CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2016

Second Edition – Issue 75

Medtronic

CRHF Product Performance Report

2016

Second Edition
Issue 75

Cutoff date for this edition is 31 July 2016 for Lead Study data and 3 August 2016 for all other data, unless otherwise stated.

Our Commitment to Quality

Medtronic was founded in 1949 and has grown to become a global leader in medical technology. Seeing what a difference medical technology could make in the lives of patients inspired our founder to develop the Medtronic Mission, which remains unchanged today.

The third tenet of the mission is all about quality:

"To strive without reserve for the greatest possible reliability and quality in our products, to be the unsurpassed standard of comparison, and to be recognized as a company of dedication, honesty, integrity, and service."

Regardless of function, all CRHF employees play a role in product quality. Whether designing new therapies, sourcing components, manufacturing products, hiring talented people, assigning financial resources to project teams, or serving in one of the hundreds of other roles, every employee has an influence on product quality.

Product performance information is received from many sources through various channels. Medtronic monitors information from many sources from Research and Development through Manufacturing and Field Performance Vigilance.

When a device is returned to Medtronic, laboratory technicians and engineers assess overall device function. Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate a performance concern from a customer, or to collect specific reliability data.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRHF maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Analysis results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause. Each event is then compared to other events. If a pattern is detected, actions are taken to identify a common root cause, assess patient risk and an appropriate course of action.

Medtronic instituted the industry's first product performance reports in 1983 by publishing data on our chronic lead studies. Pacemakers and other devices followed as our performance reporting has constantly evolved based on customer needs and feedback. One thing has been a constant. It is our sincere commitment to communicate clearly, offering timely and appropriate product performance data and reliability information. This has always been and will continue to be our goal.

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure
Medtronic, Inc.

Contact Information

We invite our customers to use these telephone numbers to call with suggestions, inquiries, or specific problems related to our products.

US Technical Services Department

Phone: 1 (800) 723-4636 (Tachy)
1 (800) 505-4636 (Brady)

Fax: 1 (800) 824-2362

http://www.medtronic.com/for-healthcare-professionals/products-therapies/crdm-technical-services/index.htm

International Technical Centers

Europe (Heerlen NL) +31-45-566-8844
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For questions related to returning explanted product or returning product that shows signs of malfunction, please contact:

Outside the United States:
Your Medtronic representative or international technical center at the number above.

Within the United States:
Your Medtronic representative or
CRHF Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email:
crdm.returnedproduct@medtronic.com

Editorial Staff

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Introduction

For 33 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.

This Product Performance Report (PPR) presents device survival estimates, advisory summaries, performance notes, and other information pertinent to assessing the performance of Medtronic implantable pulse generators (IPGs), implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implantable pacing and defibrillation leads.

This Product Performance Report has been prepared in accordance with International Standard ISO 5841- 2:2000(E).

The survival estimates provided in this report are considered to be representative of worldwide performance.

Survival Estimates

Medtronic, like other companies, monitors CRT, ICD, and IPG device performance using returned product analysis. We also monitor CRT, ICD, and IPG device performance using an active multicenter clinical study.

Returned product analysis is a passive approach to assessing product performance. This approach provides a suitable measure of product performance only when a significant number of explanted products are returned to the manufacturer. Returned product analysis provides a measure of hardware performance, but not necessarily the total clinical performance (e.g., the incidence of complications such as infection, erosion, muscle stimulation, etc. are not estimated).

The survival estimates provided in this report for CRT, ICD, and IPG devices are based on returned product analysis. This approach is suitable because a significant number of explanted generators are returned for analysis.

Lead performance is monitored differently. In contrast to CRT, ICD, and IPG devices, a very small percentage of leads are returned to the manufacturer due to the difficulty of explanting them. For leads, an active clinical study provides more accurate survival estimates compared to estimates based solely on returned product analysis.

Survival estimates for leads are based on clinical observations recorded via Medtronic's PAN Registry. This multicenter clinical study is designed to record clinical observations representative of the total clinical experience. Therefore, the lead survival estimates include both lead hardware failure and lead-related medical complications, and do not differentiate a lead hardware failure from other clinical events such as exit block, perforation, dislodgement, or concurrent pulse generator failure.

The actuarial life table method is applied to the data collected for CRT, ICD, and IPG devices and leads to provide the survival estimates included in this report. A general introduction to understanding this method of survival analysis is given later in this introduction.

ICD Charge Times

Since May 2000, Medtronic has provided important information on charge time performance of ICDs. The information provided in this report shows how ICD charge time can vary during the time a device is implanted. The information is presented in graphical format showing charge time as a function of implant time. The data for charge times are collected from devices enrolled in the PAN registry.

Introduction continued

Advisory Summaries

This Product Performance Report includes summaries of all advisories applicable to the performance of the products included in the report. An advisory is added to the report when any product affected by the advisory remains in service and at risk of experiencing the behavior described in the advisory. The advisory will remain in the report until Medtronic estimates no product affected by the advisory remains active, or the risk of experiencing the behavior described in the advisory has passed.

For most advisories, the products subject to the advisory retain essentially the same survival probability as the products of the same model(s) not affected by the advisory. For those advisories where the survival probabilities of the affected and non-affected populations do differ significantly, Medtronic will provide separate survival data for each population. The separate survival data will remain in the report until Medtronic estimates no affected product remains in active service.

Performance Notes

This report concludes with a number of Performance Notes developed by Medtronic to provide additional product performance information relevant to follow-up practice and patient management.

How You Can Help

Medtronic urges all physicians to return explanted products and to notify Medtronic when a product is no longer in use, regardless of the reason for explant or removal from use. The procedures for returning products vary by geographic location.

Mailer kits with prepaid US postage are available for use within the United States to send CRTs, ICDs, IPGs, ICMs, and leads to Medtronic's Cardiac Rhythm and Heart Failure (CRHF) Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

If the product being returned is located outside the United States, please contact your local Medtronic representative for instructions.

Medtronic also requests the return of explanted products from non-clinical sources, such as funeral homes, and will assume responsibility for storage and disposal of the product once received.

Mailer kits can be obtained by contacting the Returned Product Lab. For information on how to contact the Lab, refer to the Contact Information page of this report.

We continually strive to improve this CRHF Product Performance Report. In keeping with this philosophy, we ask for your suggestions on the content and format of this report, as well as any information you have regarding the performance of Medtronic products. For information on how to comment on this report, see the Contact Information page.

Overview of Survival Analysis

Medtronic uses the Cutler-Ederer actuarial life table method for devices and Kaplan-Meier for leads to estimate the length of time over which they will perform within performance limits established by Medtronic. This probability to perform within performance limits over time is called the survival probability.

Devices and leads are followed until an event occurs where the device or lead ceases to operate within performance limits. The length of time from implant to the event is recorded for individual devices and leads in the population sample. The population sample for CRT, ICD, and IPG devices is made up of patients whose devices are registered as implanted in the United States. For leads, the population sample is the patients enrolled in our multicenter, international prospective Product Surveillance Registry.

Introduction continued

For CRTs, IPGs and ICDs, the events can be normal battery depletion or a device malfunction. For leads, the events are complications as defined in the study protocol.

The actuarial life table method allows Medtronic to account for devices and leads removed from service for reasons unrelated to performance and for device and leads still in service. Devices and leads removed for reasons unrelated to performance or are still in service are said to be suspended. Examples of devices and leads removed from service for reasons unrelated to performance include:

- Removed to upgrade the device or lead
- No longer in service due to the death of the patient for reasons unrelated to the device or leads
- Implanted in patients who are lost to follow-up

For each suspension, the device or lead has performed within performance limits for a period of time, after which its performance is unknown.

An Example

The following example describes the survival analysis method used to establish the survival probability estimates for Medtronic CRHF devices and leads. The example is intended to provide an overview of the analysis process. The definitions of malfunctions and complications, and other details specific to calculating device and lead survival estimates, are provided in the articles Method for Estimating CRT, ICD, and IPG Device Performance and Method for Estimating Lead Performance.

Figure 1 Implant times for devices of 16 patients. Gray bars with a yellow X indicate devices removed from service due to an event. Blue bars indicate suspended devices.

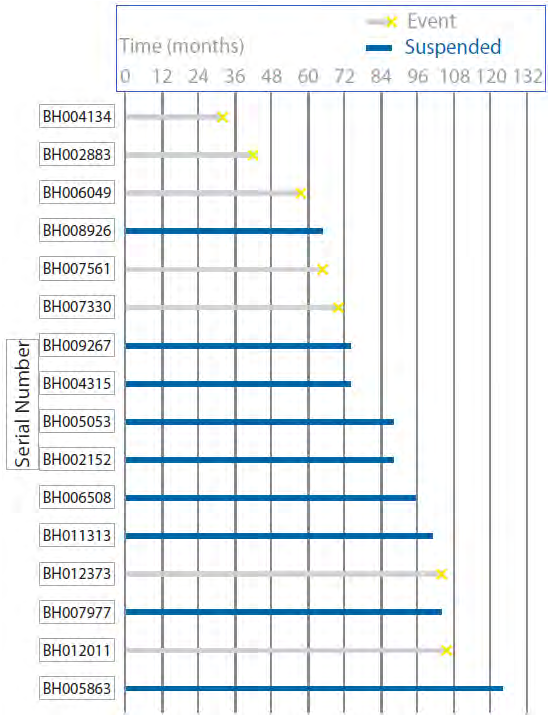


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because it was still in service at the time of the analysis. This patient had 66 months of implant experience. In this example, Figure 1 shows that seven of the 16 devices suffered events, and nine are suspended.

The first step in the life table method is to divide the implant time into intervals of a specific length. This example will use 12-month intervals.

The number of devices entered, suspended, and removed due to an event are counted and summarized, as shown in Table 1. For the first two intervals, all 16 devices survived and none were removed. In the interval (24-36 months), device BH004134 was removed due to an event. Therefore the table entries show that 16 entered the interval, none were suspended, and one was removed due to an event.

For the interval from 36-48 months, only 15 devices entered the interval and one was removed for an event. The remaining intervals are examined and the data entered in columns A, B, and C in like manner. The rest of the columns are filled in using calculations on the data in columns A, B, and C.

Introduction continued

The Effective Sample Size (D) is the number of devices with full opportunity to experience a qualifying event in the interval. This is computed by subtracting one half the number suspended in the interval from the number that entered the interval. This calculation more accurately reflects the number of devices that could have experienced a qualifying event than simply using the number that entered the interval. Using the number of devices that enter an interval overestimates the sample size because the suspended devices do not complete the interval. Ignoring the suspended devices underestimates the sample size because suspended devices are not credited with their full service time. Using one half the number of suspended devices effectively splits the difference.

The next column in the table is the Proportion with Event (E). This is the proportion of devices that had an event in the interval. It is calculated by dividing the Number of Events (C) by the Effective Sample Size (D). The number can be interpreted as the estimated rate at which events occur in the time interval.

The Interval Survival Probability (F) is the estimate of probability of surviving to the end of the interval assuming the device was working at the beginning of the interval. It is calculated as 1 minus the Proportion with Event (E). This number can be interpreted as the estimated rate at which events do not occur in the time interval.

Table 1 Life Table for Figure 1

	A	B	C	D	E	F	G
Interval in Months	Number Entered	Number Suspended	Number of Events	Effective Sample Size	Proportion with Event	Interval Survival Probability	Cumulative Survival Probability
0	16	0	0	16	0.000	1.000	1.000
0-12	16	0	0	16	0.000	1.000	1.000
12-24	16	0	0	16	0.000	1.000	1.000
24-36	16	0	1	16	0.063	0.938	0.938
36-48	15	0	1	15	0.067	0.933	0.875
48-60	14	0	1	14	0.071	0.929	0.813
60-72	13	1	2	12.5	0.160	0.840	0.683
72-84	10	2	0	9	0.000	1.000	0.683
84-96	8	3	0	6.5	0.000	1.000	0.683
96-108	5	2	2	4	0.500	0.500	0.341
108-120	1	0	0	1	0.000	1.000	0.341
120-132	1	1	0	0.5	0.000	1.000	0.341

Definitions:

A	B	C	D	E	F	G
Number Entered	**Number Suspended**	**Number of Events**	**Effective Sample Size**	**Proportion with Event**	**Interval Survival Probability**	**Cumulative Survival Probability**
Number of devices active at the start of the interval	Number of devices removed from service for reasons other than an event	Number of units removed from service due to an event	Number of units with full opportunity to experience a qualifying event in the interval. Computed by subtracting one half the Number Suspended from the Number Entered.	Proportion of devices that had an event in the interval. Computed by dividing the Number of Events by the Effective Sample Size.	The probability of surviving to the end of the interval, assuming the device was working at the beginning of the interval. Computed as 1 minus the Proportion With Event.	The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

Introduction continued

Cumulative Survival Probability (G) is the estimate of the unconditional probability of surviving to the end of the interval. It is computed by multiplying the Interval Survival Probability (F) by the previous interval's Cumulative Survival Probability. The probability of surviving to 132 months in the example is estimated for the table to be 0.341, or 34.1%. The Cumulative Survival Probabilities (G) of the life table can be plotted versus time intervals in the first column to give a survival curve. Figure 2 shows the survival curve for the data in Table 1.

Figure 2 Survival Curve for Data Given in Table 1

%	0	12	24	36	48	60	72	84	96	108	120	132
#	100	100	100	93.8	87.5	81.3	68.3	68.3	68.3	34.1	34.1	34.1
	16	16	16	16	15	14	12.5	9	6.5	4	1	0.5
	Effective Sample Size											

Confidence Intervals

Since survival curves are based on a sample of the device and lead population, they are only estimates of survival. The larger the effective sample size, the more confident the estimate. A confidence interval can be calculated to assess the confidence in an estimate. In the Product Performance Report, Medtronic provides a 95% confidence interval. This can be interpreted as meaning that 95% of the time, the true survival of the device will fall somewhere in the interval.

Survival Curves in the Product Performance Report

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRTs, ICDs, and IPGs, and when the number entered is less than 50 for leads. The survival charts in the Product Performance Report show the effective sample size for each year interval where Medtronic has experience. When the effective sample size reaches 100 for CRTs, ICDs, and IPGs or when the number entered reaches 50 for leads, the next data point is added to the survival curve.

Although the report provides tabular data in one-year intervals, the device curves are actually computed and plotted using the Cutler-Ederer method and 1-month intervals (for CRT, ICD, and IPG devices) and leads curves are computed and plotted using Kaplan-Meier, which uses individual survival times.

A number of references are available for additional information on survival analysis using the Cutler-Ederer life table method[1] and for the Kaplan-Meier method.[2]

[1] Lee, Elisa T.(2003) Statistical Methods for Survival Data Analysis – 3rd Edition (Wiley Series in Probability and Statistics).

[2] Klein, John P., Moeschberger, Melvin L. Survival Analysis Techniques for Censored and Truncated Data, New York: Springer-Verlag New York, Inc., 1997.

Method for Estimating CRT, ICD, and IPG Device Performance

The performance of CRT, ICD, and IPG devices is expressed in terms of device survival estimates, where "survival" refers to the function of the device, not the survival of the patient. These survival estimates are intended to illustrate the probability that a device will survive for a given number of years without malfunction or battery depletion.

The survival estimates are determined from the analysis of Medtronic Cardiac Rhythm and Heart Failure (CRHF's) United States device registration data and US returned product analysis data. These data are presented graphically and numerically.

Because this analysis is based on returned product analysis, the performance data does not reflect any device-related medical complications such as erosion, infection, muscle stimulation, or muscle inhibition.

Categorization of Depleted and Malfunctioning Devices for Survival Analysis

For survival estimation, every device returned to Medtronic CRHF and analyzed in the CRHF Returned Product Analysis laboratory is assigned to one of three categories. The device 1) is functioning normally, 2) has reached normal battery depletion, or 3) has malfunctioned. This categorization is combined with data from our device registry for the total number of implants and the implant durations to create the survival curves presented on the following pages.

Definition of Malfunction

Medtronic CRHF considers a device as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service. To be considered a malfunction or battery depletion, the device must have been returned to Medtronic and analyzed.

Devices damaged after explant, damaged due to failure to heed warnings or contraindications in the labeling, or damaged due to interaction with other implanted devices (including leads) are not considered device malfunctions.

A device subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRHF and found, through analysis, to actually have performed outside the performance limits established by Medtronic.

Not all malfunctions expose the patient to a loss of therapy. Some malfunctions included in the following survival estimates may not have been detected at all by the physician or the patient. These malfunctions, however, are included in the survival estimates and provide important feedback to our product development organization.

To provide insight into the nature of malfunctions, each malfunction is categorized as Malfunction with Compromised Therapy Function or Malfunction without Compromised Therapy Function.

For this report, Normal Battery Depletion, Malfunction with Compromised Therapy Function, and Malfunction without Compromised Therapy Function are defined as follows:

Normal Battery Depletion – 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 80% of the expected longevity calculated using the available device setting information.

Medtronic CRHF establishes expected longevity by statistically characterizing the power consumed by the device and the power available from the device battery. This characterization is applied to a number of parameter configurations to derive a statistical mean longevity value and standard deviation for each parameter configuration. The statistical mean value minus three standard deviations is used as the expected longevity for determining if a battery depleted normally. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from these estimates.

Malfunction with Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation), while implanted and in service, as confirmed by returned product analysis.

Examples: 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 delivery of therapy, intermittent malfunction where therapy is compromised while in the malfunction state.

Malfunction without Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy, while implanted and in service, as confirmed by returned product analysis.

Examples: Error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power quickly enough to cause 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.

Expanded Malfunction Detail

The malfunctions are further divided into categories that identify the subject area of the malfunction. The malfunctions are divided into the following subject areas:

Electrical Component – Findings linked to electrical components such as integrated circuits, resistors, capacitors, diodes, etc.

Electrical Interconnect – Findings linked to the connections between electrical components such as wires, solder joints, wire bonds, etc.

Battery – Findings linked to the battery and its components

Software/Firmware – Findings linked to software or firmware function

Possible Early Battery Depletion – Findings where the actual reported implant time is less than 80% of the expected longevity calculated using the available device setting information with no device malfunction observed. There may not be sufficient device setting information to determine conclusively if battery depletion was normal or premature in the absence of a specific root cause finding. However, returned devices meeting the above criteria are conservatively classified as Possible Early Battery Depletion malfunctions.

Other – Findings related to other components such as insulators, grommets, setscrews, and packaging, and findings where analysis is inconclusive.

Returned Product Analysis Process

Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate a performance concern from a customer, or to collect specific reliability data.

When a device is returned with a performance concern from a customer, the general analysis process includes a preliminary analysis of the device in its as-received condition, followed by an automated functional test using test equipment equivalent to the equipment used in manufacturing.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRHF maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Statistical Methods for Survival Analysis

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions assumed distributed evenly within the intervals (Cutler-Ederer Method), is used to determine survival estimates for CRT, IPG and ICD devices. Implant times are calculated from the implant date to the earlier of the explant date or the cutoff date of the report. From this data an estimate of the probability of device survival is calculated at each monthly interval.

On the following pages, each graph includes a survival curve where events include malfunctions and normal battery depletions. This survival curve is a good representation of the probability a device will survive a period of time without malfunction and without battery depletion. For example, if a device survival probability is 95% after 5 years of service, then the device has a 5% chance of being removed due to battery depletion or malfunction in the first 5 years following implant.

In addition, a second curve is included to show survival excluding normal battery depletion. This curve is a good representation of the probability for a device to survive without malfunction. This curve includes only malfunctions as events and excludes normal battery depletion.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRT, ICD, and IPG devices. The survival charts in the Product Performance Report show the effective sample size for each year interval where we have experience. When the effective sample size reaches 100, the next data point is added to the survival curve.

Although the report provides tabular data in one-year intervals, the curves are actually computed and plotted using one-month intervals.

The data in the tables are rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have one or more malfunctions or battery depletions. This occurs because, even with the malfunctions or battery depletions, the data rounds to 100%.

Sample Size and How the Population and Population Samples Are Defined

The population sample from which the survival estimates are derived is comprised of the devices registered as implanted in the United States as of the report cutoff date. The number of registered implants, as well as an estimate of the number that remain in active service, is listed for each model. To be included in the population, the device must have been registered with Medtronic's registration system and implanted for at least one day.

This sample based on US implants is considered to be representative of the worldwide population, and therefore the survival estimates shown in this report should be representative of the performance worldwide of these models.

A CRT, ICD, or IPG model or model family will be included in this report when it has accumulated at least 10,000 implant months and will remain in the report as long as at least 500 devices remain active.

Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion

The tables on the following pages show the actual number of malfunctions and battery depletions recorded by the analysis lab for US registered devices. Since not all devices are returned to Medtronic CRHF for analysis, these numbers underestimate the true number of malfunctions and battery depletions. To more accurately estimate the all-cause device survival probabilities, the number of malfunctions and battery depletions used to plot each interval of the all-cause survival curves is adjusted (multiplied) by a factor that is based on an estimate of the magnitude of underreporting. The magnitude of underreporting is estimated by comparing data in Medtronic's Device And Registrant Tracking (DART) system with data from Returned Product Analysis.

The DART system is an important element of Medtronic's Quality System. The DART system is designed to meet or exceed the US FDA's device tracking requirements set forth by the Safe Medical Devices Act. In the United States, over 98% of Medtronic's CRT, ICD, and IPG implants become registered in the DART system.

Because pacemakers do not cure the patient's underlying health problem, when a pacemaker stops functioning (due to either normal battery replacement or malfunction) it is replaced with a new pacemaker. Therefore, the replacement recorded in the DART system is a good indication that the previous pacemaker experienced either battery depletion or malfunction. The fraction of replaced devices that are subsequently returned can be used to estimate the correction factor for the under reporting of the combination of battery depletion and malfunction.

Note that devices of patients who have expired do not factor into the calculation of the correction. It is possible some proportion of these devices experienced battery depletion or malfunction. Since these are not counted into the correction factor based on the return rate of replaced devices, a correction factor based only on the return rate of replaced devices may still underestimate the true rate of battery depletion and malfunction. However, devices that are replaced because the patient is receiving a system upgrade or are removed because the patient no longer needs it (e.g., due to heart transplant) do contribute to the calculation of the correction factor and therefore impart an opposite bias.

Also note that this method of calculating the correction factor cannot distinguish between devices that are removed due to malfunction and those due to normal battery depletion. It might seem intuitive that devices that unexpectedly malfunction should be much more likely to be returned to the manufacturer than a device with ordinary normal battery depletion. But this has not been conclusively demonstrated. Therefore, this method only provides a correction factor reflecting the combination of battery depletion and malfunction.

No adjustment for underreporting is applied to the malfunction-free survival curve because a method for estimating malfunction-only underreporting has not been developed.

Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

Devices are at times removed from service for reasons other than device malfunction or battery depletion. Examples are devices removed from service due to non-device related patient mortality and devices removed due to changes in the patient's medical condition. Because an accurate estimate of device survival depends on an accurate estimate of the number of devices in service, it is important not to overstate the number of devices in service.

Medtronic addresses this under reporting to ensure the number of devices in service is not overstated . Regular updates obtained from the Social Security Administration about deceased persons are used to update Medtronic's DART data about patients who have died but whose deaths had not been reported to Medtronic. In addition, the patient mortality rate derived from our DART system is monitored and compared to published mortality rates for comparable patient populations. If, during calculation of the survival curves, the patient mortality indicated by the data in DART is significantly different from published rates, an adjustment is applied to correct the difference. The correction factor for under reporting devices is also applied to account for devices that were removed and not reported or returned.

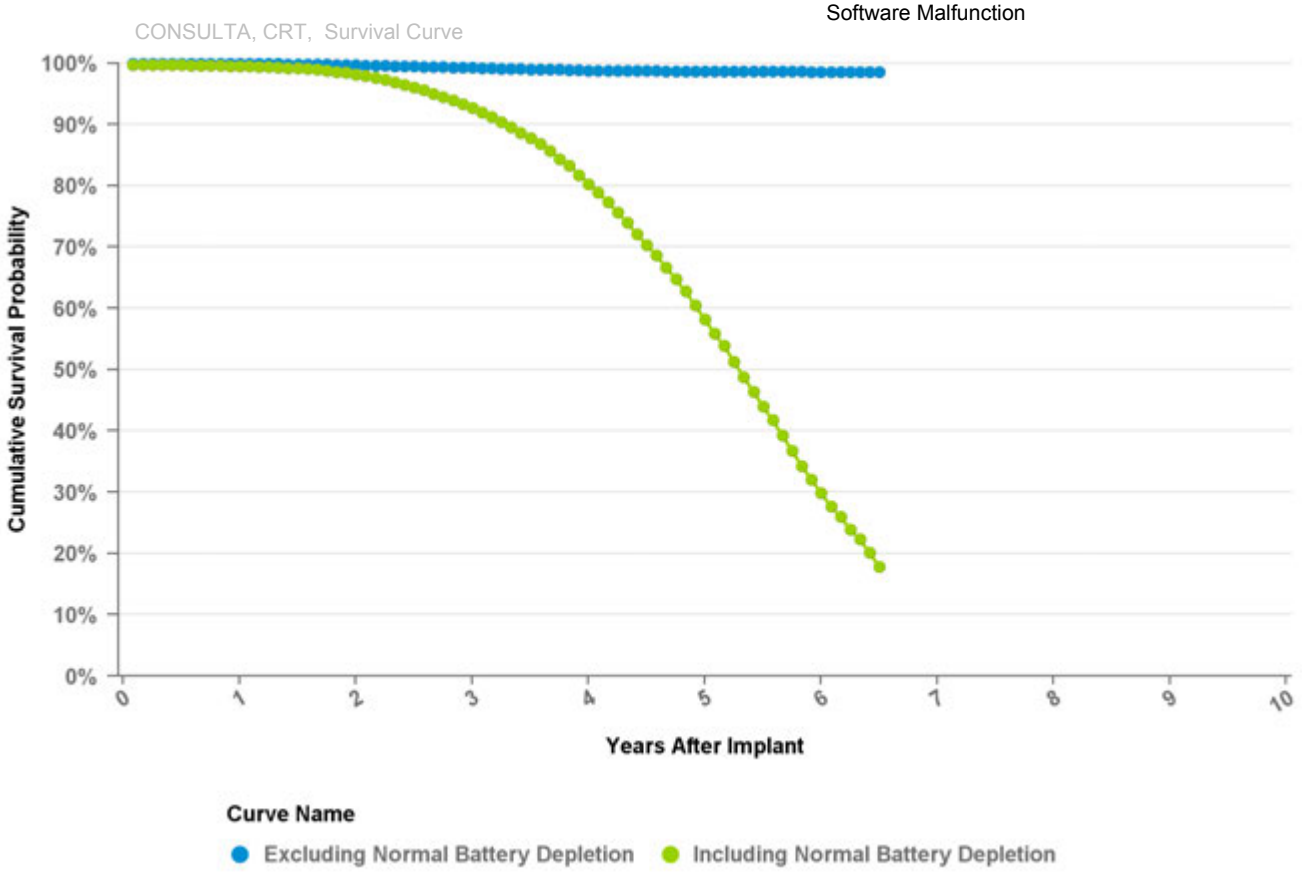
Cardiac Resynchronization Therapy

D204TRM Consulta CRT-D

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	2,080
Estimated Active US Implants	1,570
Normal Battery Depletions (US)	104

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.6%	98.2%	92.7%	80.3%	58.3%	29.9%	17.9%
Effective Sample Size	57793	52638	45377	33357	18145	3583	358

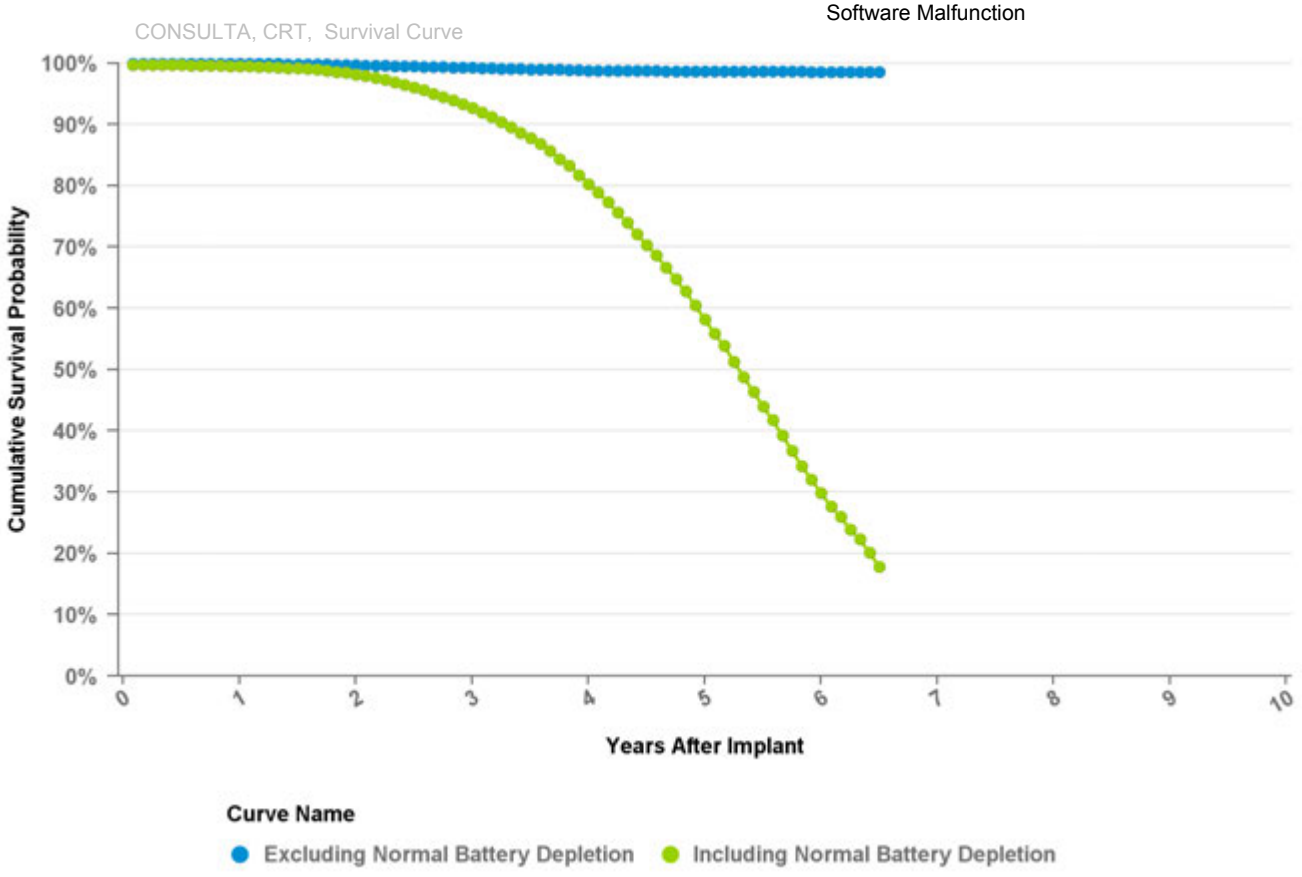
Cardiac Resynchronization Therapy

D214TRM Consulta CRT-D

US Market Release Date	
CE Market Approval Date	7/22/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.6%	98.2%	92.7%	80.3%	58.3%	29.9%	17.9%
Effective Sample Size	57793	52638	45377	33357	18145	3583	358

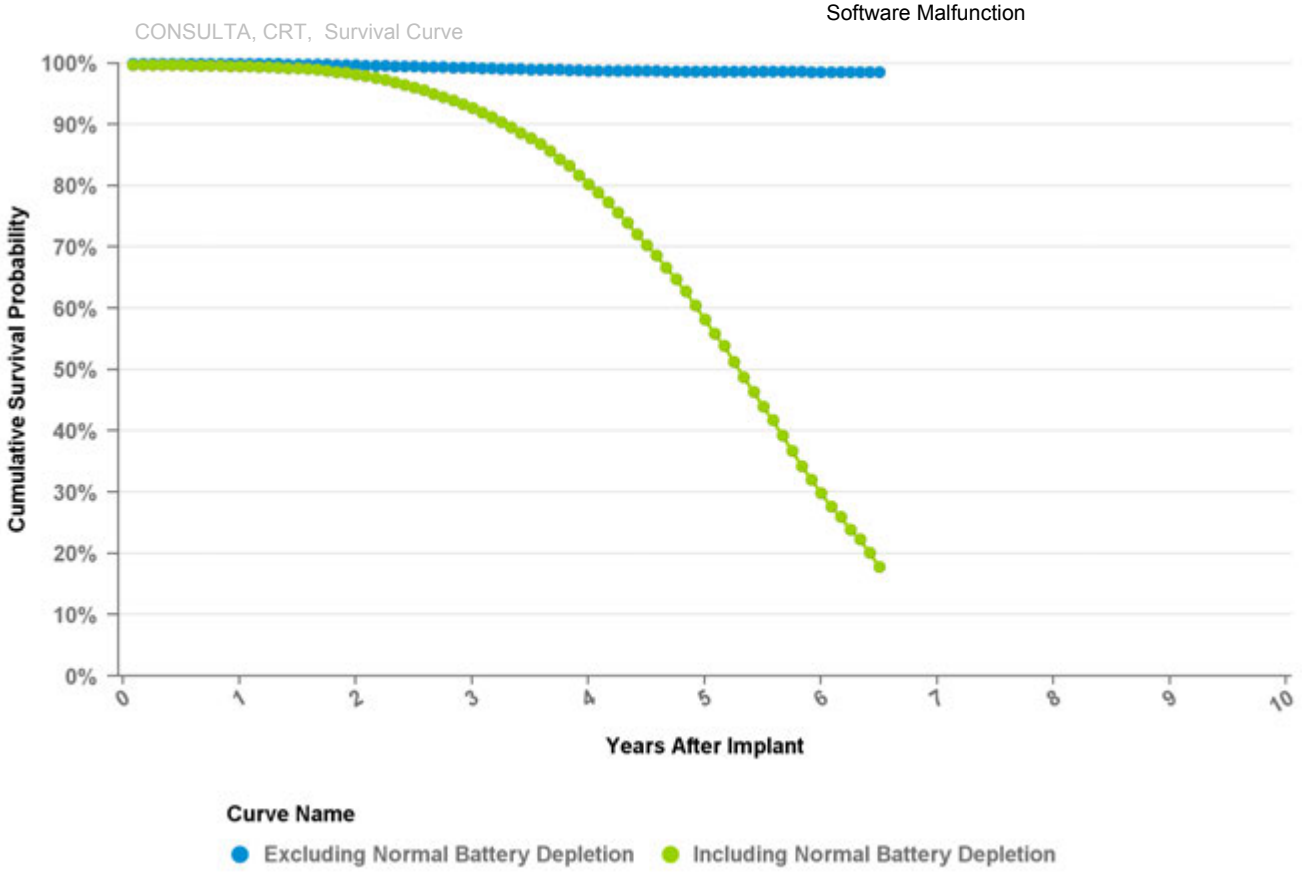
Cardiac Resynchronization Therapy

D224TRK Consulta CRT-D

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	65,777
Estimated Active US Implants	18,750
Normal Battery Depletions (US)	15,499

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	595
Therapy Not Compromised Malfunctions	570
Battery Malfunction	2
Electrical Component	64
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	496
Software Malfunction	6
Therapy Compromised Malfunctions	25
Battery Malfunction	1
Electrical Component	24
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.6%	98.2%	92.7%	80.3%	58.3%	29.9%	17.9%
Effective Sample Size	57793	52638	45377	33357	18145	3583	358

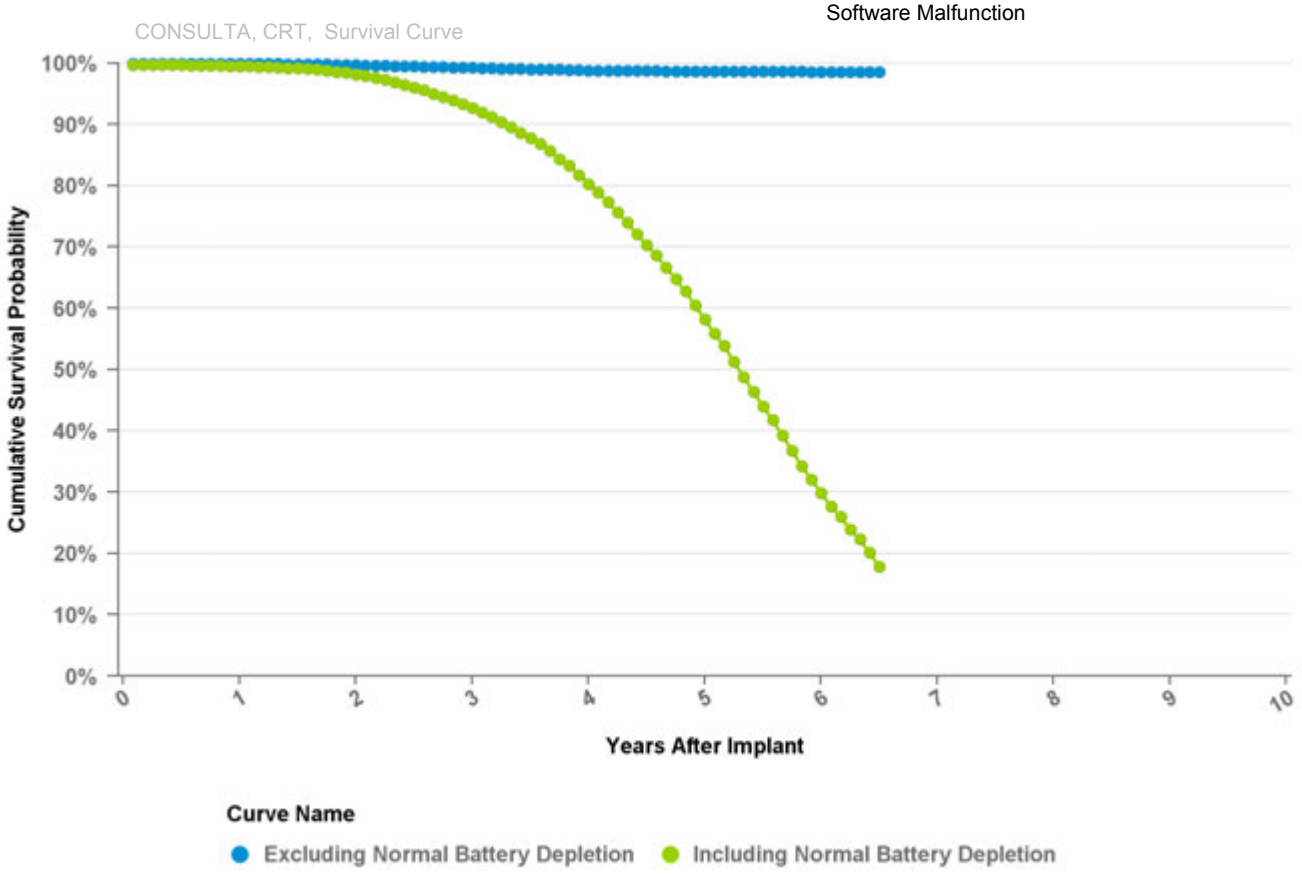
Cardiac Resynchronization Therapy

D234TRK Consulta CRT-D

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	2
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.6%	98.2%	92.7%	80.3%	58.3%	29.9%	17.9%
Effective Sample Size	57793	52638	45377	33357	18145	3583	358

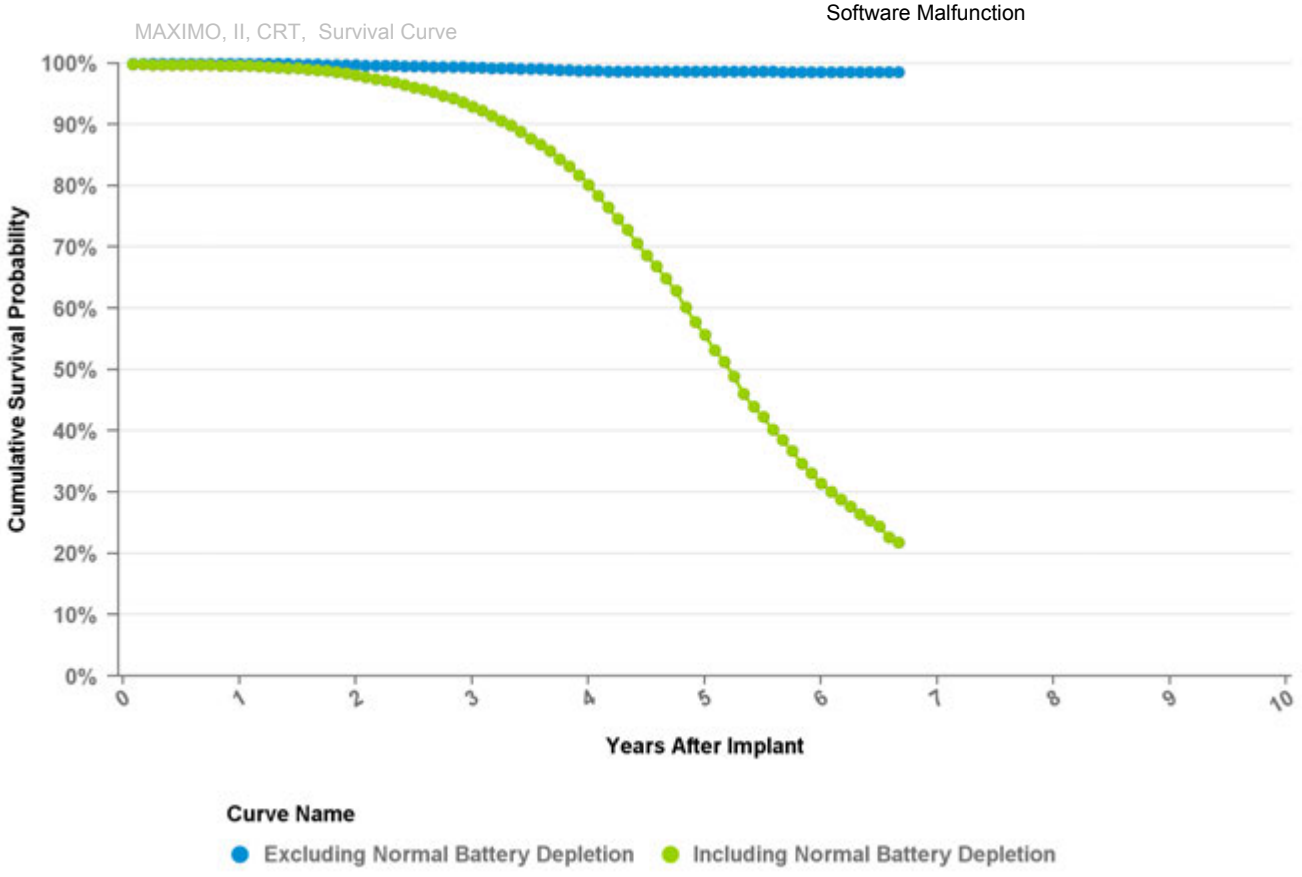
Cardiac Resynchronization Therapy

D264TRM Maximo II CRT-D

US Market Release Date	1/9/2012
CE Market Approval Date	7/22/2010
Registered US Implants	15
Estimated Active US Implants	10
Normal Battery Depletions (US)	1

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.7%	98.1%	93.0%	80.2%	55.7%	31.5%	21.9%
Effective Sample Size	12820	11574	9956	7284	3496	876	113

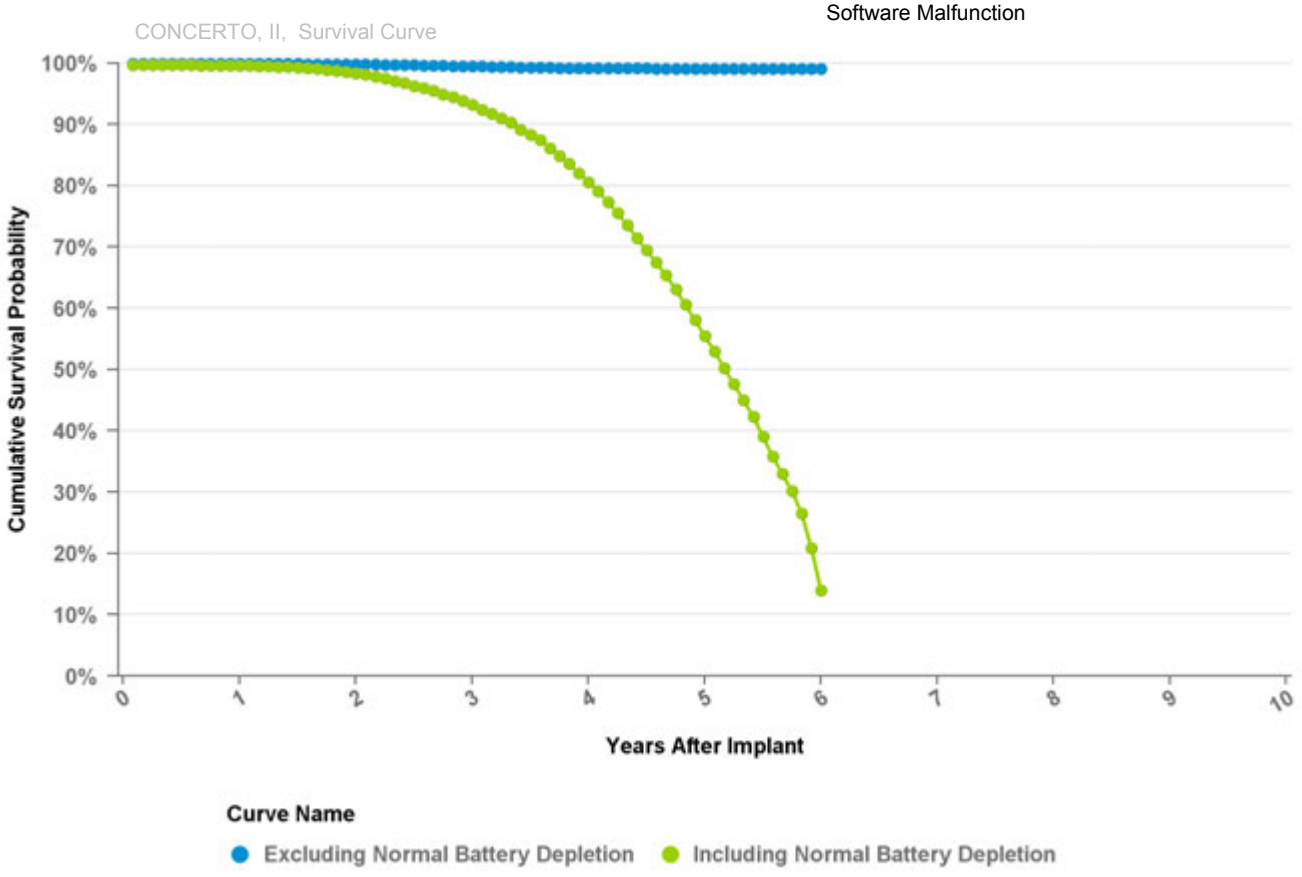
Cardiac Resynchronization Therapy

D274TRK Concerto II CRT-D

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	30,166
Estimated Active US Implants	8,329
Normal Battery Depletions (US)	7,220

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	184
Therapy Not Compromised Malfunctions	174
Battery Malfunction	1
Electrical Component	21
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	151
Software Malfunction	1
Therapy Compromised Malfunctions	10
Battery Malfunction	1
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 72 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%
Including NBD	99.6%	98.4%	93.3%	80.6%	55.5%	14.0%
Effective Sample Size	25414	23234	20258	15504	7885	220

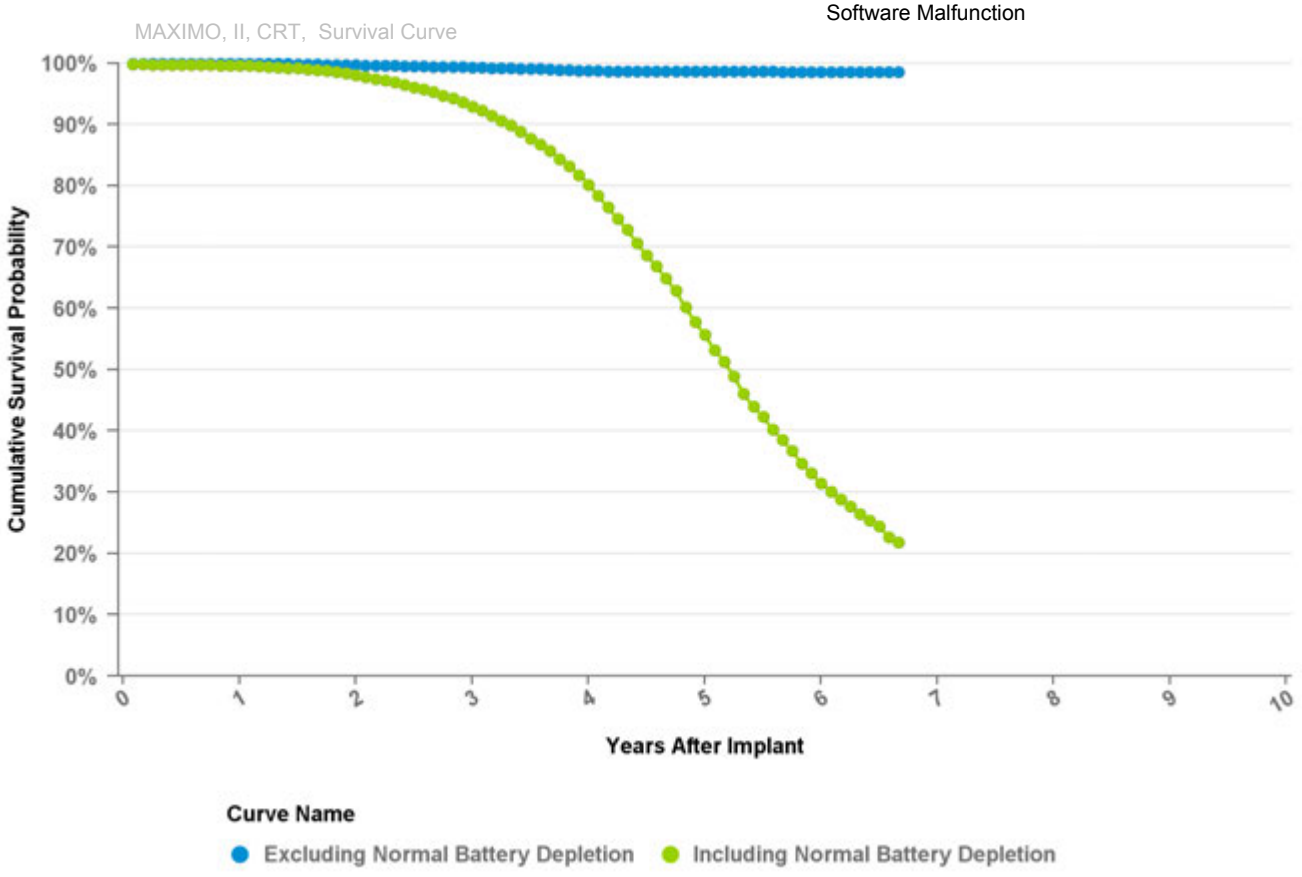
Cardiac Resynchronization Therapy

D284TRK Maximo II CRT-D

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	15,130
Estimated Active US Implants	4,510
Normal Battery Depletions (US)	3,399

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	135
Therapy Not Compromised Malfunctions	130
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	124
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.6%	98.6%
Including NBD	99.7%	98.1%	93.0%	80.2%	55.7%	31.5%	21.9%
Effective Sample Size	12820	11574	9956	7284	3496	876	113

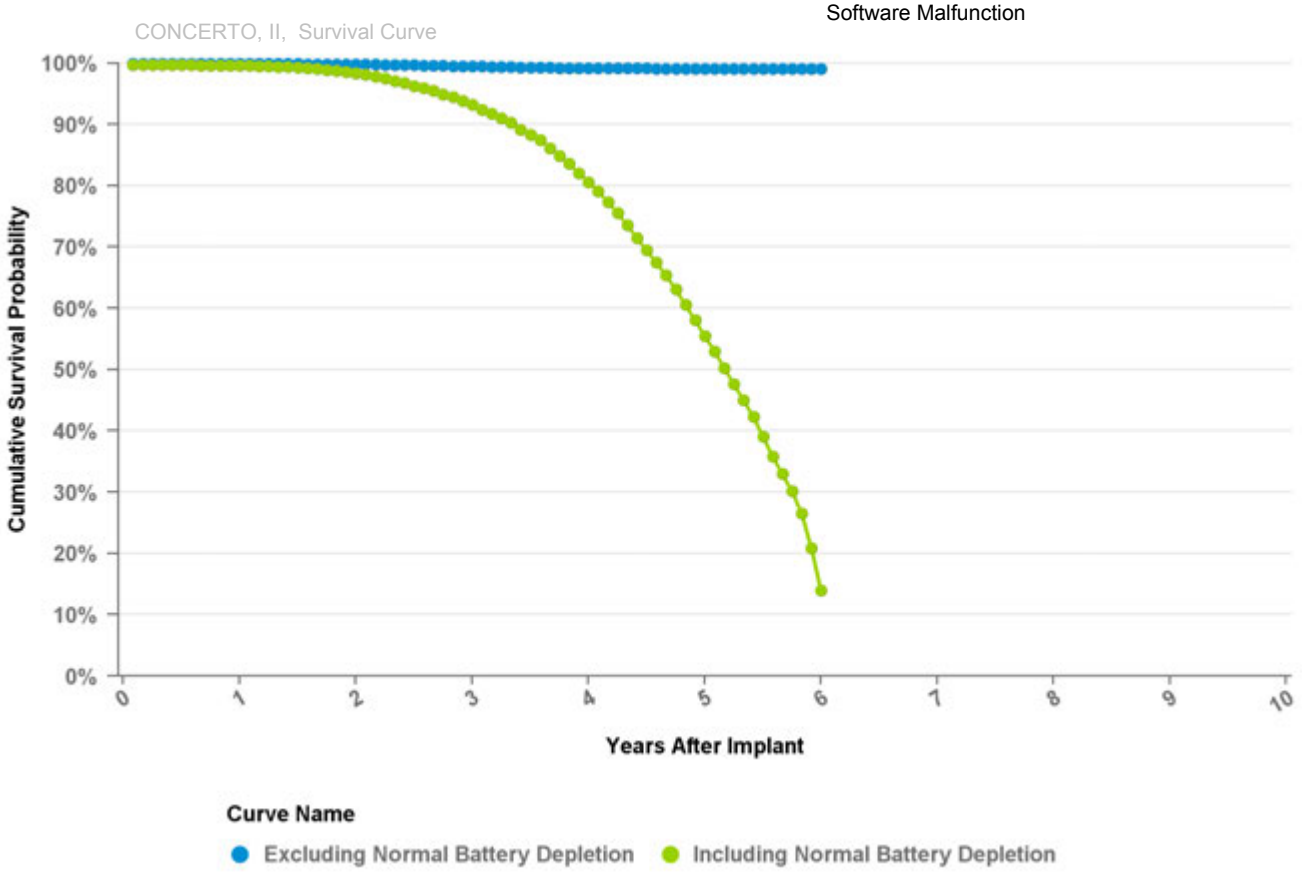
Cardiac Resynchronization Therapy

D294TRK Concerto II CRT-D

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 72 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%
Including NBD	99.6%	98.4%	93.3%	80.6%	55.5%	14.0%
Effective Sample Size	25414	23234	20258	15504	7885	220

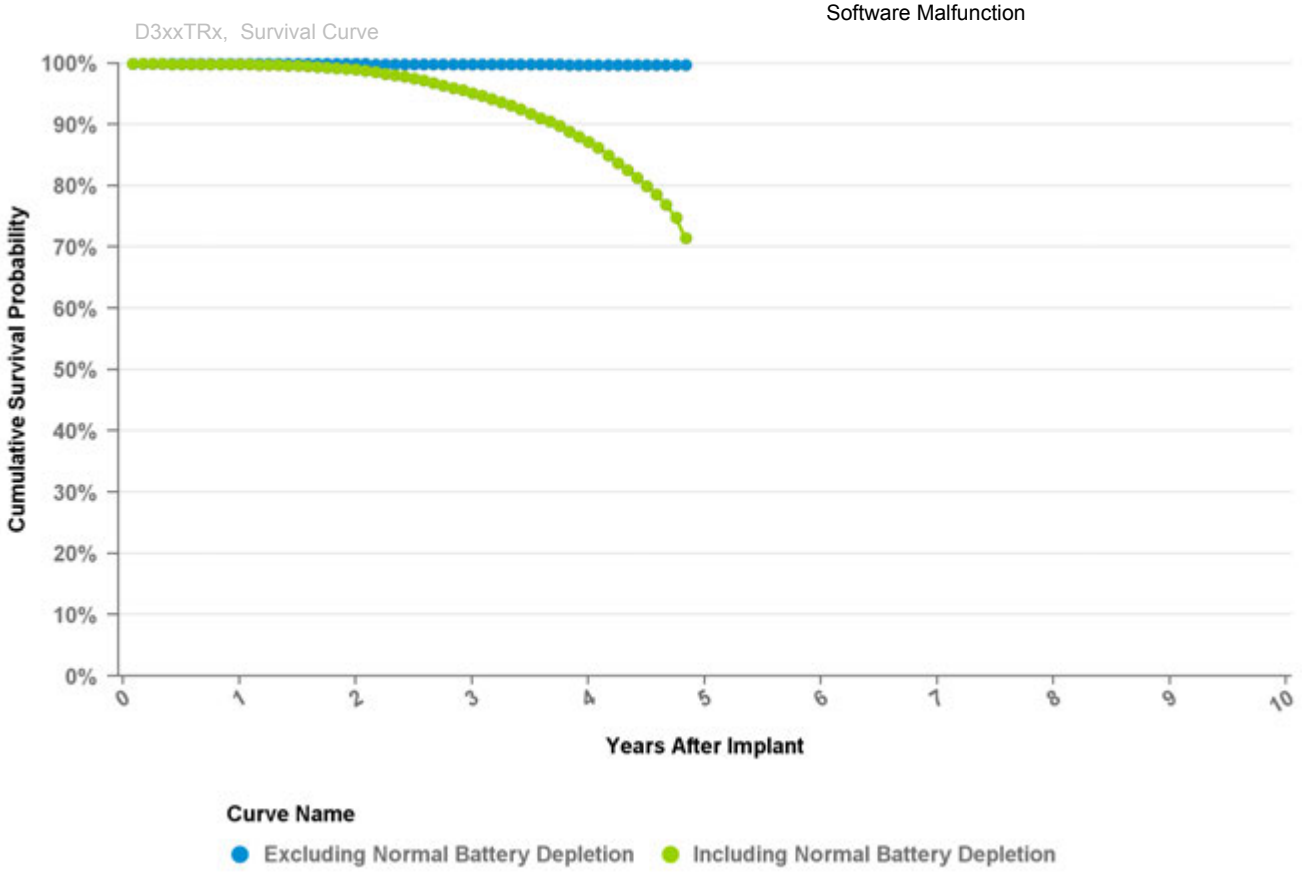
Cardiac Resynchronization Therapy

D314TRG Protecta XT CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	42,268
Estimated Active US Implants	27,194
Normal Battery Depletions (US)	3,073

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	73
Therapy Not Compromised Malfunctions	66
Battery Malfunction	0
Electrical Component	31
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	34
Software Malfunction	0
Therapy Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

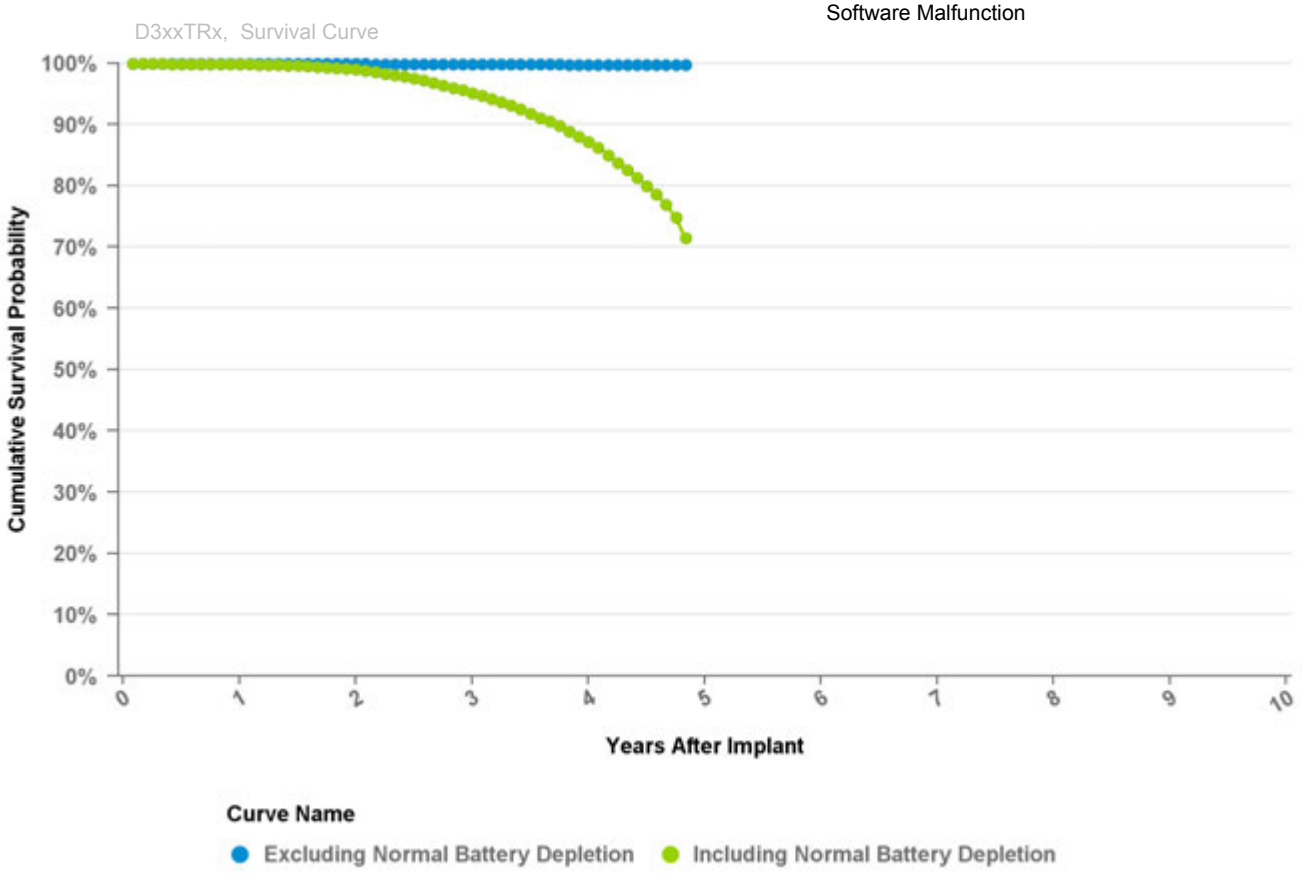
Cardiac Resynchronization Therapy

D314TRM Protecta XT CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	12,220
Estimated Active US Implants	9,572
Normal Battery Depletions (US)	386

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	12
Therapy Not Compromised Malfunctions	11
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

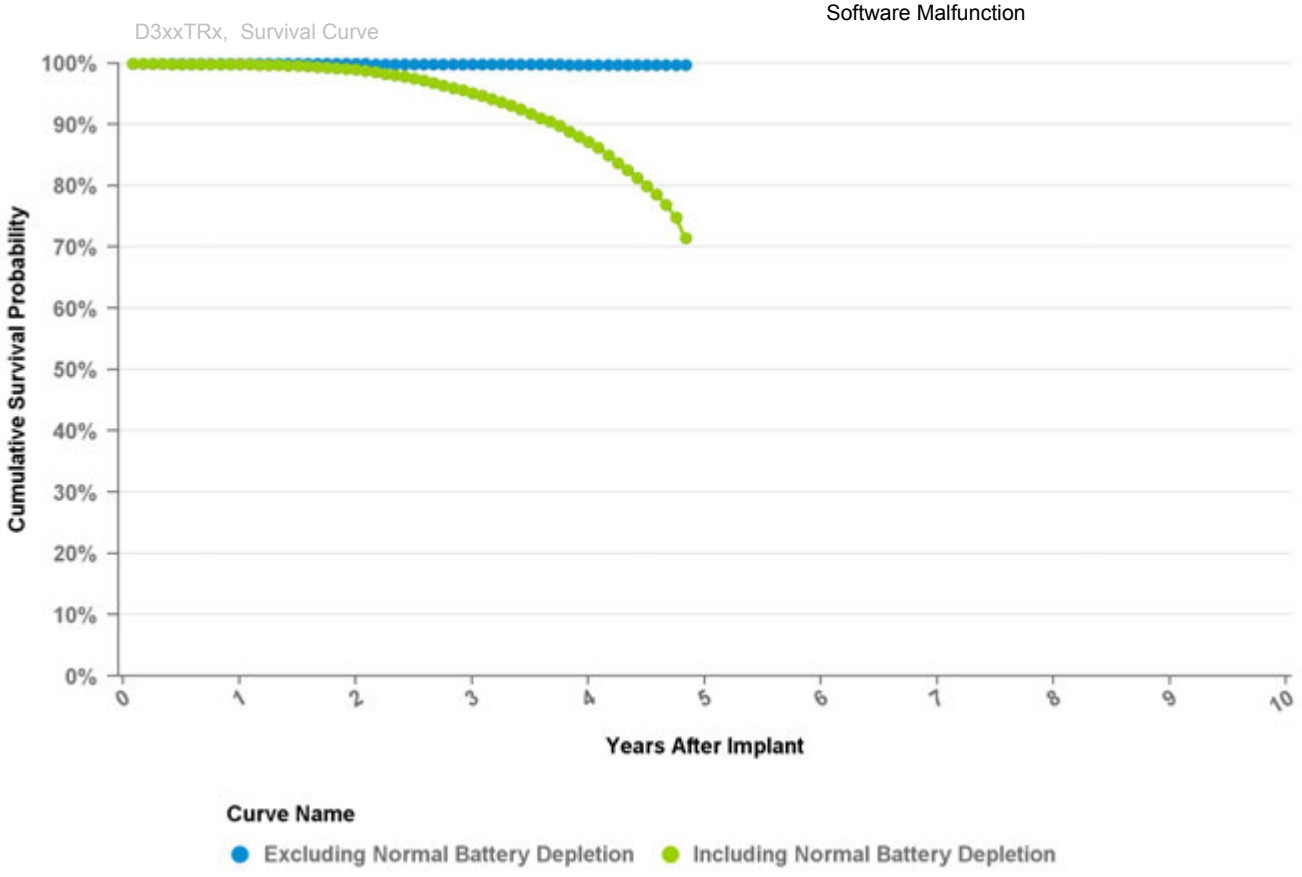
Cardiac Resynchronization Therapy

D334TRG Protecta CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	8,090
Estimated Active US Implants	5,463
Normal Battery Depletions (US)	519

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	14
Therapy Not Compromised Malfunctions	12
Battery Malfunction	0
Electrical Component	8
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

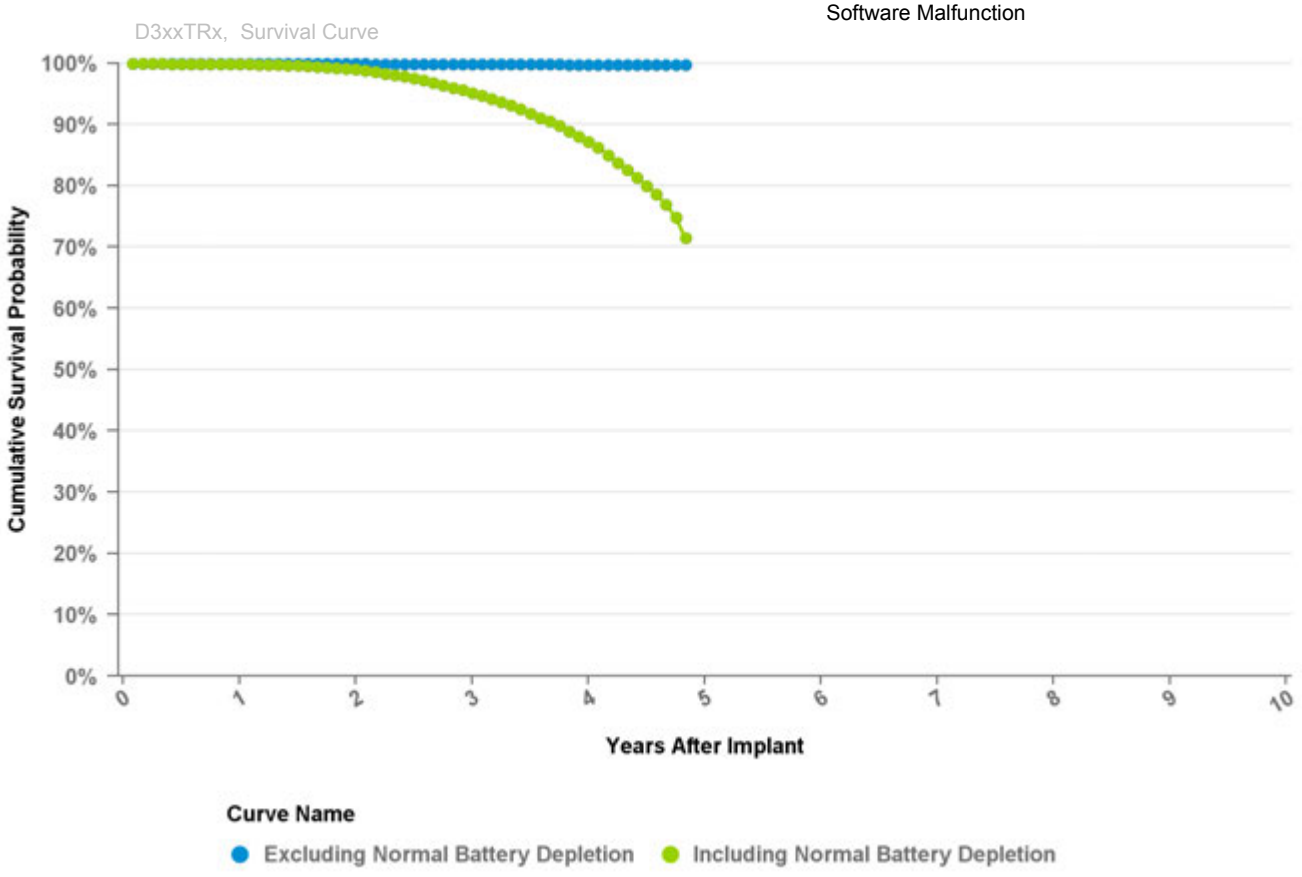
Cardiac Resynchronization Therapy

D334TRM Protecta CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	1,776
Estimated Active US Implants	1,383
Normal Battery Depletions (US)	58

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

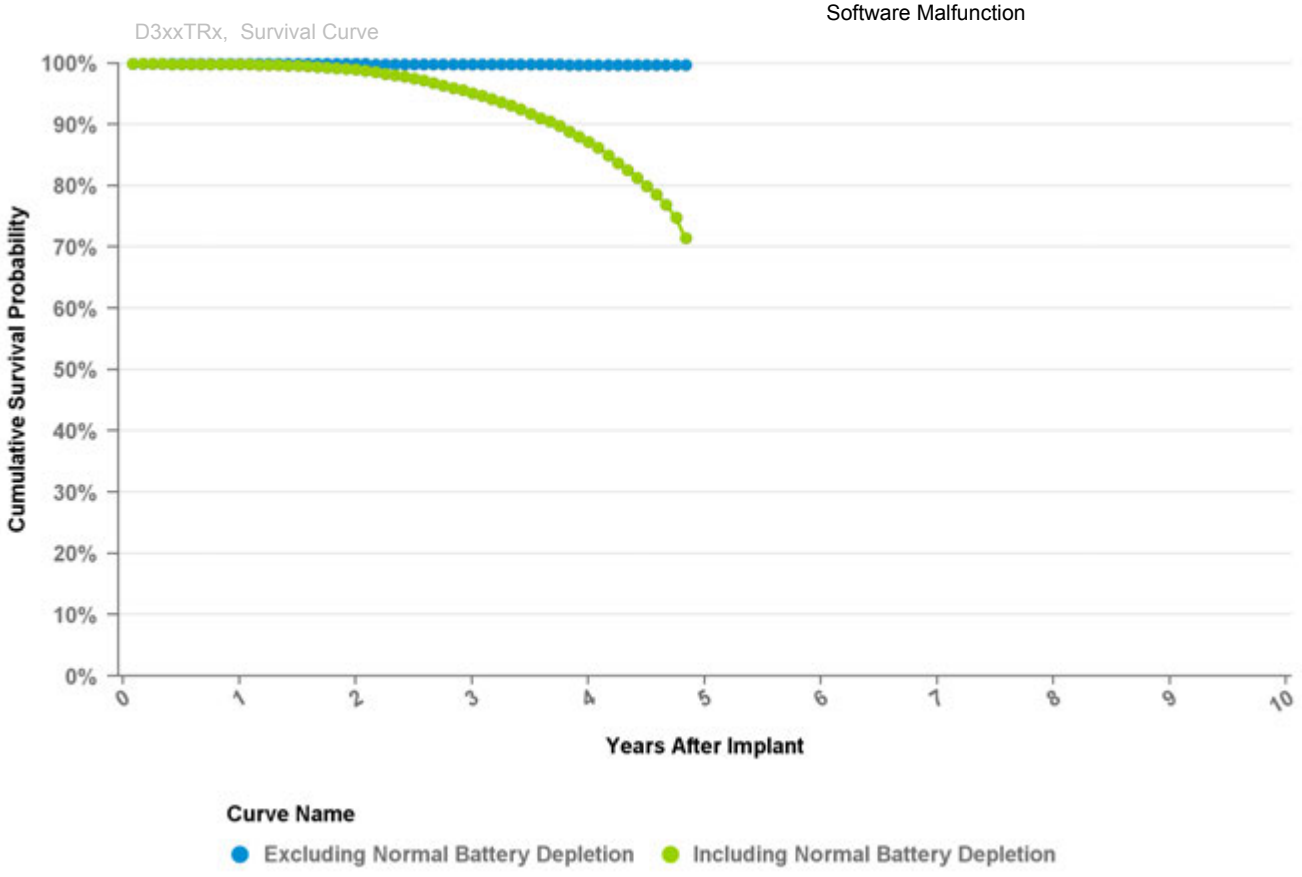
Cardiac Resynchronization Therapy

D354TRG Protecta XT CRT-D

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	2
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

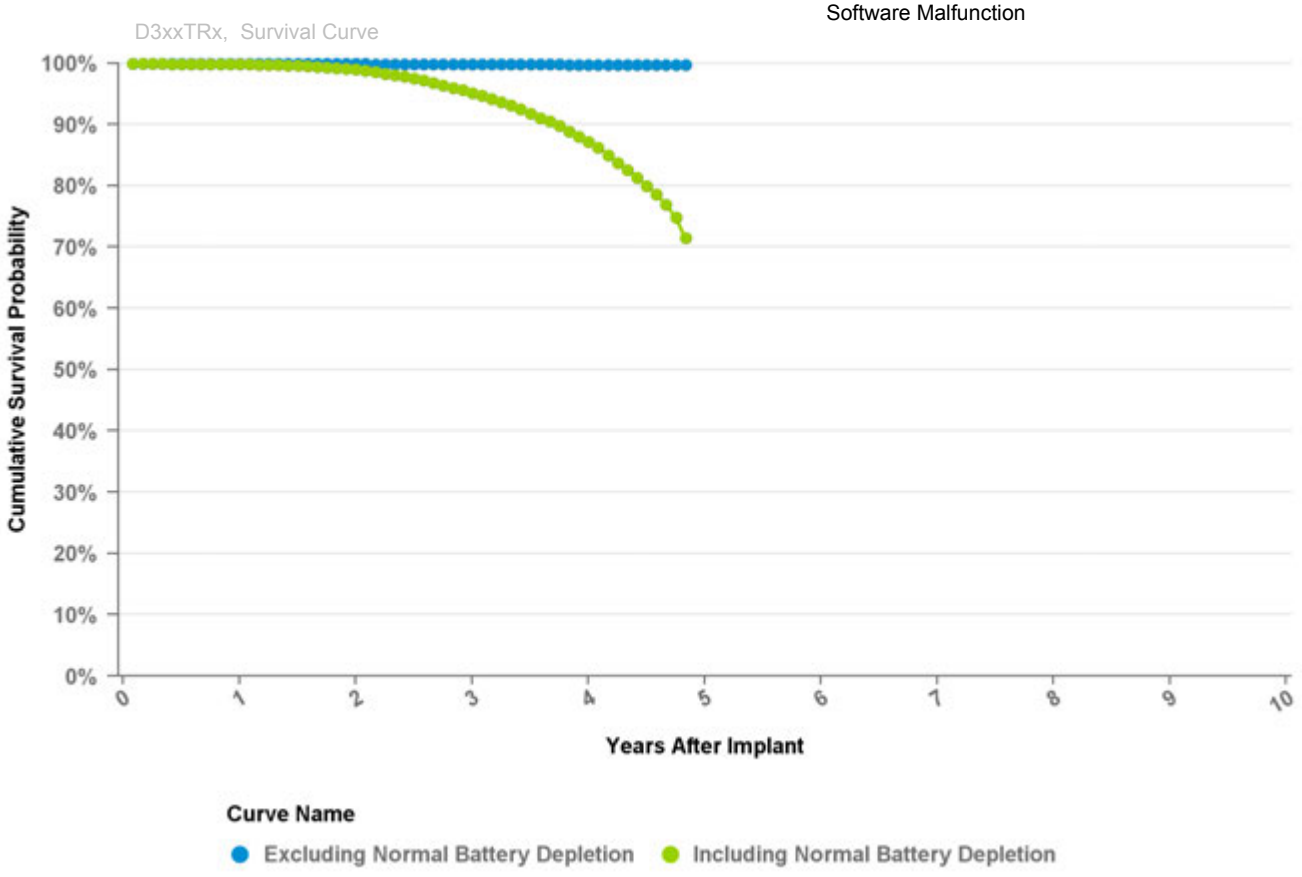
Cardiac Resynchronization Therapy

D354TRM Protecta XT CRT-D

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

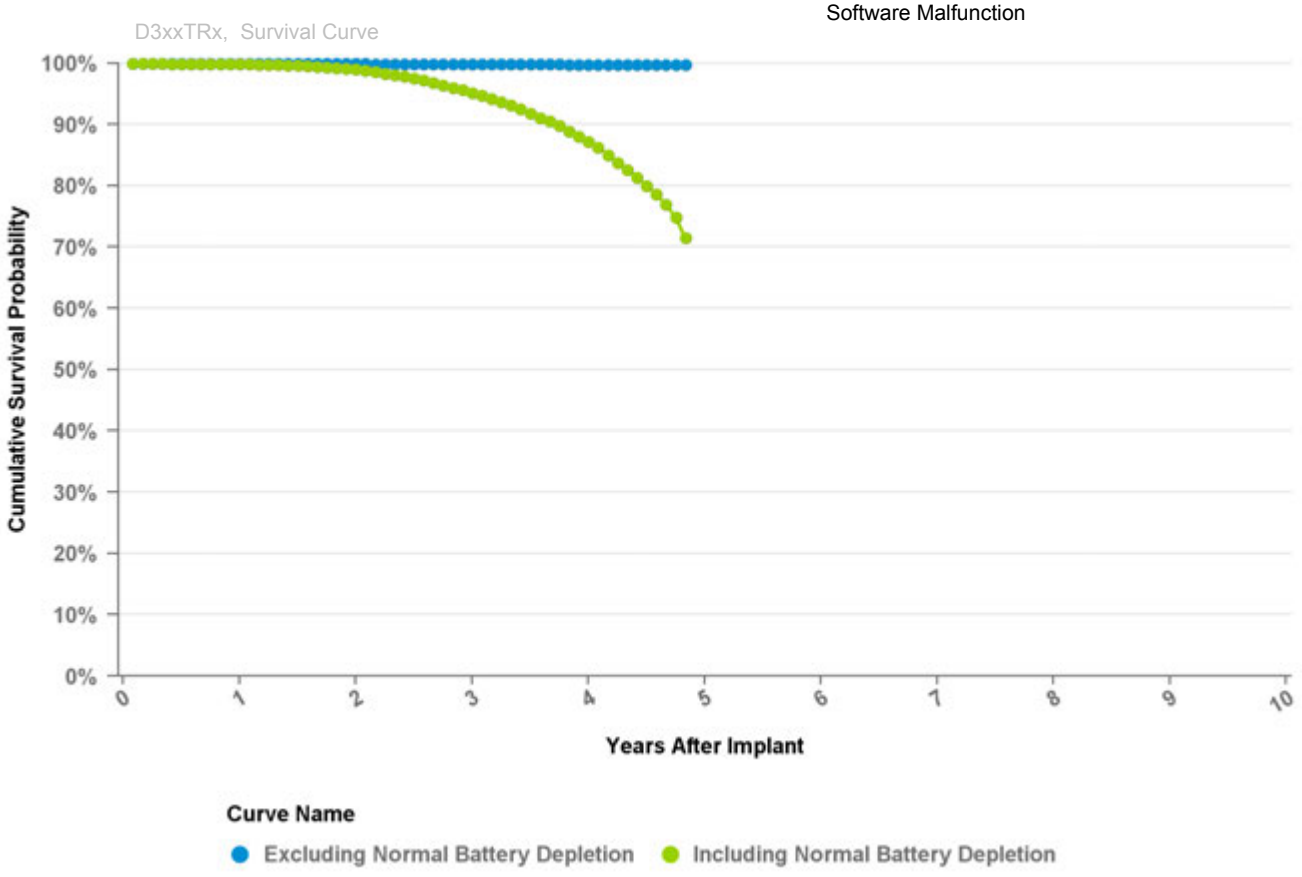
Cardiac Resynchronization Therapy

D364TRG Protecta CRT-D

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

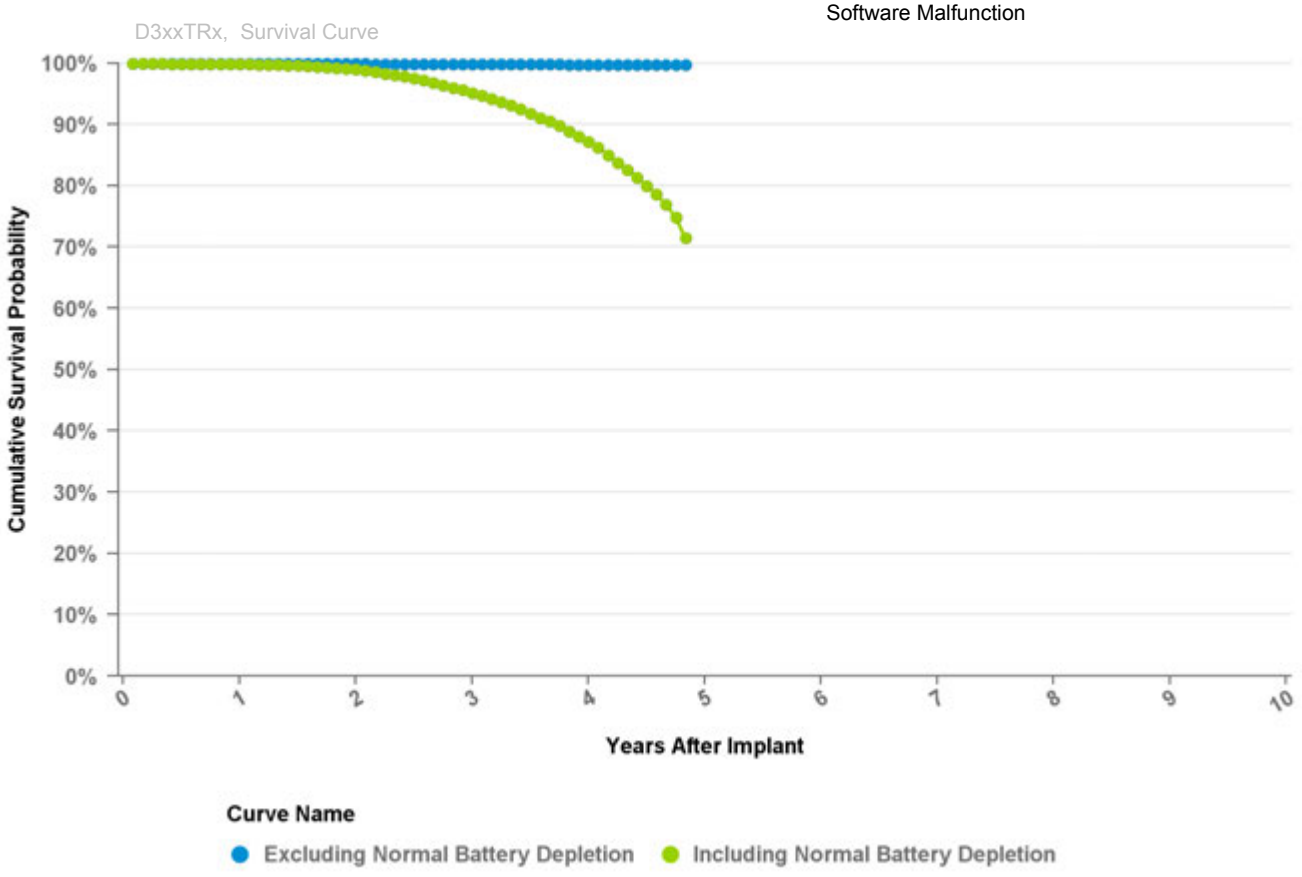
Cardiac Resynchronization Therapy

D364TRM Protecta CRT-D

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

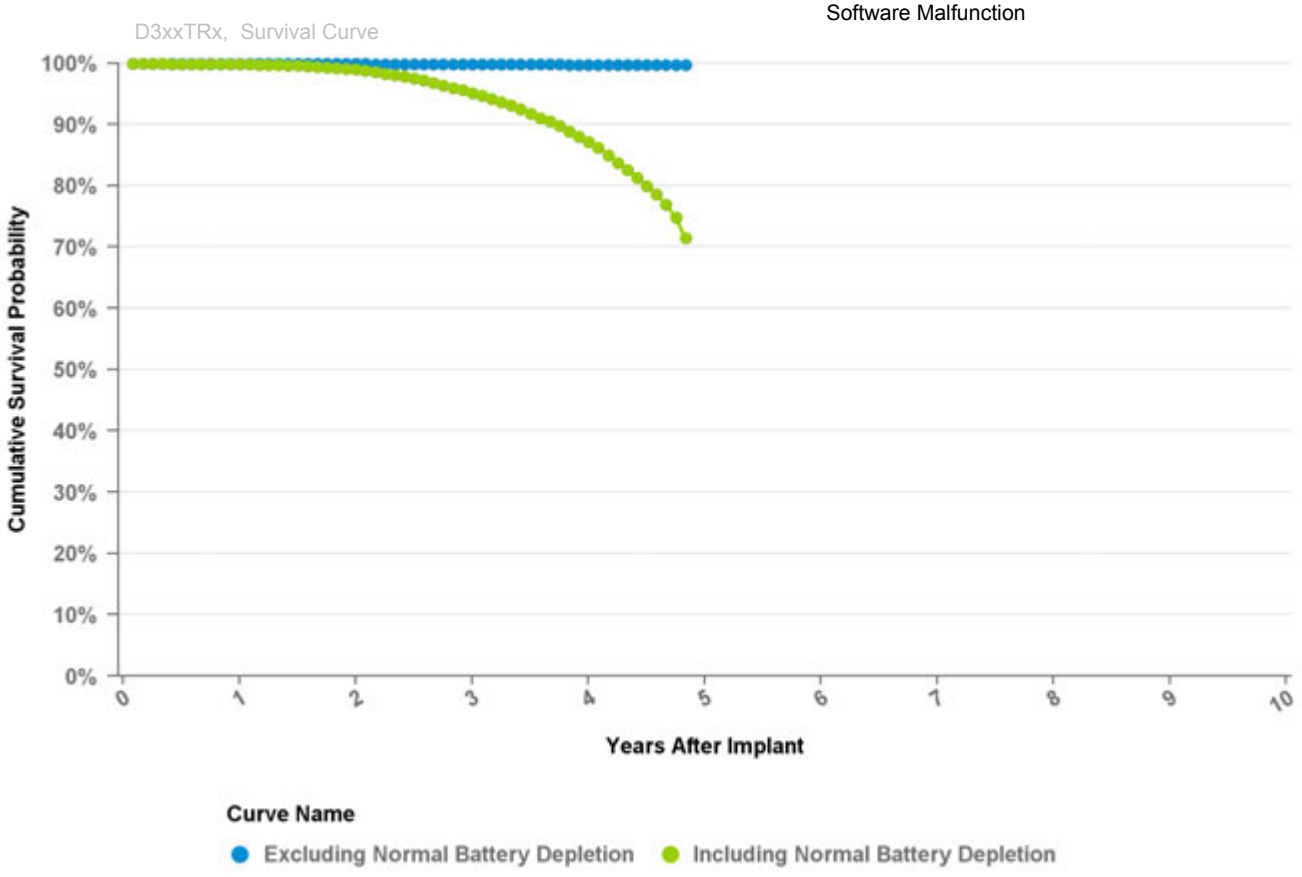
Cardiac Resynchronization Therapy

D384TRG Cardia CRT-D

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

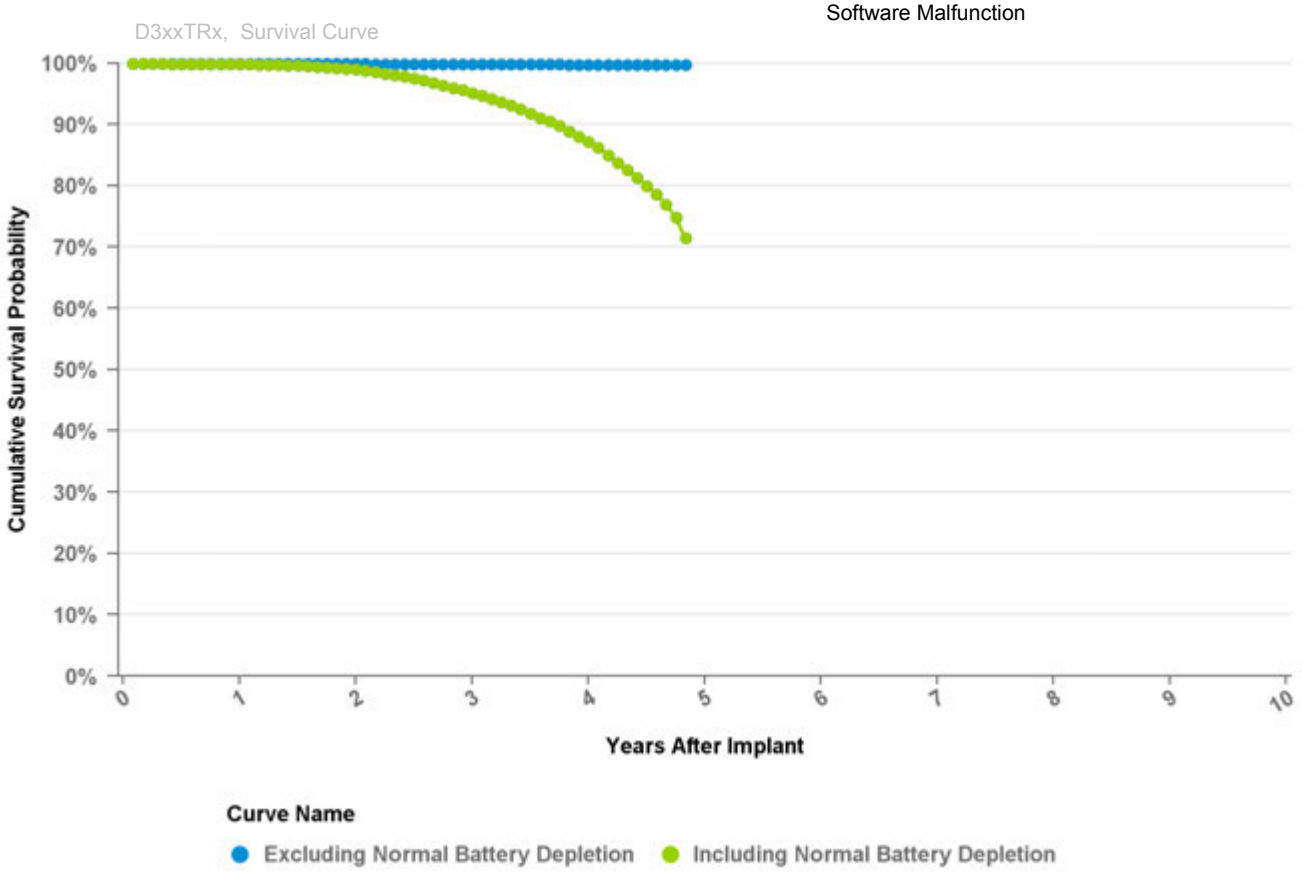
Cardiac Resynchronization Therapy

D394TRG Egida CRT-D

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.2%	87.2%	71.5%
Effective Sample Size	55869	51147	42448	16858	960

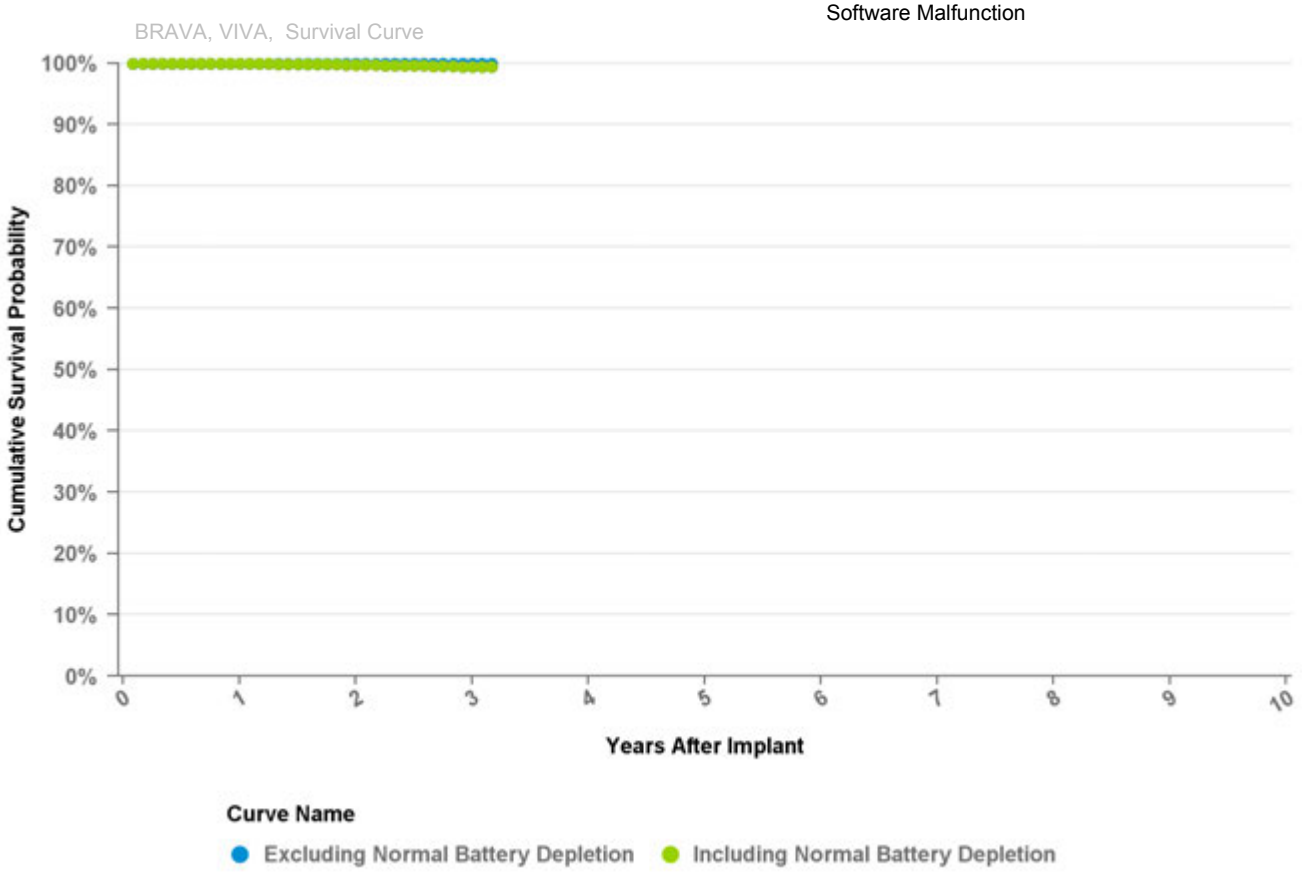
Cardiac Resynchronization Therapy

DTBA1D1 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	43,167
Estimated Active US Implants	39,650
Normal Battery Depletions (US)	33

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	15
Therapy Not Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

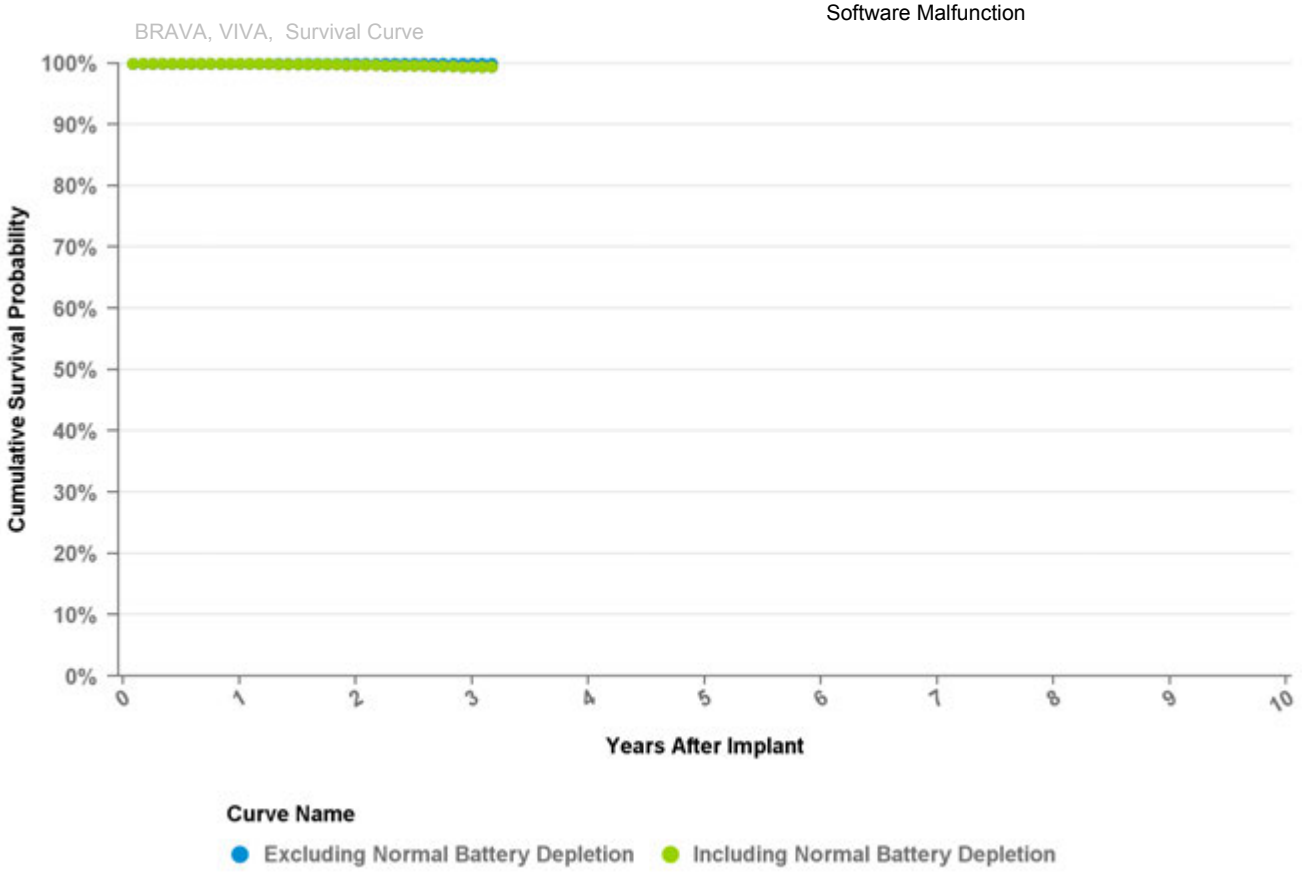
Cardiac Resynchronization Therapy

DTBA1D4 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	16,143
Estimated Active US Implants	14,785
Normal Battery Depletions (US)	8

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	11
Therapy Not Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

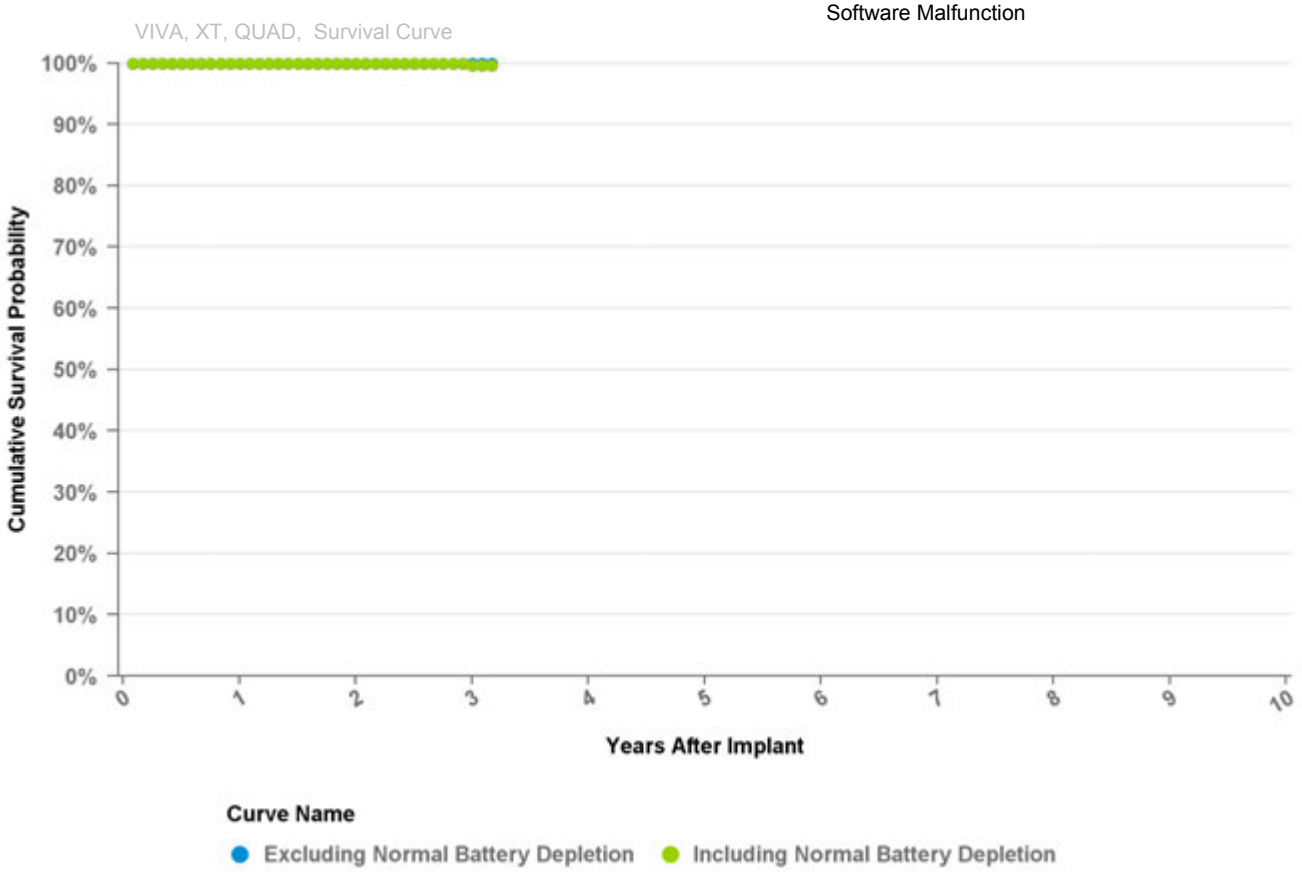
Cardiac Resynchronization Therapy

DTBA1Q1 Viva Quad XT

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	7,676
Estimated Active US Implants	7,242
Normal Battery Depletions (US)	4

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

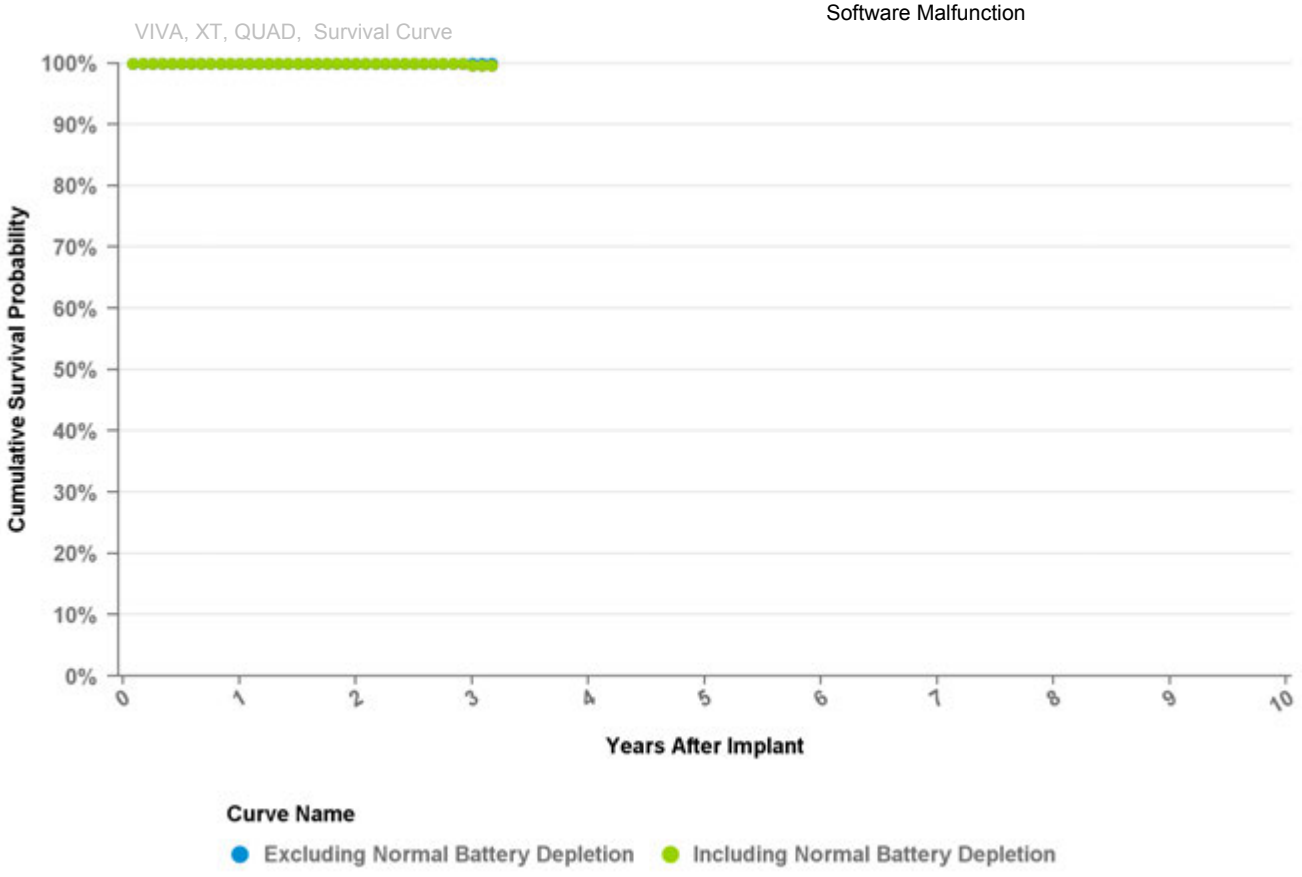
Cardiac Resynchronization Therapy

DTBA1QQ Viva Quad XT

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	22,097
Estimated Active US Implants	21,362
Normal Battery Depletions (US)	2

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	7
Therapy Not Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

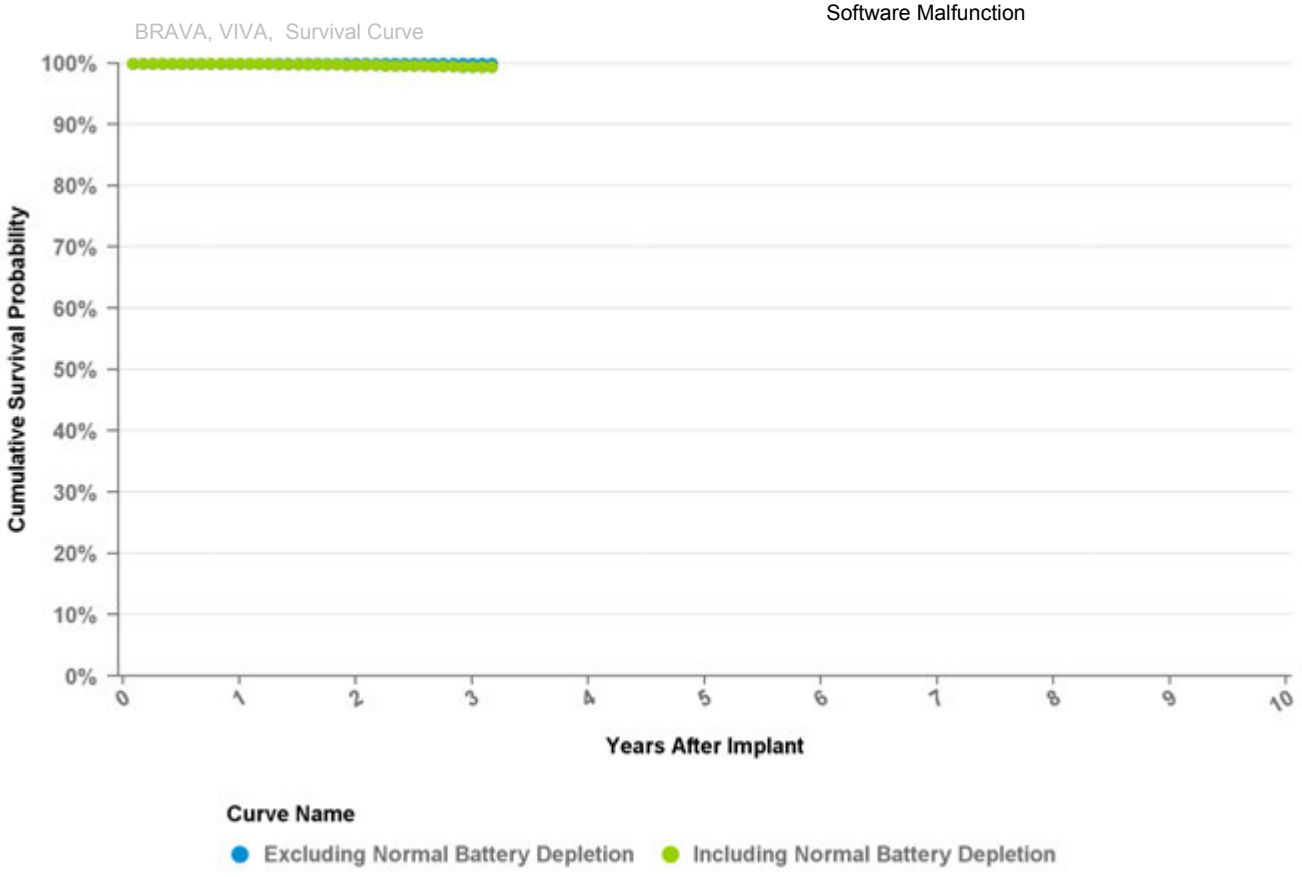
Cardiac Resynchronization Therapy

DTBA2D1 Viva XT

US Market Release Date	
CE Market Approval Date	8/29/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

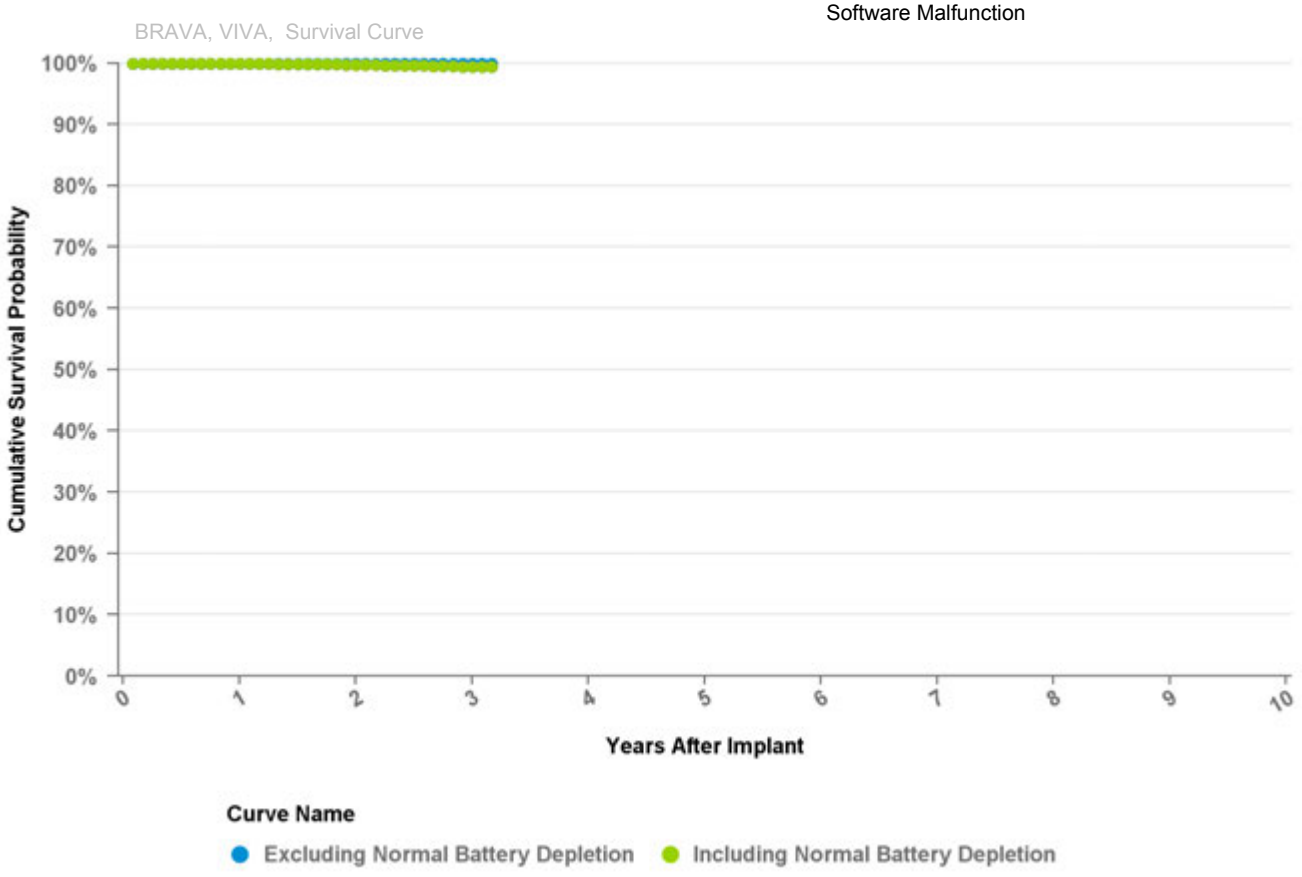
Cardiac Resynchronization Therapy

DTBA2D4 Viva XT

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

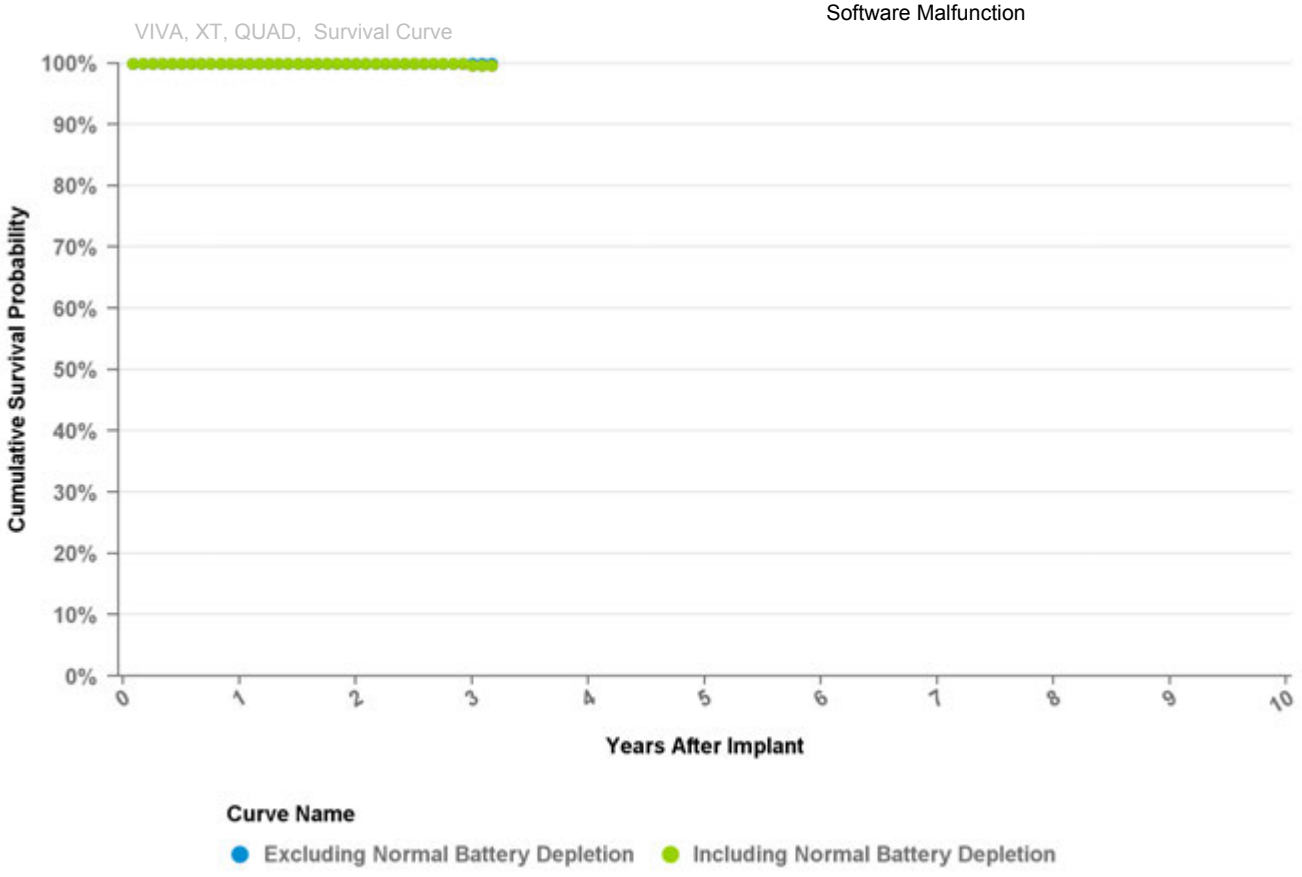
Cardiac Resynchronization Therapy

DTBA2Q1 Viva Quad XT

US Market Release Date	
CE Market Approval Date	9/12/2013
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

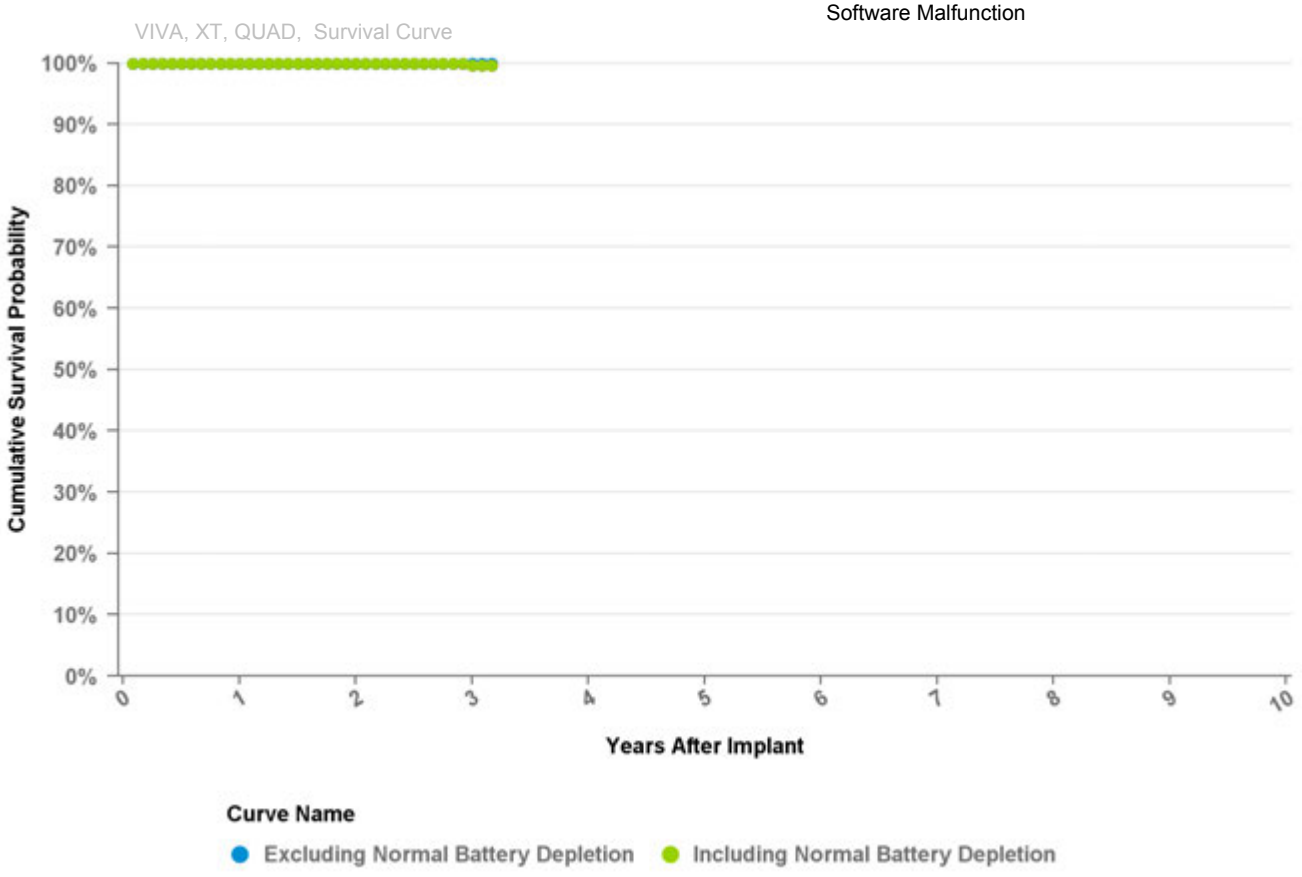
Cardiac Resynchronization Therapy

DTBA2QQ Viva Quad XT

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

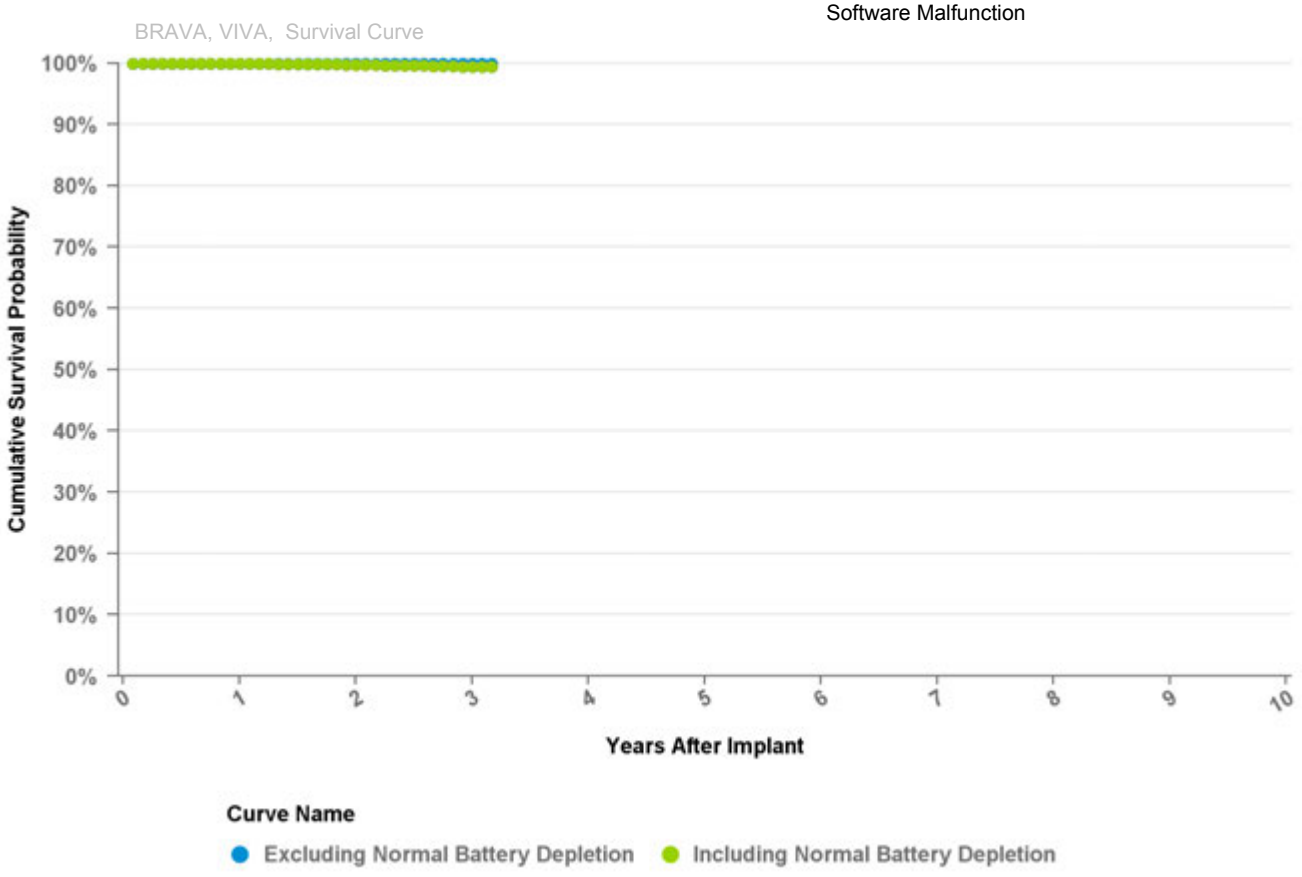
Cardiac Resynchronization Therapy

DTBB1D1 Viva S

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	11,064
Estimated Active US Implants	10,007
Normal Battery Depletions (US)	23

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

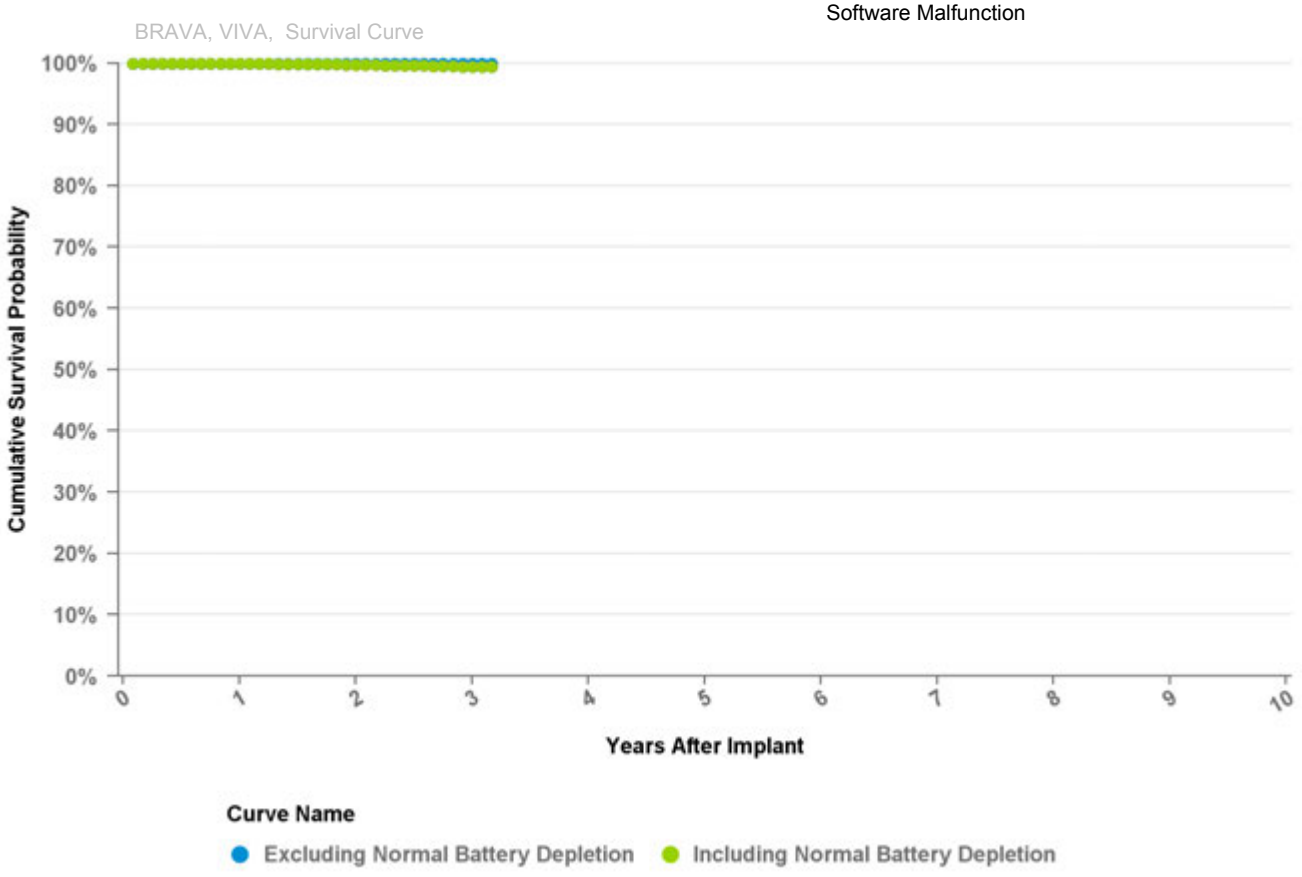
Cardiac Resynchronization Therapy

DTBB1D4 Viva S

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	3,569
Estimated Active US Implants	3,298
Normal Battery Depletions (US)	6

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

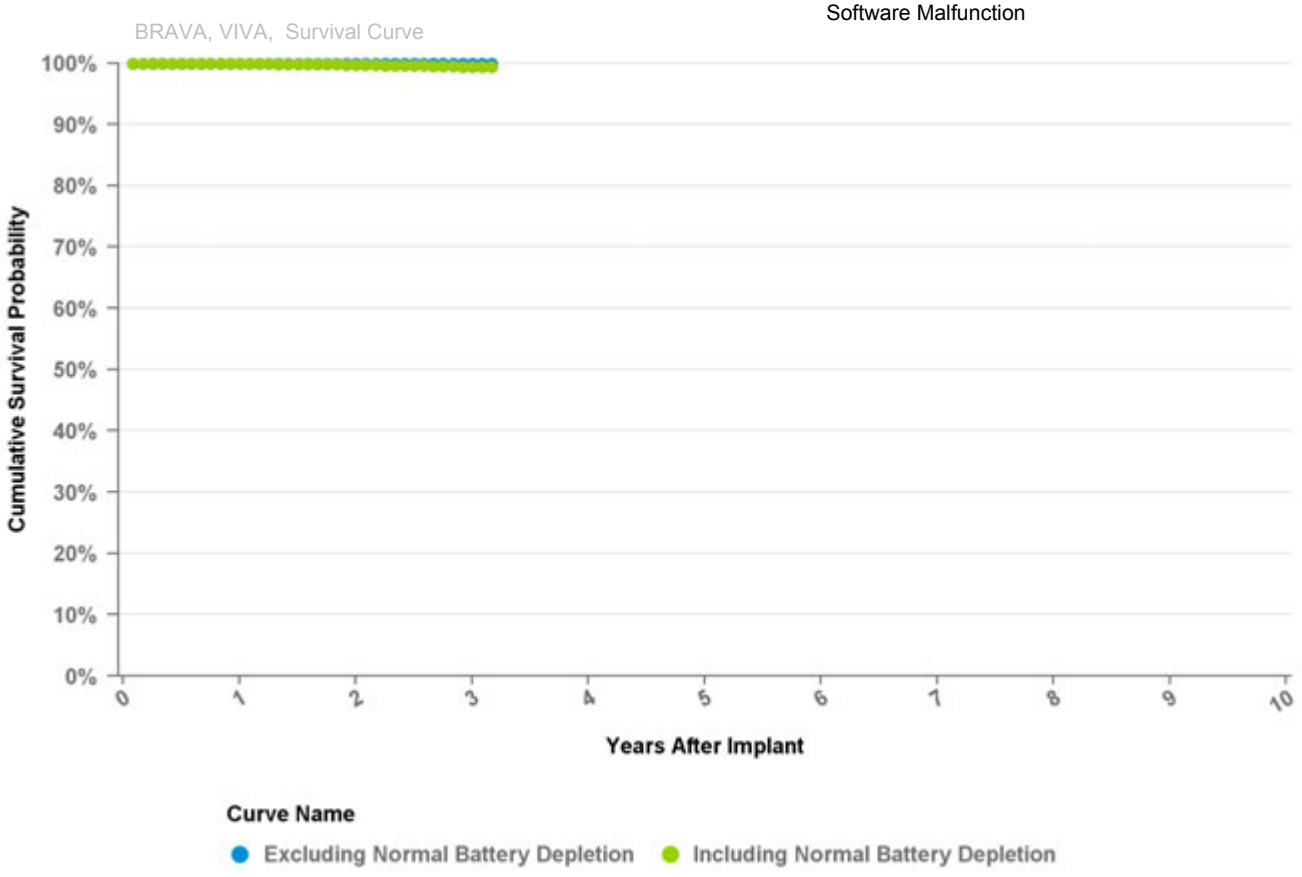
Cardiac Resynchronization Therapy

DTBB1Q1 Viva Quad S

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	1,410
Estimated Active US Implants	1,335
Normal Battery Depletions (US)	1

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

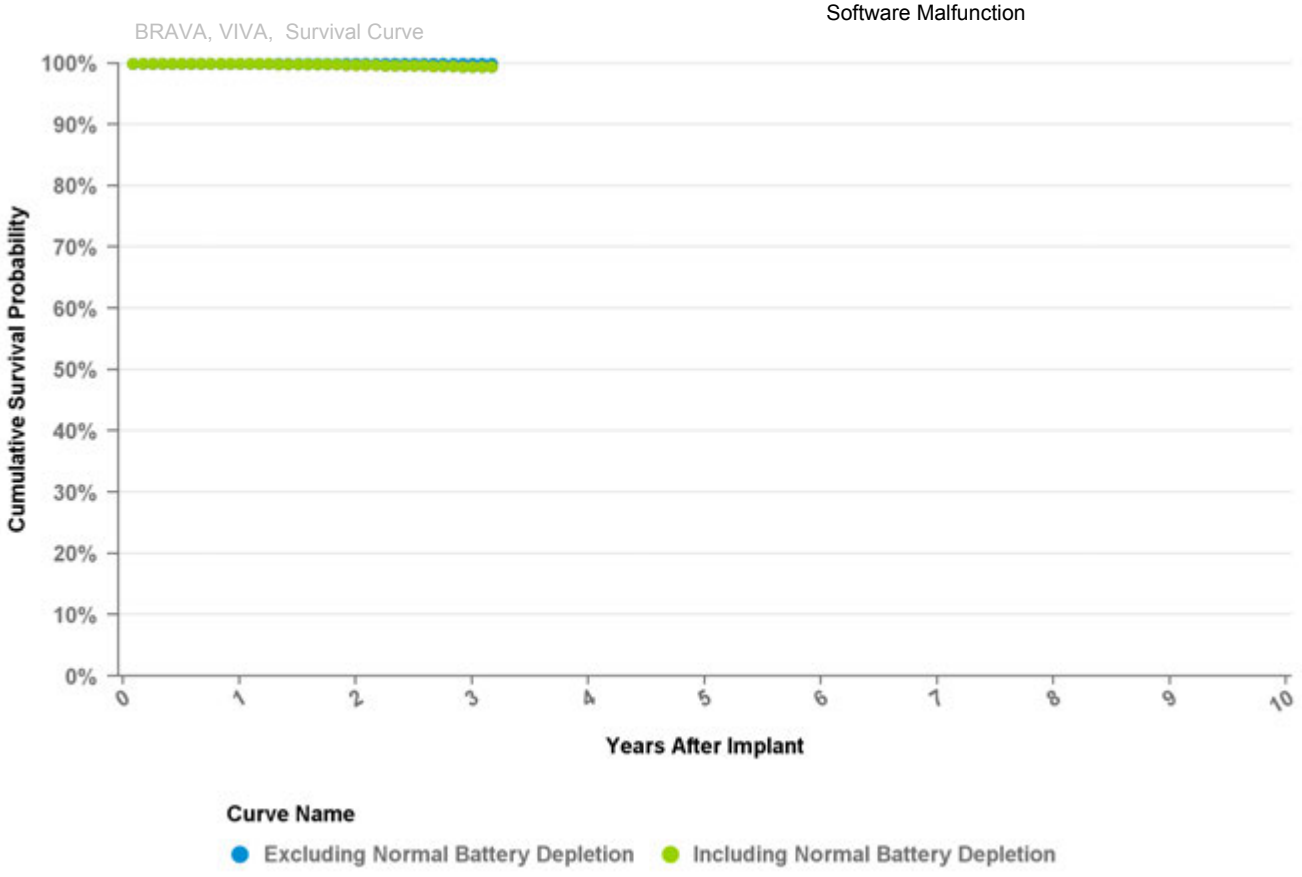
Cardiac Resynchronization Therapy

DTBB1QQ Viva Quad S

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	3,567
Estimated Active US Implants	3,450
Normal Battery Depletions (US)	1

