scientific has determined that a specific subset of SQ-RX pulse generators may not achieve the five (5) year typical longevity due to premature battery depletion. Although the longevity of these devices may be shortened, therapy remains available through the onset of the Elective Replacement Indicator (ERI). This subset of devices also has the potential for the time between the onset of the ERI and End of Life (EOL) indicators to be less than the nominal three (3) months. The risk for premature battery depletion is due to a specific condition within an individual battery cell. No affected devices remain available for implant. *Rate of Occurrence* Cameron Health has confirmed one (1) occurrence of a device experiencing premature battery depletion due to this condition. Cameron Health conducted a systematic analysis of all implanted devices worldwide and identified two populations at risk for premature battery depletion due to this condition: – Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date. – Population II consists of 386 devices for which manufacturing records cannot exclude the possibility of the condition existing within a battery cell. Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There have been zero (0) confirmed occurrences in this population to date.
CURRENT STATUS **08-Jul-16**	
No devices in the advisory population remain available for implant. *Confirmed Malfunctions (worldwide)* Three (3) malfunctions have been confirmed worldwide of devices experiencing High Cathode Condition. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* – Population I – Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. – Population II - Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity.	
CURRENT RECOMMENDATION **08-Jul-16**	
– If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible. – Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone. For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.	
Standard Warranty program available, please contact your local representative for terms and conditions.	

PRODUCT	ORIGINAL COMMUNICATION **July 2010— Magnetic Reed Switch 2010**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II 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.
CONTAK RENEWAL 3 Models H170/H175 **CONTAK RENEWAL 3 HE** Models H177/H179	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	CURRENT STATUS **08-Jul-16** 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.
VITALITY DR HE Model T180	CURRENT RECOMMENDATION **08-Jul-16** 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:
Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010	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.
Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010	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.]

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 here: Device Lookup Tool	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.
Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*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 **08-Jul-16** COGNIS and TELIGEN devices are available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired. *Reported events (worldwide)* Ninety-four (95) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.

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

CURRENT RECOMMENDATION **08-Jul-16**

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

For affected devices implanted in a subpectoral location:
– Follow patient at least once every three months as recommended in device instructions for use.
– Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.
– Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

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

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

PRODUCT	ORIGINAL COMMUNICATION **05-Apr-07 and 04-Mar-09— Shortened Replacement Window**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: 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	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.
CONTAK RENEWAL 4 RF Models H230/H235	
CONTAK RENEWAL 4 HE Models H197/H199	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.
CONTAK RENEWAL 4 Models H190/H195	
CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179	CURRENT STATUS **08-Jul-16**
CONTAK RENEWAL 3 RF HE Models H217/H219	*Confirmed Malfunctions (worldwide)* **April 2007 Population** 2,566 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices.
CONTAK RENEWAL 3 RF Models H210/H215	115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).
CONTAK RENEWAL 3 HE Models H177/H179	**March 2009 Population** 117 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).
CONTAK RENEWAL 3 Models H170/H175	
	There have been no reported patient deaths associated with either advisory population.
CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159	No devices currently being distributed are susceptible to this malfunction mode.
	Rate of Occurrence
VITALITY 2 EL VR/DR Models T177/T167	**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.
VITALITY 2 VR/DR Models T175/T165	**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.
VITALITY DR HE Model T180	
VITALITY DS VR/DR Model T135/T125	Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.

VITALITY EL
Model T127

VITALITY AVT A155
Model A155

Shortened Replacement Window Physician Letter, Mar 04, 2009

Shortened Replacement Window Patient Letter, Mar 04, 2009

Shortened Replacement Window Physician Letter, Apr 5, 2007

Shortened Replacement Window Patient Letter, Apr 5, 2007

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

CURRENT RECOMMENDATION **08-Jul-16**

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 here: Device Lookup Tool	FDA Classification: Devices in Table 1, Column 1 of this *Product Update* were classified as Class II (27-November-07)
CONTAK RENEWAL 4 RF HE Model H239	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.
CONTAK RENEWAL 4 RF / HE Models H230/H235/H197/H199	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.
CONTAK RENEWAL 4 and 4 AVT / AVT HE Models H190/H195/M170/M175/ M177/M179	*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:
CONTAK RENEWAL 3 RF HE Models H217/H219	– 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%**)
CONTAK RENEWAL 3 RF / HE Models H210/H215/H177/H179	– 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%**)
CONTAK RENEWAL 3 and 3 AVT / AVT HE Models H170/H175/M155/M159	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.
VITALITY 2 EL VR/DR Models T177/T167	CURRENT STATUS **08-Jul-16**
VITALITY 2 VR/DR Models T175/T165	*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.”
VITALITY DR HE and EL Model T180 and Model T127	*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.”
VITALITY DS VR/DR Model T135/T125	
VITALITY AVT A135 / A155 Models A135/A155	
VITALITY VR/DR and DR+ Models 1871/1870/1872	CURRENT RECOMMENDATION **08-Jul-16** Patient management recommendations from the March 10, 2007 Product Update remain unchanged.
ASSURE Model B301	*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 a manual capacitor reform may be helpful in characterizing the current charge time.
Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007 Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007	
	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 here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II
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 **VITALITY VR/DR and EL** Models 1870/1871/T127	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 **08-Jul-16** *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 **08-Jul-16** 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

VENTAK PRIZM 2 VR/DR
Models 1860/1861

Low Voltage Capacitor, Physician Letter, Aug 24, 2006

Low Voltage Capacitor, Patient Letter, Aug 24, 2006

Low Voltage Capacitor, Physician Letter, Jun 23, 2006

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

CURRENT RECOMMENDATION, continued…

CRT-Ps: RENEWAL TR/TR2
– ERI or EOL indicator message displayed earlier than expected
– Fault Code 11 message (high current indicator)
– A gas gauge less than BOL within six months of implant

ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2
– ERI or EOL indicator message displayed earlier than expected
– A battery voltage **less than 3.10V** within six months of implant

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

PRODUCT	ORIGINAL COMMUNICATION **12-May-06 and 04-Jan-08 Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool *This advisory is limited to those models listed below implanted subpectorally 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.
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	This failure mechanism can result in one or more of the following device behaviors: – Loss of shock therapy – Loss of pacing therapy (intermittent or permanent) – Loss of telemetry communications – Beeping (16 tones every six hours), and a programmer warning screen upon interrogation *Reported Events* Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism. *Rate of Occurrence* The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.
	CURRENT STATUS **08-Jul-16**
	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 **08-Jul-16**
Subpectoral Implant, Physician Letter, Jan 04, 2008 Subpectoral Implant, Patient Letter, Jan 04, 2008	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 here: Device Lookup Tool **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	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 **08-Jul-16**
	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 4,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **08-Jul-16**
Crystal Timing Component, Physician Letter, Dec 12, 2005 Crystal Timing Component, Patient Letter, Oct 03, 2005 Crystal Timing Component, Physician Letter, Sep 22, 2005	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 here: Device Lookup Tool **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 **08-Jul-16**
	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.

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

CURRENT RECOMMENDATION **08-Jul-16**

Hermetic Sealing Component, Physician Letter, Jan 21, 2006

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.

Hermetic Sealing Component, Patient Letter, Jan 21, 2006

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

Hermetic Sealing Component, Physician Letter, Jul 18, 2005

– 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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