Medtronic

Cardiac Rhythm Disease Management

Product Performance Report

Important Patient Management Information for Physicians

2011

Second Edition – Issue 65

This report is available online at
www.medtronic.com/CRDMProductPerformance

A Message from the Vice President

Dear Customer,

At Medtronic, product quality and reliability have been and will continue to be a priority. For over 28 years, Medtronic has compiled and produced product performance reports with one primary goal, to provide you with the product information you need to best care for your patients.

Our commitment to you is best expressed in Medtronic's mission: "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." To this end, we continually explore new ways to expand, improve, and learn from our product performance systems and measures.

Our quality goals cannot be reached alone. We welcome your collaboration, insight, and recommendations. Please contact our Technical Services Department at 1 (800) 723-4636 with your feedback comments and any questions.

Your participation and assistance in returning explanted products are also critical. Returned products are tested and evaluated so that we can fully measure the performance of our devices. Please refer to the instructions on the next page for assistance in returning products to the Medtronic CRDM Returned Product Analysis Laboratory.

As we constantly strive to exceed your expectations, we thank you for your dedication to improving and saving the lives of those suffering from cardiac rhythm disorders.

With appreciation and warm regards,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Disease Management
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)
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For questions related to this CRDM Product Performance Report, please call US Technical Services at the number above, or write to:

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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

CRDM Returned Product Analysis Laboratory

Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

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CRDM Product Performance Report

2011 Second Edition
Issue 65

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Introduction

All product performance reports are not created equal. For 28 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 CRDM's System Longevity Study. 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 System Longevity Study.

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.

continued

Introduction continued

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.

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, and leads to Medtronic's CRDM 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 CRDM 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 of this report.

Overview of Survival Analysis

Medtronic uses the Cutler-Ederer actuarial life table method to estimate the length of time over which devices and leads 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 System Longevity Study.

For 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. Devices and leads removed for these reasons are said to be *suspended*. Examples include devices and leads:

- still in service at the time the analysis is performed
- 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 CRDM 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 (page 6)* and *Method for Estimating Lead Performance (page 81)*.

continued

Introduction continued

This simple example describes the survival analysis method used to establish the survival probability estimates for Medtronic CRDM devices and leads.

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.

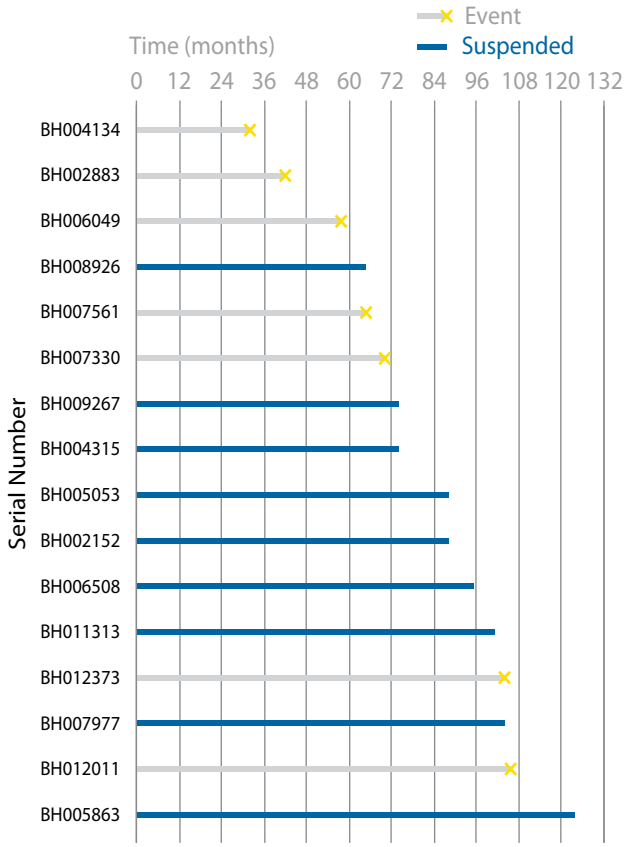


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because 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.

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.

continued

Introduction continued

The Cumulative Survival Probabilities (G) from the last column 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 shown in Table 1.

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:

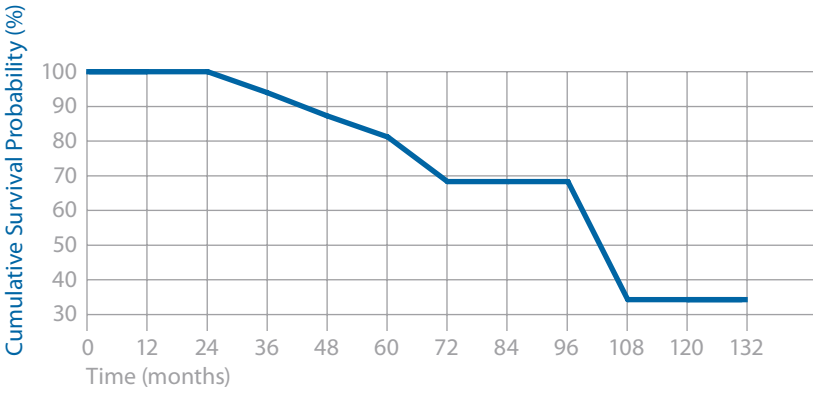
A	B	C	D	E	F	G
Number Entered	**Number Suspended**	**Number of Events**	**Effective Sample Size**	**Proportion with Event**	**Interval Survival Probability**	**Cumulative Survival Probability**
Number of devices active at the start of the interval	Number of devices removed from service for reasons other 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.

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.

continued

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 curves are actually computed and plotted using 1-month intervals (for CRT, ICD, and IPG devices) or 3-month intervals (for leads).

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

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

Method for Estimating CRT, ICD, and IPG Device Performance

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 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 with neither malfunction nor battery depletion.

The survival estimates are determined from the analysis of Medtronic CRDM'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 CRDM and analyzed in the CRDM 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 CRDM 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 CRDM 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 pacing or defibrillation 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. A summary of these malfunctions is presented for the most recently market-released models.

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 CRDM 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.

continued

Method for Estimating CRT, ICD, and IPG Device Performance

continued

The Standard Actuarial Method is used to estimate IPG and ICD survival. This product performance report has been prepared in accordance with International Standard ISO 5841-2:2000(E).

For reference purposes, the following pages include estimated longevities for each model. 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 CRDM maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

continued

Method for Estimating CRT, ICD, and IPG Device Performance

continued

Medtronic CRDM adjusts all-cause survival estimates to account for underreporting. While this lowers our all-cause survival estimates, we feel it gives a more accurate perspective on real performance.

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 estimates of IPG and ICD survival. This method is commonly used by medical researchers and clinicians.

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%.

The survival curves are statistical estimates. As 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 corresponding 95% confidence intervals for the standard errors, and the complementary log-log method is used to produce the confidence bounds.

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 CRDM 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 analyzing experience in Medtronic's Device And Registrant Tracking (DART) system.

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.

continued

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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 device 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.

To ensure the number of devices in service is not overstated, Medtronic addresses this underreporting in two ways. Regular updates obtained from the Social Security Administration about deceased persons is 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.

7289 InSync II Marquis

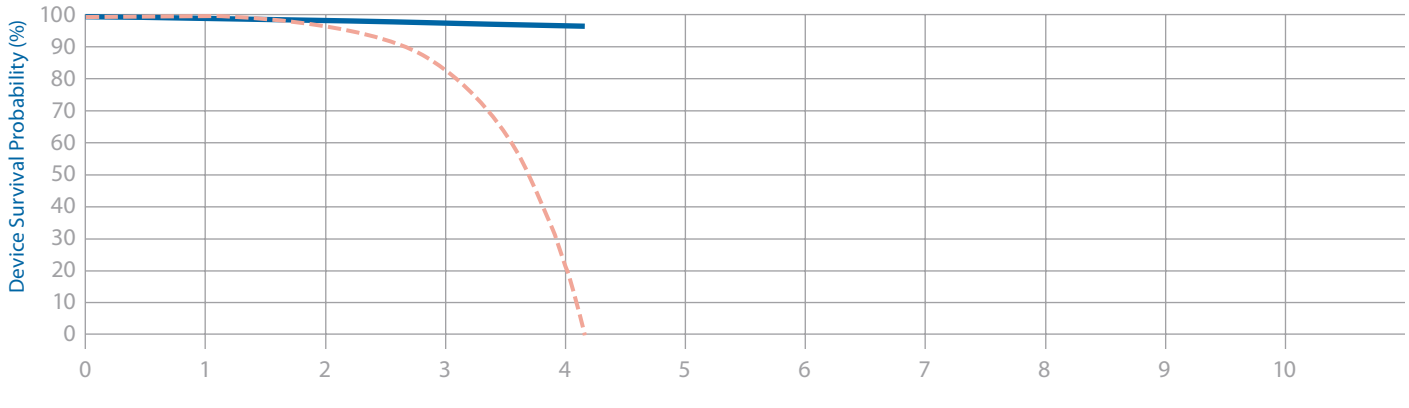
Product Characteristics

US Market Release	Aug-03
Registered US Implants	28,000
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	6,538

Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	304
Therapy Function Not Compromised	272
Electrical Component	25
Software/Firmware	1
Possible Early Battery Depletion	246
Therapy Function Compromised	32
Battery *(9 malfunctions related to advisory)*	10
Electrical Component	22

NBD Code	VVED
Serial Number Prefix	PRJ
Max Delivered Energy	30 J
Estimated Longevity	See page 22



		1 yr	2 yr	3 yr	4 yr	at 50 mo
%	———	99.9	99.7	98.8	98.0	97.9
%	- - - -	99.6	96.7	83.1	23.8	0.4
#		24,000	18,000	13,000	2,400	600

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

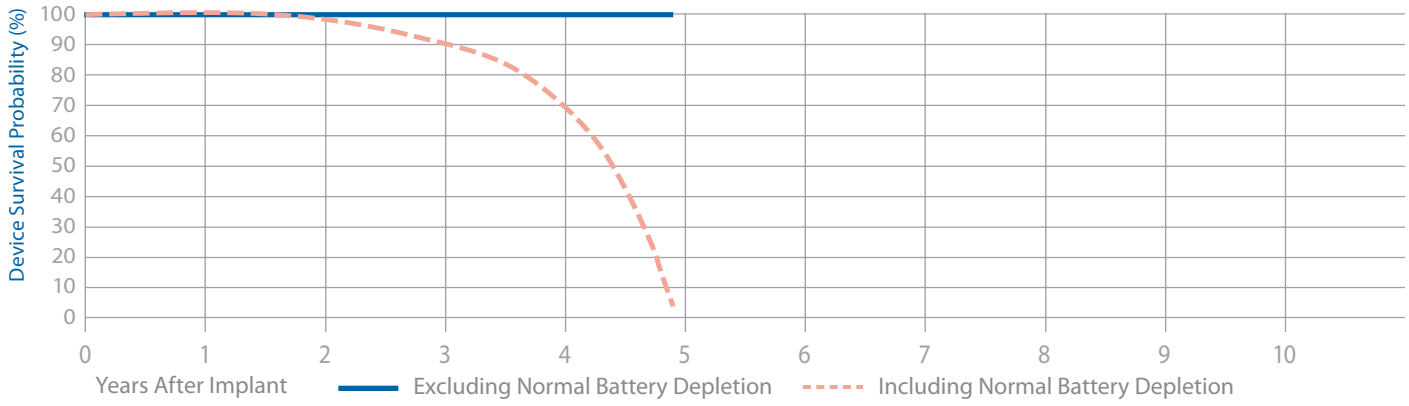
7297 InSync Sentry

Product Characteristics

US Market Release	Nov-04
Registered US Implants	9,000
Estimated Active US Implants	700
Normal Battery Depletions (US)	2,479
Advisories	None

Malfunctions (US)	39
Therapy Function Not Compromised	37
Battery	1
Electrical Component	10
Software/Firmware	1
Possible Early Battery Depletion	25
Therapy Function Compromised	2
Electrical Component	2

NBD Code	VVED
Serial Number Prefix	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 22



		1 yr	2 yr	3 yr	4 yr	at 59 mo
%	———	100.0	99.9	99.6	99.5	99.4
%	- - - -	99.8	97.8	89.8	70.0	3.4
#	Effective Sample Size	7,700	6,700	5,200	3,300	300

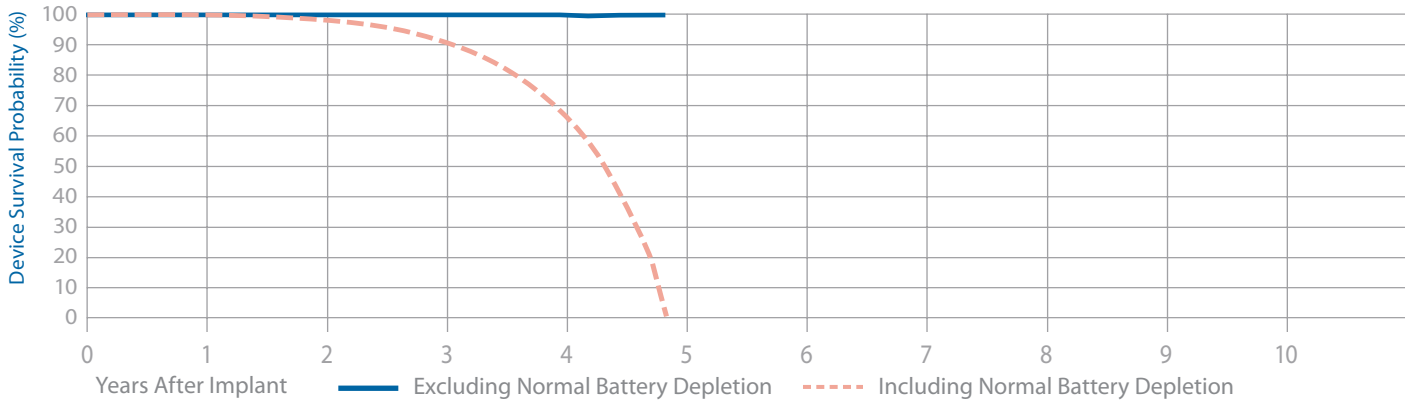
7299 InSync Sentry

Product Characteristics

US Market Release	Apr-05
Registered US Implants	31,000
Estimated Active US Implants	4,700
Normal Battery Depletions (US)	7,907
Advisories	None

Malfunctions (US)	162
Therapy Function Not Compromised	152
Electrical Component	16
Software/Firmware	2
Possible Early Battery Depletion	133
Other	1
Therapy Function Compromised	10
Electrical Component	10

NBD Code	VVED
Serial Number Prefix	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 22



		1 yr	2 yr	3 yr	4 yr	at 58 mo
%	———	100.0	99.9	99.7	99.3	99.1
%	- - - -	99.8	97.9	90.2	66.4	1.5
#	Effective Sample Size	27,000	24,000	19,000	11,000	700

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

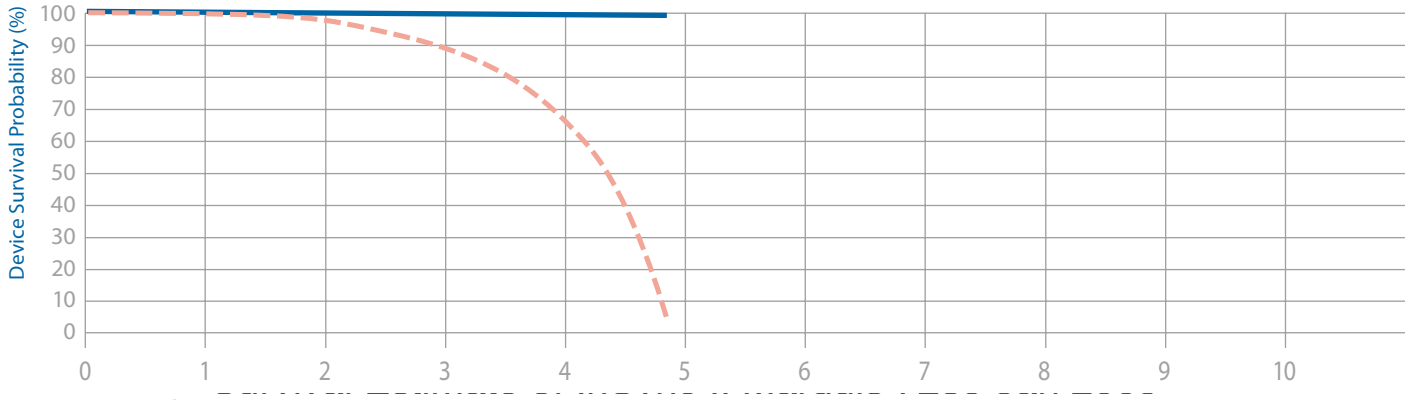
7303 InSync Maximo

Product Characteristics

US Market Release	Jun-04
Registered US Implants	17,000
Estimated Active US Implants	1,200
Normal Battery Depletions (US)	4,713
Advisories	None

Malfunctions (US)	73
Therapy Function Not Compromised	66
Electrical Component	15
Software/Firmware	2
Possible Early Battery Depletion	49
Therapy Function Compromised	7
Electrical Component	7

NBD Code	VVED
Serial Number Prefix	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 22



		1 yr	2 yr	3 yr	4 yr	at 58 mo
%	———	100.0	99.8	99.6	99.4	99.4
%	- - - -	99.8	97.7	89.0	66.2	4.2
#		15,000	13,000	10,000	5,700	500

Effective Sample Size

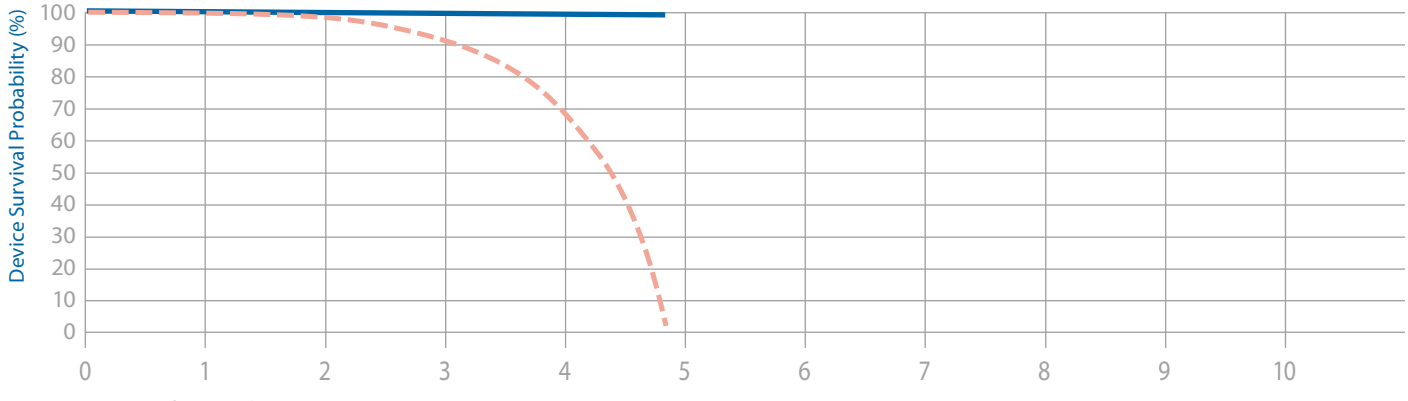
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	19,000
Estimated Active US Implants	4,000
Normal Battery Depletions (US)	3,975
Advisories	None

Malfunctions (US)	92
Therapy Function Not Compromised	89
Battery	1
Electrical Component	12
Possible Early Battery Depletion	76
Therapy Function Compromised	3
Electrical Component	3

NBD Code	VVED
Serial Number Prefix	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 22



		1 yr	2 yr	3 yr	4 yr	at 58 mo
%	———	100.0	99.9	99.6	99.2	99.2
%	- - - -	99.8	97.9	90.9	69.4	4.1
#		17,000	14,000	11,000	5,800	400

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

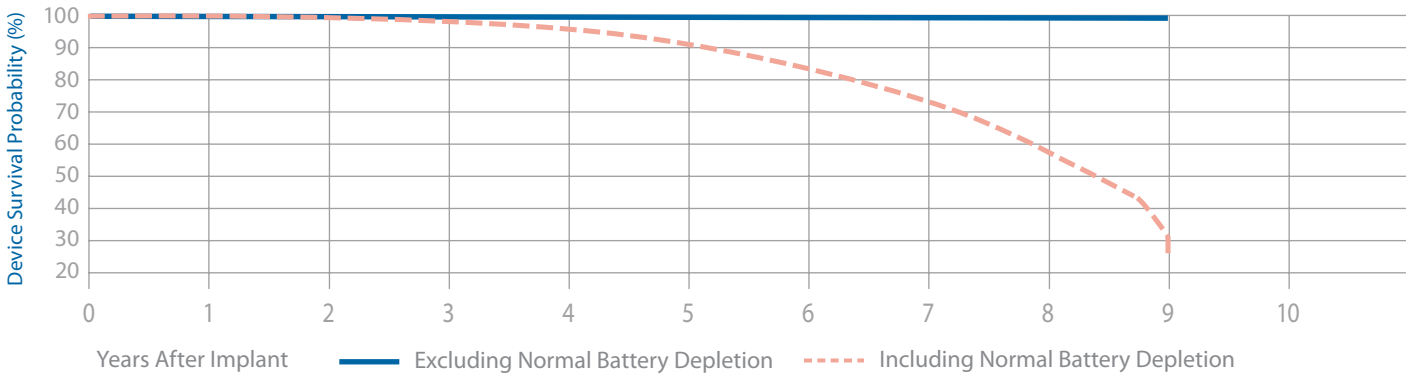
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,000
Estimated Active US Implants	1,900
Normal Battery Depletions (US)	1,103
Advisories	None

Malfunctions (US)	32
Therapy Function Not Compromised	8
Electrical Component	4
Possible Early Battery Depletion	3
Other	1
Therapy Function Compromised	24
Electrical Interconnect	24

NBG Code	DDDR
Serial Number Prefix	PIN
Estimated Longevity	See page 23



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7yr	8 yr	9 yr
%	100.0	100.0	99.9	99.8	99.7	99.6	99.5	99.5	99.4
%	99.9	99.7	98.2	96.1	91.2	84.0	73.7	58.2	29.6
#	12,000	10,000	8,000	6,300	4,900	3,600	2,600	1,500	100

Effective Sample Size

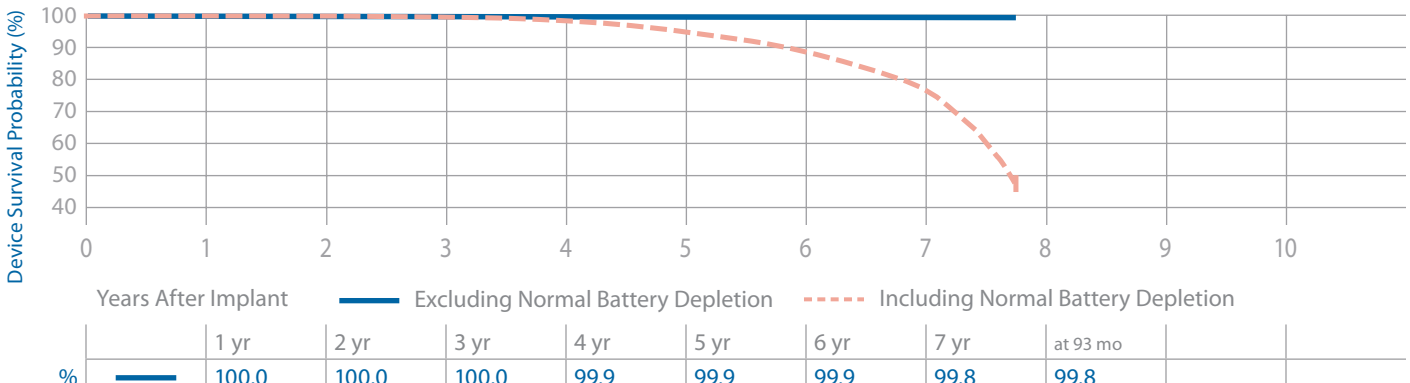
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	39,000
Estimated Active US Implants	18,000
Normal Battery Depletions (US)	963
Advisories	None

Malfunctions (US)	18
Therapy Function Not Compromised	10
Electrical Component	5
Electrical Interconnect	2
Possible Early Battery Depletion	1
Other	2
Therapy Function Compromised	8
Electrical Component	3
Electrical Interconnect	5

NBG Code	DDDR
Serial Number Prefix	PKF
Estimated Longevity	See page 23



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.8
%	99.9	99.8	99.3	97.6	94.6	88.4	76.0	47.6
#	31,000	23,000	16,000	12,000	7,600	4,400	2,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

C154DWK, C164AWK, C174AWK Concerto

Product Characteristics

	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	81,000	3,500
Estimated Active US Implants	49,000	300
Normal Battery Depletions (US)	3,893	222

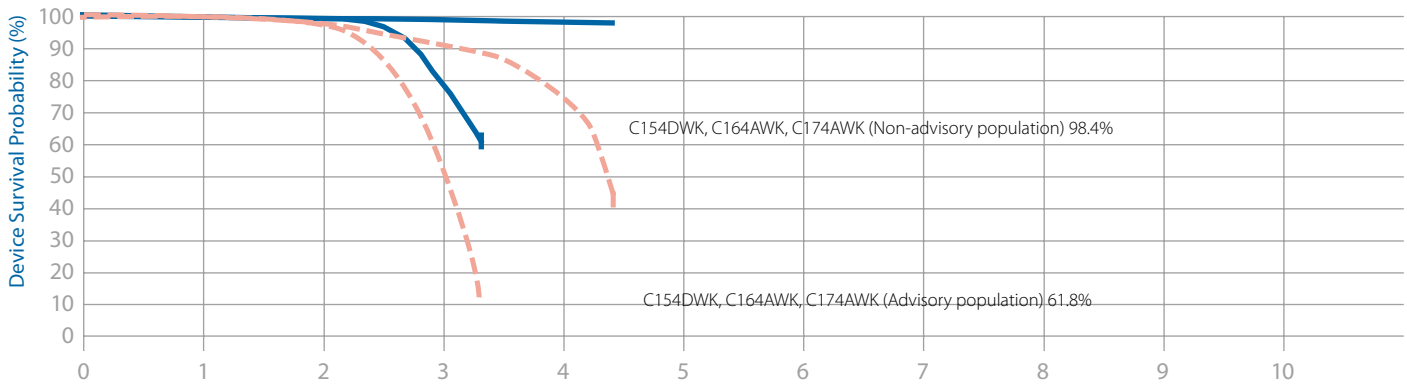
Advisories: See page 148 – 2009 Potential Reduced Device Longevity

Performance Note: See page 159 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	429	1,286
Therapy Function Not Compromised	398	1,272
Electrical Component	24	1,269
Electrical Interconnect	1	
Software/Firmware	1	
Possible Early Battery Depletion	369	3
Other	3	
Therapy Function Compromised	31	14
Electrical Component	29	13
Electrical Interconnect	2	1

NBD Code	DDED
Serial Number Prefix	PVU, PVT, PVR
Max Delivered Energy	35 J
Estimated Longevity	See page 22

(N) = Non-advisory population
(A) = Advisory population



Non-Adv	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	99.8	99.5	99.0	98.4
%	99.8	98.1	92.0	75.6	43.3
#	72,000	60,000	35,000	8,200	400
Effective Sample Size					

Adv Pop	1 yr	2 yr	3 yr	at 40 mo
%	99.9	99.5	79.3	61.8
%	99.8	97.1	50.7	11.5
#	3,100	2,700	1,300	400
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

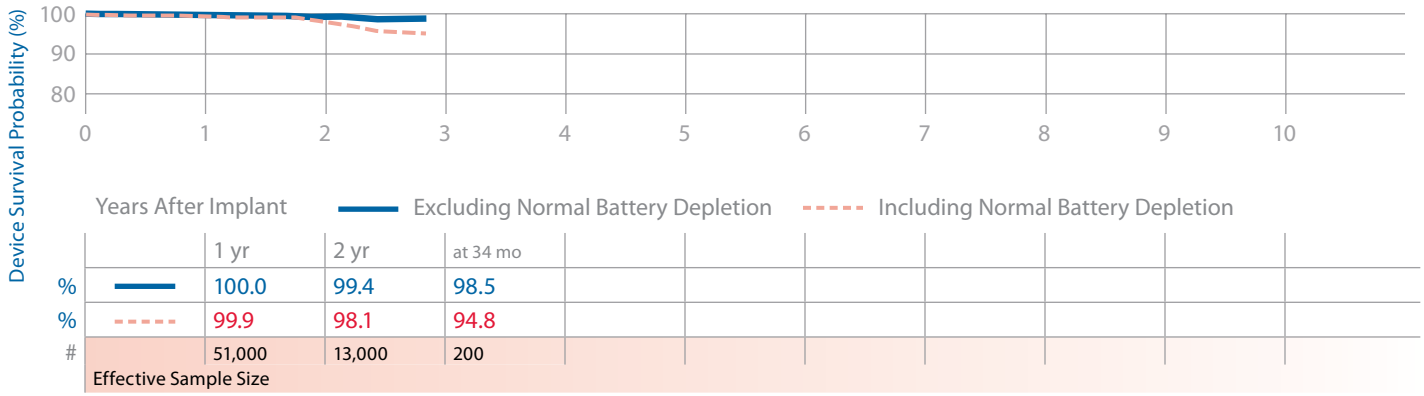
D224TRK Consulta CRT-D

US Market Release	Sep-08
Registered US Implants	54,000
Estimated Active US Implants	46,000
Normal Battery Depletions (US)	93
Advisories	None

Malfunctions (US)	155
Therapy Function Not Compromised	150
Electrical Component	8
Software/Firmware	1
Possible Early Battery Depletion	141
Therapy Function Compromised	5
Electrical Component	5

Product Characteristics

NBD Code	DDED
Serial Number Prefix	PUD
Max Delivered Energy	35 J
Estimated Longevity	See page 22



	1 yr	2 yr	at 34 mo
%	100.0	99.4	98.5
%	99.9	98.1	94.8
#	51,000	13,000	200

Effective Sample Size

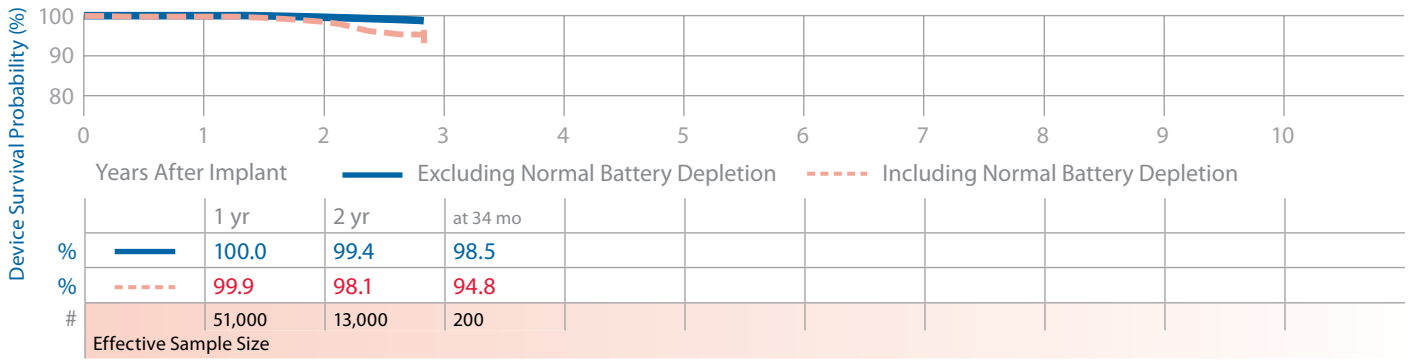
D274TRK Concerto II CRT-D

US Market Release	Aug-09
Registered US Implants	27,000
Estimated Active US Implants	24,000
Normal Battery Depletions (US)	14
Advisories	None

Malfunctions (US)	7
Therapy Function Not Compromised	6
Possible Early Battery Depletion	6
Therapy Function Compromised	1
Electrical Component	1

Product Characteristics

NBD Code	DDED
Serial Number Prefix	PZV
Max Delivered Energy	35 J
Estimated Longevity	See page 22



	1 yr	2 yr	at 34 mo
%	100.0	99.4	98.5
%	99.9	98.1	94.8
#	51,000	13,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

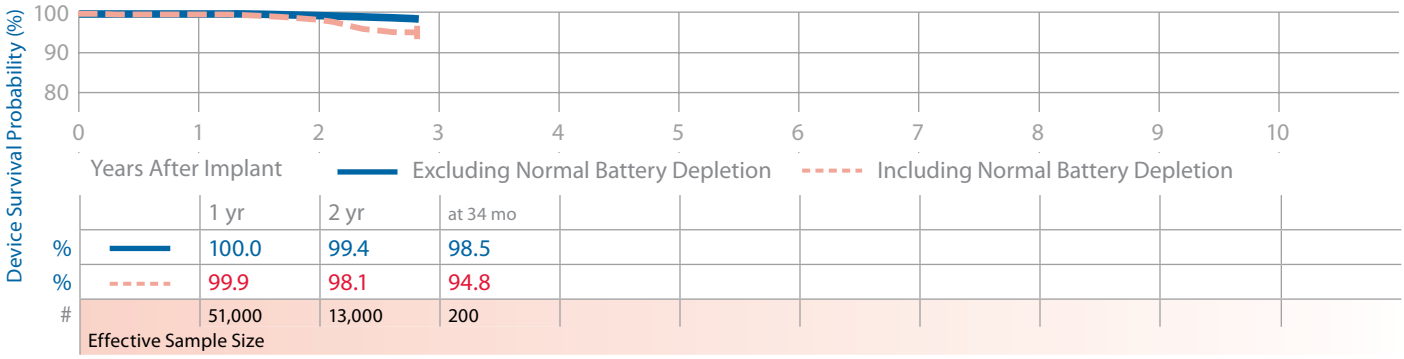
D284TRK Maximo II CRT-D

Product Characteristics

US Market Release	Sep-08
Registered US Implants	12,000
Estimated Active US Implants	9,900
Normal Battery Depletions (US)	39
Advisories	None

Malfunctions (US)	39
Therapy Function Not Compromised	39
Possible Early Battery Depletion	39
Therapy Function Compromised	0

NBD Code	DDED
Serial Number Prefix	PZP
Max Delivered Energy	35 J
Estimated Longevity	See page 22



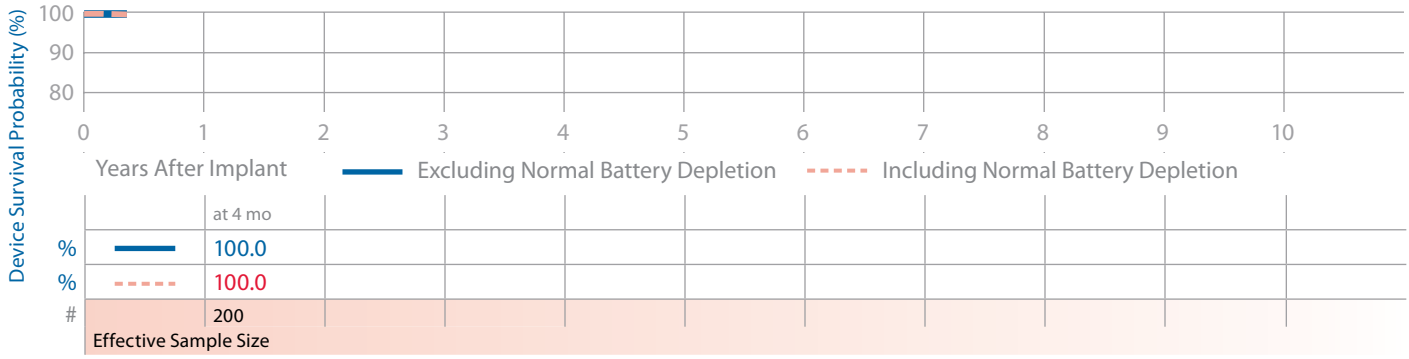
		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	99.4	98.5
%	Including Normal Battery Depletion	99.9	98.1	94.8
#	Effective Sample Size	51,000	13,000	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

D314TRG Protecta XT CRT-D

US Market Release	Mar-11	Malfunctions (US)	0	NBD Code	DDED
Registered US Implants	2,300	**Therapy Function Not Compromised**	0	Serial Number Prefix	PFS
Estimated Active US Implants	2,200	Possible Early Battery Depletion	0	Max Delivered Energy	35J
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 22
Advisories	None				

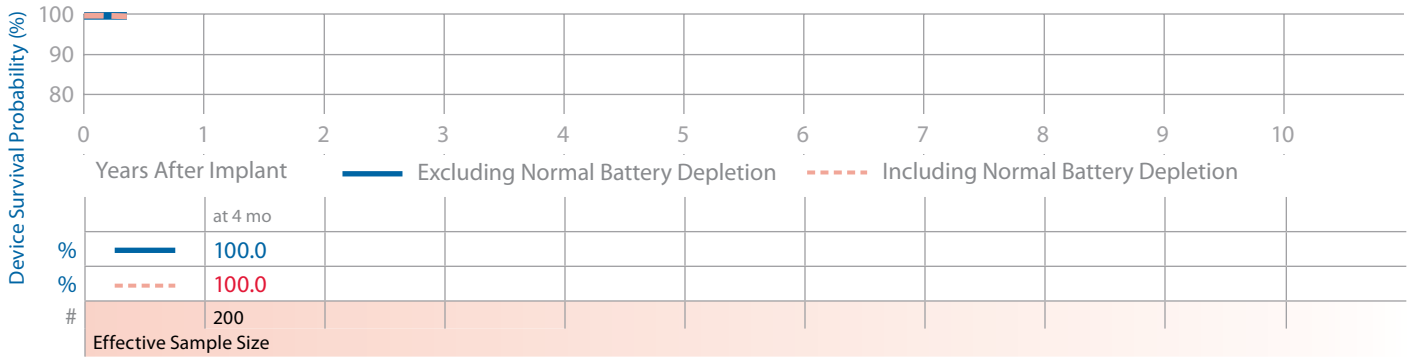
Product Characteristics



D334TRG Protecta CRT-D

US Market Release	Mar-11	Malfunctions (US)	0	NBD Code	DDED
Registered US Implants	500	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSO
Estimated Active US Implants	500	Possible Early Battery Depletion	0	Max Delivered Energy	35J
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 22
Advisories	None				

Product Characteristics

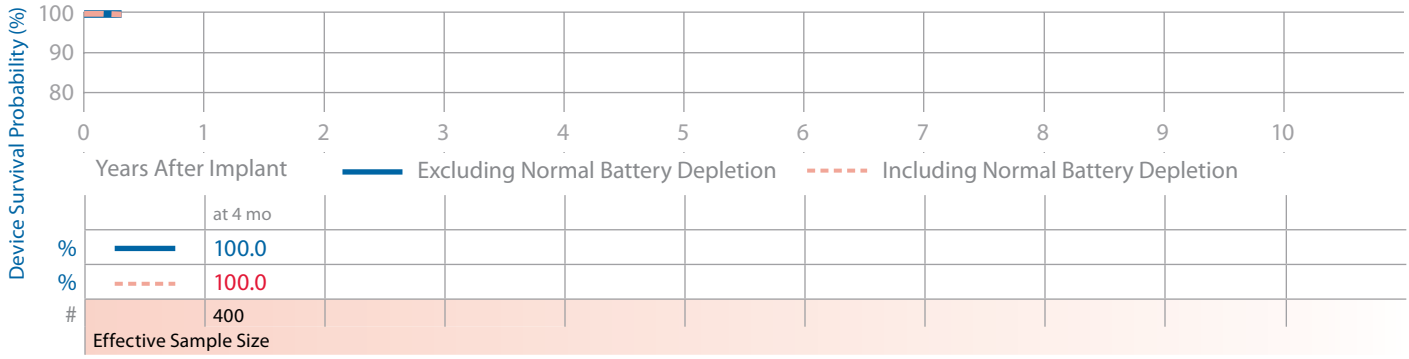


Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

C2TR01 Syncra CRT-P

Product Characteristics

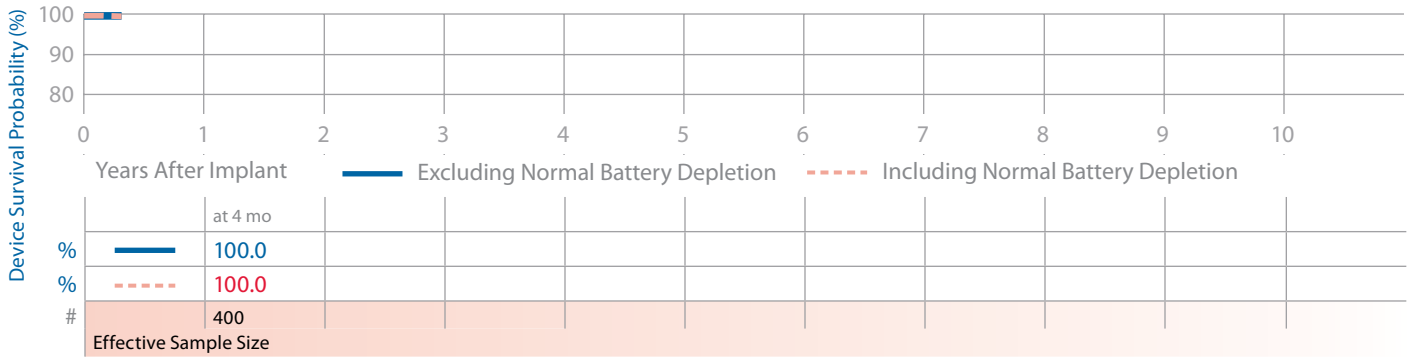
US Market Release	Mar-11	Malfunctions (US)	0	NBG Code	OOED
Registered US Implants	1,200	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZX
Estimated Active US Implants	1,200	Possible Early Battery Depletion	0	Max Delivered Energy	NA
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 23
Advisories	None				



C4TR01 Consulta CRT-P

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	0	NBG Code	OAED
Registered US Implants	700	**Therapy Function Not Compromised**	0	Serial Number Prefix	PVX
Estimated Active US Implants	700	Possible Early Battery Depletion	0	Max Delivered Energy	NA
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 23
Advisories	None				



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary (95% Confidence Interval)