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

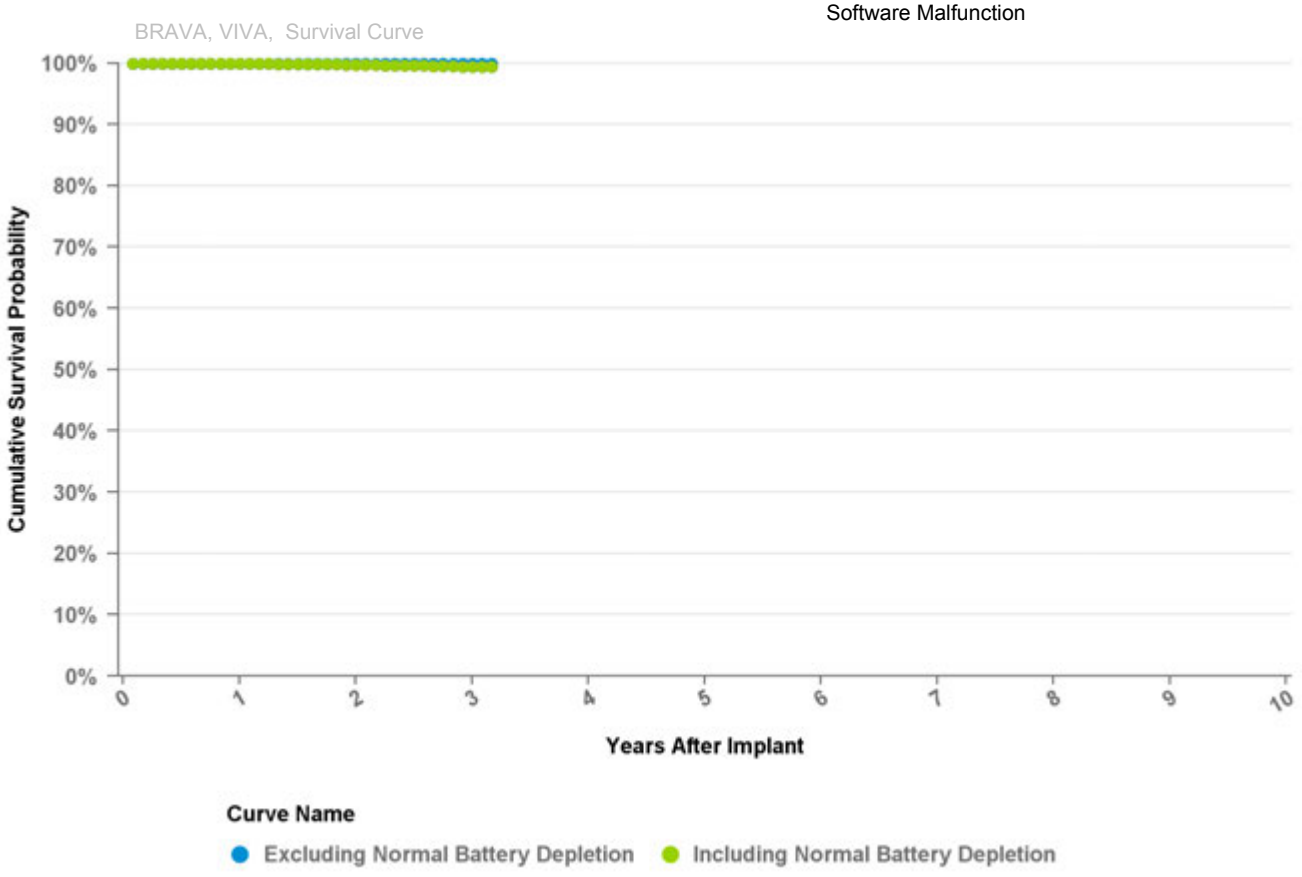
Cardiac Resynchronization Therapy

DTBB2D1 Viva S

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

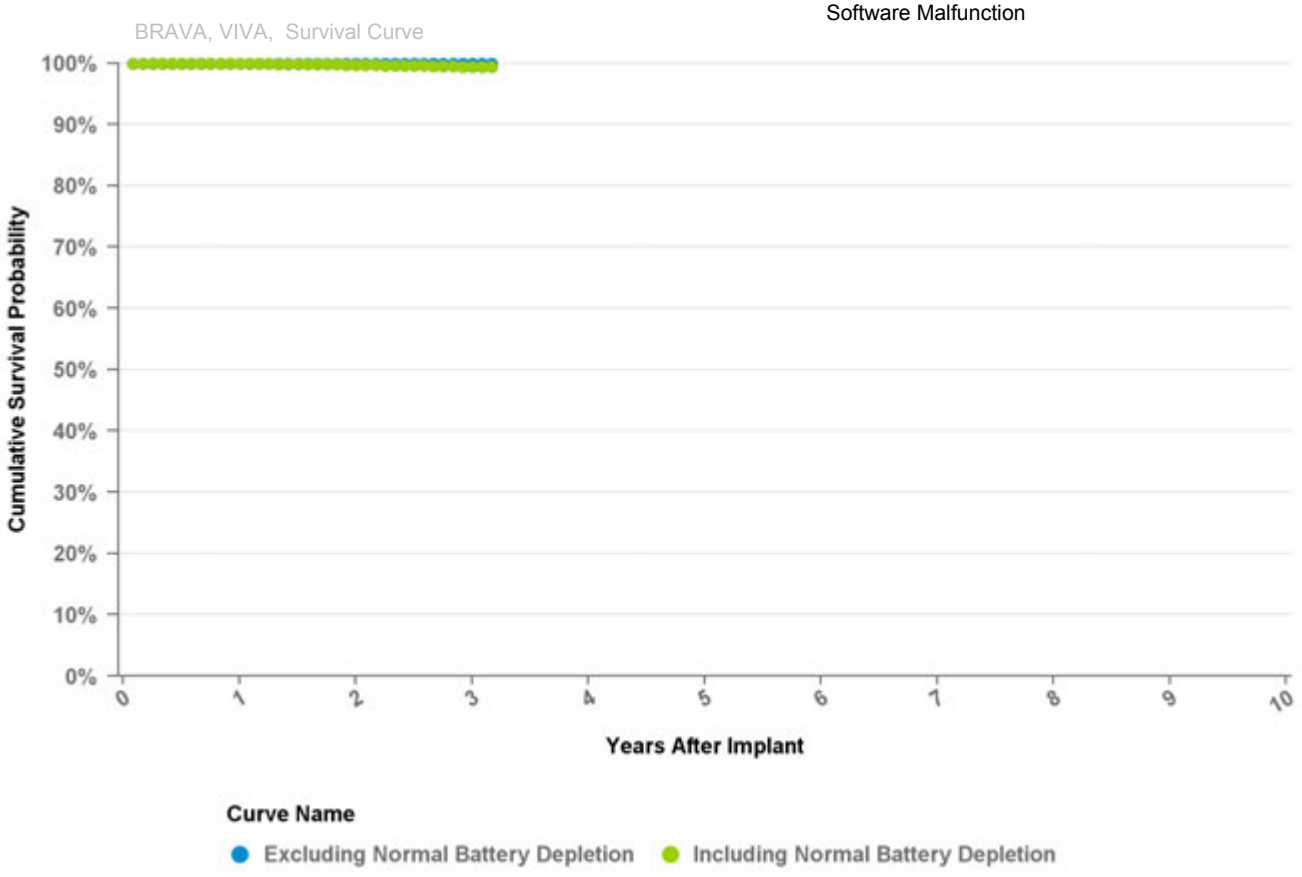
Cardiac Resynchronization Therapy

DTBB2D4 Viva S

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

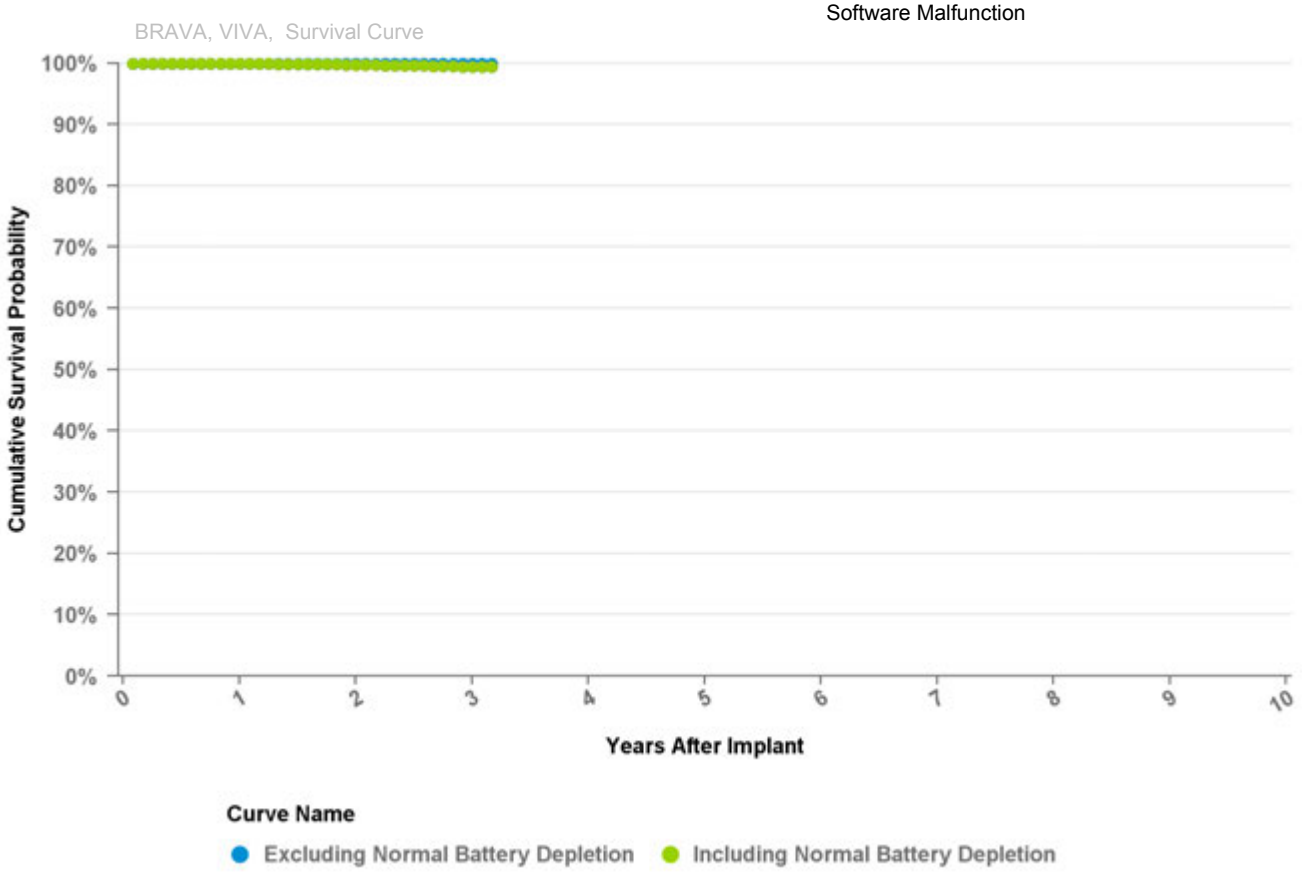
Cardiac Resynchronization Therapy

DTBB2QQ Viva Quad S

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

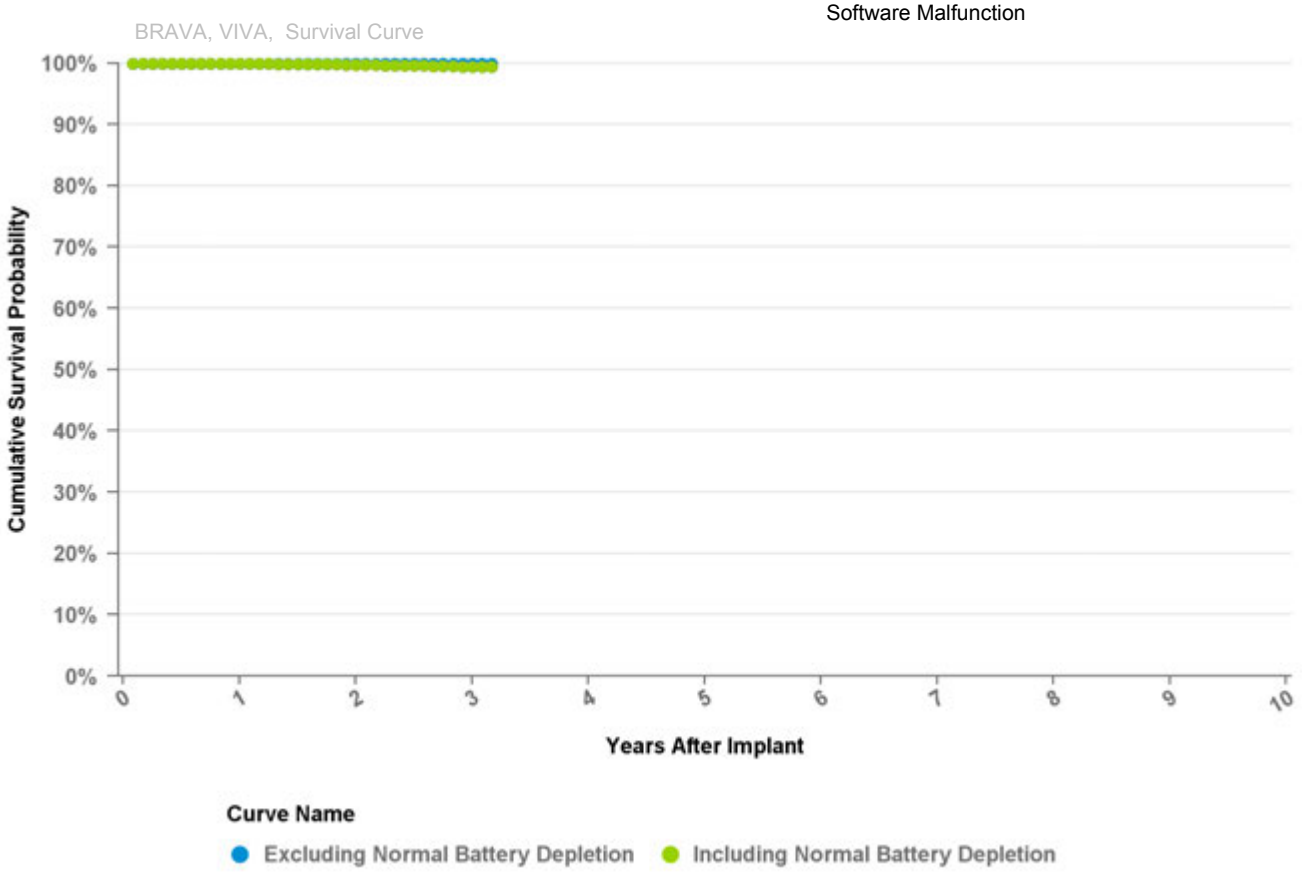
Cardiac Resynchronization Therapy

DTBC2D1 Brava

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

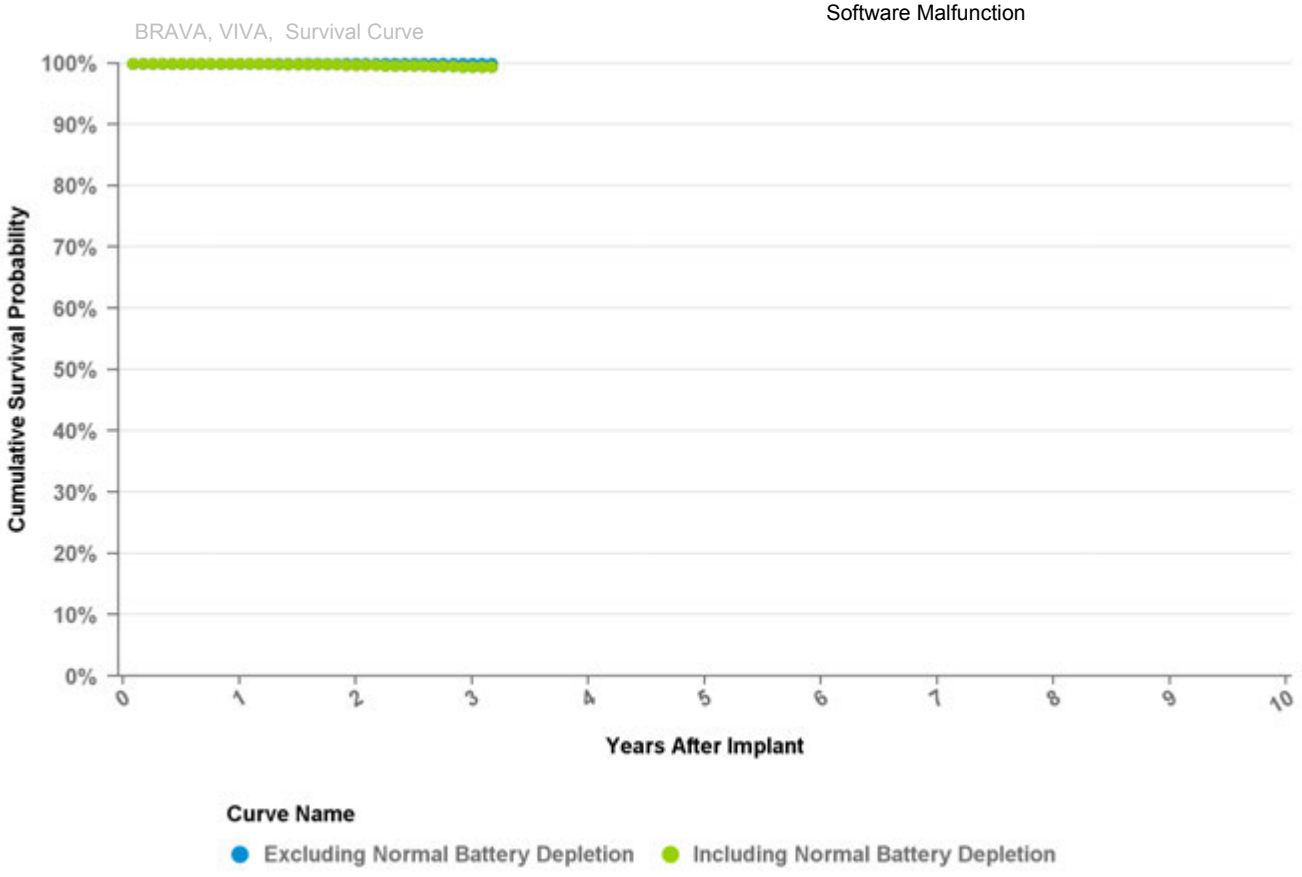
Cardiac Resynchronization Therapy

DTBC2D4 Brava

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

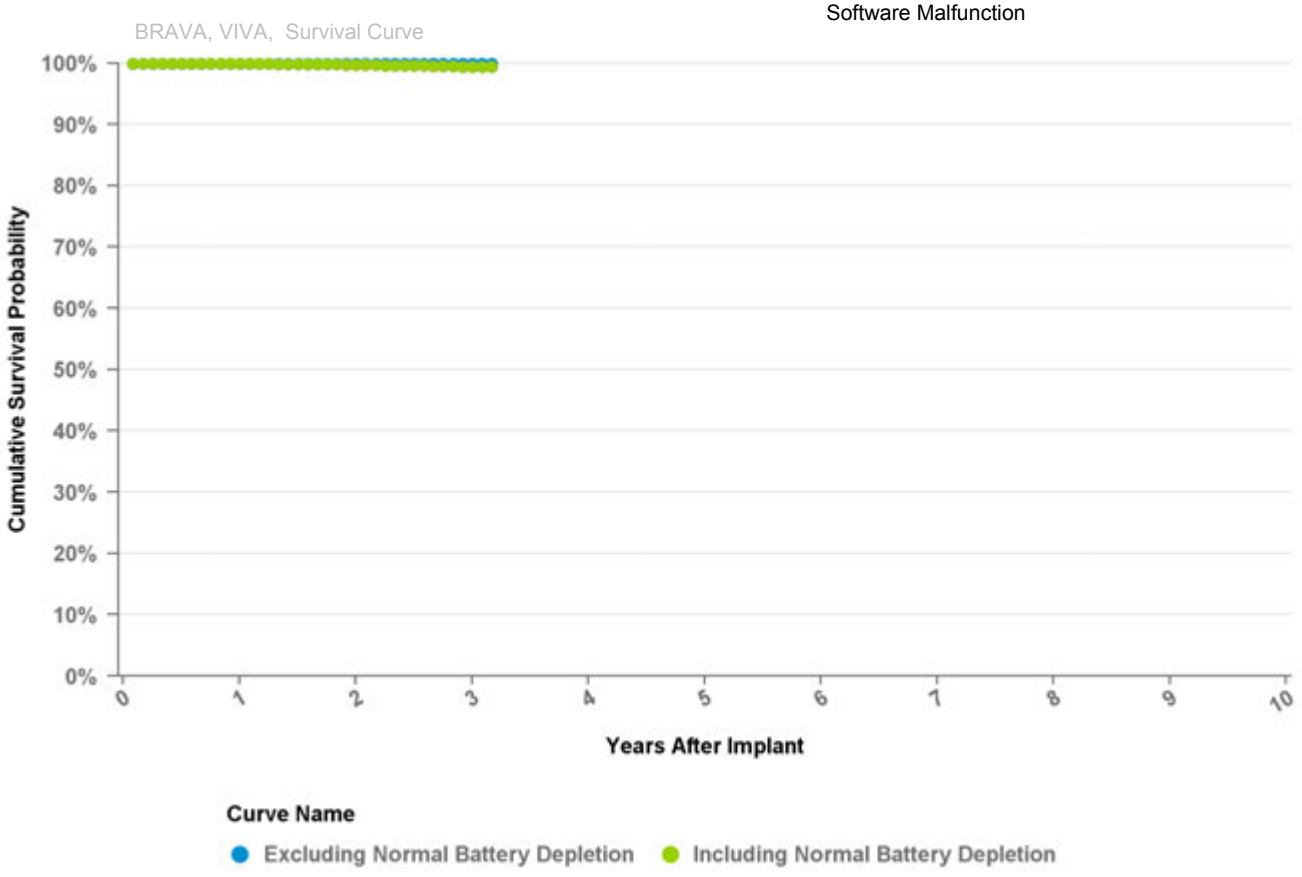
Cardiac Resynchronization Therapy

DTBC2Q1 Brava Quad

US Market Release Date	
CE Market Approval Date	9/12/2013
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

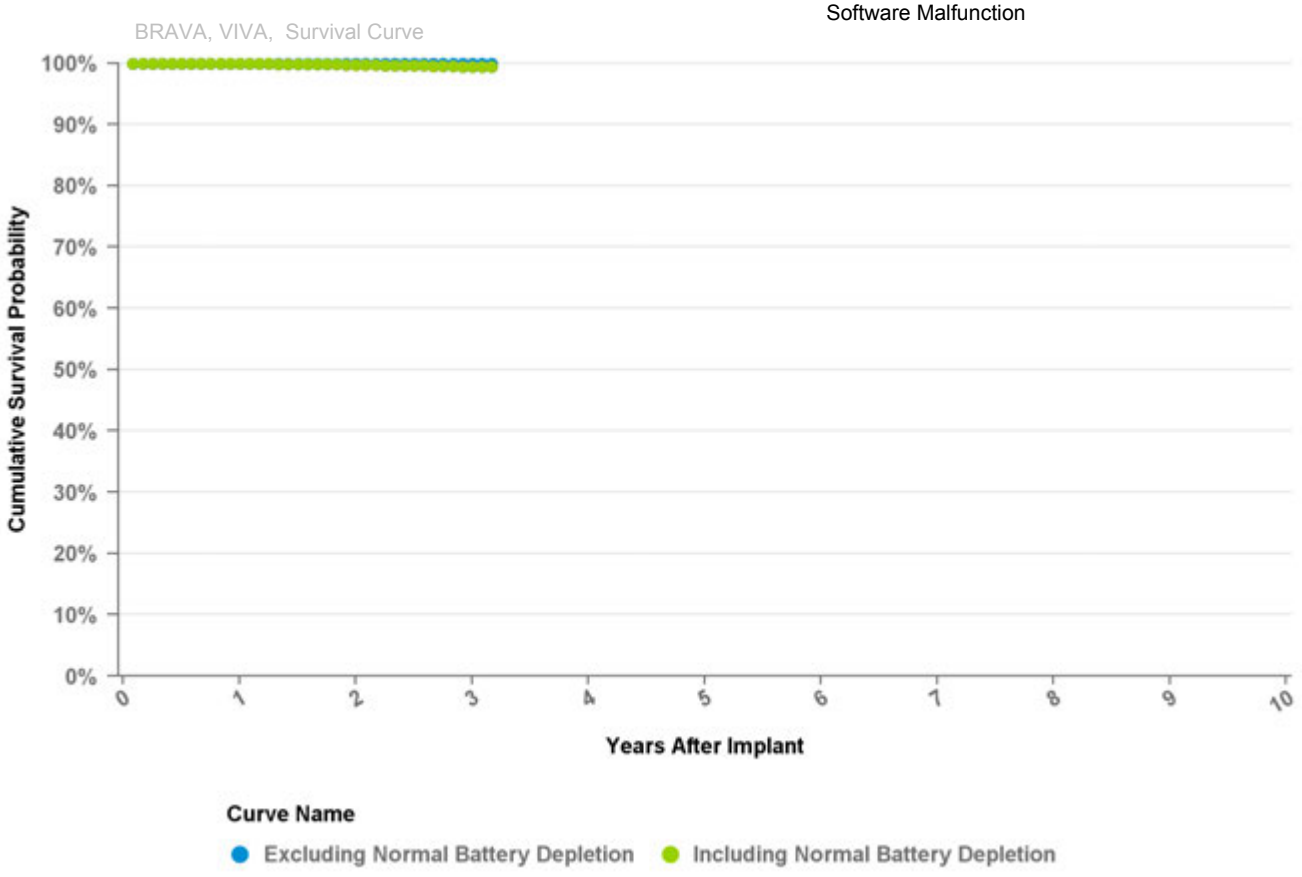
Cardiac Resynchronization Therapy

DTBC2QQ Brava Quad

US Market Release Date	
CE Market Approval Date	8/8/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	99.4%
Effective Sample Size	53840	28728	2275	225

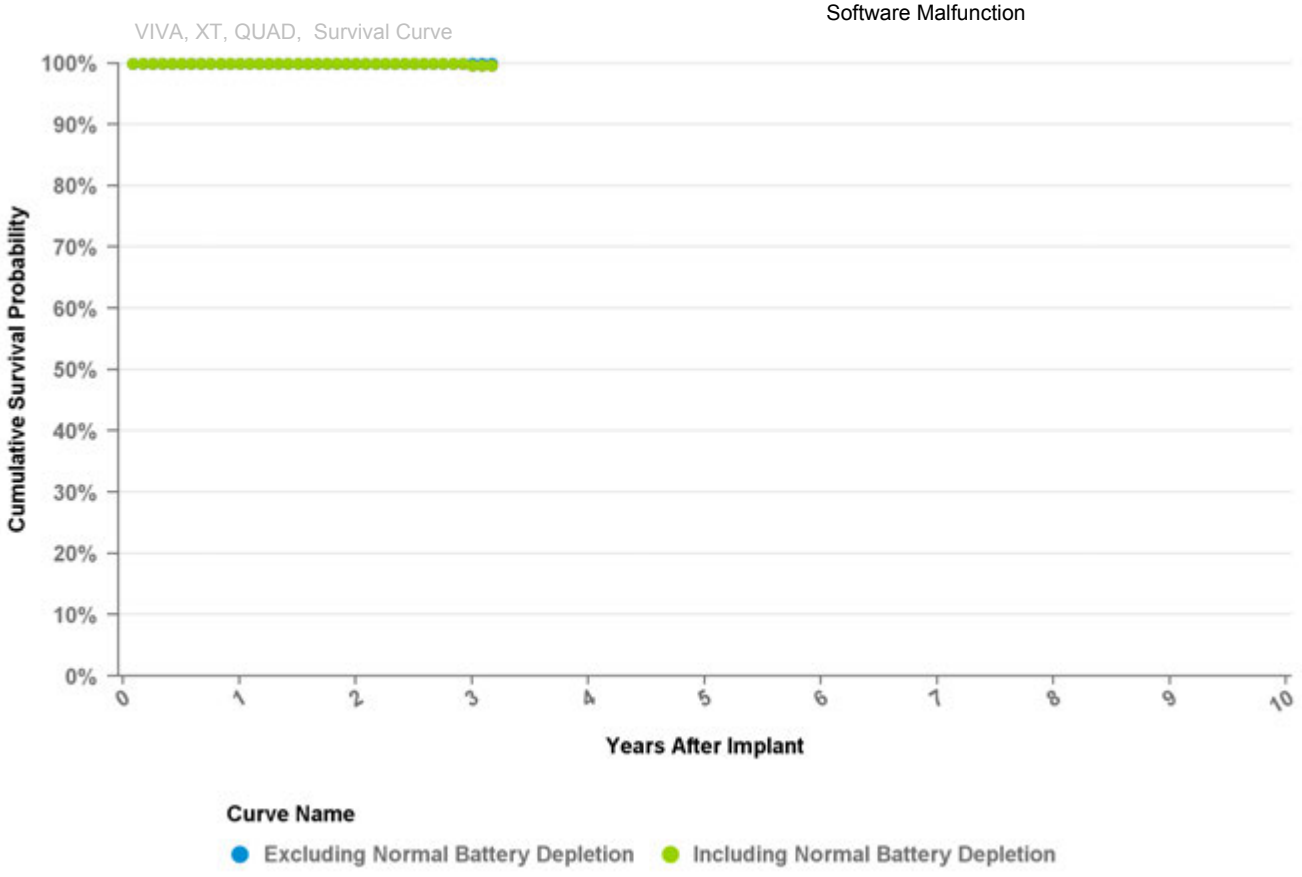
Cardiac Resynchronization Therapy

DTBX1QQ Viva Quad C

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	638
Estimated Active US Implants	581
Normal Battery Depletions (US)	1

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

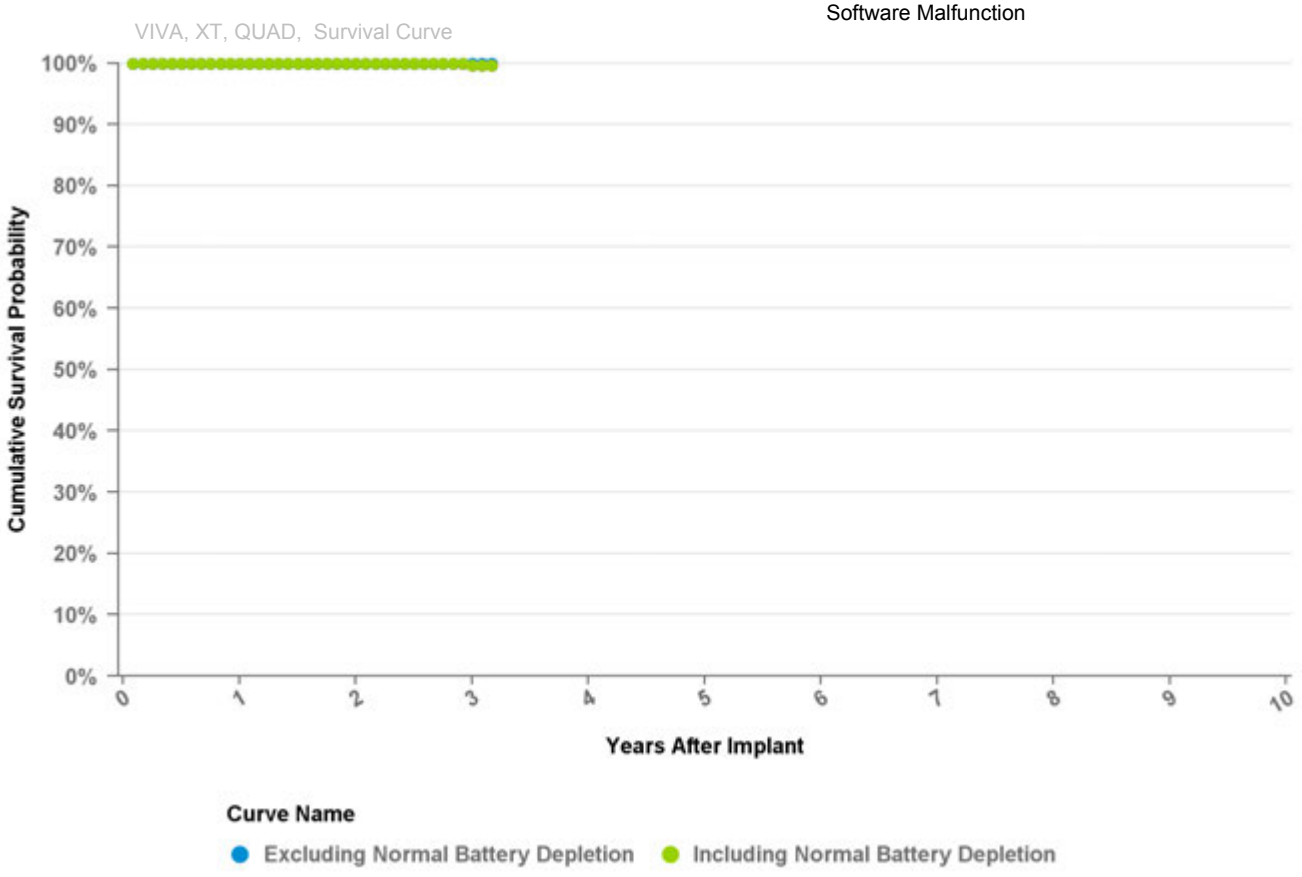
Cardiac Resynchronization Therapy

DTBX2QQ Viva Quad C

US Market Release Date	7/3/2014
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.7%
Effective Sample Size	15909	740	408	180

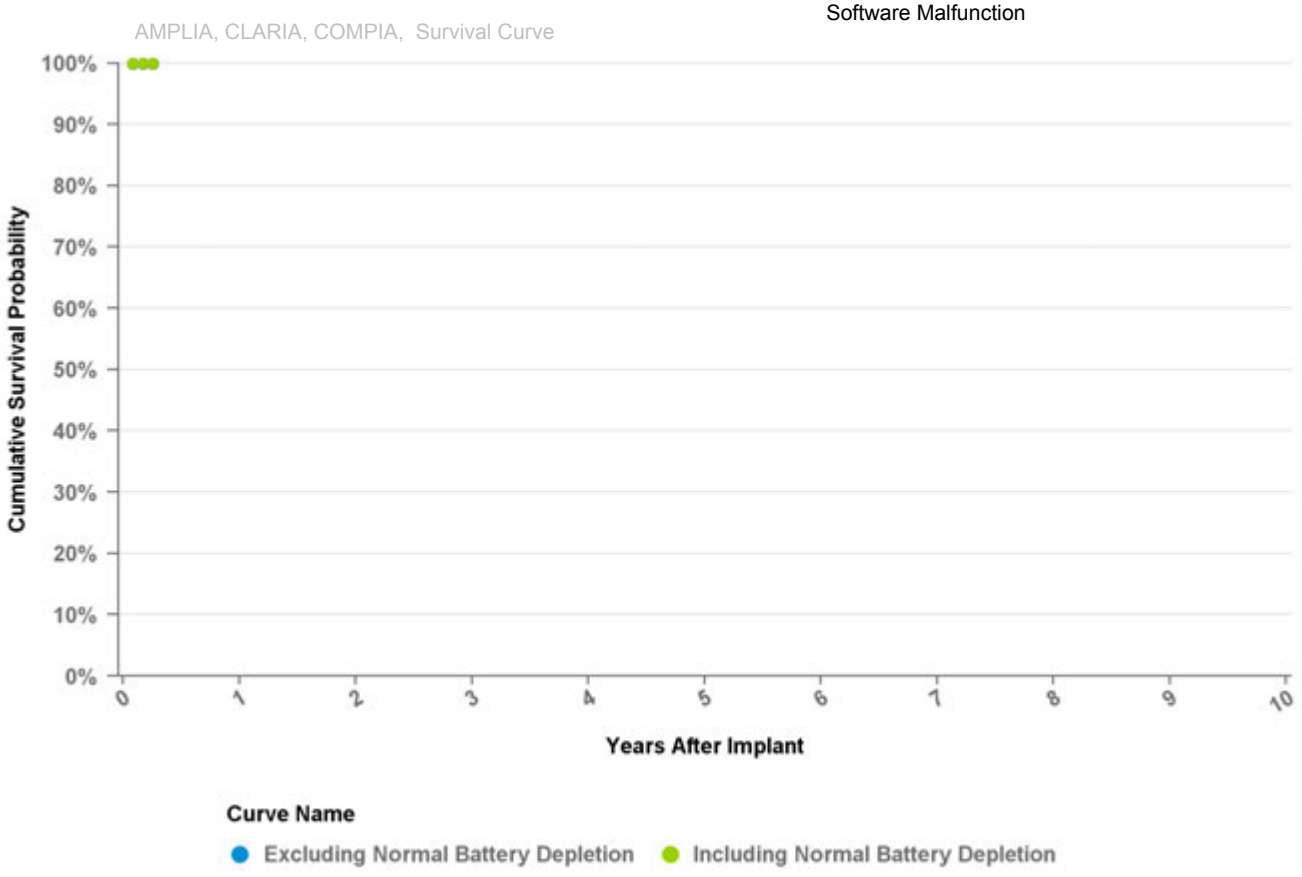
Cardiac Resynchronization Therapy

DTMA2D4 Claria MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 3 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	104

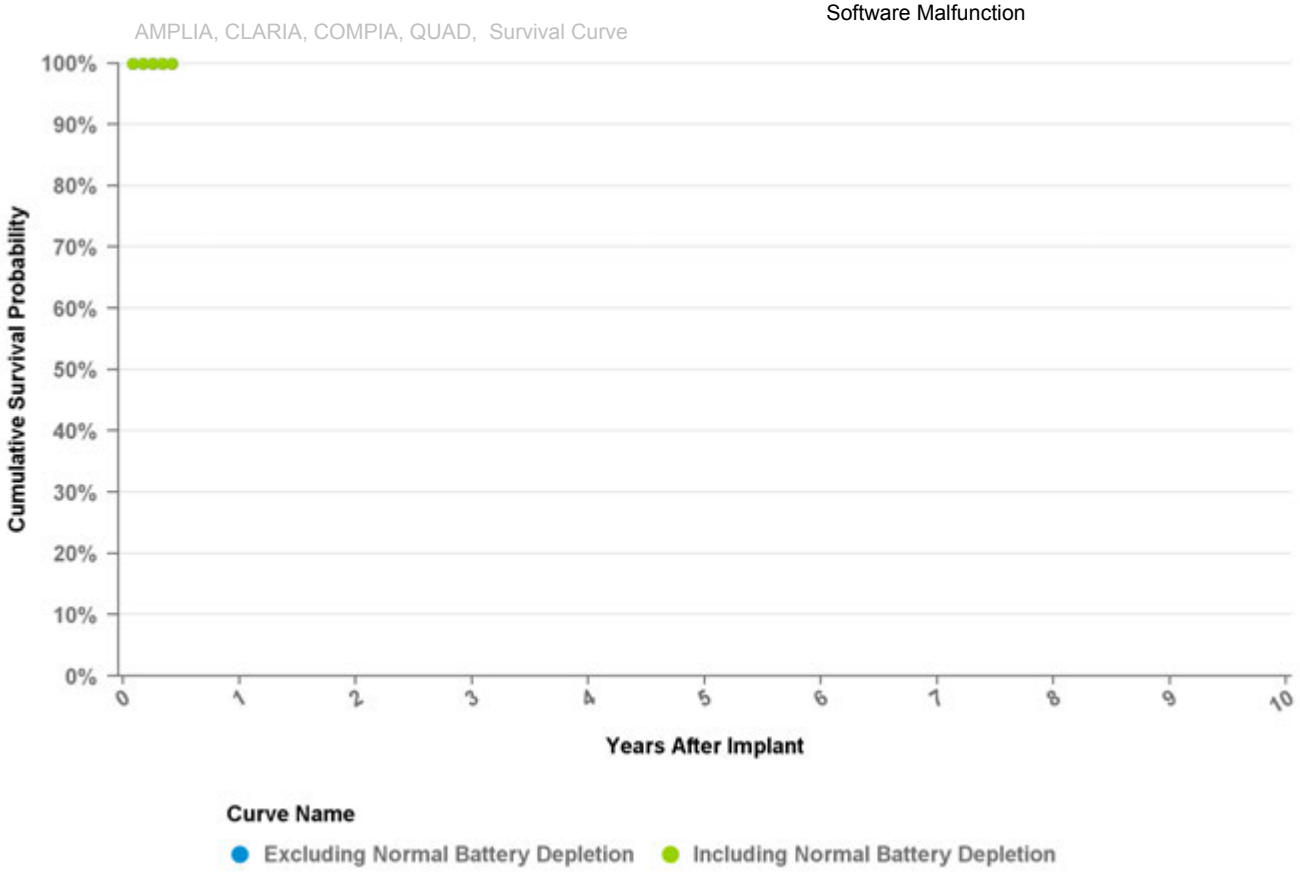
Cardiac Resynchronization Therapy

DTMA2QQ Claria MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	290

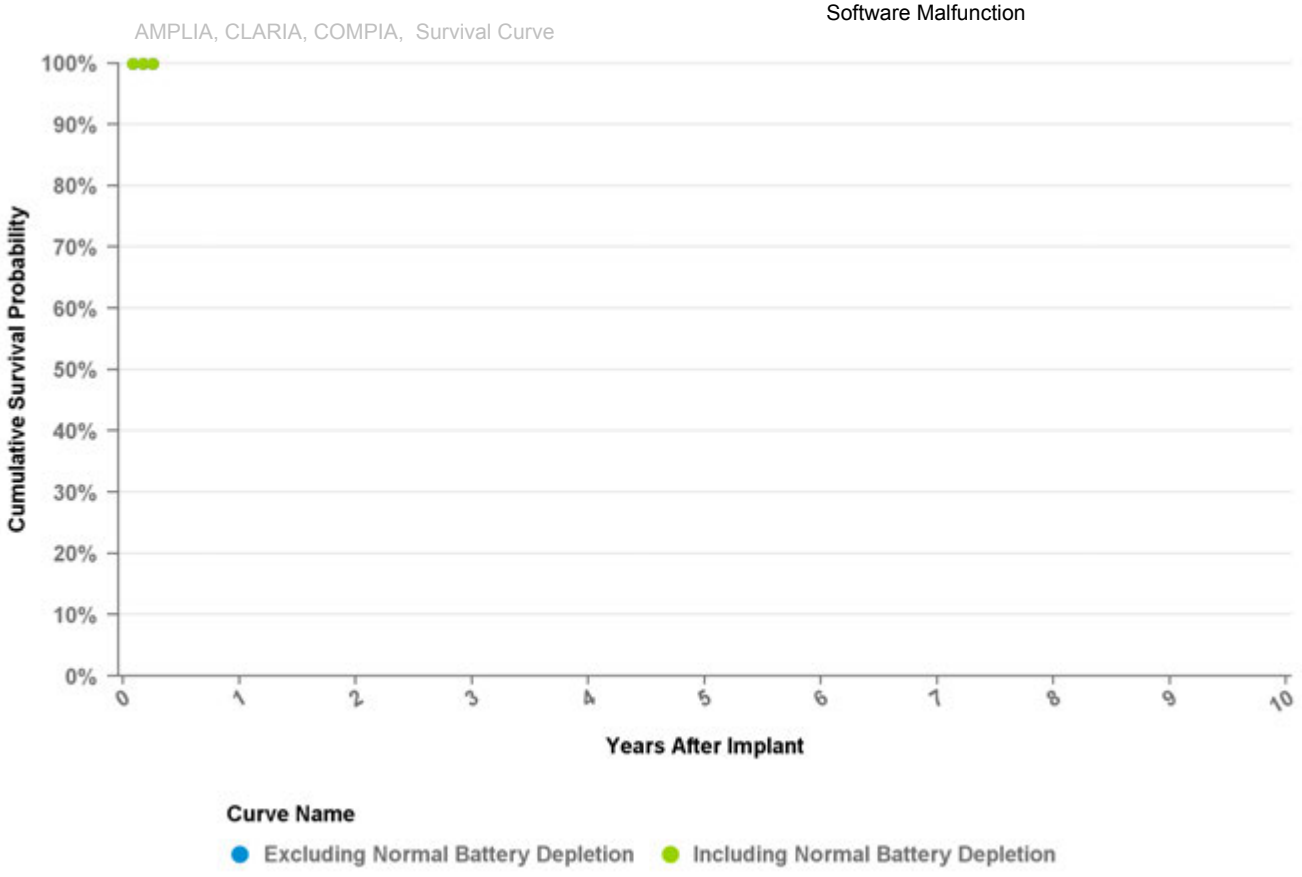
Cardiac Resynchronization Therapy

DTMB1D4 Amplia MRI

US Market Release Date	2/1/2016
CE Market Approval Date	
Registered US Implants	283
Estimated Active US Implants	282
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 3 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	104

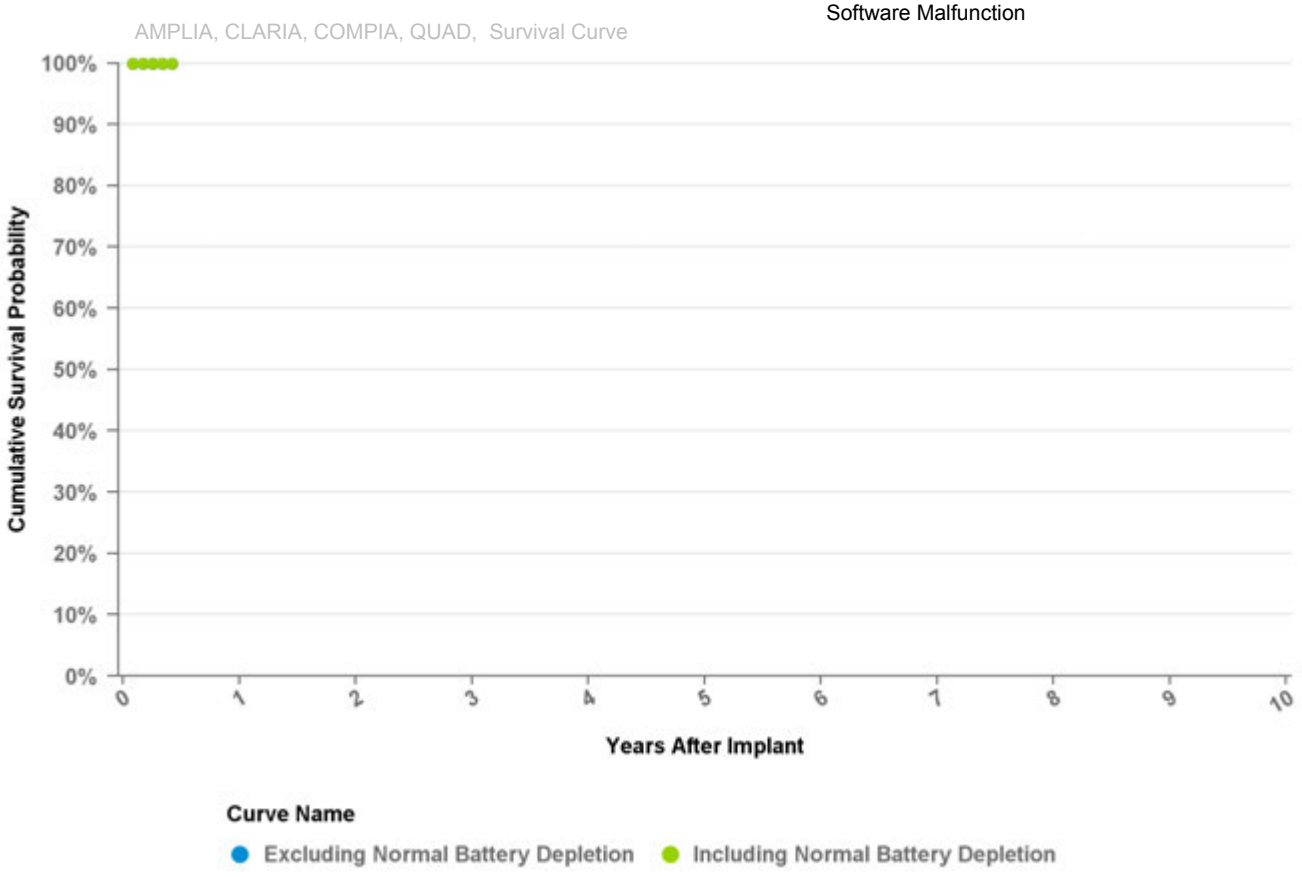
Cardiac Resynchronization Therapy

DTMB1QQ Amplia MRI

US Market Release Date	2/1/2016
CE Market Approval Date	
Registered US Implants	3,597
Estimated Active US Implants	3,564
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	290

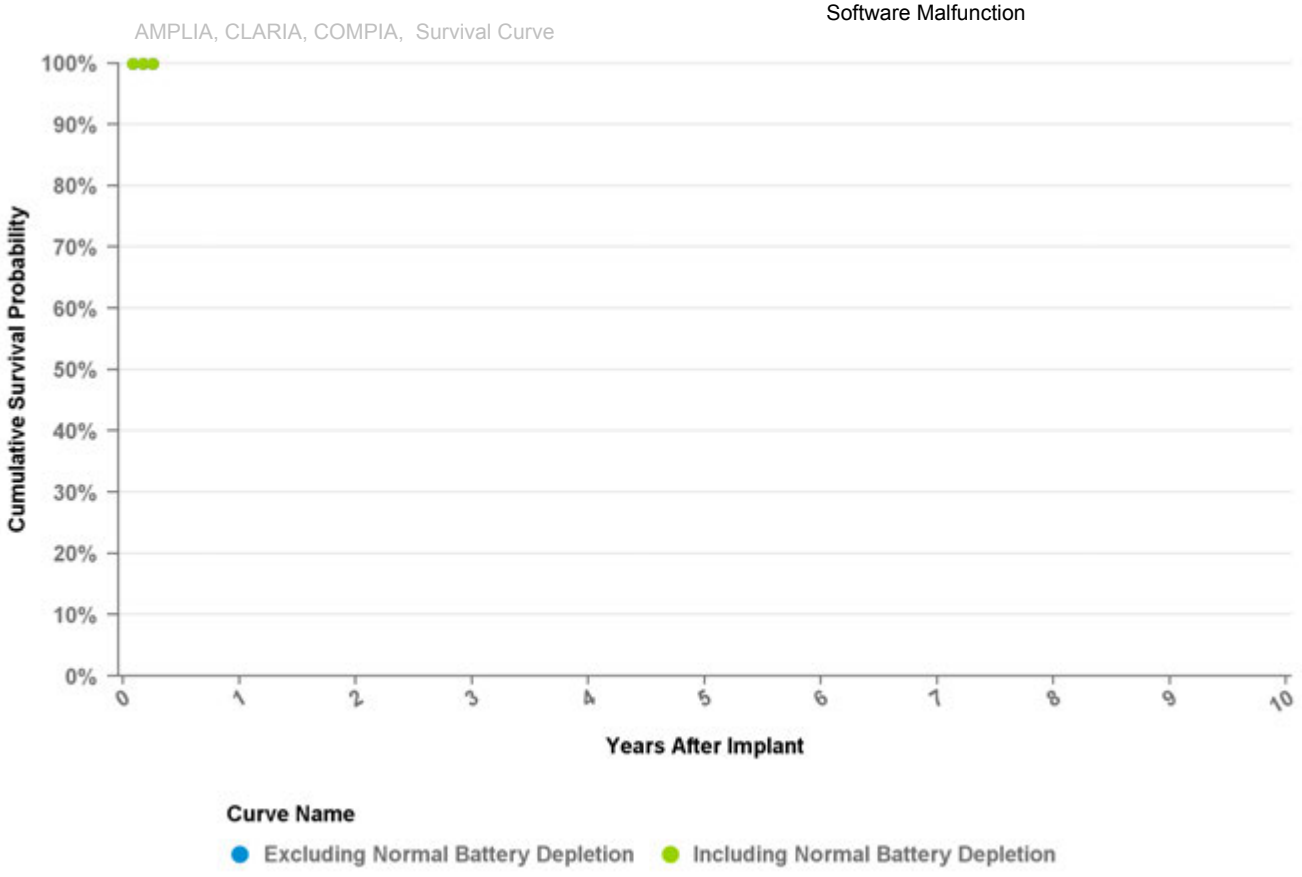
Cardiac Resynchronization Therapy

DTMB2D4 Amplia MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 3 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	104

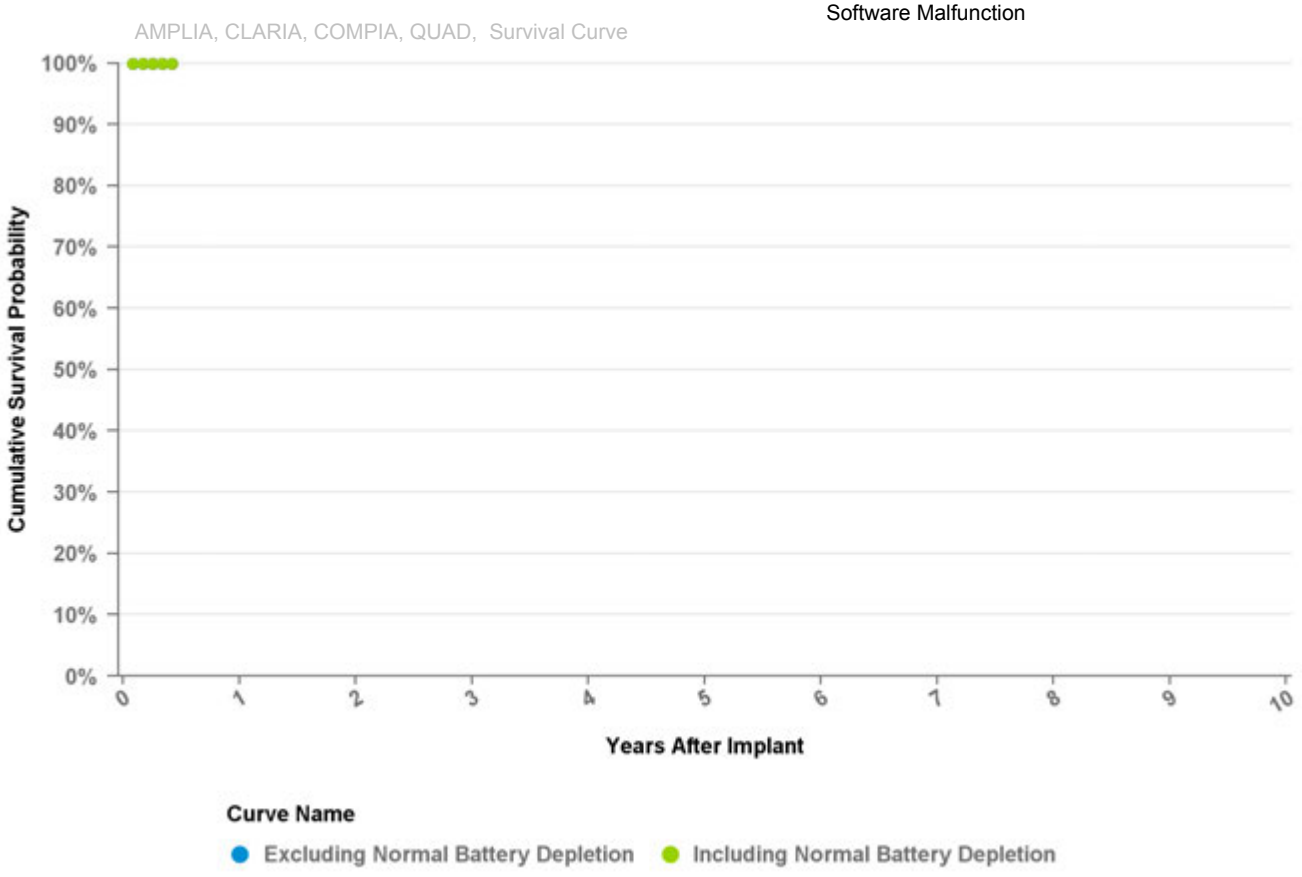
Cardiac Resynchronization Therapy

DTMB2QQ Amplia MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	290

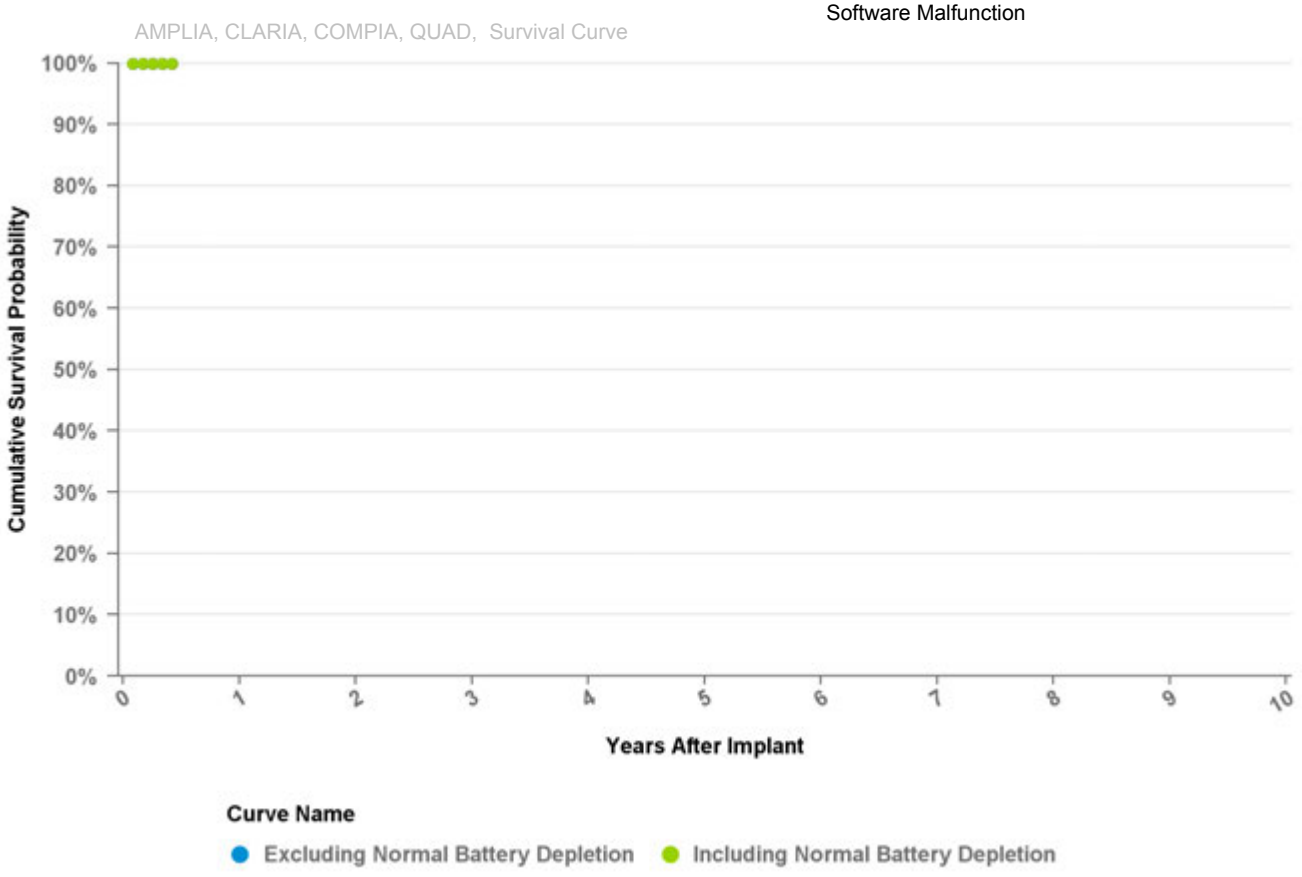
Cardiac Resynchronization Therapy

DTMC1QQ Compia MRI

US Market Release Date	2/1/2016
CE Market Approval Date	
Registered US Implants	268
Estimated Active US Implants	267
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	290

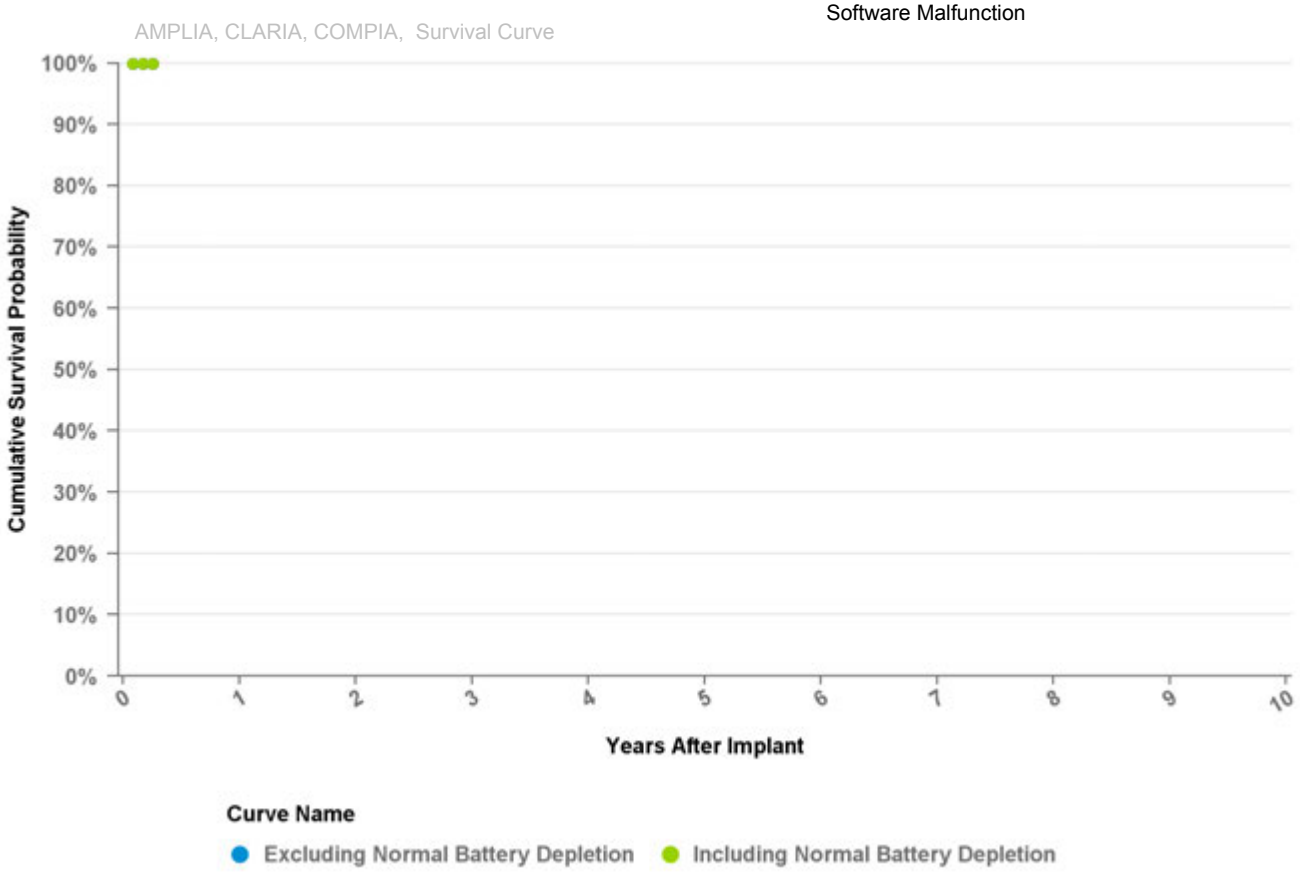
Cardiac Resynchronization Therapy

DTMC2D4 Compia MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 3 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	104

Cardiac Resynchronization Therapy

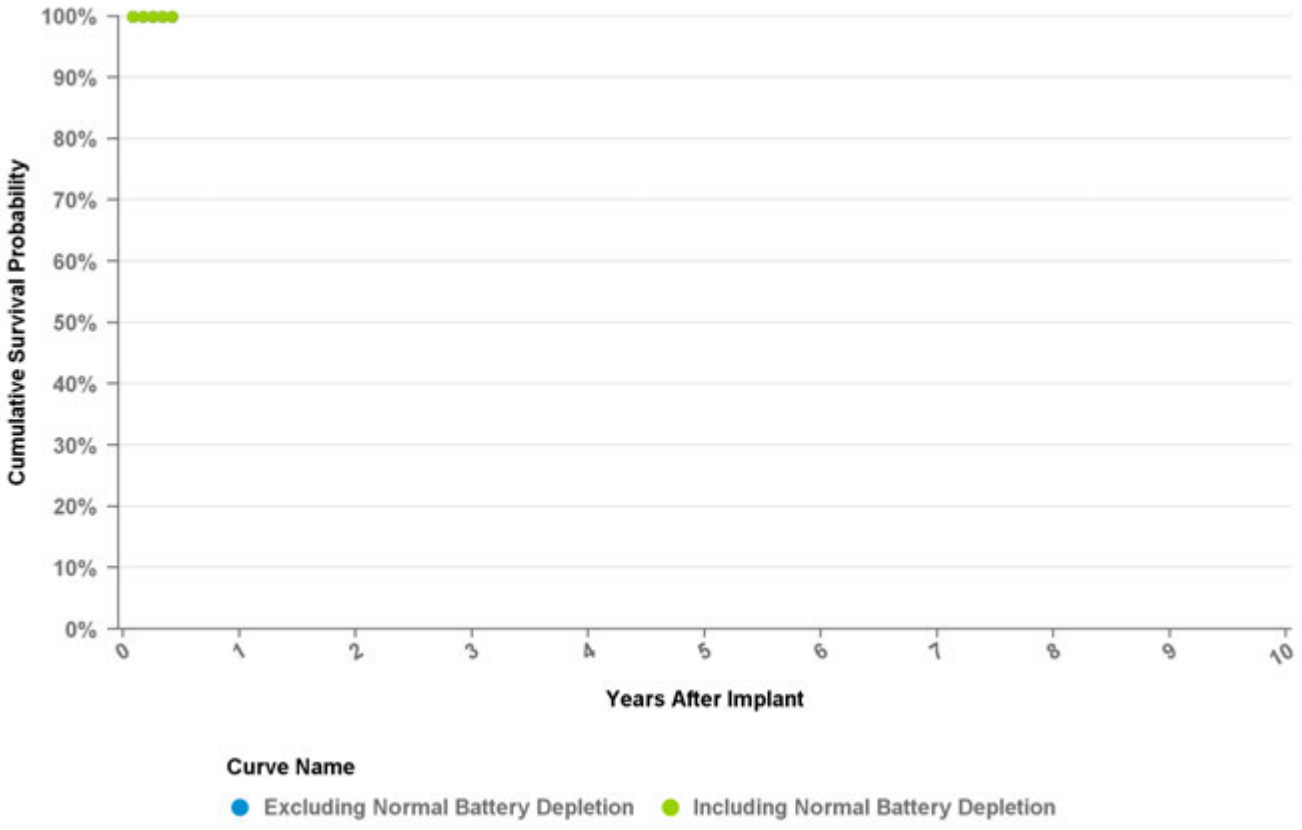
DTMC2QQ Compia MRI

US Market Release Date	
CE Market Approval Date	2/19/2016
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

AMPLIA, CLARIA, COMPIA, QUAD, Survival Curve



Years	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	290

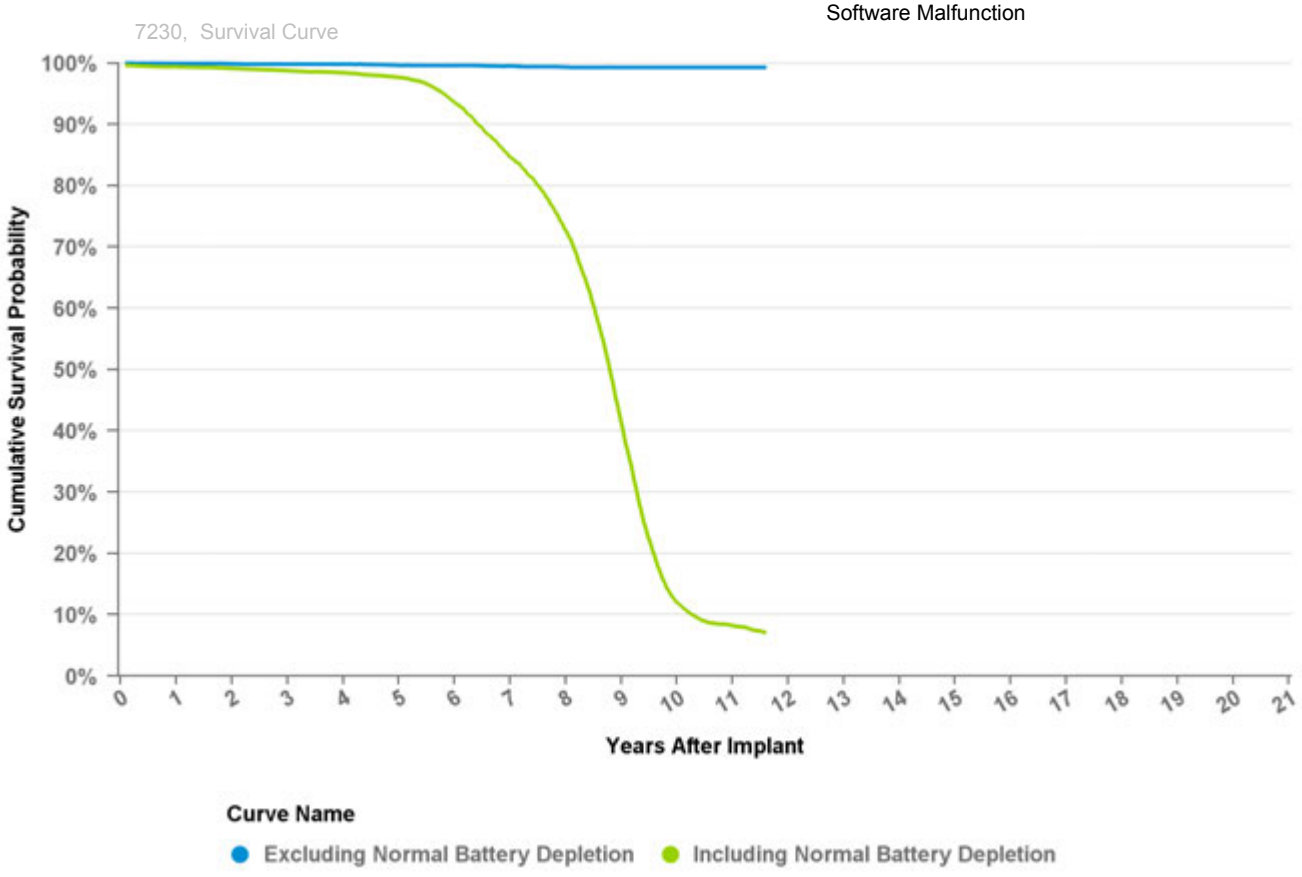
Implantable Cardioverter Defibrillator

7230B Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	8/21/2002
Registered US Implants	237
Estimated Active US Implants	12
Normal Battery Depletions (US)	26

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	1
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	11	at 139 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.8%	41.4%	12.0%	8.2%	7.1%
Effective Sample Size	16512	12761	10569	9433	8390	7292	6060	4819	2555	580	311	128

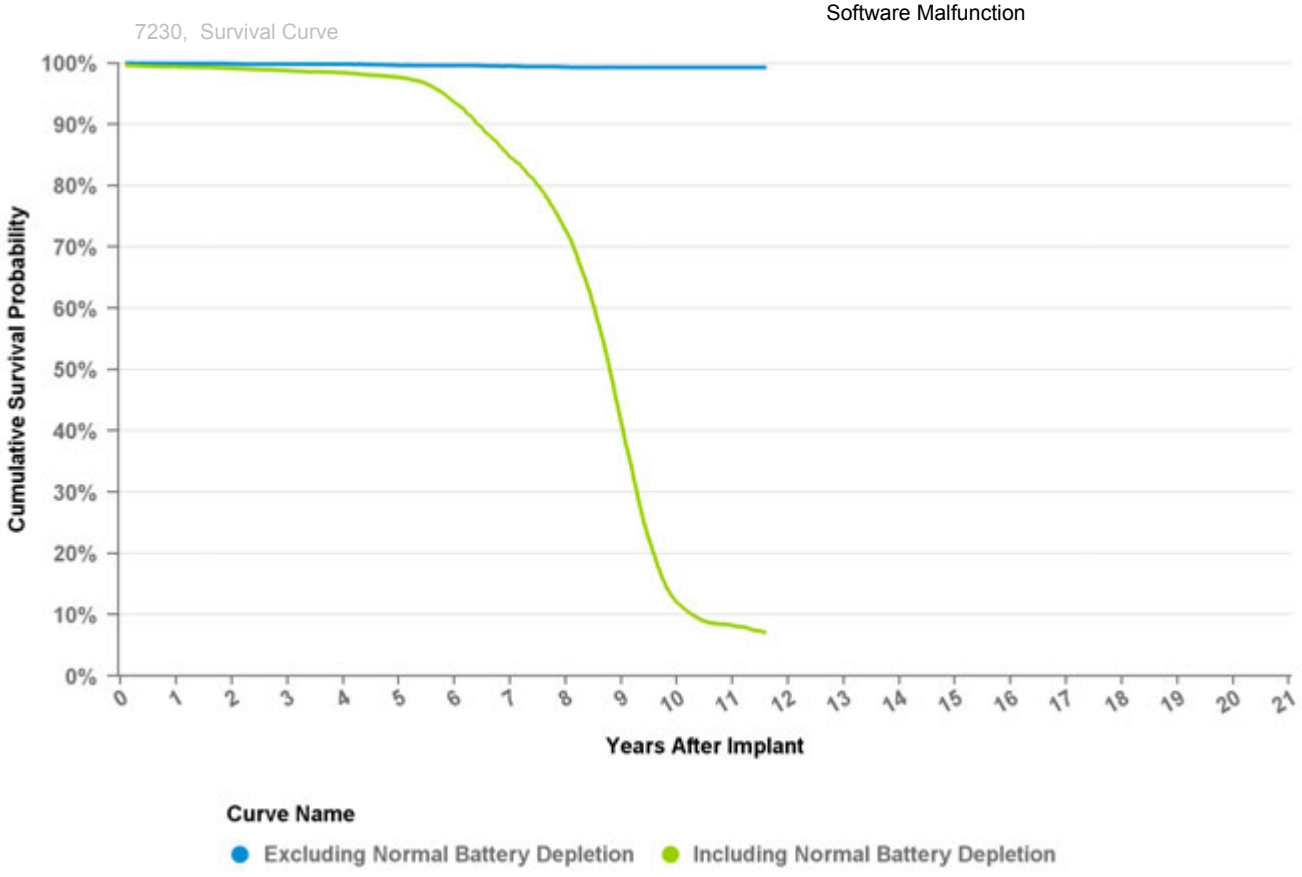
Implantable Cardioverter Defibrillator

7230Cx Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	4/10/2002
Registered US Implants	18,517
Estimated Active US Implants	1,256
Normal Battery Depletions (US)	3,408

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	57
Therapy Not Compromised Malfunctions	31
Battery Malfunction	1
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	14
Software Malfunction	1
Therapy Compromised Malfunctions	26
Battery Malfunction	17
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	11	at 139 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.8%	41.4%	12.0%	8.2%	7.1%
Effective Sample Size	16512	12761	10569	9433	8390	7292	6060	4819	2555	580	311	128

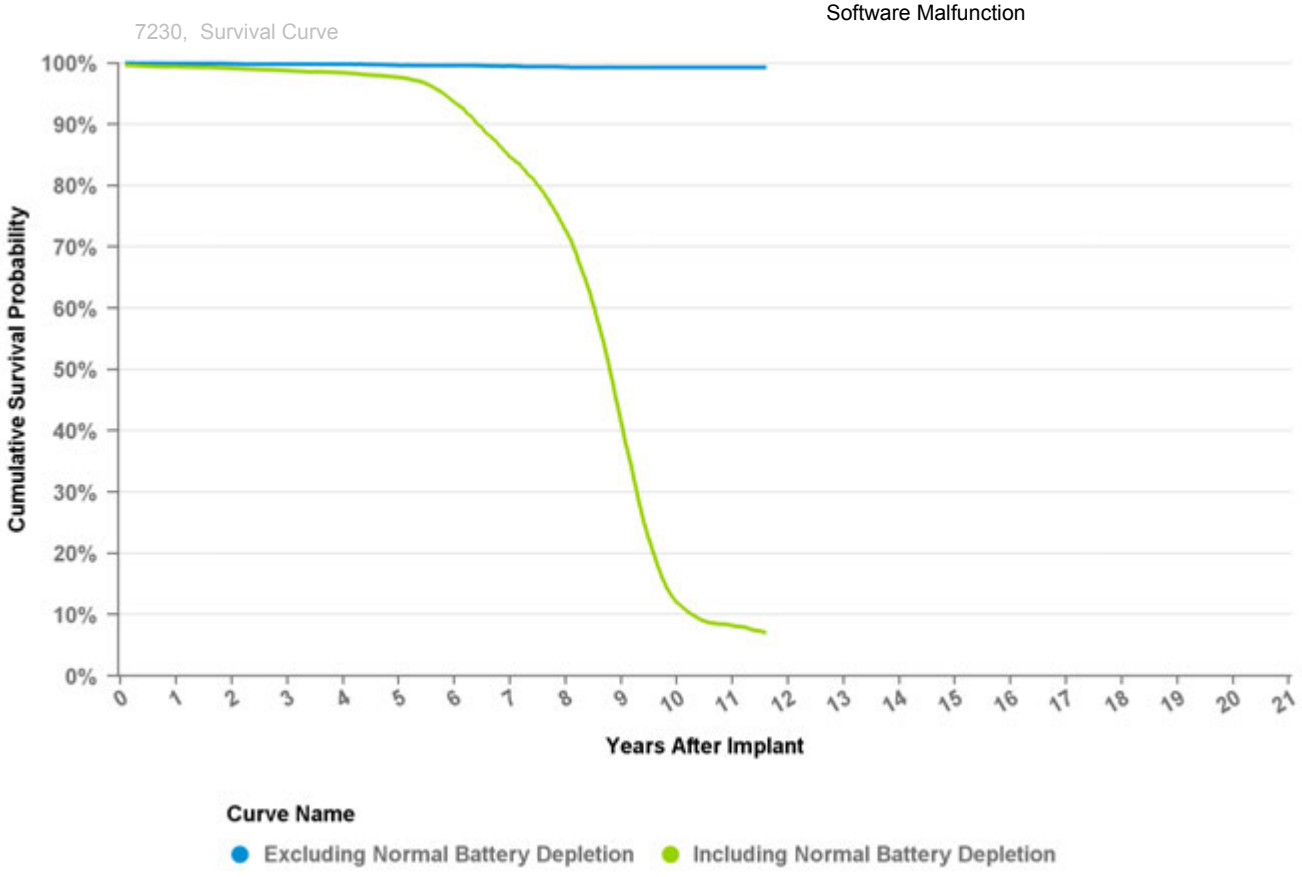
Implantable Cardioverter Defibrillator

7230E Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	8/21/2002
Registered US Implants	632
Estimated Active US Implants	42
Normal Battery Depletions (US)	78

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	2
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	11	at 139 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.8%	41.4%	12.0%	8.2%	7.1%
Effective Sample Size	16512	12761	10569	9433	8390	7292	6060	4819	2555	580	311	128

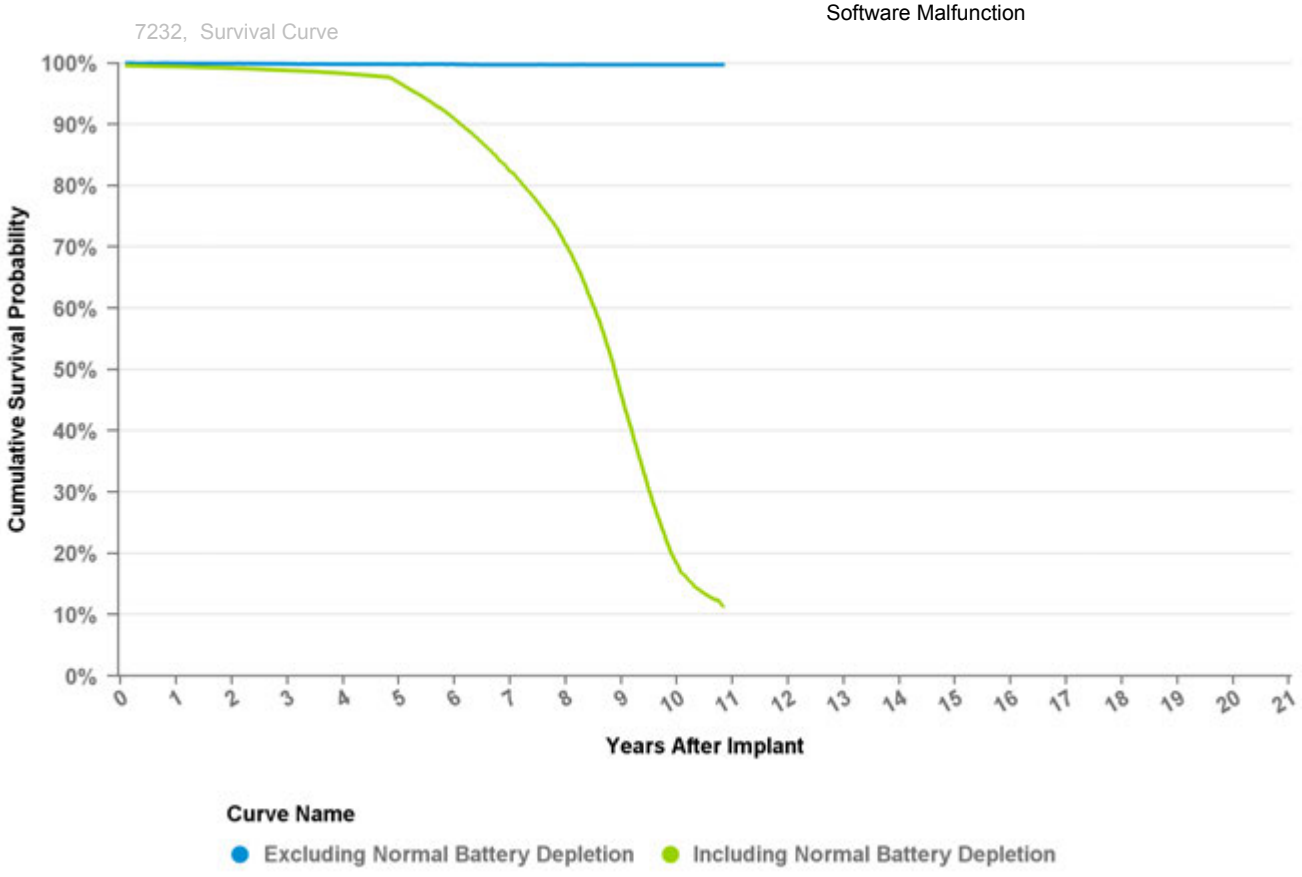
Implantable Cardioverter Defibrillator

7232B Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	170
Estimated Active US Implants	37
Normal Battery Depletions (US)	30

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.5%	45.9%	18.4%	11.4%
Effective Sample Size	38272	34243	30524	26915	23708	20587	17364	13739	7999	2264	250

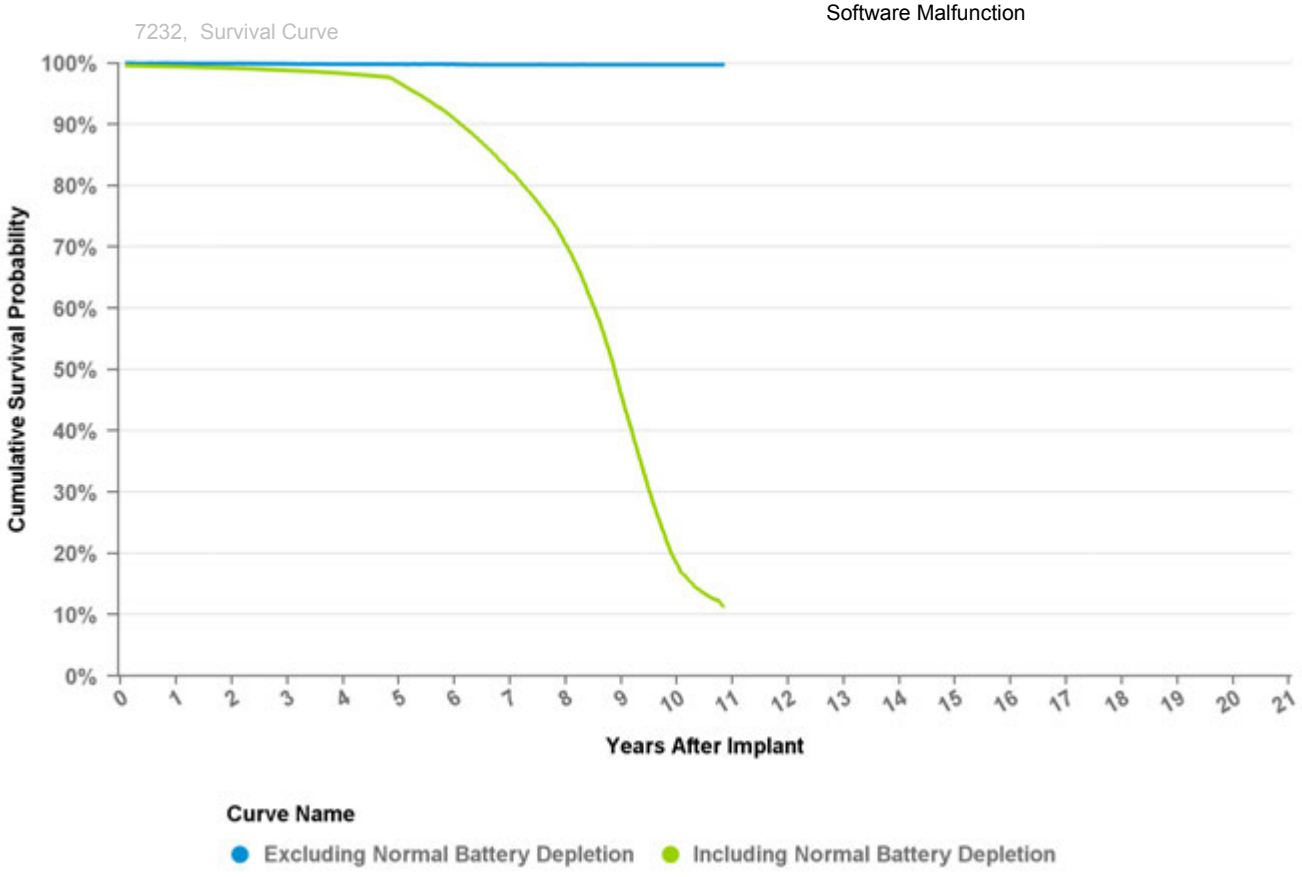
Implantable Cardioverter Defibrillator

7232Cx Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	43,671
Estimated Active US Implants	5,882
Normal Battery Depletions (US)	10,191

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	76
Therapy Not Compromised Malfunctions	61
Battery Malfunction	0
Electrical Component	28
Electrical Interconnect	0
Other Malfunction	6
Poss Early Battery Depltn	25
Software Malfunction	2
Therapy Compromised Malfunctions	15
Battery Malfunction	0
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.5%	45.9%	18.4%	11.4%
Effective Sample Size	38272	34243	30524	26915	23708	20587	17364	13739	7999	2264	250

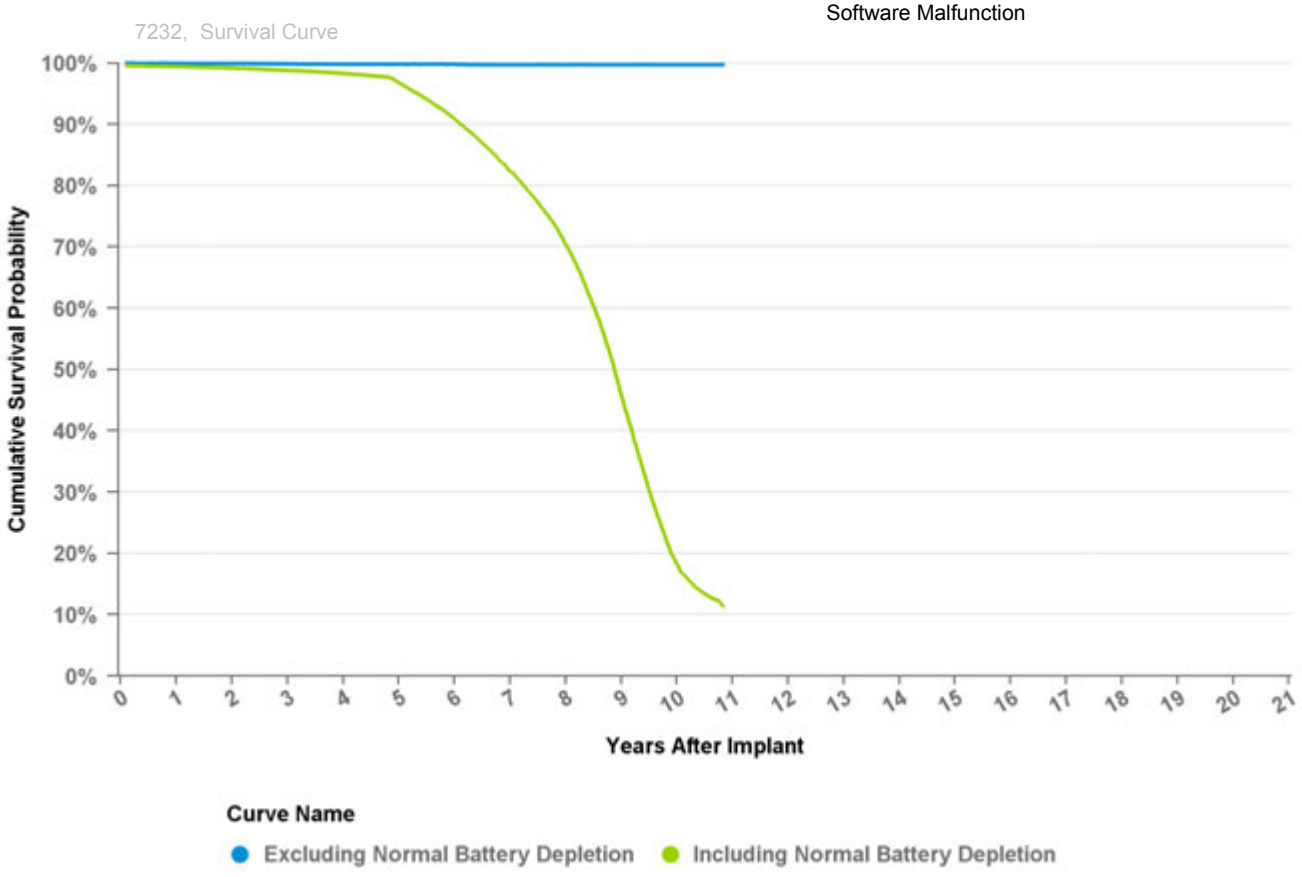
Implantable Cardioverter Defibrillator

7232E Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	490
Estimated Active US Implants	98
Normal Battery Depletions (US)	69

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.5%	45.9%	18.4%	11.4%
Effective Sample Size	38272	34243	30524	26915	23708	20587	17364	13739	7999	2264	250

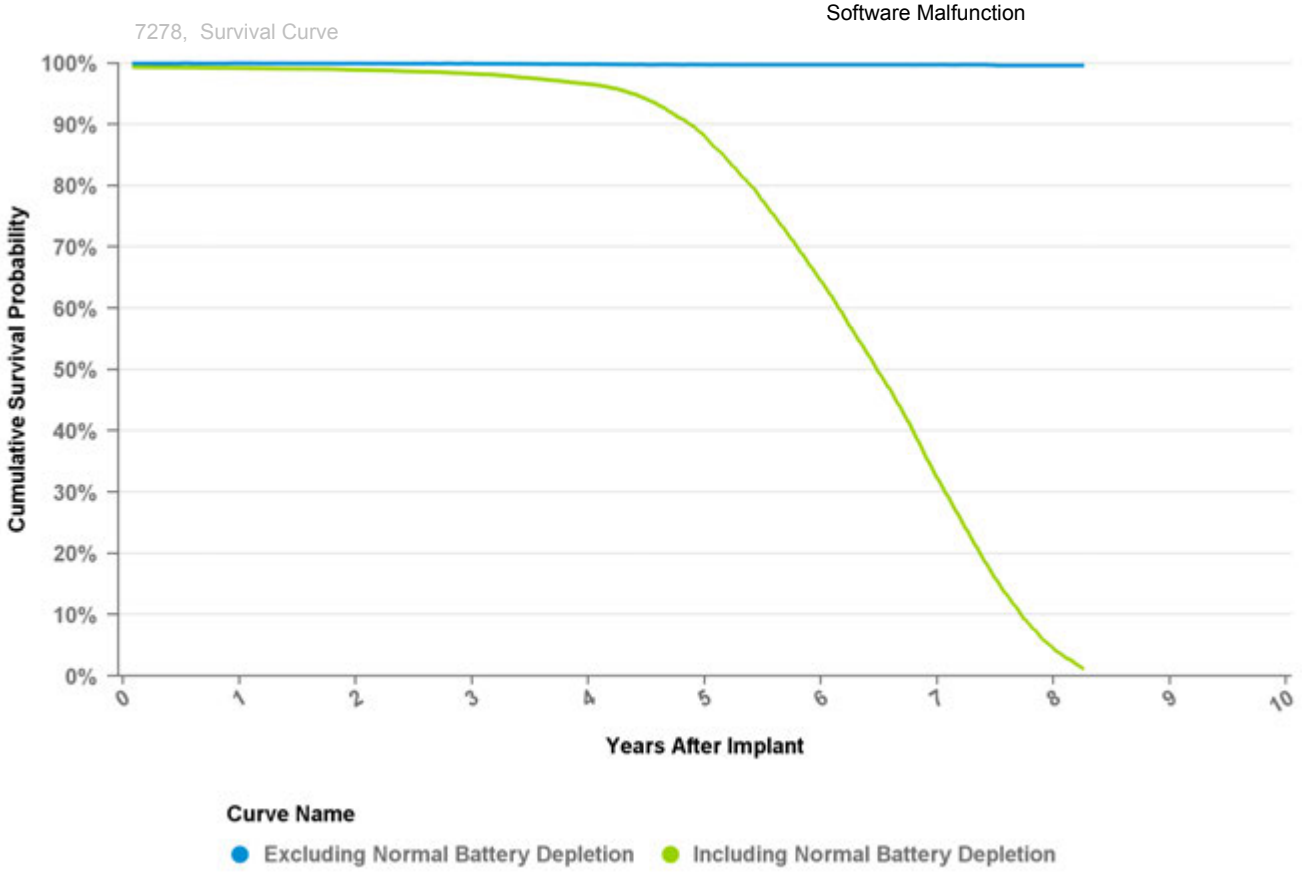
Implantable Cardioverter Defibrillator

7278 Maximo DR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	37,641
Estimated Active US Implants	2,745
Normal Battery Depletions (US)	10,788

NBG Code	VVE-DDDR
Max Delivered Energy	35J

Total Malfunctions (US)	72
Therapy Not Compromised Malfunctions	62
Battery Malfunction	0
Electrical Component	24
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	34
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.2%	98.9%	98.3%	96.6%	88.0%	64.5%	32.3%	4.4%	1.2%
Effective Sample Size	32688	29142	26022	22811	18810	12479	5579	614	167

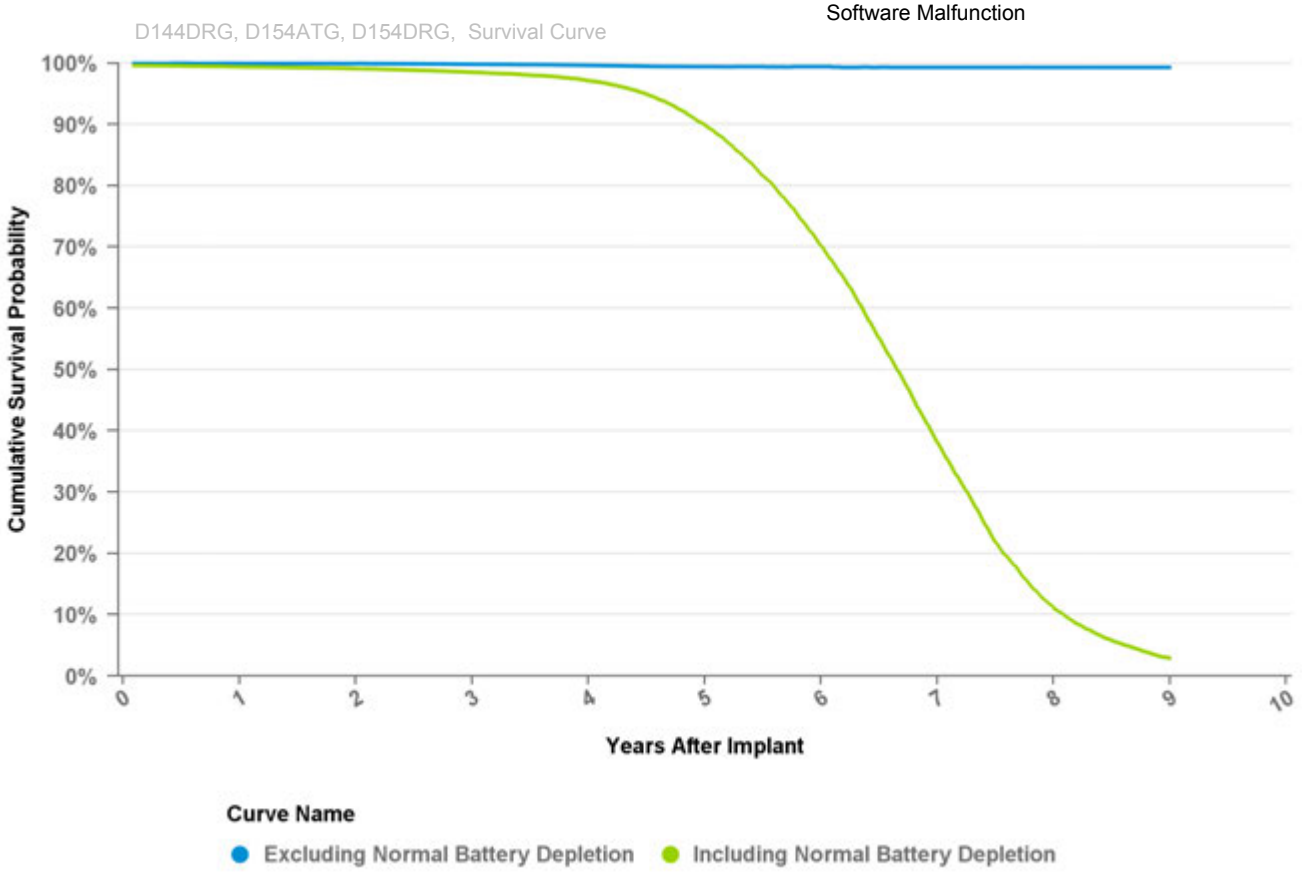
Implantable Cardioverter Defibrillator

D144DRG Entrust Escudo

US Market Release Date	
CE Market Approval Date	6/5/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.3%	38.2%	11.1%	2.9%
Effective Sample Size	24906	22705	20360	17948	14886	10828	5380	1332	129

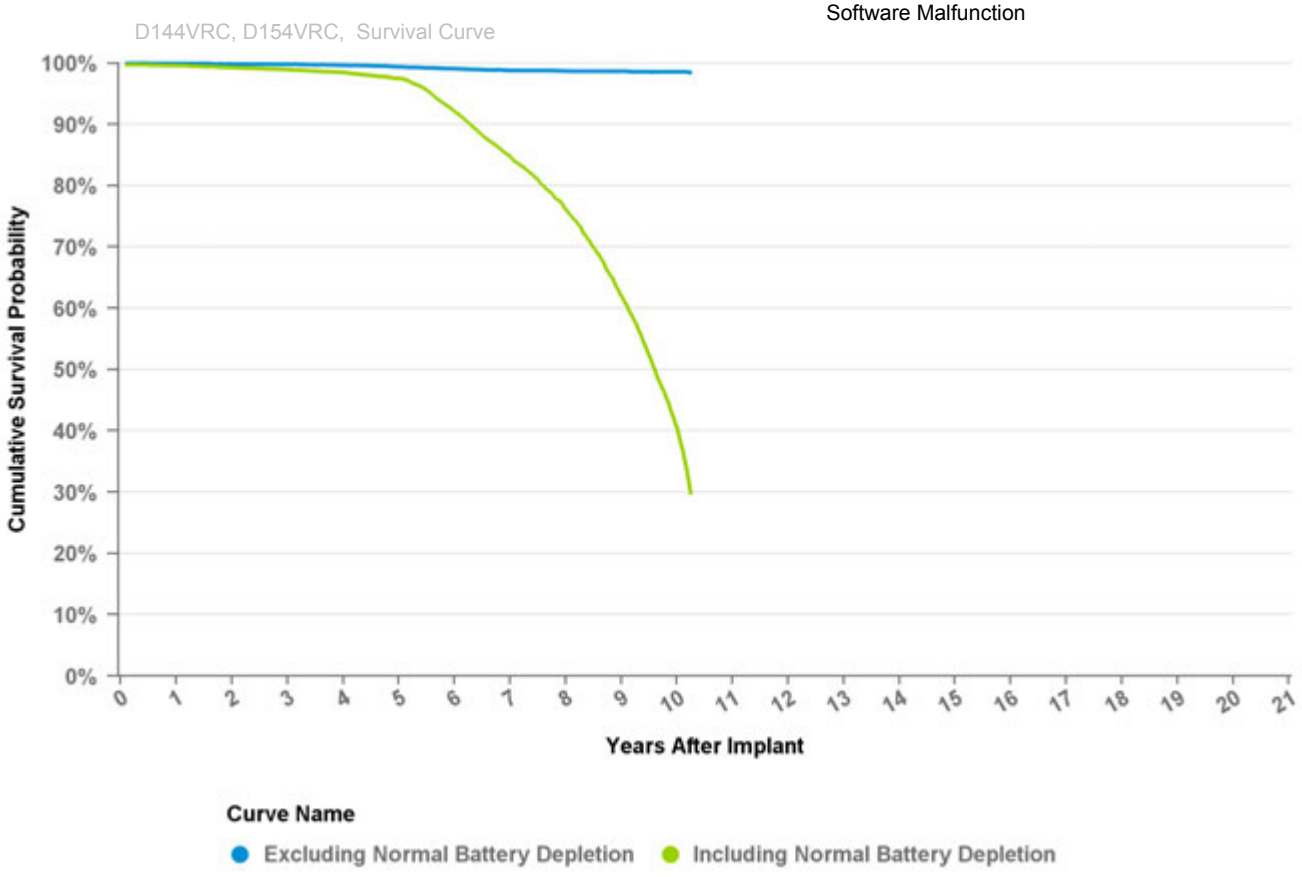
Implantable Cardioverter Defibrillator

D144VRC Entrust Escudo

US Market Release Date	
CE Market Approval Date	6/5/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.6%	98.5%
Including NBD	99.6%	99.3%	99.0%	98.5%	97.5%	92.1%	84.8%	76.2%	62.1%	40.6%	29.8%
Effective Sample Size	12676	11479	10257	9059	7995	6995	5998	5083	3472	1017	283

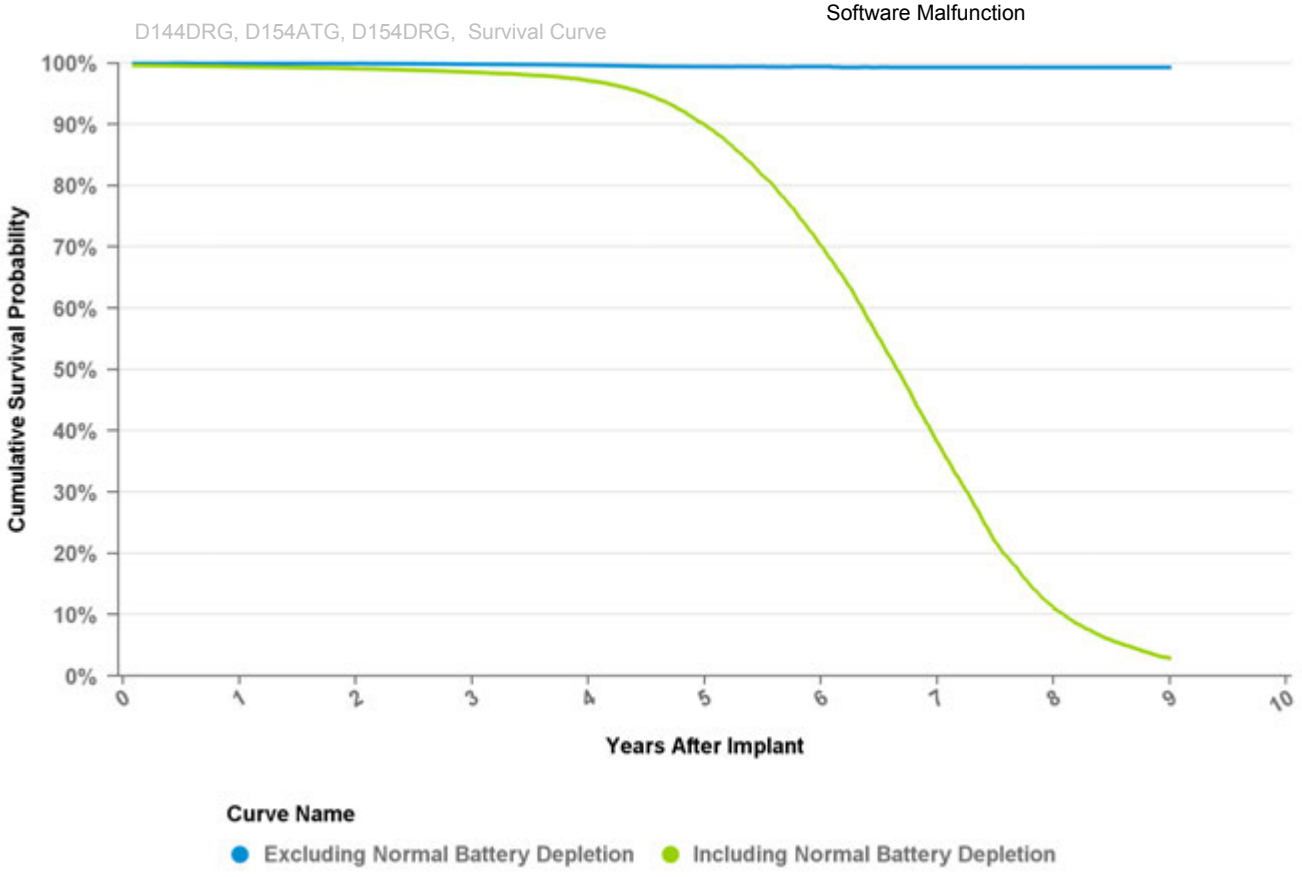
Implantable Cardioverter Defibrillator

D154ATG Entrust AT

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	28,151
Estimated Active US Implants	2,436
Normal Battery Depletions (US)	8,962

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	126
Therapy Not Compromised Malfunctions	110
Battery Malfunction	0
Electrical Component	30
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	74
Software Malfunction	3
Therapy Compromised Malfunctions	16
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.3%	38.2%	11.1%	2.9%
Effective Sample Size	24906	22705	20360	17948	14886	10828	5380	1332	129

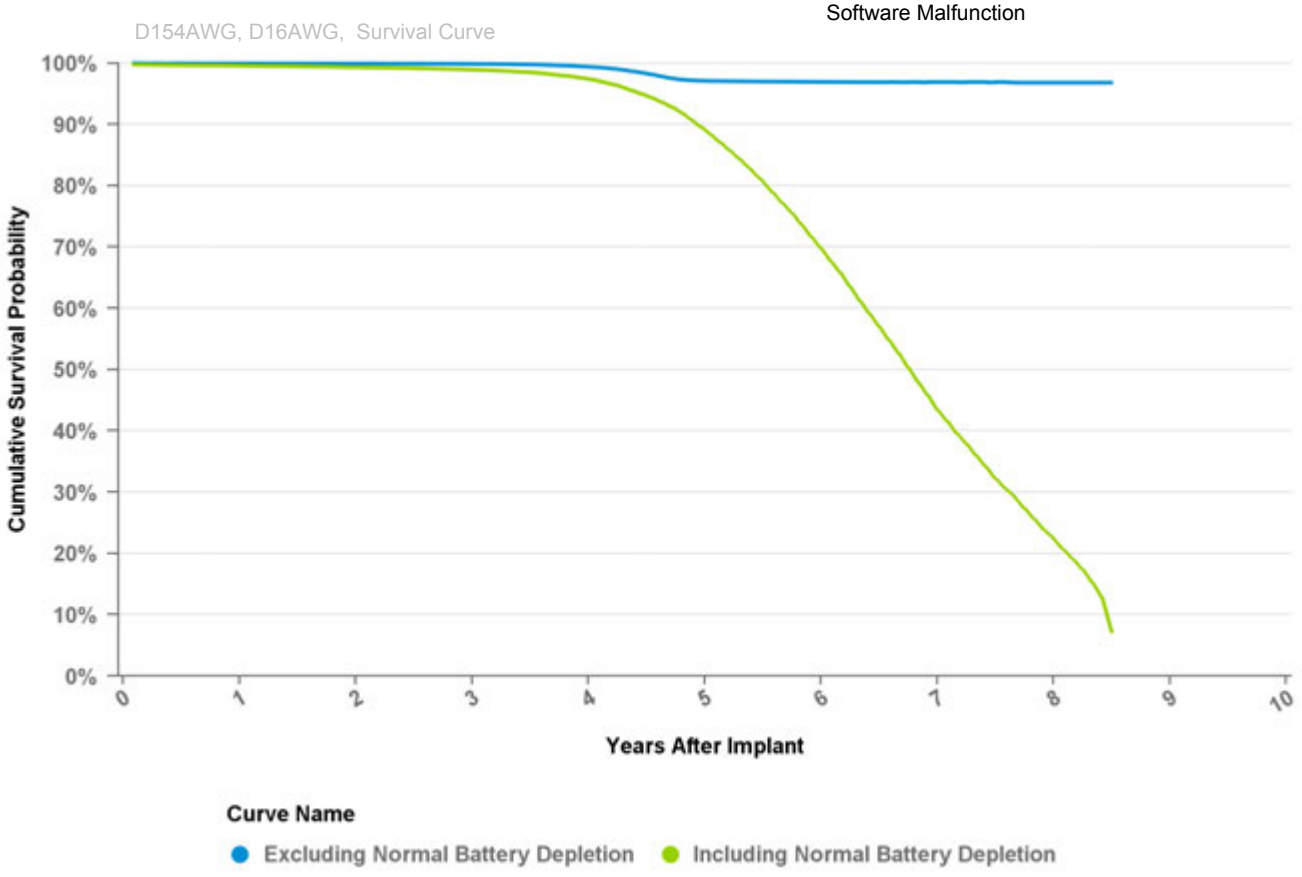
Implantable Cardioverter Defibrillator

D154AWG Virtuoso DR

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	72,682
Estimated Active US Implants	14,342
Normal Battery Depletions (US)	19,423

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,459
Therapy Not Compromised Malfunctions	1,430
Battery Malfunction	7
Electrical Component	1,282
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	132
Software Malfunction	3
Therapy Compromised Malfunctions	29
Battery Malfunction	0
Electrical Component	26
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	1
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.9%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.5%	22.3%	7.3%
Effective Sample Size	63400	58145	52984	48147	40923	29848	16055	4238	420

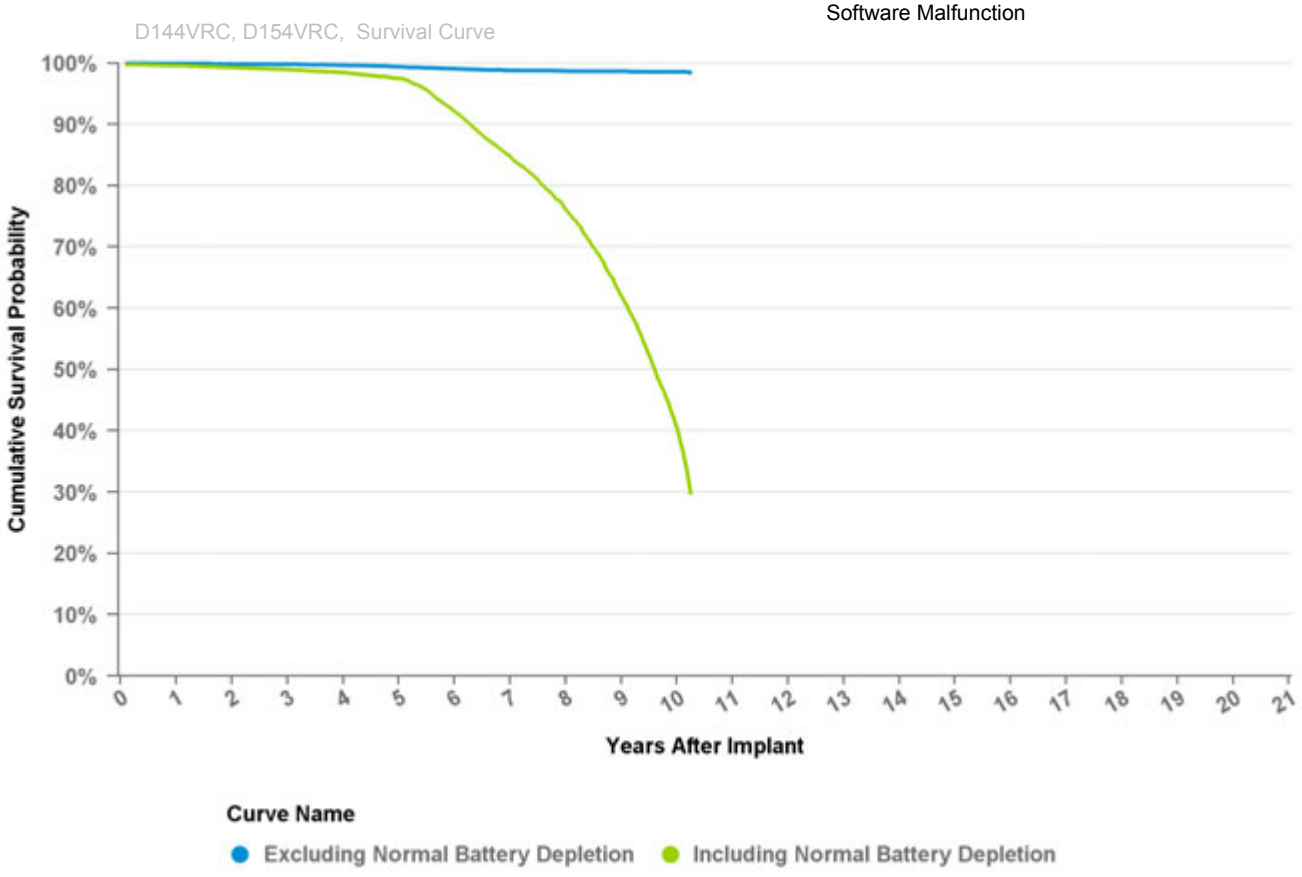
Implantable Cardioverter Defibrillator

D154VRC Entrust VR

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	14,463
Estimated Active US Implants	3,523
Normal Battery Depletions (US)	2,404

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	117
Therapy Not Compromised Malfunctions	92
Battery Malfunction	12
Electrical Component	46
Electrical Interconnect	0
Other Malfunction	10
Poss Early Battery Depltn	24
Software Malfunction	0
Therapy Compromised Malfunctions	25
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.6%	98.5%
Including NBD	99.6%	99.3%	99.0%	98.5%	97.5%	92.1%	84.8%	76.2%	62.1%	40.6%	29.8%
Effective Sample Size	12676	11479	10257	9059	7995	6995	5998	5083	3472	1017	283

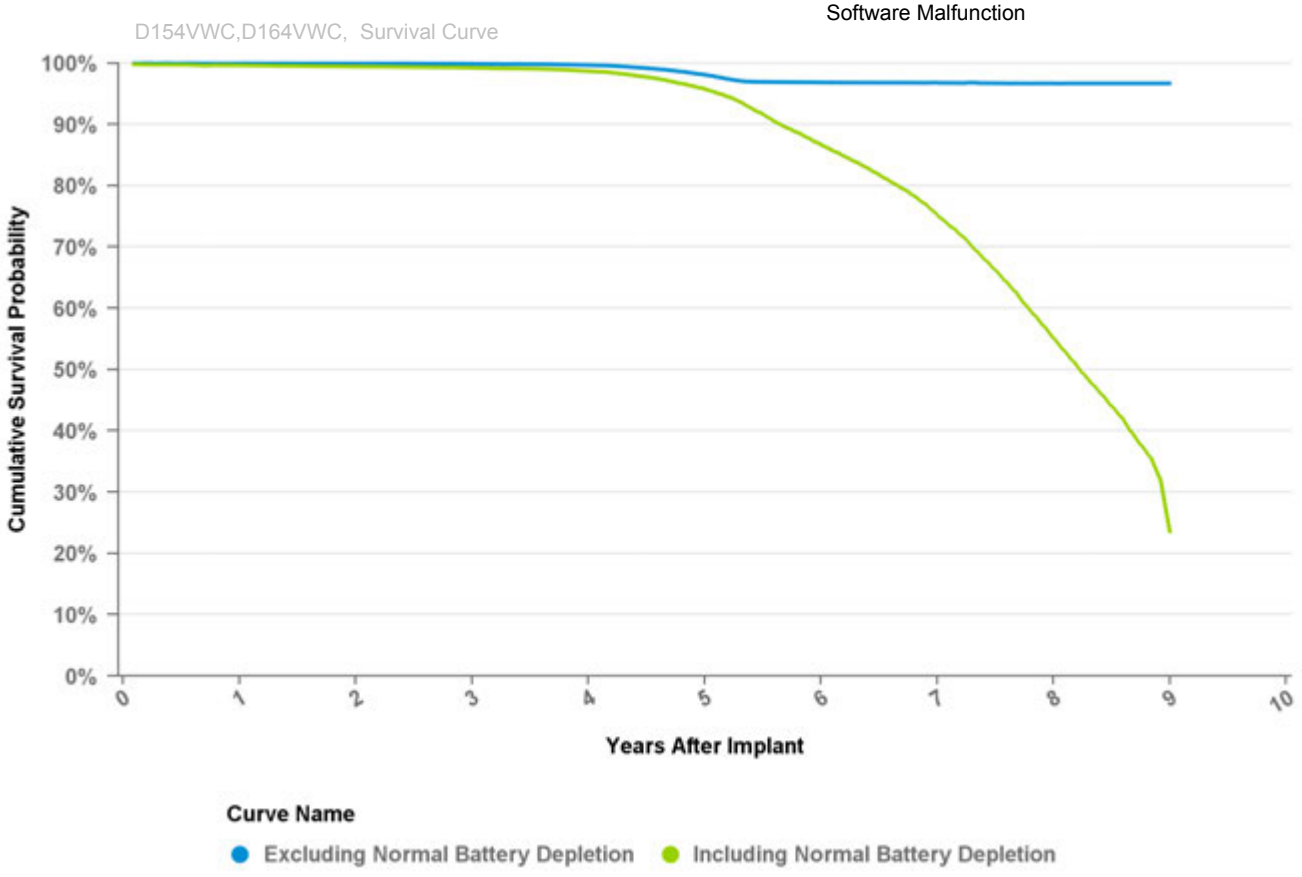
Implantable Cardioverter Defibrillator

D154VWC Virtuoso VR

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	33,130
Estimated Active US Implants	10,732
Normal Battery Depletions (US)	5,188

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	680
Therapy Not Compromised Malfunctions	662
Battery Malfunction	10
Electrical Component	632
Electrical Interconnect	1
Other Malfunction	4
Poss Early Battery Depltn	15
Software Malfunction	0
Therapy Compromised Malfunctions	18
Battery Malfunction	1
Electrical Component	17
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%
Including NBD	99.7%	99.5%	99.2%	98.7%	95.8%	86.7%	75.2%	55.2%	23.6%
Effective Sample Size	28597	26080	23763	21736	19320	16189	12590	6038	168

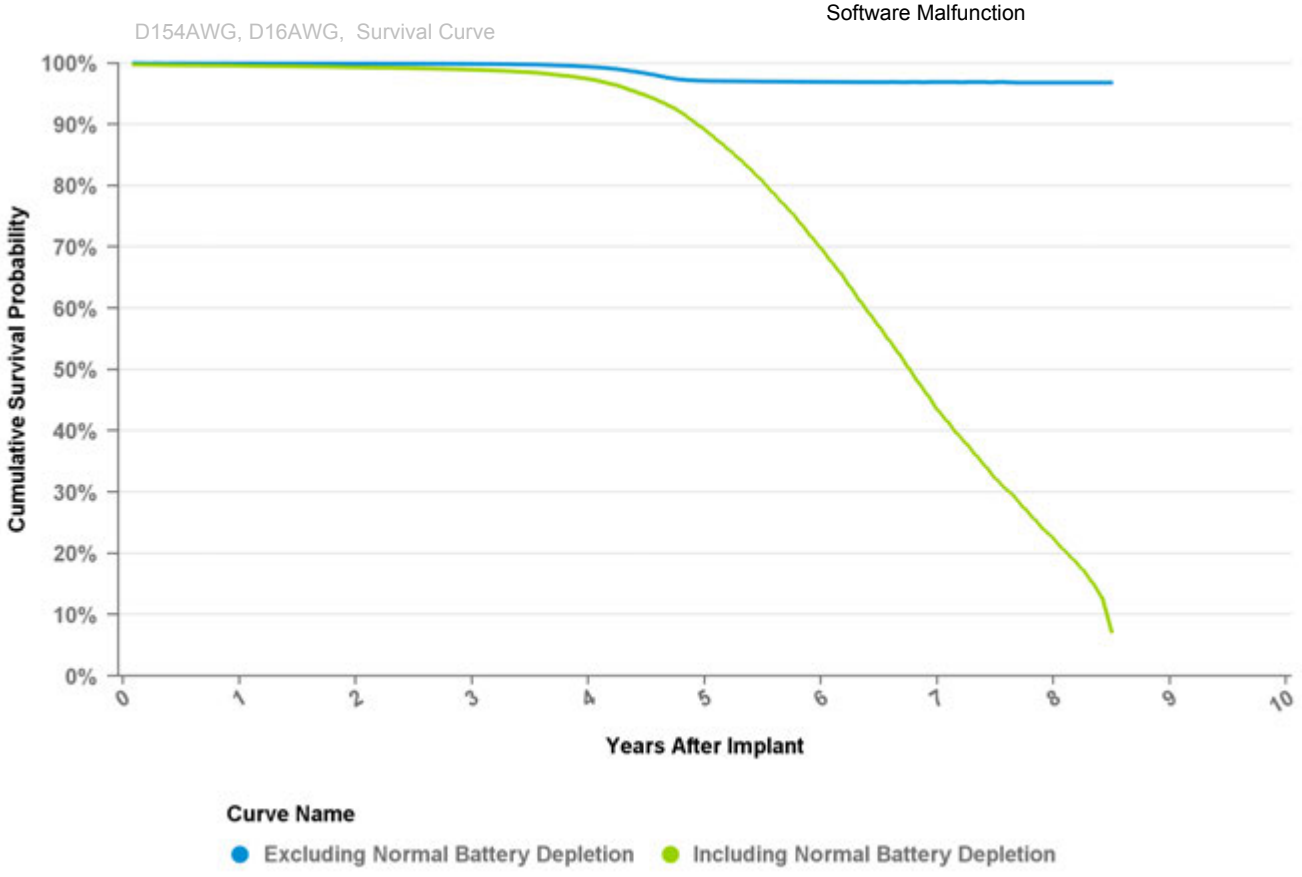
Implantable Cardioverter Defibrillator

D164AWG Virtuoso DR

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	10
Estimated Active US Implants	3
Normal Battery Depletions (US)	4

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.9%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.5%	22.3%	7.3%
Effective Sample Size	63400	58145	52984	48147	40923	29848	16055	4238	420

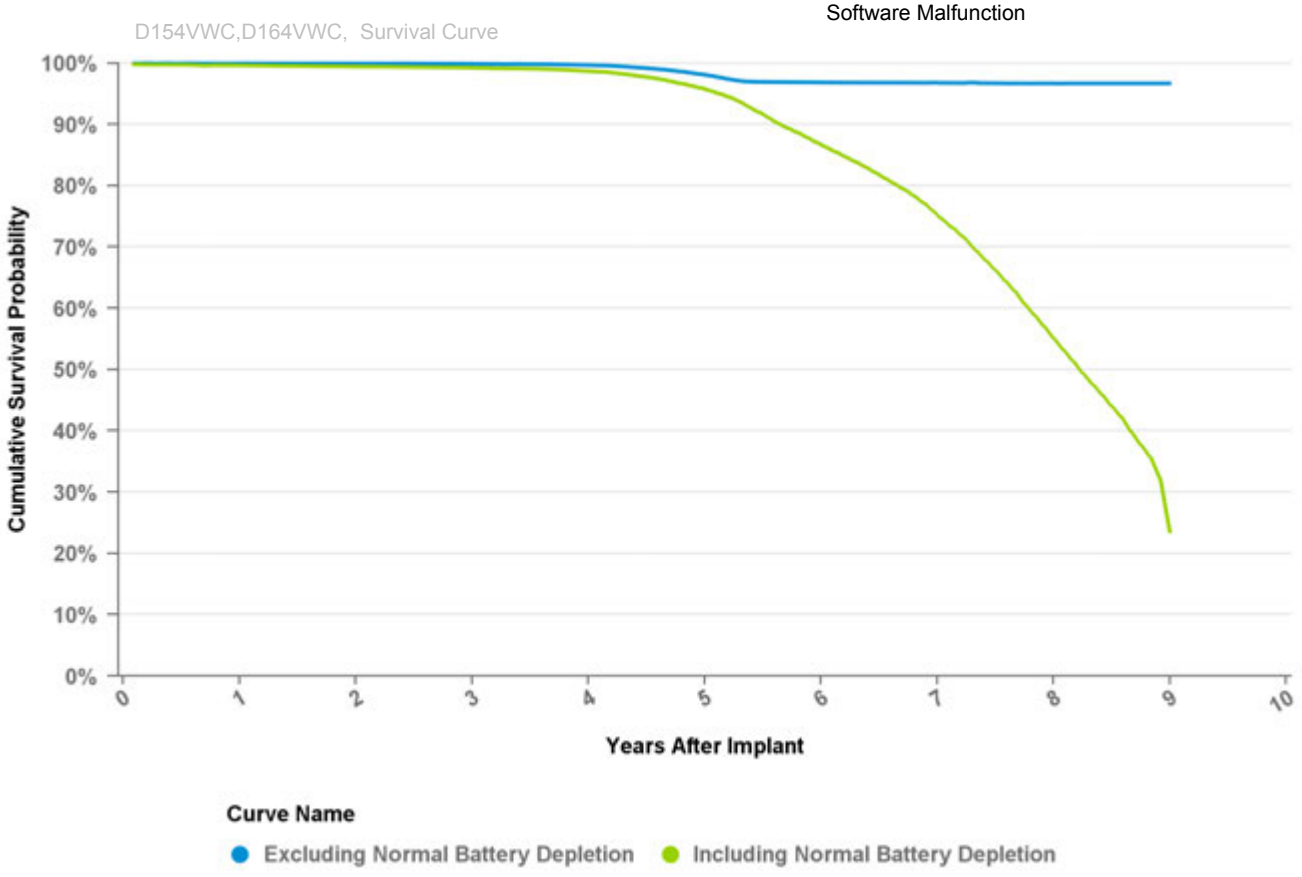
Implantable Cardioverter Defibrillator

D164VWC Virtuoso VR

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	6
Estimated Active US Implants	3
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%
Including NBD	99.7%	99.5%	99.2%	98.7%	95.8%	86.7%	75.2%	55.2%	23.6%
Effective Sample Size	28597	26080	23763	21736	19320	16189	12590	6038	168

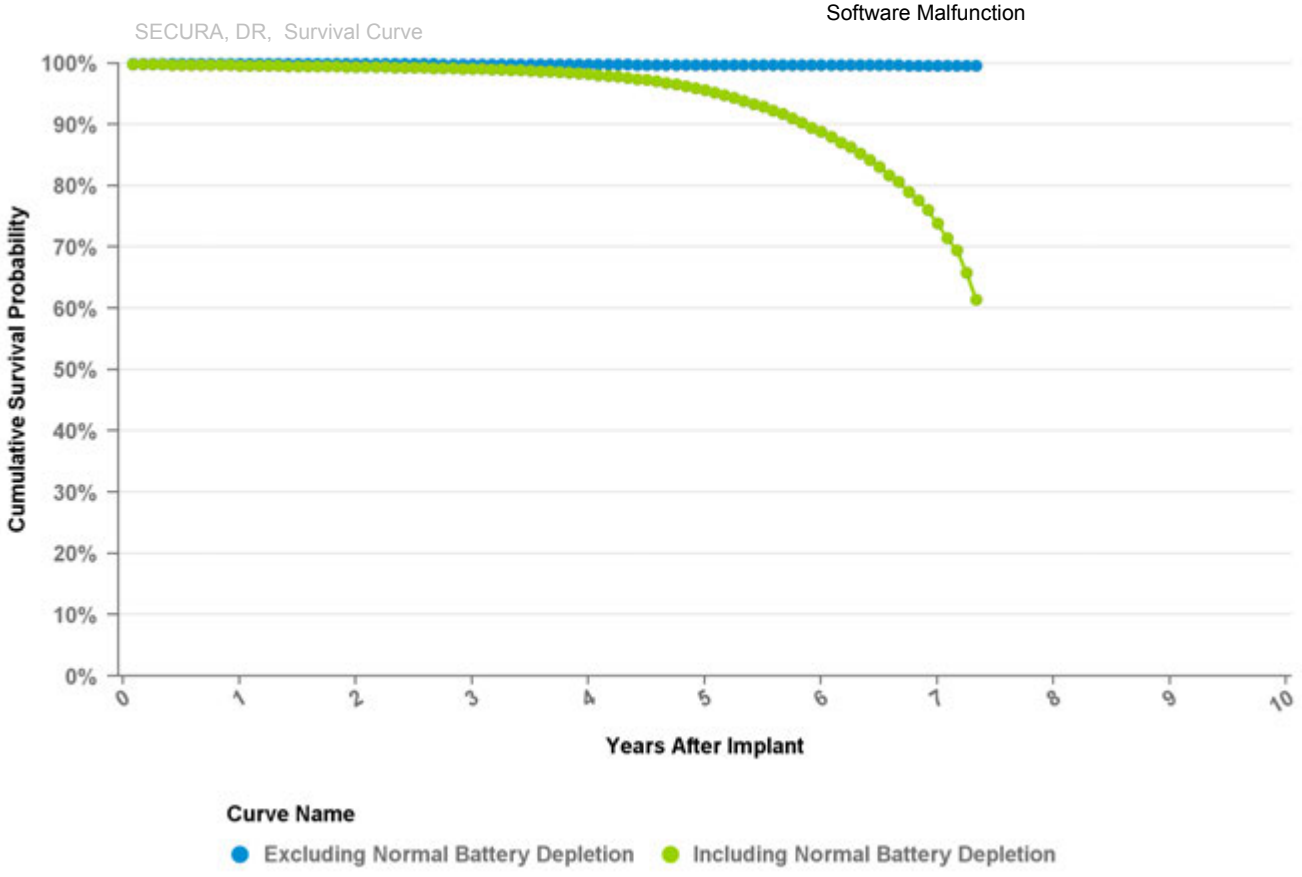
Implantable Cardioverter Defibrillator

D204DRM Secura DR

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	1,877
Estimated Active US Implants	1,591
Normal Battery Depletions (US)	5

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.8%	73.9%	61.5%
Effective Sample Size	45277	42395	39311	34437	28028	13991	2773	512

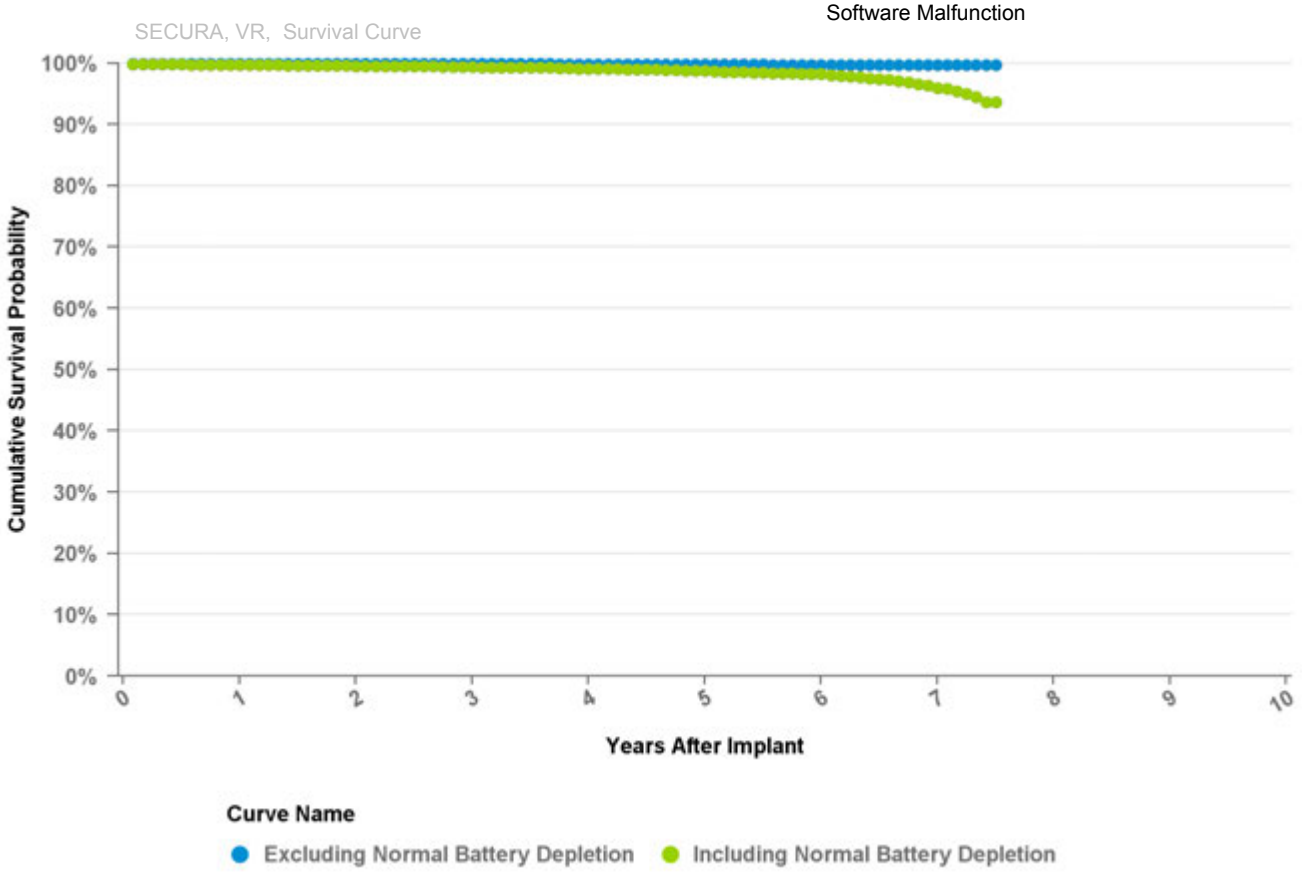
Implantable Cardioverter Defibrillator

D204VRM Secura VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	1,172
Estimated Active US Implants	1,006
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	95.9%	93.6%
Effective Sample Size	18185	16975	15596	13296	10684	6236	1983	312

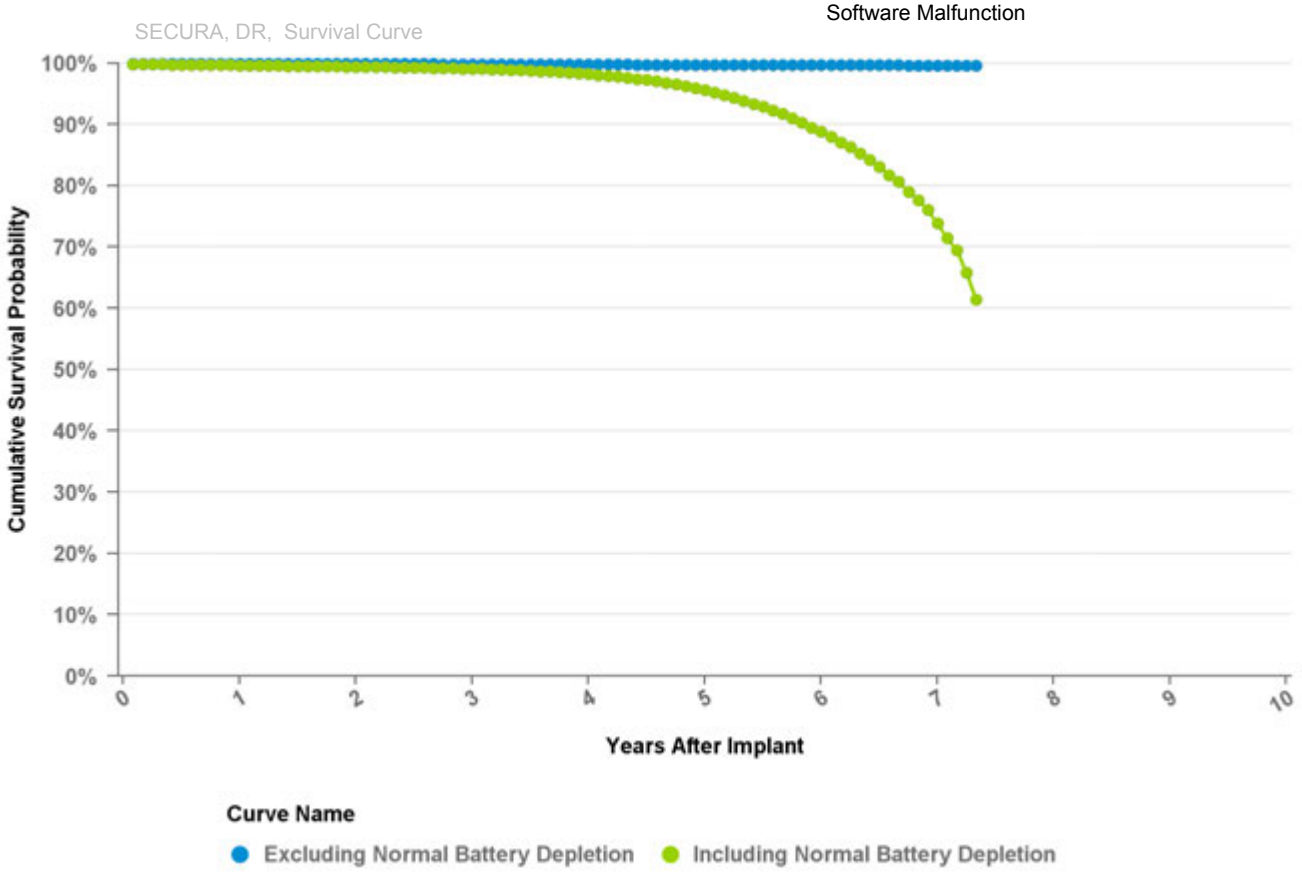
Implantable Cardioverter Defibrillator

D214DRM Secura DR

US Market Release Date	
CE Market Approval Date	7/22/2010
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.8%	73.9%	61.5%
Effective Sample Size	45277	42395	39311	34437	28028	13991	2773	512

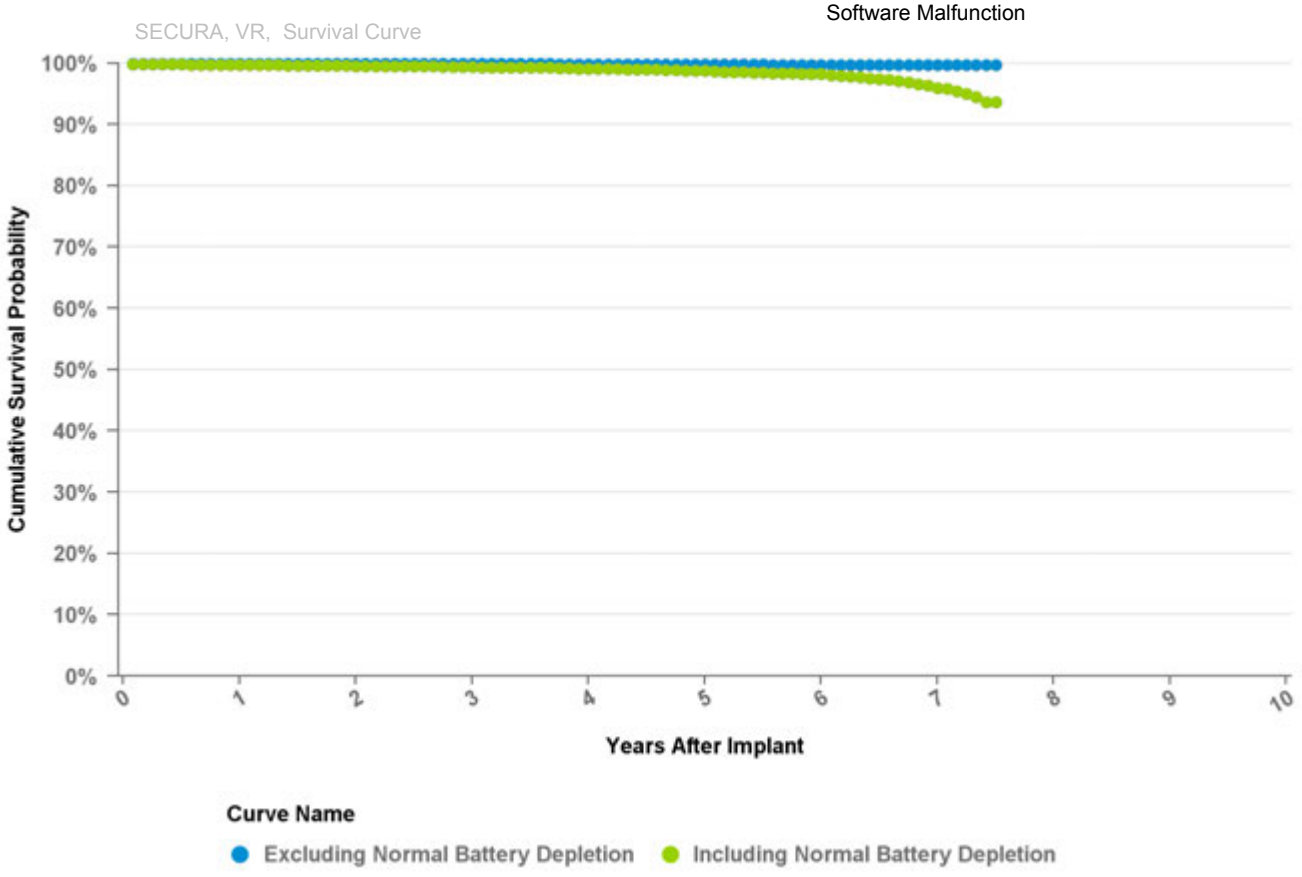
Implantable Cardioverter Defibrillator

D214VRM Secura VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	95.9%	93.6%
Effective Sample Size	18185	16975	15596	13296	10684	6236	1983	312

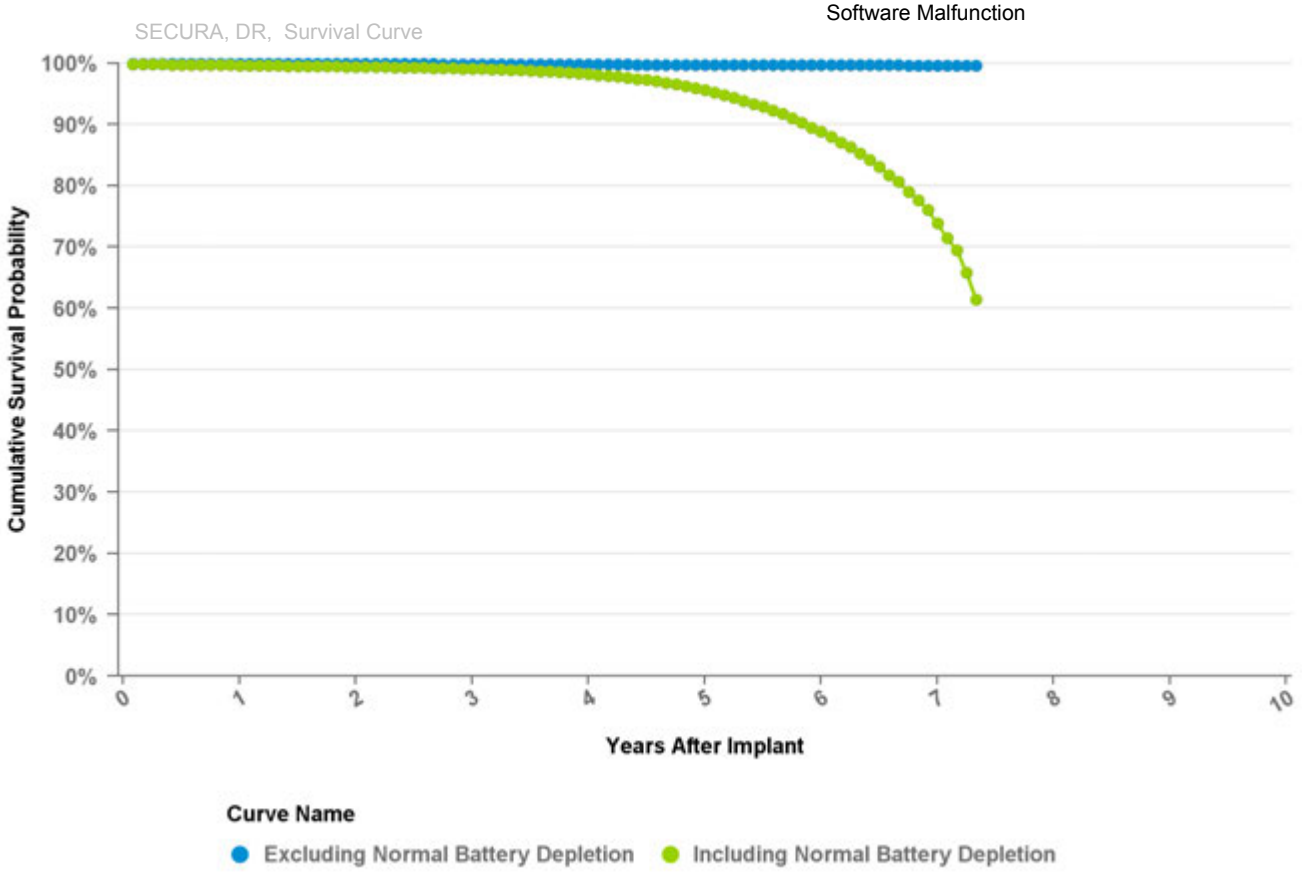
Implantable Cardioverter Defibrillator

D224DRG Secura DR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	49,849
Estimated Active US Implants	28,406
Normal Battery Depletions (US)	2,721

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	109
Therapy Not Compromised Malfunctions	93
Battery Malfunction	2
Electrical Component	31
Electrical Interconnect	0
Other Malfunction	3
Poss Early Battery Depltn	48
Software Malfunction	9
Therapy Compromised Malfunctions	16
Battery Malfunction	1
Electrical Component	13
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.8%	73.9%	61.5%
Effective Sample Size	45277	42395	39311	34437	28028	13991	2773	512

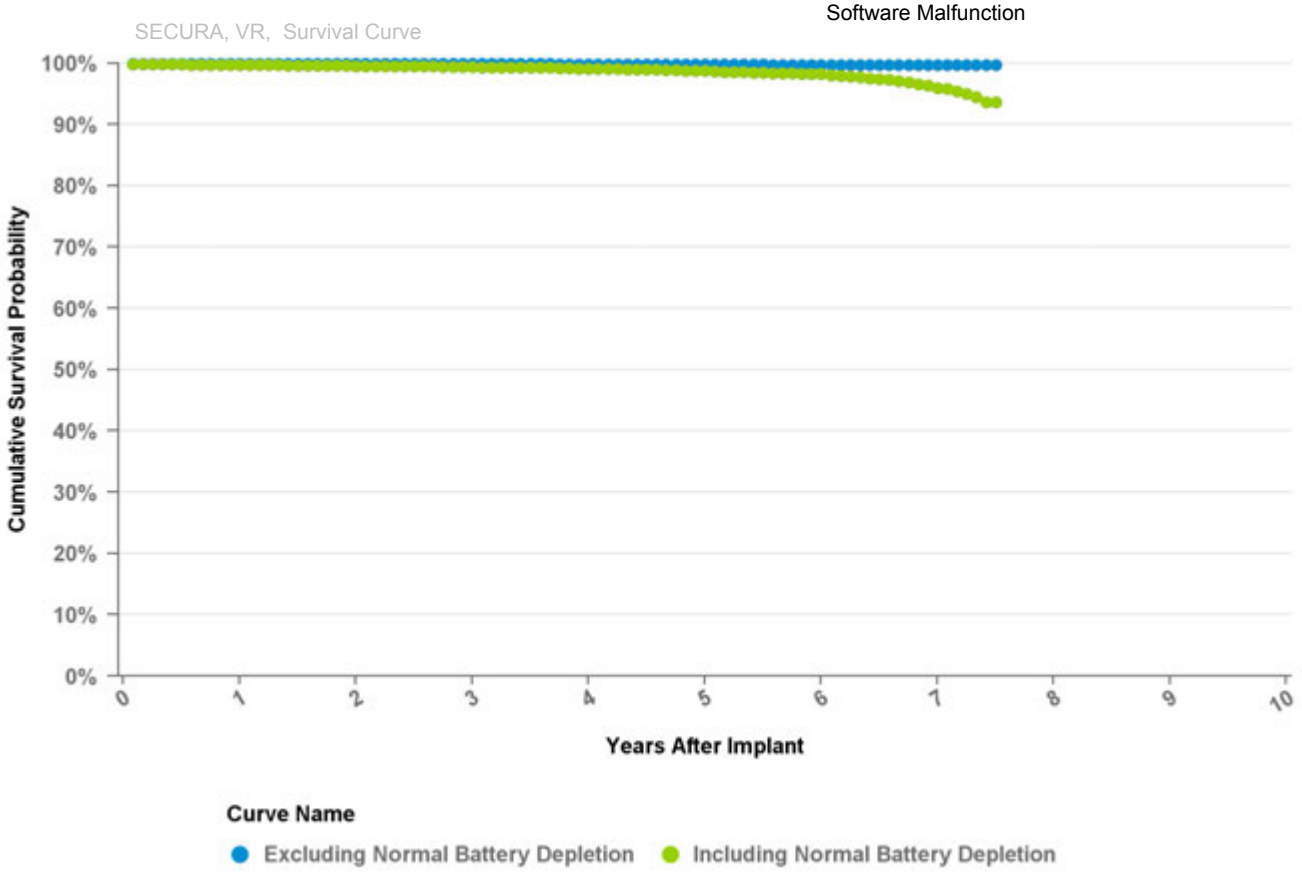
Implantable Cardioverter Defibrillator

D224VRC Secura VR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	19,937
Estimated Active US Implants	13,356
Normal Battery Depletions (US)	168

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	33
Therapy Not Compromised Malfunctions	27
Battery Malfunction	8
Electrical Component	8
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	8
Software Malfunction	2
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	1



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	95.9%	93.6%
Effective Sample Size	18185	16975	15596	13296	10684	6236	1983	312

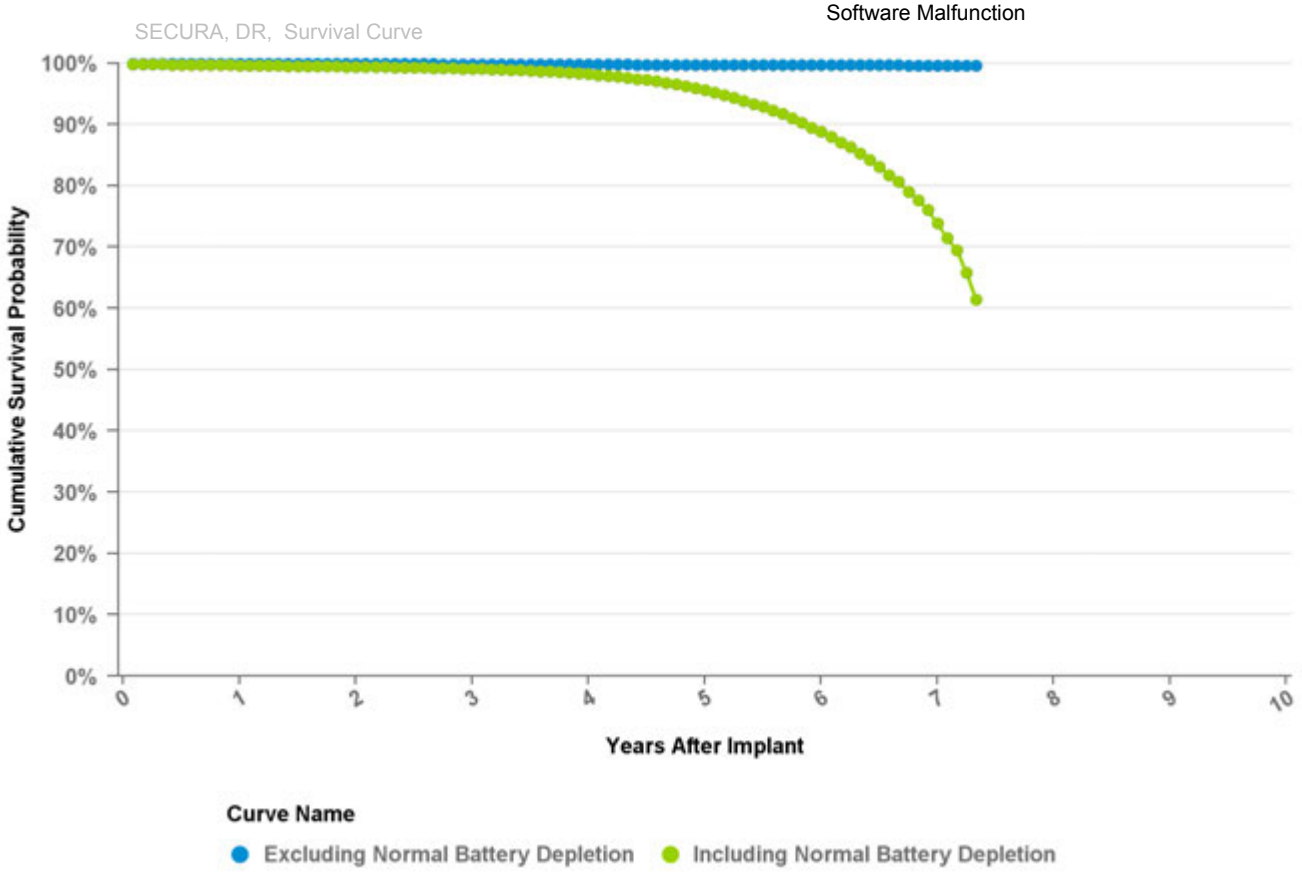
Implantable Cardioverter Defibrillator

D234DRG Secura DR

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.8%	73.9%	61.5%
Effective Sample Size	45277	42395	39311	34437	28028	13991	2773	512

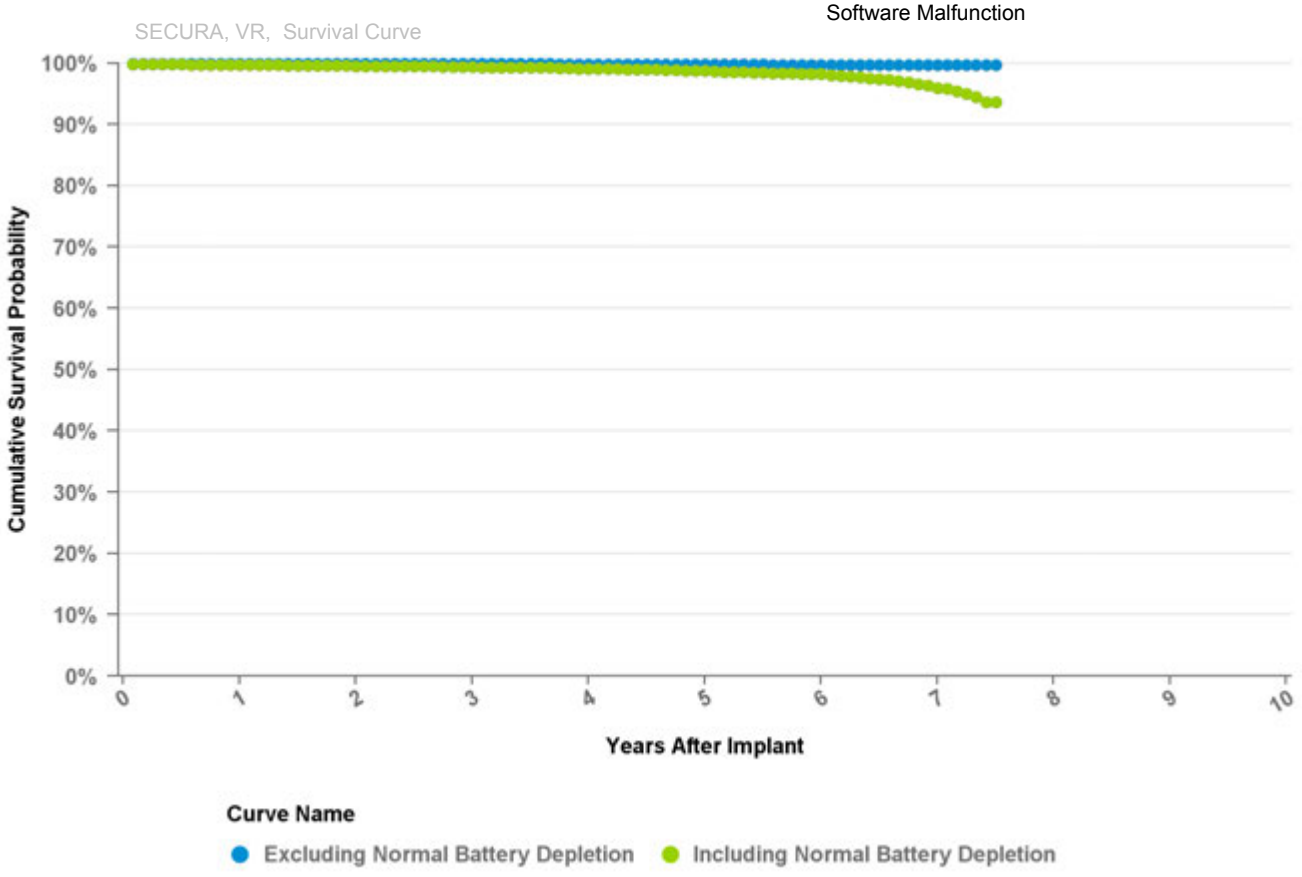
Implantable Cardioverter Defibrillator

D234VRC Secura VR

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	95.9%	93.6%
Effective Sample Size	18185	16975	15596	13296	10684	6236	1983	312

