Boston Scientific
Advancing science for life™

2018

Rhythm Management Product Performance Report

Q2 Edition

RESONATE™
FAMILY OF ICDs AND CRT-Ds

Emblem™ MRI S-ICD
System

ACUITY™ X4
Quadripolar LV Lead

CRM Quality Pledge

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

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2018 report includes data through April 10, 2018.

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
- ✓ 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 the U.S. Registered Implant population 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. 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.

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

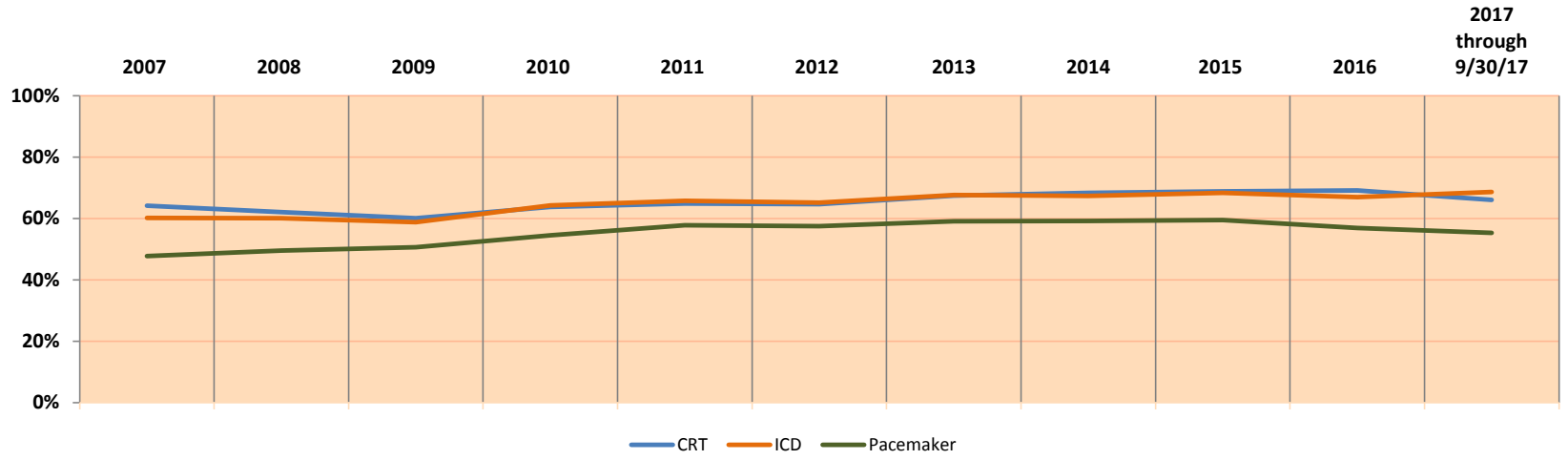
Reporting Adverse Events

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	2017 through 9/30/17
Explants	4248	5682	9273	10494	9341	8071	8349	6940	5084	4661	3953
Returns	2726	3530	5573	6697	6064	5222	5633	4743	3504	3225	2613
% Returned	**64%**	**62%**	**60%**	**64%**	**65%**	**65%**	**67%**	**68%**	**69%**	**69%**	**66%**
Explants	11544	15564	19519	19961	16595	12004	11947	11303	10050	8427	5966
Returns	6954	9356	11476	12844	10922	7828	8083	7617	6873	5648	4097
% Returned	**60%**	**60%**	**59%**	**64%**	**66%**	**65%**	**68%**	**67%**	**68%**	**67%**	**69%**
Explants	18426	20476	21043	21168	20060	18747	18841	19364	19718	19541	14626
Returns	8798	10152	10660	11546	11608	10784	11143	11473	11734	11125	8101
% Returned	**48%**	**50%**	**51%**	**55%**	**58%**	**58%**	**59%**	**59%**	**60%**	**57%**	**55%**

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

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models G124/G125/G126/G128/G138/
G224/G225/G228/G237/G247/
G248/G324/G325/G347/G348/
G424/G425/G426/G428/G437/
G447/G448/G524/G525/G526/
G528/G537/G547/G548

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

RESONATE/MOMENTUM/CHARISMA/ VIGILANT CRT-D
Models G124/G125/G126/G128/G138/ G224/G225/G228/G237/G247/ G248/G324/G325/G347/G348/ G424/G425/G426/G428/G437/ G447/G448/G524/G525/G526/ G528/G537/G547/G548

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

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: 22,000
Worldwide Confirmed Malfunctions: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**8**	**1**	**9**
[62] High voltage circuit component	4	-	
[63] Integrated circuit	4	1	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[1] Safety Core-unintended biventricular pacing	1	-	
Other	**3**	**1**	**4**
Non-patterned	3	1	
WW Confirmed Malfunctions	**12**	**2**	**14**

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

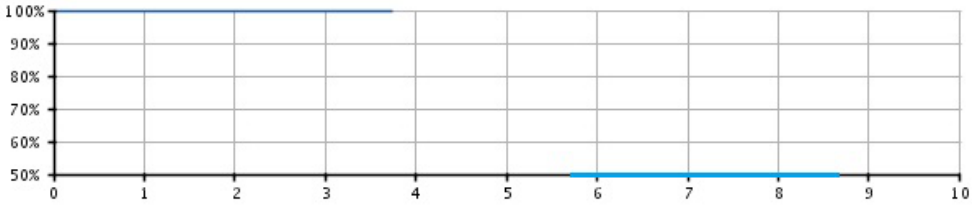
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

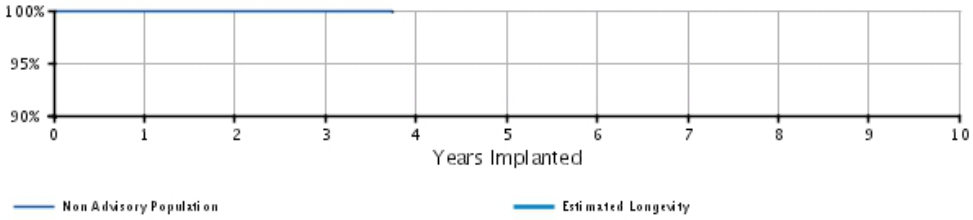
U.S. Registered Implants: 49,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 46,000

U.S. Normal Battery Depletions: 8
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:20
Without Compromised Therapy:17
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: 49000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.85 (-0.1/+0.1)	99.81 @ 45 mo. (-0.1/+0.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.90 @ 45 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	30959	14773	3590	251	–	–	–	–	–	–

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: 74,000
Worldwide Confirmed Malfunctions: 34

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**18**	**3**	**21**
[62] High voltage circuit component	9	-	
[63] Integrated circuit	9	2	
[64] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**9**	**1**	**10**
[1] Safety Core-unintended biventricular pacing	1	-	
[51] Memory errors	8	1	
Other	**1**	**2**	**3**
Non-patterned	1	2	
WW Confirmed Malfunctions	**28**	**6**	**34**

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

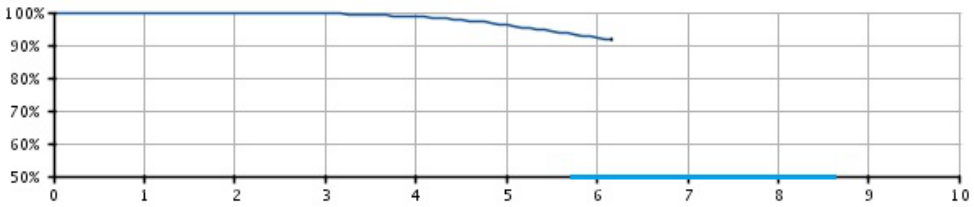
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

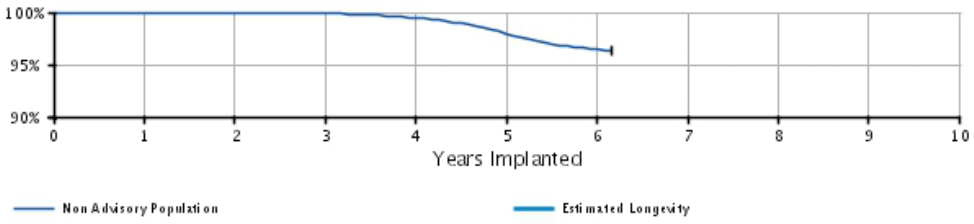
U.S. Registered Implants: 52,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 38,000

U.S. Normal Battery Depletions: 468
U.S. Unconfirmed Reports of Premature Battery Depletion : 56
U.S. Malfunctions:458
Without Compromised Therapy:443
With Compromised Therapy:15

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)	99.88 (-0.0/+0.0)	99.63 (-0.1/+0.1)	98.68 (-0.1/+0.1)	96.06 (-0.3/+0.3)	92.30 (-0.7/+0.7)	91.87 @ 74 mo. (-0.9/+0.8)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.46 (-0.1/+0.1)	97.95 (-0.2/+0.2)	96.46 (-0.4/+0.4)	96.31 @ 74 mo. (-0.5/+0.5)	–	–	–
	Effective Sample Size	46508	41041	34370	22406	9907	1178	235	–	–	–

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: 719

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**677**	**11**	**688**
[42] Safety Core-electrocautery	5	1	
[43] High-voltage capacitor	-	3	
[47] Low-voltage capacitors	1	-	
[50] Integrated circuit	2	6	
[53] Battery	3	-	
[54] Low-voltage capacitor	666	1	
Mechanical	**-**	**6**	**6**
[38] Transformer	-	6	
Software	**9**	**-**	**9**
[51] Memory errors	9	-	
Other	**11**	**5**	**16**
Non-patterned	11	5	
WW Confirmed Malfunctions	**697**	**22**	**719**

More details about malfunctions

References cited in table above

COGNIS

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

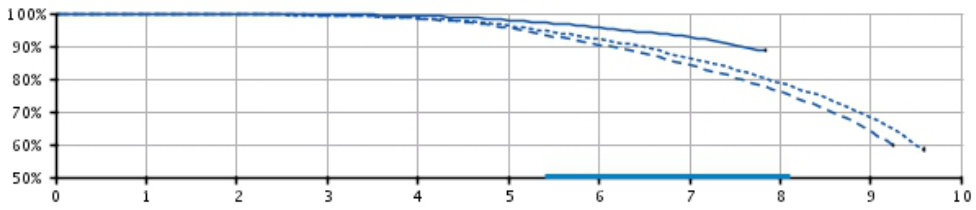
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

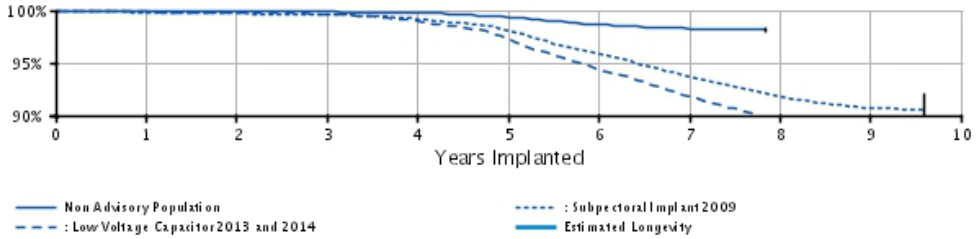
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 33,000

U.S. Normal Battery Depletions: 4,207
U.S. Unconfirmed Reports of Premature Battery Depletion : 149
U.S. Malfunctions:1846
Without Compromised Therapy:1666
With Compromised Therapy:180

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)	99.20 (-0.1/+0.1)	97.96 (-0.2/+0.2)	95.73 (-0.3/+0.3)	92.71 (-0.4/+0.4)	88.67 @ 94 mo. (-1.0/+1.0)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.34 (-0.1/+0.1)	98.63 (-0.2/+0.2)	98.27 (-0.2/+0.2)	98.15 @ 94 mo. (-0.2/+0.2)	–	–
	Effective Sample Size	31501	28110	25049	22235	19471	16375	7000	387	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.0)	99.37 (-0.1/+0.0)	98.55 (-0.1/+0.0)	96.36 (-0.1/+0.0)	92.07 (-0.1/+0.1)	86.40 (-0.1/+0.1)	78.80 (-0.4/+0.5)	68.37 (-1.6/+1.5)	58.44 @ 115 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)	98.10 (-0.1/+0.1)	95.82 (-0.2/+0.3)	93.69 (-0.3/+0.3)	91.85 (-0.4/+0.5)	90.76 (-0.4/+0.5)	90.61 @ 115 mo. (-1.6/+1.5)
	Effective Sample Size	27490	24358	21663	19172	16706	14173	11815	9579	2883	312
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.41 (-0.1/+0.1)	95.53 (-0.1/+0.1)	90.48 (-0.1/+0.1)	84.14 (-0.3/+0.1)	76.06 (-0.3/+0.2)	64.06 (-1.4/+1.0)	58.82 @ 111 mo. (-1.4/+1.0)

26,000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.35 (-0.1/+0.1)	91.81 (-0.3/+0.1)	89.54 (-0.4/+0.2)	87.50 (-1.4/+1.0)	87.34 @ 111 mo. (-1.4/+1.0)
	Effective Sample Size	22614	20017	17821	15742	13643	11461	9458	6107	871	201

*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: 2498

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2157**	**142**	**2299**
[3] Low Voltage Capacitor 2014 (Advisory issued)	1513	77	
[42] Safety Core-electrocautery	50	21	
[43] High-voltage capacitor	1	6	
[47] Low-voltage capacitors	7	-	
[50] Integrated circuit	8	20	
[52] High voltage circuit	-	1	
[53] Battery	45	7	
[54] Low-voltage capacitor	533	10	
Mechanical	**44**	**95**	**139**
[6] Subpectoral implant 2009 (Advisory issued)	20	52	
[38] Transformer	-	9	
[41] Difficulty securing lead	9	9	
[45] Header contacts	9	8	
[67] Header	6	17	
Software	**16**	**1**	**17**
[46] Safety Core-programming	1	-	
[48] Alert messages not displayed post-EOL	2	-	
[51] Memory errors	13	1	
Other	**34**	**9**	**43**
Non-patterned	34	9	
WW Confirmed Malfunctions	**2251**	**247**	**2498**

More details about malfunctions

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

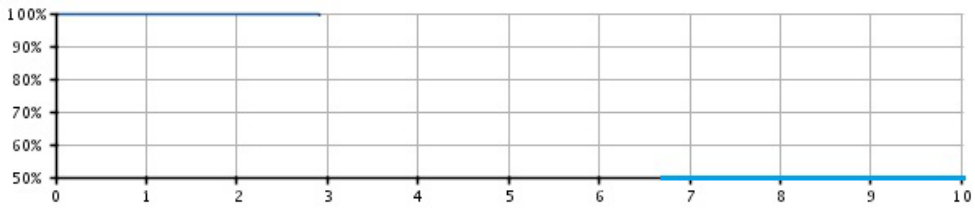
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

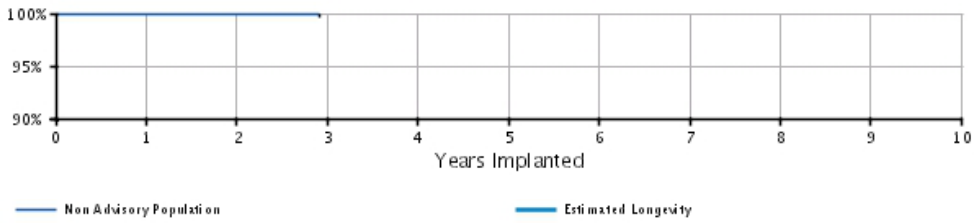
U.S. Registered Implants: 17,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:11
Without Compromised Therapy:10
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: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.70 @ 35 mo. (-0.4/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.86 @ 35 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Effective Sample Size	9530	3112	282	–	–	–	–	–	–	–

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: 35,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**1**	**10**
[47] Low-voltage capacitors	1	-	
[63] Integrated circuit	5	1	
[65] Capacitor	2	-	
[66] Telemetry	1	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[51] Memory errors	1	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**12**	**1**	**13**

More details about malfunctions

References cited in table above

INVIVE

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

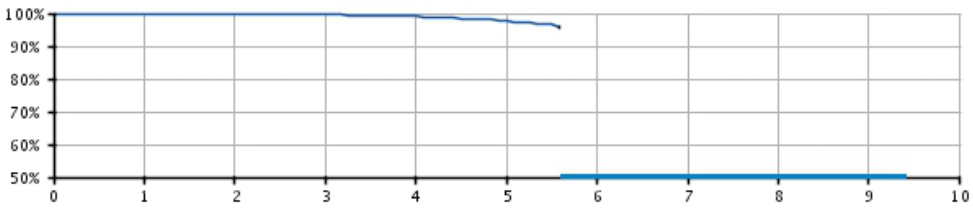
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

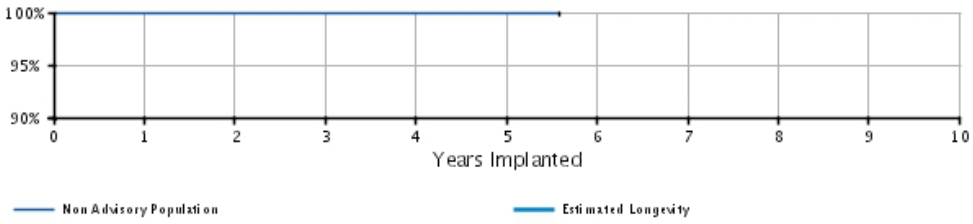
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 77
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.54 (-0.2/+0.1)	99.03 (-0.3/+0.2)	97.67 (-0.7/+0.6)	95.89 @ 67 mo. (-1.7/+1.2)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.92 (-0.3/+0.1)	99.92 @ 67 mo. (-0.3/+0.1)	–	–	–	–
	Effective Sample Size	6750	5931	4816	3109	1028	259	–	–	–	–

INVIVE

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

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

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

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[47] Low-voltage capacitors	-	1	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[51] Memory errors	3	-	
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**3**	**2**	**5**

More details about malfunctions

References cited in table above

INTUA

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

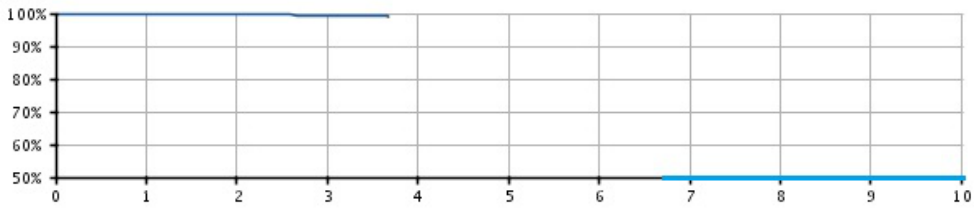
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

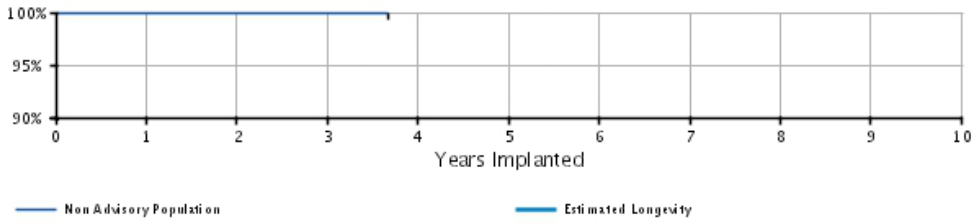
U.S. Registered Implants: 3,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 11
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:1
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.39 (-0.5/+0.3)	99.05 @ 44 mo. (-0.8/+0.4)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.96 (-0.3/+0.0)	99.87 (-0.5/+0.1)	99.87 @ 44 mo. (-0.5/+0.1)	–	–	–	–	–	–
	Effective Sample Size	2263	1861	979	227	–	–	–	–	–	–

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: 2

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

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: 32

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[15] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[19] Seal plug	1	-	
[25] Setscrew block	2	-	
[33] Seal plug	1	-	
Software	**15**	**-**	**15**
[23] Memory error	1	-	
[28] Stored EGMs	14	-	
Other	**11**	**1**	**12**
Non-patterned	10	1	
[31] Alert messages	1	-	
WW Confirmed Malfunctions	**31**	**1**	**32**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

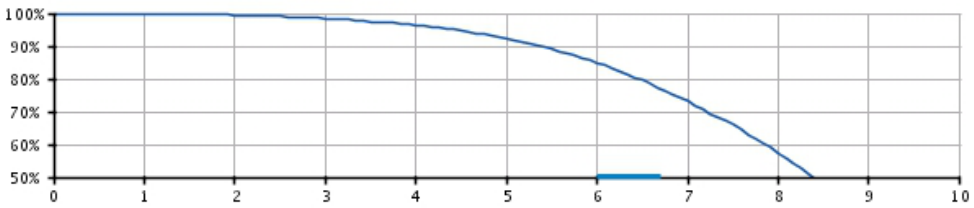
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