The following table shows CRT device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)						Device Survival Probability (%)								
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant								
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
7289	InSync II Marquis	Aug-03	28,000	1,500	6,538	32	+	272	=	304	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	98.8 +0.2/-0.2	98.0 +0.2/-0.3	97.9 +0.2/-0.3 at 50 mo				
	Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9)	+	0	=	9 (advisory-related subset)	Including Normal Battery Depletion	99.6 +0.1/-0.1	96.7 0.2/-0.3	83.1 +0.6/-0.6	23.8 +0.9/-0.9	0.4 +0.2/-0.2 at 50 mo				
7297	InSync Sentry	Nov-04	9,000	700	2,479	2	+	37	=	39	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 0.1/-0.1	99.6 0.1/-0.2	99.5 0.1/-0.2	99.4 0.2/-0.3 at 59 mo				
											Including Normal Battery Depletion	99.8 0.1/-0.1	97.8 0.3/-0.4	89.8 +0.7/-0.8	70.0 +1.2/-1.3	3.4 +0.9/-0.8 at 59 mo				
7299	InSync Sentry	Apr-05	31,000	4,700	7,907	10	+	152	=	162	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.3 +0.1/-0.1	99.1 +0.1/-0.2 at 58 mo				
											Including Normal Battery Depletion	99.8 +0.0/-0.1	97.9 +0.2/-0.2	90.2 +0.4/-0.4	66.4 +0.7/-0.7	1.5 +0.4/-0.3 at 58 mo				
7303	InSync Maximo	Jun-04	17,000	1,200	4,713	7	+	66	=	73	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.2	99.4 +0.1/-0.2 at 58 mo				
											Including Normal Battery Depletion	99.8 +0.1/-0.1	97.7 +0.2/-0.3	89.0 +0.5/-0.6	66.2 +0.9/-0.9	4.2 +0.7/-0.6 at 58 mo				
7304	InSync Maximo	Apr-05	19,000	4,000	3,975	3	+	89	=	92	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.2	99.2 +0.2/-0.2 at 58 mo				
											Including Normal Battery Depletion	99.8 +0.1/-0.1	97.9 +0.2/-0.2	90.9 +0.5/-0.5	69.4 +0.9/-0.9	4.1 +0.9/-0.8 at 58 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)						Device Survival Probability (%)								
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant								
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
8040	InSync	Aug-01	15,000	1,900	1,103	24	+	8	=	32	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.5 +0.1/-0.2	99.5 +0.1/-0.2	99.4 +0.2/-0.3 at 9 yr
								-			Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	98.2 +0.3/-0.3	96.1 +0.4/-0.4	91.2 +0.7/-0.7	84.0 +0.9/-1.0	73.7 +1.3/-1.3	58.2 +1.6/-1.6	29.6 +3.4/-3.3 at 9 yr
8042	InSync III	Feb-03	39,000	18,000	963	8	+	10	=	18	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.3 at 93 mo	
								-			Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.3 +0.1/-0.1	97.6 +0.2/-0.3	94.6 +0.4/-0.4	88.4 +0.7/-0.7	76.0 +1.2/-1.3	47.6 +2.9/-3.0 at 93 mo	
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	81,000	49,000	3,893	31	+	398	=	429	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.5 +0.1/-0.1	99.0 +0.1/-0.1	98.4 +0.2/-0.2 at 53 mo				
	See page 159 – Performance note on Anomalies in MOSFET Integrated Circuit Technology										Including Normal Battery Depletion	99.8 +0.0/-0.0	98.1 +0.1/-0.1	92.0 +0.2/-0.2	75.6 +0.6/-0.6	43.3 +2.6/-2.6 at 53 mo				
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	3,500	300	222	14	+	1,272	=	1,286	Excluding Normal Battery Depletion	99.9 +0.1/-0.2	99.5 +0.2/-0.4	79.3 +1.6/-1.7	61.8 +2.0/-2.1 at 40 mo					
	Advisories: See page 148 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.8 +0.1/-0.3	97.1 +0.6/-0.7	50.7 +2.0/-2.0	11.5 +1.5/-1.4 at 40 mo					
	See page 159 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)						Device Survival Probability (%)								
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant								
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
D224TRK	Consulta CRT-D	Sep-08	54,000	46,000	93	5	+	150	=	155	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.4 +0.1/-0.1	98.5 +0.3/-0.3 at 34 mo						
											Including Normal Battery Depletion	99.9 +0.0/-0.0	98.1 +0.2/-0.2	94.8 +0.5/-0.6 at 34 mo						
D274TRK	Concerto II CRT-D	Aug-09	27,000	24,000	14	1	+	6	=	7	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.4 +0.1/-0.1	98.5 +0.3/-0.3 at 34 mo						
											Including Normal Battery Depletion	99.9 +0.0/-0.0	98.1 +0.2/-0.2	94.8 +0.5/-0.6 at 34 mo						
D284TRK	Maximo II CRT-D	Sep-08	12,000	9,900	39	0	+	39	=	39	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.4 +0.1/-0.1	98.5 +0.3/-0.3 at 34 mo						
											Including Normal Battery Depletion	99.9 +0.0/-0.0	98.1 +0.2/-0.2	94.8 +0.5/-0.6 at 34 mo						
D314TRG	Protecta XT CRT-D	Mar-11	2,300	2,200	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
D334TRG	Protecta CRT-D	Mar-11	500	500	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
C2TR01	Syncra CRT-P	Mar-11	1,200	1,200	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
C4TR01	Consulta CRT-P	Mar-11	700	700	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo								

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Elective Replacement (ERI)***		End of Life (EOL) Battery Voltage
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
7289	InSync II Marquis	DR+LV true	38 cc 76 g	30 J	Monthly Quarterly Semiannual	3.3 4.2 4.5	3.6 4.9 5.4	4.0 5.5 6.1	4.2 5.8 6.6	≤ 2.62 V	> 16 second charge time	3 months after ERI
7297	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	> 16 second charge time	3 months after ERI
7299	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	> 16 second charge time	3 months after ERI
7303	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	> 16 second charge time	3 months after ERI
7304	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	> 16 second charge time	3 months after ERI

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Recommended Replacement (RRT)***		End of Service (EOS)
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
C154DWK, C164AWK, C174AWK	Concerto	DR+LV true	38 cc 68 g	35 J	Monthly Quarterly Semiannual	3.8 5.5 6.3	4.3 6.8 8.0	4.8 8.0 9.8	5.0 8.8 10.9	≤ 2.62 V	—	3 month after RRT or › 16-second charge time
D224TRK	Consulta CRT-D	DR+LV true	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT or › 16-second charge time
D274TRK	Concerto II	DR+LV true	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT or › 16-second charge time
D284TRK	Maximo II CRT-D	DR+LV true	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT or › 16-second charge time
D314TRG	Protecta XT CRT-D	CRT-D	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT
D334TRG	Protecta CRT-D	CRT-D	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT

* Volume and mass differ by connector style.

** A full charge is a full energy therapeutic shock or capacitor reformation.

*** The minimum time between ERI and EOL (or RRT and EOS) is 3 months (100% pacing, two charges per month).

‡ Pacing mode is DDD for CRT models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510-ohm pace load per applicable channel. CRT models with shared biventricular pacing; InSync Marquis 7277 (LV impedance set to 510 ohms), InSync ICD 7272 (RV amplitude set to 4.0 V).

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.

Model Number	Family	Estimated Longevity			Elective Replacement Time Indicators
		Amplitude Setting	500 Lead Ω	1,000 Lead Ω	
8040	InSync	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	11.9 8.9 6.6	13.7 11.4 9.1	*
8042	InSync III	Low 2.5 V (A, RV, LV) Nominal 3.5 V (A, RV, LV) High 5.0 V (A, RV, LV)	8.3 5.9 4.1	9.9 7.8 6.0	*
C2TR01	Syncra CRT-P	Low 2.5 V (A, RV) Normal 3.5 V (A, RV) High 5.0 V (A, RV)	8.7 6.0 3.3	10.7 8.2 5.1	*
C4TR01	Consulta CRT-P	Low 2.5 V (A, RV) Normal 3.5 V (A, RV) High 5.0 V (A, RV)	8.7 6.0 3.3	10.7 8.2 5.1	*

*Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

7230 Marquis VR

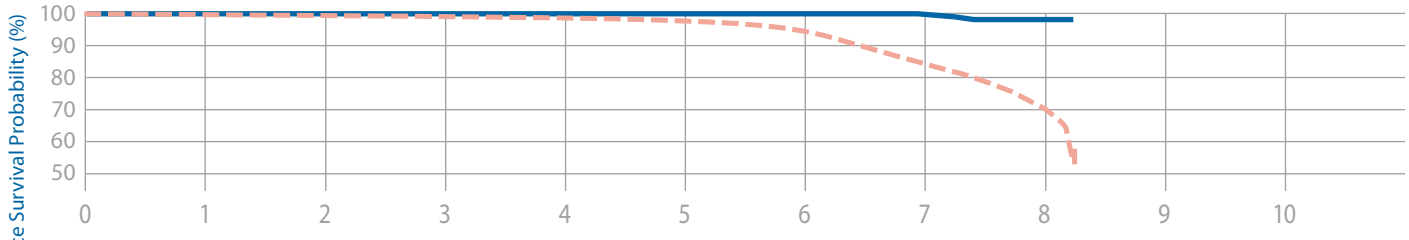
Product Characteristics

US Market Release	Dec-02
Registered US Implants	19,000
Estimated Active US Implants	6,200
Normal Battery Depletions (US)	794

Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	57
Therapy Function Not Compromised	28
Electrical Component	12
Battery *(1 malfunction related to advisory)*	1
Software/Firmware	1
Possible Early Battery Depletion	13
Other	1
Therapy Function Compromised	29
Battery *(19 malfunctions related to advisory)*	20
Electrical Component	9

NBD Code	VVEV
Serial Number Prefix	PKD, PLW, PLY
Max Delivered Energy	30 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.3	99.2
%	99.8	99.6	99.3	99.0	98.3	93.9	84.2	70.1	52.2
#	17,000	13,000	11,000	9,800	8,700	7,400	4,500	900	100

Effective Sample Size

7231Cx GEM III VR

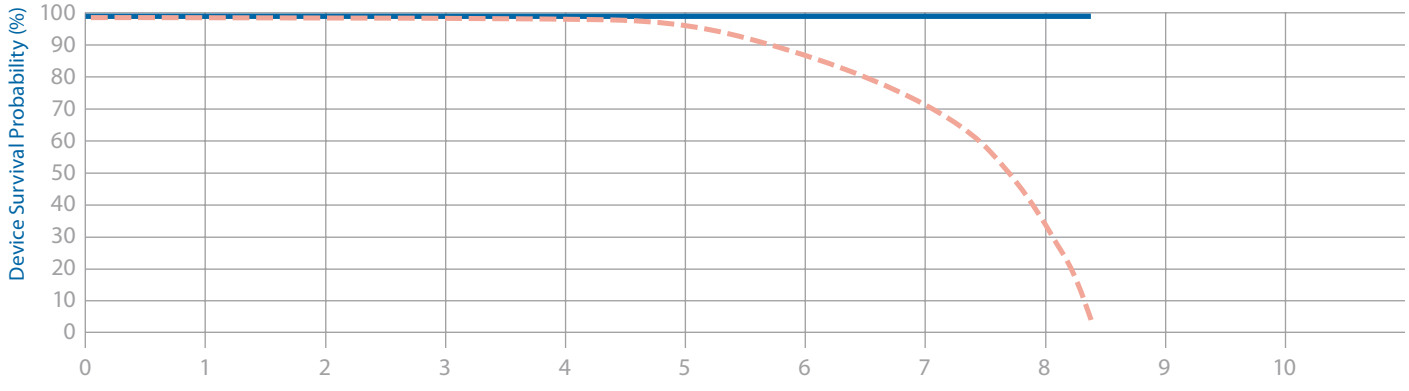
Product Characteristics

US Market Release	Dec-00
Registered US Implants	17,000
Estimated Active US Implants	2,900
Normal Battery Depletions (US)	2,986

Performance Note: See page 165– Performance note on ICD Battery Discharge Behavior

Malfunctions (US)	37
Therapy Function Not Compromised	27
Battery	1
Electrical Component	22
Possible Early Battery Depletion	4
Therapy Function Compromised	10
Battery	1
Electrical Component	9

NBD Code	VVEV
Serial Number Prefix	PJL
Max Delivered Energy	30 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 101 mo
%	99.9	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7
%	99.7	99.4	99.0	98.5	97.0	87.1	71.9	37.4	4.0
#	15,000	14,000	12,000	11,000	9,000	6,900	4,700	1,700	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

7232 Maximo VR

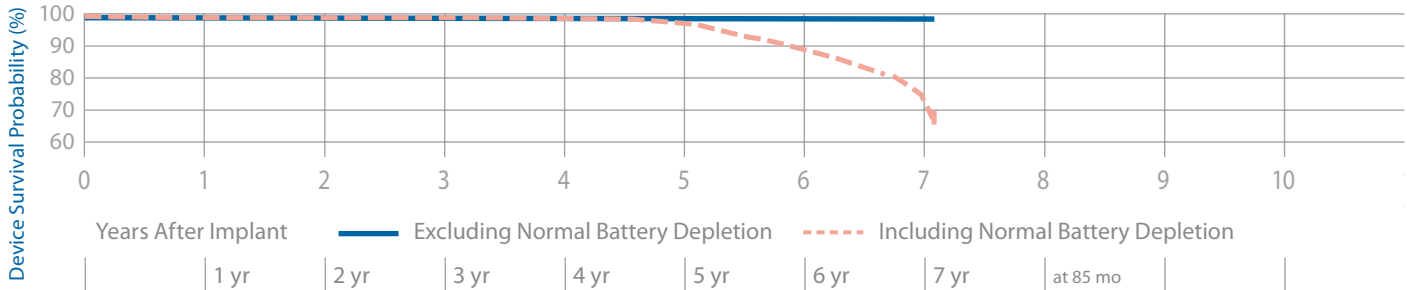
Product Characteristics

US Market Release	Oct-03
Registered US Implants	44,000
Estimated Active US Implants	23,000
Normal Battery Depletions (US)	1,037

Advisories: See page 154– 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	60
Therapy Function Not Compromised	45
Electrical Component	20
Possible Early Battery Depletion	21
Other	4
Therapy Function Compromised	15
Electrical Component	13
Electrical Interconnect	1
Possible Early Battery Depletion	1

NBD Code	VVEV
Serial Number Prefix	PRN, PVF, PVG
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 85 mo
%	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.8	99.5	99.2	97.8	90.0	74.9	66.5
#	40,000	35,000	31,000	26,000	19,000	9,200	400	100

Effective Sample Size

7274 Marquis DR

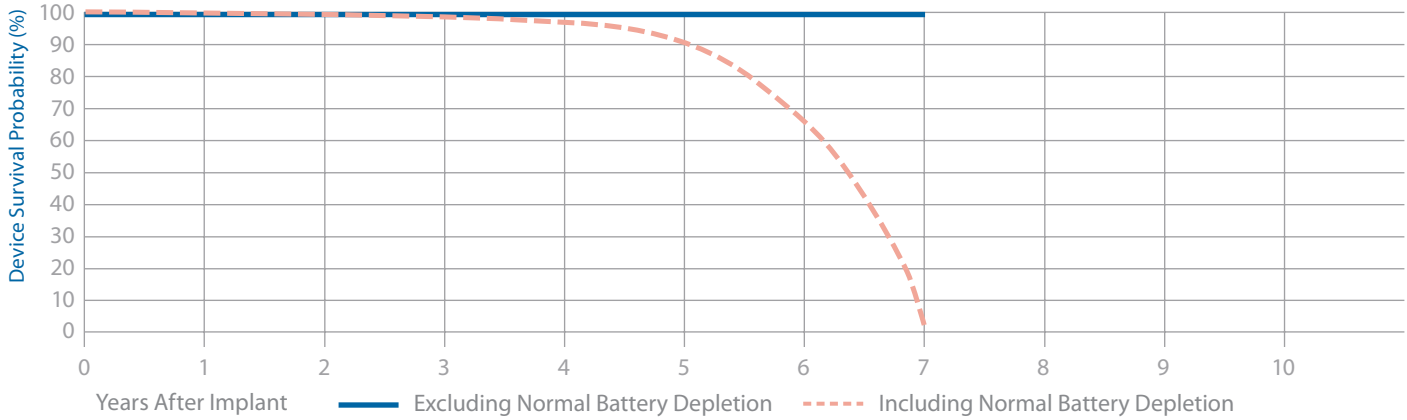
Product Characteristics

US Market Release	Mar-02
Registered US Implants	48,000
Estimated Active US Implants	4,900
Normal Battery Depletions (US)	7,545

Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	190
Therapy Function Not Compromised	83
Battery *(3 malfunctions related to advisory)*	5
Electrical Component	27
Possible Early Battery Depletion	51
Therapy Function Compromised	107
Battery *(73 malfunctions related to advisory)*	80
Electrical Component	27

NBD Code	VVED
Serial Number Prefix	PKC
Max Delivered Energy	30 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	99.9	99.9	99.8	99.6	99.4	99.3	99.2
%	99.8	99.5	98.4	96.9	90.5	65.4	5.4
#	42,000	34,000	26,000	22,000	18,000	10,000	700

Effective Sample Size

7275 GEM III DR

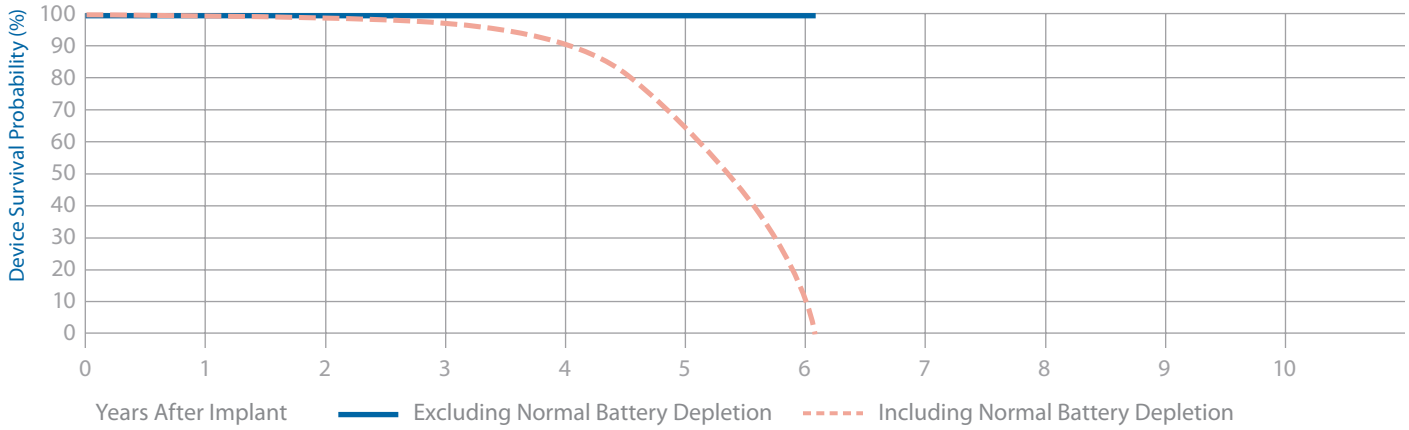
Product Characteristics

US Market Release	Nov-00
Registered US Implants	20,000
Estimated Active US Implants	1,700
Normal Battery Depletions (US)	4,359

Performance Note: See page 165 – Performance note on ICD Battery Discharge Behavior

Malfunctions (US)	43
Therapy Function Not Compromised	32
Battery	1
Electrical Component	11
Software/Firmware	1
Possible Early Battery Depletion	18
Other	1
Therapy Function Compromised	11
Battery	2
Electrical Component	8
Electrical Interconnect	1

NBD Code	VVED
Serial Number Prefix	PJM
Max Delivered Energy	30 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 mo
%	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	99.4	98.8	96.7	90.0	64.8	12.8	0.9
#	18,000	15,000	13,000	10,000	5,500	700	300

Effective Sample Size

7278 Maximo DR

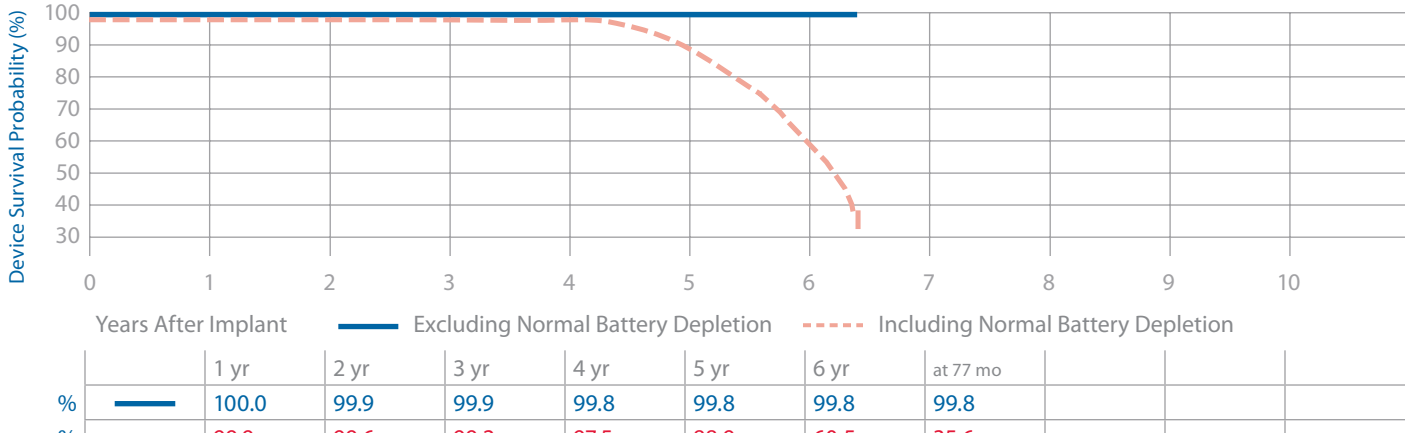
Product Characteristics

US Market Release	Oct-03
Registered US Implants	38,000
Estimated Active US Implants	14,000
Normal Battery Depletions (US)	4,176

Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	55
Therapy Function Not Compromised	46
Electrical Component	19
Possible Early Battery Depletion	25
Other	2
Therapy Function Compromised	9
Electrical Component	8
Possible Early Battery Depletion	1

NBD Code	VVED
Serial Number Prefix	PRM
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.6	99.2	97.5	88.9	60.5	35.6
#	34,000	30,000	26,000	22,000	16,000	6,100	1,000

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

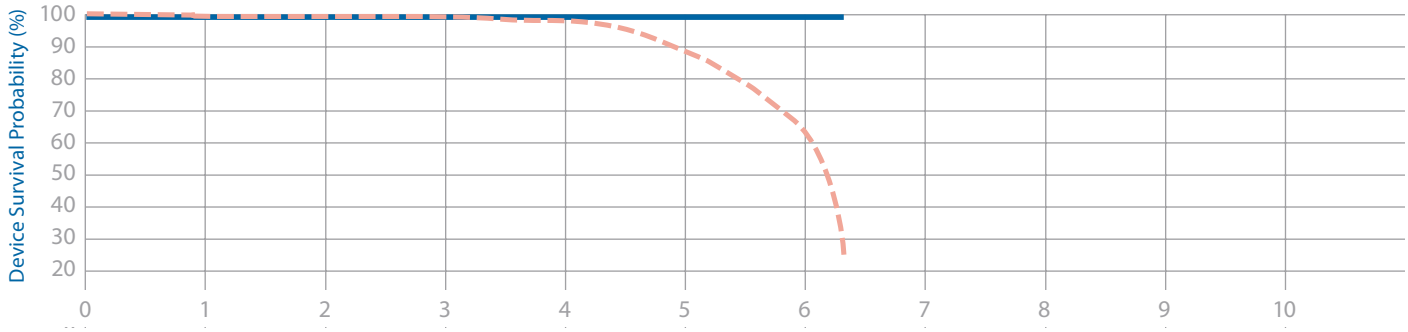
7288 Intrinsic

Product Characteristics

US Market Release	Jun-04
Registered US Implants	31,000
Estimated Active US Implants	13,000
Normal Battery Depletions (US)	3,033
Advisories	None

Malfunctions (US)	60
Therapy Function Not Compromised	53
Battery	2
Electrical Component	18
Software/Firmware	1
Possible Early Battery Depletion	31
Other	1
Therapy Function Compromised	7
Electrical Component	7

NBD Code	VVED
Serial Number Prefix	PUB
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 76 mo
%	100.0	99.9	99.9	99.8	99.8	99.7	99.7
%	99.9	99.7	99.2	98.1	89.1	64.9	27.9
#	28,000	26,000	23,000	20,000	15,000	5,100	400

Effective Sample Size

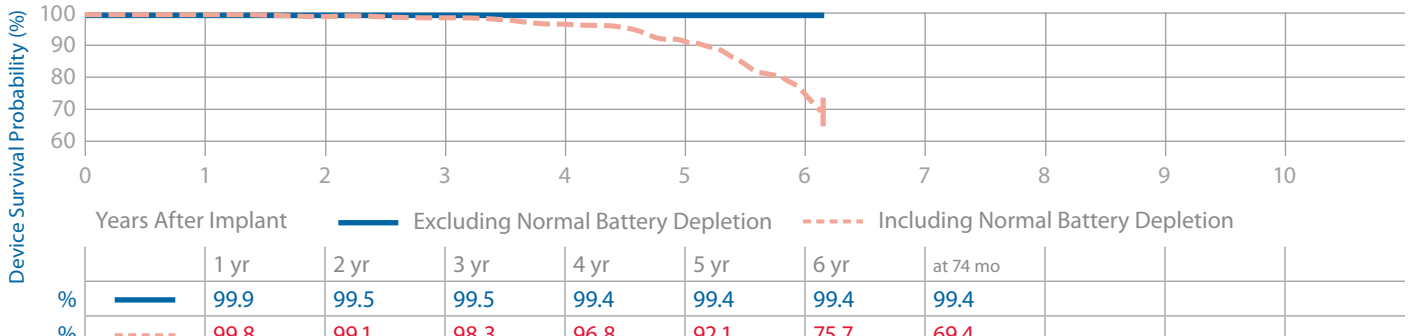
7290Cx Onyx

Product Characteristics

US Market Release	Mar-04
Registered US Implants	1,000
Estimated Active US Implants	400
Normal Battery Depletions (US)	67
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	4
Electrical Component	3
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Electrical Component	1

NBD Code	VVEV
Serial Number Prefix	PRP
Max Delivered Energy	30 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	99.9	99.5	99.5	99.4	99.4	99.4	99.4
%	99.8	99.1	98.3	96.8	92.1	75.7	69.4
#	900	800	700	600	500	200	100

Effective Sample Size

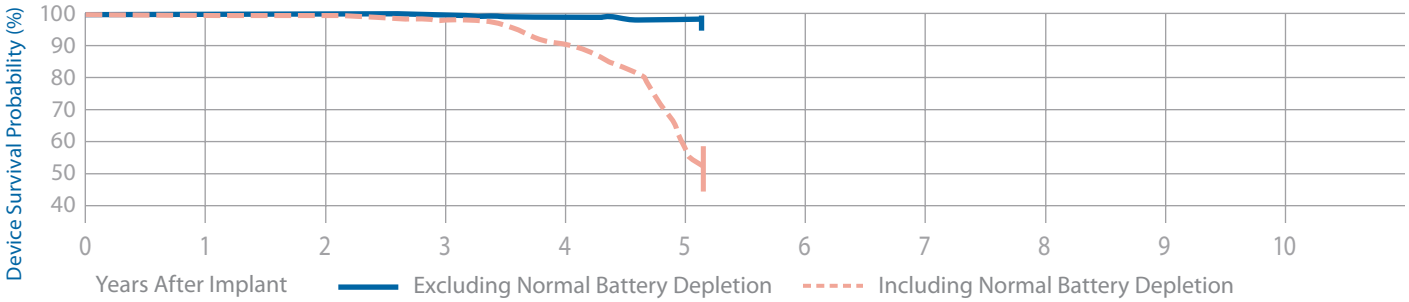
D153ATG, D153DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	500
Estimated Active US Implants	100
Normal Battery Depletions (US)	121
Advisories	None

Malfunctions (US)	8
Therapy Function Not Compromised	7
Possible Early Battery Depletion	7
Therapy Function Compromised	1
Electrical Component	1

NBD Code	DDED
Serial Number Prefix	PNR
Max Delivered Energy	30 J
Estimated Longevity	See page 41



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	99.8	99.8	99.3	98.3	97.5	97.5
%	99.6	99.6	98.0	90.2	57.2	52.0
#	400	400	400	300	100	100

Effective Sample Size

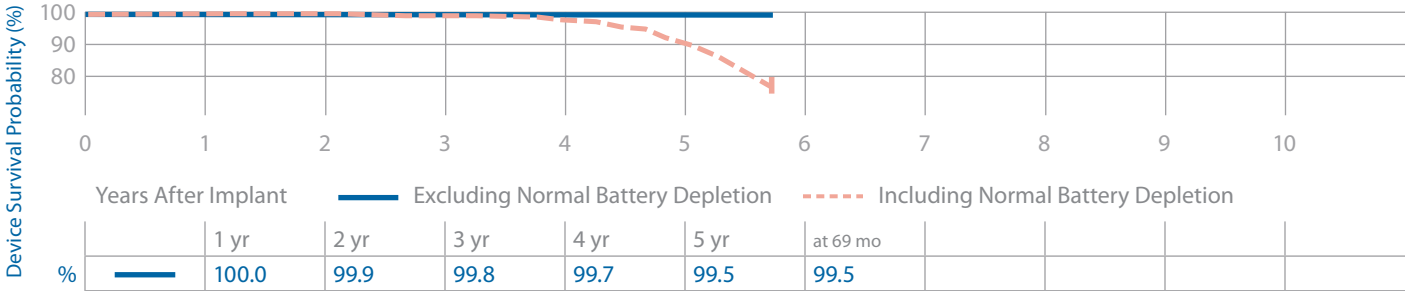
D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	28,000
Estimated Active US Implants	16,000
Normal Battery Depletions (US)	975
Advisories	None

Malfunctions (US)	97
Therapy Function Not Compromised	86
Electrical Component	24
Electrical Interconnect	1
Software/Firmware	2
Possible Early Battery Depletion	59
Therapy Function Compromised	11
Electrical Component	11

NBD Code	DDED
Serial Number Prefix	PNR
Max Delivered Energy	35 J
Estimated Longevity	See page 41



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	100.0	99.9	99.8	99.7	99.5	99.5
%	99.9	99.7	99.2	97.7	90.4	76.6
#	26,000	23,000	21,000	17,000	9,900	600

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

D154AWG, D164AWG Virtuoso DR

Product Characteristics

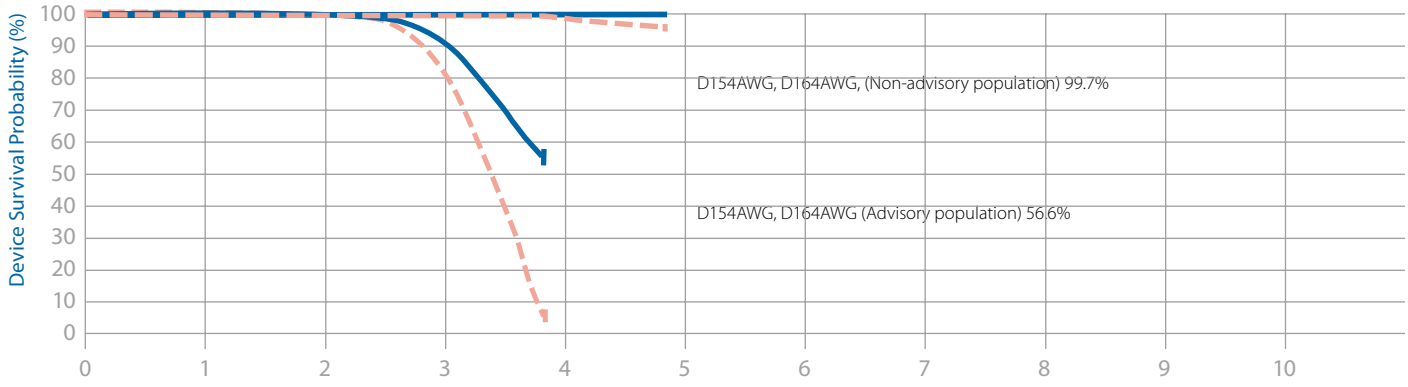
	(N)	(A)
US Market Release	May-06	
Registered US Implants	73,000	4,000
Estimated Active US Implants	54,000	500
Normal Battery Depletions (US)	247	20

Advisories: See page 148 – 2009 Potential Reduced Device Longevity

Performance Note: See page 159 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	96	1,796
Therapy Function Not Compromised	72	1,785
Electrical Component	21	1,784
Electrical Interconnect	1	0
Possible Early Battery Depletion	49	0
Other	1	1
Therapy Function Compromised	24	11
Electrical Component	24	11

NBD Code	DDED
Serial Number Prefix	PVV, PUL
Max Delivered Energy	35 J
Estimated Longevity	See page 41



Non-Adv	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	99.9	99.9	99.8	99.7
%	99.9	99.7	99.4	98.5	96.6
#	66,000	58,000	39,000	15,000	200
Effective Sample Size					

Advisory	1 yr	2 yr	3 yr	at 46 mo
%	100.0	99.9	90.6	56.6
%	99.9	99.6	80.9	7.0
#	3,800	3,500	2,700	300
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

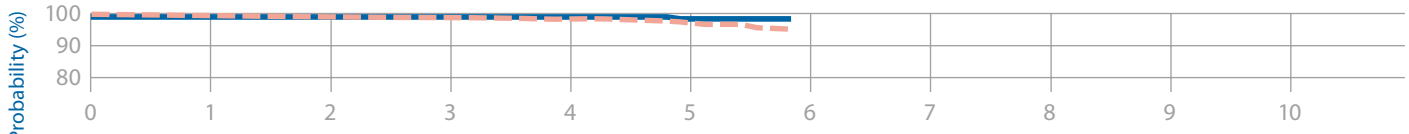
D154VRC EnTrust VR

Product Characteristics

US Market Release	Jun-05
Registered US Implants	14,000
Estimated Active US Implants	8,600
Normal Battery Depletions (US)	74
Advisories	None

Malfunctions (US)	58
Therapy Function Not Compromised	47
Battery	2
Electrical Component	19
Possible Early Battery Depletion	25
Other	1
Therapy Function Compromised	11
Electrical Component	11

NBD Code	VVEV
Serial Number Prefix	PNT
Max Delivered Energy	35 J
Estimated Longevity	See page 41



	1 yr	2 yr	3 yr	4 yr	5 yr	at 70 mo
%	99.9	99.9	99.8	99.7	99.4	99.3
%	99.9	99.6	99.3	98.7	97.6	95.6
#	13,000	12,000	11,000	8,600	4,600	200

Effective Sample Size

D154VWC, D164VWC Virtuoso VR

Product Characteristics

US Market Release	May-06
Registered US Implants	33,000
Estimated Active US Implants	24,000
Normal Battery Depletions (US)	49

Advisories: See page 148– 2009 Potential Reduced Device Longevity

Performance Note: See page 159– Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	29
Therapy Function Not Compromised	17
Electrical Component *(3 malfunctions related to advisory)*	11
Electrical Interconnect	1
Possible Early Battery Depletion	5
Therapy Function Compromised	12
Electrical Component	12

NBD Code	VVEV
Serial Number Prefix	PUN, PUP
Max Delivered Energy	35 J
Estimated Longevity	See page 41

	1 yr	2 yr	3 yr	4 yr	at 56 mo
%	100.0	100.0	99.9	99.9	99.9
%	99.9	99.8	99.6	99.4	98.9
#	30,000	26,000	18,000	6,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

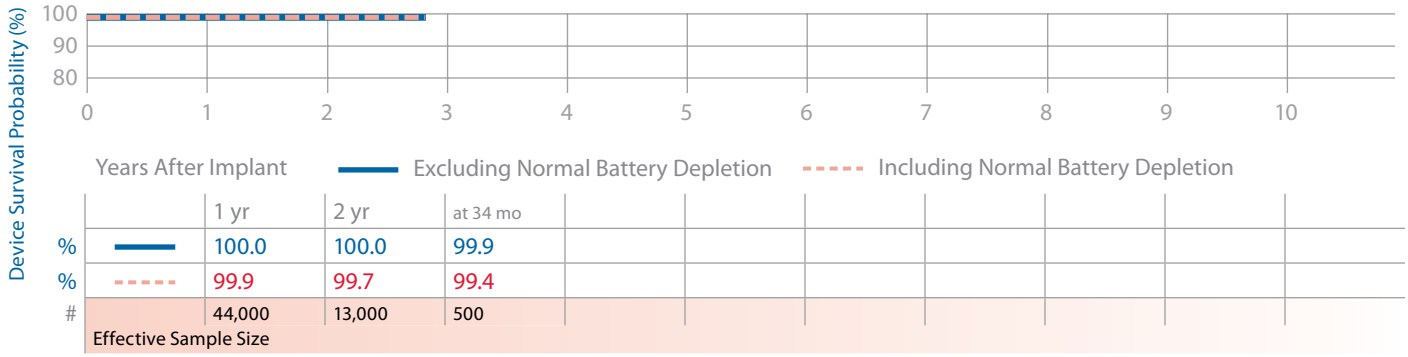
D224DRG Secura DR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	42,000
Estimated Active US Implants	38,000
Normal Battery Depletions (US)	38
Advisories	None

Malfunctions (US)	15
Therapy Function Not Compromised	9
Electrical Component	4
Possible Early Battery Depletion	3
Software/Firmware	2
Therapy Function Compromised	6
Electrical Component	5
Software/Firmware	1

NBD Code	VVED
Serial Number Prefix	PUG
Max Delivered Energy	35 J
Estimated Longevity	See page 41



		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.4
#	Effective Sample Size	44,000	13,000	500

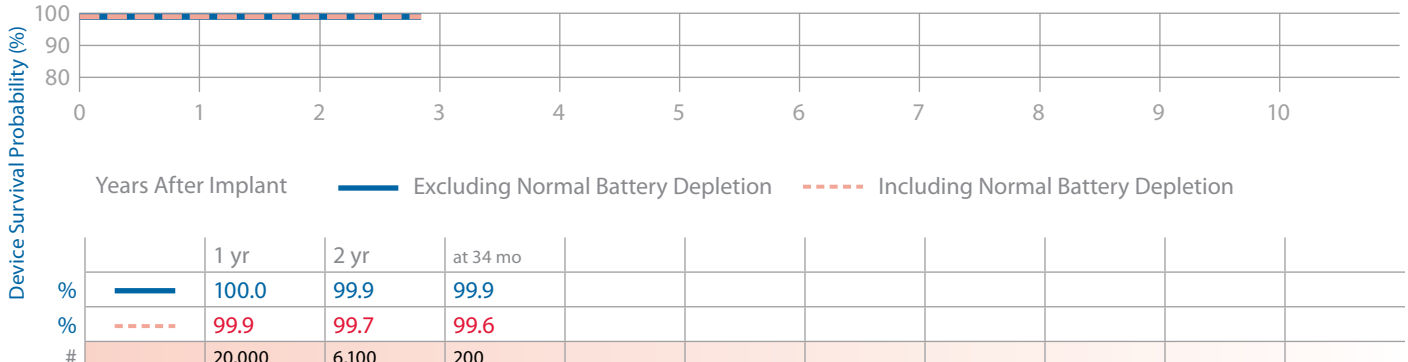
D224VRC Secura VR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	16,000
Estimated Active US Implants	14,000
Normal Battery Depletions (US)	10
Advisories	None

Malfunctions (US)	6
Therapy Function Not Compromised	4
Electrical Component	1
Possible Early Battery Depletion	2
Software/Firmware	1
Therapy Function Compromised	2
Electrical Component	1
Software/Firmware	1

NBD Code	VVEV
Serial Number Prefix	PUX
Max Delivered Energy	35 J
Estimated Longevity	See page 41



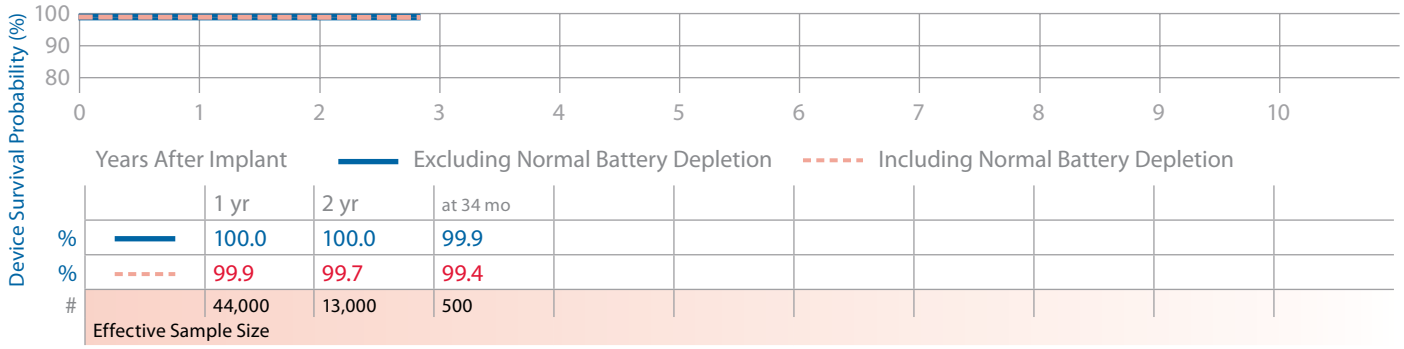
		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.6
#	Effective Sample Size	20,000	6,100	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

D274DRG Virtuoso II DR

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVED
Registered US Implants	19,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZT
Estimated Active US Implants	18,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2			Estimated Longevity	See page 41
Advisories	None				