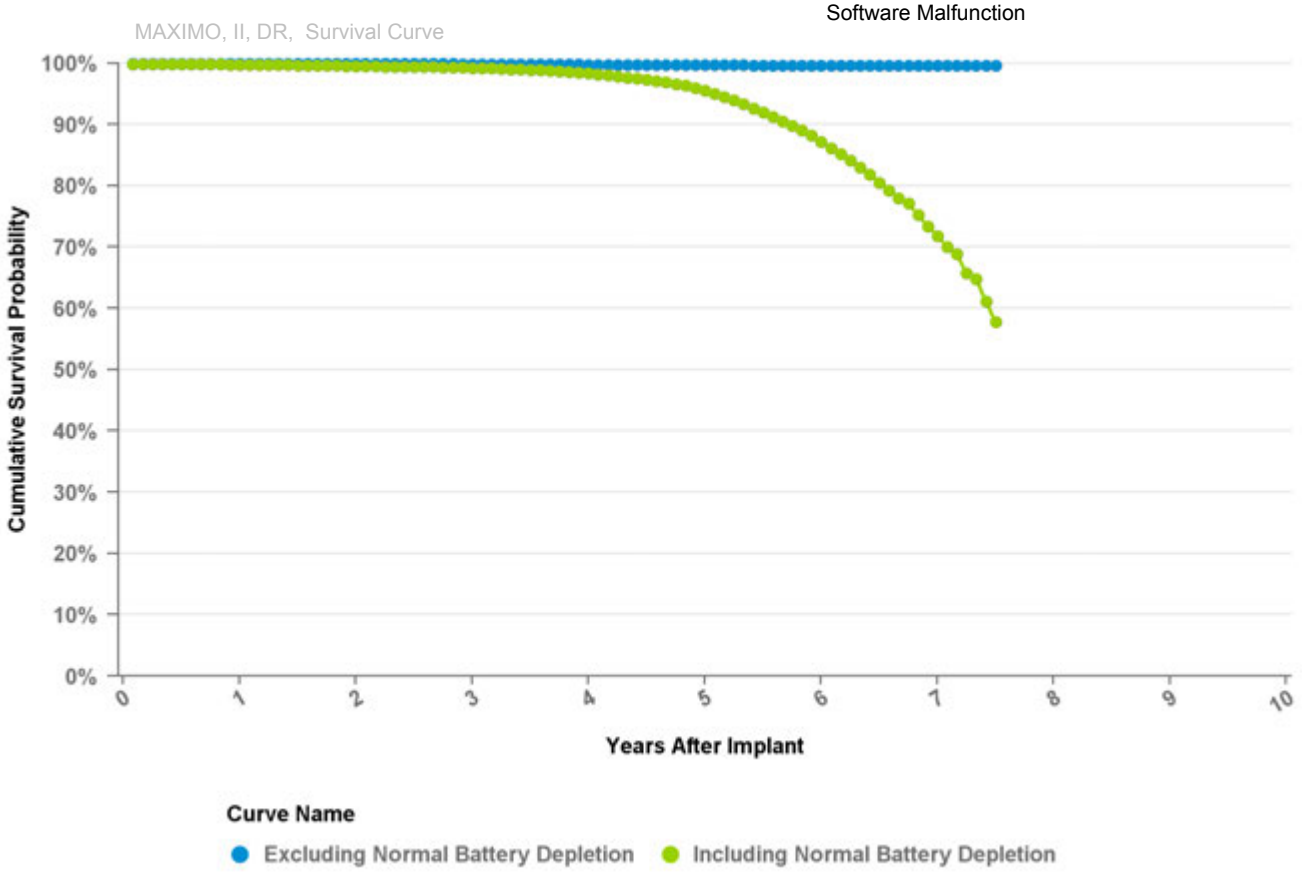
Implantable Cardioverter Defibrillator

D264DRM Maximo II DR

US Market Release Date	1/9/2012
CE Market Approval Date	7/22/2010
Registered US Implants	6
Estimated Active US Implants	5
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%
Including NBD	99.8%	99.5%	99.2%	98.3%	95.5%	87.2%	71.9%	57.8%
Effective Sample Size	17535	16374	15153	13213	10296	5789	1485	109

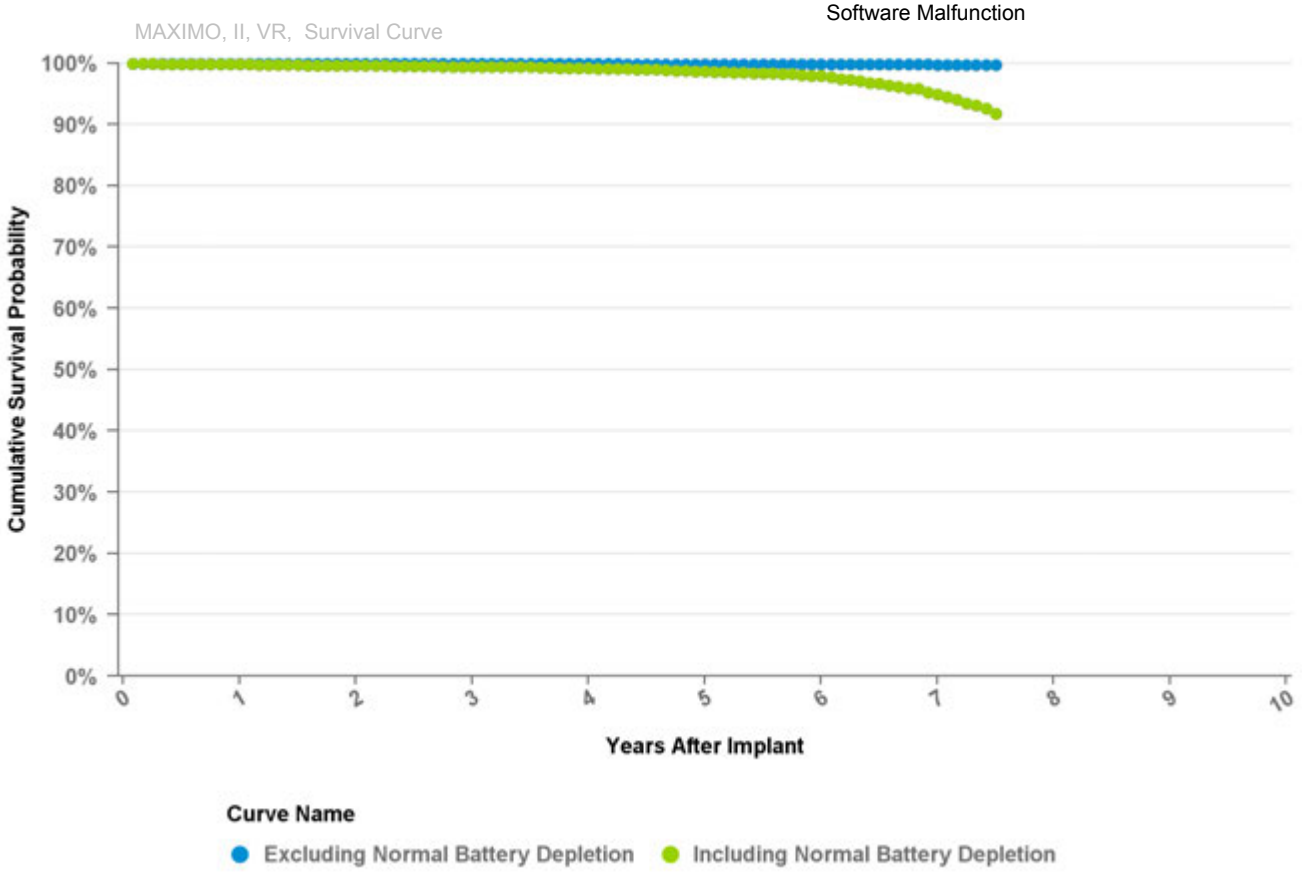
Implantable Cardioverter Defibrillator

D264VRM Maximo II VR

US Market Release Date	5/2/2012
CE Market Approval Date	12/17/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.7%	97.9%	94.9%	91.8%
Effective Sample Size	11178	10477	9637	8323	6555	4035	1333	211

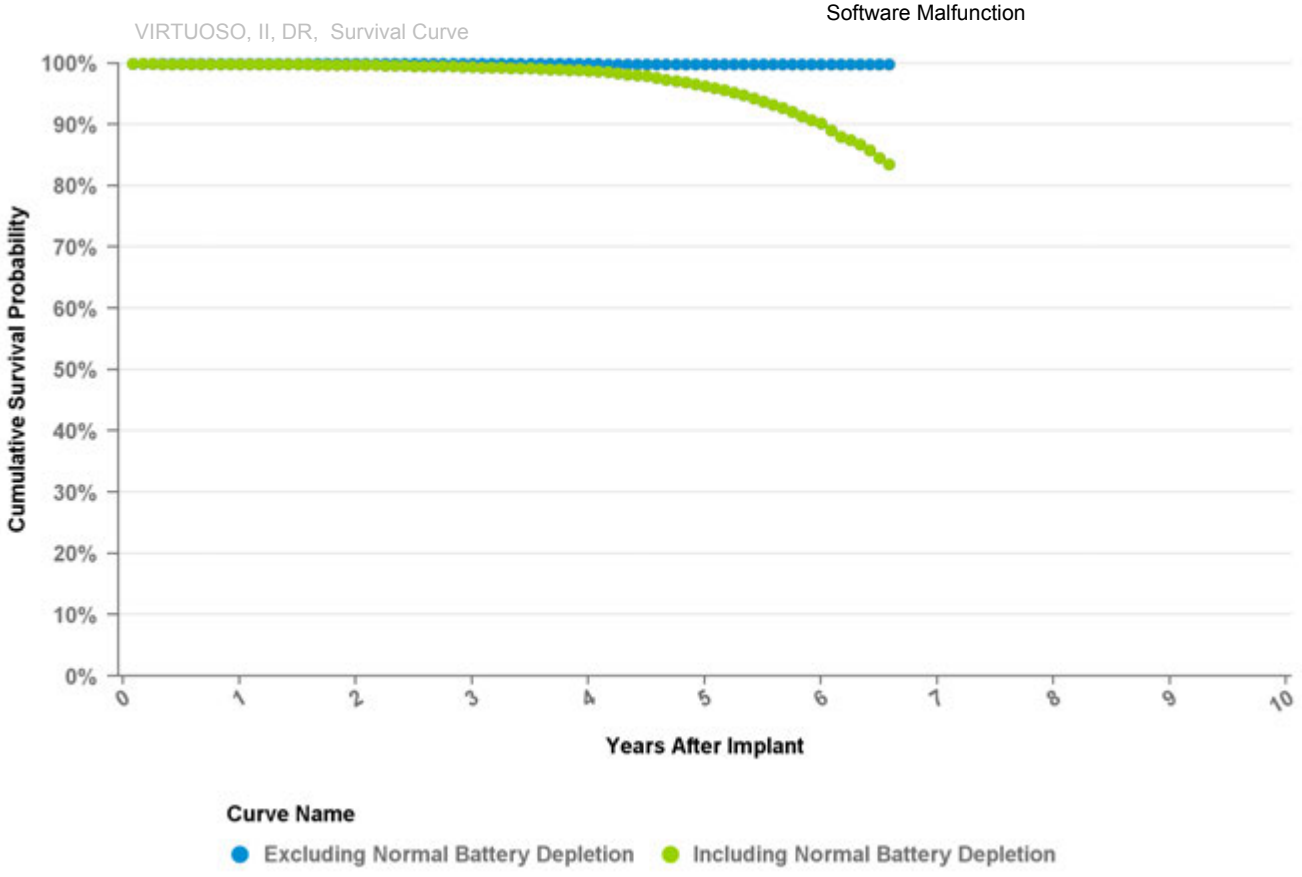
Implantable Cardioverter Defibrillator

D274DRG Virtuoso II DR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	22,228
Estimated Active US Implants	13,498
Normal Battery Depletions (US)	796

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	25
Therapy Not Compromised Malfunctions	22
Battery Malfunction	4
Electrical Component	10
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	7
Software Malfunction	1
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%
Including NBD	99.9%	99.7%	99.4%	98.8%	96.3%	90.2%	83.5%
Effective Sample Size	19323	18151	17088	15874	12985	4978	452

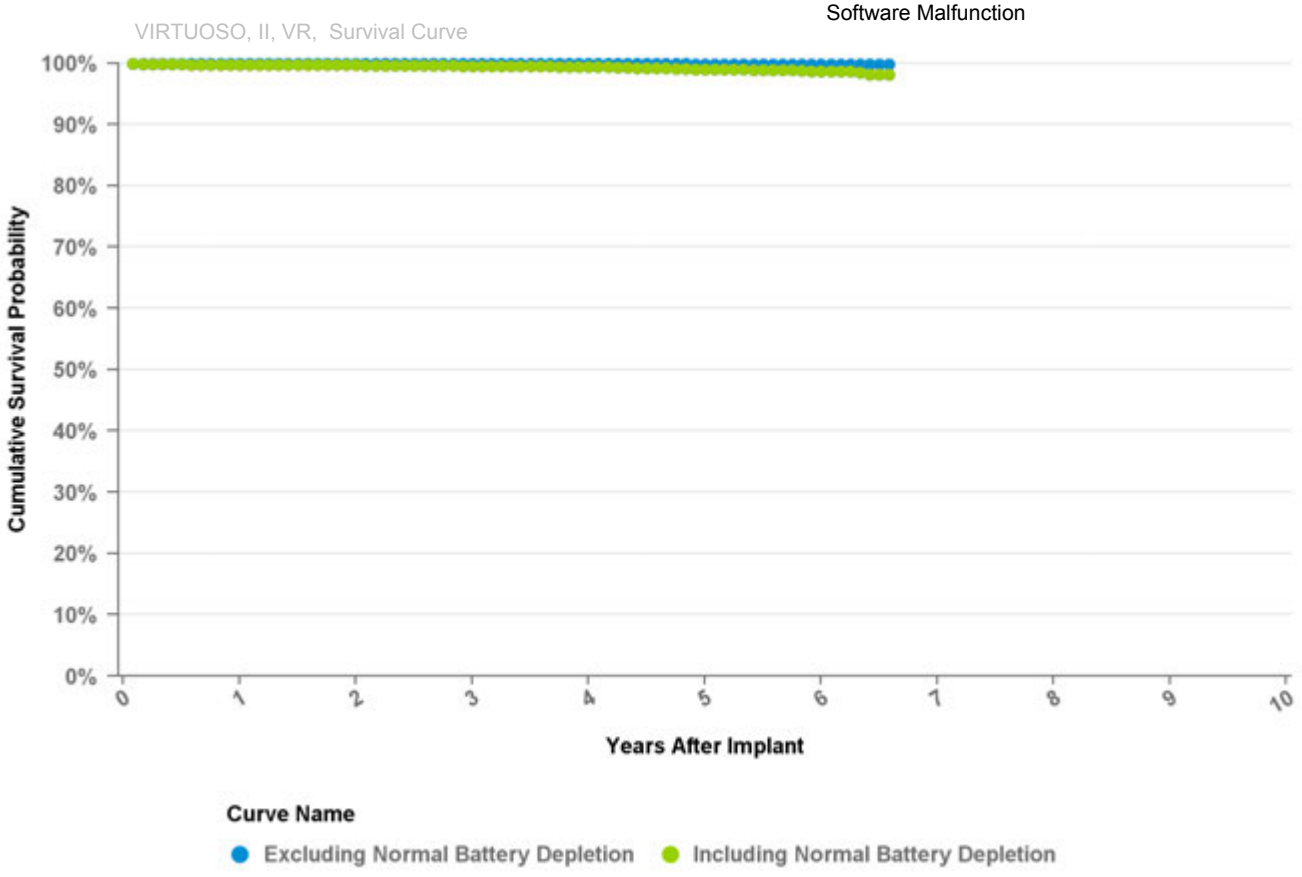
Implantable Cardioverter Defibrillator

D274VRC Virtuoso II VR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	9,115
Estimated Active US Implants	6,364
Normal Battery Depletions (US)	41

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	10
Battery Malfunction	5
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	1
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.0%	98.7%	98.2%
Effective Sample Size	7784	7309	6900	6420	5299	2142	190

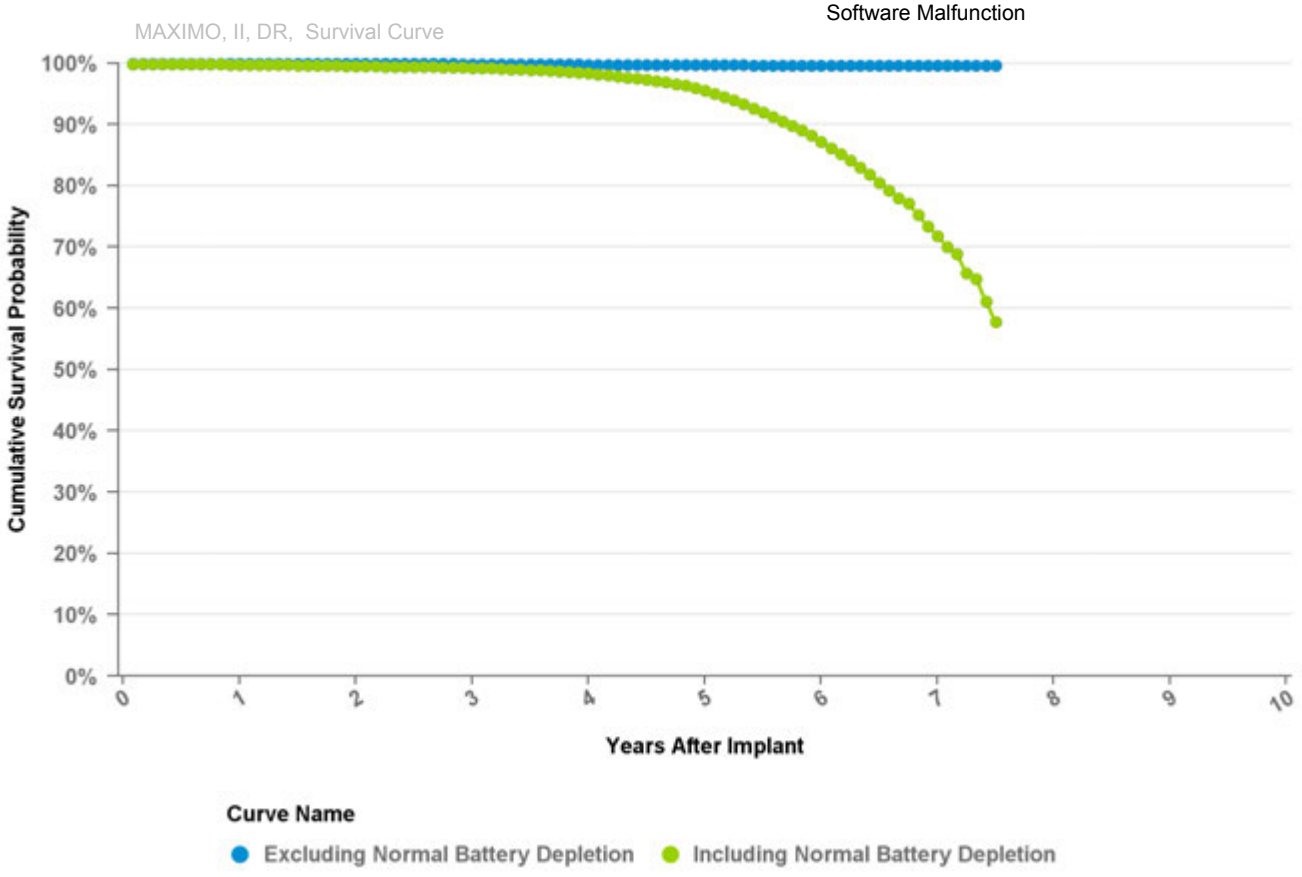
Implantable Cardioverter Defibrillator

D284DRG Maximo II DR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	20,048
Estimated Active US Implants	11,145
Normal Battery Depletions (US)	1,320

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	48
Therapy Not Compromised Malfunctions	42
Battery Malfunction	1
Electrical Component	11
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	30
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%
Including NBD	99.8%	99.5%	99.2%	98.3%	95.5%	87.2%	71.9%	57.8%
Effective Sample Size	17535	16374	15153	13213	10296	5789	1485	109

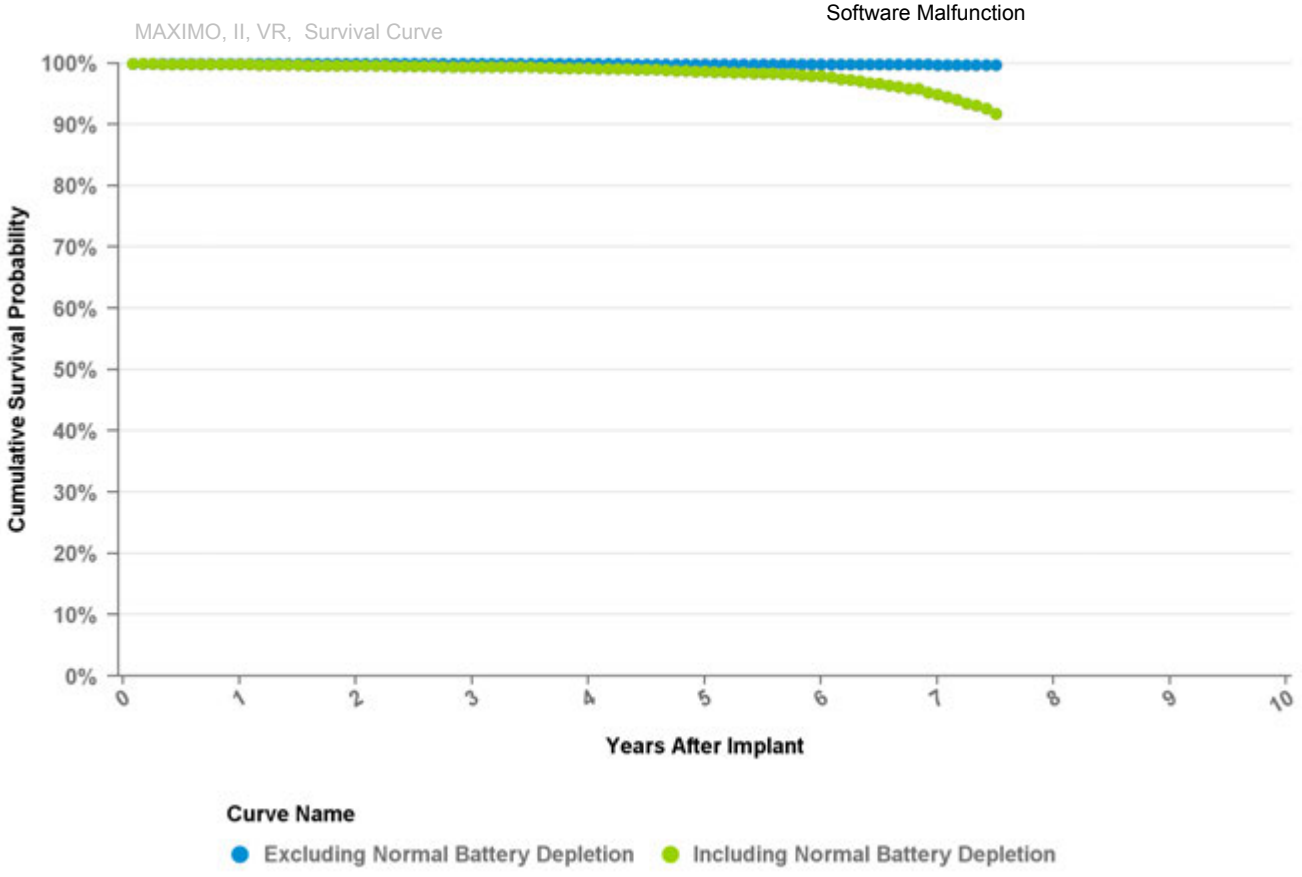
Implantable Cardioverter Defibrillator

D284VRC Maximo II VR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	12,963
Estimated Active US Implants	8,853
Normal Battery Depletions (US)	151

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	17
Therapy Not Compromised Malfunctions	13
Battery Malfunction	3
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	3
Software Malfunction	3
Therapy Compromised Malfunctions	4
Battery Malfunction	1
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	1



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.7%	97.9%	94.9%	91.8%
Effective Sample Size	11178	10477	9637	8323	6555	4035	1333	211

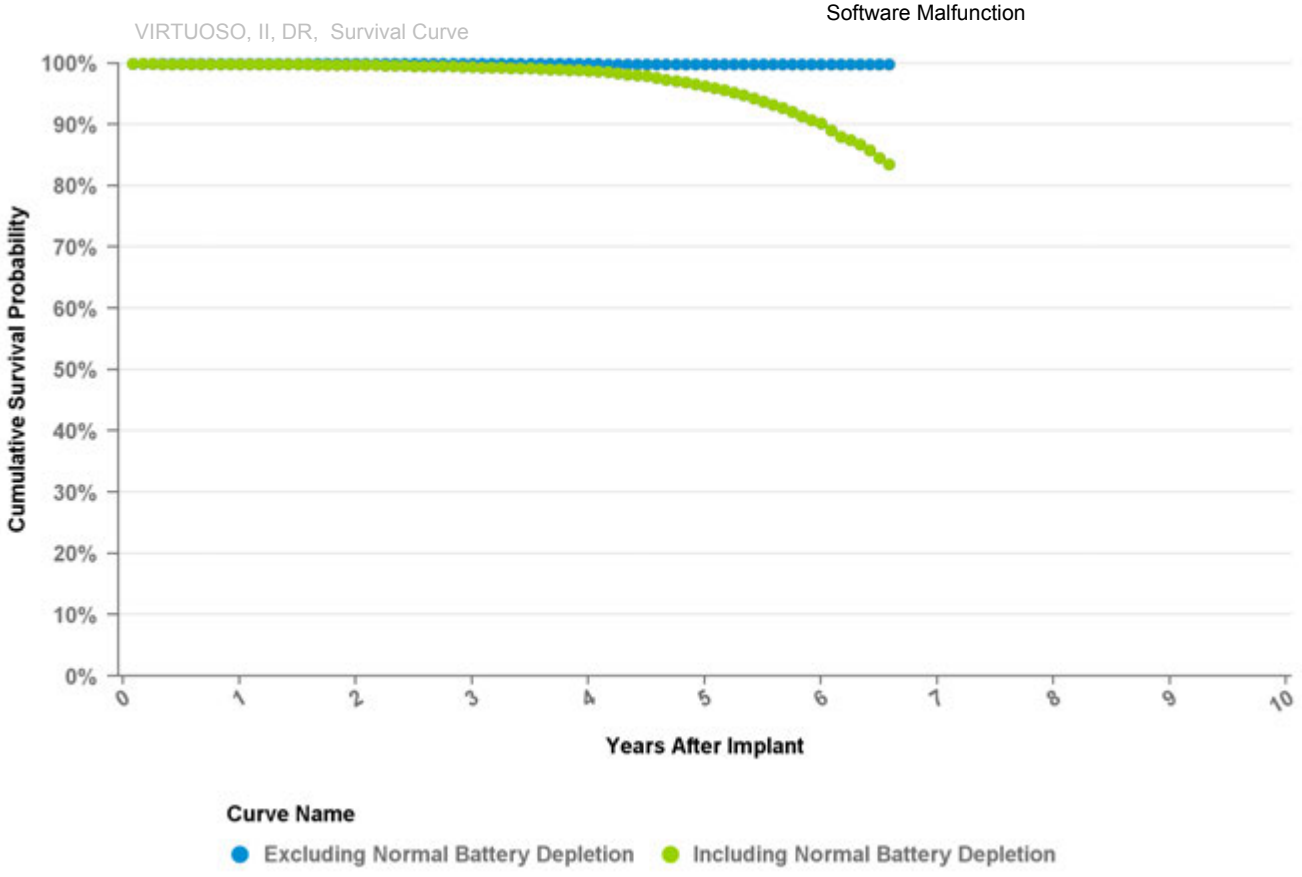
Implantable Cardioverter Defibrillator

D294DRG Virtuoso II DR

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%
Including NBD	99.9%	99.7%	99.4%	98.8%	96.3%	90.2%	83.5%
Effective Sample Size	19323	18151	17088	15874	12985	4978	452

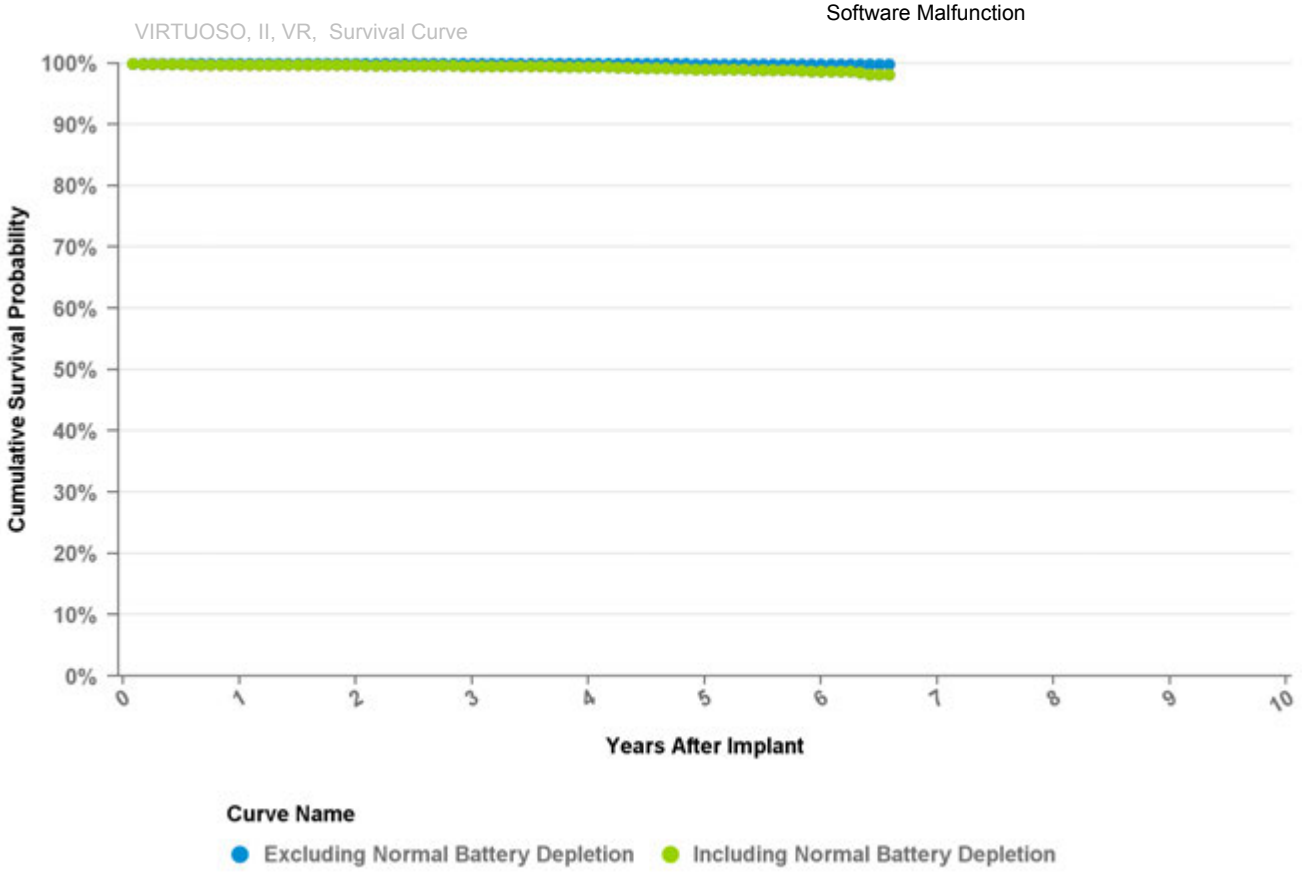
Implantable Cardioverter Defibrillator

D294VRC Virtuoso II VR

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.0%	98.7%	98.2%
Effective Sample Size	7784	7309	6900	6420	5299	2142	190

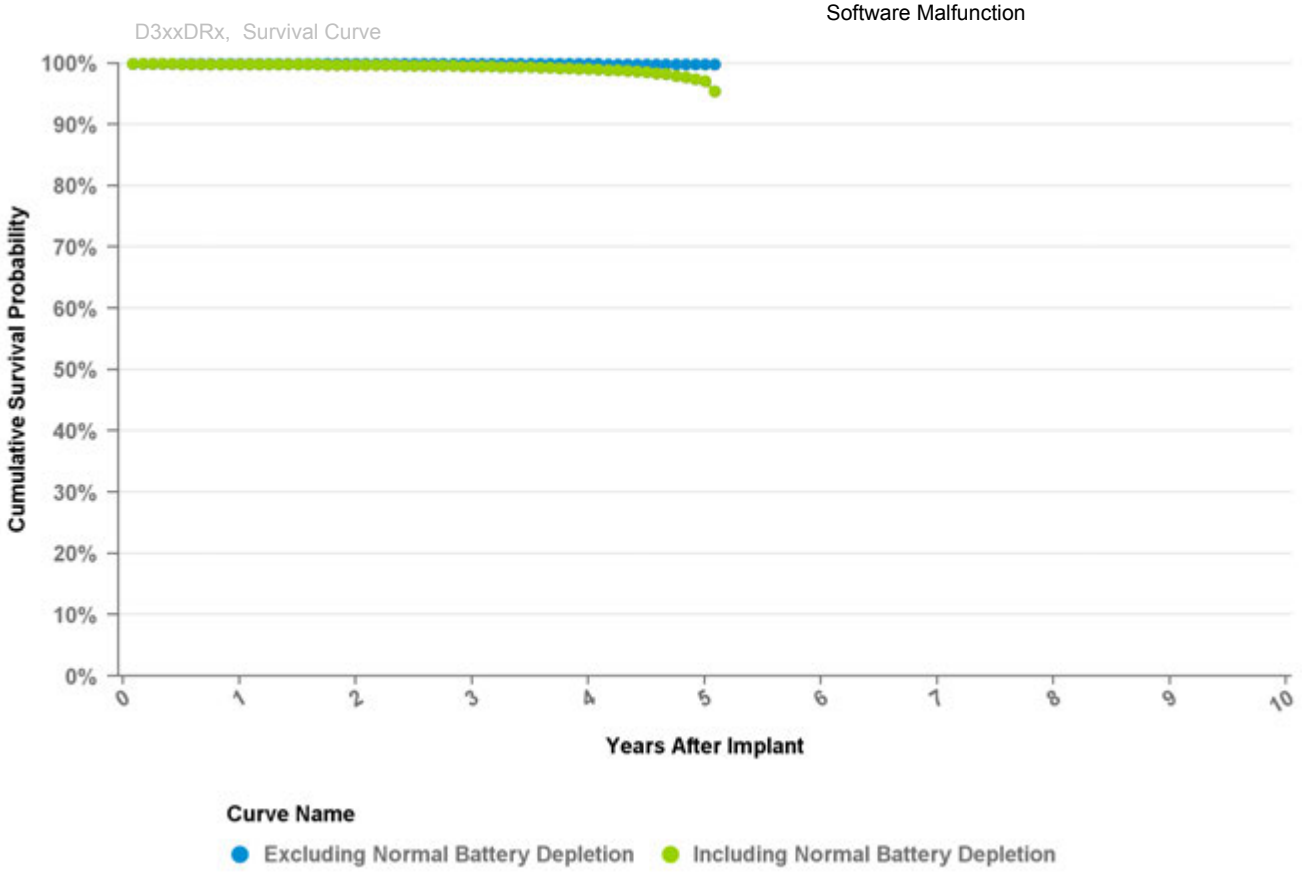
Implantable Cardioverter Defibrillator

D314DRG Protecta XT DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	34,755
Estimated Active US Implants	27,778
Normal Battery Depletions (US)	183

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	30
Therapy Not Compromised Malfunctions	24
Battery Malfunction	2
Electrical Component	20
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

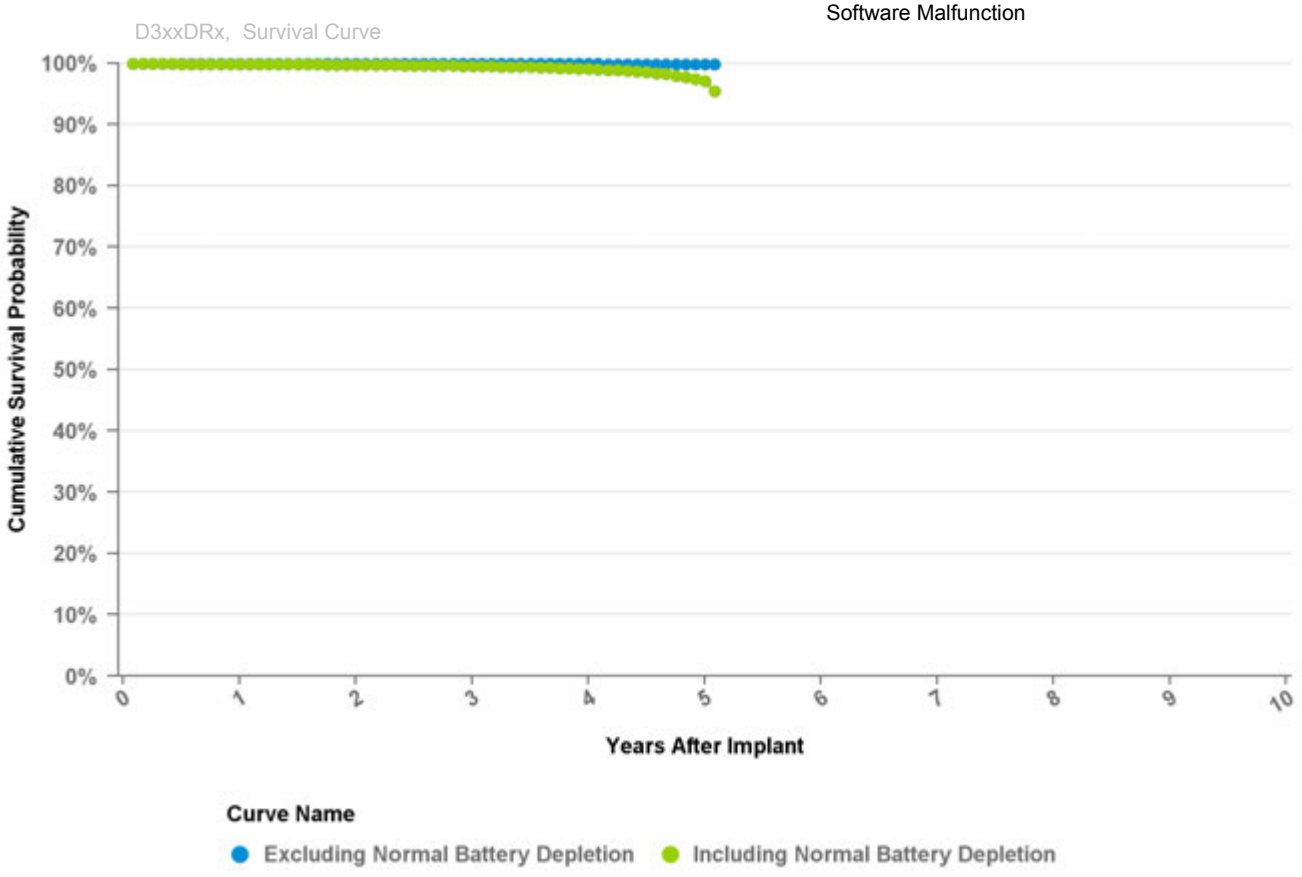
Implantable Cardioverter Defibrillator

D314DRM Protecta XT DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	13,881
Estimated Active US Implants	11,876
Normal Battery Depletions (US)	29

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	11
Therapy Not Compromised Malfunctions	11
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

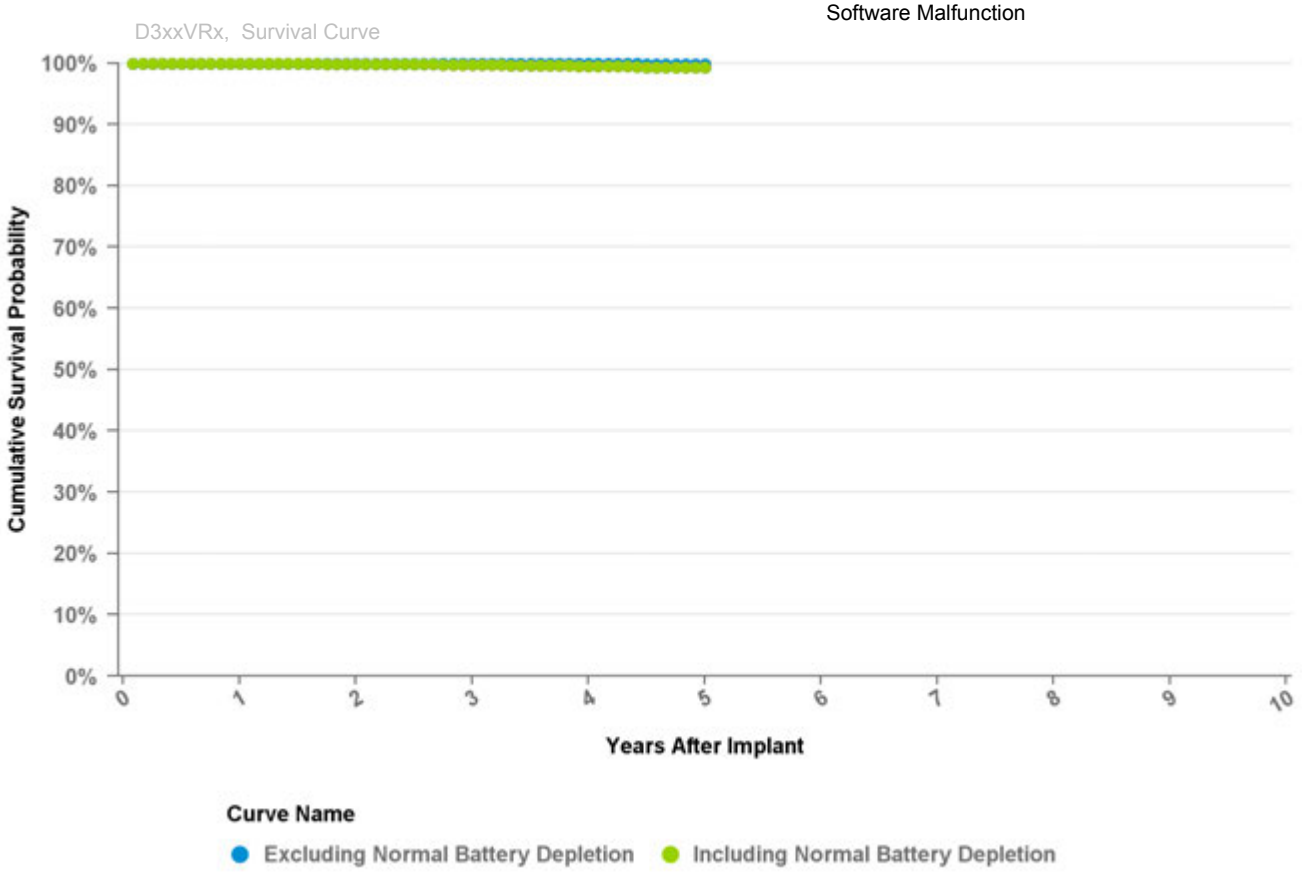
Implantable Cardioverter Defibrillator

D314VRG Protecta XT VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	14,173
Estimated Active US Implants	11,600
Normal Battery Depletions (US)	27

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	9
Therapy Not Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

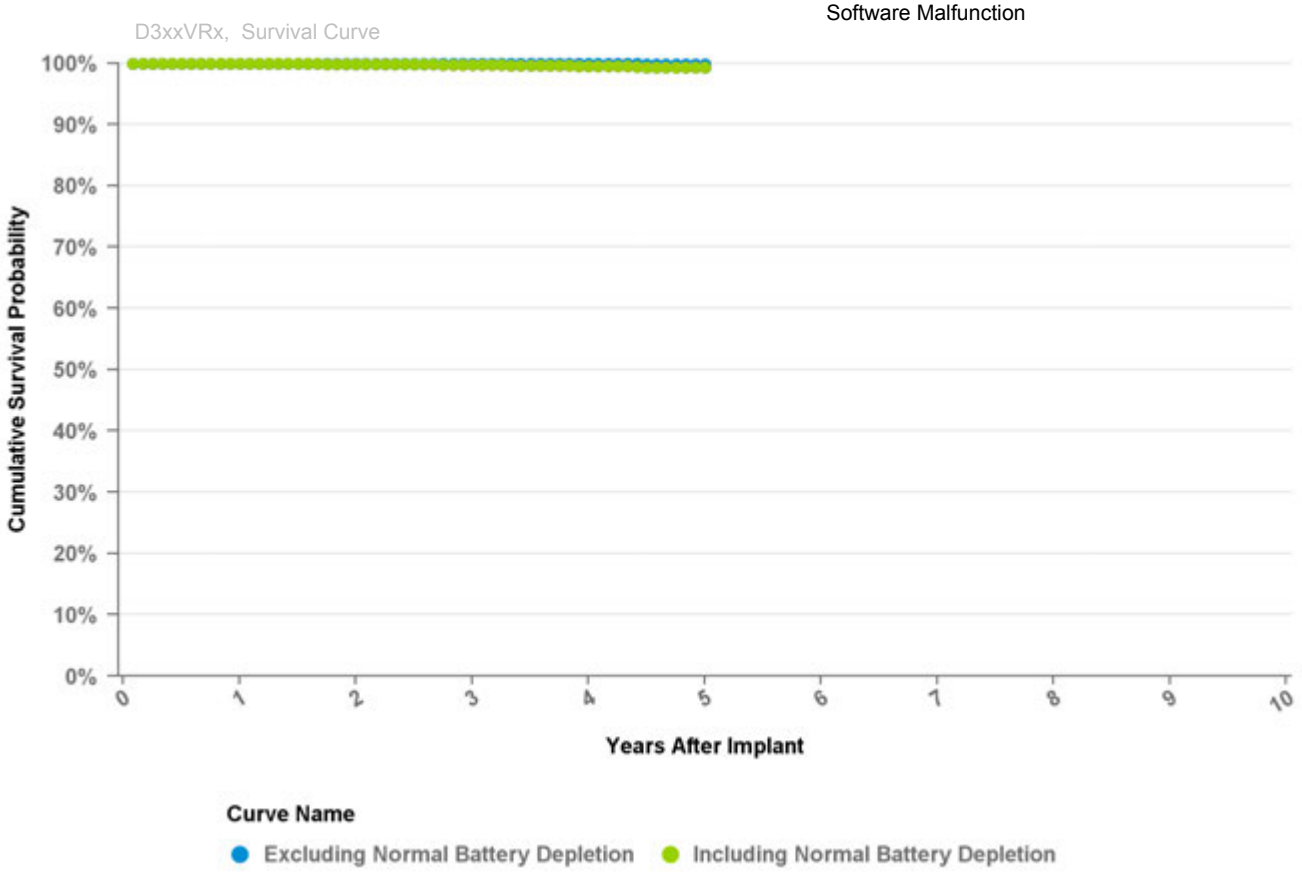
Implantable Cardioverter Defibrillator

D314VRM Protecta XT VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	7,356
Estimated Active US Implants	6,282
Normal Battery Depletions (US)	7

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

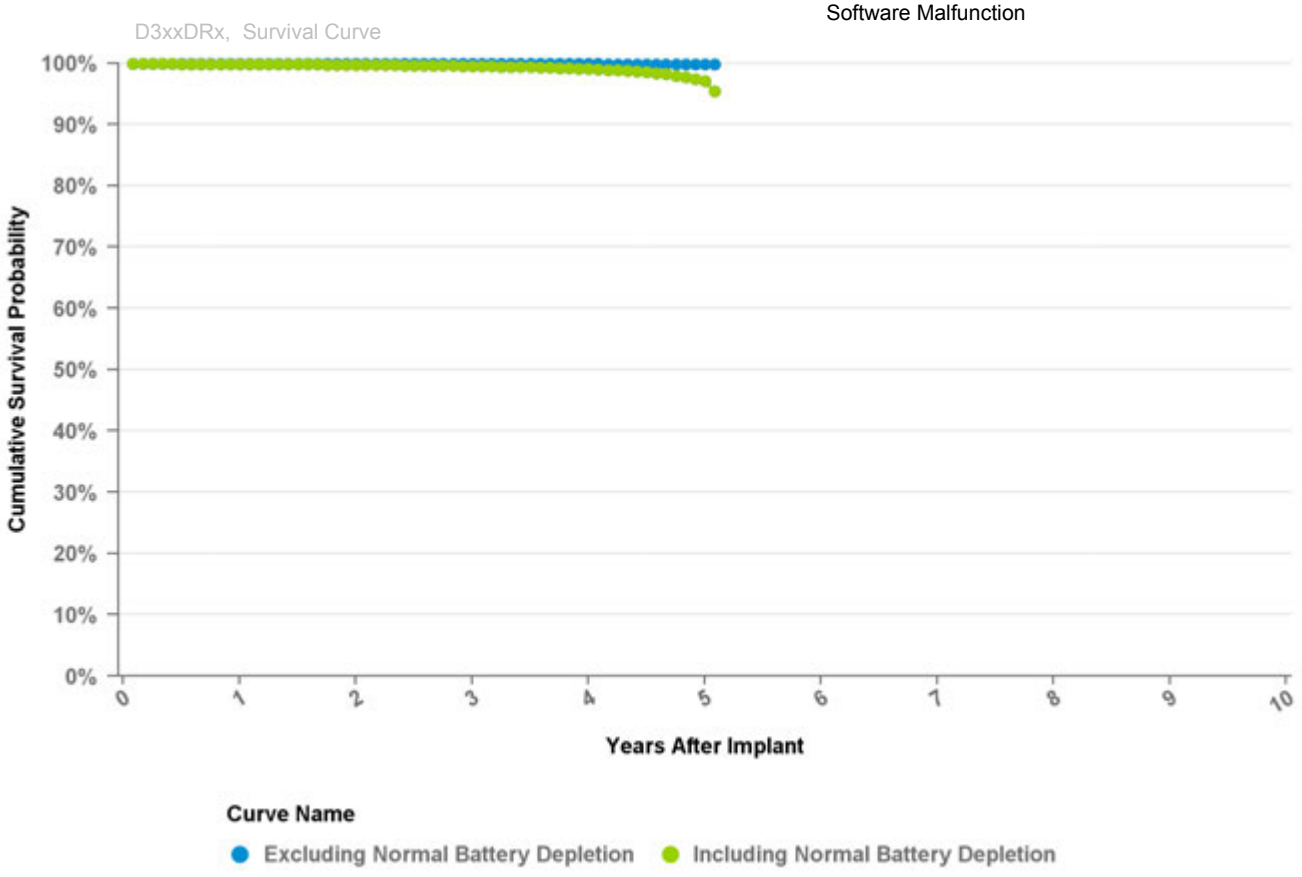
Implantable Cardioverter Defibrillator

D334DRG Protecta DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	10,681
Estimated Active US Implants	8,697
Normal Battery Depletions (US)	59

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	8
Therapy Not Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

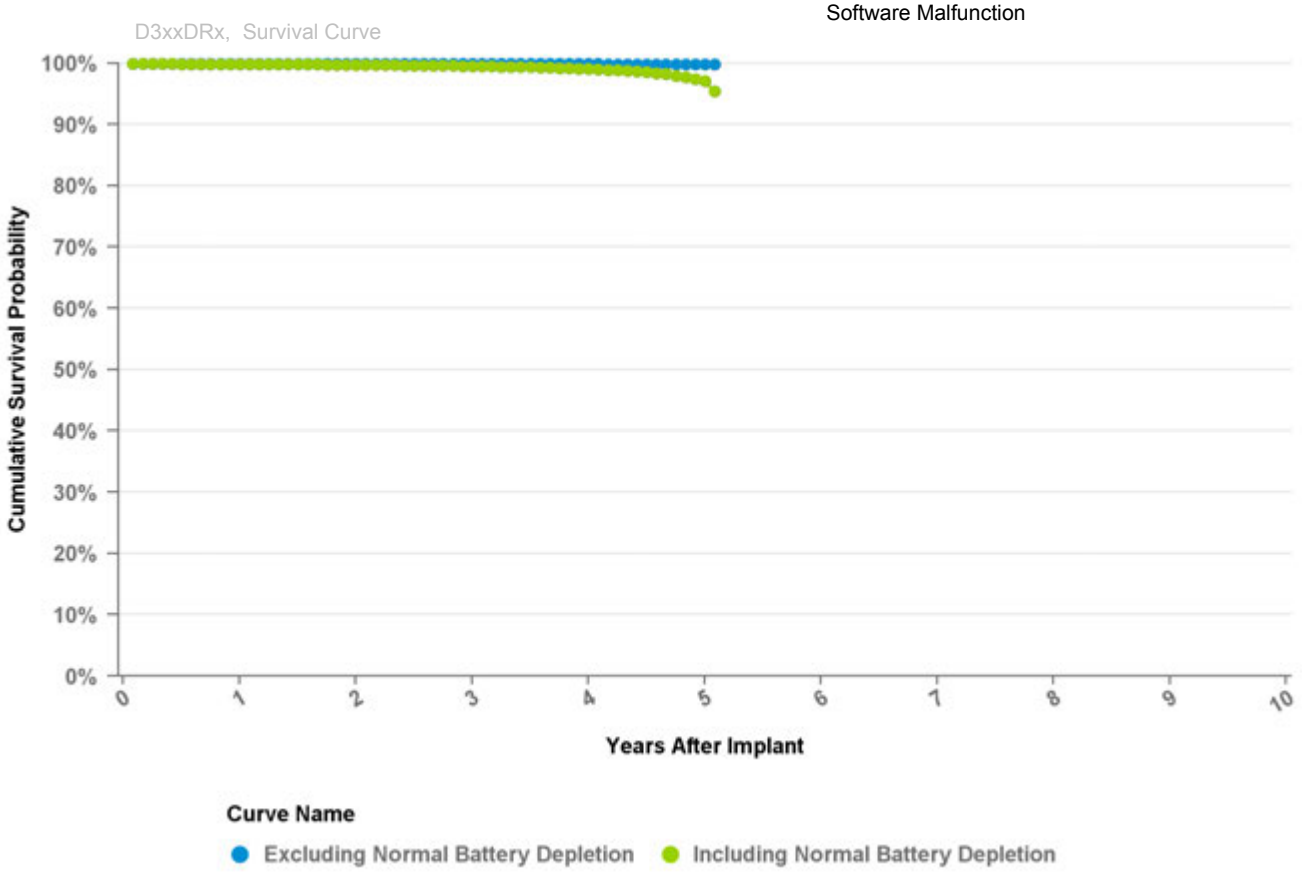
Implantable Cardioverter Defibrillator

D334DRM Protecta DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	2,983
Estimated Active US Implants	2,616
Normal Battery Depletions (US)	6

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

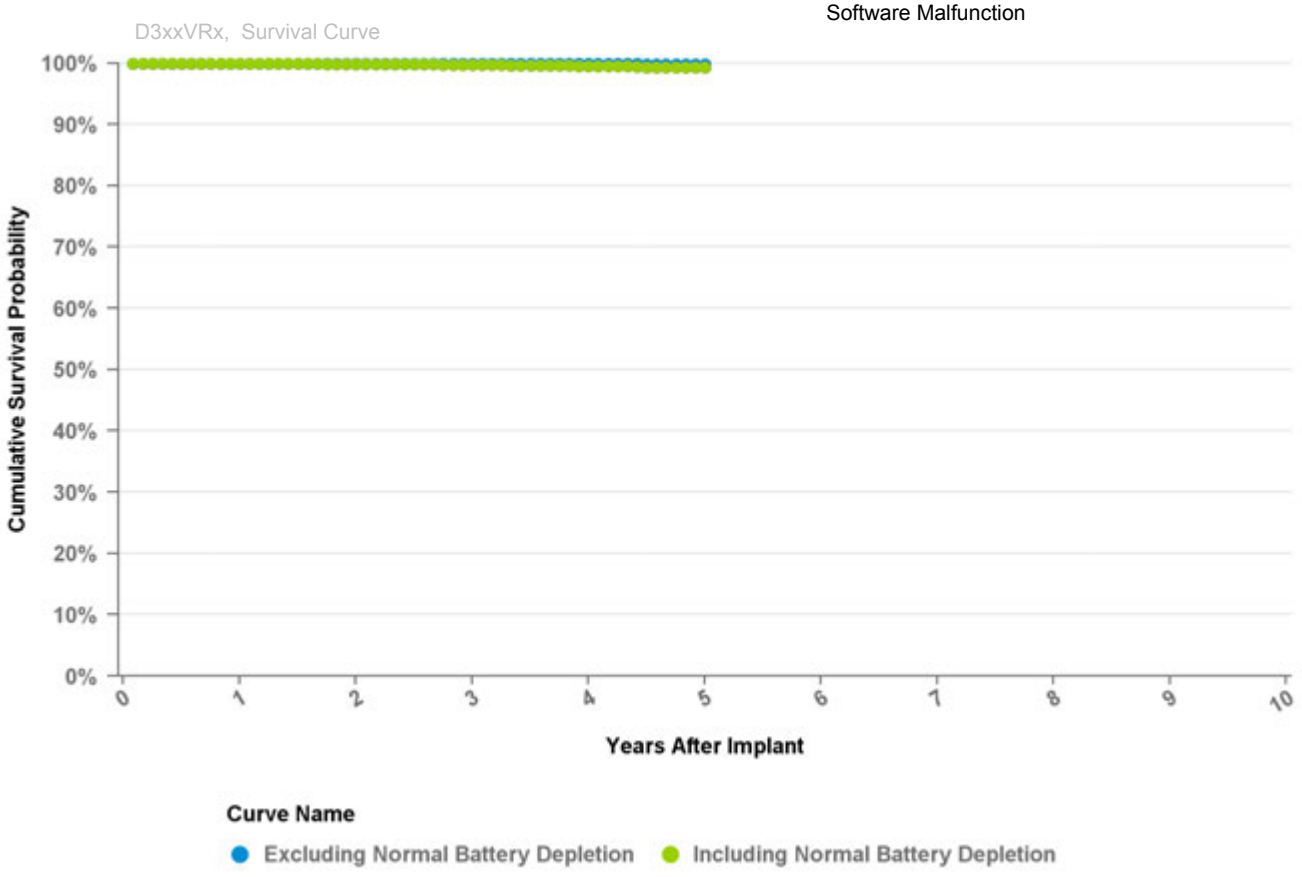
Implantable Cardioverter Defibrillator

D334VRG Protecta VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	6,471
Estimated Active US Implants	5,377
Normal Battery Depletions (US)	10

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	4
Battery Malfunction	1
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

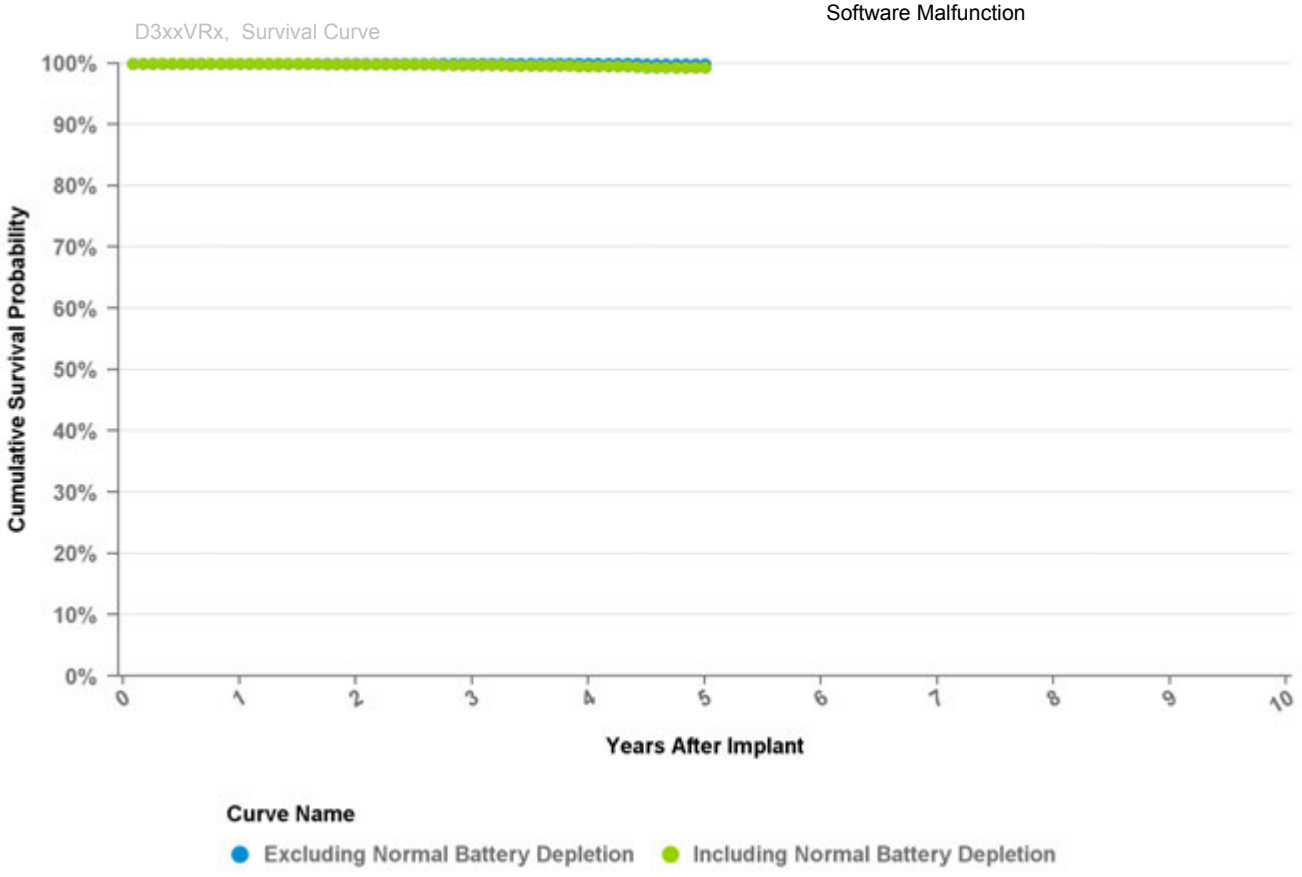
Implantable Cardioverter Defibrillator

D334VRM Protecta VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	2,154
Estimated Active US Implants	1,874
Normal Battery Depletions (US)	1

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

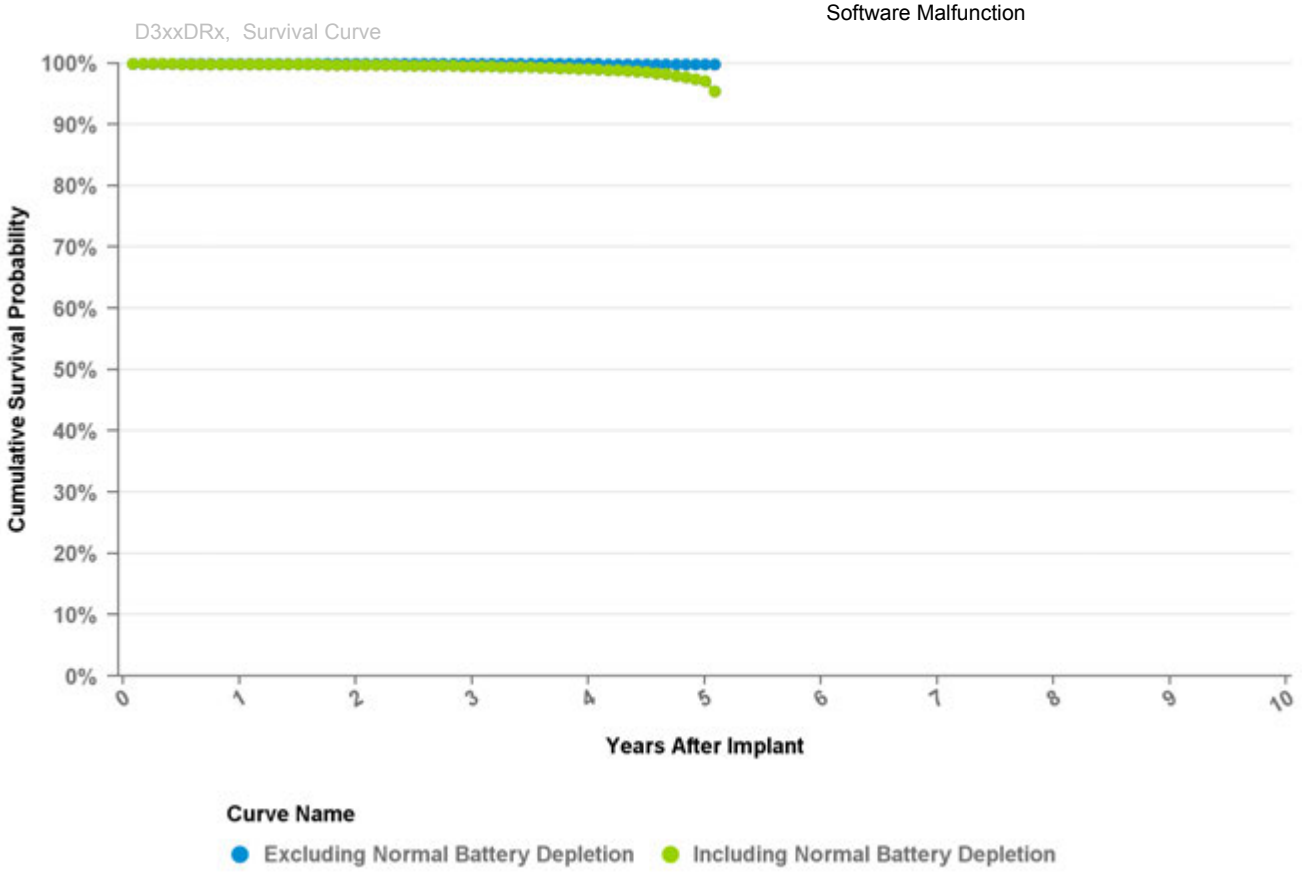
Implantable Cardioverter Defibrillator

D354DRG Protecta XT DR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	2
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

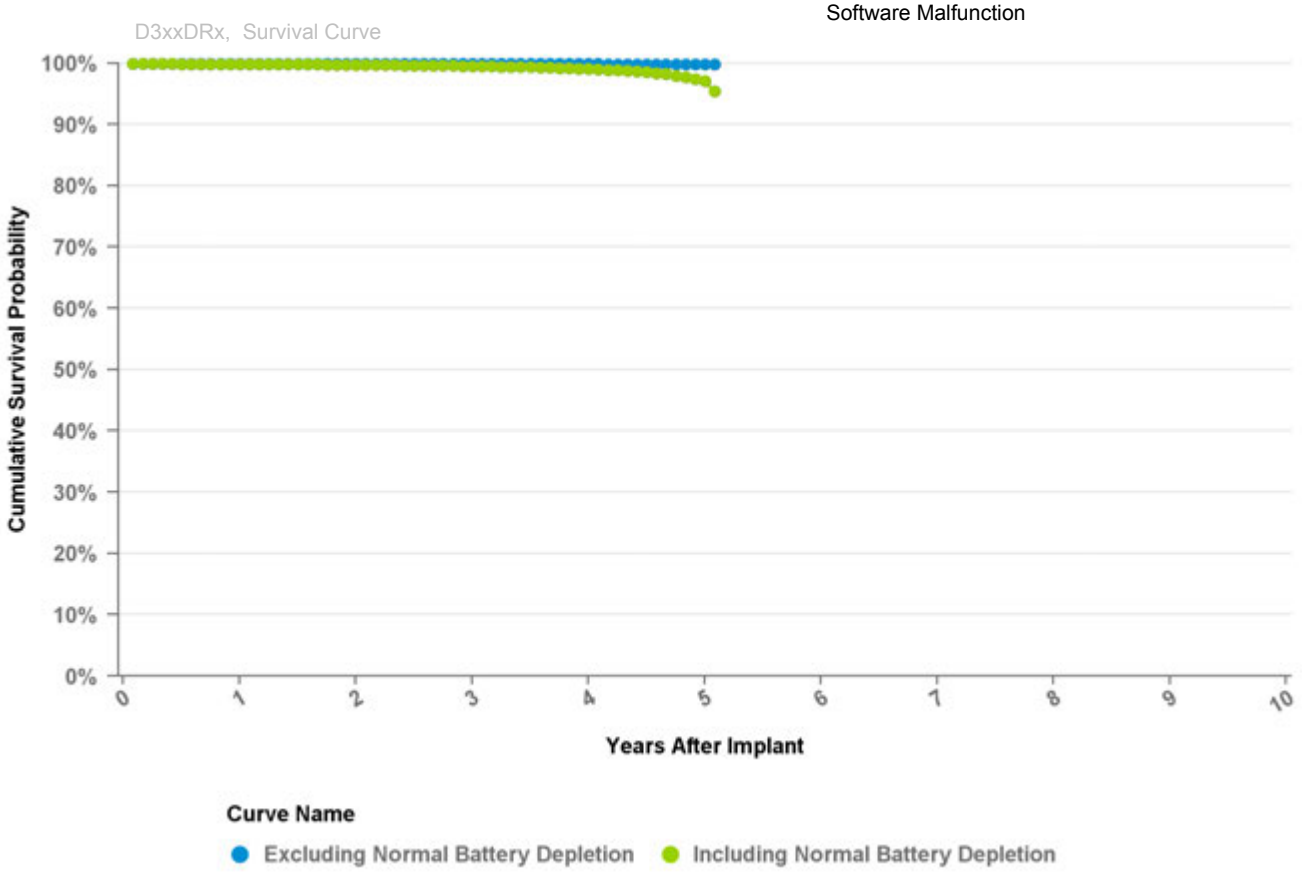
Implantable Cardioverter Defibrillator

D354DRM Protecta XT DR

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

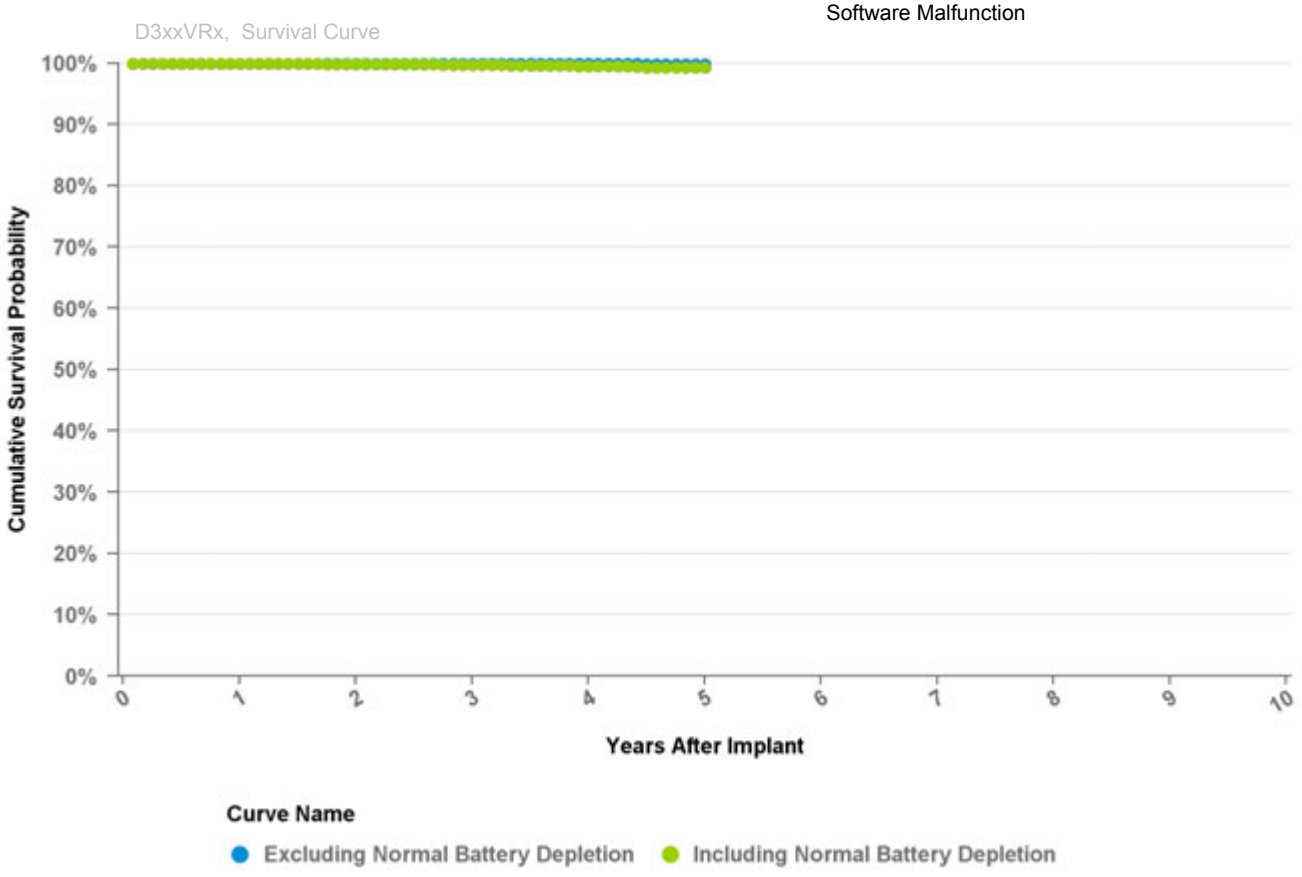
Implantable Cardioverter Defibrillator

D354VRG Protecta XT VR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

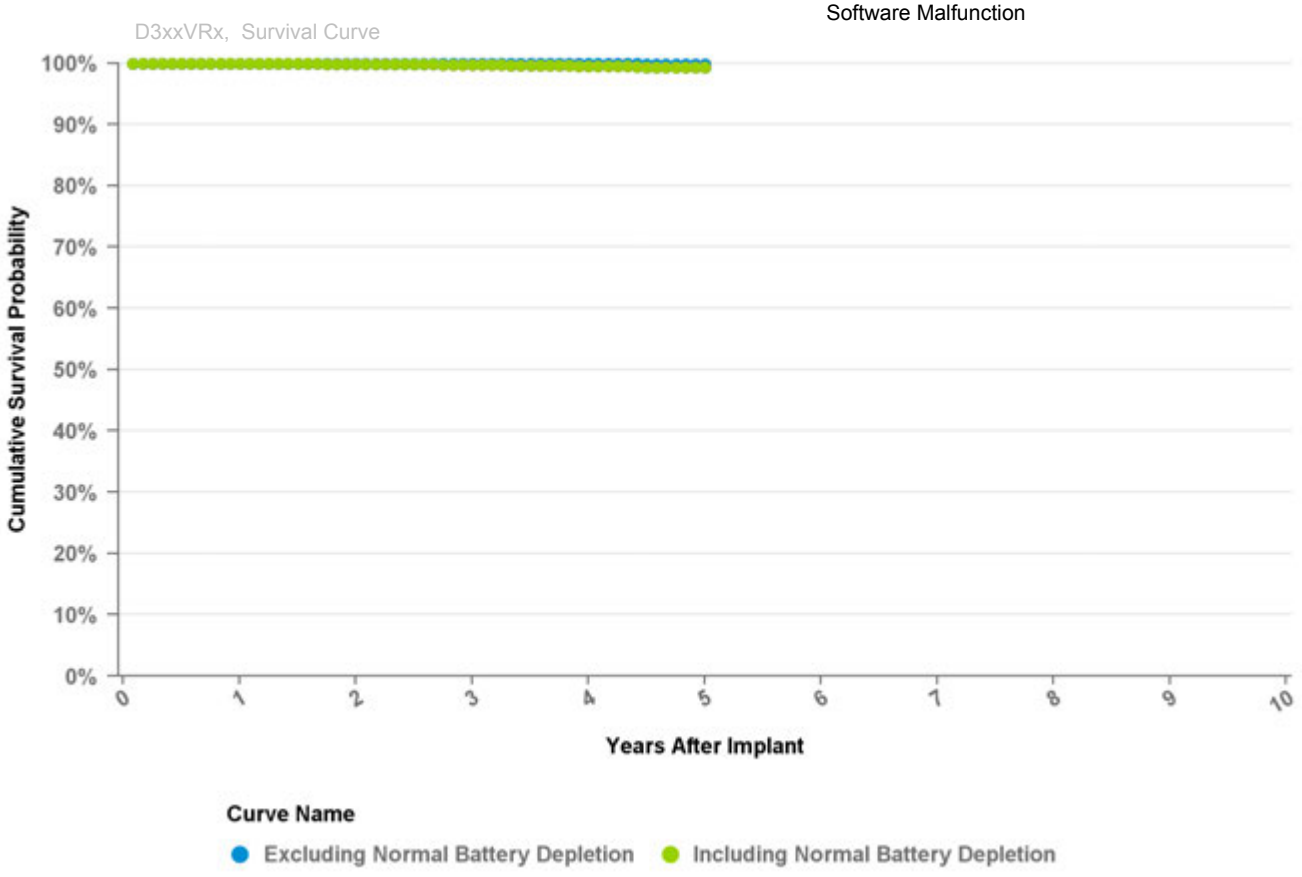
Implantable Cardioverter Defibrillator

D354VRM Protecta XT VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

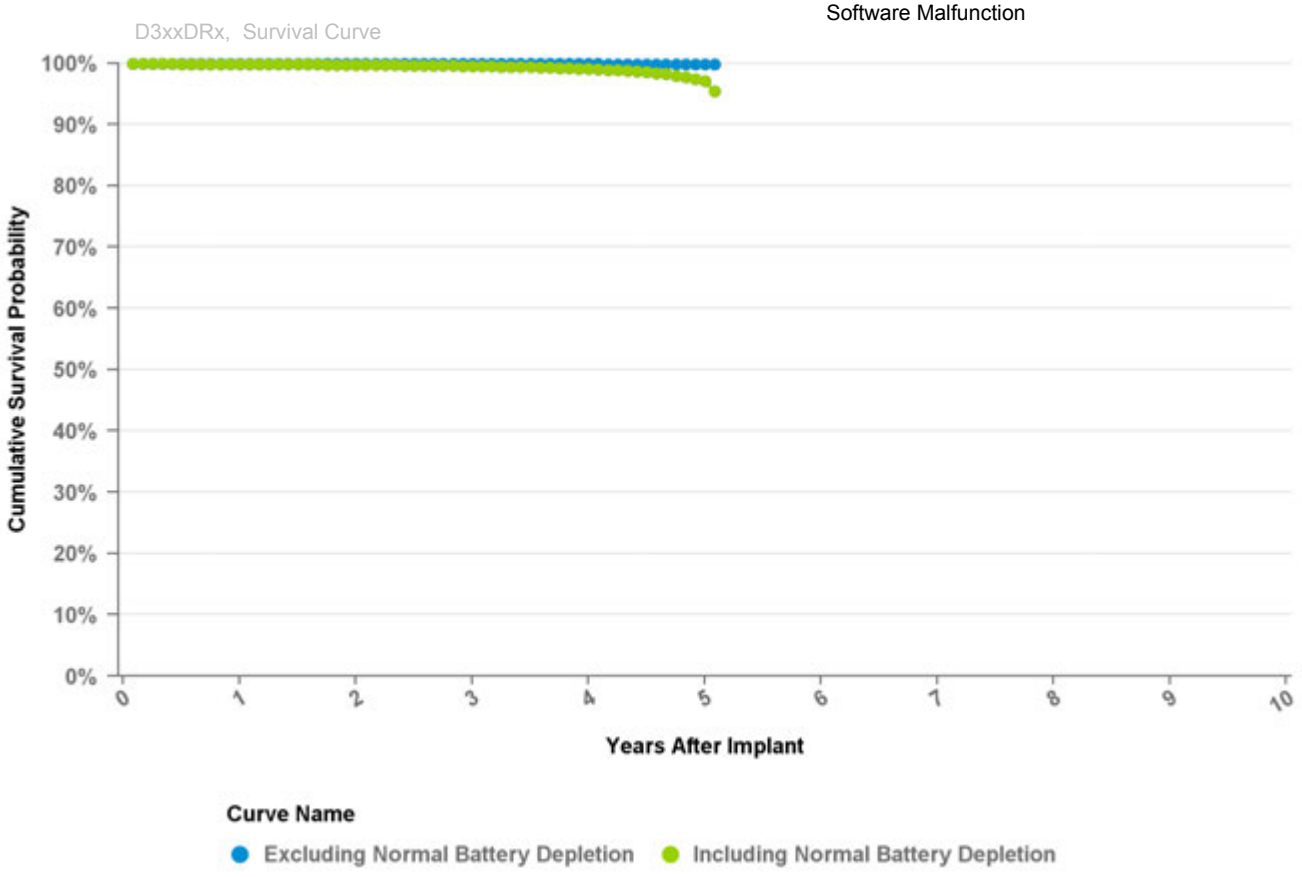
Implantable Cardioverter Defibrillator

D364DRG Protecta DR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

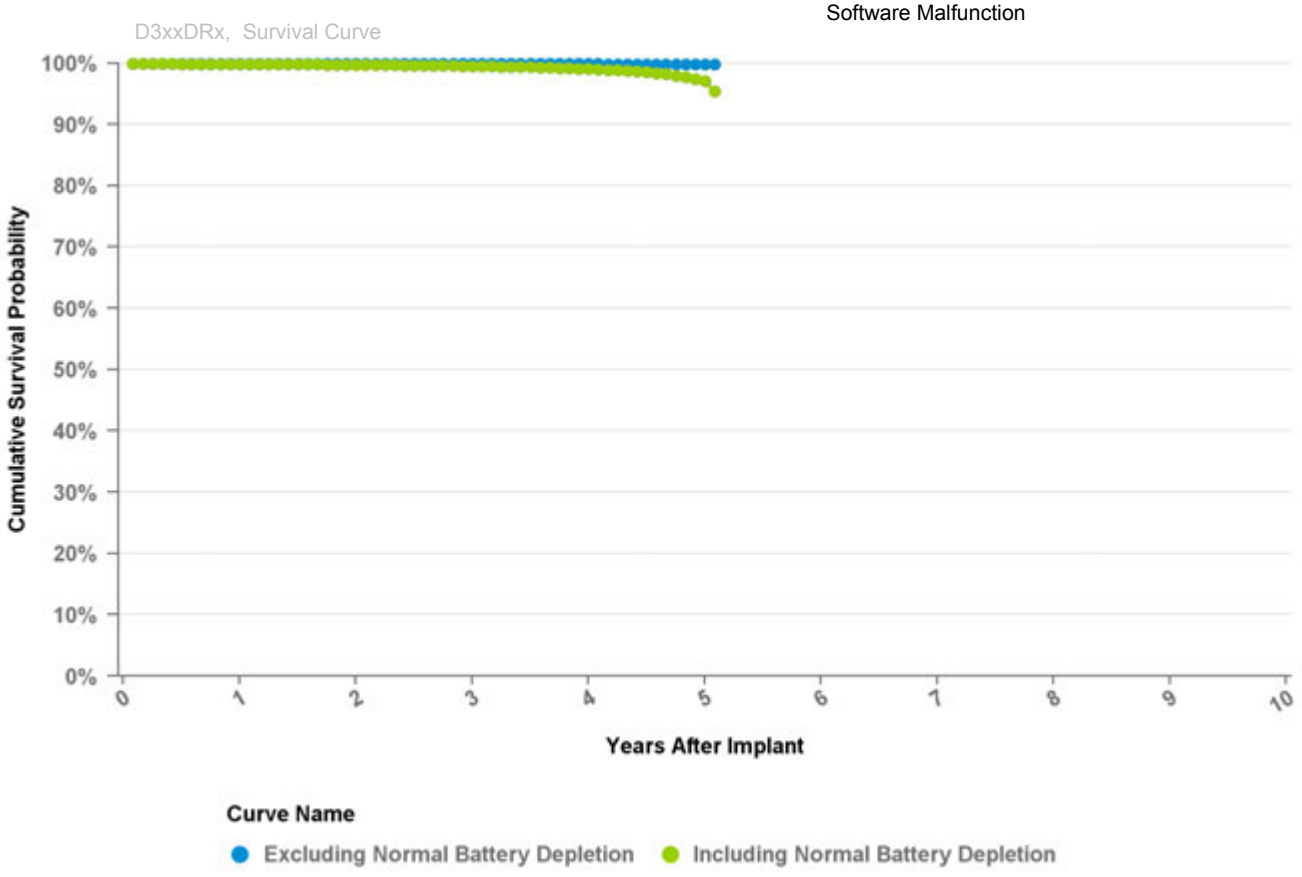
Implantable Cardioverter Defibrillator

D364DRM Protecta DR

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

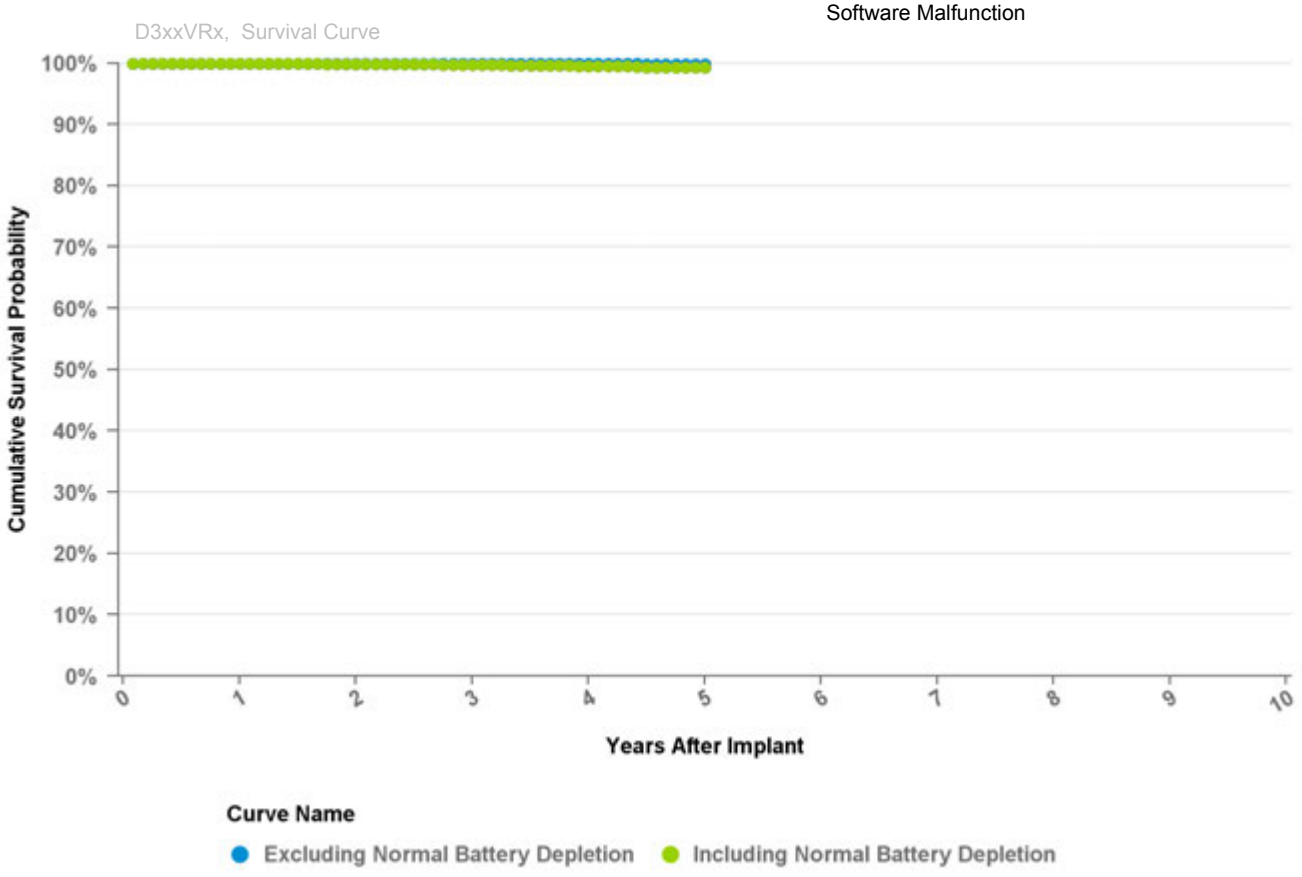
Implantable Cardioverter Defibrillator

D364VRG Protecta VR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

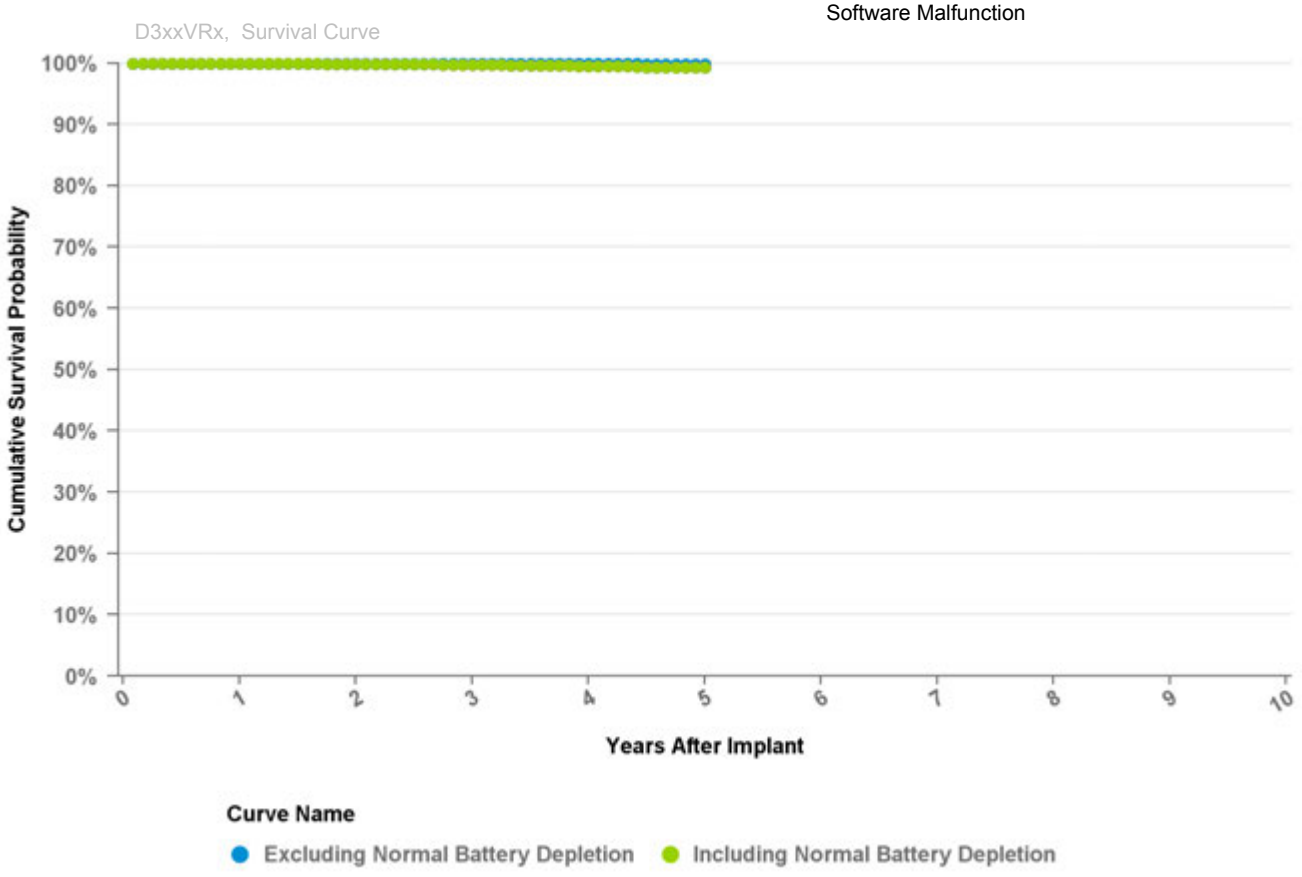
Implantable Cardioverter Defibrillator

D364VRM Protecta VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

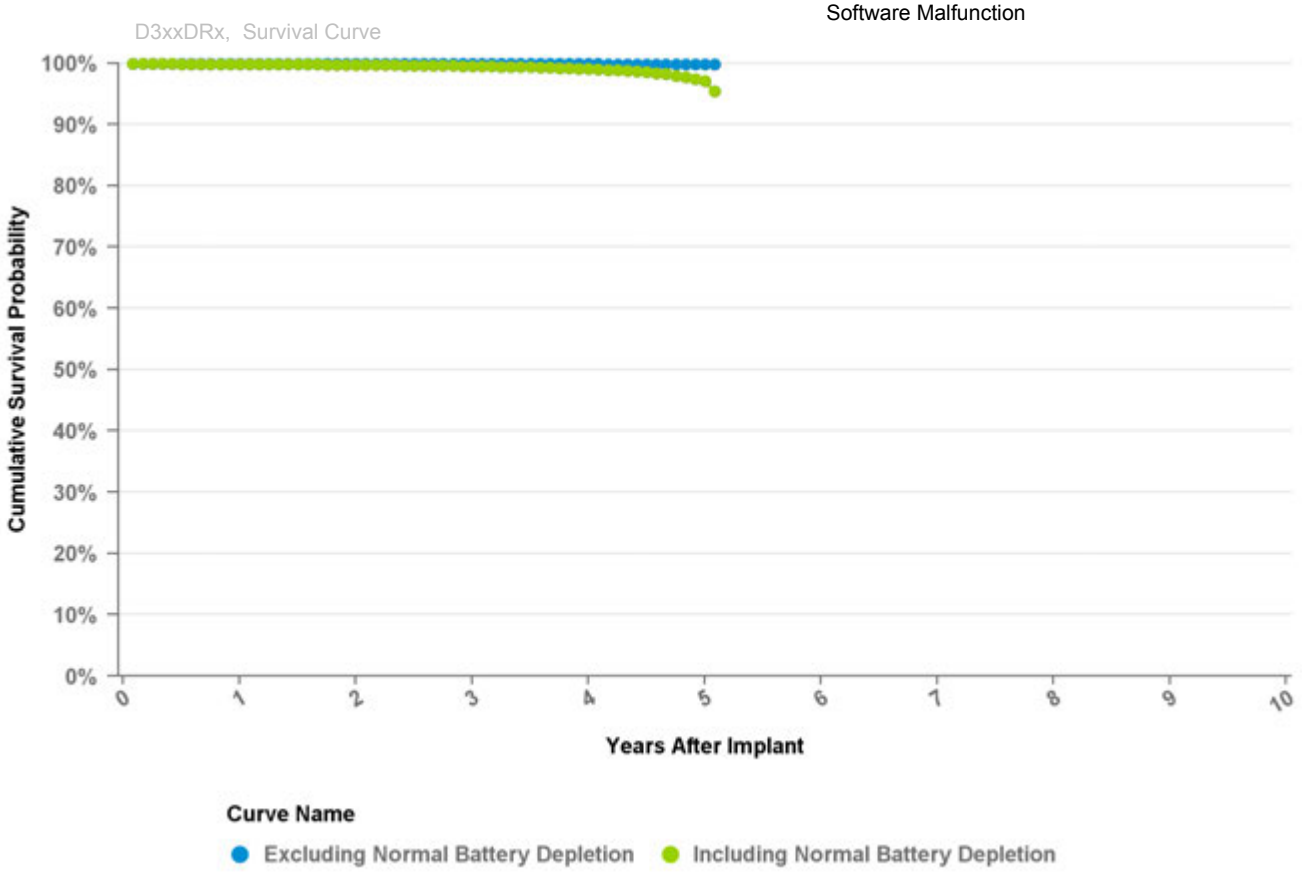
Implantable Cardioverter Defibrillator

D384DRG Cardia DR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

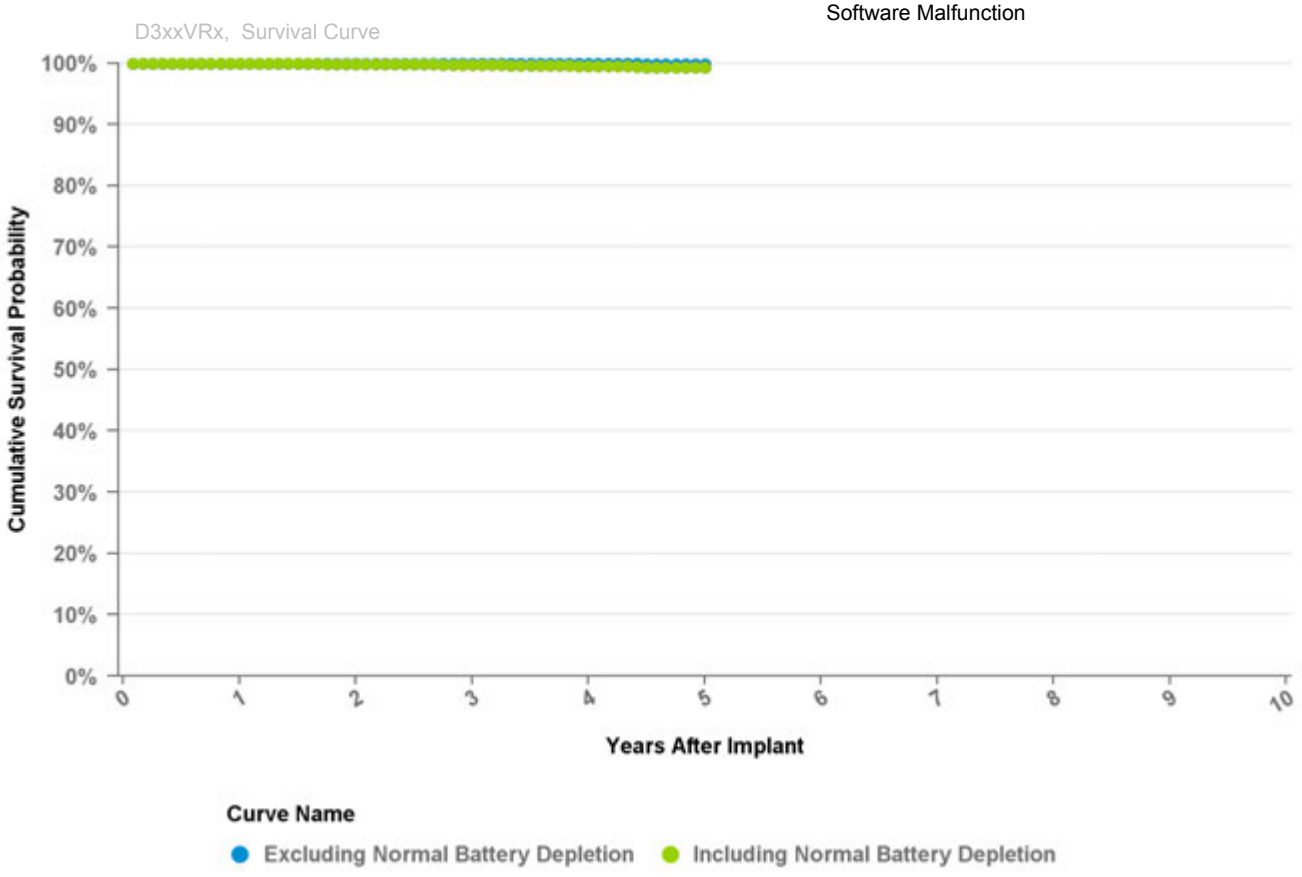
Implantable Cardioverter Defibrillator

D384VRG Cardia VR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

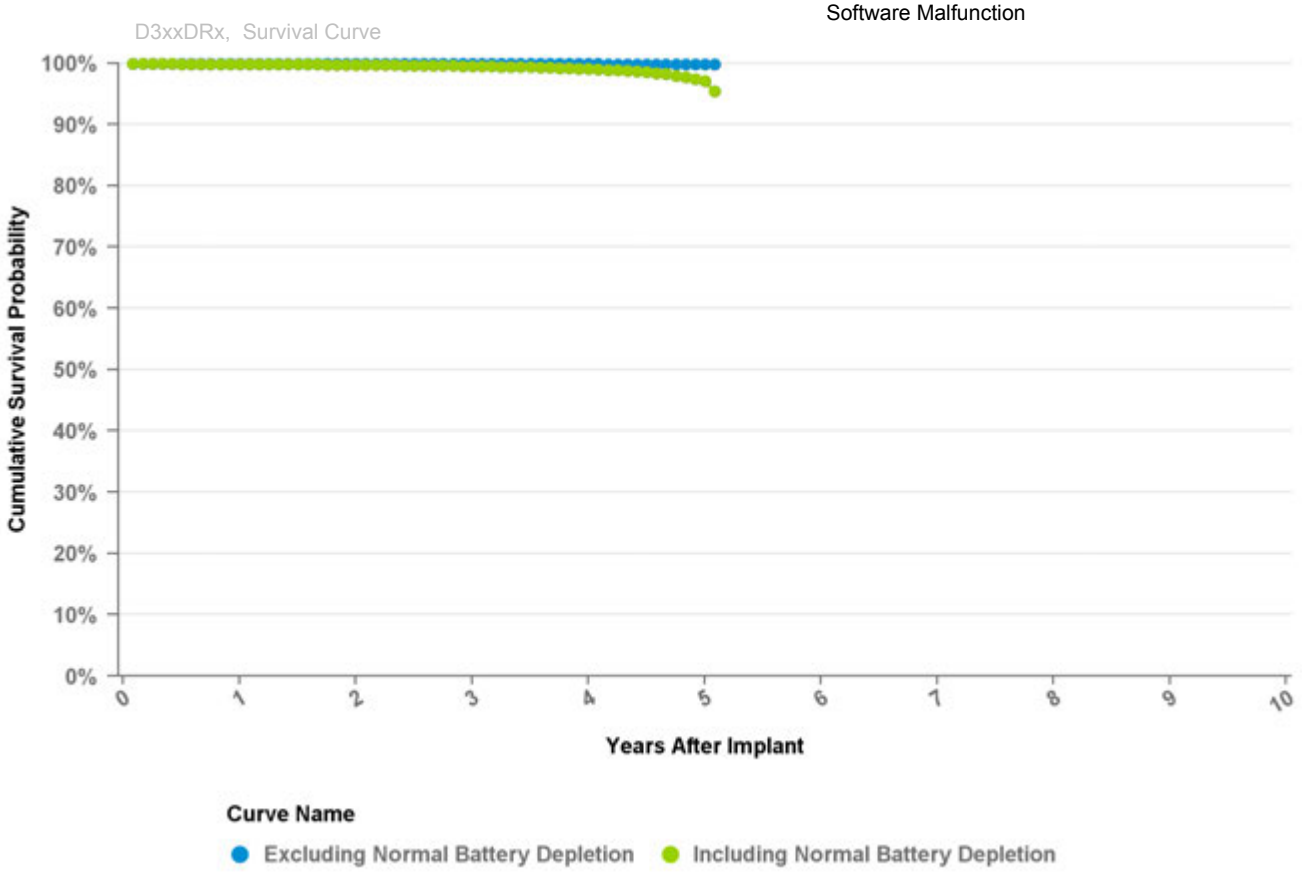
Implantable Cardioverter Defibrillator

D394DRG Egida DR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.1%	97.1%	95.4%
Effective Sample Size	55614	51704	44753	20541	1080	228

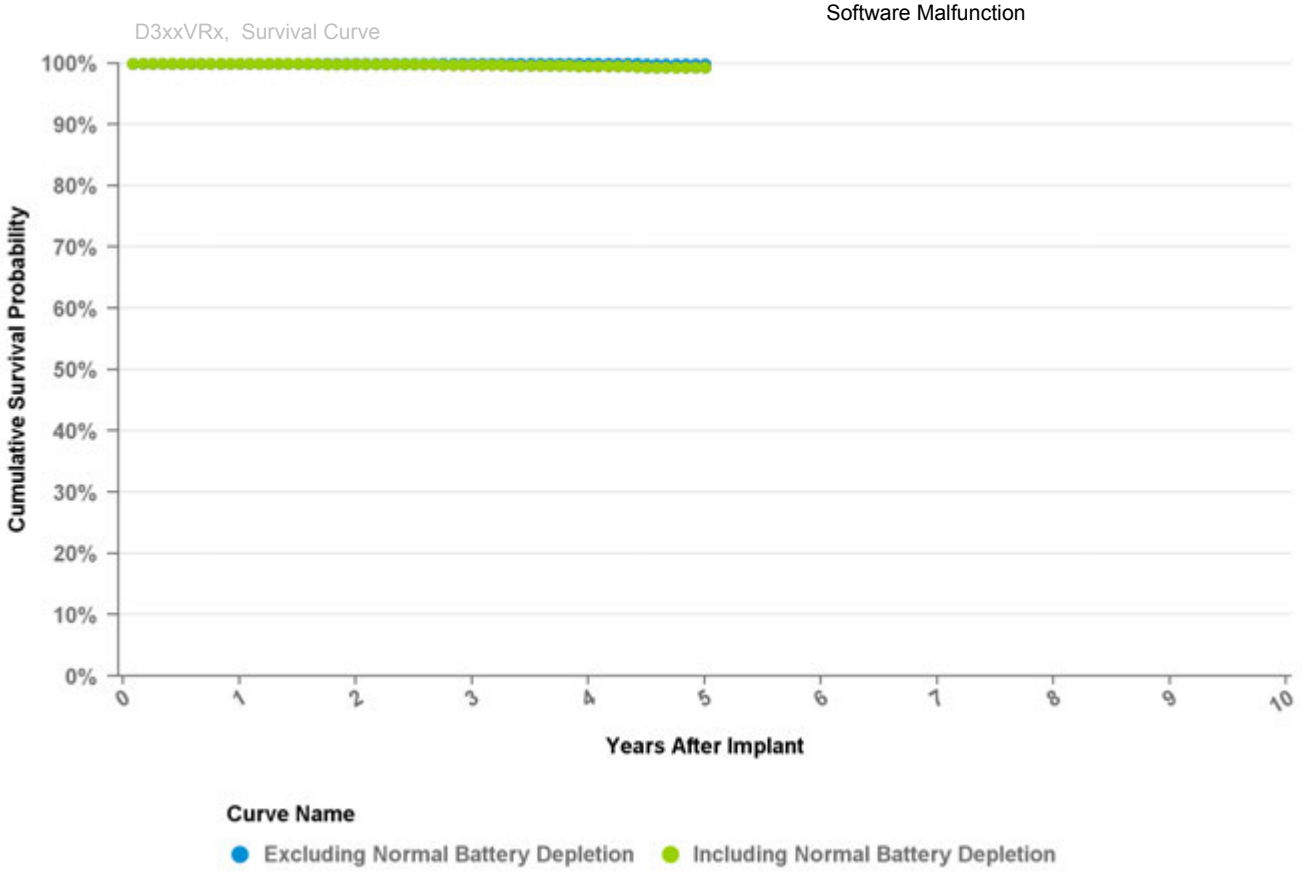
Implantable Cardioverter Defibrillator

D394VRG Egida VR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%
Effective Sample Size	26606	24435	20532	8578	125

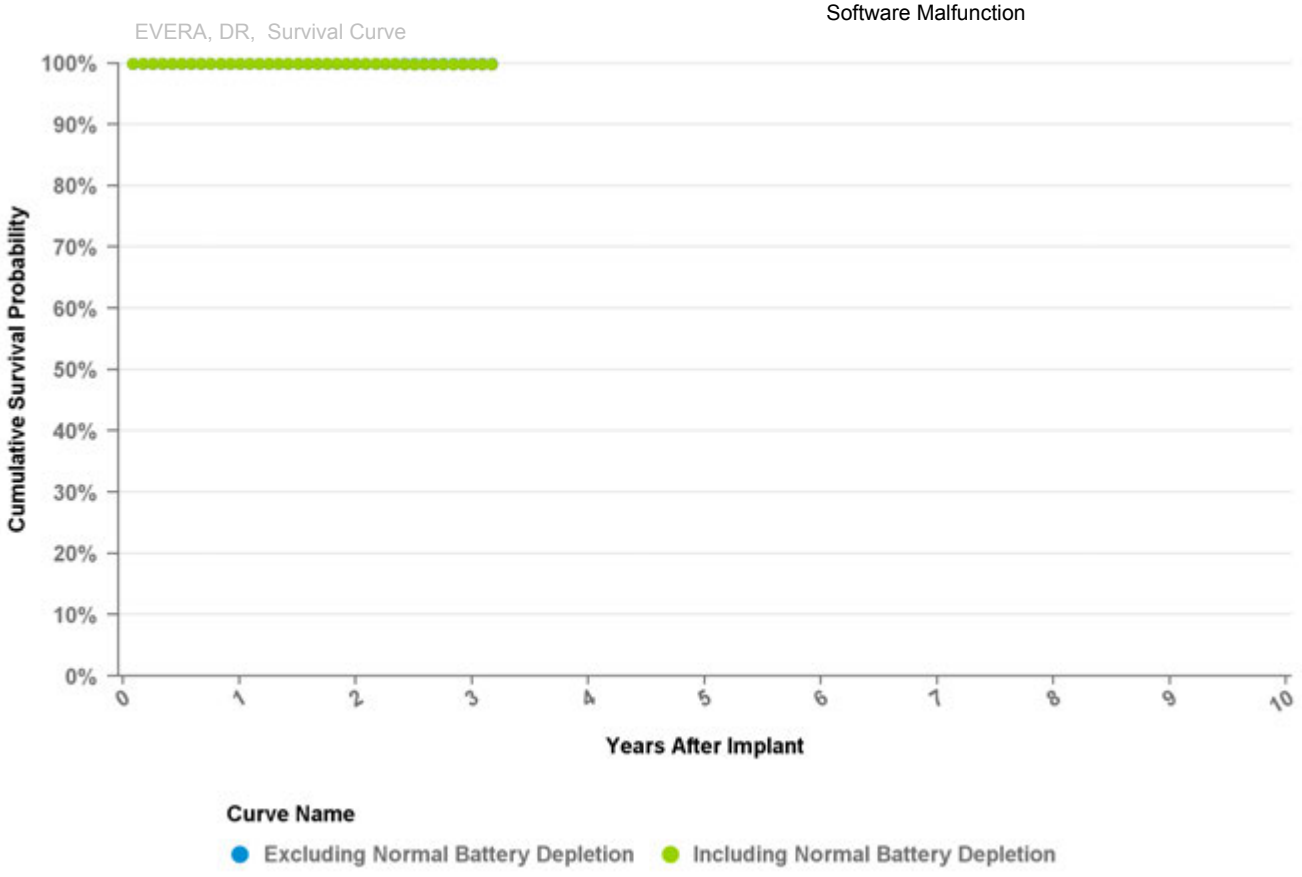
Implantable Cardioverter Defibrillator

DDBB1D1 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	30,747
Estimated Active US Implants	28,721
Normal Battery Depletions (US)	6

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

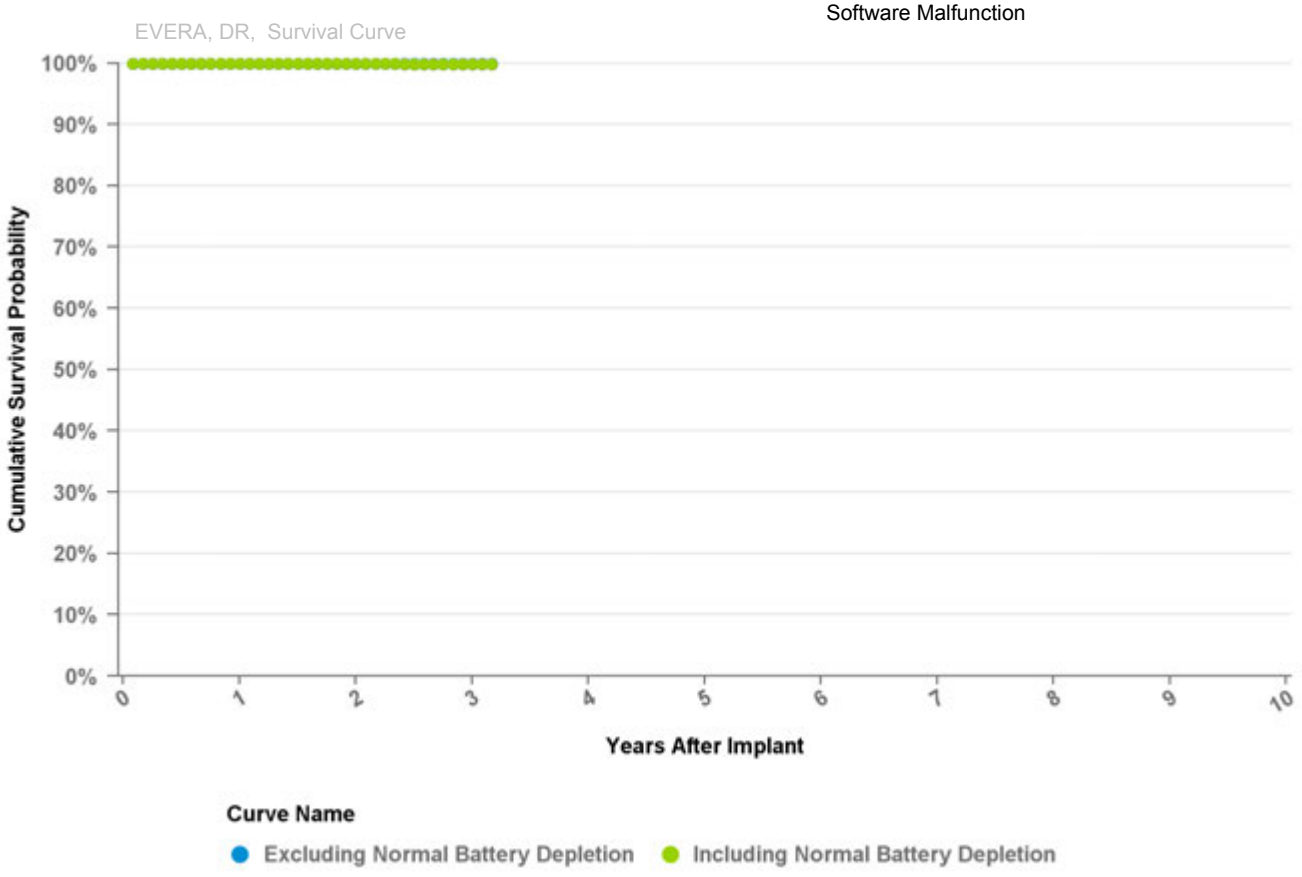
Implantable Cardioverter Defibrillator

DDBB1D4 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	27,365
Estimated Active US Implants	25,741
Normal Battery Depletions (US)	6

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

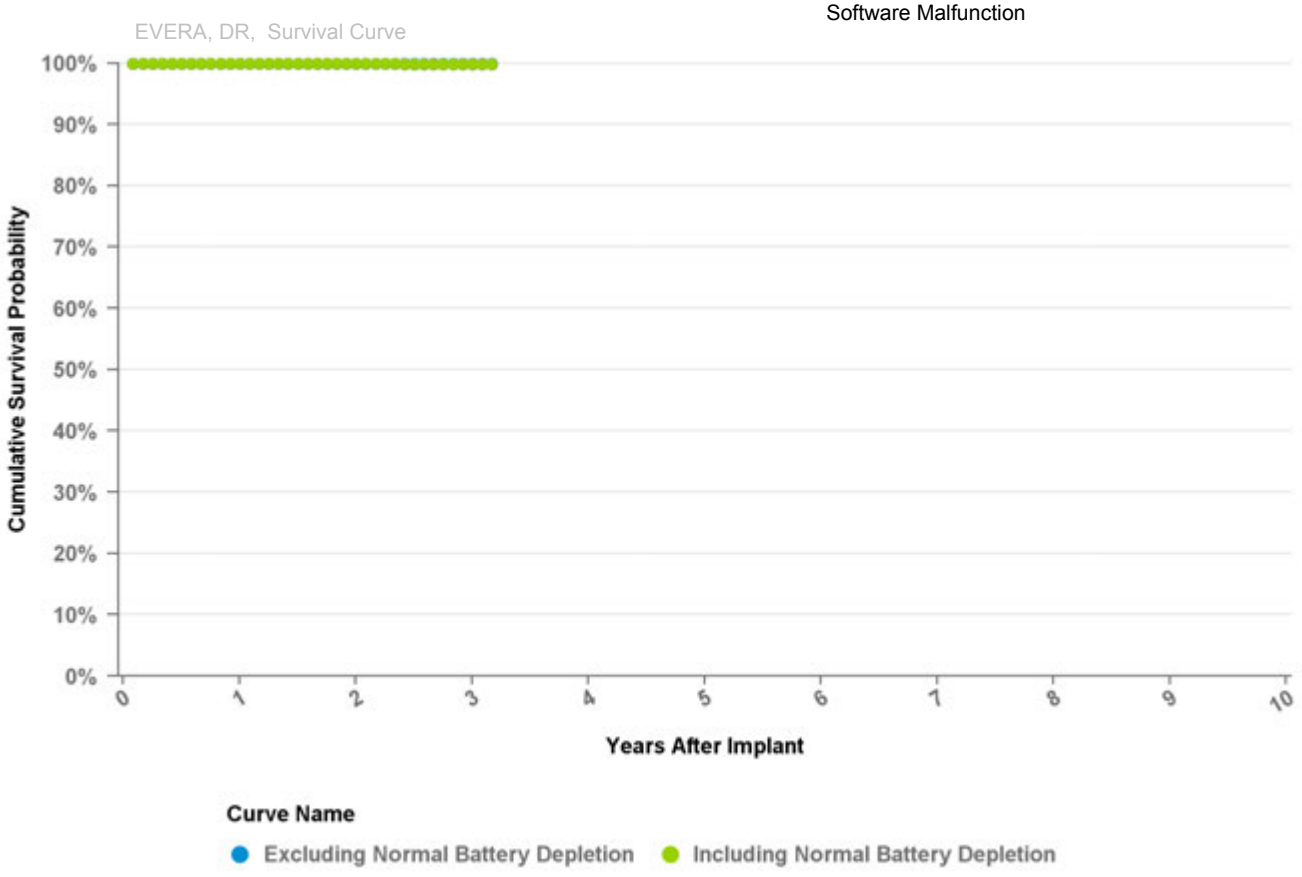
Implantable Cardioverter Defibrillator

DDBB2D1 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

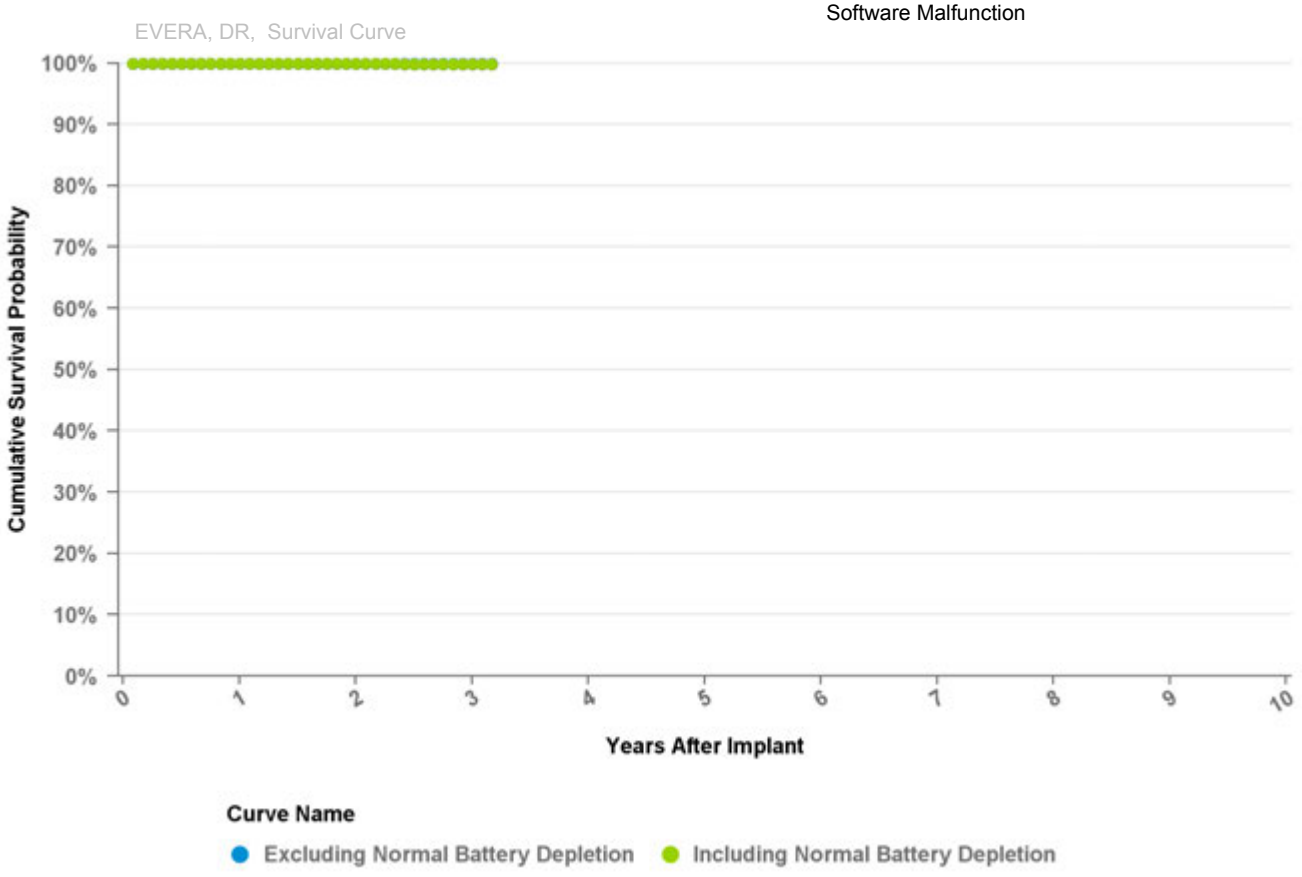
Implantable Cardioverter Defibrillator

DDBB2D4 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

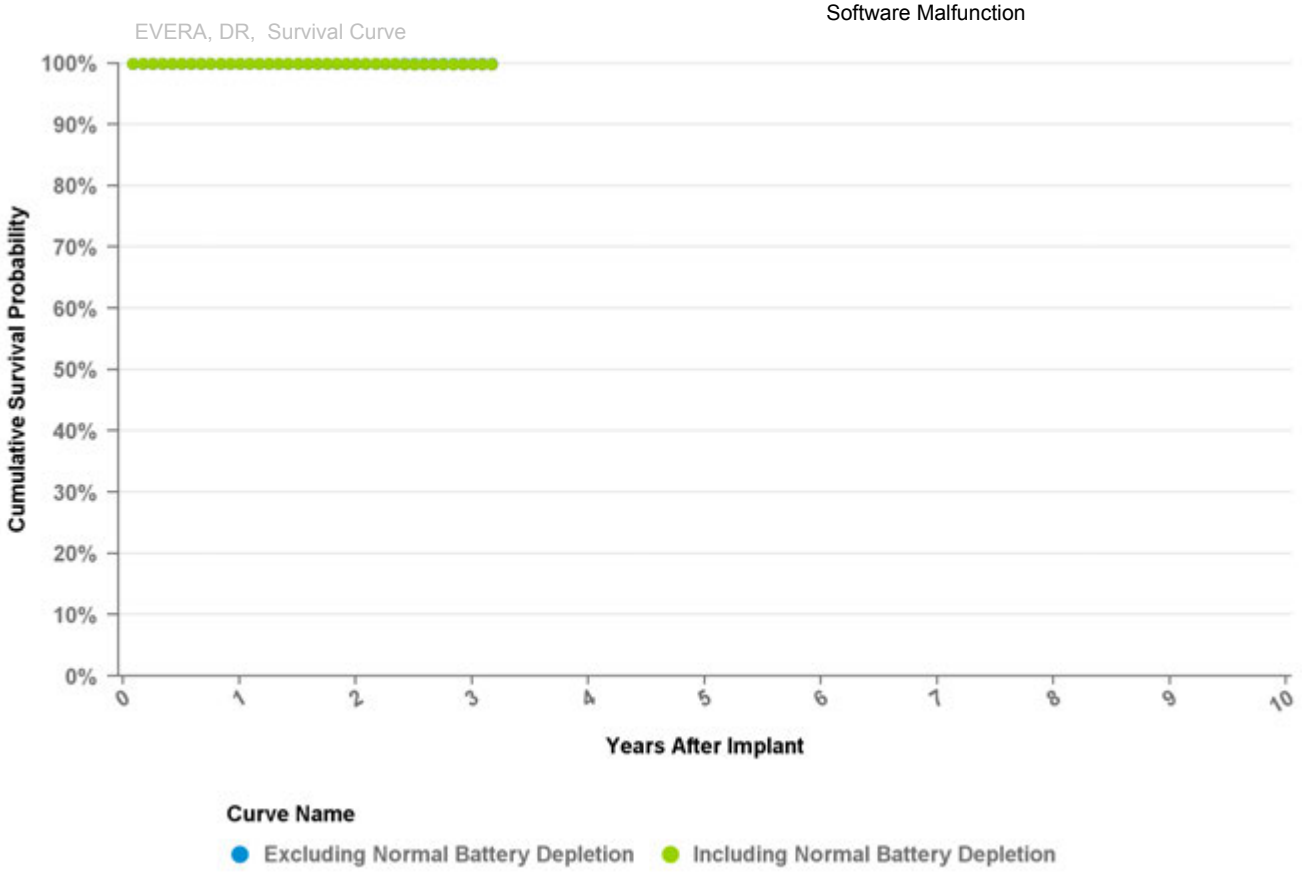
Implantable Cardioverter Defibrillator

DDBC3D1 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	6,091
Estimated Active US Implants	5,666
Normal Battery Depletions (US)	2

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

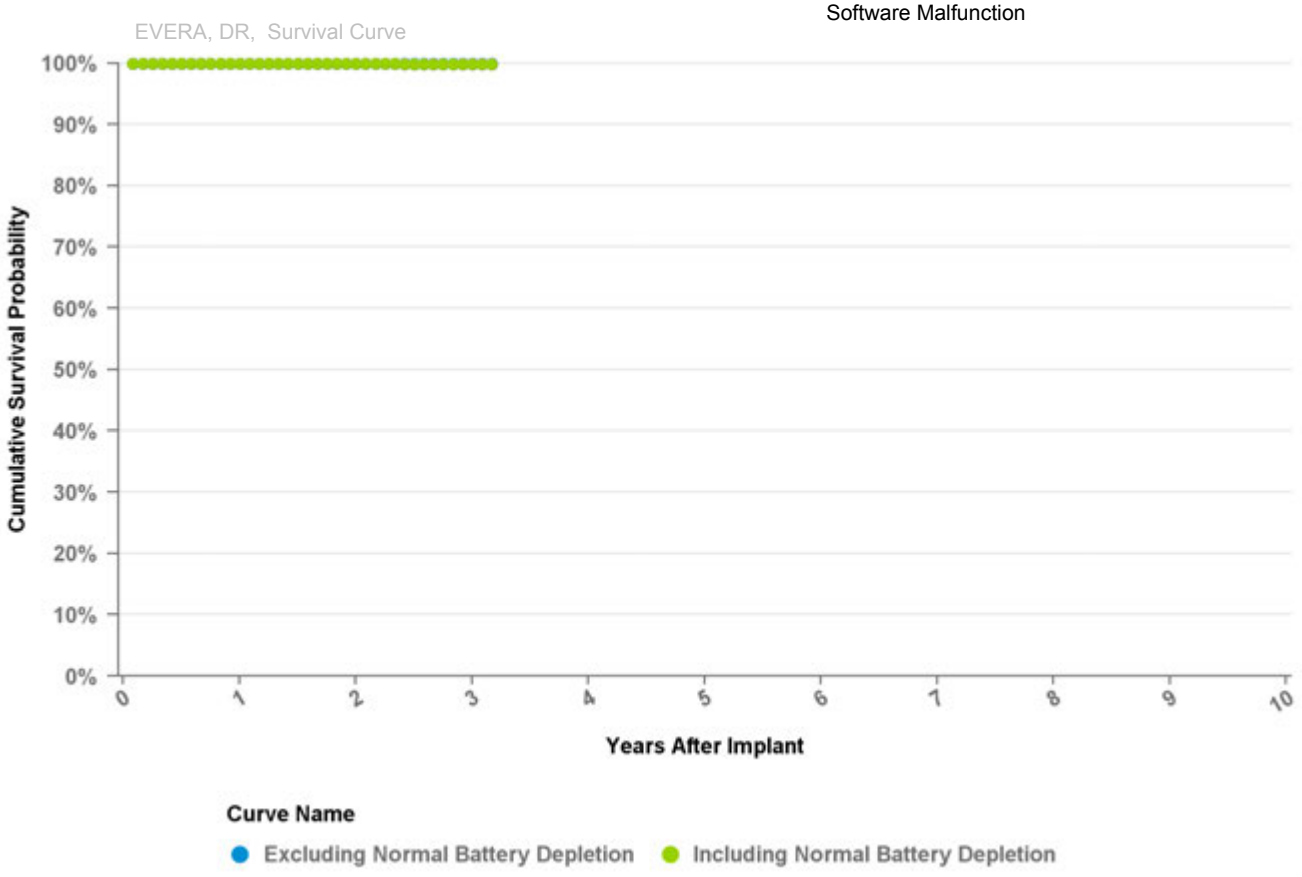
Implantable Cardioverter Defibrillator

DDBC3D4 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2013
Registered US Implants	4,982
Estimated Active US Implants	4,636
Normal Battery Depletions (US)	2

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	1
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

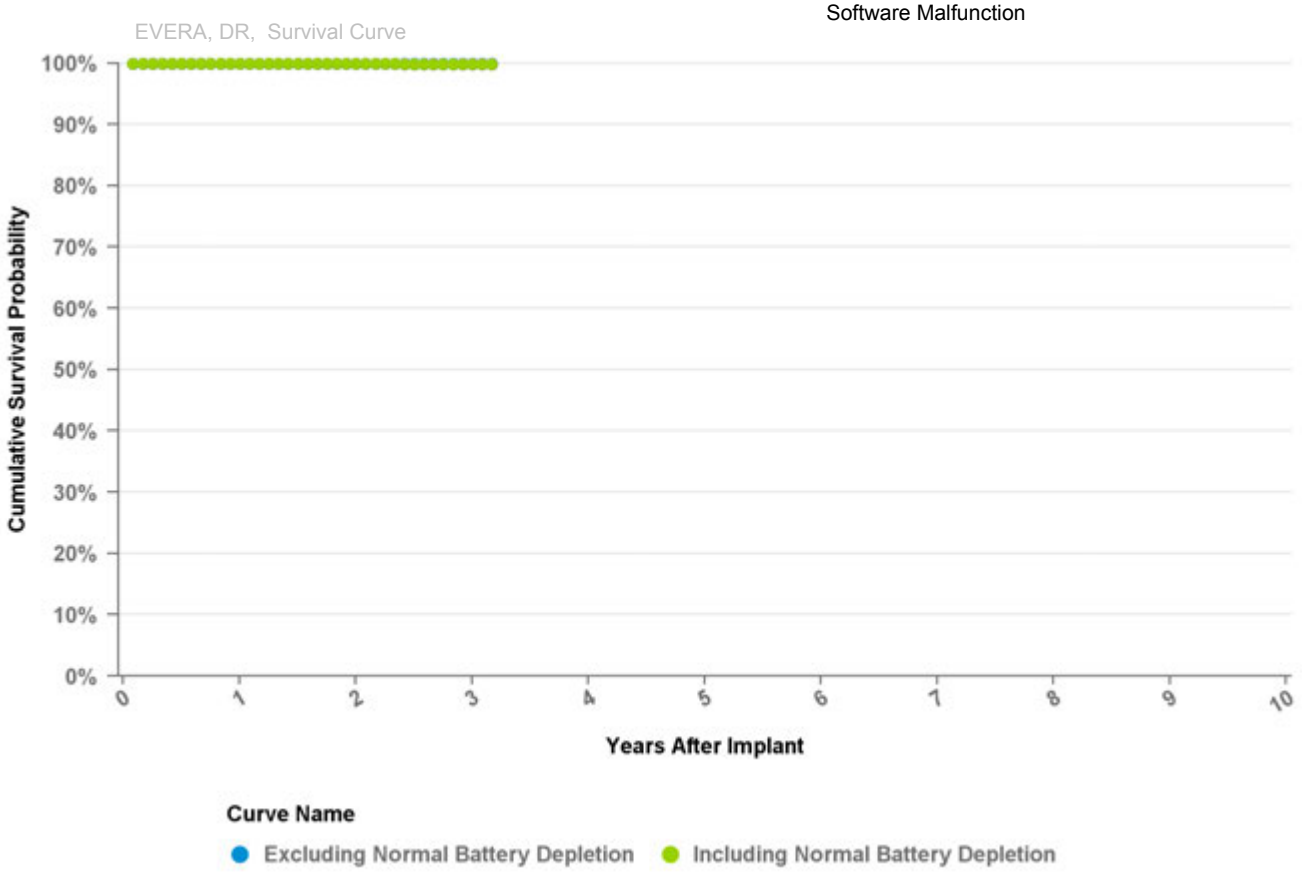
Implantable Cardioverter Defibrillator

DDMB1D4 Evera MRI XT

US Market Release Date	9/11/2015
CE Market Approval Date	
Registered US Implants	10,349
Estimated Active US Implants	10,189
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

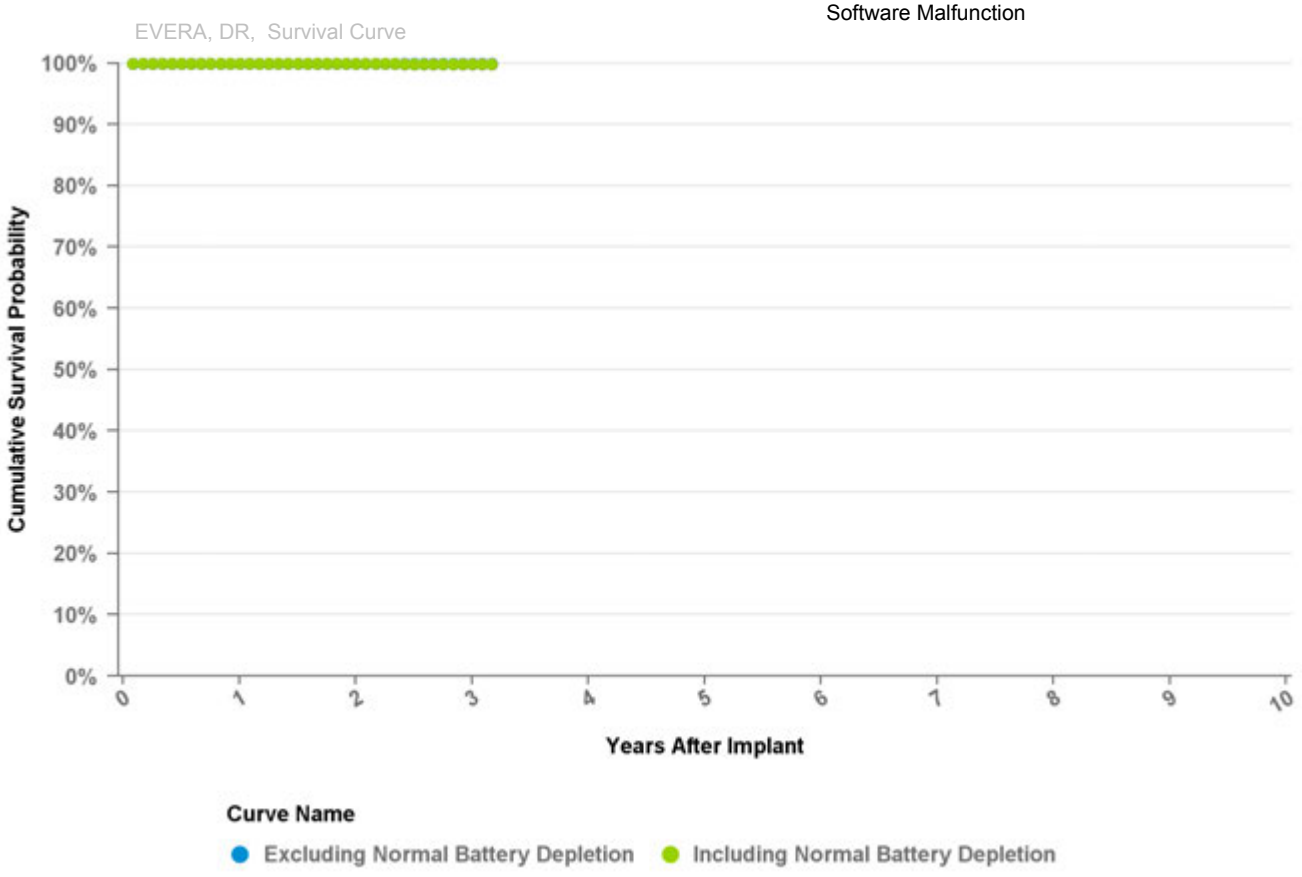
Implantable Cardioverter Defibrillator

DDMB2D4 Evera MRI XT

US Market Release Date	
CE Market Approval Date	3/31/2014
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

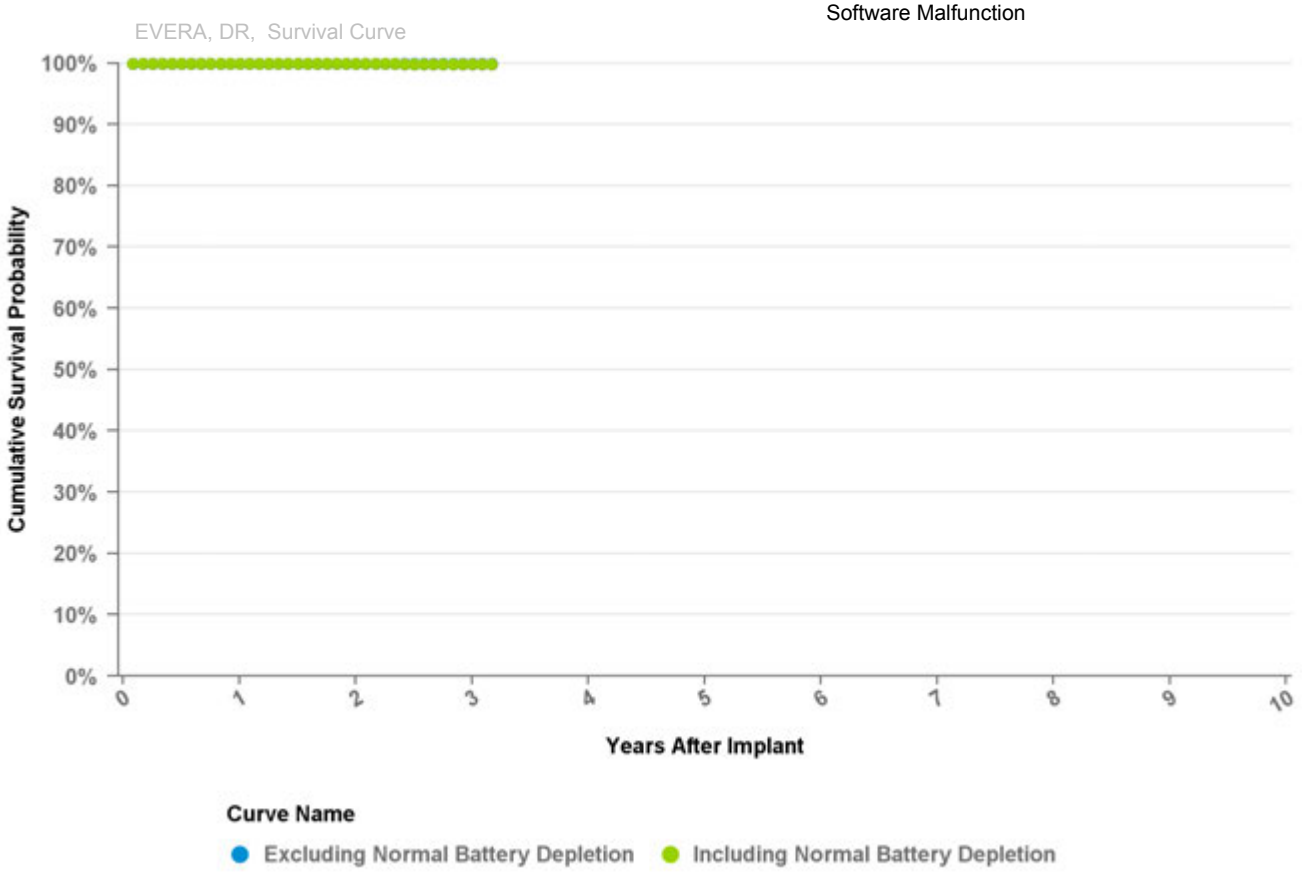
Implantable Cardioverter Defibrillator

DDMC3D4 Evera MRI

US Market Release Date	9/11/2015
CE Market Approval Date	3/31/2014
Registered US Implants	630
Estimated Active US Implants	621
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	49908	23636	2010	179

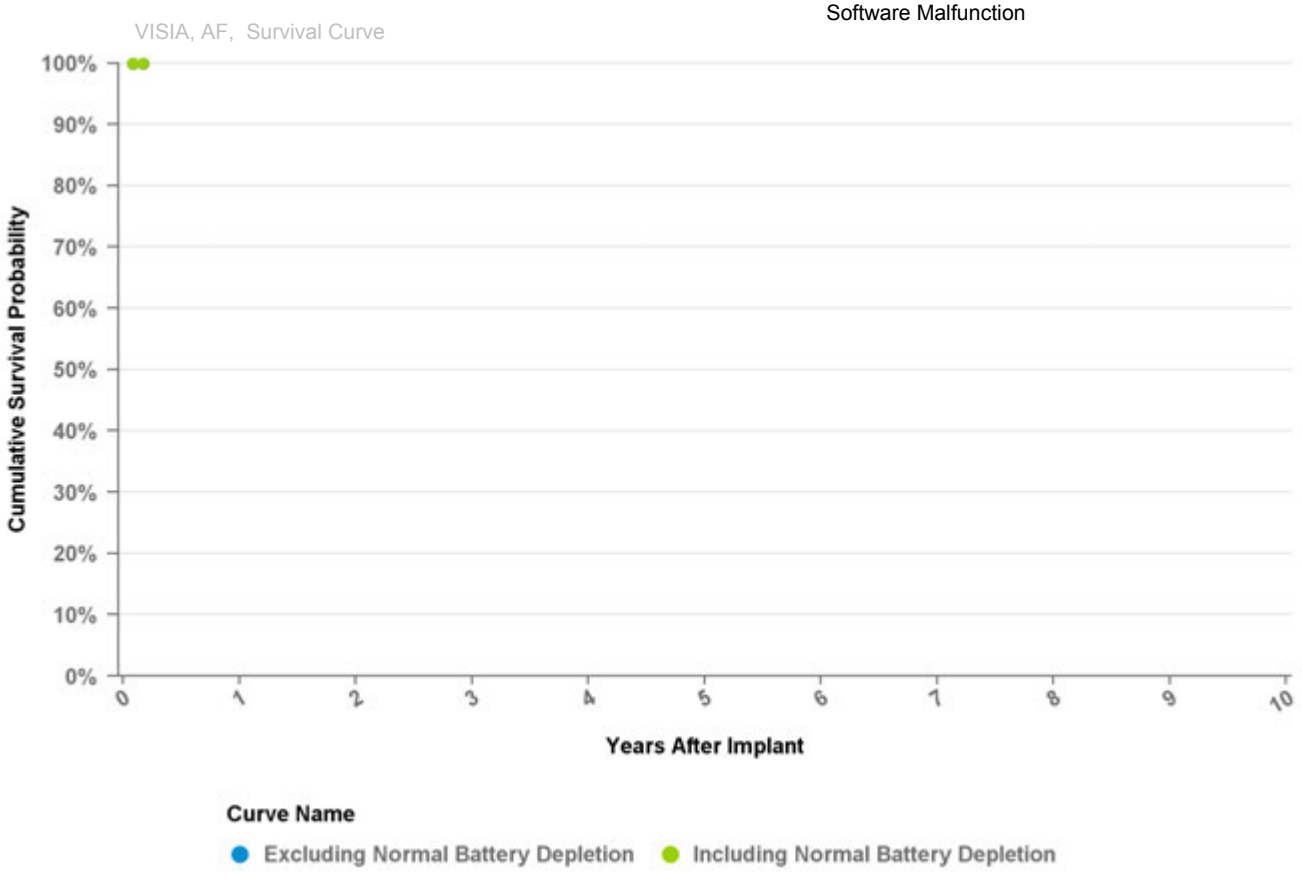
Implantable Cardioverter Defibrillator

DVAB1D1 Visia AF

US Market Release Date	1/19/2016
CE Market Approval Date	
Registered US Implants	104
Estimated Active US Implants	104
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

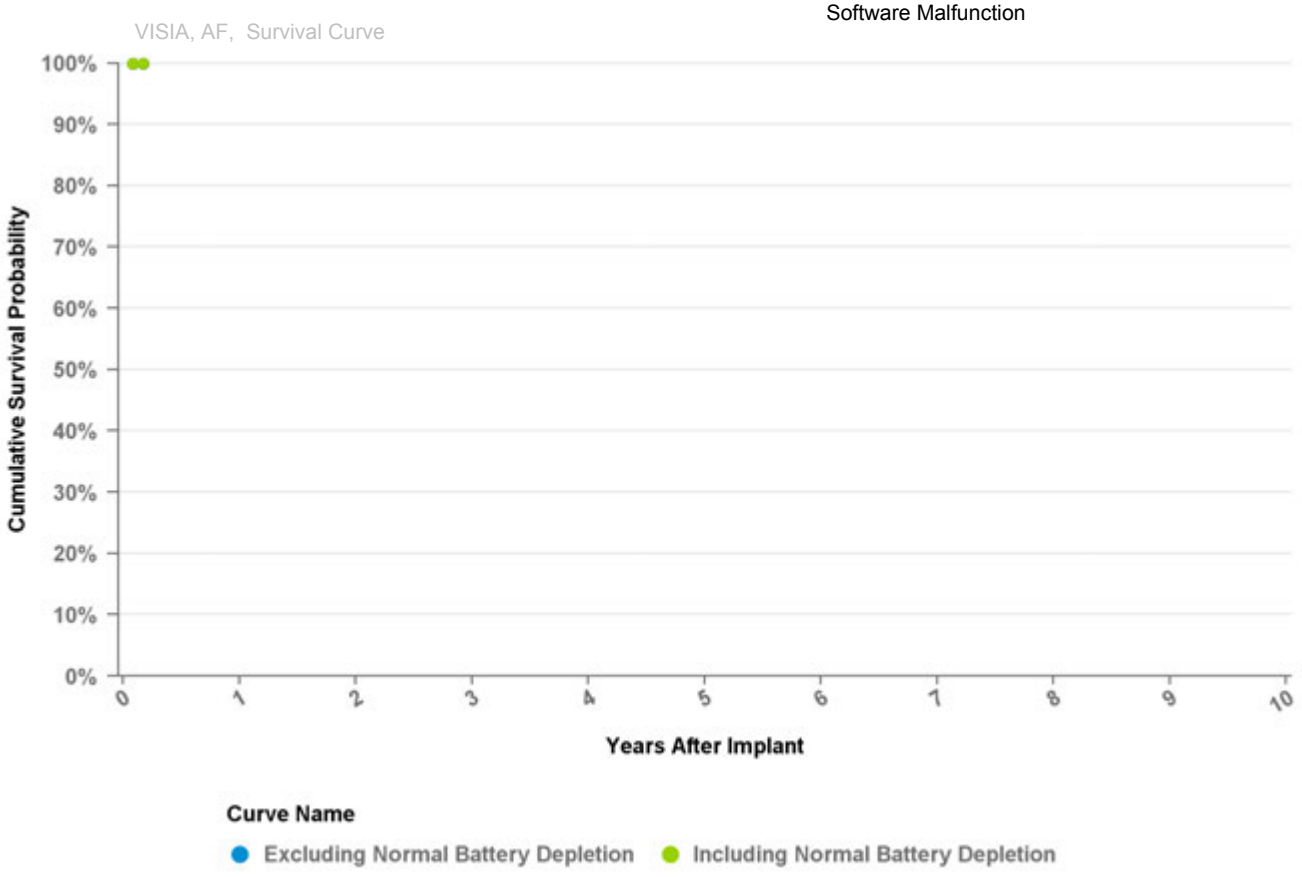
Implantable Cardioverter Defibrillator

DVAB1D4 Visia AF

US Market Release Date	1/19/2016
CE Market Approval Date	
Registered US Implants	73
Estimated Active US Implants	73
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