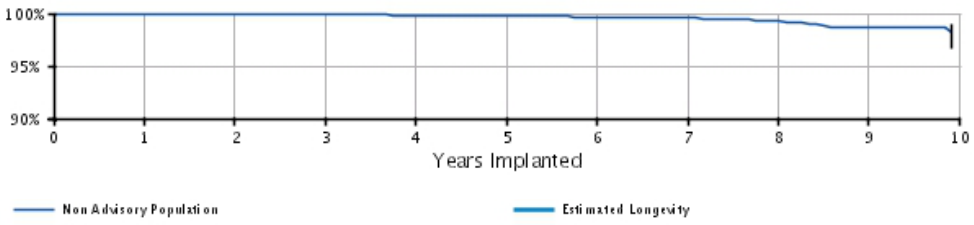
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 3,501
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:60
Without Compromised Therapy:58
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)	98.47 (-0.2/+0.2)	96.34 (-0.4/+0.3)	92.35 (-0.5/+0.5)	84.97 (-0.7/+0.7)	73.06 (-1.0/+1.0)	57.16 (-1.3/+1.3)	39.95 (-1.7/+1.7)	26.81 @ 119 mo. (-2.1/+2.2)
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.67 (-0.1/+0.1)	99.55 (-0.2/+0.1)	99.28 (-0.3/+0.2)	98.68 (-0.6/+0.4)	98.19 @ 119 mo. (-1.5/+0.8)
	Effective Sample Size	15561	13546	11803	10221	8657	6654	4073	1916	700	201
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: 60

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[8] Low-voltage capacitor (Advisory issued)	1	-	
[15] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[19] Seal plug	5	-	
Software	**32**	**-**	**32**
[28] Stored EGMs	32	-	
Other	**20**	**1**	**21**
Non-patterned	13	1	
[31] Alert messages	6	-	
[44] Magnet rate	1	-	
WW Confirmed Malfunctions	**58**	**2**	**60**

More details about malfunctions

References cited in table above

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

Models D121/D221/D233/D321/D333/
D421/D433/D521/D533

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

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR
Models D121/D221/D233/D321/D333/ D421/D433/D521/D533

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

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

Models D120/D220/D232/D320/D332/
D420/D432/D520/D532

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

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR
Models D120/D220/D232/D320/D332/ D420/D432/D520/D532

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

EMBLEM S-ICD

Models A209/A219

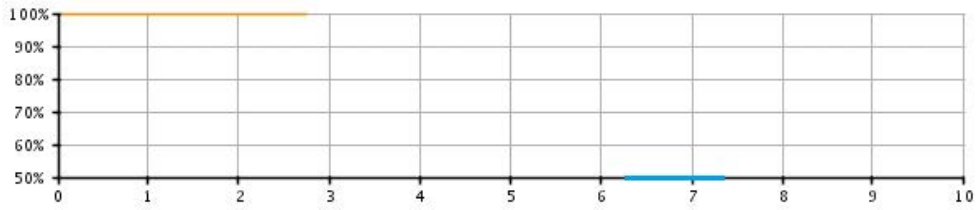
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

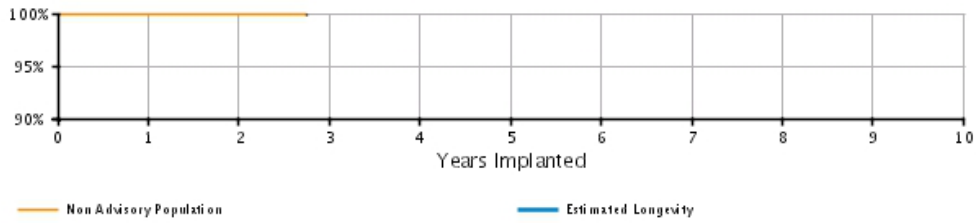
U.S. Registered Implants: 18,000
U.S. Approval Date: March 2015
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:10
Without Compromised Therapy:5
With Compromised Therapy:5

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.85 @ 33 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 @ 33 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Effective Sample Size	9861	3756	272	–	–	–	–	–	–	–

EMBLEM S-ICD

Models A209/A219

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

EMBLEM S-ICD Models A209/A219

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 20

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**-**	**0**
Software	**-**	**1**	**1**
[2] Memory corruption	-	1	
Other	**11**	**8**	**19**
Non-patterned	9	4	
[56] Telemetry	2	4	
WW Confirmed Malfunctions	**11**	**9**	**20**

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: 14,000
Worldwide Confirmed Malfunctions: 5

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

More details about malfunctions

References cited in table above

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: 14,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

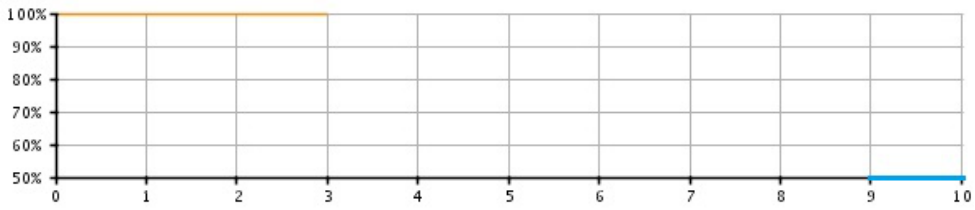
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

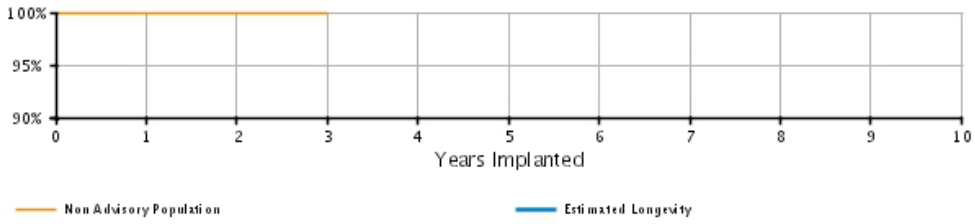
U.S. Registered Implants: 27,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 26,000

U.S. Normal Battery Depletions: 5
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:5
Without Compromised Therapy:3
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: 27000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	15248	6051	281	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

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

Worldwide Distribution: 38,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**2**	**6**
[47] Low-voltage capacitors	1	-	
[62] High voltage circuit component	3	-	
[63] Integrated circuit	-	1	
[64] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[51] Memory errors	1	-	
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**6**	**2**	**8**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

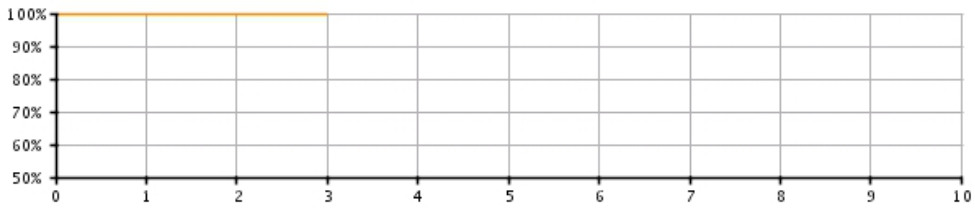
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

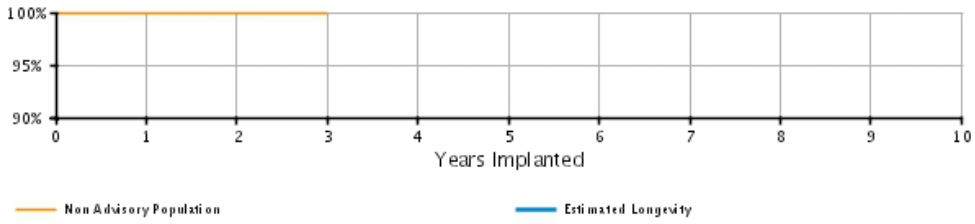
U.S. Registered Implants: 24,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 22,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:4
Without Compromised Therapy:4
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	14127	5990	273	–	–	–	–	–	–	–

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: 38,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[62] High voltage circuit component	1	-	
Mechanical	**-**	**-**	**0**
Software	**3**	**-**	**3**
[51] Memory errors	3	-	
Other	**4**	**-**	**4**
Non-patterned	4	-	
WW Confirmed Malfunctions	**8**	**0**	**8**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

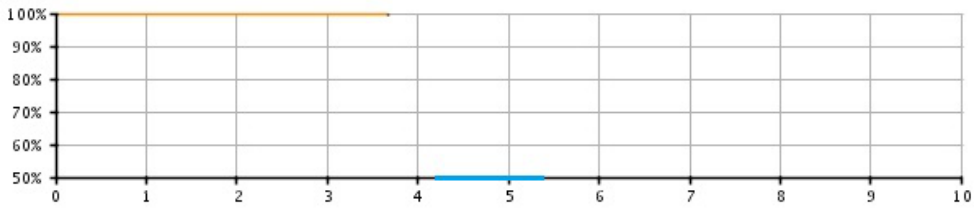
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

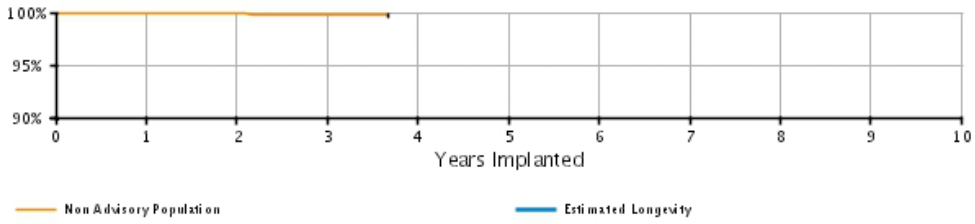
U.S. Registered Implants: 7,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 5
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.64 (-0.3/+0.2)	99.55 @ 44 mo. (-0.4/+0.2)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.91 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.77 @ 44 mo. (-0.3/+0.1)	–	–	–	–	–	–
	Effective Sample Size	4925	3158	1308	255	–	–	–	–	–	–

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: 17,000
Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**1**	**7**
[62] High voltage circuit component	6	-	
[64] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**1**	**3**
Non-patterned	2	1	
WW Confirmed Malfunctions	**8**	**2**	**10**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

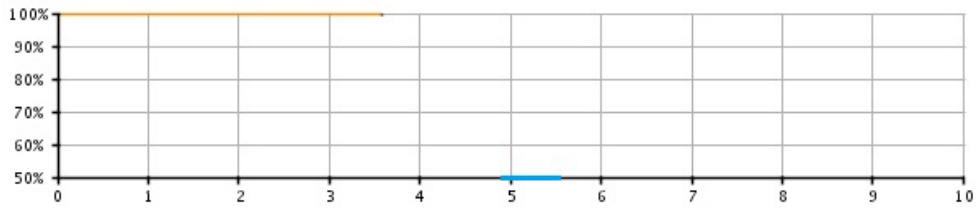
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

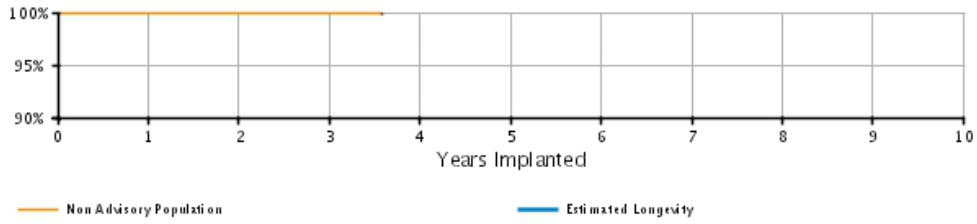
U.S. Registered Implants: 7,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:5
Without Compromised Therapy:4
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.88 (-0.1/+0.1)	99.81 (-0.2/+0.1)	99.66 @ 43 mo. (-0.6/+0.2)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.89 (-0.2/+0.1)	99.89 @ 43 mo. (-0.2/+0.1)	–	–	–	–	–	–
	Effective Sample Size	4931	3128	1184	289	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

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

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**6**	**2**	**8**
[47] Low-voltage capacitors	2	-	
[62] High voltage circuit component	4	-	
[64] High voltage capacitor	-	2	
Mechanical	**-**	**-**	**0**
Software	**1**	**1**	**2**
[51] Memory errors	1	1	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**9**	**3**	**12**

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

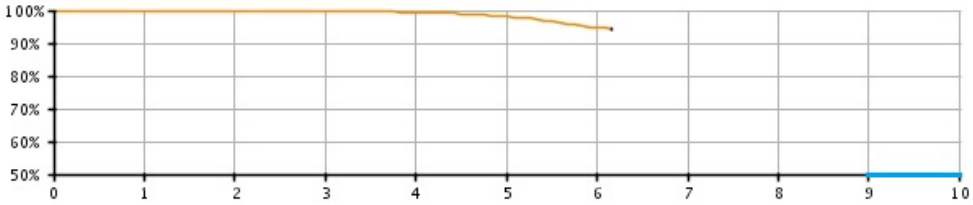
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

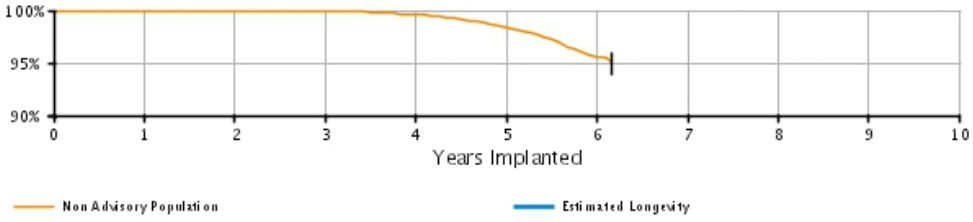
U.S. Registered Implants: 47,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 37,000

U.S. Normal Battery Depletions: 63
U.S. Unconfirmed Reports of Premature Battery Depletion : 26
U.S. Malfunctions:348
Without Compromised Therapy:338
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: 47000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.44 (-0.1/+0.1)	98.12 (-0.2/+0.2)	94.70 (-0.8/+0.7)	94.25 @ 74 mo. (-1.2/+1.0)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.62 (-0.1/+0.1)	98.43 (-0.2/+0.2)	95.54 (-0.7/+0.6)	95.09 @ 74 mo. (-1.2/+1.0)	–	–	–
	Effective Sample Size	41378	36088	29877	18423	8134	938	213	–	–	–

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: 534

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**503**	**9**	**512**
[43] High-voltage capacitor	1	2	
[47] Low-voltage capacitors	4	-	
[50] Integrated circuit	7	4	
[53] Battery	23	2	
[54] Low-voltage capacitor	467	1	
[58] High voltage circuit	1	-	
Mechanical	**-**	**2**	**2**
[38] Transformer	-	2	
Software	**4**	**-**	**4**
[51] Memory errors	4	-	
Other	**11**	**5**	**16**
Non-patterned	11	5	
WW Confirmed Malfunctions	**518**	**16**	**534**

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

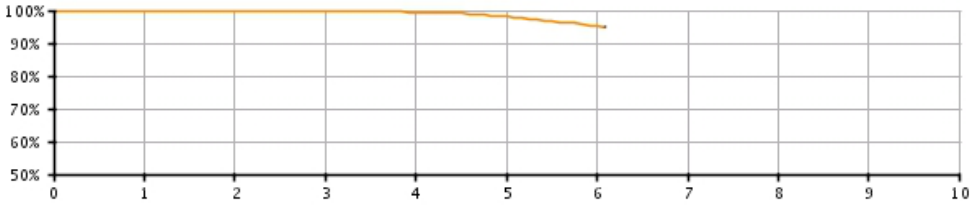
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

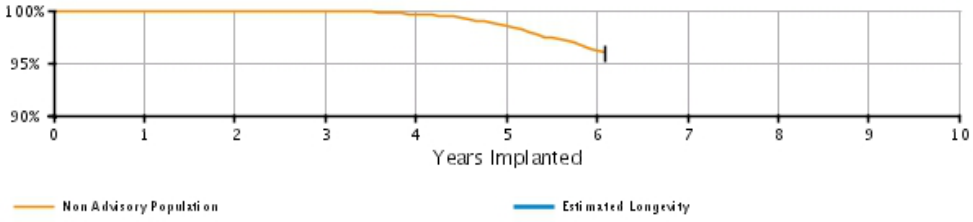
U.S. Registered Implants: 39,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 31,000

U.S. Normal Battery Depletions: 66
U.S. Unconfirmed Reports of Premature Battery Depletion : 31
U.S. Malfunctions:258
Without Compromised Therapy:243
With Compromised Therapy:15

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)	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.42 (-0.1/+0.1)	98.12 (-0.3/+0.2)	95.17 (-0.8/+0.7)	94.96 @ 73 mo. (-0.9/+0.8)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.63 (-0.1/+0.1)	98.53 (-0.2/+0.2)	96.20 (-0.7/+0.6)	95.99 @ 73 mo. (-0.9/+0.7)	–	–	–
	Effective Sample Size	34825	30425	25011	15217	6584	798	462	–	–	–

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: 417

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**378**	**14**	**392**
[43] High-voltage capacitor	1	3	
[50] Integrated circuit	2	5	
[53] Battery	30	3	
[54] Low-voltage capacitor	345	2	
[58] High voltage circuit	-	1	
Mechanical	**-**	**6**	**6**
[38] Transformer	-	6	
Software	**5**	**-**	**5**
[51] Memory errors	5	-	
Other	**8**	**6**	**14**
Non-patterned	8	6	
WW Confirmed Malfunctions	**391**	**26**	**417**

More details about malfunctions

References cited in table above

SQ-RX S-ICD

Model 1010

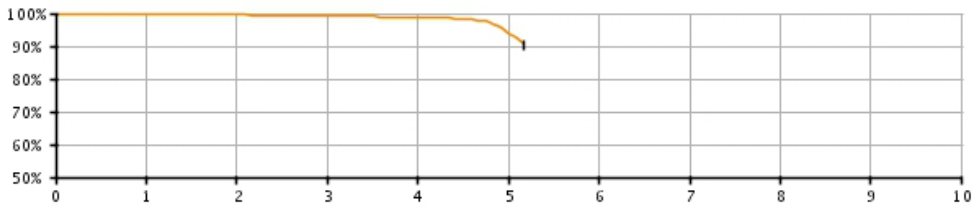
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

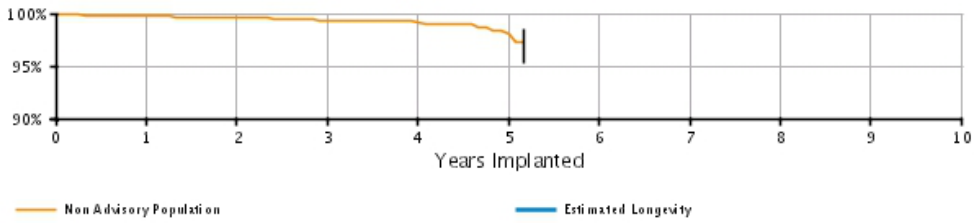
U.S. Registered Implants: 8,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 164
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:49
Without Compromised Therapy:16
With Compromised Therapy:33

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)	99.51 (-0.2/+0.1)	99.19 (-0.3/+0.2)	98.80 (-0.4/+0.3)	93.92 (-2.9/+2.0)	90.59 @ 62 mo. (-3.7/+2.7)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.77 (-0.1/+0.1)	99.56 (-0.2/+0.1)	99.32 (-0.2/+0.2)	99.15 (-0.3/+0.2)	98.04 (-1.6/+0.9)	97.30 @ 62 mo. (-2.1/+1.2)	–	–	–	–
	Effective Sample Size	6542	5738	4226	1127	275	241	–	–	–	–

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: 132

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**10**	**3**	**13**
[4] Unintended Fuse Activation 2013	-	3	
[61] Charge Timeout Alert	10	-	
Mechanical	**20**	**33**	**53**
[5] High cathode condition	1	2	
[55] Battery depletion	19	31	
Software	**3**	**-**	**3**
[57] Unintended Battery Depletion Alert	3	-	
Other	**19**	**44**	**63**
Non-patterned	16	34	
[56] Telemetry	3	10	
WW Confirmed Malfunctions	**52**	**80**	**132**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

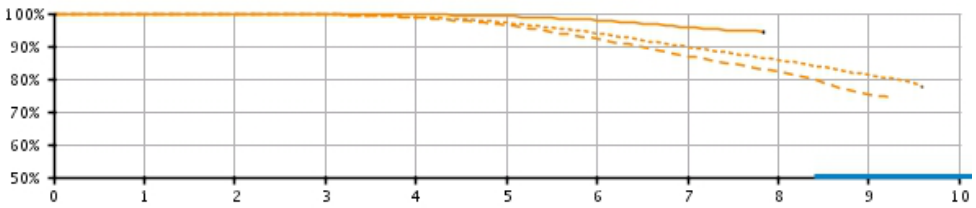
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

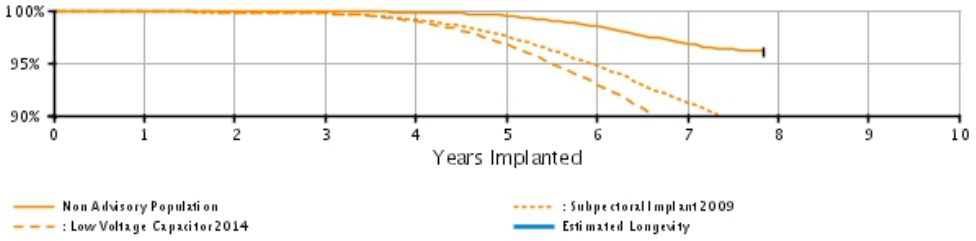
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 35,000

U.S. Normal Battery Depletions: 633
U.S. Unconfirmed Reports of Premature Battery Depletion : 196
U.S. Malfunctions:2381
Without Compromised Therapy:2245
With Compromised Therapy:136

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)	99.17 (-0.1/+0.1)	97.95 (-0.2/+0.2)	95.81 (-0.4/+0.3)	94.35 @ 94 mo. (-0.7/+0.7)	–	–
	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)	99.48 (-0.1/+0.1)	98.45 (-0.2/+0.2)	96.80 (-0.3/+0.3)	96.10 @ 94 mo. (-0.5/+0.4)	–	–
	Effective Sample Size	26441	23337	20590	18090	15822	13418	6216	440	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.1)	98.88 (-0.1/+0.1)	97.17 (-0.1/+0.1)	93.93 (-0.1/+0.1)	89.76 (-0.2/+0.1)	85.77 (-0.2/+0.3)	81.23 (-1.2/+0.5)	77.70 @ 115 mo. (-1.2/+0.5)
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.56 (-0.1/+0.1)	94.69 (-0.1/+0.1)	91.20 (-0.2/+0.3)	88.38 (-0.2/+0.3)	86.50 (-0.4/+0.3)	86.39 @ 115 mo. (-1.2/+0.5)
	Effective Sample Size	26746	23498	20668	18049	15603	13217	11045	9163	3288	418
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.73 (-0.1/+0.1)	96.36 (-0.1/+0.1)	92.11 (-0.1/+0.1)	86.91 (-0.1/+0.2)	81.81 (-0.3/+0.3)	75.49 (-0.4/+0.3)	74.26 @ 111 mo. (-0.4/+0.3)
	Malfunctions Only(%)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.95 (-0.1/+0.1)	96.76 (-0.1/+0.1)	92.93 (-0.1/+0.1)	88.46 (-0.1/+0.1)	84.95 (-0.2/+0.1)	81.42 (-0.4/+0.3)	81.32 @ 111 mo.