Product Characteristics

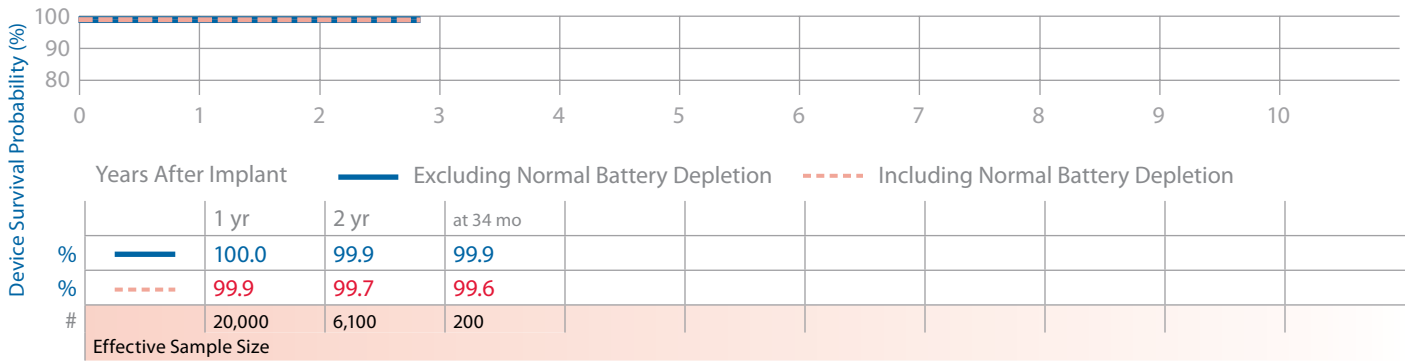


		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.4
#	Effective Sample Size	44,000	13,000	500

D274VRC Virtuoso II VR

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVEV
Registered US Implants	8,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZR
Estimated Active US Implants	7,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2			Estimated Longevity	See page 41
Advisories	None				

Product Characteristics



		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.6
#	Effective Sample Size	20,000	6,100	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

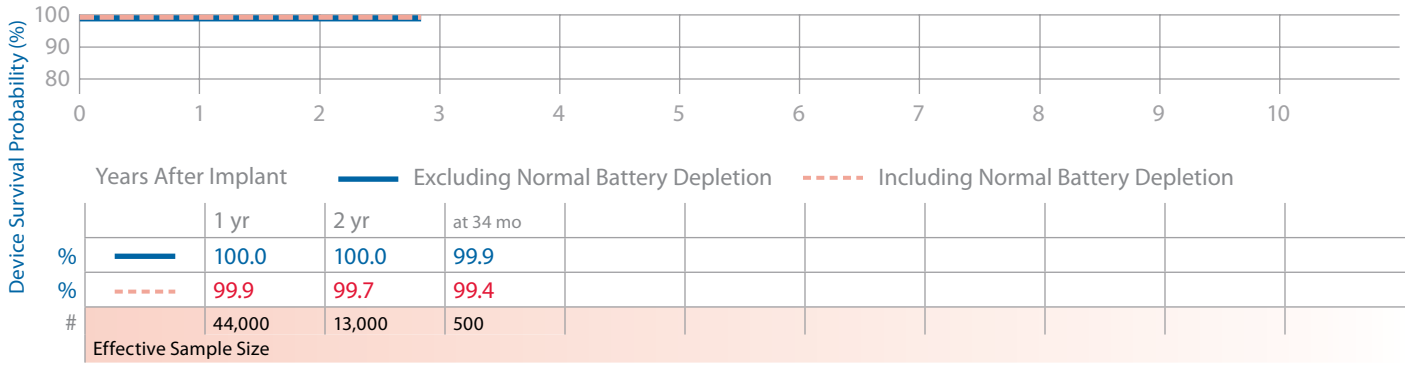
D284DRG Maximo II DR

US Market Release	Sep-08
Registered US Implants	16,000
Estimated Active US Implants	14,000
Normal Battery Depletions (US)	11
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	3
Electrical Component	3

Product Characteristics

NBD Code	VVED
Serial Number Prefix	PZM
Max Delivered Energy	35 J
Estimated Longevity	See page 41



		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.4
#	Effective Sample Size	44,000	13,000	500

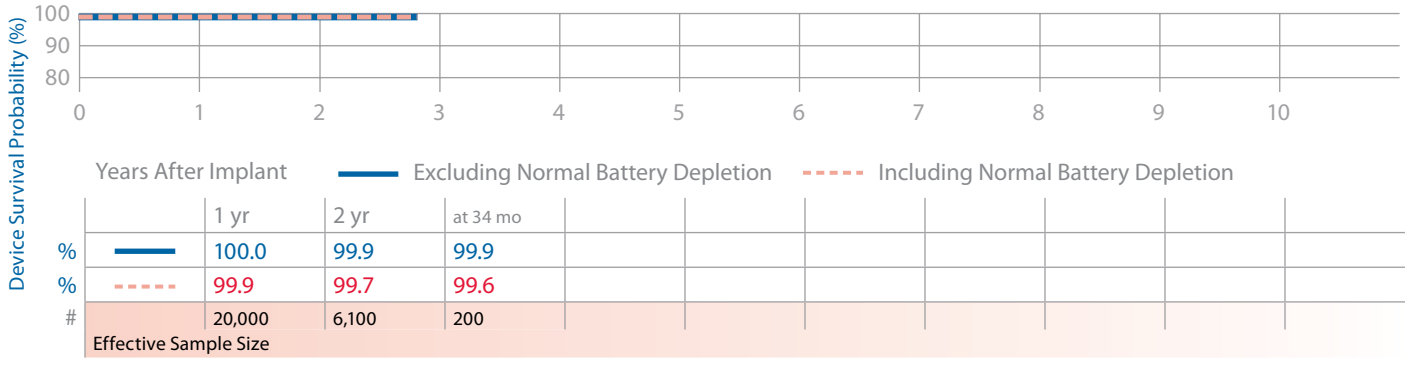
D284VRC Maximo II VR

US Market Release	Sep-08
Registered US Implants	10,000
Estimated Active US Implants	8,700
Normal Battery Depletions (US)	8
Advisories	None

Malfunctions (US)	4
Therapy Function Not Compromised	1
Possible Early Battery Depletion	1
Therapy Function Compromised	3
Electrical Component	2
Software/Firmware	1

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PZN
Max Delivered Energy	35 J
Estimated Longevity	See page 41



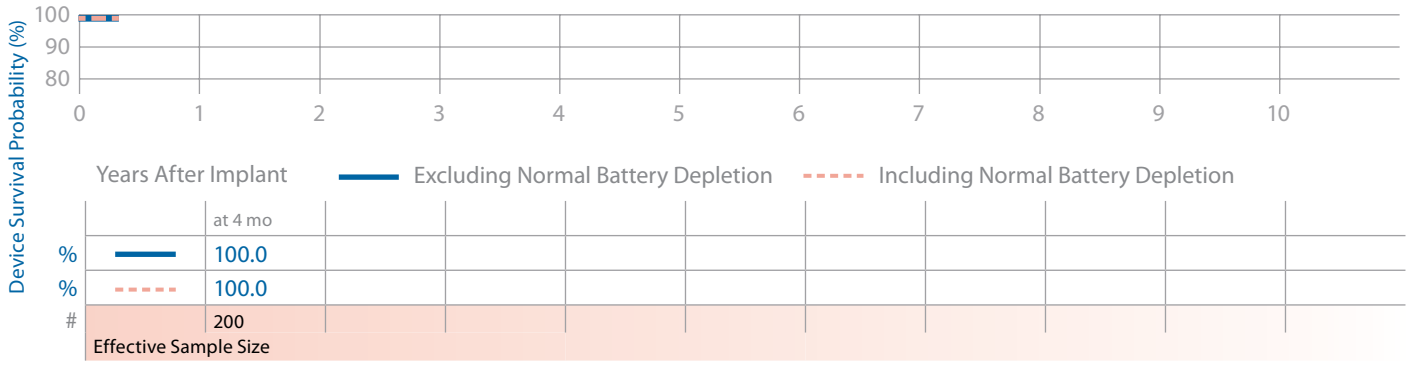
		1 yr	2 yr	at 34 mo
%	Excluding Normal Battery Depletion	100.0	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.6
#	Effective Sample Size	20,000	6,100	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

D314DRG Protecta XT DR

Product Characteristics

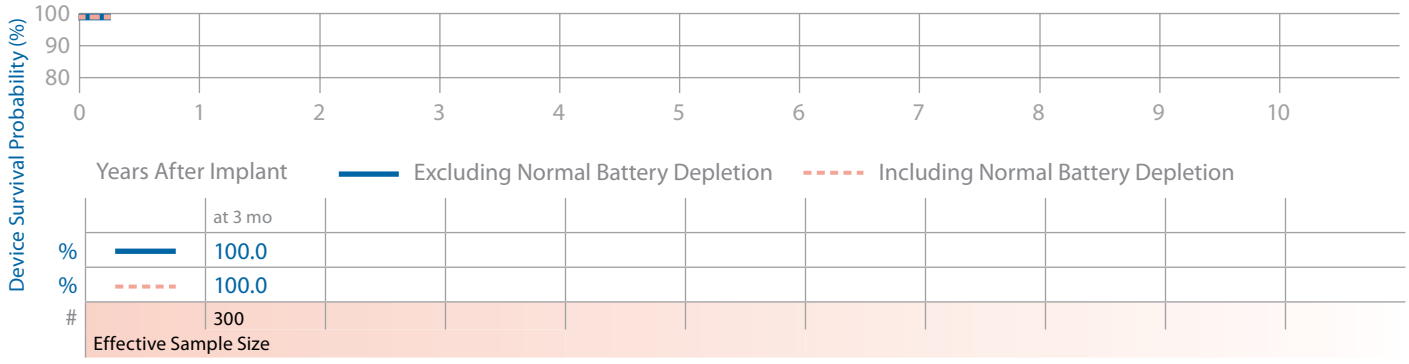
US Market Release	Mar-11	Malfunctions (US)		NBD Code	DDED
Registered US Implants	2,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSK
Estimated Active US Implants	2,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		



D314VRG Protecta XT VR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)		NBD Code	VVEV
Registered US Implants	700	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSA
Estimated Active US Implants	700	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		

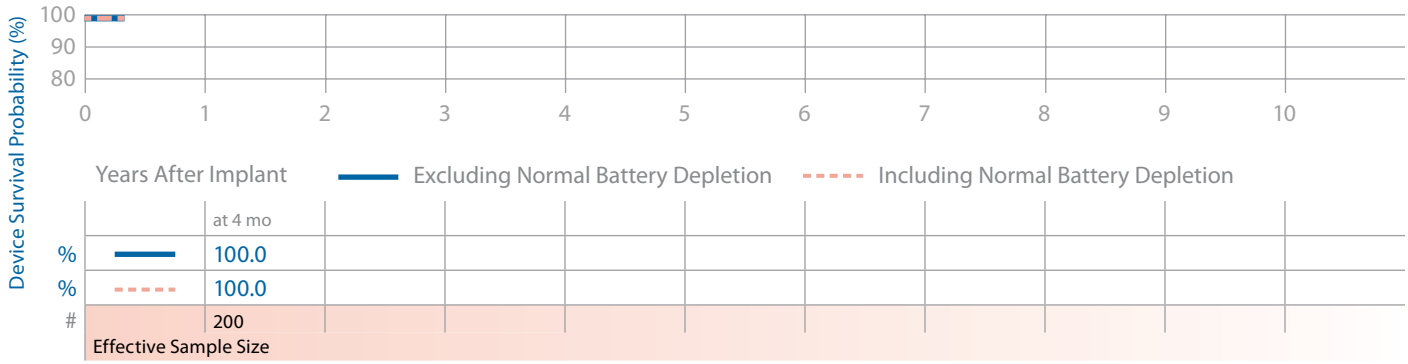


Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

D334DRG Protecta DR

Product Characteristics

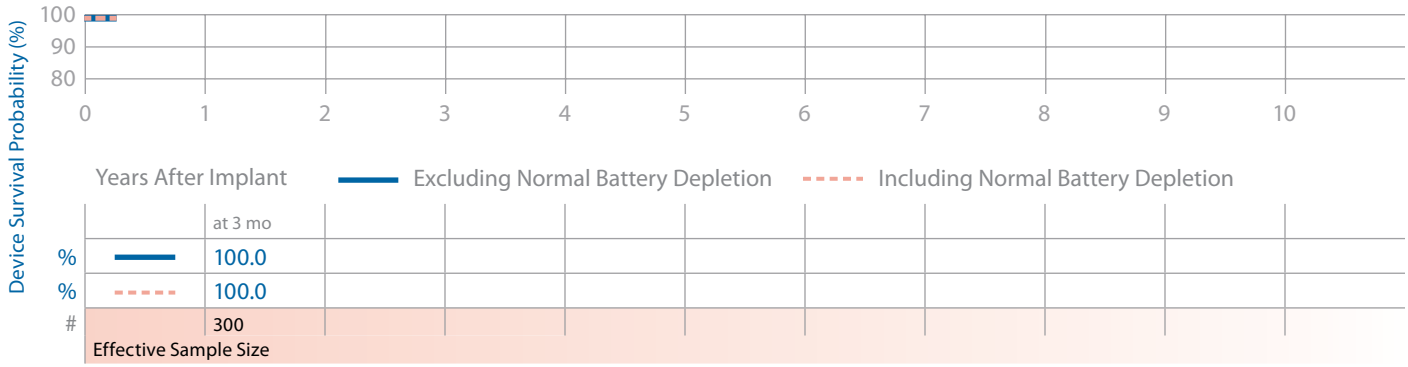
US Market Release	Mar-11	Malfunctions (US)		NBD Code	DDED
Registered US Implants	800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSP
Estimated Active US Implants	800	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		



D334VRG Protecta VR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)		NBD Code	VVEV
Registered US Implants	300	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSX
Estimated Active US Implants	300	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary (95% Confidence Interval)

The following table shows ICD device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US): Therapy Function Compromised	Malfunctions (US): Therapy Function Not Compromised	Malfunctions (US): Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
7230	Marquis VR	Dec-02	19,000	6,200	794	29	+ 28	= 57	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.2	99.3 +0.2/-0.3	99.2 +0.2/-0.3 at 99 mo
	Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short					(19)	+ (1)	(20) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.3 +0.1/-0.2	99.0 +0.2/-0.2	98.3 +0.2/-0.3	93.9 +0.5/-0.5	84.2 +0.8/-0.9	70.1 +1.6/-1.6	52.2 +5.2/-5.5 at 99 mo
7231	GEM III VR	Dec-00	17,000	2,900	2,986	10	+ 27	= 37	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 101 mo
	See page 165 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.7 +0.1/-0.1	99.4 +0.1/-0.1	99.0 +0.2/-0.2	98.5 +0.2/-0.2	97.0 +0.3/-0.3	87.1 +0.7/-0.7	71.9 +1.0/-1.0	37.4 +1.3/-1.3	4.0 +0.9/-0.8 at 101 mo
7232	Maximo VR	Oct-03	44,000	23,000	1,037	15	+ 45	= 60	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/0.0	99.9 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 85 mo	
	Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.1	97.8 +0.2/-0.2	90.0 +0.5/-0.5	74.9 +2.0/-2.2	66.5 +4.6/-5.1 at 85 mo	
7274	Marquis DR	Mar-02	48,000	4,900	7,545	107	+ 83	= 190	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.1	99.3 +0.1/-0.1	99.2 +0.1/-0.1		
	Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short					(73)	+ (3)	= (76) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.0/-0.1	99.5 +0.1/-0.1	98.4 +0.1/-0.1	96.9 +0.2/-0.2	90.5 +0.4/-0.4	65.4 +0.7/-0.7	5.4 +0.7/-0.6		
7275	GEM III DR	Nov-00	20,000	1,700	4,359	11	+ 32	= 43	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 73 mo		
	See page 165 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.4 +0.1/-0.1	98.8 +0.1/-0.2	96.7 +0.3/-0.3	90.0 +0.5/-0.5	64.8 +0.9/-1.0	12.8 +1.0/-1.0	0.9 +0.4/-0.3 at 73 mo		
7278	Maximo DR	Oct-03	38,000	14,000	4,176	9	+ 46	= 55	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 77 mo		
	Advisories: See page 154 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.1/-0.1	97.5 +0.2/-0.2	88.9 +0.4/-0.4	60.5 +0.8/-0.8	35.6 +1.4/-1.4 at 77 mo		
7288	Intrinsic	Jun-04	31,000	13,000	3,033	7	+ 53	= 60	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 76 mo		
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.2 +0.1/-0.1	98.1 +0.2/-0.2	89.1 +0.4/-0.5	64.9 +0.8/-0.9	27.9 +2.4/-2.4 at 76 mo		

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
7290Cx	Onyx	Mar-04	1,000	400	67	1	+	4	=	5	Excluding Normal Battery Depletion	99.9 +0.1/-0.8	99.5 +0.3/-0.8	99.5 +0.3/-0.8	99.4 +0.4/-0.9	99.4 +0.4/-0.9	99.4 +0.4/-0.9	99.4 +0.4/-0.9 at 74 mo		
											Including Normal Battery Depletion	99.8 +0.2/-0.7	99.1 +0.5/-1.0	98.3 +0.7/-1.2	96.8 +1.1/-1.6	92.1 +1.9/-2.4	75.7 +4.0/-4.6	69.4 +4.9/-5.5 at 74 mo		
D153ATG, D153DRG	EnTrust	Jun-05	500	100	121	1	+	7	=	8	Excluding Normal Battery Depletion	99.8 +0.2/-1.6	99.8 +0.2/-1.6	99.3 +0.5/-1.6	98.3 +0.9/-2.0	97.5 +1.3/-2.5	97.5 +1.3/-2.5 at 62 mo			
											Including Normal Battery Depletion	99.6 +0.3/-1.5	99.6 +0.3/-1.5	98.0 +1.0/-2.0	90.2 +2.8/-3.8	57.2 +5.9/-6.4	52.0 +6.2/-6.6 at 62 mo			
D154ATG, D154DRG	EnTrust	Jun-05	28,000	16,000	975	11	+	86	=	97	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 69 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.2 +0.1/-0.1	97.7 +0.2/-0.2	90.4 +0.5/-0.5	76.6 +1.5/-1.5 at 69 mo			
D154AWG D164AWG (Non-advisory population)	Virtuoso DR	May-06	73,000	54,000	247	24	+	72	=	96	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.7 +0.1/-0.1 at 58 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.4 +0.1/-0.1	98.5 +0.1/-0.1	96.6 +0.5/-0.6 at 58 mo				
D154AWG D164AWG (Advisory population)	Virtuoso DR	May-06	4,000	500	20	11	+	1,785	=	1,796	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.2	90.6 +1.0/-1.1	56.6 +1.8/-1.9 at 46 mo					
	Advisories: See page 148 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.9 +0.1/-0.1	99.6 +0.2/-0.3	80.9 +1.3/-1.4	7.0 +1.2/-1.1 at 46 mo					
	See page 159 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			
D154VRC	EnTrust VR	Jun-05	14,000	8,600	74	11	+	47	=	58	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.2	99.3 +0.2/-0.3 at 70 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.3 +0.1/-0.2	98.7 +0.2/-0.2	97.6 +0.3/-0.4	95.6 +0.7/-0.8 at 70 mo			
D154VWC D164VWC (Non-advisory population)	Virtuoso VR	May-06	33,000	24,000	49	12	+	17	=	29	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 56 mo				
	Advisories: See page 148 – 2009 Potential Reduced Device Longevity					(0) (advisory-related subset)	+	(3)	=	3	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.1	98.9 +0.2/-0.3 at 56 mo				
	See page 159 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D224DRG	Secura DR	Sep-08	42,000	38,000	38	6	+	9	=	15	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.2 at 34 mo					
D224VRC	Secura VR	Sep-08	16,000	14,000	10	2	+	4	=	6	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.6 +0.1/-0.1 at 34 mo					
D274DRG	Virtuoso II DR	Aug-09	19,000	18,000	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.2 at 34 mo					
D274VRC	Virtuoso II VR	Aug-09	8,000	7,000	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.6 +0.1/-0.1 at 34 mo					
D284DRG	Maximo II DR	Sep-08	16,000	14,000	11	3	+	2	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.2 at 34 mo					
D284VRC	Maximo II VR	Sep-08	10,000	8,700	8	3	+	1	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 34 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.6 +0.1/-0.1 at 34 mo					

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised		Malfunctions: Therapy Function Not Compromised		Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D314DRG	Protecta XT DR	Mar-11	2,000	2,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo							
D314VRG	Protecta XT VR	Mar-11	700	700	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 3 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 3 mo							
D334DRG	Protecta DR	Mar-11	800	800	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 4 mo							
D334VRG	Protecta VR	Mar-11	300	300	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 3 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 3 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

continued

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Elective Replacement (ERI)***		End of Life (EOL) Battery Voltage
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
7227	GEM	B, Cx, D, E	49 cc* 90 g	35 J	Monthly Quarterly Semiannual	5.3 7.7 8.8	5.7 8.5 10.0	6.0 9.3 11.0	6.1 9.6 11.5	≤ 2.55 V	—	≤ 2.40 V§
7230	Marquis VR	B, Cx, E	36 cc 75 g	30 J	Monthly Quarterly Semiannual	4.9 7.3 8.5	5.2 8.0 9.3	5.4 8.5 10.0	5.5 8.7 10.4	≤ 2.62 V	> 16-second charge time	3 months after ERI
7231Cx	GEM III VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Semiannual	4.3 6.0 6.6	4.7 6.8 7.5	5.0 7.4 8.5	5.2 7.8 8.9	≤ 2.55 V	—	≤ 2.40 V
7232	Maximo VR	B, Cx, E	39 cc 76 g	35 J	Monthly Quarterly Semiannual	4.4 7.0 8.2	4.7 7.5 9.0	4.8 8.0 9.7	4.9 8.3 10.0	≤ 2.62 V	> 16-second charge time	3 months after ERI
7271	GEM DR	DR	62 cc 115 g	35 J	Monthly Quarterly Semiannual	6.0 7.4 7.9	6.9 8.4 9.0	7.5 9.3 10.0	7.8 9.8 10.6	≤ 4.91 V	—	≤ 4.57 V§
7274	Marquis DR	DR+LV	36 cc 75 g	30 J	Monthly Quarterly Semiannual	4.0 5.6 6.2	4.4 6.4 7.2	4.8 7.1 8.1	4.9 7.5 8.6	≤ 2.62 V	> 16-second charge time	3 months after ERI
7275	GEM III DR	DR	39.5 cc 78 g	30 J	Monthly Quarterly Semiannual	3.3 4.2 4.5	3.8 5.0 5.5	4.3 5.8 6.5	4.4 6.3 7.0	≤ 2.55 V	—	≤ 2.40 V
7278	Maximo DR	DR	39 cc 77 g	35 J	Monthly Quarterly Semiannual	3.7 5.3 6.0	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	> 16-second charge time	3 months after ERI
7288	Intrinsic	DR	38 cc 76 g	35 J	Monthly Quarterly Semiannual	3.7 5.3 6.0	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	> 16-second charge time	3 months after ERI
7290Cx	Onyx	Cx	39 cc 77 g	30 J	Monthly Quarterly Semiannual	3.8 5.0 5.4	4.1 5.6 6.1	4.3 6.2 6.7	4.5 6.4 7.0	≤ 2.55 V		≤ 2.40 V

* Volume and mass differ by connector style.

** A full charge is a full energy therapeutic shock or capacitor reformation.

*** The minimum time between ERI and EOL is 3 months (100% pacing, two charges per month).

‡ Pacing mode is VVI for single chamber models and DDD for dual chamber and CRT models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510-ohm pace load per applicable channel. CRT models with shared biventricular pacing; InSync Marquis 7277 (LV impedance set to 510 ohms), InSync ICD 7272 (RV amplitude set to 4.0 V).

§ For Model 7271 and 7227 devices, if charge time exceeds 30 seconds, the device is at EOL. Immediate replacement is recommended. If three consecutive charge cycles exceed 30 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency VVI pacing are disabled.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart continued

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Recommended Replacement (RRT)***		End of Service (EOS)
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
D153ATG, D153DRG	EnTrust	DR	33 cc 63 g	30 J	Monthly Quarterly Semiannual	3.5 4.8 5.3	3.8 5.4 6.1	4.1 6.0 6.9	4.2 6.3 7.2	≤ 2.61 V	—	3 months after RRT or > 16-second charge time
D154ATG, D154DRG	EnTrust	DR	35 cc 68 g	35 J	Monthly Quarterly Semiannual	3.8 5.5 6.1	4.2 6.1 7.0	4.4 6.8 7.9	4.6 7.0 8.3	≤ 2.61 V	—	3 months after RRT or > 16-second charge time
D154AWG, D164AWG	Virtuoso DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.1 6.3 7.3	4.5 7.3 8.7	4.8 8.3 10.1	5.0 8.8 11.0	≤ 2.62 V	—	3 months after RRT or > 16-second charge time
D154VRC	EnTrust VR	Cx	35 cc 68 g	35 J	Monthly Quarterly Semiannual	4.8 7.5 9.0	5.0 8.3 10.0	5.2 8.8 10.7	5.3 9.0 11.0	≤ 2.61 V	—	3 months after RRT or > 16-second charge time
D154VWC, D164VWC	Virtuoso	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.8 8.1 10.0	5.1 9.0 11.2	5.3 9.6 12.3	5.4 10.0 12.9	≤ 2.62 V	—	3 months after RRT or > 16-second charge time
D224DRG	Secura DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.1 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D224VRC	Secura VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.7 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D274DRG	Virtuoso II DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D274VRC	Virtuoso II VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D284DRG	Maximo II DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.1 7.0	4.5 7.0 8.2	4.6 7.5 9.0	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D284VRC	Maximo II VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.6 7.7	4.6 7.4 8.8	4.9 8.1 9.7	5.0 8.4 10.2	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D314DRG	Protecta XT DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT
D314VRG	Protecta XT VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT
D334DRG	Protecta DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT
D334VRG	Protecta VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT

* Volume and mass differ by connector style.

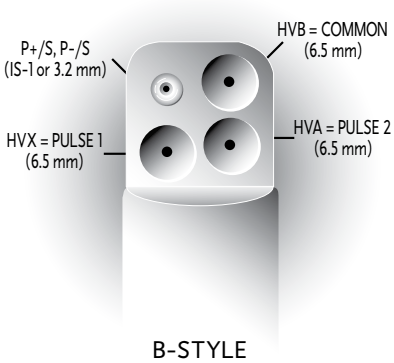
** A full charge is a full energy therapeutic shock or capacitor reformation.

*** The minimum time between RRT and EOS is 3 months (100% pacing, two charges per month).

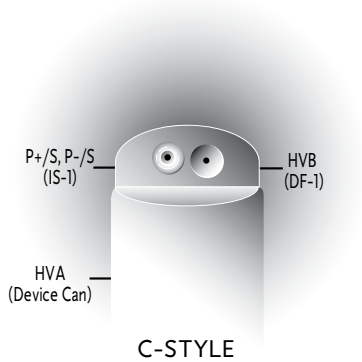
‡ Pacing mode is VVI for single chamber models and DDD for dual chamber models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510-ohm pace load per applicable channel.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

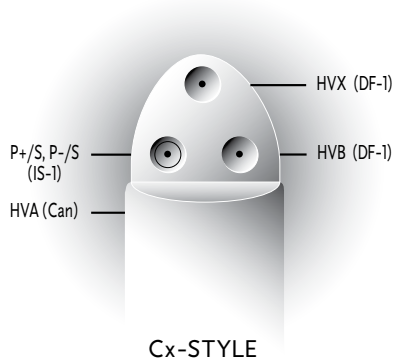
ICD Connector Styles



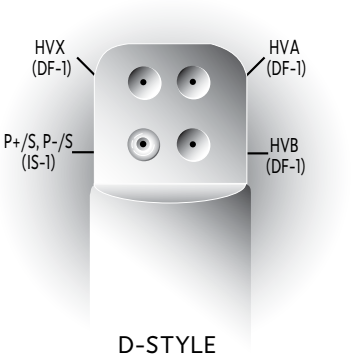
B-STYLE CONNECTOR



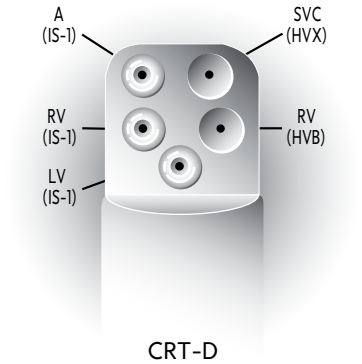
C-STYLE CONNECTOR



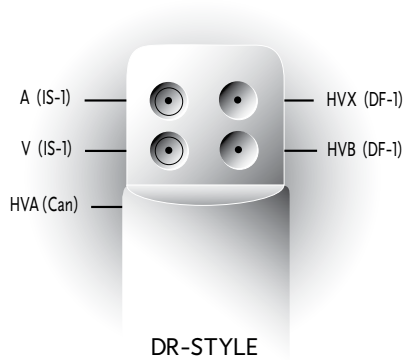
Cx-STYLE CONNECTOR



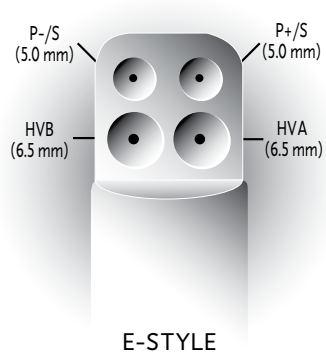
D-STYLE CONNECTOR



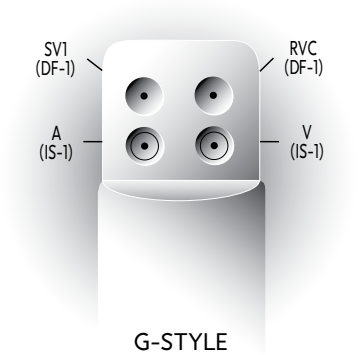
CRT-D CONNECTOR



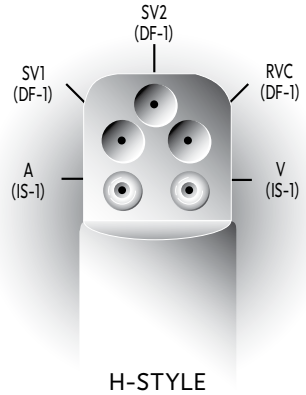
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR



H-STYLE CONNECTOR

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Adapta DR ADDR01, ADDR03, ADDR06, ADD01

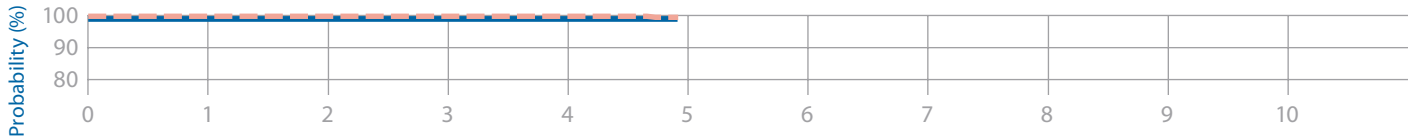
US Market Release	Jul-06
Registered US Implants	266,000
Estimated Active US Implants	224,000
Normal Battery Depletions (US)	92

Malfunctions (US)	47
Therapy Function Not Compromised	30
Electrical Component	30
Therapy Function Compromised	17
Electrical Component	15
Electrical Interconnect	2

Product Characteristics

NBG Code	DDDR, DDD
Serial Number Prefix	PWB, PWD, PWC, PWF, NWB, NWC, NWD, NWF
Estimated Longevity	See page 78

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	1 yr	2 yr	3 yr	4 yr	at 59 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.5
#	200,000	136,000	79,000	31,000	200

Effective Sample Size

Adapta DR ADDRL1

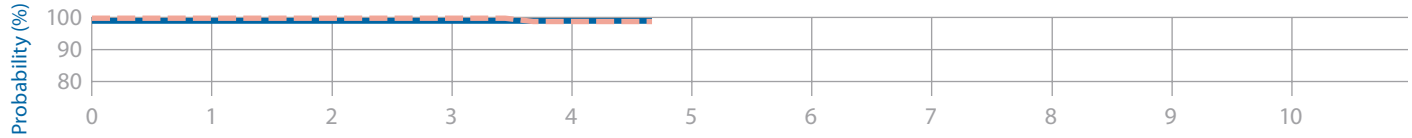
US Market Release	Jul-06
Registered US Implants	45,000
Estimated Active US Implants	41,000
Normal Battery Depletions (US)	6

Malfunctions (US)	3
Therapy Function Not Compromised	2
Electrical Component	2
Therapy Function Compromised	1
Electrical Interconnect	1

Product Characteristics

NBG Code	DDDR
Serial Number Prefix	PWE, NWE
Estimated Longevity	See page 78

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	1 yr	2 yr	3 yr	4 yr	at 56 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.7
#	29,000	16,000	7,000	1,800	200

Effective Sample Size

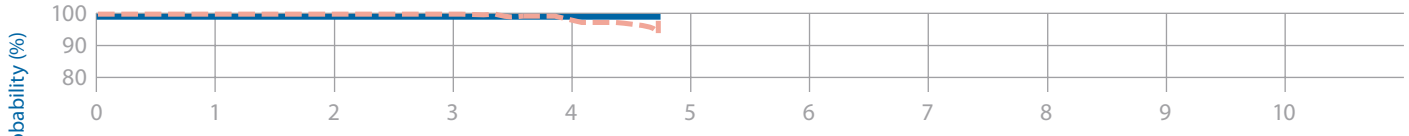
Adapta DR ADDRS1

US Market Release	Jul-06
Registered US Implants	25,000
Estimated Active US Implants	20,000
Normal Battery Depletions (US)	40
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	4
Therapy Function Not Compromised	2
Electrical Component	2
Therapy Function Compromised	2
Electrical Component	2

Product Characteristics

NBG Code	DDDR
Serial Number Prefix	PWA, NWA
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	99.8	99.7	98.8	96.0
#	18,000	12,000	6,300	2,400	200

Effective Sample Size

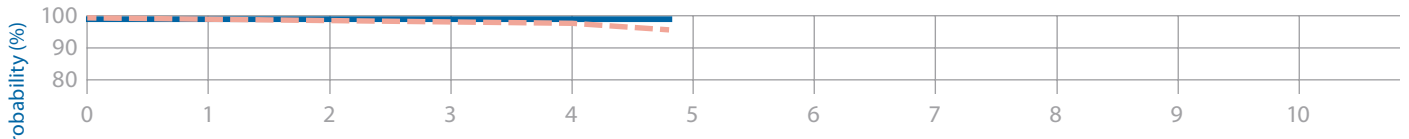
Adapta SR ADSR01, ADSR03, ADSR06

US Market Release	Jul-06
Registered US Implants	49,000
Estimated Active US Implants	35,000
Normal Battery Depletions (US)	44
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	4
Electrical Component	3
Electrical Interconnect	1

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	NWN, NWM, NWP, PWP, PWM, PWN
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.7	99.4	98.3
#	34,000	22,000	12,000	4,600	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

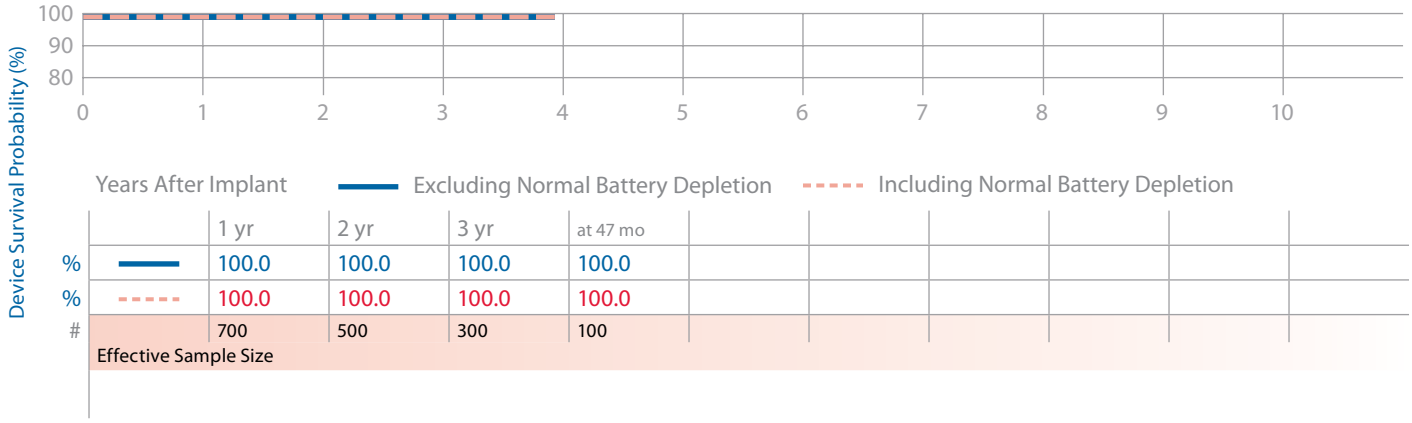
Adapta VDD ADVDD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	800
Estimated Active US Implants	700
Normal Battery Depletions (US)	0
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PWG, NWG
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	at 47 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0
#	700	500	300	100

Effective Sample Size

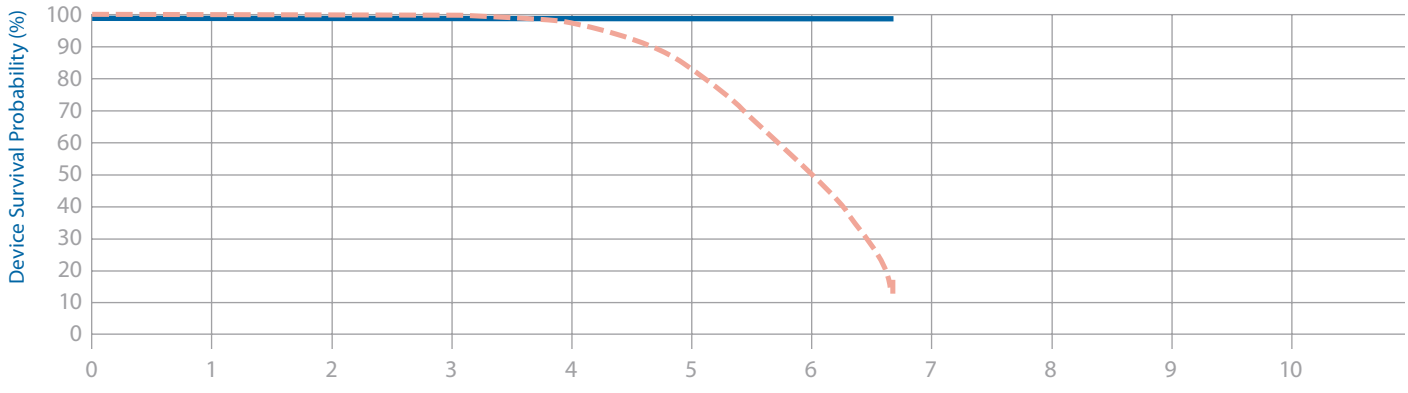
AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03
Registered US Implants	11,000
Estimated Active US Implants	1,600
Normal Battery Depletions (US)	2,410
Performance Note: See page 163 – Performance note on AT500 Pacing System Follow-Up Protocol	

Malfunctions (US)	9
Therapy Function Not Compromised	4
Electrical Component	1
Possible Early Battery Depletion	3
Therapy Function Compromised	5
Electrical Component	3
Electrical Interconnect	1
Possible Early Battery Depletion	1

NBG Code	DDDRP
Serial Number Prefix	IJF
Estimated Longevity	See page 78



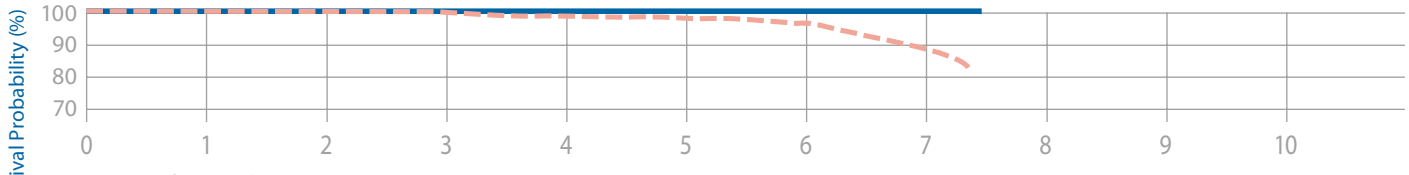
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.8	99.5	97.6	84.4	51.0	15.1
#	9,700	8,900	8,200	7,400	5,500	2,400	300

Effective Sample Size

EnPulse DR E1DR01, E1DR03, E1DR06

US Market Release	Dec-03	Malfunctions (US)	1	NBG Code	DDDR
Registered US Implants	7,000	**Therapy Function Not Compromised**	1	Serial Number Prefix	PRA, PRB, PRE
Estimated Active US Implants	3,000	Electrical Component	1	Estimated Longevity	See page 78
Normal Battery Depletions (US)	319	**Therapy Function Compromised**	0		
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					

Product Characteristics



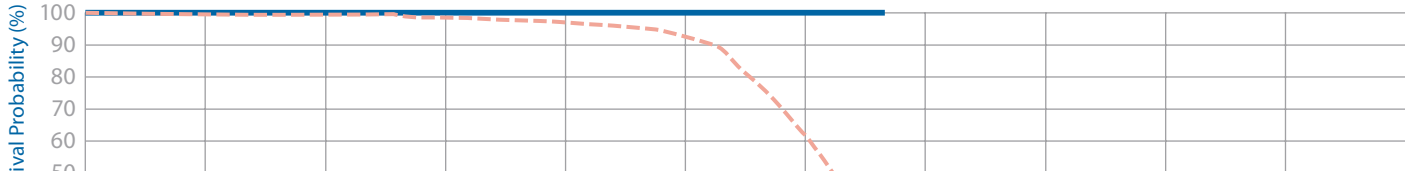
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.2	98.4	96.9	87.9	80.5
#	6,200	5,700	5,300	4,800	4,400	3,900	2,900	400

Effective Sample Size

EnPulse DR E1DR21

US Market Release	Dec-03	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	1,900	**Therapy Function Not Compromised**	0	Serial Number Prefix	PPT
Estimated Active US Implants	200	**Therapy Function Compromised**	0	Estimated Longevity	See page 78
Normal Battery Depletions (US)	323				
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.7	99.0	96.8	92.6	63.5	25.2
#	1,600	1,500	1,300	1,200	1,000	500	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