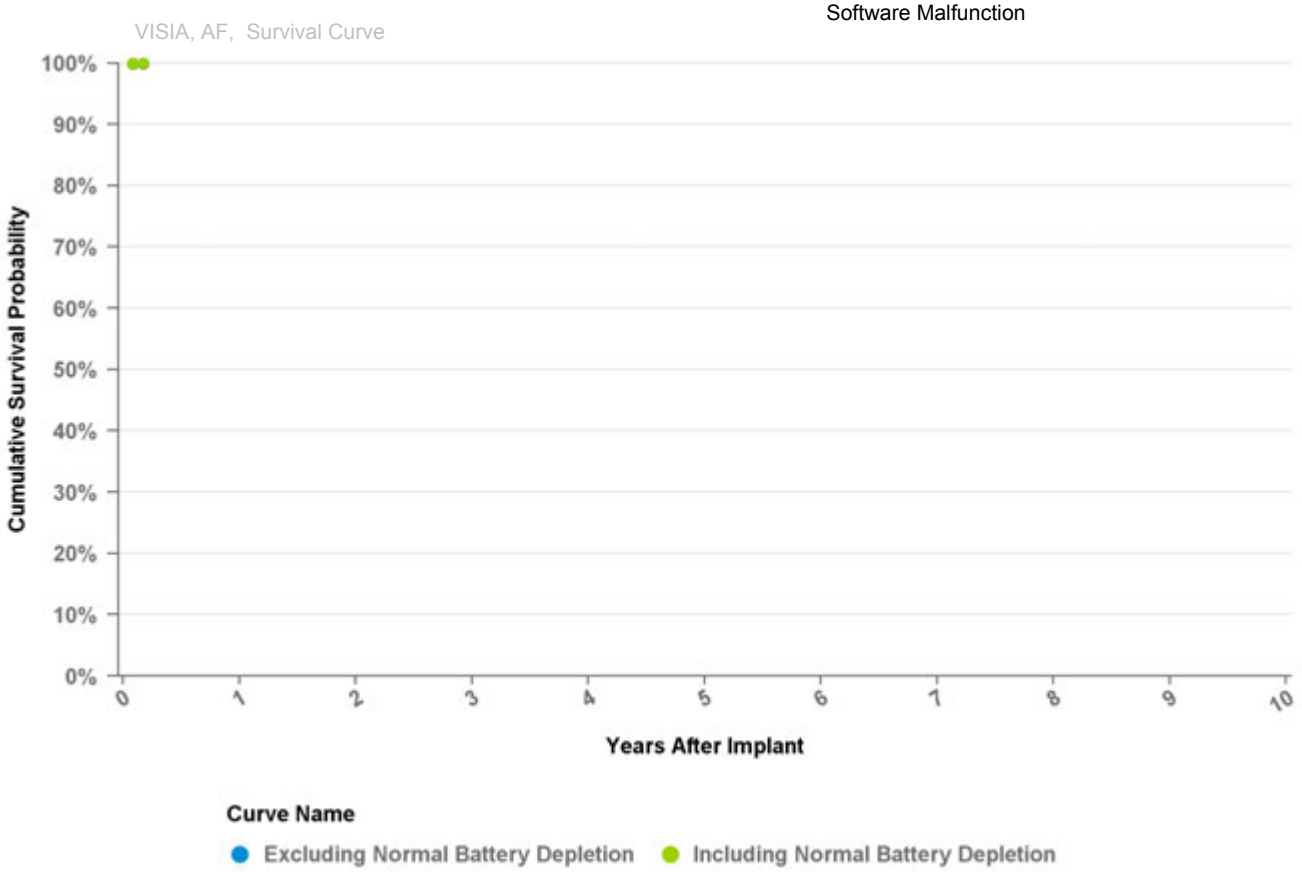
Implantable Cardioverter Defibrillator

DVAB2D1 Visia AF XT

US Market Release Date	
CE Market Approval Date	10/19/2015
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

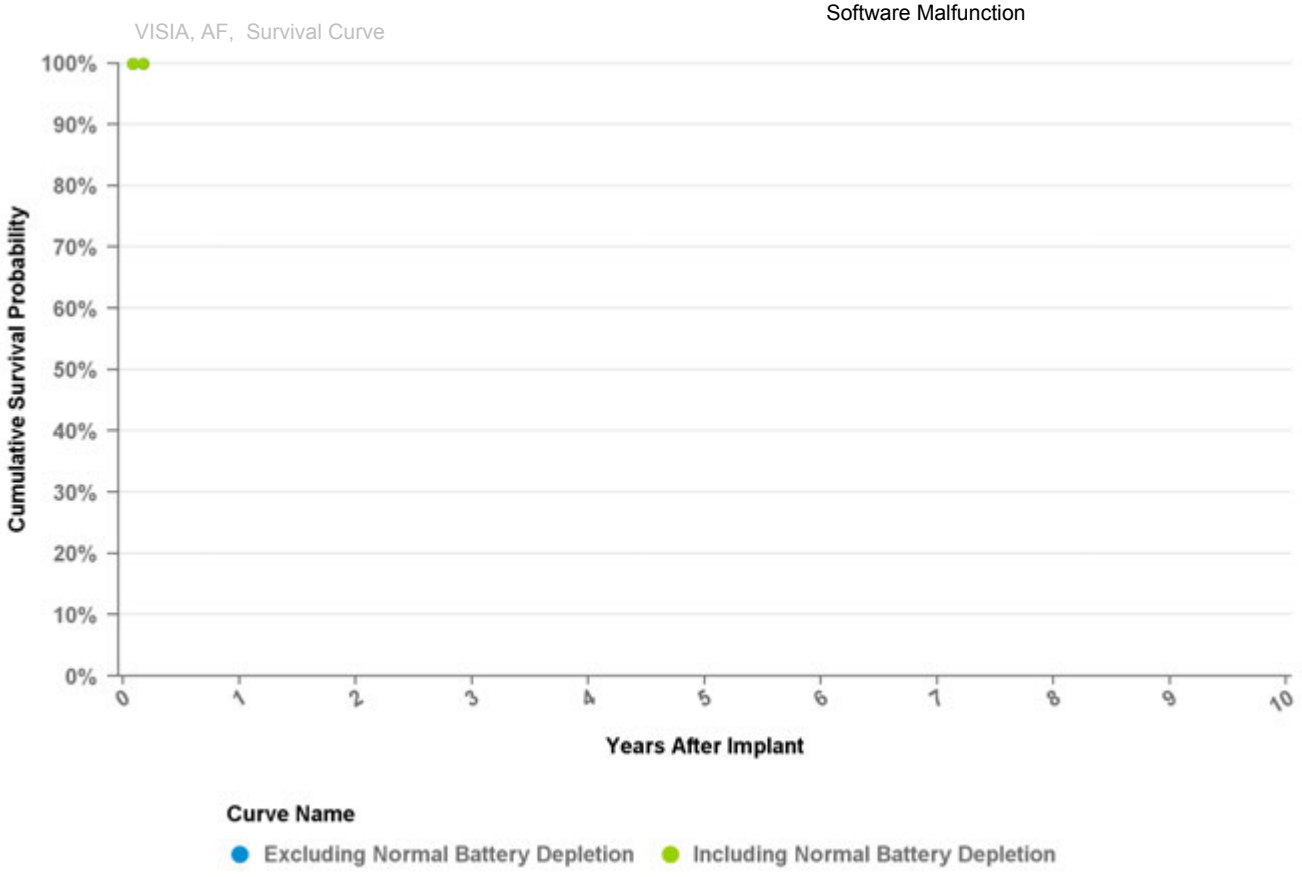
Implantable Cardioverter Defibrillator

DVAC3D1 Visia AF S

US Market Release Date	1/19/2016
CE Market Approval Date	10/19/2015
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

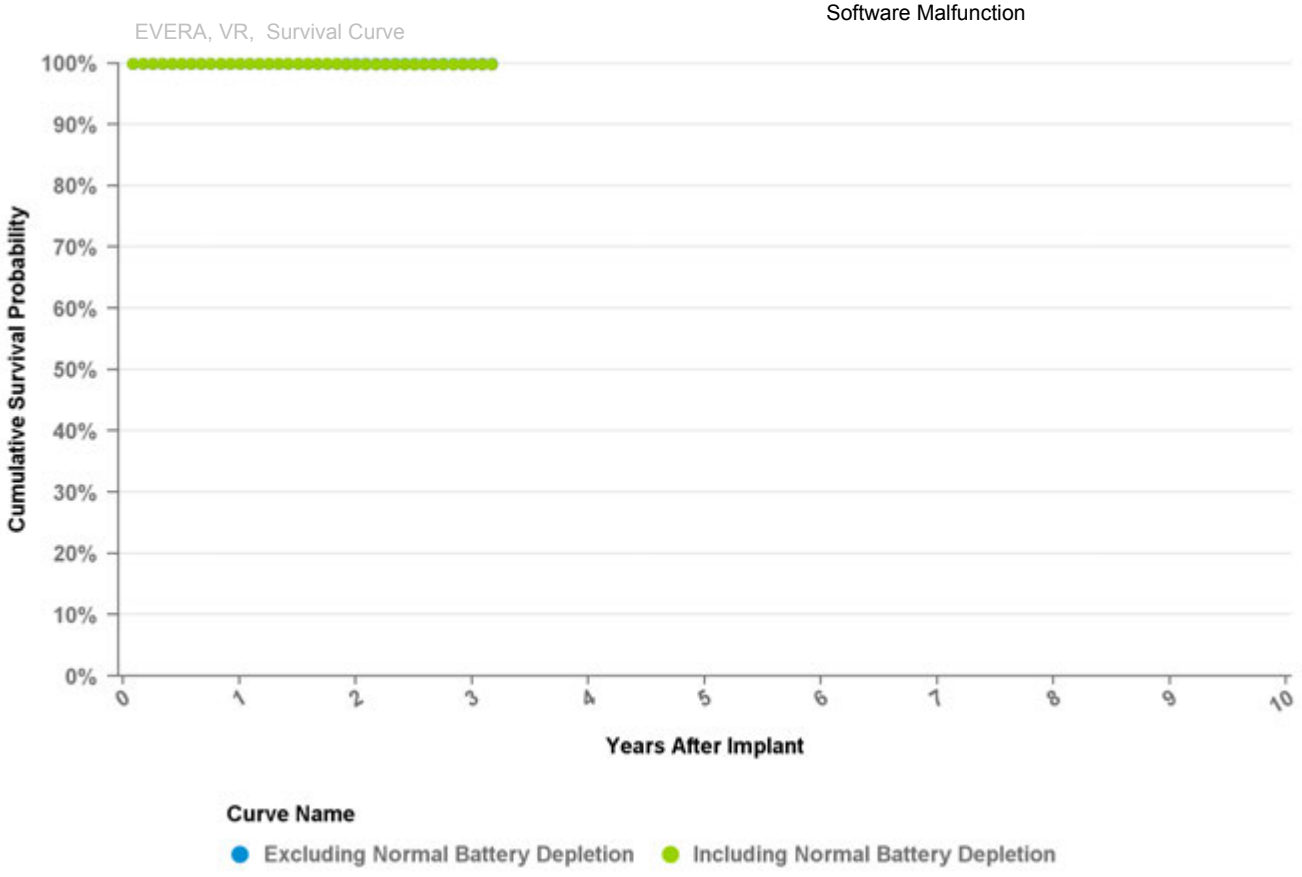
Implantable Cardioverter Defibrillator

DVBB1D1 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	14,671
Estimated Active US Implants	13,727
Normal Battery Depletions (US)	5

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	3
Battery Malfunction	1
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

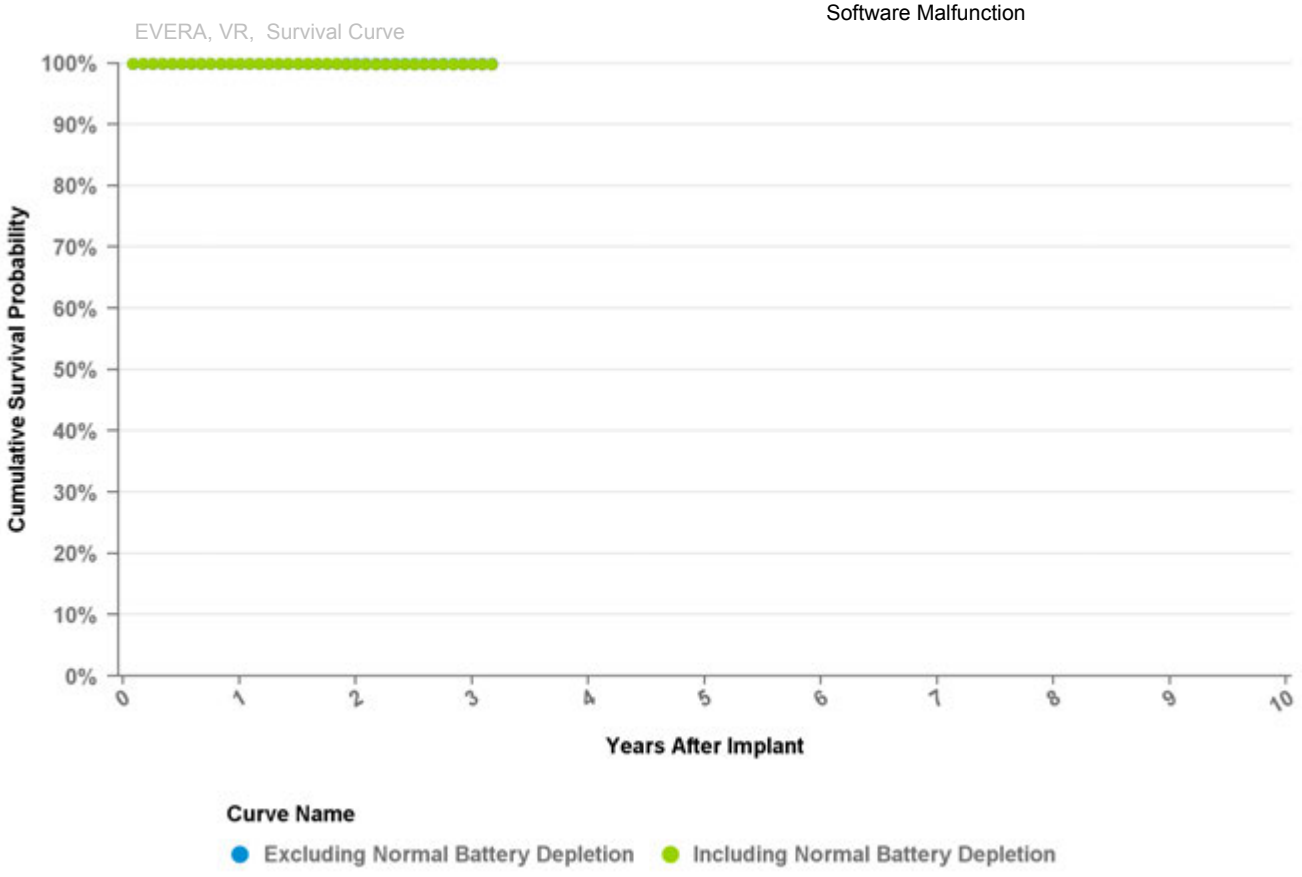
Implantable Cardioverter Defibrillator

DVBB1D4 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	21,651
Estimated Active US Implants	20,363
Normal Battery Depletions (US)	5

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	6
Therapy Not Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

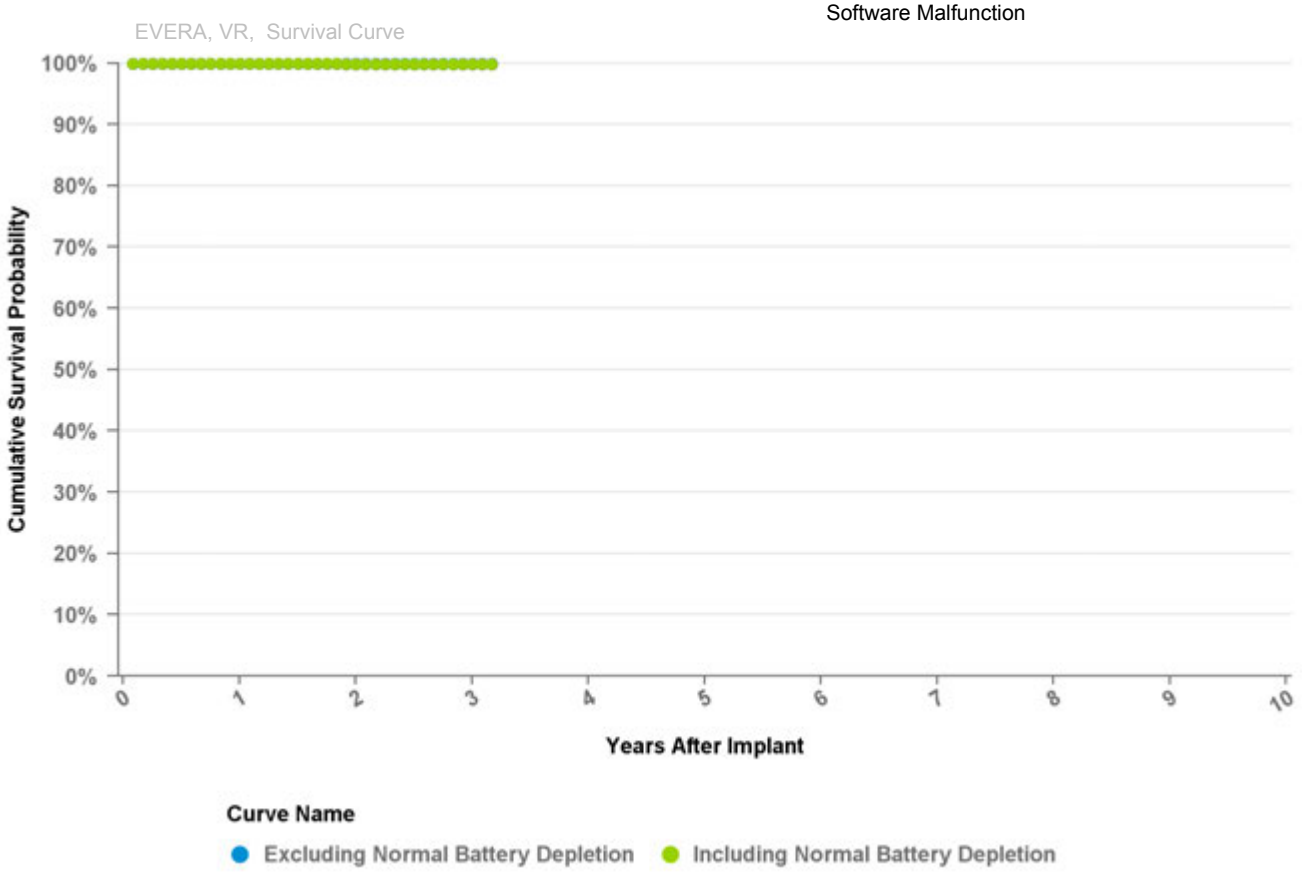
Implantable Cardioverter Defibrillator

DVBB2D1 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

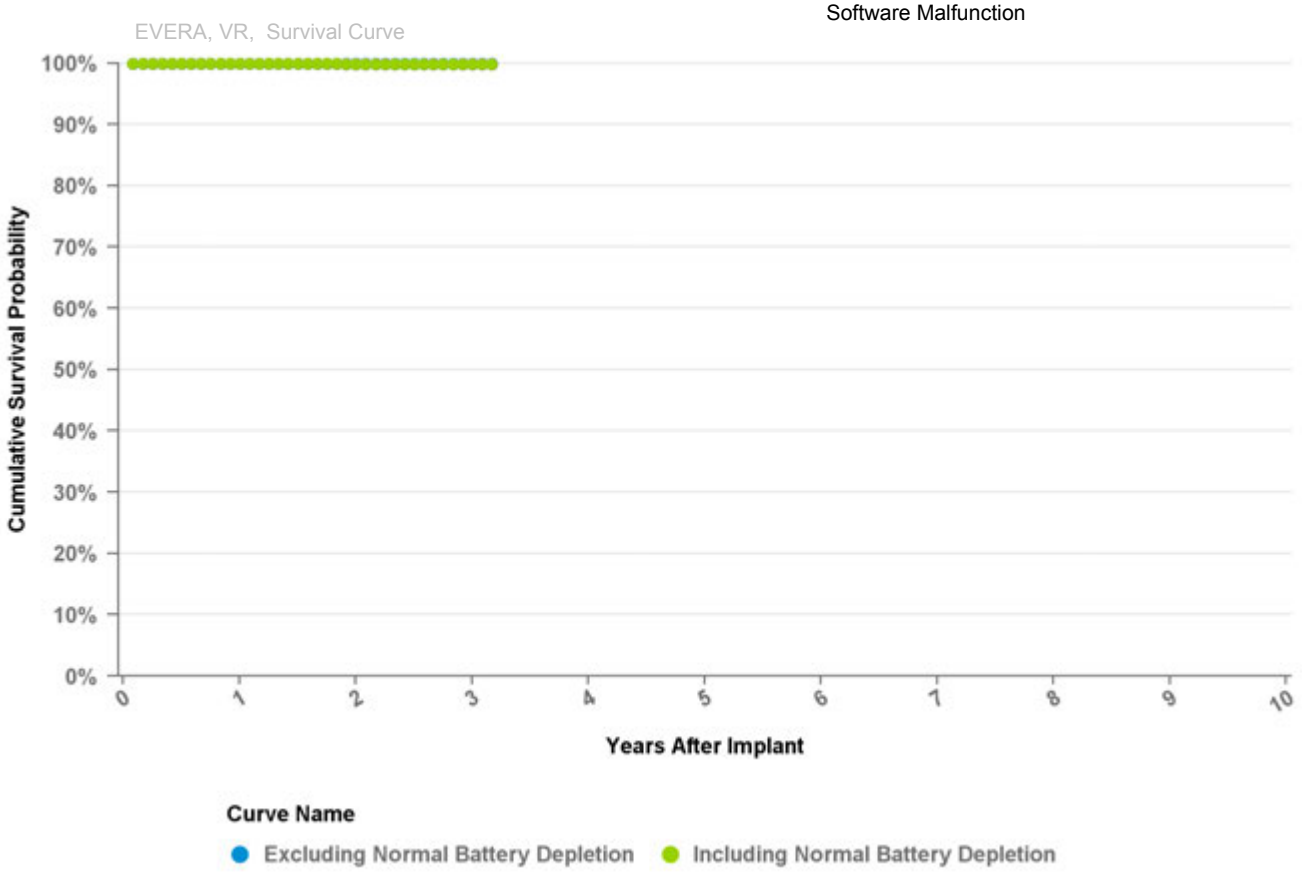
Implantable Cardioverter Defibrillator

DVBB2D4 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

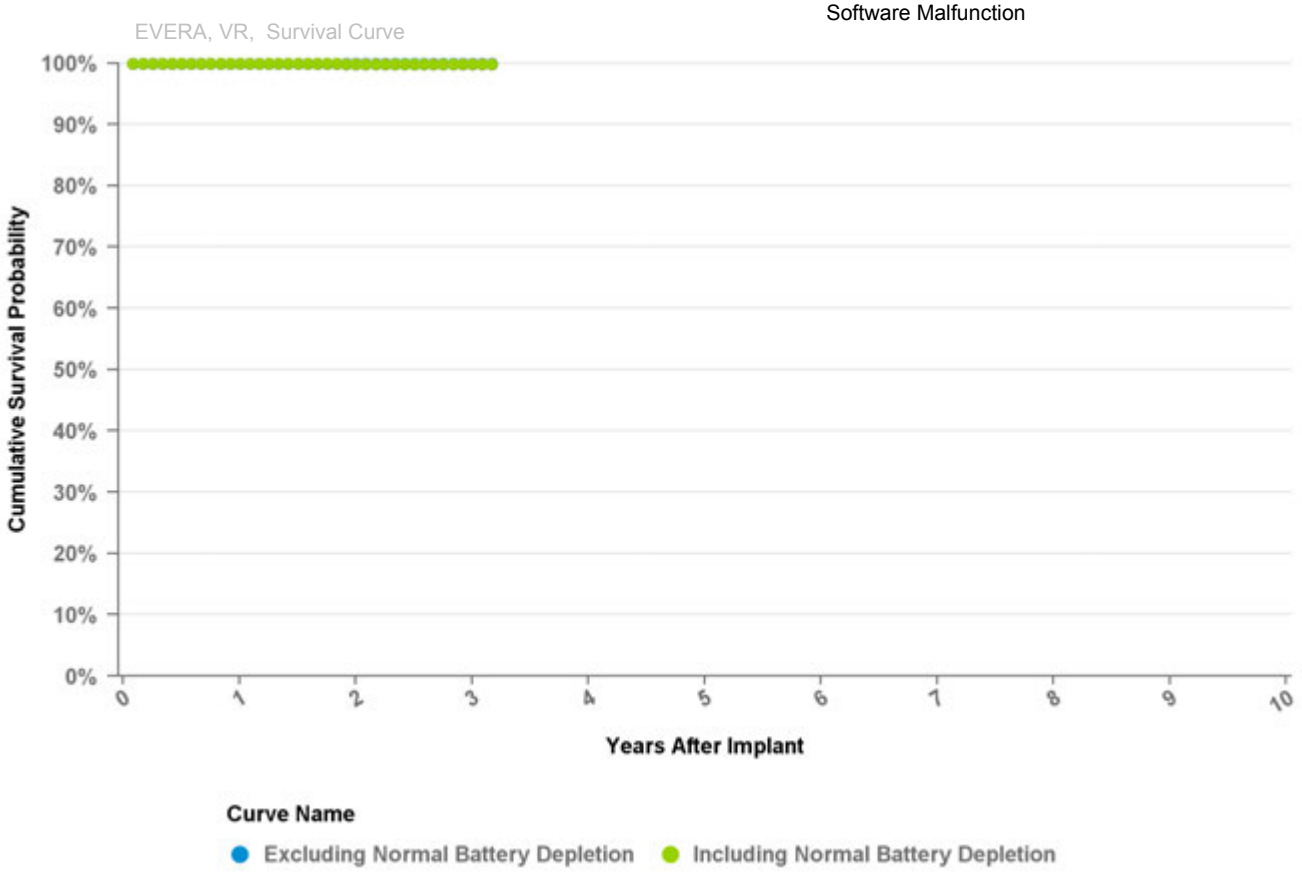
Implantable Cardioverter Defibrillator

DVBC3D1 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	3,681
Estimated Active US Implants	3,451
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

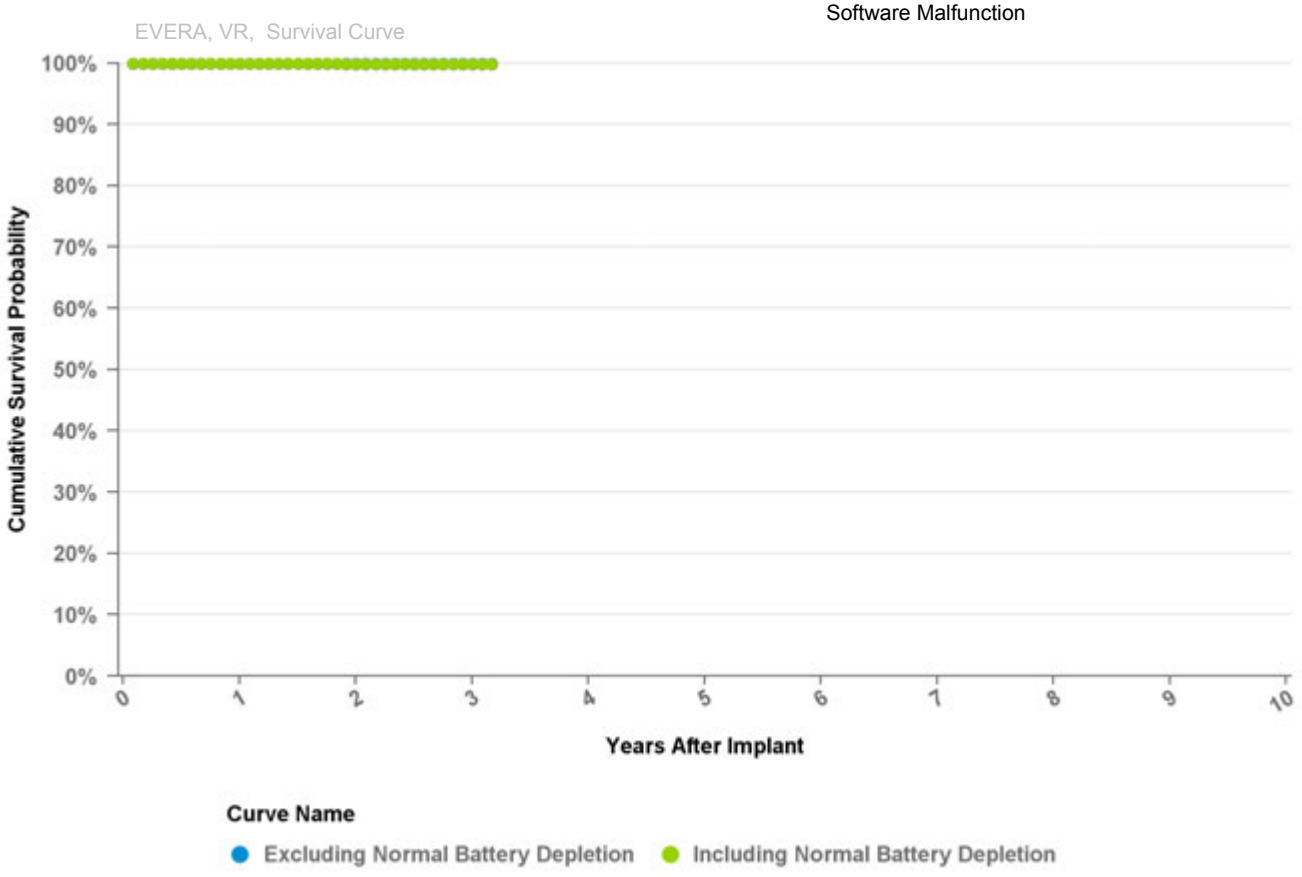
Implantable Cardioverter Defibrillator

DVBC3D4 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	4,868
Estimated Active US Implants	4,570
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	1
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

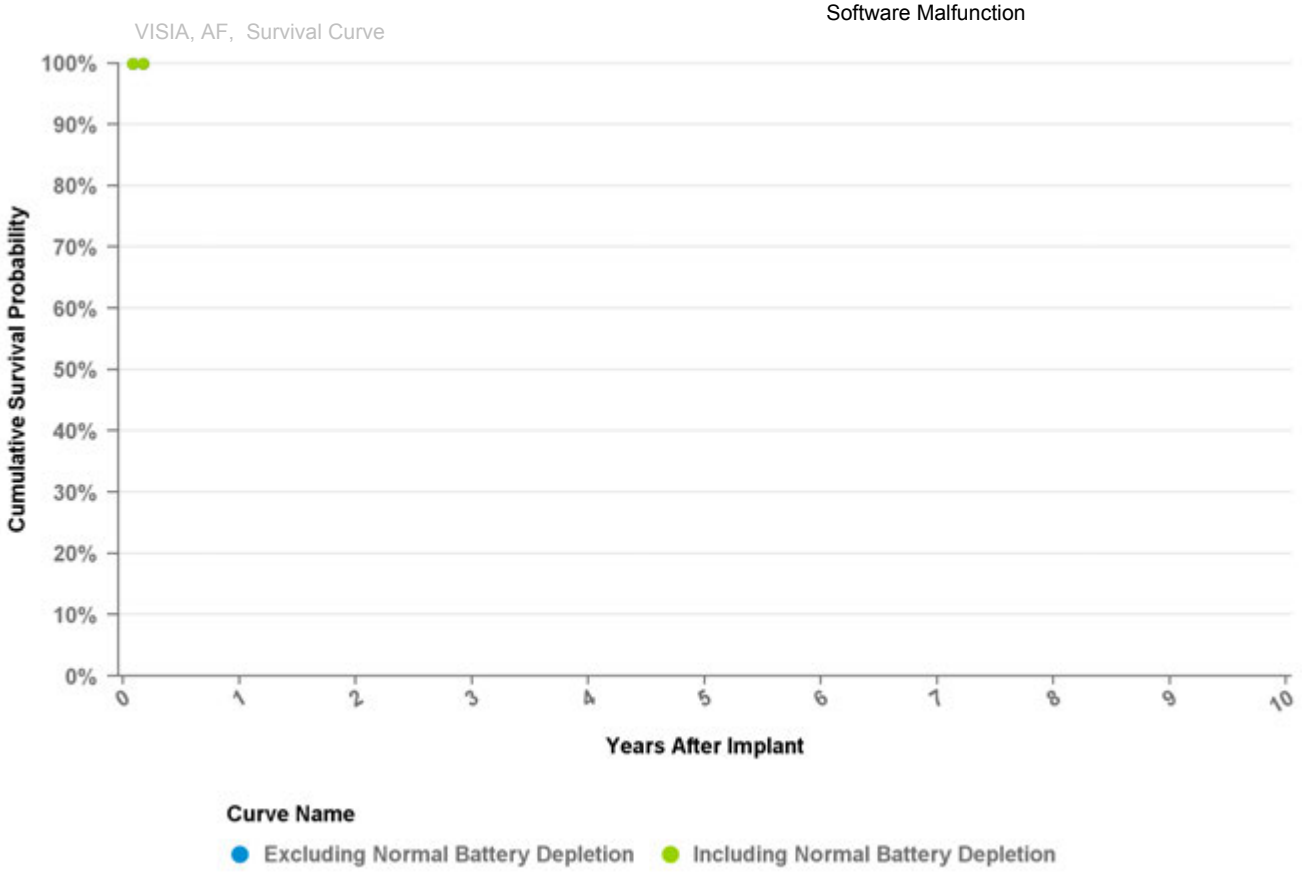
Implantable Cardioverter Defibrillator

DVFB1D4 Visia MRI AF

US Market Release Date	1/19/2016
CE Market Approval Date	
Registered US Implants	587
Estimated Active US Implants	587
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

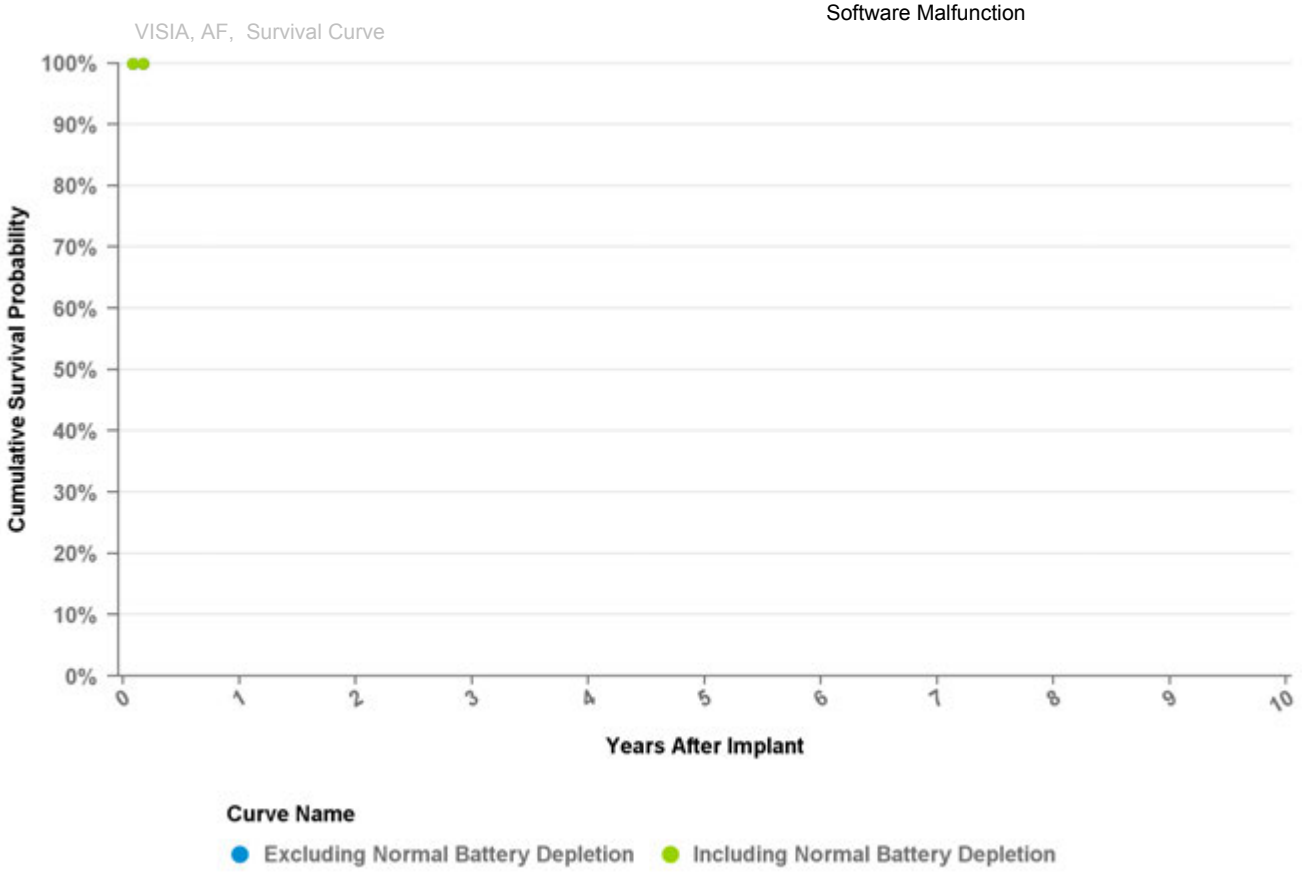
Implantable Cardioverter Defibrillator

DVFB2D4 Visia MRI AF XT

US Market Release Date	
CE Market Approval Date	10/19/2015
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

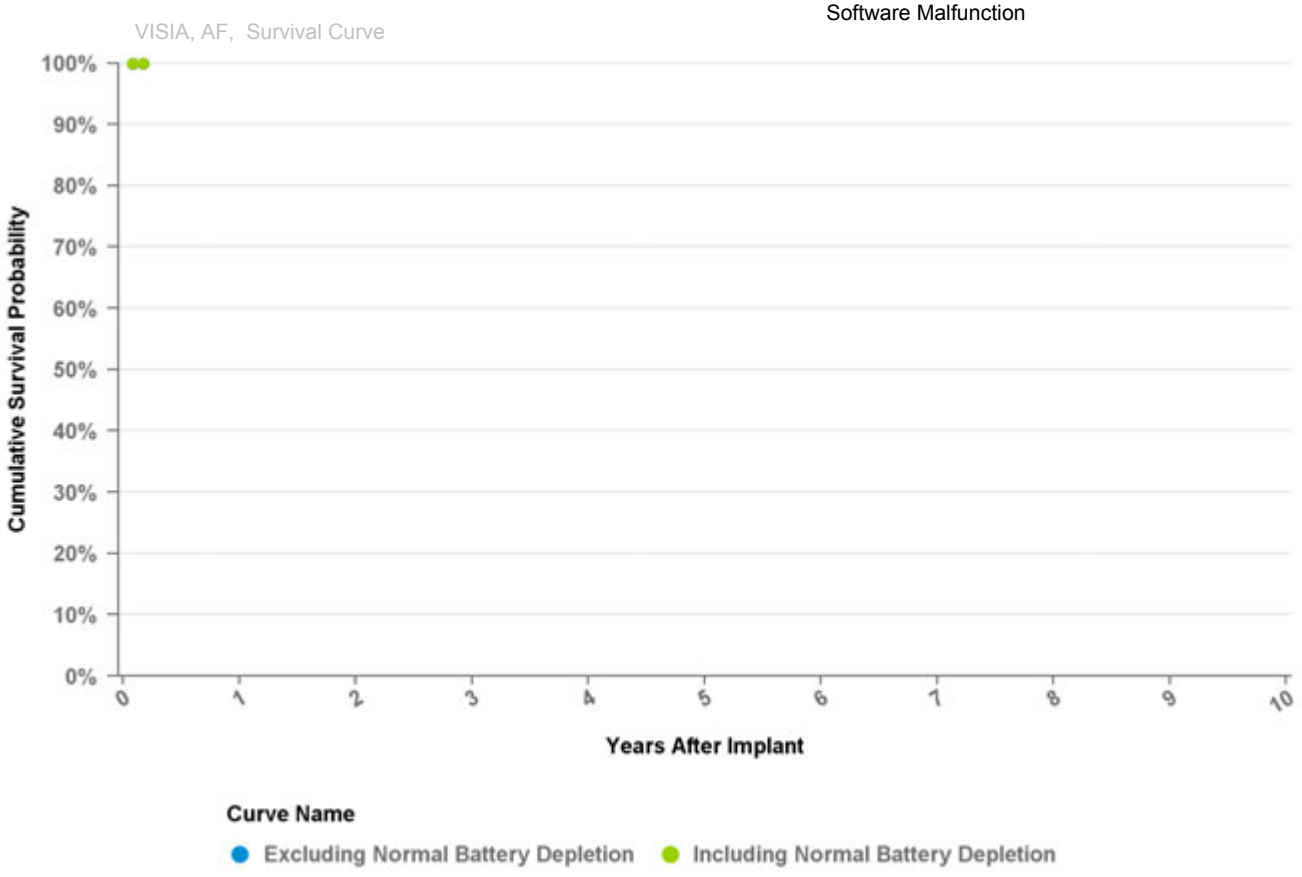
Implantable Cardioverter Defibrillator

DVFC3D4 Visia MRI AF S

US Market Release Date	1/19/2016
CE Market Approval Date	10/19/2015
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	at 2 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	145

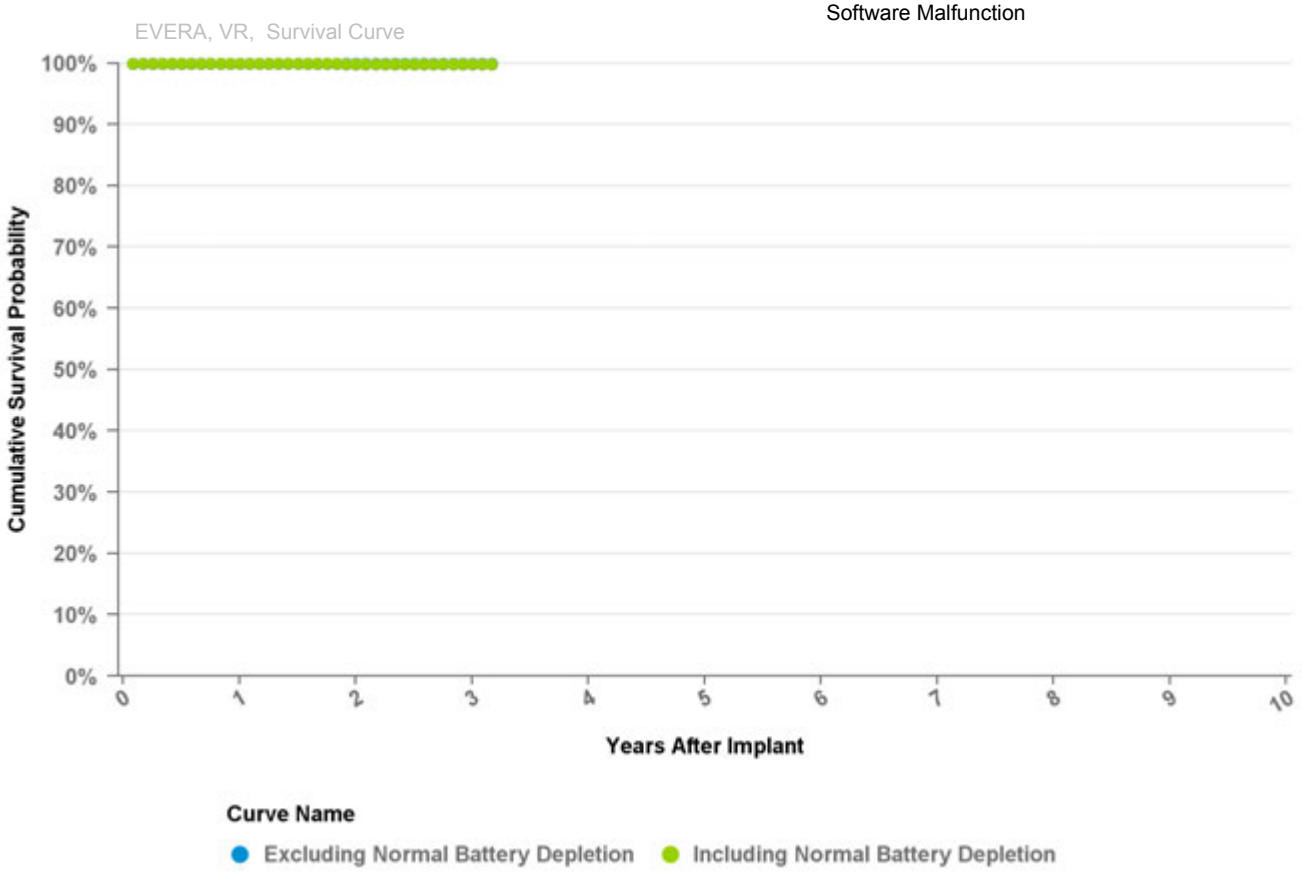
Implantable Cardioverter Defibrillator

DVMB1D4 Evera MRI XT

US Market Release Date	9/11/2015
CE Market Approval Date	
Registered US Implants	7,795
Estimated Active US Implants	7,685
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

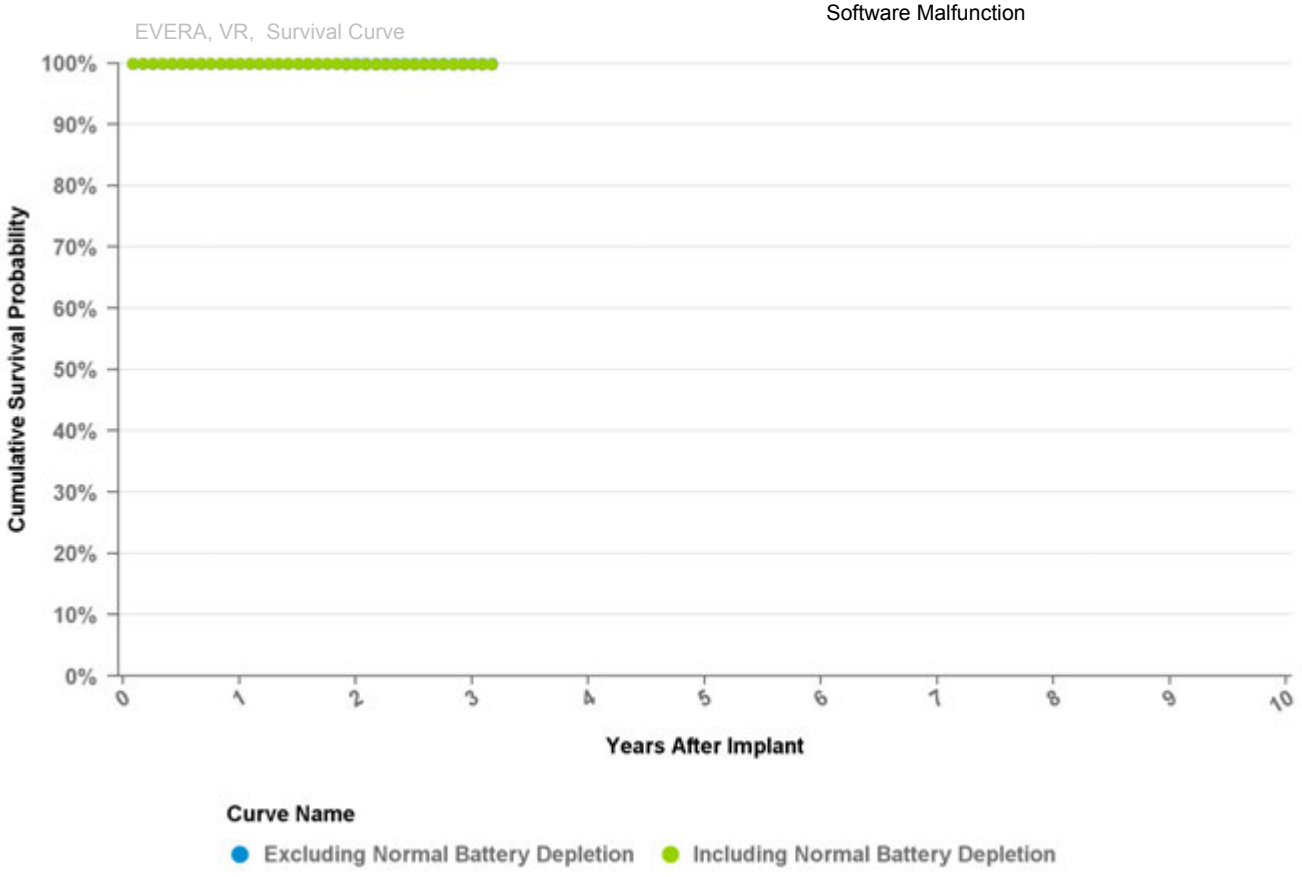
Implantable Cardioverter Defibrillator

DVMB2D4 Evera MRI XT

US Market Release Date	
CE Market Approval Date	3/31/2014
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

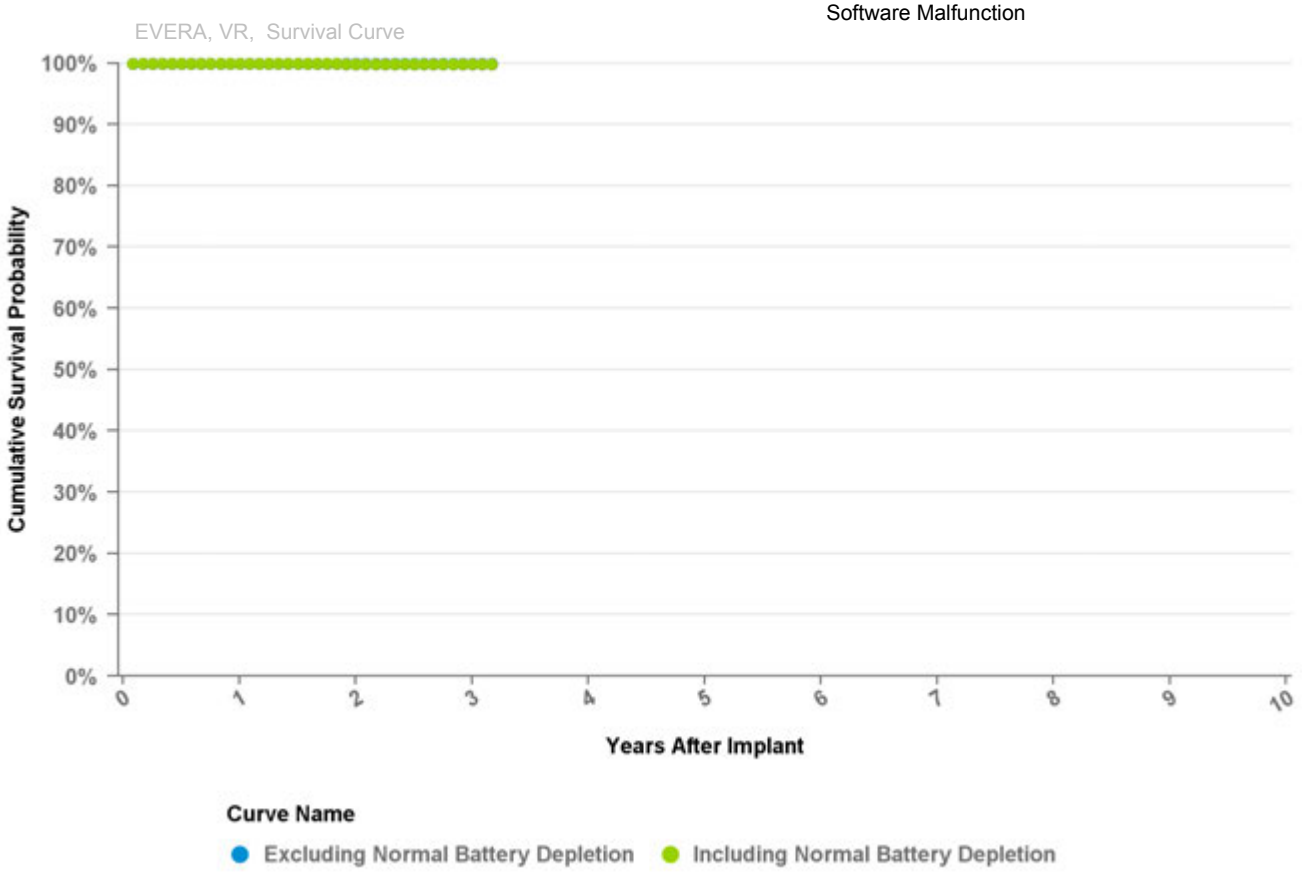
Implantable Cardioverter Defibrillator

DVMC3D4 Evera MRI S

US Market Release Date	9/11/2015
CE Market Approval Date	3/31/2014
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



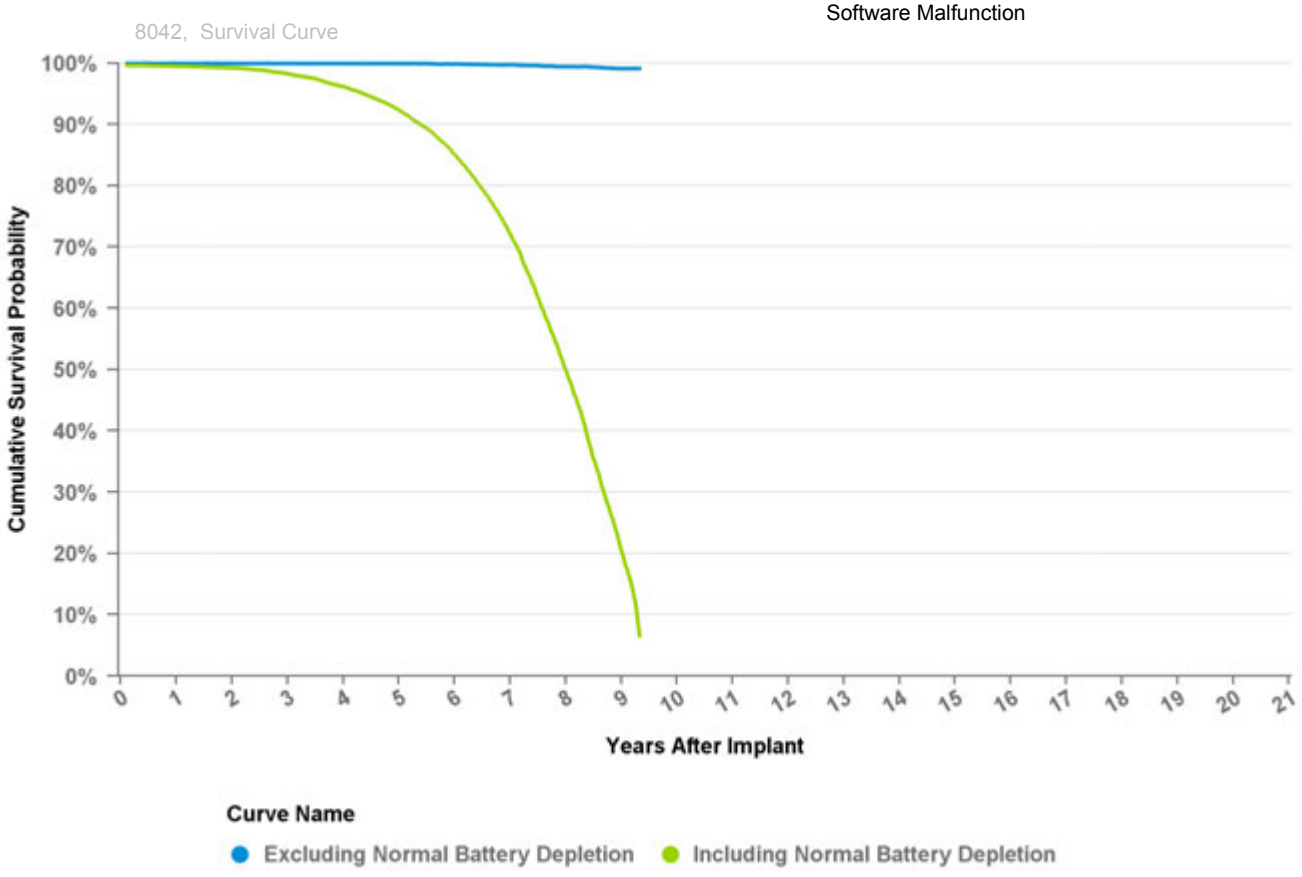
Years	1	2	3	at 38 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	32988	14285	1095	112

Cardiac Resynchronization Therapy

8042 InSync III

US Market Release Date	2/25/2003
CE Market Approval Date	2/7/2001
Registered US Implants	39,413
Estimated Active US Implants	6,422
Normal Battery Depletions (US)	4,534
NBG Code	DDDR

Total Malfunctions (US)	74
Therapy Not Compromised Malfunctions	45
Battery Malfunction	31
Electrical Component	2
Electrical Interconnect	3
Other Malfunction	7
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	29
Battery Malfunction	17
Electrical Component	0
Electrical Interconnect	12
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.4%	99.1%	99.1%
Including NBD	99.5%	99.2%	98.3%	96.2%	92.4%	85.2%	72.2%	49.9%	20.6%	6.5%
Effective Sample Size	30486	26134	22475	19215	16040	11639	6594	2986	613	128

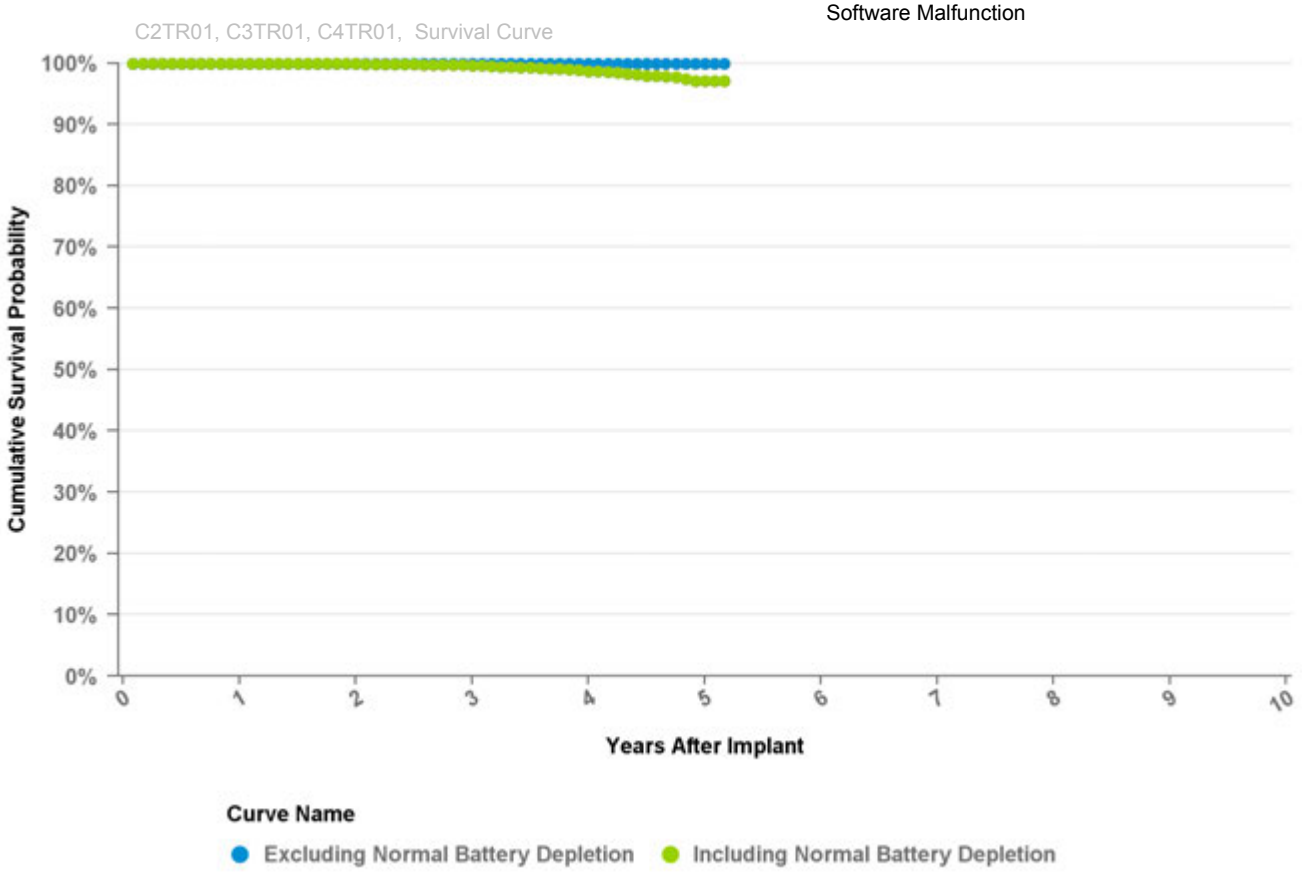
Cardiac Resynchronization Therapy

C2TR01 Syncra CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	5/11/2010
Registered US Implants	9,524
Estimated Active US Implants	7,340
Normal Battery Depletions (US)	43

NBG Code	OOE-DDDR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 62 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	97.1%
Effective Sample Size	23991	18054	11511	5767	1067	415

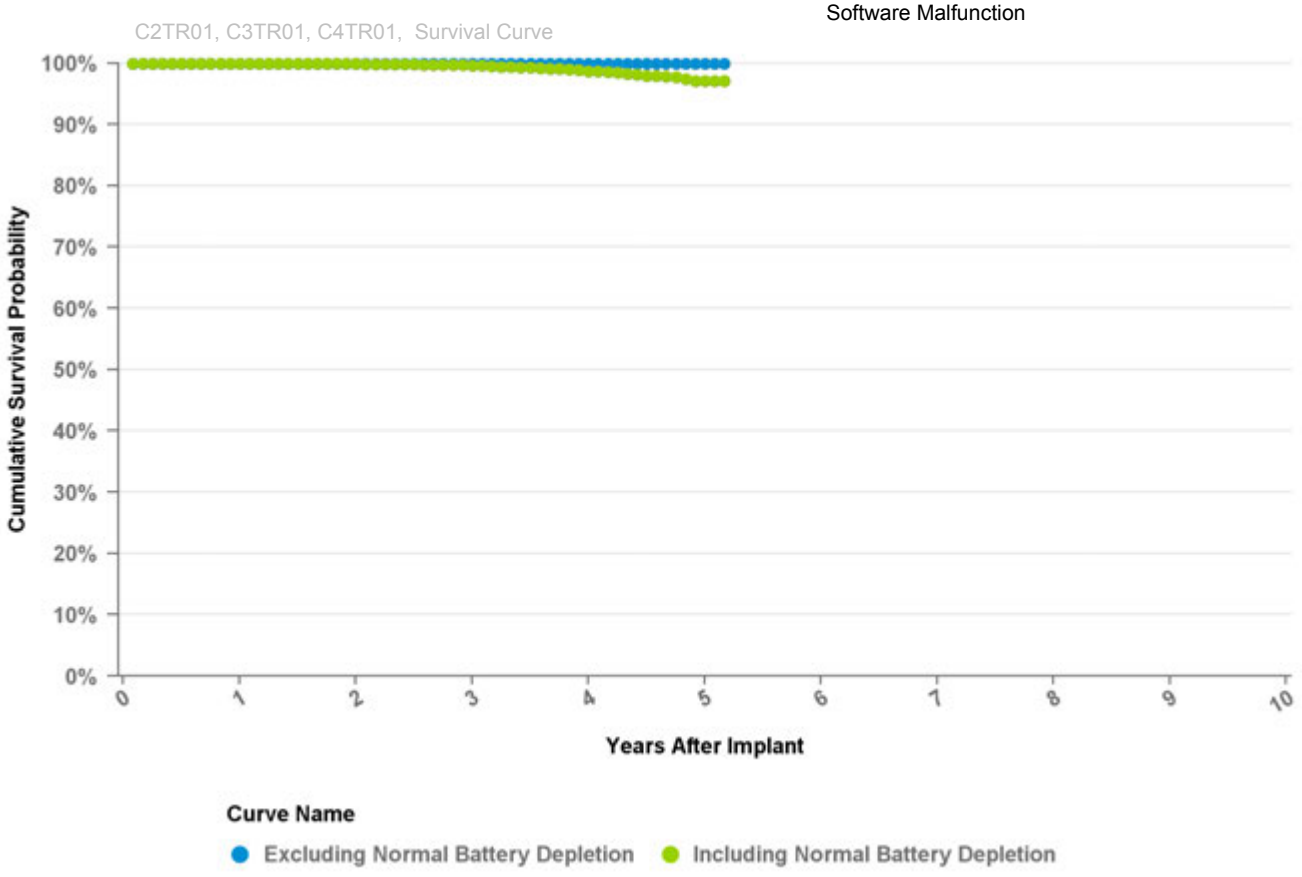
Cardiac Resynchronization Therapy

C3TR01 Consulta CRT-P

US Market Release Date	
CE Market Approval Date	5/11/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 62 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	97.1%
Effective Sample Size	23991	18054	11511	5767	1067	415

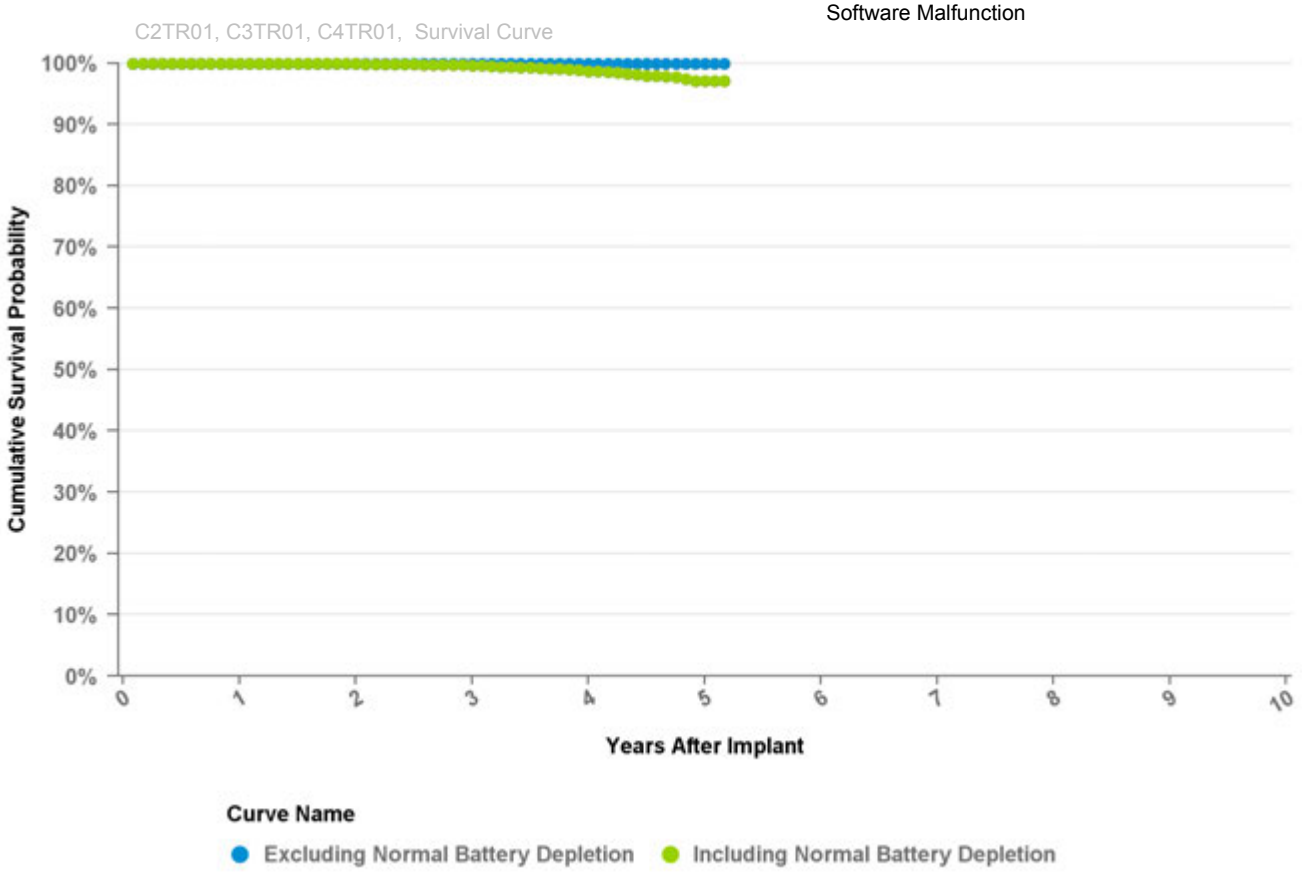
Cardiac Resynchronization Therapy

C4TR01 Consulta CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	
Registered US Implants	21,544
Estimated Active US Implants	17,967
Normal Battery Depletions (US)	60

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 62 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	97.1%
Effective Sample Size	23991	18054	11511	5767	1067	415

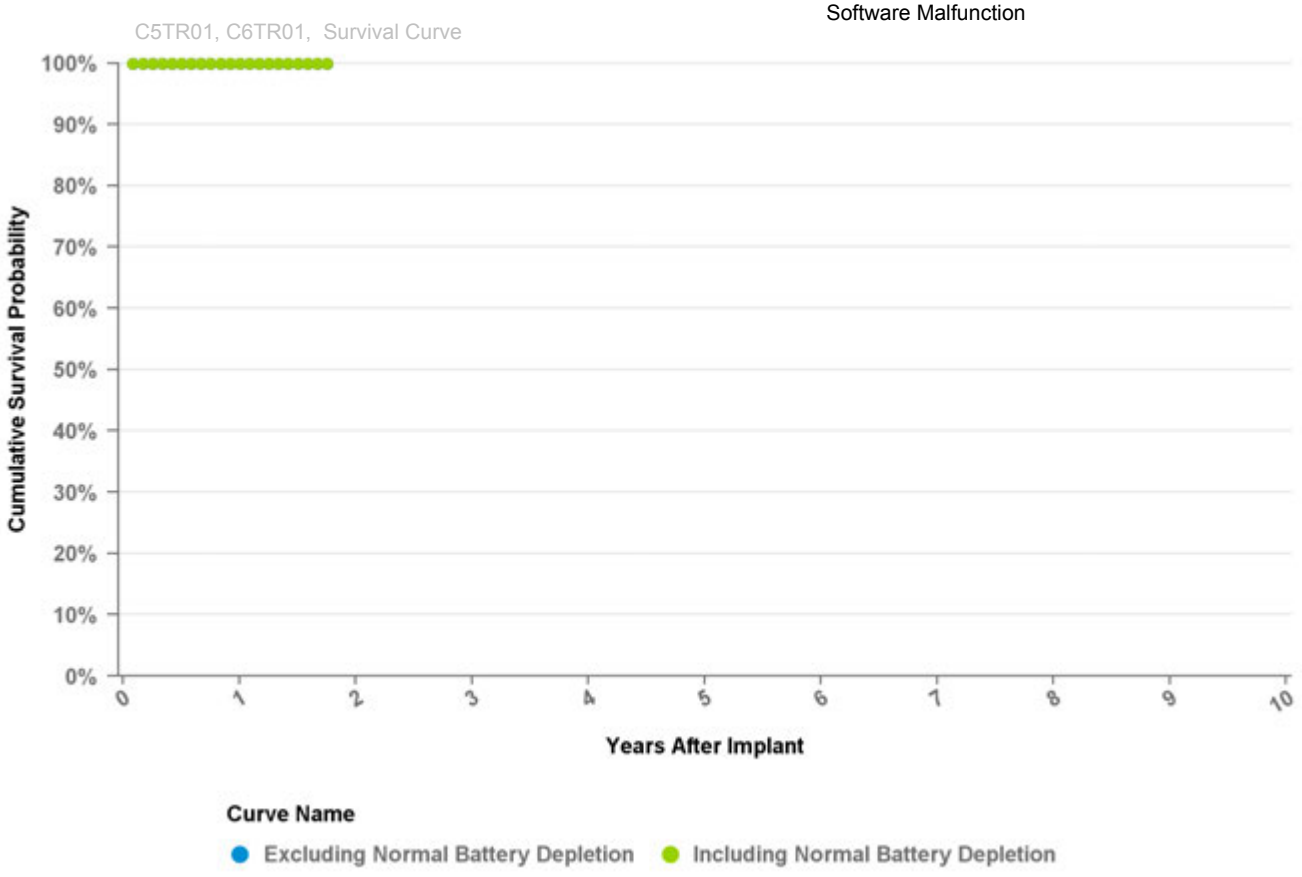
Cardiac Resynchronization Therapy

C5TR01 Viva CRT-P

US Market Release Date	
CE Market Approval Date	4/4/2014
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	at 21 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1522	114

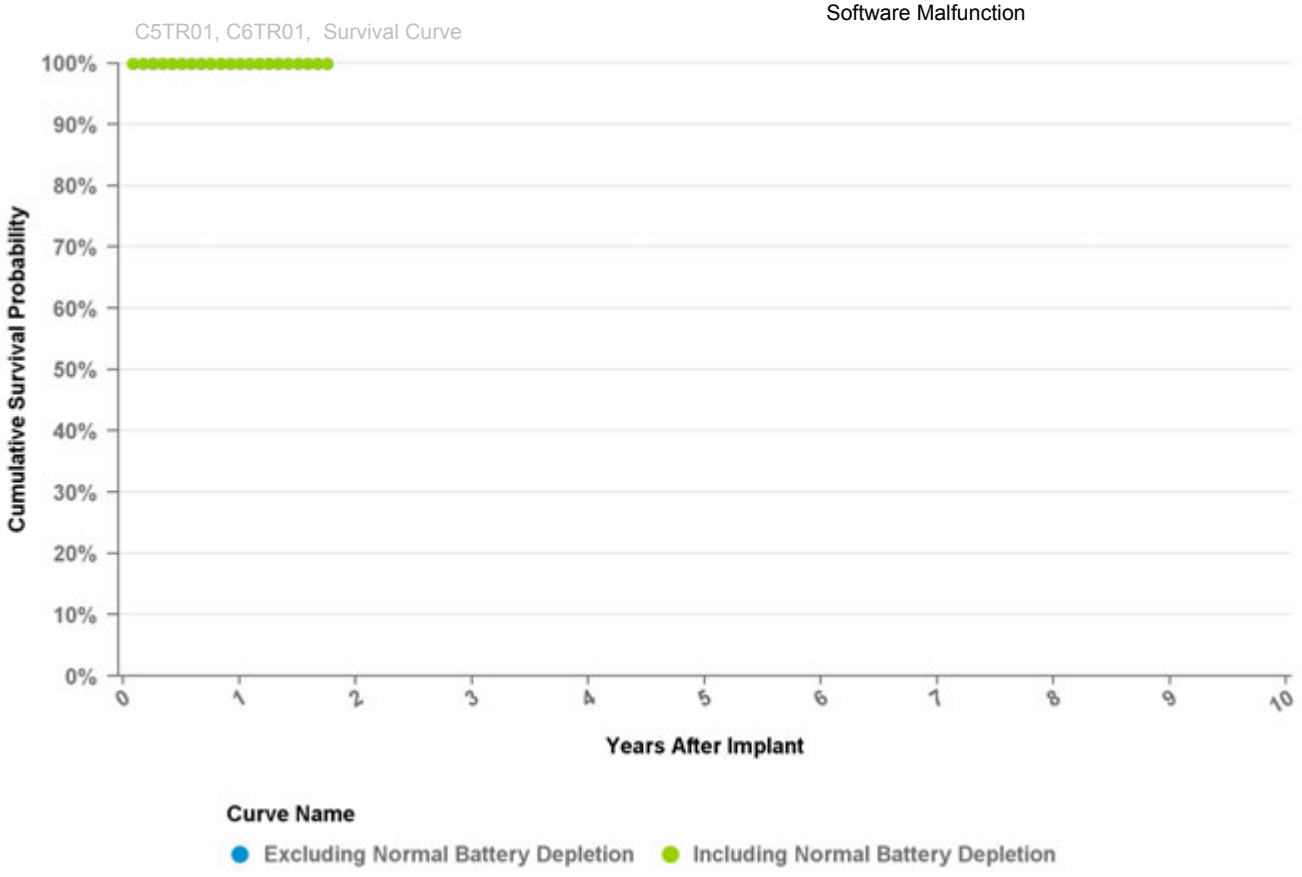
Cardiac Resynchronization Therapy

C6TR01 Viva CRT-P

US Market Release Date	7/9/2014
CE Market Approval Date	
Registered US Implants	5,100
Estimated Active US Implants	4,905
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	at 21 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1522	114

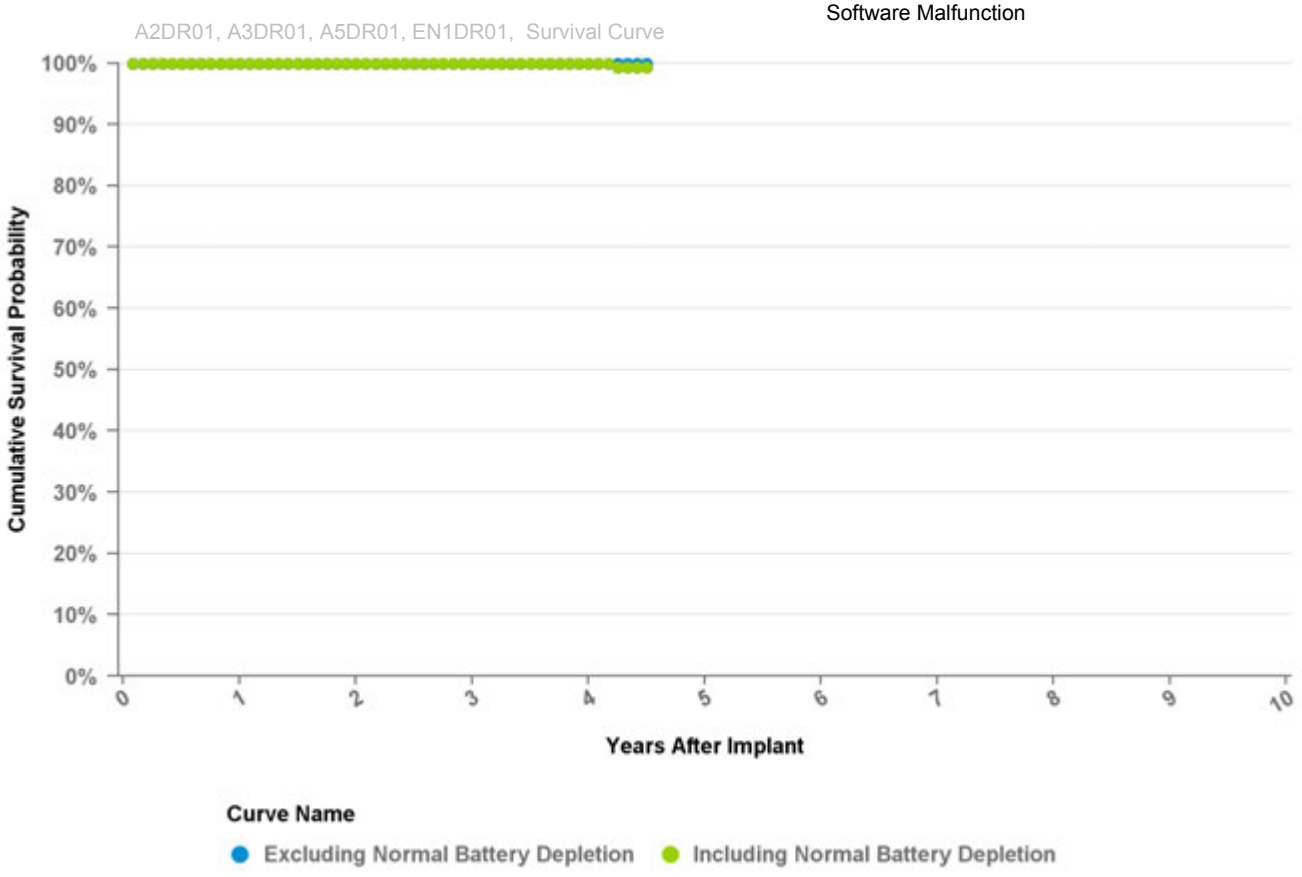
Implantable Pulse Generator

A2DR01 Advisa DR MRI

US Market Release Date	1/15/2013
CE Market Approval Date	
Registered US Implants	186,364
Estimated Active US Implants	179,424
Normal Battery Depletions (US)	7

NBG Code	OAE-DDDR

Total Malfunctions (US)	17
Therapy Not Compromised Malfunctions	15
Battery Malfunction	0
Electrical Component	8
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	2
Software Malfunction	2
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 54 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.3%
Effective Sample Size	106872	41829	8531	490	122

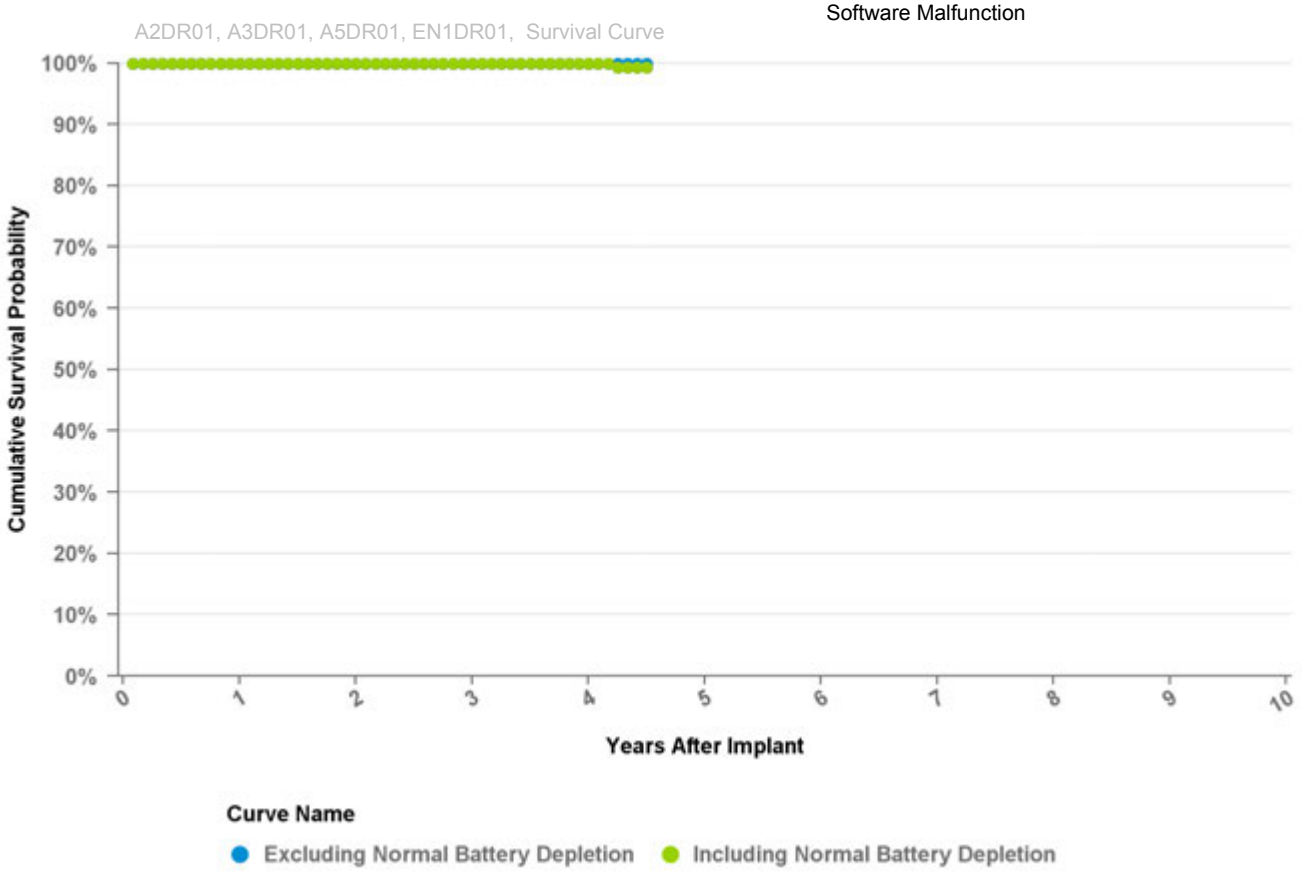
Implantable Pulse Generator

A3DR01 Advisa DR MRI

US Market Release Date	
CE Market Approval Date	6/2/2009
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	1

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 54 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.3%
Effective Sample Size	106872	41829	8531	490	122

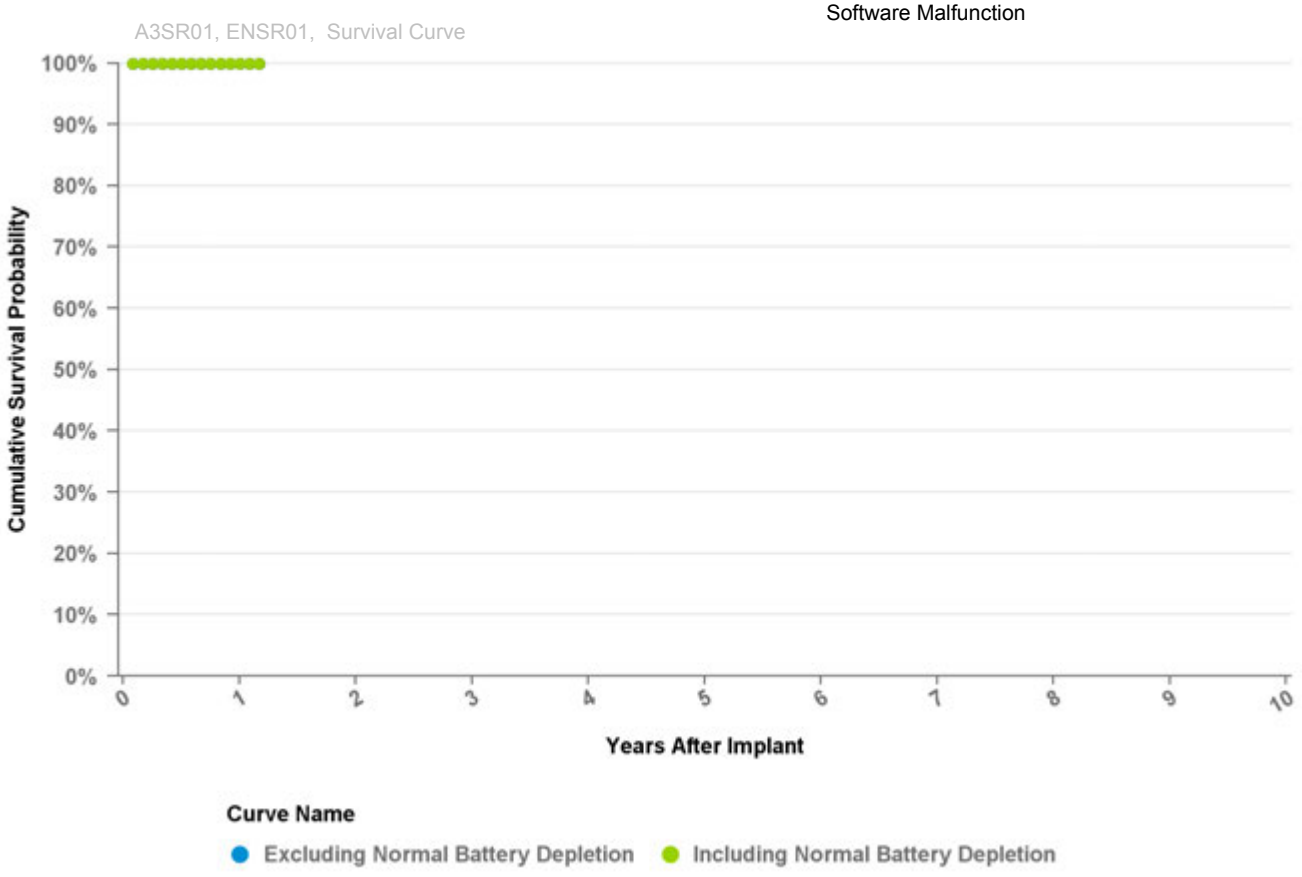
Implantable Pulse Generator

A3SR01 Advisa SR MRI

US Market Release Date	3/19/2015
CE Market Approval Date	4/24/2014
Registered US Implants	8,869
Estimated Active US Implants	8,606
Normal Battery Depletions (US)	0

NBG Code	VVIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	912	195

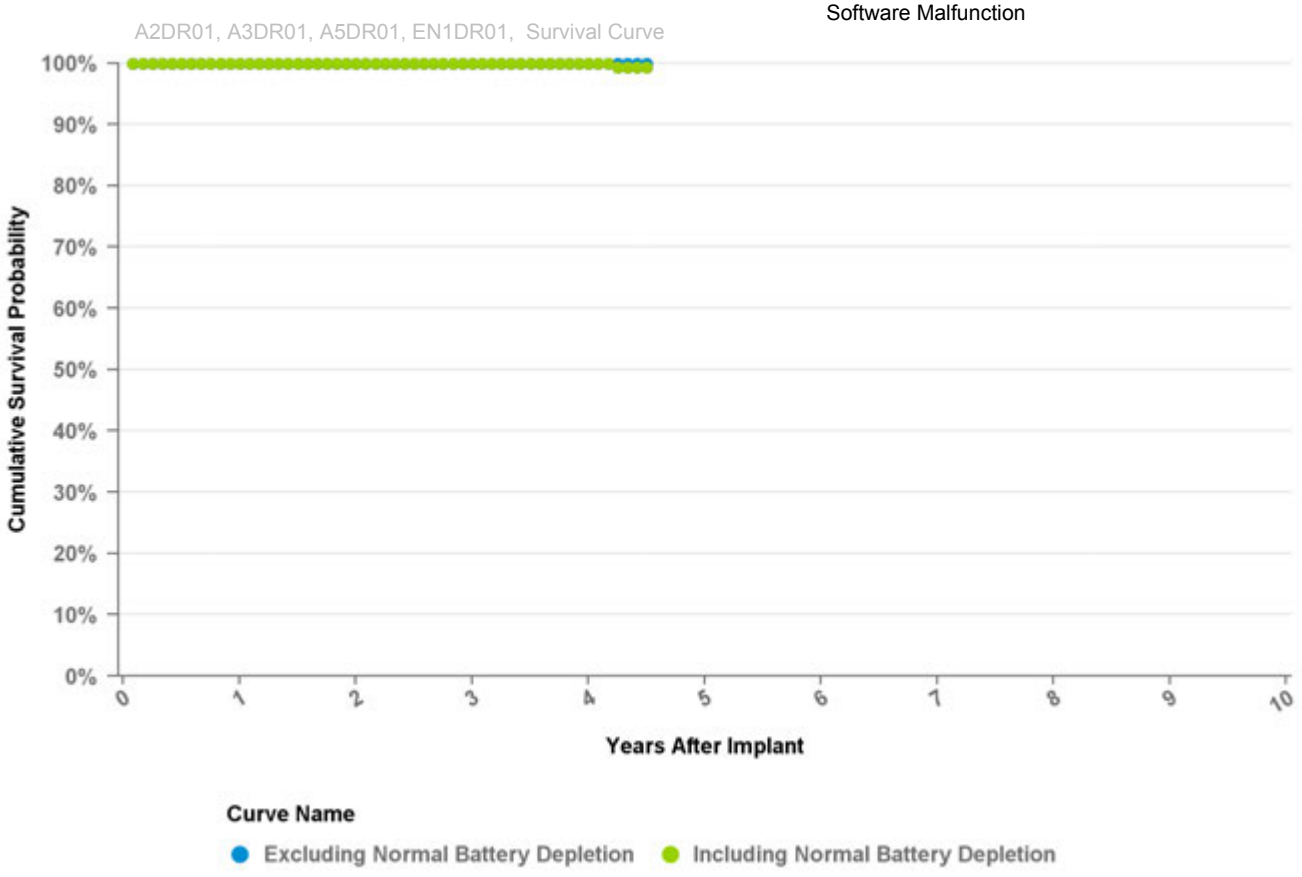
Implantable Pulse Generator

A4DR01 Advisa DR

US Market Release Date	4/4/2011
CE Market Approval Date	
Registered US Implants	1,535
Estimated Active US Implants	1,336
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 54 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.3%
Effective Sample Size	106872	41829	8531	490	122

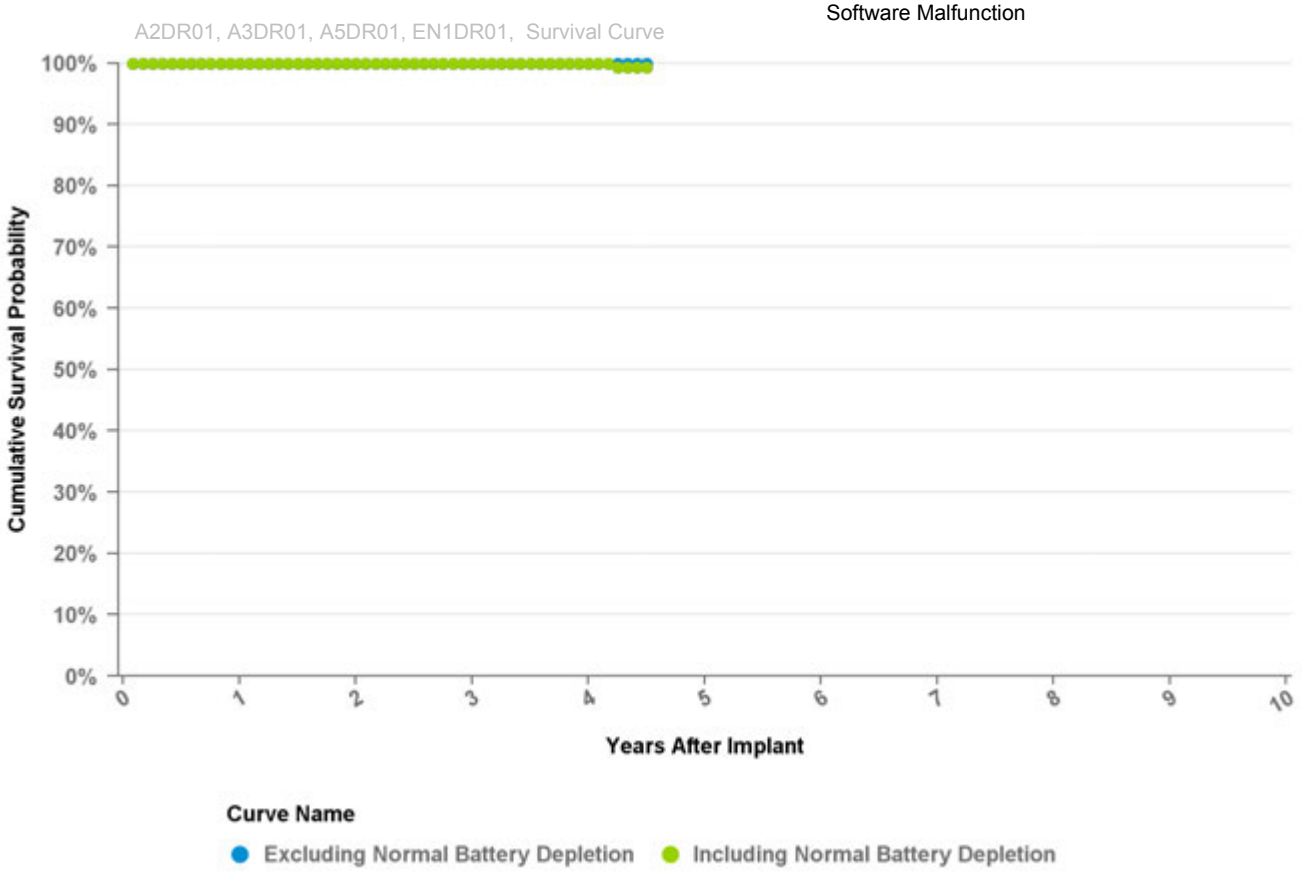
Implantable Pulse Generator

A5DR01 Advisa DR

US Market Release Date	
CE Market Approval Date	6/2/2009
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



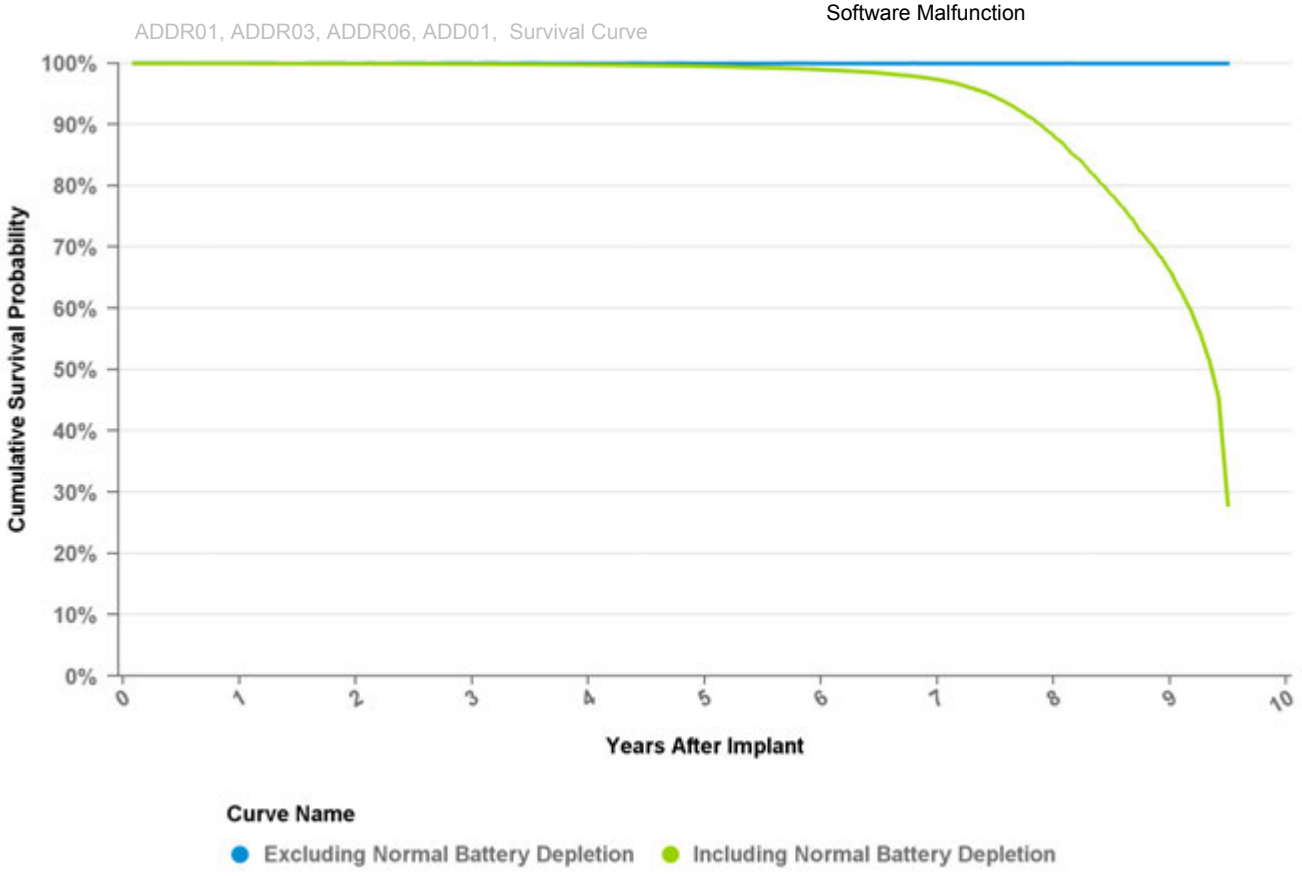
Years	1	2	3	4	at 54 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.3%
Effective Sample Size	106872	41829	8531	490	122

Implantable Pulse Generator

ADD01 Adapta D

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



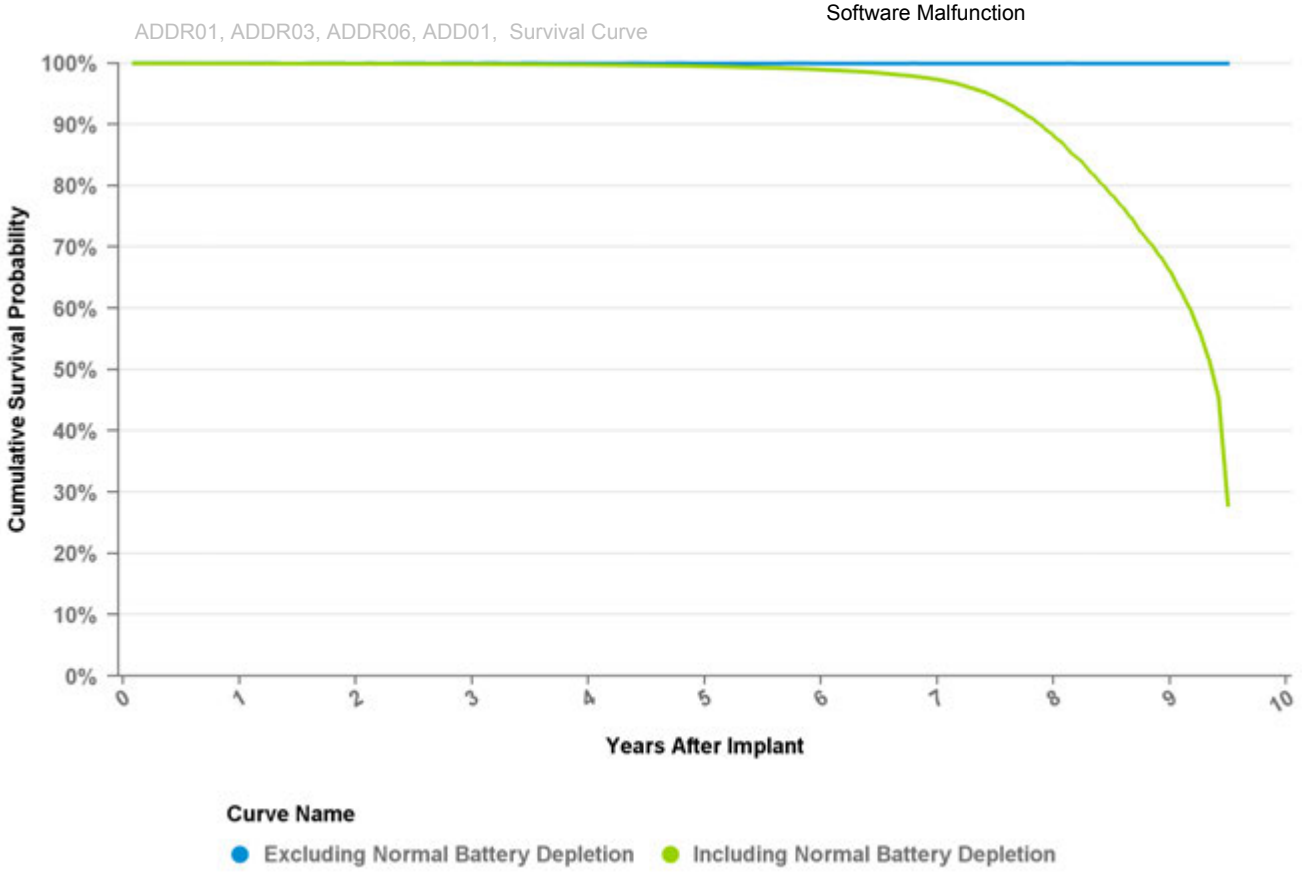
Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

Implantable Pulse Generator

ADDR01 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	435,737
Estimated Active US Implants	305,895
Normal Battery Depletions (US)	10,215
NBG Code	DDDR

Total Malfunctions (US)	76
Therapy Not Compromised Malfunctions	51
Battery Malfunction	0
Electrical Component	49
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	25
Battery Malfunction	0
Electrical Component	20
Electrical Interconnect	3
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



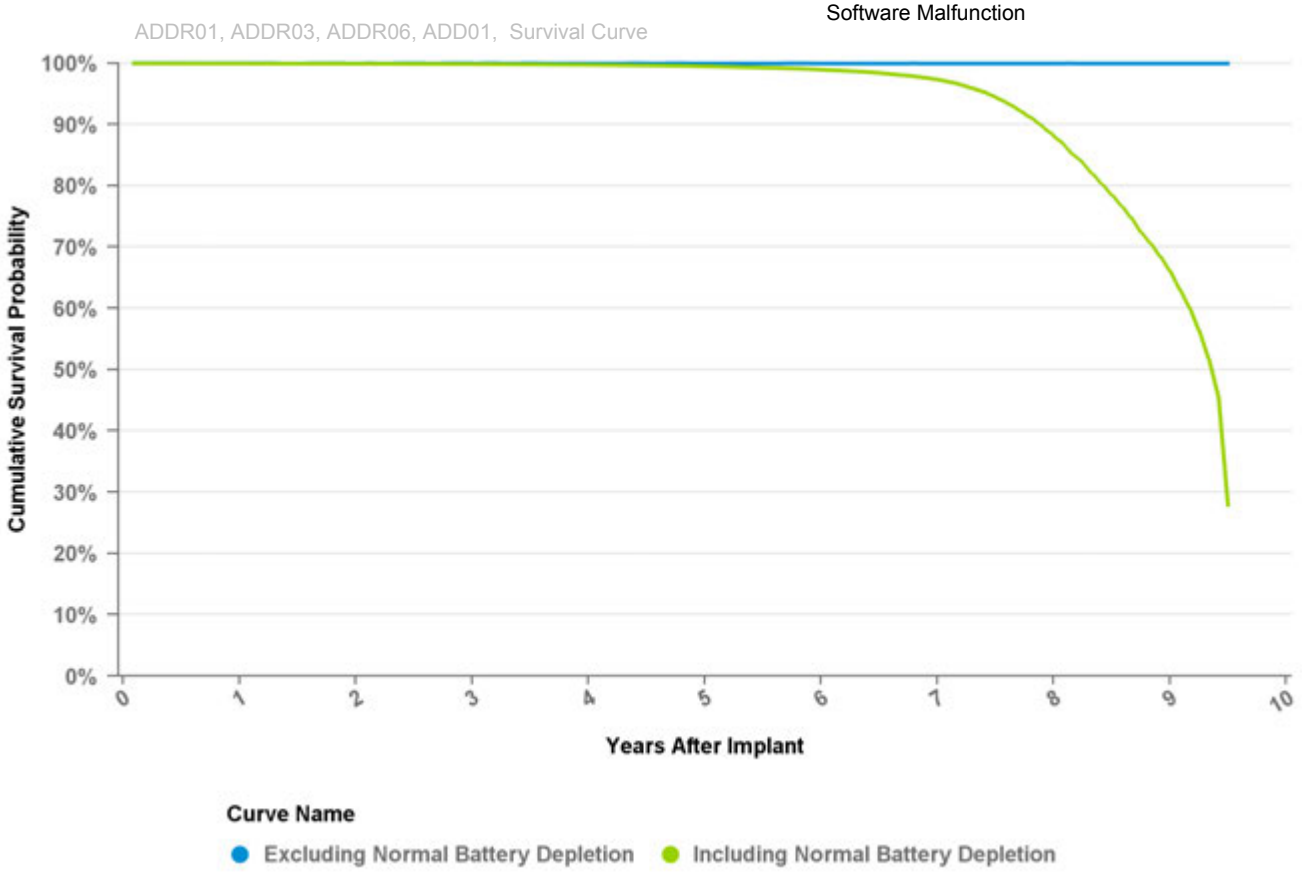
Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

Implantable Pulse Generator

ADDR03 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	4,074
Estimated Active US Implants	2,627
Normal Battery Depletions (US)	154
NBG Code	DDDR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

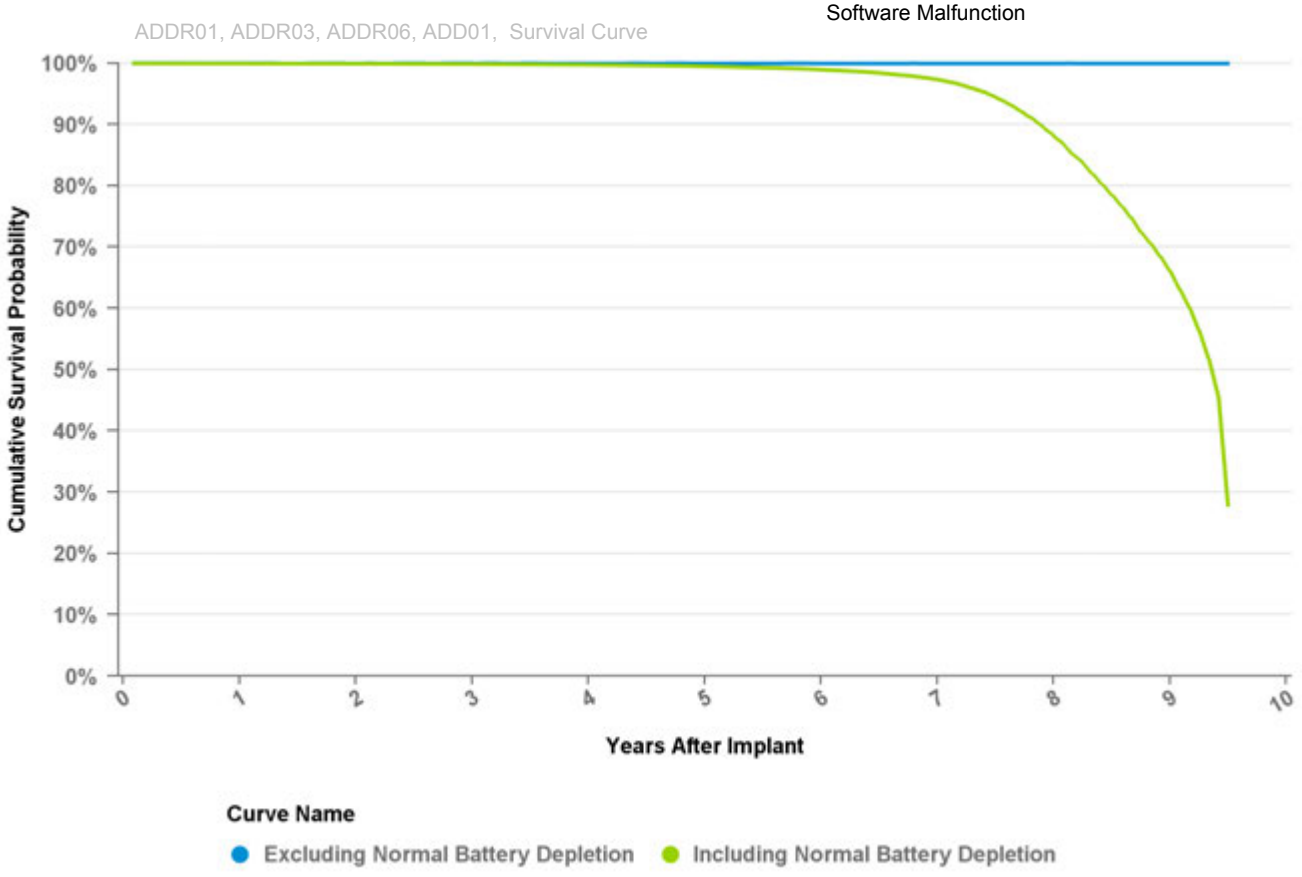
Implantable Pulse Generator

ADDR06 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	3,139
Estimated Active US Implants	1,667
Normal Battery Depletions (US)	188

NBG Code	DDDR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



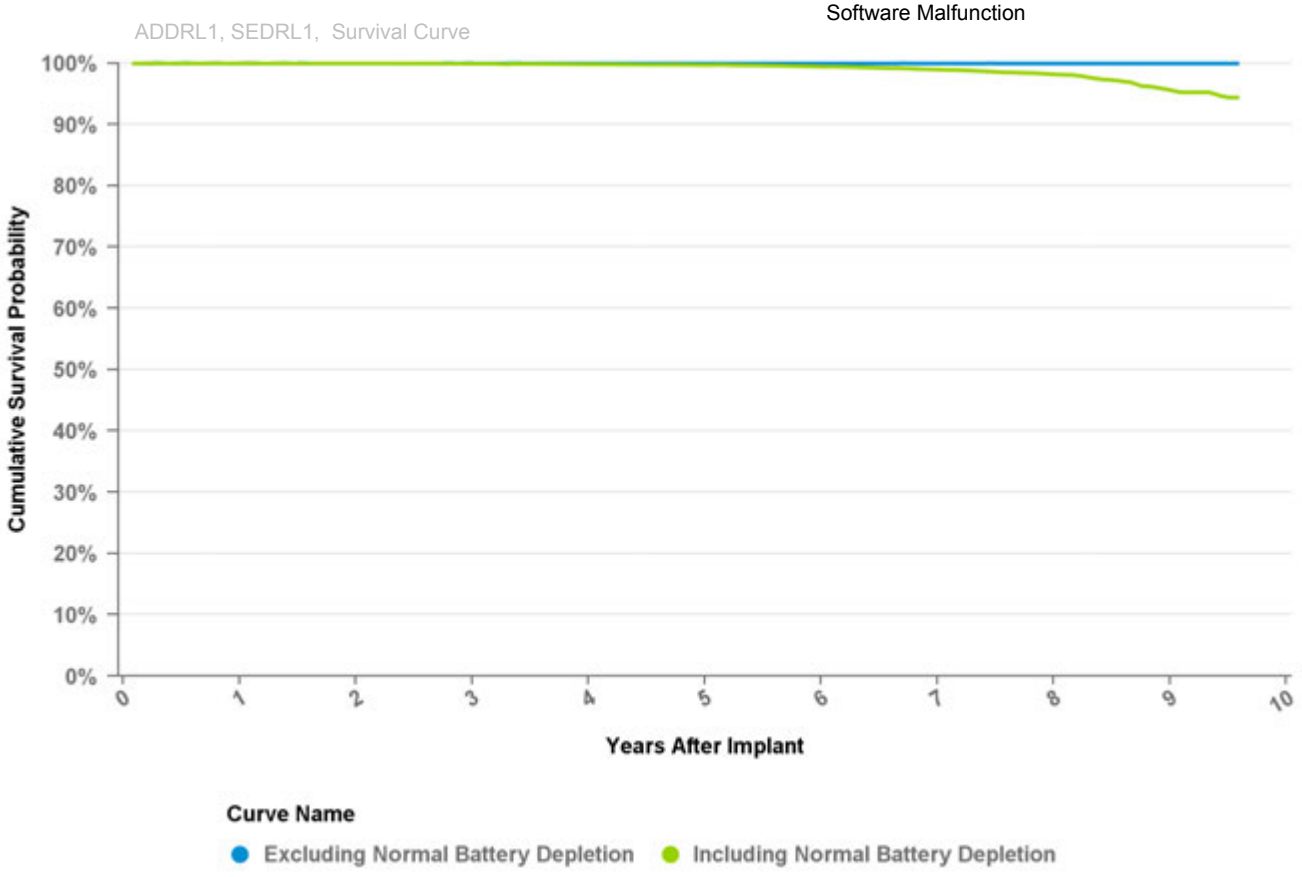
Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

Implantable Pulse Generator

ADDRL1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	125,168
Estimated Active US Implants	104,504
Normal Battery Depletions (US)	263
NBG Code	DDDR

Total Malfunctions (US)	14
Therapy Not Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



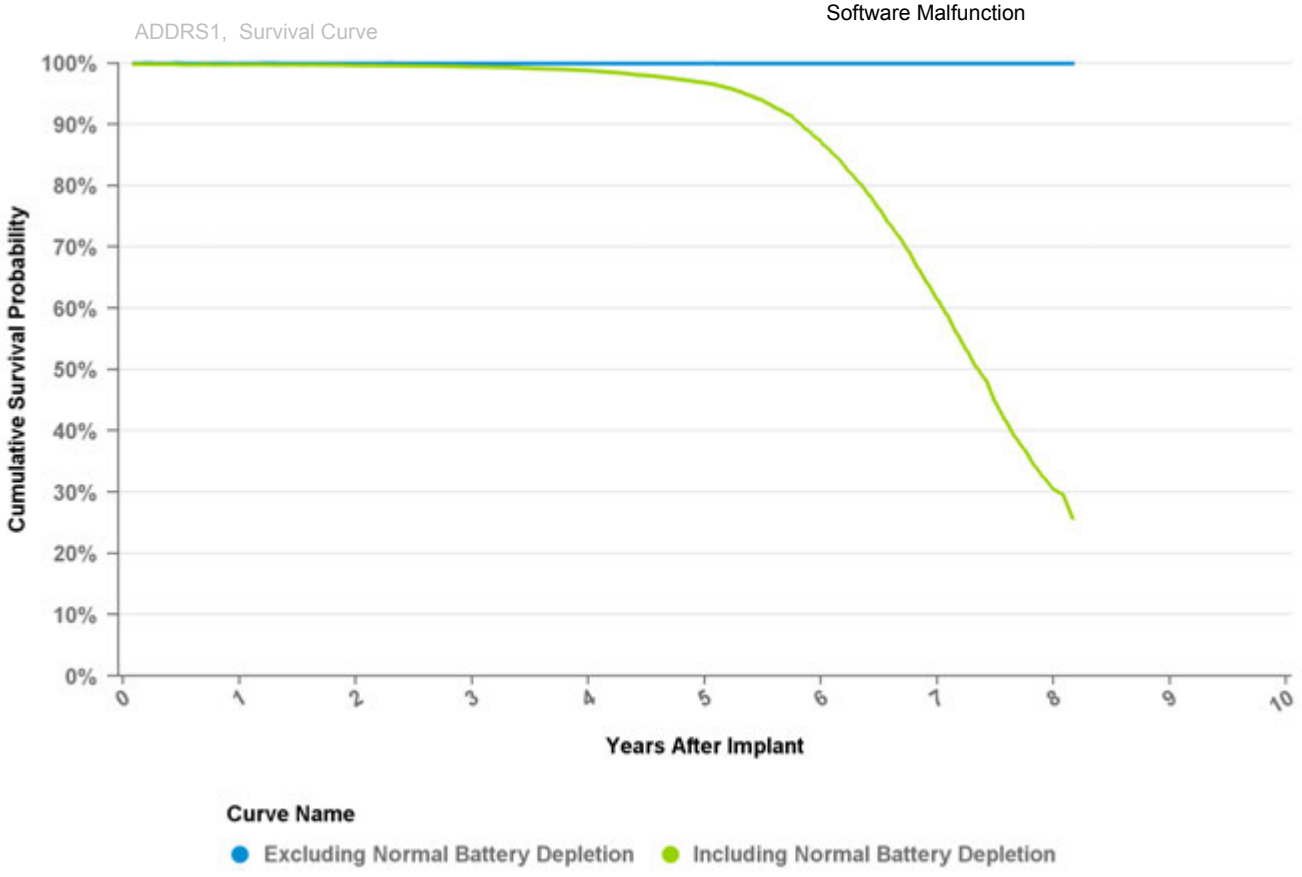
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.0%	98.2%	95.6%	94.4%
Effective Sample Size	106194	88997	69960	51570	35276	22064	11834	5158	1289	139

Implantable Pulse Generator

ADDRS1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	45,293
Estimated Active US Implants	27,349
Normal Battery Depletions (US)	2,661
NBG Code	DDDR

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



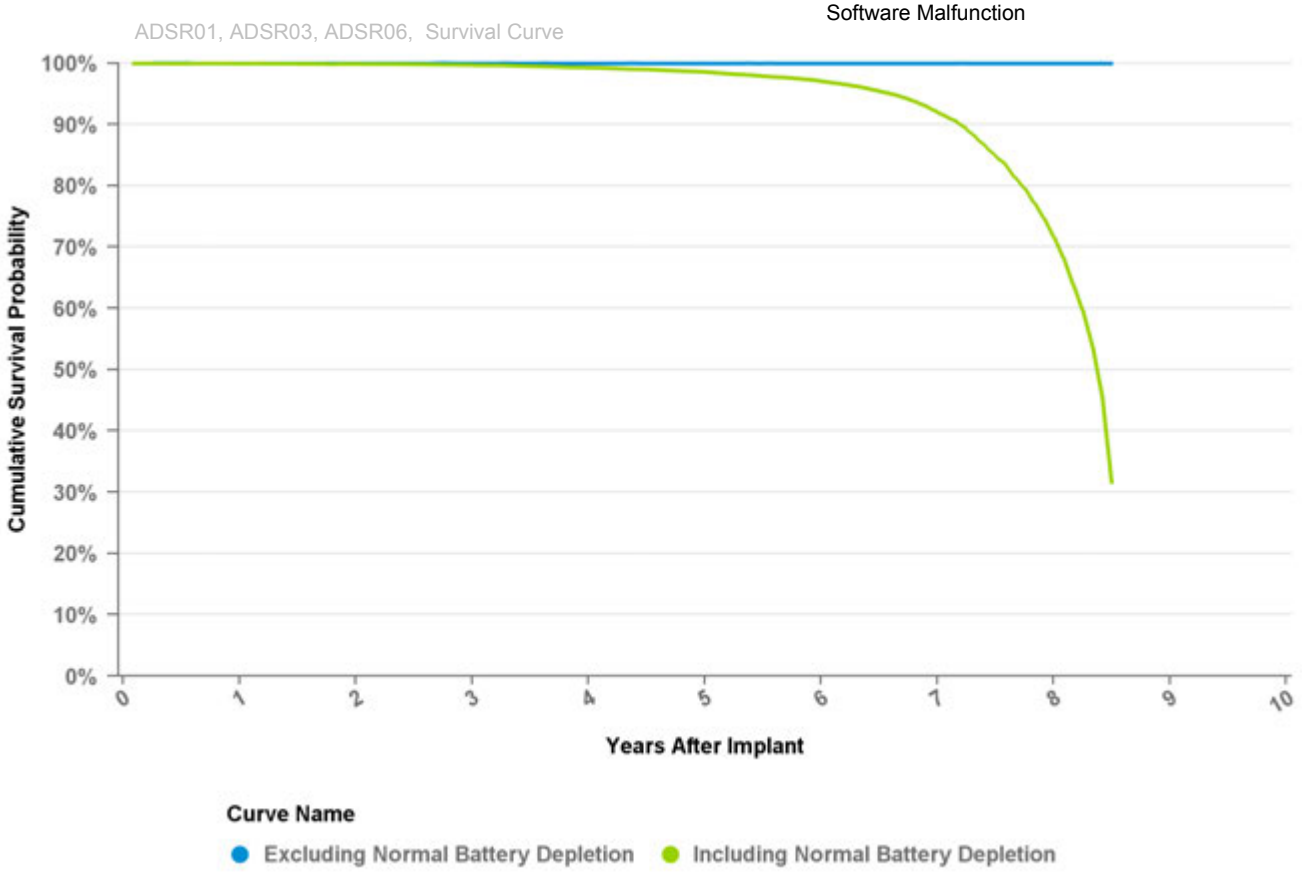
Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.6%	99.4%	98.8%	96.8%	87.1%	61.5%	30.5%	25.7%
Effective Sample Size	36795	31313	25454	20215	15151	9704	3712	364	126

Implantable Pulse Generator

ADSR01 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	87,040
Estimated Active US Implants	52,592
Normal Battery Depletions (US)	1,837
NBG Code	SSIR

Total Malfunctions (US)	13
Therapy Not Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.0%	71.8%	31.5%
Effective Sample Size	69779	55737	43382	32309	23193	15856	9212	2901	330

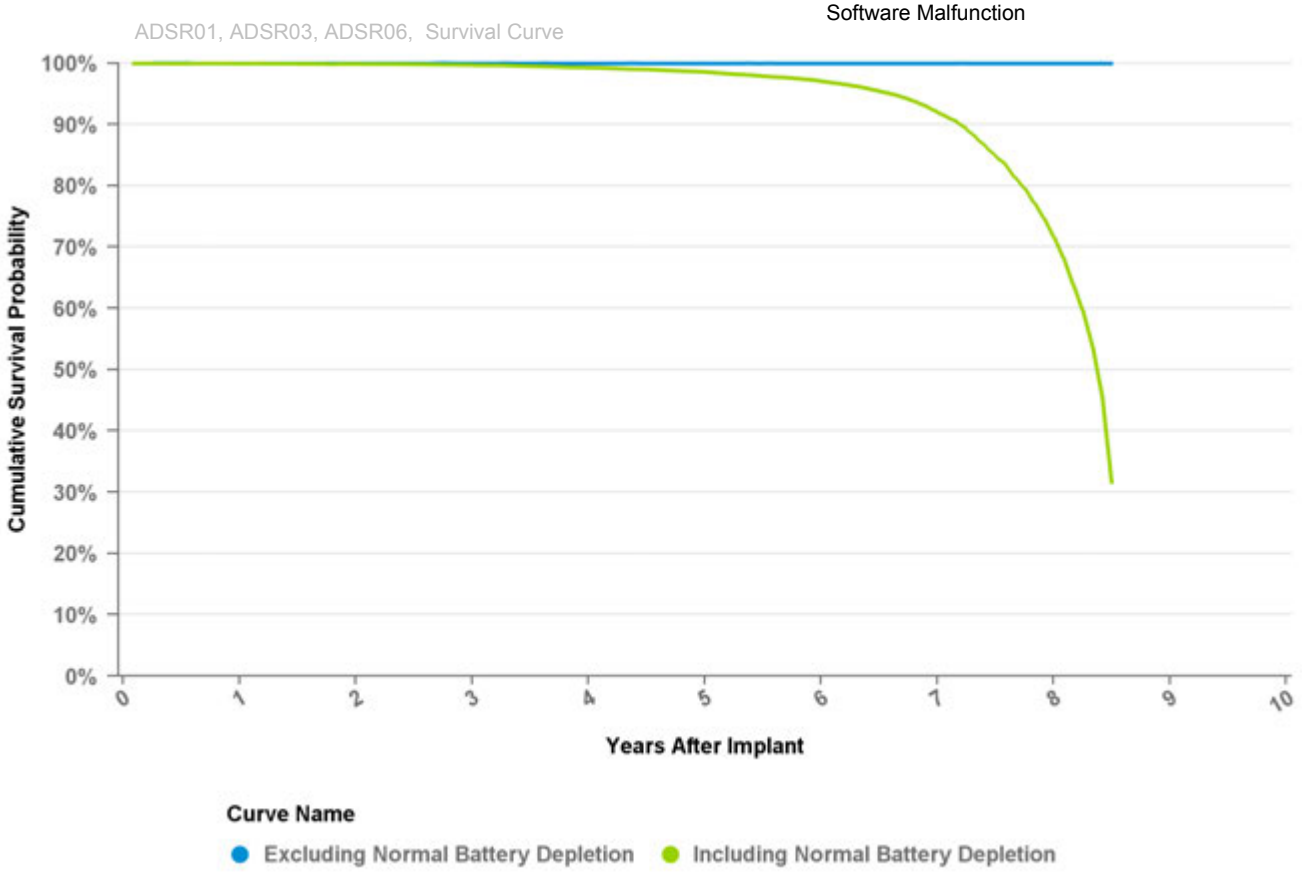
Implantable Pulse Generator

ADSR03 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1,940
Estimated Active US Implants	1,040
Normal Battery Depletions (US)	59

NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.0%	71.8%	31.5%
Effective Sample Size	69779	55737	43382	32309	23193	15856	9212	2901	330

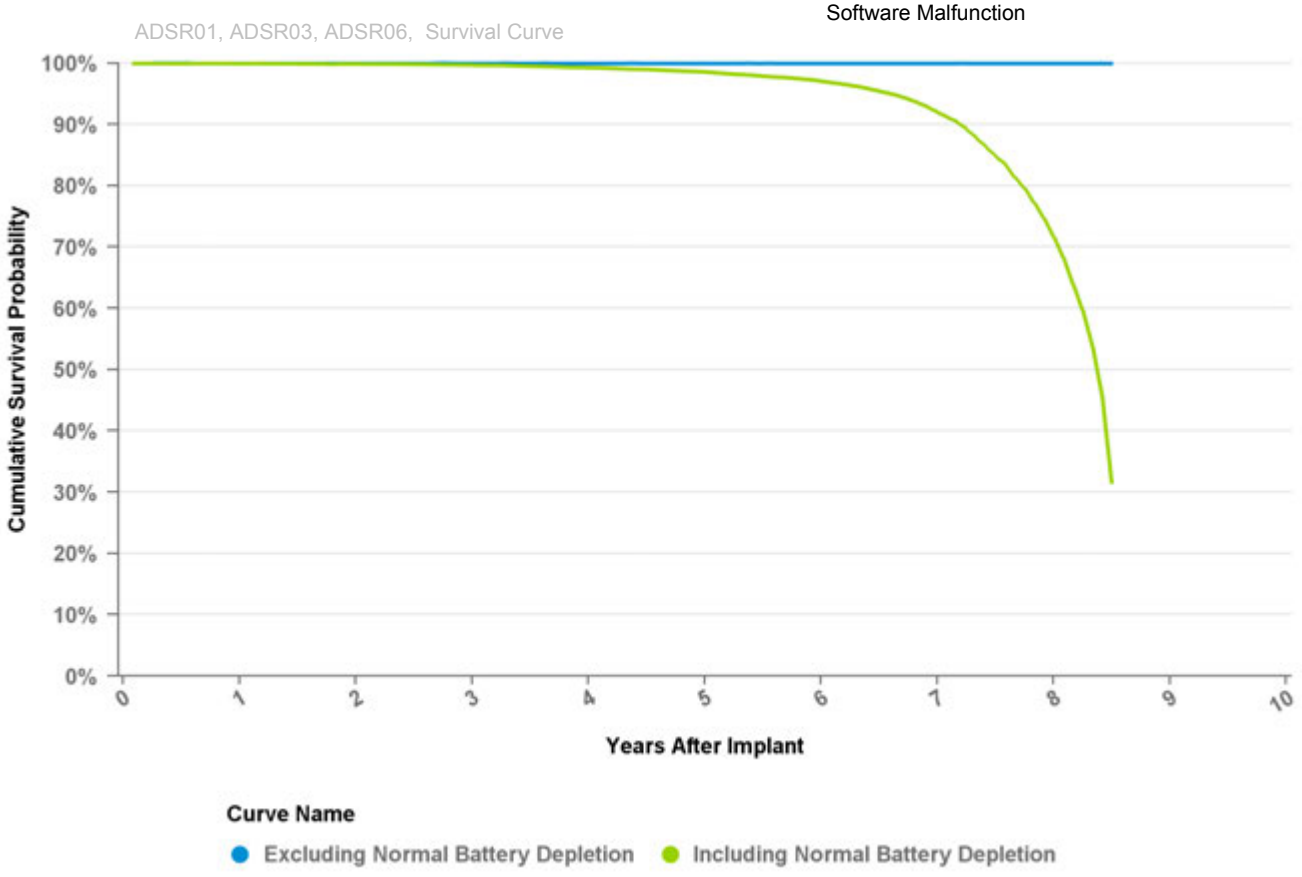
Implantable Pulse Generator

ADSR06 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2,629
Estimated Active US Implants	1,288
Normal Battery Depletions (US)	106

NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.0%	71.8%	31.5%
Effective Sample Size	69779	55737	43382	32309	23193	15856	9212	2901	330

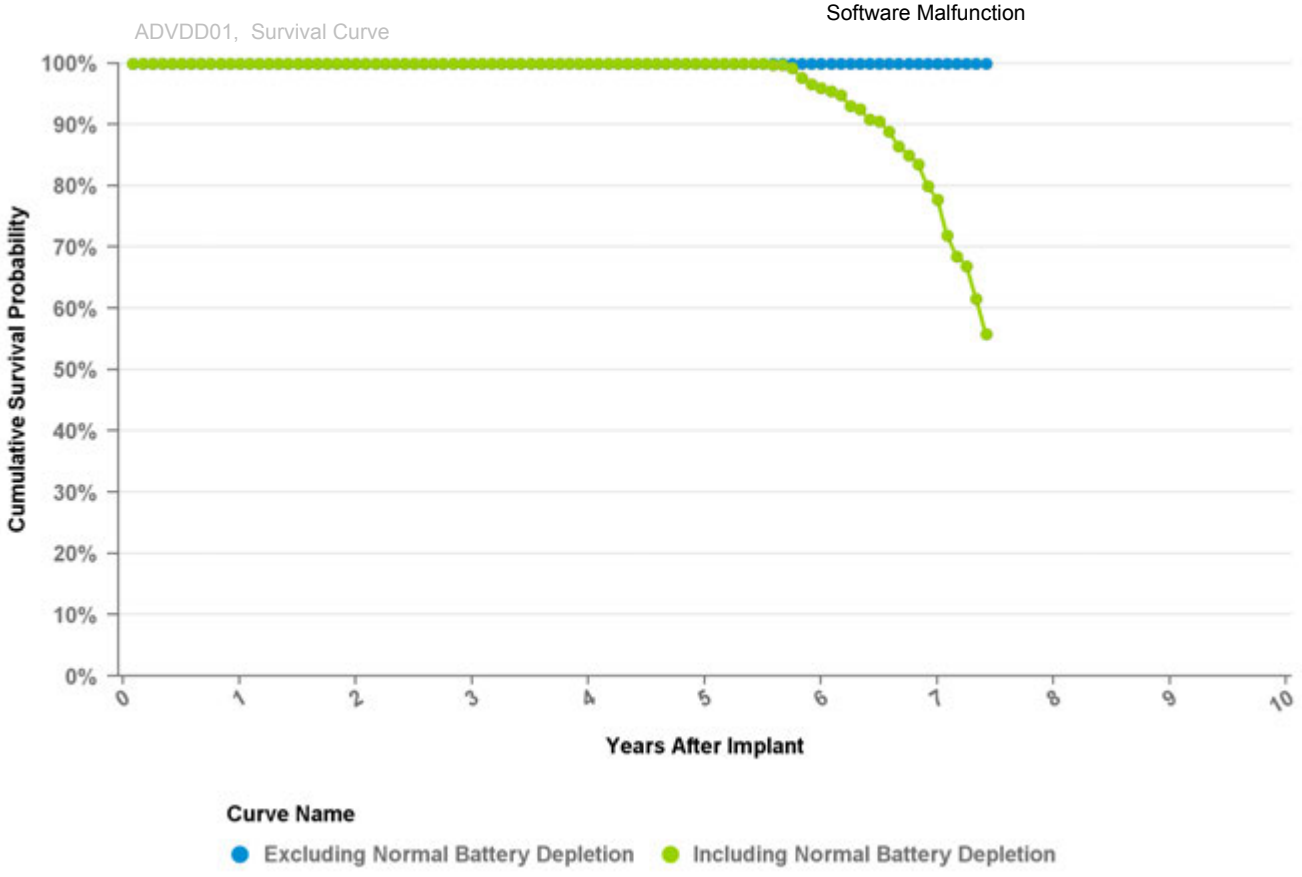
Implantable Pulse Generator

ADVDD01 Adapta VDD

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1,067
Estimated Active US Implants	563
Normal Battery Depletions (US)	65

NBG Code	VDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	96.0%	77.8%	55.8%
Effective Sample Size	905	811	693	570	456	352	188	108

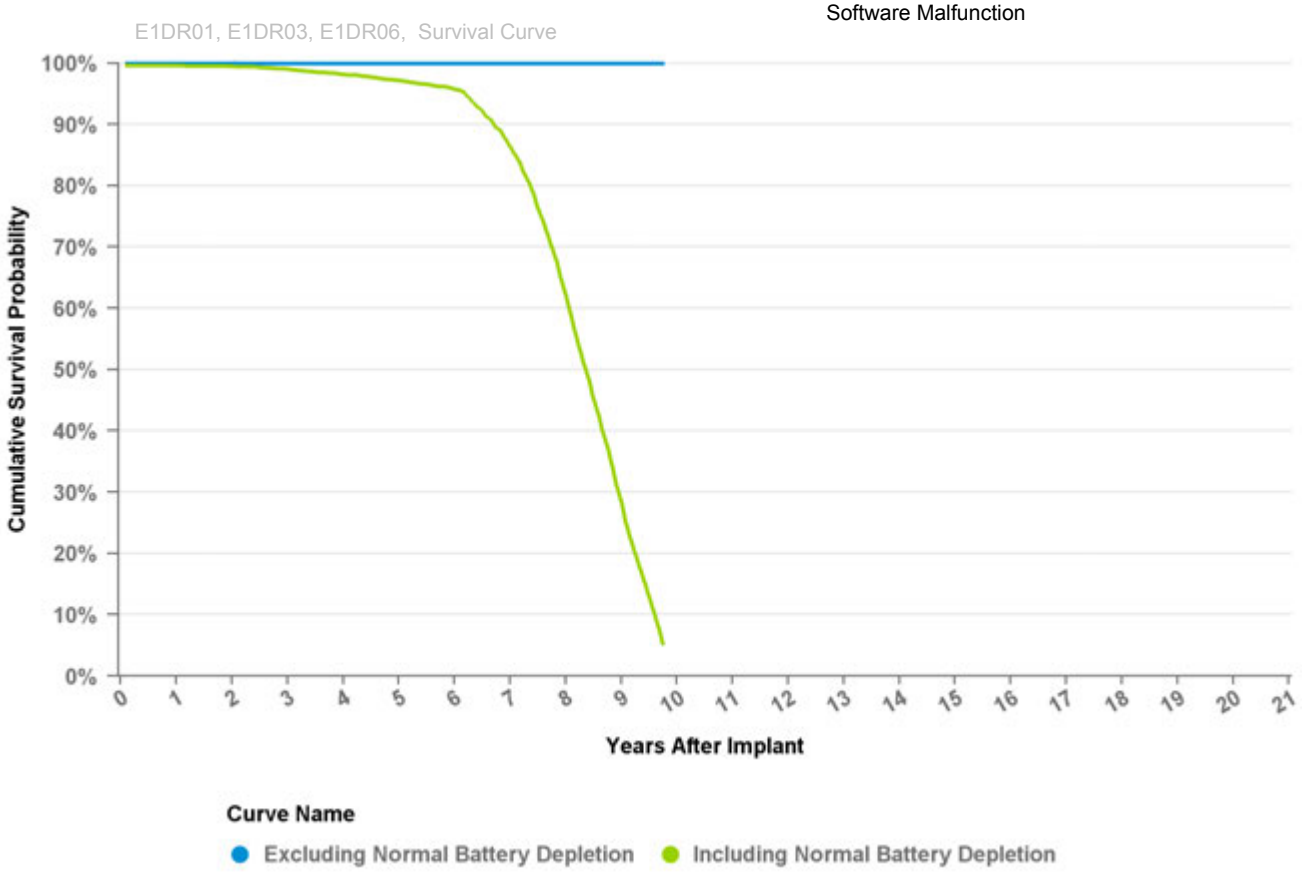
Implantable Pulse Generator

E1DR01 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	6,842
Estimated Active US Implants	531
Normal Battery Depletions (US)	1,717

NBG Code	DDDR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.6%	5.3%
Effective Sample Size	6003	5550	5102	4636	4200	3759	3069	1975	777	137

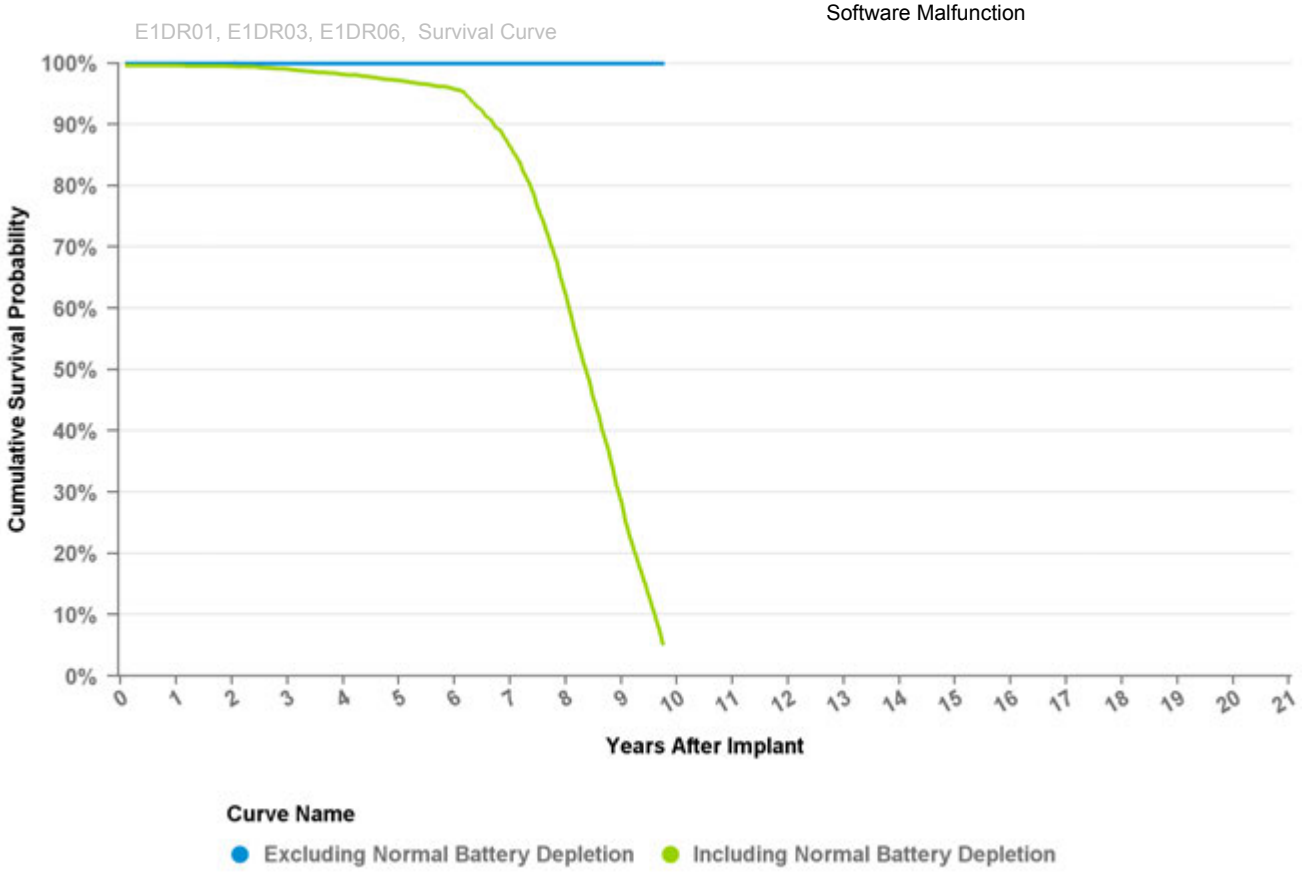
Implantable Pulse Generator

E1DR03 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.6%	5.3%
Effective Sample Size	6003	5550	5102	4636	4200	3759	3069	1975	777	137

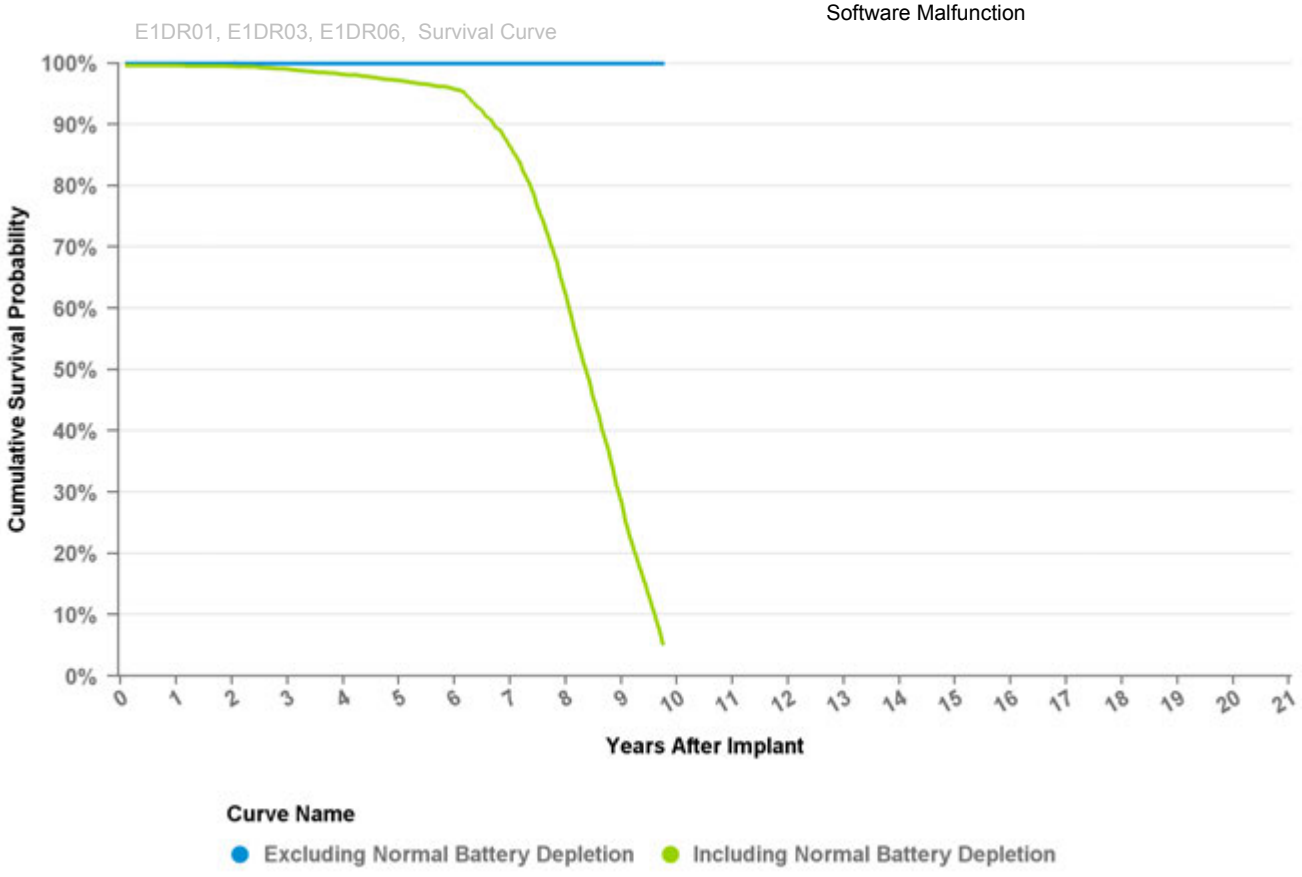
Implantable Pulse Generator

E1DR06 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.6%	5.3%
Effective Sample Size	6003	5550	5102	4636	4200	3759	3069	1975	777	137

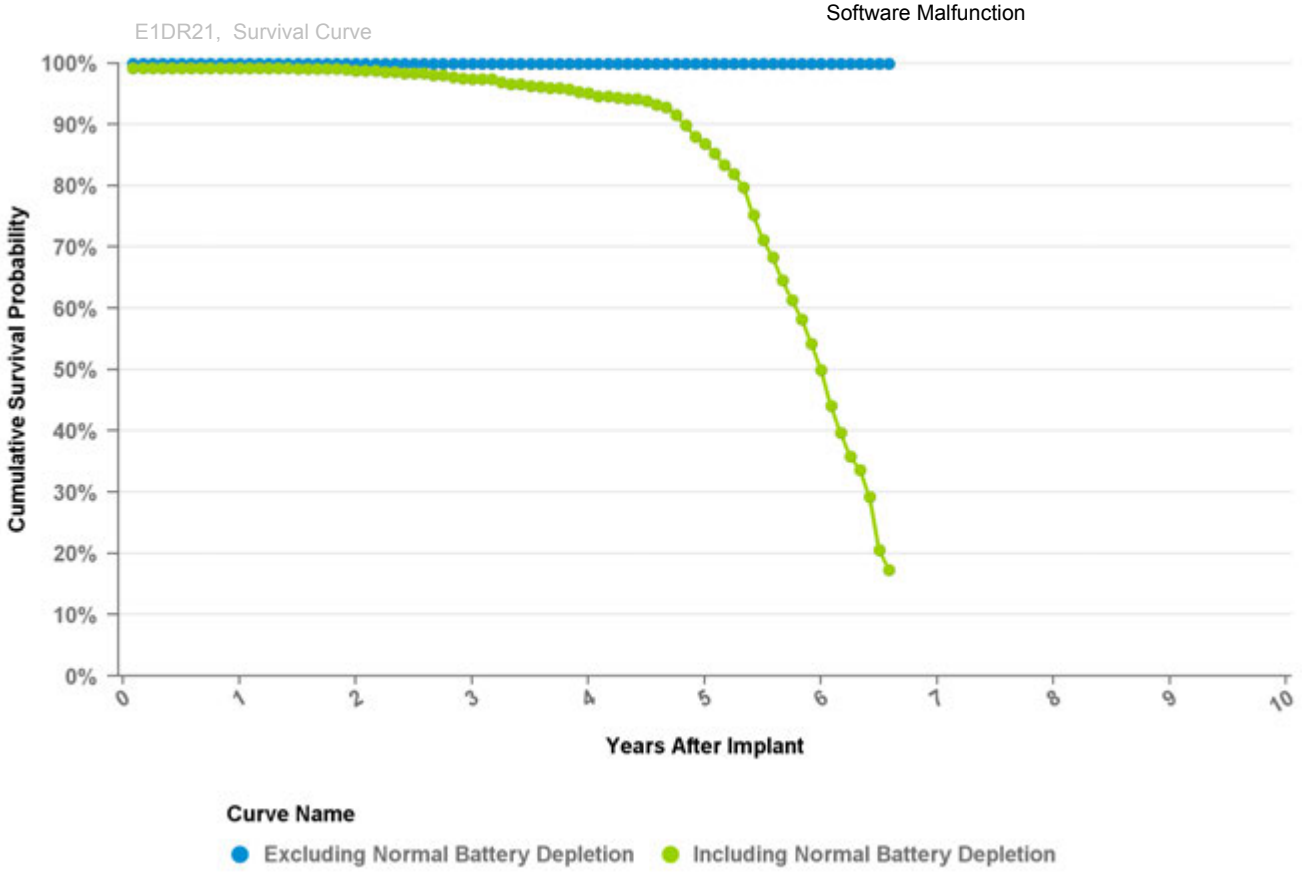
Implantable Pulse Generator

E1DR21 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	1,856
Estimated Active US Implants	99
Normal Battery Depletions (US)	382

NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.2%	98.8%	97.4%	95.2%	86.9%	49.9%	17.4%
Effective Sample Size	1594	1440	1282	1123	910	417	111

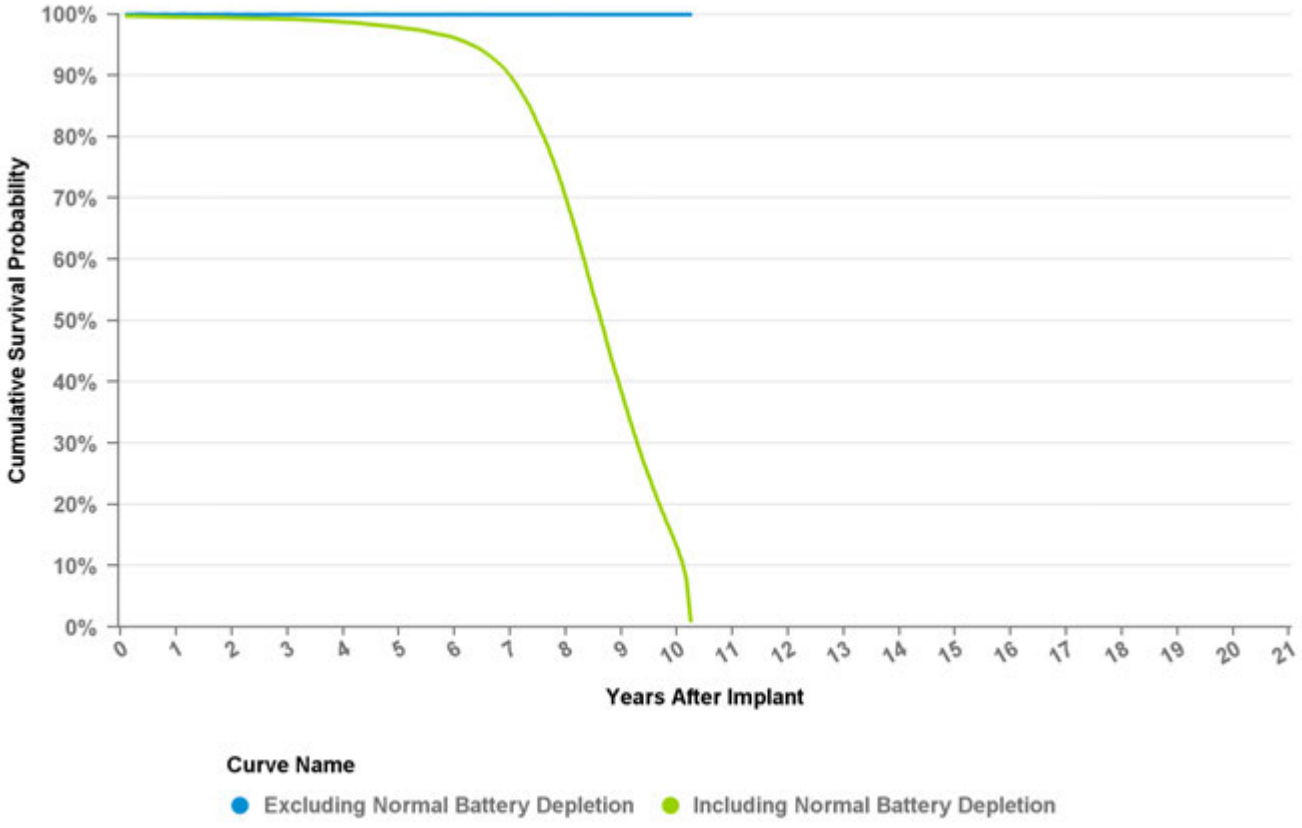
Implantable Pulse Generator

E2D01 EnPulse

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.1%	38.5%	13.1%	1.0%
Effective Sample Size	87684	80565	73628	67090	60673	54455	46834	33237	15933	3390	300

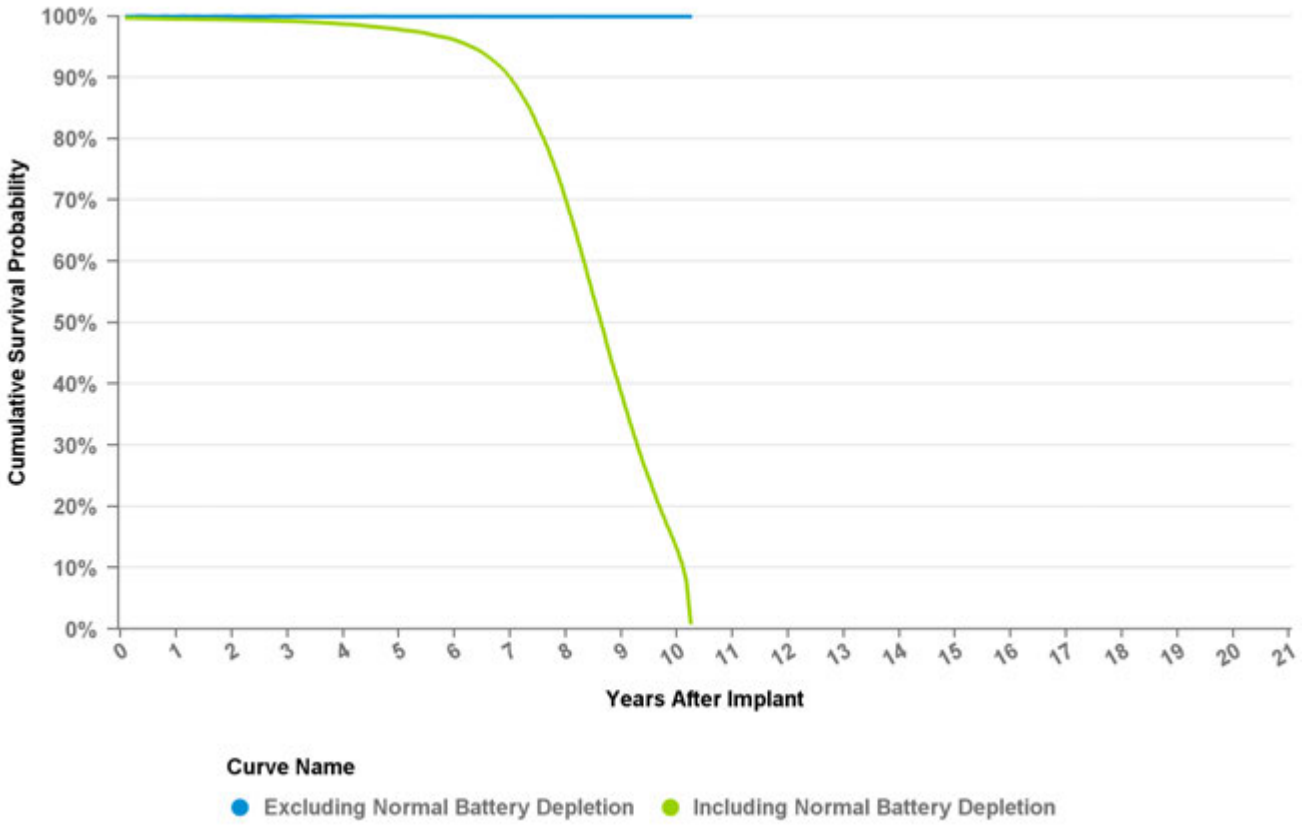
Implantable Pulse Generator

E2D03 EnPulse

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



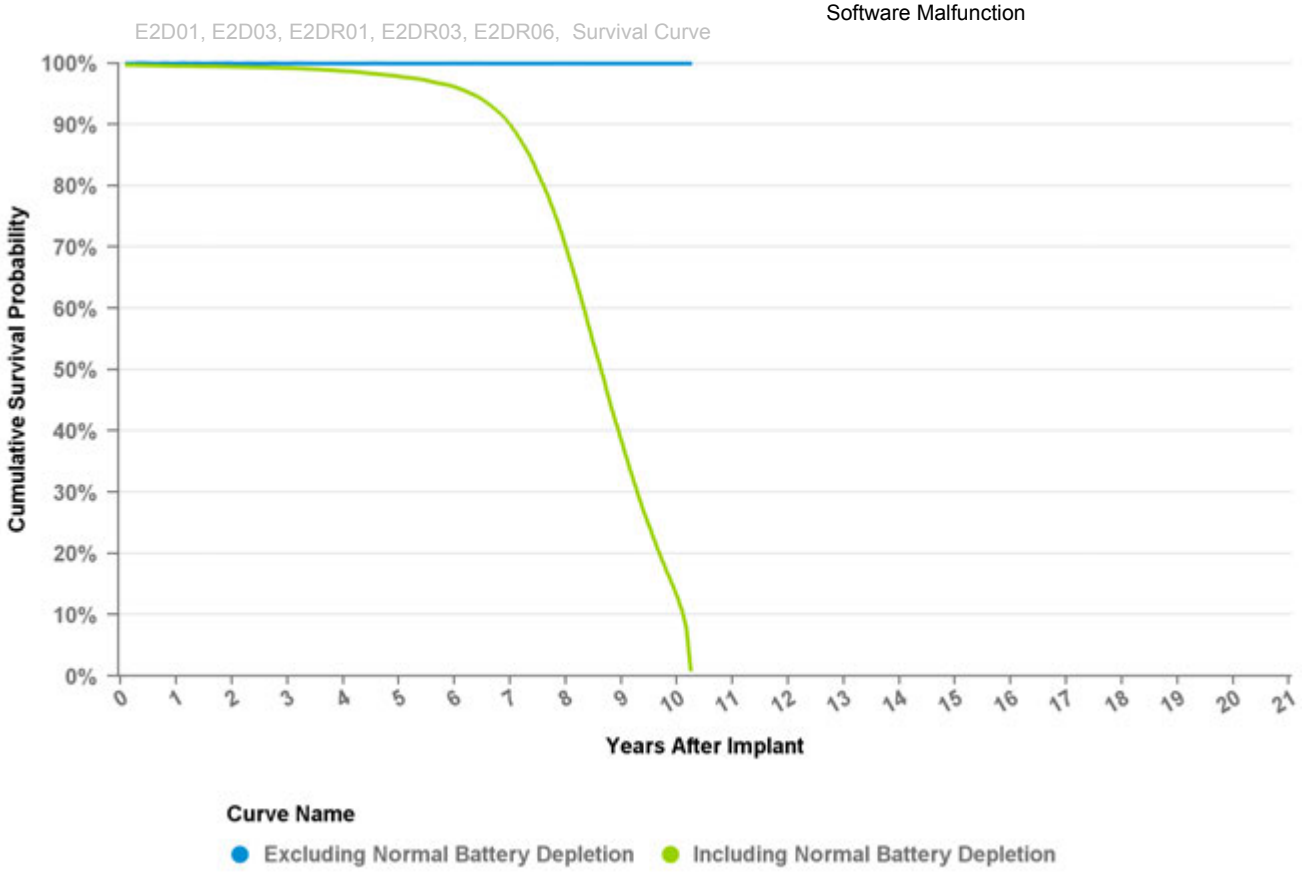
Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.1%	38.5%	13.1%	1.0%
Effective Sample Size	87684	80565	73628	67090	60673	54455	46834	33237	15933	3390	300

Implantable Pulse Generator

E2DR01 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	97,134
Estimated Active US Implants	12,352
Normal Battery Depletions (US)	21,740
NBG Code	DDDR

Total Malfunctions (US)	27
Therapy Not Compromised Malfunctions	20
Battery Malfunction	0
Electrical Component	18
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	7
Battery Malfunction	1
Electrical Component	3
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.1%	38.5%	13.1%	1.0%
Effective Sample Size	87684	80565	73628	67090	60673	54455	46834	33237	15933	3390	300

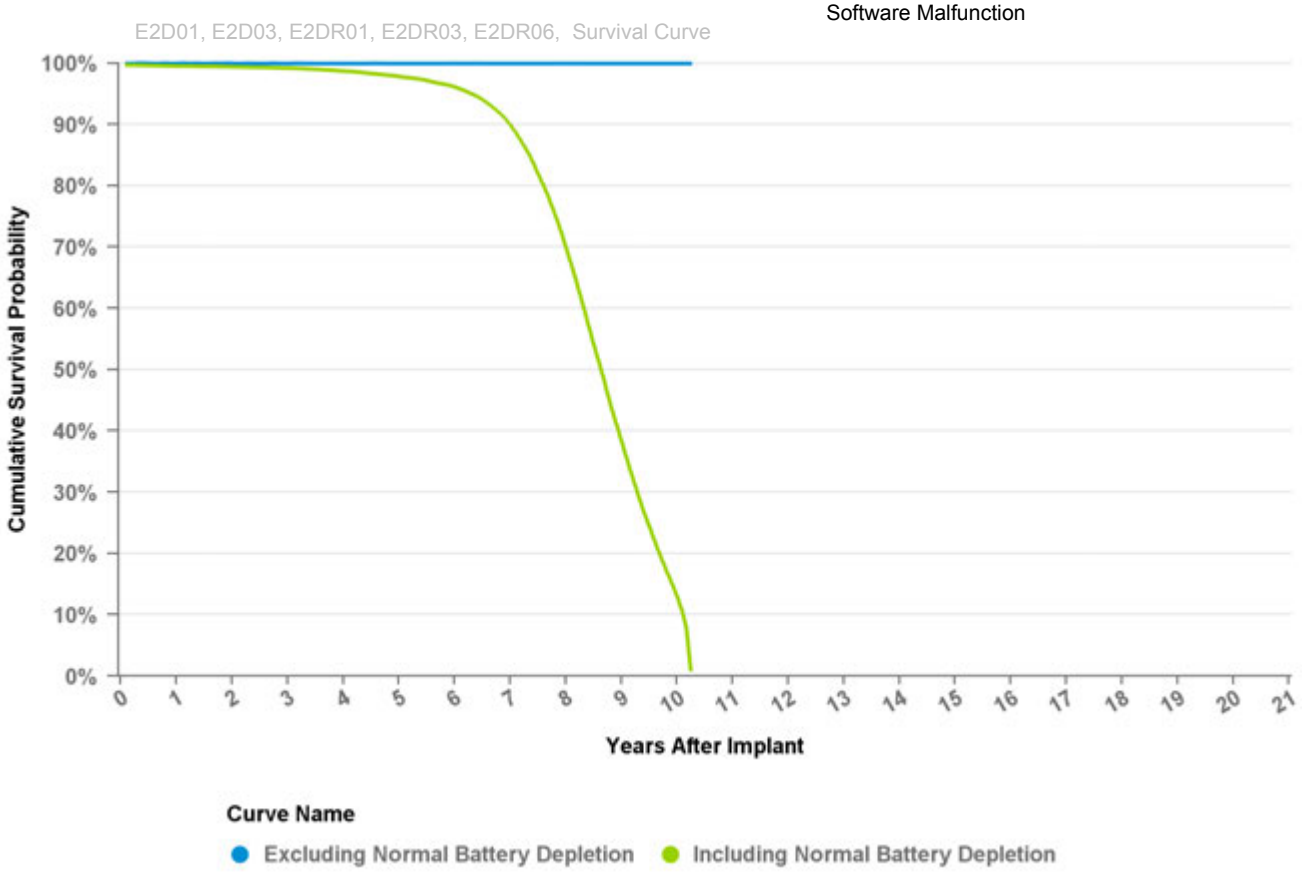
Implantable Pulse Generator

E2DR03 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	2,050
Estimated Active US Implants	306
Normal Battery Depletions (US)	434

NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.1%	38.5%	13.1%	1.0%
Effective Sample Size	87684	80565	73628	67090	60673	54455	46834	33237	15933	3390	300

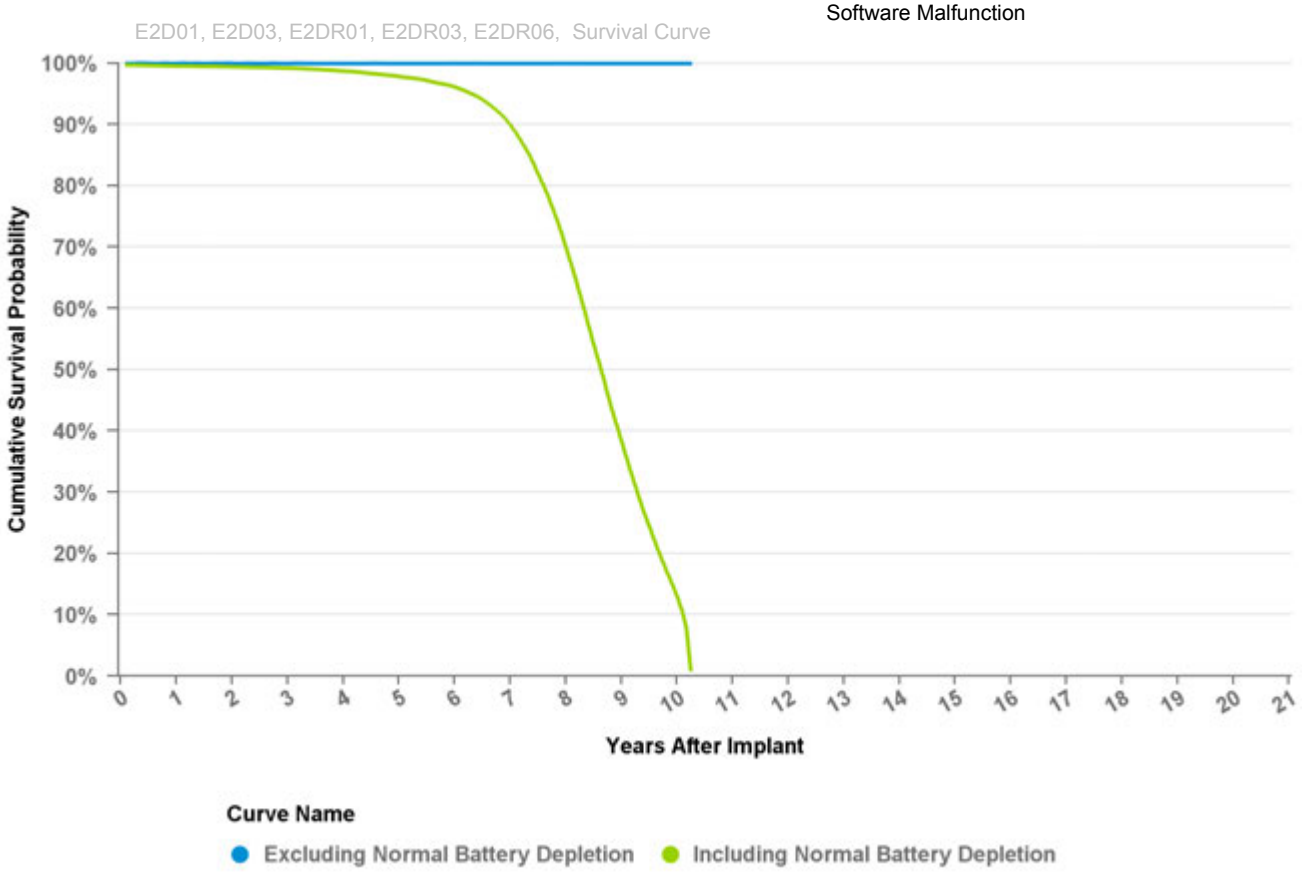
Implantable Pulse Generator

E2DR06 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	1,624
Estimated Active US Implants	187
Normal Battery Depletions (US)	307

NBG Code	DDDR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



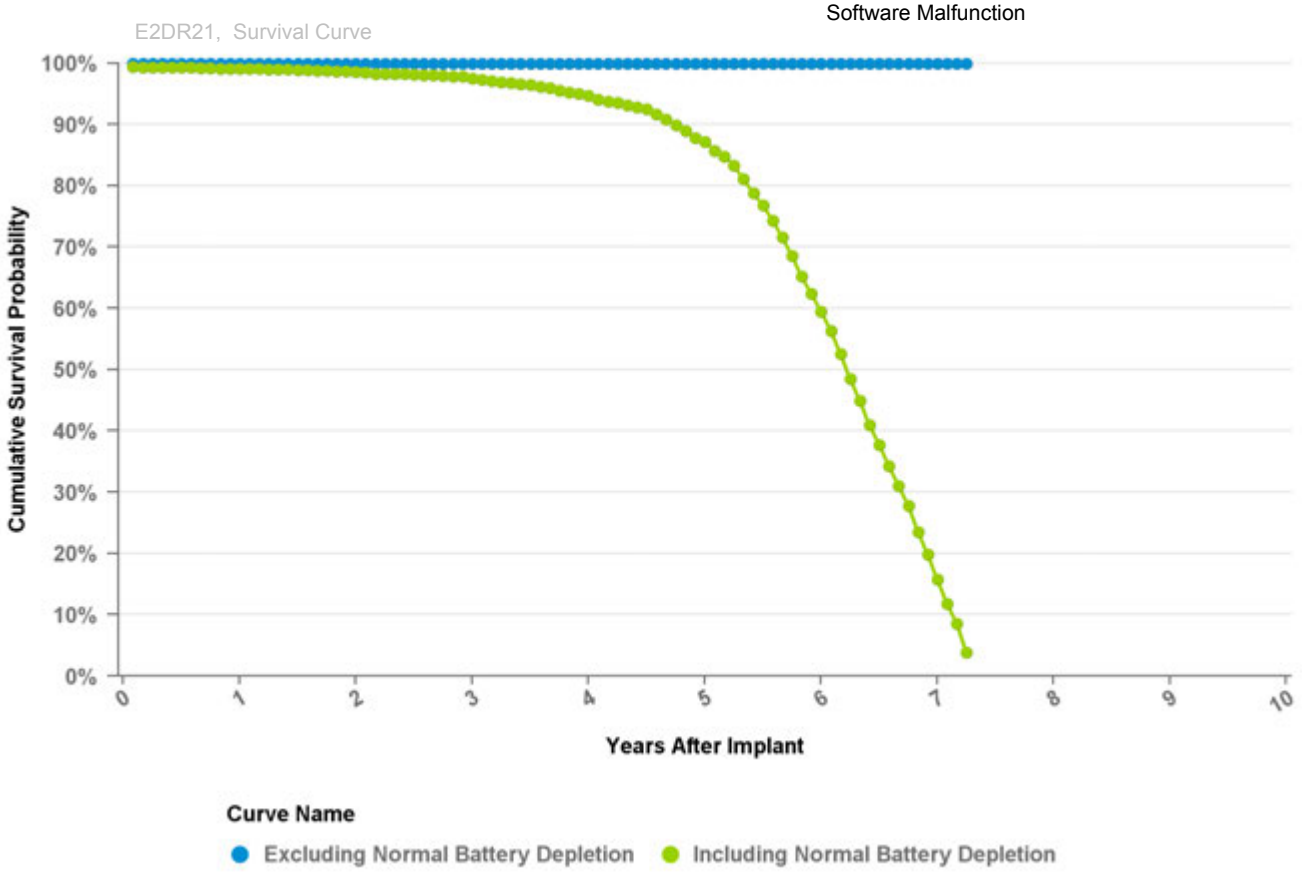
Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.1%	38.5%	13.1%	1.0%
Effective Sample Size	87684	80565	73628	67090	60673	54455	46834	33237	15933	3390	300

Implantable Pulse Generator

E2DR21 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	12,196
Estimated Active US Implants	1,066
Normal Battery Depletions (US)	2,315
NBG Code	DDDR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	98.6%	97.6%	94.8%	87.2%	59.5%	15.7%	3.8%
Effective Sample Size	10174	9051	8058	6955	5660	3273	641	186

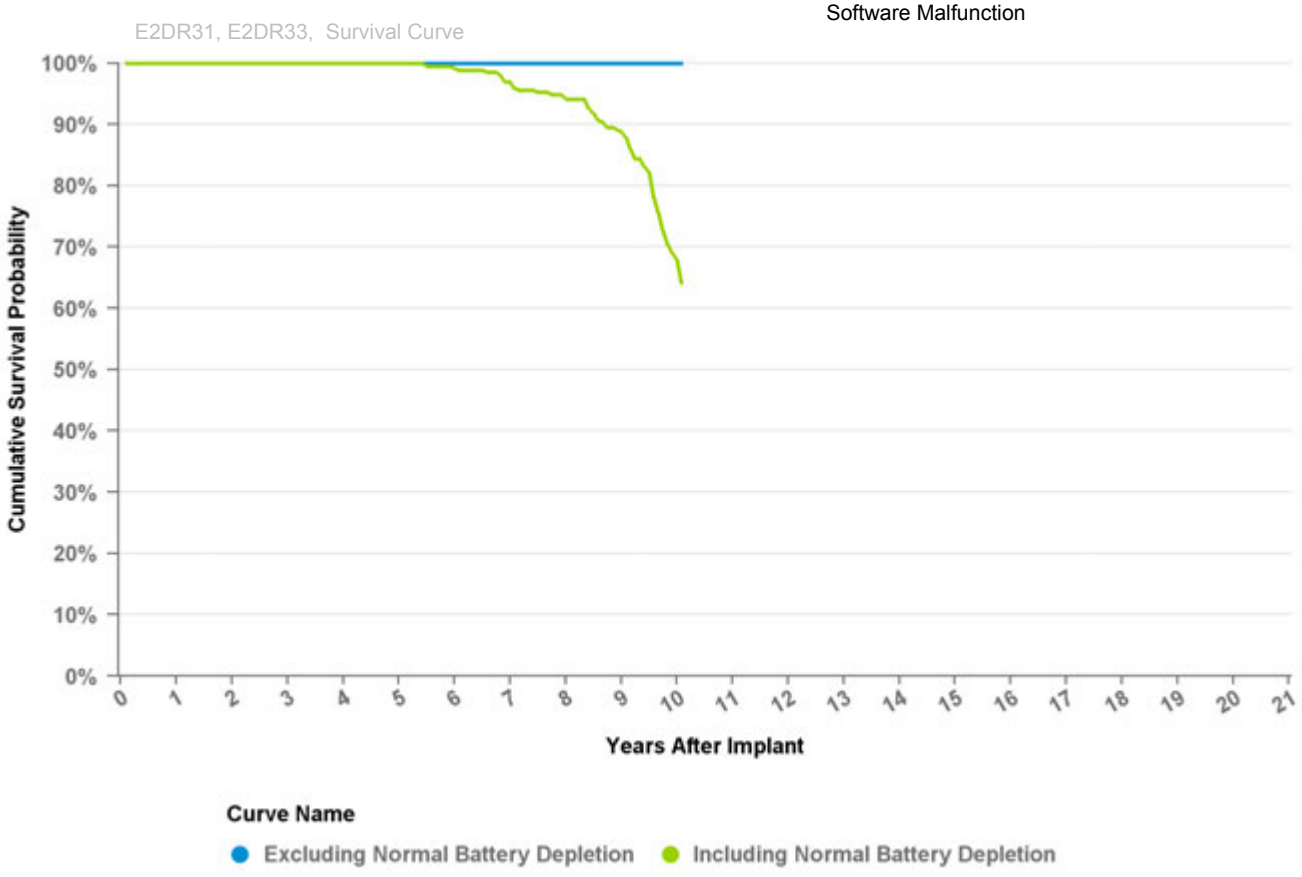
Implantable Pulse Generator

E2DR31 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	588
Estimated Active US Implants	242
Normal Battery Depletions (US)	87

NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



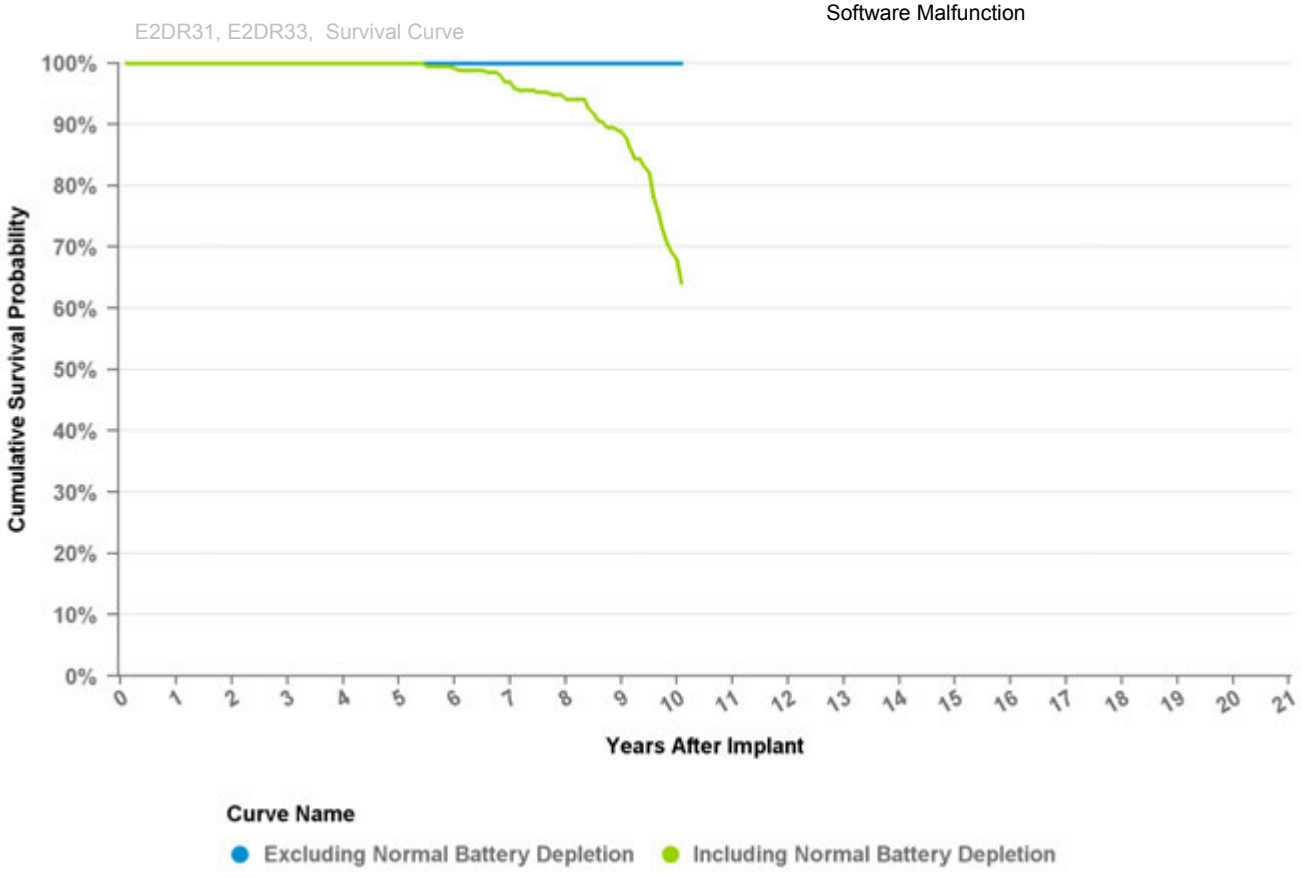
Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.9%	94.1%	88.8%	68.0%	64.1%
Effective Sample Size	523	489	455	414	372	334	295	259	227	136	122

Implantable Pulse Generator

E2DR33 EnPulse DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	5
Estimated Active US Implants	4
Normal Battery Depletions (US)	2
NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.9%	94.1%	88.8%	68.0%	64.1%
Effective Sample Size	523	489	455	414	372	334	295	259	227	136	122

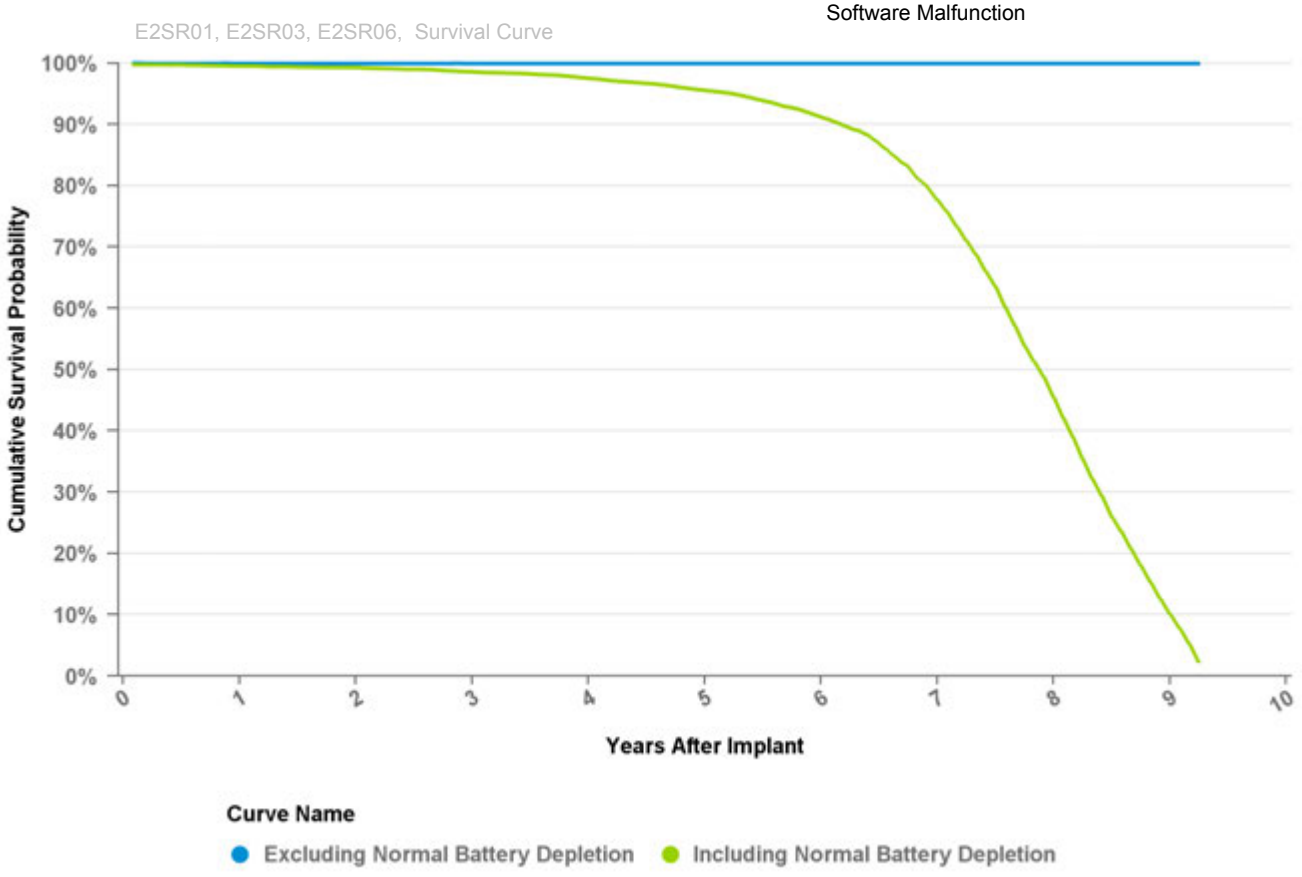
Implantable Pulse Generator

E2SR01 EnPulse SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	22,527
Estimated Active US Implants	2,114
Normal Battery Depletions (US)	2,978

NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



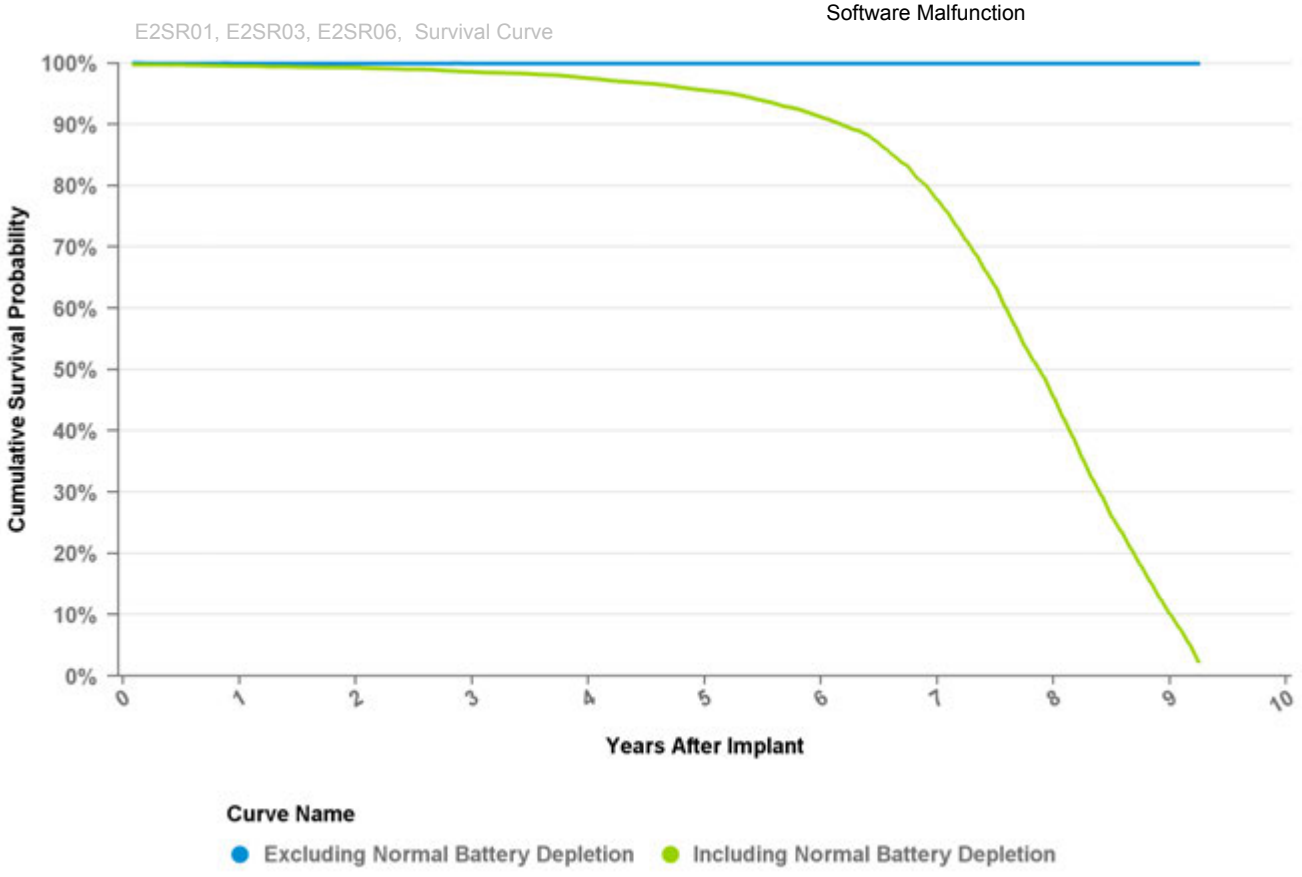
Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.7%	45.5%	10.2%	2.3%
Effective Sample Size	19601	16653	14192	12093	10000	8125	5888	2826	440	113

Implantable Pulse Generator

E2SR03 EnPulse SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,099
Estimated Active US Implants	104
Normal Battery Depletions (US)	148
NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.7%	45.5%	10.2%	2.3%
Effective Sample Size	19601	16653	14192	12093	10000	8125	5888	2826	440	113

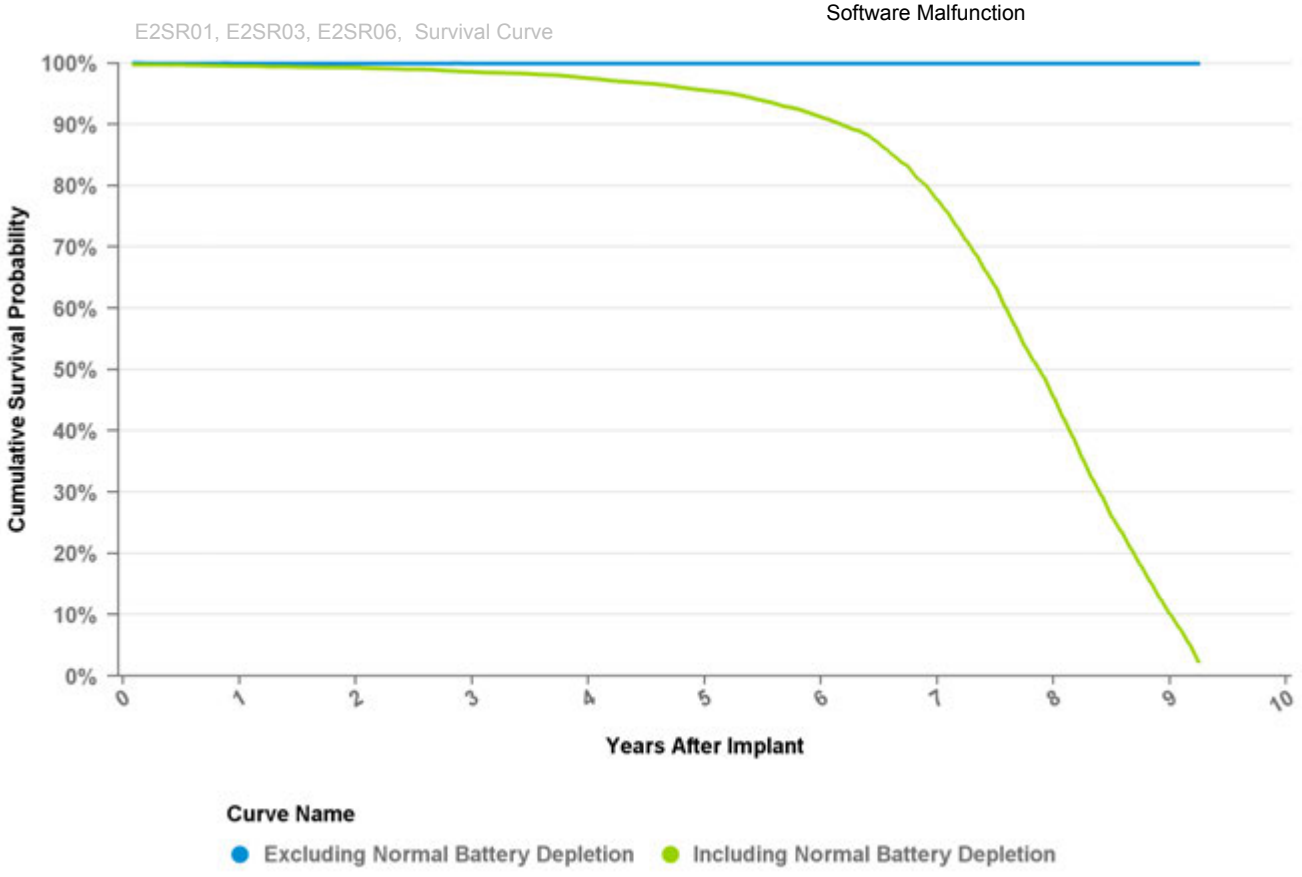
Implantable Pulse Generator

E2SR06 EnPulse SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,749
Estimated Active US Implants	147
Normal Battery Depletions (US)	218

NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.7%	45.5%	10.2%	2.3%
Effective Sample Size	19601	16653	14192	12093	10000	8125	5888	2826	440	113

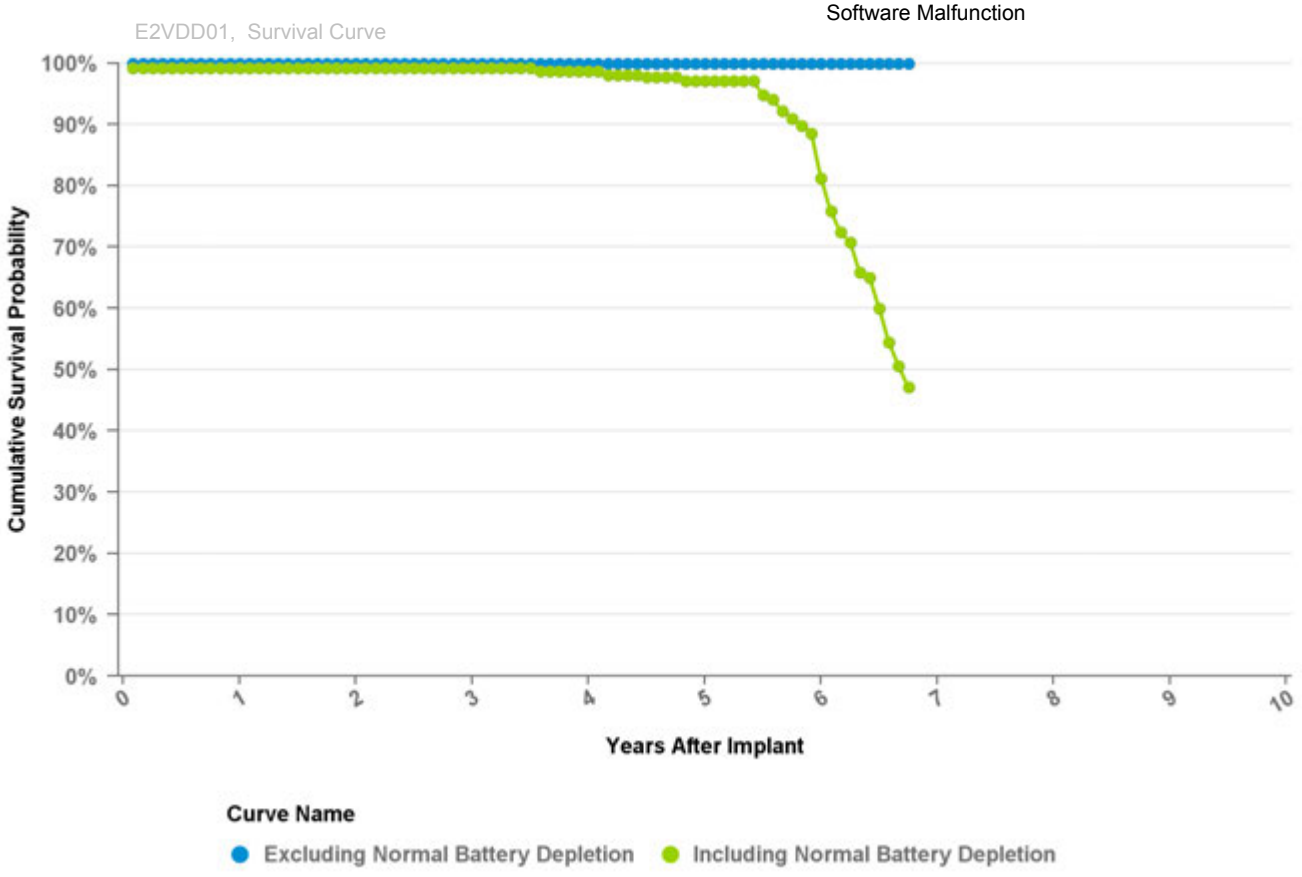
Implantable Pulse Generator

E2VDD01 EnPulse VDD

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	555
Estimated Active US Implants	79
Normal Battery Depletions (US)	93

NBG Code	VDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.3%	99.3%	99.3%	98.7%	97.1%	81.2%	47.1%
Effective Sample Size	472	421	376	331	286	218	102

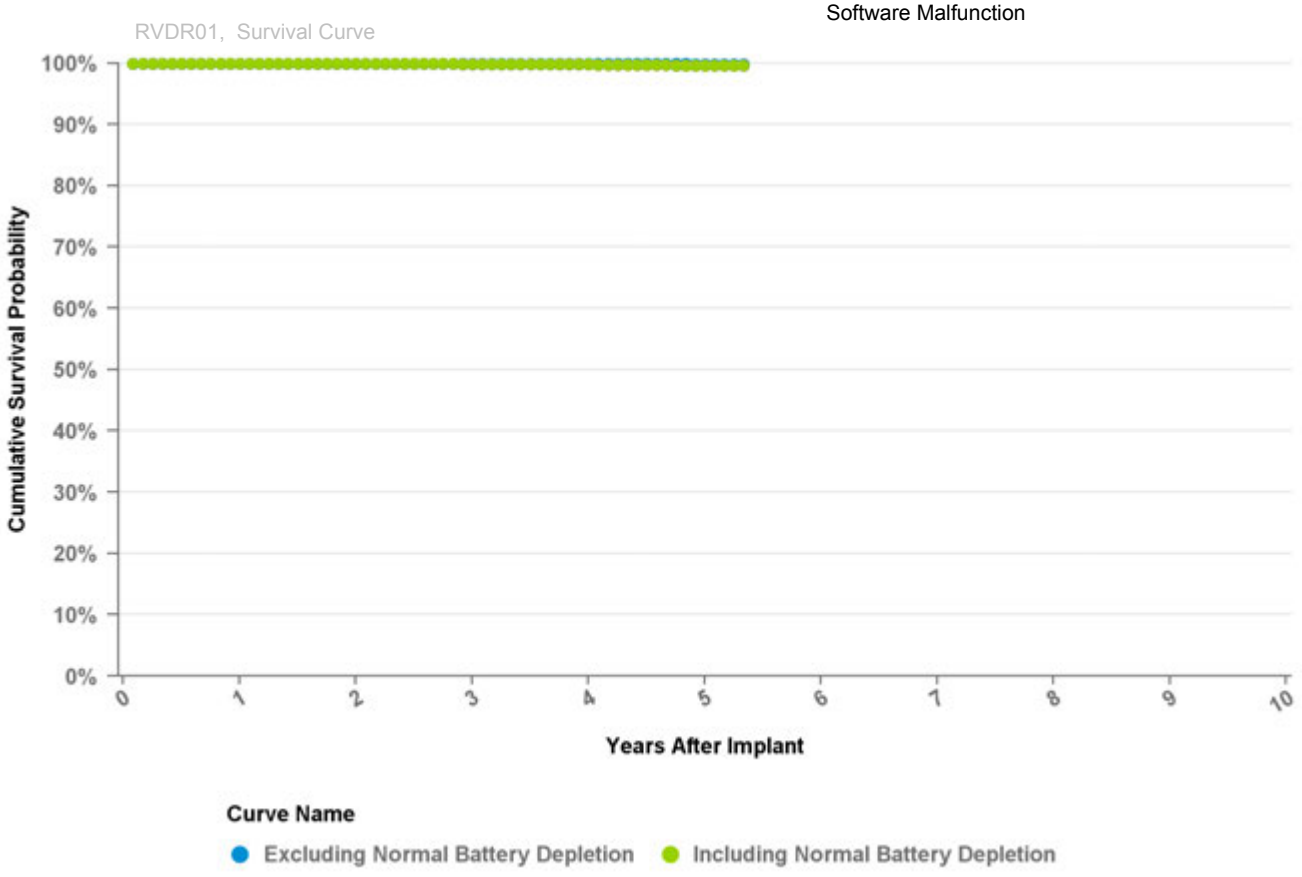
Implantable Pulse Generator

EMDR01 EnRhythm MRI

US Market Release Date	
CE Market Approval Date	9/30/2008
Registered US Implants	111
Estimated Active US Implants	30
Normal Battery Depletions (US)	10

NBG Code	DDDRP

Total Malfunctions (US)	22
Therapy Not Compromised Malfunctions	22
Battery Malfunction	22
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	59522	55815	50342	30434	6942	557

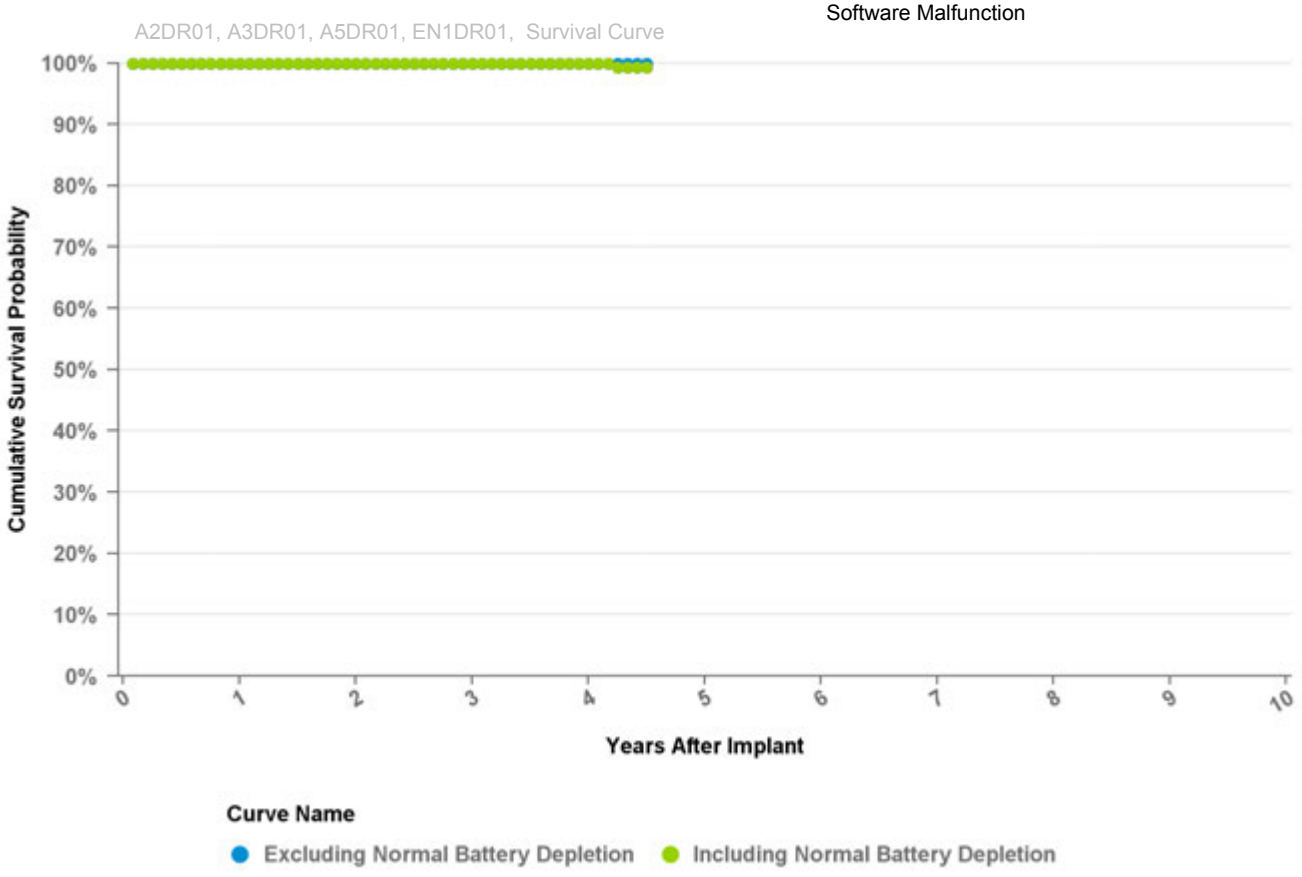
Implantable Pulse Generator

EN1DR01 Ensura MRI

US Market Release Date	
CE Market Approval Date	6/23/2010
Registered US Implants	7
Estimated Active US Implants	5
Normal Battery Depletions (US)	0

NBG Code	OOE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 54 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.3%
Effective Sample Size	106872	41829	8531	490	122

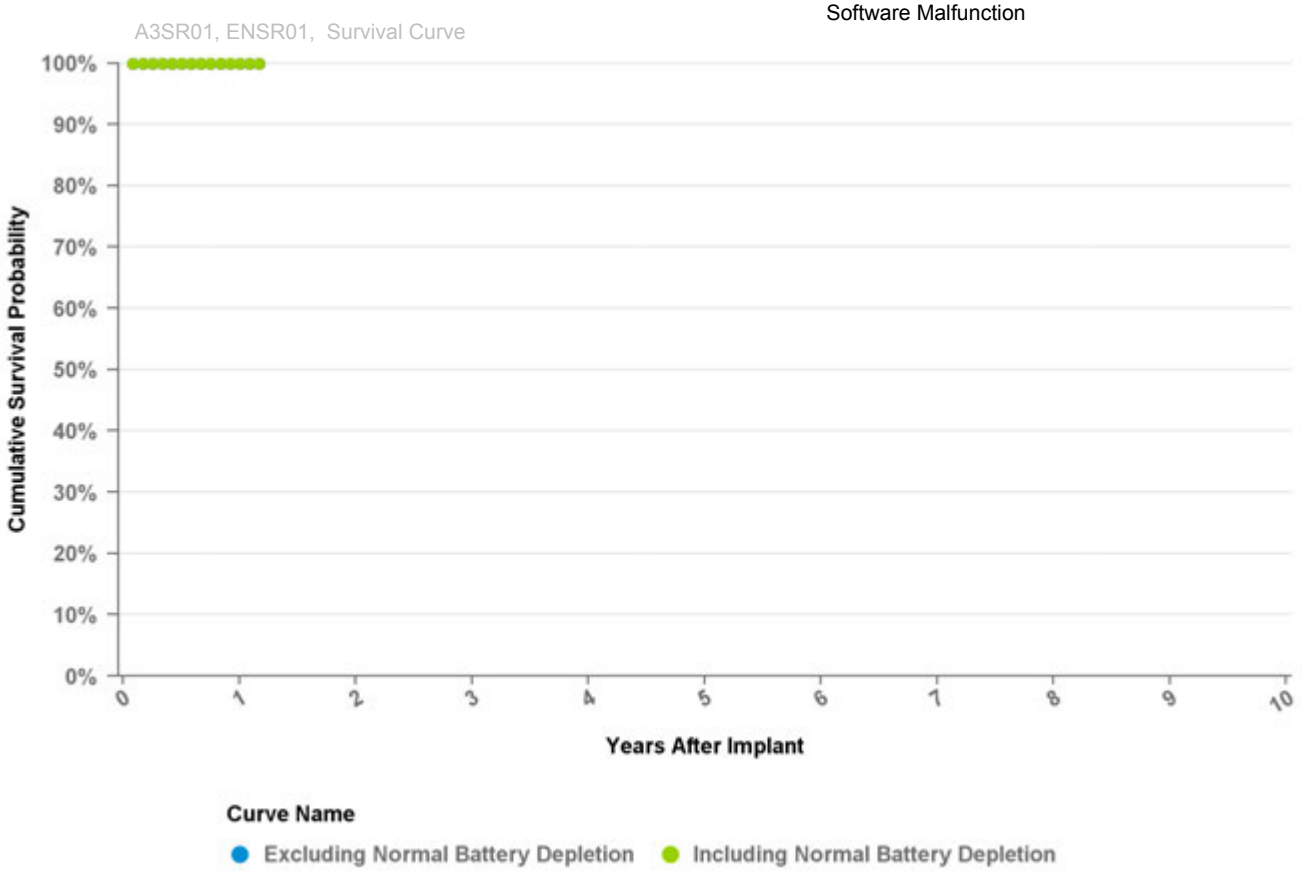
Implantable Pulse Generator

EN1SR01 Ensura SR MRI

US Market Release Date	
CE Market Approval Date	4/24/2014
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	912	195

Implantable Pulse Generator

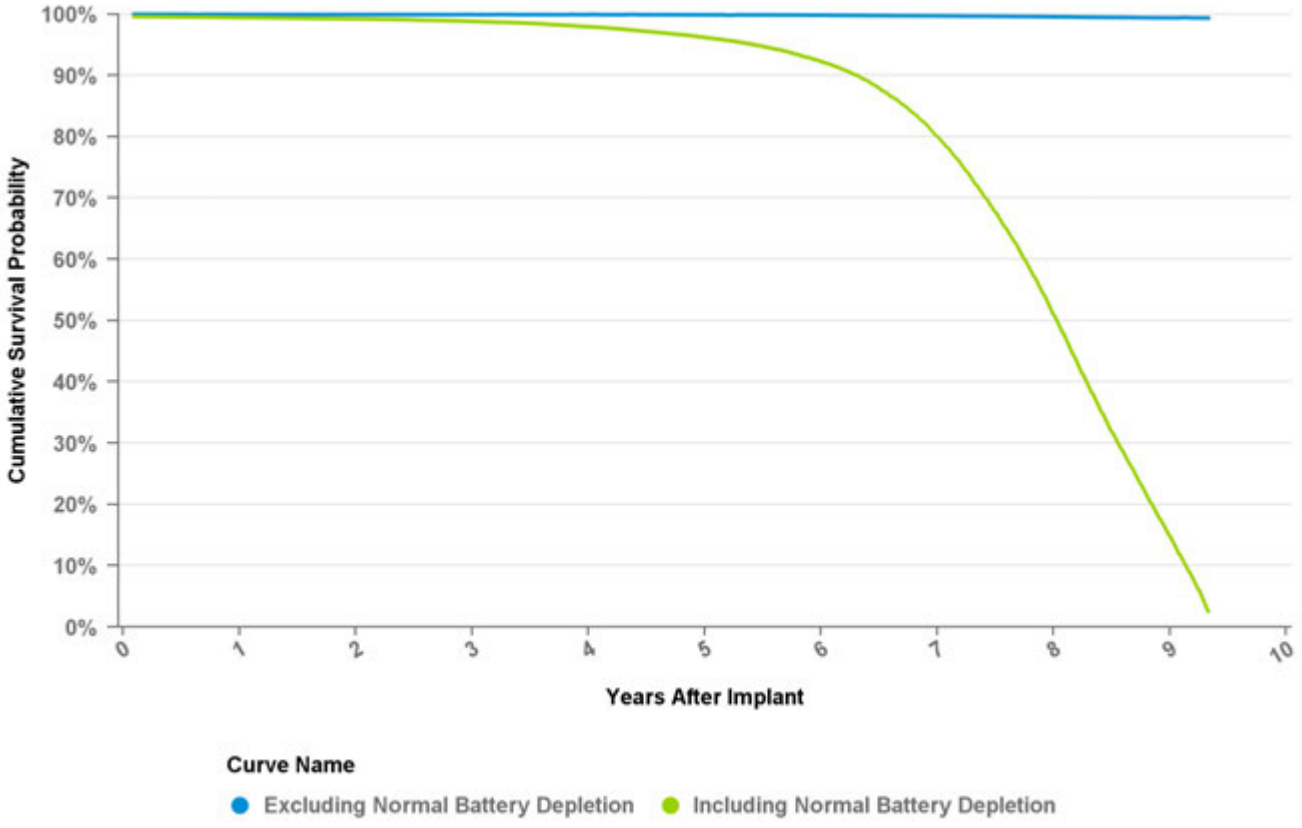
KD700 Kappa 700 DR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



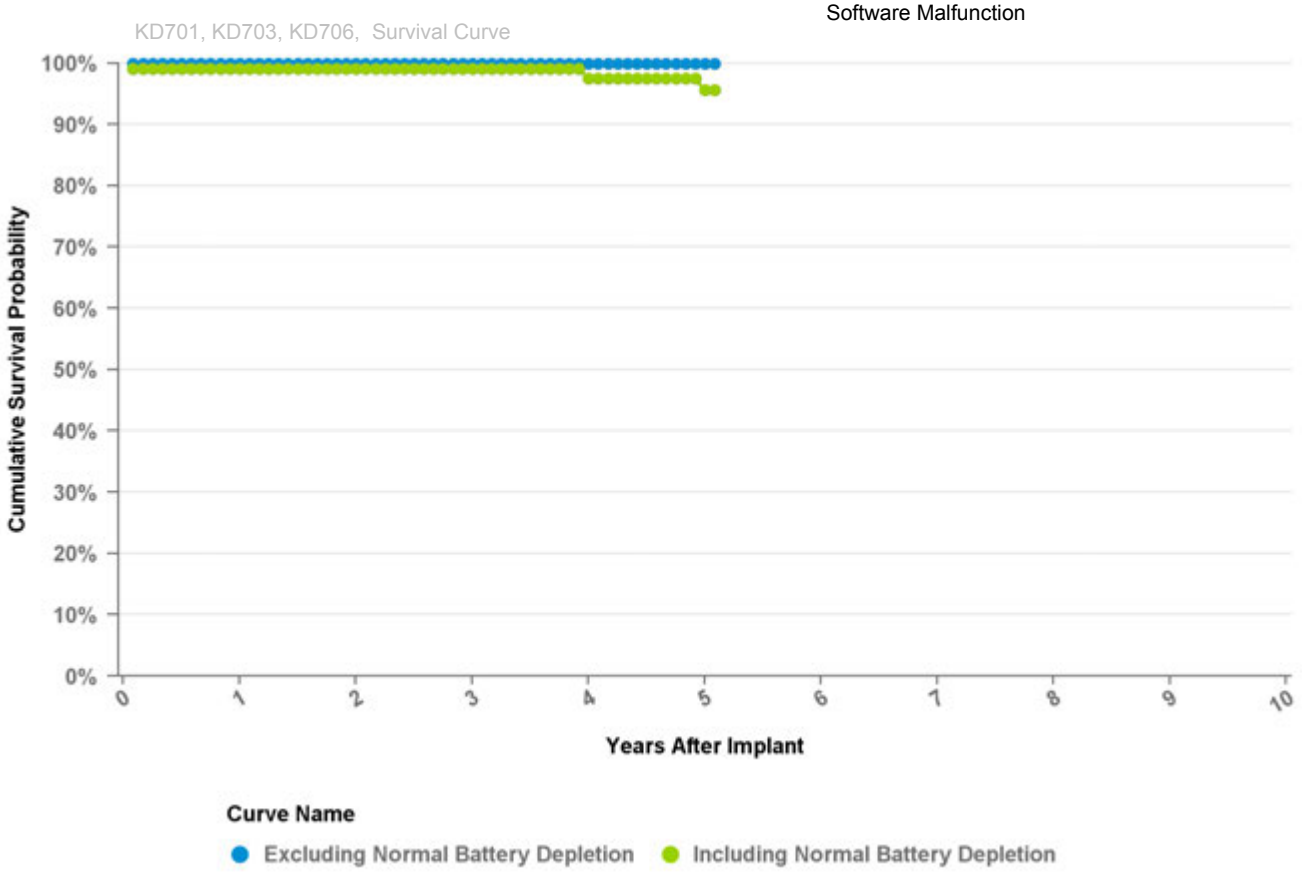
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	98.0%	96.2%	92.3%	80.1%	51.0%	14.9%	2.5%
Effective Sample Size	167404	152500	138020	123518	109365	93975	72158	38467	8001	1689

Implantable Pulse Generator

KD701 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	242
Estimated Active US Implants	38
Normal Battery Depletions (US)	21
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.7%	95.7%
Effective Sample Size	198	173	146	125	105	100

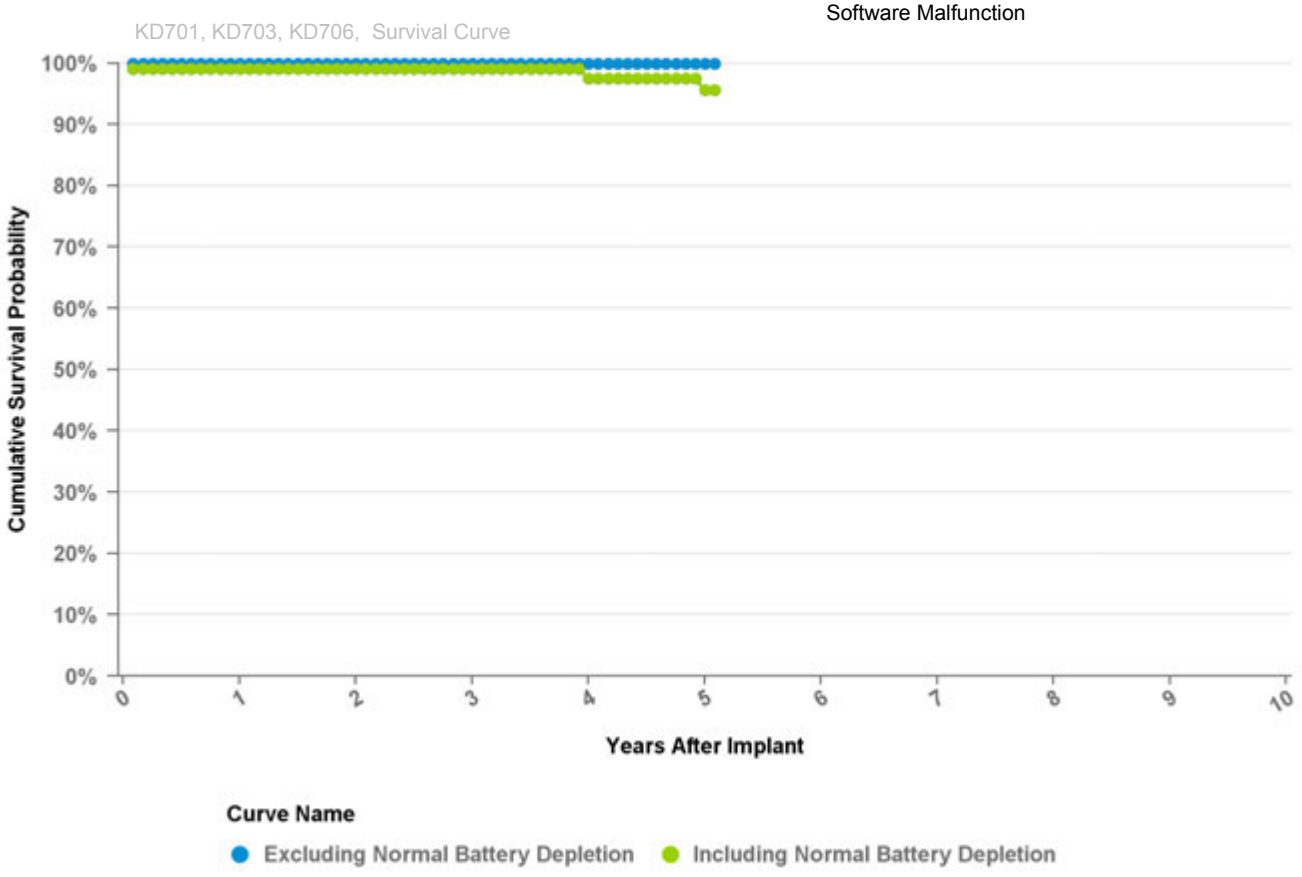
Implantable Pulse Generator

KD703 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.7%	95.7%
Effective Sample Size	198	173	146	125	105	100

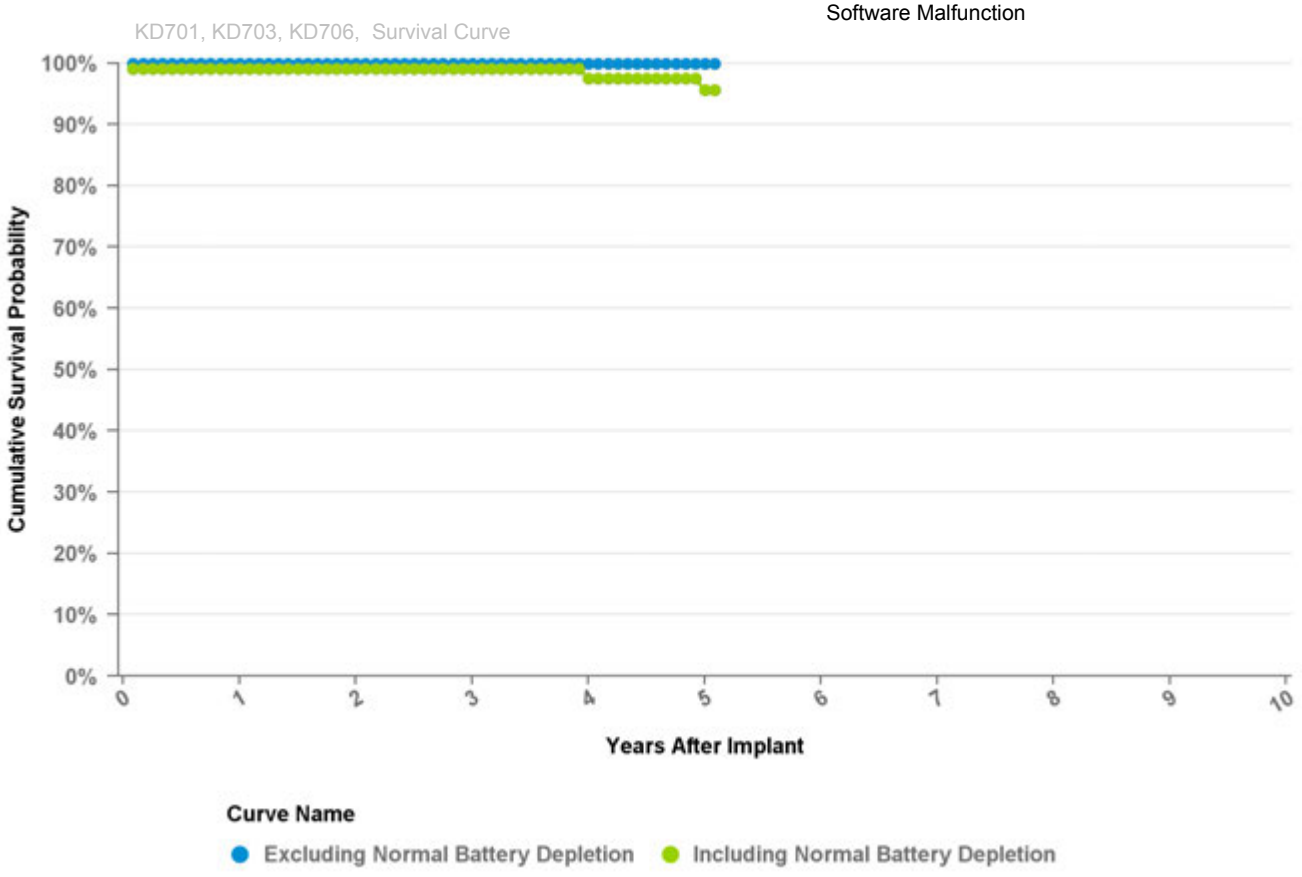
Implantable Pulse Generator

KD706 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.7%	95.7%
Effective Sample Size	198	173	146	125	105	100

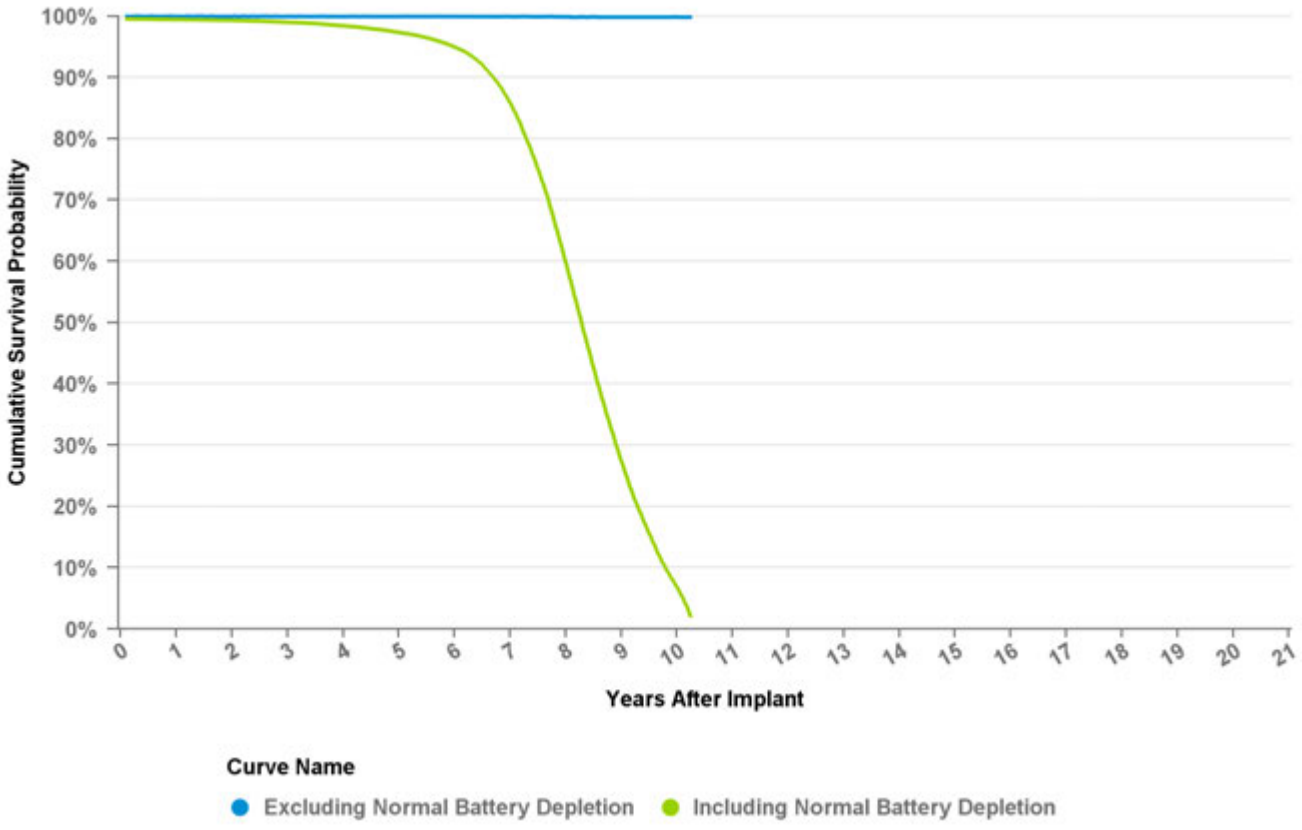
Implantable Pulse Generator

KD901 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

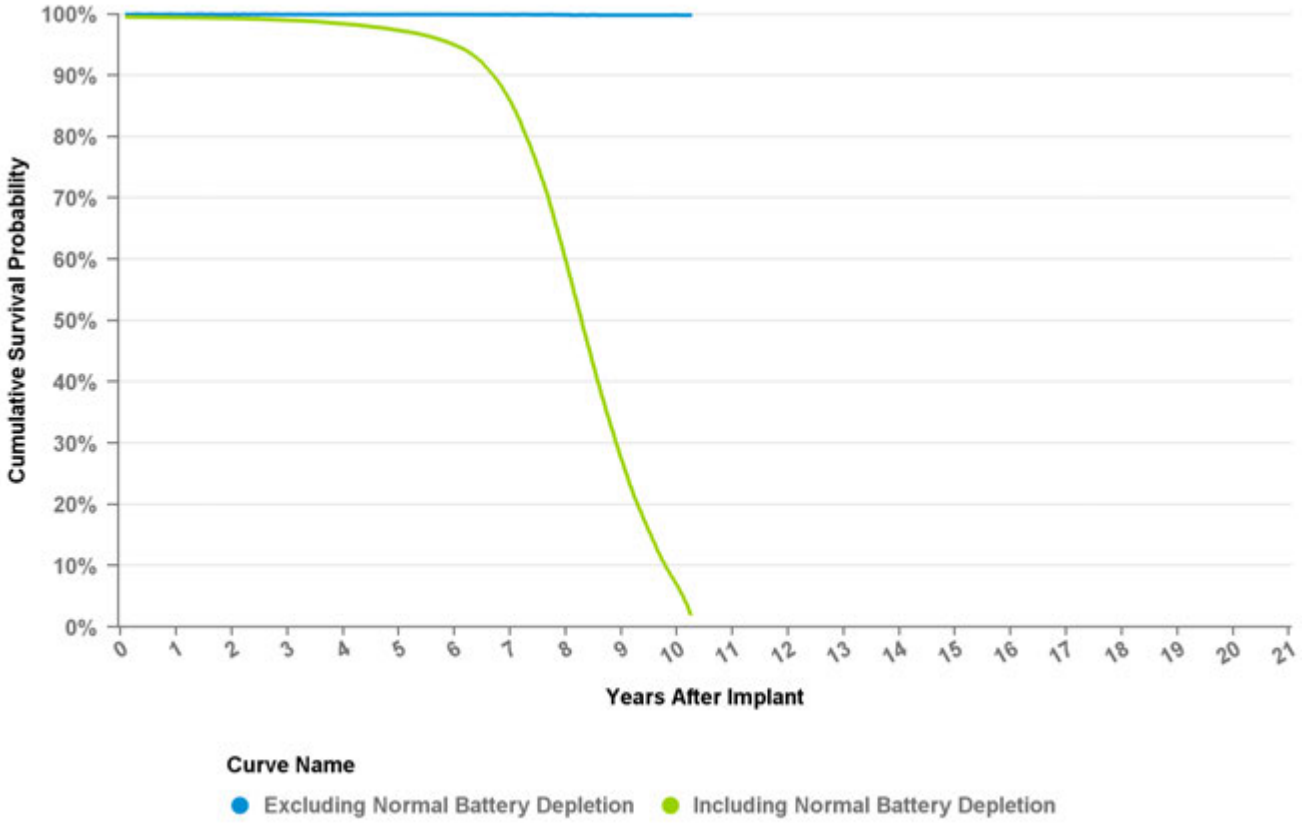
Implantable Pulse Generator

KD903 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

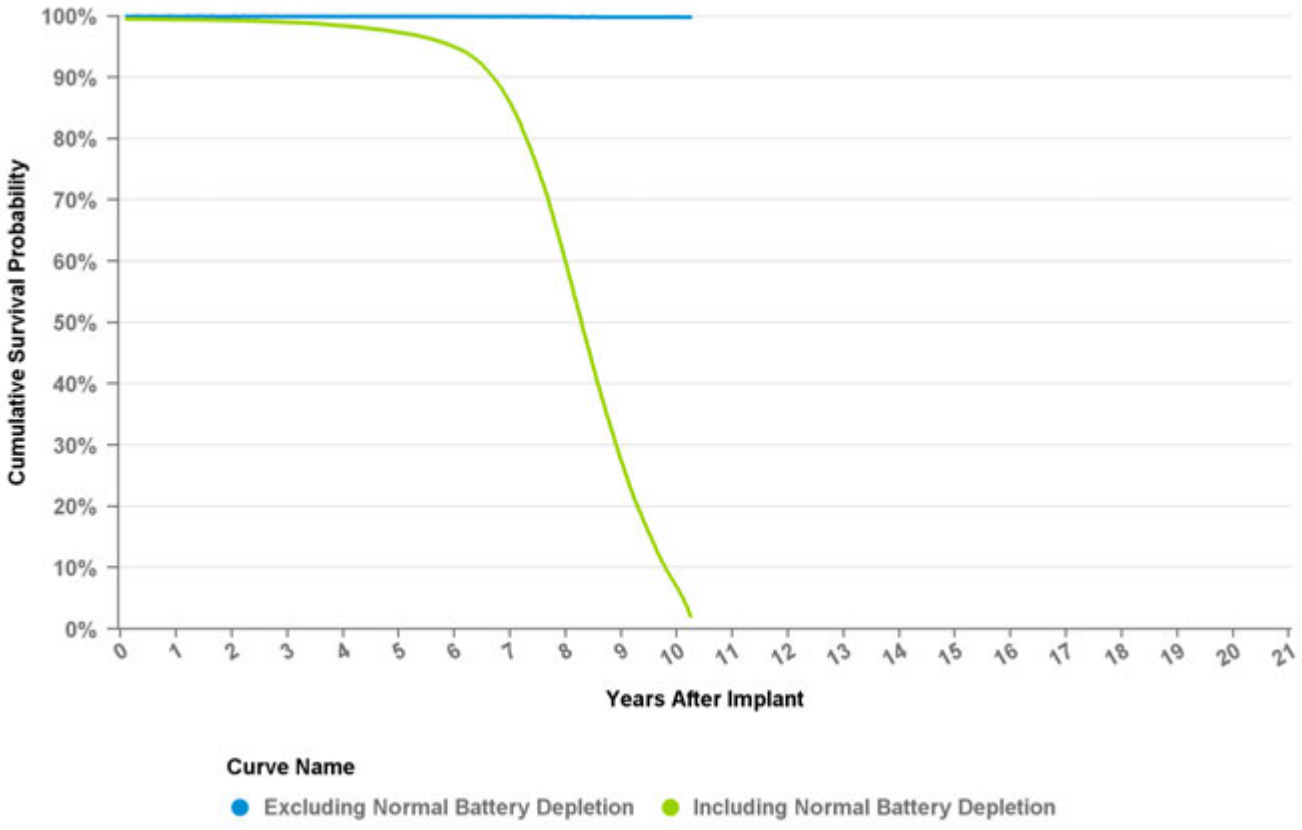
Implantable Pulse Generator

KD906 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

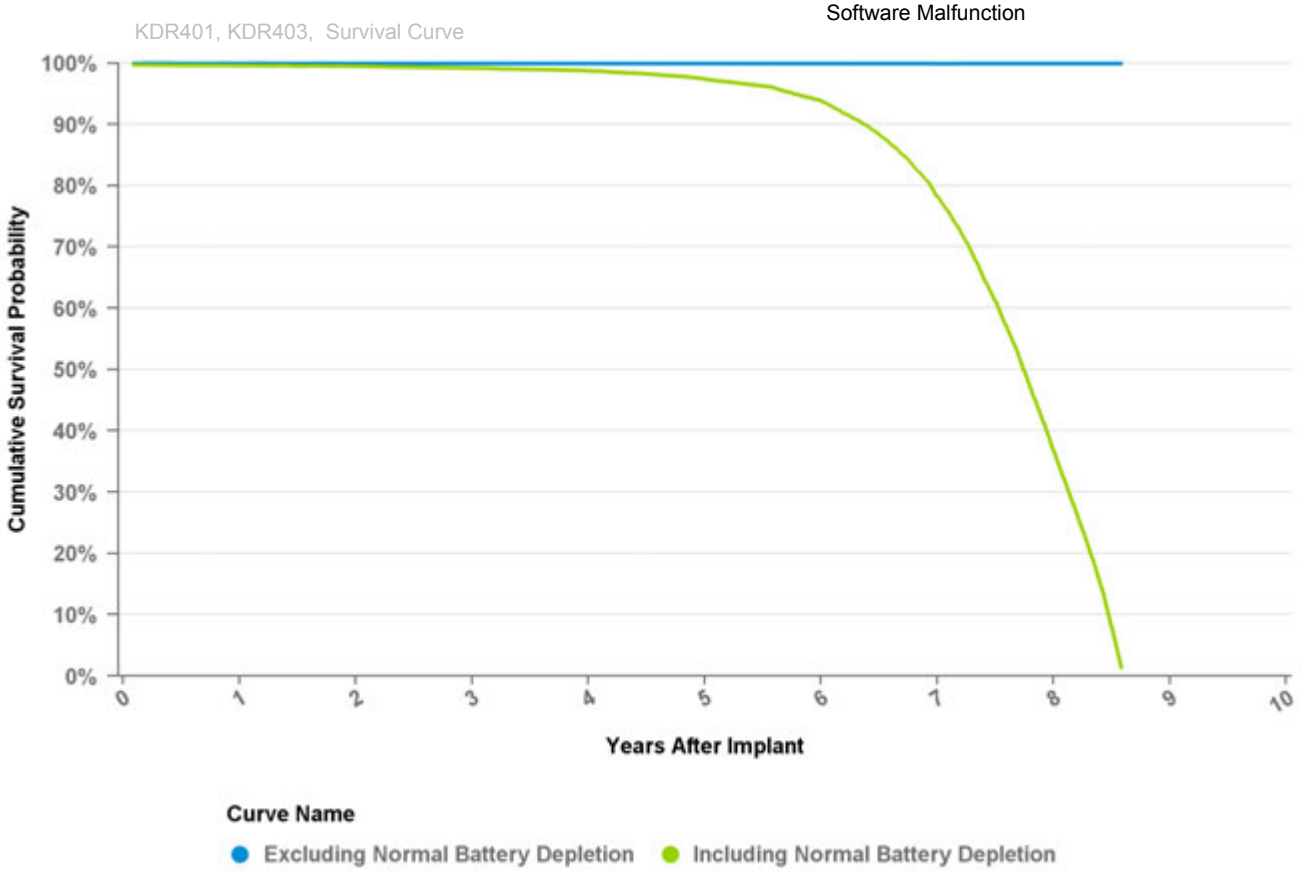
Implantable Pulse Generator

KDR401 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	39,352
Estimated Active US Implants	1,874
Normal Battery Depletions (US)	7,230

NBG Code	DDDR

Total Malfunctions (US)	23
Therapy Not Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



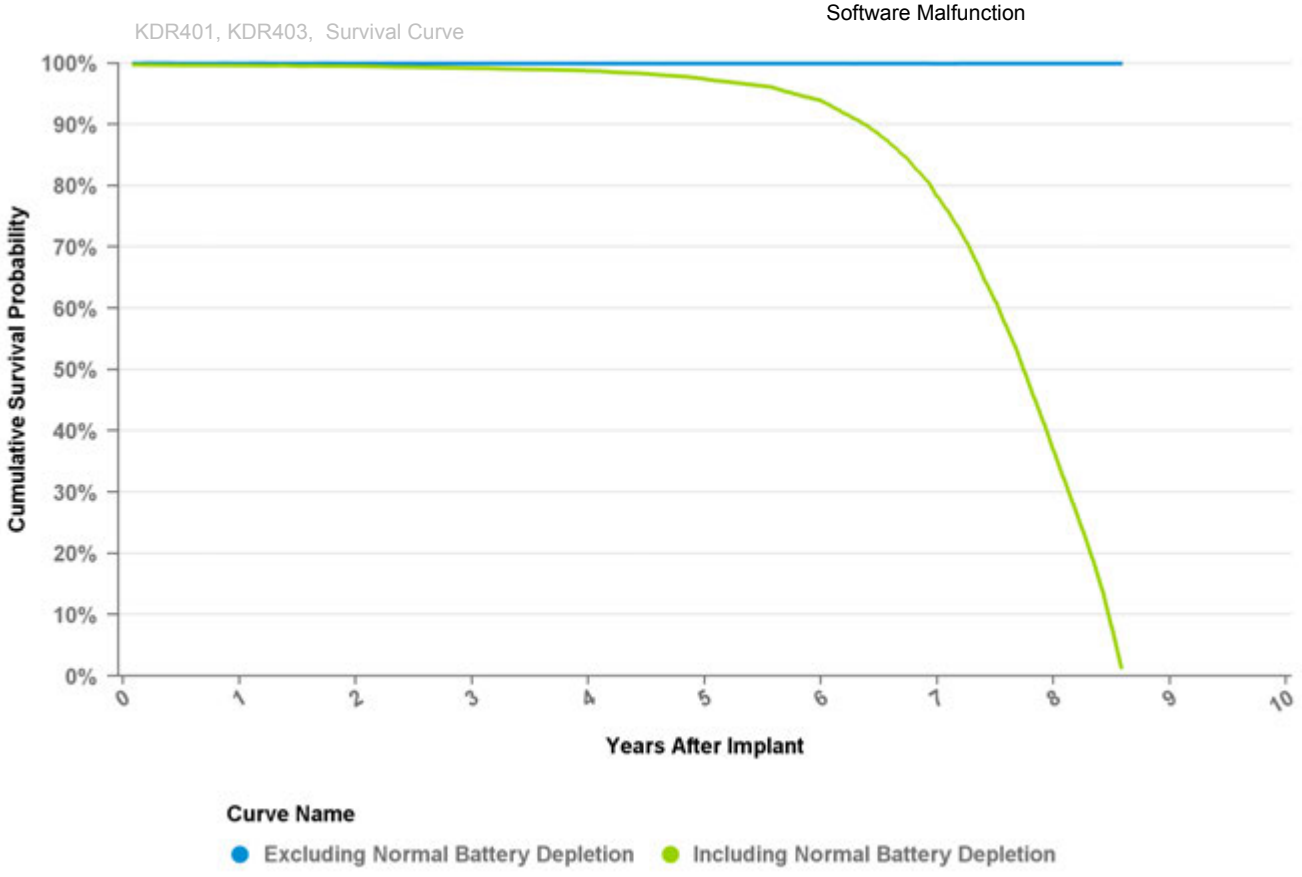
Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.4%	93.9%	78.3%	36.8%	1.4%
Effective Sample Size	41423	38325	35195	32190	28859	24921	18082	6467	562

Implantable Pulse Generator

KDR403 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	7,305
Estimated Active US Implants	561
Normal Battery Depletions (US)	1,181
NBG Code	DDDR

Total Malfunctions (US)	6
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.4%	93.9%	78.3%	36.8%	1.4%
Effective Sample Size	41423	38325	35195	32190	28859	24921	18082	6467	562

Implantable Pulse Generator

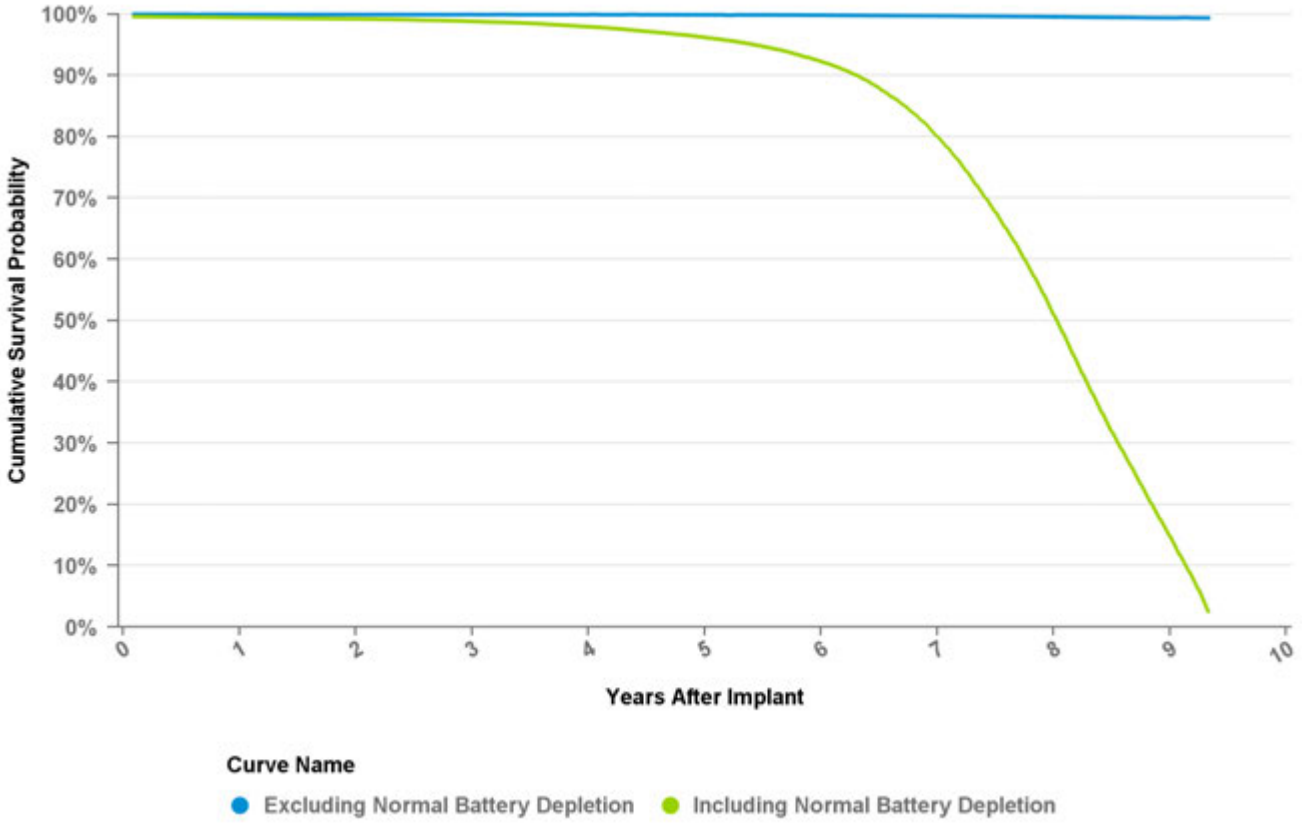
KDR700 Kappa 700 DR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	15
Estimated Active US Implants	0
Normal Battery Depletions (US)	4

NBG Code	DDD/RO

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	98.0%	96.2%	92.3%	80.1%	51.0%	14.9%	2.5%
Effective Sample Size	167404	152500	138020	123518	109365	93975	72158	38467	8001	1689

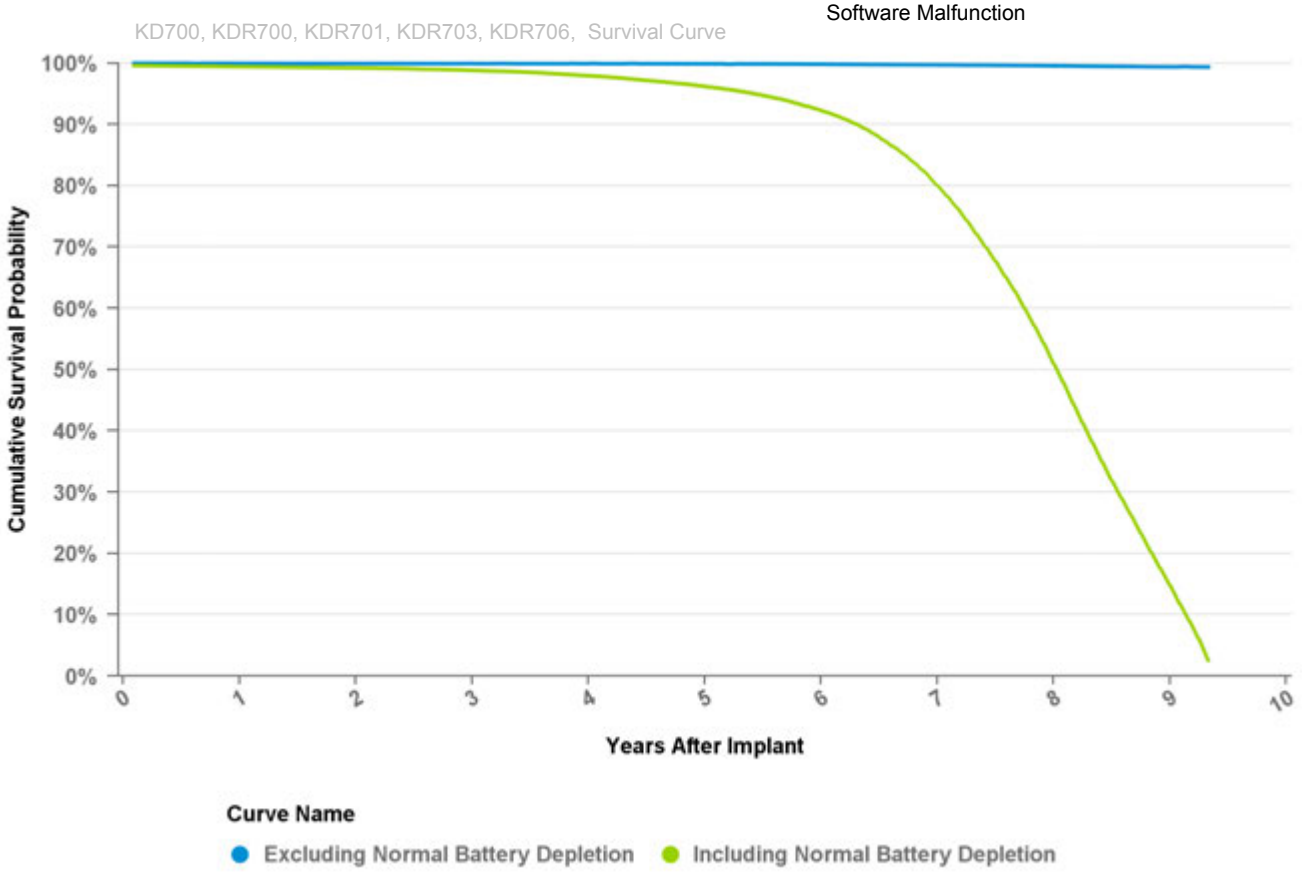
Implantable Pulse Generator

KDR701 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	194,057
Estimated Active US Implants	11,193
Normal Battery Depletions (US)	37,127

NBG Code	DDD/RO

Total Malfunctions (US)	701
Therapy Not Compromised Malfunctions	48
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	18
Other Malfunction	3
Poss Early Battery Depltn	3
Software Malfunction	0
Therapy Compromised Malfunctions	653
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	636
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0



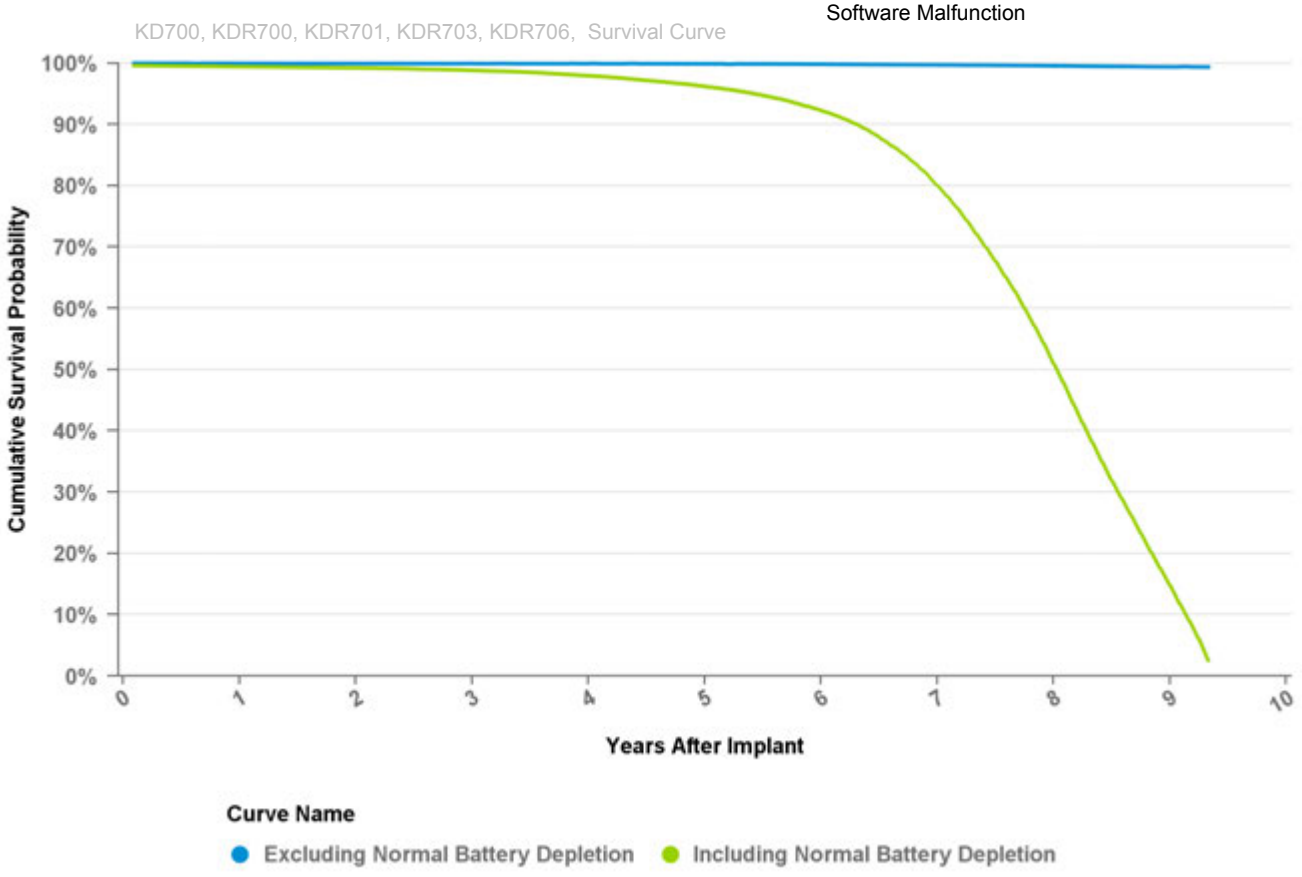
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	98.0%	96.2%	92.3%	80.1%	51.0%	14.9%	2.5%
Effective Sample Size	167404	152500	138020	123518	109365	93975	72158	38467	8001	1689

Implantable Pulse Generator

KDR703 Kappa 700 DR

US Market Release Date	2/5/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,226
Estimated Active US Implants	536
Normal Battery Depletions (US)	1,534
NBG Code	DDD/RO

Total Malfunctions (US)	34
Therapy Not Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	30
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	29
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



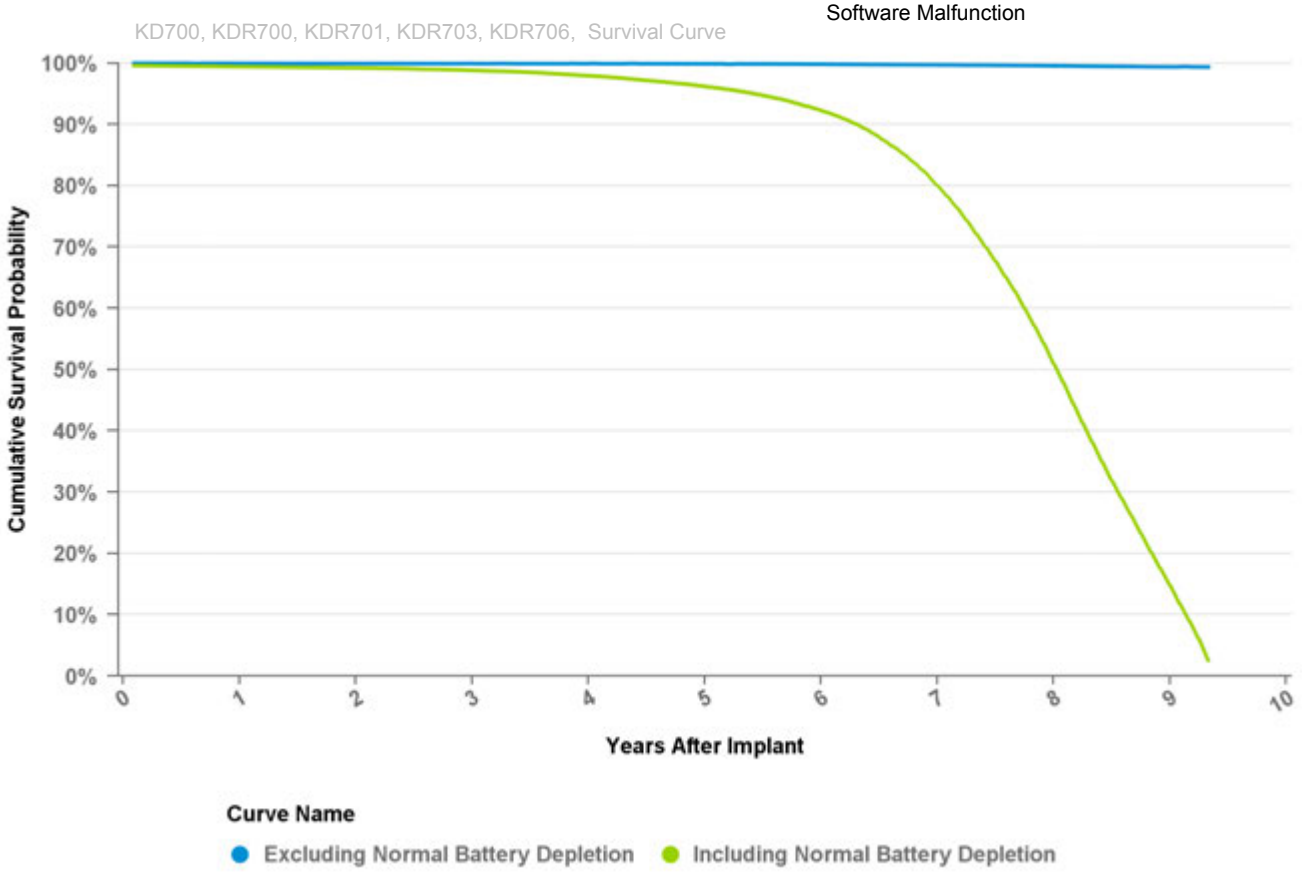
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	98.0%	96.2%	92.3%	80.1%	51.0%	14.9%	2.5%
Effective Sample Size	167404	152500	138020	123518	109365	93975	72158	38467	8001	1689

Implantable Pulse Generator

KDR706 Kappa 700 DR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,631
Estimated Active US Implants	122
Normal Battery Depletions (US)	405
NBG Code	DDD/RO

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	9
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	98.0%	96.2%	92.3%	80.1%	51.0%	14.9%	2.5%
Effective Sample Size	167404	152500	138020	123518	109365	93975	72158	38467	8001	1689

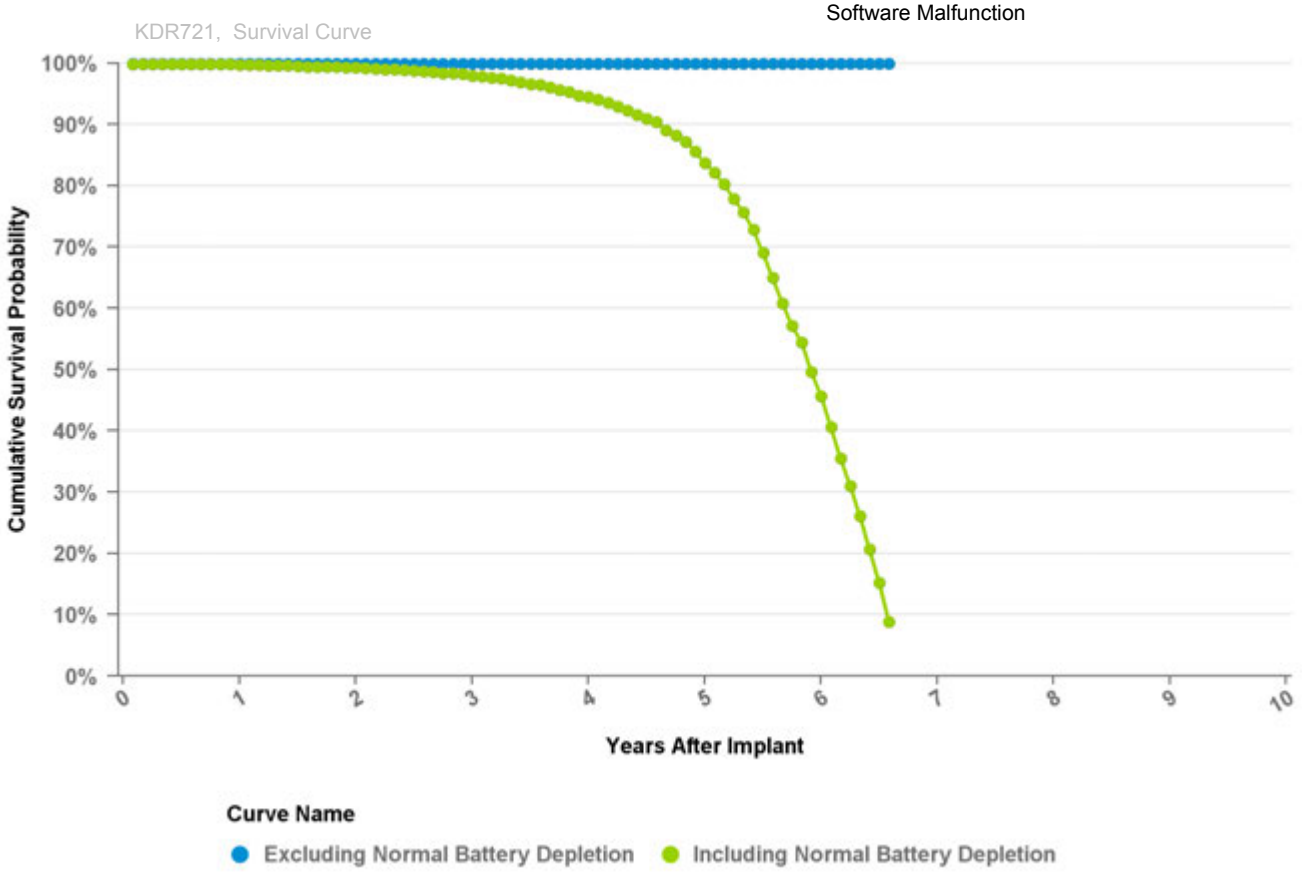
Implantable Pulse Generator

KDR721 Kappa 700 DR

US Market Release Date	2/11/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,828
Estimated Active US Implants	484
Normal Battery Depletions (US)	1,365

NBG Code	DDD/RO

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	4
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



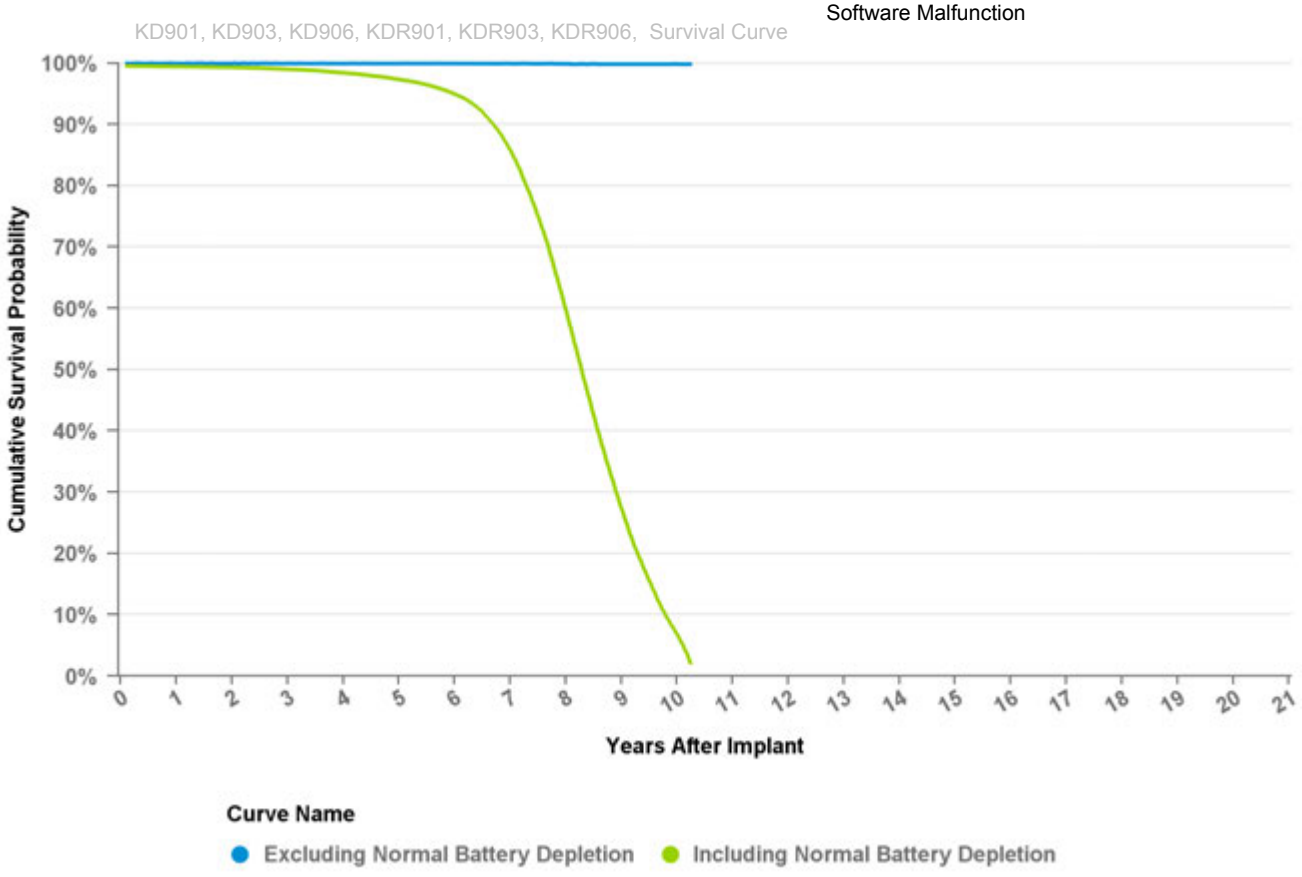
Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.8%	99.3%	98.0%	94.5%	83.7%	45.7%	8.9%
Effective Sample Size	8255	7242	6279	5252	3978	1531	238

Implantable Pulse Generator

KDR901 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	120,697
Estimated Active US Implants	9,748
Normal Battery Depletions (US)	27,052
NBG Code	DDDR

Total Malfunctions (US)	71
Therapy Not Compromised Malfunctions	21
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	4
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	50
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	40
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

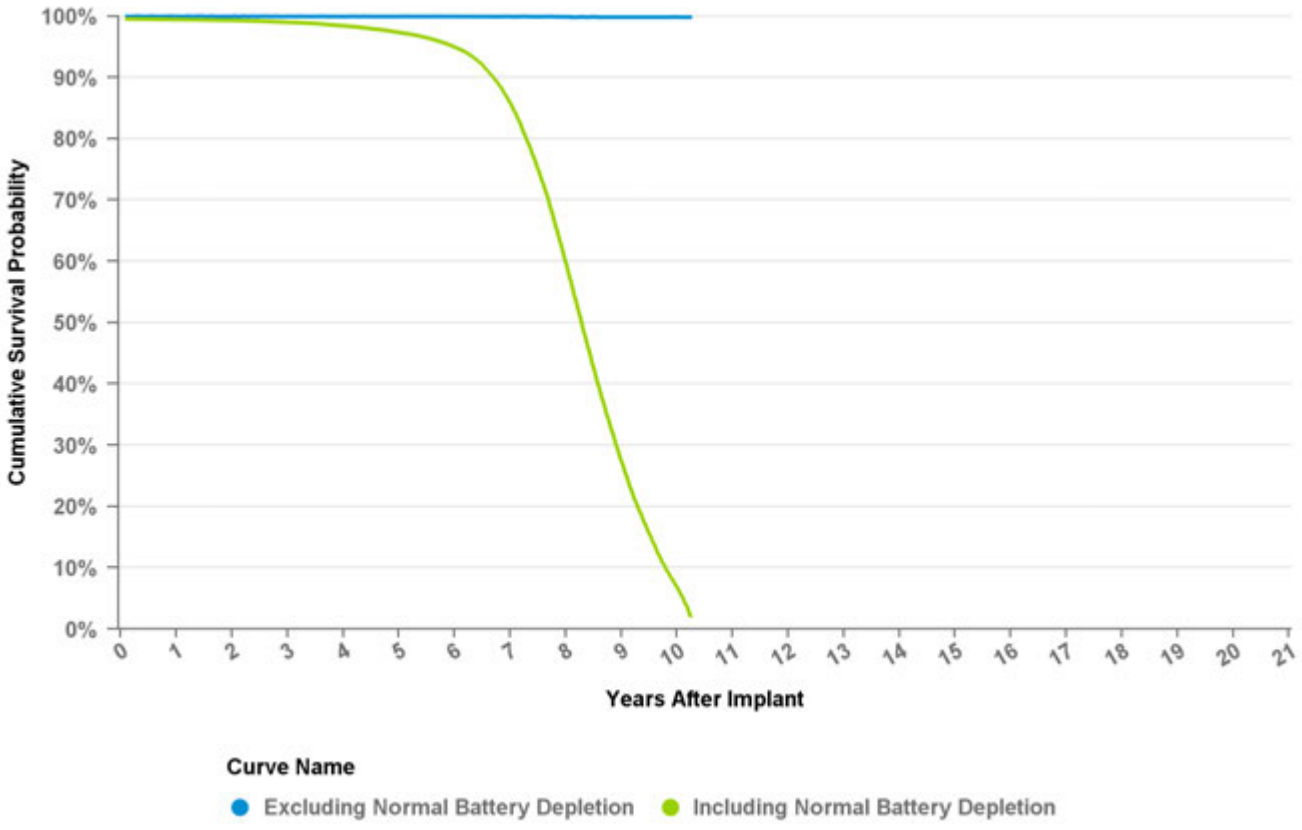
Implantable Pulse Generator

KDR903 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	3,172
Estimated Active US Implants	236
Normal Battery Depletions (US)	621
NBG Code	DDDR

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

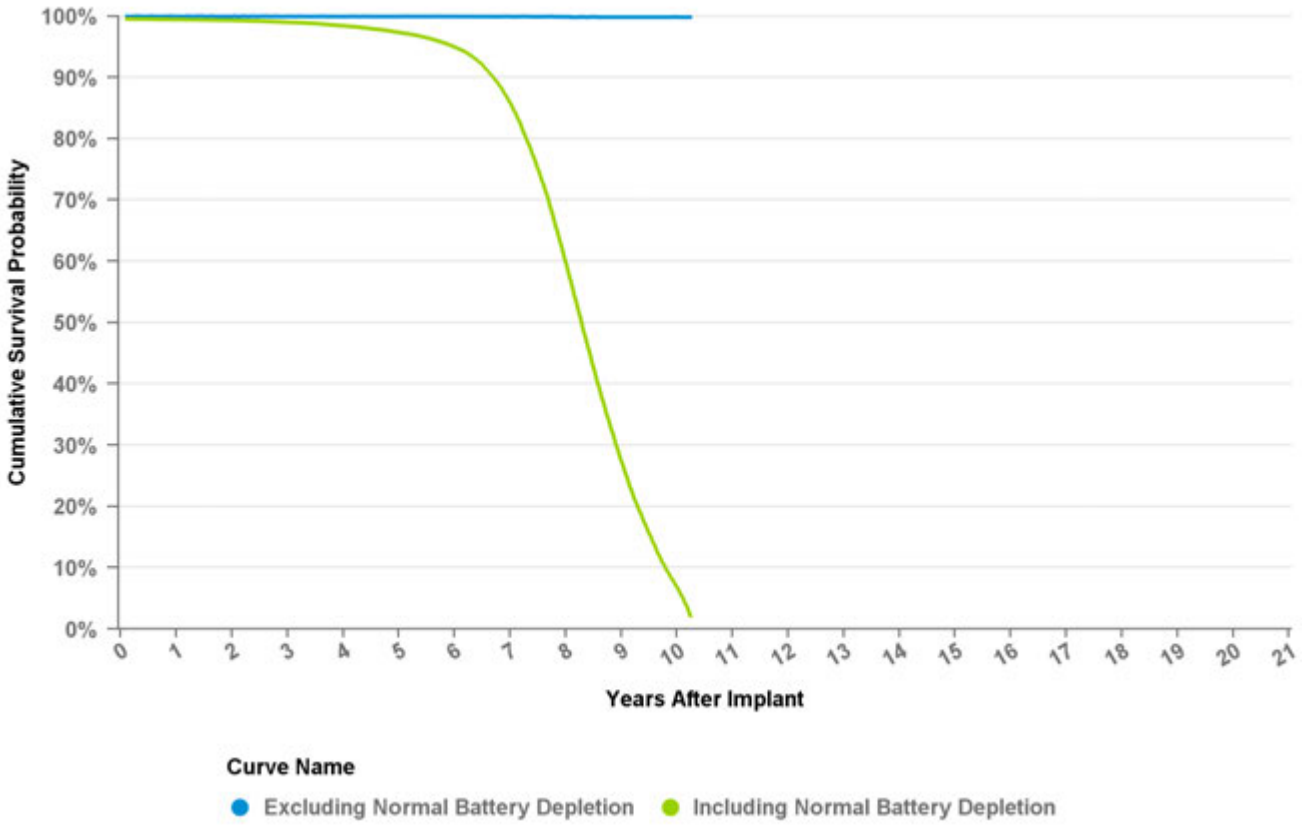
Implantable Pulse Generator

KDR906 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,508
Estimated Active US Implants	89
Normal Battery Depletions (US)	302
NBG Code	DDDR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



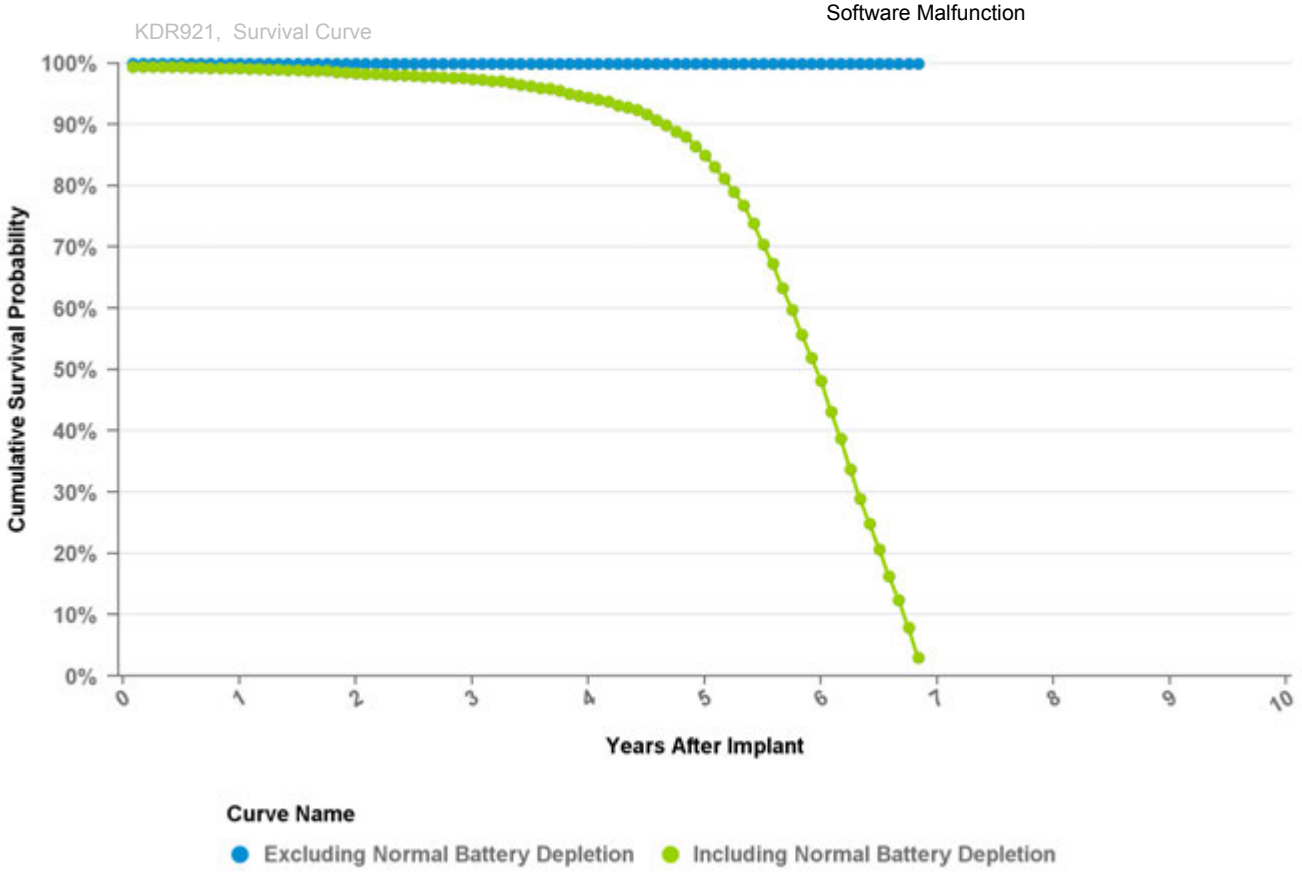
Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	6.9%	2.1%
Effective Sample Size	108925	99610	90568	81908	73458	65024	53593	33164	12702	2073	463

Implantable Pulse Generator

KDR921 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	16,324
Estimated Active US Implants	922
Normal Battery Depletions (US)	2,909
NBG Code	DDDR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.2%	98.4%	97.5%	94.4%	85.0%	48.2%	3.0%
Effective Sample Size	13656	12087	10614	9082	7144	3108	186

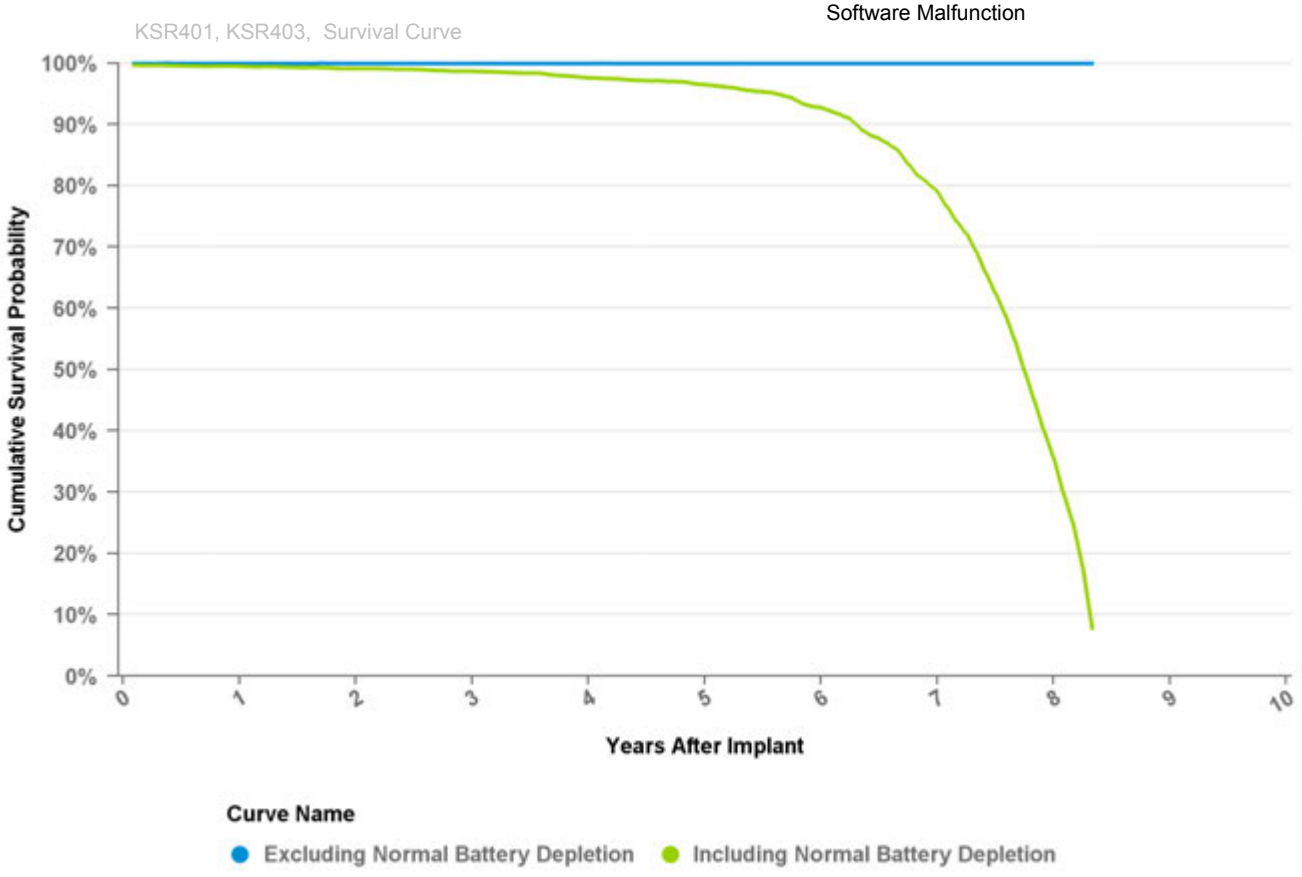
Implantable Pulse Generator

KSR401 Kappa 400 SR

US Market Release Date	2/18/1998
CE Market Approval Date	11/12/1996
Registered US Implants	11,781
Estimated Active US Implants	514
Normal Battery Depletions (US)	1,296

NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.1%	98.7%	97.6%	96.5%	92.7%	79.0%	35.7%	7.7%
Effective Sample Size	12148	10497	9012	7720	6468	5184	3588	1114	273

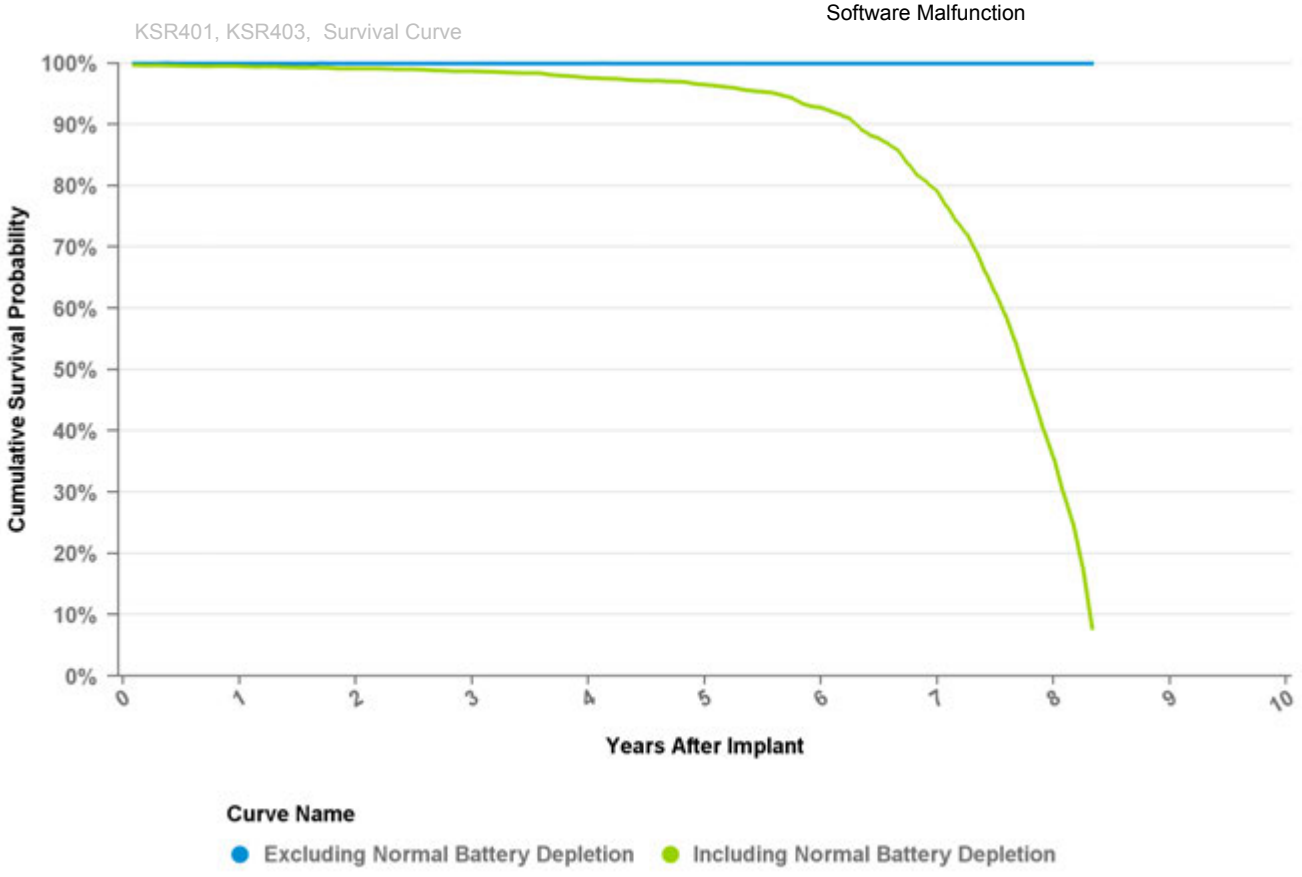
Implantable Pulse Generator

KSR403 Kappa 400 SR

US Market Release Date	2/24/1998
CE Market Approval Date	11/12/1996
Registered US Implants	3,621
Estimated Active US Implants	248
Normal Battery Depletions (US)	401

NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.1%	98.7%	97.6%	96.5%	92.7%	79.0%	35.7%	7.7%
Effective Sample Size	12148	10497	9012	7720	6468	5184	3588	1114	273

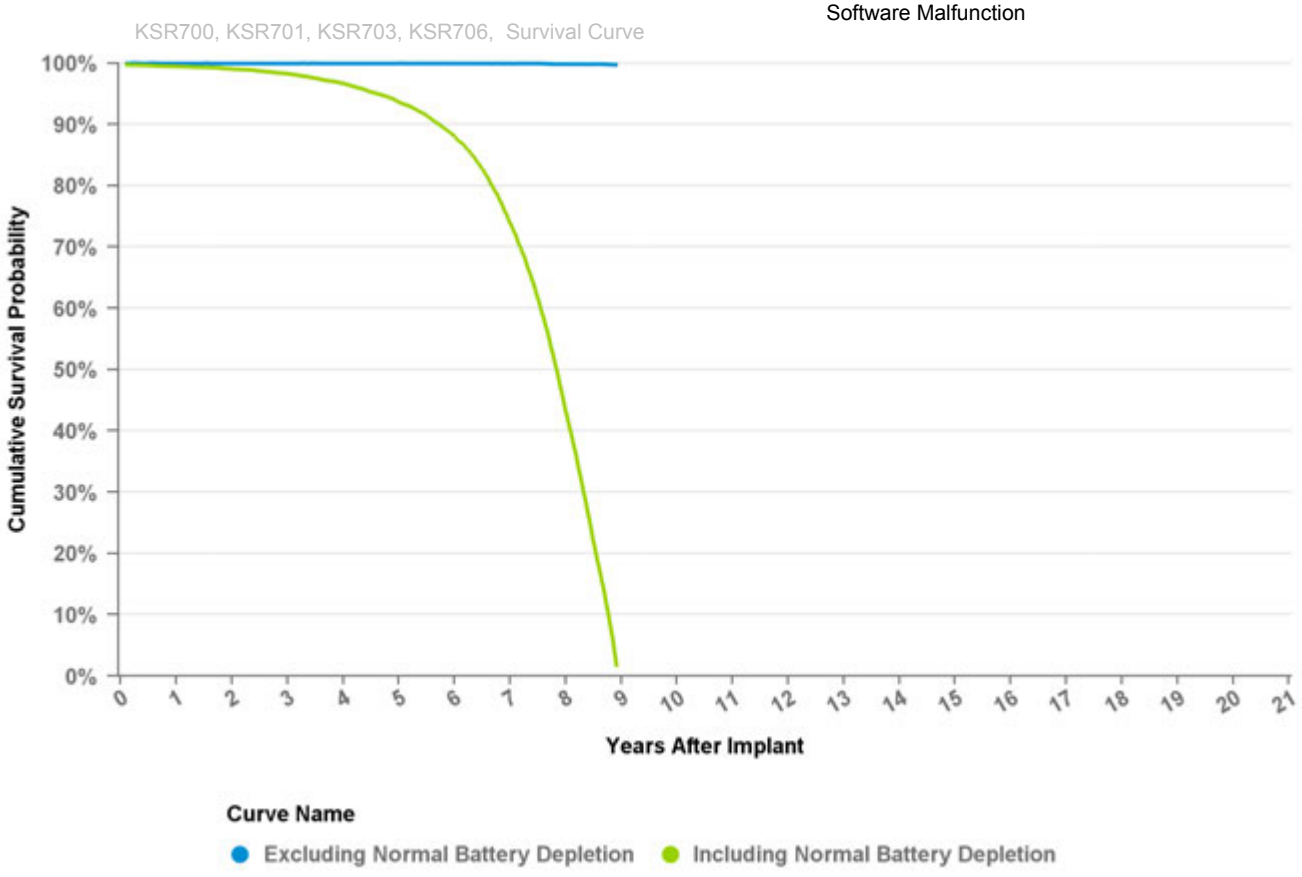
Implantable Pulse Generator

KSR700 Kappa 700 SR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.3%	1.7%
Effective Sample Size	42989	36388	30508	25423	20691	16234	11242	5052	259

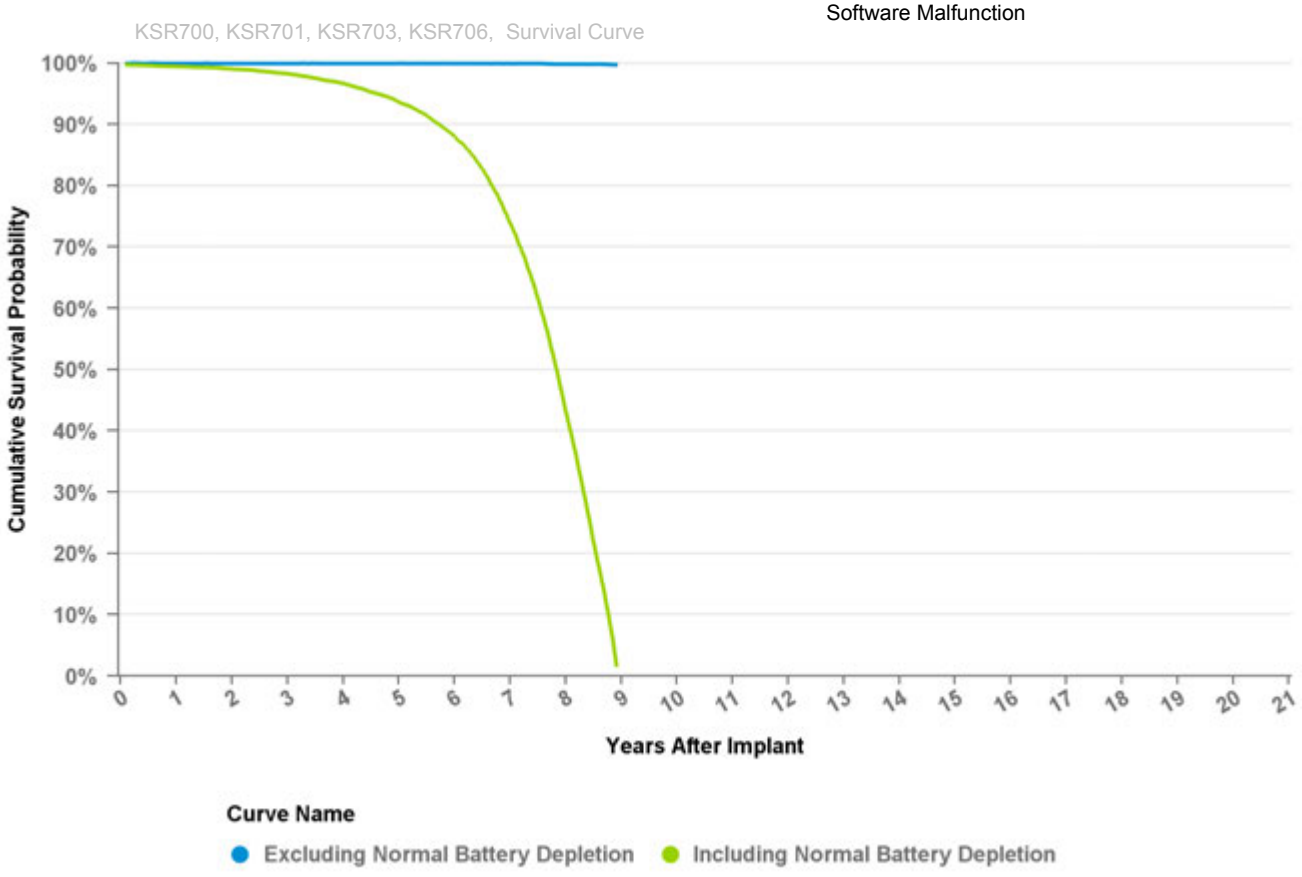
Implantable Pulse Generator

KSR701 Kappa 700 SR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	48,451
Estimated Active US Implants	2,645
Normal Battery Depletions (US)	5,185

NBG Code	SSIR

Total Malfunctions (US)	22
Therapy Not Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	19
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	17
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.3%	1.7%
Effective Sample Size	42989	36388	30508	25423	20691	16234	11242	5052	259

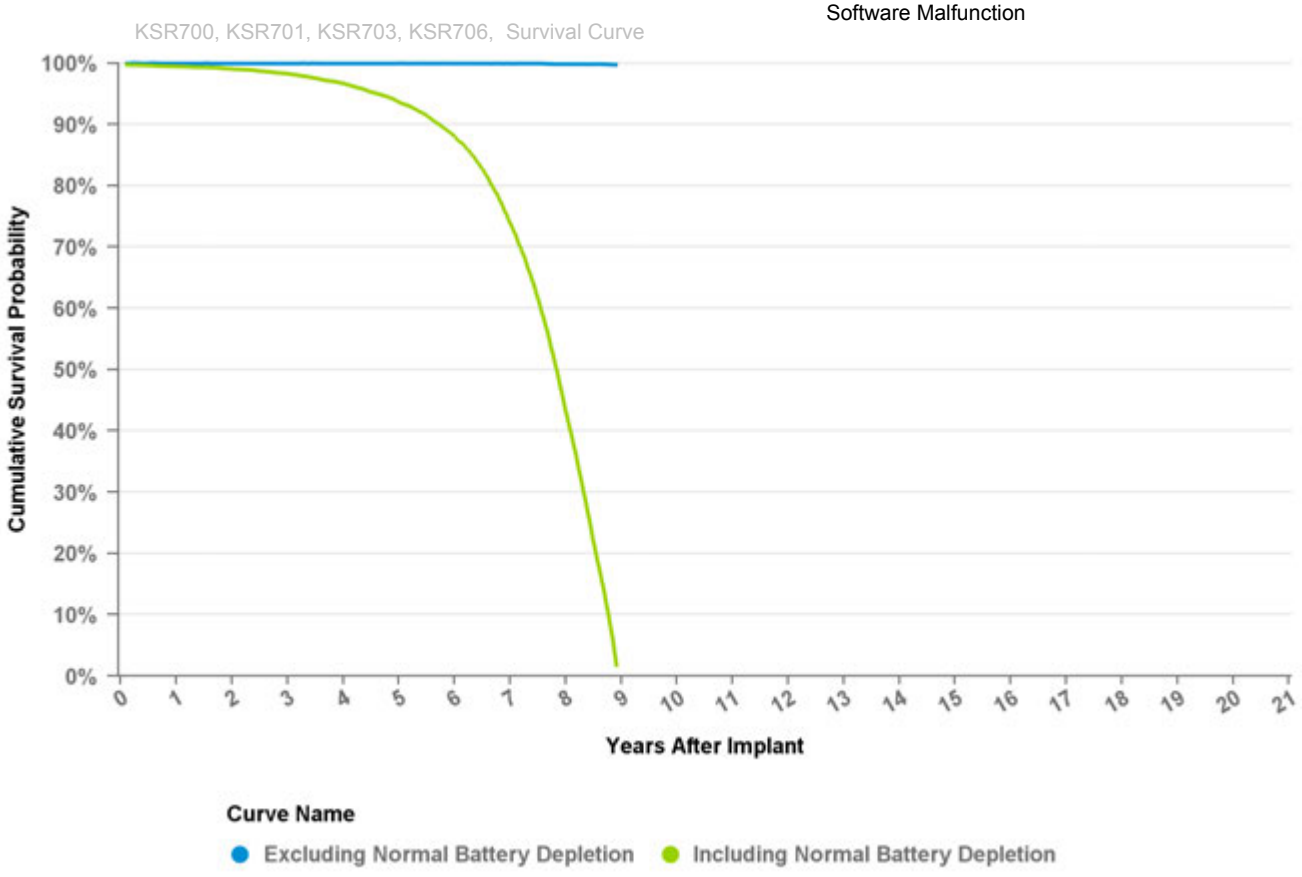
Implantable Pulse Generator

KSR703 Kappa 700 SR

US Market Release Date	2/8/1999
CE Market Approval Date	3/20/1998
Registered US Implants	3,604
Estimated Active US Implants	178
Normal Battery Depletions (US)	395

NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.3%	1.7%
Effective Sample Size	42989	36388	30508	25423	20691	16234	11242	5052	259