	(Confidence Interval)									(-0.4/+0.3)
	Effective Sample Size 20715	18217	16008	13971	11982	10026	8276	5769	1074	273

*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: 3139

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2904**	**106**	**3010**
[3] Low Voltage Capacitor 2014 (Advisory issued)	2044	47	
[42] Safety Core-electrocautery	3	-	
[43] High-voltage capacitor	1	7	
[47] Low-voltage capacitors	8	-	
[50] Integrated circuit	20	21	
[53] Battery	216	26	
[54] Low-voltage capacitor	612	5	
Mechanical	**20**	**54**	**74**
[6] Subpectoral implant 2009	3	12	
[38] Transformer	-	20	
[40] Seal plug	3	-	
[41] Difficulty securing lead	9	8	
[45] Header contacts	3	11	
[67] Header	2	3	
Software	**18**	**-**	**18**
[48] Alert messages not displayed post-EOL	3	-	
[51] Memory errors	15	-	
Other	**26**	**11**	**37**
Non-patterned	26	11	
WW Confirmed Malfunctions	**2968**	**171**	**3139**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

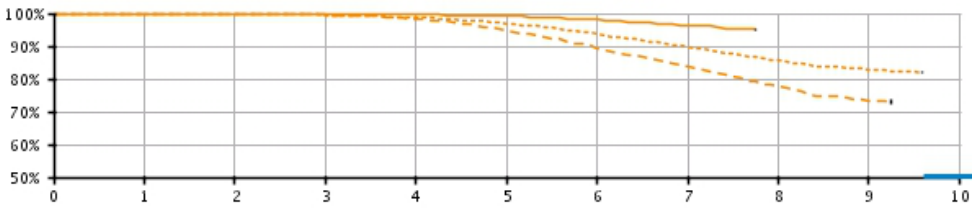
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

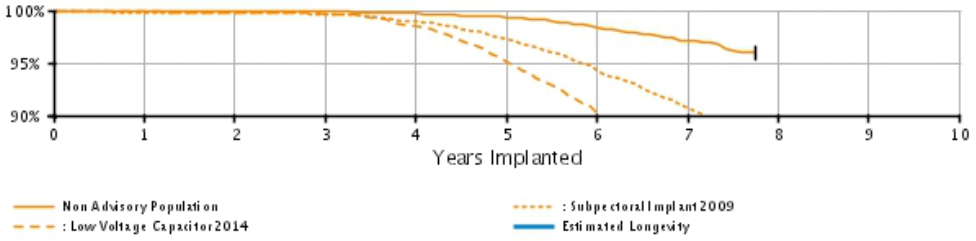
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 122
U.S. Unconfirmed Reports of Premature Battery Depletion : 138
U.S. Malfunctions:1606
Without Compromised Therapy:1500
With Compromised Therapy:106

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)	99.13 (-0.2/+0.2)	98.05 (-0.3/+0.3)	96.38 (-0.5/+0.4)	95.08 @ 93 mo. (-0.8/+0.7)	–	–
	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)	98.41 (-0.3/+0.2)	97.18 (-0.4/+0.4)	96.01 @ 93 mo. (-0.8/+0.7)	–	–
	Effective Sample Size	16274	14323	12580	11030	9635	8175	3011	280	–	–
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.0/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.1/+0.1)	96.93 (-0.1/+0.1)	93.68 (-0.1/+0.1)	89.64 (-0.1/+0.1)	85.54 (-0.2/+0.1)	82.88 (-0.6/+0.5)	81.86 @ 115 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)	97.31 (-0.1/+0.1)	94.36 (-0.1/+0.2)	90.65 (-0.4/+0.3)	87.15 (-0.5/+0.6)	84.89 (-0.6/+0.9)	84.83 @ 115 mo. (-0.6/+0.5)
	Effective Sample Size	13679	11990	10509	9145	7858	6656	5547	4582	1746	235
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.1)	98.23 (-0.1/+0.1)	94.78 (-0.2/+0.1)	89.46 (-0.3/+0.2)	83.60 (-0.4/+0.2)	77.60 (-0.5/+0.6)	73.46 (-1.5/+1.6)	72.87 @ 111 mo. (-1.5/+1.6)
	Malfunctions Only(%)	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)	90.24 (-0.1/+0.1)	84.89 (-0.3/+0.2)	79.67 (-0.5/+0.6)	76.09 (-1.5/+1.6)	75.84 @ 111 mo.

	(Confidence Interval)									(-1.5/+1.6)
	Effective Sample Size 10903	9575	8397	7284	6163	5085	4122	2555	543	216

*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: 2600

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2376**	**89**	**2465**
[3] Low Voltage Capacitor 2014 (Advisory issued)	1653	36	
[42] Safety Core-electrocautery	1	1	
[43] High-voltage capacitor	-	3	
[47] Low-voltage capacitors	5	-	
[50] Integrated circuit	11	15	
[53] Battery	316	33	
[54] Low-voltage capacitor	390	1	
Mechanical	**24**	**73**	**97**
[6] Subpectoral implant 2009 (Advisory issued)	7	19	
[24] Transformer	-	2	
[38] Transformer	-	14	
[40] Seal plug	1	-	
[41] Difficulty securing lead	-	10	
[45] Header contacts	14	20	
[67] Header	2	8	
Software	**16**	**-**	**16**
[7] Respiratory Sensor Oversensing	1	-	
[48] Alert messages not displayed post-EOL	4	-	
[51] Memory errors	11	-	
Other	**11**	**11**	**22**
Non-patterned	11	11	
WW Confirmed Malfunctions	**2427**	**173**	**2600**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR

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

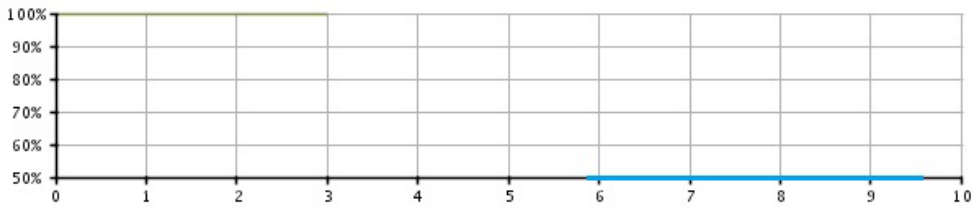
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

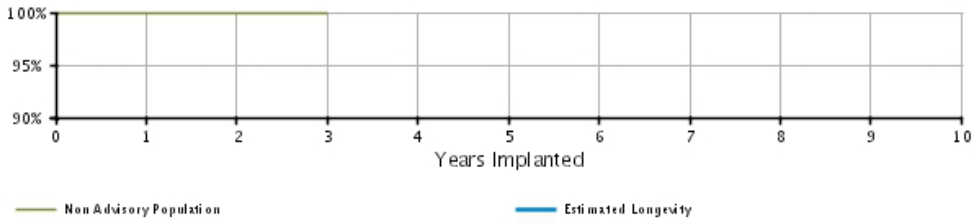
U.S. Registered Implants: 107,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 101,000

U.S. Normal Battery Depletions: 28
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:37
Without Compromised Therapy:32
With Compromised Therapy:5

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 107000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.84 (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	62717	23022	413	–	–	–	–	–	–	–

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: 205,000
Worldwide Confirmed Malfunctions: 65

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**36**	**5**	**41**
[47] Low-voltage capacitors	2	-	
[63] Integrated circuit	13	4	
[65] Capacitor	15	-	
[66] Telemetry	6	1	
Mechanical	**-**	**-**	**0**
Software	**9**	**-**	**9**
[51] Memory errors	9	-	
Other	**12**	**3**	**15**
Non-patterned	12	3	
WW Confirmed Malfunctions	**57**	**8**	**65**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

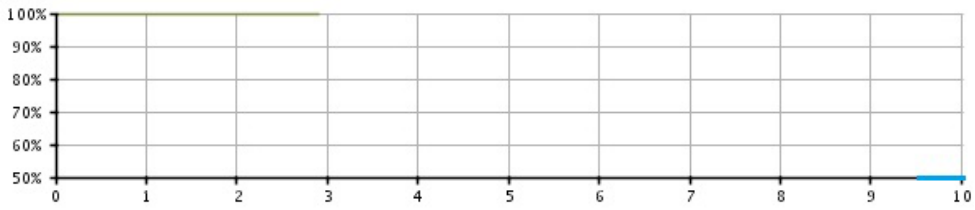
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

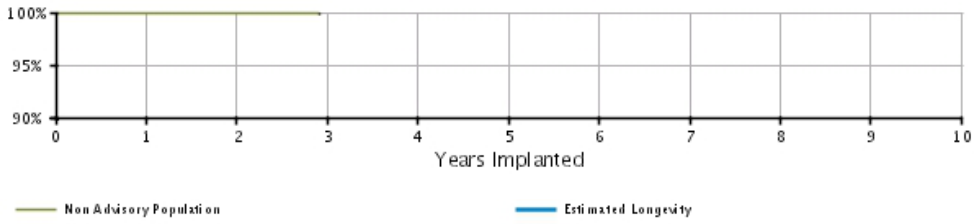
U.S. Registered Implants: 43,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 41,000

U.S. Normal Battery Depletions: 6
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
U.S. Malfunctions:19
Without Compromised Therapy:18
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: 43000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.83 @ 35 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.89 @ 35 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	22402	6910	378	–	–	–	–	–	–	–

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: 104,000
Worldwide Confirmed Malfunctions: 42

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**26**	**1**	**27**
[47] Low-voltage capacitors	2	-	
[63] Integrated circuit	4	1	
[65] Capacitor	14	-	
[66] Telemetry	6	-	
Mechanical	**-**	**-**	**0**
Software	**12**	**-**	**12**
[51] Memory errors	12	-	
Other	**3**	**-**	**3**
Non-patterned	3	-	
WW Confirmed Malfunctions	**41**	**1**	**42**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

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

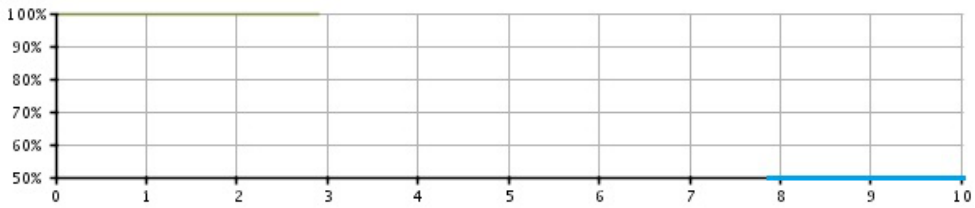
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

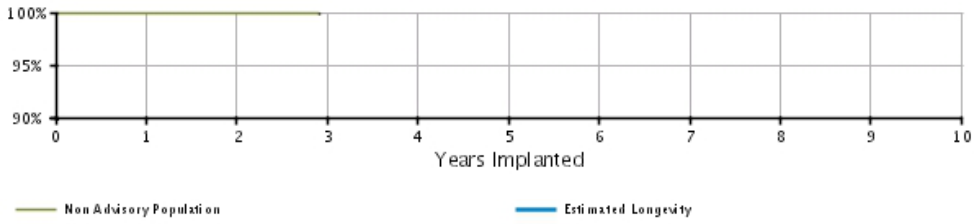
U.S. Registered Implants: 22,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 19,000

U.S. Normal Battery Depletions: 8
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:9
Without Compromised Therapy:8
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)	99.95 (-0.0/+0.0)	99.85 (-0.1/+0.1)	99.81 @ 35 mo. (-0.1/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.91 @ 35 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	12231	4180	200	–	–	–	–	–	–	–

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: 73,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**8**	**3**	**11**
[47] Low-voltage capacitors	2	-	
[63] Integrated circuit	1	3	
[65] Capacitor	3	-	
[66] Telemetry	2	-	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[51] Memory errors	2	-	
Other	**3**	**-**	**3**
Non-patterned	3	-	
WW Confirmed Malfunctions	**13**	**3**	**16**

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

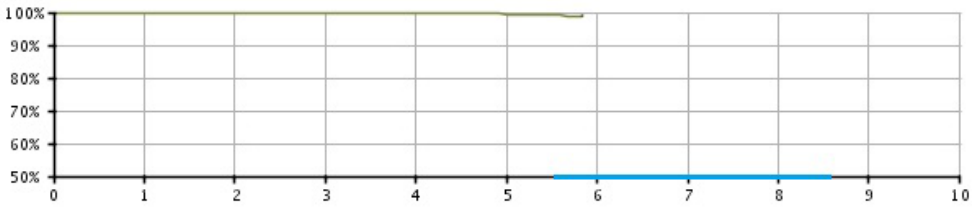
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

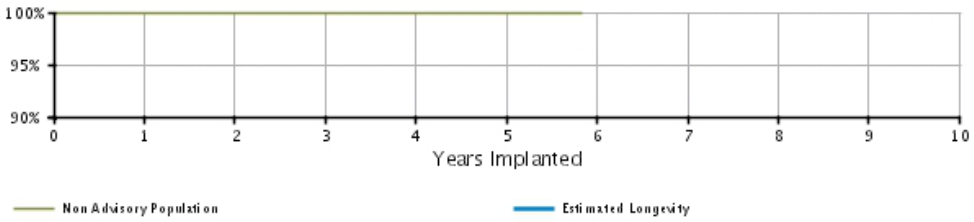
U.S. Registered Implants: 121,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 97,000

U.S. Normal Battery Depletions: 253
U.S. Unconfirmed Reports of Premature Battery Depletion : 15
U.S. Malfunctions:45
Without Compromised Therapy:34
With Compromised Therapy:11

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 121000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.46 (-0.1/+0.1)	98.97 @ 70 mo. (-0.2/+0.2)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.93 @ 70 mo. (-0.0/+0.0)	–	–	–	–
	Effective Sample Size	107670	95533	79583	44216	15375	370	–	–	–	–

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: 218,000
Worldwide Confirmed Malfunctions: 74

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**10**	**9**	**19**
[47] Low-voltage capacitors	7	-	
[50] Integrated circuit	3	7	
[60] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**20**	**1**	**21**
[51] Memory errors	20	1	
Other	**28**	**6**	**34**
Non-patterned	28	6	
WW Confirmed Malfunctions	**58**	**16**	**74**

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

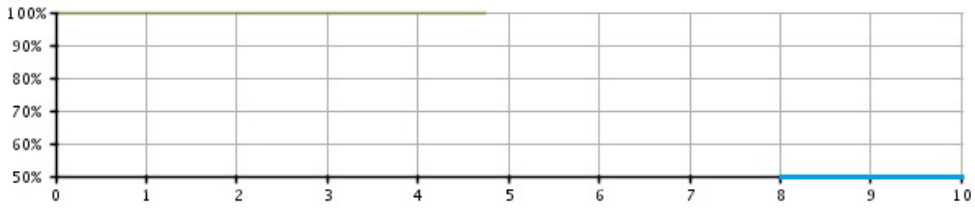
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

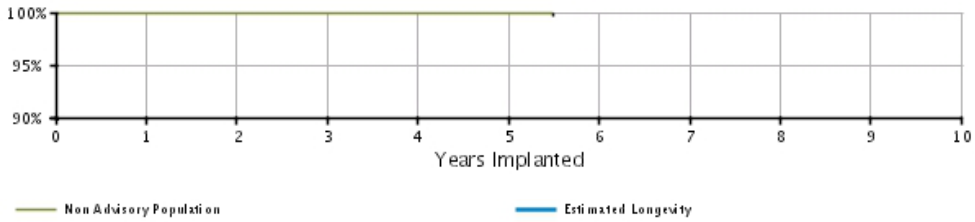
U.S. Registered Implants: 11,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:5
Without Compromised Therapy:4
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.85 @ 57 mo. (-0.2/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.89 @ 57 mo. (-0.3/+0.1)	–	–	–	–	–
	Effective Sample Size	9702	8463	6500	1867	269	–	–	–	–	–

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: 73,000
Worldwide Confirmed Malfunctions: 35

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**5**	**10**
[47] Low-voltage capacitors	5	1	
[50] Integrated circuit	-	2	
[60] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**5**	**-**	**5**
[51] Memory errors	4	-	
[59] Respiratory sensor	1	-	
Other	**18**	**2**	**20**
Non-patterned	18	2	
WW Confirmed Malfunctions	**28**	**7**	**35**

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

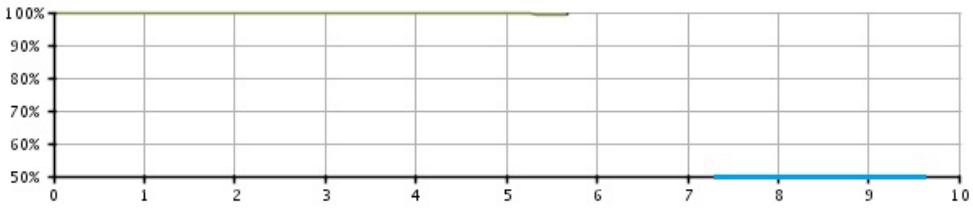
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

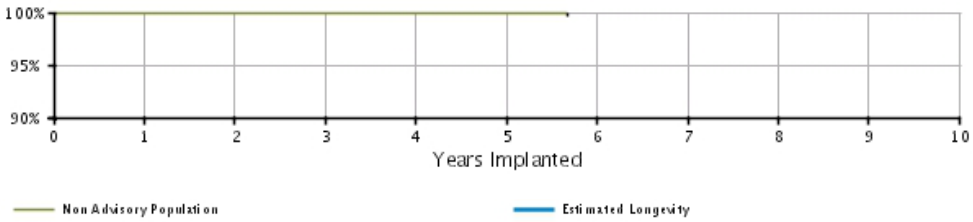
U.S. Registered Implants: 27,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 19,000

U.S. Normal Battery Depletions: 32
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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: 27000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.79 (-0.1/+0.1)	99.72 (-0.1/+0.1)	99.45 @ 68 mo. (-0.3/+0.2)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.85 @ 68 mo. (-0.3/+0.1)	–	–	–	–
	Effective Sample Size	23053	20187	15963	8537	2800	338	–	–	–	–

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: 85,000
Worldwide Confirmed Malfunctions: 22

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**5**	**10**
[47] Low-voltage capacitors	3	1	
[50] Integrated circuit	2	3	
[60] Titanium case material	-	1	
Mechanical	**-**	**-**	**0**
Software	**7**	**-**	**7**
[51] Memory errors	7	-	
Other	**2**	**3**	**5**
Non-patterned	2	3	
WW Confirmed Malfunctions	**14**	**8**	**22**

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

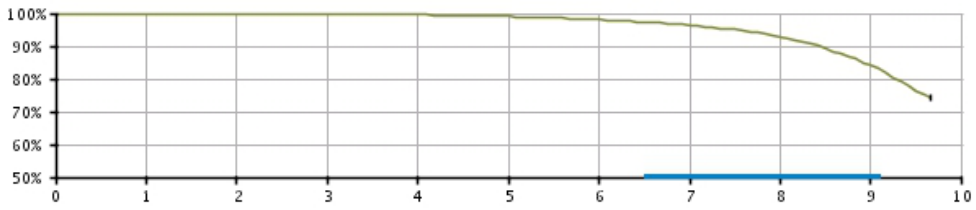
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

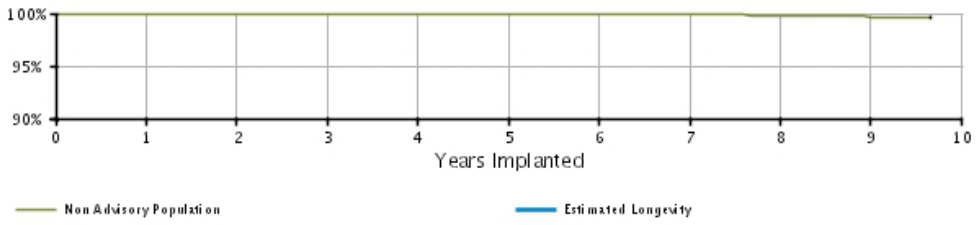
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 12,000

U.S. Normal Battery Depletions: 1,192
U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Malfunctions:24
Without Compromised Therapy:22
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: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.02 (-0.2/+0.2)	98.03 (-0.3/+0.2)	96.42 (-0.4/+0.3)	92.93 (-0.6/+0.5)	84.09 (-1.0/+0.9)	74.36 @ 116 mo. (-1.9/+1.8)
	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 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	99.67 (-0.2/+0.1)	99.62 @ 116 mo. (-0.2/+0.1)
	Effective Sample Size	19624	17392	15362	13483	11708	9934	7890	5845	2861	339