EnPulse 2 DR E2DR01, E2DR03, E2DR06

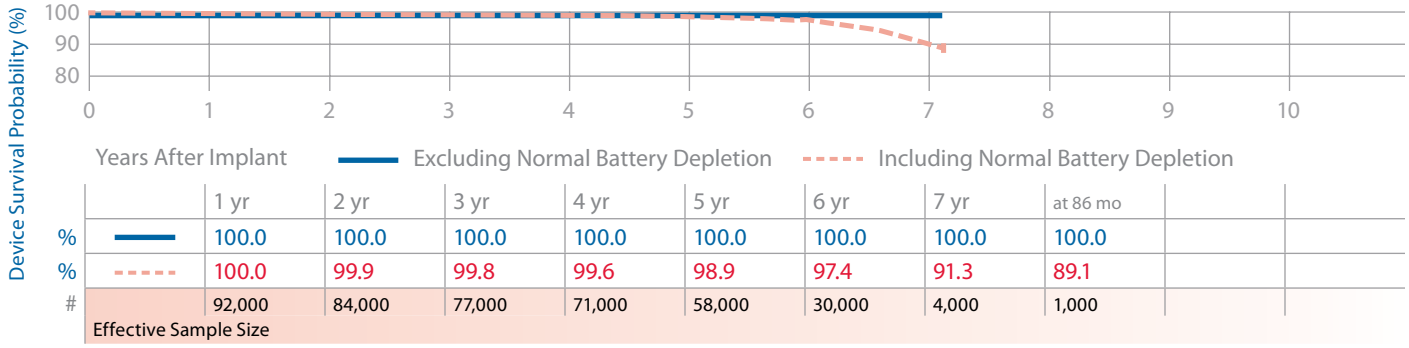
Product Characteristics

US Market Release	Feb-04
Registered US Implants	101,000
Estimated Active US Implants	59,000
Normal Battery Depletions (US)	1,122

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	22
Therapy Function Not Compromised	17
Electrical Component	14
Electrical Interconnect	1
Possible Early Battery Depletion	2
Therapy Function Compromised	5
Battery	1
Electrical Component	3
Electrical Interconnect	1

NBG Code	DDDR
Serial Number Prefix	PNB, PNC, PNH
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.6	98.9	97.4	91.3	89.1
#	92,000	84,000	77,000	71,000	58,000	30,000	4,000	1,000

Effective Sample Size

EnPulse 2 DR E2DR21

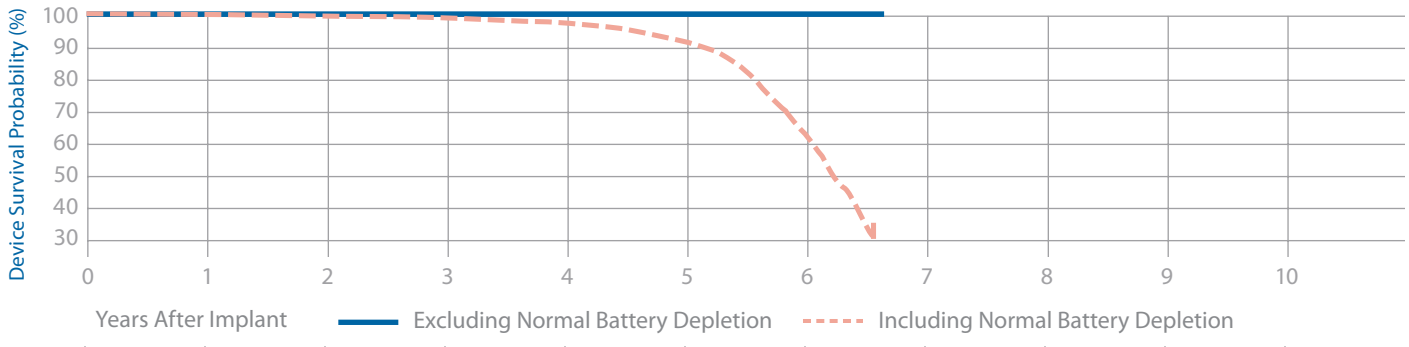
Product Characteristics

US Market Release	Feb-04
Registered US Implants	12,000
Estimated Active US Implants	4,500
Normal Battery Depletions (US)	903

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Component	1

NBG Code	DDDR
Serial Number Prefix	PMU
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.3	97.7	92.0	67.9	31.7
#	11,000	9,500	8,500	7,400	5,400	1,400	200

Effective Sample Size

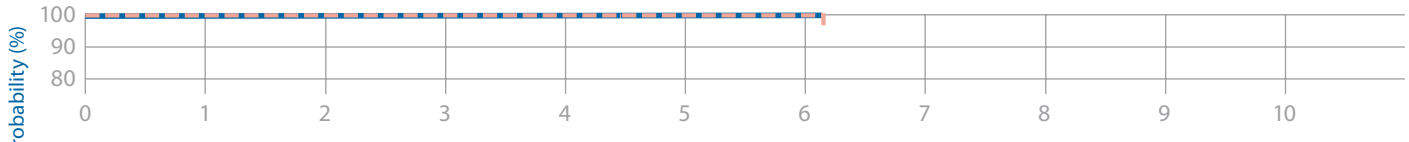
IPG

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

EnPulse 2 DR E2DR31, E2DR33

Product Characteristics

US Market Release	Feb-04	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	600	**Therapy Function Not Compromised**	0	Serial Number Prefix	PNL, PNM
Estimated Active US Implants	400	**Therapy Function Compromised**	0	Estimated Longevity	See page 78
Normal Battery Depletions (US)	1				
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					



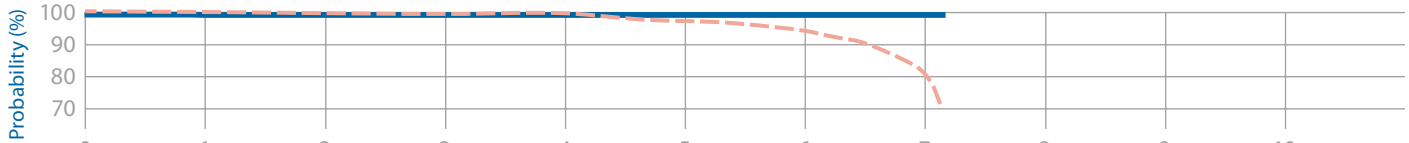
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0	99.2	99.2
#	600	500	500	500	400	100	100

Effective Sample Size

EnPulse 2 SR E2SR01, E2SR03, E2SR06

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	4	NBG Code	SSIR
Registered US Implants	25,000	**Therapy Function Not Compromised**	3	Serial Number Prefix	PMW, PMY, PNA
Estimated Active US Implants	10,000	Electrical Component	2		
Normal Battery Depletions (US)	386	Possible Early Battery Depletion	1	Estimated Longevity	See page 78
Advisories	None	**Therapy Function Compromised**	1		
		Other	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.5	98.9	97.8	94.2	82.0	71.5
#	21,000	18,000	16,000	14,000	10,000	4,000	500	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

EnPulse 2 VDD E2VDD01

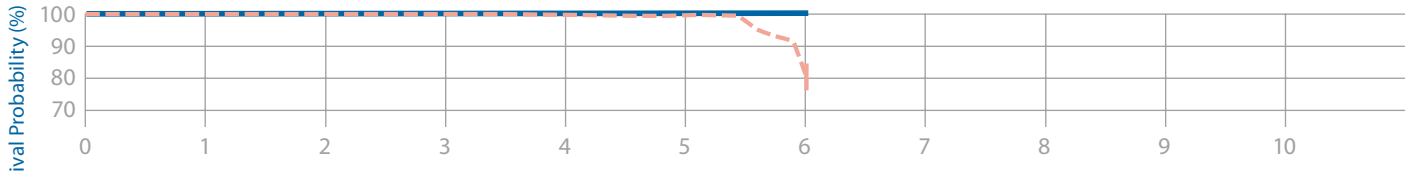
Product Characteristics

US Market Release	Dec-03
Registered US Implants	600
Estimated Active US Implants	300
Normal Battery Depletions (US)	28

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PMV
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.5	99.5	82.8
#	600	500	500	400	300	100

Effective Sample Size

EnRhythm DR P1501DR

Product Characteristics

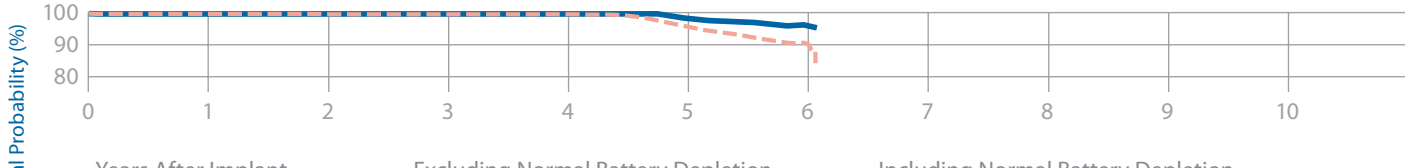
US Market Release	May-05
Registered US Implants	108,000
Estimated Active US Implants	81,000
Normal Battery Depletions (US)	113

Advisories: See page 146 – 2010 Low Battery Voltage Displayed at Device Interrogation

Performance Note: See page 159 – Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	1,055
Therapy Function Not Compromised	1,009
Battery *(112 malfunctions related to advisory)*	967
Electrical Component *(1 malfunction related to advisory)*	19
Possible Early Battery Depletion *(1 malfunction related to advisory)*	22
Electrical Interconnect	1
Therapy Function Compromised	46
Battery	5
Electrical Component	36
Electrical Interconnect	3
Possible Early Battery Depletion	2

NBG Code	DDDRP
Serial Number Prefix	PNP
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 mo
%	100.0	100.0	99.9	99.8	98.1	95.6	95.2
%	100.0	99.9	99.8	99.4	95.8	89.7	86.7
#	92,000	75,000	59,000	44,000	26,000	1,500	500

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

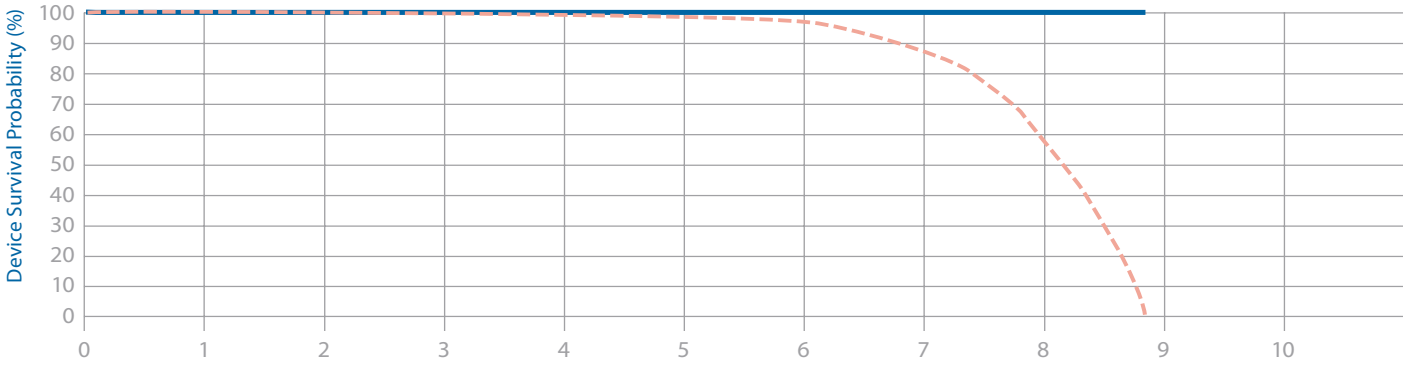
Kappa 400 DR KDR401, KDR403

US Market Release	Jan-98
Registered US Implants	47,000
Estimated Active US Implants	5,300
Normal Battery Depletions (US)	7,358
Advisories	None

Malfunctions (US)	24
Therapy Function Not Compromised	14
Electrical Component	10
Electrical Interconnect	1
Possible Early Battery Depletion	2
Other	1
Therapy Function Compromised	10
Electrical Component	7
Electrical Interconnect	3

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix	PER, PET
Estimated Longevity	See page 78



Years After Implant — Excluding Normal Battery Depletion — Including Normal Battery Depletion

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 106 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	99.8	99.8	99.6	99.5	98.9	97.2	88.0	57.4	1.0
#	42,000	39,000	36,000	33,000	29,000	26,000	19,000	8,200	300

Effective Sample Size

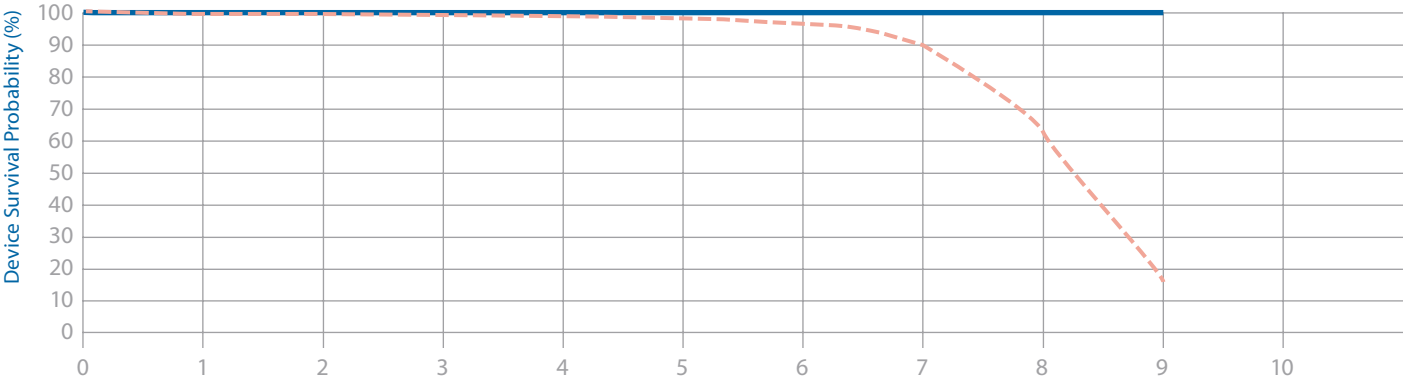
Kappa 400 SR KSR401, KSR403

US Market Release	Feb-98
Registered US Implants	15,000
Estimated Active US Implants	1,900
Normal Battery Depletions (US)	1,368
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	4
Electrical Component	3
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Electrical Interconnect	1

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PEU, PGD
Estimated Longevity	See page 78



Years After Implant — Excluding Normal Battery Depletion — Including Normal Battery Depletion

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.7	99.5	99.1	98.6	96.9	90.8	64.6	17.4
#	13,000	11,000	9,800	8,500	7,200	5,900	4,400	2,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 600 DR KDR601, KDR603, KDR606

Product Characteristics

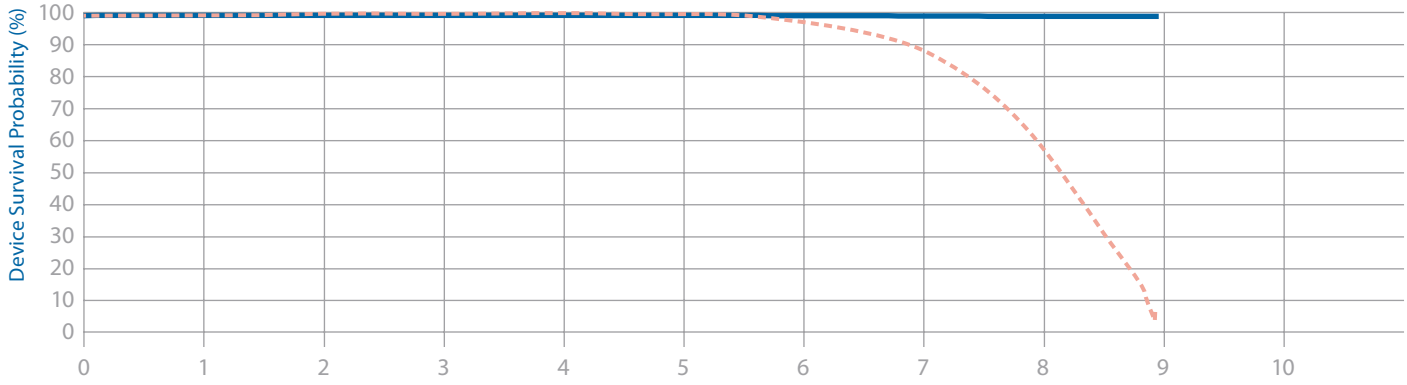
US Market Release	Jan-99
Registered US Implants	25,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	3,759

Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	63
Therapy Function Not Compromised	5
Electrical Component	4
Other	1
Therapy Function Compromised	58
Electrical Component	3
Electrical Interconnect *(34 malfunctions related to advisory)*	55

NBG Code	DDD/RO
Serial Number Prefix	PHF, PHH, PHG
Estimated Longevity	See page 78



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 107 mo
%	———	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.7	99.6
%	- - -	99.9	99.8	99.8	99.5	98.8	96.9	87.8	57.6	5.2
#		21,000	19,000	17,000	15,000	13,000	12,000	8,800	4,100	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 600 DR KDR651, KDR653

Product Characteristics

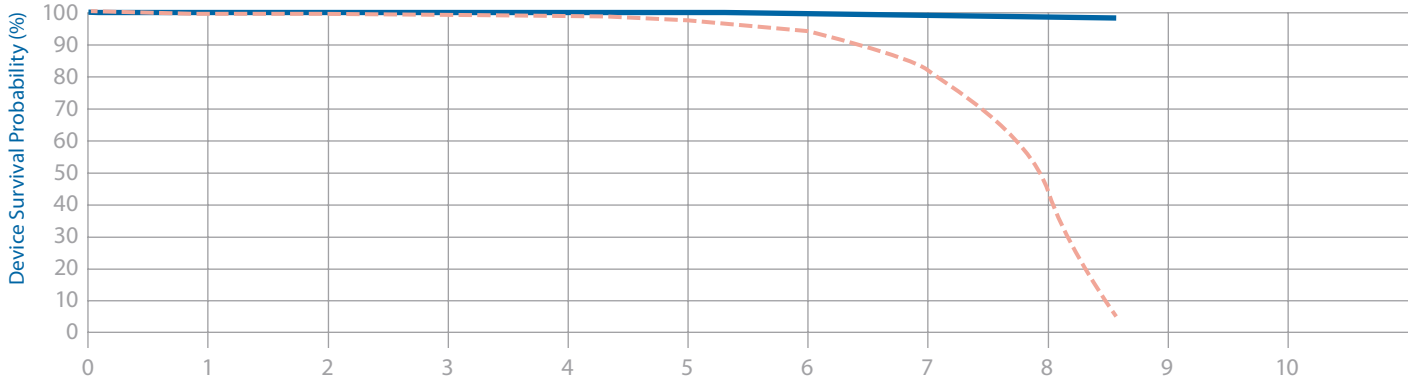
US Market Release	Mar-01
Registered US Implants	16,000
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	2,633

Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	56
Therapy Function Not Compromised	3
Electrical Component	1
Possible Early Battery Depletion	2
Therapy Function Compromised	53
Electrical Component	1
Electrical Interconnect *(30 malfunctions related to advisory)*	52

NBG Code	DDD/RO
Serial Number Prefix	PLJ, PLK
Estimated Longevity	See page 78



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 103 mo
%	———	100.0	100.0	100.0	100.0	100.0	99.9	99.7	99.5	99.4
%	- - - -	100.0	99.9	99.8	99.4	98.2	94.9	81.3	43.8	6.3
#		13,000	11,000	10,000	9,200	8,100	7,000	5,000	1,800	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 700 D KD701, KD703, KD706

Product Characteristics

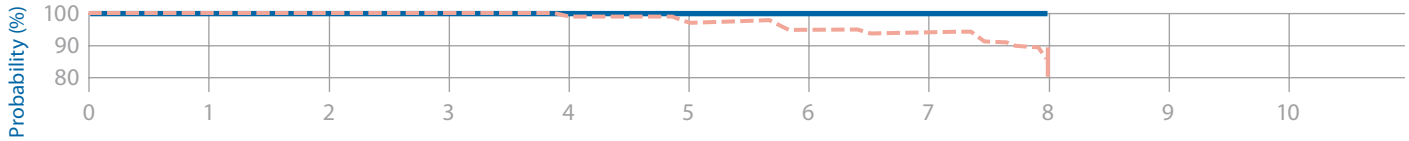
US Market Release	Jan-99
Registered US Implants	300
Estimated Active US Implants	70
Normal Battery Depletions (US)	17

Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDD
Serial Number Prefix	PHK, PHM, PHL
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.0	97.8	95.4	94.2	86.4
#	300	200	200	200	200	200	100	100

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

Product Characteristics

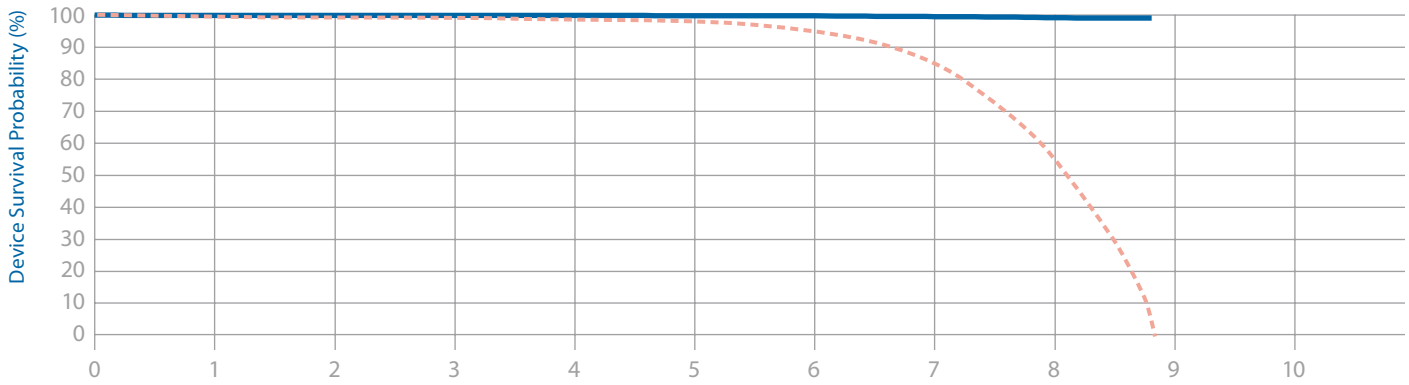
US Market Release	Jan-99
Registered US Implants	206,000
Estimated Active US Implants	34,000
Normal Battery Depletions (US)	30,156

Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	736
Therapy Function Not Compromised	37
Battery	1
Electrical Component	27
Electrical Interconnect	2
Possible Early Battery Depletion	4
Other	3
Therapy Function Compromised	699
Electrical Component	17
Electrical Interconnect *(414 malfunctions related to advisory)*	681
Possible Early Battery Depletion	1

NBG Code	DDD/RO
Serial Number Prefix	PGU, PGY, PGW
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 106 mo
%	100.0	100.0	99.9	99.9	99.9	99.9	99.7	99.6	99.4
%	99.9	99.8	99.6	99.2	98.2	95.5	85.5	56.2	0.2
#	173,000	158,000	143,000	129,000	114,000	95,000	68,000	30,000	1,100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 700 DR KDR721

Product Characteristics

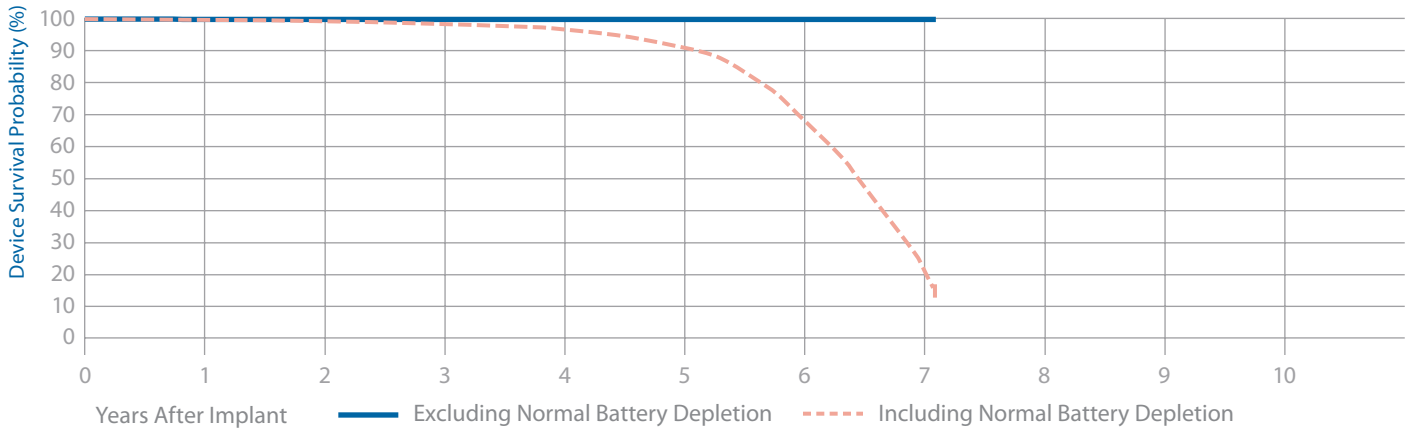
US Market Release	Feb-99
Registered US Implants	9,800
Estimated Active US Implants	800
Normal Battery Depletions (US)	1,330

Advisories: See page 155– 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	5
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	4
Electrical Interconnect *(4 malfunctions related to advisory)*	4

NBG Code	DDD/RO
Serial Number Prefix	PGR
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 85 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.8	99.5	98.7	96.7	91.0	69.0	21.1	14.9
#	8,400	7,400	6,500	5,500	4,300	2,200	300	200

Effective Sample Size

Kappa 700 SR KSR701, KSR703, KSR706

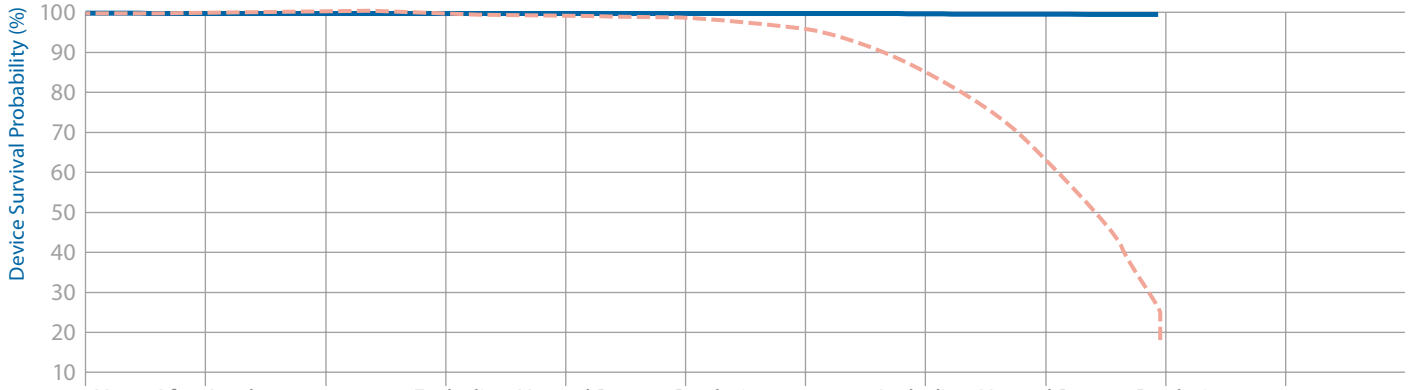
Product Characteristics

US Market Release	Jan-99
Registered US Implants	55,000
Estimated Active US Implants	7,700
Normal Battery Depletions (US)	4,500

Advisories: See page 149 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	28
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	25
Electrical Component	4
Electrical Interconnect *(20 malfunctions related to advisory)*	21

NBG Code	SSIR
Serial Number Prefix	PHT, PHW, PHU
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 107 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.8
%	99.9	99.8	99.4	98.7	97.2	93.7	83.6	56.6	11.4
#	46,000	39,000	33,000	28,000	23,000	17,000	12,000	5,100	400

Effective Sample Size

Kappa 700 VDD KVDD701

Product Characteristics

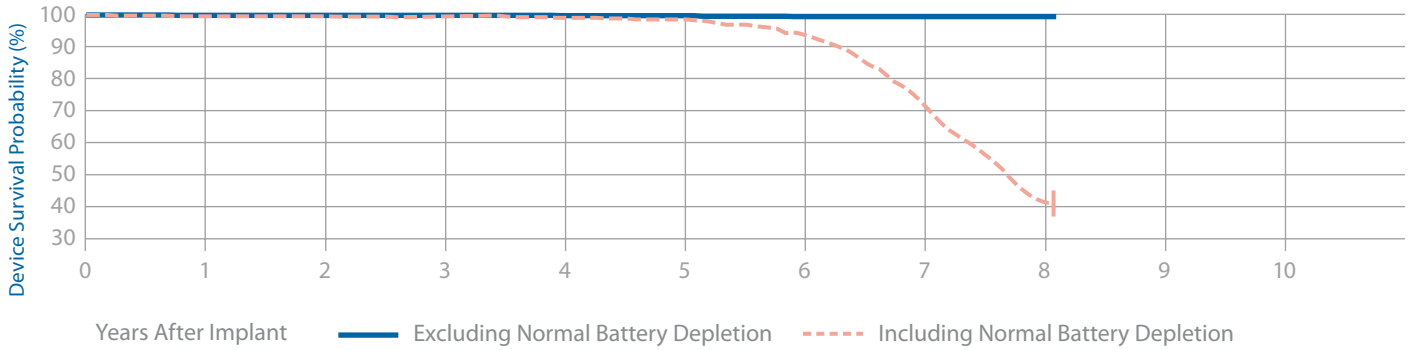
US Market Release	Jan-99
Registered US Implants	1,700
Estimated Active US Implants	200
Normal Battery Depletions (US)	171

Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	4
Therapy Function Not Compromised	0
Therapy Function Compromised	4
Electrical Interconnect *(4 malfunctions related to advisory)*	4

NBG Code	VDD/RO
Serial Number Prefix	PHP
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 97 mo
%	99.9	99.9	99.9	99.8	99.8	99.6	99.6	99.6	99.6
%	99.8	99.8	99.3	98.7	98.5	94.2	72.8	42.1	41.3
#	1,500	1,300	1,200	1,000	1,000	800	400	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 800 DR KDR801, KDR803

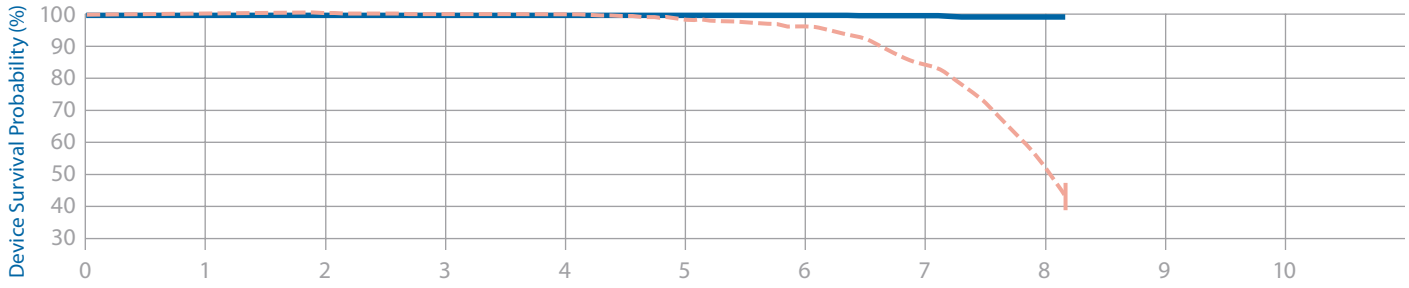
Product Characteristics

US Market Release	Jan-02
Registered US Implants	4,300
Estimated Active US Implants	1,100
Normal Battery Depletions (US)	474

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	3
Therapy Function Not Compromised	0
Therapy Function Compromised	3
Electrical Interconnect	3

NBG Code	DDD/RO
Serial Number Prefix	PKW, PKY
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 98 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9
%	100.0	99.9	99.8	99.5	98.5	96.2	84.7	53.2	42.8
#	3,800	3,500	3,200	2,900	2,500	2,200	1,700	400	200

Effective Sample Size

Kappa 900 DR KDR901, KDR903, KDR906

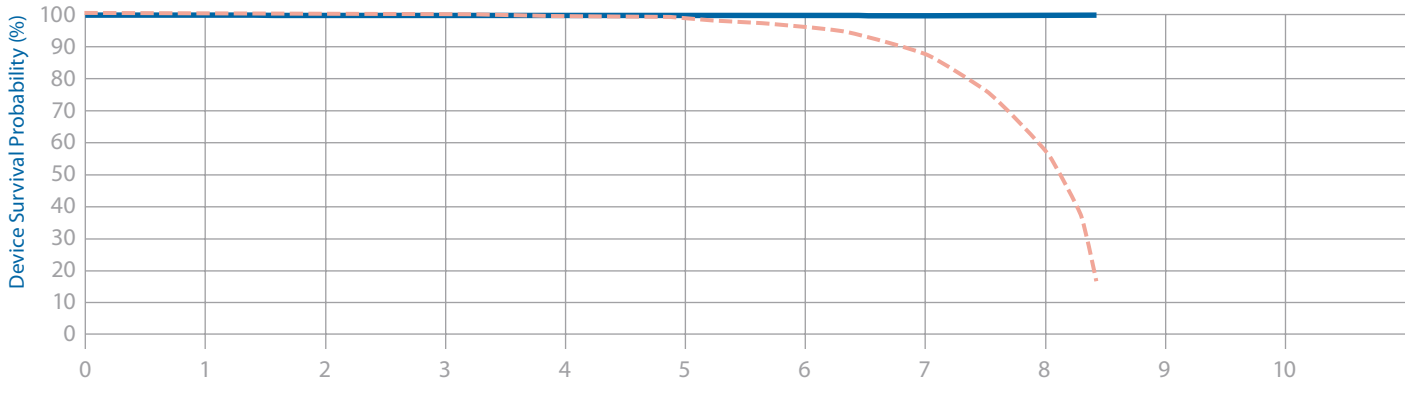
Product Characteristics

US Market Release	Jan-02
Registered US Implants	125,000
Estimated Active US Implants	45,000
Normal Battery Depletions (US)	10,541

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	72
Therapy Function Not Compromised	19
Electrical Component	17
Electrical Interconnect	1
Other	1
Therapy Function Compromised	53
Electrical Component	9
Electrical Interconnect	44

NBG Code	DDR/RO
Serial Number Prefix	PKM, PKN, PKP
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 101 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9
%	100.0	99.9	99.8	99.4	98.6	96.5	87.7	57.2	18.2
#	113,000	103,000	94,000	86,000	75,000	59,000	40,000	11,000	900

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 900 SR KSR901, KSR903, KSR906

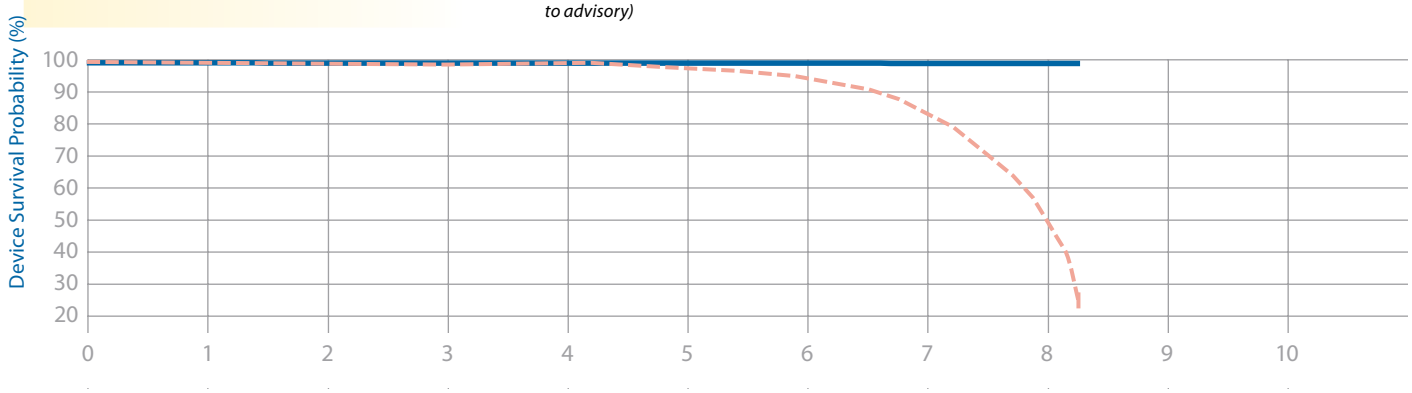
Product Characteristics

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	9,500
Normal Battery Depletions (US)	1,844

Advisories: See page 149 – 2009
Potential Separation of Interconnect Wires

Malfunctions (US)	17
Therapy Function Not Compromised	9
Electrical Component	7
Electrical Interconnect *(1 malfunction related to advisory)*	1
Possible Early Battery Depletion	1
Therapy Function Compromised	8
Electrical Interconnect *(7 malfunctions related to advisory)*	8

NBG Code	SSIR
Serial Number Prefix	PLF, PLG, PLH
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.8	99.6	98.9	97.5	94.5	83.9	49.4	25.2
#	30,000	26,000	22,000	19,000	15,000	10,000	6,000	1,100	200

Effective Sample Size

Kappa 900 VDD KVDD901

Product Characteristics

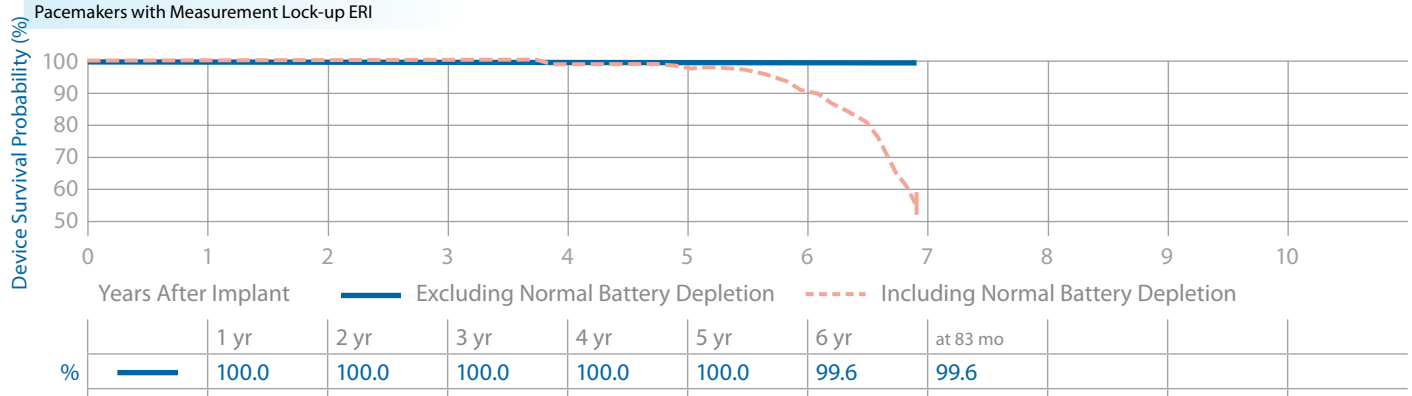
US Market Release	Jan-02
Registered US Implants	600
Estimated Active US Implants	90
Normal Battery Depletions (US)	79

Advisories: See page 149 – 2009
Potential Separation of Interconnect Wires

Performance Note: See page 157 –
Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	2
Therapy Function Not Compromised	2
Software/Firmware Malfunction	1
Other	1
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PLE
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 83 mo
%	100.0	100.0	100.0	100.0	100.0	99.6	99.6
%	100.0	100.0	100.0	99.0	97.9	90.7	54.7
#	600	500	400	400	300	300	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Kappa 900 DR KDR921

US Market Release	Jan-02
Registered US Implants	16,000
Estimated Active US Implants	2,200
Normal Battery Depletions (US)	2,493

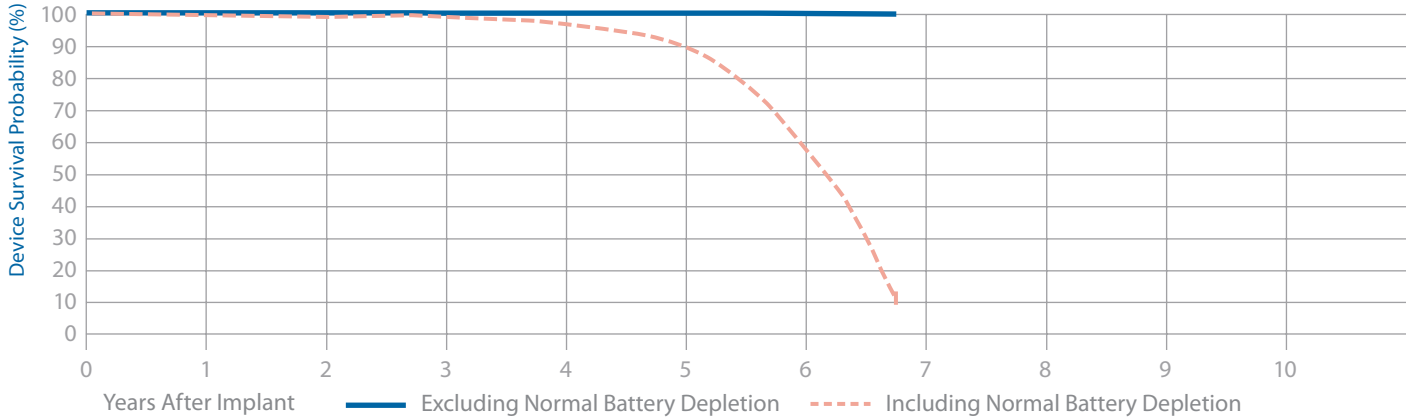
Advisories: See page 149 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	4
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	3
Electrical Interconnect *(3 malfunctions related to advisory)*	3

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix	PKR
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	99.9	99.7	99.2	97.2	90.3	59.5	12.1
#	14,000	12,000	11,000	9,500	7,400	3,100	300