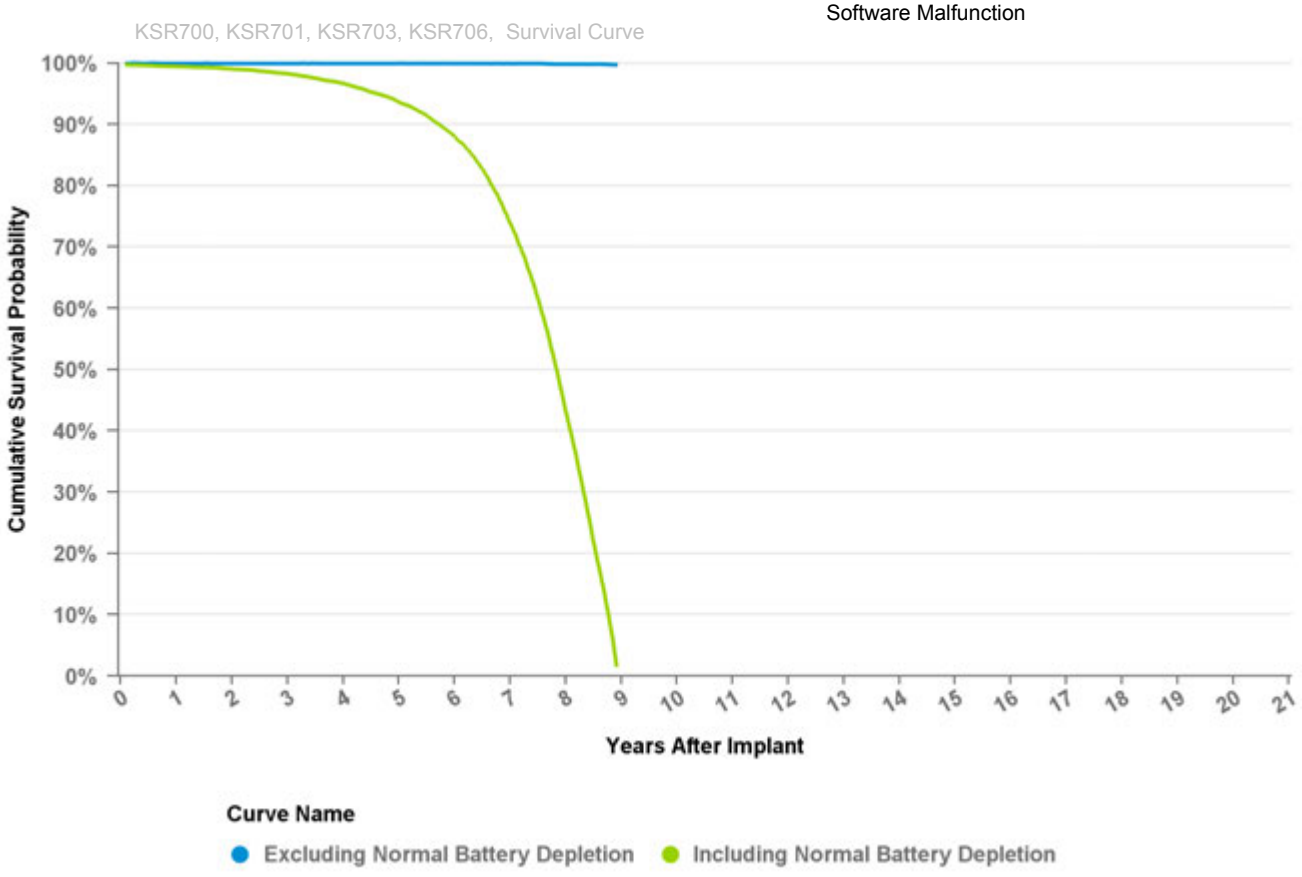
Implantable Pulse Generator

KSR706 Kappa 700 SR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,920
Estimated Active US Implants	157
Normal Battery Depletions (US)	302

NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



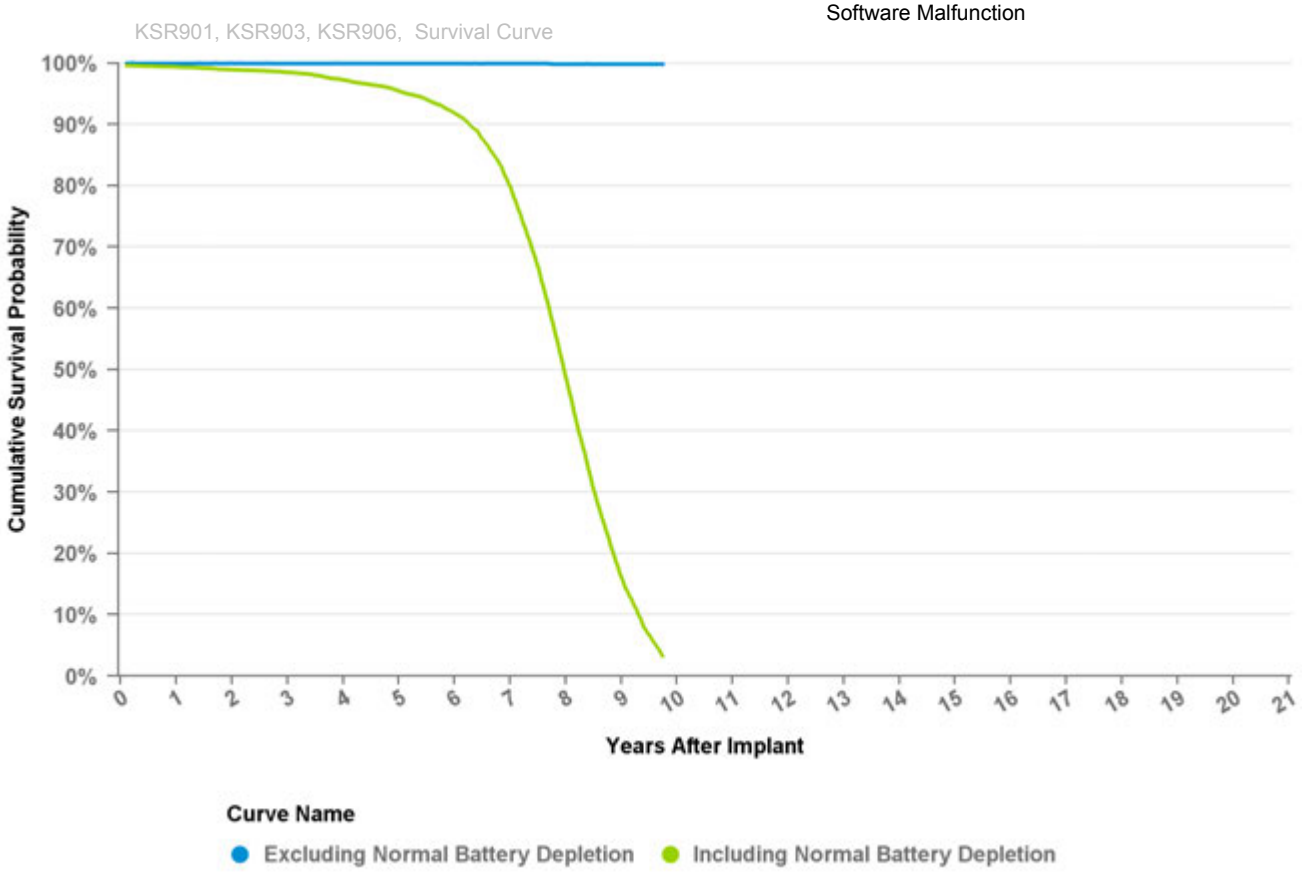
Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.3%	1.7%
Effective Sample Size	42989	36388	30508	25423	20691	16234	11242	5052	259

Implantable Pulse Generator

KSR901 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	34,126
Estimated Active US Implants	2,421
Normal Battery Depletions (US)	4,243
NBG Code	SSIR

Total Malfunctions (US)	15
Therapy Not Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	8
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



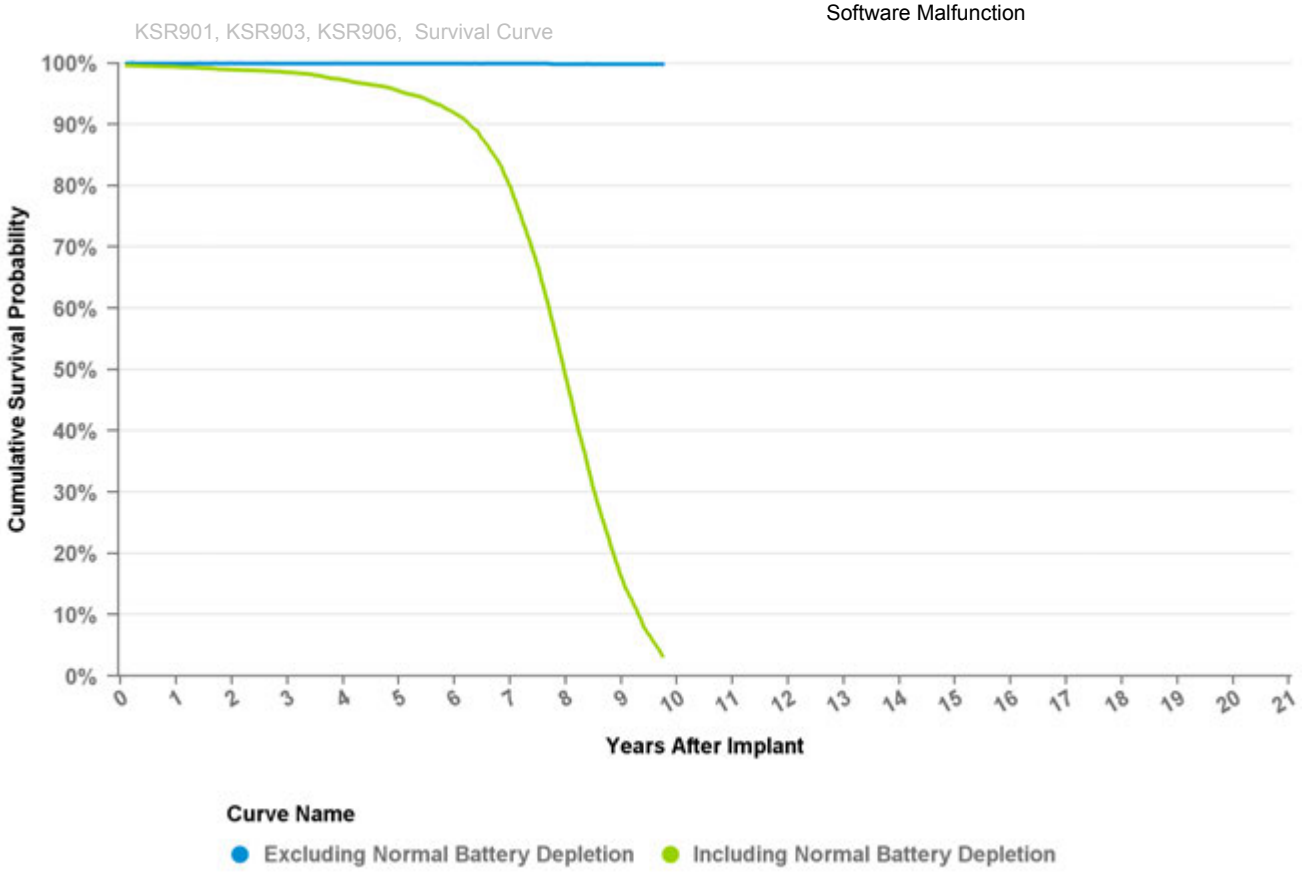
Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.4%	98.9%	98.5%	97.3%	95.5%	91.8%	79.9%	48.9%	16.2%	3.2%
Effective Sample Size	28471	24072	20499	17228	14352	11719	8639	4329	1059	110

Implantable Pulse Generator

KSR903 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,372
Estimated Active US Implants	85
Normal Battery Depletions (US)	166
NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



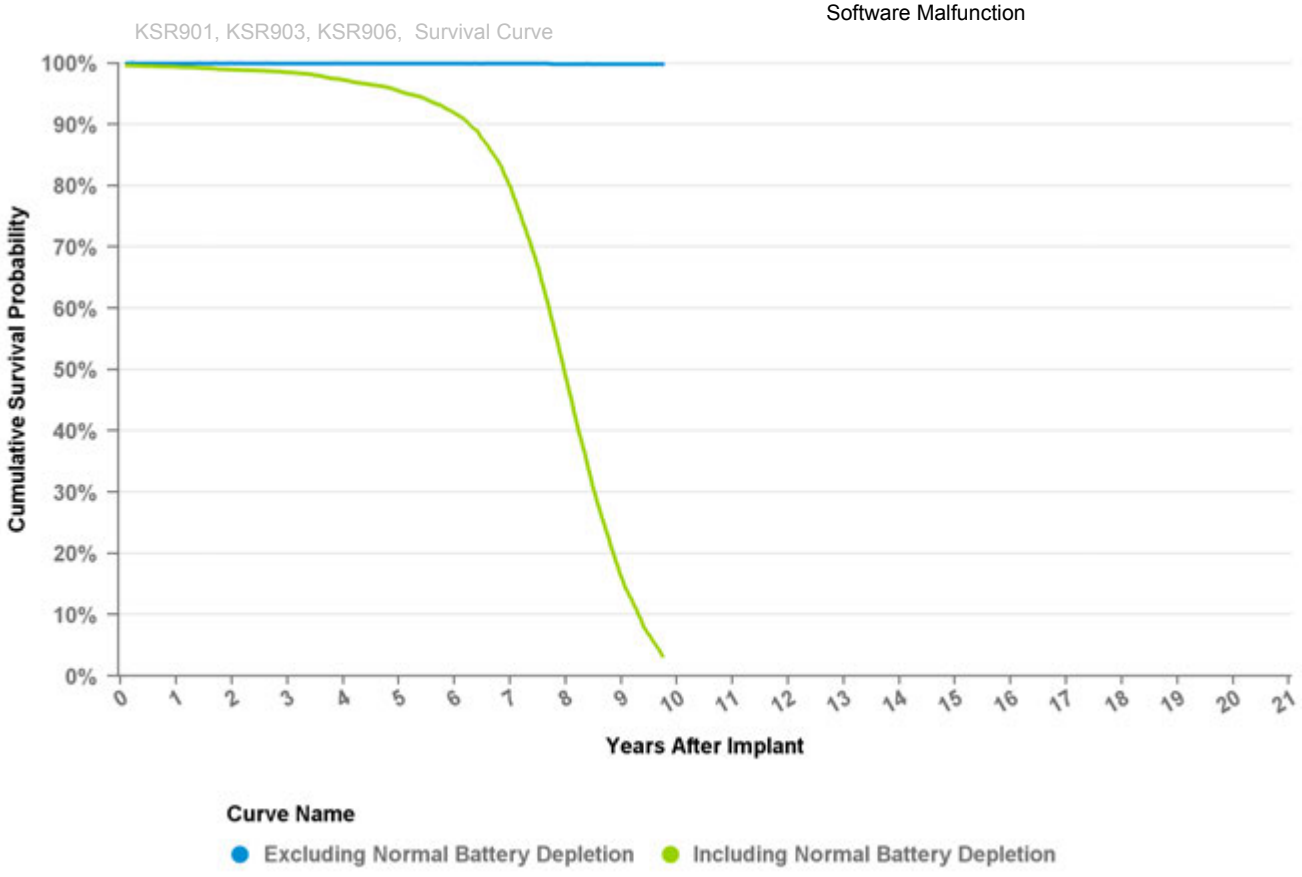
Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.4%	98.9%	98.5%	97.3%	95.5%	91.8%	79.9%	48.9%	16.2%	3.2%
Effective Sample Size	28471	24072	20499	17228	14352	11719	8639	4329	1059	110

Implantable Pulse Generator

KSR906 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,319
Estimated Active US Implants	90
Normal Battery Depletions (US)	184
NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



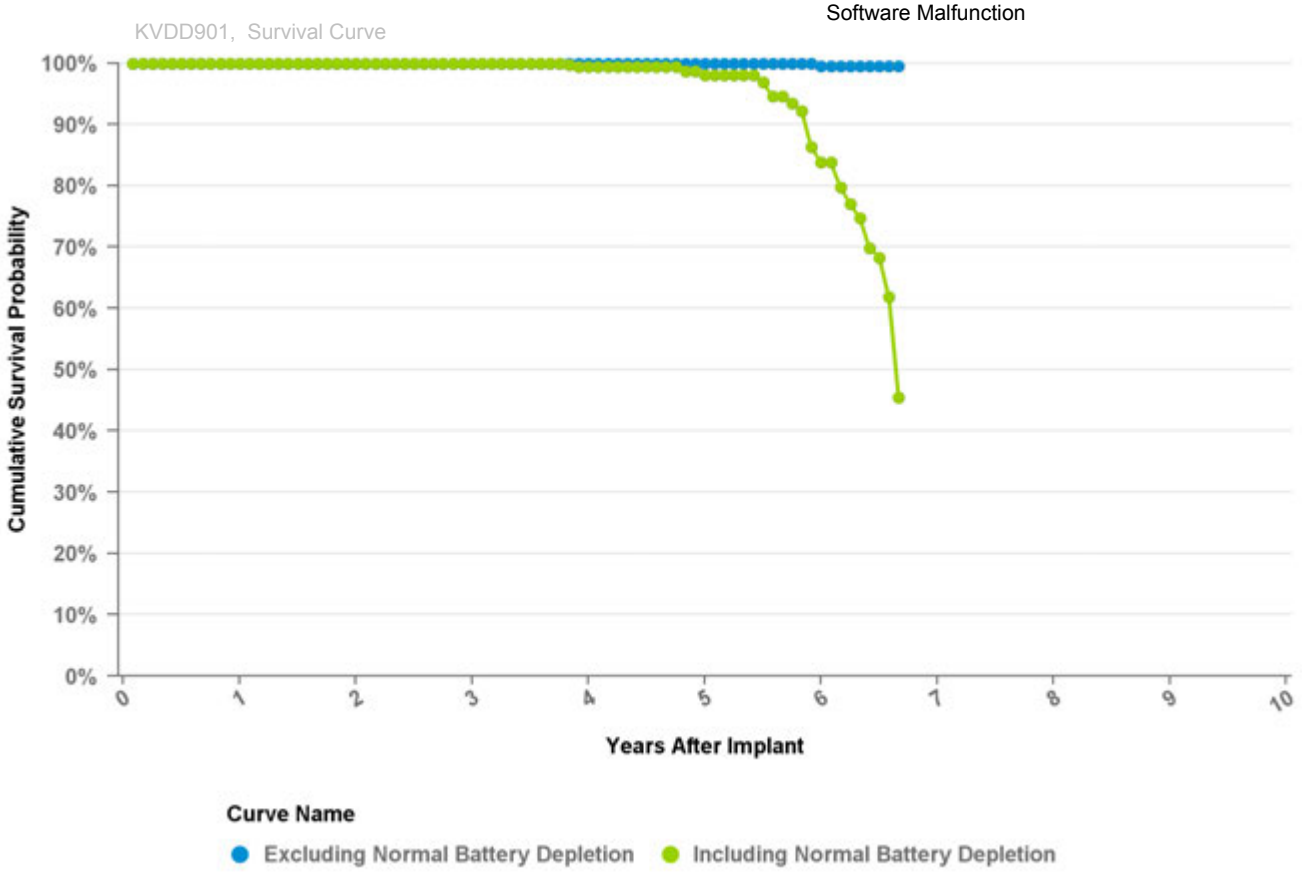
Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.4%	98.9%	98.5%	97.3%	95.5%	91.8%	79.9%	48.9%	16.2%	3.2%
Effective Sample Size	28471	24072	20499	17228	14352	11719	8639	4329	1059	110

Implantable Pulse Generator

KVDD901 Kappa 900 VDD

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	566
Estimated Active US Implants	47
Normal Battery Depletions (US)	81
NBG Code	VDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



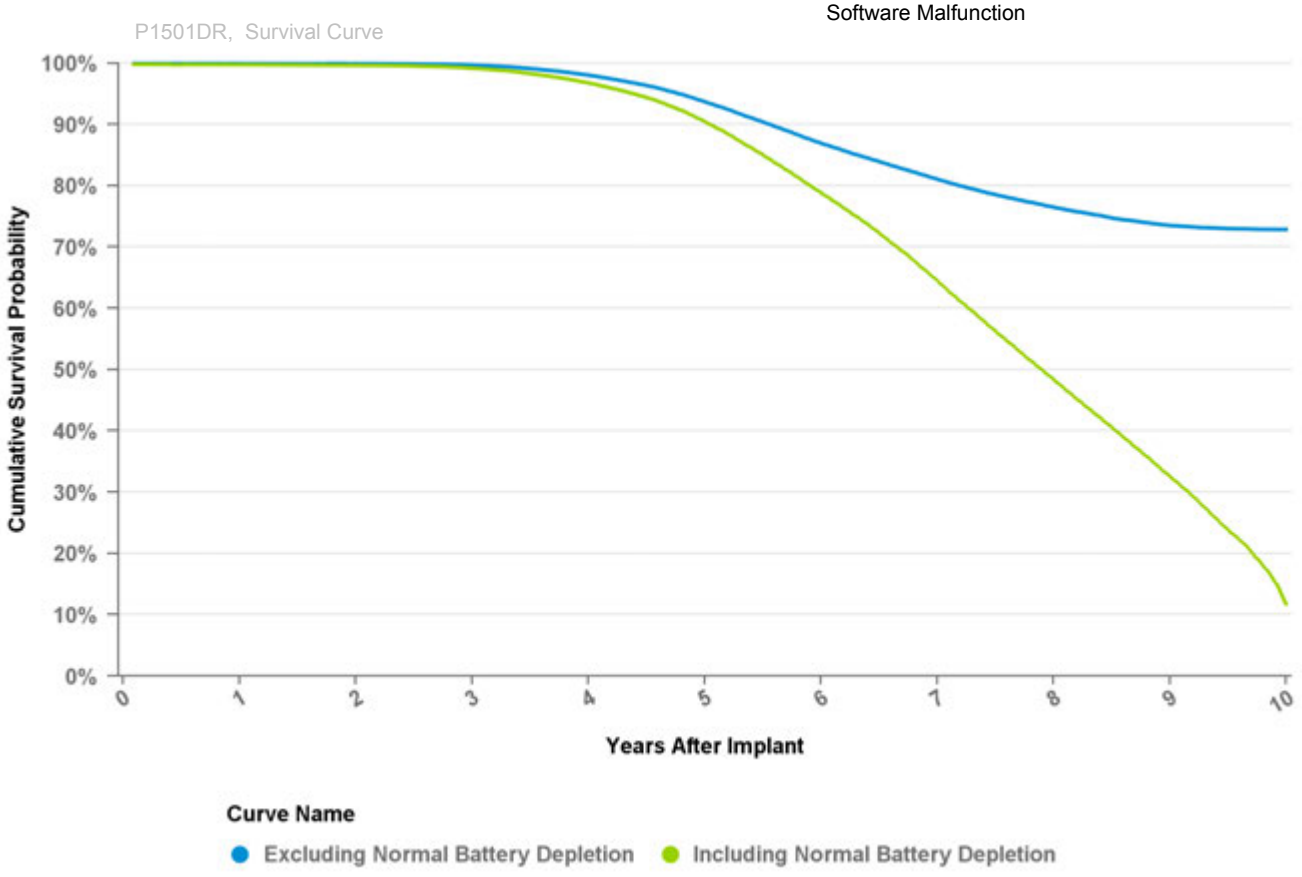
Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.6%	99.6%
Including NBD	100.0%	100.0%	100.0%	99.4%	98.0%	83.8%	45.5%
Effective Sample Size	468	422	376	325	286	203	110

Implantable Pulse Generator

P1501DR EnRhythm DR

US Market Release Date	5/5/2005
CE Market Approval Date	8/13/2004
Registered US Implants	110,081
Estimated Active US Implants	30,601
Normal Battery Depletions (US)	11,246
NBG Code	DDDRP

Total Malfunctions (US)	14,640
Therapy Not Compromised Malfunctions	14,585
Battery Malfunction	14,457
Electrical Component	58
Electrical Interconnect	2
Other Malfunction	2
Poss Early Battery Depltn	66
Software Malfunction	0
Therapy Compromised Malfunctions	55
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2
Software Malfunction	0



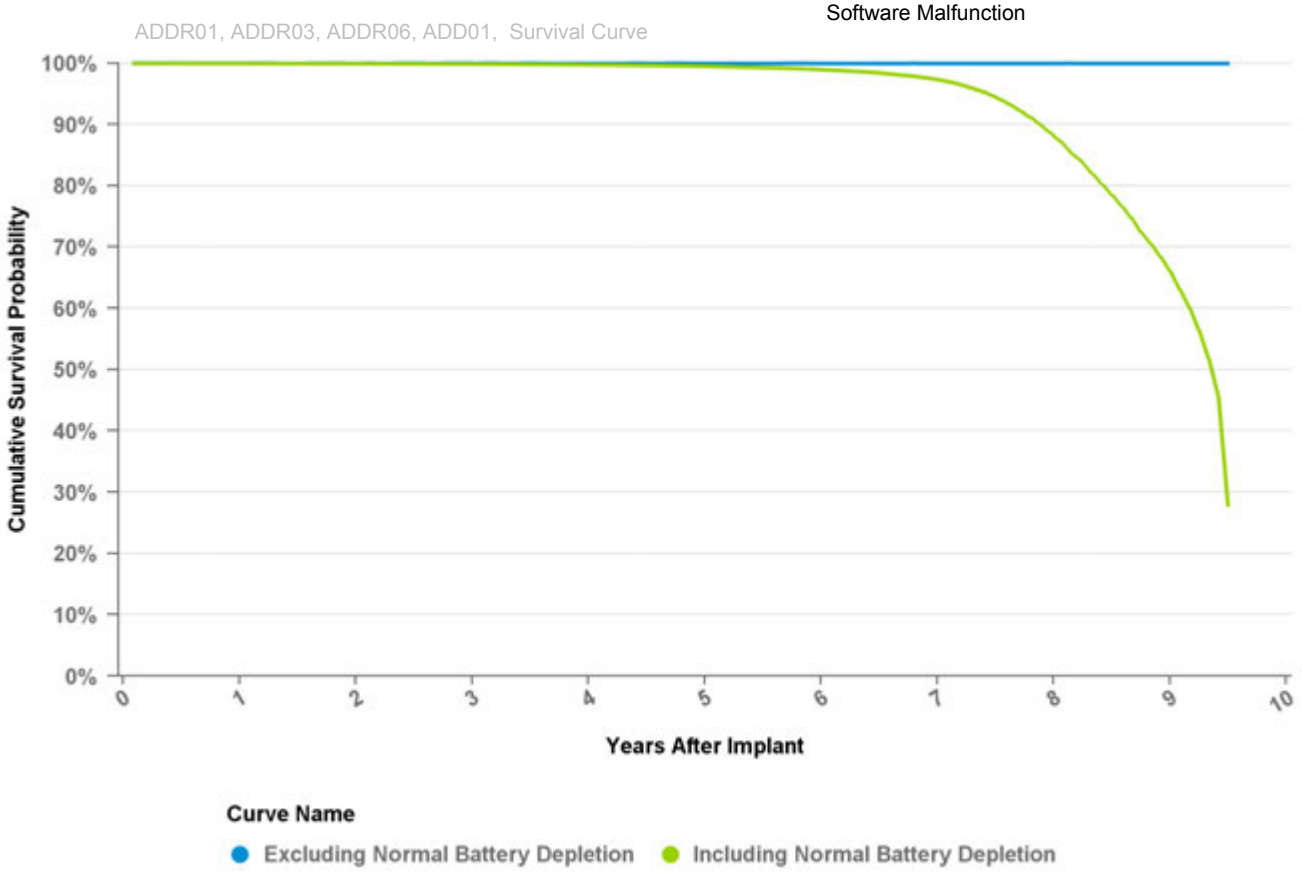
Years	1	2	3	4	5	6	7	8	9	at 120 mo
Excluding NBD	99.9%	99.9%	99.7%	98.0%	93.7%	86.9%	81.0%	76.5%	73.5%	72.9%
Including NBD	99.8%	99.7%	99.2%	96.8%	90.5%	78.8%	64.5%	48.3%	32.5%	11.8%
Effective Sample Size	95517	89181	83136	76123	66052	48910	31940	18235	8367	805

Implantable Pulse Generator

RED01 Relia D

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



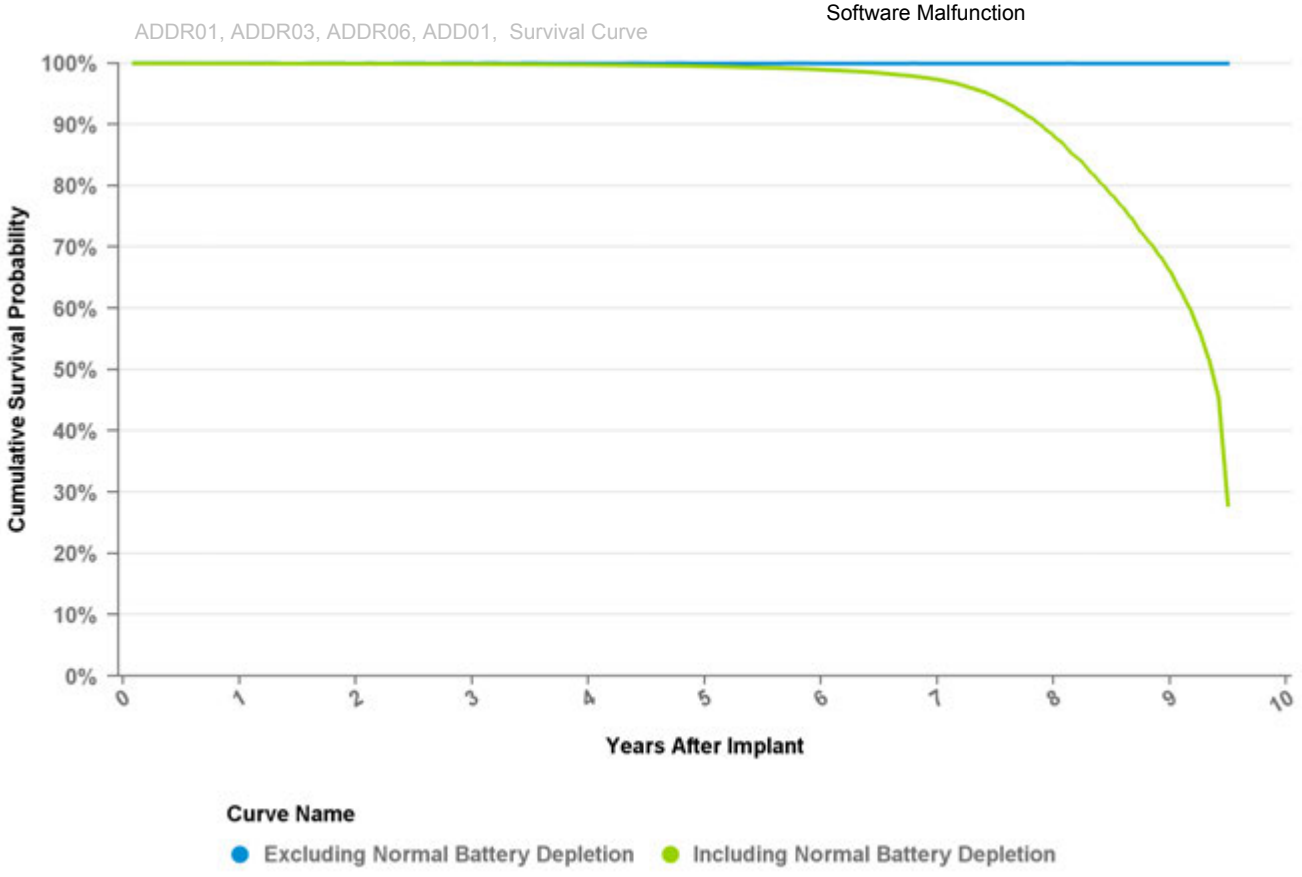
Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

Implantable Pulse Generator

REDR01 Relia DR

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	2
Estimated Active US Implants	1
Normal Battery Depletions (US)	0
NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.5%	98.9%	97.3%	88.1%	66.2%	27.8%
Effective Sample Size	380481	337610	288000	237151	187891	139376	92838	47913	11196	377

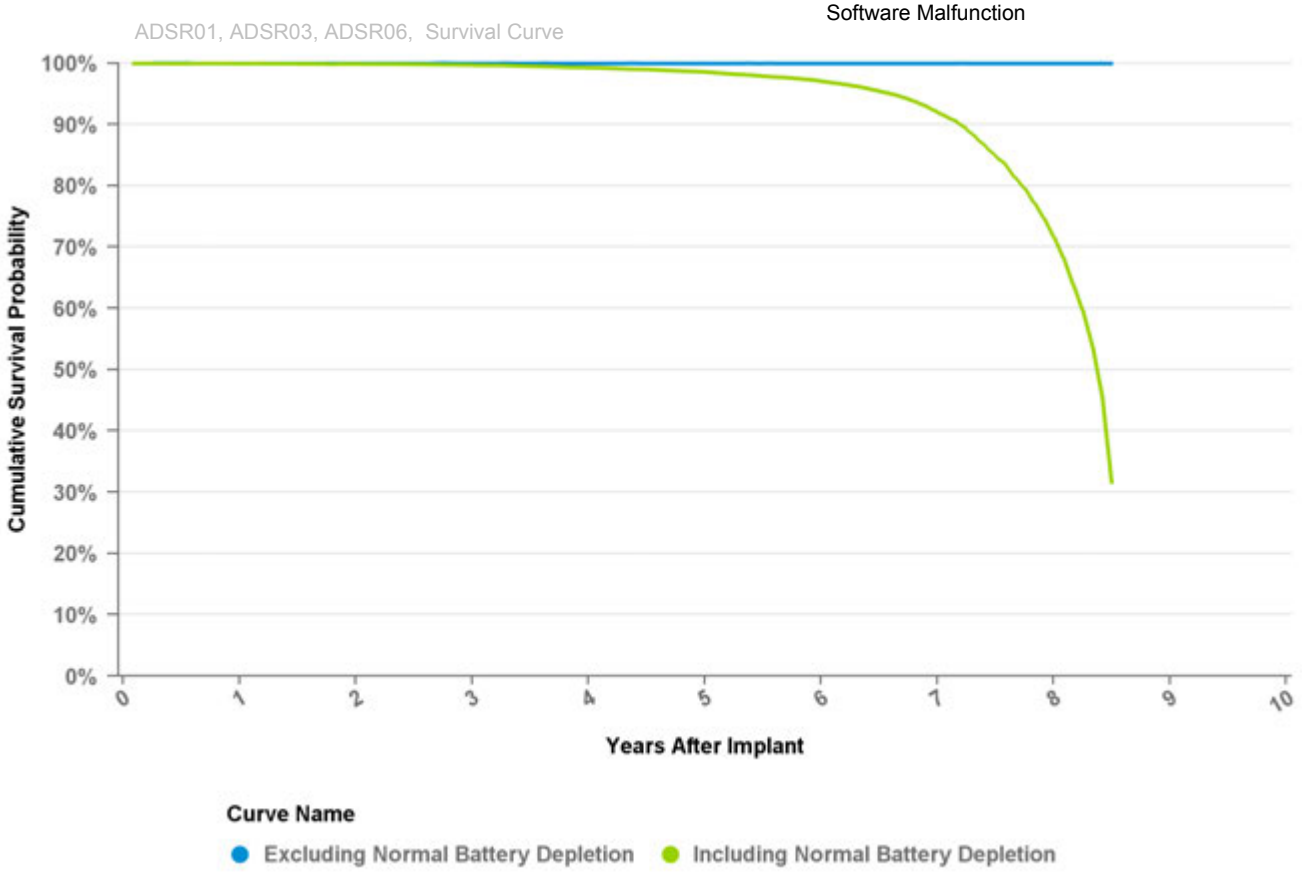
Implantable Pulse Generator

RES01 Relia S

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	2
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	AAI/VVI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.0%	71.8%	31.5%
Effective Sample Size	69779	55737	43382	32309	23193	15856	9212	2901	330

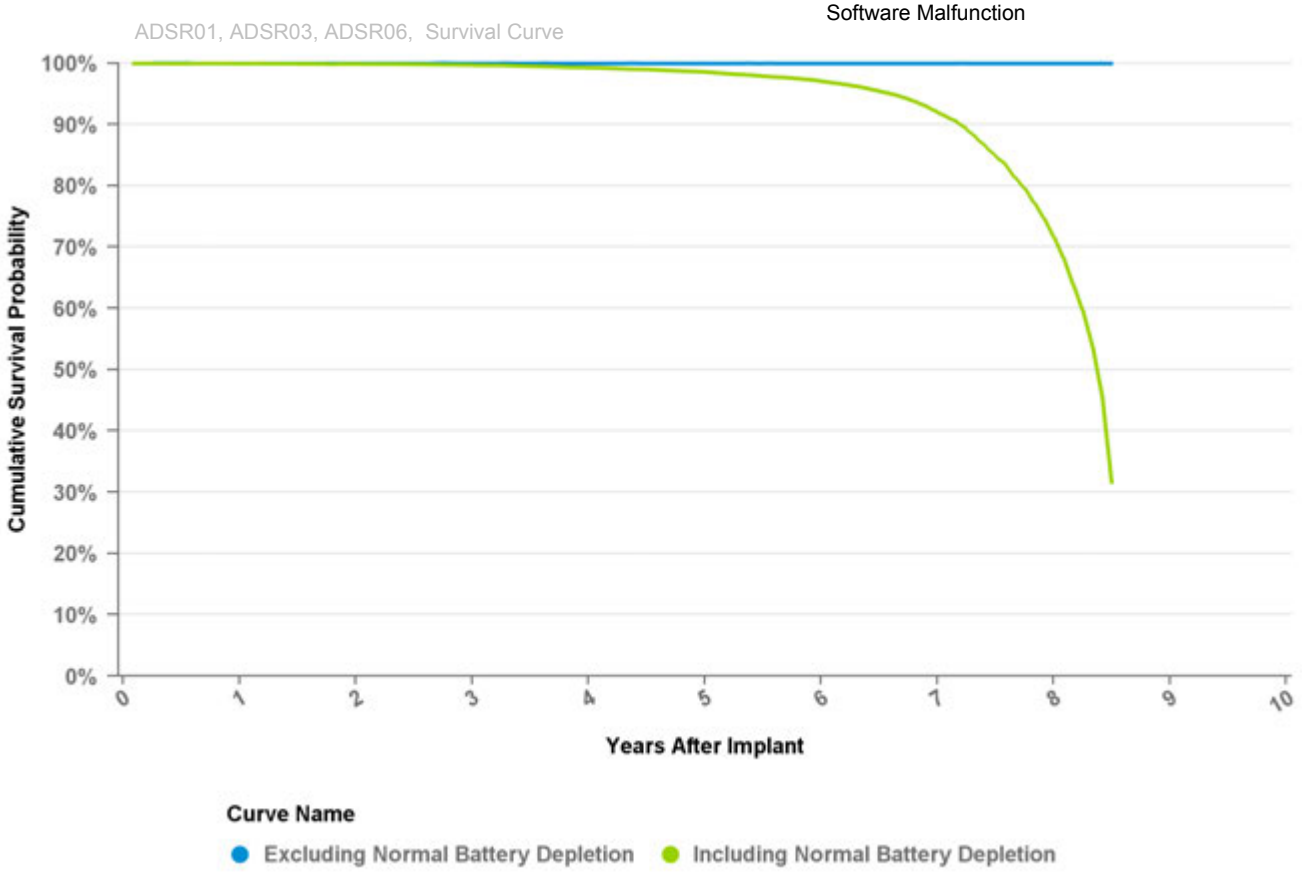
Implantable Pulse Generator

RESR01 Relia SR

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	AAIR/VVIR, AAI/VVI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.0%	71.8%	31.5%
Effective Sample Size	69779	55737	43382	32309	23193	15856	9212	2901	330

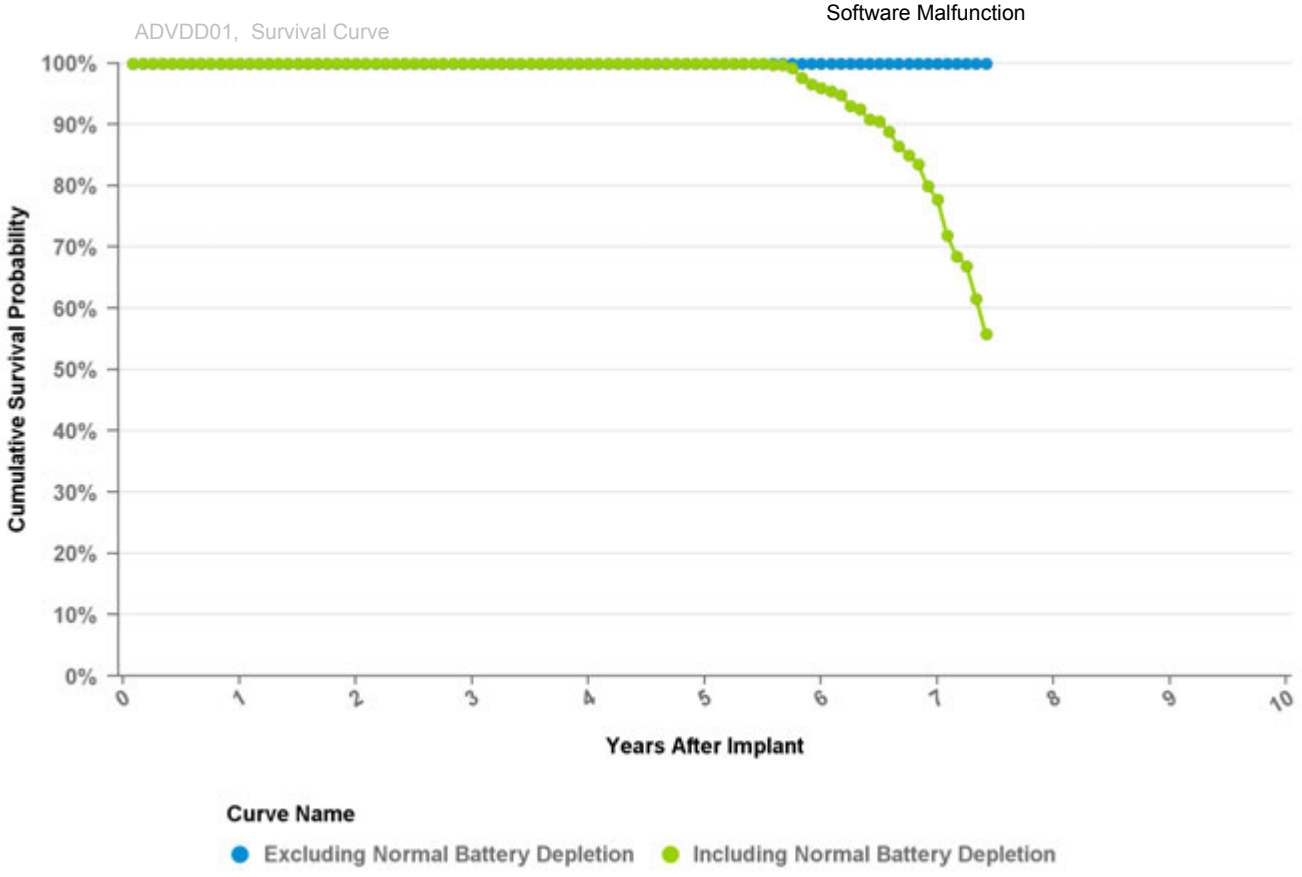
Implantable Pulse Generator

REVDD01 Relia VDD

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	96.0%	77.8%	55.8%
Effective Sample Size	905	811	693	570	456	352	188	108

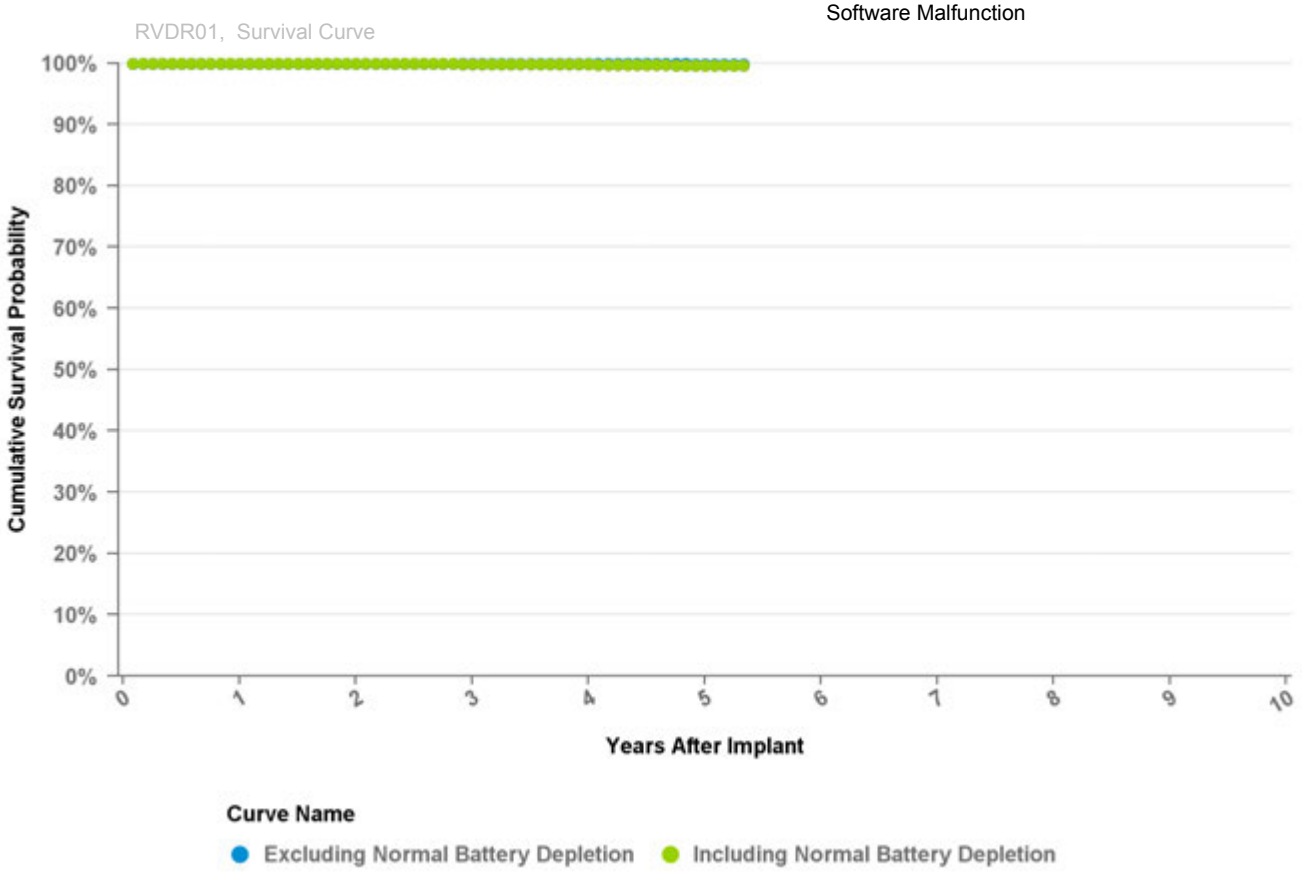
Implantable Pulse Generator

RVDR01 Revo MRI SureScan

US Market Release Date	2/8/2011
CE Market Approval Date	
Registered US Implants	67,354
Estimated Active US Implants	58,836
Normal Battery Depletions (US)	24

NBG Code	DDDRP

Total Malfunctions (US)	40
Therapy Not Compromised Malfunctions	37
Battery Malfunction	1
Electrical Component	26
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	7
Software Malfunction	3
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



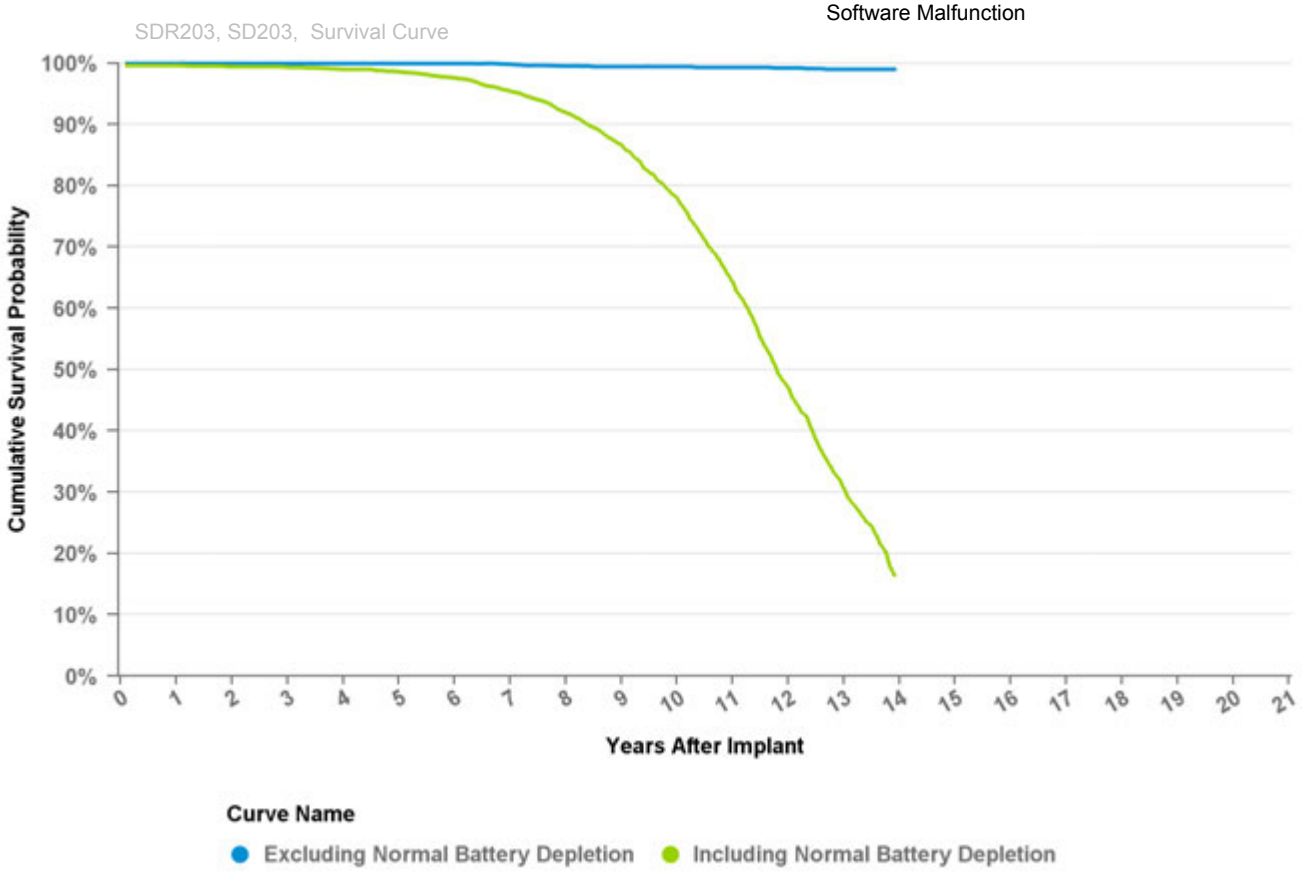
Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	59522	55815	50342	30434	6942	557

Implantable Pulse Generator

SD203 Sigma 200 D

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	226
Estimated Active US Implants	16
Normal Battery Depletions (US)	19
NBG Code	DDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



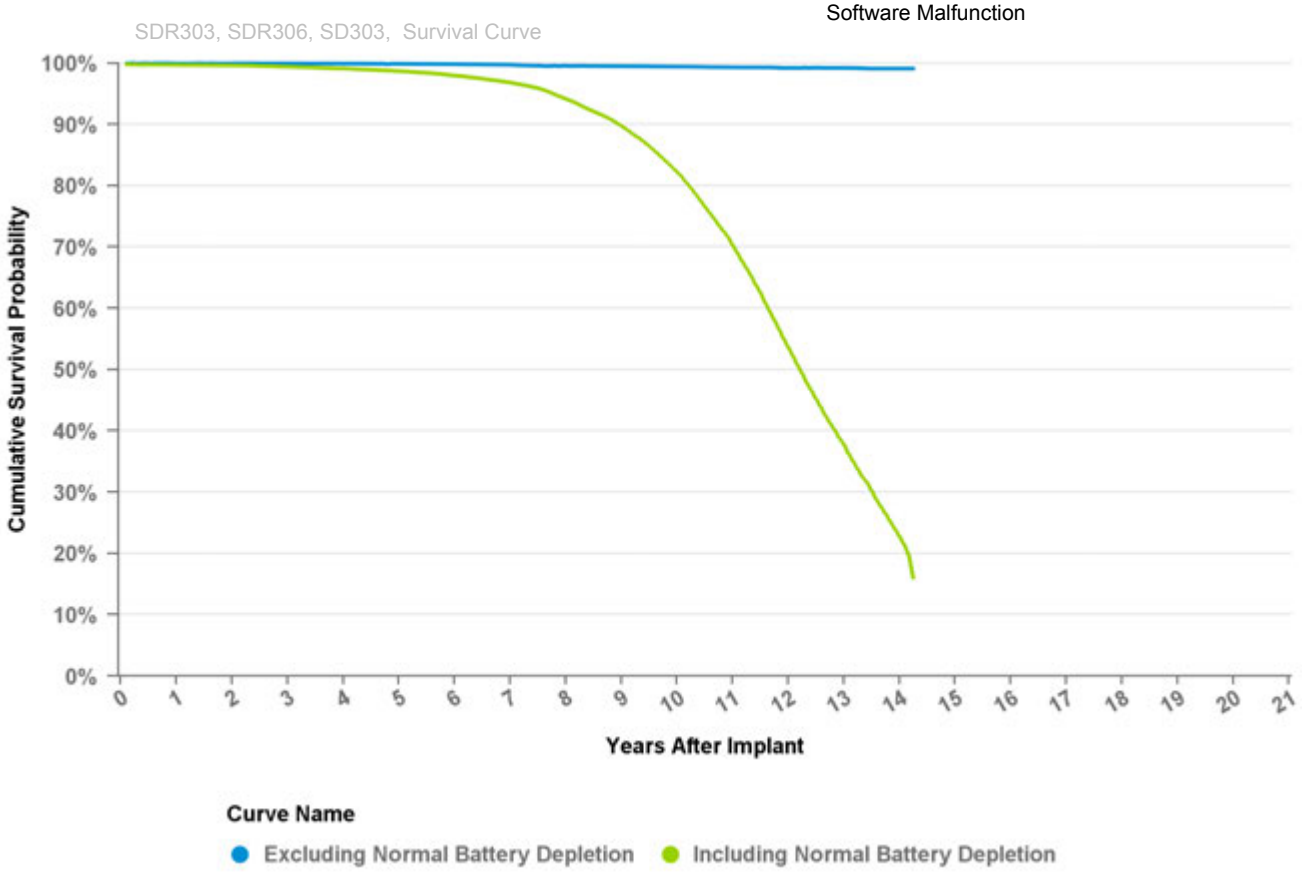
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 167 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.4%	99.4%	99.2%	99.1%	99.1%
Including NBD	99.6%	99.5%	99.4%	99.0%	98.6%	97.6%	95.4%	91.9%	86.7%	78.0%	64.4%	47.1%	30.7%	16.5%
Effective Sample Size	12992	11523	10116	8936	7803	6770	5737	4824	4012	3179	2266	1292	565	104

Implantable Pulse Generator

SD303 Sigma 300 D

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	123
Estimated Active US Implants	22
Normal Battery Depletions (US)	7
NBG Code	DDD

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



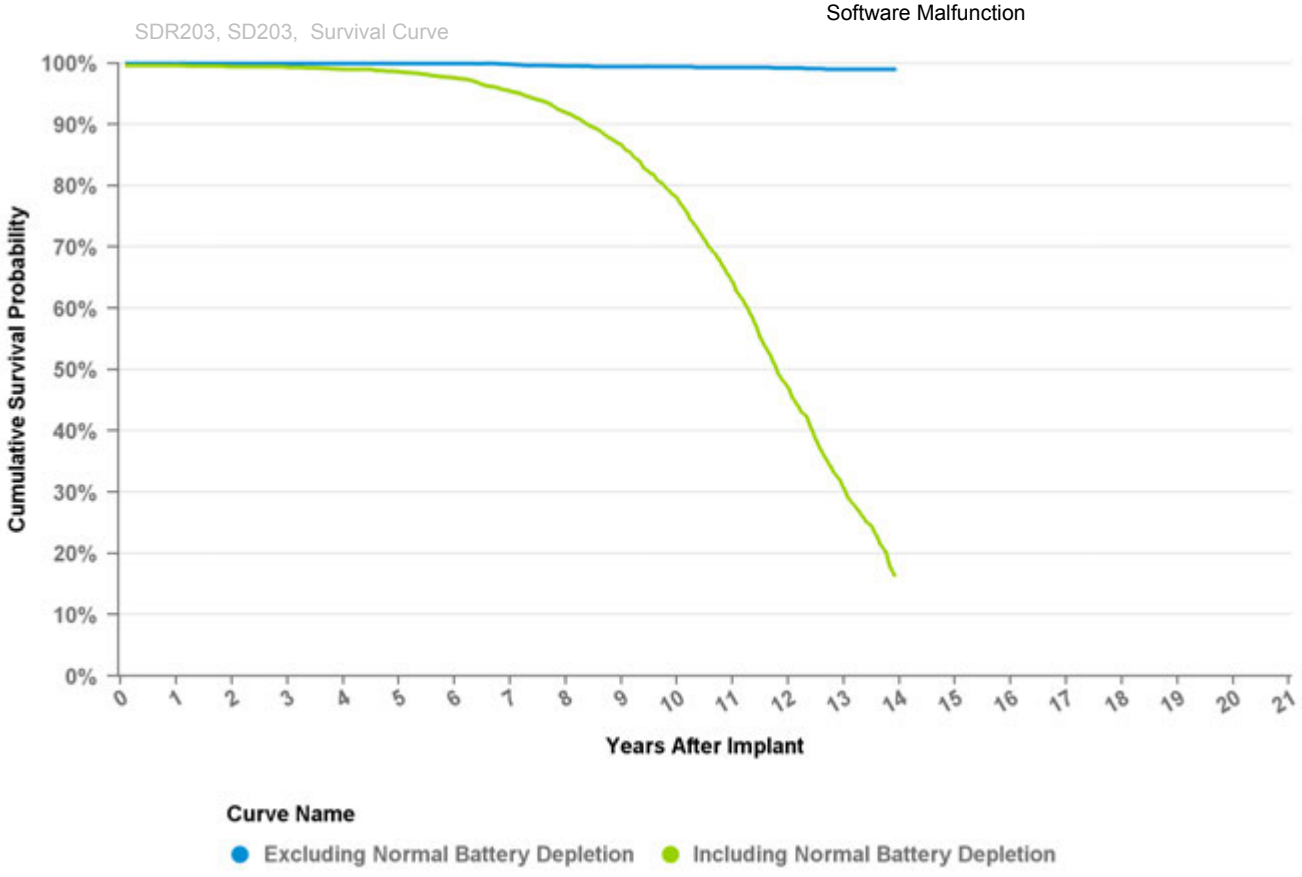
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 171 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.4%	99.1%	98.7%	98.0%	96.8%	94.2%	89.7%	82.2%	70.4%	53.7%	37.9%	22.8%	16.0%
Effective Sample Size	88288	78244	69192	60866	53383	46750	40551	35058	29679	23095	15666	8774	3720	663	188

Implantable Pulse Generator

SDR203 Sigma 200 DR

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	15,631
Estimated Active US Implants	1,412
Normal Battery Depletions (US)	1,391
NBG Code	DDDR

Total Malfunctions (US)	41
Therapy Not Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	9
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	31
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	28
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 167 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.4%	99.4%	99.2%	99.1%	99.1%
Including NBD	99.6%	99.5%	99.4%	99.0%	98.6%	97.6%	95.4%	91.9%	86.7%	78.0%	64.4%	47.1%	30.7%	16.5%
Effective Sample Size	12992	11523	10116	8936	7803	6770	5737	4824	4012	3179	2266	1292	565	104

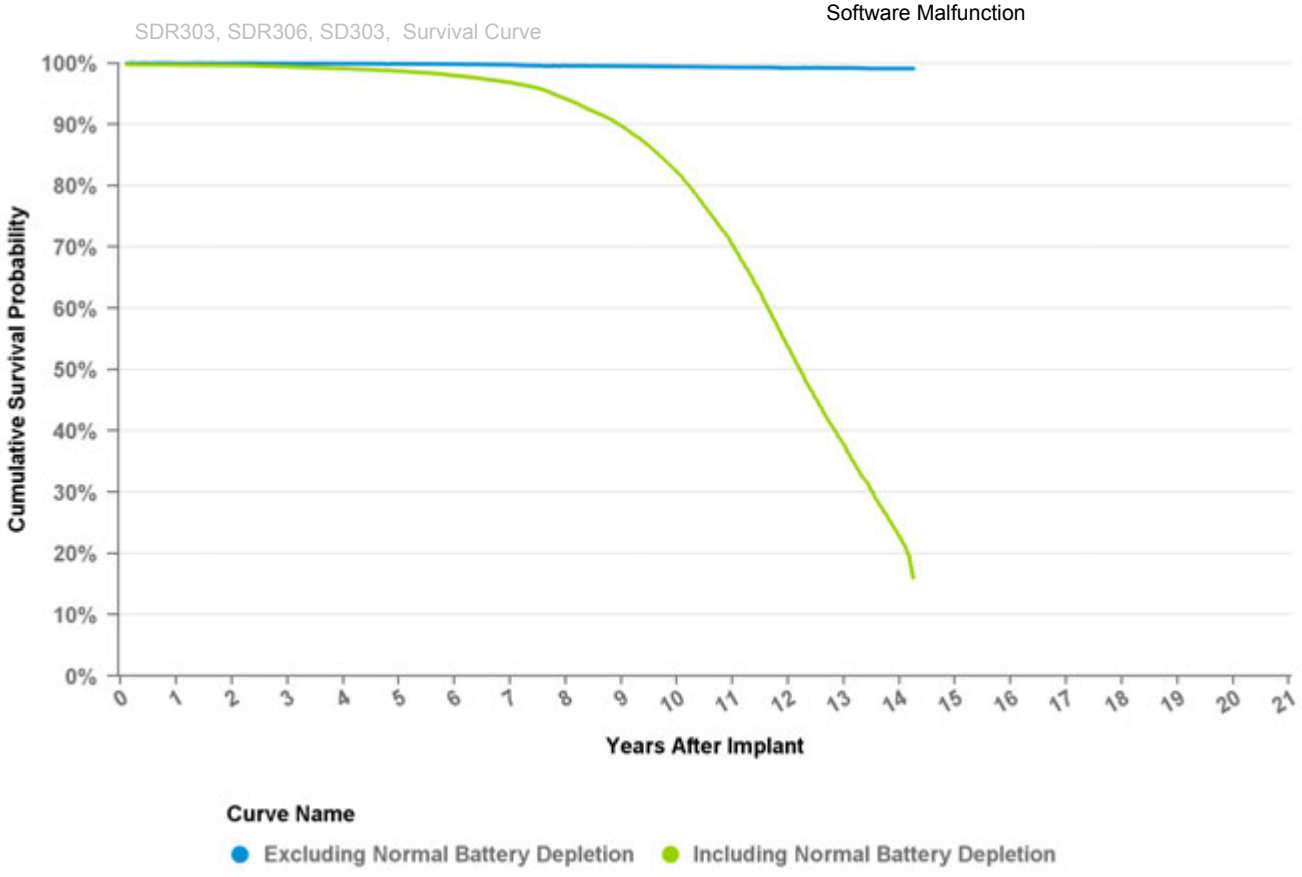
Implantable Pulse Generator

SDR303 Sigma 300 DR

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	105,508
Estimated Active US Implants	15,454
Normal Battery Depletions (US)	8,799

NBG Code	DDD/RO

Total Malfunctions (US)	283
Therapy Not Compromised Malfunctions	60
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	49
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	223
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	215
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



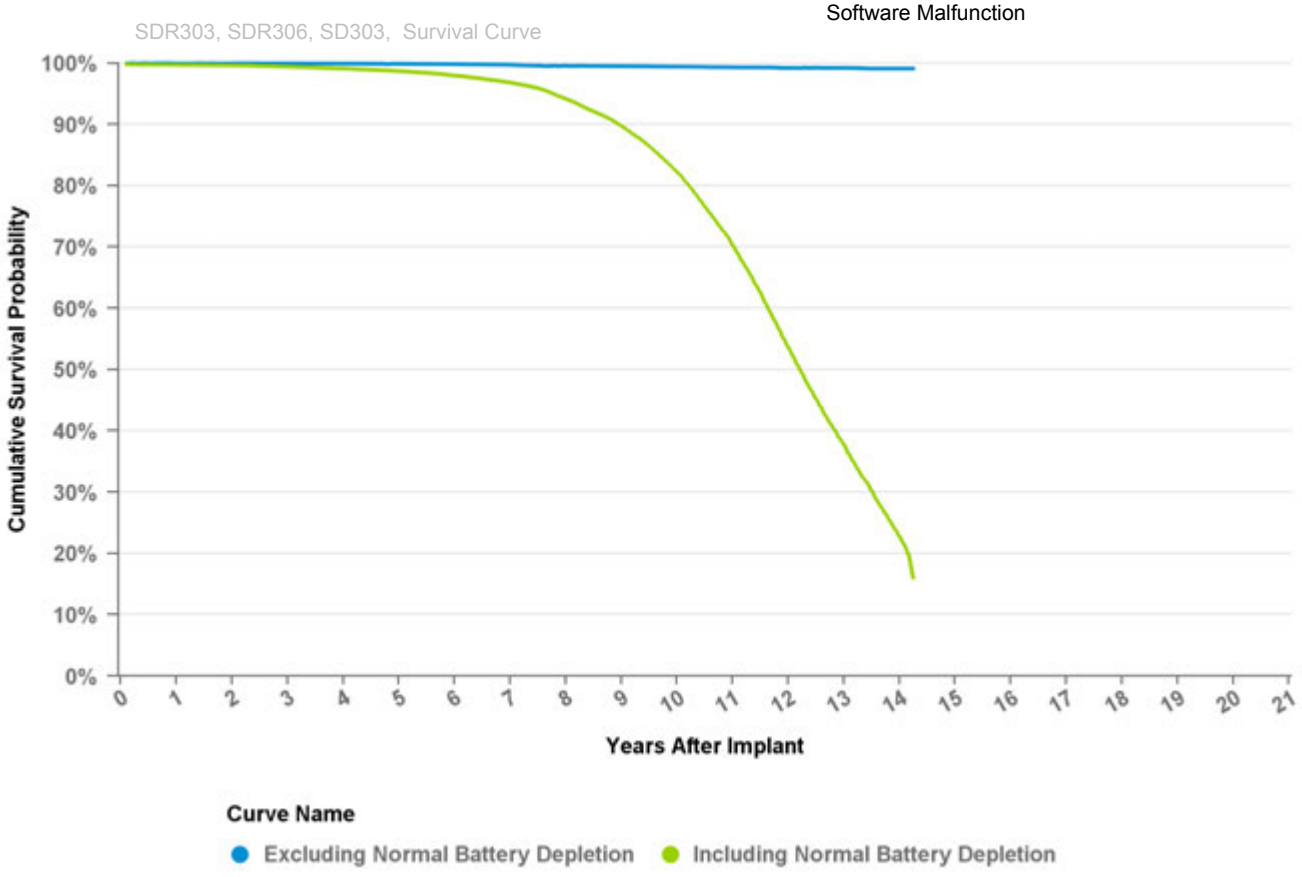
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 171 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.4%	99.1%	98.7%	98.0%	96.8%	94.2%	89.7%	82.2%	70.4%	53.7%	37.9%	22.8%	16.0%
Effective Sample Size	88288	78244	69192	60866	53383	46750	40551	35058	29679	23095	15666	8774	3720	663	188

Implantable Pulse Generator

SDR306 Sigma 300 DR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	1,209
Estimated Active US Implants	99
Normal Battery Depletions (US)	159
NBG Code	DDD/RO

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	5
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



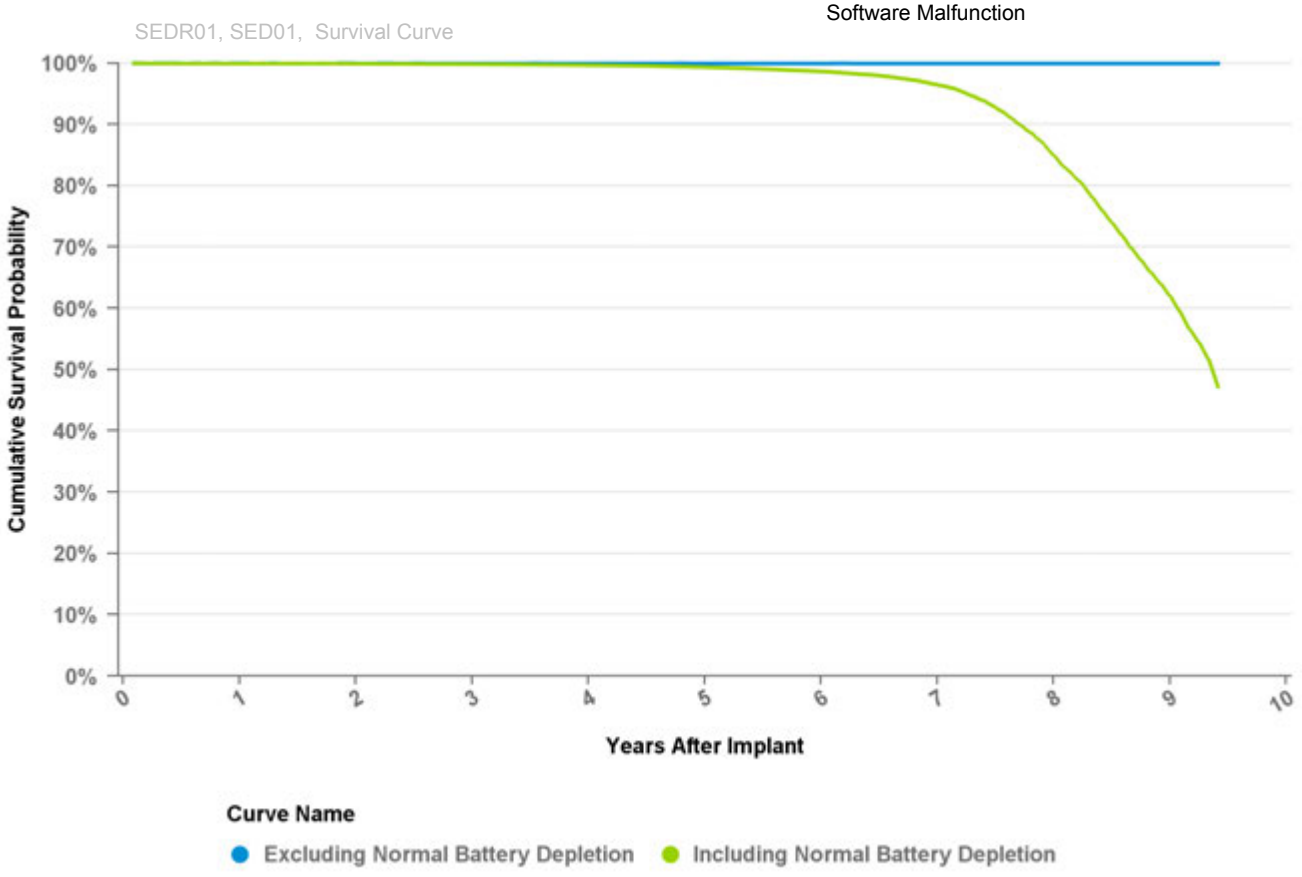
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 171 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.4%	99.1%	98.7%	98.0%	96.8%	94.2%	89.7%	82.2%	70.4%	53.7%	37.9%	22.8%	16.0%
Effective Sample Size	88288	78244	69192	60866	53383	46750	40551	35058	29679	23095	15666	8774	3720	663	188

Implantable Pulse Generator

SED01 Sensia D

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	5
Estimated Active US Implants	4
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



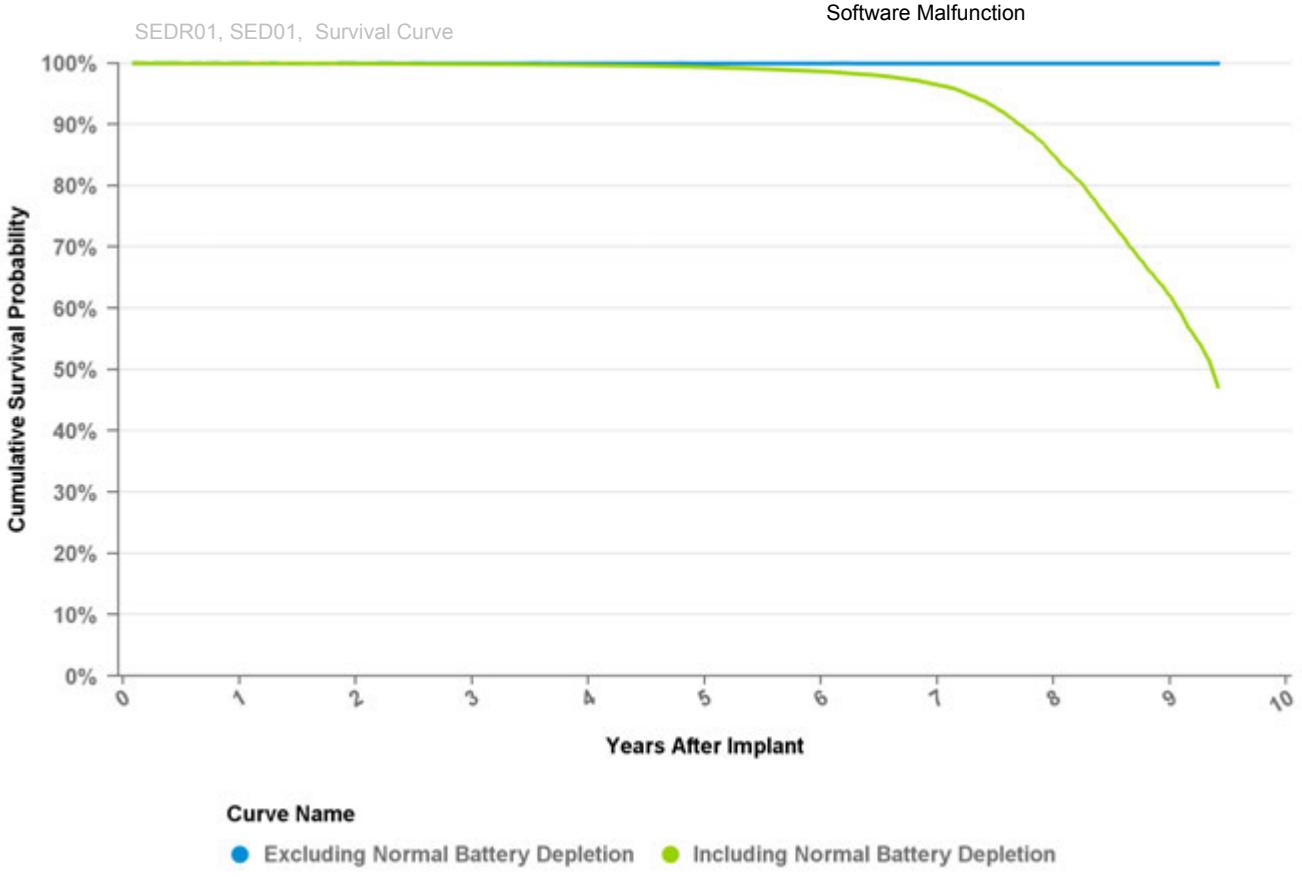
Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.6%	96.5%	85.0%	62.1%	47.1%
Effective Sample Size	122706	106587	89963	73718	57997	42733	28185	13149	2600	374

Implantable Pulse Generator

SEDR01 Sensia DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	148,819
Estimated Active US Implants	90,156
Normal Battery Depletions (US)	3,799
NBG Code	DDDR

Total Malfunctions (US)	29
Therapy Not Compromised Malfunctions	15
Battery Malfunction	0
Electrical Component	13
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	3
Other Malfunction	5
Poss Early Battery Depltn	0
Software Malfunction	0



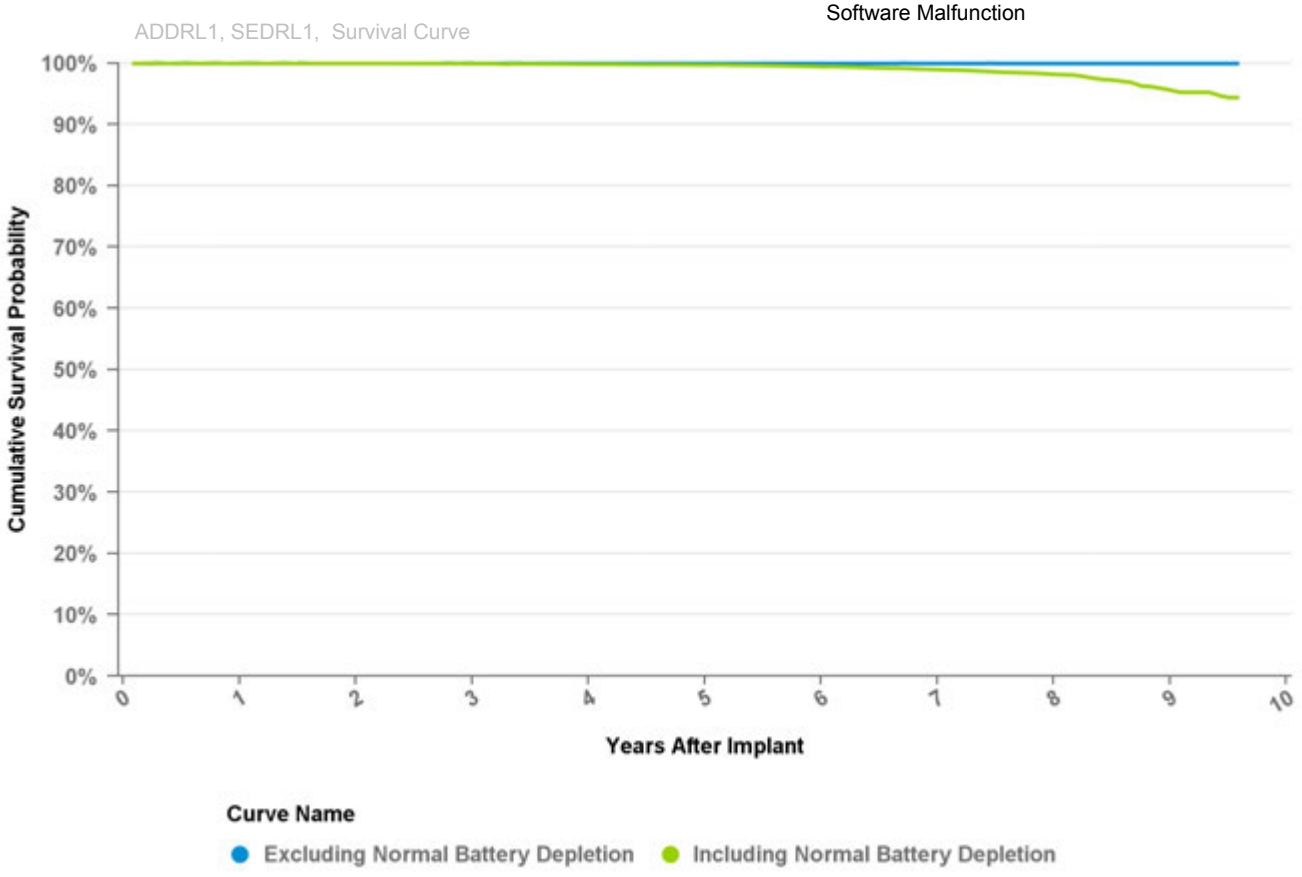
Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.6%	96.5%	85.0%	62.1%	47.1%
Effective Sample Size	122706	106587	89963	73718	57997	42733	28185	13149	2600	374

Implantable Pulse Generator

SEDRL1 Sensia DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0
NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



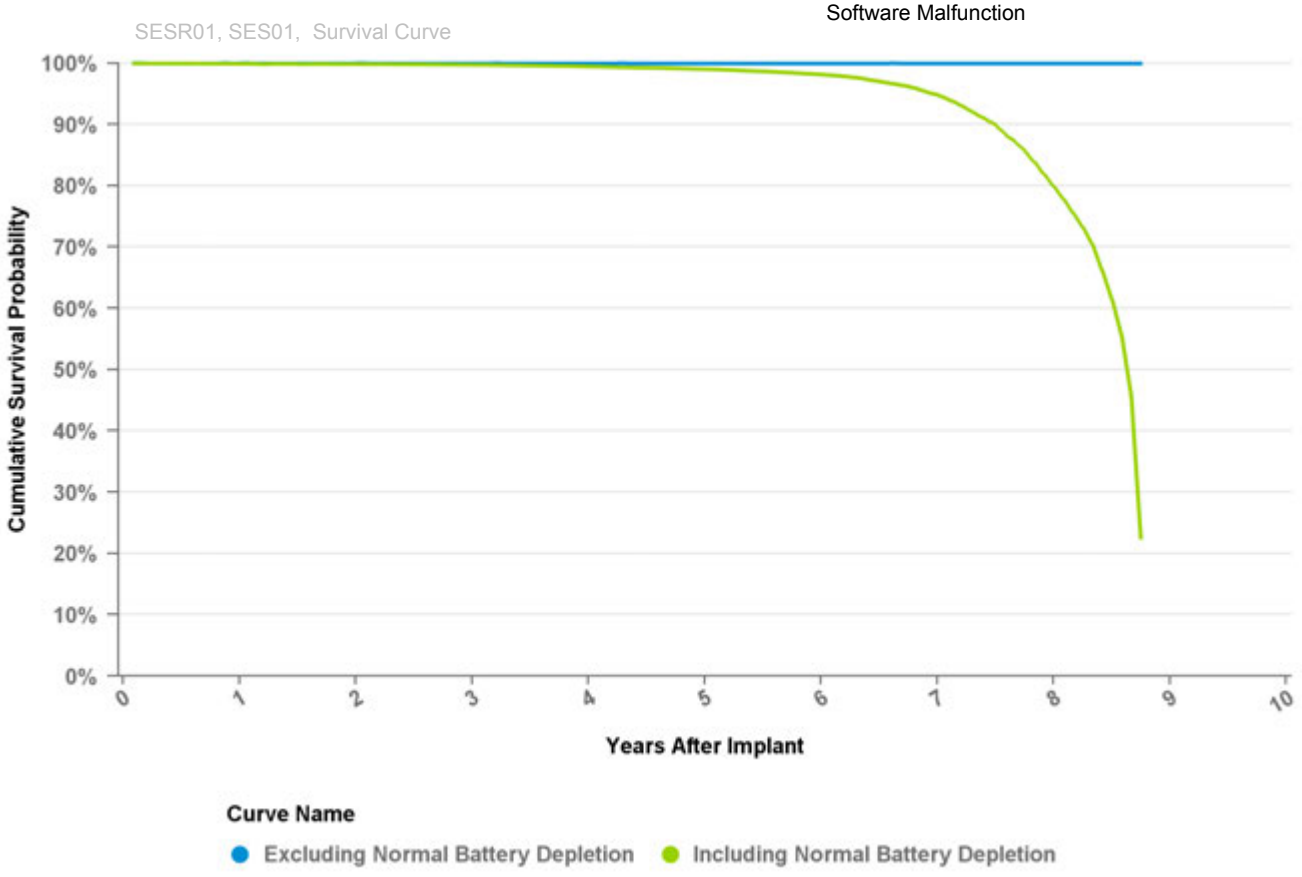
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.0%	98.2%	95.6%	94.4%
Effective Sample Size	106194	88997	69960	51570	35276	22064	11834	5158	1289	139

Implantable Pulse Generator

SES01 Sensia S

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	6
Estimated Active US Implants	1
Normal Battery Depletions (US)	0
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



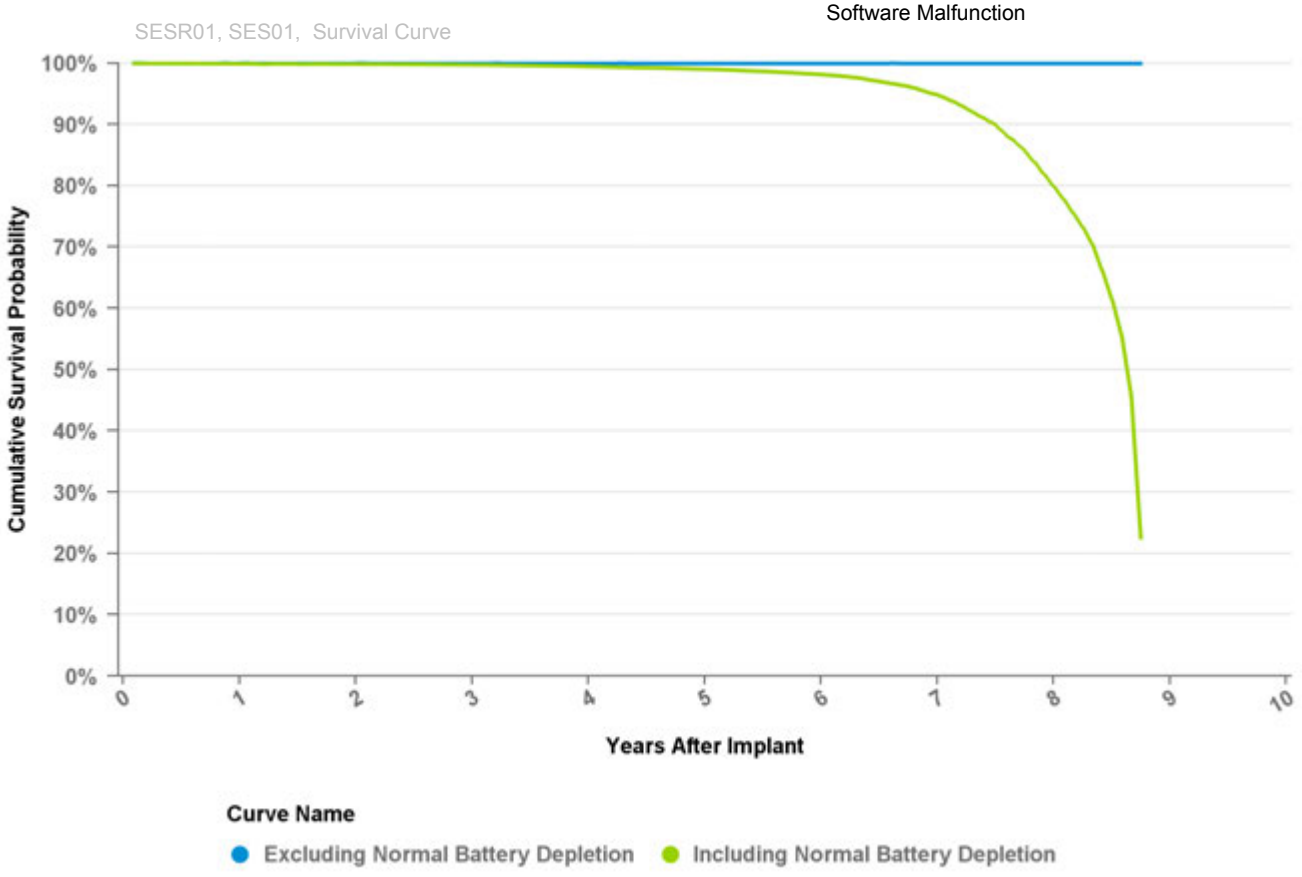
Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.0%	98.2%	94.8%	80.0%	22.5%
Effective Sample Size	84405	68624	54213	41190	29655	20080	11678	4073	133

Implantable Pulse Generator

SESR01 Sensia SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	112,372
Estimated Active US Implants	64,346
Normal Battery Depletions (US)	1,988
NBG Code	SSIR

Total Malfunctions (US)	11
Therapy Not Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



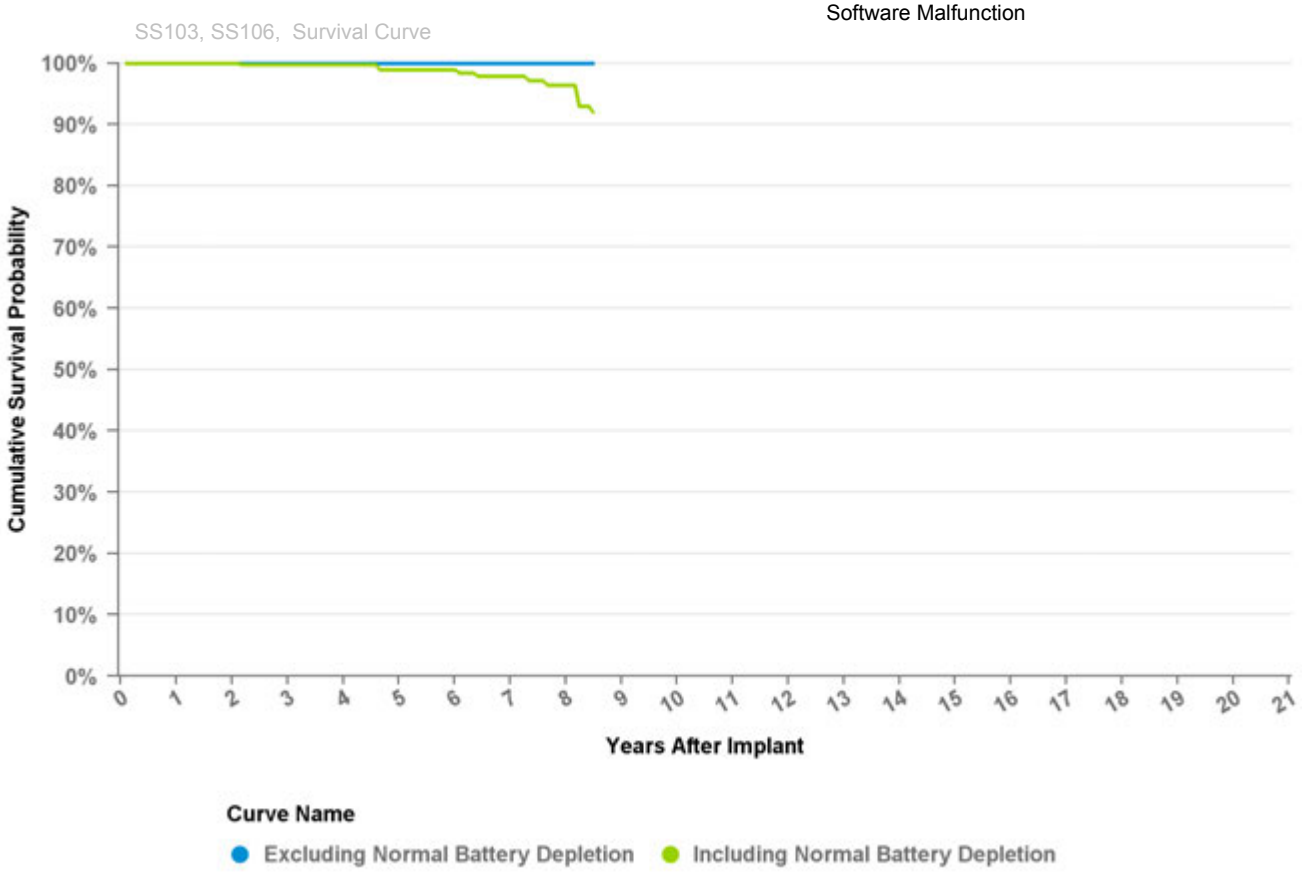
Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.0%	98.2%	94.8%	80.0%	22.5%
Effective Sample Size	84405	68624	54213	41190	29655	20080	11678	4073	133

Implantable Pulse Generator

SS103 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	773
Estimated Active US Implants	71
Normal Battery Depletions (US)	32
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



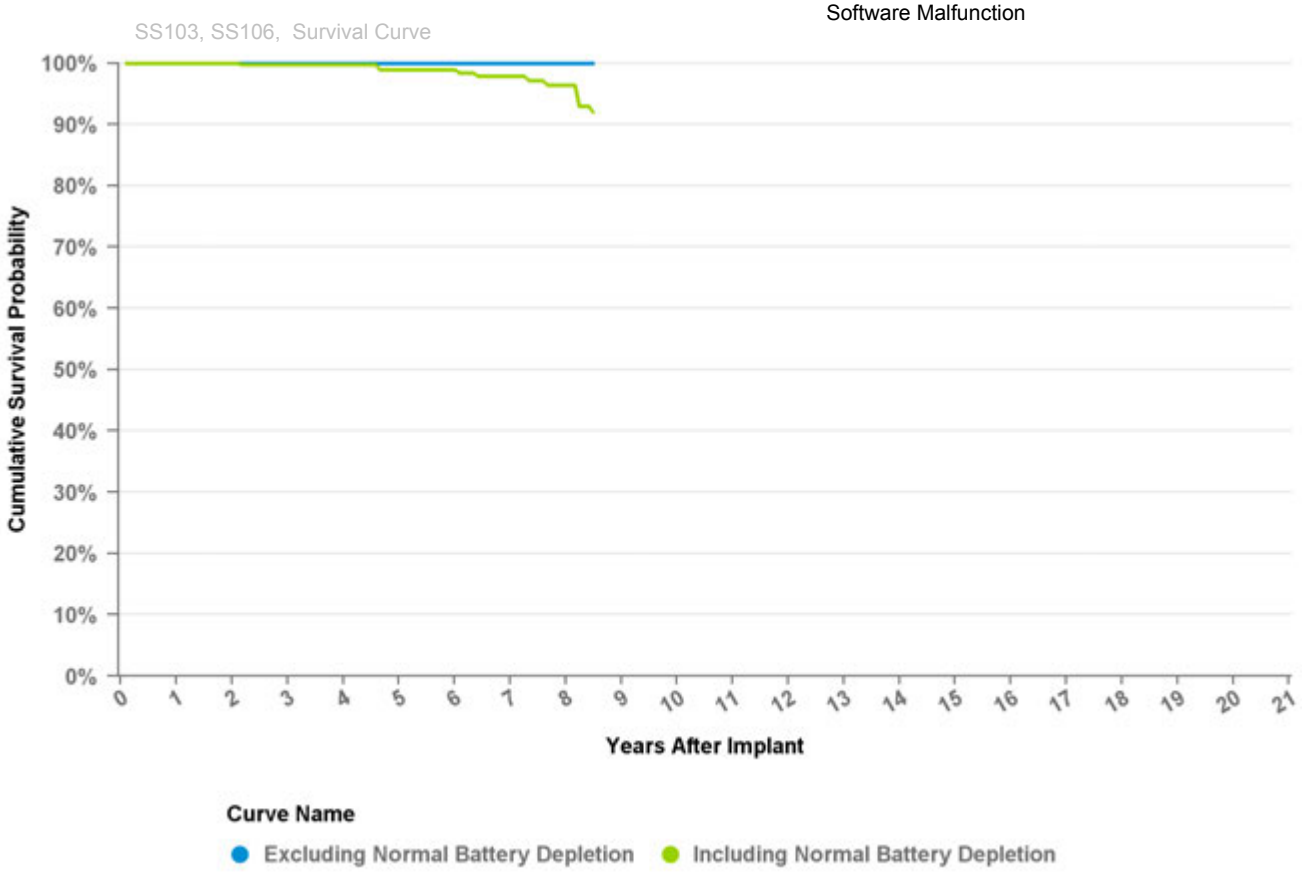
Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	92.0%
Effective Sample Size	599	472	370	293	224	188	153	121	102

Implantable Pulse Generator

SS106 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	68
Estimated Active US Implants	2
Normal Battery Depletions (US)	8
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



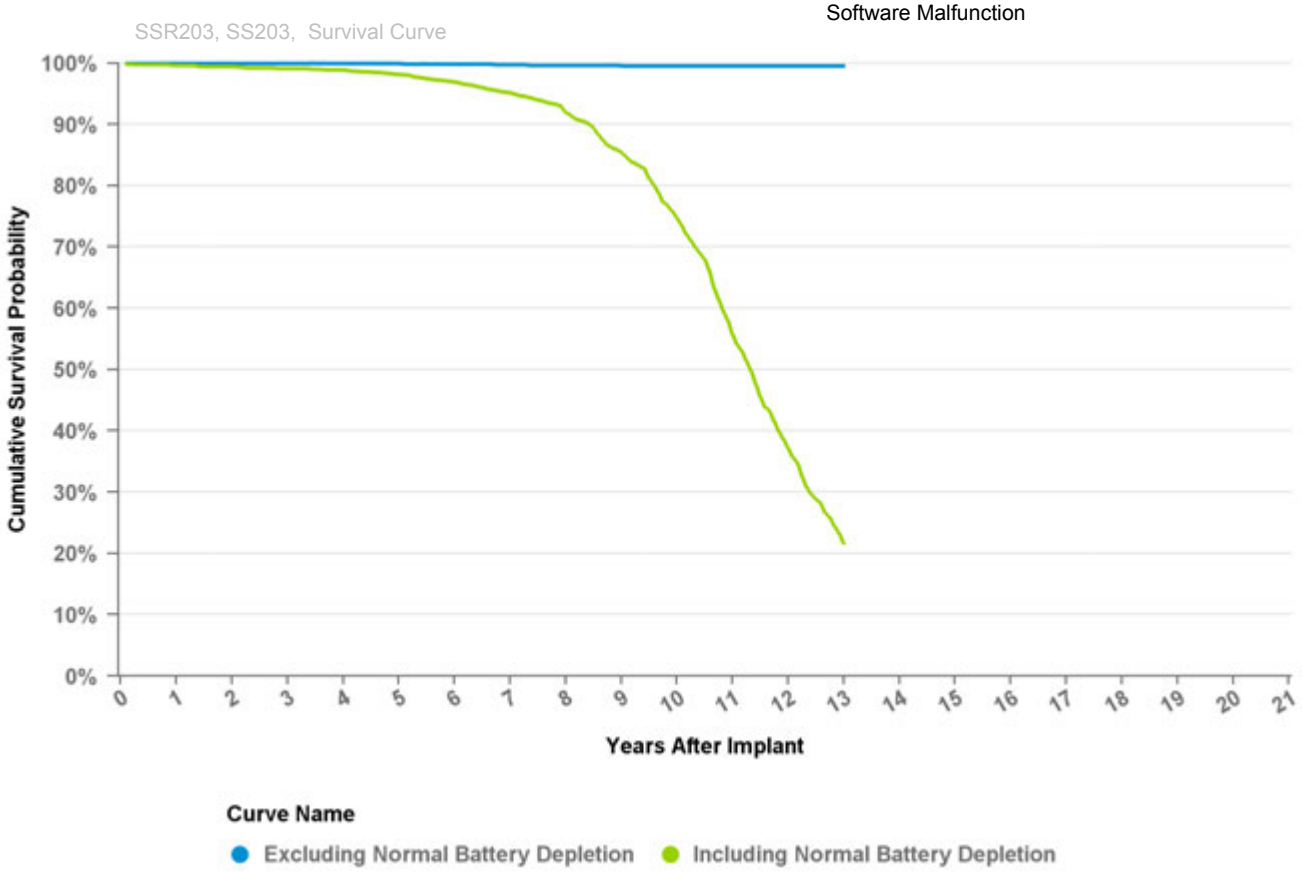
Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	92.0%
Effective Sample Size	599	472	370	293	224	188	153	121	102

Implantable Pulse Generator

SS203 Sigma 200 S

US Market Release Date	8/30/1999
CE Market Approval Date	
Registered US Implants	5
Estimated Active US Implants	0
Normal Battery Depletions (US)	1
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



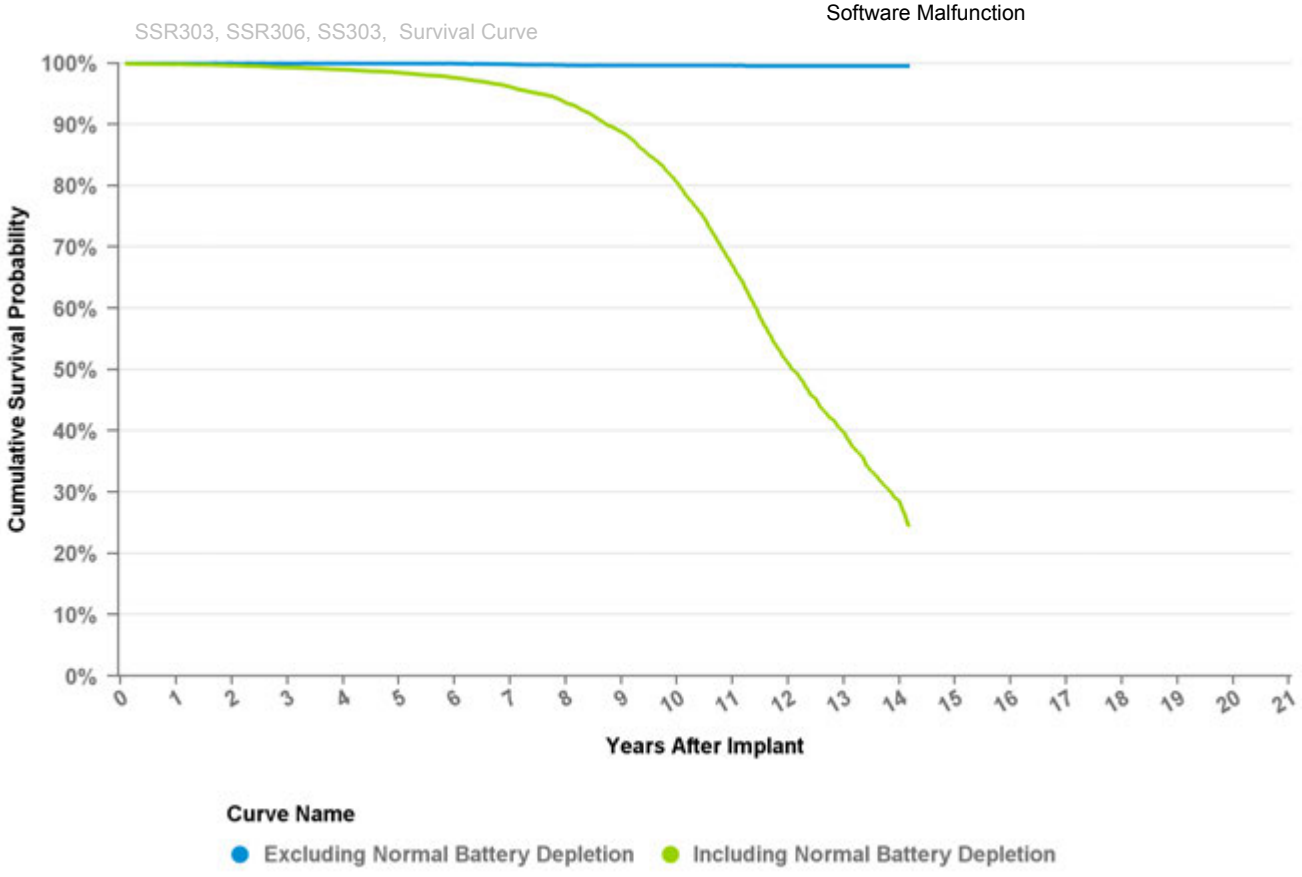
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.9%	98.2%	96.9%	95.2%	92.0%	85.4%	74.8%	55.7%	37.2%	21.7%
Effective Sample Size	9080	7460	6154	5108	4215	3486	2817	2326	1819	1339	829	380	113

Implantable Pulse Generator

SS303 Sigma 300 S

US Market Release Date	9/15/1999
CE Market Approval Date	12/17/1998
Registered US Implants	221
Estimated Active US Implants	38
Normal Battery Depletions (US)	0
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



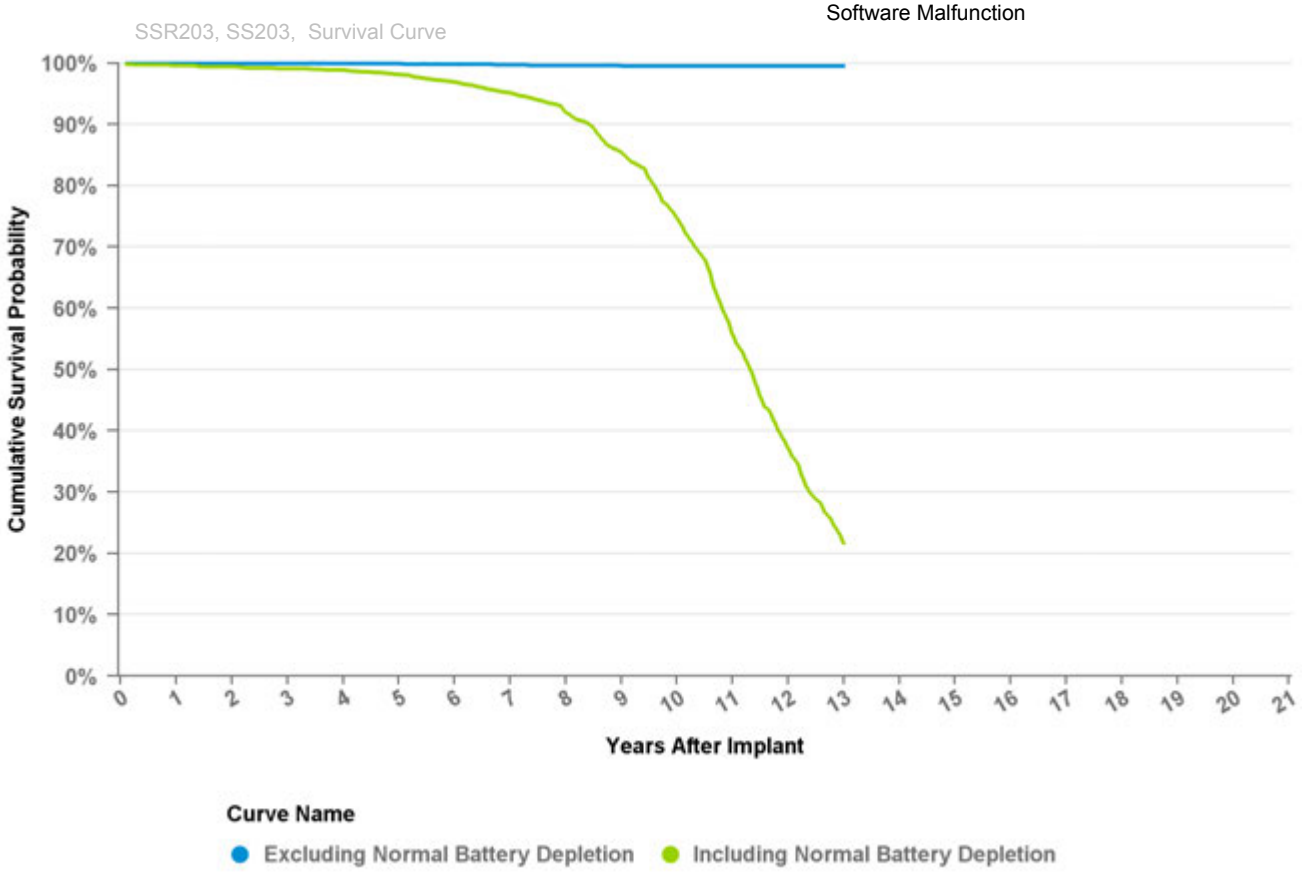
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.8%	80.6%	67.0%	51.1%	39.8%	28.4%	24.5%
Effective Sample Size	41022	33898	28080	23351	19463	16193	13464	11197	8990	6600	4258	2324	1062	205	114

Implantable Pulse Generator

SSR203 Sigma 200 SR

US Market Release Date	9/2/1999
CE Market Approval Date	
Registered US Implants	12,119
Estimated Active US Implants	877
Normal Battery Depletions (US)	649
NBG Code	SSIR

Total Malfunctions (US)	14
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	14
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.9%	98.2%	96.9%	95.2%	92.0%	85.4%	74.8%	55.7%	37.2%	21.7%
Effective Sample Size	9080	7460	6154	5108	4215	3486	2817	2326	1819	1339	829	380	113

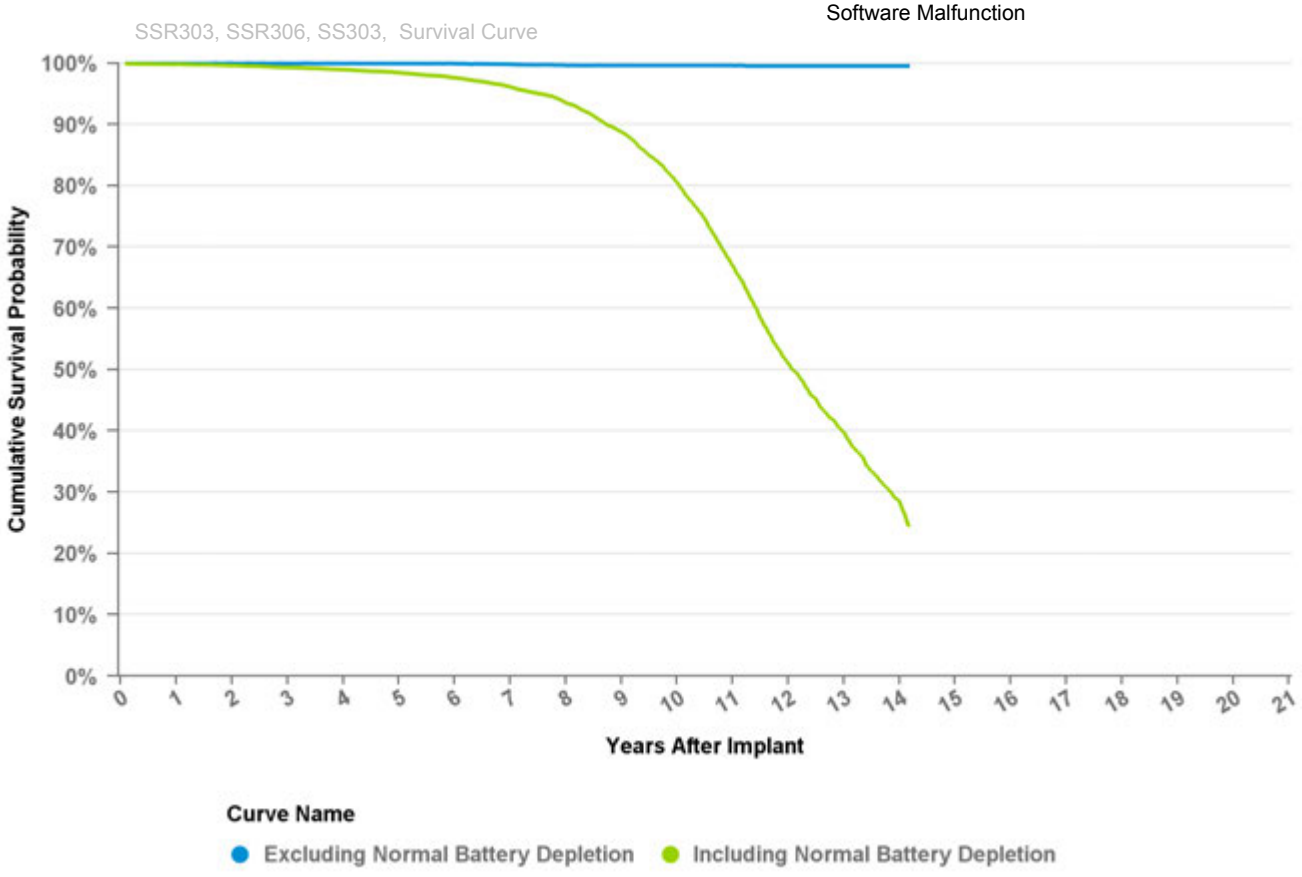
Implantable Pulse Generator

SSR303 Sigma 300 SR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	51,668
Estimated Active US Implants	5,363
Normal Battery Depletions (US)	2,537

NBG Code	SSIR

Total Malfunctions (US)	57
Therapy Not Compromised Malfunctions	11
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	9
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	46
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	43
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



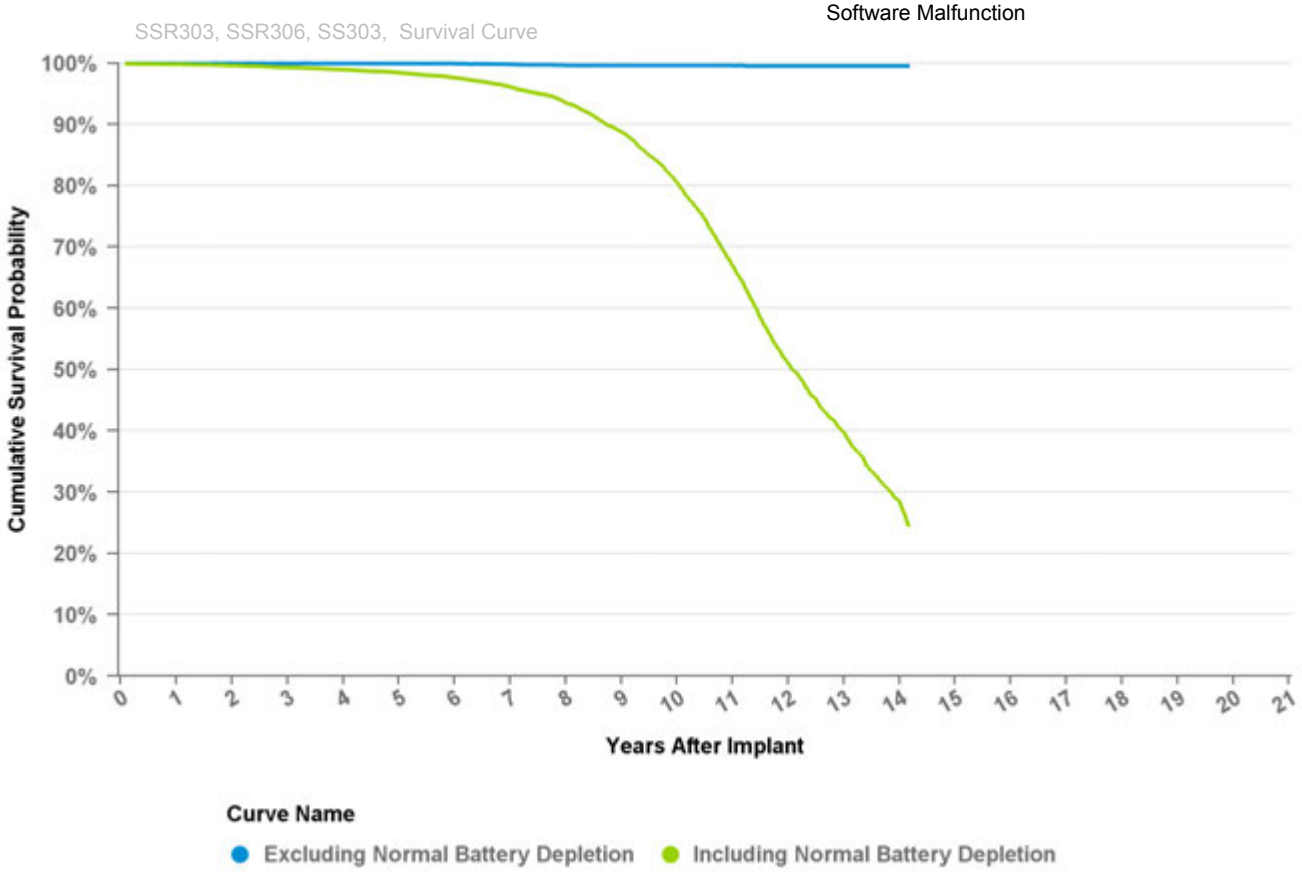
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.8%	80.6%	67.0%	51.1%	39.8%	28.4%	24.5%
Effective Sample Size	41022	33898	28080	23351	19463	16193	13464	11197	8990	6600	4258	2324	1062	205	114

Implantable Pulse Generator

SSR306 Sigma 300 SR

US Market Release Date	9/7/1999
CE Market Approval Date	12/17/1998
Registered US Implants	2,216
Estimated Active US Implants	181
Normal Battery Depletions (US)	150
NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



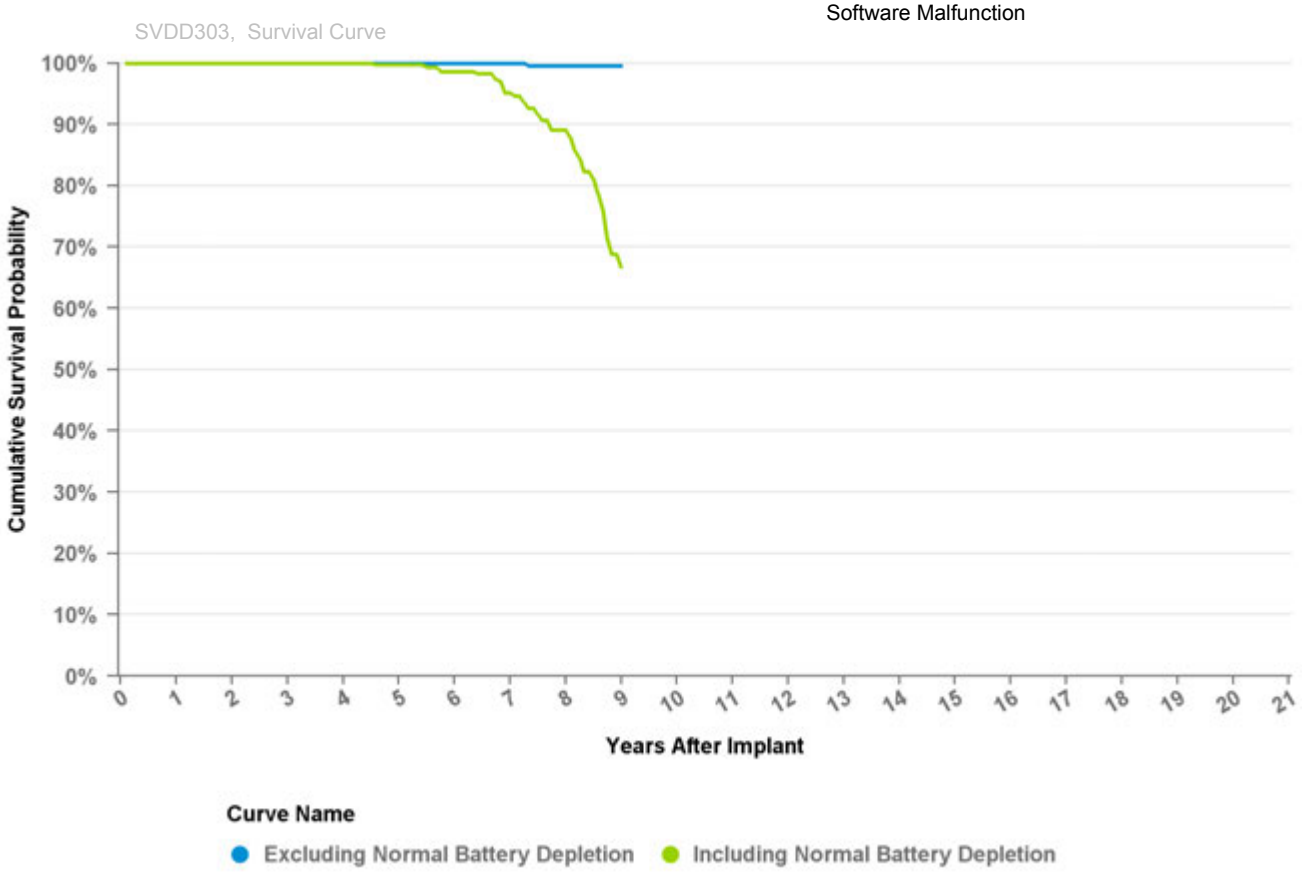
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.8%	80.6%	67.0%	51.1%	39.8%	28.4%	24.5%
Effective Sample Size	41022	33898	28080	23351	19463	16193	13464	11197	8990	6600	4258	2324	1062	205	114

Implantable Pulse Generator

SVDD303 Sigma 300 VDD

US Market Release Date	9/15/1999
CE Market Approval Date	12/17/1998
Registered US Implants	650
Estimated Active US Implants	44
Normal Battery Depletions (US)	81
NBG Code	VDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



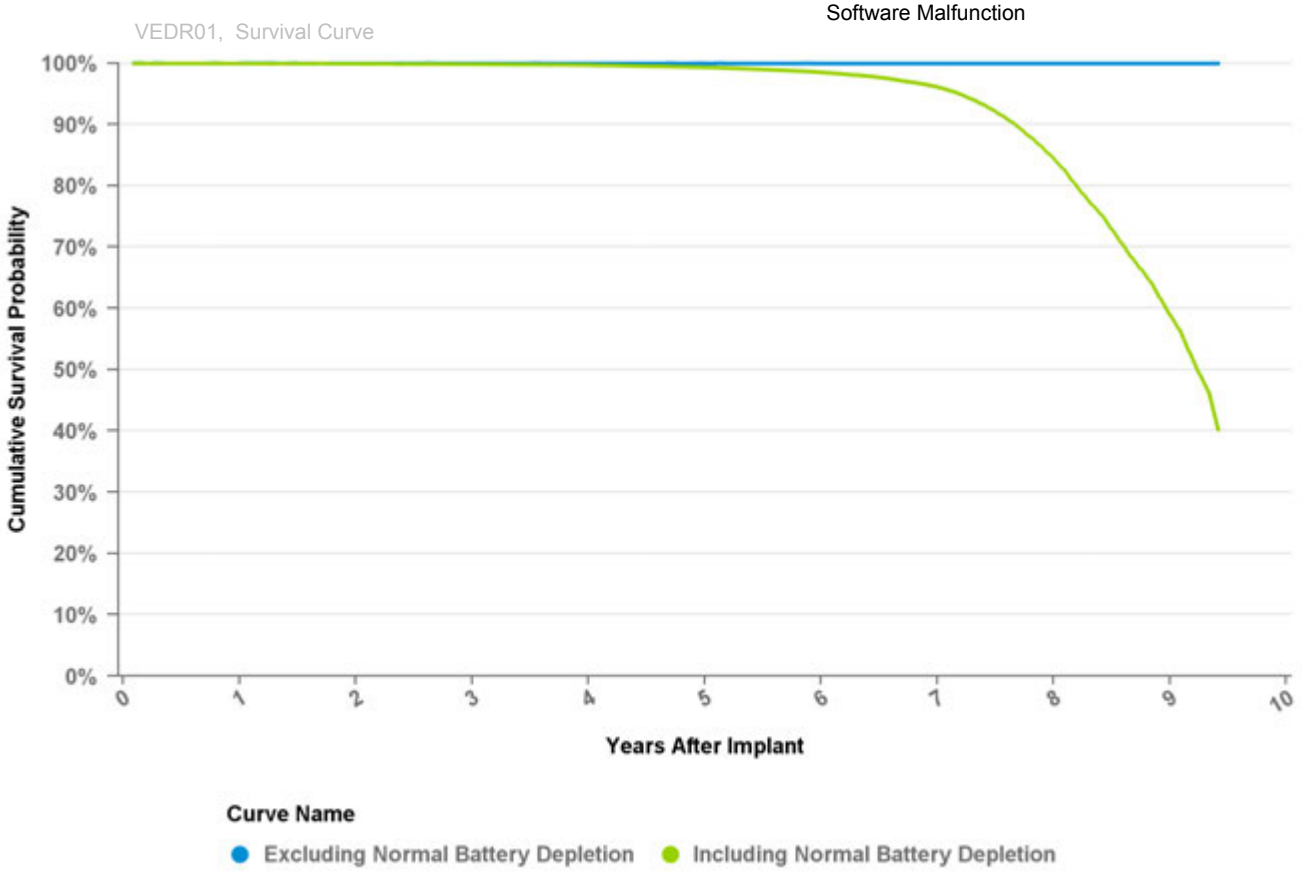
Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.5%	99.5%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.7%	98.6%	95.1%	89.1%	66.7%
Effective Sample Size	528	458	410	362	314	262	208	163	102

Implantable Pulse Generator

VEDR01 Versa DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	112,645
Estimated Active US Implants	68,262
Normal Battery Depletions (US)	4,004
NBG Code	DDDR

Total Malfunctions (US)	17
Therapy Not Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.3%	98.5%	96.1%	84.4%	59.0%	40.2%
Effective Sample Size	94878	84116	72728	61101	49102	37639	26006	13409	3110	425

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm and Heart Failure (CRHF) has tracked lead survival for over 32 years with its multicenter, global chronic lead studies.

Leads Performance Analysis

Implanted leads operate in the challenging biochemical environment of the human body and the body's response to foreign objects. Implanted leads are also subject to mechanical stresses associated with heart motion, body motion, and patient anatomy.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. While IPGs and ICDs have a battery that will deplete after a predictable length of time, a lead's longevity cannot be predicted easily based on mechanical measurements, nor are there simple indicators that a lead is approaching the end of its service life. Therefore, regular monitoring while implanted, and evaluation of lead integrity upon IPG or ICD replacement, is necessary to determine if a lead may be approaching the end of its service life.

Shortfalls Of Using Returned Product And Complaints To Estimate Lead Performance

Leads and lead segments returned to Medtronic are analyzed to determine whether or not they meet performance limits established by Medtronic. Although returned product analyses are valuable for gaining insight into lead failure mechanisms, this data cannot be used by itself for determining the survival probability of leads because only a small fraction of leads are explanted and returned for analysis. Some leads are modified due to adverse device effect, however may not be explanted. Additionally, those leads that are returned cannot be assumed to be statistically representative of the performance of the total population for a given lead model. Partial or total lead extraction can result in significant damage to a lead, making a definitive analysis of a suspected failure, and its cause, impossible.

To account for the under reporting inherent with lead survival analysis based solely on returned product, some manufacturers add reported complaints where adverse product performance is evident but the product itself has not been returned. The improvement to the accuracy of survival estimates depends on the degree to which all complaints are actually communicated to the manufacturer. Since not all complaints are communicated to the manufacturer, adding complaints to the survival analysis does not completely solve the under reporting problem.

Lead survival probabilities are more appropriately determined through a prospective clinical surveillance study that includes active follow up with the patients. Although Medtronic monitors returned product analysis and complaints, these are not used to determine lead survival estimates.

Medtronic consolidated all cardiac rhythm surveillance registries into the PAN Registry. The PAN Registry is a patient centric surveillance platform which follows patients implanted with Medtronic cardiac rhythm product(s). The Product Performance Report (PPR) tracks PAN Registry enrolled patients to monitor lead performance status in vivo. The PAN Registry is designed to record clinical observations representative of the total clinical experience. Lead survival estimates include both lead hardware failure and lead-related clinical events that are classified as product performance events, and do not differentiate a lead hardware failure from other clinical events such as Failure to capture, perforation, dislodgement, or concurrent pulse generator failure.

PAN Registry

Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study since 1983 and has evaluated the performance of more than 95,000 leads, with data reported from countries around the world. Throughout this time period, Medtronic has continually worked to adapt systems and processes to more effectively monitor product performance following market release. The following summarizes current registry requirements.

Method for Estimating Lead Performance continued

Medtronic's product surveillance registry is a world-wide study that has a prospective, non-randomized, observational design. A key purpose of the registry is to provide continuing evaluation and periodic reporting of the long-term reliability and performance of Medtronic market-released cardiac rhythm therapy products. Product-related adverse events, indicating the status of the product, are collected to measure product survival probabilities. The data gathered may also be used to support the design and development of new cardiac therapy products. The registry is designed to continue indefinitely, encompassing new products as they become commercially available.

To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria. Patients are enrolled upon implantation of a Medtronic Cardiac rhythm product. Every effort is made to ensure participants are representative of the range of clinical environments in which Medtronic cardiac rhythm products are used. Eligible products for enrollment include Medtronic market-released cardiac rhythm therapy products for which additional information to further characterize product performance following market release is desired. Number of enrollments is reviewed regularly to ensure adequate sample size is obtained for each individual product. Enrollment may be capped and follow-up discontinued when sufficient duration and precision is achieved to effectively characterize product survivability.

Enrolled patients are followed in accordance with the standard care practices of their care provider from their implant date until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum annual follow-up requirement. Product-related adverse events, system modifications and changes in patient status (e.g. death and withdrawal from the study) are required to be reported upon occurrence. This active surveillance model ensures a robust dataset for effectively monitoring product performance.

Patients are eligible for enrollment if:

- Patient is intended to be implanted or is within 30 days post-implant of a Medtronic market-released cardiac lead connected to a market-released CRT, ICD, or IPG device, and the lead is used for a pacing, sensing, or defibrillation application, or
- Patient participated in a qualifying investigational study of a Medtronic cardiac rhythm product that is now market-released; complete implant and follow-up data are available; and the data can be appropriately and legally released

Each site is require to inform Medtronic whenever a lead event has occurred, a lead is modified, or when a patient is no longer participating. Timely, accurate, and complete reporting and analysis of safety information for surveillance is crucial for the protection of patients, clinicians, and the sponsor Medtronic continually evaluates the quality and integrity of the data through a combination of on-site and centralized monitoring activities.

Lead Complications

Chronic lead performance is characterized by estimating lead related complication free survival probabilities. For analysis purposes, the complication criteria, which align with the AdvaMed 'Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads', are defined below. These criteria do not, however, enable a lead integrity or "hardware" failure to be conclusively differentiated from other clinical events such as an undetected lead dislodgement, perforation, or concurrent pulse generator failure manifested as a sensing or capture problem.

Method for Estimating Lead Performance continued

All reported lead-related adverse events are classified by the reporting investigator and are adjudicated by an independent event adjudication committee[1]. A lead-related event with at least one of the following classifications that is adjudicated by the committee as a complication and occurs more than 30 days after implant is considered a product performance event and will contribute to the survival analysis endpoint. Events with an onset date of 30 days or less after the implant are considered procedure related and therefore are not included as product performance events. Product performance events include, but are not limited to:

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Elevated pacing thresholds
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 - 2,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20 - 200 ohms)
- Lead Insulation breach
- Lead Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement
- Structural Lead Failure

Data Analysis Methods

The performance of leads is expressed in terms of lead survival estimates, where "survival" refers to the function of the lead, not the survival of the patient.. These survival estimates are intended to illustrate the probability that a lead will survive for a given number of years without a chronic lead-related complication.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases in the PAN Registry, active surveillance of a device starts after the device was implanted. The survival probability of such device is conditional on survival to the time when the device enters the Registry. This phenomenon is called Left-truncation[2]. PPR lead survival analysis is estimated using the Kaplan-Meier method, a statistical method to incorporate data from these retrospectively enrolled devices, left-truncated data, was applied. The statistical technique uses data from existing devices while appropriately adjusting the device survival curves for the time the device was not actively followed in the registry. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

On the following pages, each graph includes a survival curve for each lead model. The survival estimates is the probability that a lead is free of a product performance event at a given time point. For example, if a survival probability is 95% after 5 years of service, then the lead has a 5% chance of experiencing a lead-related complication in the first 5 years following implant.

The data in the tables is rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have one or more complications. This occurs because even with the complications, the data rounds to 100%.

The survival curves are statistical estimates. As sample size increases and performance experience accumulates, the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the number of leads entering an interval is less than 50 leads. When the number of leads entering an interval reaches 50, the next data point is added to the survival

Method for Estimating Lead Performance continued

curve. For those lead models that do not have sufficient sample size, a survival curve will not be presented.

Definition of Analysis Dataset

The survival estimates are derived from all device components successfully enrolled as of the data received cut-off date (e.g. date of data entry at a study site). The number of enrollments is listed for each lead model.

This sample is considered to be representative of the worldwide population, and therefore the survival estimates shown should be representative of the performance worldwide of these models.

Criteria for Model Inclusion

Performance information for a model or model family will be published when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Medtronic, at its discretion, may stop providing updated performance information on lead models that received original US market-release approval 20 or more years ago.

Returned Product Analysis Results

Although the returned product analysis data is not used to generate the survival estimates, the data provides valuable insight into the causes of lead malfunction.

For reporting returned product analysis results, Medtronic CRHF considers a lead as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service. To be considered a malfunction for returned product analysis reporting, the lead must have been returned to Medtronic and analyzed.

The results of the analysis is presented in four categories. The lead reporting categories are:

> **Conductor Fracture**: Conductor malfunction with complete or intermittent loss of continuity that could interrupt current flow (e.g., fractured conductors), including those associated with clavicle flex fatigue or crush damage.
>
> **Insulation Breach**: A malfunction of the insulation allowing inappropriate entry of body fluids or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, abrasions, and material degradation.
>
> **Crimps/Welds/Bonds**: Any malfunction in a conductor or lead body associated with a point of connection.
>
> **Other:** Malfunctions of specific lead mechanical attributes, such as sensors, connectors, seal rings, or malfunction modes not included in the three categories above.

A lead subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRHF and found, through analysis, to actually have performed outside the performance limits established by Medtronic.

For leads designed for either ventricular or atrial use, the numbers listed in the Returned Product Analysis tables include both.

The numbers of malfunctions listed in the Returned Product Analysis tables are the actual numbers confirmed in the returned product analysis. The numbers of complications listed in the complications tables are the actual numbers observed in the PSR centers around the world.

Method for Estimating Lead Performance continued

US Reports of Acute Lead Observations (Occurring within First Month of Service)

In the first weeks following lead implantation, physiologic responses and lead performance can vary until long-term lead stability is attained. Acute (defined as the first month after implant) lead performance may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. After a period of time, the implant and the lead performance stabilizes. It is for this reason that the Product Surveillance Registry results, which are intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

Information about the clinical experience in the first month of service is included in our reporting. The source for this information is Medtronic's complaint handling system database. The information is summarized in tables titled "US Reports of Acute Lead Observations."

Each Event Report received by Medtronic's complaint handling system is assigned one or more Reason for Report codes based on the information received. The Reason for Report codes have been grouped into Acute Lead Observation categories. The categories used for this product performance reporting are drawn from the "FDA Guidance for Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adapter 510(k) Submissions." The categories are:

1. Cardiac Perforation
2. Conductor Fracture
3. Lead Dislodgement
4. Failure to Capture
5. Oversensing
6. Failure to Sense
7. Insulation Breach
8. Impedance Abnormal
9. Extracardiac Stimulation
10. Unspecified

Although multiple observations are possible for any given lead, only one observation is reported per lead. The observation reported is the observation highest on the list. For example, if an Event Report includes observations for both Lead Dislodgement and Failure to Sense, Lead Dislodgement is reported.

The lead event reported to Medtronic may or may not have involved clinical action or product returned to Medtronic. The lead may have remained implanted and in service.

Estimated Number of Implanted and Active Leads in the United States

In addition to providing the number of leads enrolled in the PSR, we also provide the number of leads registered as implanted and the number remaining active in the United States based on the status recorded in the Medtronic Device and Registrant Tracking system.

Footnotes:

1: During the evolution of SLS, event adjudication was transitioned from a Medtronic technical review committee to an independent event adjudication committee in 2011. Data analyses include adjudication using both methods.

2: Klein, John P., Moeschberger, Melvin L. Survival Analysis Techniques for Censored and Truncated Data, New York: Springer-Verlag New York, Inc., 1997.