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: 36

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[15] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[16] Capacitor array	1	-	
[41] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**30**	**3**	**33**
Non-patterned	2	2	
[26] Battery depletion	1	1	
[49] Battery status	27	-	
WW Confirmed Malfunctions	**32**	**4**	**36**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

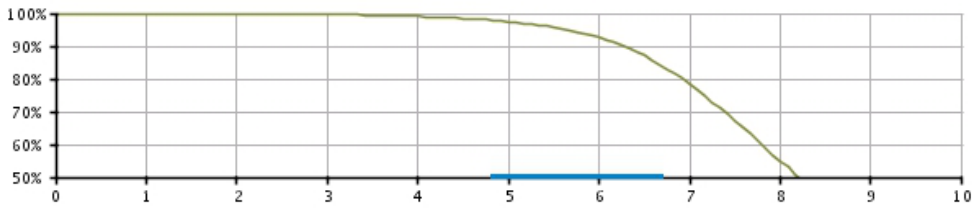
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

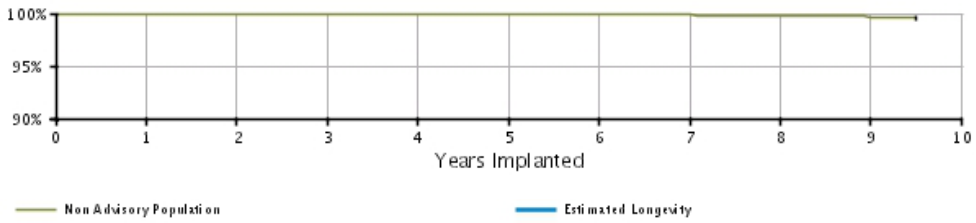
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 40,000

U.S. Normal Battery Depletions: 14,625
U.S. Unconfirmed Reports of Premature Battery Depletion : 45
U.S. Malfunctions:83
Without Compromised Therapy:74
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: 90000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.09 (-0.1/+0.1)	97.47 (-0.1/+0.1)	92.66 (-0.2/+0.2)	78.31 (-0.4/+0.4)	54.86 (-0.7/+0.7)	33.23 (-0.9/+0.9)	21.39 @ 114 mo. (-1.3/+1.4)
	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)	99.90 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.76 (-0.1/+0.1)	99.62 (-0.2/+0.1)	99.54 @ 114 mo. (-0.3/+0.2)
	Effective Sample Size	79405	70670	62798	55553	48136	37166	20819	7683	1488	270

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: 105

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**8**	**13**
[15] Capacitor	4	7	
[30] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[39] Connector block	1	-	
[41] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**86**	**4**	**90**
Non-patterned	3	3	
[21] Magnet response	2	-	
[26] Battery depletion	3	1	
[49] Battery status	78	-	
WW Confirmed Malfunctions	**93**	**12**	**105**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

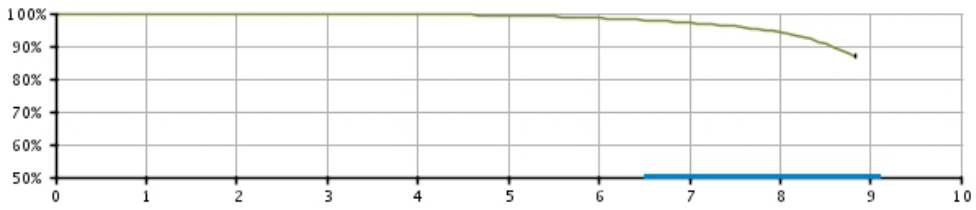
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

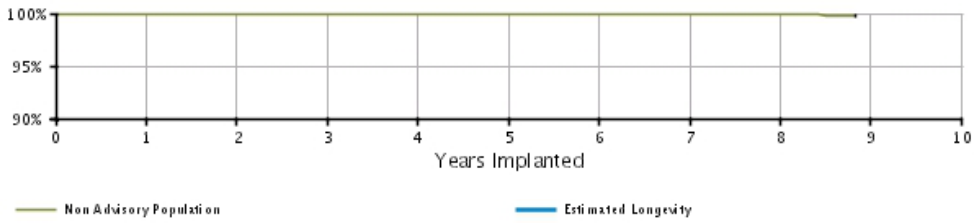
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 39,000

U.S. Normal Battery Depletions: 1,057
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:20
Without Compromised Therapy:16
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: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.34 (-0.1/+0.1)	98.57 (-0.1/+0.1)	97.17 (-0.2/+0.2)	94.19 (-0.5/+0.4)	86.98 @ 106 mo. (-1.9/+1.7)	–
	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)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.81 @ 106 mo. (-0.2/+0.1)	–
	Effective Sample Size	52722	46895	41635	36903	32260	24919	13247	4500	233	–

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: 23

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[15] Capacitor	3	-	
[17] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[41] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**15**	**3**	**18**
Non-patterned	1	1	
[26] Battery depletion	-	2	
[44] Magnet rate	1	-	
[49] Battery status	13	-	
WW Confirmed Malfunctions	**19**	**4**	**23**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

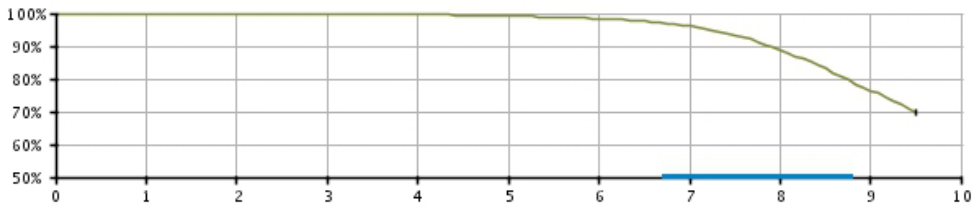
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

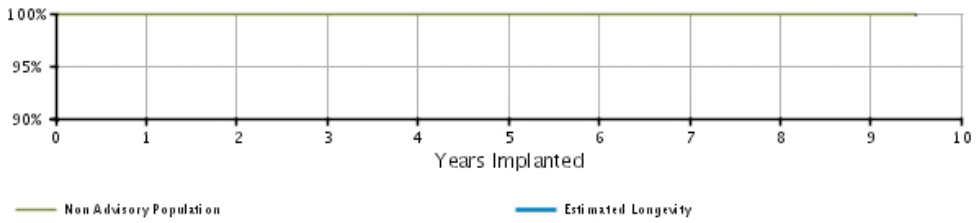
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 1,273
U.S. Unconfirmed Reports of Premature Battery Depletion : 5
U.S. Malfunctions:12
Without Compromised Therapy:10
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)	99.62 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.41 (-0.2/+0.2)	96.18 (-0.4/+0.3)	88.78 (-0.8/+0.7)	76.47 (-1.5/+1.5)	69.76 @ 114 mo. (-2.4/+2.3)
	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)	99.92 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.87 (-0.1/+0.1)	99.87 @ 114 mo. (-0.1/+0.1)
	Effective Sample Size	26716	23510	20890	18518	16102	12679	7812	3860	1024	300

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: 23

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[15] Capacitor	1	2	
[30] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**15**	**3**	**18**
Non-patterned	1	2	
[26] Battery depletion	-	1	
[49] Battery status	14	-	
WW Confirmed Malfunctions	**16**	**7**	**23**

More details about malfunctions

References cited in table above

ALTRUA 50 SR

Model S501

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

ALTRUA 50 SR
Model S501

Worldwide Distribution: 25,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[15] Capacitor	1	4	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**3**	**4**
Non-patterned	-	1	
[26] Battery depletion	-	2	
[49] Battery status	1	-	
WW Confirmed Malfunctions	**2**	**7**	**9**

More details about malfunctions

References cited in table above

ALTRUA 50 DR (Downsize)

Model S502

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

ALTRUA 50 DR (Downsize) Model S502

Worldwide Distribution: 48,000
Worldwide Confirmed Malfunctions: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**1**	**4**
[15] Capacitor	2	1	
[30] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[41] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**22**	**-**	**22**
Non-patterned	1	-	
[26] Battery depletion	2	-	
[49] Battery status	19	-	
WW Confirmed Malfunctions	**25**	**2**	**27**

More details about malfunctions

References cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

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

ALTRUA 50 DDD (Downsize) Model S503

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	6	3	9
Non-patterned	-	-	
[26] Battery depletion	-	3	
[49] Battery status	6	-	
WW Confirmed Malfunctions	6	3	9

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	-	-	
[49] 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: 4

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

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

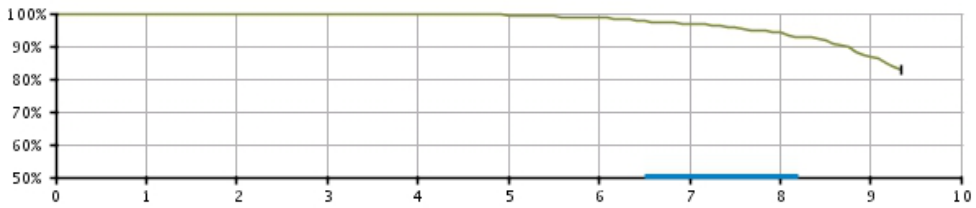
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

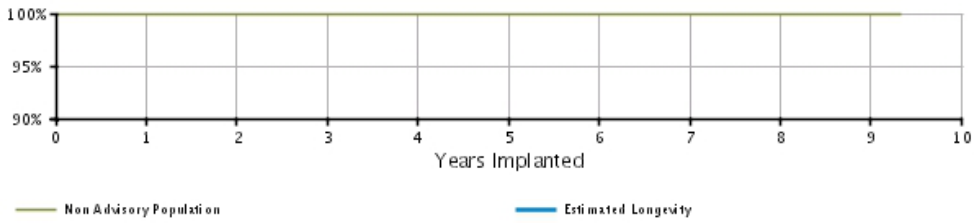
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 107
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)	96.78 (-1.4/+1.0)	94.08 (-1.9/+1.5)	86.75 (-2.8/+2.4)	82.81 @ 112 mo. (-3.5/+3.0)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	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 @ 112 mo. (-0.0/+0.0)
	Effective Sample Size	1517	1346	1194	1064	945	835	728	625	421	213

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	-	-	
[26] Battery depletion	-	1	
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

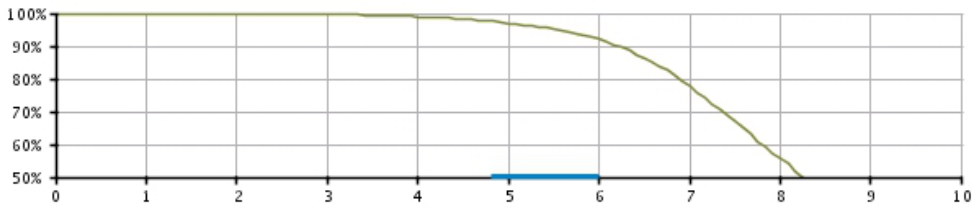
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

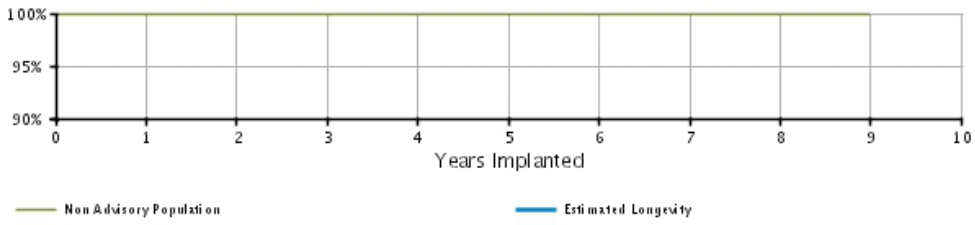
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 2,303
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
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)	96.94 (-0.4/+0.3)	92.09 (-0.6/+0.6)	77.83 (-1.1/+1.1)	55.92 (-1.7/+1.7)	35.33 (-2.4/+2.5)	–
	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 (-0.1/+0.0)	99.97 (-0.1/+0.0)	–
	Effective Sample Size	12514	11156	9913	8778	7665	6108	3315	1134	237	–

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**
[40] Seal plug	1	-	
[41] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	-	-	
[49] Battery status	2	-	
WW Confirmed Malfunctions	**4**	**0**	**4**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

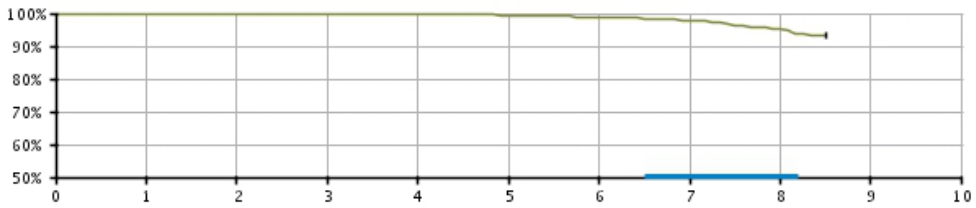
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

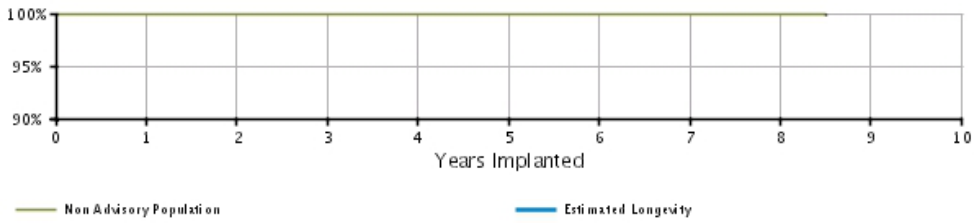
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 87
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
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)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.41 (-0.3/+0.2)	98.71 (-0.5/+0.4)	97.88 (-0.7/+0.5)	95.08 (-1.4/+1.1)	93.33 @ 102 mo. (-1.9/+1.5)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.96 @ 102 mo. (-0.2/+0.0)	–
	Effective Sample Size	4474	3985	3561	3164	2803	2293	1348	587	201	–

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ALTRUA 40 SR

Model S401

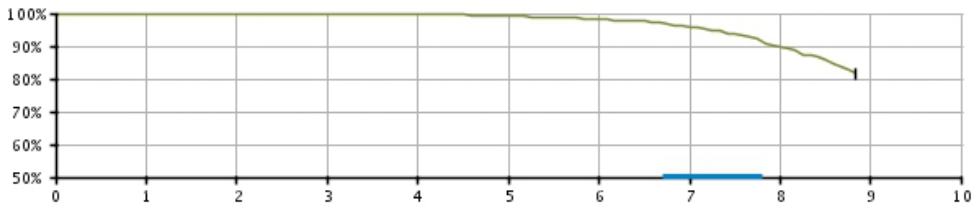
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

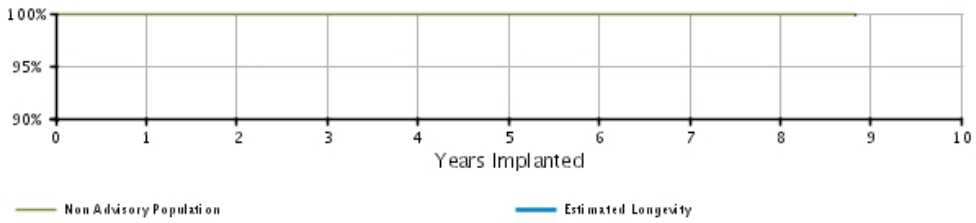
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 173
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/+0.2)	98.20 (-0.6/+0.5)	95.94 (-1.0/+0.8)	89.71 (-2.0/+1.7)	81.55 @ 106 mo. (-3.4/+3.0)	–
	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 (-0.2/+0.0)	99.94 @ 106 mo. (-0.2/+0.0)	–
	Effective Sample Size	3951	3456	3025	2686	2373	1943	1222	579	228	–

ALTRUA 40 SR

Model S401

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

ALTRUA 40 SR
Model S401

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**1**	**3**
[15] Capacitor	2	-	
[30] 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

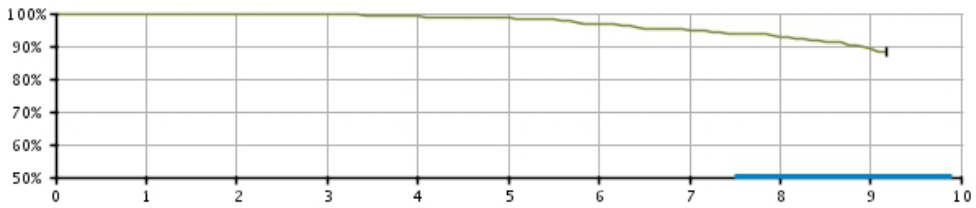
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

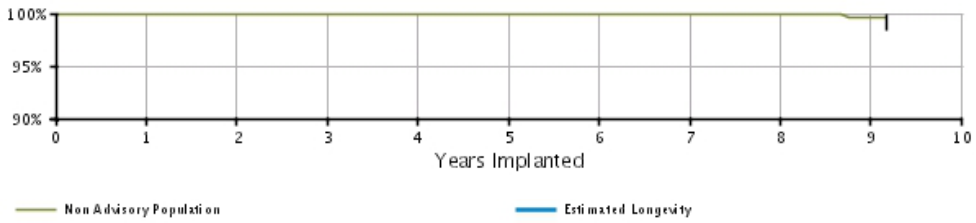
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 72
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:1
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 (-0.4/+0.1)	99.61 (-0.5/+0.2)	99.15 (-0.7/+0.4)	98.53 (-0.9/+0.6)	96.64 (-1.4/+1.0)	94.70 (-1.8/+1.4)	92.87 (-2.2/+1.7)	89.40 (-2.8/+2.3)	88.36 @ 110 mo. (-3.0/+2.5)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.65 (-1.3/+0.3)	99.65 @ 110 mo. (-1.3/+0.3)
	Effective Sample Size	1550	1359	1172	1008	863	730	589	471	307	211

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: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	1	3
Non-patterned	-	-	
[26] Battery depletion	-	1	
[44] Magnet rate	1	-	
[49] Battery status	1	-	
WW Confirmed Malfunctions	2	1	3

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

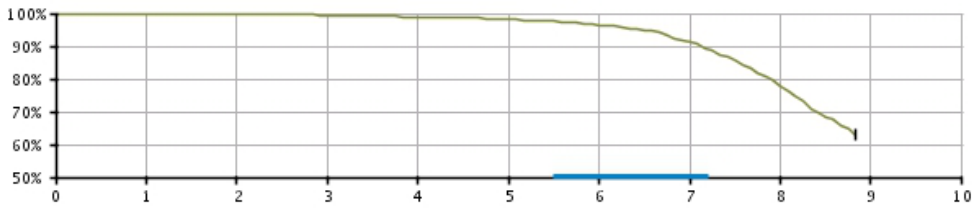
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

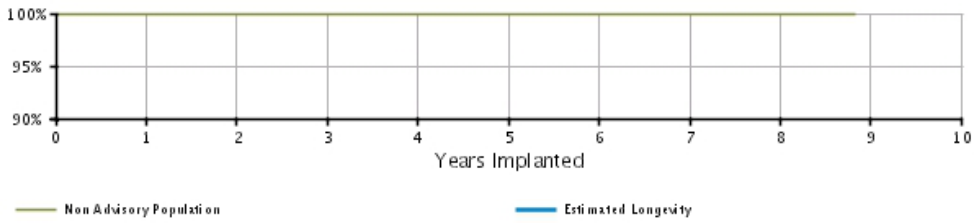
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 436
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)	99.42 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.17 (-0.5/+0.4)	96.43 (-0.8/+0.6)	91.24 (-1.3/+1.1)	77.75 (-2.4/+2.2)	62.93 @ 106 mo. (-3.7/+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 @ 106 mo. (-0.0/+0.0)	–
	Effective Sample Size	4401	3886	3452	3059	2709	2238	1406	621	NaN	–

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

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

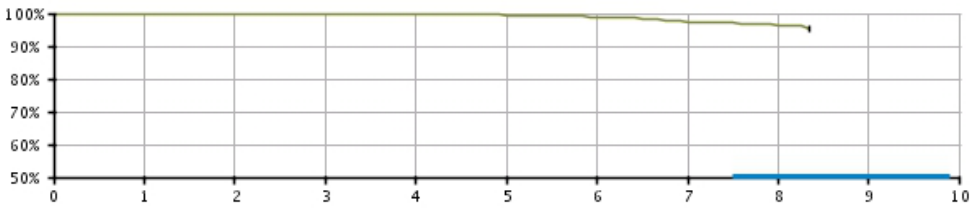
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

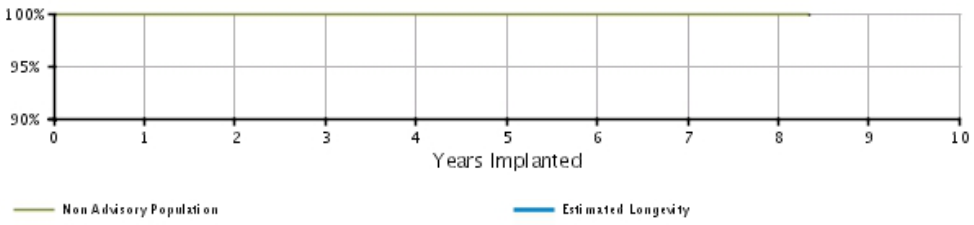
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 43
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)	99.46 (-0.4/+0.2)	98.88 (-0.6/+0.4)	97.48 (-1.0/+0.7)	96.35 (-1.5/+1.1)	95.40 @ 100 mo. (-2.2/+1.5)	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 100 mo. (-0.2/+0.0)	–
	Effective Sample Size	2770	2465	2187	1954	1730	1406	824	337	204	–