Effective Sample Size

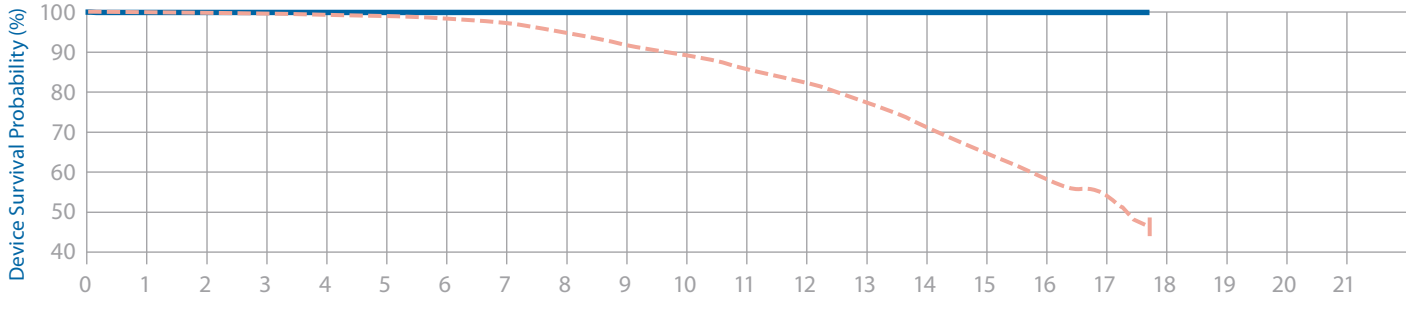
Legend II 8424, 8426, 8427

US Market Release	Nov-91
Registered US Implants	59,000
Estimated Active US Implants	5,900
Normal Battery Depletions (US)	2,567
Advisories	None

Malfunctions (US)	35
Therapy Function Not Compromised	24
Battery Malfunction	2
Electrical Component	18
Possible Early Battery Depletion	4
Therapy Function Compromised	11
Electrical Component	9
Electrical Interconnect	2

Product Characteristics

NBG Code	SSIRO
Serial Number Prefix	2P, 2T, 2U
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	at 212 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.7	99.5	99.2	98.9	98.2	97.3	94.8	91.6	88.7	85.5	82.2	77.2	71.0	64.5	58.4	52.7	46.4
#	52,000	46,000	41,000	36,000	31,000	27,000	24,000	20,000	16,000	13,000	10,000	8,200	6,400	4,900	3,800	2,700	1,300	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Minix/Minix ST 8340, 8341, 8341M, 8342, 8330, 8331, 8331M

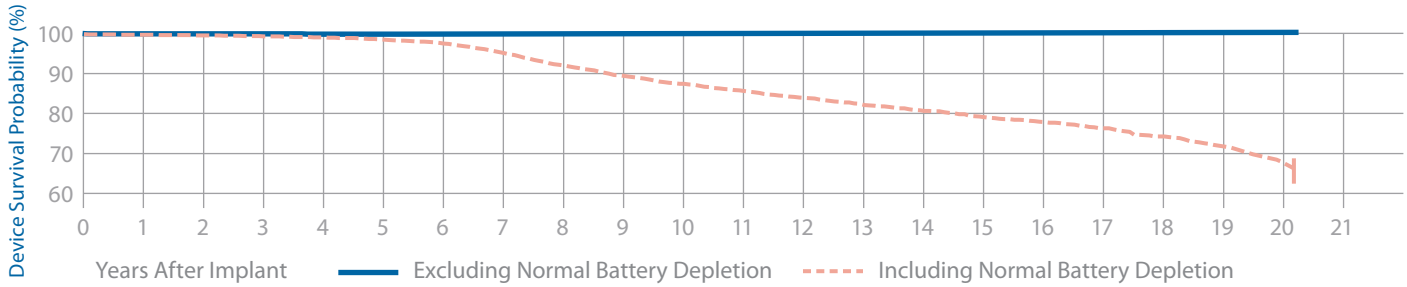
US Market Release	Nov-88
Registered US Implants	59,000
Estimated Active US Implants	7,600
Normal Battery Depletions (US)	1,741

Advisories: See page 156– 1991 Potential Delayed Restoration of Permanent Settings

Malfunctions (US)	50
Therapy Function Not Compromised	15
Electrical Component	13
Battery Malfunction	1
Possible Early Battery Depletion	1
Therapy Function Compromised	35
Electrical Component	32
Electrical Interconnect	1
Battery Malfunction	1
Other	1

Product Characteristics

NBG Code	SSICO, VVICO
Serial Number Prefix	UQ, US, 8W, UU, UV, UX, 7W
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr	20 yr	at 242 mo
%	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.8	99.7	99.5	99.2	98.8	97.8	95.4	92.3	89.6	87.5	85.7	84.0	82.3	80.9	79.3	78.0	76.2	74.2	71.5	69.2	66.9
#	50,000	43,000	37,000	32,000	27,000	23,000	19,000	15,000	13,000	11,000	9,200	8,100	7,100	6,400	5,700	4,700	3,500	2,300	1,300	300	100

Effective Sample Size

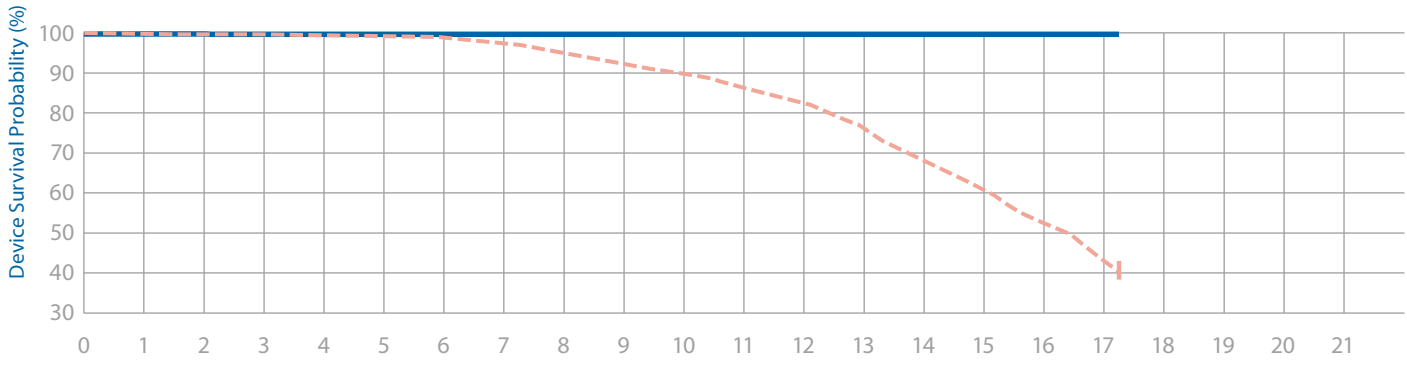
Minuet 7107, 7108

US Market Release	Mar-92
Registered US Implants	17,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	950
Advisories	None

Malfunctions (US)	3
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	0

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix	1Z1, 2G1
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	at 207 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.8	99.5	99.0	98.2	97.1	94.8	92.2	89.2	85.7	82.0	76.4	68.1	61.0	52.1	43.2	40.8
#	15,000	13,000	12,000	11,000	9,500	8,400	7,300	6,200	5,200	4,300	3,500	2,900	2,300	1,700	1,300	800	300	100

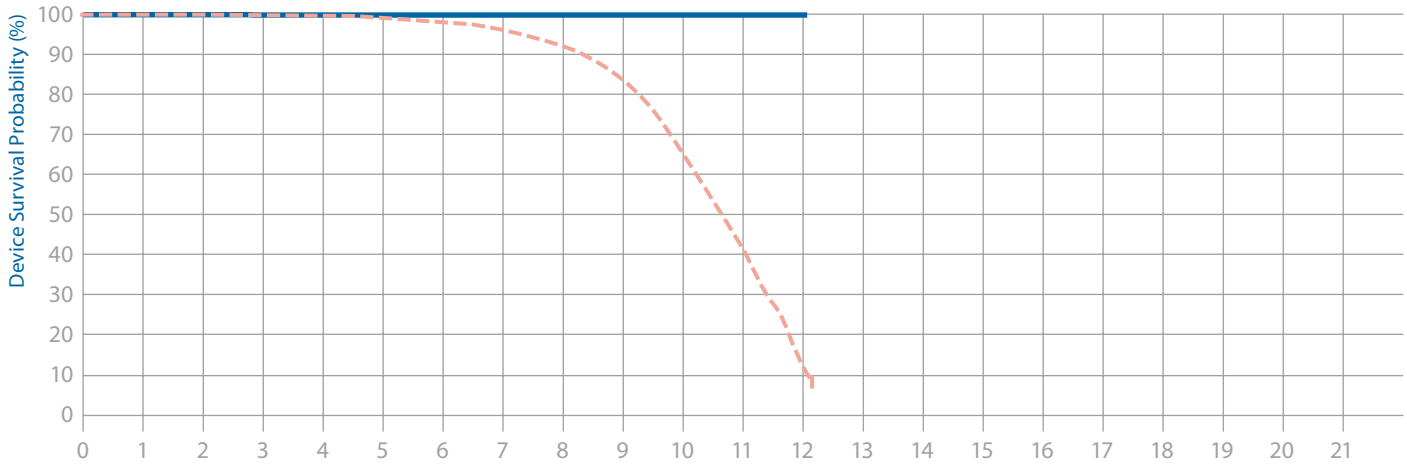
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Preva DR 7088, 7089

Product Characteristics

US Market Release	Jul-96	Malfunctions (US)	4	NBG Code	DDD/RO
Registered US Implants	26,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PGJ, PGK
Estimated Active US Implants	2,600	**Therapy Function Compromised**	4	Estimated Longevity	See page 79
Normal Battery Depletions (US)	2,807	Electrical Component	2		
Advisories	None	Electrical Interconnect	2		

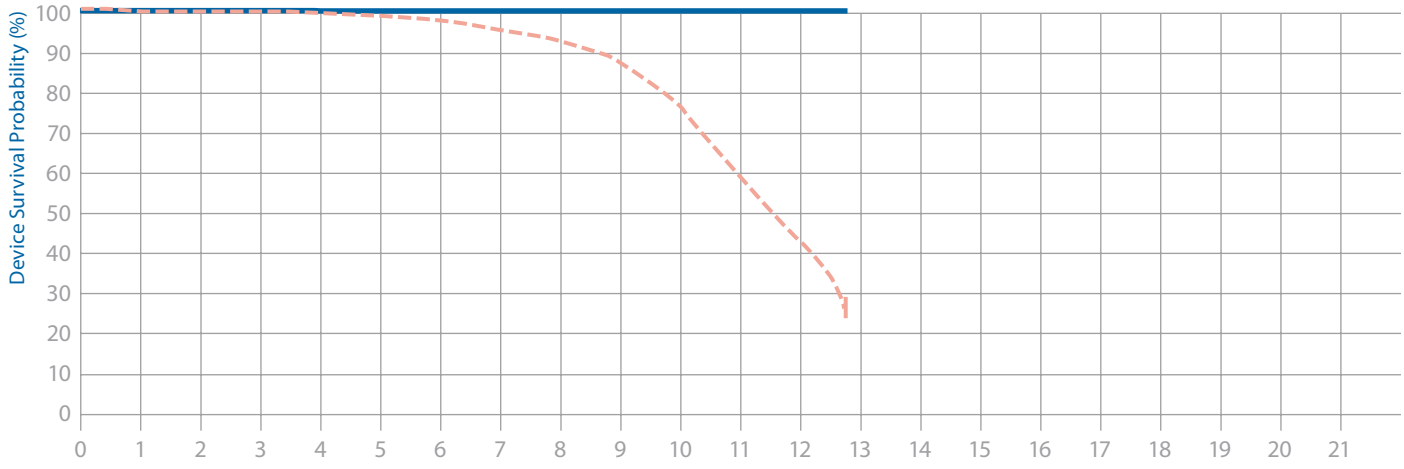


	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 145 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.8	99.5	99.3	98.7	97.7	96.2	92.4	84.5	66.5	41.8	12.8	8.0
#	22,000	20,000	18,000	16,000	14,000	12,000	11,000	8,900	6,900	4,300	2,000	200	100

Effective Sample Size

Preva SR 8088, 8089

				Product Characteristics	
US Market Release	Jul-96	Malfunctions (US)	1	NBG Code	SSIR
Registered US Implants	18,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PGL, PGM
Estimated Active US Implants	1,700	**Therapy Function Compromised**	1	Estimated Longevity	See page 79
Normal Battery Depletions (US)	1,057	Possible Early Battery Depletion	1		
Advisories	None				

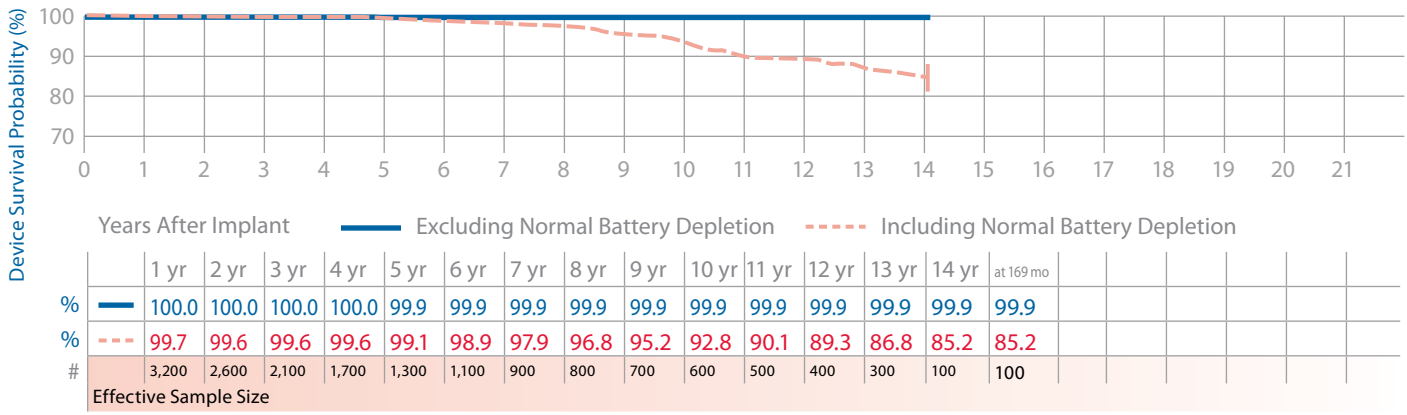


	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 153 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.7	99.4	99.0	98.3	97.2	95.0	92.1	87.3	75.2	59.1	43.4	25.9
#	15,000	12,000	11,000	8,900	7,500	6,300	5,200	4,200	3,400	2,300	1,400	700	100

Effective Sample Size

Prevail S 8085, 8086

				Product Characteristics	
US Market Release	Oct-95	Malfunctions (US)	1	NBG Code	SSI
Registered US Implants	4,200	**Therapy Function Not Compromised**	0	Serial Number Prefix	PEY, PFA
Estimated Active US Implants	500	**Therapy Function Compromised**	1	Estimated Longevity	See page 79
Normal Battery Depletions (US)	55	Electrical Component	1		
Advisories	None				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	at 169 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.7	99.6	99.6	99.6	99.1	98.9	97.9	96.8	95.2	92.8	90.1	89.3	86.8	85.2	85.2
#	3,200	2,600	2,100	1,700	1,300	1,100	900	800	700	600	500	400	300	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

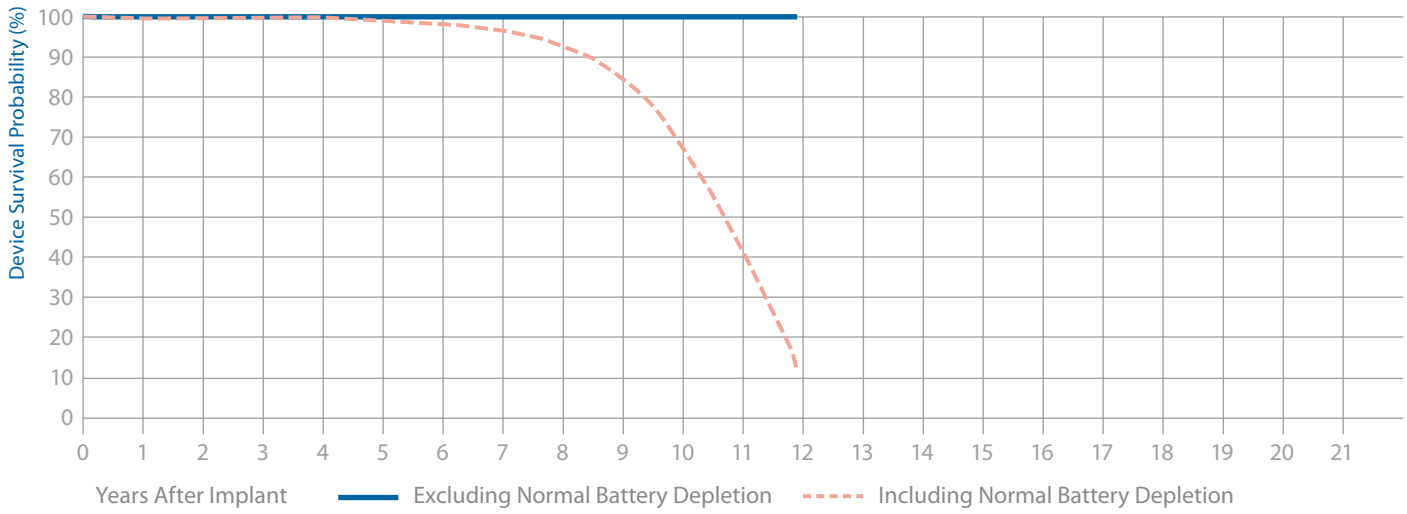
Prodigy DR 7860, 7861, 7862

Product Characteristics

US Market Release	Oct-95
Registered US Implants	37,000
Estimated Active US Implants	3,400
Normal Battery Depletions (US)	3,831
Advisories	None

Malfunctions (US)	11
Therapy Function Not Compromised	5
Electrical Component	2
Possible Early Battery Depletion	2
Other	1
Therapy Function Compromised	6
Electrical Component	2
Electrical Interconnect	4

NBG Code	DDD/RO
Serial Number Prefix	PDH, PDJ, PDK
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 143 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.8	99.6	99.3	98.7	97.9	96.3	92.4	84.6	68.4	42.3	12.1
#	33,000	30,000	27,000	24,000	21,000	19,000	16,000	13,000	9,800	6,200	2,600	300

Effective Sample Size

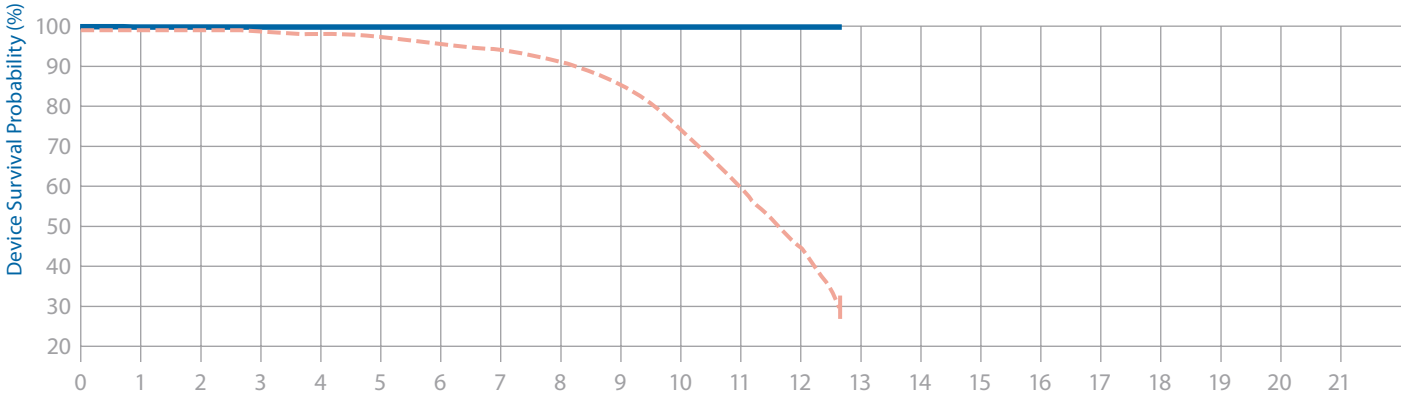
Prodigy SR 8158, 8160, 8161, 8162

US Market Release	Oct-95
Registered US Implants	22,000
Estimated Active US Implants	2,500
Normal Battery Depletions (US)	1,292
Advisories	None

Malfunctions (US)	4
Therapy Function Not Compromised	2
Battery Malfunction	1
Possible Early Battery Depletion	1
Therapy Function Compromised	2
Electrical Component	1
Electrical Interconnect	1

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PEM, PED, PEE, PEF
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 152 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.7	99.6	99.2	98.7	97.8	96.5	94.8	91.6	86.1	74.3	60.0	44.8	30.7
#	19,000	16,000	14,000	12,000	9,700	8,100	6,600	5,400	4,100	2,800	1,700	700	100

Effective Sample Size

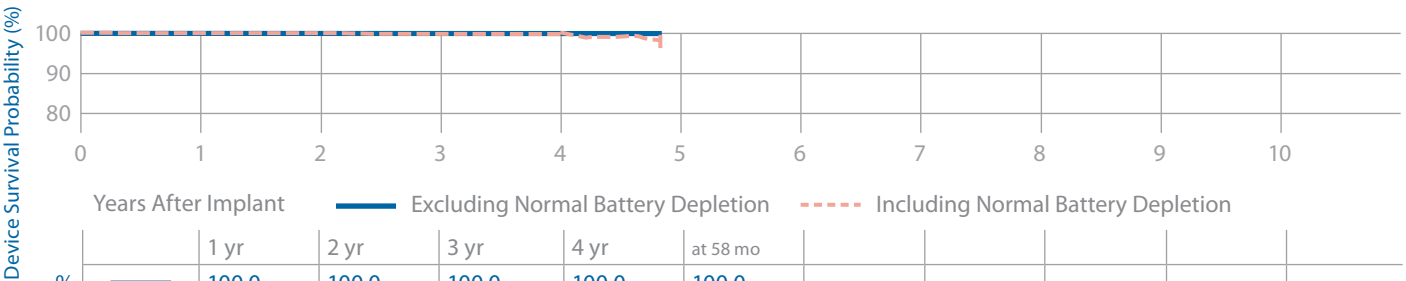
Sensia DR SEDR01, SED01

US Market Release	Jul-06
Registered US Implants	95,000
Estimated Active US Implants	75,000
Normal Battery Depletions (US)	52
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	10
Therapy Function Not Compromised	6
Electrical Component	6
Therapy Function Compromised	4
Electrical Component	3
Electrical Interconnect	1

Product Characteristics

NBG Code	DDD, DDDR
Serial Number Prefix	PWL, PWK, NWL, NWK
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.6	99.0
#	70,000	47,000	26,000	9,000	200

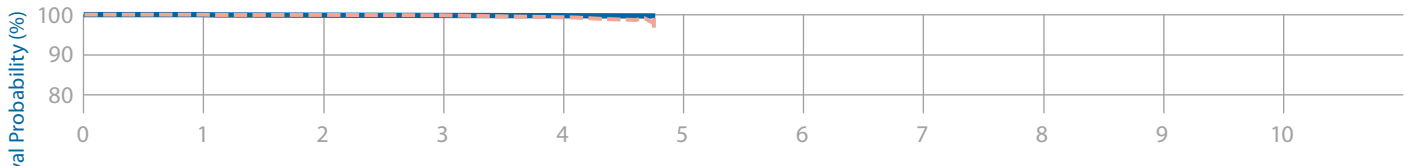
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Sensia SR SESR01, SES01

US Market Release	Jul-06	Malfunctions (US)	4	NBG Code	SSIR, SSI
Registered US Implants	63,000	**Therapy Function Not Compromised**	3	Serial Number Prefix	PWR, PWS, NWR, NWS
Estimated Active US Implants	45,000	Electrical Component	3		
Normal Battery Depletions (US)	41	**Therapy Function Compromised**	1	Estimated Longevity	See page 80
Advisories	None	Electrical Interconnect	1		

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.5	98.2
#	43,000	27,000	14,000	4,600	300

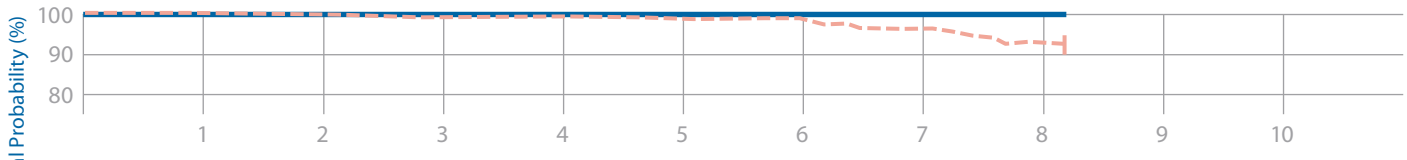
Effective Sample Size

Sigma 100 S SS103, SS106

US Market Release	Aug-99	Malfunctions (US)	0	NBG Code	SSI
Registered US Implants	800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PJG, PJH
Estimated Active US Implants	100	**Therapy Function Compromised**	0	Estimated Longevity	See page 80
Normal Battery Depletions (US)	17				

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 98 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.5	99.5	98.7	98.7	96.5	93.6	93.6
#	600	500	400	300	200	200	200	100	100

Effective Sample Size

Sigma 200 DR SDR203

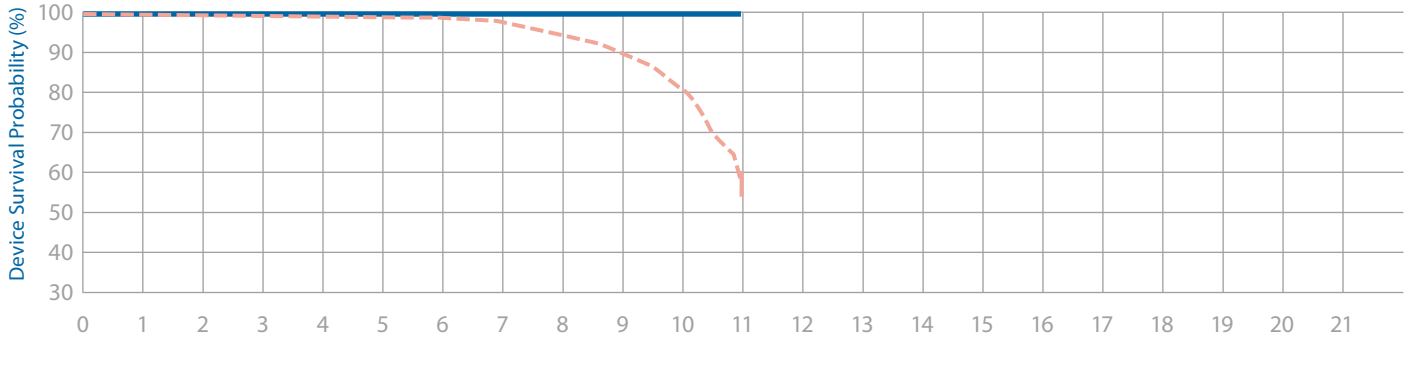
US Market Release	Aug-99
Registered US Implants	16,000
Estimated Active US Implants	4,300
Normal Battery Depletions (US)	475

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	31
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	30
Electrical Component	1
Electrical Interconnect *(19 malfunctions related to advisory)*	29

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix	PJD
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.6	99.5	99.5	99.5
%	100.0	99.9	99.9	99.8	99.5	99.0	97.6	94.1	89.5	80.8	55.6
#	14,000	12,000	11,000	9,600	8,400	7,400	6,100	4,600	3,100	1,500	100

Effective Sample Size

Sigma 200 SR SSR203

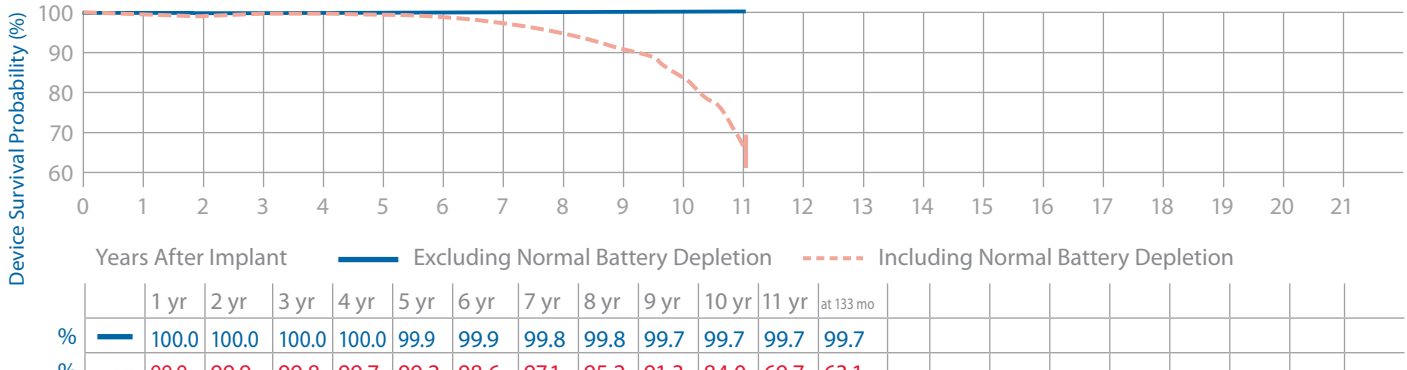
US Market Release	Sep-99
Registered US Implants	12,000
Estimated Active US Implants	2,300
Normal Battery Depletions (US)	225

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	11
Therapy Function Not Compromised	0
Therapy Function Compromised	11
Electrical Interconnect *(11 malfunctions related to advisory)*	11

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PJG
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 133 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7	99.7
%	99.9	99.9	99.8	99.7	99.2	98.6	97.1	95.2	91.3	84.0	69.7	63.1
#	9,600	7,900	6,700	5,600	4,700	4,000	3,200	2,400	1,600	900	200	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Sigma 300 DR SDR303, SDR306

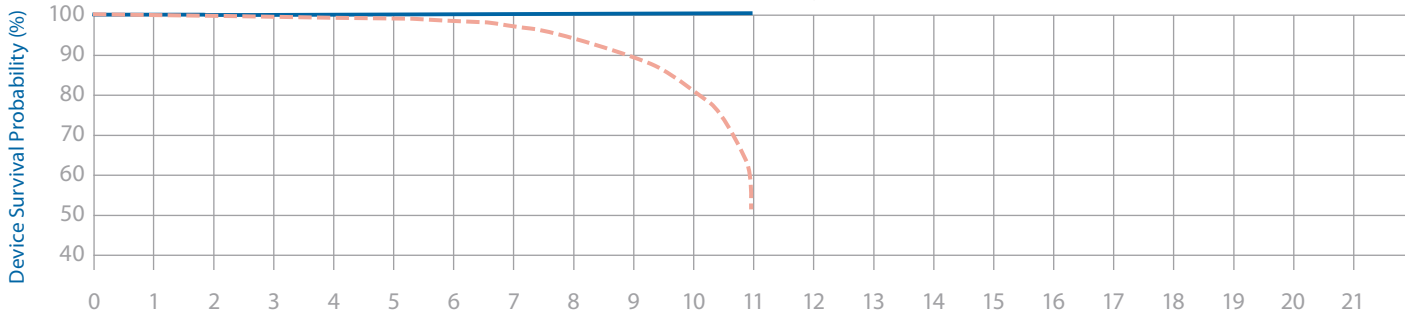
Product Characteristics

US Market Release	Aug-99
Registered US Implants	107,000
Estimated Active US Implants	37,000
Normal Battery Depletions (US)	1,982

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	200
Therapy Function Not Compromised	8
Electrical Component	5
Electrical Interconnect	2
Possible Early Battery Depletion	1
Therapy Function Compromised	192
Electrical Component	8
Electrical Interconnect *(137 malfunctions related to advisory)*	184

NBG Code	DDD/RO
Serial Number Prefix	PJD, PJE
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.6	99.5	99.5	99.5
%	100.0	99.9	99.9	99.7	99.4	98.9	97.9	95.1	90.3	81.6	51.6
#	92,000	82,000	73,000	64,000	54,000	43,000	32,000	22,000	13,000	6,000	300

Effective Sample Size

Sigma 300 SR SSR303, SSR306

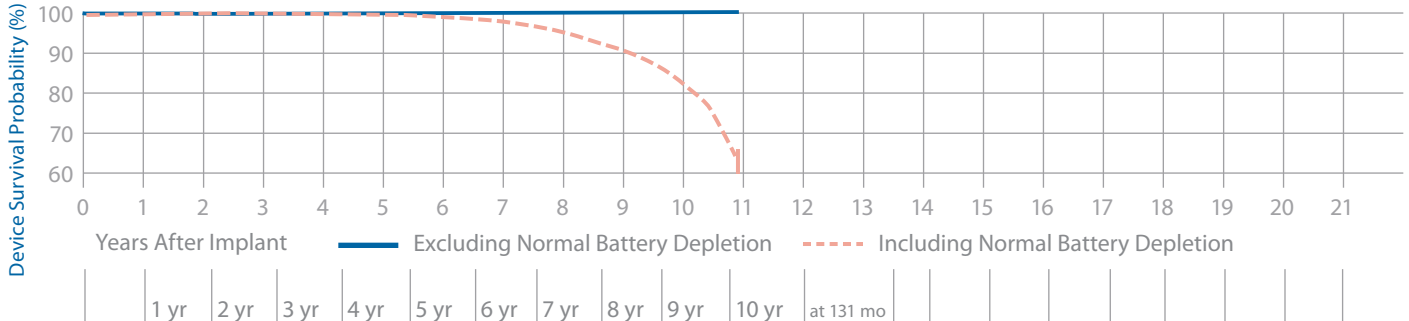
Product Characteristics

US Market Release	Aug-99
Registered US Implants	54,000
Estimated Active US Implants	13,000
Normal Battery Depletions (US)	713

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	45
Therapy Function Not Compromised	3
Electrical Component	1
Electrical Interconnect	1
Other	1
Therapy Function Compromised	42
Electrical Component	3
Electrical Interconnect *(34 malfunctions related to advisory)*	39

NBG Code	SSIR
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 131 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.7	99.7	99.7	99.7
%	100.0	99.9	99.8	99.6	99.2	98.5	97.2	94.8	90.2	81.9	62.3
#	43,000	36,000	30,000	25,000	20,000	15,000	11,000	7,200	4,200	1,900	200

Effective Sample Size

Sigma 300 VDD SVDD303

Product Characteristics

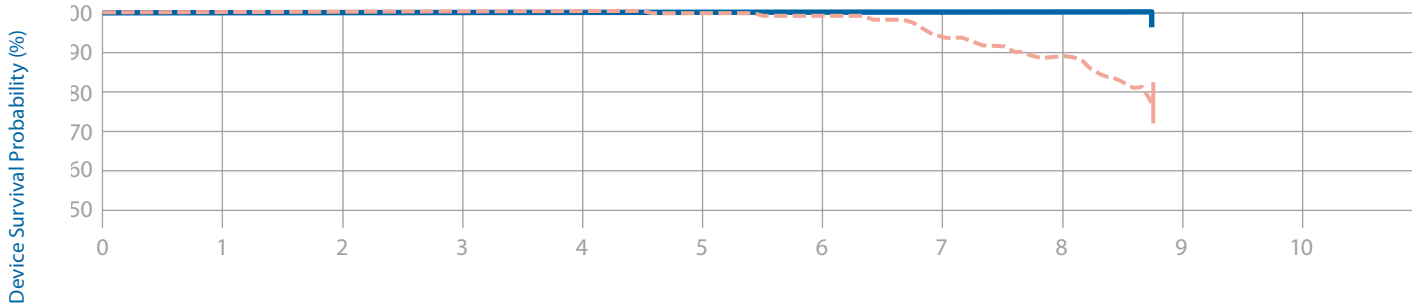
US Market Release	Sep-99
Registered US Implants	600
Estimated Active US Implants	100
Normal Battery Depletions (US)	41

Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Interconnect	1

(1 malfunction related to advisory)

NBG Code	VDDD
Serial Number Prefix	PJD
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.5	99.5
%	100.0	100.0	100.0	100.0	99.4	98.1	94.1	89.4	77.0
#	500	500	400	400	300	300	200	200	100

Effective Sample Size

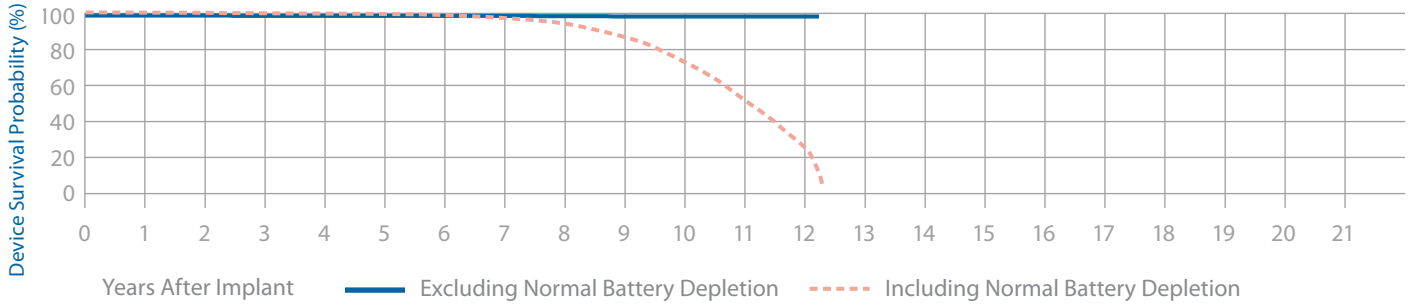
Thera-i DR 7960i, 7961i, 7962i

Product Characteristics

US Market Release	Oct-95
Registered US Implants	121,000
Estimated Active US Implants	11,000
Normal Battery Depletions (US)	13,712
Advisories	None

Malfunctions (US)	49
Therapy Function Not Compromised	23
Battery Malfunction	3
Electrical Interconnect	1
Electrical Component	7
Possible Early Battery Depletion	9
Other	3
Therapy Function Compromised	26
Electrical Interconnect	20
Electrical Component	6

NBG Code	DDD/RO
Serial Number Prefix	PDB, PDC, PDD
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 147 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.8	99.6	99.4	99.0	98.1	96.7	93.2	85.8	71.3	48.2	19.2	3.3
#	109,000	100,000	92,000	83,000	75,000	66,000	57,000	48,000	37,000	24,000	11,000	2,100	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

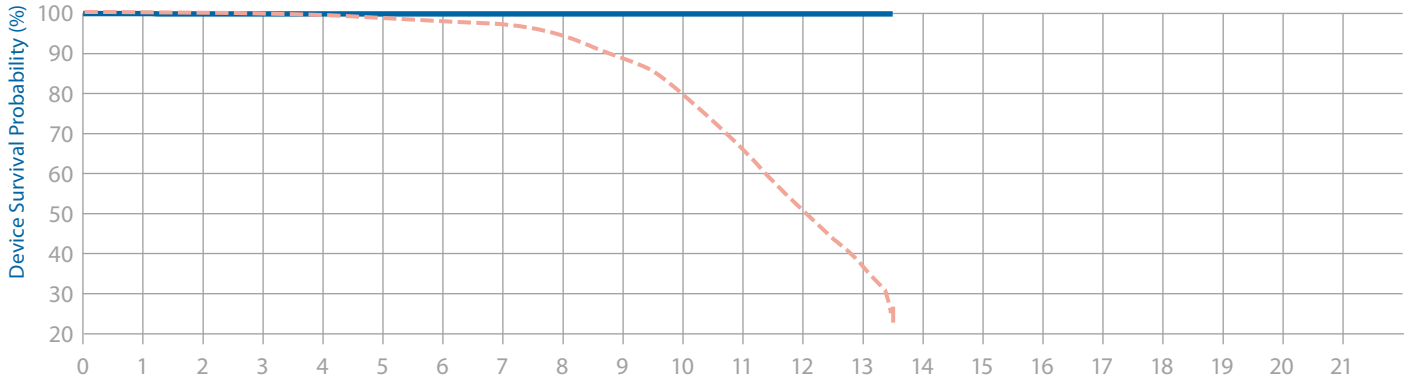
Thera-i SR 8960i, 8961i, 8962i

US Market Release	Oct-95
Registered US Implants	50,000
Estimated Active US Implants	4,700
Normal Battery Depletions (US)	2,817
Advisories	None

Malfunctions (US)	8
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	6
Electrical Component	3
Electrical Interconnect	3

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PDU, PDV, PDW
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 162 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.8	99.6	99.3	98.9	98.2	96.9	94.5	88.8	80.1	65.9	51.5	36.6	24.4
#	42,000	37,000	32,000	27,000	23,000	20,000	17,000	14,000	11,000	7,800	5,000	2,700	800	100

Effective Sample Size

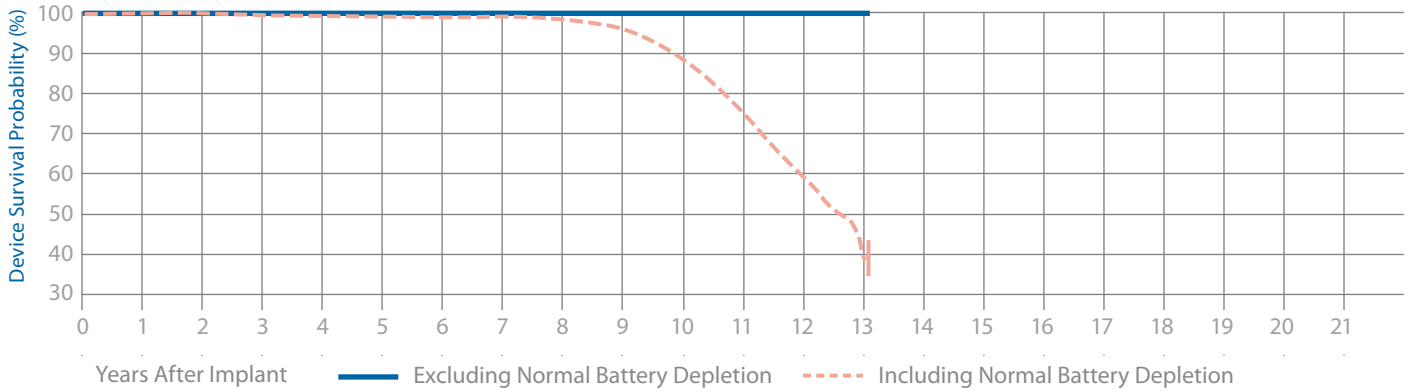
Thera-i VDD 8968i

US Market Release	Mar-95
Registered US Implants	4,900
Estimated Active US Implants	600
Normal Battery Depletions (US)	322
Advisories	None