LEFT HEART PACING LEAD 2187

Distribution Data	
US Market Release	8/28/2001
CE Approval Date	
Registered US Implants	11,976
Estimated Active US	1,879

Product Characteristics	
Fixation Type	Distal Continous Curve
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Unipolar

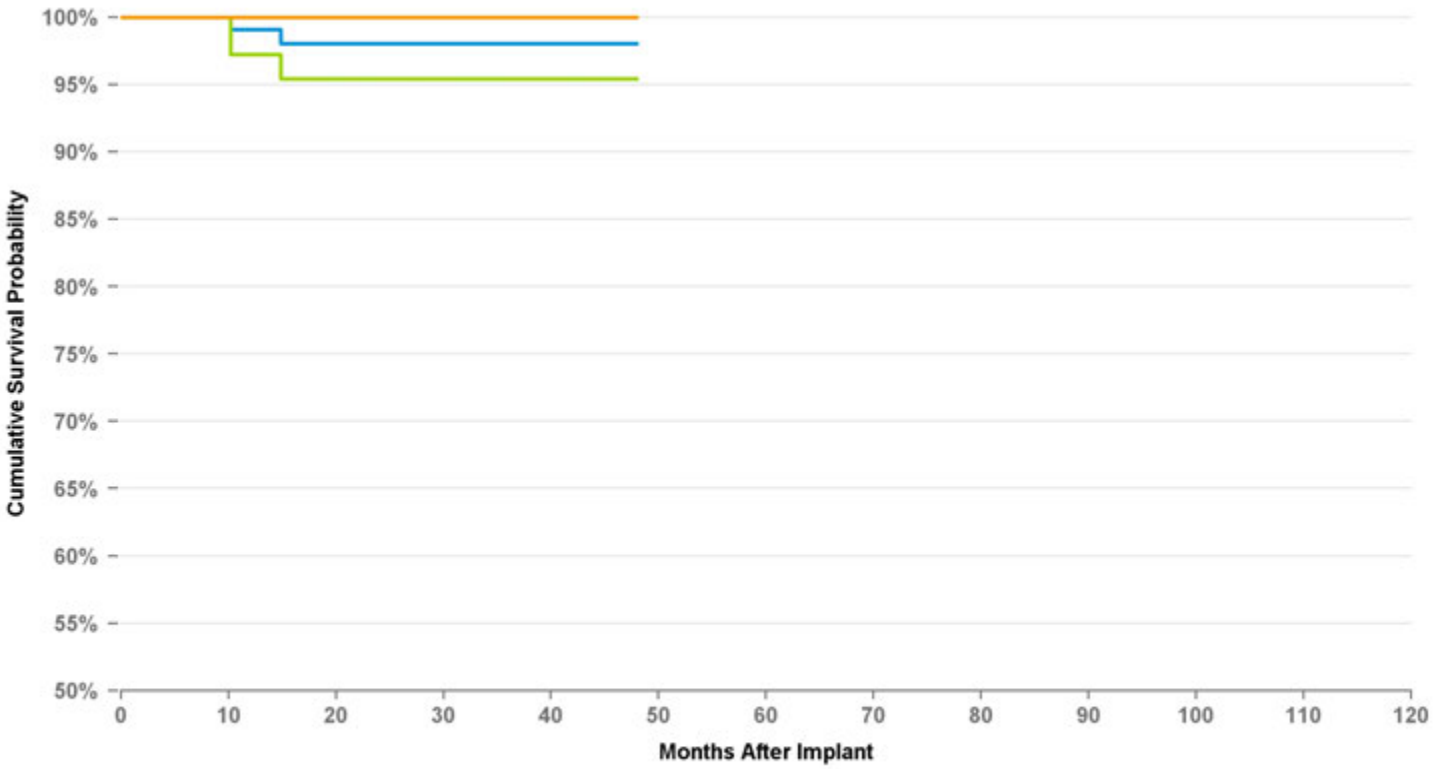
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	139
Cumulative Months of Follow-Up	6,676
Number of Leads Active in Study	8

Product Surveilance Registry Qualifying Complications	3
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	9
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	1
Other	4

2187, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 48 mo
%	99.1%	98.0%	98.0%	98.0%
#	105	89	66	52

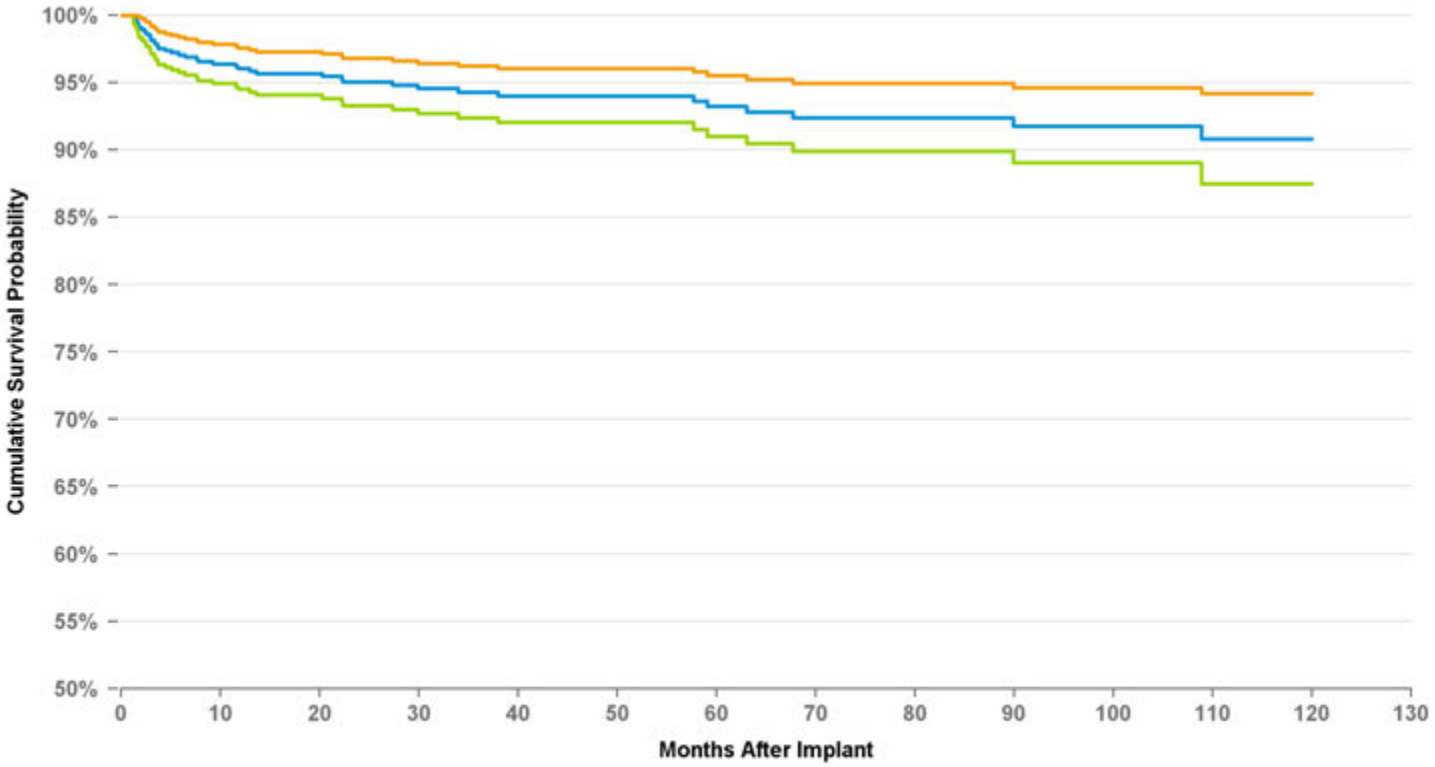
LEFT HEART PACING LEAD 4193

Distribution Data	
US Market Release	5/3/2002
CE Approval Date	12/22/2000
Registered US Implants	100,749
Estimated Active US	24,952
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Unipolar
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	764
Cumulative Months of Follow-Up	35,049
Number of Leads Active in Study	93

Product Surveillance Registry Qualifying Complications	41
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	14
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	13
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	3

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	18
Failure To Capture	11
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	45
Oversensing	1
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	67
Crimp Weld Bond	0
Insulation Breach	19
Other	48

4193, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.0%	95.0%	94.3%	94.0%	93.2%	92.4%	92.4%	91.8%	91.8%	90.8%
#	597	455	364	282	225	186	147	119	81	53

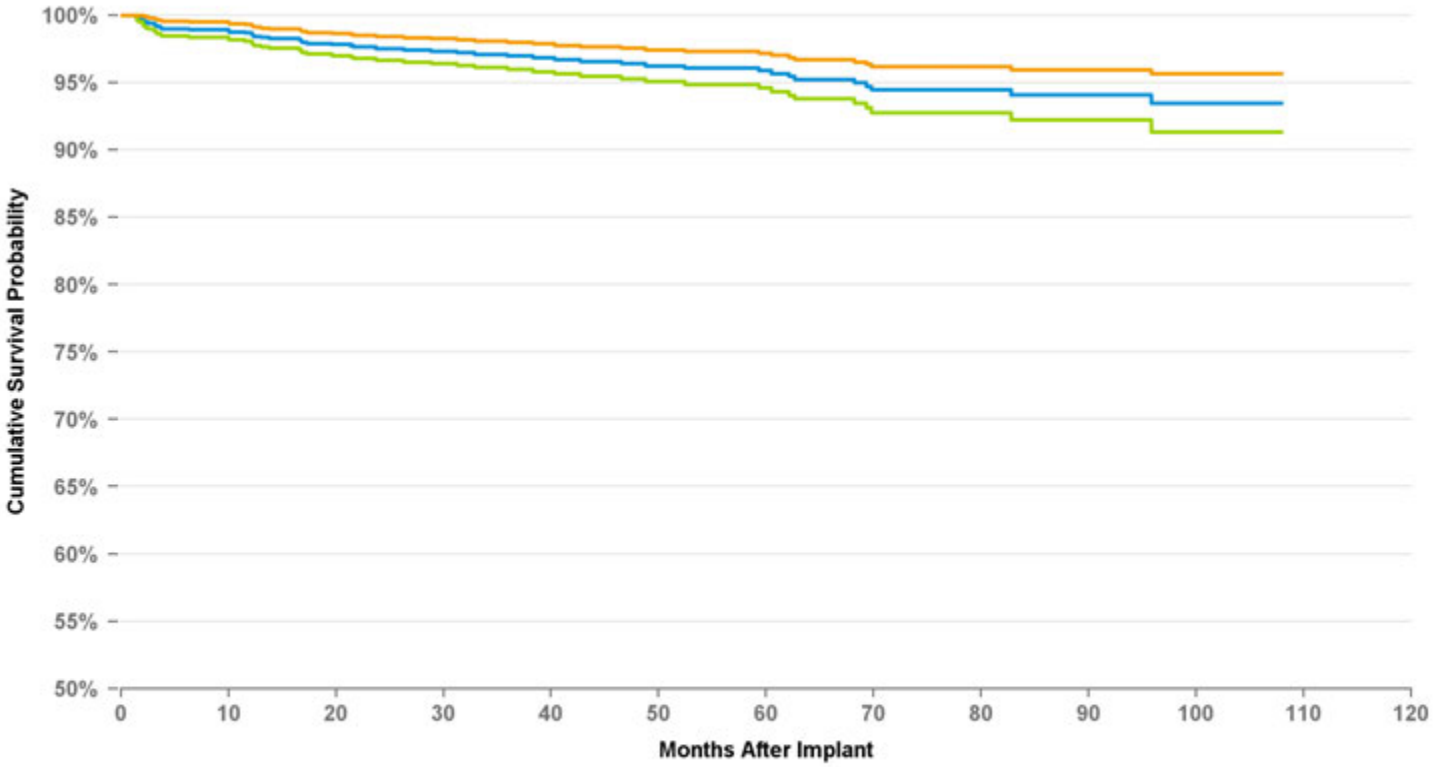
LEFT HEART PACING LEAD 4194

Distribution Data	
US Market Release	8/24/2004
CE Approval Date	7/14/2003
Registered US Implants	114,264
Estimated Active US	55,225
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,574
Cumulative Months of Follow-Up	66,770
Number of Leads Active in Study	603

Product Surveillance Registry Qualifying Complications	53
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	13
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	1
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	26
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	48
Failure To Capture	42
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	148
Oversensing	2
Unspecified	5
USA Returned Product Analysis	
Conductor Fracture	22
Crimp Weld Bond	0
Insulation Breach	92
Other	9

4194, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	98.7%	97.5%	97.0%	96.4%	95.9%	94.5%	94.1%	93.5%	93.5%
#	1,301	1,048	800	601	432	260	167	106	65

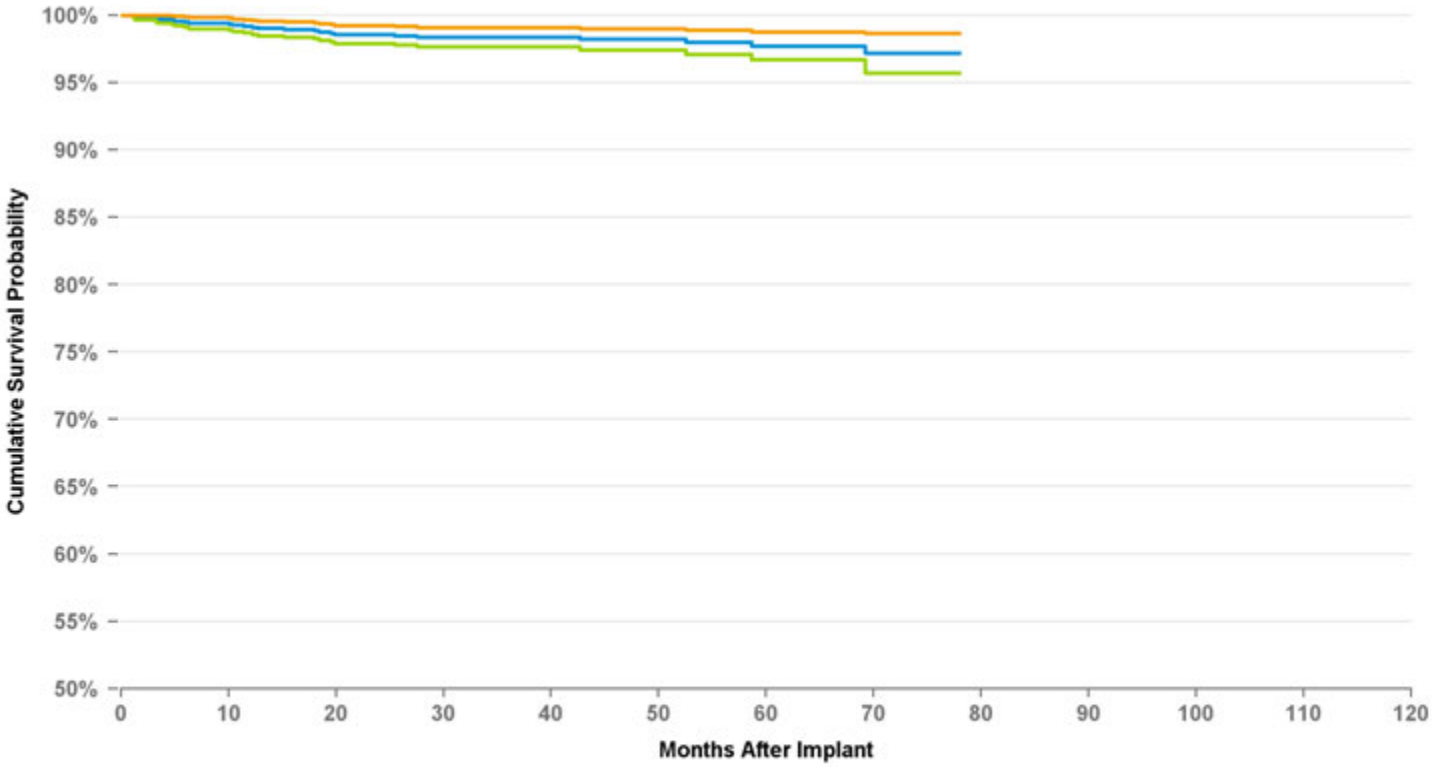
LEFT HEART PACING LEAD 4195

Distribution Data	
US Market Release	8/15/2008
CE Approval Date	5/13/2005
Registered US Implants	17,219
Estimated Active US	11,518
Product Characteristics	
Fixation Type	Deployable Lobe Fixation
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Unipolar
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,474
Cumulative Months of Follow-Up	57,619
Number of Leads Active in Study	605

Product Surveillance Registry Qualifying Complications	24
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	3
Lead Dislodgement	5
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	29
Failure To Capture	19
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	0
Lead Dislodgement	30
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	2
Other	4

4195, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 78 mo
%	99.2%	98.6%	98.4%	98.2%	97.7%	97.2%	97.2%
#	1,242	1,022	794	520	321	124	66

LEFT HEART PACING LEAD 4196

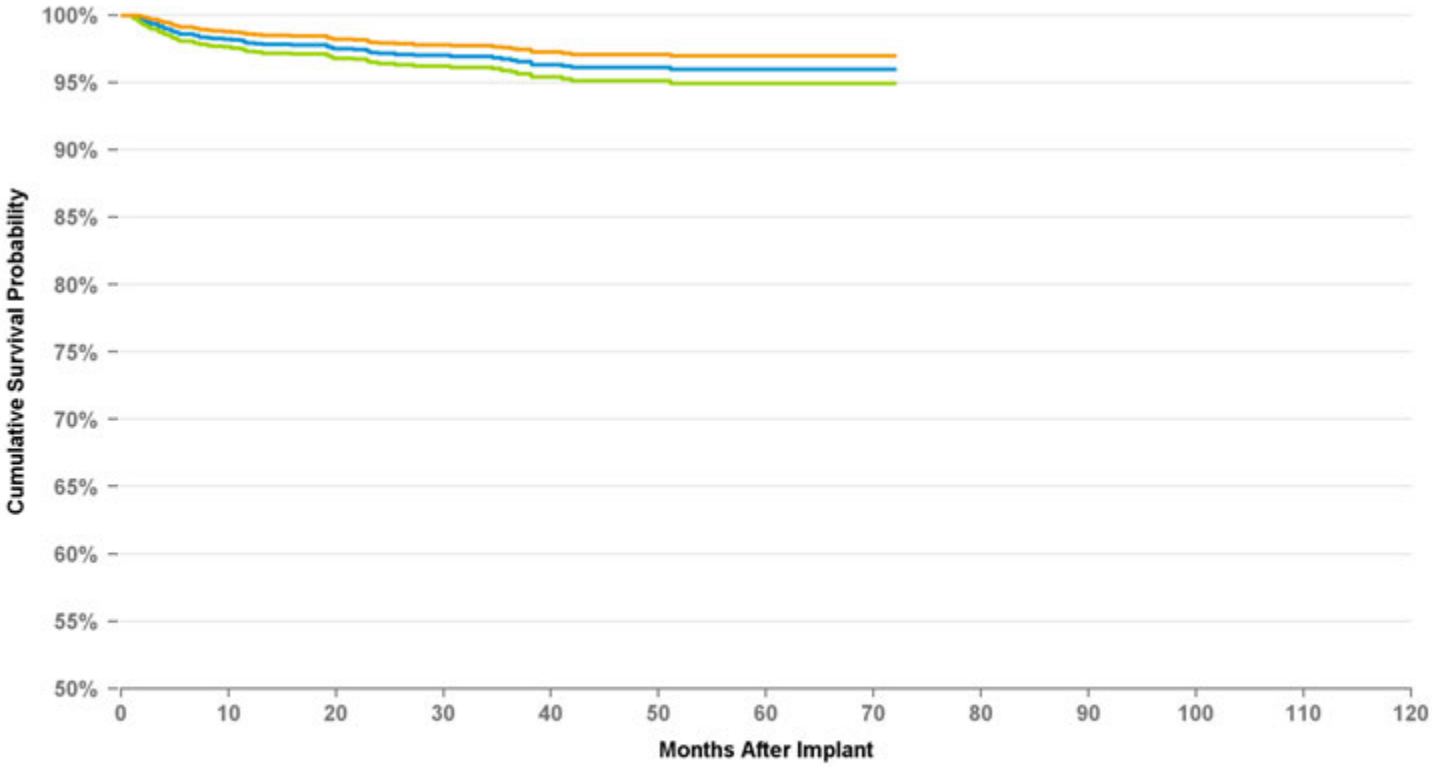
Distribution Data	
US Market Release	5/15/2009
CE Approval Date	7/24/2007
Registered US Implants	65,271
Estimated Active US	46,852
Product Characteristics	
Fixation Type	Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	2,181
Cumulative Months of Follow-Up	76,330
Number of Leads Active in Study	757

Product Surveillance Registry Qualifying Complications	64
Cardiac Perforation	0
Conductor Fracture	2
Electrical Abandonment	0
Extracardiac Stimulation	13
Failure To Capture	19
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	21
Medical Judgment	0
Other Complication	7
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	84
Failure To Capture	53
Failure To Sense	1
Impedance Abnormal	8
Insulation Breach	1
Lead Dislodgement	192
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	19
Crimp Weld Bond	0
Insulation Breach	0
Other	12

4196, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	at 72 mo
%	97.9%	97.2%	96.7%	96.1%	96.0%	96.0%
#	1,777	1,347	991	705	399	81

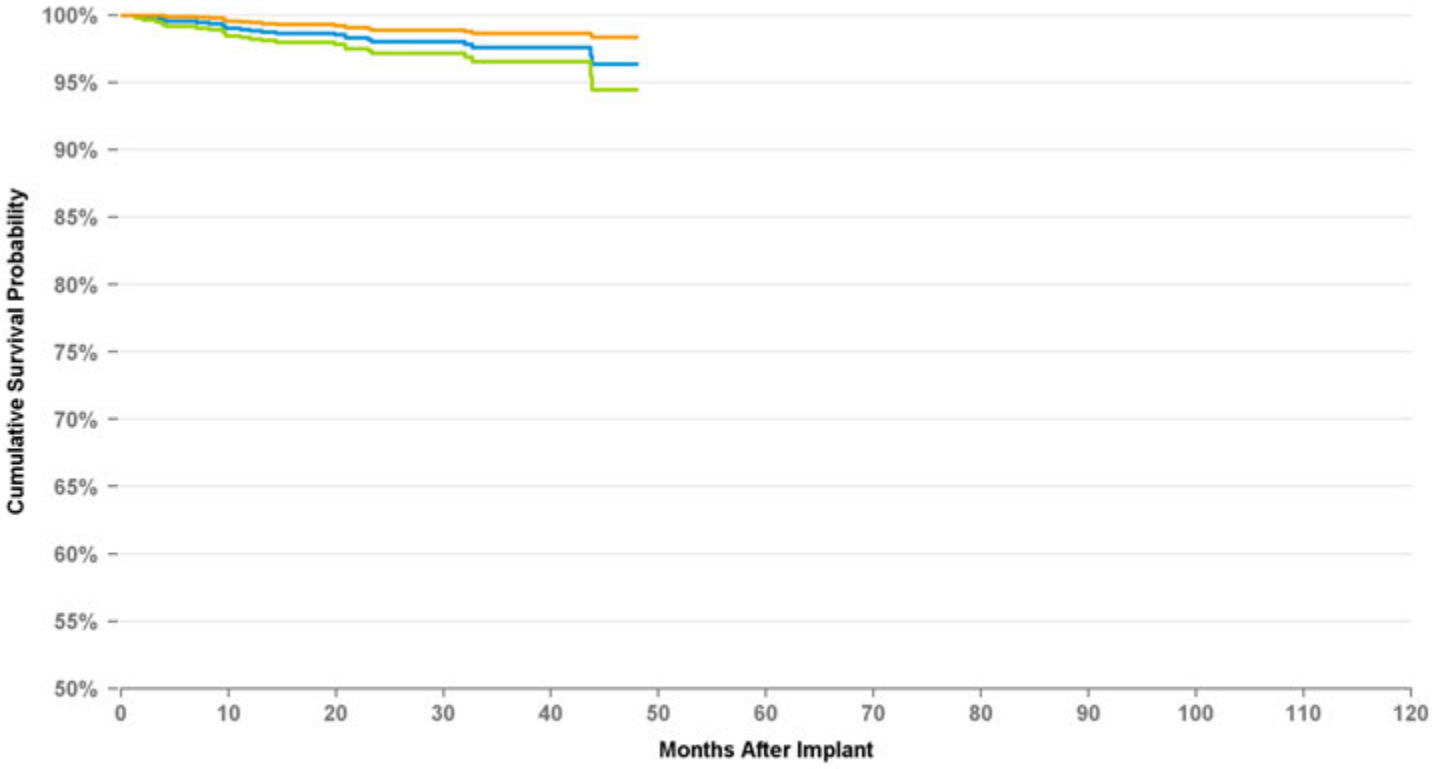
LEFT HEART PACING LEAD 4296

Distribution Data	
US Market Release	4/1/2011
CE Approval Date	12/18/2009
Registered US Implants	31,867
Estimated Active US	27,077
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Dual Electrodes
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,410
Cumulative Months of Follow-Up	34,500
Number of Leads Active in Study	800

Product Surveilance Registry Qualifying Complications	25
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	7
Failure To Capture	6
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	11
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	53
Failure To Capture	20
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	4
Lead Dislodgement	109
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	2
Crimp Weld Bond	2
Insulation Breach	0
Other	3

4296, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

Years	1	2	3	at 48 mo
%	98.8%	98.0%	97.6%	96.4%
#	1,075	719	350	79

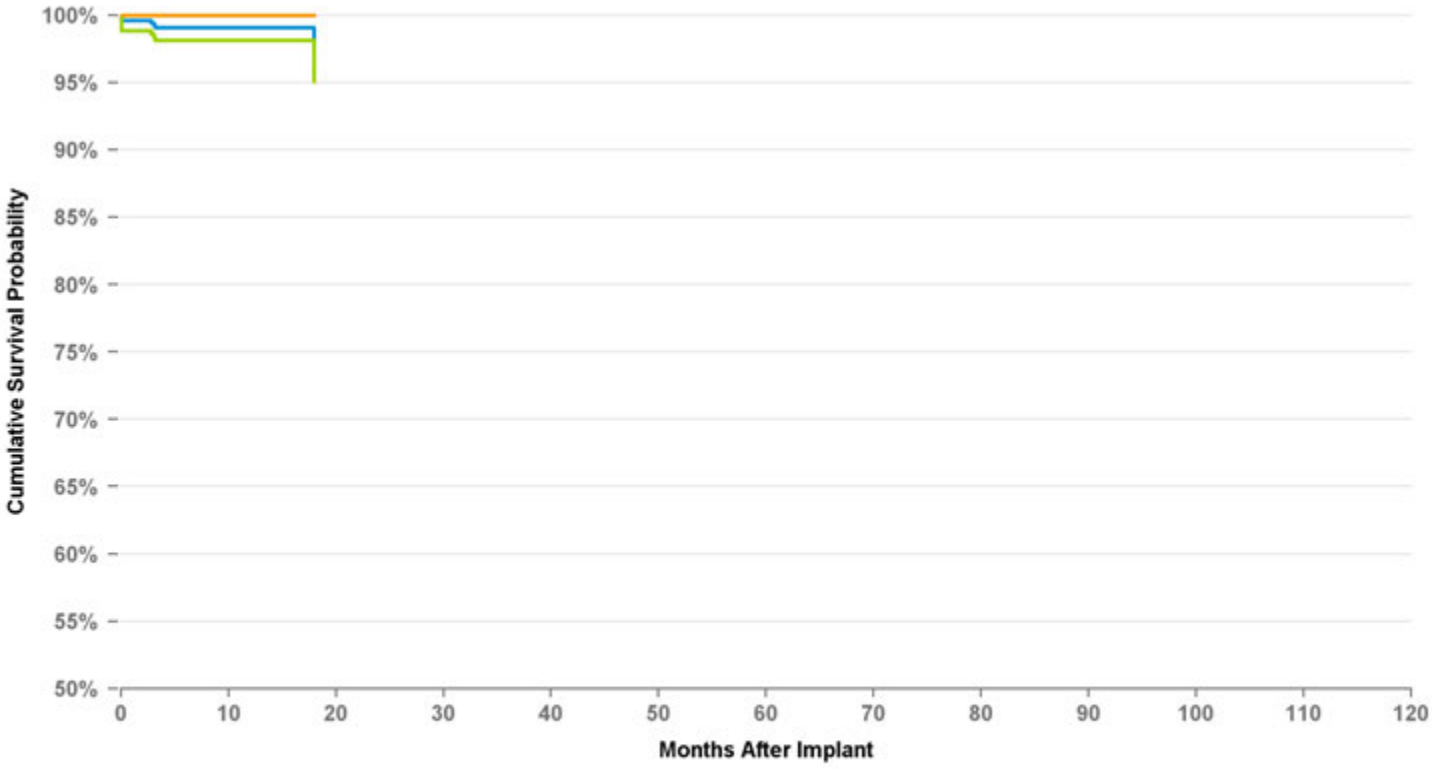
LEFT HEART PACING LEAD 4298

Distribution Data	
US Market Release	8/1/2014
CE Approval Date	1/1/2013
Registered US Implants	29,013
Estimated Active US	27,751
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	970
Cumulative Months of Follow-Up	6,878
Number of Leads Active in Study	866

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	65
Failure To Capture	40
Failure To Sense	0
Impedance Abnormal	11
Insulation Breach	0
Lead Dislodgement	59
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	0
Other	9

4298, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	at 18 mo
%	99.1%	97.8%
#	224	68

LEFT HEART PACING LEAD 4396

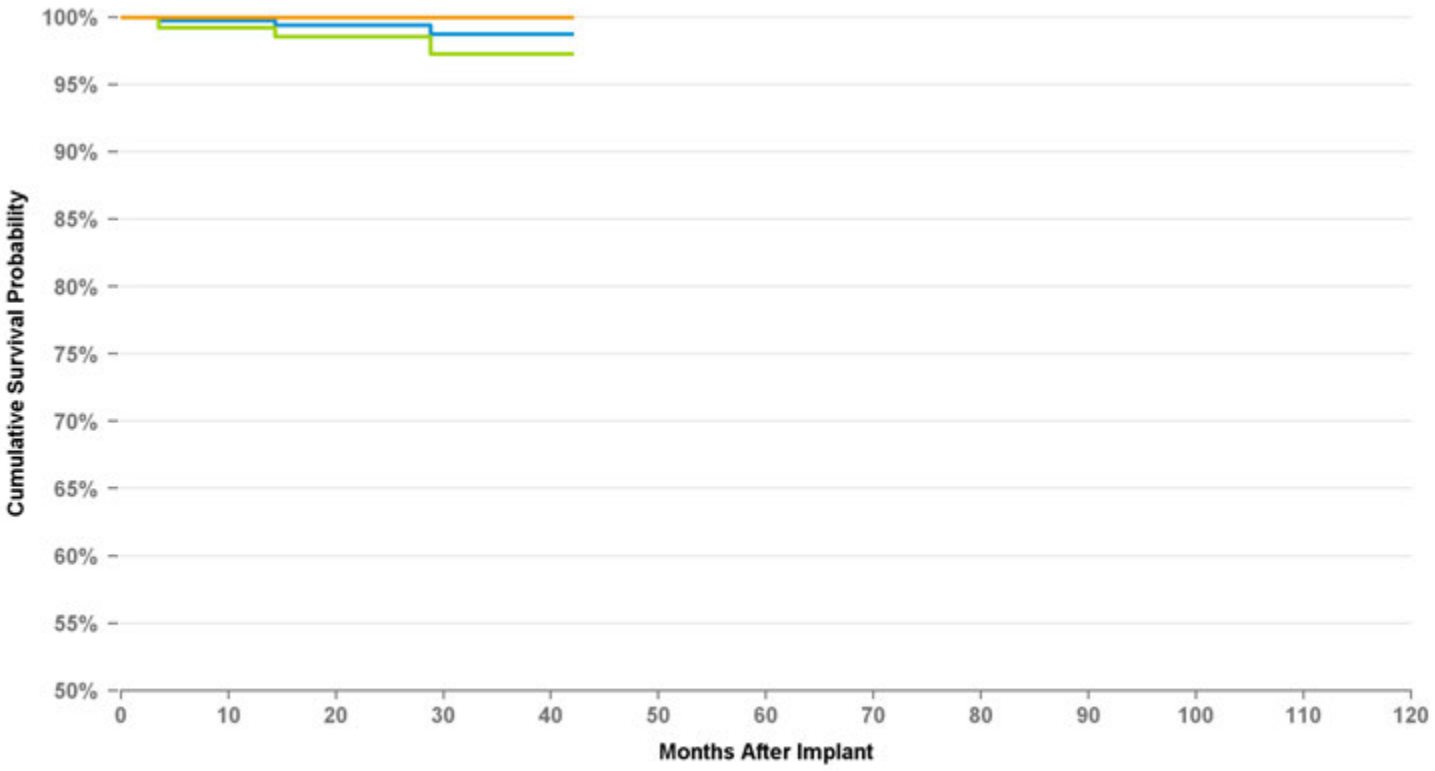
Distribution Data	
US Market Release	3/31/2011
CE Approval Date	12/18/2009
Registered US Implants	6,733
Estimated Active US	5,577
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Dual Electrodes

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	417
Cumulative Months of Follow-Up	10,541
Number of Leads Active in Study	251

Product Surveillance Registry Qualifying Complications	3
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	2
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	14
Failure To Capture	5
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	32
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	0
Other	1

4396, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 42 mo
%	99.7%	99.4%	98.8%	98.8%
#	307	199	114	74

LEFT HEART PACING LEAD 4398

Distribution Data	
US Market Release	12/10/2014
CE Approval Date	1/1/2013
Registered US Implants	5,359
Estimated Active US	5,162
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar

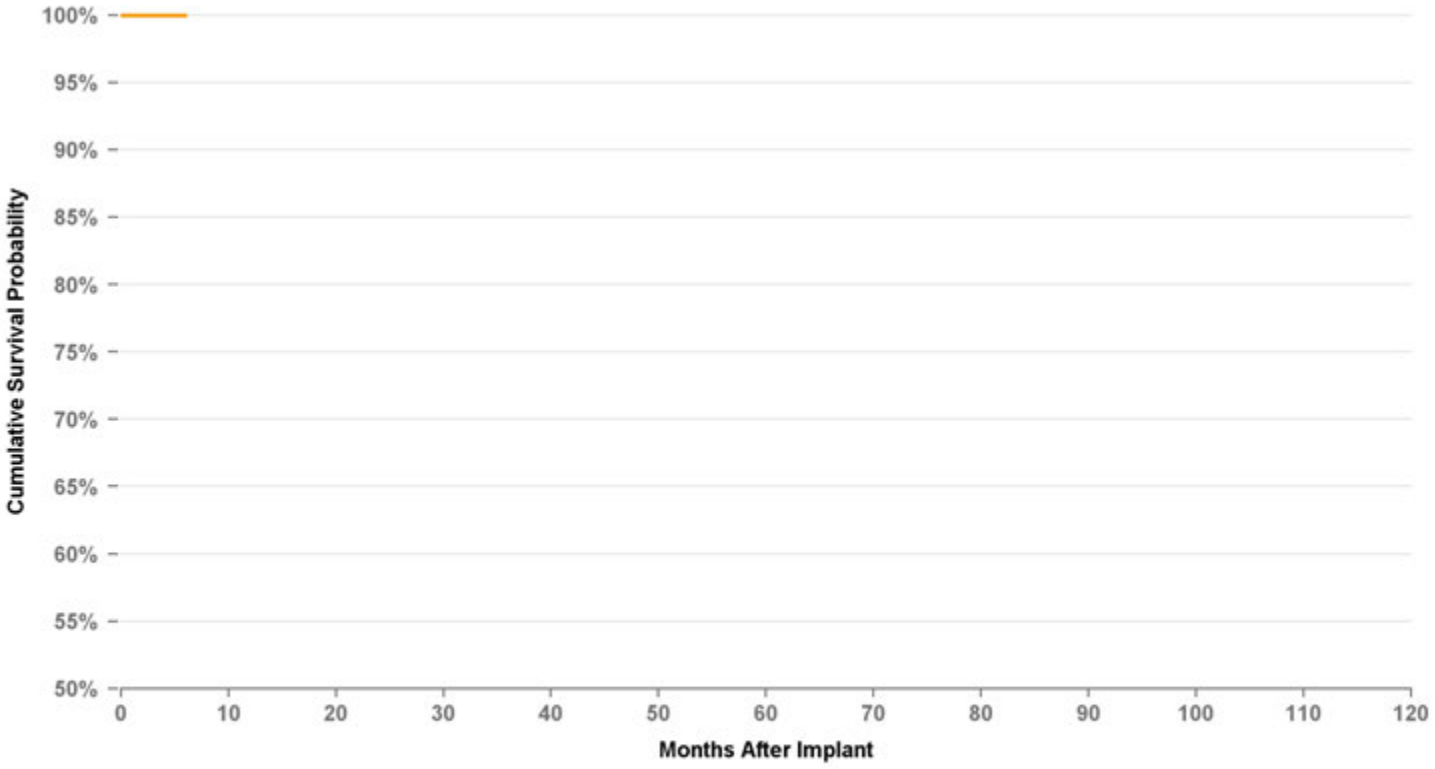
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	218
Cumulative Months of Follow-Up	1,442
Number of Leads Active in Study	193

Product Surveillance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	17
Failure To Capture	11
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	3

4398, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	at 6 mo
%	100.0%
#	80

LEFT HEART PACING LEAD 4598

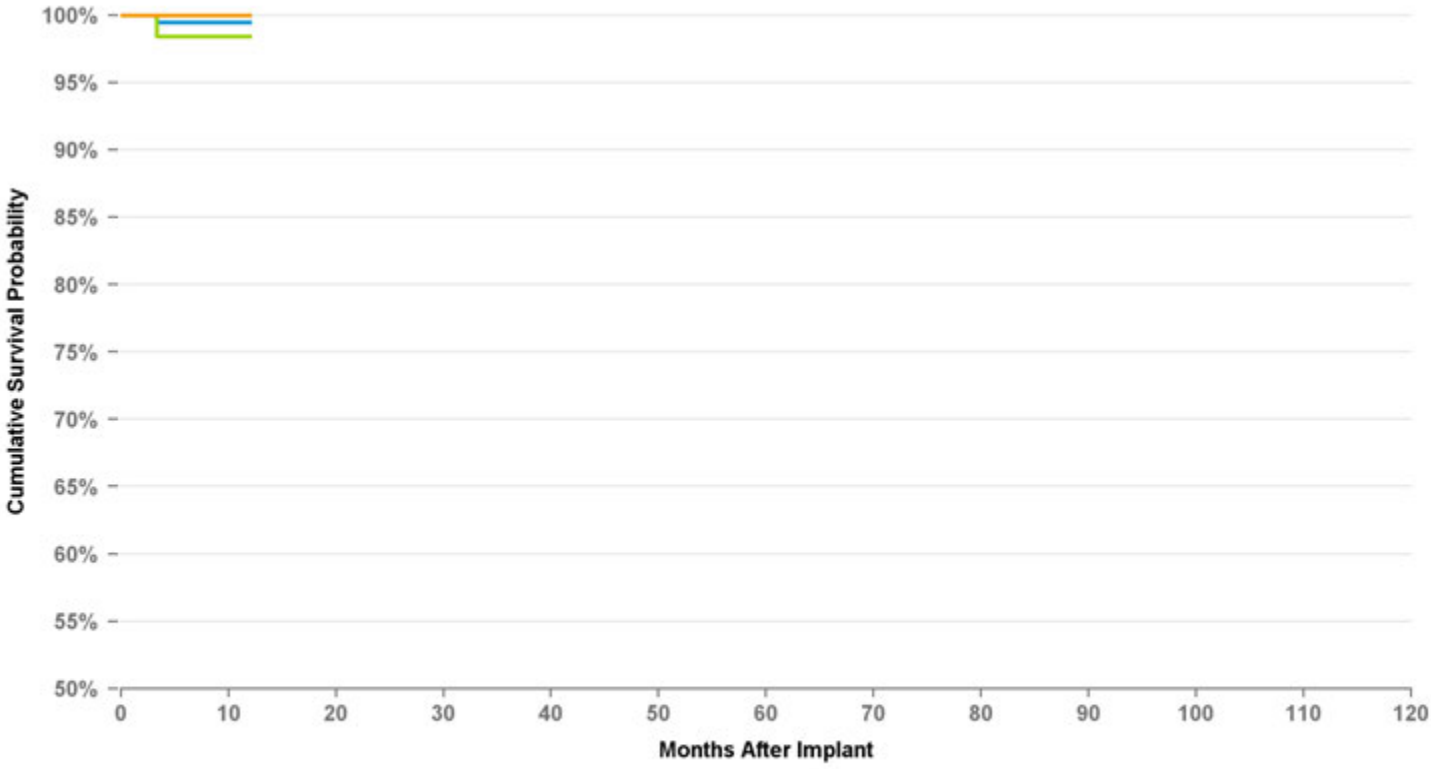
Distribution Data	
US Market Release	12/10/2014
CE Approval Date	1/1/2013
Registered US Implants	10,812
Estimated Active US	10,462
Product Characteristics	
Fixation Type	Canted
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Quad Pole

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	362
Cumulative Months of Follow-Up	2,050
Number of Leads Active in Study	338

Product Surveillance Registry Qualifying Complications	1
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	20
Failure To Capture	7
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	0
Lead Dislodgement	16
Oversensing	1
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	1

4598, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	at 12 mo
%	99.5%
#	60

DEFIBRILLATION LEAD 6721

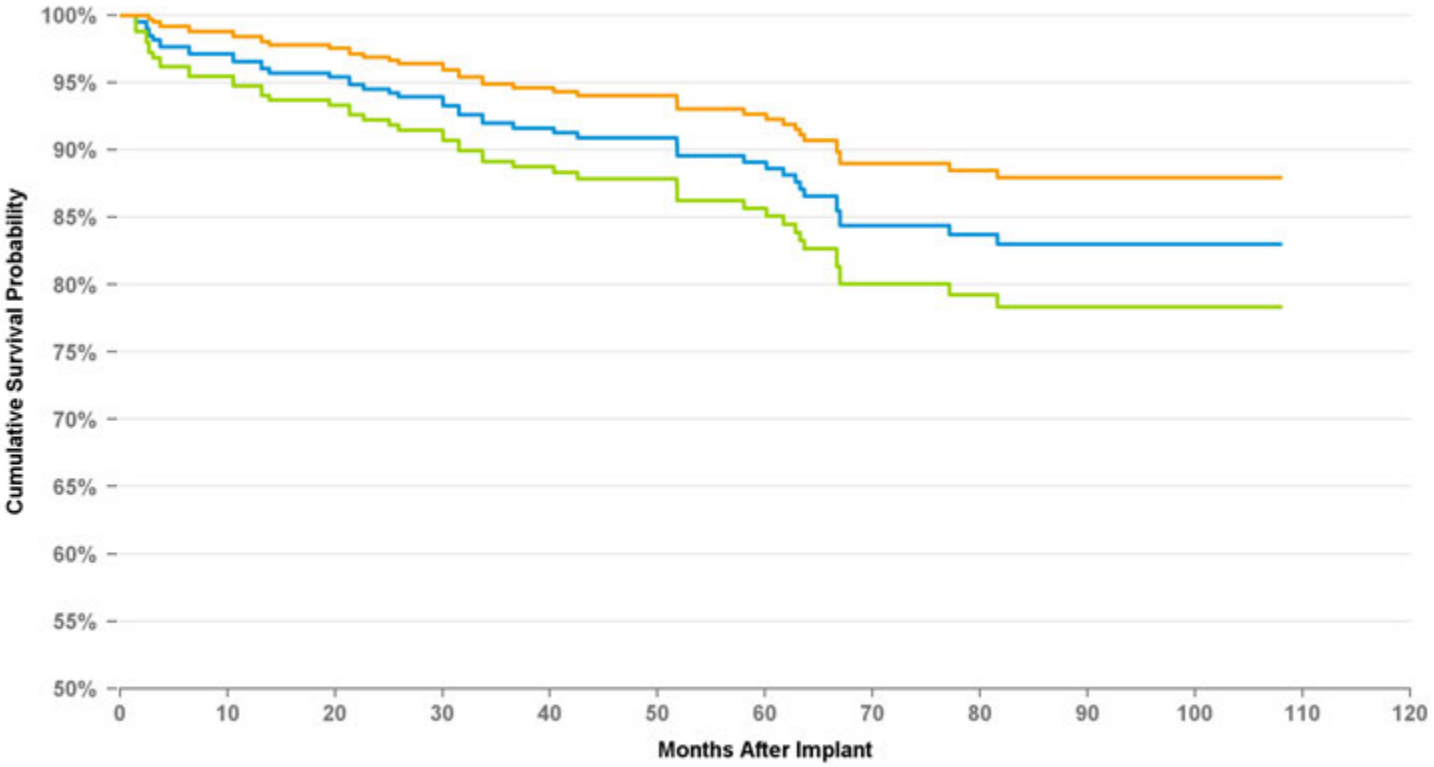
Distribution Data	
US Market Release	3/31/1994
CE Approval Date	1/1/1993
Registered US Implants	3,096
Estimated Active US	1,045
Product Characteristics	
Fixation Type	Suture
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Epi Patch
Lead Tip Location	Epicardial
Pace/Sense Polarity	n/a

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	413
Cumulative Months of Follow-Up	23,676
Number of Leads Active in Study	3

Product Surveillance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	21
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	8
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	12
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	1
Other	0

6721, 6921, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.5%	92.0%	90.9%	89.1%	84.4%	83.0%	83.0%	83.0%
#	344	315	268	216	185	132	99	64	55

DEFIBRILLATION LEAD 6930

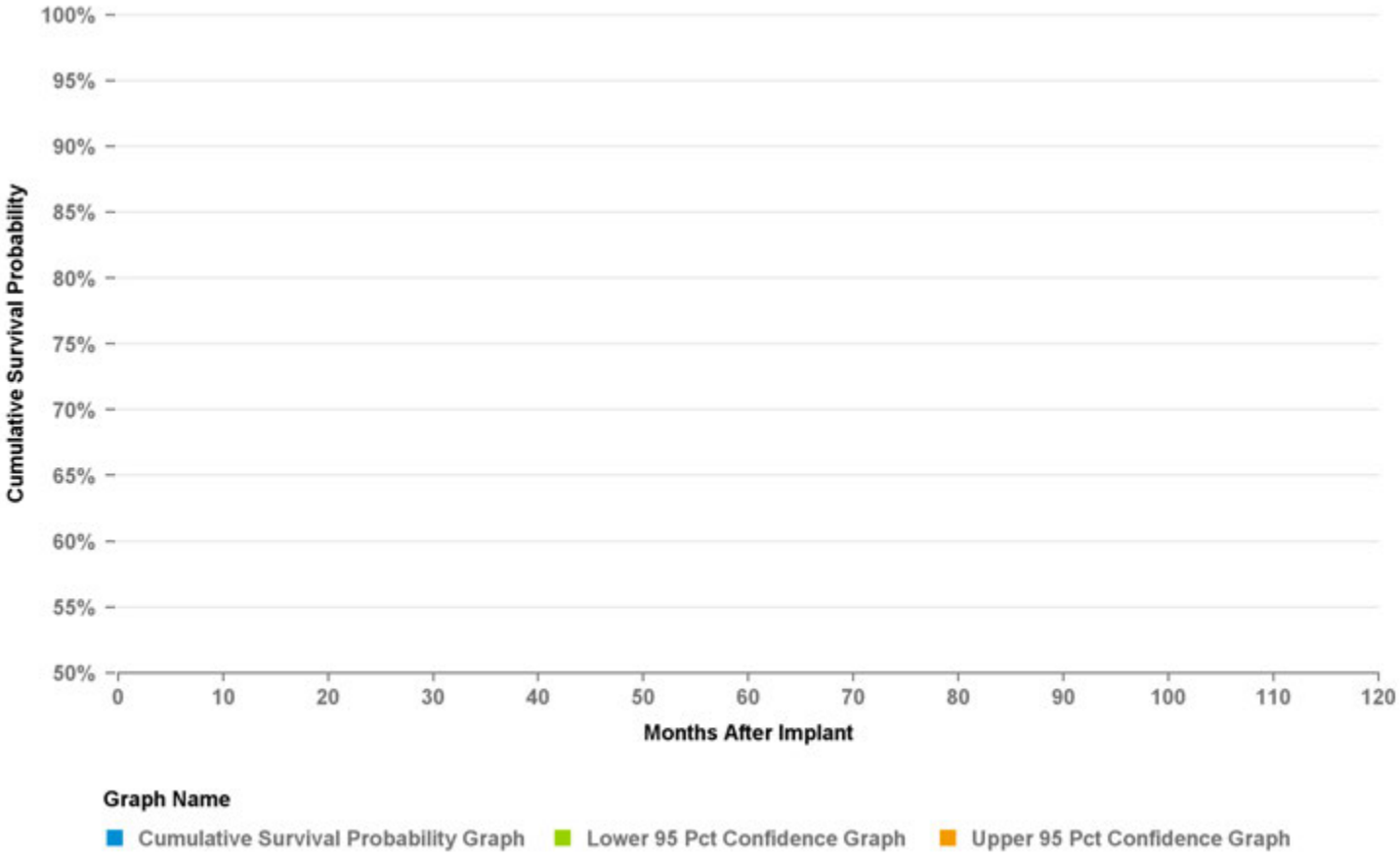
Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implants	354
Estimated Active US	126
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	221
Number of Leads Active in Study	1

Product Surveillance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6930, Survival Curve



Years	
%	
#	

DEFIBRILLATION LEAD 6931

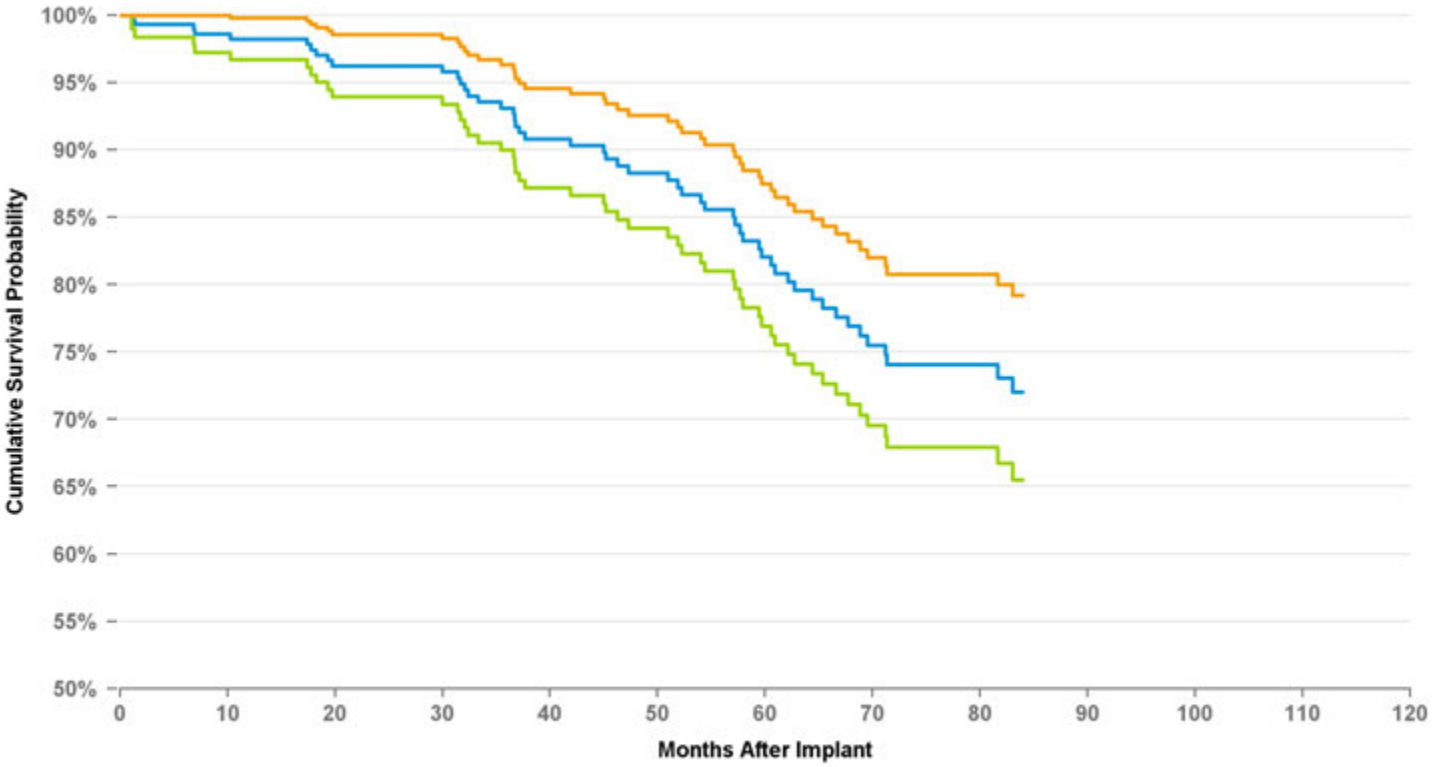
Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implants	8,074
Estimated Active US	2,398
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	308
Cumulative Months of Follow-Up	16,400
Number of Leads Active in Study	42

Product Surveillance Registry Qualifying Complications	58
Cardiac Perforation	0
Conductor Fracture	36
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	9
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	7
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	3
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	618
Crimp Weld Bond	0
Insulation Breach	1
Other	5

6931, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 84 mo
%	98.2%	96.2%	93.1%	88.3%	82.0%	74.1%	72.0%
#	269	237	208	166	134	99	61

DEFIBRILLATION LEAD 6935

Distribution Data	
US Market Release	11/1/2008
CE Approval Date	3/31/2008
Registered US Implants	54,495
Estimated Active US	44,820
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

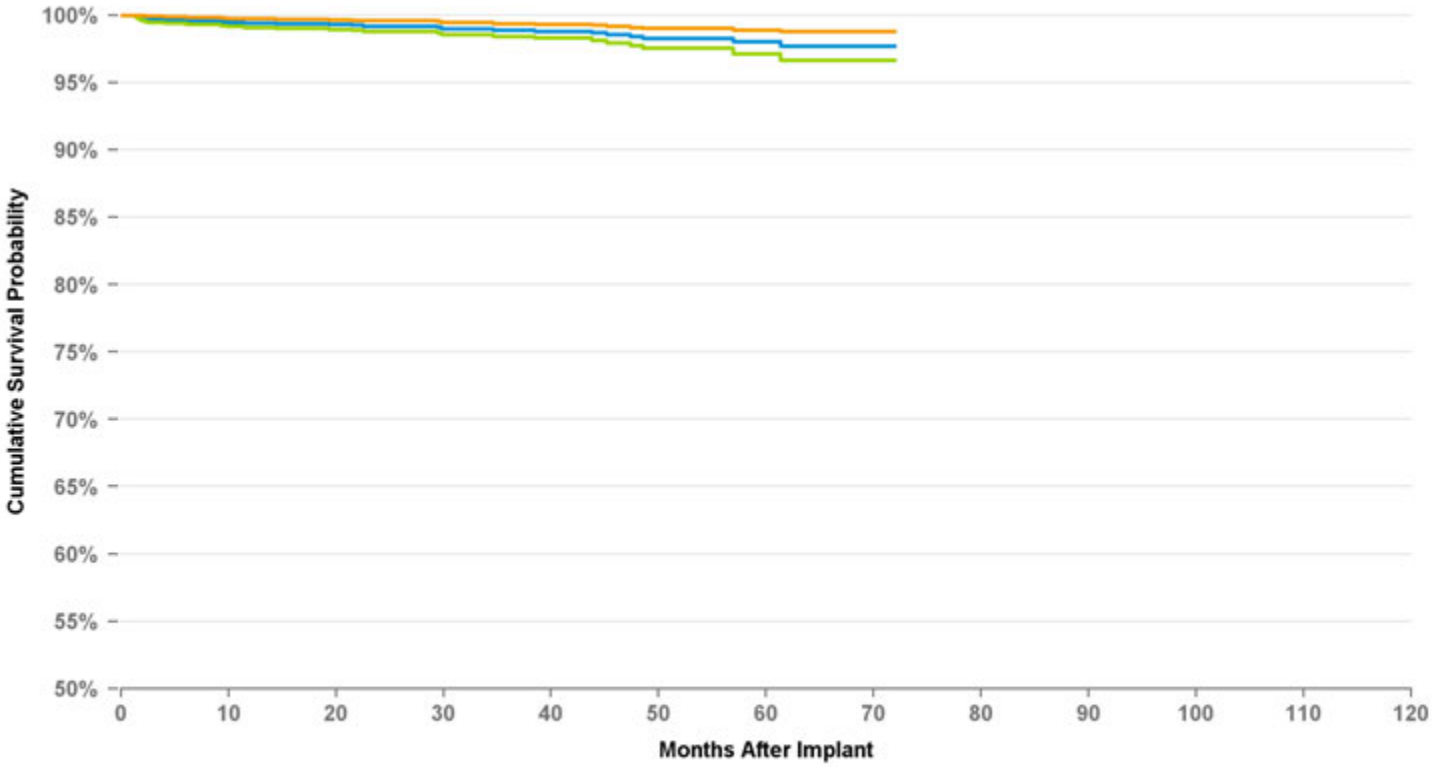
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	2,491
Cumulative Months of Follow-Up	85,451
Number of Leads Active in Study	1,242

Product Surveillance Registry Qualifying Complications	29
Cardiac Perforation	0
Conductor Fracture	10
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	7
Medical Judgment	0
Other Complication	1
Oversensing	5
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	21
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	20
Failure To Sense	8
Impedance Abnormal	16
Insulation Breach	1
Lead Dislodgement	41
Oversensing	47
Unspecified	5

USA Returned Product Analysis	
Conductor Fracture	186
Crimp Weld Bond	0
Insulation Breach	7
Other	40

6935, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	at 72 mo
%	99.4%	99.2%	98.9%	98.4%	98.0%	97.7%
#	2,092	1,648	1,132	633	316	88

DEFIBRILLATION LEAD 6935M

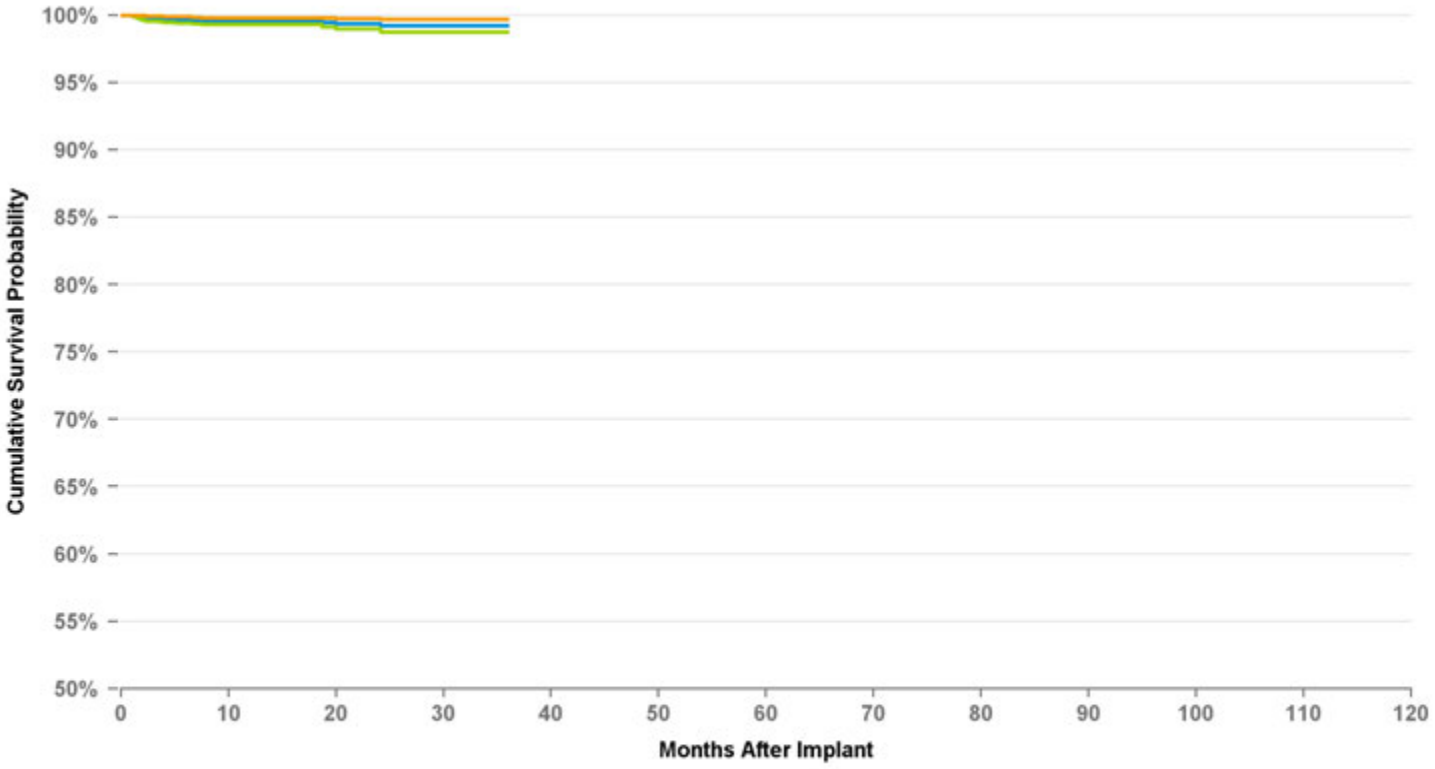
Distribution Data	
US Market Release	8/2/2012
CE Approval Date	7/12/2012
Registered US Implants	94,508
Estimated Active US	89,781
Product Characteristics	
Fixation Type	Active Screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	3,935
Cumulative Months of Follow-Up	46,048
Number of Leads Active in Study	3,346

Product Surveillance Registry Qualifying Complications	15
Cardiac Perforation	1
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	2
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	36
Conductor Fracture	2
Extracardiac Stimulation	8
Failure To Capture	84
Failure To Sense	13
Impedance Abnormal	26
Insulation Breach	1
Lead Dislodgement	116
Oversensing	65
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	48
Crimp Weld Bond	0
Insulation Breach	2
Other	9

6935M, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

Years	1	2	at 36 mo
%	99.6%	99.4%	99.2%
#	1,677	630	106

DEFIBRILLATION LEAD 6937A

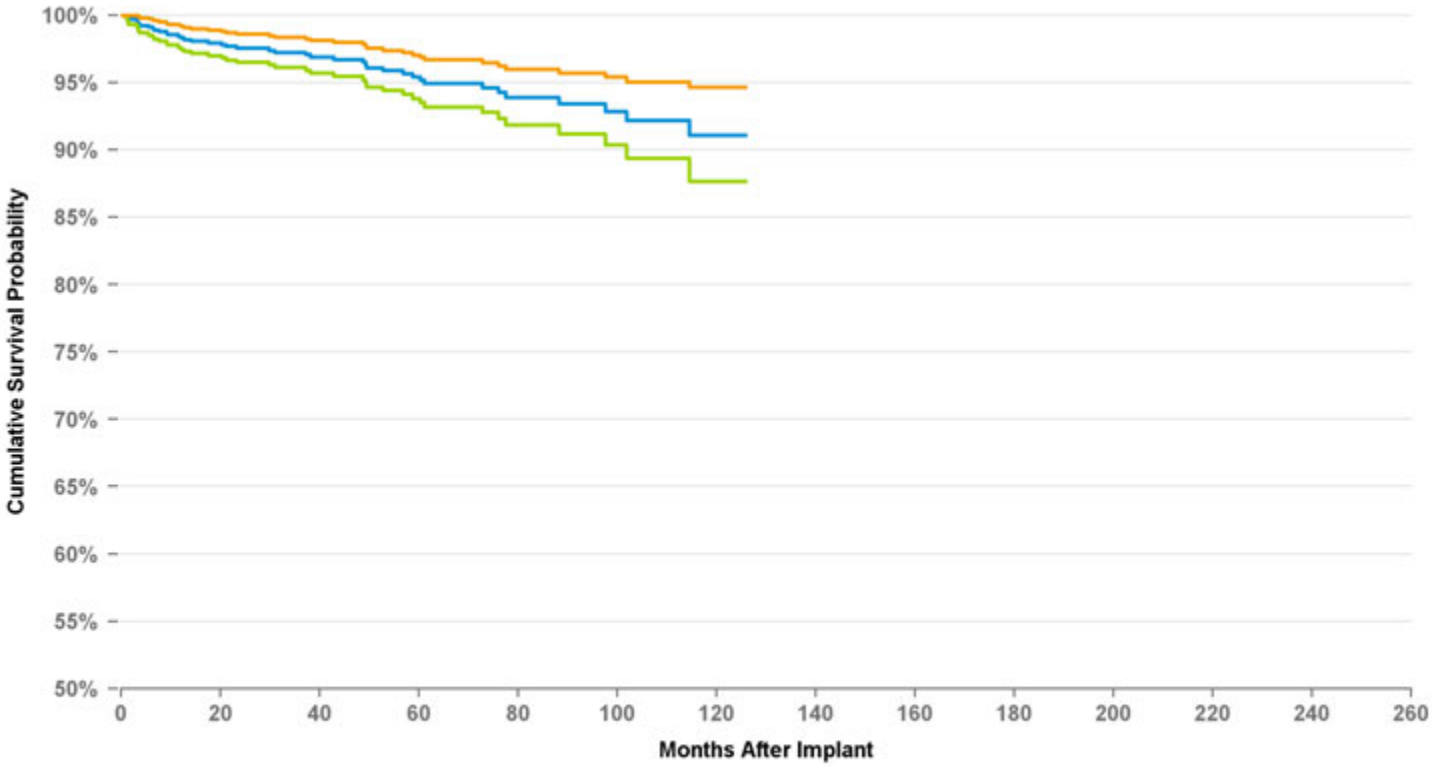
Distribution Data	
US Market Release	4/6/2001
CE Approval Date	
Registered US Implants	2,235
Estimated Active US	1,318
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarity	One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	972
Cumulative Months of Follow-Up	54,288
Number of Leads Active in Study	10

Product Surveillance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	16
Electrical Abandonment	0
Extracardiac Stimulation	4
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	10
Unspecified	4

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	3
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6933, 6937, 6937A, 6963, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	825	693	579	486	386	310	217	168	109	71	56

DEFIBRILLATION LEAD 6942

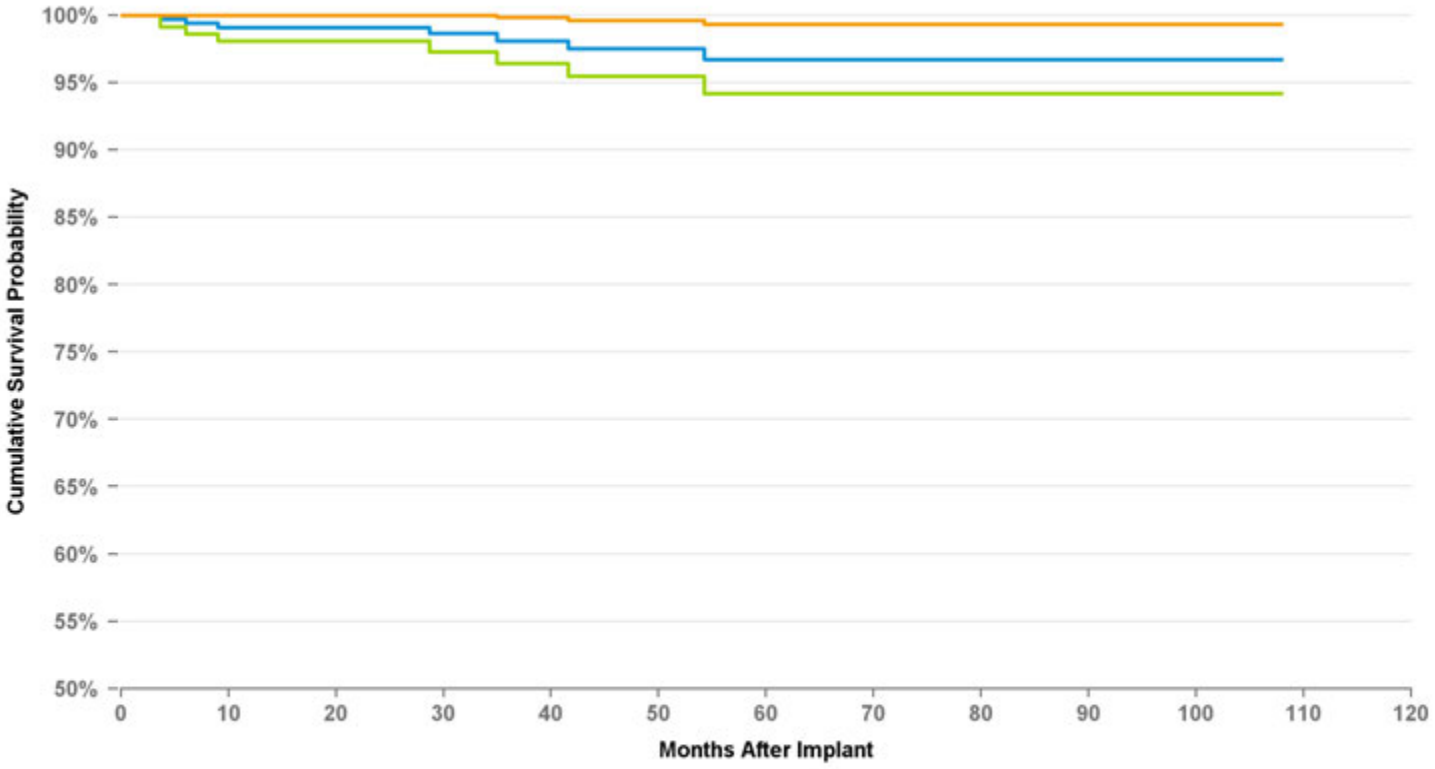
Distribution Data	
US Market Release	7/18/1997
CE Approval Date	
Registered US Implants	17,673
Estimated Active US	4,024
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Integrated Bipolar/ Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	364
Cumulative Months of Follow-Up	19,378
Number of Leads Active in Study	14

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	3
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	1
Oversensing	2
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	16
Crimp Weld Bond	1
Insulation Breach	26
Other	4

6942, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.1%	99.1%	98.1%	97.5%	96.7%	96.7%	96.7%	96.7%	96.7%
#	307	240	181	140	112	93	72	63	51

DEFIBRILLATION LEAD 6943

Distribution Data	
US Market Release	10/6/1997
CE Approval Date	
Registered US Implants	20,580
Estimated Active US	4,806
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

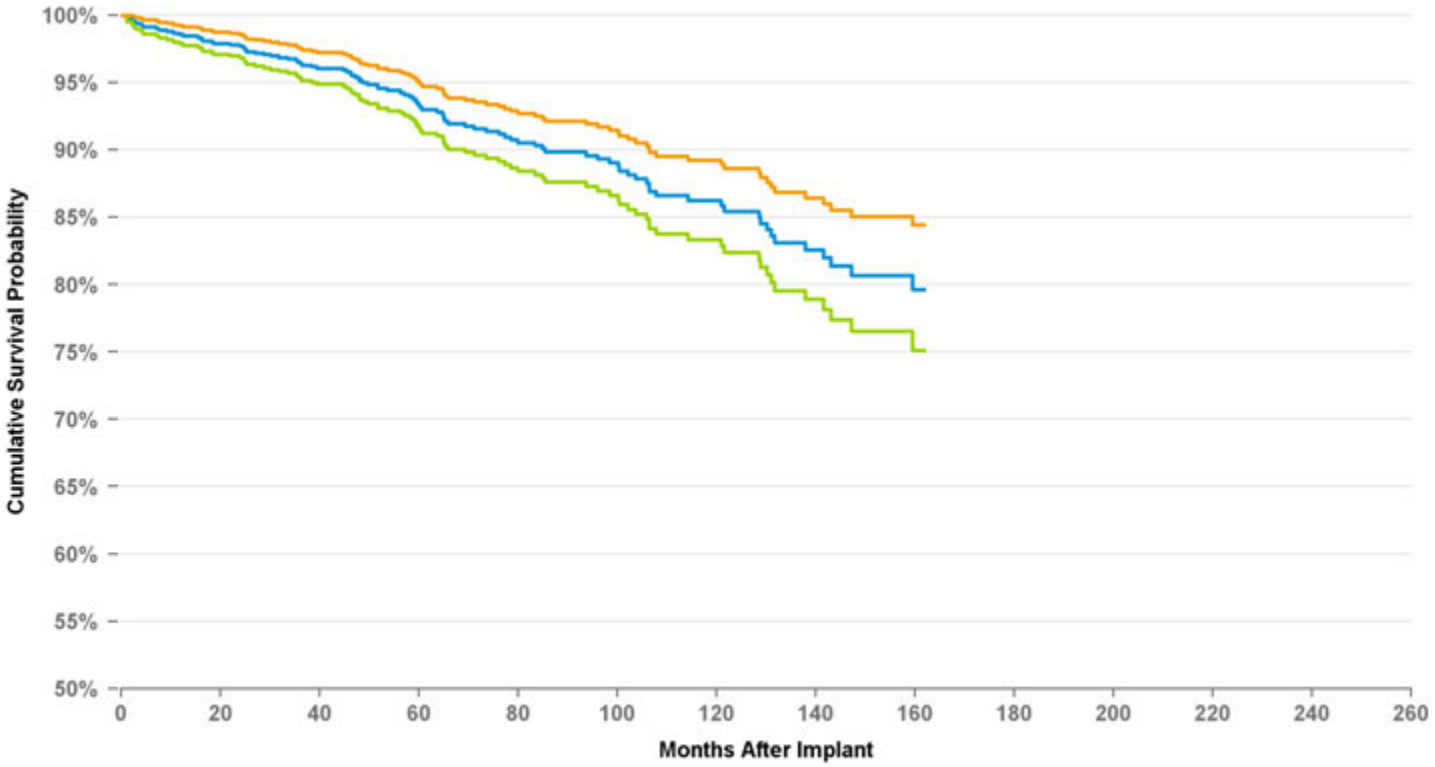
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,336
Cumulative Months of Follow-Up	84,390
Number of Leads Active in Study	113

Product Surveillance Registry Qualifying Complications	108
Cardiac Perforation	0
Conductor Fracture	30
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	11
Failure To Sense	7
Impedance Abnormal	8
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	2
Medical Judgment	0
Other Complication	2
Oversensing	43
Unspecified	3

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	0
Oversensing	1
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	86
Crimp Weld Bond	1
Insulation Breach	31
Other	5

6943, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	98.5%	97.7%	96.5%	95.4%	93.3%	91.6%	90.3%	89.6%	86.6%	86.2%	83.1%	81.4%	80.7%	79.6%
#	1,159	975	847	700	581	475	393	323	269	213	166	120	78	59

DEFIBRILLATION LEAD 6944

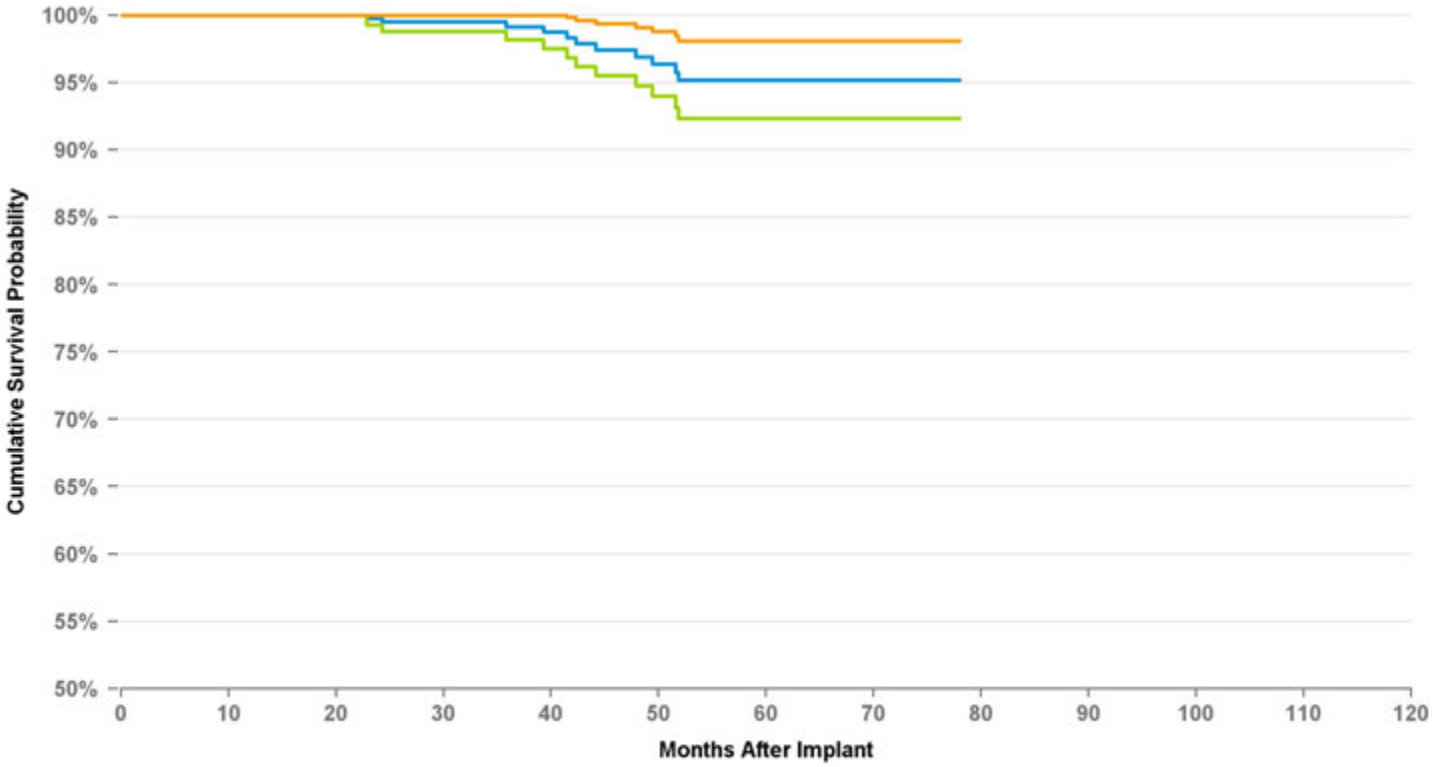
Distribution Data	
US Market Release	12/13/2000
CE Approval Date	11/5/1999
Registered US Implants	44,644
Estimated Active US	20,458
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	594
Cumulative Months of Follow-Up	24,645
Number of Leads Active in Study	214

Product Surveillance Registry Qualifying Complications	16
Cardiac Perforation	0
Conductor Fracture	9
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	16
Failure To Sense	3
Impedance Abnormal	11
Insulation Breach	0
Lead Dislodgement	22
Oversensing	13
Unspecified	6
USA Returned Product Analysis	
Conductor Fracture	157
Crimp Weld Bond	1
Insulation Breach	4
Other	6

6944, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 78 mo
%	100.0%	99.7%	99.1%	96.9%	95.2%	95.2%	95.2%
#	504	402	293	190	99	59	55

DEFIBRILLATION LEAD 6945

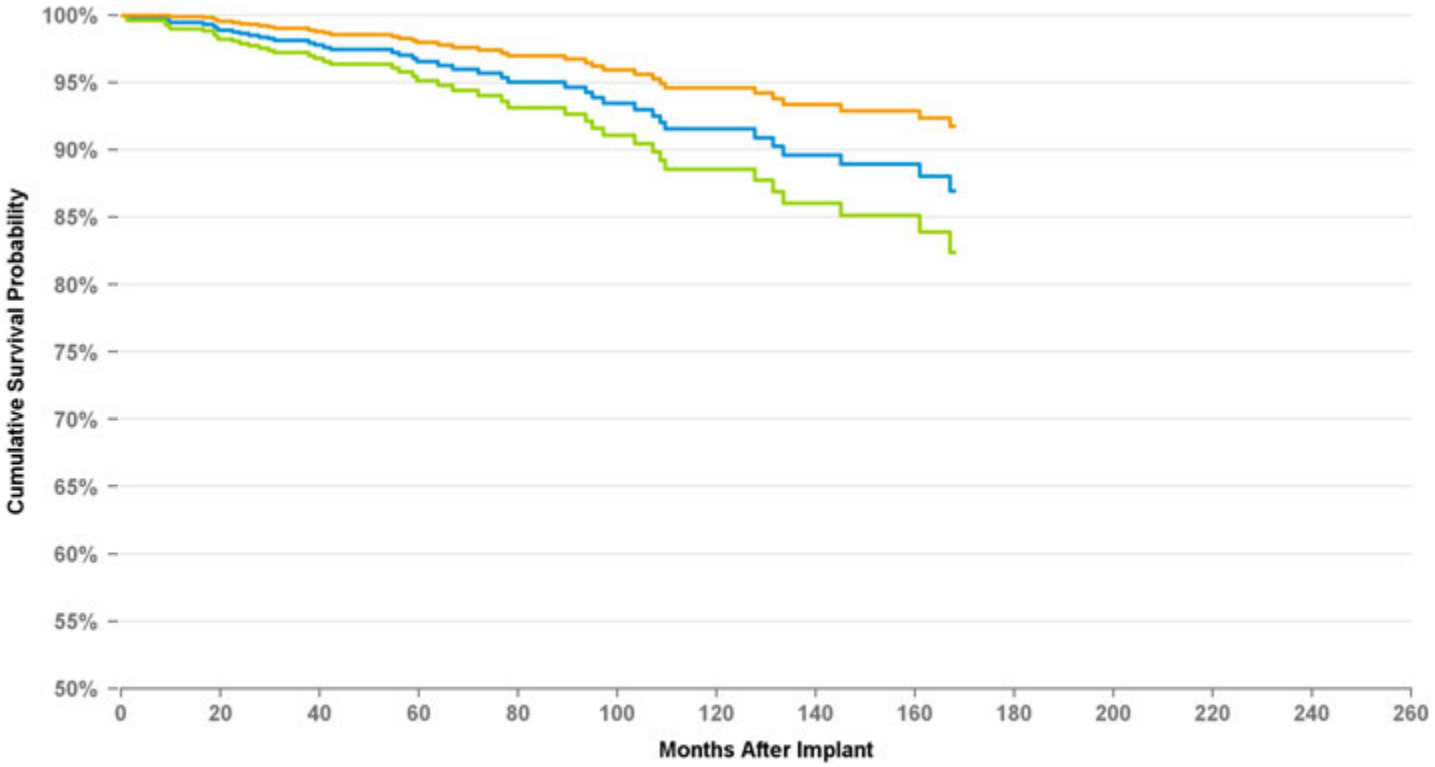
Distribution Data	
US Market Release	9/26/1997
CE Approval Date	
Registered US Implants	42,696
Estimated Active US	9,729
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Integrated Bipolar/ Two Coils

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,194
Cumulative Months of Follow-Up	67,333
Number of Leads Active in Study	81

Product Surveillance Registry Qualifying Complications	45
Cardiac Perforation	0
Conductor Fracture	11
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	4
Impedance Abnormal	6
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	19
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	2
Lead Dislodgement	4
Oversensing	8
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	146
Crimp Weld Bond	1
Insulation Breach	45
Other	6

6945, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.4%	98.6%	98.1%	97.5%	96.5%	95.7%	95.0%	93.9%	92.5%	91.5%	90.3%	89.6%	88.9%	86.9%
#	1,022	830	654	520	403	313	273	229	186	155	133	118	94	61

DEFIBRILLATION LEAD 6946M

Distribution Data	
US Market Release	1/5/2016
CE Approval Date	9/12/2013
Registered US Implants	
Estimated Active US	

Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

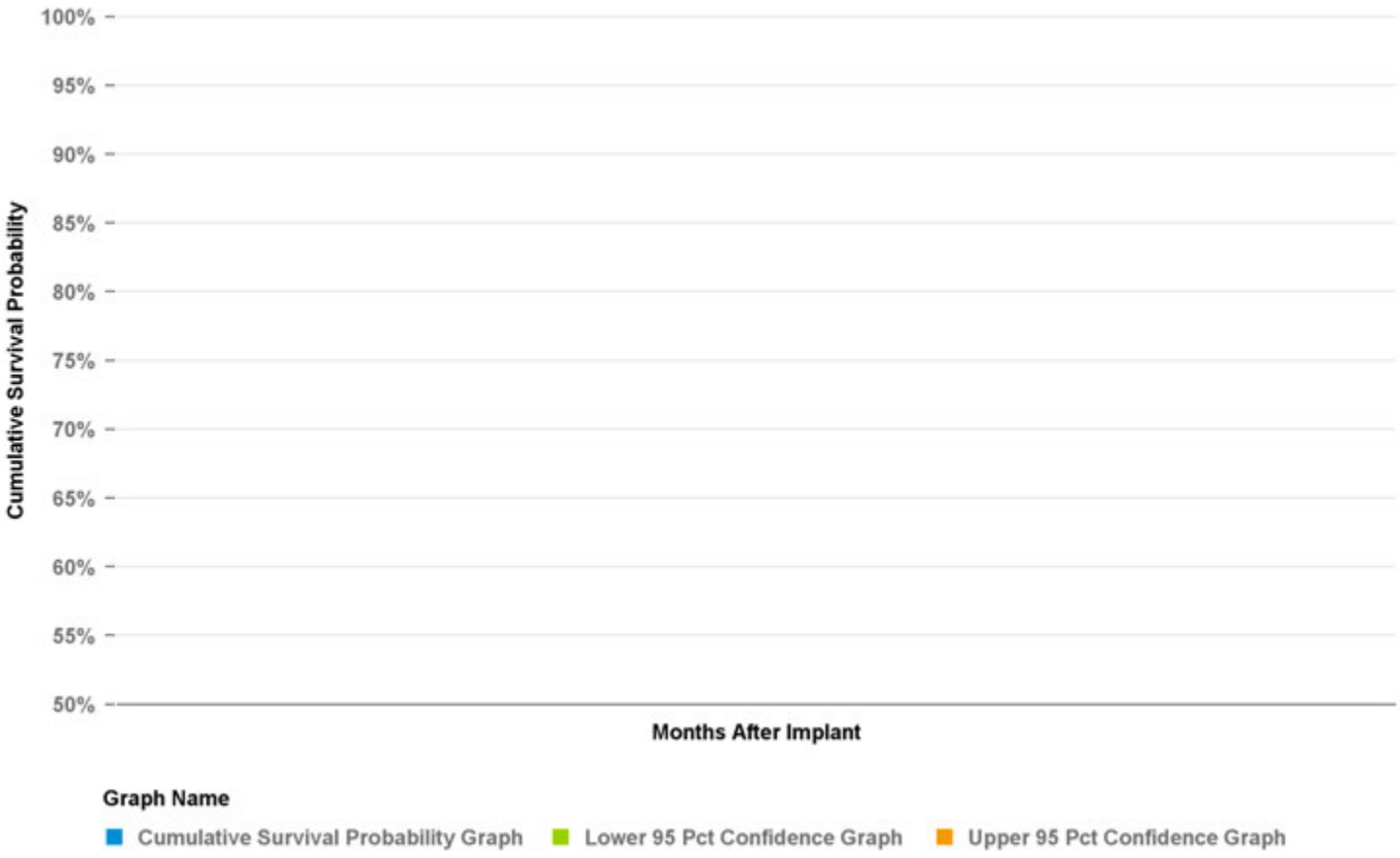
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0
Number of Leads Active in Study	0

Product Surveillance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6946M, Survival Curve



Years
%
#

DEFIBRILLATION LEAD 6947

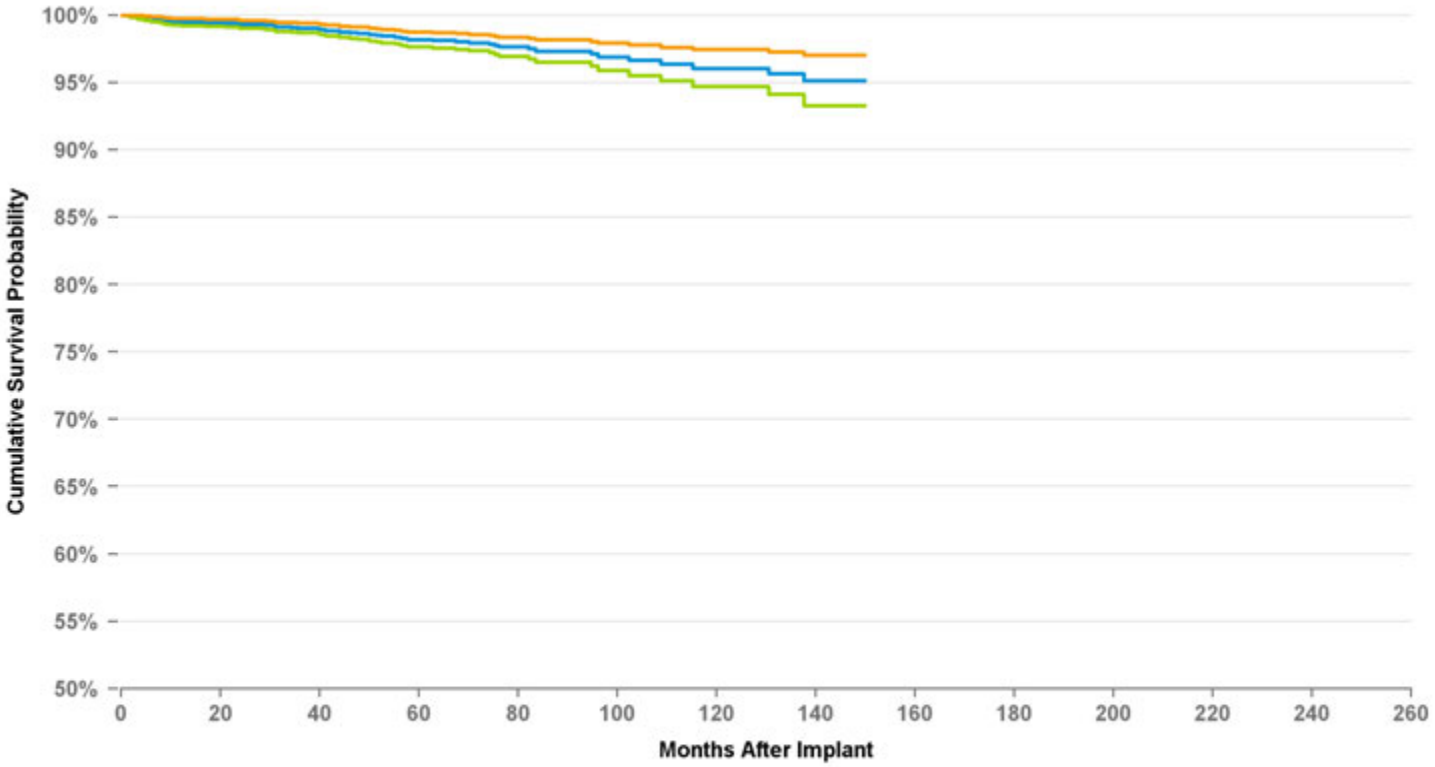
Distribution Data	
US Market Release	11/12/2001
CE Approval Date	10/4/2001
Registered US Implants	372,231
Estimated Active US	210,448
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	4,049
Cumulative Months of Follow-Up	194,186
Number of Leads Active in Study	1,473

Product Surveillance Registry Qualifying Complications	61
Cardiac Perforation	0
Conductor Fracture	20
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	7
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	5
Lead Dislodgement	5
Medical Judgment	0
Other Complication	3
Oversensing	15
Unspecified	2

US Acute Lead Observations	
Cardiac Perforation	28
Conductor Fracture	21
Extracardiac Stimulation	2
Failure To Capture	77
Failure To Sense	33
Impedance Abnormal	55
Insulation Breach	4
Lead Dislodgement	115
Oversensing	125
Unspecified	22
USA Returned Product Analysis	
Conductor Fracture	803
Crimp Weld Bond	4
Insulation Breach	75
Other	215

6947, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	97.9%	97.3%	97.1%	96.6%	96.1%	95.7%	95.1%	95.1%
#	3,427	2,896	2,338	1,864	1,331	848	468	358	289	203	144	71	51

DEFIBRILLATION LEAD 6947M

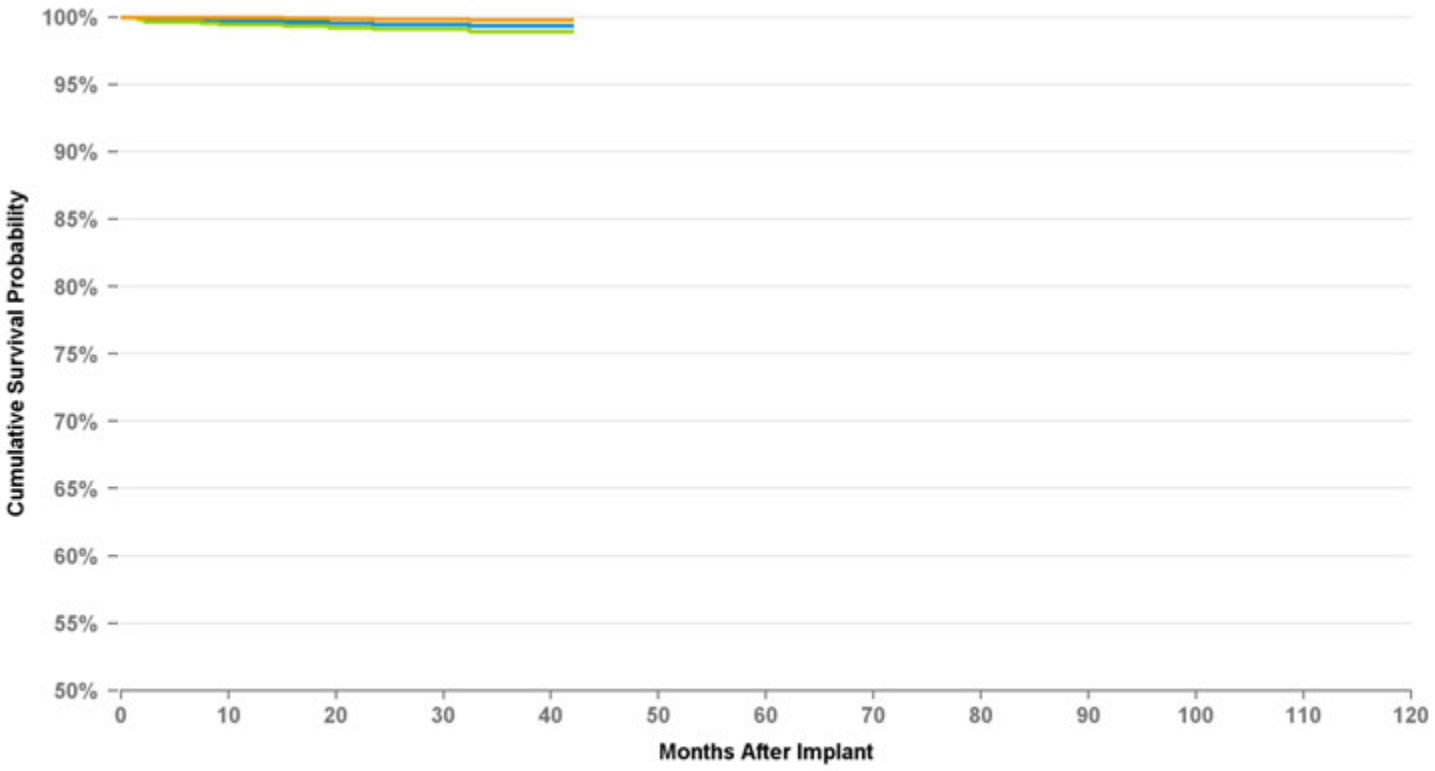
Distribution Data	
US Market Release	2/13/2012
CE Approval Date	3/12/2010
Registered US Implants	80,248
Estimated Active US	73,520
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,933
Cumulative Months of Follow-Up	51,455
Number of Leads Active in Study	1,276

Product Surveillance Registry Qualifying Complications	9
Cardiac Perforation	0
Conductor Fracture	2
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	22
Conductor Fracture	8
Extracardiac Stimulation	9
Failure To Capture	60
Failure To Sense	18
Impedance Abnormal	18
Insulation Breach	0
Lead Dislodgement	111
Oversensing	41
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	39
Crimp Weld Bond	0
Insulation Breach	4
Other	10

6947M, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 42 mo
%	99.7%	99.5%	99.4%	99.4%
#	1,502	1,161	672	290

DEFIBRILLATION LEAD 6948

Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implants	10,372
Estimated Active US	3,400
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

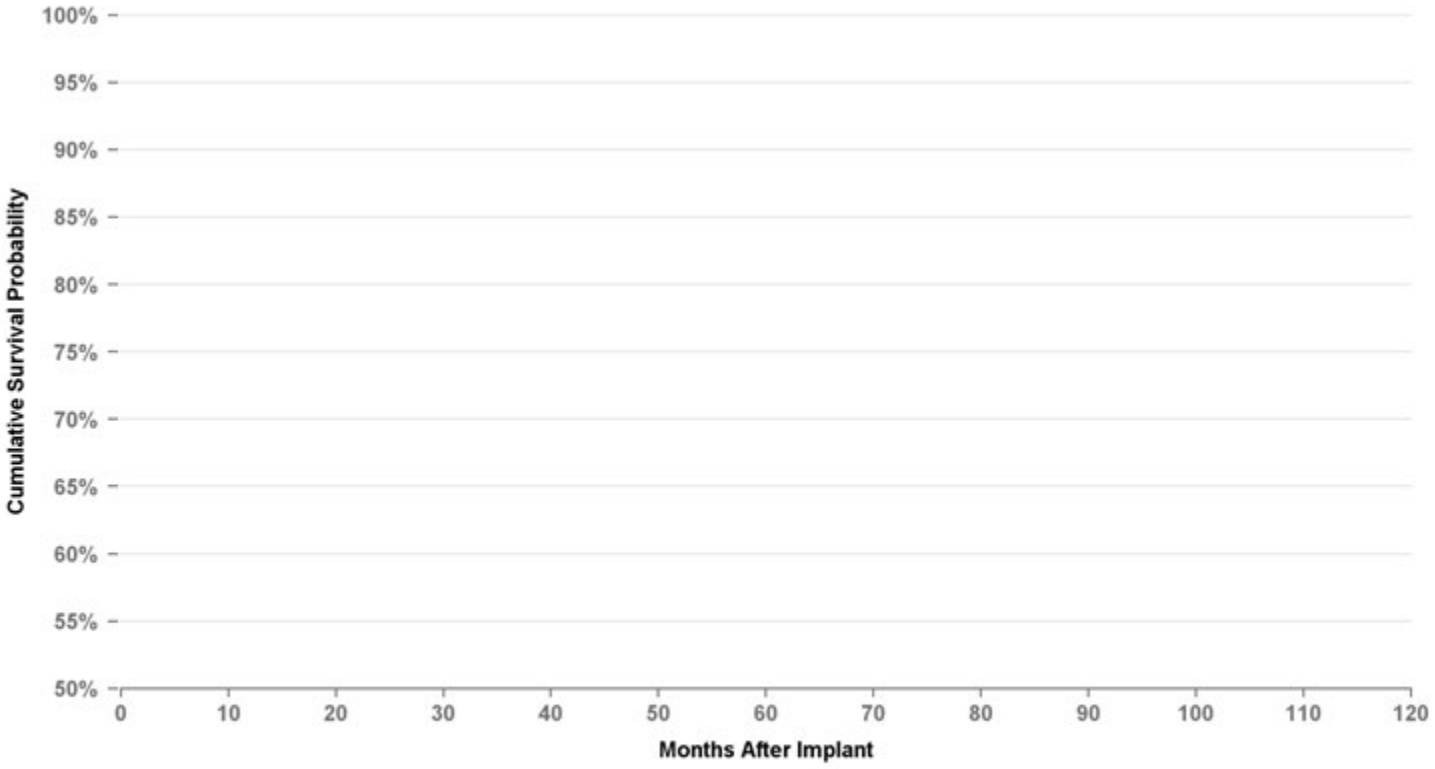
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	39
Cumulative Months of Follow-Up	2,020
Number of Leads Active in Study	9

Product Surveillance Registry Qualifying Complications	4
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	7
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	7
Oversensing	1
Unspecified	3

USA Returned Product Analysis	
Conductor Fracture	189
Crimp Weld Bond	0
Insulation Breach	3
Other	2

6948, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	
%	
#	

DEFIBRILLATION LEAD 6949

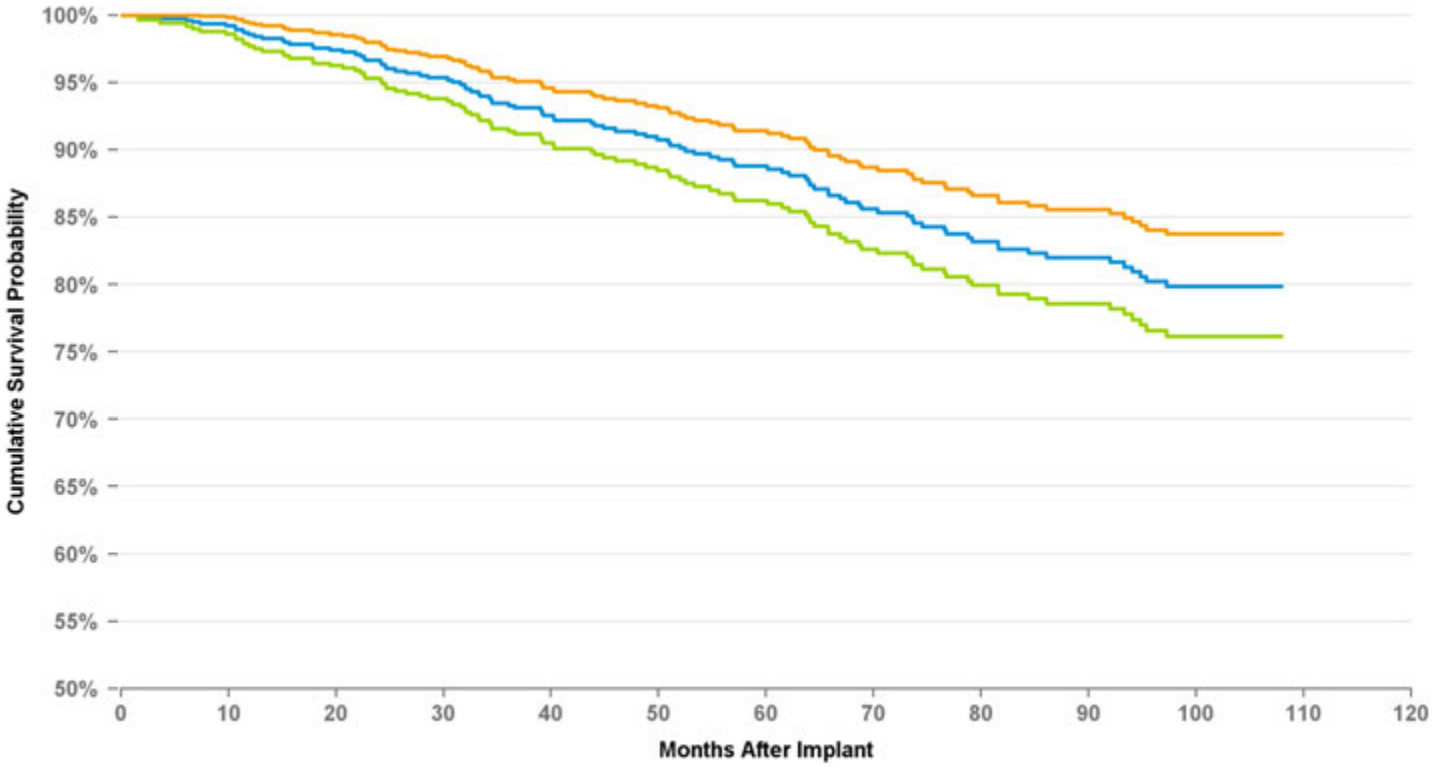
Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implants	186,703
Estimated Active US	52,050
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	950
Cumulative Months of Follow-Up	49,422
Number of Leads Active in Study	178

Product Surveillance Registry Qualifying Complications	99
Cardiac Perforation	0
Conductor Fracture	54
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	6
Impedance Abnormal	16
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	2
Oversensing	15
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	10
Conductor Fracture	44
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	19
Impedance Abnormal	17
Insulation Breach	6
Lead Dislodgement	22
Oversensing	31
Unspecified	25
USA Returned Product Analysis	
Conductor Fracture	7,415
Crimp Weld Bond	3
Insulation Breach	35
Other	71

6949, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	98.5%	96.6%	93.5%	91.2%	88.8%	85.4%	82.6%	80.2%	79.9%
#	819	699	567	461	378	292	198	136	76

DEFIBRILLATION LEAD 6996

Distribution Data	
US Market Release	6/11/2001
CE Approval Date	12/19/1997
Registered US Implants	4,582
Estimated Active US	2,503

Product Characteristics	
Fixation Type	Suture on Anchor Sleeve
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Subcutaneous
Lead Tip Location	Defibrillation
Pace/Sense Polarity	One Coil

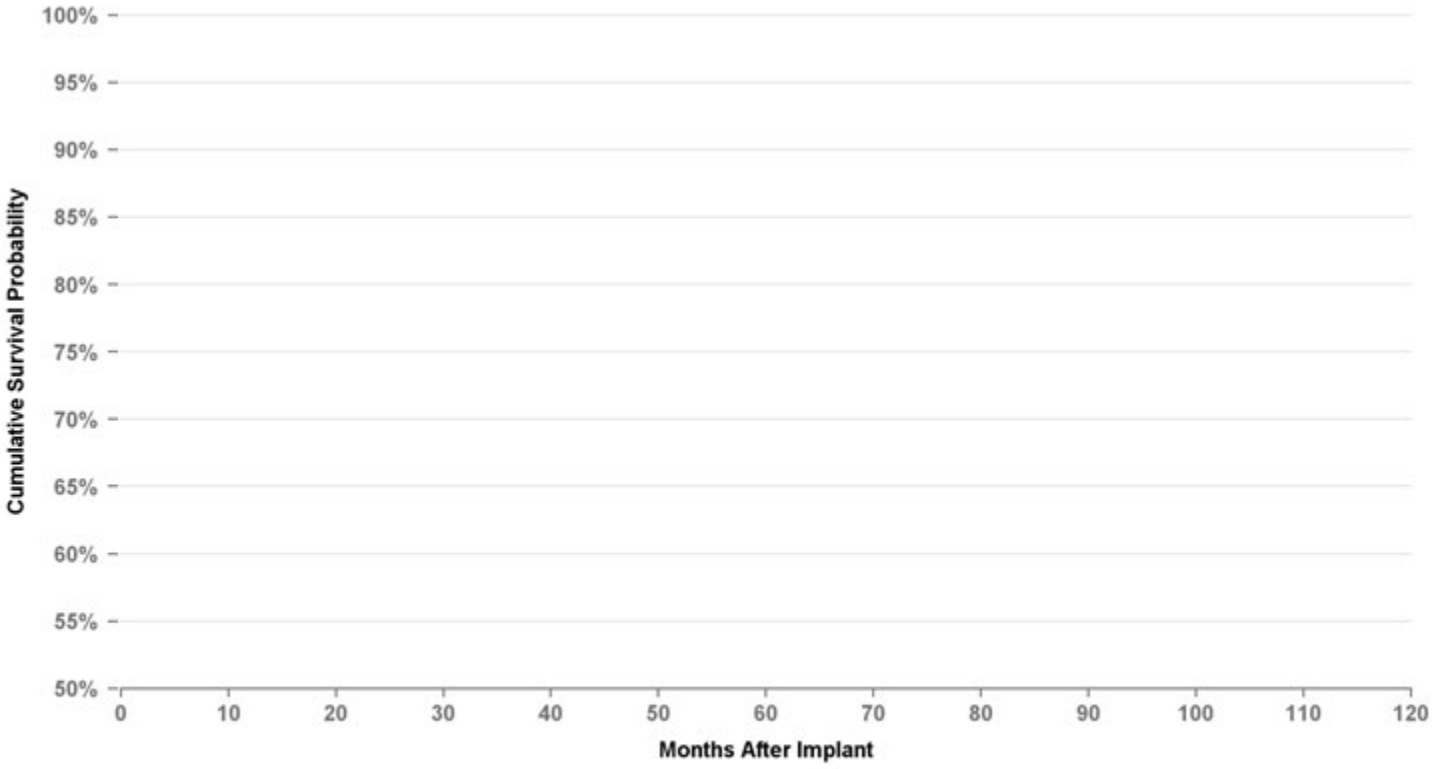
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	46
Cumulative Months of Follow-Up	1,694
Number of Leads Active in Study	11

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	26
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6996, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	
%	
#	

PACING LEAD

Distribution Data	
US Market Release	8/3/2005
CE Approval Date	1/31/2003
Registered US Implants	26,630
Estimated Active US	18,604
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	927
Cumulative Months of Follow-Up	41,345
Number of Leads Active in Study	454

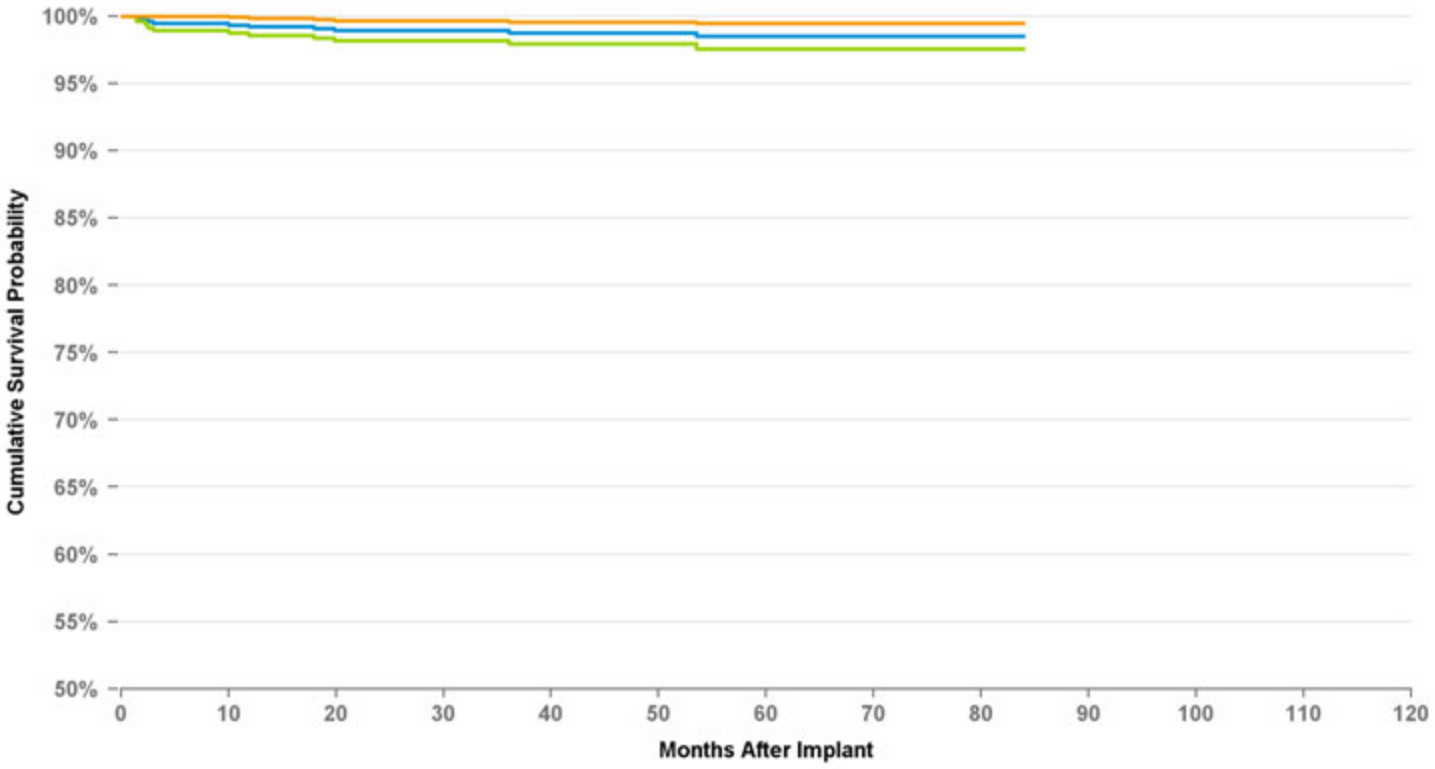
3830

Product Surveillance Registry Qualifying Complications	13
Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	8
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	29
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	50
Oversensing	5
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	26
Other	3

3830, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 84 mo
%	99.2%	98.9%	98.9%	98.7%	98.5%	98.5%	98.5%
#	790	663	565	450	280	116	55

PACING LEAD

3830

VENTRICULAR PLACEMENT

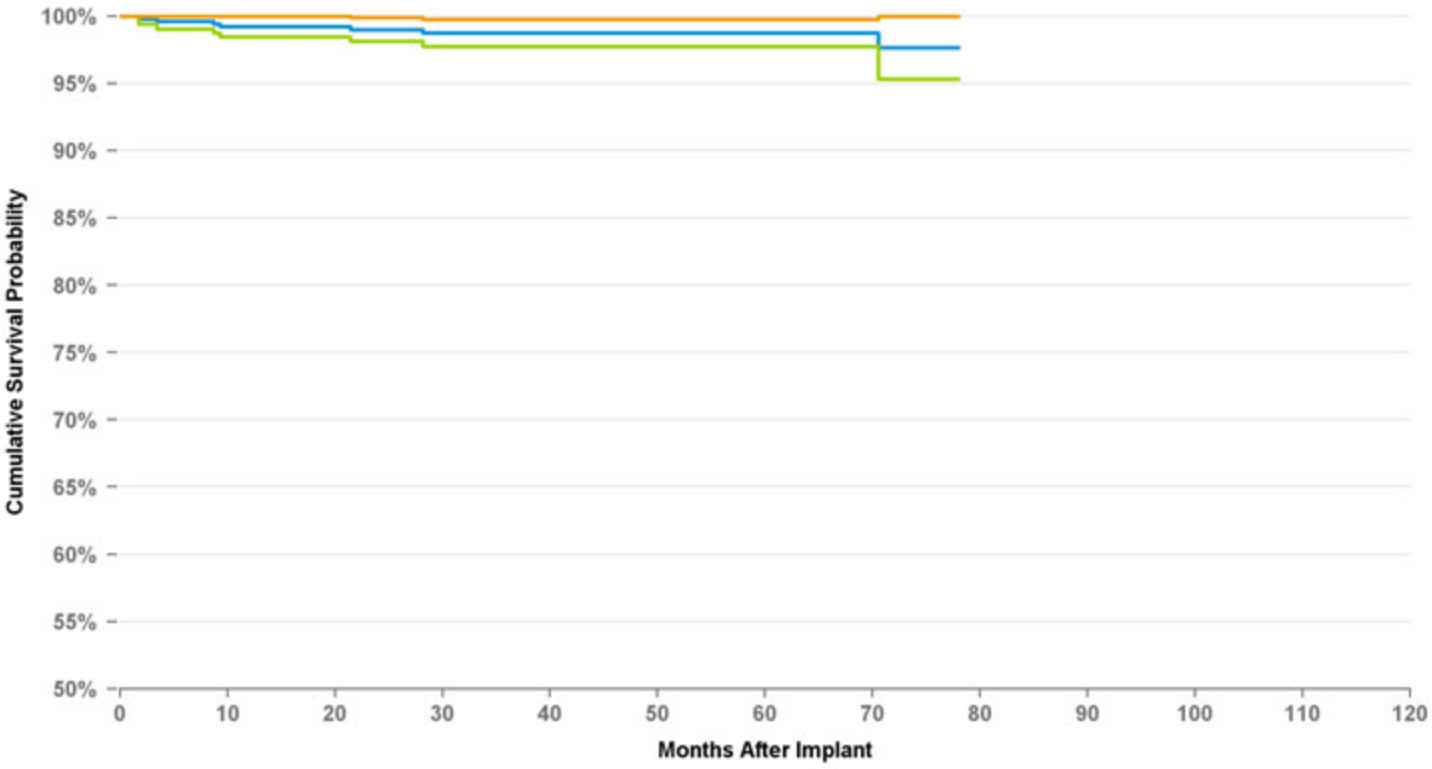
Distribution Data	
US Market Release	8/3/2005
CE Approval Date	1/31/2003
Registered US Implants	26,630
Estimated Active US	18,604
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	629
Cumulative Months of Follow-Up	26,910
Number of Leads Active in Study	309

Product Surveillance Registry Qualifying Complications	8
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	4
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	8
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	29
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	50
Oversensing	5
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	26
Other	3

3830, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 78 mo
%	99.2%	99.0%	98.7%	98.7%	98.7%	97.7%	97.7%
#	507	439	358	272	173	76	58

PACING LEAD

4073

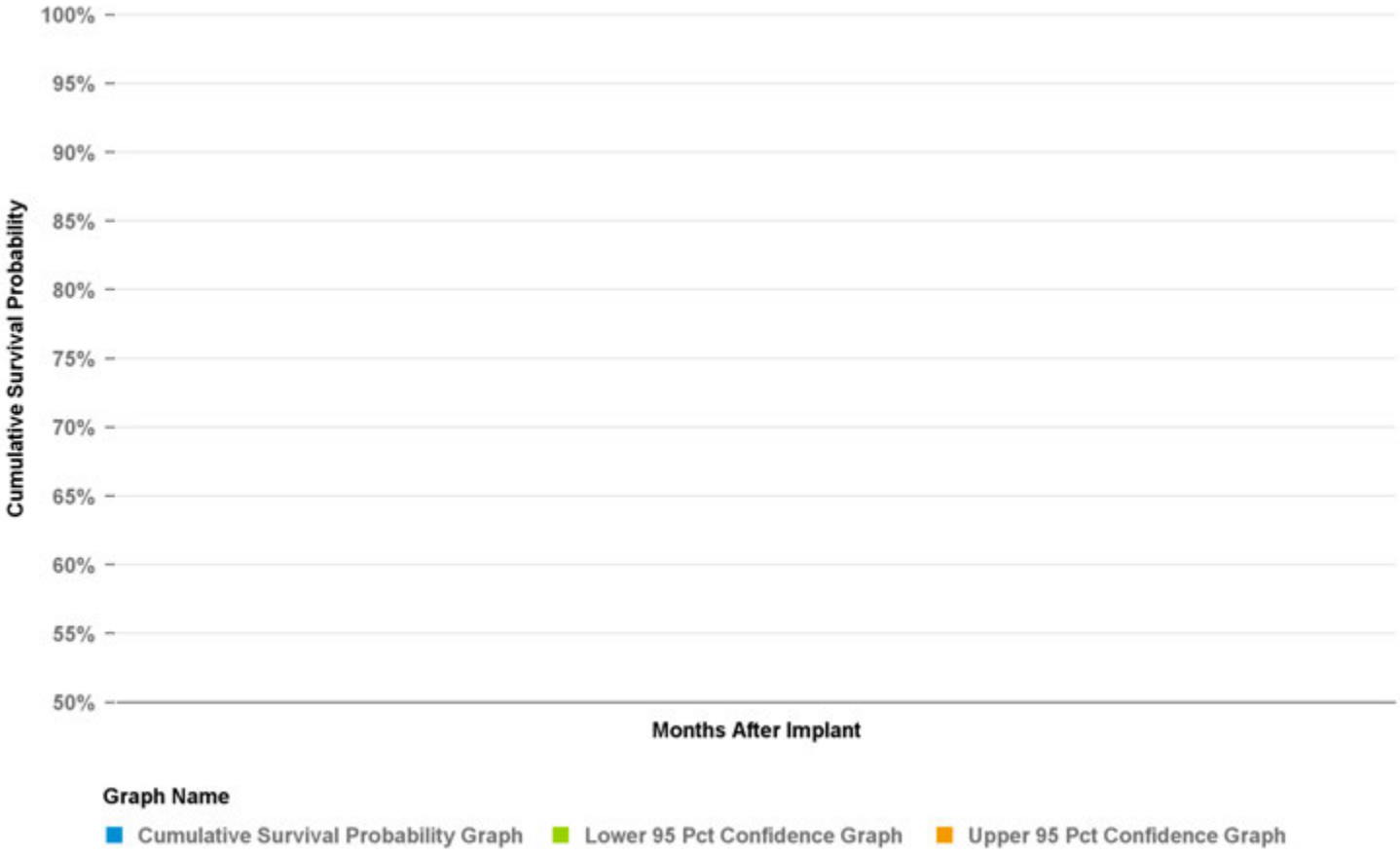
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implants	770
Estimated Active US	296
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0
Number of Leads Active in Study	0

Product Surveilance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	0

4073, Survival Curve



Years	
%	
#	

PACING LEAD

4074

ATRIAL PLACEMENT

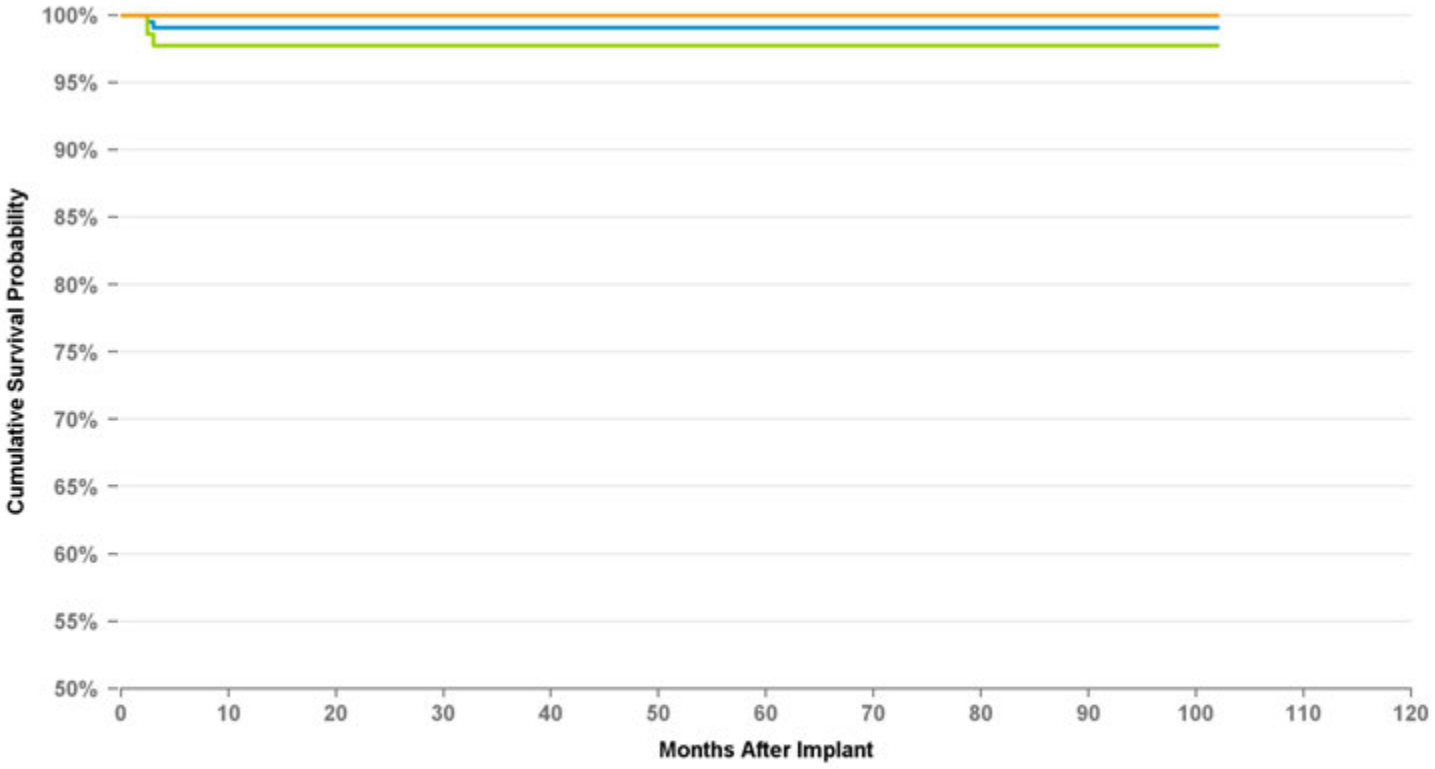
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implants	106,383
Estimated Active US	59,745
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	17,044
Number of Leads Active in Study	114

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	18
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	52
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	63
Oversensing	2
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	33
Other	0

4074, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	201	191	184	167	152	140	123	90	69

PACING LEAD

4074

VENTRICULAR PLACEMENT

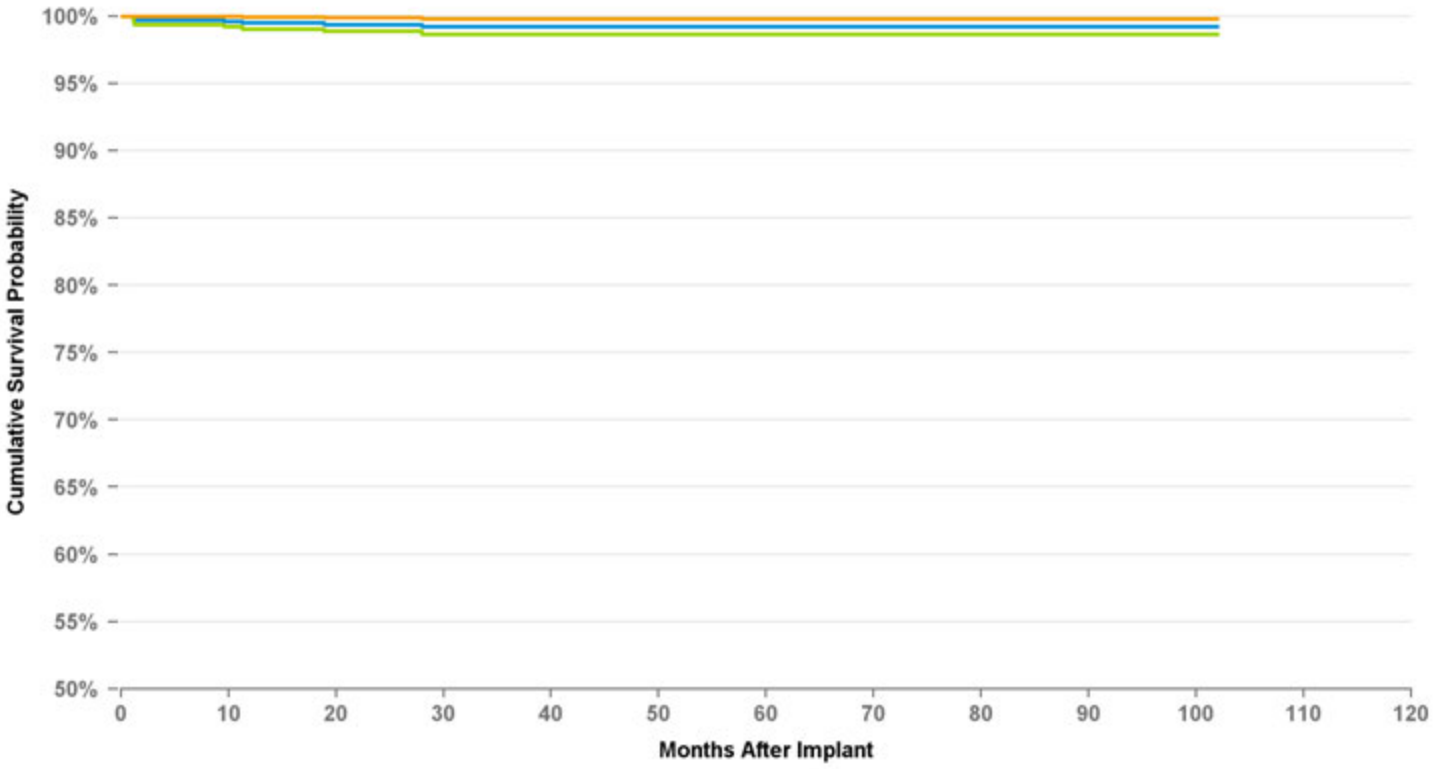
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implants	106,383
Estimated Active US	59,745
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,100
Cumulative Months of Follow-Up	49,073
Number of Leads Active in Study	476

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	18
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	52
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	63
Oversensing	2
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	33
Other	0

4074, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.5%	99.4%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%
#	937	770	576	416	298	224	166	97	69

PACING LEAD

Distribution Data	
US Market Release	2/25/2004
CE Approval Date	6/14/2004
Registered US Implants	527,089
Estimated Active US	360,778
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	3,031
Cumulative Months of Follow-Up	128,582
Number of Leads Active in Study	1,598

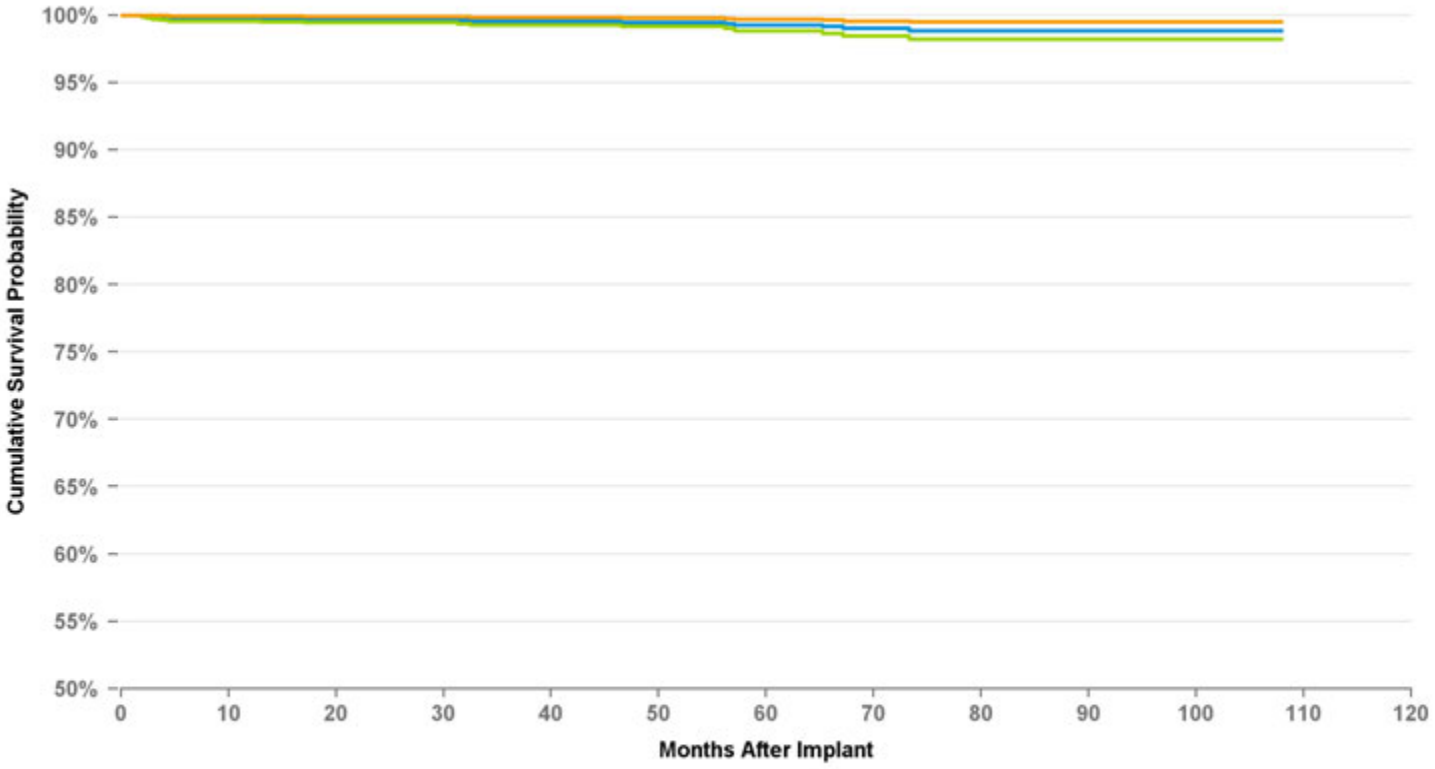
4076

Product Surveilance Registry Qualifying Complications	16
Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	78
Conductor Fracture	5
Extracardiac Stimulation	12
Failure To Capture	101
Failure To Sense	28
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	245
Oversensing	16
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	68
Crimp Weld Bond	1
Insulation Breach	84
Other	22

4076, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.8%	99.7%	99.6%	99.5%	99.3%	99.0%	98.8%	98.8%	98.8%
#	2,507	2,060	1,592	1,190	860	521	292	183	73

PACING LEAD

4076

VENTRICULAR PLACEMENT

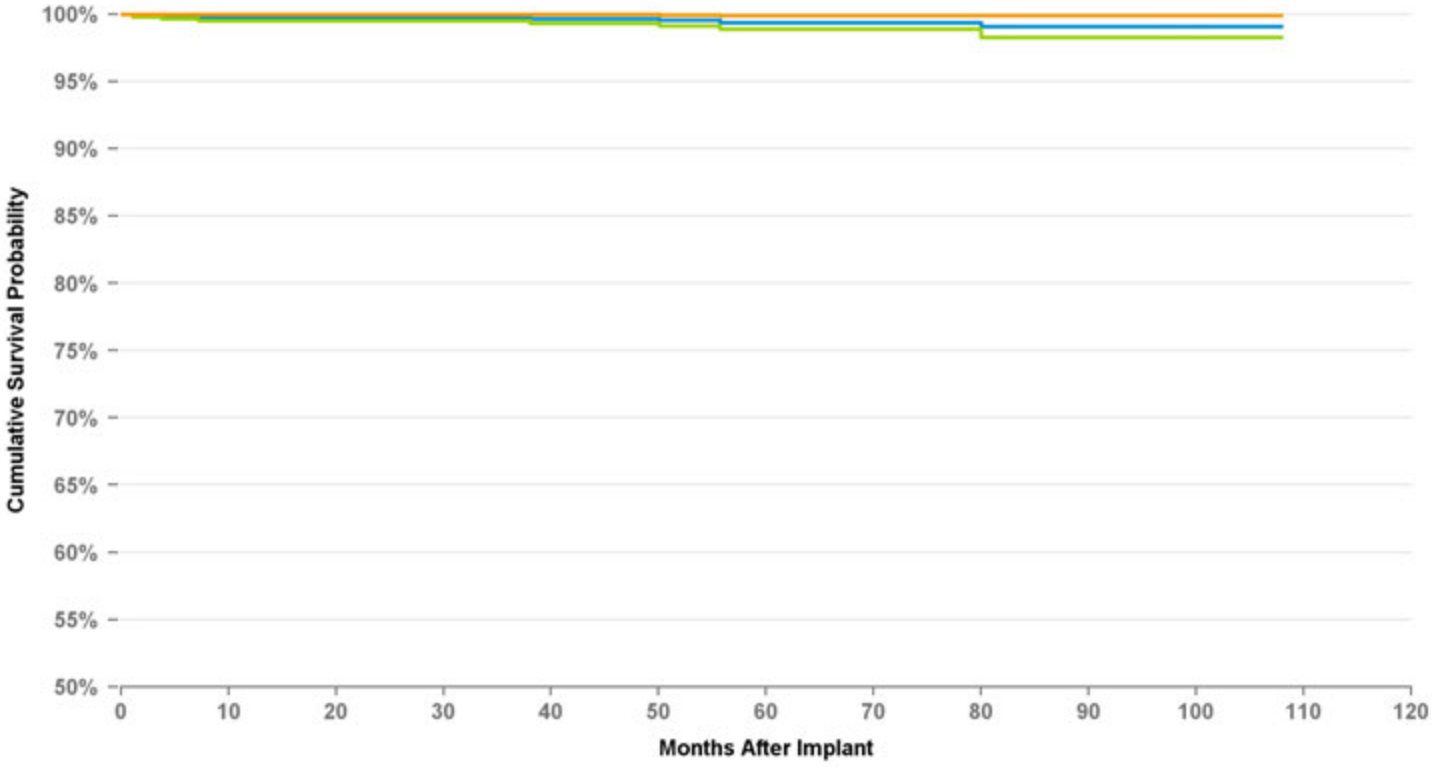
Distribution Data	
US Market Release	2/25/2004
CE Approval Date	6/14/2004
Registered US Implants	527,089
Estimated Active US	360,778
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,489
Cumulative Months of Follow-Up	76,821
Number of Leads Active in Study	572

Product Surveillance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	78
Conductor Fracture	5
Extracardiac Stimulation	12
Failure To Capture	101
Failure To Sense	28
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	245
Oversensing	16
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	68
Crimp Weld Bond	1
Insulation Breach	84
Other	22

4076, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.8%	99.8%	99.8%	99.7%	99.4%	99.4%	99.1%	99.1%	99.1%
#	1,287	1,104	930	775	596	420	266	183	84

PACING LEAD

4092

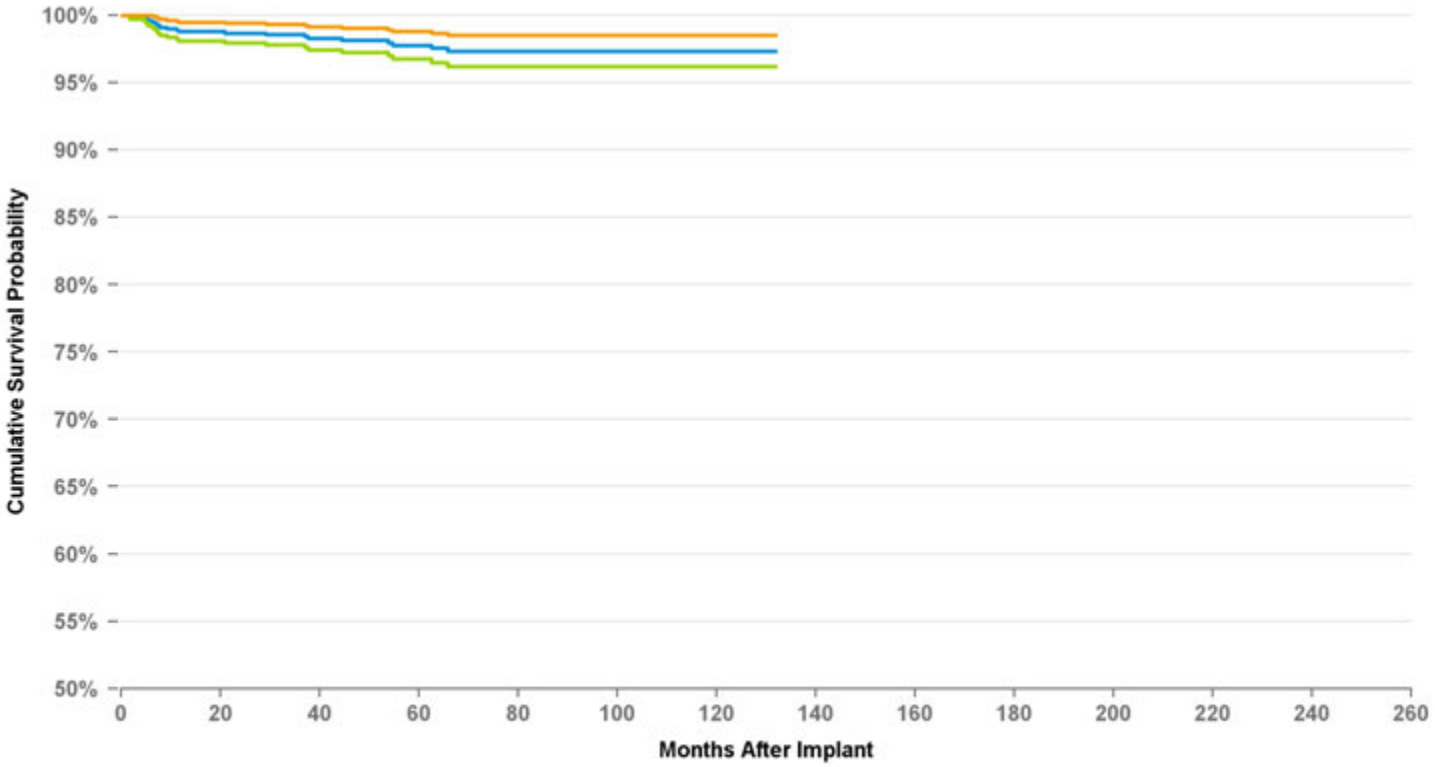
Distribution Data	
US Market Release	9/17/1998
CE Approval Date	4/15/1998
Registered US Implants	186,031
Estimated Active US	69,083
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,182
Cumulative Months of Follow-Up	66,823
Number of Leads Active in Study	36

Product Surveillance Registry Qualifying Complications	21
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	11
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	4
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	3
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	34
Oversensing	1
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	15
Crimp Weld Bond	0
Insulation Breach	64
Other	2

4092, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.8%	98.7%	98.5%	98.1%	97.8%	97.3%	97.3%	97.3%	97.3%	97.3%	97.3%
#	939	829	728	621	504	391	319	259	210	130	66

PACING LEAD

4568

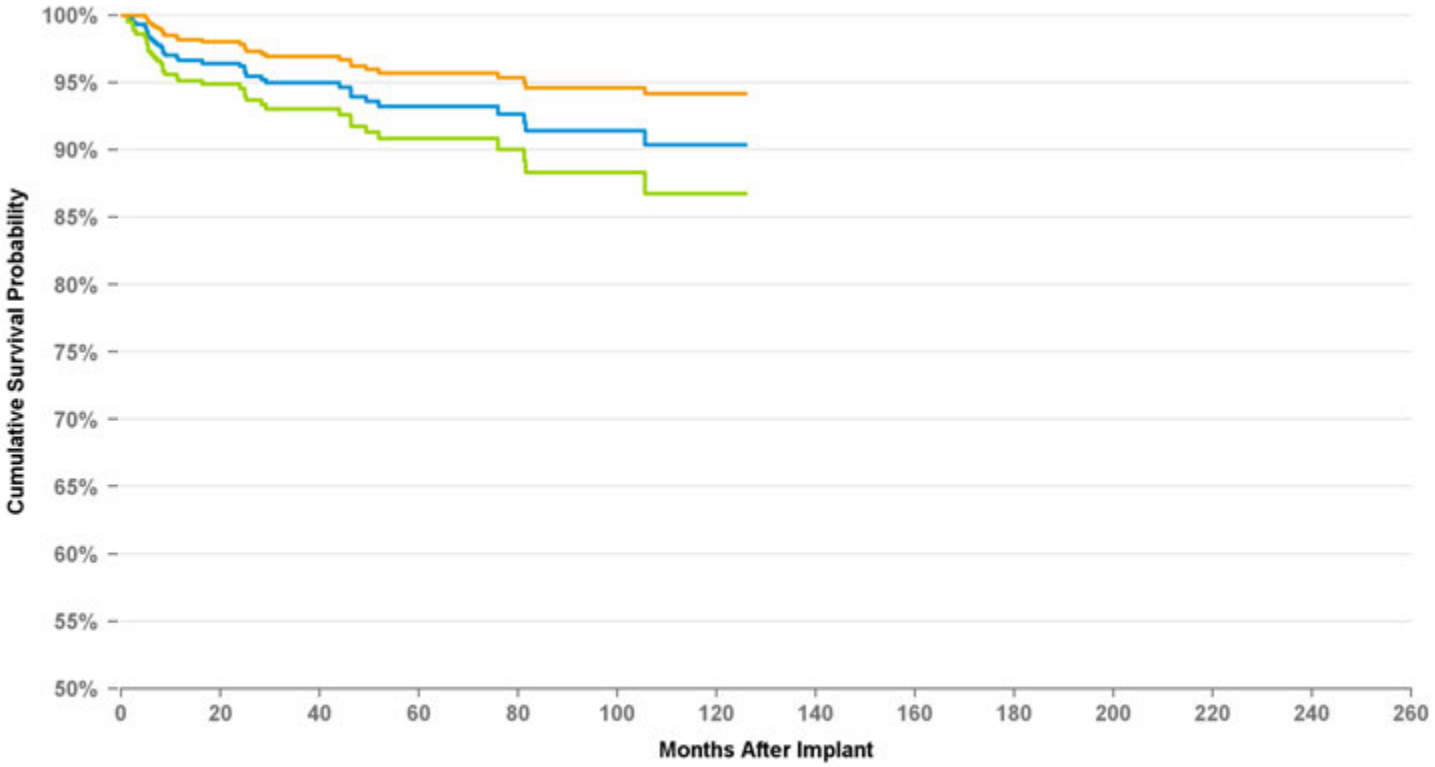
Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implants	69,189
Estimated Active US	15,347
Product Characteristics	
Fixation Type	J-shape, screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	671
Cumulative Months of Follow-Up	31,987
Number of Leads Active in Study	10

Product Surveillance Registry Qualifying Complications	38
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	19
Failure To Sense	4
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	9
Medical Judgment	1
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	3
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	4
Oversensing	1
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	107
Other	52

4568, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	96.6%	96.2%	95.0%	94.0%	93.2%	93.2%	91.4%	91.4%	90.4%	90.4%	90.4%
#	493	419	327	276	228	173	138	105	84	63	51

PACING LEAD

4574

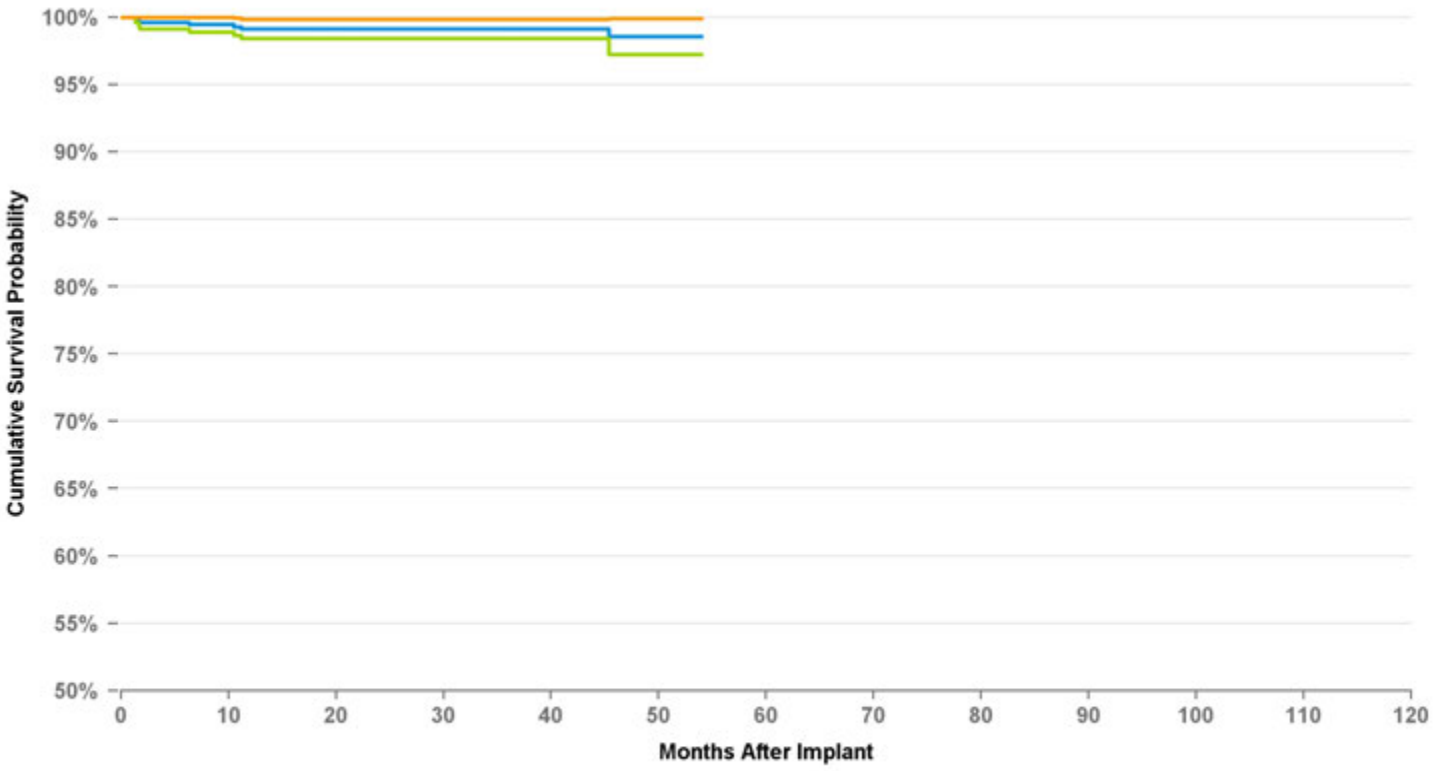
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implants	73,014
Estimated Active US	44,339
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	905
Cumulative Months of Follow-Up	23,484
Number of Leads Active in Study	589

Product Surveillance Registry Qualifying Complications	8
Cardiac Perforation	0
Conductor Fracture	2
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	29
Failure To Sense	10
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	76
Oversensing	1
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	10
Other	0

4574, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	at 54 mo
%	99.1%	99.1%	99.1%	98.5%	98.5%
#	628	418	279	136	87

PACING LEAD

4592

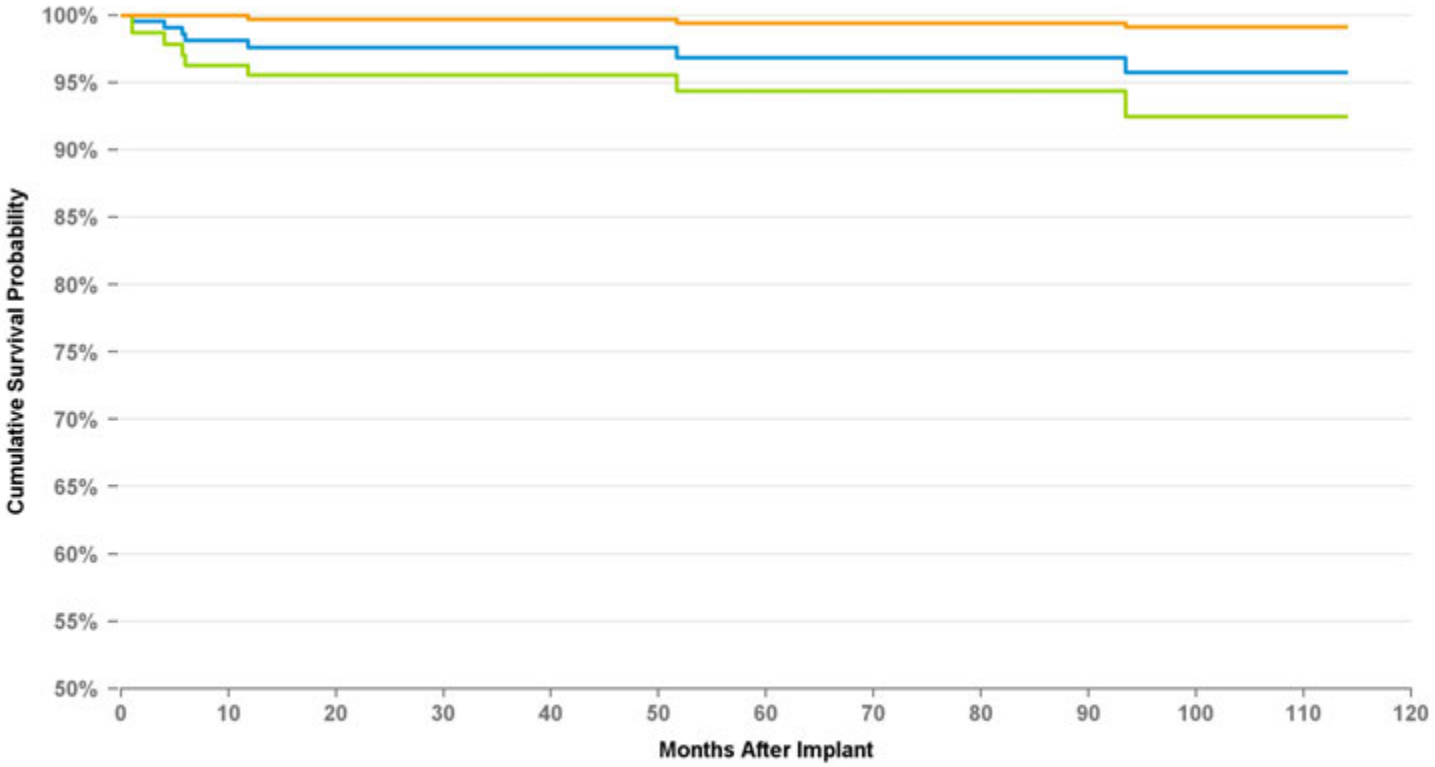
Distribution Data	
US Market Release	10/5/1998
CE Approval Date	4/15/1998
Registered US Implants	89,244
Estimated Active US	34,877
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	342
Cumulative Months of Follow-Up	17,469
Number of Leads Active in Study	60

Product Surveillance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	8
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	36
Oversensing	2
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	8
Crimp Weld Bond	0
Insulation Breach	26
Other	1

4592, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	97.6%	97.6%	97.6%	97.6%	96.9%	96.9%	96.9%	95.7%	95.7%	95.7%
#	229	196	164	149	121	106	83	74	62	54

PACING LEAD

Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implants	99,230
Estimated Active US	34,885
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	426
Cumulative Months of Follow-Up	37,288
Number of Leads Active in Study	84

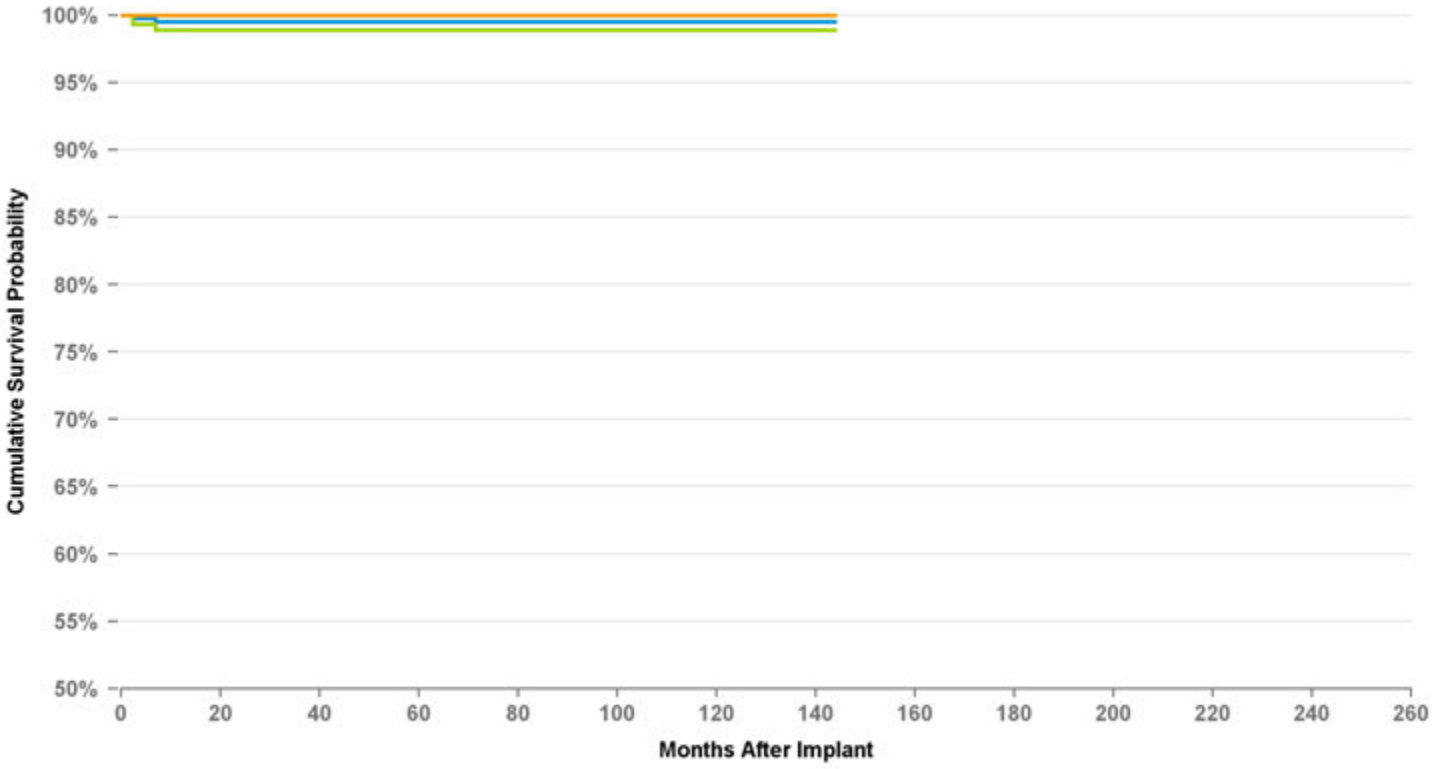
5054

Product Surveillance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	29
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	13
Crimp Weld Bond	1
Insulation Breach	35
Other	3

5054, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
#	412	392	358	322	289	252	219	185	152	121	92	65

PACING LEAD

5054

VENTRICULAR PLACEMENT

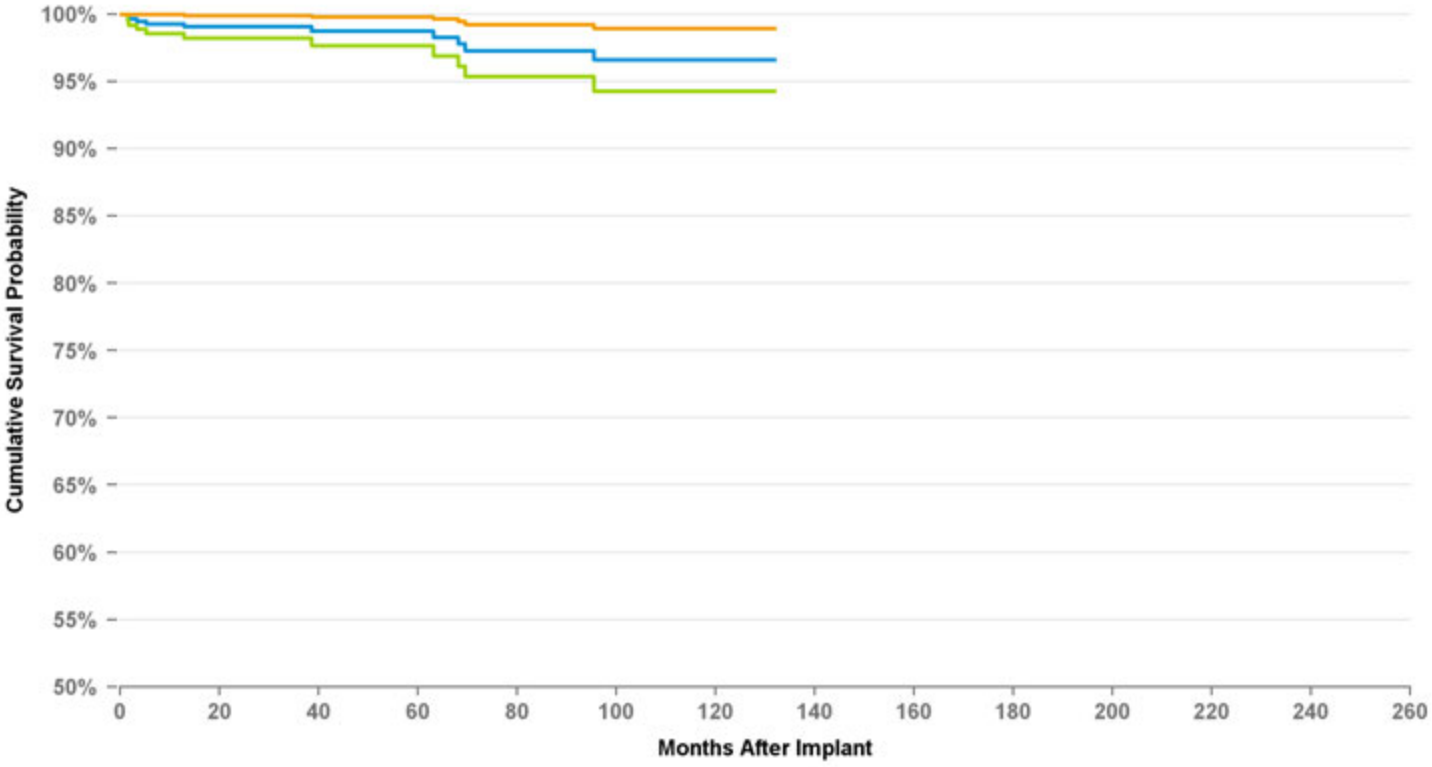
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implants	99,230
Estimated Active US	34,885
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	983
Cumulative Months of Follow-Up	32,652
Number of Leads Active in Study	40

Product Surveillance Registry Qualifying Complications	10
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	29
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	13
Crimp Weld Bond	1
Insulation Breach	35
Other	3

5054, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.3%	99.1%	99.1%	98.7%	98.7%	97.3%	97.3%	96.6%	96.6%	96.6%	96.6%
#	480	391	302	261	225	187	162	137	102	81	58

PACING LEAD

5068

ATRIAL PLACEMENT

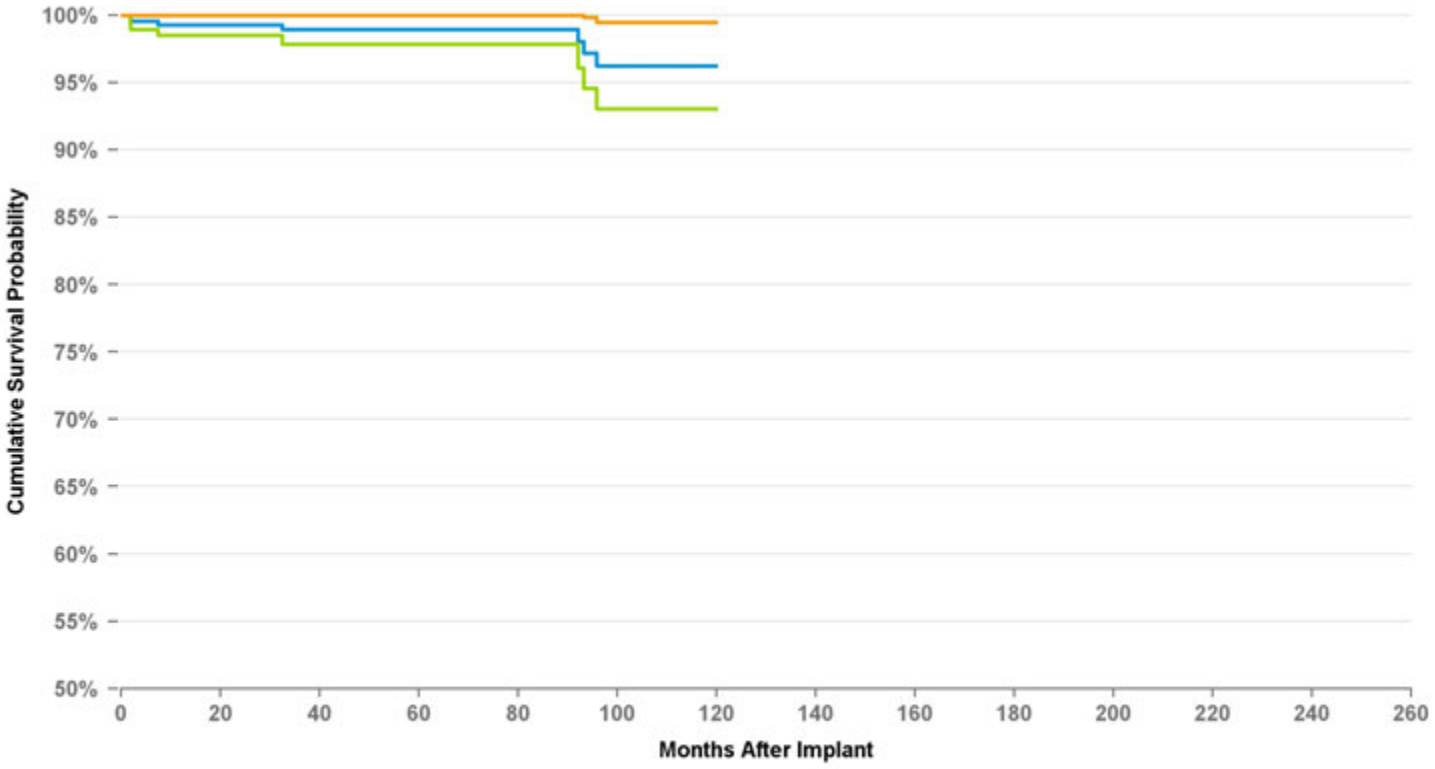
Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implants	102,325
Estimated Active US	21,400
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	985
Cumulative Months of Follow-Up	27,587
Number of Leads Active in Study	26