ALTRUA 20 DR EL

Model S208

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

ALTRUA 20 DR EL
Model S208

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 3

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

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

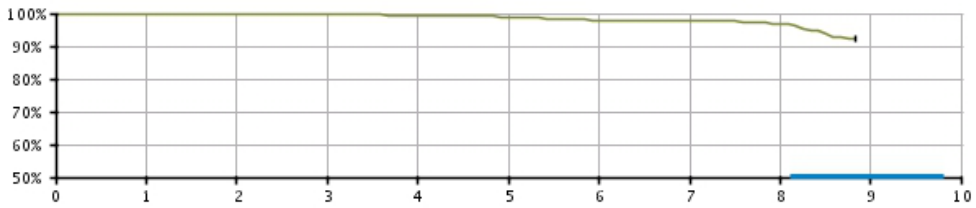
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

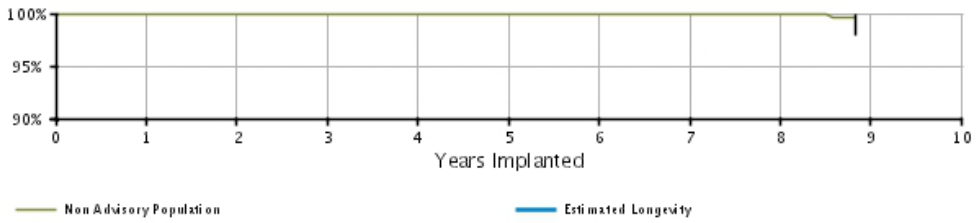
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 72
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
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)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.68 (-0.3/+0.2)	99.34 (-0.4/+0.2)	98.77 (-0.5/+0.4)	97.91 (-0.7/+0.5)	97.60 (-0.8/+0.6)	96.85 (-1.1/+0.8)	92.39 @ 106 mo. (-2.6/+2.0)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.61 @ 106 mo. (-1.7/+0.3)	–
	Effective Sample Size	3614	3077	2631	2284	1962	1577	995	520	213	–

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: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[15] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**1**	**3**
Non-patterned	-	1	
[49] Battery status	2	-	
WW Confirmed Malfunctions	**3**	**1**	**4**

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

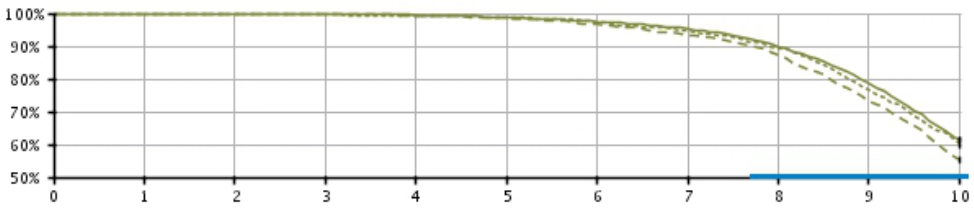
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

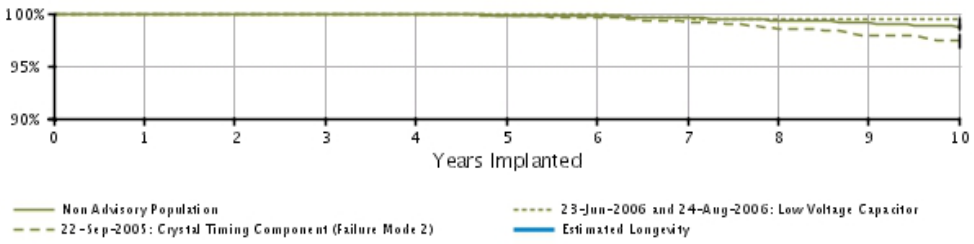
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 6,260
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:197
Without Compromised Therapy:183
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: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.50 (-0.1/+0.1)	98.71 (-0.2/+0.2)	97.43 (-0.3/+0.3)	95.30 (-0.4/+0.4)	89.76 (-0.6/+0.6)	78.55 (-0.9/+0.8)	61.46 (-1.1/+1.1)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.07 (-0.2/+0.2)	98.71 (-0.3/+0.2)
	Effective Sample Size	21003	18658	16559	14650	12904	11298	9791	8150	6266	3555
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.47 (-1.1/+0.8)	94.62 (-1.5/+1.2)	89.39 (-2.2/+1.8)	76.96 (-3.1/+2.8)	60.37 (-3.7/+3.6)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.63 (-0.6/+0.2)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	843	692	519	349
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)	73.46 (-1.8/+1.7)	55.45 (-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)	97.95 (-0.7/+0.5)	97.38 (-0.8/+0.6)
	Effective Sample Size	5703	5046	4467	3938	3451	2977	2553	2093	1548	991

*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: 246

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[14] Capacitor	1	-	
[15] Capacitor	4	2	
[30] Integrated circuit	2	1	
Mechanical	**8**	**5**	**13**
[19] Seal plug	5	4	
[20] Header	2	1	
[32] Setscrew	1	-	
Software	**4**	**-**	**4**
[34] Underestimation of battery status	3	-	
[36] Pacing rate limit	1	-	
Other	**208**	**9**	**217**
Non-patterned	10	8	
[11] Longevity labeling	75	-	
[21] Magnet response	1	-	
[26] Battery depletion	3	1	
[49] Battery status	119	-	
WW Confirmed Malfunctions	**227**	**19**	**246**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

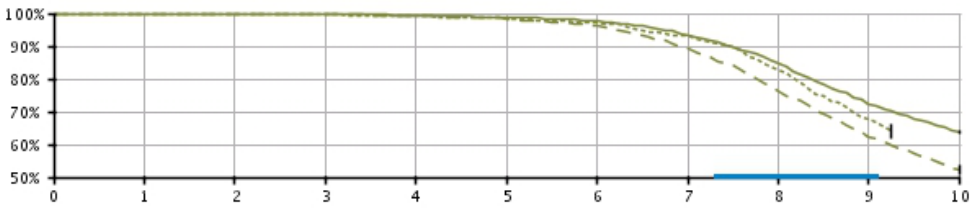
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

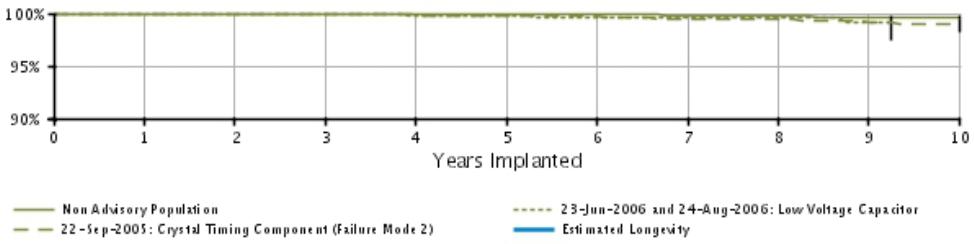
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 3,116
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:45
Without Compromised Therapy:40
With Compromised Therapy:5

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.70 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.53 (-0.4/+0.3)	93.43 (-0.6/+0.6)	84.53 (-0.9/+0.9)	72.46 (-1.2/+1.2)	63.84 (-1.4/+1.3)
	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)	99.62 (-0.2/+0.1)	99.59 (-0.2/+0.1)
	Effective Sample Size	14134	12065	10276	8805	7662	6691	5689	4543	3393	2216
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)	97.19 (-1.6/+1.0)	93.16 (-2.5/+1.9)	82.90 (-3.8/+3.2)	67.54 (-4.8/+4.5)	64.11 @ 111 mo. (-5.0/+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)	99.19 (-1.7/+0.6)	99.19 @ 111 mo. (-1.7/+0.6)
	Effective Sample Size	1146	961	810	696	584	494	412	323	223	204
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)	96.23 (-0.9/+0.7)	89.32 (-1.5/+1.3)	76.18 (-2.2/+2.1)	62.23 (-2.6/+2.5)	52.28 (-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)	99.00 (-0.8/+0.4)
	Effective Sample Size	4143	3554	2996	2523	2106	1763	1412	1022	722	517

*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: 80

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[8] Low-voltage capacitor (Advisory issued)	1	3	
[15] Capacitor	1	-	
[30] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[19] Seal plug	3	-	
[20] Header	-	1	
Software	**1**	**-**	**1**
[23] Memory error	1	-	
Other	**67**	**1**	**68**
Non-patterned	1	-	
[11] Longevity labeling	23	-	
[26] Battery depletion	2	1	
[49] Battery status	41	-	
WW Confirmed Malfunctions	**73**	**7**	**80**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

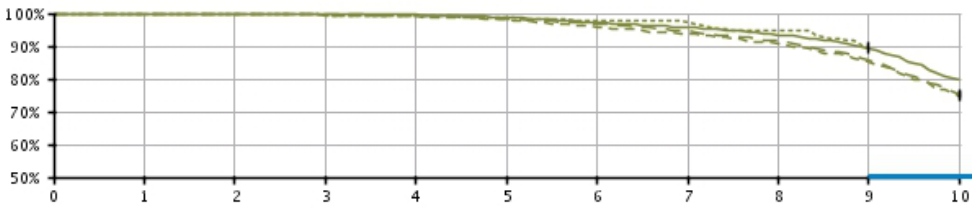
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

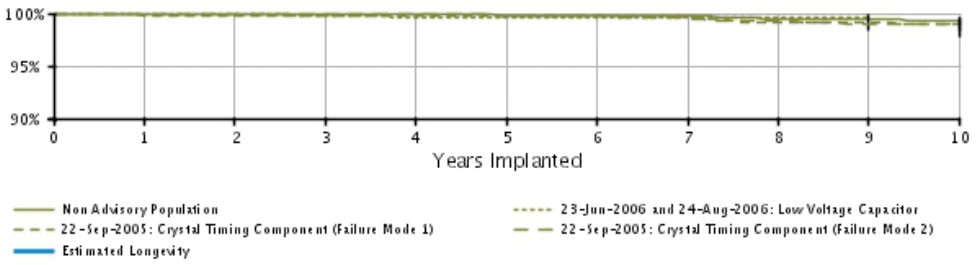
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 2,401
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:70
Without Compromised Therapy:62
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: 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)	97.04 (-0.6/+0.5)	95.65 (-0.7/+0.6)	93.49 (-0.9/+0.8)	89.39 (-1.2/+1.1)	79.64 (-1.7/+1.6)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.44 (-0.3/+0.2)	99.34 (-0.4/+0.2)
	Effective Sample Size	6261	5547	4913	4353	3801	3300	2886	2517	2121	1436
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)	97.32 (-2.1/+1.2)	94.51 (-3.1/+2.0)	89.82 (-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)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	99.61 (-1.2/+0.3)	–
	Effective Sample Size	693	607	528	451	393	336	292	245	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)	93.68 (-1.8/+1.4)	90.90 (-2.2/+1.8)	85.16 (-2.9/+2.5)	74.93 (-3.8/+3.4)

	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.18 (-1.0/+0.5)	99.18 (-1.0/+0.5)	98.94 (-1.2/+0.6)
	Effective Sample Size	1676	1453	1212	1062	922	783	659	552	449	331
22-Sep-05 Crystal Timing Component (Failure Mode 2)* 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)	98.37 (-0.4/+0.3)	96.89 (-0.6/+0.5)	94.56 (-0.8/+0.7)	91.52 (-1.0/+0.9)	85.53 (-1.4/+1.3)	75.35 (-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	6208	5480	4822	4228	3691	3185	2674	2255	1841	1390

*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: 88

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[13] Integrated circuit	-	1	
[15] Capacitor	-	1	
[30] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[9] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[19] Seal plug	3	-	
[20] Header	-	2	
Software	**1**	**-**	**1**
[34] Underestimation of battery status	1	-	
Other	**68**	**6**	**74**
Non-patterned	4	6	
[11] Longevity labeling	49	-	
[49] Battery status	15	-	
WW Confirmed Malfunctions	**72**	**16**	**88**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

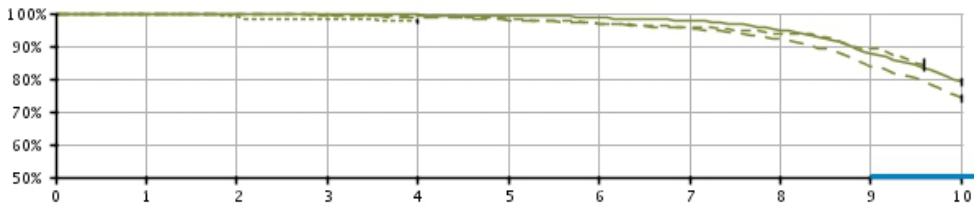
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

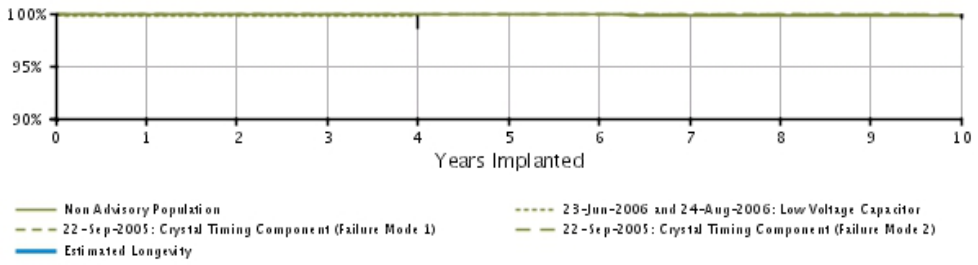
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 1,134
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)	97.88 (-0.7/+0.5)	94.84 (-1.1/+0.9)	87.81 (-1.7/+1.5)	79.04 (-2.3/+2.1)
	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	3870	3246	2729	2300	1966	1710	1460	1171	762
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 500	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.10 (-1.9/+0.6)	98.39 (-2.2/+0.9)	97.94 (-2.5/+1.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	–	–	–	–	–	–
	Effective Sample Size	348	284	236	203	–	–	–	–	–	–
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)	84.27 @ 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	242	202
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.94 (-0.8/+0.6)	95.24 (-1.0/+0.8)	92.14 (-1.3/+1.2)	83.97 (-2.0/+1.8)	74.17 (-2.5/+2.3)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	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	2629	2172	1814	1524	1269	1003	766

*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: 29

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[15] Capacitor	2	2	
[30] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[9] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[10] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[16] Capacitor array	-	2	
[19] Seal plug	-	2	
[33] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**12**	**3**	**15**
Non-patterned	1	2	
[11] Longevity labeling	6	-	
[26] Battery depletion	-	1	
[49] Battery status	5	-	
WW Confirmed Malfunctions	**16**	**13**	**29**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

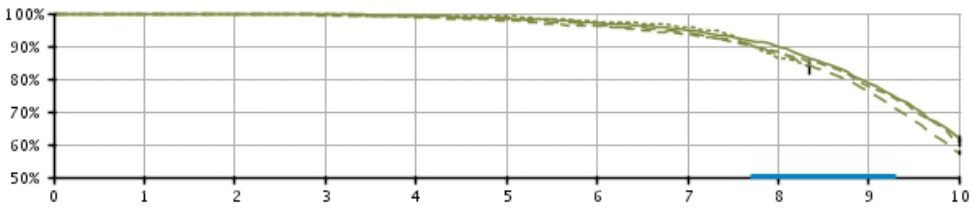
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

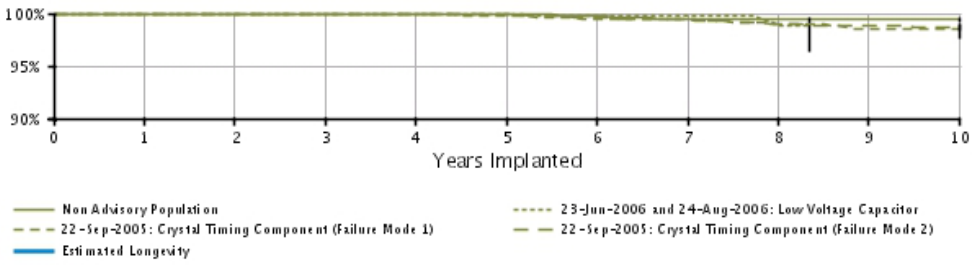
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 6,142
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:133
Without Compromised Therapy:122
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: 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)	78.54 (-1.5/+1.5)	62.00 (-2.0/+1.9)
	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	5160	4546	3996	3494	3028	2529	1948	1173
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)	99.18 (-1.3/+0.5)	99.18 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.94 (-2.6/+1.6)	86.15 (-4.5/+3.6)	83.65 @ 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 (-2.5/+0.8)	98.85 @ 100 mo. (-2.5/+0.8)	–
	Effective Sample Size	664	580	510	441	385	333	283	219	200	–
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)	88.08 (-1.7/+1.5)	77.78 (-2.2/+2.1)	60.51 (-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	1970	1703	1455	1208	926	609
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)	87.77 (-0.8/+0.8)	76.03 (-1.2/+1.1)	57.46 (-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)	98.69 (-0.3/+0.3)
	Effective Sample Size	12755	11251	9911	8722	7618	6593	5623	4600	3457	2234

*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: 175

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[8] Low-voltage capacitor (Advisory issued)	1	1	
[15] Capacitor	2	1	
[30] Integrated circuit	-	1	
Mechanical	**17**	**9**	**26**
[9] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[10] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[12] Solder bond	1	-	
[16] Capacitor array	1	-	
[19] Seal plug	6	-	
[20] Header	8	6	
Software	**7**	**-**	**7**
[34] Underestimation of battery status	4	-	
[35] Interrupted telemetry	2	-	
[36] Pacing rate limit	1	-	
Other	**127**	**9**	**136**
Non-patterned	7	9	
[11] Longevity labeling	89	-	
[26] Battery depletion	2	-	
[49] Battery status	29	-	
WW Confirmed Malfunctions	**154**	**21**	**175**

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: 114

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[15] Capacitor	-	1	
[30] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[19] Seal plug	1	-	
[20] Header	1	-	
Software	**-**	**-**	**0**
Other	**105**	**2**	**107**
Non-patterned	3	1	
[11] Longevity labeling	43	-	
[26] Battery depletion	-	1	
[49] Battery status	59	-	
WW Confirmed Malfunctions	**107**	**7**	**114**

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. **Safety Core-unintended biventricular pacing**— *Dec 2017 Voluntary Physician Advisory.*Device enters Safety Core after detecting unintended asynchronous biventricular pacing due to software issue.
2. **Memory corruption**— *Jun 2017 Voluntary Physician Advisory.*Atypical energy delivery, error messages upon interrogation, loss of tachy therapy. Memory corruption. Improvement implemented.
3. **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.
4. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.*Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
5. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory.*Premature battery depletion. Misaligned battery component. Improvement implemented.
6. **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.
7. **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.
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. **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.
10. **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.
11. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
12. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
13. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
14. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
15. **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.
16. **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.
17. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
18. **Battery depletion**— Premature battery depletion and loss of capture.
19. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
20. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
21. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
22. **Battery depletion**— Premature battery depletion.
23. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device

memory.

24. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
25. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
26. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
27. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
28. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
29. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
30. **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.
31. **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.
32. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
33. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
34. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
35. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
36. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
37. **Solder joint**— Inappropriate shocks, beeping, fallback mode, errors or inability to interrogate or program. Cracked solder joint due to repetitive mechanical stress-induced component damage, only when implanted subpectorally with serial number facing the ribs.
38. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
39. **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.
40. **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.
41. **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.
42. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
43. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
44. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
45. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
46. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
47. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
48. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
49. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
50. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
51. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
52. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
53. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
54. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
55. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
56. **Telemetry**— Inability to interrogate, premature battery depletion.
57. **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.
58. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
59. **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.