Malfunctions (US)	0

Product Characteristics

NBG Code	VDD
Serial Number Prefix	PEC
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 157 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.8	99.6	99.6	99.3	99.2	99.1	98.0	95.8	89.1	75.5	59.0	40.3	38.8
#	4,200	3,800	3,400	3,000	2,700	2,400	2,100	1,900	1,600	1,300	900	500	100	100

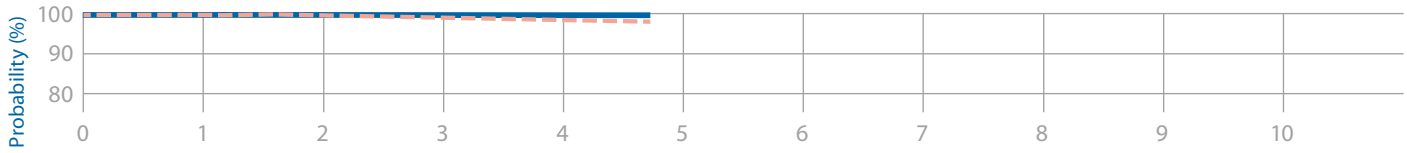
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Versa DR VEDR01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	6	NBG Code	DDDR
Registered US Implants	77,000	**Therapy Function Not Compromised**	4	Serial Number Prefix	PWH, NWH
Estimated Active US Implants	61,000	Electrical Component	4	Estimated Longevity	See page 80
Normal Battery Depletions (US)	46	**Therapy Function Compromised**	2		
Performance Note: See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI		Electrical Component	2		



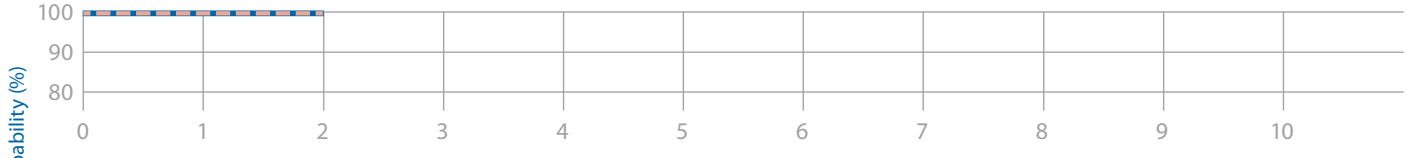
	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.2
#	59,000	42,000	25,000	10,000	300

Effective Sample Size

Revo MRI SureScan RVDR01

Product Characteristics

US Market Release	Feb-11	Malfunctions (US)	0	NBG Code	DDDRP
Registered US Implants	8,600	**Therapy Function Not Compromised**	0	Serial Number Prefix	PTN
Estimated Active US Implants	8,500	**Therapy Function Compromised**	0	Estimated Longevity	See page 80
Normal Battery Depletions (US)	0				



	1 yr	2 yr
%	100.0	100.0
%	100.0	100.0
#	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary (95% Confidence Interval)

The following table shows IPG device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US): Therapy Function Compromised		Therapy Function Not Compromised		Total		Device Survival Probability (%): Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Jul-06	266,000	224,000	92	17	+	30	=	47	Excluding Normal Battery Depletion	100.0 +0.0/0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 59 mo							
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.1/-0.1 at 59 mo							
Adapta DR	ADDRL1	Jul-06	45,000	41,000	6	1	+	2	=	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 56 mo							
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.3	99.7 +0.1/-0.3 at 56 mo							
Adapta DR	ADDRS1	Jul-06	25,000	20,000	40	2	+	2	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 57 mo							
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.7 +0.1/-0.1	98.8 +0.3/-0.4	96.0 +1.3/-1.8 at 57 mo							
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	49,000	35,000	44	4	+	1	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 58 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.2	98.3 +0.5/-0.7 at 58 mo							
Adapta VDD	ADVDD01	Jul-06	800	700	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 47 mo								
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 47 mo								
AT500	AT501, 7253	Mar-03	11,000	1,600	2,410	5	+	4	=	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 80 mo					
	See page 163 – Performance note on AT500 Pacing System Follow-Up Protocol										Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.2	97.6 +0.3/-0.4	84.4 +0.8/-0.9	51.0 +1.3/-1.3	15.1 +1.5/-1.4 at 80 mo					
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	7,000	3,000	319	0	+	1	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 90 mo				
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.1	99.2 +0.2/-0.3	98.4 +0.3/-0.4	96.9 +0.5/-0.6	87.9 +1.0/-1.1	80.5 +1.6/-1.7 at 90 mo				
EnPulse DR	E1DR21	Dec-03	1,900	200	323	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 80 mo					
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.7 +0.2/-0.4	99.0 +0.4/-0.7	96.8 +0.8/-1.1	92.6 +1.4/-1.7	63.5 +3.1/-3.3	25.2 +4.0/-3.8 at 80 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US): Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	101,000	59,000	1,122	5	+	17	=	22	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 86 mo				
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	98.9 +0.1/-0.1	97.4 +0.1/-0.1	91.3 +0.5/-0.5	89.1 +0.9/-0.9 at 86 mo				
EnPulse 2 DR	E2DR21	Feb-04	12,000	4,500	903	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 77 mo					
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.3 +0.1/-0.2	97.7 +0.3/-0.3	92.0 +0.6/-0.7	67.9 +1.6/-1.6	31.7 +3.6/-3.5 at 77 mo					
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	600	400	1	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 74 mo					
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.2 +0.6/-2.4	99.2 +0.6/-2.4 at 74 mo					
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,000	10,000	386	1	+	3	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 86 mo				
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	97.8 +0.2/-0.3	94.2 +0.5/-0.5	82.0 +1.9/-2.1	71.5 +4.3/-4.9 at 86 mo				
EnPulse 2 VDD	E2VDD01	Dec-03	600	300	28	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0						
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.5 +0.4/-1.3	99.5 +0.4/-1.3	82.8 +5.3/-7.4						
EnRhythm DR	P1501DR	May-05	108,000	81,000	113	46	+	1,009	=	1,055	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	98.1 +0.1/-0.1	95.6 +0.3/-0.4	95.2 +0.4/-0.5 at 73 mo					
	Advisories: See page 146 – 2010 Low Battery Voltage Displayed at Device Interrogation					(0)	+	(114)	=	114	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.1/-0.1	95.8 +0.2/-0.2	89.7 +0.6/-0.6	86.7 +1.5/-1.7 at 73 mo					
	See page 159 – Performance note on anomalies in MOSFET Integrated Circuit Technology					(advisory-related subset)																	
Kappa 400 DR	KDR401, KDR403	Jan-98	47,000	5,300	7,358	10	+	14	=	24	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 106 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.8 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.1/-0.1	97.2 +0.2/-0.2	88.0 +0.4/-0.4	57.4 +0.7/-0.7	1.0 +0.4/-0.3 at 106 mo			
Kappa 400 SR	KSR401, KSR403	Feb-98	15,000	1,900	1,368	1	+	4	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 9 yr			
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.1 +0.2/-0.2	98.6 +0.2/-0.3	96.9 +0.4/-0.4	90.8 +0.7/-0.8	64.6 +1.5/-1.5	17.4 +2.2/-2.1 at 9 yr			

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US): Therapy Function Compromised	Malfunctions (US): Therapy Function Not Compromised	Malfunctions (US): Total		Device Survival Probability (%): Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	25,000	2,000	3,759	58	+ 5	= 63	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2 at 107 mo			
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(34)	+ (0)	= (34) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.1	98.8 +0.2/-0.2	96.9 +0.3/-0.3	87.8 +0.6/-0.6	57.6 +1.1/-1.1	5.2 +1.0/-0.9 at 107 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 600 DR	KDR651, KDR653	Mar-01	16,000	1,500	2,633	53	+ 3	= 56	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.2	99.5 +0.2/-0.2	99.4 +0.2/-0.3 at 103 mo			
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(30)	+ (0)	= (30) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.4 +0.1/-0.2	98.2 +0.3/-0.3	94.9 +0.5/-0.5	81.3 +0.9/-1.0	43.8 +1.4/-1.4	6.3 +1.3/-1.1 at 103 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 700 D	KD701, KD703, KD706	Jan-99	300	70	17	0	+ 0	= 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0				
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.0 +0.8/-3.2	97.8 +1.4/-3.5	95.4 +2.3/-4.4	94.2 +2.7/-4.8	86.4 +4.7/-6.9				
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 700 DR	KDR701, KDR703, KDR706	Jan-99	206,000	34,000	30,156	699	+ 37	= 736	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.6 +0.0/-0.0	99.4 +0.1/-0.1 at 106 mo			
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(414)	+ (0)	= (414) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	99.2 +0.0/-0.0	98.2 +0.1/-0.1	95.5 +0.1/-0.1	85.5 +0.2/-0.2	56.2 +0.4/0.4	0.2 +0.1/-0.1 at 106 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 700 DR	KDR721	Feb-99	9,800	800	1,330	4	+ 1	= 5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 85 mo				
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(4)	+ (0)	= (4) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.2	98.7 +0.2/-0.3	96.7 +0.4/-0.5	91.0 +0.7/-0.8	69.0 +1.4/-1.5	21.1 +2.0/-1.9	14.9 +2.0/-1.9 at 85 mo				
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 700 SR	KSR701, KSR703, KSR706	Jan-99	55,000	7,700	4,500	25	3	28	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1 at 107 mo			
	Advisories: See also page 149 – 2009 Potential Separation of Interconnect Wires					(20) (advisory-related subset)	+ (0)	= (20)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.1/-0.1	98.7 +0.1/-0.1	97.2 +0.2/-0.2	93.7 +0.3/-0.3	83.6 +0.5/-0.6	56.6 +0.9/-0.9	11.4 +1.2/-1.1 at 107 mo			
Kappa 700 VDD	KVDD701	Jan-99	1,700	200	171	4	0	4	Excluding Normal Battery Depletion	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.8 +0.1/-0.4	99.8 +0.1/-0.4	99.6 +0.2/-0.6	99.6 +0.2/-0.6	99.6 +0.2/-0.6	99.6 +0.2/-0.6 at 97 mo			
	Advisories: See page 155 – 2002 Potential Fractured Power Supply Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(4) (advisory-related subset)	+ (0)	= (4)	Including Normal Battery Depletion	99.8 +0.1/-0.5	99.8 +0.1/-0.5	99.3 +0.3/-0.6	98.7 +0.5/-0.8	98.5 +0.5/-0.9	94.2 +1.3/-1.7	72.8 +3.1/-3.5	42.1 +4.7/-4.7	41.3 +4.7/-4.8 at 97 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 800 DR	KDR801, KDR803	Jan-02	4,300	1,100	474	3	0	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.9 +0.1/-0.4 at 98 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI								Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.5 +0.2/-0.3	98.5 +0.4/-0.5	96.2 +0.7/-0.8	84.7 +1.4/-1.6	53.2 +2.7/-2.7	42.8 +3.4/-3.4 at 98 mo			
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,000	45,000	10,541	53	19	72	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 101 mo			
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.0/-0.0	98.6 +0.1/-0.1	96.5 +0.1/-0.1	87.7 +0.3/-0.3	57.2 +0.6/-0.6	18.2 +1.2/-1.1 at 101 mo			
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	9,500	1,844	8	9	17	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 99 mo			
	Advisories: See page 149 – 2009 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	98.9 +0.1/-0.1	97.5 +0.2/-0.2	94.5 +0.4/-0.4	83.9 +0.7/-0.8	49.4 +1.6/-1.6	25.2 +3.1/-3.0 at 99 mo			
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 900 VDD	KVDD901	Jan-02	600	90	79	0	2	2	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.6 +0.3/-1.9	99.6 +0.3/-1.9 at 83 mo					
	Advisories: See page 149 – 2009 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.0 +0.6/-1.6	97.9 +1.1/-2.1	90.7 +2.7/-3.8	54.7 +6.5/-7.0 at 83 mo					

Device Survival Summary continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 900 DR	KDR921	Jan-02	16,000	2,200	2,493	3	+ 1	= 4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 81 mo					
	Advisories: See page 149 – 2009 Potential Separation of Interconnect Wires					(3)	+ (0)	= 3 (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.2 +0.1/-0.2	97.2 +0.3/-0.3	90.3 +0.6/-0.6	59.5 +1.2/-1.2	12.1 +1.5/-1.4 at 81 mo					
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Legend II	8424, 8426, 8427	Nov-91	59,000	5,900	2,567	11	+ 24	= 35	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 212 mo
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.9 +0.1/-0.1	98.2 +0.1/-0.1	97.3 +0.2/-0.2	94.8 +0.3/-0.3	88.7 +0.4/-0.5	82.2 +0.6/-0.6	71.0 +0.9/-0.9	46.4 +1.8/-1.9 at 212 mo
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Nov-88	59,000	7,600	1,741	35	+ 15	= 50	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 242 mo
	Advisories: See page 156 – 1991 Potential Delayed Restoration of Permanent Settings					—	—	—	Including Normal Battery Depletion	99.8 +0.0/-0.0	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.8 +0.1/-0.1	97.8 +0.2/-0.2	95.4 +0.3/-0.3	92.3 +0.4/-0.4	87.5 +0.5/-0.5	84.0 +0.6/-0.6	80.9 +0.7/-0.7	66.9 +2.3/-2.4 at 242 mo
Minuet	7107, 7108	Mar-92	17,000	2,000	950	0	+ 3	= 3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 207 mo
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.2/-0.2	98.2 +0.2/-0.3	97.1 +0.3/-0.4	94.8 +0.5/-0.5	89.2 +0.7/-0.8	82.0 +1.0/-1.1	68.1 +1.5/-1.5	40.8 +2.7/-2.7 at 207 mo
Preva DR	7088, 7089	Jul-96	26,000	2,600	2,807	4	+ 0	= 4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 145 mo	
									Including Normal Battery Depletion	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.3 +0.1/-0.1	98.7 +0.2/-0.2	97.7 +0.2/-0.3	96.2 +0.3/-0.3	92.4 +0.5/-0.5	66.5 +1.0/-1.1	12.8 +1.3/-1.2	8.0 +1.5/-1.3 at 145 mo	
Preva SR	8088, 8089	Jul-96	18,000	1,700	1,057	1	+ 0	= 1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 153 mo	
									Including Normal Battery Depletion	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.2	99.0 +0.2/-0.2	98.3 +0.2/-0.3	97.2 +0.3/-0.4	95.0 +0.5/-0.5	92.1 +0.7/-0.7	75.2 +1.3/-1.4	43.4 +2.0/-2.0	25.9 +2.9/-2.8 at 153 mo	
Prevail S	8085, 8086	Oct-95	4,200	500	55	1	+ 0	= 1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.9 +0.1/-0.3 at 169 mo
									Including Normal Battery Depletion	99.7 +0.1/-0.2	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.1 +0.3/-0.5	98.9 +0.4/-0.6	97.9 +0.7/-1.0	96.8 +0.9/-1.2	92.8 +1.6/-2.0	89.3 +2.1/-2.5	85.2 +2.8/-3.4	85.2 +2.8/-3.4 at 169 mo

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised + Therapy Function Not Compromised = Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Prodigy DR	7860, 7861, 7862	Oct-95	37,000	3,400	3,831	6 + 5 = 11	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 143 mo		
							Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.3 +0.1/-0.1	98.7 +0.1/-0.1	97.9 +0.2/-0.2	96.3 +0.3/-0.3	92.4 +0.4/-0.4	68.4 +0.9/-0.9	12.1 +1.2/-1.2 at 143 mo		
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,000	2,500	1,292	2 + 2 = 4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 152 mo	
							Including Normal Battery Depletion	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.7 +0.2/-0.2	97.8 +0.2/-0.3	96.5 +0.3/-0.4	94.8 +0.4/-0.5	91.6 +0.6/-0.6	74.3 +1.2/-1.3	44.8 +1.8/-1.8	30.7 +2.7/-2.6 at 152 mo	
Sensia DR	SEDR01, SED01	Jul-06	95,000	75,000	52	4 + 6 = 10	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 58 mo							
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI						Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.0 +0.4/-0.6 at 58 mo							
Sensia SR	SESR01, SES01	Jul-06	63,000	45,000	41	1 + 3 = 4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 57 mo							
							Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.5 +0.1/-0.2	98.2 +0.8/-1.5 at 57 mo							
Sigma 100 S	SS103, SS106	Aug-99	800	100	17	0 + 0 = 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 98 mo			
	Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires					(0) + (0) = (0) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.5 +0.4/-1.3	99.5 +0.4/-1.3	98.7 +0.8/-2.3	98.7 +0.8/-2.3	96.5 +1.8/-3.6	93.6 +2.8/-4.9	93.6 +2.8/-4.9 at 98 mo			
Sigma 200 DR	SDR203	Aug-99	16,000	4,300	475	30 + 1 = 31	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.2/-0.2	99.5 +0.2/-0.2 at 11 yr		
	Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(19) + (0) = (19) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.2	99.0 +0.2/-0.2	97.6 +0.3/-0.4	94.1 +0.6/-0.6	80.8 +1.3/-1.4	55.6 +4.2/-4.5 at 11 yr		
Sigma 200 SR	SSR203	Sep-99	12,000	2,300	225	11 + 0 = 11	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.8 +0.1/-0.2	99.7 +0.1/-0.3	99.7 +0.1/-0.3 at 133 mo		
	Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(11) + (0) = (11) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.2 +0.2/-0.3	98.6 +0.3/-0.4	97.1 +0.5/-0.6	95.2 +0.7/-0.8	84.0 +1.6/-1.8	63.1 +4.7/-5.1 at 133 mo		
Sigma 300 DR	SDR303, SDR306	Aug-99	107,000	37,000	1,982	192 + 8 = 200	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 11 yr		
	Advisories: See page 153 – 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(137) + (0) = (137) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.4 +0.1/-0.1	98.9 +0.1/-0.1	97.9 +0.1/-0.1	95.1 +0.2/-0.2	81.6 +0.6/-0.7	51.6 +3.2/-3.3 at 11 yr		

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Sigma 300 SR	SSR303, SSR306	Aug-99	54,000	13,000	713	42	+ 3	= 45	Excluding Normal Battery Depletio	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 131 mo		
	Advisories: See page 153– 2005 Potential Separation of Interconnect Wires; See also page 149 – 2009 Potential Separation of Interconnect Wires					(34)	+ (0)	= (34) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.5 +0.2/-0.2	97.2 +0.2/-0.3	94.8 +0.4/-0.4	81.9 +1.1/-1.2	62.3 +3.0/-3.1 at 131 mo		
Sigma 300 VDD	SVDD303	Sep-99	600	100	41	1	+ 0	= 1	Excluding Normal Battery Depletio	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.5 +0.4/-2.6	99.5 +0.4/-2.6 at 105 mo			
	Advisories: See page 153– 2005 Potential Separation of Interconnect Wires					(1)	+ 0	= (1) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.4 +0.4/-1.6	98.1 +1.0/-2.2	94.1 +2.2/-3.6	89.4 +3.3/-4.7	77.0 +5.7/-7.1 at 105 mo			
Thera-i DR	7960i, 7961i, 7962i	Oct-95	121,000	11,000	13,712	26	+ 23	= 49	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 147 mo	
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	99.4 +0.0/-0.1	99.0 +0.1/-0.1	98.1 +0.1/-0.1	96.7 +0.1/-0.1	93.2 +0.2/-0.2	71.3 +0.4/-0.4	19.2 +0.6/-0.6	3.3 +0.6/-0.6 at 147 mo	
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	4,700	2,817	6	+ 2	= 8	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 162 mo	
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.3 +0.1/-0.1	98.9 +0.1/-0.1	98.2 +0.2/-0.2	96.9 +0.2/-0.2	94.5 +0.3/-0.3	80.1 +0.7/-0.7	51.5 +1.1/-1.1	24.4 +2.4/-2.4 at 162 mo	
Thera-i VDD	8968i	Mar-95	4,900	600	322	0	+ 0	= 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 157 mo	
									Including Normal Battery Depletion	99.9 +0.1/-0.1	99.8 +0.1/-0.2	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.3 +0.2/-0.3	99.2 +0.3/-0.4	99.1 +0.3/-0.4	98.0 +0.5/-0.7	89.1 +1.4/-1.6	59.0 +2.9/-3.0	38.8 +4.1/-4.2 at 157 mo	
Versa DR	VEDR01	Jul-06	77,000	61,000	46	2	+ 4	= 6	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 58 mo							
	See page 157 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI								Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.2 +0.2/-0.3 at 58 mo							
Revo MRI SureScan	RVDR01	Feb-11	8,600	8,500	0	0	+ 0	= 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0										
									Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0										

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. The longevity estimates shown here assume a lower rate of 60 ppm, 100% pacing, and pulse width of 0.4 ms unless noted otherwise. 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. **The elective replacement time is indicated via telemetry indication, and rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet), unless noted otherwise.**

		Estimated Longevity			
Family	Model Number	Amplitude Setting	500 Lead Ω	1000 Lead Ω	Elective Replacement Indicators
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.4 6.0	**
Adapta DR	ADDRS1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.3 3.2	6.1 5.4 4.4	**
Adapta DR	ADDRL1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.0 7.3 5.4	10.0 8.9 7.2	**
Adapta SR	ADSR01, ADSR03, ADSR06	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 5.1	7.9 7.5 6.3	**
Adapta VDD	ADVDD01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.5 4.4	6.5 6.2 5.4	**
AT500	AT501, 7253	Low 2.0 V (A, RV) Nominal 3.0 V (A, RV) High 5.0 V (A, RV)	7.7 5.8 3.7	8.3 7.0 5.2	Telemetry indication. Pacing mode and rate (magnet and non-magnet) as programmed.
EnPulse DR	E1DR01, E1DR03, E1DR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.2 4.4	8.5 7.6 5.9	**
EnPulse DR	E1DR21	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.4 4.3 3.0	6.0 5.4 4.2	**
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.2 4.4	8.5 7.6 5.9	**
EnPulse 2 DR	E2DR21	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.4 4.3 3.0	6.0 5.4 4.2	**
EnPulse 2 DR	E2DR31, E2DR33	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.0 7.4 5.2	10.1 9.1 7.1	**
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.2 6.3 4.8	7.7 7.3 6.1	**
EnPulse 2 VDD	E2VDD01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.1 5.5 4.3	6.5 6.2 5.4	**
EnRhythm DR	P1501DR	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.7 7.3 4.9	11.2 9.4 7.1	**
Kappa 400 DR	KDR401, KDR403	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.8 6.4 5.1	8.5 7.5 6.5	**
Kappa 400 SR	KSR401, KSR403	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.9 6.9 5.8	8.4 7.7 7.0	**
Kappa 600 DR	KDR601, KDR603, KDR606	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 600 DR	KDR651, KDR653	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
Kappa 700 D	KD701, KD703, KD706	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 700 DR	KDR701, KDR703, KDR706	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 700 DR	KDR721	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.4 3.0	6.1 5.5 4.2	**
Kappa 700 SR	KSR701, KSR703, KSR706	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 4.9	7.9 7.5 6.2	**
Kappa 700 VDD	KVDD701	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.6 4.4	6.6 6.3 5.3	**
Kappa 800 DR	KDR801, KDR803	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 900 DR	KDR901, KDR903, KDR906	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 900 DR	KDR921	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.4 3.0	6.1 5.5 4.3	**
Kappa 900 SR	KSR901, KSR903, KSR906	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.3 6.4 4.9	7.9 7.4 6.1	**
Kappa 900 VDD	KVDD901	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.6 4.4	6.6 6.3 5.4	**
Legend II	8424, 8426, 8427	Low 2.5 V, 0.36 ms (RV) Nominal 3.3 V, 0.36 ms (RV) High 5.0 V, 0.36 ms (RV)	12.9 9.4 7.8	14.5 11.8 10.5	If programmed to non-rate responsive mode (e.g., VVI), rate decrease of 10% from programmed rate. Telemetry indication. If programmed to rate responsive mode (e.g., VVIR), rate change to 65 ppm and mode change to VVI. Telemetry indication.
Minix	8340, 8341, 8341M, 8342	Low 2.5 V (RV) Nominal 3.3 V (RV) High 5.0 V (RV)	14.9 10.2 7.9	17.3 13.6 11.3	Telemetry indication. Rate decrease of 10% from programmed rate.
Minix ST	8330, 8331, 8331M	Low 2.5 V (RV) Nominal 5.0 V (RV) High 8.0 V (RV)	14.9 7.9 4.0	17.3 11.4 7.0	Telemetry indication. Rate decrease of 10% from programmed rate.
Minuet	7107, 7108	Low 2.5 V, 0.36 ms (RV) Nominal 3.3 V, 0.36 ms (RV) High 5.0 V, 0.36 ms (RV)	12.5 7.7 4.7	15.6 10.9 7.6	**
Preva DR	7088, 7089	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Preva SR	8088, 8089	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Prevail S	8085, 8086	Low 2.5 V, 0.42 ms (RV) Nominal 3.3 V, 0.42 ms (RV) High 5.0 V, 0.42 ms (RV)	16.4 10.8 8.6	19.4 14.4 12.4	Telemetry indication. Rate decrease of 10% from programmed rate.

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
Prodigy DR	7860, 7861, 7862	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Prodigy SR	8158, 8160, 8161, 8162	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Sensia DR	SEDR01, SED01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.4 6.0	**
Sensia SR	SESR01, SES01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 5.1	7.9 7.5 6.3	**
Sigma 100 S	SS103, SS106	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 200 DR	SDR203	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.1 7.5 5.5	11.7 9.6 7.8	**
Sigma 200 SR	SSR203	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 300 DR	SDR303, SDR306	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.1 7.5 5.5	11.7 9.6 7.8	**
Sigma 300 SR	SSR303, SSR306	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 300 VDD	SVDD303	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	8.9 7.3 5.8	9.7 8.6 7.4	**
Thera-i DR	7960i, 7961i, 7962i	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Thera-i SR	8960i, 8961i, 8962i	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Thera-i VDD	8968i	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	11.5 9.6 7.7	12.4 11.1 9.7	**
Versa DR	VEDR01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.4 6.0	**
Revo MRI SureScan	RVDR01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.7 7.3 4.9	11.2 9.4 7.1	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Method for Estimating Lead Performance

Medtronic CRDM has tracked lead survival for over 28 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, 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.

Returned Product Analysis Shortfalls

All 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. 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. Thus, lead survival probabilities are more appropriately determined through a clinical surveillance study. Although returned product analysis results are presented in this report, Medtronic tracks lead survival through its System Longevity Study.

System Longevity Study (SLS)

The SLS is a prospective, non-randomized multicenter, global study designed to monitor the performance of market-released cardiac therapy products. Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study for 28 years and has evaluated the performance of more than 75,000 leads, with data reported from 14 countries on four continents.

The primary purpose of the SLS is to evaluate and publish the long-term reliability and performance of Medtronic market-released cardiac therapy products by analyzing product survival probabilities. Product-related adverse events, indicating the status of the product, are collected to measure survival probabilities. The data gathered in this study may also be used to support the design and development of investigational plans for new cardiac therapy products. The SLS is designed to continue indefinitely, encompassing new products as they become commercially available.

Eligible products for study enrollment include all Medtronic market-released cardiac therapy products. Medtronic may limit overall enrollment of any product when the number of enrollments provides an adequate number to effectively assess product survivability. Medtronic reserves the right to close enrollment of a product at a site level in order to ensure all participating sites have an equal opportunity to enroll.

To ensure a sufficiently large and representative source of data, participating clinical centers must meet specific selection criteria. In addition, centers are selected to be representative of the range of clinical environments in which Medtronic conducts business.

Investigators enroll qualified subjects with specific Medtronic market-released cardiac therapy products and follow these subjects from their implant date until they can no longer be followed (e.g., death and lost to follow-up). Using a Clinical Investigation Plan, each center monitors and reports on the performance of specific Medtronic market-released cardiac therapy products (e.g., product-related adverse events, replacements and abandonments) and subject status (e.g., subject death and subject withdrawal from the study). Subjects will be followed by their respective center in accordance with the center's established practices for routine follow-up.

Patients are eligible for enrollment in the study if:

1. They are within 6 months post-implant of a Medtronic market-released lead connected to a market-released CRT, ICD, or IPG device, and the lead is used for a pacing, sensing, or defibrillation application, or

2. They participated in a qualifying study of a market-released Medtronic cardiac therapy product; complete implant and follow-up data are available; and the data is appropriately and legally released for use in the study.

continued

Method for Estimating Lead Performance continued

The Standard Actuarial Method is used to determine estimates of lead survival.

The SLS protocol requires regular follow-up reporting on all leads actively followed in the study. The follow-up schedule for this study is based on utilizing routine, scheduled office/clinic visits and unscheduled office/clinic visits prompted by symptoms or complaints. Data collected at each follow-up includes routine clinical electrical data, any system modifications, and any lead or generator adverse events.

Each study center must inform Medtronic whenever a lead complication has occurred or when a patient is no longer participating in the study. Under the study protocol, each lead is assumed to be normally active unless a lead-related complication is confirmed, the lead is abandoned or explanted, the patient is no longer available for follow-up, or more than 24 months have passed since last follow-up. The data analyses assume that the patient is still part of the study and no lead complications had occurred as of the report cutoff date unless specifically reported by the center.

Medtronic evaluates center compliance with study protocol through clinical monitoring at each study site. Additionally, study center personnel must be trained in the study procedures prior to participating, and they must adhere to the policies and procedures of their local ethics boards.

Lead Complications

All adverse events are critically evaluated by a Medtronic technical review committee and the investigator is asked to assess the relationship of the adverse event to the presence or performance of the implanted system, generator and/or lead(s).

The SLS complication criteria 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, exit block, or concurrent pulse generator failure manifested as a sensing or capture problem.

A lead-related complication is considered to have occurred if at least one of the following clinical observations is reported and at least one of the following clinical actions is made 30 days or more after the implant.

Clinical Observations

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200-3,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20-200 ohms)
- Insulation breach, observed visually, that has degraded system performance
- Conductor fracture, observed visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

Clinical Actions

- Lead surgically abandoned/capped
- Lead electrically abandoned/capped
- Lead explanted
- Lead replaced
- Polarity reprogrammed (i.e., bipolar to unipolar; unipolar to bipolar)
- Lead use continued based on medical judgment despite a known clinical performance issue
- Other lead-related surgery performed (e.g., lead mechanical alteration or unsuccessful repositioning)

Note: Successful lead repositioning is not a qualifying action.

continued

Method for Estimating Lead Performance continued

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 lead-related complication.

The survival estimates are determined from the analysis of the data collected through the SLS. These data are presented graphically and numerically.

Survival times are calculated from the implant date to the earlier of the complication date, out-of-service date (for example, subject leaves the study, the lead is no longer being used, or no data has been reported within a specified time interval), or the cutoff date of the report. If a lead experiences more than one complication, the first is used to calculate survival time; although all complications associated with a lead are in the tables in this report.

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions assumed distributed across the intervals (Cutler-Ederer Method), is used to determine estimates of lead survival. This method is commonly used by medical researchers and clinicians.

On the following pages, each graph includes a survival curve where events include qualifying lead-related complications. This survival estimate is a good representation of the probability a lead will survive a period of time without a lead-related complication. 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.

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 curve.

Although the report provides tabular data in 1-year intervals, the curves are actually computed and plotted using 3-month intervals.

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 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 corresponding 95% confidence intervals for the standard errors, and the complementary log-log method is used to produce the confidence bounds.

continued

Method for Estimating Lead Performance continued

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.

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 patients successfully enrolled in the SLS as of the report cutoff date. The number of enrolled implants is listed for each model.

This sample based on SLS enrollments is considered to be representative of the worldwide population, including data from 14 countries on four continents, and therefore the survival estimates shown in this report should be representative of the performance worldwide of these models.

In general, a model or model family will be included in this report when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Models will remain in the report for at least 20 years as long as Medtronic estimates at least 500 leads remain active in the United States, based on estimated US implants.

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. These models may be removed from this report at that time.

Returned Product Analysis Results

Every lead or lead portion returned to Medtronic receives an analysis. 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 CRDM 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 CRDM 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 from the United States. The numbers of complications listed in the complications tables are the actual numbers observed in the SLS centers around the world.

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,

continued

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 System Longevity Study 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 this report. 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." To be included in this summary of observations, a lead must first be successfully implanted and registered in Medtronic's Device and Registrant Tracking system.

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 report 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 SLS, this report also provides 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.

Some lead models do not have a survival curve presented in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Returned Product Analysis results for these models are included here for reference and comparison.

Left-Heart Leads continued

2187 Attain LV

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEY
Registered US Implants	11,900	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Estimated Active US Implants	3,100	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

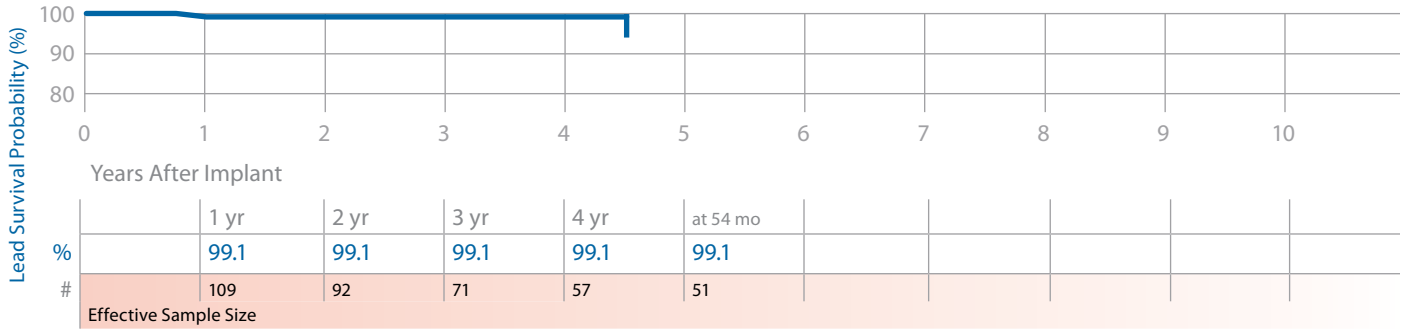
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	134
Cumulative Months of Follow-Up	6,409
Number of Leads Active in Study	22

Qualifying Complications 1 Total

Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	99.1	99.1	99.1	99.1	99.1
#	109	92	71	57	51

Effective Sample Size

2188 Attain CS

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEB
Registered US Implants	1,800	Type and/or Fixation	Transvenous, Coronary Sinus/ Cardiac Vein, Canted
Estimated Active US Implants	300	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

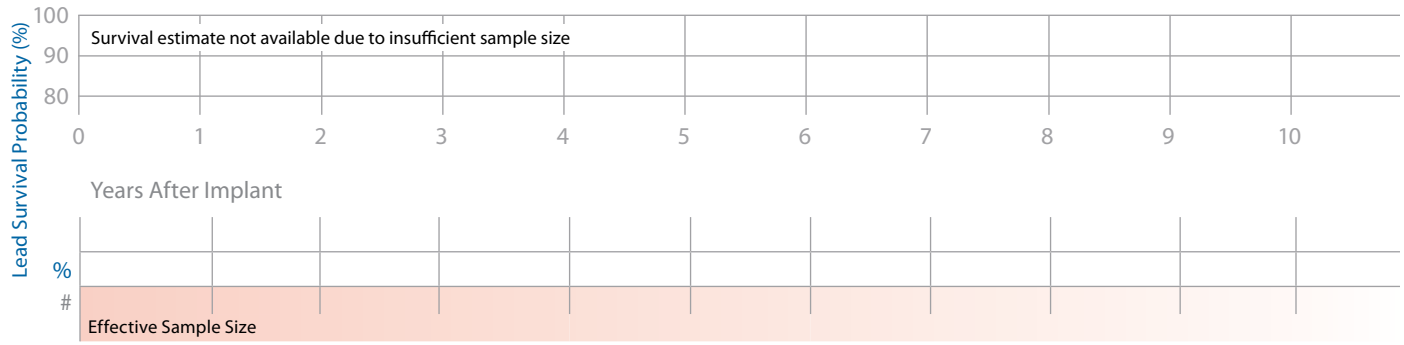
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	15
Cumulative Months of Follow-Up	487
Number of Leads Active in Study	0

Qualifying Complications 1 Total

Extra Cardiac Stimulation	1



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Left-Heart Leads continued

4193 Attain OTW

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Registered US Implants	100,600	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	40,200	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

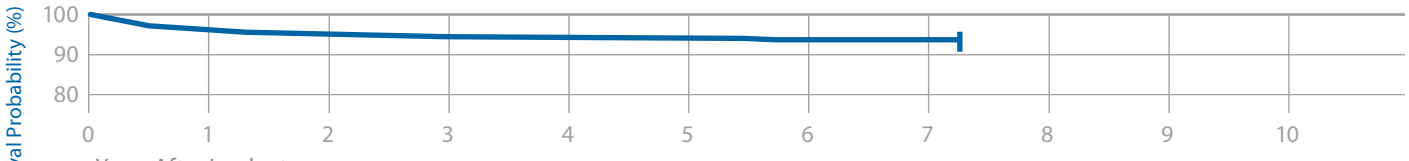
Conductor Fracture	41
Crimp/Weld/Bond	0
Insulation Breach	4
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	675
Cumulative Months of Follow-Up	28,734
Number of Leads Active in Study	166

Qualifying Complications 37 Total

Lead Dislodgement	14
Failure to Capture	12
Conductor Fracture	1
Unspecified Clinical Failure	3
Extra Cardiac Stimulation	7



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 87 mo
%	95.9	95.0	94.3	94.3	94.3	93.2	93.2	93.2
#	545	438	358	273	189	116	57	49

Effective Sample Size

4194 Attain OTW

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Registered US Implants	99,800	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	64,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

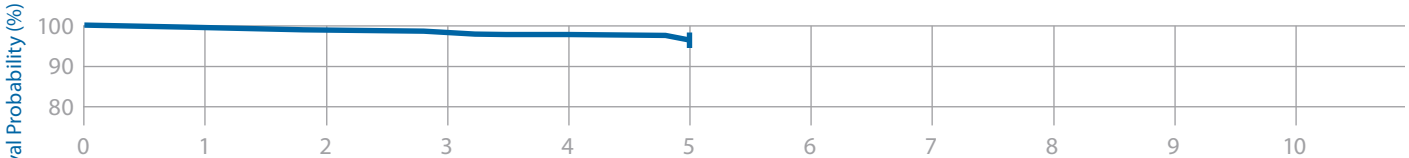
Conductor Fracture	8
Crimp/Weld/Bond	0
Insulation Breach	35
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	1,151
Cumulative Months of Follow-Up	25,774
Number of Leads Active in Study	839

Qualifying Complications 16 Total

Lead Dislodgement	9
Failure to Capture	4
Insulation (ESC)	1
Extra Cardiac Stimulation	2



	1 yr	2 yr	3 yr	4 yr	5 yr
%	99.1	98.2	98.2	97.8	96.4
#	669	408	237	143	50

Effective Sample Size

Left-Heart Leads continued

4195 Attain StarFix

Product Characteristics

US Market Release	Aug-08	Serial Number Prefix	AAD
Registered US Implants	11,500	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Deployable Lobe Fixation
Estimated Active US Implants	9,600	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	1
Other	7

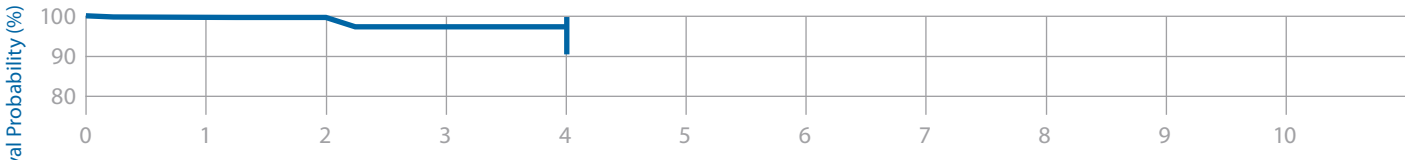
System Longevity Study Results

Number of Leads Enrolled in Study	814
Cumulative Months of Follow-Up	11,995
Number of Leads Active in Study	719

Qualifying Complications

6 Total

Lead Dislodgement	3
Conductor Fracture	1
Extra Cardiac Stimulation	2



	1 yr	2 yr	3 yr	4 yr
%	99.2	99.2	98.1	98.1
#	328	92	66	50

Effective Sample Size

4196 Attain Ability

Product Characteristics

US Market Release	May-09	Serial Number Prefix	PVI
Registered US Implants	33,300	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Preformed Body, Double Curve
Estimated Active US Implants	29,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

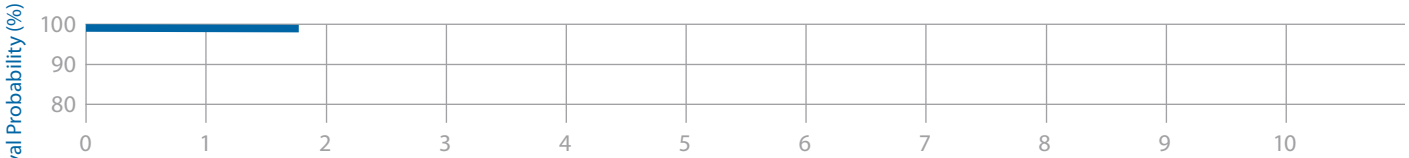
System Longevity Study Results

Number of Leads Enrolled in Study	1,655
Cumulative Months of Follow-Up	14,612
Number of Leads Active in Study	1,456

Qualifying Complications

10 Total

Lead Dislodgement	4
Failure to Capture	3
Extra Cardiac Stimulation	3



	1 yr	at 21 mo
%	99.2	99.2
#	371	38

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Left-Heart Leads continued

4296 Attain Ability Plus

Product Characteristics

US Market Release	Apr-11	Serial Number Prefix	RRA
Registered US Implants	500	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