Product Surveillance Registry Qualifying Complications	8
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	18
Conductor Fracture	4
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	5
Impedance Abnormal	1
Insulation Breach	1
Lead Dislodgement	20
Oversensing	1
Unspecified	7
USA Returned Product Analysis	
Conductor Fracture	47
Crimp Weld Bond	2
Insulation Breach	64
Other	82

5068, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.3%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	96.2%	96.2%	96.2%
#	363	316	261	228	195	156	129	99	66	56

PACING LEAD

5068

VENTRICULAR PLACEMENT

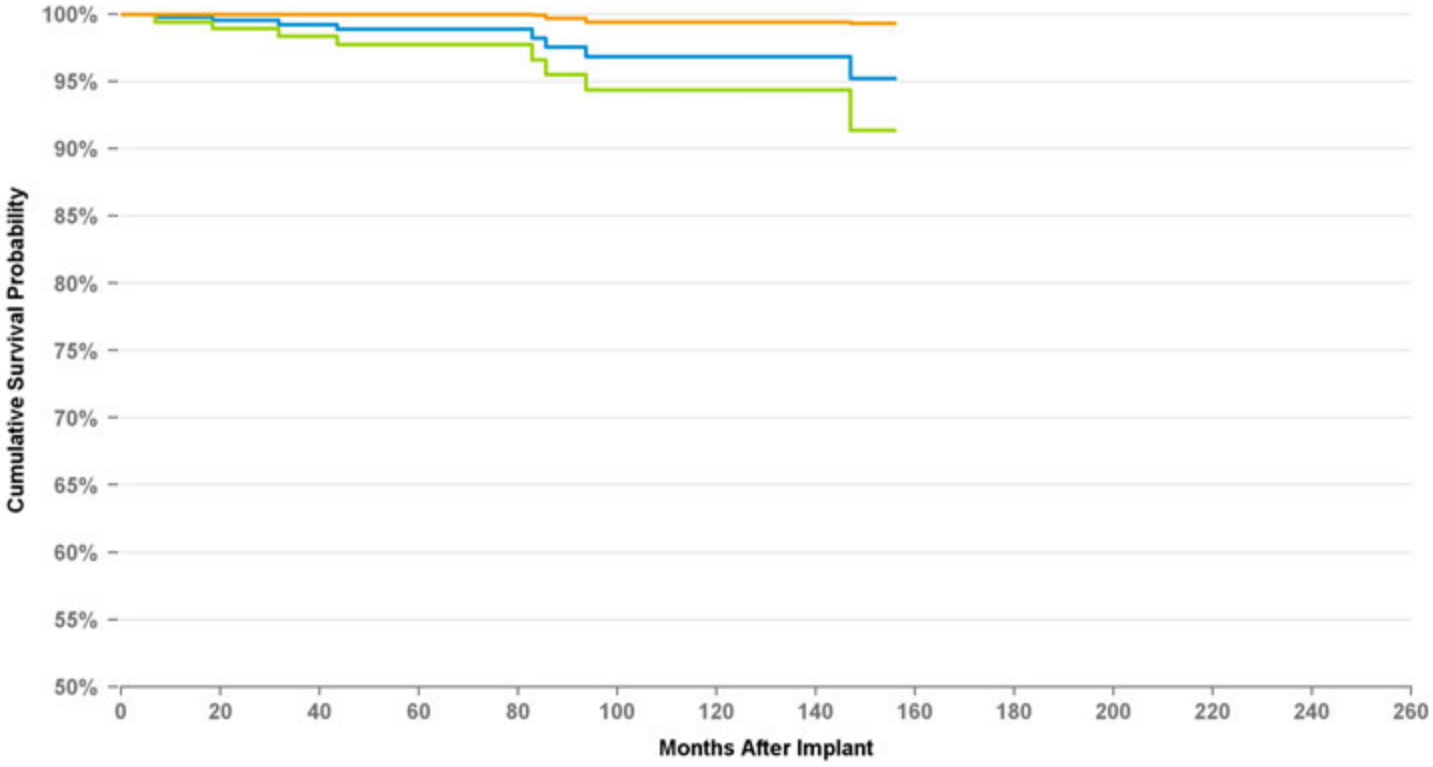
Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implants	102,325
Estimated Active US	21,400
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,372
Cumulative Months of Follow-Up	33,147
Number of Leads Active in Study	39

Product Surveillance Registry Qualifying Complications	9
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	18
Conductor Fracture	4
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	5
Impedance Abnormal	1
Insulation Breach	1
Lead Dislodgement	20
Oversensing	1
Unspecified	7
USA Returned Product Analysis	
Conductor Fracture	47
Crimp Weld Bond	2
Insulation Breach	64
Other	82

5068, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.8%	99.6%	99.2%	98.9%	98.9%	98.9%	98.2%	96.8%	96.8%	96.8%	96.8%	96.8%	95.2%
#	453	363	291	246	221	187	150	125	104	88	72	60	51

PACING LEAD

5072

Distribution Data	
US Market Release	6/5/1998
CE Approval Date	9/25/1997
Registered US Implants	10,053
Estimated Active US	3,225
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

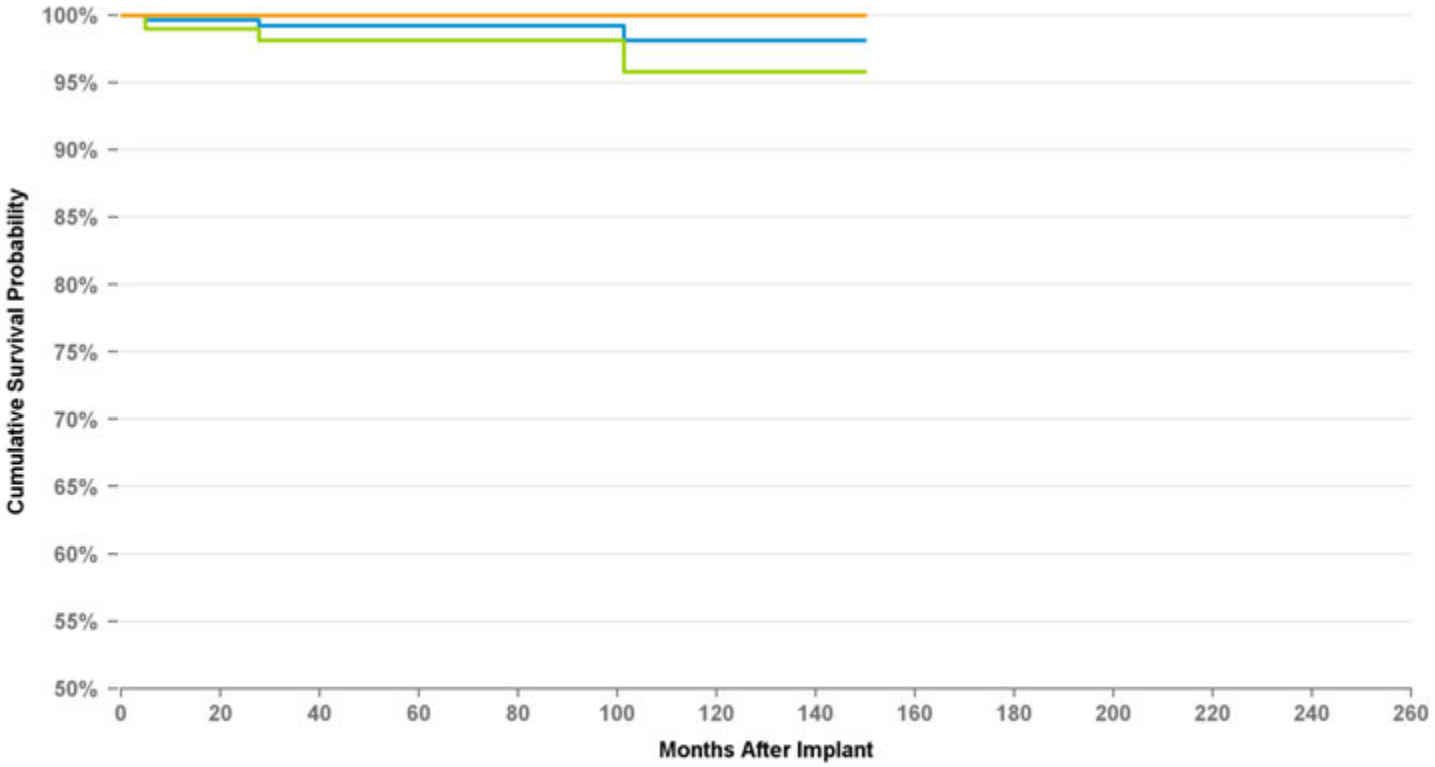
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	514
Cumulative Months of Follow-Up	23,107
Number of Leads Active in Study	13

Product Surveillance Registry Qualifying Complications	3
Cardiac Perforation	1
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	2
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	9
Other	0

5072, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.7%	99.7%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.1%	98.1%	98.1%	98.1%	98.1%
#	263	234	217	192	157	136	109	92	81	72	63	54	52

PACING LEAD

Distribution Data	
US Market Release	8/31/2000
CE Approval Date	8/12/1999
Registered US Implants	2,034,856
Estimated Active US	1,267,531
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	6,802
Cumulative Months of Follow-Up	253,638
Number of Leads Active in Study	3,548

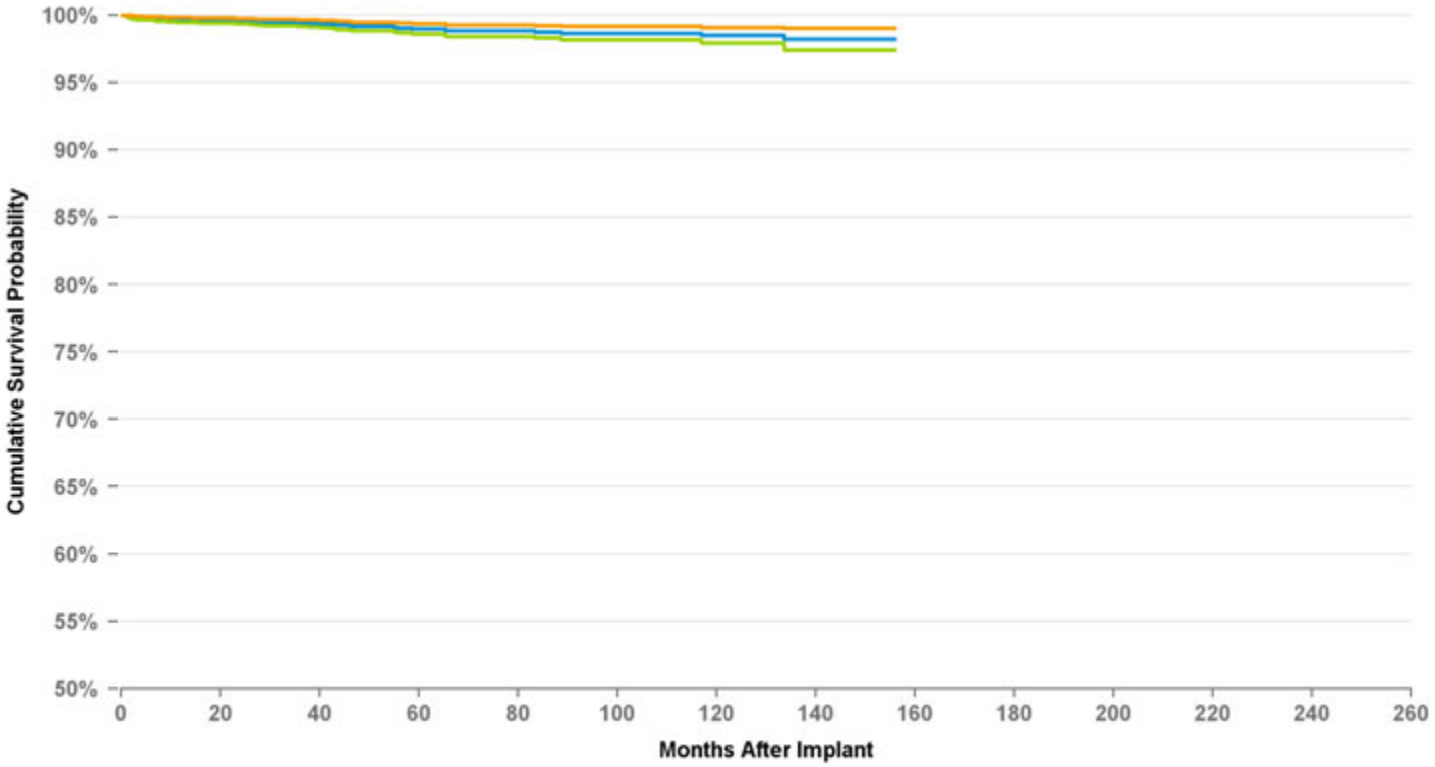
5076

Product Surveillance Registry Qualifying Complications	40
Cardiac Perforation	2
Conductor Fracture	7
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	7
Failure To Sense	2
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	11
Medical Judgment	0
Other Complication	2
Oversensing	2
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	517
Conductor Fracture	19
Extracardiac Stimulation	38
Failure To Capture	583
Failure To Sense	136
Impedance Abnormal	41
Insulation Breach	8
Lead Dislodgement	1,530
Oversensing	109
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	702
Crimp Weld Bond	0
Insulation Breach	699
Other	205

5076, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.6%	99.6%	99.4%	99.1%	99.0%	98.8%	98.8%	98.7%	98.7%	98.5%	98.5%	98.2%	98.2%
#	4,586	3,634	2,628	1,945	1,522	1,130	868	709	544	372	241	131	65

PACING LEAD

5076

VENTRICULAR PLACEMENT

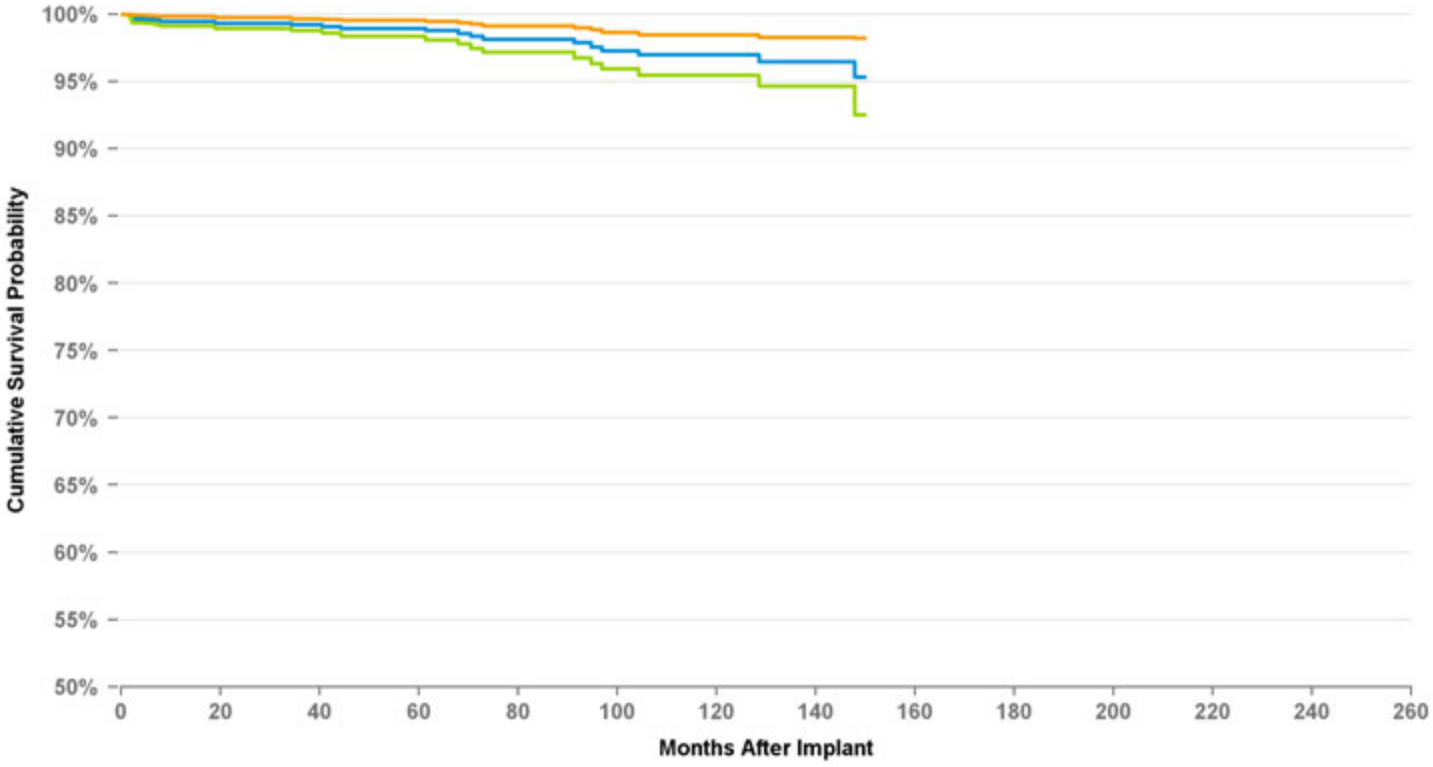
Distribution Data	
US Market Release	8/31/2000
CE Approval Date	8/12/1999
Registered US Implants	2,034,856
Estimated Active US	1,267,531
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	2,301
Cumulative Months of Follow-Up	92,556
Number of Leads Active in Study	652

Product Surveillance Registry Qualifying Complications	24
Cardiac Perforation	1
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	9
Failure To Sense	1
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	1
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	517
Conductor Fracture	19
Extracardiac Stimulation	38
Failure To Capture	583
Failure To Sense	136
Impedance Abnormal	41
Insulation Breach	8
Lead Dislodgement	1,530
Oversensing	109
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	702
Crimp Weld Bond	0
Insulation Breach	699
Other	205

5076, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.2%	99.0%	99.0%	98.4%	98.1%	97.6%	97.0%	97.0%	96.4%	96.4%	95.3%
#	1,613	1,283	902	661	541	434	357	291	230	182	137	85	63

PACING LEAD

Distribution Data	
US Market Release	2/8/2011
CE Approval Date	1/21/2009
Registered US Implants	208,046
Estimated Active US	188,247
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	3,069
Cumulative Months of Follow-Up	99,896
Number of Leads Active in Study	1,907

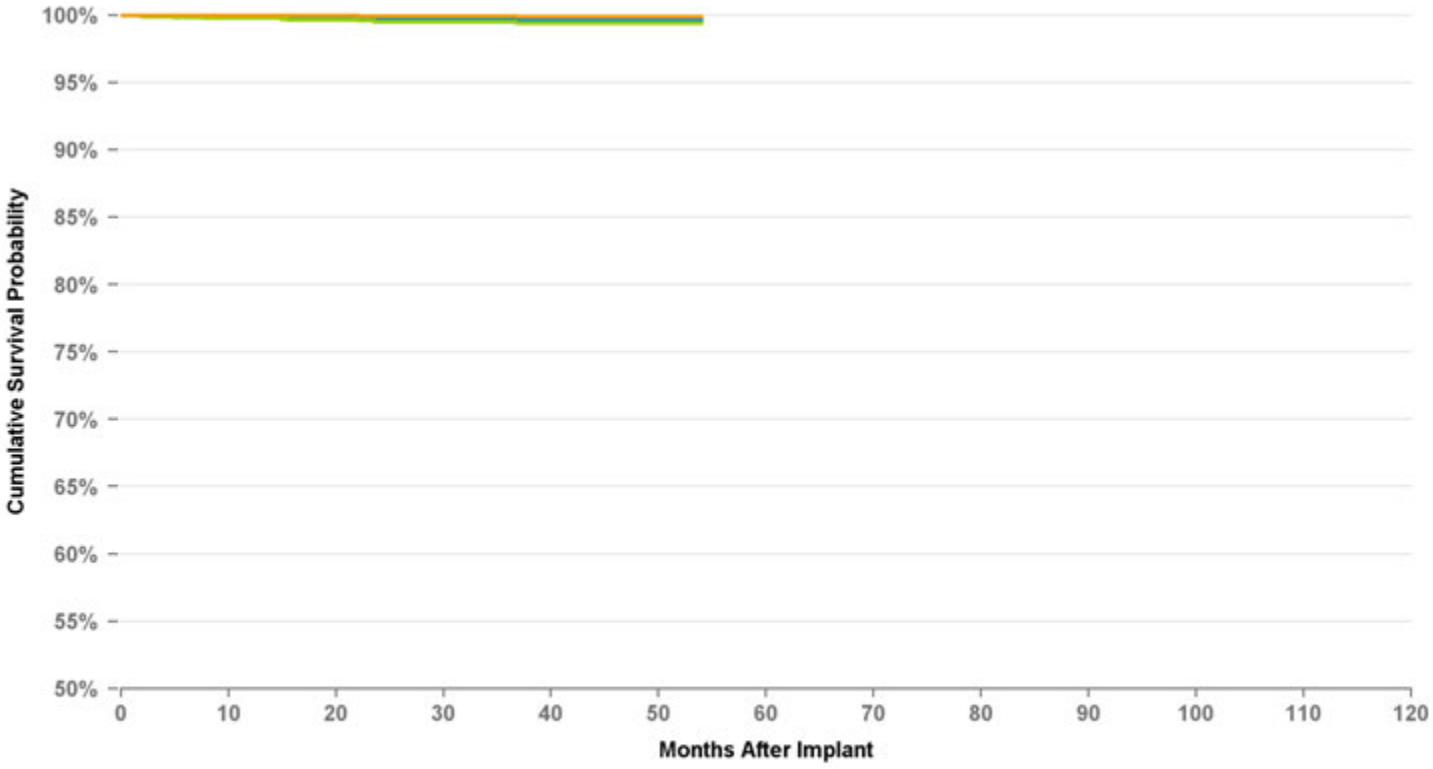
5086MRI

Product Surveillance Registry Qualifying Complications	8
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	212
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	140
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	307
Oversensing	30
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	25
Crimp Weld Bond	0
Insulation Breach	66
Other	12

5086MRI, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	at 54 mo
%	99.9%	99.7%	99.7%	99.7%	99.7%
#	2,648	2,187	1,547	471	118

PACING LEAD

Distribution Data	
US Market Release	2/8/2011
CE Approval Date	1/21/2009
Registered US Implants	208,046
Estimated Active US	188,247
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	3,033
Cumulative Months of Follow-Up	99,351
Number of Leads Active in Study	1,875

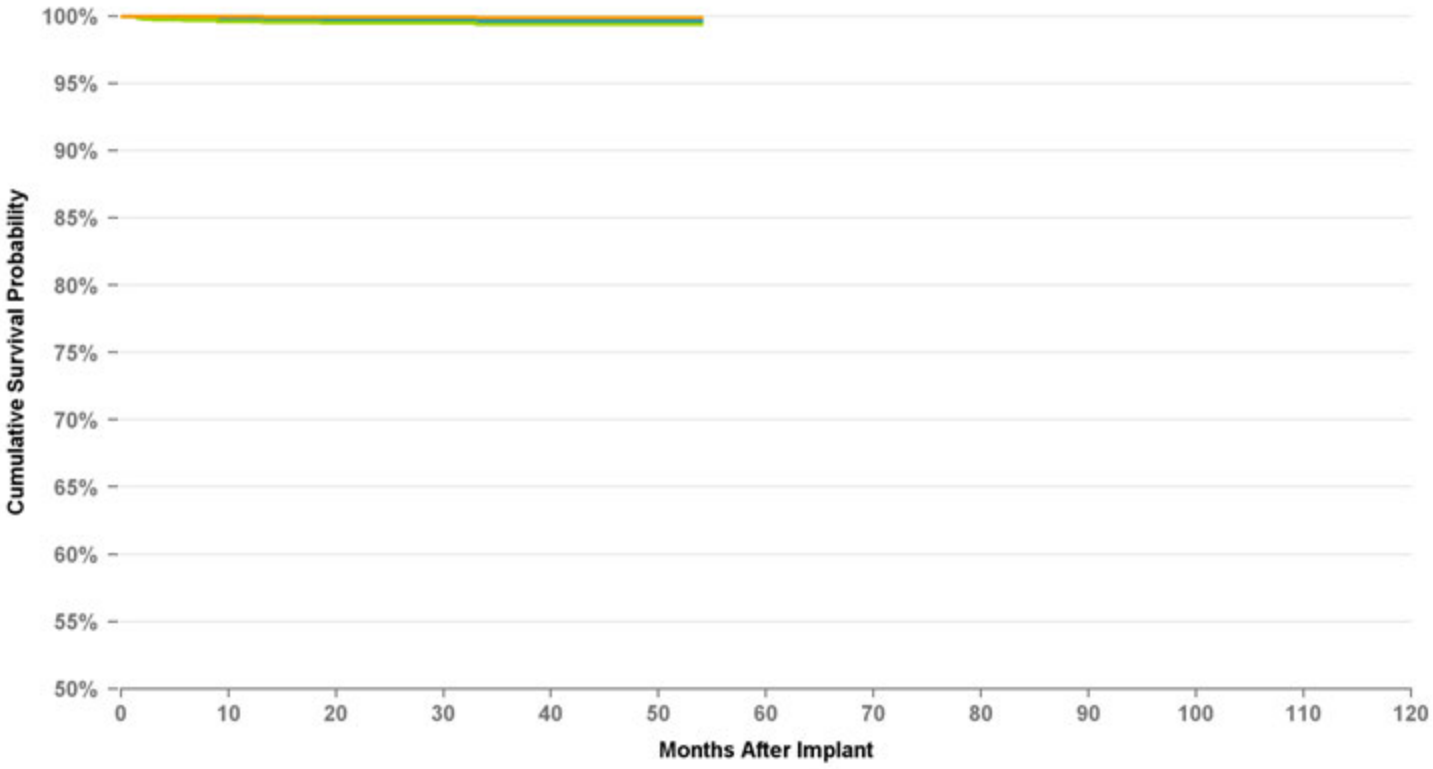
5086MRI

Product Surveillance Registry Qualifying Complications	9
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	1
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

VENTRICULAR PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	212
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	140
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	307
Oversensing	30
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	25
Crimp Weld Bond	0
Insulation Breach	66
Other	12

5086MRI, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	at 54 mo
%	99.8%	99.7%	99.7%	99.7%	99.7%
#	2,639	2,175	1,536	464	114

PACING LEAD

5092

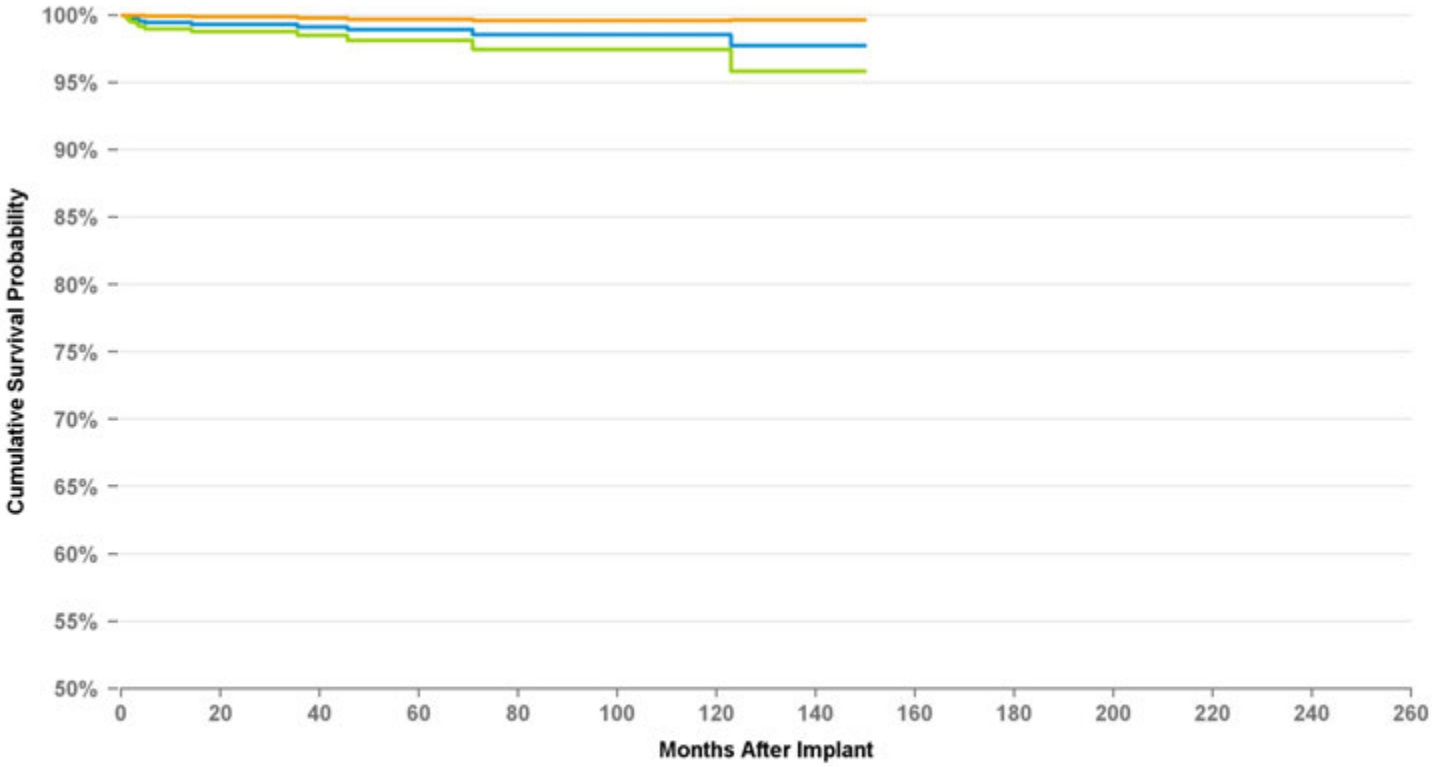
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	9/25/1997
Registered US Implants	140,656
Estimated Active US	54,173
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,205
Cumulative Months of Follow-Up	51,911
Number of Leads Active in Study	43

Product Surveillance Registry Qualifying Complications	10
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	49
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	71
Oversensing	1
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	19
Crimp Weld Bond	0
Insulation Breach	47
Other	3

5092, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.7%	97.7%	97.7%
#	823	657	516	413	321	252	207	163	136	117	94	69	58

PACING LEAD

5554

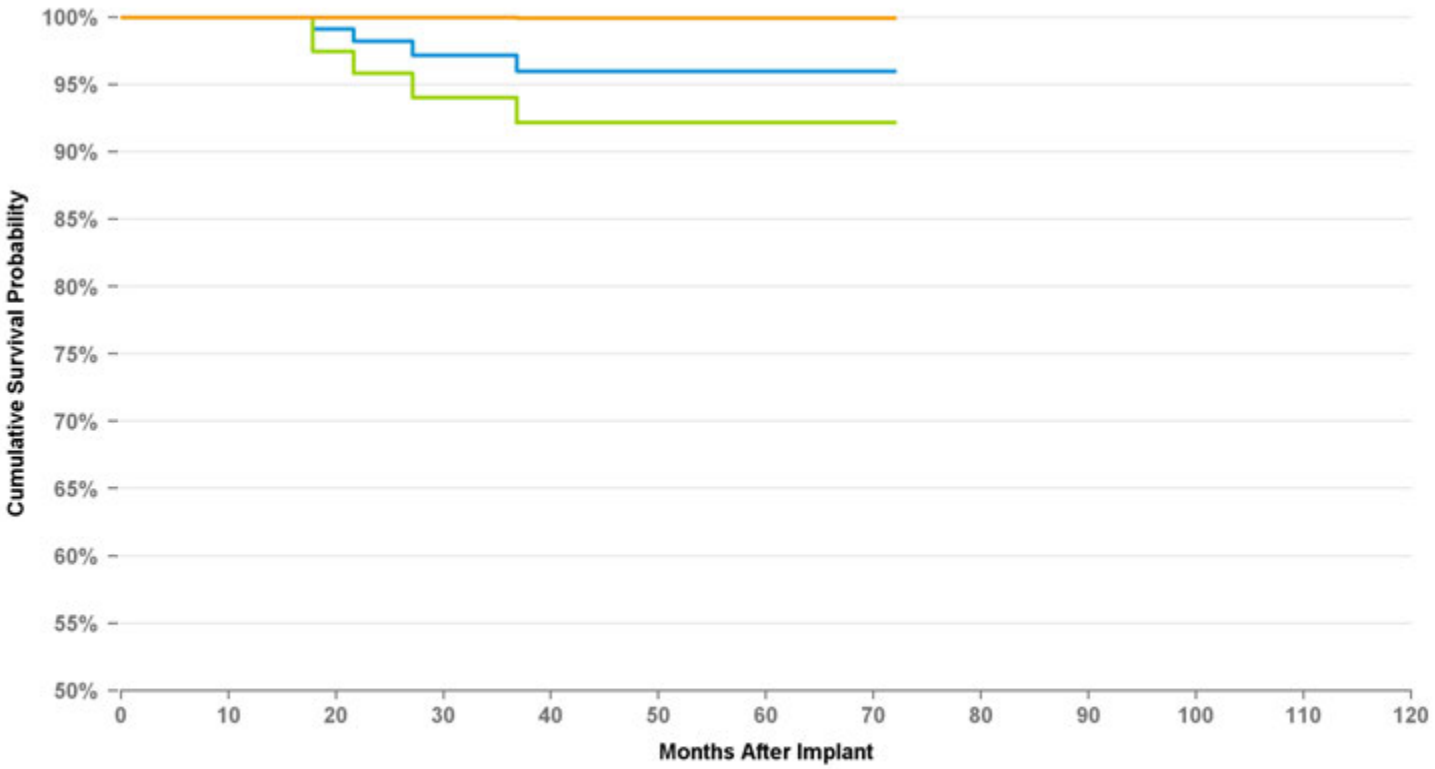
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implants	64,294
Estimated Active US	25,016
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	358
Cumulative Months of Follow-Up	8,530
Number of Leads Active in Study	9

Product Surveillance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	37
Oversensing	0
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	29
Other	2

5554, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	at 72 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%
#	151	113	87	76	59	50

PACING LEAD

5592

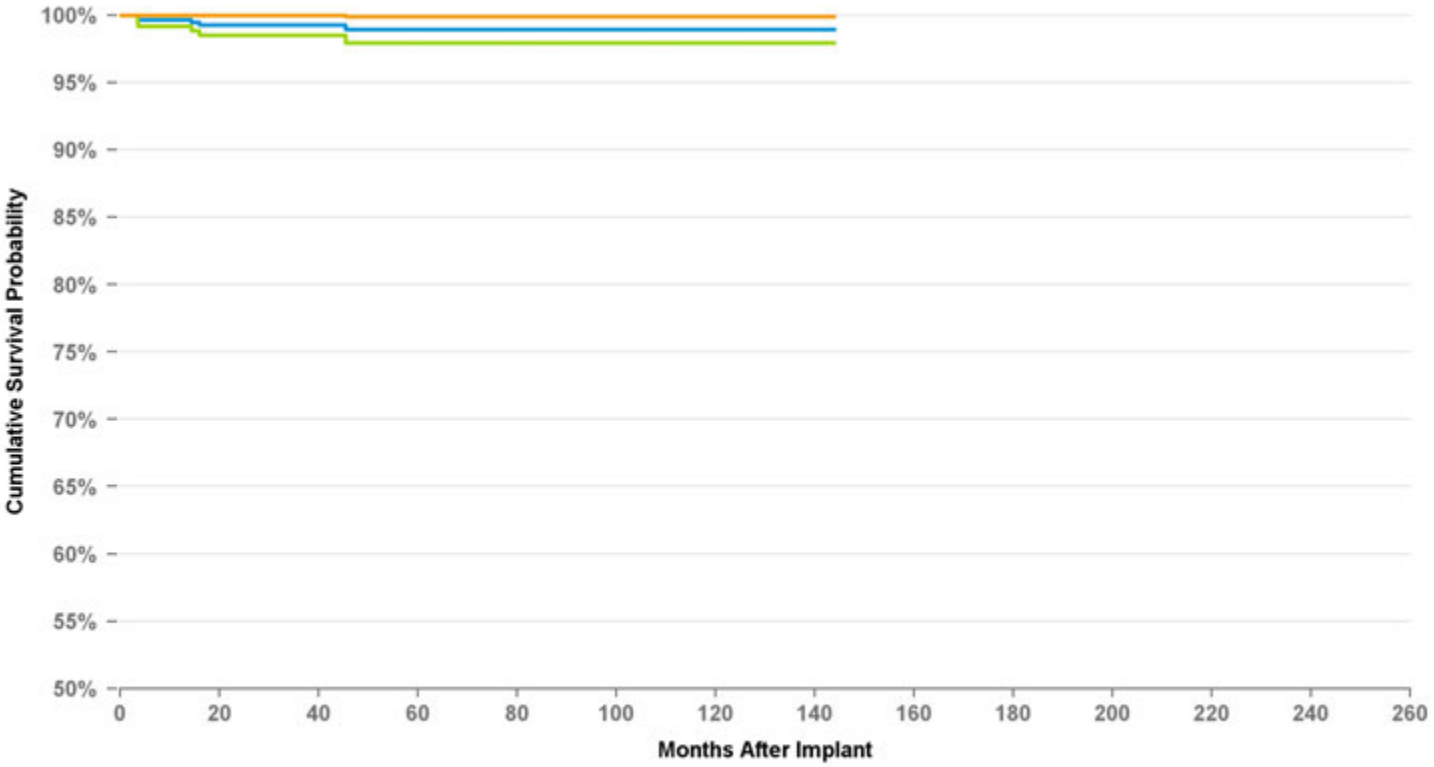
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	9/25/1997
Registered US Implants	37,003
Estimated Active US	17,341
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	706
Cumulative Months of Follow-Up	35,785
Number of Leads Active in Study	49

Product Surveillance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	41
Oversensing	1
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	4
Other	1

5592, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.6%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	531	435	347	291	233	180	148	130	109	92	78	53

PACING LEAD

5594

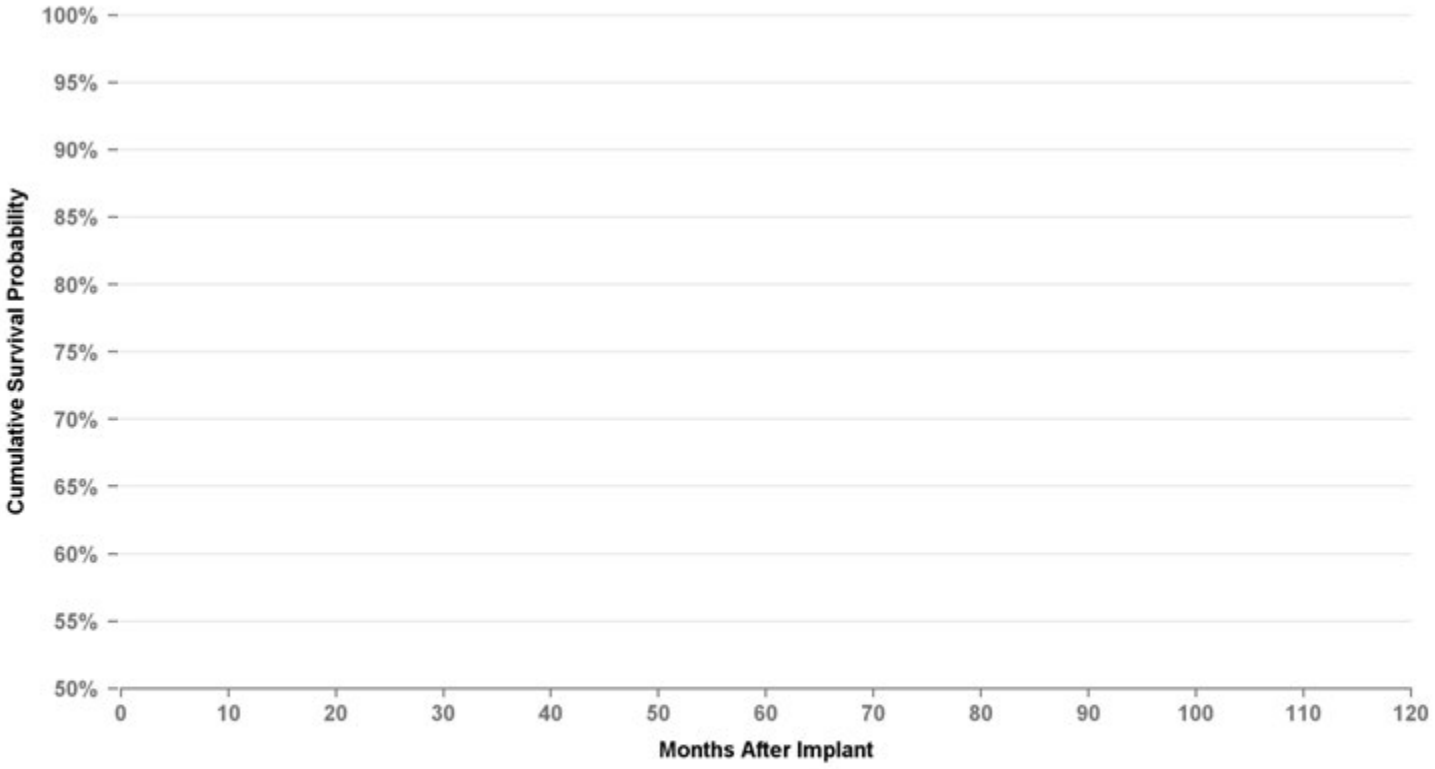
Distribution Data	
US Market Release	6/25/2001
CE Approval Date	3/23/2001
Registered US Implants	17,522
Estimated Active US	9,853
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	28
Cumulative Months of Follow-Up	2,003
Number of Leads Active in Study	11

Product Surveillance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	14
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	12
Other	1

5594, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	
%	
#	

PACING LEAD

6940

Distribution Data	
US Market Release	10/9/1998
CE Approval Date	
Registered US Implants	25,368
Estimated Active US	5,454
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

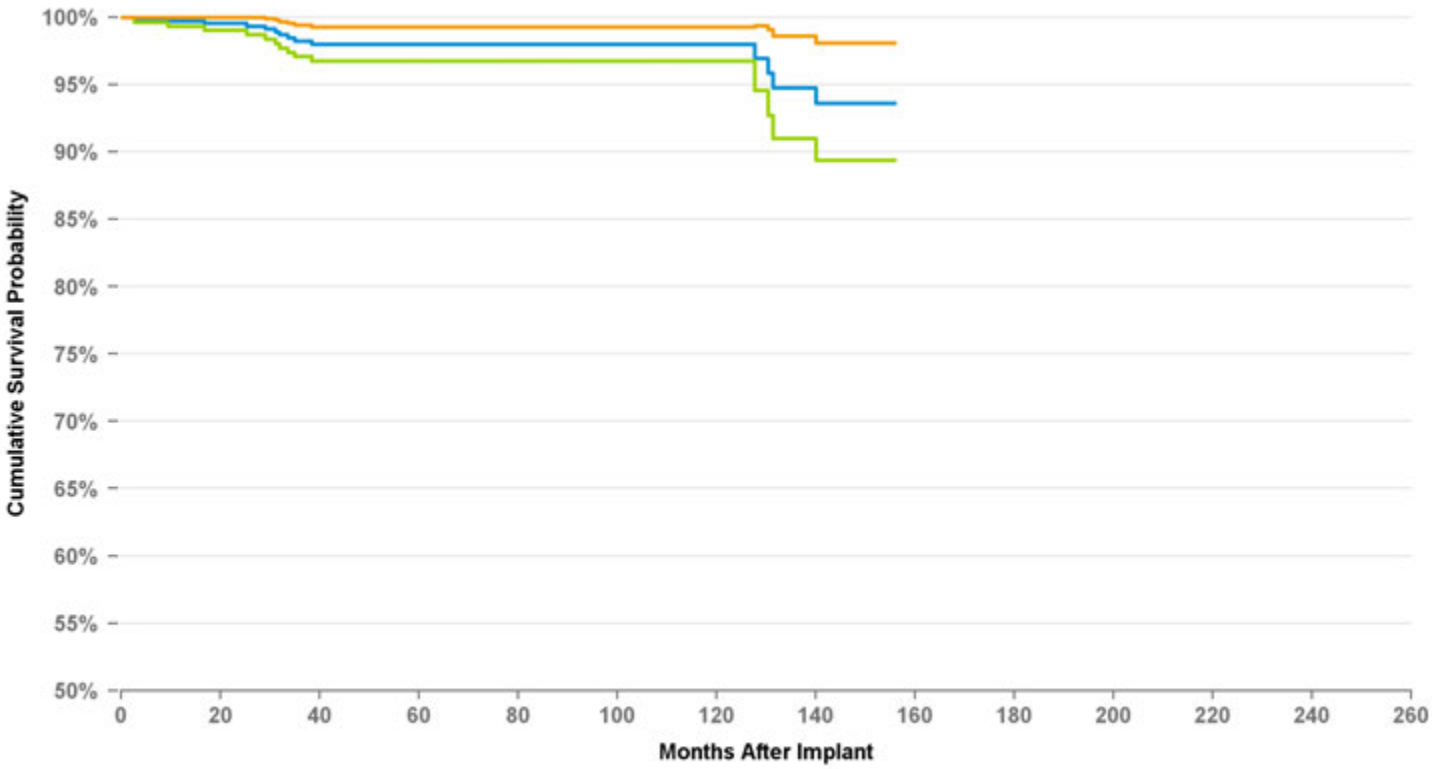
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	847
Cumulative Months of Follow-Up	43,633
Number of Leads Active in Study	34

Product Surveillance Registry Qualifying Complications	14
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	6
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	20
Other	12

6940, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.7%	99.5%	98.2%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	94.7%	93.6%	93.6%
#	644	527	424	347	276	218	188	151	125	96	80	70	52

EPI MYOCARDIAL LEAD 4965

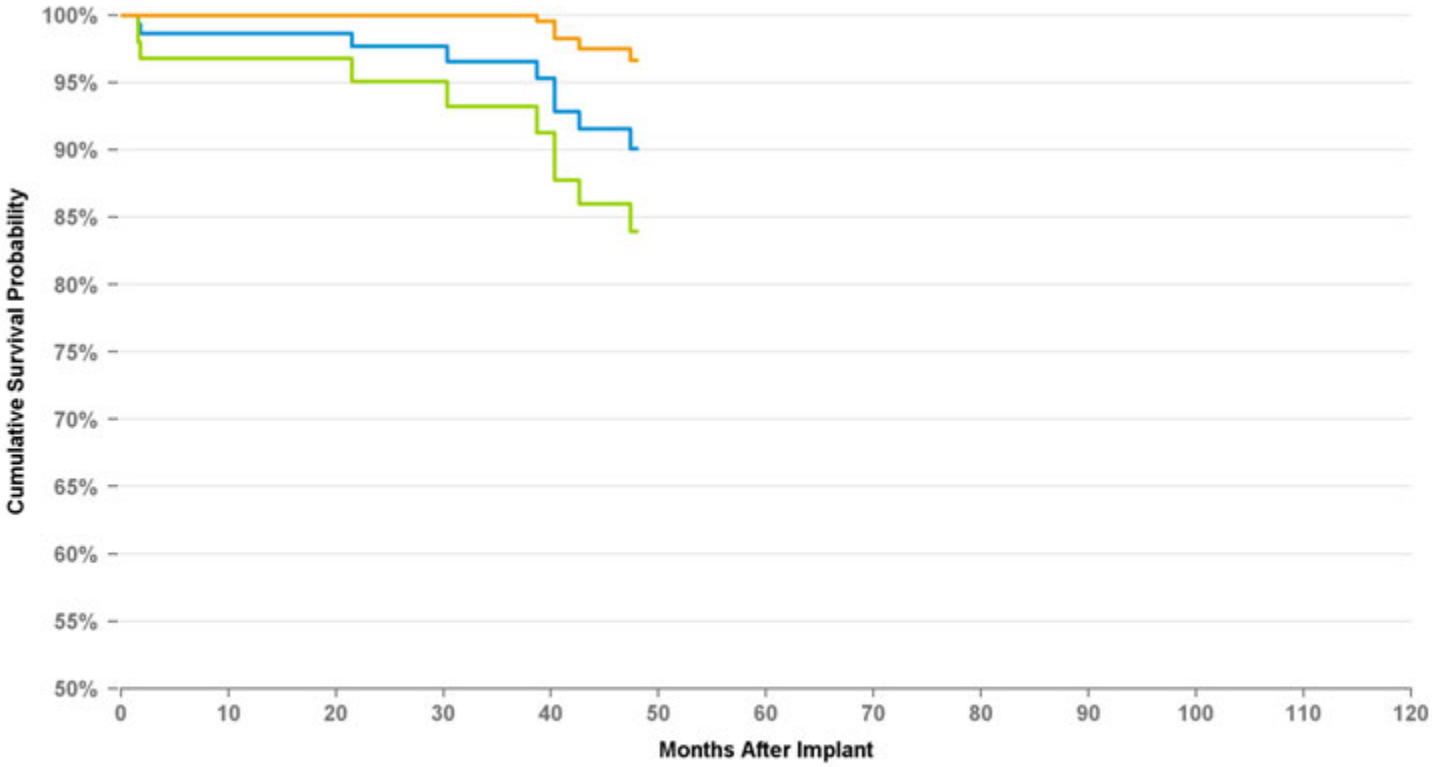
Distribution Data	
US Market Release	9/6/1996
CE Approval Date	1/1/1993
Registered US Implants	22,478
Estimated Active US	8,772
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	231
Cumulative Months of Follow-Up	7,011
Number of Leads Active in Study	7

Product Surveillance Registry Qualifying Complications	13
Cardiac Perforation	0
Conductor Fracture	6
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	5
Failure To Sense	5
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	223
Crimp Weld Bond	1
Insulation Breach	47
Other	0

4965, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 48 mo
%	98.6%	97.7%	96.6%	90.1%
#	129	110	88	64

EPI MYOCARDIAL LEAD 4968

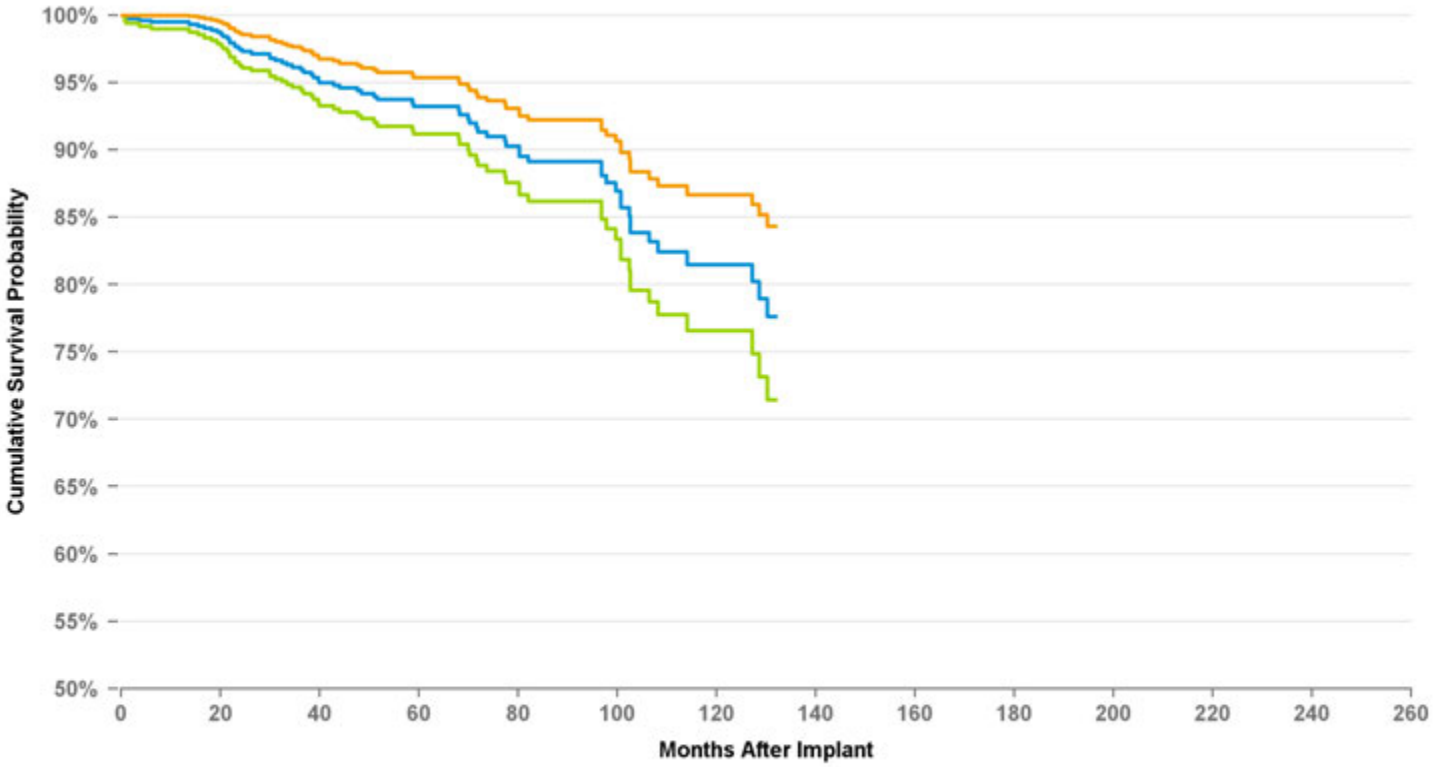
Distribution Data	
US Market Release	9/16/1999
CE Approval Date	4/21/1998
Registered US Implants	38,467
Estimated Active US	23,276
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	48,484
Number of Leads Active in Study	284

Product Surveillance Registry Qualifying Complications	74
Cardiac Perforation	0
Conductor Fracture	19
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	25
Failure To Sense	3
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	3
Lead Dislodgement	0
Medical Judgment	0
Other Complication	2
Oversensing	16
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	2
Failure To Capture	27
Failure To Sense	2
Impedance Abnormal	5
Insulation Breach	1
Lead Dislodgement	6
Oversensing	12
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	62
Crimp Weld Bond	0
Insulation Breach	39
Other	1

4968, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	97.5%	96.1%	94.4%	93.2%	91.3%	89.1%	89.1%	83.2%	81.5%	77.6%
#	715	627	540	437	355	270	210	165	100	67	50

EPI MYOCARDIAL LEAD 5071

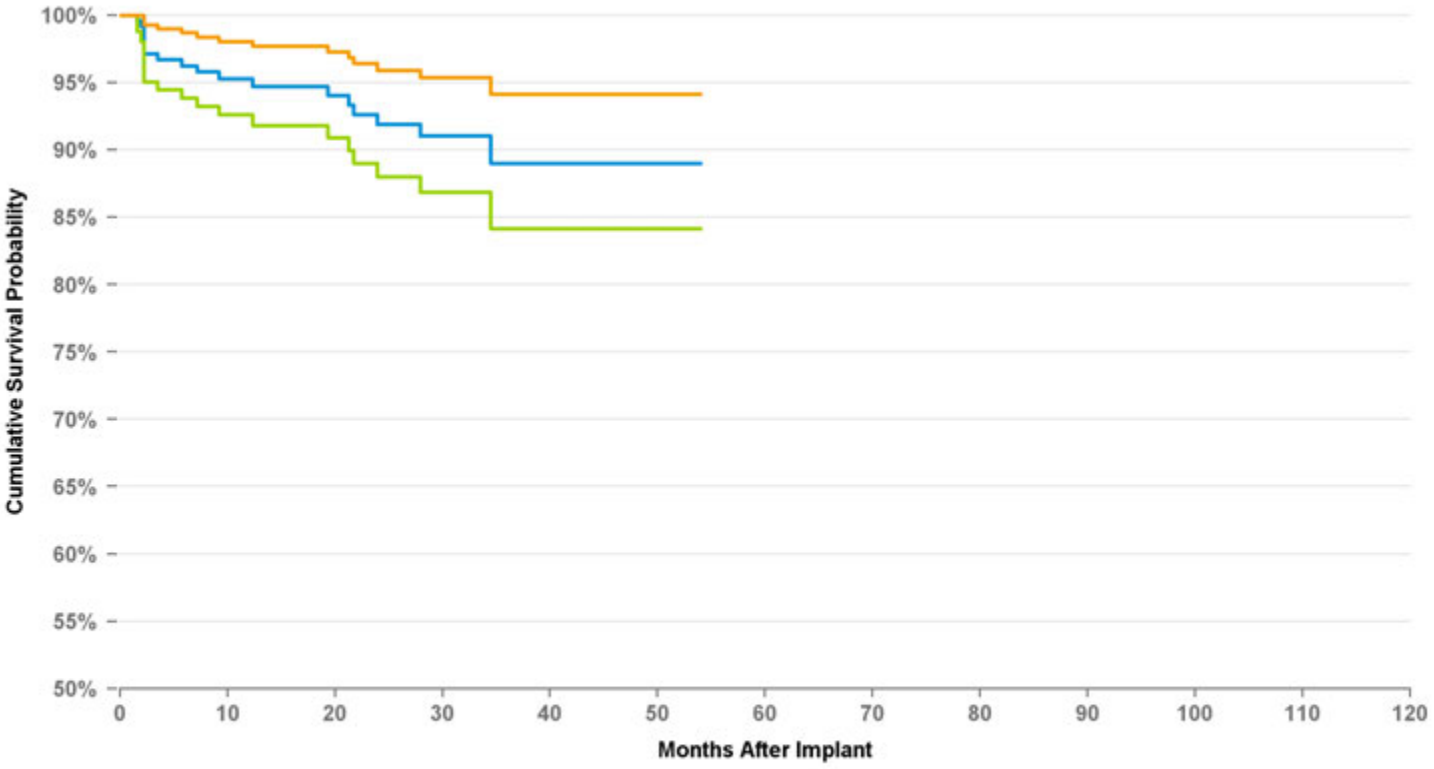
Distribution Data	
US Market Release	12/3/1992
CE Approval Date	1/1/1993
Registered US Implants	50,284
Estimated Active US	15,476
Product Characteristics	
Fixation Type	Fixed Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Myocardial
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	395
Cumulative Months of Follow-Up	9,553
Number of Leads Active in Study	96

Product Surveillance Registry Qualifying Complications	25
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	17
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	1
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	6
Failure To Capture	52
Failure To Sense	3
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	19
Crimp Weld Bond	0
Insulation Breach	2
Other	0

5071, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	at 54 mo
%	95.3%	91.9%	89.0%	89.0%	89.0%
#	185	132	91	65	57

VDD SINGLE PASS LEAD 5038

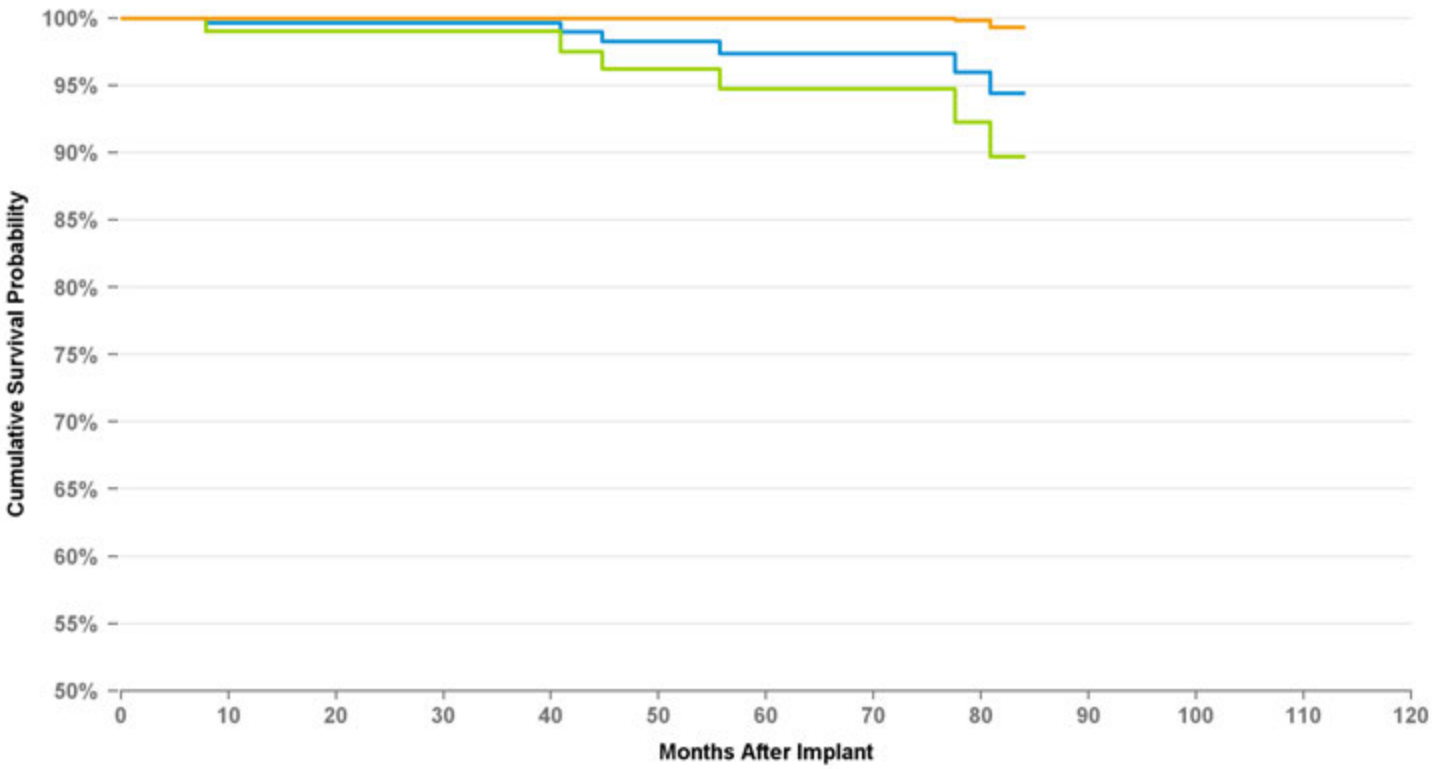
Distribution Data	
US Market Release	9/10/1998
CE Approval Date	4/15/1997
Registered US Implants	9,426
Estimated Active US	3,186
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Quadripolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	567
Cumulative Months of Follow-Up	15,675
Number of Leads Active in Study	3

Product Surveillance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	4
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	6
Crimp Weld Bond	0
Insulation Breach	2
Other	0

5038, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.7%	99.7%	98.2%	97.4%	97.4%	94.4%
#	292	219	161	132	105	77	55

ICD and CRT-D Charge Time Performance

Medtronic continues its commitment to providing updated information on charge time performance.

Introduction

Information on charge time performance of Medtronic products is presented in this section of the CRHF Product Performance Report. Medtronic implemented the collection of charge time data on July 1, 1999. The data are collected via our ongoing active clinical study of long-term system performance called the Product Surveillance Registry. The study protocol requests device data be routinely taken and sent to Medtronic at no more than 6-month intervals.

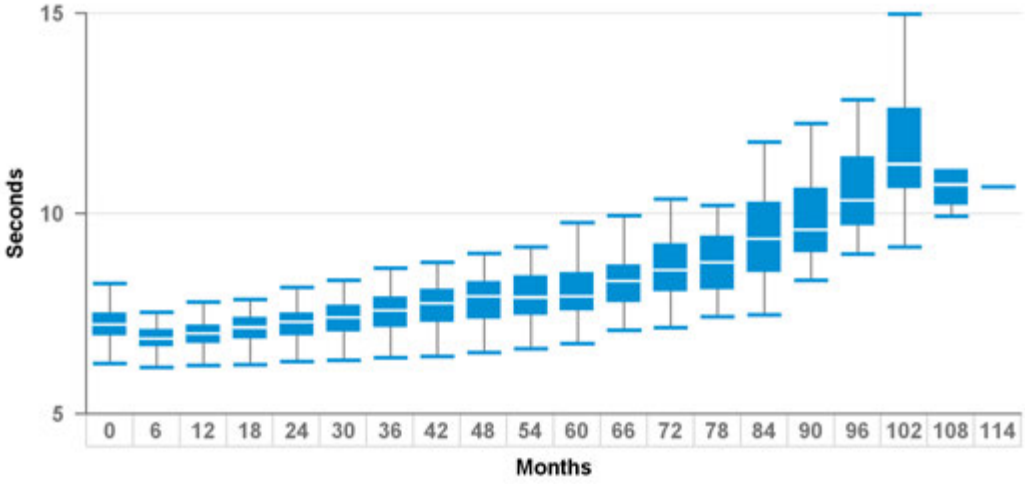
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available in a 6-month interval, a conservative approach has been adopted whereby only the maximum charge time in each 6-month interval is reported. As charge time is directly proportional to the time elapsed since the last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.

Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide charge times that are short and consistent over the life of the product.

Charge time data for ICD and CRT-D models are presented using boxplots at 6-month intervals. The shaded box on the plots represents the middle half of the data – the Interquartile Range (IQR). The white line in the middle of each box is the median charge time. The top of the box representing the IQR is the third quartile or the 75th percentile (i.e., 75% of all charge times fall below this line), whereas the bottom of the box represents the first quartile or the 25th percentile. Vertical lines are drawn from the quartiles to the farthest value not more than 1.5 times the interquartile range. Any values more extreme than the vertical lines are considered outliers.

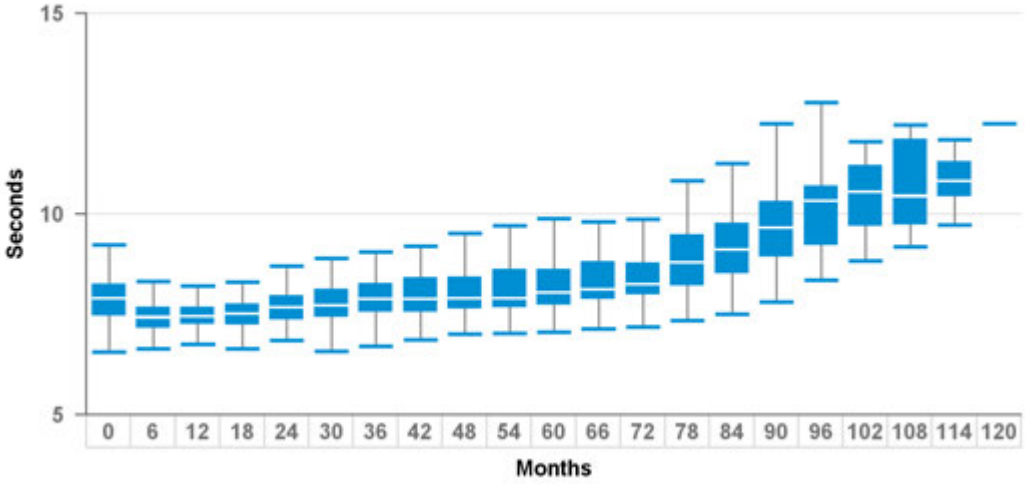
7230 Charge Time

Model Number	Brand
7230B	Marquis VR
7230Cx	Marquis VR
7230E	Marquis VR



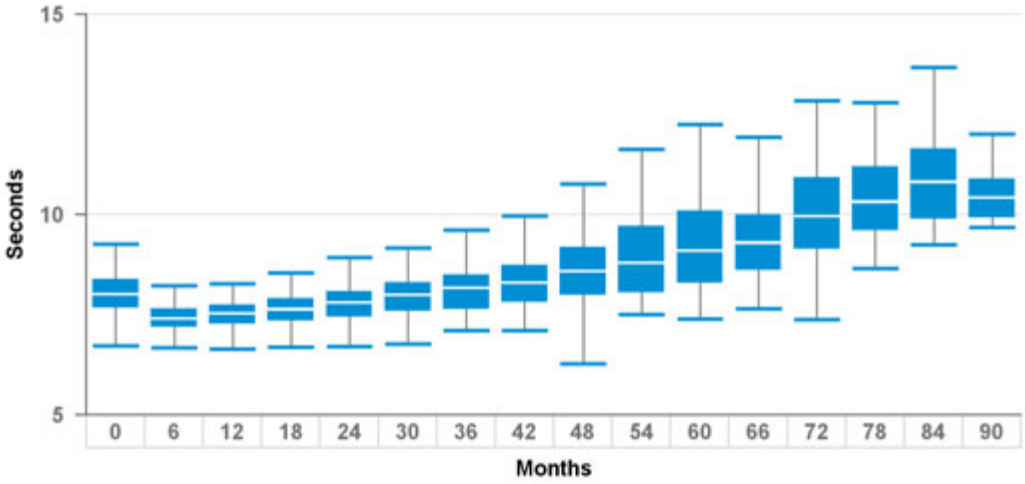
7232 Charge Time

Model Number	Brand
7232B	Maximo VR
7232Cx	Maximo VR
7232E	Maximo VR



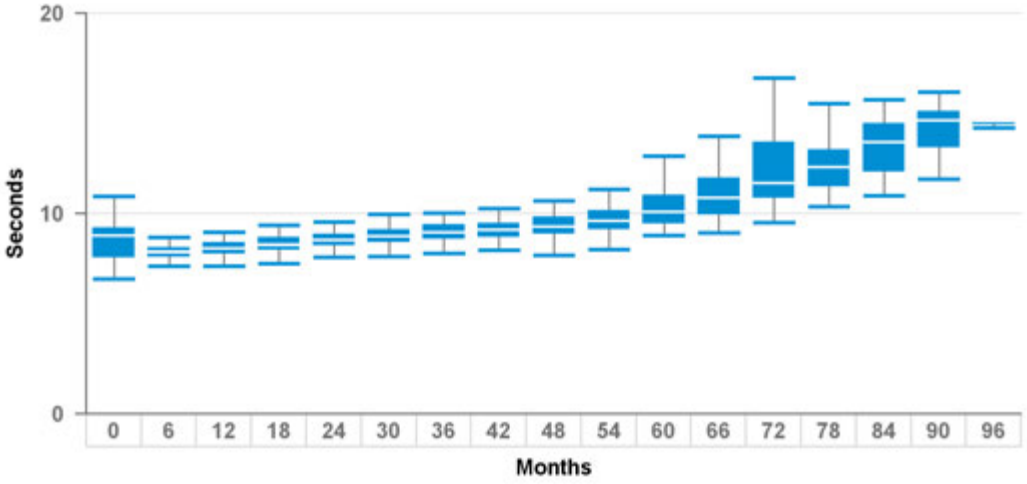
7278 Charge Time

Model Number	Brand
7278	Maximo DR



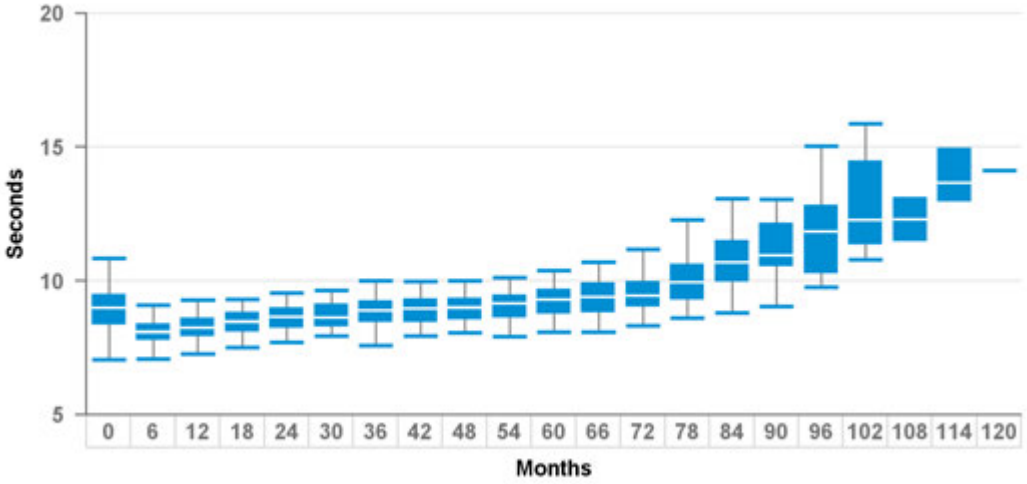
D144DRG, D154ATG, D154DRG Charge Time

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT



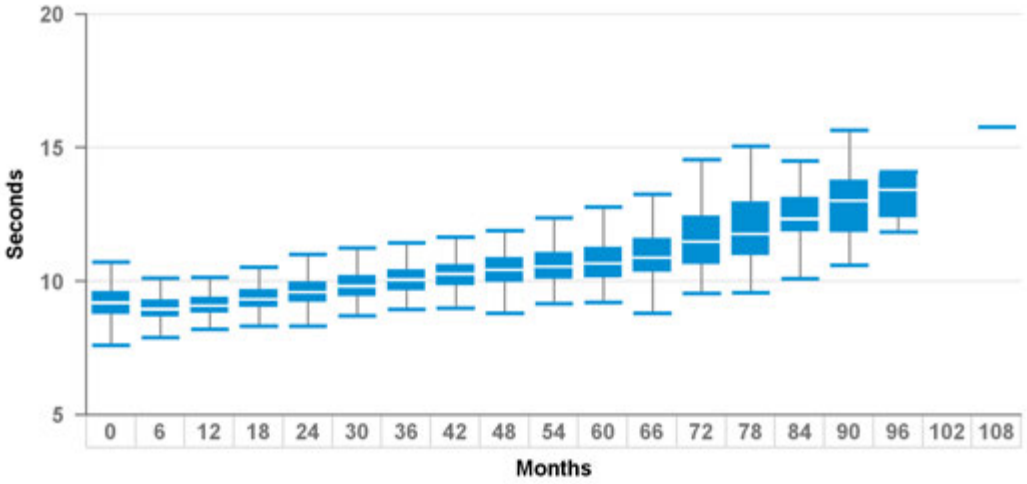
D144VRC, D154VRC Charge Time

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



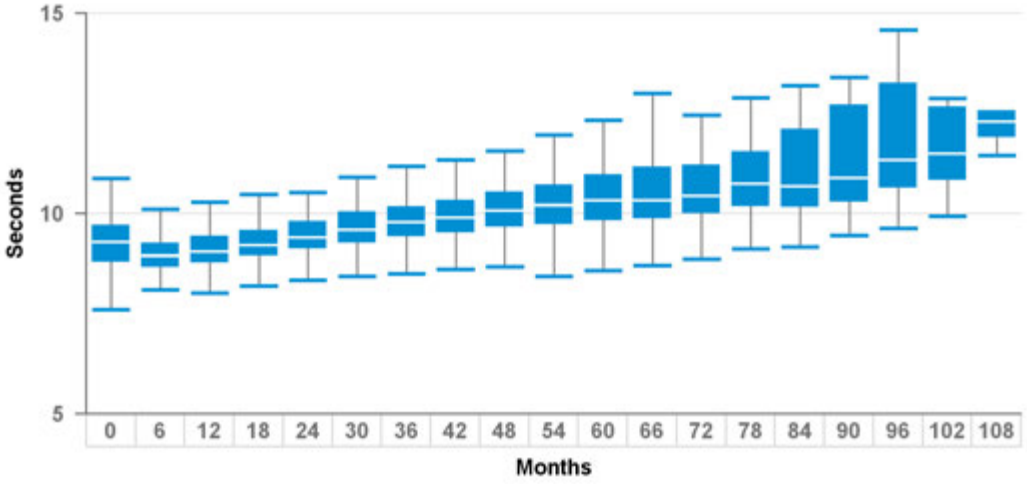
D154AWG, D164AWG Charge Time

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



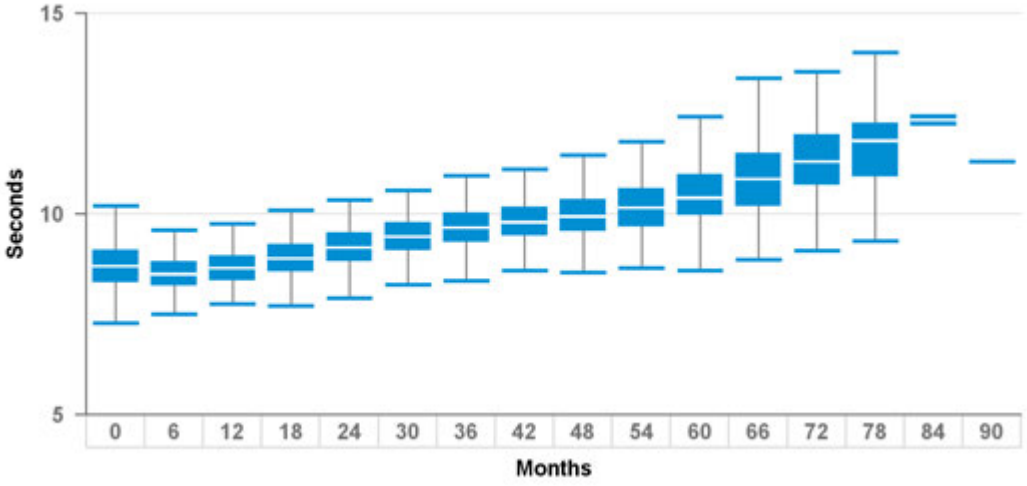
D154VWC, D164VWC Charge Time

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



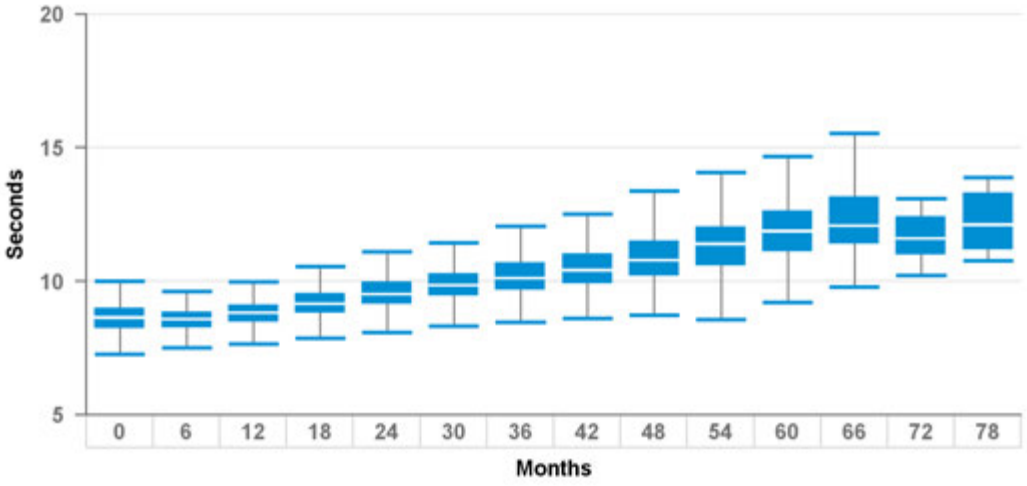
D204DRM, D214DRM, D224DRG, D234DRG Charge Time

Model Number	Brand
D204DRM	Secura DR
D214DRM	Secura DR
D224DRG	Secura DR
D234DRG	Secura DR



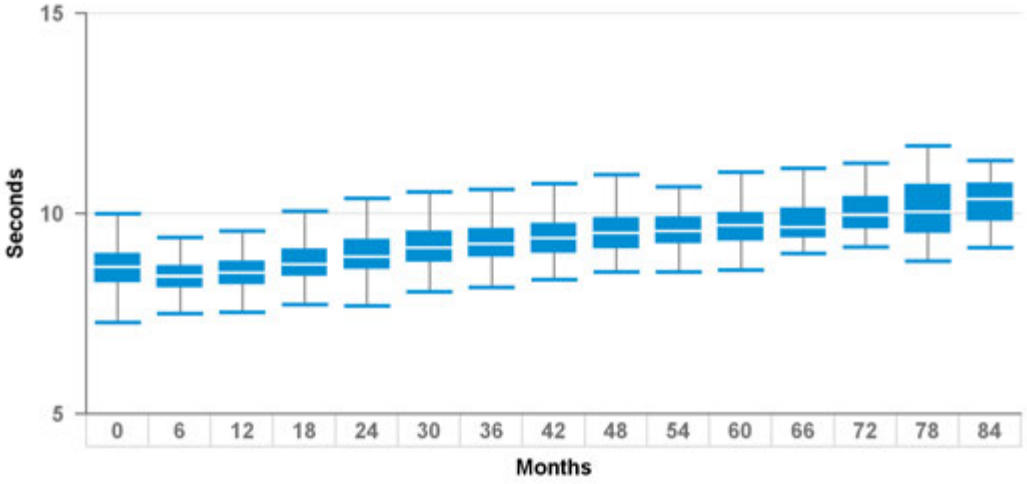
D204TRM, D214TRM, D224TRK, D234TRK Charge Time

Model Number	Brand
D204TRM	Consulta CRT-D
D214TRM	Consulta CRT-D
D224TRK	Consulta CRT-D
D234TRK	Consulta CRT-D



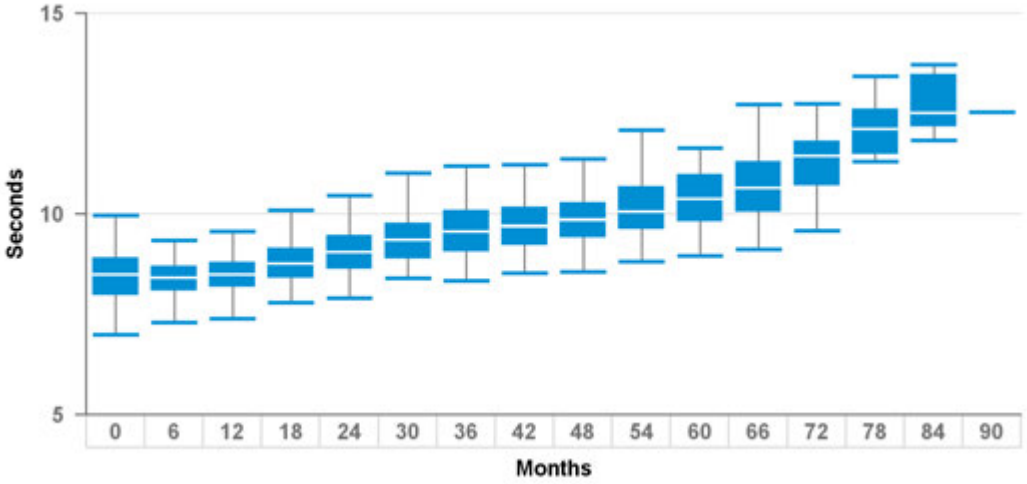
D204VRM, D214VRM, D224VRC, D234VRC Charge Time

Model Number	Brand
D204VRM	Secura VR
D214VRM	Secura VR
D224VRC	Secura VR
D234VRC	Secura VR



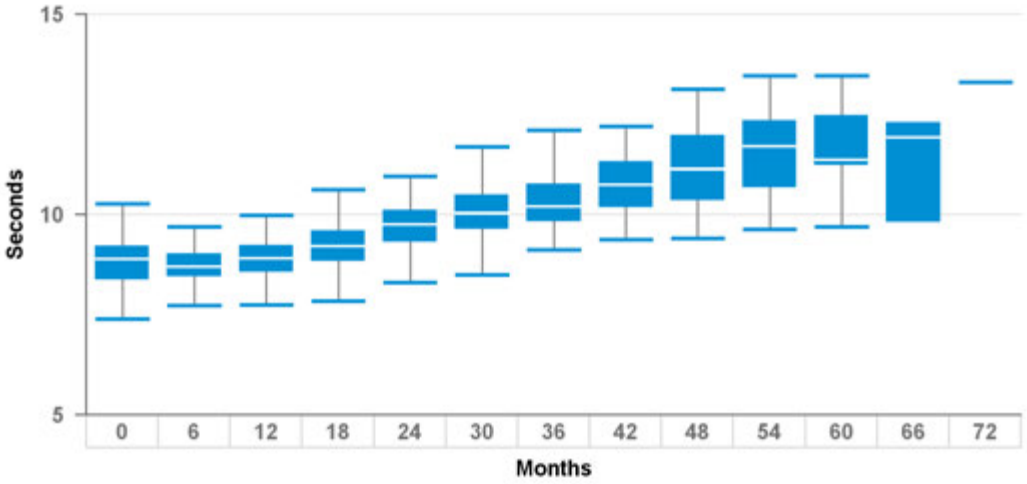
D264DRG, D284DRG, D384DRx, D394DRx Charge Time

Model Number	Brand
D264DRM	Maximo II DR
D284DRG	Maximo II DR
D384DRG	Cardia DR
D394DRG	Egida DR



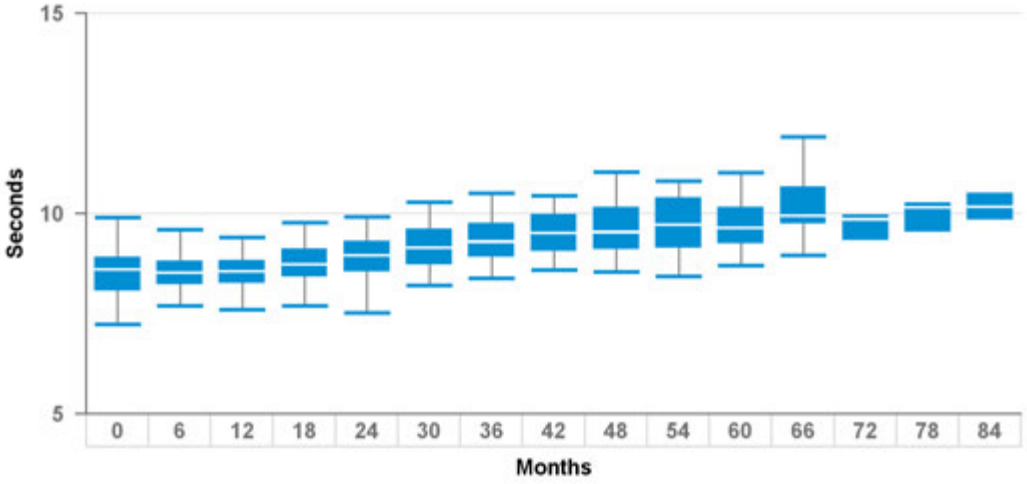
D264TRM, D284TRK, D384TRx, D394TRx Charge Time

Model Number	Brand
D264TRM	Maximo II CRT-D
D284TRK	Maximo II CRT-D
D384TRG	Cardia CRT-D
D394TRG	Egida CRT-D



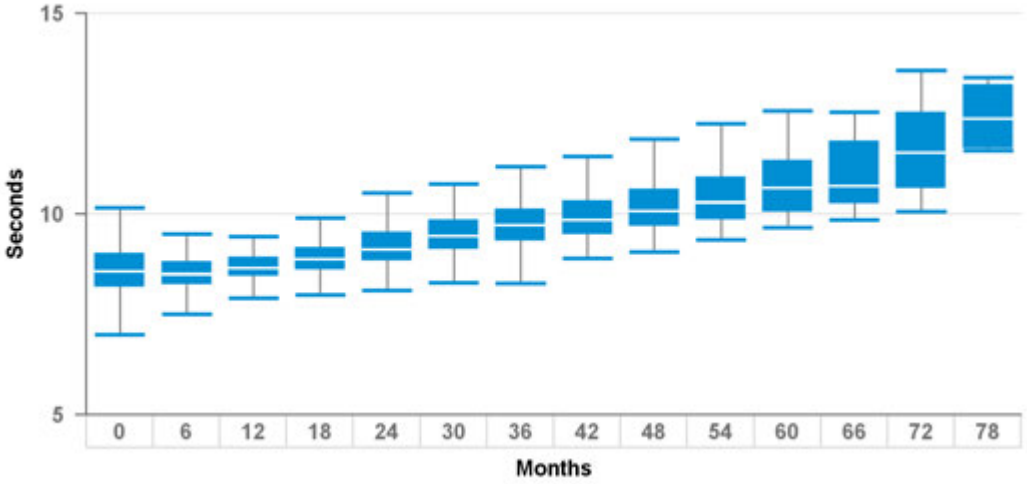
D264VRM, D284VRC, D384VRx, D394VRx Charge Time

Model Number	Brand
D264VRM	Maximo II VR
D284VRC	Maximo II VR
D384VRG	Cardia VR
D394VRG	Egida VR



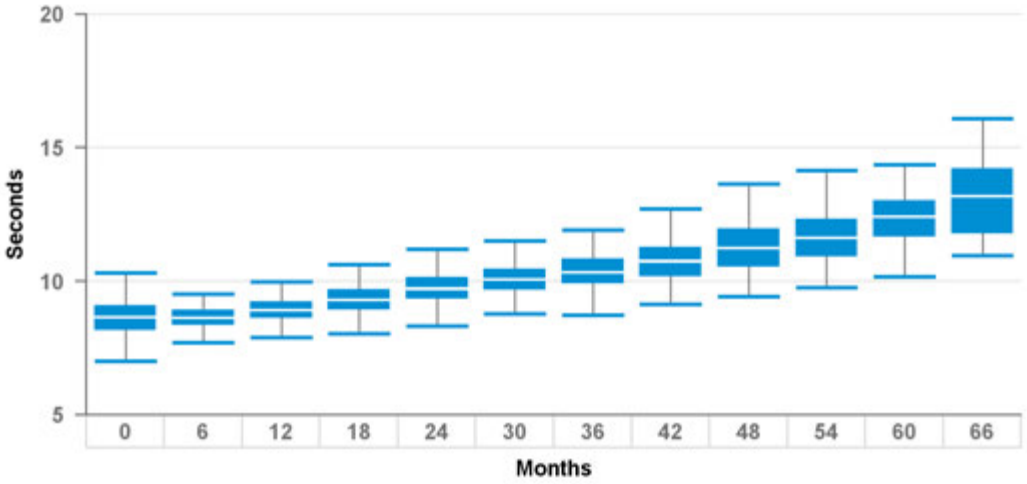
D274DRG, D294DRG Charge Time

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



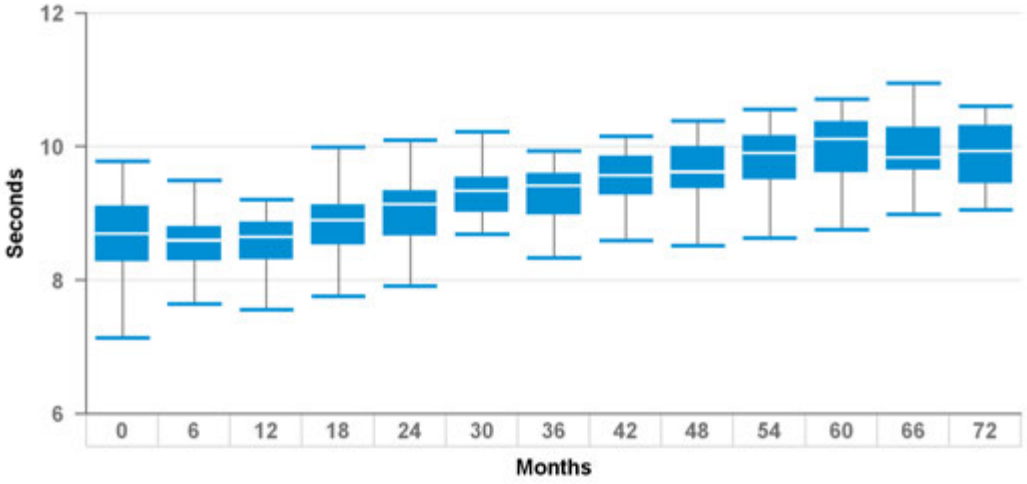
D274TRK, D294TRK Charge Time

Model Number	Brand
D274TRK	Concerto II CRT-D
D294TRK	Concerto II CRT-D



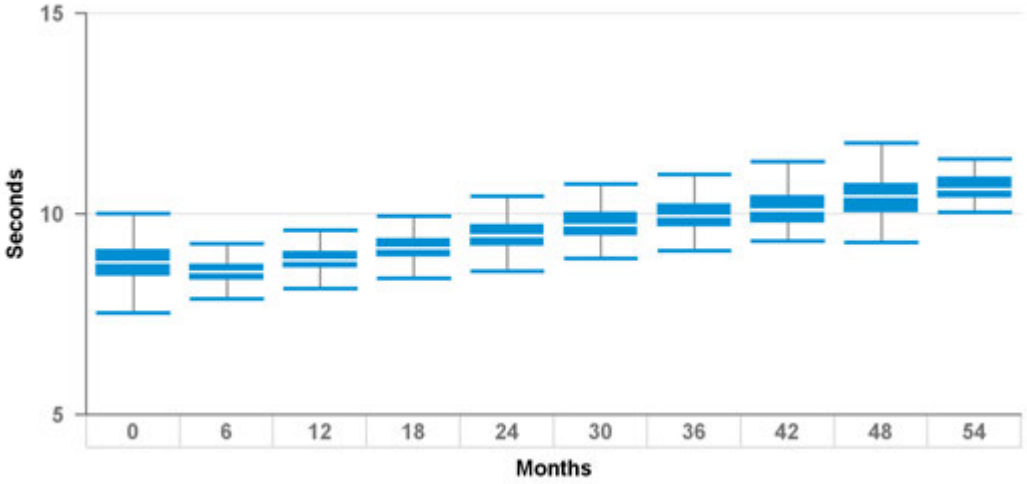
D274VRC, D294VRC Charge Time

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



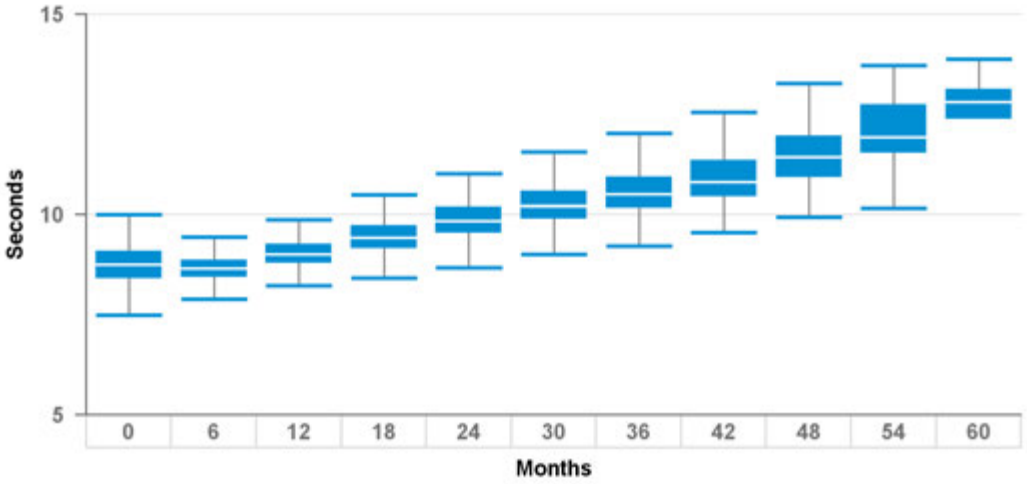
D314DRx Charge Time

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



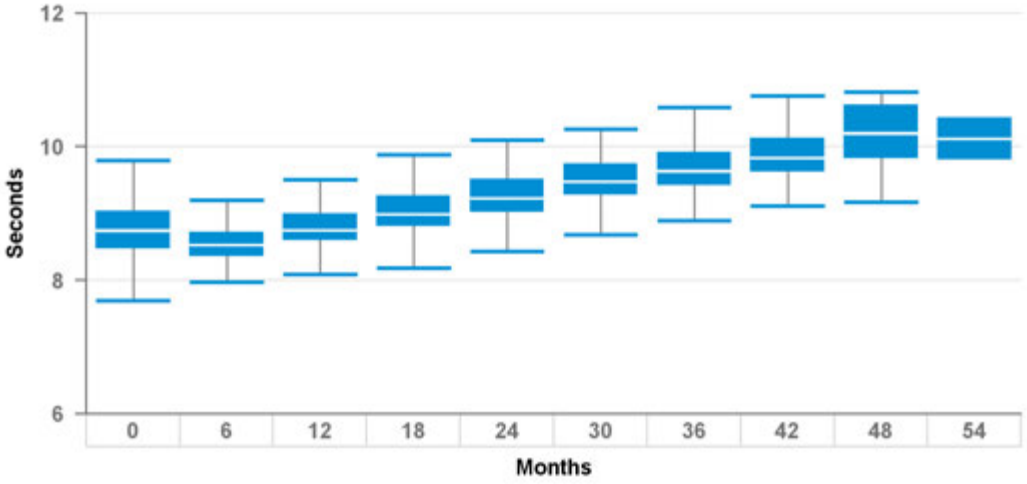
D314TRx Charge Time

Model Number	Brand
D314TRG	Protecta XT CRT-D
D314TRM	Protecta XT CRT-D



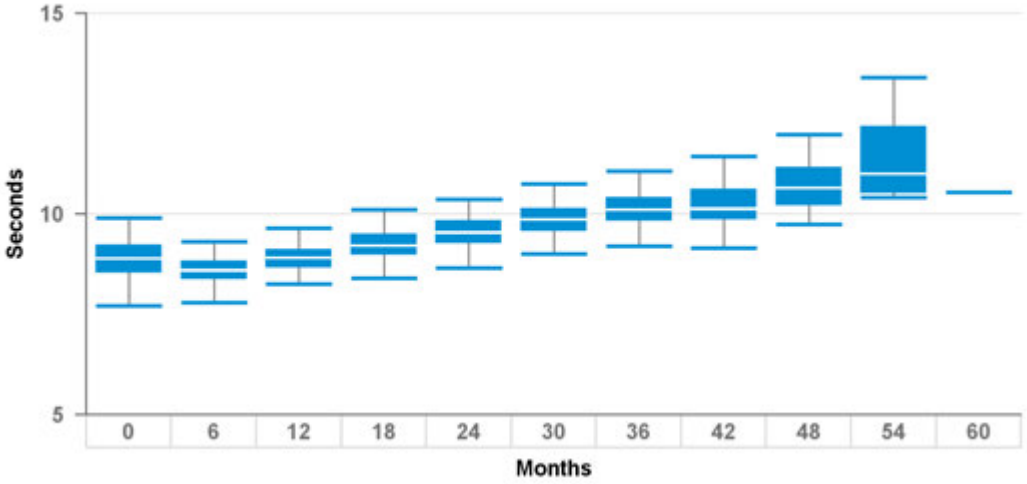
D314VRx Charge Time

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



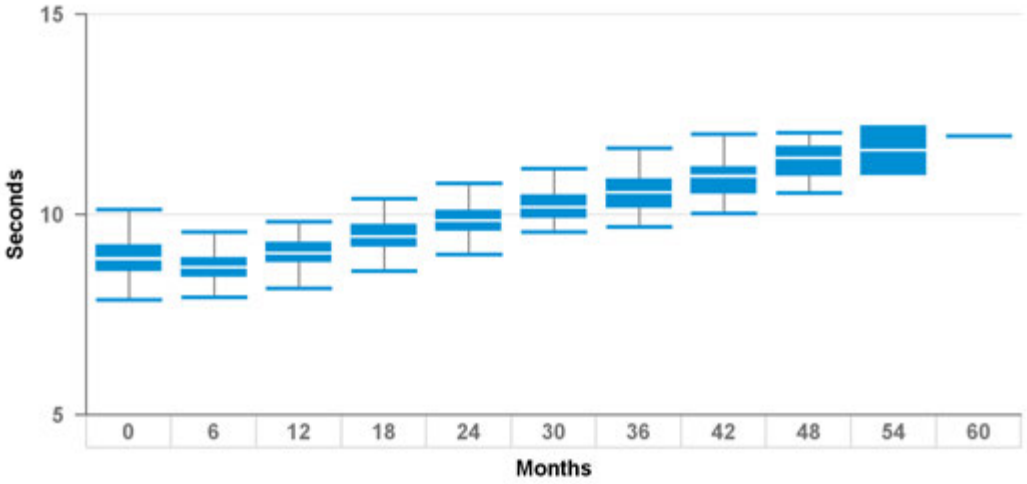
D334DRx, D364DRx Charge Time

Model Number	Brand
D334DRG	Protecta DR
D334DRM	Protecta DR
D364DRG	Protecta DR
D364DRM	Protecta DR



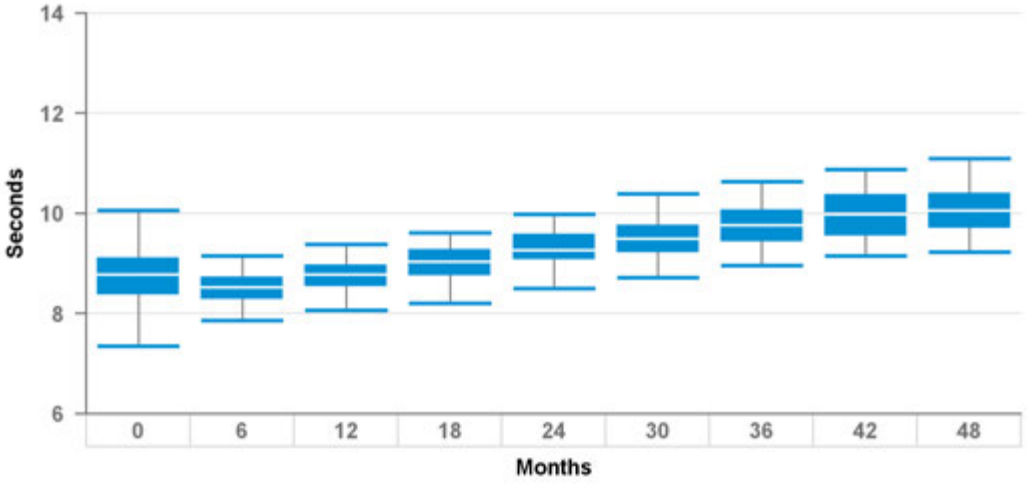
D334TRx, D364TRx Charge Time

Model Number	Brand
D334TRG	Protecta CRT-D
D334TRM	Protecta CRT-D
D364TRG	Protecta CRT-D
D364TRM	Protecta CRT-D



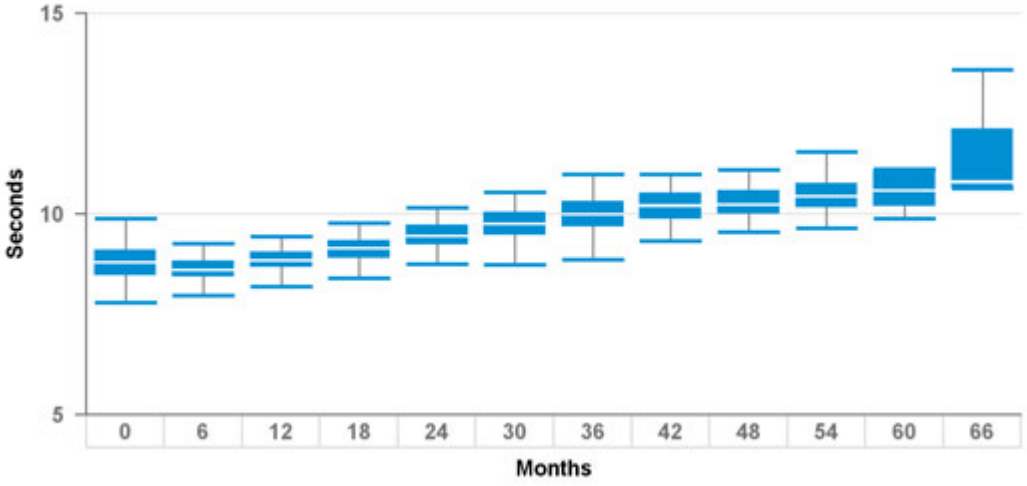
D334VRx, D364VRx Charge Time

Model Number	Brand
D334VRG	Protecta VR
D334VRM	Protecta VR
D364VRG	Protecta VR
D364VRM	Protecta VR



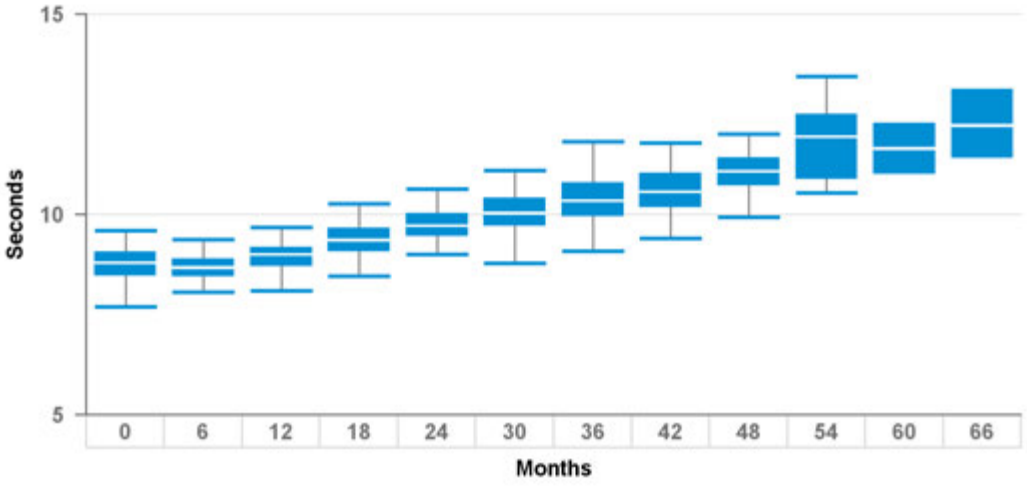
D354DRx Charge Time

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



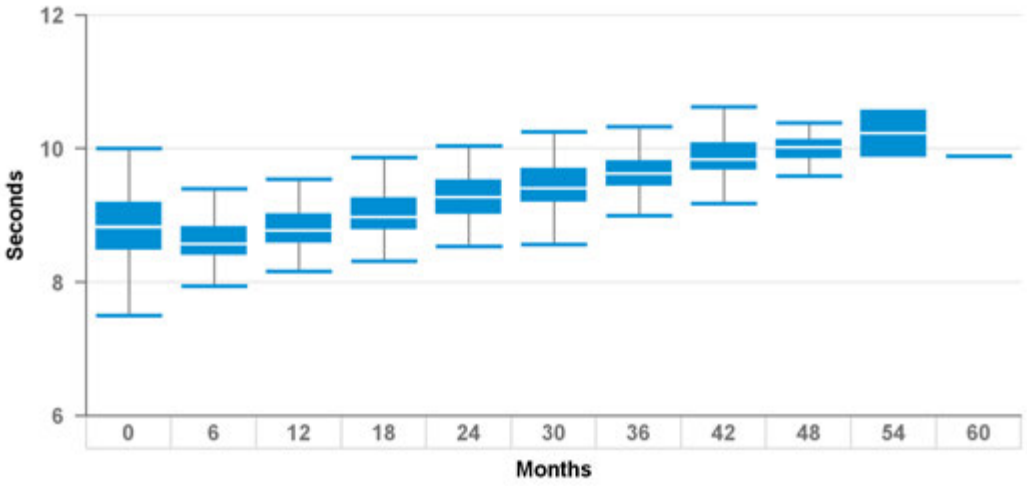
D354TRx Charge Time

Model Number	Brand
D354TRG	Protecta XT CRT-D
D354TRM	Protecta XT CRT-D



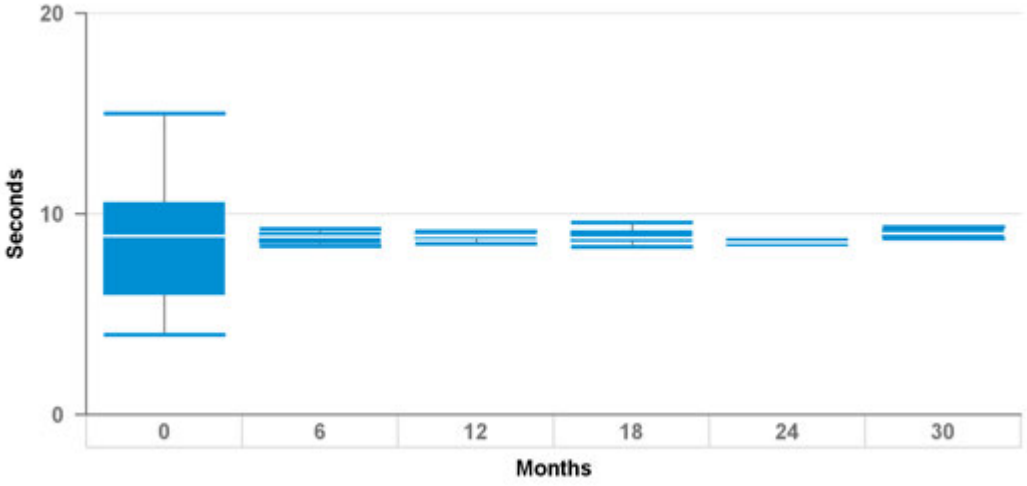
D354VRx Charge Time

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



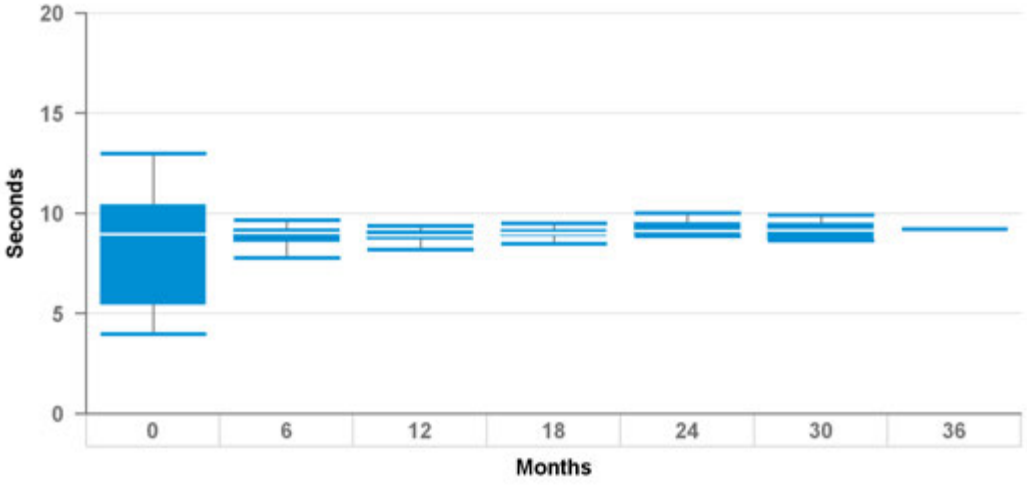
DDxxxx, DR Charge Time

Model Number	Brand
DDBB1D1	Evera XT
DDBB1D4	Evera XT
DDBB2D1	Evera XT
DDBB2D4	Evera XT
DDBC3D1	Evera S
DDBC3D4	Evera S
DDMB1D4	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D4	Evera MRI



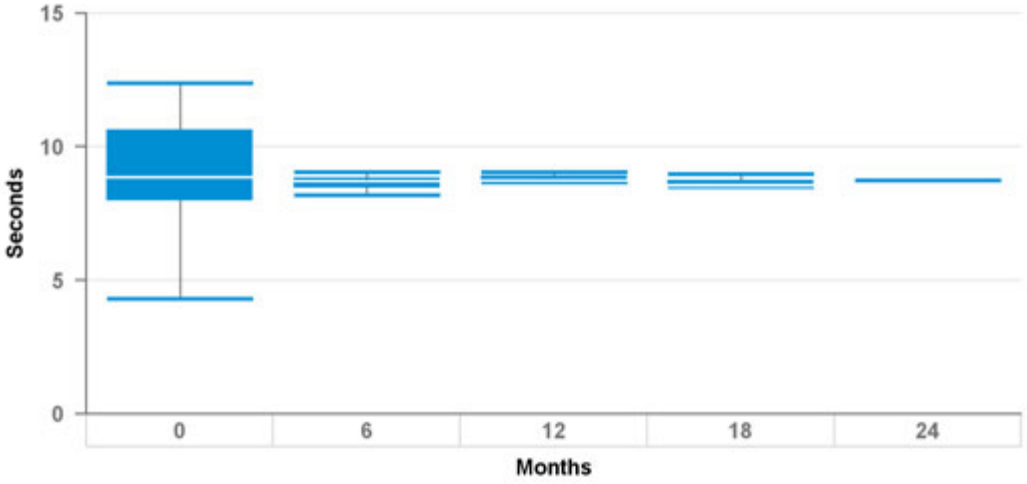
DTxxxxx, CRT-D Charge Time

Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava
DTBC2D4	Brava
DTBC2Q1	Brava Quad
DTBC2QQ	Brava Quad
DTBX1QQ	Viva Quad C
DTBX2QQ	Viva Quad C
DTMA2D4	Claria MRI
DTMA2QQ	Claria MRI
DTMB1D4	Amplia MRI
DTMB1QQ	Amplia MRI
DTMB2D4	Amplia MRI
DTMB2QQ	Amplia MRI
DTMC1QQ	Compia MRI
DTMC2D4	Compia MRI
DTMC2QQ	Compia MRI



DVxxxxx, VR Charge Time

Model Number	Brand
DVAB1D1	Visia AF
DVAB1D4	Visia AF
DVAB2D1	Visia AF XT
DVAC3D1	Visia AF S
DVBB1D1	Evera XT
DVBB1D4	Evera XT
DVBB2D1	Evera XT
DVBB2D4	Evera XT
DVBC3D1	Evera S
DVBC3D4	Evera S
DVFB1D4	Visia MRI AF
DVFB2D4	Visia MRI AF XT
DVFC3D4	Visia MRI AF S
DVMB1D4	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D4	Evera MRI S



Advisories

Potential Rapid Battery Depletion Due To Circuit Component

Viva™ CRT-D and Evera™ ICD

Original Date of Advisory: August 2016

Product
A specific subset of 78 Viva CRT-D and Evera ICD may experience rapid battery depletion due to a low resistance path developing within a circuit component. You may use the "Search for Information by Serial Number" tool on home page of this web site to determine if a specific device is affected.

Advisory
Devices in the affected population may experience rapid battery depletion due to a low resistance path developing within a circuit component. This is not related to a failure within the battery.

Development of a low resistance path in the circuit component in some cases has been reported to cause battery depletion in seven (7) days or less and may present clinically during a patient follow-up visit as:

- One or more electrical resets, which will display as an observation on the programmer.
- No pacing or defibrillation therapy output.
- No telemetry.
- Programmer screen display of "SERIOUS DEVICE MEMORY FAILURE."

Patient audible alerts and CareAlerts™ may not reliably notify the patient or clinician, due to this issue.

Reported complications have included shortness of breath, pocket heating, low heart rate, and early device explant.

Patient Management Recommendations
We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following options for managing patients implanted with an affected device:

Advise patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness) or if the audible patient alert sounds.

For pacemaker-dependent patients or those at a higher risk of Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF):

- Physicians should consider device replacement.

For patients where the physician does not believe device explant is the best course of action, Medtronic offers these additional options:

- Program the audible alerts for "Low Battery Voltage RRT" to "On-High". It is possible that alerts may not sound if the battery is depleted. Therefore physicians should also consider one of the following:
  - Provide a handheld magnet to patients to frequently check device status.
    - Requires one or more audible alerts be programmed ON.
    - Device operation may be monitored frequently (e.g., daily) by patients placing the magnet over the device for **1-2 seconds and then removing the magnet**. If the device is functional, a steady tone will sound for approximately 10 seconds. If no tone or an oscillating high/low tone is heard, advise patients to seek care immediately.
  - Prescribe either a CareLink™ transmission be performed by the patient, or a maintenance transmission by the clinic, on a more frequent basis (e.g., weekly or daily) based on the unique patient considerations. The clinic should review these transmissions upon receipt.
    - If the transmission is unsuccessful the patient should be brought into the clinic for immediate follow-up as this may be an indication that the device battery has depleted to a level where it can no longer support telemetry.

- Review transmissions for any signs of this issue (e.g., one or more electrical resets, or notification that a device alert has occurred).
- Each transmission will decrease battery longevity by approximately one day.

Status Update

Within the 78 devices, there have been seven (7) confirmed failures (9%) through September 27, 2016. Medtronic modeling predicts an additional six (6) failures may occur in the remaining active population. An estimated 38 devices remain active

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
78 Worldwide	**7** Worldwide	**38** Worldwide	**9%** Worldwide

Advisories

Premature RRT alert in some LINQ devices

Reveal LINQ Model LNQ11

Original Date of Advisory: February 2016

Product

All Reveal LINQ™ Insertable Cardiac Monitor (ICM)

Advisory

Medtronic has identified an issue with the sensitivity of an algorithm used in the Reveal LINQ ICM that may prematurely trigger the Recommended Replacement Time (RRT) alert in some devices. As of February 12, 2016, Medtronic had observed an occurrence rate of 0.45% of devices experiencing this issue. Battery capacity is not affected and the device will continue to support data collection and manual data transmissions. As stated in Reveal LINQ labeling, the typical device will experience an average of 3 years longevity (refer to the device labelling for the corresponding use conditions). As part of the normal behavior of the device, 30 days after RRT status is reached, Reveal LINQ devices will display an End of Service (EOS) status at which time the device disables automatic wireless alerts and transmissions. Thereafter, patients will still be able to send remote manual transmissions allowing clinics to receive alerts and stored device data. Due to the design of the RRT algorithm, devices are not susceptible to this issue until 200 days (6.5 months) post-implant. As of February 12, 2016 the earliest reported occurrence of RRT is 7.3 months post-implant, with median implant to RRT duration of 16.5 months.

Medtronic has obtained the necessary regulatory approvals to begin applying a software update to prevent and correct this issue in the field. Once installed, this software update will reset RRT & End of Service (EOS) status and re-enable wireless transmissions for devices that have experienced premature RRT /EOS. The update will also prevent the occurrence of premature RRT alerts due to this issue.

How do clinics apply this update to Reveal LINQ ICMs?

During the course of their follow-up care, patients' devices can receive the update via a programmer interrogation. Clinics with Reveal LINQ ICM patients will be contacted by Medtronic with instructions on how to install the update via the CareLink™ 2090 or Encore™ Programmer. Once programmers are updated, clinics will be provided further direction by their Medtronic Representative to contact patients who have experienced a premature RRT/EOS status in order to apply the update to individual Reveal LINQ ICMs. For new implants, the updated software will automatically be loaded on the Reveal LINQ ICM during interrogation of the device using a programmer that has previously been loaded with the new software.

Medtronic is also working on functionality to allow patients the ability to receive this update via their MyCareLink™ Monitor. More information will be provided regarding this update method as it becomes available.

How can I get more information on this update?

Additional information, including direction on how to apply this update, can be found at MedtronicDiagnostics.com/us/linq-software-update or by contacting your Medtronic Representative. Medtronic Diagnostic Patient Services is available to assist patients at 800-929-4043. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Diagnostic Technical Services at 800-929-4043.

Advisories

Potential High Battery Impedance

InSync® III Model 8042

Original Date of Advisory: November 2015

Product

All InSync® III Model 8042 Pacemakers

Advisory

Medtronic has identified an issue related to long-term battery performance. Through 27 October 2015, Medtronic has confirmed 30 devices (0.03%) worldwide have been impacted by this issue, for which the root cause is unexpected high battery impedance.

Unexpected high battery impedance can result in the battery's inability to supply sufficient electrical current, impacting device function. Twelve (12) of the 30 devices had reports of unexpected loss of pacing capture. The other 18 devices experienced some form of erratic behavior, including early elective replacement indication (ERI), significant fluctuations in remaining longevity estimates, and inaccurate lead impedances. Through 27 October 2015, events associated with this issue have occurred in devices with implant durations of 53 months or more. Medtronic has received one report of a patient death, where it is possible, but unconfirmed, that this issue was a contributing factor.

If pacing capture is compromised, some patients may experience a return of heart failure symptoms due to loss of biventricular pacing. In cases involving pacemaker-dependent patients, a loss of pacing capture could result in serious injury or death.

The Physician Letter for this issue is available at http://www.medtronic.com/insync-iii-crt-p

Patient Management Recommendations (As of November 2015)

We realize that each patient requires unique clinical consideration. After consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic offers the following recommendations for patients with an InSync III CRT-pacemaker:

- Prophylactic device replacement in non-pacemaker-dependent patients is not recommended.
- For pacemaker-dependent patients, physicians should carefully weigh the risks and benefits of device replacement to mitigate this issue on an individual patient basis
    - The estimated per patient mortality risk of this issue (0.007% to 0.02%) is comparable to the estimated per patient mortality risk of complications associated with an incremental, early device replacement (0.005%).
- Continue routine patient follow up in accordance with standard practice, and advise patients to seek medical attention immediately if they experience new or unexpected symptoms.

Status Update

As of September 27, 2016, approximately 15,500 devices remain active worldwide, from an original implant population of 96,800. In the United States, 6,400 active devices remain. Our modeling predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency. InSync III CRT-pacemakers are no longer distributed.

Advisories

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
96,800 Worldwide (**39,900** United States)	**97** Worldwide (**37** United States)	**15,500** Worldwide (**6,400** United States)	**0.18%** Worldwide (**0.1%** United States)

Advisories

Potential Rapid Battery Depletion

EnTrust® VR/DR/AT ICDs

Original Date of Advisory: March 2012

Product

All EnTrust ICDs.

Advisory

A small percentage of EnTrust ICDs may not meet expected longevity or provide at least three months of device operation between the Elective Replacement Indicator (ERI) and End of Life (EOL) due to a more-rapid-than-expected drop in battery voltage. No patient deaths or serious injuries have been reported as a result of this issue.

The reported events have involved a drop in battery voltage from ~3.0 V to ERI (2.61 V) over a time period ranging from approximately one week to six months. All reported events have occurred at least 30 months after implant.

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed. The Physician Letter is available at http://www.medtronic.com/product-advisories/entrust/physician/index.htm

Patient Management Recommendations (As of March 2012)

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient managementrecommendations:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.

- Physicians should program the audible patient alerts for "Low Battery Voltage ERI" and "Excessive Charge Time EOL" to ON.

- Physicians should replace devices promptly after they reach ERI if the decline in voltage is more rapid than expected.

- Prophylactic replacement of EnTrust ICDs is not recommended.

Status Update

As of September 27, 2016, there have been 96 confirmed events. No patient deaths have been reported due to this issue. No reports have been made of a failure to deliver high voltage therapy.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
69,200 Worldwide (**44,300** United States)	**96** Worldwide (**75** United States)	**7,400** Worldwide (**4,800** United States)	**0.14%** Worldwide (**0.17%** United States)

Advisories

Low Battery Voltage Displayed at Device Interrogation

EnRhythm and EnRhythm MRI Pacemakers

Original Date of Advisory: February 2010

Product

All EnRhythm and EnRhythm MRI pacemakers.

Original Advisory Information (February 2010)

Two specific battery issues with EnRhythm pacemakers were identified. The risks to patients for both issue have been addressed by a Medtronic software update. The Physician Letter is available at http://www.medtronic.com/enrhythm-advisory/physician.html

First Issue

In February 2010, Medtronic had received 62 reports (out of approximately 110,000 devices worldwide) indicating that the battery voltage at device interrogation was lower than the battery voltage that is tracked by the device to provide data for the elective replacement indicator (ERI) notification.

Medtronic's investigation found that none of these reports resulted in loss of therapy. Importantly, the original ERI notification, which uses the nightly battery voltage measurement, was unaffected and accurate. Medtronic identified the root cause as higher than expected battery impedance.

Medtronic's internal testing showed there was no current risk for compromised therapy delivery. If the software update referenced above is not implemented, there will be a potential risk of loss of device functionality in a small percent (less than 0.08% 6 years post-implant) of devices. The software update obviates this risk.

Second Issue

Through internal accelerated testing, Medtronic identified a second issue that projects battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion near end of device life. This issue has not been clinically observed and is not expected to occur until approximately 9 years post-implant. If the software update referenced above is not implemented, there may be a potential risk for loss of therapy at or near ERI in a small number of devices. The software eliminates this issue by changing ERI criteria.

Software Update (As of October 2010)

The battery issues described above and subsequent software update are summarized in the table below. When a device receives the software update, if battery impedance is greater than the new ERI threshold ERI will be triggered shortly thereafter. Therefore, clinicians may observe an ERI/EOL indicator at the next patient follow-up. When ERI is triggered by battery impedance, additional battery capacity remains and can support device function at ERI parameters for at least one year. Medtronic is not aware of any reports of loss of therapy due to this issue.

As a reminder, when ERI is triggered, EnRhythm devices revert to VVI pacing at 65 ppm at the programmed output settings. EOL is declared 90 days after ERI or at a battery voltage of 2.69V, whichever comes sooner.

Advisories

Battery Issue	Software Update
Battery voltage could decrease sooner that expected due to a slightly increased rate of lithium depletion	Changed ERI battery voltage threshold from 2.59V to 2.81V to ensure 90 days of therapy from ERI to EOL
Higher than expected battery impedance	Added a secondary ERI trigger based on battery impedance. This new criteria will identify devices with increased battery impedance before device performance is impacted. If triggered, displayed battery voltage is reset to 2.81 V to ensure alignment with ERI battery voltage threshold

Updated Performance Information (as of August 2011)

We now have access to battery impedance and ERI performance on more than 5000 EnRhythm devices that have received the EnRhythm software update. Our modeling based on these data shows that approximately 6-10% of devices will reach ERI within 5 years post-implant. Consistent with our previous communications, we continue to expect average device longevity to be reduced by approximately 10 –15%, with the expected average longevity remaining at 8.5 to 10.5 years, depending on device settings.[1]

Updated Patient Management Recommendations (as of August 2011)

After consultation with Medtronic's Independent Physician Quality Panel, we recommend:

- Performing a device follow-up within 90 days after the software download to identify devices that triggered ERI shortly after the software update. Subsequent follow up can be performed per standard practice. During programmer interrogation of a device at ERI, there is a slight possibility a transient drop in pacing amplitude could occur. If this is noted, either remove the programmer head or temporarily program to a higher output voltage.
- If an unanticipated ERI/EOL is declared, it is likely due to battery impedance. In such cases, additional battery capacity remains and can support device function at ERI parameters for at least one year. However, when ERI or EOL (typically 90 days after ERI) declaration is seen, schedule device replacement.

Status Update

First Issue

Included in the August 2011 Performance Update was information about the projected percentage of devices that would encounter an early ERI due to unexpected high battery impedance. As of September 27, 2016, the percentage of devices that encountered ERI due to battery impedance has not exceeded the rate of 6-10% within 5 years of post-implant as communicated with our August 2011 Performance Update. Only devices using the updated software can trigger ERI due to impedance.

Initial Affected Population	Number of Confirmed ERIs due to impedance	Number of Confirmed ERIs due to impedance within 5 years post-implant	Estimated ERI rate due to impedance within 5 years post-implant[2]	Confirmed events of loss of therapy due to battery impedance	Estimated Remaining Active Population
All EnRhythm pacemakers (**146,500** Worldwide)	**17,497** Worldwide	**5,877**	**6.4%**	**0**	**40,700** Worldwide

Advisories

Second Issue

Initial Affected Population	Number of Events of Loss of Therapy Due to Increased Rate of Lithium Depletion	Estimated Remaining Active Population
All EnRhythm pacemakers (**146,500** Worldwide)	**0** Worldwide	**40,700** Worldwide

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[1] *The 8.5 year estimate represents a high use scenario (DDD, 100% pacing in atrium and ventricle with 3.0 V output in both chambers). The 10.5 year estimate represents a typical use scenario for a sinus node dysfunction patient with the MVP function ON (AAI(R) <=> DDD(R), 50% pacing in atrium and 5% pacing in ventricle with 3.0 V output in both chambers). Projections are based on modeling and not actual field returns, due to limited availability of implant experience beyond 6 years. Field performance will continue to be monitored and modeling updated to reflect actual data.*

[2] *Accounts for underreporting of impedance ERIs based on the fraction of replaced devices in the U.S. registration system that are subsequently returned.*

Advisories

Potential Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Product

All Model 6930, 6931, 6948, and 6949 implantable defibrillation leads.

Advisory

There are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. These two locations account for approximately 90% of the chronic fractures identified in Returned Product Analysis (RPA). The remaining 10% of chronic fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

Patient Management Recommendations (Updated April 2011)

The Lead Integrity Alert (LIA) provides three days advance notice prior to inappropriate therapy to 76% of patients with lead fractures[1]. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks.

- **If a Fidelis lead fracture of any type has occurred,we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred. This data is available at http://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/sprint-fidelis-11-2015-update.html
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Advisories

Status Update

As of March 10, 2016, of the initial implant population of 205,600 in the United States, approximately 60,700 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 78.9% (+4.3/-4.0%) at 102 months. As the implanted population ages and the sample size increases for each time interval, the accuracy of the estimated survival probability will increase as shown by tighter confidence intervals.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	
279,500 Worldwide (**205,600** United States)	**6,776** Worldwide **(4,865** United States)	**80,00** Worldwide (**59,000** United States)	

Footnotes:

1: Swerdlow C, Gunderson, B, et al."Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Advisories

Potential Separation of Interconnect Wires (2005)

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. You may use the "Search forDevice Information" tool at http://wwwp.medtronic.com/productperformance/ to determine if a specific device is affected.

Advisory

This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output.

Separation of redundant interconnect wires has been observed on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. In October 2005, testing and analysis identified the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

No provocative testing can predict which devices may fail.

Patient Management Recommendations

Recommendation for the management of patients who have pacemakers affected by this advisory were changed in May 2009. Current recommendations are:

We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients in the 2005 Sigma advisory:

- Physicians should advise their patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness).
- Physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets. Medtronic will offer a supplemental device warranty if the device is not already at elective replacement time.
- Physicians should continue routine follow-up in accordance with standard practice for those patients who are not pacemaker dependent.

Status Update
Patient management recommendations remain unchanged. As of September 27, 2016, 850 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred eighty-four(484) of the Sigma devices (1.1%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 366 Sigma devices (0.90%) were returned with no information indicating a potential malfunction while implanted or with insufficient information to determine the state of the device at explant. Lacking definite information indicating proper operation until explant, these remaining devices are conservatively categorized as having experienced interconnect wire separation while implanted.

Advisories

Our original modeling predicted a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. However, as of May 2009 updated modeling now predicts a failure rate of 3.9% over the remaining device life of those devices still in service at that time.

Out of the initial advisory population of 40,000 worldwide, approximately 1,200 remain implanted. Approximately 300 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted
40,000 Implanted Worldwide (est.) (**9,900** United States)	**484** Worldwide (**98** United States) with information indicating a clinical presentation. An additional **366** Worldwide (**67** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**1,200** Worldwide (**300** United States)	**1.1%** Worldwide (**1.0%** United States)	**3.9%**

Performance Notes

Dual Chamber Pacemakers with Measurement Lock-up ERI
Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, and Vitatron Models E50A1, E60A1, and G70A1

Purpose of this Information

This Performance Note describes a rare measurement lock-up issue that impacts the Medtronic dual chamber pacemakers listed above. If this measurement lock-up occurs, the device will trigger a false Elective Replacement Indicator (ERI). A reset is available to clear this condition and there is no need to explant the device. This issue does not impact battery longevity.

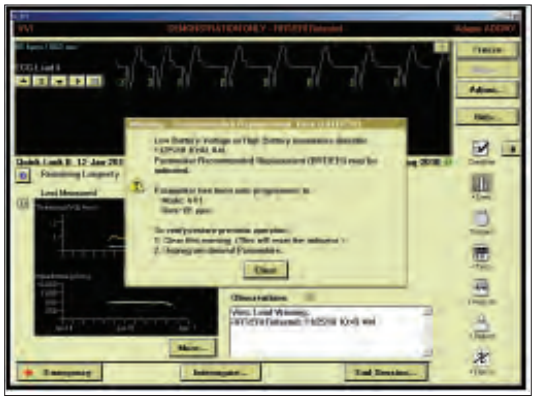
Background

If this rare measurement lock-up occurs in the pacemaker, it causes the device to read a value of zero for battery voltage. After four measurements of zero, the device will trigger ERI and revert to a VVI pacing mode at 65 bpm. There is no loss of ventricular pacing and the output voltage will remain the same.

Programmer Software Reset Method (Adapta, Versa, Sensia, Relia, Vitatron Series E and G)

Programmer software is available which can differentiate a regular ERI and an ERI caused by the measurement lock-up issue. Upon interrogation of a device with the measurement lock-up ERI, the programmer software recognizes the issue and guides the clinician to clear the ERI (Example 1). Following an ERI reset, the device parameters should be reviewed and reprogrammed to clinician specifications.

Example 1 – Programmer Software Detects Measurement Lock-up ERI

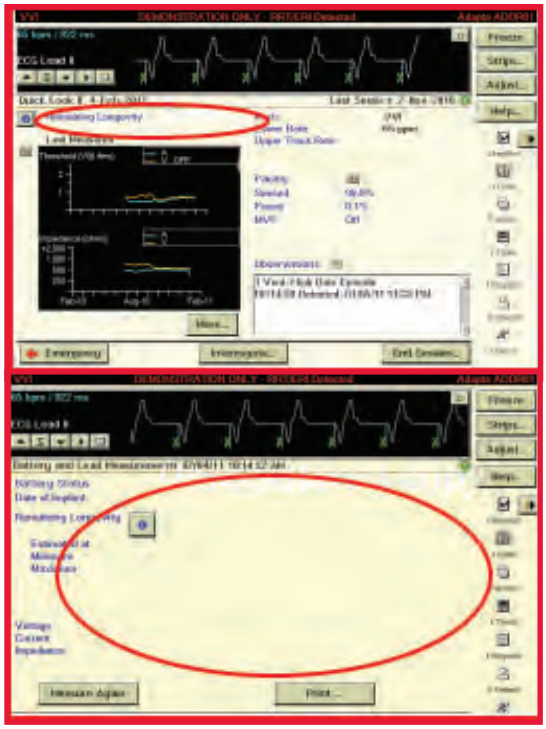


Reset Method for Kappa and EnPulse

A service tool continues to be available through Medtronic Technical Services to clear the measurement lock-up issue for Kappa and EnPulse devices.

The issue can be identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values (Example 2). If this measurement lock-up occurs, contact Medtronic Brady Technical Services at 1-800-505-4636 for assistance.

Example 2 – Programmer Screens for Measurement Lock-up ERI (Kappa and EnPulse)



Clinical Management of VCM near Elective Replacement

Background

Medtronic Technical Services has received reports of devices going to ERI or end of life (EOL) sooner than expected after a normal follow-up in which the device longevity was projected to be approximately 18 months. It has been noted that these cases typically involve Kappa 700 devices where Ventricular Capture Management set the ventricular lead to high output (5 V, 1 ms), which occurs by device design when a high threshold is measured. It is important for physicians and allied professionals to understand VCM behavior as it relates to longevity so that they can, in turn, understand how this affects It is important for physicians and allied professionals to understand VCM behavior as it relates to longevity so that they can, in turn, understand how this affects management of the device and follow-up visits as VCM equipped IPGs near the end of their expected life.

Device Longevity and VCM Behavior

Ventricular Capture Management is a feature that uses evoked response sensing to determine the stimulation threshold needed to capture the ventricular chamber. Proper detection of the evoked response is crucial to the VCM algorithm determining an accurate capture threshold. There are rare conditions, however, during which the VCM algorithm will not be able to measure the evoked response accurately.[1] When this occurs, for safety reasons the VCM algorithm will reprogram the output to 5 V, 1 ms until the subsequent VCM measurement.

If the device has considerable remaining longevity, these occasional excursions to high output do not substantially affect remaining longevity. However, if the device has less than approximately 18 months remaining longevity, there is the possibility that the high output condition caused by the 5 V, 1 ms output will drain the battery and trigger ERI.

When ERI is declared by the device, VCM is disabled and the outputs are left at 5 V, 1 ms until the device is reprogrammed at an in-office follow-up. This increased current drain of a high output condition will speed depletion of the device, possibly resulting in the device getting to the EOL (battery voltage ≤ 2.15 V).

Please note that the following parameter changes occur when the device goes to ERI:

Table: IPG Therapy Parameter Changes at ERI

Parameter	Value
Pacing Mode	VVI
Lower Rate	65 bpm
Single Chamber Hysteresis	OFF
Sleep Function	OFF
Ventricular Capture Management	OFF
Atrial Sensing Assurance	OFF
Ventricular Sensing Assurance	OFF

Kappa 700 is Medtronic's first-generation VCM algorithm, which has a relatively higher incidence of evoked response undersensing compared to subsequent algorithms, resulting in more frequent high output conditions. Therefore, Kappa 700 products are the primary focus of this note. It should be noted that IPGs equipped with the second-generation VCM algorithm (Kappa 900, EnPulse, Adapta/Versa/Sensia, and Relia) have not been observed with evoked response undersensing in the general population, though the items listed in "Follow-Up Considerations" may also be used on these devices.

Follow-Up Considerations

- Estimated longevity in the event the device goes to high output can be determined by the following steps. This allows the clinician to determine follow-up frequency if he or she is concerned the device may go to ERI due to high output.
  - Program the ventricular channel to 5 V, 1 ms
  - Navigate to Data/Battery and Lead Measurements
  - When the message stating "Warning – Old Data" is displayed, select "Yes" to measure battery voltage and lead impedance at the new ventricular outputs
  - An updated remaining longevity estimate will be calculated on the elevated outputs. Note the "Minimum Remaining Longevity." Clinical decisions can be based on this value.
  - Program the Amplitude and Pulse Widths back to their original values before leaving the session
- If the capture trends and lead impedance trends are stable, VCM can be programmed to "Monitor Only" for the remaining device life. This should be considered only if remaining longevity is 18 months or less.
- Follow-up frequency can be increased for those patients who do not have stable capture or lead impedance trends. This can be done via a CareLink Home Monitor, or in-office.

[1] Medtronic, Inc. (2001). Medtronic Kappa 700/600 Series Pacemaker Reference Guide (Chapter 4, p. 27). Can be retrieved from http://manuals.medtronic.com.

Performance Notes

General Follow-Up and Replacement of ICD Leads

Implanted leads operate in the challenging biochemical environment of the human body and the body's response to foreign objects. Implanted leads are also subject to mechanical stresses associated with heart motion, body motion, and patient anatomy.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. Unlike implantable cardioverter defibrillators (ICDs), a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. The determination that a lead may be approaching end of service life requires follow-up of the chronically implanted lead and thorough evaluation of lead integrity at ICD replacement.

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/clinic follow-up practice, and Medicare guidelines.

In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity.

- Measure pacing and sensing threshold and compare to the chronic baseline. Significant increases or decreases may be indicative of lead failure, dislodgement, perforation, exit block, etc.
- Measure pacing impedance where possible and compare to the chronic baseline. Decreases of 30% or more or pacing impedances below 200-250 ohms may be indicative of insulation failure. Sudden and significant increases in pacing impedance may be indicative of conductor fracture.
- High voltage lead circuit impedance should be between 10-75 ohms at system implant. Chronic measurements below 10 and above 200 ohms may be indicative of high voltage lead circuit failure.
- Carefully review ECGs or the nonsustained detection log on Medtronic ICDs for indications of pacing and/or sensing abnormalities such as oversensing, undersensing, and loss of capture
- Elicit and investigate any patient complaints/symptoms that may be suggestive of potential lead failure

Where routine follow-up indicates, additional tools should be used to further evaluate performance. Tools include radiographic data, ICD electrograms, ICD Patient Alert and performance information from the Product Surveillance Registry (PSR).

The final decision on the functional integrity and continued use of an implanted lead must be a matter of medical judgment based on these factors as well as specific patient conditions.

General Criteria for Lead Replacement

The evaluation of a chronically implanted lead is an important part of the decision to continue to use the lead with a new ICD. However, these results alone do not necessarily predict the future integrity of that lead. With the expected longevity of today's ICDs varying between approximately 5 and 10 years, a physician replacing a device should consider a number of factors, including those listed below.

Factors that should be considered in a decision to replace or continue to use include:

- Pacing and sensing thresholds should be evaluated for the potential to maintain acceptable levels
- Pacing impedance should be measured. Bear in mind that pacing impedance below 250 ohms results in excessive battery current drain, which may seriously compromise ICD longevity, regardless of lead integrity.
- The physical appearance of the lead should be examined for insulation cracks, breaches, or other indications of lead wear or degradation
- Medtronic System Longevity Study data should be referenced. Actuarial survival of the lead and the observed lead failure mechanisms are specific factors to consider. Use of a new lead should be considered if failure mechanisms suggest an increased time dependency as suggested in the shape of performance curve for the specific lead model.
- Current publications may provide additional information on the clinical management of leads.[1-3] Ultimately, the decision to replace an implanted lead involves medical judgment.

[1] Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE.* June 2002;25(6):879-882.

[2] Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol.* January 1, 2003;41(1):73-80.

[3] Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. July 2007;4(7):892-896.

Clinical Management of High-Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus, ICD systems attempt to dynamically adjust sensing of electrical events and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T and far-field P waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high-voltage therapies. This is due, in part, to the desire to err on the side of delivering lifesaving high voltage therapy rather than withholding it. Thus, an ICD system that is experiencing oversensing issues will continue to deliver therapeutic shocks as required, but may also subject the patient to unnecessary shocks.

Oversensing can be difficult to manage, in that the precipitating cause of the oversensing can be problematic to isolate. Oversensing can be caused by many factors, including myopotentials/far-field sensing, electromagnetic interference, T wave sensing, connector issues, incomplete or complete conductor fractures, and insulation breaches. While the individual physician must exercise medical judgment in determination of appropriate clinical management of ICD systems, the chart below may assist in the process of causal factor differentiation and possible intervention.

Phenomenon	Causal Factors	Characteristics	Management/Comments
Myopotentials/ Far-field sensing	Diaphragmatic muscle potentials in breathing, wide tip-to-ring (coil on integrated bipolar leads) spacing	Nonphysiological sensed event on EGM, which may confuse detection potentially resulting in false positive shocks	Check R waves for deterioration. Reprogram sensitivity. Try repositioning lead. Consider change-out to true bipolar lead, or if true bipolar lead in use, one with closer tip-to-ring spacing than current lead.
EMI (Electro-Magnetic Interference)	Arc welders, electrical generators, store walk-through security scanners, poorly insulated electrical equipment	Multiple and consecutive short intervals (< 140 ms) independent of underlying sinus beats. Associated with proximity to the EMI source.	Avoid EMI areas. True bipolar leads less susceptible.
T-wave sensing	Drugs, ischemic tissue, exercise, Long QT syndrome, electrolyte imbalance	Sense markers seen on EGM related to T wave. False positive detection.	Check for R wave deterioration and characteristics. If R wave > 3.0 mV, reprogram sensitivity. If R wave < 3.0 mV, reposition/replace lead. Address causal factor (e.g., drugs [if appropriate/medically viable]).
Connector problems	Loose setscrew, cross-threaded setscrew, incomplete lead insertion into header	This is an acute phenomenon seen within 6 months of implant (usually sooner)	Requires invasive check of connections. May be reproducible with pocket manipulation.
Incomplete conductor fracture	One or more filars of a multifilar conductor fracturing while leaving enough filars intact to provide a conduction circuit	Characterized by chaotic oversensing related to motion of the fracture site	Check EGMs and x-rays. Manipulate lead at suspected fracture site if possible as a provocative test. If confirmed, replace lead.
Lead insulation breach	Cuts, tears, metal ion oxidization, abrasion, cold flow, environmental stress cracking	Characterized by cyclical and/or erratic, intermittent, spontaneous oversensing; often post-pace or post-shock can cause false positives	Replace lead. If acute, usually secondary to implant damage/replacement damage. If late, material characteristic.
Oversensing during interrogation with programming head (not wireless telemetry) with complete lead fracture	Interrogation with a programming head in combination with complete lead fracture that creates an open circuit can induce noise on the sensing circuitry inside the ICD can	Nonphysiologic sensed event on EGM. If detection is enabled during interrogation, oversensing may result in inappropriate therapy.	Quickly remove the programming head. CANCEL the interrupted interrogation and manually load the software for the specific device model. Reposition the programmer head over the device and immediately select SUSPEND. Device will resume detection when programming head is removed, or when RESUME is selected. Replace lead.

Technical Services is available at all times to advise clinicians in the troubleshooting and management of Medtronic products. For assistance in the United States, please call 1 (800) 723-4636. In other countries, please contact your local Medtronic representative.

Performance Notes

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

Test/Observation	Possible Insulation Failure	Possible Conductor Failure	Possible Other System Failure	Effect on Test/ Observation
Pacing Impedance (Telemetered or Measured Invasively)	Sudden and Significant Decrease	Sudden and Significant Increase	Dislodgement Perforation Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Increase or Decrease Increase or Decrease Increase or Decrease
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase, Especially in Bipolar System	Sudden and Significant Increase	Dislodgement Exit Block Infarct at Electrode Site Perforation Improper IPG/Lead Connection	Increase Increase Increase Increase Increase
Electrograms (Telemetered or Measured Invasively)	Sudden and Significant Decrease in Amplitudes and/or Slew Rates for P and/or R Waves	Sudden and Significant Decrease or Disappearance of Amplitudes and/or Slew Rates for P and/or R Waves	Dislodgement Perforation Infarct at Electrode Site Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Decrease Decrease Decrease Decrease
Waveform Analysis (Oscillographs of Pacer Artifact from ECG Electrodes)	Sudden Increase in Ratios of Leading-Edge Voltages to Trailing-Edge Voltages (i.e., over 25% increase)	Intermittent or No Pacer Artifacts (Even in Asynchronous Mode)	Improper IPG/Lead Connection	Intermittent or No Pacer Artifacts (Even in Asynchronous Mode)
Radiographs (Post-Implant, Recent, Current)	Not Discernible	Visual Observation of Conductor/Connector/ Electrode Fracture (Sometimes Discernible)	Dislodgement or Perforation. Improper IPG/Lead Connection.	Sometimes Discernible
Visual Inspection (Invasive)	Insulation Breach and/or Degradation, or Ligature Cut-Through	Not Easily Discernible	Connector Defect or Connector Pulled Apart. Improper IPG/ Lead Connection.	Sometimes Discernible
Pectoral Muscle Stimulation	Sudden Onset, Especially in Bipolar System		Connector Defect in Bipolar or Unipolar. Hypersensitivity to Unipolar Pulse Generator Can. Anti-Stim Coating or Protection Deficient.	
Phrenic Nerve/ Diaphragmatic Stimulation	Sudden Onset in Bipolar or Unipolar Systems		Perforation or Displacement of Atrial Lead (Phrenic Nerve)	
Pacemaker ECG Stimulus Artifact Size and Morphology Change (May Not Be Possible with Digital ECG)	Sudden Onset and Significant Change, Especially in Bipolar System (Increase in Size)	Sudden Changes, Usually a Decrease in Size	Perforation or Dislodgement. Connector Defect. Improper IPG/ Lead Connection.	Sometimes Discernible
Oversensing (Intermittent or Continuous)	Sudden Onset, Especially in Bipolar Systems		Physical Contact between the Electrode(s) on the Lead and that of Another Lead. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection.	Sometimes Discernible
Undersensing (Intermittent or Continuous)	Sudden Onset in Either Unipolar or Bipolar Systems	Sudden Onset in Either Unipolar or Bipolar Systems	Dislodgement or Perforation. Infarct at Electrode Site. Electrolyte Imbalance. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection.	Sometimes Discernible
Loss of Capture	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	

Mailer Kits Available for Returning Product

Medtronic urges all physicians to return explanted products and to notify Medtronic when a product is no longer in use, regardless of reason for explant or removal from use. The procedures for returning products vary by geographic location.

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRHF Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

If the product being returned is located outside the United States, please contact your local Medtronic representative for instructions.

Medtronic also requests the return of devices from non-clinical sources, such as funeral homes, and will assume responsibility for storage and disposal of the product once received.

Mailer kits can be obtained by contacting the Returned Product Lab.

CRHF Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

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