60. **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.
61. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
62. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
63. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented.
64. **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.
65. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.
66. **Telemetry**— Alert message during followup, inability to interrogate, premature battery depletion, loss of pacing therapy. Telemetry component.
67. **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
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/ G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/ G447/G448/G524/G525/G526/G528/G537/G547/G548	7,000	0	0	0	0	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	22,000	3	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	74,000	3	3	2	9	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	35,000	4	0	1	1	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	1,000	0	0	1	0	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	1,000	0	0	1	0	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	14,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	14,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	38,000	1	0	1	2	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	38,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	18,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	17,000	2	0	0	2	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	36,000	0	0	2	27	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	104,000	3	0	1	1	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	205,000	2	0	2	11	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	73,000	0	0	1	7	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	73,000	1	1	0	4	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	218,000	4	0	1	15	0	0
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	85,000	0	0	1	4	0	0

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]
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/ G324/G325/G347/G348/G424/G425/G426/G428/G437/G447/G448/ G524/G525/G526/G528/G537/G547/G548	2000	0	0	2	0	5	16
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	49000	8	3	95	21	610	3066
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	468	56	180	463	1020	11937
COGNIS N118/N119/N120/P106/P107/P108	75000	4207	149	184	1855	1823	33115

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	17000	4	0	228	11	128	1018
INTUA V272/V273/V282/V283/W272/W273	3000	11	0	45	2	25	395
INVIVE V172/V173/V182/V183/W172/W173	8000	77	0	85	2	69	1896
CONTAK RENEWAL TR H120/H125	19000	3501	16	189	60	263	10310

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	18000	2	1	59	10	377	709
SQ-RX S-ICD 1010	8000	164	4	73	52	278	969

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	27000	5	1	364	5	243	999
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	24000	1	2	353	4	187	800
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	7000	5	1	121	7	84	591
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	7000	4	0	122	5	84	526
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	66	31	908	260	550	6275
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	63	26	1107	349	680	7953

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	122	138	1043	1610	700	13388
TELIGEN DR E110/E111/F110/F111	66000	633	196	1587	2390	1216	24355

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	43000	6	4	482	19	189	1228
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	107000	28	3	1058	37	511	4832
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	22000	8	1	319	9	107	1793
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	4	0	214	5	57	1128
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	253	15	1726	47	765	20668
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	32	0	378	11	149	7249

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 60 SR S601	32000	1273	5	342	12	178	15787
ALTRUA 60 DR (Downsize) S603	90000	14625	45	903	83	580	33356
ALTRUA 60 DR S602	22000	1192	8	303	24	201	8161
ALTRUA 60 DR EL S606	59000	1057	14	773	20	442	18040
ALTRUA 40 SR S401	5000	173	0	35	2	24	2542
ALTRUA 40 DR (downsize) S403	14000	2303	4	113	3	80	5534
ALTRUA 40 DR S402	2000	107	1	24	0	8	800
ALTRUA 40 DR EL S404	5000	87	2	54	1	43	1940
ALTRUA 20 SR S201/S204	5000	72	1	30	2	36	2642
ALTRUA 20 DR (downsize) S203	5000	436	3	36	0	39	2444
ALTRUA 20 DR S202/S205	2000	72	0	11	2	15	886
ALTRUA 20 DR EL S208	3000	43	0	30	1	11	1368
INSIGNIA Ultra SR 1190 [4]	24000	3116	9	230	46	146	16877
INSIGNIA Ultra DR 1291 [4]	32000	6260	20	408	198	318	16573
INSIGNIA Entra SR 1195/1198 [4]	14000	1134	10	97	9	75	10785
INSIGNIA Entra DR 1294/1295 [4]	17000	2401	16	152	70	185	11368
INSIGNIA Plus DR 1297 [4]	27000	6142	20	284	135	262	15745

[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

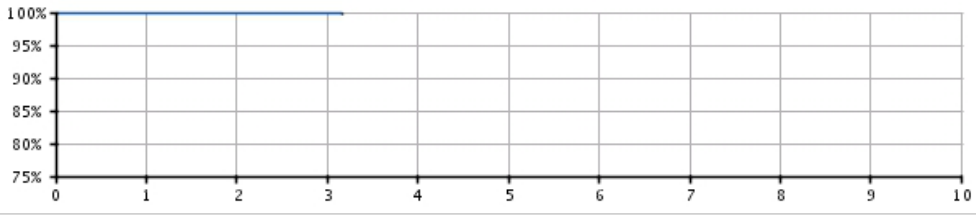
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 7,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 8
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: 7000	99.88 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.80 (-0.2/+0.1)	99.80 @ 38 mo. (-0.2/+0.1)	–	–	–	–	–	–
Effective Sample Size	3415	733	246	201	–	–	–	–	–	–

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: 17,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ACUITY X4 Spiral S

Models 4674/4675

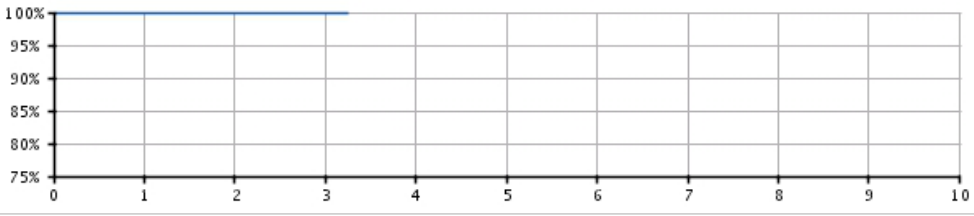
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 17,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 18
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: 17000	99.86 (-0.1/+0.1)	99.86 (-0.1/+0.1)	99.86 (-0.1/+0.1)	99.86 @ 39 mo. (-0.1/+0.1)	–	–	–	–	–	–
Effective Sample Size	8371	1301	323	215	–	–	–	–	–	–

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: 38,000
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

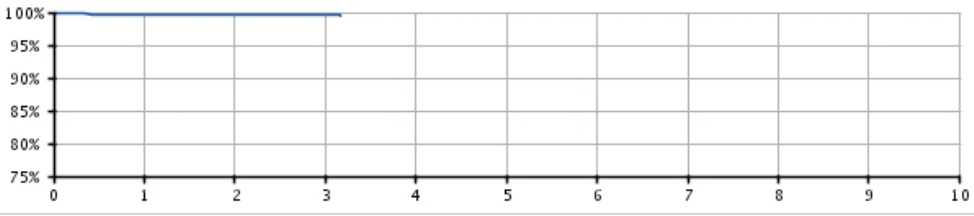
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 12,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 28
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: 12000	99.67 (-0.1/+0.1)	99.53 (-0.4/+0.2)	99.53 (-0.4/+0.2)	99.53 @ 38 mo. (-0.4/+0.2)	–	–	–	–	–	–
Effective Sample Size	5600	822	252	203	–	–	–	–	–	–

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672

Worldwide Distribution: 32,000
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

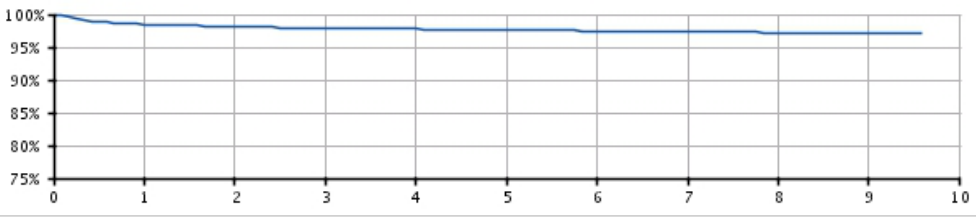
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 23,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 14,000

U.S. Chronic Lead Complications: 471
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: 23000	98.49 (-0.2/+0.2)	98.13 (-0.2/+0.2)	97.91 (-0.2/+0.2)	97.76 (-0.2/+0.2)	97.62 (-0.2/+0.2)	97.48 (-0.2/+0.2)	97.39 (-0.3/+0.2)	97.17 (-0.3/+0.3)	97.12 (-0.3/+0.3)	97.12 @ 115 mo. (-0.3/+0.3)
Effective Sample Size	19358	16890	14202	11299	8516	6061	3960	2173	809	219

ACUITY Spiral

Models 4591/4592/4593

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

ACUITY Spiral Models 4591/4592/4593

Worldwide Distribution: 44,000
Worldwide Confirmed Malfunctions: 8

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

More details about malfunctions

References cited in table above

ACUITY Steerable

Models 4554/4555/4556

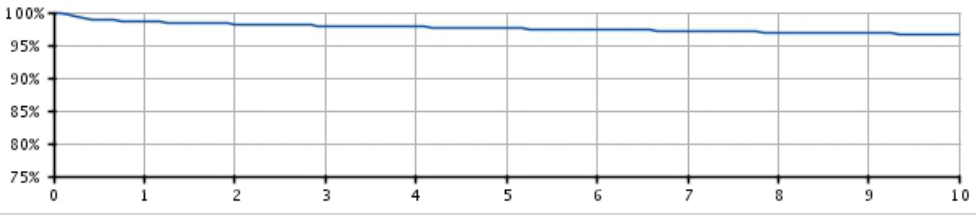
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 15,000

U.S. Chronic Lead Complications: 611
U.S. Malfunctions:33
Without Compromised Therapy:12
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	98.59 (-0.1/+0.1)	98.24 (-0.2/+0.2)	97.98 (-0.2/+0.2)	97.78 (-0.2/+0.2)	97.54 (-0.2/+0.2)	97.32 (-0.2/+0.2)	97.14 (-0.2/+0.2)	96.97 (-0.3/+0.3)	96.77 (-0.3/+0.3)	96.66 (-0.4/+0.3)
Effective Sample Size	24358	21564	18668	15480	12252	9523	7083	4794	2754	1086

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 65,000
Worldwide Confirmed Malfunctions: 57

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**13**	**36**	**49**
[27] Non-patterned, Conductor	8	9	
[34] Extracardiac fracture	5	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	**19**	**38**	**57**

More details about malfunctions

References cited in table above

EASYTRAK 3

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

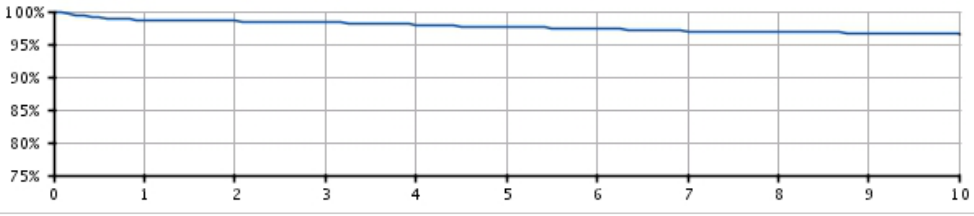
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 22,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 9,000

U.S. Chronic Lead Complications: 455
U.S. Malfunctions:31
Without Compromised Therapy:8
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	98.70 (-0.2/+0.1)	98.51 (-0.2/+0.2)	98.29 (-0.2/+0.2)	98.00 (-0.2/+0.2)	97.65 (-0.2/+0.2)	97.36 (-0.3/+0.2)	97.00 (-0.3/+0.3)	96.86 (-0.3/+0.3)	96.69 (-0.3/+0.3)	96.60 (-0.4/+0.3)
Effective Sample Size	18421	16334	14230	12022	9799	7903	6391	5097	3944	2922

EASYTRAK 3

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

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

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

Worldwide Distribution: 43,000
Worldwide Confirmed Malfunctions: 50

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**34**	**45**
[25] Conductor fracture	1	-	
[27] Non-patterned, Conductor	6	5	
[34] Extracardiac fracture	4	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**1**	**4**
[28] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[26] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**15**	**35**	**50**

More details about malfunctions

References cited in table above

EASYTRAK 2

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

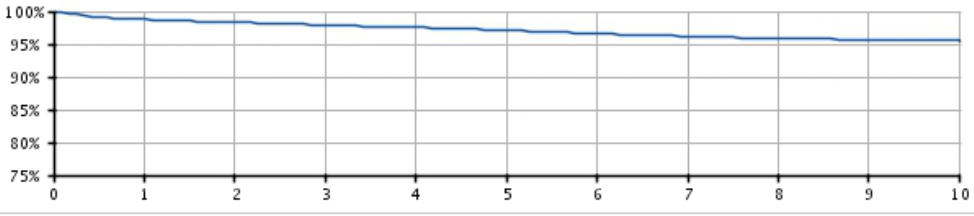
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 97,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 40,000

U.S. Chronic Lead Complications: 2,309
U.S. Malfunctions:373
Without Compromised Therapy:117
With Compromised Therapy:256

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 97000	98.78 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.91 (-0.1/+0.1)	97.55 (-0.1/+0.1)	97.11 (-0.1/+0.1)	96.61 (-0.1/+0.1)	96.20 (-0.2/+0.2)	95.90 (-0.2/+0.2)	95.70 (-0.2/+0.2)	95.51 (-0.2/+0.2)
Effective Sample Size	81590	72004	62378	52717	43432	35364	28322	21835	16172	11457

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: 179,000
Worldwide Confirmed Malfunctions: 513

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**128**	**358**	**486**
[25] Conductor fracture	118	311	
[27] Non-patterned, Conductor	10	47	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**12**	**2**	**14**
[28] Non-patterned, Insulation	12	2	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**148**	**365**	**513**

More details about malfunctions

References cited in table above

EASYTRAK

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

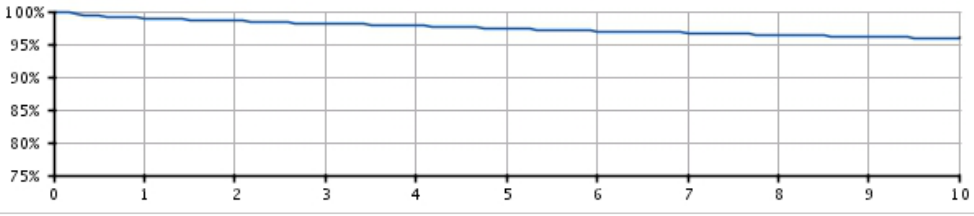
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 914
U.S. Malfunctions:25
Without Compromised Therapy:10
With Compromised Therapy:15

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.83 (-0.2/+0.2)	97.35 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.74 (-0.2/+0.2)	96.35 (-0.3/+0.2)	96.10 (-0.3/+0.3)	95.94 (-0.3/+0.3)
Effective Sample Size	30530	26243	22509	19335	16497	14096	12089	10513	9267	8164

EASYTRAK

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

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

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

Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**13**	**13**
[27] Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**3**	**6**
[28] Non-patterned, Insulation	3	3	
Other	**7**	**1**	**8**
[26] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**17**	**27**

More details about malfunctions

References cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401/3501

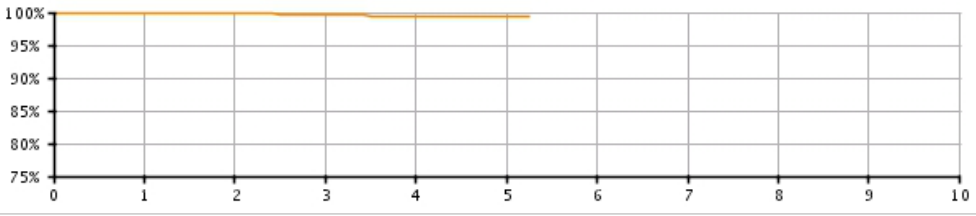
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 25,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 23,000

U.S. Chronic Lead Complications: 20
U.S. Malfunctions:3
Without Compromised Therapy:1
With Compromised Therapy:2

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 25000	99.88 (-0.1/+0.0)	99.80 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.36 (-0.3/+0.2)	99.36 (-0.3/+0.2)	99.36 @ 63 mo. (-0.3/+0.2)	–	–	–	–
Effective Sample Size	16228	9414	4147	1111	288	223	–	–	–	–

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401/3501

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

EMBLEM/Q-TRAK S-ICD Electrode Models 3010/3401/3501

Worldwide Distribution: 46,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	3	3
[37] Weld fracture	-	3	
Insulation	-	-	0
Other	1	5	6
WW Confirmed Malfunctions	1	8	9

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: 12,000

Worldwide Confirmed Malfunctions: 1

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

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: 52,000

Worldwide Confirmed Malfunctions: 24

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**19**	**19**
[27] Non-patterned, Conductor	-	5	
[38] Conductor cable fracture	-	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**4**	**4**
[28] Non-patterned, Insulation	-	4	
Other	**-**	**1**	**1**
[26] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**0**	**24**	**24**

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: 3,000

Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276/0295/0296

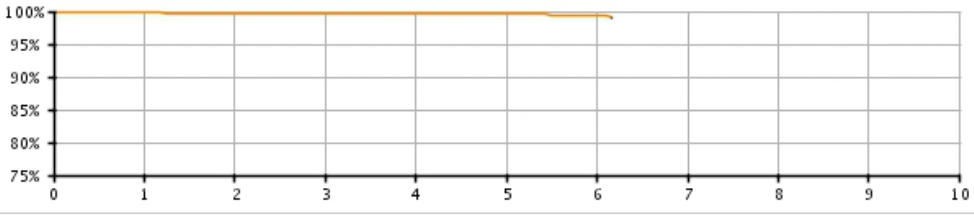
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 67,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 57,000

U.S. Chronic Lead Complications: 205
U.S. Malfunctions:17
Without Compromised Therapy:0
With Compromised Therapy:17

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 67000	99.78 (-0.0/+0.0)	99.69 (-0.0/+0.0)	99.63 (-0.1/+0.0)	99.58 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.43 (-0.1/+0.1)	99.14 @ 74 mo. (-0.8/+0.4)	–	–	–
Effective Sample Size	53574	41699	30811	20266	10292	1450	347	–	–	–

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: 106,000
Worldwide Confirmed Malfunctions: 48

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**5**	**5**
[24] Conductor fracture	-	1	
[27] Non-patterned, Conductor	-	4	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**7**	**34**	**41**
[28] Non-patterned, Insulation	7	34	
Other	**2**	**-**	**2**
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**9**	**39**	**48**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

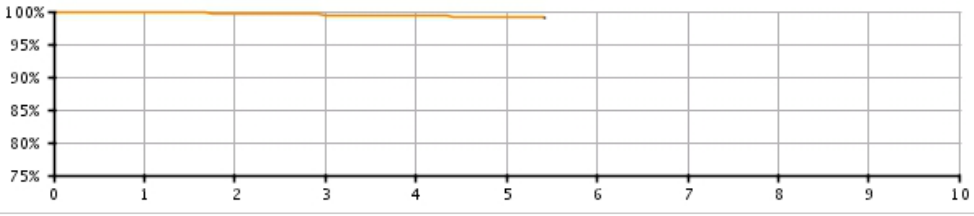
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 14
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	99.77 (-0.3/+0.1)	99.61 (-0.4/+0.2)	99.47 (-0.4/+0.2)	99.29 (-0.5/+0.3)	99.12 (-0.7/+0.4)	99.12 @ 65 mo. (-0.7/+0.4)	–	–	–	–
Effective Sample Size	2304	1790	1298	767	354	213	–	–	–	–

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

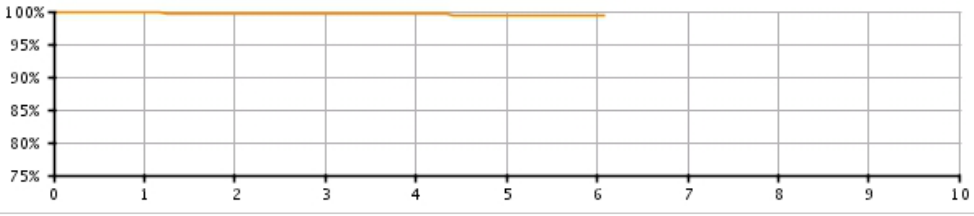
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 93,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 84,000

U.S. Chronic Lead Complications: 258
U.S. Malfunctions:16
Without Compromised Therapy:1
With Compromised Therapy:15

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.78 (-0.0/+0.0)	99.69 (-0.0/+0.0)	99.61 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.44 (-0.1/+0.1)	99.31 (-0.2/+0.2)	99.31 @ 73 mo. (-0.2/+0.2)	–	–	–
Registered Implants: 93000										
Effective Sample Size	64309	42593	25662	13078	5025	579	348	–	–	–

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: 144,000

Worldwide Confirmed Malfunctions: 37

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[24] Conductor fracture	-	1	
[27] Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**28**	**30**
[28] Non-patterned, Insulation	2	28	
Other	**-**	**4**	**4**
[26] Non-patterned, Other	-	4	
WW Confirmed Malfunctions	**2**	**35**	**37**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

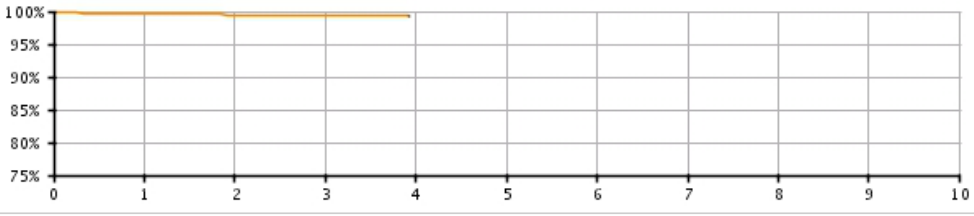
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 6
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	99.64 (-0.4/+0.2)	99.40 (-0.6/+0.3)	99.40 (-0.6/+0.3)	99.40 @ 47 mo. (-0.6/+0.3)	–	–	–	–	–	–
Registered Implants: 2000										
Effective Sample Size	1215	766	403	208	–	–	–	–	–	–

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: 5,000

Worldwide Confirmed Malfunctions: 2

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

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation

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

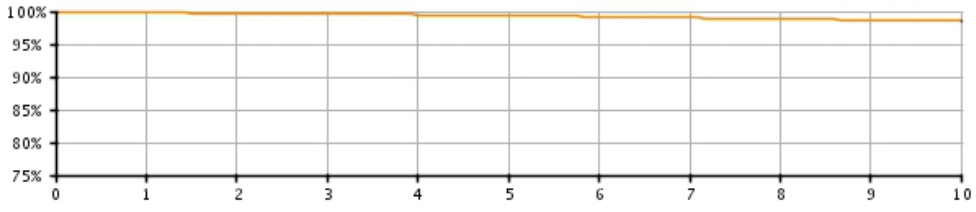
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 287,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 128,000

U.S. Chronic Lead Complications: 2,109
U.S. Malfunctions:311
Without Compromised Therapy:109
With Compromised Therapy:202

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 287000	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)	99.22 (-0.0/+0.0)	99.03 (-0.0/+0.0)	98.88 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.51 (-0.1/+0.1)
Effective Sample Size	252123	224777	200200	177770	157062	137456	112025	88006	66099	46900

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: 377,000

Worldwide Confirmed Malfunctions: 483

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**138**	**140**
[24] Conductor fracture	-	94	
[27] Non-patterned, Conductor	2	44	
Crimp/Weld/Bond	**5**	**2**	**7**
[5] Seal rings	2	2	
[31] Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	**147**	**141**	**288**
[28] Non-patterned, Insulation	147	141	
Other	**28**	**20**	**48**
[26] Non-patterned, Other	28	20	
WW Confirmed Malfunctions	**182**	**301**	**483**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