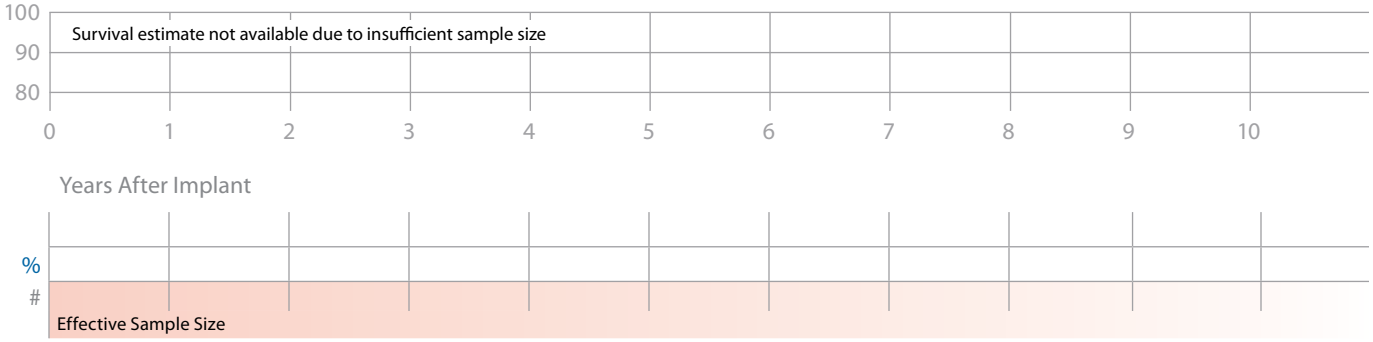
System Longevity Study Results

Number of Leads Enrolled in Study
Cumulative Months of Follow-Up
Number of Leads Active in Study

Qualifying Complications

Total

Lead Dislodgement
Conductor Fracture
Extra Cardiac Stimulation



4396 Attain Ability Straight

Product Characteristics

US Market Release	Mar-11	Serial Number Prefix	RAE
Registered US Implants	300	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Tines
Estimated Active US Implants	300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

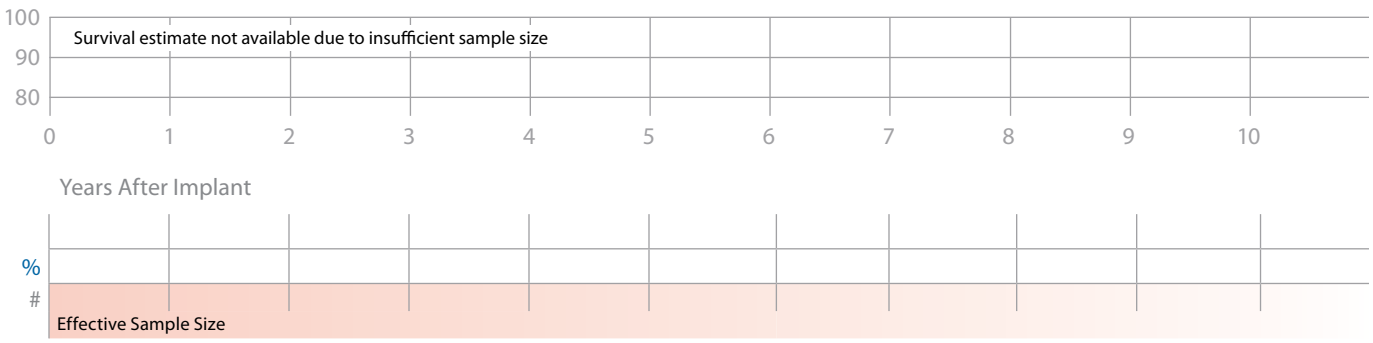
System Longevity Study Results

Number of Leads Enrolled in Study
Cumulative Months of Follow-Up
Number of Leads Active in Study

Qualifying Complications

Total

Lead Dislodgement
Failure to Capture
Extra Cardiac Stimulation



Leads

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Left-Heart Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
2187	Attain LV	Aug-01	134	22	1	6,409	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1 at 54 mo					
2188	Attain CS	Aug-01	15	0	1	487	100.0 at 0 mo									
4193	Attain OTW	May-02	675	166	37	28,734	95.9 +1.3/-1.8	95.0 +1.4/-2.1	94.3 +1.6/-2.3	94.3 +1.6/-2.3	94.3 +1.6/-2.3	93.2 +2.0/-2.9	93.2 +2.0/-2.9	93.2 +2.0/-2.9 at 87 mo		
4194	Attain OTW	Aug-04	1,151	839	16	25,774	99.1 +0.4/-0.8	98.2 +0.8/-1.2	98.2 +0.8/-1.2	97.8 +1.0/-1.7	96.4 +2.1/-4.7					
4195	Attain StarFix	Aug-08	814	719	6	11,995	99.2 +0.5/-1.2	99.2 +0.5/-1.2	98.1 +1.3/-4.2	98.1 +1.3/-4.2						
4196	Attain Ability	May-09	1,655	1,456	10	14,612	99.2 +0.4/-0.7	99.2 +0.4/-0.7 at 21 mo								
4296	Attain Ability Plus	Apr-11	500	500												
4396	Attain Ability Straight	Mar-11	300	300												

Source: System Longevity Study
Data as of July 31, 2011

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
2187	Attain LV	Aug-01	11,900	3,100	0	0	0	1
2188	Attain CS	Aug-01	1,800	300	1	0	0	0
4193	Attain OTW	May-02	100,600	40,200	41	0	4	8
4194	Attain OTW	Aug-04	99,800	64,100	8	0	35	6
4195	Attain StarFix	Aug-08	11,500	9,600	1	0	1	7
4196	Attain Ability	May-09	33,300	29,100	2	0	0	0
4296	Attain Ability Plus	Apr-11	500	500	0	0	0	0
4396	Attain Ability Straight	Mar-11	300	300	0	0	0	0

Source: Returned Product Analysis
Data as of July 31, 2011

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
2187	Attain LV	11,900	0	0	9	4	0	1	0	0	1	0
2188	Attain CS	1,800	0	0	2	0	0	0	0	0	0	0
4193	Attain OTW	100,600	0	0	45	11	1	0	0	0	15	2
4194	Attain OTW	99,800	1	2	85	19	1	0	1	6	18	3
4195	Attain StarFix	11,500	0	0	20	6	0	0	0	0	15	0
4196	Attain Ability	33,300	1	2	70	22	0	0	1	3	31	2
4296	Attain Ability Plus	500	0	0	0	0	0	0	0	0	0	0
4396	Attain Ability Straight	300	0	1	1	0	0	0	0	0	1	0

Report Cutoff Date: July 31, 2011

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Left-Heart Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
2187	Attain LV	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
2188	Attain CS	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 BI
4193	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
4194	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)/ Silicone (4719)	MP35N	Platinum Alloy	IS-1 BI
4195	Attain StarFix	Transvenous Cardiac Vein Deployable Lobes	Polyurethane (55D)	MP35N	Platinum Alloy	IS-1 UNI
4196	Attain Ability	Transvenous Cardiac Vein Preformed Body	Polyurethane (outer) SI-polyimide (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI
4296	Attain Ability Plus	Transvenous Cardiac Vein Distal Double Curve	Polyurethane (outer) Silicone (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI
4396	Attain Ability Straight	Transvenous Cardiac Vein Tines	Polyurethane (outer) Silicone (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads

6721, 6921 Epicardial Patch

Product Characteristics

US Market Release	Feb-93	Serial Number Prefix	TBH, TBG, TBB, TAD, TAC, or TAB
Registered US Implants	8,700	Type and/or Fixation	Epicardial Defib Patch, Suture
Estimated Active US Implants	1,400	Polarity	Defib Electrode only
Advisories	None	Steroid	No

US Returned Product Analysis

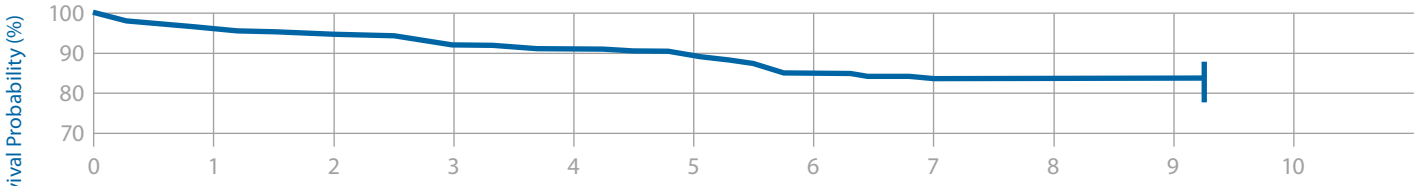
Conductor Fracture	66
Crimp/Weld/Bond	1
Insulation Breach	9
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	407
Cumulative Months of Follow-Up	23,289
Number of Leads Active in Study	7

Qualifying Complications 47 Total

Failure to Capture	8			Impedance Out of Range	4
Conductor Fracture	21			Oversensing	12
Insulation (not further defined)	2				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	96.5	95.0	92.7	91.9	90.0	85.1	83.7	83.7	83.7	83.7
#	330	301	256	209	176	132	95	64	56	51

Effective Sample Size of Lead Group Overall

6930 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFK
Registered US Implants	400	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	200	Polarity	True Bipolar/One Coil
Advisories		Steroid	Yes
See page 151 – 2007 Potential Conductor Wire Fracture			

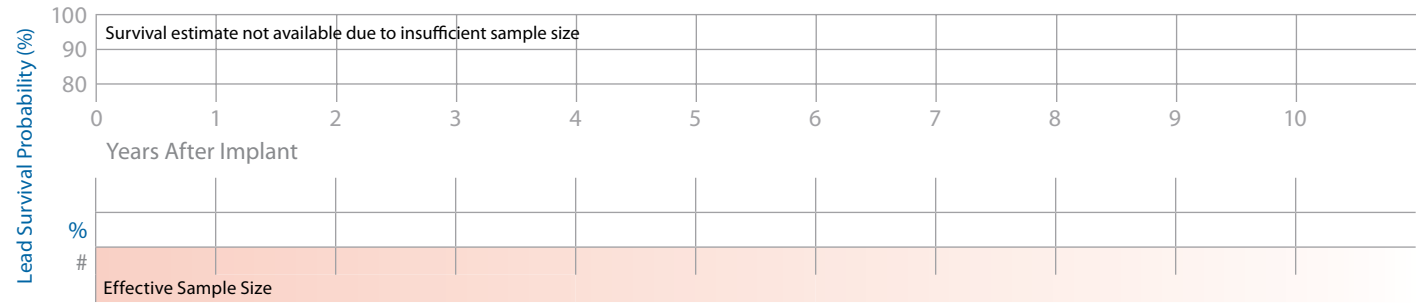
US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	143
Number of Leads Active in Study	2

Qualifying Complications 0 Total



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

6931 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFL
Registered US Implants	8,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	4,400	Polarity	True Bipolar/One Coil
Advisories		Steroid	Yes
See page 151 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

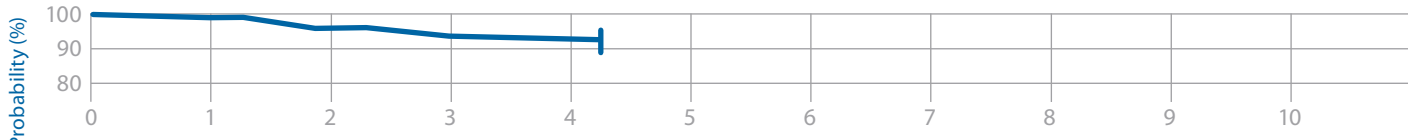
Conductor Fracture	404
Crimp/Weld/Bond	0
Insulation Breach	0
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	10,789
Number of Leads Active in Study	177

Qualifying Complications 18 Total

Lead Dislodgement	2	Impedance Out of Range	4
Failure to Capture	3	Oversensing	3
Conductor Fracture	4	Other	1
Failure to Sense	1		



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	98.2	95.8	93.8	92.5	92.5
#	259	222	160	75	46

Effective Sample Size

6932 Sprint

Product Characteristics

US Market Release	Aug-96	Serial Number Prefix	TCA
Registered US Implants	14,900	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	4,700	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

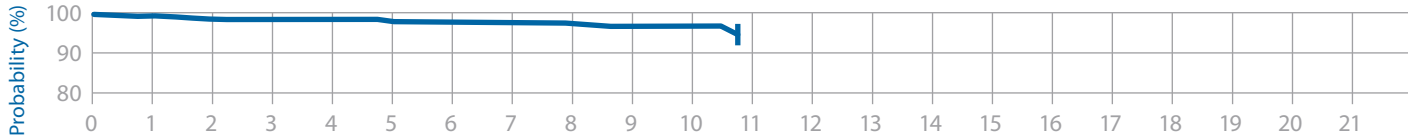
Conductor Fracture	20
Crimp/Weld/Bond	0
Insulation Breach	21
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	411
Cumulative Months of Follow-Up	24,716
Number of Leads Active in Study	53

Qualifying Complications 10 Total

Failure to Capture	2	Extra Cardiac Stimulation	1
Failure to Sense	2	Oversensing	4
Impedance Out of Range	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 mo
%	99.2	98.3	98.3	98.3	97.8	97.8	97.8	96.8	96.8	96.8	95.1
#	355	296	239	198	160	128	108	93	80	66	50

Effective Sample Size

Defibrillation Leads continued

6933, 6937, 6937A, 6963 SVC/CS

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAT, TBU, TDB, TAF
Registered US Implants	16,100	Type and/or Fixation	Transvenous CS or SVC Defib
Estimated Active US Implants	2,500	Polarity	One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	165
Crimp/Weld/Bond	0
Insulation Breach	31
Other	3

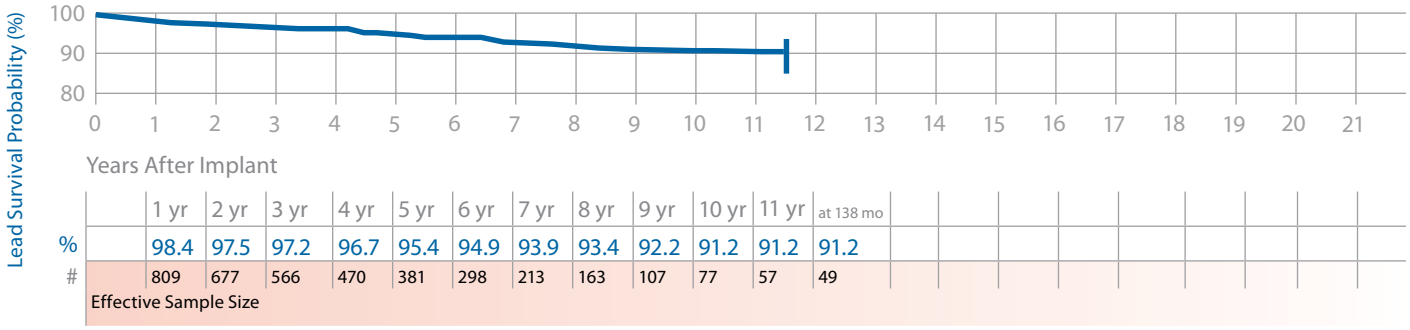
System Longevity Study Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,319
Number of Leads Active in Study	22

Qualifying Complications

47 Total

Lead Dislodgement	1	Impedance Out of Range	3
Failure to Capture	6	Unspecified Clinical Failure	4
Conductor Fracture	16	Extra Cardiac Stimulation	4
Failure to Sense	1	Oversensing	10
Insulation (not further defined)	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 138 mo
%	98.4	97.5	97.2	96.7	95.4	94.9	93.9	93.4	92.2	91.2	91.2	91.2
#	809	677	566	470	381	298	213	163	107	77	57	49

Effective Sample Size

6935 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-08	Serial Number Prefix	TAU
Registered US Implants	21,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	20, 200	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Performance Note: See page 158 –
Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	0
Insulation Breach	0
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	1,040
Cumulative Months of Follow-Up	10,220
Number of Leads Active in Study	955

Qualifying Complications

5 Total

Conductor Fracture	1
Failure to Sense	1
Oversensing	3

	1 yr	at 21 mo
%	99.5	98.5
#	327	77

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

6936, 6966 Transvene

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAV, TAL
Registered US Implants	23,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	2,500	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

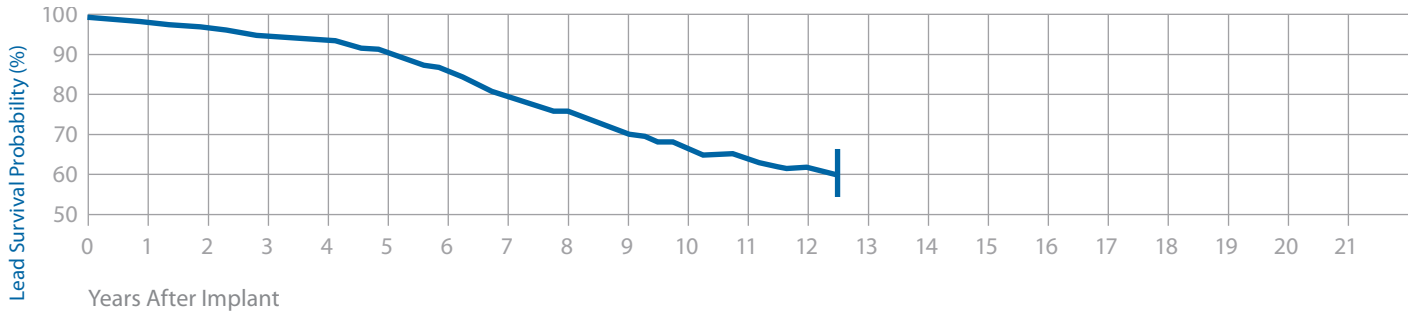
Conductor Fracture	176
Crimp/Weld/Bond	0
Insulation Breach	336
Other	7

System Longevity Study Results

Number of Leads Enrolled in Study	1,349
Cumulative Months of Follow-Up	75,048
Number of Leads Active in Study	21

Qualifying Complications 187 Total

Failure to Capture	15	Impedance Out of Range	7
Conductor Fracture	21	Unspecified Clinical Failure	5
Failure to Sense	7	Extra Cardiac Stimulation	6
Insulation (not further defined)	14	Oversensing	112



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 150 mo
%	98.2	97.0	95.2	94.3	91.1	86.8	79.8	75.9	70.2	65.8	63.6	61.8	59.5
#	1,140	956	807	659	530	414	284	210	142	104	75	56	49

Effective Sample Size

6939, 6999 Sub-Q Patch

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TBA, TAP
Registered US Implants	3,700	Type and/or Fixation	Subcutaneous Defib Patch, Suture
Estimated Active US Implants	300	Polarity	Defib Electrode Only
Advisories	None	Steroid	No

US Returned Product Analysis

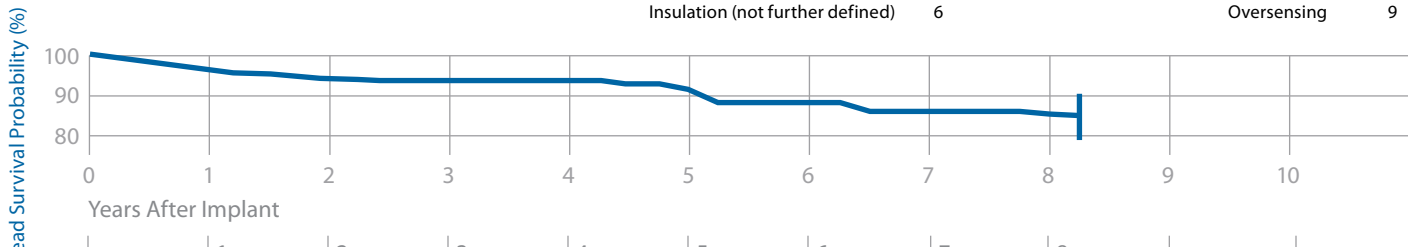
Conductor Fracture	28
Crimp/Weld/Bond	0
Insulation Breach	4
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	384
Cumulative Months of Follow-Up	20,615
Number of Leads Active in Study	1

Qualifying Complications 41 Total

Failure to Capture	8	Impedance Out of Range	1
Conductor Fracture	10	Unspecified Clinical Failure	2
Failure to Sense	1	Extra Cardiac Stimulation	4
Insulation (not further defined)	6	Oversensing	9



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	96.0	94.1	93.7	93.7	91.6	89.2	86.7	85.3	85.3
#	312	273	233	189	155	116	79	54	51

Effective Sample Size of Lead Group Overall

Leads

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

6942 Sprint

Product Characteristics

US Market Release	Jul-97	Serial Number Prefix	TCB
Registered US Implants	17,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	5,900	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

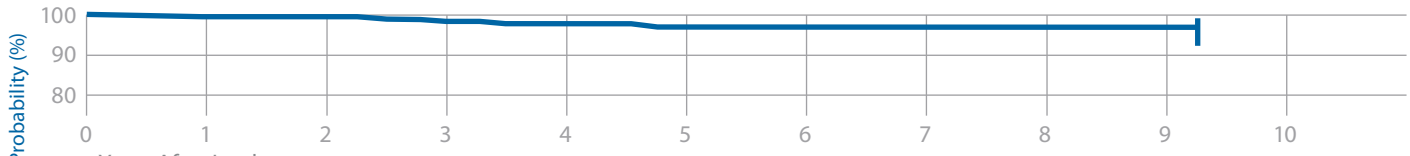
Conductor Fracture	14
Crimp/Weld/Bond	1
Insulation Breach	21
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	18,609
Number of Leads Active in Study	39

Qualifying Complications 7 Total

Lead Dislodgement	1
Conductor Fracture	1
Failure to Sense	1
Unspecified Clinical Failure	1
Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.1	99.1	98.1	97.5	96.7	96.7	96.7	96.7	96.7	96.7
#	294	231	179	140	117	100	78	67	53	48

Effective Sample Size

6943 Sprint

Product Characteristics

US Market Release	Oct-97	Serial Number Prefix	TCE
Registered US Implants	20,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	7,000	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

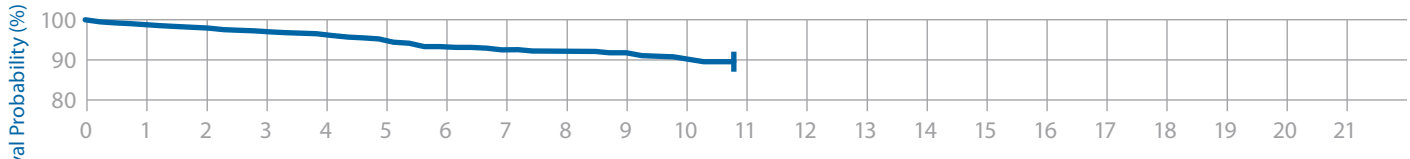
Conductor Fracture	59
Crimp/Weld/Bond	1
Insulation Breach	23
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	1,311
Cumulative Months of Follow-Up	77,836
Number of Leads Active in Study	269

Qualifying Complications 81 Total

Lead Dislodgement	1
Failure to Capture	8
Conductor Fracture	17
Failure to Sense	6
Insulation (not further defined)	1
Impedance Out of Range	8
Unspecified Clinical Failure	3
Oversensing	36
Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	98.6	97.7	96.5	95.6	93.7	92.4	91.5	91.2	89.9	87.9	87.9
#	1,146	981	874	745	615	478	347	248	144	64	46

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Registered US Implants	38,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	21,100	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	65
Crimp/Weld/Bond	1
Insulation Breach	2
Other	1

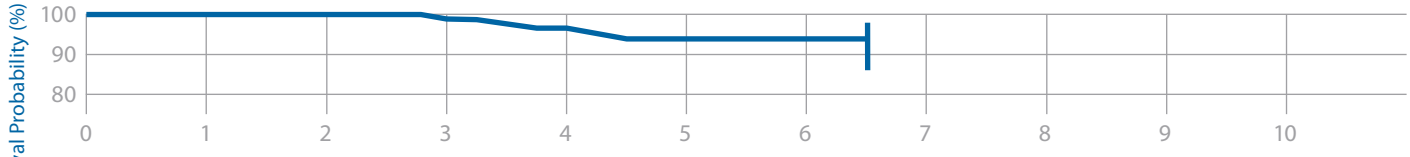
System Longevity Study Results

Number of Leads Enrolled in Study	425
Cumulative Months of Follow-Up	12,245
Number of Leads Active in Study	258

Qualifying Complications

5 Total

Failure to Sense	1
Impedance Out of Range	1
Unspecified Clinical Failure	1
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	100.0	99.1	97.0	94.6	94.6	94.6
#	239	140	102	82	61	56	51

Effective Sample Size

6945 Sprint

Product Characteristics

US Market Release	Sep-97	Serial Number Prefix	TDA
Registered US Implants	42,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	14,100	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	108
Crimp/Weld/Bond	1
Insulation Breach	32
Other	6

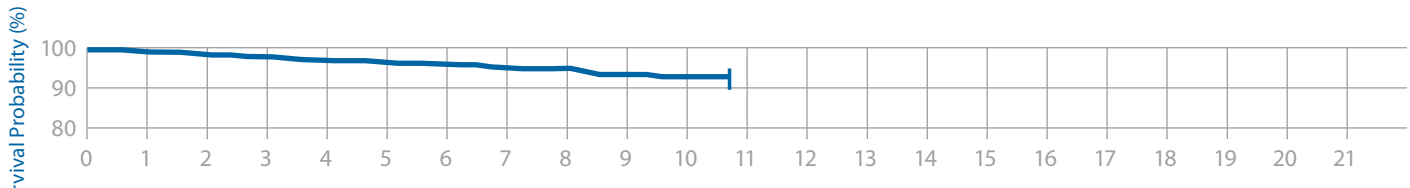
System Longevity Study Results

Number of Leads Enrolled in Study	1,154
Cumulative Months of Follow-Up	65,570
Number of Leads Active in Study	147

Qualifying Complications

37 Total

Failure to Capture	2
Conductor Fracture	7
Failure to Sense	4
Impedance Out of Range	5
Unspecified Clinical Failure	1
Extra Cardiac Stimulation	1
Oversensing	17



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 mo
%	99.4	98.7	98.2	97.6	96.8	96.1	95.6	94.5	93.6	93.0	93.0
#	996	821	683	565	465	381	313	233	166	99	51

Effective Sample Size

Defibrillation Leads continued

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Registered US Implants	321,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	225,900	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Performance Note: See page 158 –
Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

US Returned Product Analysis

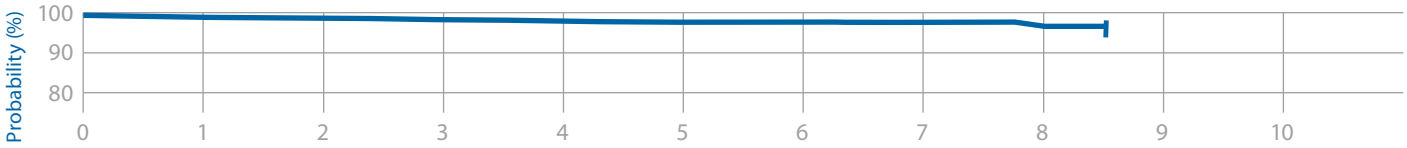
Conductor Fracture	265
Crimp/Weld/Bond	4
Insulation Breach	15
Other	54

System Longevity Study Results

Number of Leads Enrolled in Study	2,703
Cumulative Months of Follow-Up	96,273
Number of Leads Active in Study	1,537

Qualifying Complications 29 Total

Lead Dislodgement	3	Impedance Out of Range	6
Failure to Capture	1	Unspecified Clinical Failure	2
Conductor Fracture	4	Oversensing	9
Failure to Sense	2		
Insulation (not further defined)	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.5	99.3	99.0	98.7	98.2	97.9	97.6	96.8	96.8
#	2,267	1,175	900	732	577	407	223	91	43

Effective Sample Size

6948 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFH
Registered US Implants	10,400	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	5,800	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes

See page 151 – 2007 Potential Conductor Wire Fracture

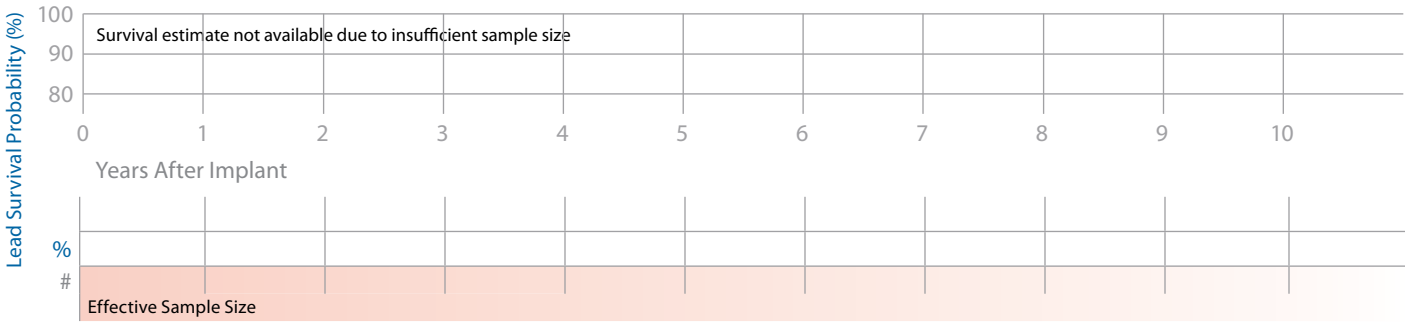
US Returned Product Analysis

Conductor Fracture	102
Crimp/Weld/Bond	0
Insulation Breach	1
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	30
Cumulative Months of Follow-Up	1,253
Number of Leads Active in Study	19

Qualifying Complications 0 Total



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

6949 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFJ
Registered US Implants	186,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	97,400	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes
See page 151 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

Conductor Fracture	4,724
Crimp/Weld/Bond	2
Insulation Breach	11
Other	45

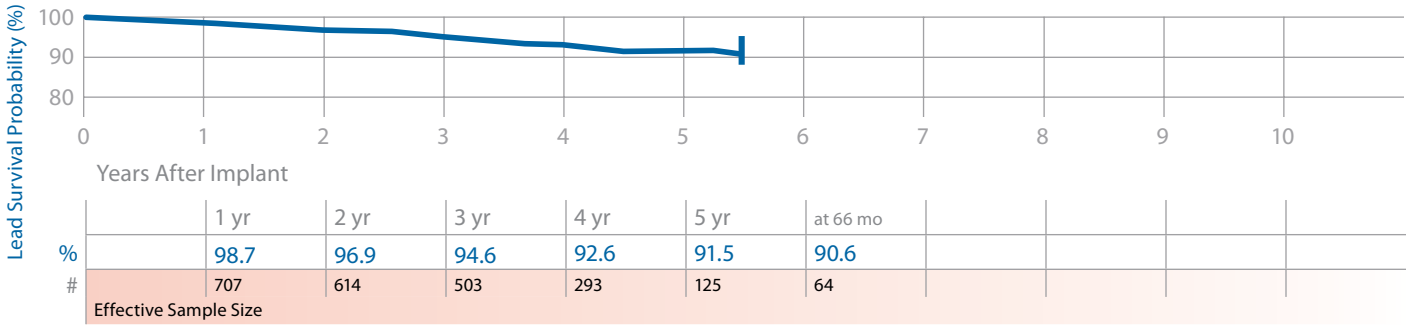
System Longevity Study Results

Number of Leads Enrolled in Study	795
Cumulative Months of Follow-Up	33,013
Number of Leads Active in Study	388

Qualifying Complications

49 Total

Lead Dislodgement	1	Insulation (not further defined)	1
Failure to Capture	2	Impedance Out of Range	9
Conductor Fracture	20	Oversensing	13
Failure to Sense	2	Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	98.7	96.9	94.6	92.6	91.5	90.6
#	707	614	503	293	125	64

Effective Sample Size

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Registered US Implants	3,200	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated Active US Implants	1,900	Polarity	One Defib Coil
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

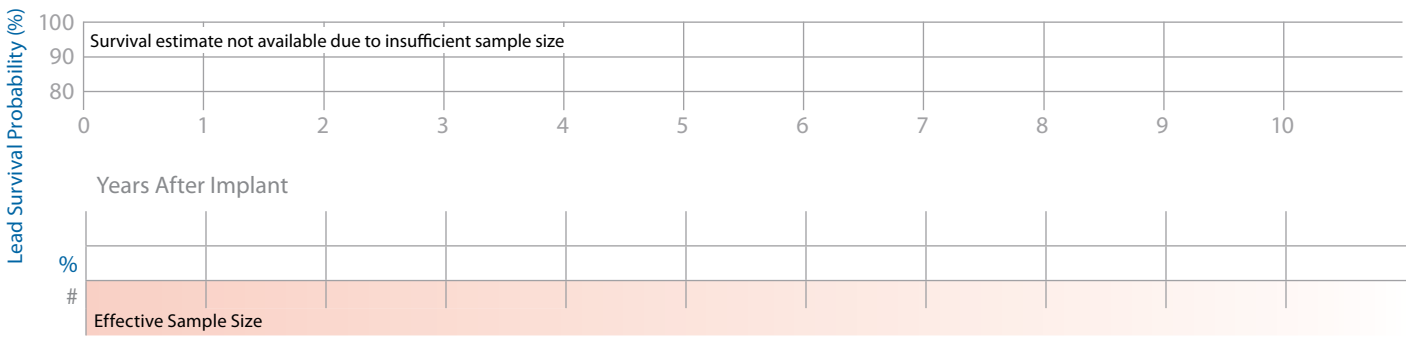
System Longevity Study Results

Number of Leads Enrolled in Study	30
Cumulative Months of Follow-Up	822
Number of Leads Active in Study	17

Qualifying Complications

1 Total

Conductor Fracture	1



%						
#						

Effective Sample Size

Leads

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr
6721, 6921	Epicardial Patch	Feb-93	407	7	47	23,289	96.5 +1.5/-2.4	95.0 +1.8/-2.8	92.7 +2.3/-3.4	91.9 +2.5/-3.5	90.0 +2.9/-4.0	85.1 +3.9/-5.2	83.7 +4.2/-5.6	83.7 +4.2/-5.6	83.7 +4.2/-5.6 at 111 mo				
6930	Sprint Fidelis	Sep-04	4	2	0	143	100.0 at 0 mo												
	Advisories: See page 151 – 2007 Potential Conductor Wire Fracture																		
6931	Sprint Fidelis	Sep-04	294	177	18	10,789	98.2 +1.1/-2.5	95.8 +1.9/-3.2	93.8 +2.4/-3.9	92.5 +2.8/-4.4	92.5 +2.8/-4.4 at 51 mo								
	Advisories: See page 151 – 2007 Potential Conductor Wire Fracture																		
6932	Sprint	Aug-96	411	53	10	24,716	99.2 +0.5/-1.7	98.3 +0.9/-2	98.3 +0.9/-2	98.3 +0.9/-2	97.8 +1.2/-2.6	97.8 +1.2/-2.6	97.8 +1.2/-2.6	96.8 +1.8/-3.8	96.8 +1.8/-3.8	95.1 +2.8/-6.4 at 129 mo			
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	966	22	47	54,319	98.4 +0.7/-1.0	97.5 +0.9/-1.3	97.2 +0.9/-1.4	96.7 +1/-1.6	95.4 +1.4/-2	94.9 +1.5/-2.1	93.9 +1.7/-2.5	93.4 +1.9/-2.7	91.2 +2.8/-4.2	91.2 +2.8/-4.2 at 138 mo			
6935	Sprint Quattro Secure	Nov-08	1,040	955	5	10,220	99.5 +0.3/-1.2	98.5 +1.0/-2.7 at 21 mo											
	See page 158 – Performance note on Helix Retraction 6935 and 6947																		
6936, 6966	Transvene	Dec-93	1,349	21	187	75,048	98.2 +0.6/-1	97.0 +0.8/-1.2	95.2 +1.2/-1.4	94.3 +1.3/-1.6	91.1 +1.8/-2.1	86.8 +2.3/-2.8	79.8 +3.1/-3.6	75.9 +3.5/-4	65.8 +4.9/-5.5	61.8 +5.6/-6.2	59.5 +6.2/-6.8 at 150 mo		
6939, 6999	Sub-Q Patch	Dec-93	384	1	41	20,615	96.0 +1.6/-2.7	94.1 +2/-3.1	93.7 +2.2/-3.2	93.7 +2.2/-3.2	91.6 +2.7/-4	89.2 +3.3/-4.7	86.7 +4/-5.5	85.3 +4.6/-6.4	85.3 +4.6/-6.4 at 99 mo				
6942	Sprint	Jul-97	351	39	7	18,609	99.1 +0.6/-1.9	99.1 +0.6/-1.9	98.1 +1.1/-2.7	97.5 +1.4/-3.1	96.7 +1.8/-3.7	96.7 +1.8/-3.7	96.7 +1.8/-3.7	96.7 +1.8/-3.7	96.7 +1.8/-3.7 at 111 mo				
6943	Sprint	Oct-97	1,311	269	81	77,836	98.6 +0.5/-0.9	97.7 +0.7/-1.1	96.5 +1.0/-1.2	95.6 +1.1/-1.5	93.7 +1.4/-1.8	92.4 +1.6/-2.0	91.5 +1.8/-2.2	91.2 +1.8/-2.3	87.9 +3.2/-4.3	87.9 +3.2/-4.3 at 126 mo			
6944	Sprint Quattro	Dec-00	425	258	5	12,245	100.0	100.0	99.1 +0.8/-5.5	97.0 +2/-5.9	94.6 +3.1/-7.2	94.6 +3.1/-7.2	94.6 +3.1/-7.2 at 78 mo						
6945	Sprint	Sep-97	1,154	147	37	65,570	99.4 +0.4/-0.6	98.7 +0.5/-1	98.2 +0.7/-1.1	97.6 +0.8/-1.3	96.8 +1.1/-1.6	96.1 +1.2/-1.8	95.6 +1.4/-2	94.5 +1.7/-2.5	93.0 +2.2/-3.1	93.0 +2.2/-3.1 at 129 mo			
6947	Sprint Quattro Secure	Nov-01	2,703	1,537	29	96,273	99.5 +0.2/-0.3	99.3 +0.3/-0.4	99.0 +0.4/-0.6	98.7 +0.5/-0.8	98.2 +0.7/-1	97.9 +0.7/-1.2	97.6 +0.9/-1.4	96.8 +1.4/-2.6	96.8 +1.4/-2.6 at 102 mo				
	See page 158 – Performance note on Helix Retraction 6935 and 6947																		
6948	Sprint Fidelis	Sep-04	30	19	0	1,253	100.0 at 0 mo												
	Advisories: See page 151 – 2007 Potential Conductor Wire Fracture																		
6949	Sprint Fidelis	Sep-04	795	388	49	33,013	98.7 +0.6/-1.2	96.9 +1.1/-1.5	94.6 +1.5/-2.1	92.6 +1.9/-2.4	91.5 +2.1/-2.8	90.6 +2.6/-3.6 at 66 mo							
	Advisories: See page 151 – 2007 Potential Conductor Wire Fracture																		
6996	Sub-Q Lead	Jun-01	30	17	1	822	100.0 at 0 mo												

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
6721, 6921	Epicardial Patch	Feb-93	8,700	1,400	66	1	9	0
6930	Sprint Fidelis	Sep-04	400	200	3	0	0	0
6931	Sprint Fidelis	Sep-04	8,100	4,400	404	0	0	3
6932	Sprint	Aug-96	14,900	4,700	20	0	21	3
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	16,100	2,500	165	0	31	3
6935	Sprint Quattro Secure	Nov-08	21,800	20,200	10	0	0	6
6936, 6966	Transvene	Dec-93	23,600	2,500	176	0	336	7
6939, 6999	Sub-Q Patch	Dec-93	3,700	300	28	0	4	1
6942	Sprint	Jul-97	17,700	5,900	14	1	21	2
6943	Sprint	Oct-97	20,700	7,000	59	1	23	3
6944	Sprint Quattro	Dec-00	38,600	21,100	65	1	2	1
6945	Sprint	Sep-97	42,600	14,100	108	1	32	6
6947	Sprint Quattro Secure	Nov-01	321,700	225,900	265	4	15	54
6948	Sprint Fidelis	Sep-04	10,400	5,800	102	0	1	0
6949	Sprint Fidelis	Sep-04	186,600	97,400	4,724	2	11	45
6996	Sub-Q Lead	Jun-01	3,200	1,900	12	0	0	0

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
6721, 6921	Epicardial Patch	8,700	1	1	0	0	1	0	2	4	0	6
6930	Sprint Fidelis	400	0	0	0	0	0	0	0	0	0	1
6931	Sprint Fidelis	8,100	1	2	1	1	3	1	0	0	0	0
6932	Sprint	14,900	0	0	4	2	0	2	0	1	0	2
6933, 6937, 6937A, 6963	SVC/CS	16,100	0	0	1	1	1	0	1	0	0	5
6935	Sprint Quattro Secure	21,800	3	3	12	13	13	2	1	9	0	2
6936, 6966	Transvene	23,600	5	2	1	5	3	4	1	1	0	4
6939, 6999	Sub-Q Patch	3,700	0	0	0	0	0	0	0	0	0	1
6942	Sprint	17,700	0	1	1	4	1	0	0	3	0	2
6943	Sprint	20,700	1	0	0	1	1	1	1	2	0	0
6944	Sprint Quattro	38,600	0	2	11	10	10	3	0	6	0	6
6945	Sprint	42,600	0	1	4	7	9	1	2	1	1	1
6947	Sprint Quattro Secure	321,700	17	17	75	53	83	19	3	47	1	17
6948	Sprint Fidelis	10,400	0	1	7	7	2	0	0	0	0	2
6949	Sprint Fidelis	186,600	9	39	22	30	30	22	6	16	0	19
6996	SubQ	3,200	0	0	1	0	1	0	0	1	0	0

Report Cutoff Date: July 31, 2011

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Defibrillation Leads continued