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

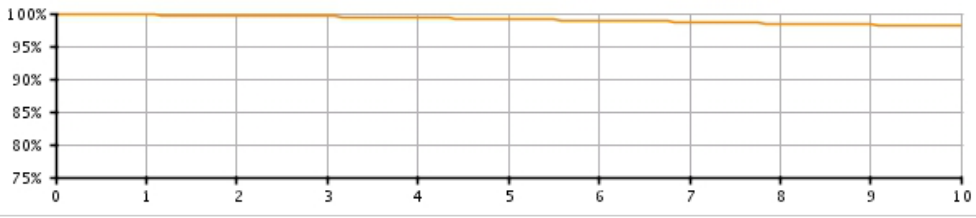
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 47,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 526
U.S. Malfunctions:43
Without Compromised Therapy:10
With Compromised Therapy:33

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 47000	99.77 (-0.0/+0.0)	99.68 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.46 (-0.2/+0.1)	98.27 (-0.2/+0.2)	98.08 (-0.2/+0.2)
Effective Sample Size	40603	36204	32232	28611	25267	22125	19048	16202	13659	11355

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: 109,000

Worldwide Confirmed Malfunctions: 133

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**32**	**32**
[24] Conductor fracture	-	18	
[27] Non-patterned, Conductor	-	14	
Crimp/Weld/Bond	**-**	**3**	**3**
[36] Conductor connection	-	3	
Insulation	**38**	**49**	**87**
[28] Non-patterned, Insulation	38	49	
Other	**7**	**4**	**11**
[6] Manufacturing material	-	1	
[26] Non-patterned, Other	7	3	
WW Confirmed Malfunctions	**45**	**88**	**133**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

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

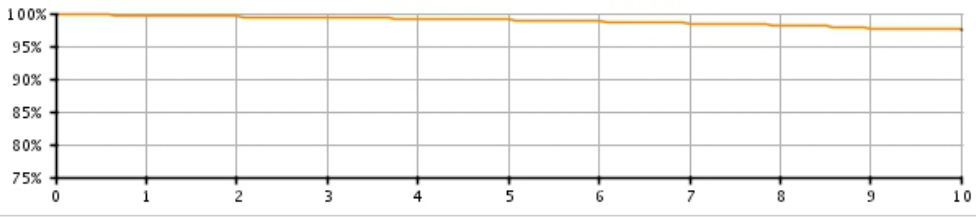
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 32,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 22,000

U.S. Chronic Lead Complications: 250
U.S. Malfunctions:64
Without Compromised Therapy:20
With Compromised Therapy:44

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	99.69 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.40 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.78 (-0.2/+0.1)	98.49 (-0.2/+0.2)	98.17 (-0.3/+0.2)	97.74 (-0.4/+0.3)	97.56 (-0.4/+0.4)
Effective Sample Size	27934	24320	20652	17073	13792	10956	6904	4118	2298	1113

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: 71,000

Worldwide Confirmed Malfunctions: 167

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**65**	**65**
[24] Conductor fracture	-	55	
[27] Non-patterned, Conductor	-	10	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**48**	**41**	**89**
[28] Non-patterned, Insulation	48	41	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**56**	**111**	**167**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

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

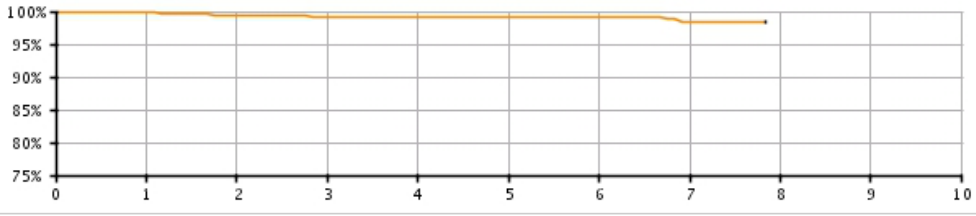
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

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

U.S. Chronic Lead Complications: 18
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.76 (-0.4/+0.2)	99.40 (-0.6/+0.3)	99.22 (-0.6/+0.4)	99.12 (-0.7/+0.4)	99.12 (-0.7/+0.4)	99.12 (-0.7/+0.4)	98.49 (-1.4/+0.7)	98.49 @ 94 mo. (-1.4/+0.7)	–	–
Effective Sample Size	1512	1280	1030	809	611	422	292	203	–	–

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: 8,000

Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**5**	**5**
[24] Conductor fracture	-	3	
[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	**7**	**9**	**16**

More details about malfunctions

References cited in table above

ENDOTAK ENDURANCE EZ
Active Fixation

Models 0154/0155/0156

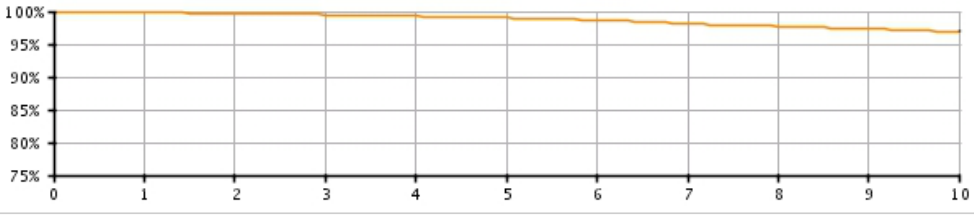
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 6,000

U.S. Chronic Lead Complications: 600
U.S. Malfunctions:26
Without Compromised Therapy:11
With Compromised Therapy:15

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-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	24451	21791	19397	17262	15329	13599	12052	10711	9489	8401

ENDOTAK ENDURANCE Rx
Passive Fixation Steroid Eluting

Models 0144/0145/0146

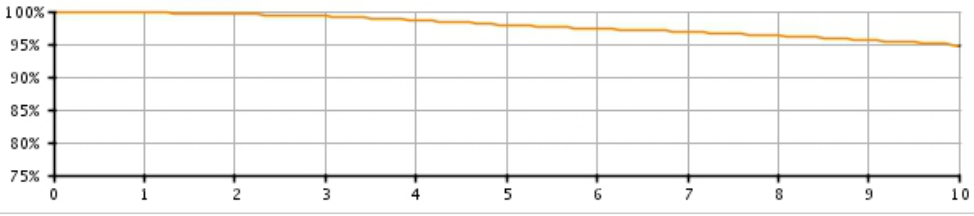
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

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

U.S. Chronic Lead Complications: 697
U.S. Malfunctions:30
Without Compromised Therapy:8
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	99.81 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.85 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15628	13937	12418	10989	9679	8564	7597	6723	5920	5203

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

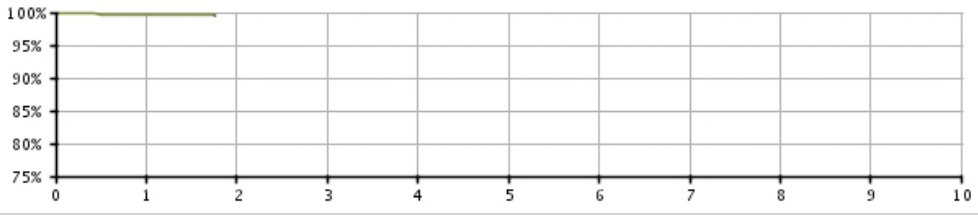
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 5,000
U.S. Approval Date: April 2006
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 13
U.S. Malfunctions:1
Without Compromised Therapy:1
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: 5000	99.67 (-0.3/+0.1)	99.52 @ 21 mo. (-0.4/+0.2)	–	–	–	–	–	–	–	–
Effective Sample Size	2063	322	–	–	–	–	–	–	–	–

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: 43,000
Worldwide Confirmed Malfunctions: 1

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

More details about malfunctions

References cited in table above

INGEVITY Positive Fixation

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

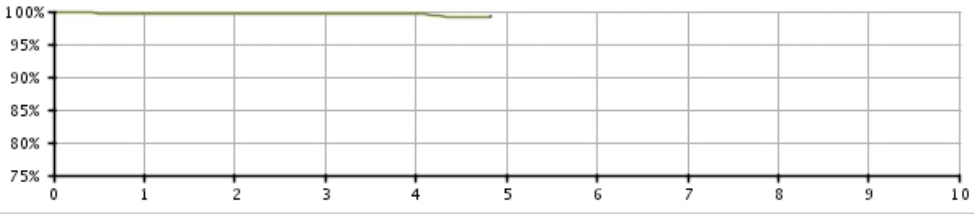
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 173,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 165,000

U.S. Chronic Lead Complications: 407
U.S. Malfunctions:45
Without Compromised Therapy:18
With Compromised Therapy:27

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 173000	99.64 (-0.0/+0.0)	99.60 (-0.0/+0.0)	99.60 (-0.0/+0.0)	99.60 (-0.0/+0.0)	99.23 @ 58 mo. (-0.7/+0.4)	–	–	–	–	–
Effective Sample Size	72754	985	809	618	206	–	–	–	–	–

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: 452,000
Worldwide Confirmed Malfunctions: 83

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**35**	**45**	**80**
[27] Non-patterned, Conductor	11	15	
[39] Inner conductor break	6	3	
[40] Extracardiac fracture	18	27	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**1**	**1**	**2**
[26] Non-patterned, Other	1	1	
WW Confirmed Malfunctions	**36**	**47**	**83**

More details about malfunctions

References cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

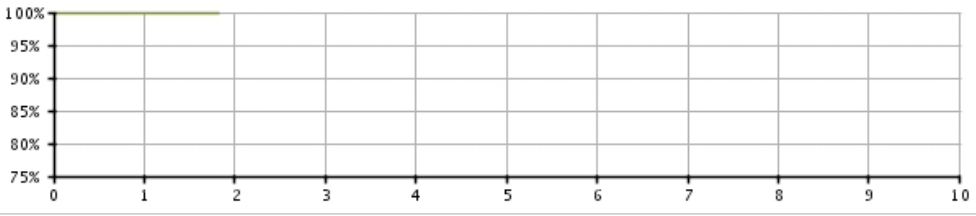
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 9,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 8,000

U.S. Chronic Lead Complications: 6
U.S. Malfunctions:3
Without Compromised Therapy:0
With Compromised Therapy:3

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 9000	99.88 (-0.1/+0.1)	99.85 @ 22 mo. (-0.1/+0.1)	–	–	–	–	–	–	–	–
Effective Sample Size	3938	332	–	–	–	–	–	–	–	–

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: 51,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**4**	**4**
[40] Extracardiac fracture	-	4	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**-**	**0**
Other	**-**	**2**	**2**
[26] Non-patterned, Other	-	2	
WW Confirmed Malfunctions	**0**	**6**	**6**

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: 185,000
Worldwide Confirmed Malfunctions: 116

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**32**	**38**
[7] Lead conductor	2	18	
[32] Conductor damage	4	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**55**	**10**	**65**
[2] Inner insulation abrasion	5	1	
[28] Non-patterned, Insulation	3	-	
[33] Insulation damage	47	9	
Other	**13**	**-**	**13**
[26] Non-patterned, Other	13	-	
WW Confirmed Malfunctions	**74**	**42**	**116**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

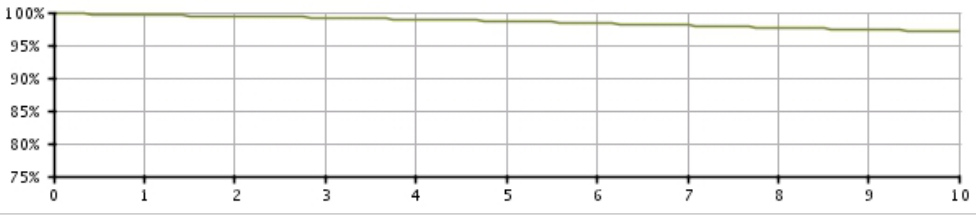
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 235,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 91,000

U.S. Chronic Lead Complications: 3,522
U.S. Malfunctions:341
Without Compromised Therapy:139
With Compromised Therapy:202

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.94 (-0.0/+0.0)	98.67 (-0.1/+0.1)	98.34 (-0.1/+0.1)	98.01 (-0.1/+0.1)	97.66 (-0.1/+0.1)	97.35 (-0.1/+0.1)	97.11 (-0.1/+0.1)
Registered Implants: 235000										
Effective Sample Size	201759	178658	155674	134879	116071	99078	83654	69300	56579	45906

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: 291,000
Worldwide Confirmed Malfunctions: 367

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**21**	**173**	**194**
[7] Lead conductor	13	81	
[27] Non-patterned, Conductor	-	7	
[32] Conductor damage	8	85	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**110**	**39**	**149**
[2] Inner insulation abrasion	19	9	
[28] Non-patterned, Insulation	9	3	
[33] Insulation damage	82	27	
Other	**18**	**6**	**24**
[26] Non-patterned, Other	18	6	
WW Confirmed Malfunctions	**149**	**218**	**367**

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

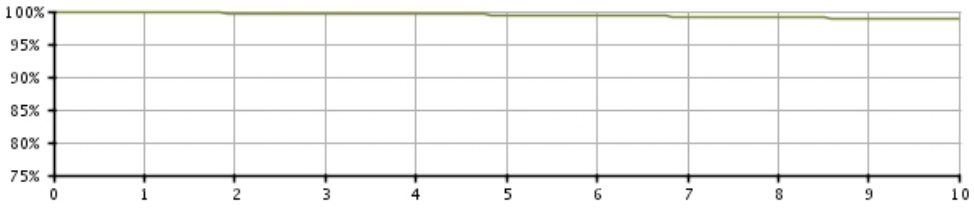
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 467,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 253,000

U.S. Chronic Lead Complications: 2,620
U.S. Malfunctions:143
Without Compromised Therapy:34
With Compromised Therapy:109

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 467000	99.82 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.67 (-0.0/+0.0)	99.58 (-0.0/+0.0)	99.48 (-0.0/+0.0)	99.36 (-0.0/+0.0)	99.21 (-0.0/+0.0)	99.09 (-0.0/+0.0)	98.93 (-0.0/+0.0)	98.80 (-0.1/+0.1)
Effective Sample Size	402014	349370	295487	247272	204732	167270	134009	104459	78263	58066

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

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

Worldwide Distribution: 723,000

Worldwide Confirmed Malfunctions: 174

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**17**	**123**	**140**
[7] Lead conductor	8	57	
[27] Non-patterned, Conductor	1	5	
[32] Conductor damage	8	61	
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	**9**	**3**	**12**
[26] Non-patterned, Other	9	3	
WW Confirmed Malfunctions	**39**	**135**	**174**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

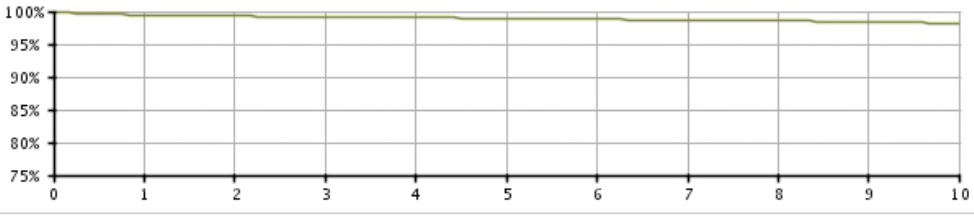
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 62,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 30,000

U.S. Chronic Lead Complications: 656
U.S. Malfunctions:27
Without Compromised Therapy:20
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.44 (-0.1/+0.1)	99.28 (-0.1/+0.1)	99.16 (-0.1/+0.1)	99.05 (-0.1/+0.1)	98.95 (-0.1/+0.1)	98.80 (-0.1/+0.1)	98.66 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.29 (-0.2/+0.1)	98.20 (-0.2/+0.2)
Registered Implants: 62000										
Effective Sample Size	53321	46902	40019	33787	28203	23270	18927	15085	11654	8943

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: 303,000

Worldwide Confirmed Malfunctions: 53

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**4**	**10**	**14**
[7] Lead conductor	1	3	
[32] Conductor damage	3	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[33] Insulation damage	-	1	
Other	**33**	**4**	**37**
[22] J-shape	30	4	
[26] Non-patterned, Other	3	-	
WW Confirmed Malfunctions	**38**	**15**	**53**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

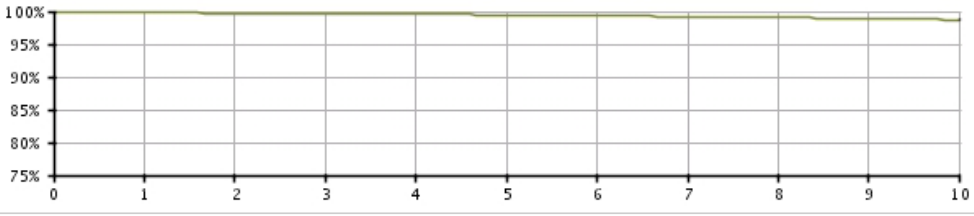
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 190,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 84,000

U.S. Chronic Lead Complications: 1180
U.S. Malfunctions:43
Without Compromised Therapy:5
With Compromised Therapy:38

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.0/+0.0)	99.73 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.56 (-0.0/+0.0)	99.47 (-0.0/+0.0)	99.36 (-0.0/+0.0)	99.20 (-0.1/+0.1)	99.06 (-0.1/+0.1)	98.86 (-0.1/+0.1)	98.74 (-0.1/+0.1)
Registered Implants: 190000										
Effective Sample Size	163392	143368	122404	103332	86449	71647	58621	47103	36756	28466

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: 532,000

Worldwide Confirmed Malfunctions: 63

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**47**	**48**
[7] Lead conductor	-	15	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	1	30	
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**	**56**	**63**

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

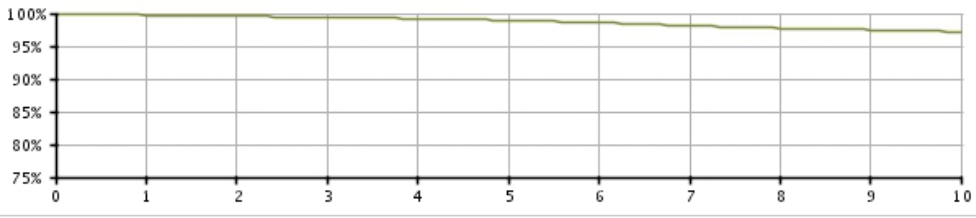
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 52,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 23,000

U.S. Chronic Lead Complications: 643
U.S. Malfunctions:127
Without Compromised Therapy:23
With Compromised Therapy:104

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)	99.58 (-0.1/+0.1)	99.40 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.56 (-0.1/+0.1)	98.14 (-0.2/+0.2)	97.74 (-0.2/+0.2)	97.48 (-0.2/+0.2)	97.20 (-0.2/+0.2)
Effective Sample Size	45791	40438	34957	29956	25382	21251	17596	14179	11299	8865

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: 141,000

Worldwide Confirmed Malfunctions: 166

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**126**	**137**
[7] Lead conductor	4	75	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	7	46	
[35] Lead conductor	-	3	
Crimp/Weld/Bond	**1**	**-**	**1**
[31] Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	**9**	**9**	**18**
[28] Non-patterned, Insulation	2	-	
[33] Insulation damage	7	9	
Other	**6**	**4**	**10**
[26] Non-patterned, Other	6	4	
WW Confirmed Malfunctions	**27**	**139**	**166**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

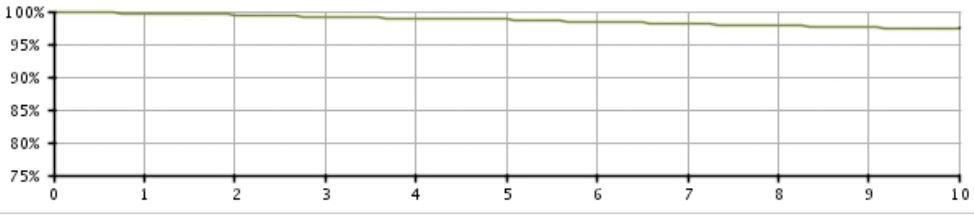
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 15,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 197
U.S. Malfunctions:24
Without Compromised Therapy:0
With Compromised Therapy:24

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.19 (-0.2/+0.1)	98.92 (-0.2/+0.2)	98.77 (-0.2/+0.2)	98.46 (-0.3/+0.2)	98.09 (-0.3/+0.3)	97.77 (-0.4/+0.3)	97.54 (-0.4/+0.3)	97.42 (-0.4/+0.4)
Registered Implants: 15000										
Effective Sample Size	12479	11049	9625	8318	7181	6114	5114	4248	3528	2920

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

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

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

Worldwide Distribution: 104,000

Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**45**	**45**
[7] Lead conductor	-	17	
[32] Conductor damage	-	28	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**4**	**6**
[33] Insulation damage	2	4	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**52**	**54**

More details about malfunctions

References cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

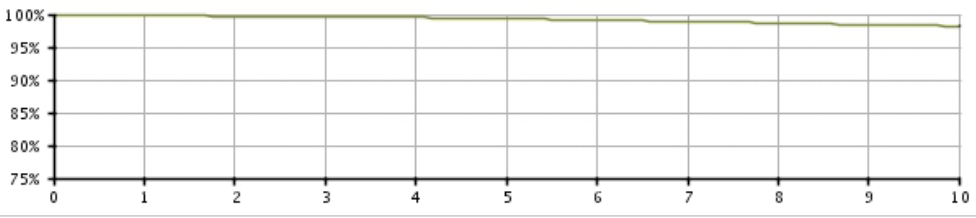
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

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

U.S. Chronic Lead Complications: 304
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)	98.69 (-0.2/+0.2)	98.44 (-0.2/+0.2)	98.22 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20916	18710	16690	14867	13216	11625	10246	9033	7925	6989

SELUTE PICOTIP Atrial J

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

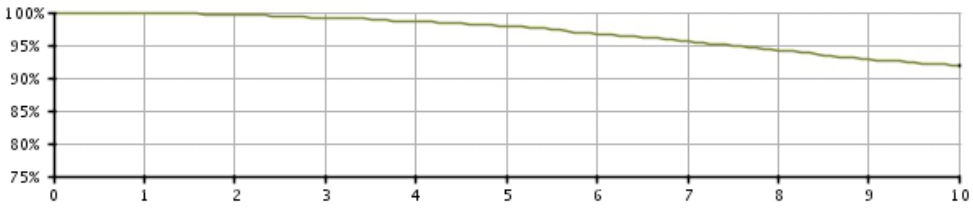
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 10,000
U.S. Approval Date: May 2000
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 452
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)	94.22 (-0.7/+0.6)	92.87 (-0.8/+0.7)	91.84 (-0.9/+0.8)
Effective Sample Size	8576	7642	6792	6022	5318	4666	4029	3475	2987	2565

SWEET PICOTIP Rx
Positive Fixation

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

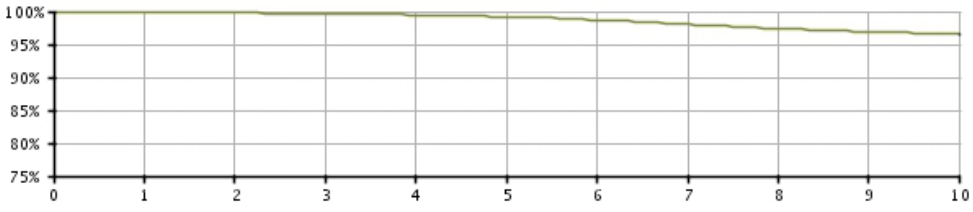
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 41,000
U.S. Approval Date: April 1999
U.S. Estimated Active Implants: 10,000

U.S. Chronic Lead Complications: 720
U.S. Malfunctions:58

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)	97.43 (-0.2/+0.2)	96.92 (-0.3/+0.2)	96.56 (-0.3/+0.3)
Effective Sample Size	35767	31935	28498	25356	22465	19812	17397	15285	13318	11286

SWEET TIP RX
Positive Fixation

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

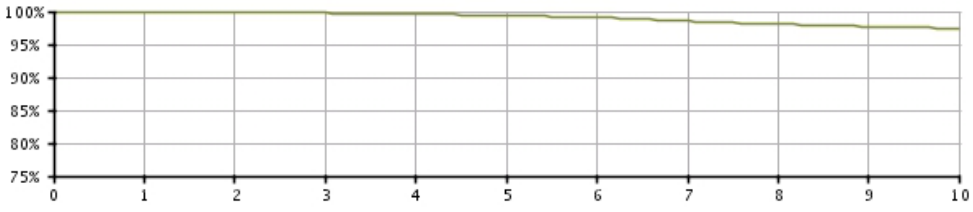
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 522
U.S. Malfunctions:29

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)	98.56 (-0.2/+0.2)	98.08 (-0.2/+0.2)	97.73 (-0.2/+0.2)	97.40 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26538	23707	21103	18666	16397	14397	12637	11148	9679

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. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **DF-1 terminal pin**— Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.
18. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
19. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
22. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.
26. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is

not associated with other malfunctions, or has not yet been identified.

27. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.
28. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.
31. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.
32. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.
33. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
34. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.
35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.
36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
37. **Weld fracture**— Noise, loss of sensing. Fractured weld.
38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable. Improvement implemented.
39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.
40. **Extracardiac fracture**— High impedance, noise, oversensing, loss of capture, loss of pacing. Flex fatigue leading to discontinuity of outer conductor.

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.

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	173000	43	144	155	33	5	4	7	5	0	11
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	5000	0	4	6	2	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	9000	0	2	3	1	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	72	795	856	733	331	94	164	411	0	66
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	190000	4	347	208	189	40	22	166	184	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	467000	21	560	680	356	95	90	423	349	0	46
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	62000	1	100	310	111	12	19	59	36	0	8
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	15000	1	90	19	37	13	4	14	18	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	224	76	85	68	16	73	97	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	7000	0	0	4	1	0	0	0	0	0	3
ACUITY X4 Spiral S 4674/4675	17000	1	0	14	0	0	0	0	0	0	3

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	12000	0	0	15	1	0	0	0	2	0	10
ACUITY Steerable 4554/4555/4556	29000	2	27	405	41	3	2	8	26	0	97
ACUITY Spiral 4591/4592/4593	23000	0	16	262	32	1	1	3	6	0	150
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	30	259	43	3	2	11	12	0	93
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	2	292	1105	260	8	6	67	90	0	479
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	65	398	107	3	1	47	31	0	261

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	67000	18	28	79	18	23	8	7	10	8	6
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	0	1	5	0	3	0	0	5	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	93000	18	32	102	30	24	11	7	9	17	8
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	2000	1	0	3	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287000	28	435	352	130	529	66	102	231	208	28
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47000	4	95	64	47	87	7	34	148	34	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	32000	9	54	46	20	46	2	7	29	34	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	3	5	1	3	0	1	3	2	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401, 3501	25000	0	0	3	0	12	1	3	0	1

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 the U.S. Registered Implant population 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	173000	218	301	461	190	59	49	12	117	0	40
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	5000	0	0	14	5	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	9000	1	2	14	12	1	3	1	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	239	195	1366	430	75	91	57	213	0	50
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	190000	15	14	452	177	9	26	25	40	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	467000	85	86	725	266	115	100	62	255	0	44
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	62000	1	18	451	94	8	29	18	22	0	11
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	15000	1	4	34	17	1	2	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/4473/4474	52000	3	18	106	28	9	11	21	13	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY X4 Spiral L 4677/4678	7000	1	0	12	9	5	0	0	6	0	18
ACUITY X4 Spiral S 4674/4675	17000	3	0	26	11	2	0	0	35	0	37

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	12000	1	0	34	19	2	0	0	24	0	29
ACUITY Steerable 4554/4555/4556	29000	1	3	327	50	25	2	7	134	0	243
ACUITY Spiral 4591/4592/4593	23000	5	4	216	68	8	2	9	38	0	245
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	274	38	12	2	8	47	0	188
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	13	10	937	137	47	9	27	201	0	731
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	19	34	0	186

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	67000	58	34	194	93	79	12	7	86	23	12
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	2	0	10	1	4	0	0	20	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	93000	80	46	256	97	107	26	10	106	87	29
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	2000	1	1	4	2	2	1	0	20	2	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287000	149	190	651	170	366	54	70	362	234	80
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47000	8	3	107	45	57	8	5	177	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	32000	30	17	78	33	33	14	3	56	123	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	3	1	1	2	0	11	1	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401/3501	25000	2	0	18	0	270	23	1	106	1

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	17,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	38,000	0	0	0	3	0	0	0
ACUITY X4 Straight 4671/4672	32,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	65,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	44,000	0	0	0	2	1	0	0

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	12,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	52,000	3	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	3,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	106,000	0	0	0	65	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	9,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	144,000	0	0	0	23	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Passive Fixation 0282/0283	5,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	377,000	0	0	44	489	0	3	14
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	71,000	0	0	7	63	0	1	3

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401, 3501	46,000	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	452,000	1286	0	0	2275	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	43,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	51,000	0	0	0	1	0	0	0
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	532,000	1	0	2	7	4	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	723,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	303,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	104,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	141,000	0	1	1	25	1	6	0

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

Product Advisories

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

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

PRODUCT

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

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

ACCOLADE Pacemaker
Models L300, L301, L310, L311, L321, L331

PROPONENT Pacemaker
Models L200, L201, L209, L210, L211, L221, L231

ESSENTIO Pacemaker
Models L100, L101, L110, L111, L121, L131

ALTRUA 2 Pacemaker
Models S701, S702, S722

Minute Ventialtion Signal Oversensing, Physician Letter,

Minute Ventialtion Signal Oversensing, Patient Letter, December 2017

ORIGINAL COMMUNICATION **December 2017 — Minute Ventilation Signal Oversensing**

Voluntary Physician Advisory
FDA Classification: Unclassified

This advisory discusses intermittent oversensing of the Minute Ventilation (MV) sensor signal with certain Boston Scientific pacemaker and cardiac resynchronization therapy pacemaker systems (pacemakers). MV sensor signal oversensing may cause pre-syncope or syncope due to periods of pacing inhibition. This MV behavior may occur with any manufacturer's pacing lead system, but Boston Scientific has determined it to be more likely for affected Boston Scientific pacemakers using Medtronic or Abbott/St. Jude (Abbott) leads implanted in either the right atrium (RA) or right ventricle (RV).

The MV sensor in Boston Scientific pacemakers can be used for RightRate™ (rate adaptive pacing), Respiratory Rate Trend, or AP Scan. When the RA/RV pacing leads and lead terminal connections are operating as intended, the MV sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on electrograms (EGMs). However, intermittency related to the lead or pacemaker-lead connection has the potential to create a transient high impedance condition. A high impedance condition may subsequently alter the MV sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels. For a technical description of the Boston Scientific's MV sensor, please refer to Appendix A in the December 2017 physician letter.

Engineering analysis and testing, as well as evaluation of post-market surveillance data, demonstrates an elevated potential for oversensing of the MV sensor signal in certain pacemaker systems connected to Medtronic or Abbott pacing leads. Although all leads evaluated in simulated testing environments comply with appropriate connector standards, we have discovered subtle differences amongst lead manufacturers in the surface finish of the lead terminal ring and amount of axial and radial terminal ring motion within the pacemaker header. These factors may result in intermittent increases in impedance leading to oversensing of the MV sensor signal or changes in daily impedance test measurements.

Estimated Rate of Occurrence

Boston Scientific investigation has shown that the probability of harm associated with MV sensor signal oversensing behavior is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

Affected pacemaker systems connected to the following RA/RV pacing leads[a]:	Probability of Injury at 5 years	Probability of Life Threatening Harm at 5 years
Medtronic or Abbott pacing leads	0.0005 (1 in 2,000)	0.00001 (1 in 100,000)
Boston Scientific pacing leads (including DEXTRUS)	0.00003 (1 in 33,333)	0.0000008 (1 in 1,250,000)
All pacing leads combined[b]	0.00008 (1 in 12,500)	0.000002 (1 in 500,000)

CURRENT STATUS **10-Apr-18**

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CURRENT RECOMMENDATION **10-Apr-18**

Until software is available to automatically resolve MV sensor signal oversensing, Boston Scientific recommends managing the risk for patients implanted with affected pacemaker systems as follows:

•For pacemaker-dependent patients, turn the MV sensor "OFF". Note when programmed to passive, the MV sensor signal is enabled and may be oversensed. See Appendix B for details on turning the MV sensor "OFF".
•For all other patients, evaluate the risks of oversensing the MV sensor signal against the benefits of MV sensor indicated pacing. If the risk outweighs the benefit, turn the MV sensor "OFF" (see Appendix B).
•If transient, abrupt changes or any out-of-range RA/RV pacing impedance measurements are observed, contact Boston Scientific Technical Services to explore all non-invasive programming options prior to surgical intervention. In most cases, management of the system can be done non-invasively through programming changes.
•In accordance with the pacemaker manual, if MV sensor signal artifacts are observed on EGMs and leads are performing appropriately, consider programming the sensor to "OFF" to prevent oversensing.
•For patients with the MV sensor enabled, periodically re-assess for pacemaker dependence.
•Enroll and follow patients using the LATITUDE™ NXT Remote Patient Management System.

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

PRODUCT	ORIGINAL COMMUNICATION **December 2017 — CRT Positive LV Offset and TPP Interaction**
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 **VALITUDE CRT-P** Models U125, U128 **VISIONIST CRT-P** Models U225, U226, U228 **RESONATE CRT-D** Models G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548 **VIGILANT CRT-D** Models G224, G225, G228, G237, G247, G248 **MOMENTUM CRT-D** Models G124, G125, G126, G128, G138 **CHARISMA CRT-D** Models G324, G325, G328, G337, G347, G348 **AUTOGEN CRT-D** Models G172, G173, G175, G177, G179 **DYNAGEN CRT-D** Models G150, G151, G156, G158 **INOGEN CRT-D** Models G140, G141, G146, G148 **ORIGEN CRT-D** Models G050, G051, G056, G058 CRT Positive LV Offset and TPP Interaction, Physician Letter, Dec 2017 CRT Positive LV Offset and TPP Interaction, Patient Letter, December 2017	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses unintended asynchronous biventricular (BiV) pacing behavior when tracking elevated atrial intrinsic rhythms in certain Boston Scientific Cardiac Resynchronization Therapy (CRT) pacemakers (CRT-Ps) and defibrillators (CRT-Ds). Repeated detection of this unintended asynchronous BiV pacing behavior may result in the implanted device reverting to a permanent Safety Mode (Safety Core™) status thus requiring early replacement. The unintended asynchronous BiV pacing behavior can only occur when an infrequent combination of parameters are programmed, specifically: • Left Ventricular (LV) Offset programmed to a positive value which exceeds the Atrial Blank after Ventricular Pace (A-Blank after V-Pace) interval; and • Tracking Preference = ON (nominal). *Observed Rate* Of the 60,500 CRT devices distributed worldwide, Boston Scientific estimates approximately 300 CRT devices are programmed with the combination of parameters which may lead to this device behavior. There have been two confirmed instances of early device replacement due to this device behavior (0.7%). Of the two cases, a single patient death occurred due to complications related to the replacement procedure. CURRENT STATUS **10-Apr-18** *Confirmed Malfunctions (worldwide)* There have been two confirmed instances of early device replacement due to this device behavior. CURRENT RECOMMENDATION **10-Apr-18** Until software is available to prevent programming of a susceptible combination of parameters, eliminate the risk associated with early replacement due to this unintended asynchronous BiV pacing behavior by performing the following steps: 1. Review programming records of patients implanted with the CRT devices included in Appendix B of the December 2017 physician letter 2. If the LV Offset parameter is programmed to Zero or a Negative value, the device is not at risk of this behavior. 3. If the LV Offset parameter is programmed to a Positive value, determine if the following conditions are met: A. The positive LV Offset value exceeds the A-Blank after V-Pace interval, where “Smart” blanking is equivalent to a value of 37.5 ms; and B. Tracking Preference programmed to ON 4. For patients whose device has a positive LV Offset value exceeding A-Blank after V-Pace value and Tracking Preference is programmed to ON, schedule a clinic appointment to reprogram the CRT device as follows according to the patient’s individual medical needs: A. Either program the CRT device such that the A-Blank after V-Pace value is greater than the positive LV Offset value; or B. Disable Tracking Preference by programming it to a value of “OFF”. 5. Devices with an A-Blank after V-Pace value exceeding the positive LV Offset value are not affected and are not at risk of this behavior. 6. Patients whose device has Tracking Preference programmed OFF are not affected and are not at risk of this behavior. Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **June 2017 — S-ICD Memory Corruption**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **S-ICD** Models 1010, A209, A219 S-ICD Memory Corruption, Physician Letter, Jun 29, 2017 S-ICD Memory Corruption, Patient Letter, Jun 29, 2017 S-ICD Software v4.04 Programmer Commands and Memory Corruption August 2017	Voluntary Physician Advisory FDA Classification: Class II This advisory discusses a single, isolated S-ICD event that resulted in a device-related patient death. Boston Scientific engineers have determined that this patient's S-ICD repeatedly delivered an atypical amount of energy (similar to the arrhythmia induction function) because a specific memory location was corrupted by radiation within the environment. This repeated atypical energy delivery prevented S-ICD arrhythmia detection/treatment and ultimately contributed to the patient death. *Estimated Rate of Occurrence* This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide. Given the rarity of this single event observed to date, a precise projection of occurrence cannot be derived with confidence. Engineering analysis of S-ICD device memory design and recorded instances of SEUs in fielded devices was conducted during our root cause investigation of this event. Based on this analysis, the probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.

CURRENT STATUS **10-Apr-18**

This experience represents one (1) observed event in approximately 48,000 S-ICDs distributed worldwide.

Estimated Rate of Occurrence
The probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years.

CURRENT RECOMMENDATION **10-Apr-18**

In consultation with our Patient Safety Advisory Board, Boston Scientific recommends NO changes to clinical follow-up due to this single event. Specifically, for patients with S-ICD systems:
• Continue using the S-ICD system to detect and treat life-threatening ventricular tachyarrhythmias;
• Keep scheduled LATITUDE™ and/or in clinic follow-ups; and
• Follow the precautions identified in the S-ICD user's manual when radiation therapy is prescribed.

Furthermore, Boston Scientific does NOT recommend the following:
• Early or off-cycle follow-ups are not recommended. This type of memory corruption cannot be detected, thus additional S-ICD checks do not reduce the potential for this device behavior.
• Prophylactic S-ICD replacement or explant is not recommended. The risks associated with such an additional surgical procedure significantly outweigh the risk of reoccurrence of this device behavior. Until the software mitigation update is available, this S-ICD behavior represents an additional, small risk that should be considered when evaluating the relative risks associated with all available ICD therapy options.

Boston Scientific is now releasing programmer software version 4.04 to address the behavior for S-ICDs and a local Boston Scientific representative will arrange to update each programmer. This advisory no longer applies after an S-ICD is interrogated by any programmer updated with version 4.04 software.

Recommendations for S-ICD and Programmers
• Confirm all Model 3200 S-ICD programmers are upgraded with version 4.04 software.
• Once your Model 3200 S-ICD programmers are upgraded, perform a standard in-clinic S-ICD followup for all patients implanted with an S-ICD at their earliest convenience. The January 2017 recommendation to perform a second interrogation is no longer required.
Note: The programmer will upgrade each S-ICD's software which takes less than 5 minutes.
• Thereafter, standard in-clinic S-ICD follow-up checks may resume at normal frequency with programmers upgraded with version 4.04 software.
Note: When an S-ICD's software has been upgraded, it can only be interrogated with programmers installed with version 4.04 or greater software. Appendix A shows how the software model and version number can be identified through the programmer or an S-ICD summary report.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **COGNIS** Models N106/N107/N108/N118/ N119/N120/P106/P107/P108 **TELIGEN VR** Models E102/E103/F102/F103 **TELIGEN DR** Models E110/E111/F110/F111	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. It also informed physicians how to identify and respond to a Safety Architecture low voltage alert. In September 2014, a second subset of devices was identified that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset. The second communication also discussed improvements to Safety Architecture's low voltage alert, which were released through a programmer software update. 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. 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. 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 **10-Apr-18** Advisory devices have not been available for implant for more than seven years. *Confirmed Malfunctions (worldwide)* 5,364 malfunctions have been confirmed from the advisory population. Approximately 32,000 devices from the advisory populations remain in service. There have been two reported patient deaths due to complications with the replacement of an advisory device. *Projected Rate of Occurrence* • COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.9% at 60 months, 6.0% at 72 months, 8.9% at 84 months and 11.2% at 96 months. The potential for life-threatening harm from loss of therapy is approximately 1 in 200,000 (0.0005%) at 60 months. • COGNIS CRT-D and TELIGEN ICD populations (advisory and non-advisory) - The overall rate of occurrence is approximately 1.1% at 60 months, 2.5% at 72 months and 3.7% at 84 months. The projected rate of occurrence is 5.0% at 96 months. Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy has decreased to approximately 1.6%. The potential for life-threatening harm from loss of therapy is approximately 1 in 500,000 (0.0002%) at 60 months. • INCEPTA, ENERGEN and PUNCTUA CRT-Ds and ICDs - The rate of occurrence is 1% at 60 months. The projected rate of occurrence is 1.8% at 72 months. The portion of malfunctions with compromised therapy is approximately 0.3%. The potential for life-threatening harm from loss of therapy is approximately 1 in 5,000,000 (0.00002%) at 60 months.
	CURRENT RECOMMENDATION **10-Apr-18** 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.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant**
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	*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.
Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
	CURRENT STATUS **10-Apr-18**
	Reported events (worldwide) Ninety-nine (99) 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.
	CURRENT RECOMMENDATION **10-Apr-18**
	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.
	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 **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 **VENTAK PRIZM 2 VR/DR** Models 1860/1861 Low Voltage Capacitor, Physician Low Voltage Capacitor, Patient Letter, Low Voltage Capacitor, Physician Letter, Jun 23, 2006	Voluntary Physician Advisory FDA Classification: Class II Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue. *Reported Events (worldwide)* At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing. *Projected Rate of Occurrence* While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future. CURRENT STATUS **10-Apr-18** *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 **10-Apr-18** 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 when making 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** – 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
	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..* **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	Voluntary Physician Advisory FDA Classification: Class II Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up. This failure mechanism can result in one or more of the following device behaviors: – Loss of shock therapy – Loss of pacing therapy (intermittent or permanent) – Loss of telemetry communications – Beeping (16 tones every six hours), and a programmer warning screen upon interrogation *Reported Events* Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism. *Rate of Occurrence* The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.
	CURRENT STATUS **10-Jan-18**
VITALITY 2 EL VR/DR Models T177/T167 **VITALITY DR HE** Model T180 **VITALITY EL** Model T127 **VITALITY DR+** Model 1872	*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 **10-Jan-18**
Subpectoral Implant, Physician Letter, Jan 04, 2008 Subpectoral Implant, Patient Letter, Dec 01, 2009	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. 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 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, 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 **10-Apr-18**
	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. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 3,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **10-Apr-18**
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.

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