Reference Chart

Model Number	Family	Type	Pin Configuration		Lead Body Diameter	Insulation, Lead Body	Fixation, Steroid
			Pace/Sense	High Voltage			
6721	Epicardial Patch	Epi Patch	—	DF-1	S, M, L	Silicone, Single Lumen	Suture
6921	Epicardial Patch	Epi Patch	—	6.5 mm	S, M, L	Silicone, Single Lumen	Suture
6930	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Passive, Steroid
6931	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6932	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6933	SVC/CS	Endo SVC/CS Coil	—	DF-1	7 Fr	Silicone, Single Lumen	Passive
6934S	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	12 Fr	Silicone, Coaxial	Passive, Steroid
6935	Sprint Quattro Secure	Endo RV True Bipolar Sensing	IS-1	DF-1	8.2 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6936	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	10 Fr	Polyurethane, Coaxial	Active
6937	SVC/CS	Endo SVC Coil	—	DF-1	5.5 Fr	Silicone, Single Lumen	Passive
6937A	SVC/CS	Endo SVC Coil	—	DF-1	7.5 Fr	Silicone with Polyurethane Overlay, Single Lumen	Passive
6939	Sub-Q Patch	SQ Patch	—	DF-1	One Size	Silicone, Single Lumen	Suture
6942	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6943	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6944	Sprint Quattro	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with Polyurethane Overlay, Multilumen	Passive, Steroid
6945	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6947	Sprint Quattro Secure	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6948	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Passive, Steroid
6949	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6963	SVC/CS	Endo SVC/CS Coil	—	6.5 mm	7 Fr	Silicone, Single Lumen	Passive
6966	Transvene	Endo RV True Bipolar Sensing	3.2 mm L.P.	6.5 mm	10 Fr	Polyurethane, Coaxial	Active
6996	Sub-Q Lead	SQ Coil	—	DF-1	7.5 Fr	Silicone, Single Lumen	Passive
6999	Sub-Q Patch	SQ Patch	—	6.5 mm	One Size	Silicone, Single Lumen	Suture

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Registered US Implants	20,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	16,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	7
Other	3

Atrial Placement

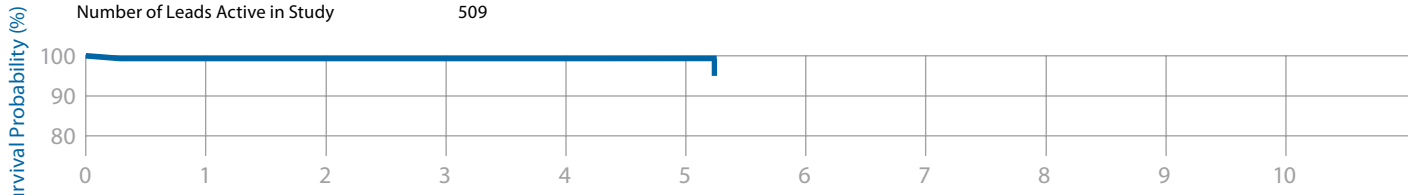
System Longevity Study Results

Number of Leads Enrolled in Study	622
Cumulative Months of Follow-Up	13,732
Number of Leads Active in Study	509

Qualifying Complications

2 Total

Failure to Sense	1
Cardiac Perforation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.7	99.7	99.7	99.7	99.7	99.7
#	304	156	132	83	56	51

Effective Sample Size

Ventricular Placement

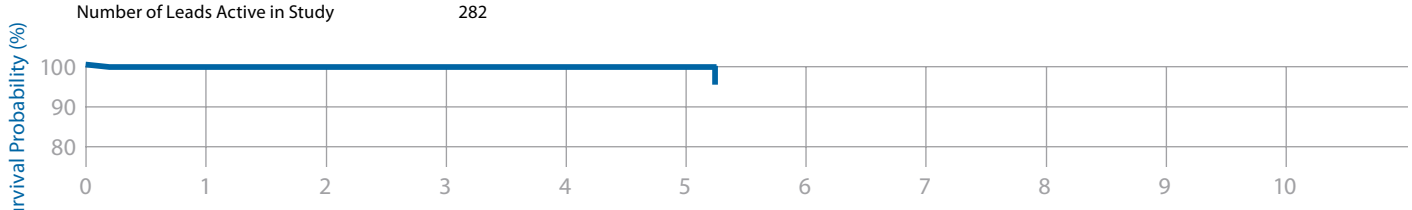
System Longevity Study Results

Number of Leads Enrolled in Study	385
Cumulative Months of Follow-Up	10,756
Number of Leads Active in Study	282

Qualifying Complications

1 Total

Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
#	220	137	123	83	58	53

Effective Sample Size

Pacing Leads continued

4023 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	LAK
Registered US Implants	41,100	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	8,000	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

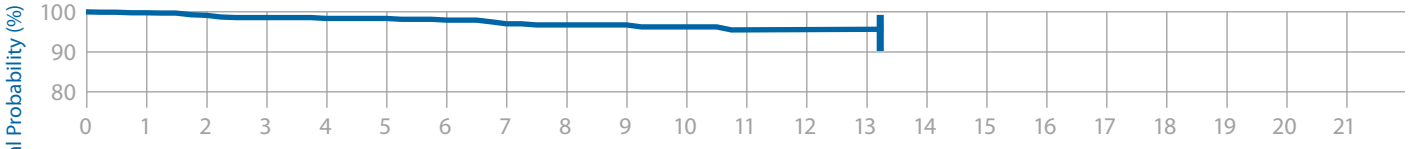
Conductor Fracture	14
Crimp/Weld/Bond	0
Insulation Breach	4
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	72,820
Number of Leads Active in Study	250

Qualifying Complications 22 Total

Lead Dislodgment	2
Failure to Capture	16
Insulation (not further defined)	1
Impedance Out of Range	2
Extra Cardiac Stimulation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 159 mo
%	99.8	99.2	98.7	98.5	98.5	98.1	97.2	96.9	96.6	96.3	95.7	95.7	95.7	95.7
#	886	765	681	605	527	454	386	348	277	189	137	93	53	48

Effective Sample Size

4024 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAJ
Registered US Implants	221,300	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	45,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

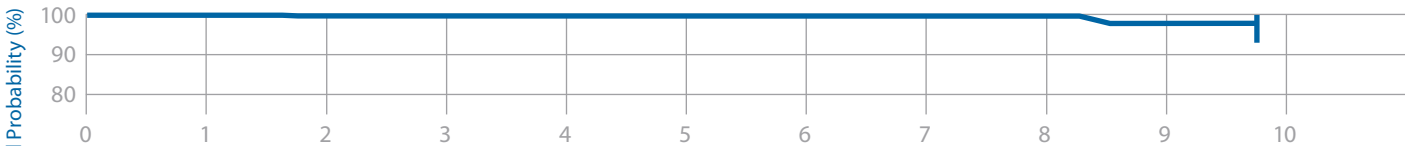
Conductor Fracture	29
Crimp/Weld/Bond	0
Insulation Breach	147
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	50,877
Number of Leads Active in Study	18

Qualifying Complications 4 Total

Failure to Capture	3
Insulation (not further defined)	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	98.8	98.8
#	870	685	556	416	323	229	167	111	63	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4033 CapSure Z

Product Characteristics

US Market Release	Not US released	Serial Number Prefix	LCA
Registered US Implants	NA	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	NA	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

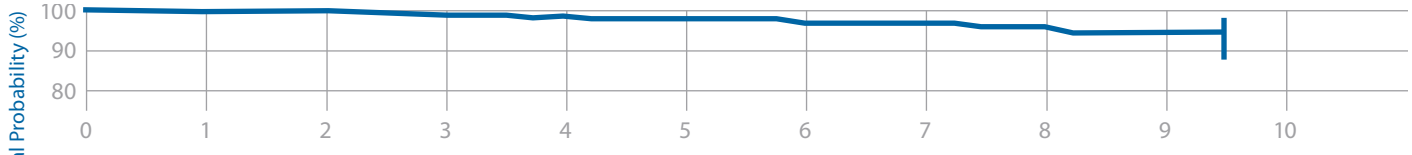
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	29,540
Number of Leads Active in Study	31

Qualifying Complications 10 Total

Failure to Capture	8
Conductor Fracture	1
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.4	99.1	98.8	98.5	98.1	97.5	97.5	96.6	95.3	95.3
#	430	382	321	251	201	162	112	78	52	49

Effective Sample Size

4067 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LCV
Registered US Implants	1,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	200	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

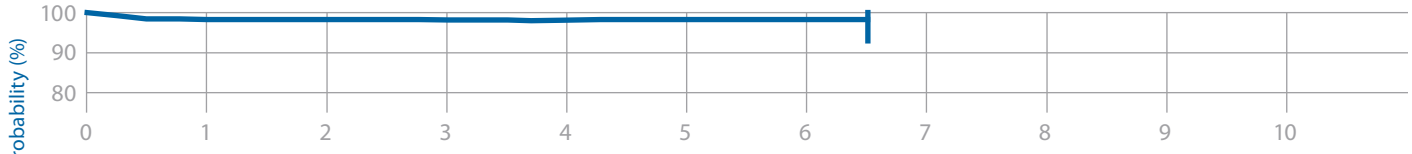
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	171
Cumulative Months of Follow-Up	11,059
Number of Leads Active in Study	48

Qualifying Complications 8 Total

Failure to Capture	6
Impedance Out of Range	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	98.1	98.1	98.1	98.1	98.1	98.1	98.1
#	131	119	107	90	82	70	54

Effective Sample Size

Pacing Leads continued

4068 CapSureFix

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCE
Registered US Implants	124,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	33,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	41
Crimp/Weld/Bond	0
Insulation Breach	125
Other	5

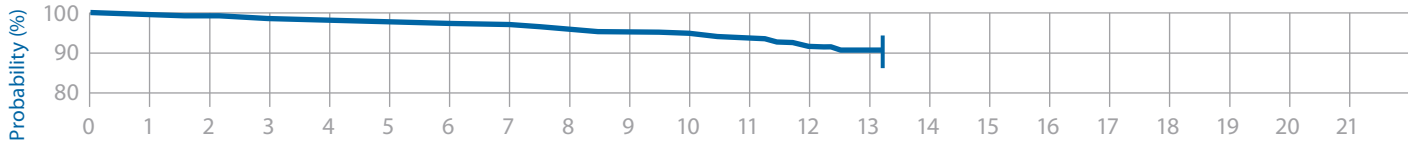
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,413
Cumulative Months of Follow-Up	131,388
Number of Leads Active in Study	339

Qualifying Complications 69 Total

Lead Dislodgement	8	Insulation (ESC)	2
Failure to Capture	22	Insulation (MIO)	2
Conductor Fracture	2	Impedance Out of Range	7
Failure to Sense	11	Unspecified Clinical Failure	3
Insulation (not further defined)	2	Extra Cardiac Stimulation	2
		Oversensing	8



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 159 mo
%	98.9	98.7	98.2	98.0	97.4	97.2	96.9	95.6	95.1	94.1	93.2	92	91.1	91.1
#	1,907	1,637	1,370	1,116	898	735	567	448	321	232	177	117	61	45

Effective Sample Size

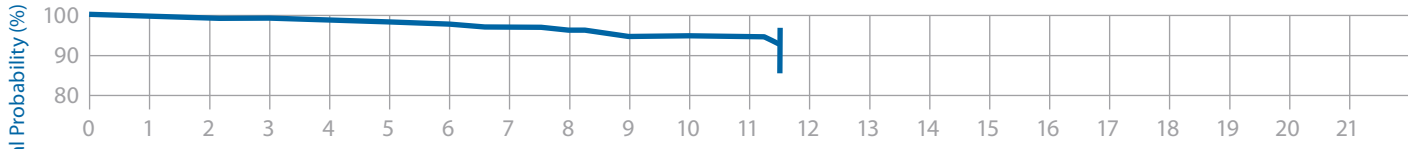
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	93,767
Number of Leads Active in Study	259

Qualifying Complications 44 Total

Failure to Capture	21	Impedance Out of Range	7
Conductor Fracture	3	Unspecified Clinical Failure	2
Failure to Sense	3	Extra Cardiac Stimulation	2
Insulation (not further defined)	1	Oversensing	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 138 mo
%	99.3	98.7	98.7	98.2	97.8	97.3	96.2	95.5	94.2	94.2	94.2	92.6
#	1,426	1,218	1,031	831	685	543	392	261	169	105	65	53

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4073 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBF
Registered US Implants	700	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	300	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

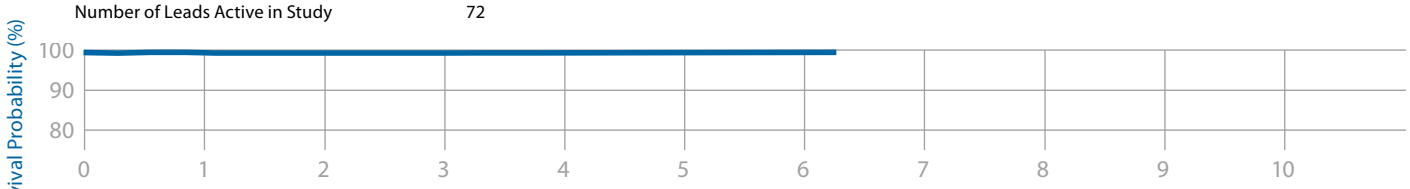
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	102
Cumulative Months of Follow-Up	6,867
Number of Leads Active in Study	72

Qualifying Complications

0 Total



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
#	100	92	85	84	81	62	39

Effective Sample Size

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Registered US Implants	82,200	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	52,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	14
Other	1

Atrial Placement

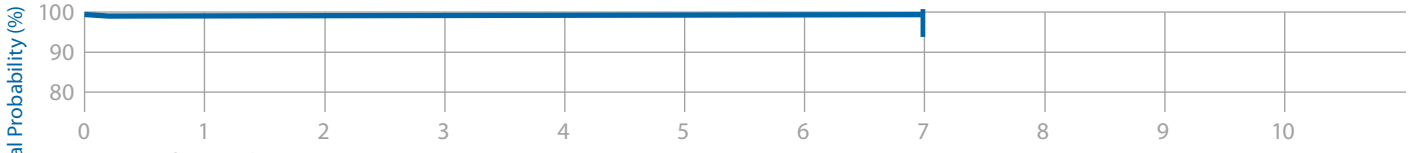
System Longevity Study Results

Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	13,314
Number of Leads Active in Study	152

Qualifying Complications

2 Total

Lead Dislodgement	1
Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	99.1	99.1	99.1	99.1	99.1	99.1	99.1
#	199	189	183	163	116	77	46

Effective Sample Size

Ventricular Placement

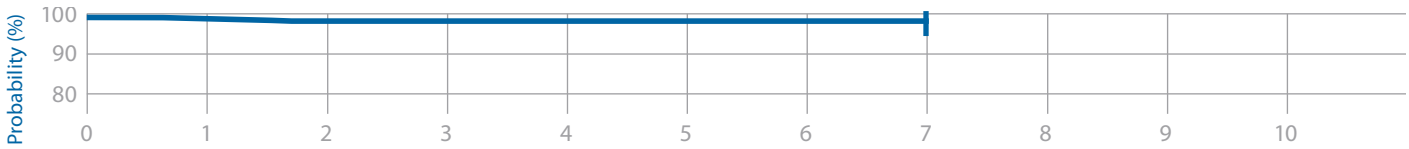
System Longevity Study Results

Number of Leads Enrolled in Study	626
Cumulative Months of Follow-Up	24,706
Number of Leads Active in Study	455

Qualifying Complications

3 Total

Lead Dislodgement	1
Failure to Capture	1
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	99.6	99.4	99.4	99.4	99.4	99.4	99.4
#	412	355	326	277	172	86	45

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Registered US Implants	349,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	271,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	17
Crimp/Weld/Bond	1
Insulation Breach	14
Other	16

Atrial Placement

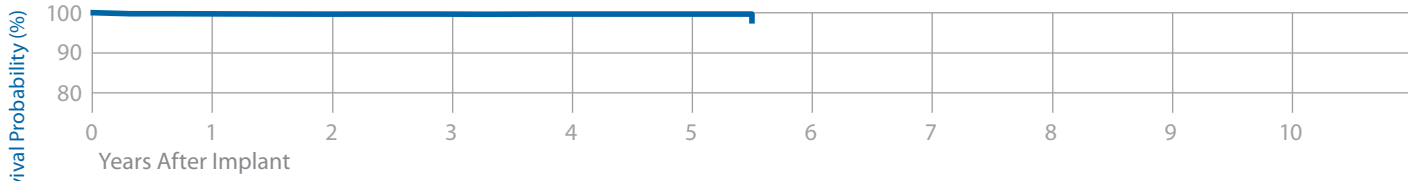
System Longevity Study Results

Number of Leads Enrolled in Study	1,657
Cumulative Months of Follow-Up	45,725
Number of Leads Active in Study	1,280

Qualifying Complications

6 Total

Lead Dislodgement	3
Failure to Capture	1
Failure to Sense	1
Insulation (not further defined)	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	99.8	99.6	99.6	99.6	99.6	99.6
#	1,370	650	427	228	99	61

Effective Sample Size

Ventricular Placement

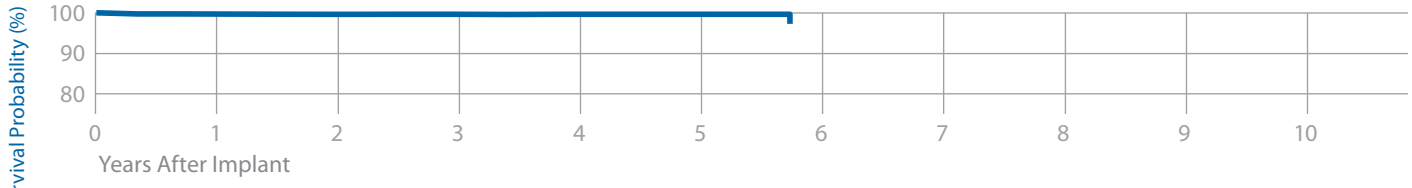
System Longevity Study Results

Number of Leads Enrolled in Study	1,226
Cumulative Months of Follow-Up	38,391
Number of Leads Active in Study	908

Qualifying Complications

3 Total

Failure to Capture	2
Extra Cardiac Stimulation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.8	99.8	99.8	99.8	99.5	99.5
#	1,025	565	418	285	127	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Registered US Implants	169,200	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	80,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

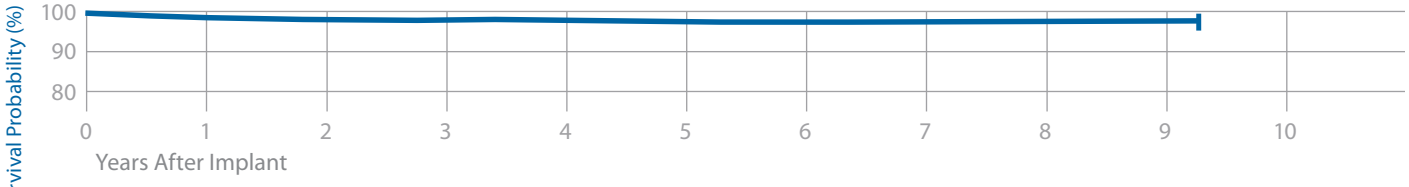
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	31
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	1,147
Cumulative Months of Follow-Up	64,757
Number of Leads Active in Study	402

Qualifying Complications 18 Total

Lead Dislodgement	4	Impedance Out of Range	1
Failure to Capture	9	Extra Cardiac Stimulation	1
Conductor Fracture	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	98.9	98.8	98.7	98.4	98.1	97.9	97.9	97.9	97.9	97.9
#	928	829	732	635	556	450	315	194	79	56

Effective Sample Size

4523 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	ZE
Registered US Implants	11,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	2,600	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

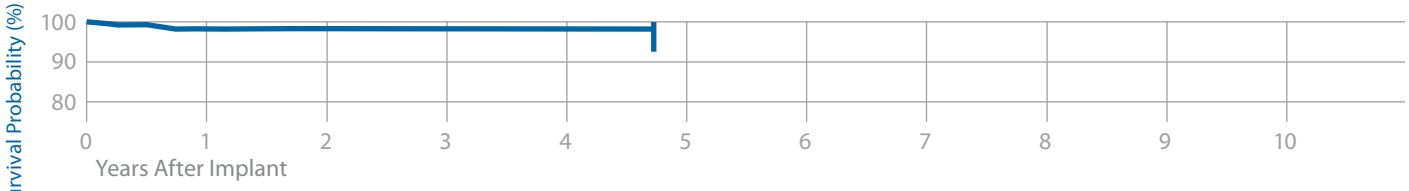
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	2
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	7,531
Number of Leads Active in Study	10

Qualifying Complications 4 Total

Lead Dislodgement	2		
Impedance Out of Range	1		
Oversensing	1		



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	98.1	98.1	98.1	98.1	98.1
#	95	81	71	58	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4524 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAR
Registered US Implants	101,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	26,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

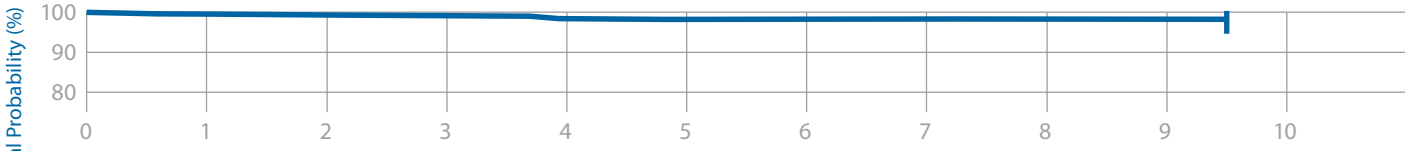
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	49
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	40,291
Number of Leads Active in Study	41

Qualifying Complications 6 Total

Lead Dislodgement	1
Failure to Capture	3
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0	99.0	99.0
#	682	537	427	329	251	182	133	87	62	52

Effective Sample Size

4533 CapSure Z

Product Characteristics

US Market Release	Not US released	Serial Number Prefix	LCB
Registered US Implants	NA	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	NA	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

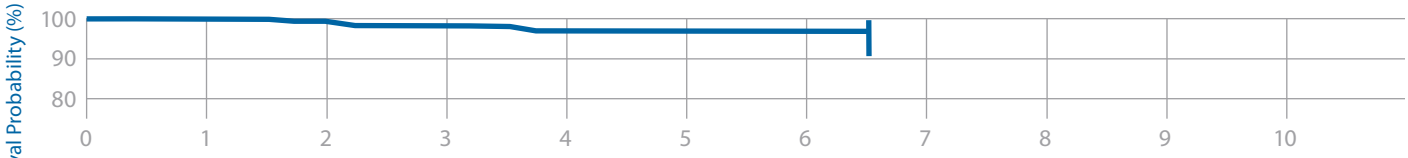
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	206
Cumulative Months of Follow-Up	11,670
Number of Leads Active in Study	13

Qualifying Complications 4 Total

Lead Dislodgement	1
Failure to Capture	1
Failure to Sense	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	99.4	98.8	97.9	97.9	97.9	97.9
#	176	158	132	101	77	60	51

Effective Sample Size

Pacing Leads continued

4558M Screw-In

Product Characteristics

US Market Release	Nov-94	Serial Number Prefix	LDC
Registered US Implants	19,900	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	4,300	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

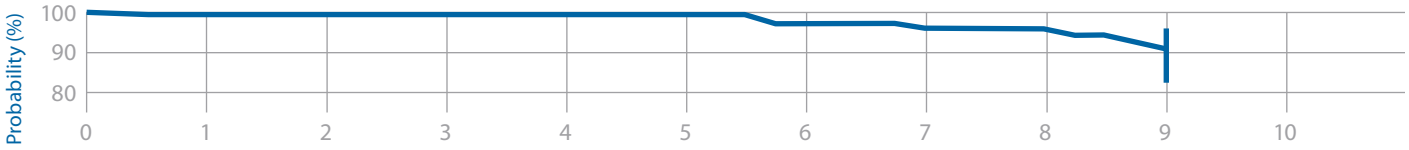
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	18
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	22,993
Number of Leads Active in Study	22

Qualifying Complications 12 Total

Electrical Abandonment	1			Insulation (not further defined)	2
Failure to Capture	3			Impedance Out of Range	2
Failure to Sense	2			Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.3	99.3	99.3	99.3	99.3	97.6	96.5	96.5	91.8
#	353	296	249	191	139	96	83	66	50

Effective Sample Size

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Registered US Implants	69,600	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	24,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

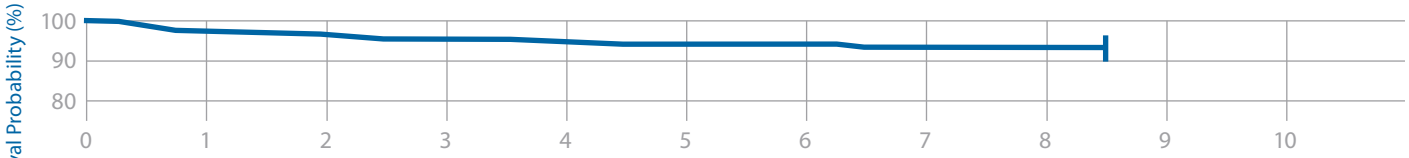
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	49
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	656
Cumulative Months of Follow-Up	31,676
Number of Leads Active in Study	170

Qualifying Complications 33 Total

Lead Dislodgement	9			Impedance Out of Range	2
Failure to Capture	18			Medical Judgment	1
Failure to Sense	3				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	96.8	96.4	95.3	94.7	94.0	94.0	93.4	93.4	93.4
#	495	431	349	292	244	189	130	71	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Registered US Implants	53,900	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	37,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

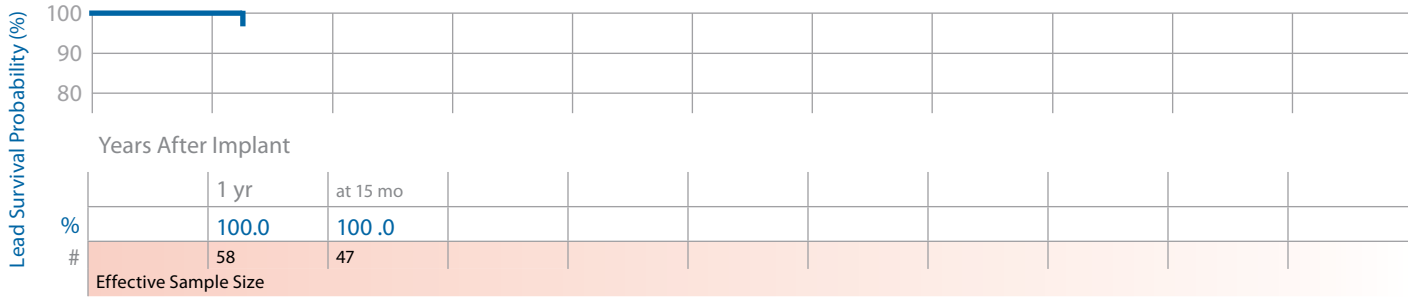
US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

System Longevity Study Results

Qualifying Complications 0 Total

Number of Leads Enrolled in Study	200
Cumulative Months of Follow-Up	2,314
Number of Leads Active in Study	163



	1 yr	at 15 mo
%	100.0	100 .0
#	58	47

Effective Sample Size

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Registered US Implants	82,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	41,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

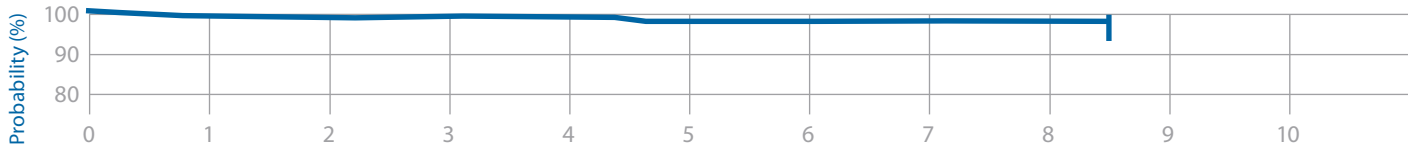
US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	11
Other	1

System Longevity Study Results

Qualifying Complications 5 Total

Number of Leads Enrolled in Study	283	Lead Dislodgement	2
Cumulative Months of Follow-Up	14,431	Failure to Capture	2
Number of Leads Active in Study	70	Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	98.2	98.2	98.2	98.2	97.4	97.4	97.4	97.4	97.4
#	194	170	152	129	110	100	80	62	51

Effective Sample Size

Pacing Leads continued

5023, 5023M CapSure SP

Product Characteristics

US Market Release	Nov-88	Serial Number Prefix	SX or LAS
Registered US Implants	9,800	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	2,200	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

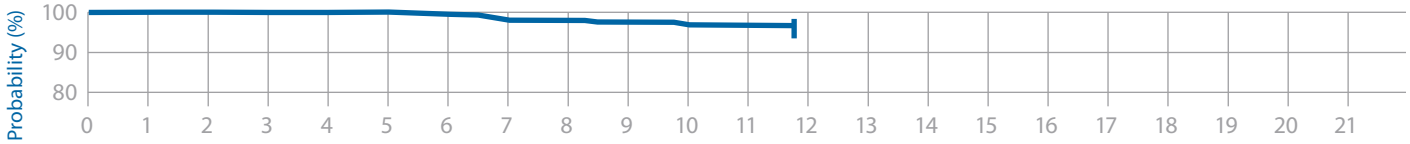
Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1,354
Cumulative Months of Follow-Up	82,541
Number of Leads Active in Study	354

Qualifying Complications 19 Total

Failure to Capture	10
Conductor Fracture	3
Impedance Out of Range	2
Extra Cardiac Stimulation	4



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 141 mo
%	99.7	99.7	99.5	99.4	99.3	98.8	97.6	97.6	97.3	96.7	95.9	95.9
#	1,076	942	833	731	636	559	440	340	240	154	91	55

Effective Sample Size

5024, 5024M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	SY or LAT
Registered US Implants	200,700	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	46,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

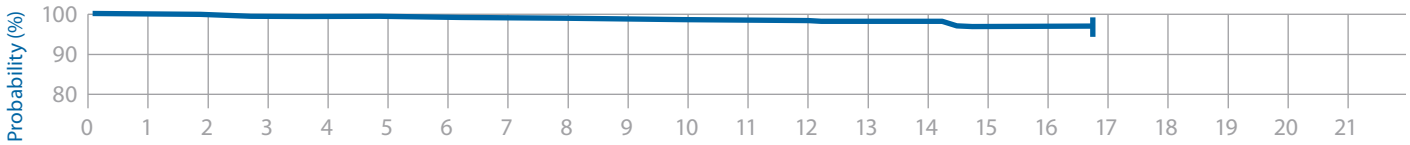
Conductor Fracture	51
Crimp/Weld/Bond	1
Insulation Breach	48
Other	9

System Longevity Study Results

Number of Leads Enrolled in Study	8,153
Cumulative Months of Follow-Up	441,293
Number of Leads Active in Study	348

Qualifying Complications 56 Total

Lead Dislodgement	6
Failure to Capture	27
Conductor Fracture	3
Failure to Sense	2
Insulation (not further defined)	5
Insulation (ESC)	1
Impedance Out of Range	3
Unspecified Clinical Failure	1
Extra Cardiac Stimulation	2
Oversensing	4
Other	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	at 201 mo
%	99.6	99.6	99.5	99.4	99.3	99.3	99.1	99.0	98.9	98.8	98.5	98.5	98.3	98.3	97.3	97.3	97.3
#	6,128	5,277	4,477	3,747	3,113	2,460	1,926	1,453	1,095	818	606	439	314	219	137	79	55

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

5033 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDK
Registered US Implants	2,300	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	500	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

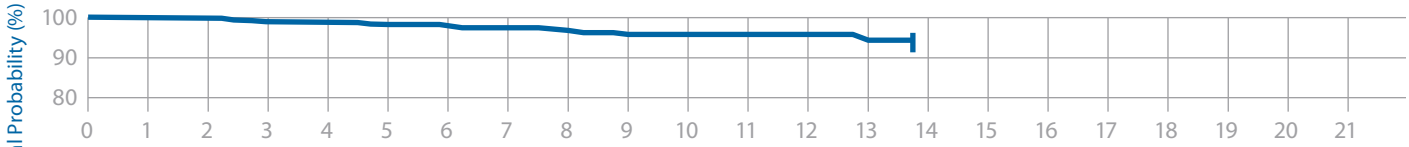
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	98,520
Number of Leads Active in Study	180

Qualifying Complications 28 Total

Lead Dislodgement	2	Insulation (not further defined)	1
Failure to Capture	12	Impedance Out of Range	4
Conductor Fracture	8	Cardiac Perforation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 165 mo
%	99.7	99.6	99.1	99.0	98.8	98.3	97.7	96.9	96.0	96.0	95.5	95.5	94.5	94.5
#	1,416	1,144	945	796	659	527	417	345	283	222	162	123	87	46

Effective Sample Size

Pacing Leads continued

5034 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDF
Registered US Implants	56,000	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	13,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	12
Other	3

Atrial Placement

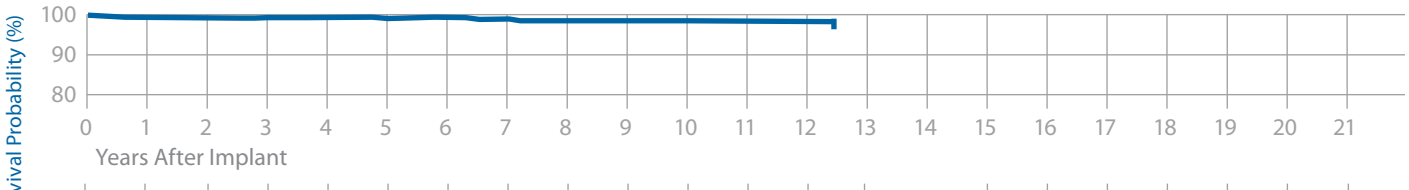
System Longevity Study Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	43,189
Number of Leads Active in Study	141

Qualifying Complications

5 Total

Failure to Capture	2
Conductor Fracture	1
Failure to Sense	1
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 150 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	98.8	98.8	98.8	98.8	98.8	98.8	98.8
#	383	382	379	373	355	330	294	250	207	174	117	75	53

Effective Sample Size

Ventricular Placement

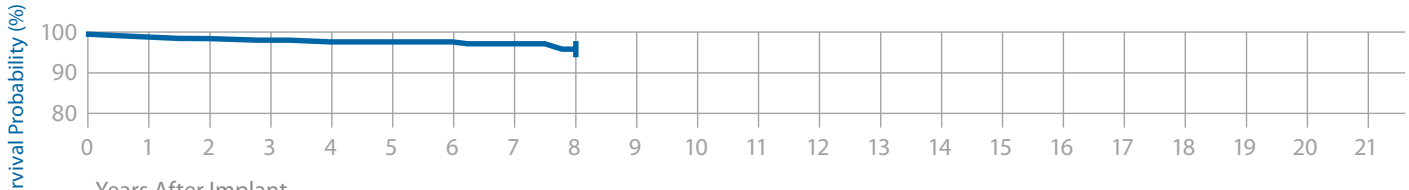
System Longevity Study Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Follow-Up	44,335
Number of Leads Active in Study	16

Qualifying Complications

11 Total

Lead Dislodgement	1
Failure to Capture	7
Conductor Fracture	1
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.7	99.4	99.1	98.8	98.8	98.8	98.1	96.6
#	886	671	507	340	211	127	77	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Registered US Implants	93,000	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	42,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	8
Crimp/Weld/Bond	1
Insulation Breach	17
Other	3

Atrial Placement

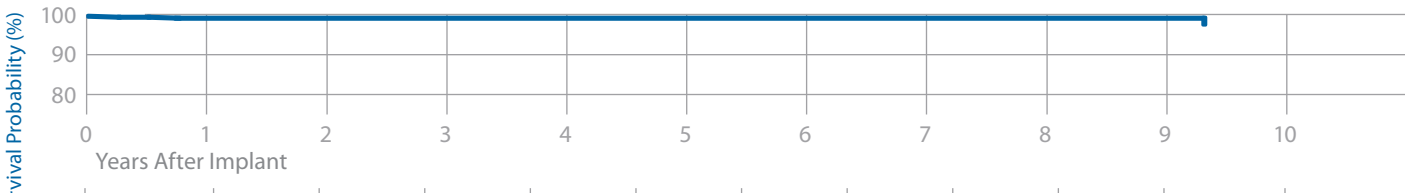
Longevity Study Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	31,594
Number of Leads Active in Study	176

Qualifying Complications

2 Total

Lead Dislodgement	1
Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
#	408	385	357	322	284	246	179	118	63	45

Effective Sample Size

Ventricular Placement

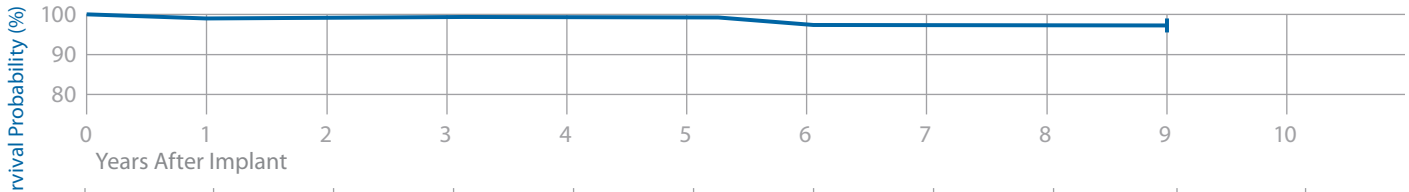
System Longevity Study Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	37,968
Number of Leads Active in Study	120

Qualifying Complications

9 Total

Lead Dislodgement	1
Failure to Capture	6
Failure to Sense	1
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.5	99.4	99.4	99.1	99.1	97.8	97.8	97.8	97.8
#	656	513	387	318	273	195	145	105	52

Effective Sample Size

Pacing Leads continued

5068 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDJ
Registered US Implants	102,800	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	32,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	35
Crimp/Weld/Bond	2
Insulation Breach	51
Other	4

Atrial Placement

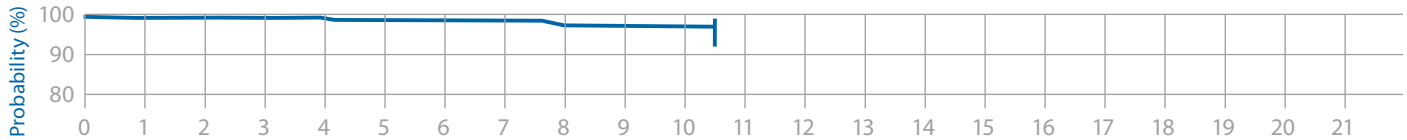
System Longevity Study Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	33,537
Number of Leads Active in Study	42

Qualifying Complications

6 Total

Lead Dislodgement	1	Impedance Out of Range	1
Failure to Capture	2	Oversensing	1
Insulation (not further defined)	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.6	99.6	99.3	99.3	99.3	99.3	99.3	97.6	97.6	97.6	97.6
#	552	424	321	253	210	159	130	103	78	62	48

Effective Sample Size

Ventricular Placement

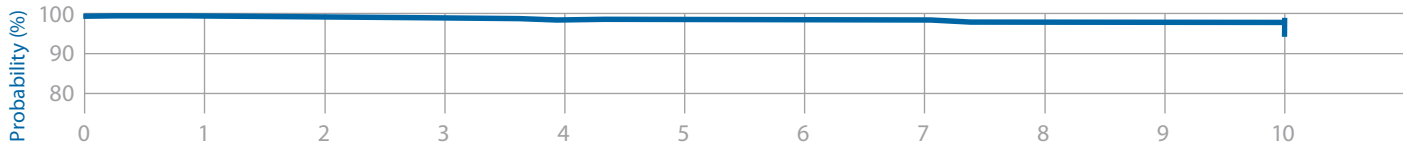
System Longevity Study Results

Number of Leads Enrolled in Study	1,362
Cumulative Months of Follow-Up	39,849
Number of Leads Active in Study	85

Qualifying Complications

5 Total

Lead Dislodgement	1	Insulation (not further defined)	1
Failure to Capture	2		
Conductor Fracture	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.9	99.7	99.5	99.2	99.2	99.2	98.5	98.5	98.5	98.5
#	700	499	363	268	228	190	152	129	94	54

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Registered US Implants	9,700	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	4,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	6
Other	0

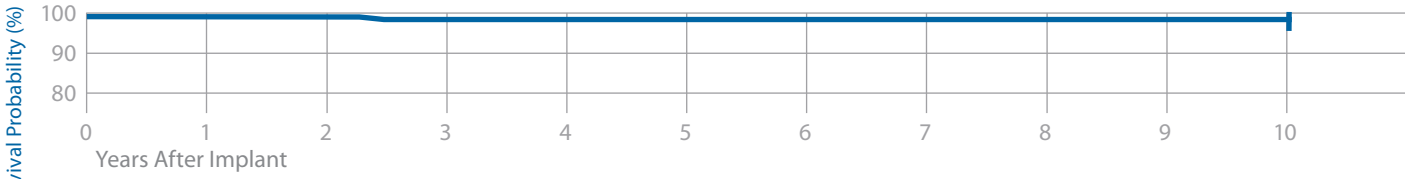
System Longevity Study Results

Number of Leads Enrolled in Study	508
Cumulative Months of Follow-Up	26,824
Number of Leads Active in Study	83

Qualifying Complications

3 Total

Failure to Capture	1
Failure to Sense	1
Cardiac Perforation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.8	99.8	99.4	99.4	99.4	99.4	99.4	99.4	98.6	98.6
#	376	316	268	223	188	165	142	119	88	46

Effective Sample Size

Leads

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Registered US Implants	1,349,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	873,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	284
Crimp/Weld/Bond	0
Insulation Breach	291
Other	86

Atrial Placement

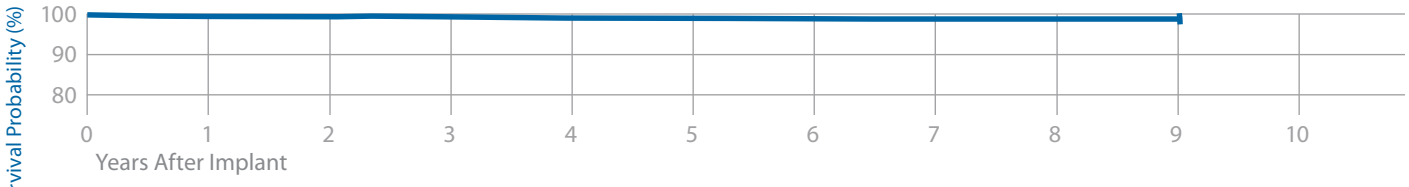
System Longevity Study Results

Number of Leads Enrolled in Study	2,737
Cumulative Months of Follow-Up	128,187
Number of Leads Active in Study	833

Qualifying Complications

19 Total

Lead Dislodgement	4	Impedance Out of Range	3
Failure to Capture	5	Extra Cardiac Stimulation	2
Conductor Fracture	1	Oversensing	2
Insulation (not further defined)	1	Cardiac Perforation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.7	99.6	99.4	99.1	99.1	99	99	98.7	98.7
#	2,071	1,765	1,514	1,305	1,027	707	428	257	73

Effective Sample Size

Ventricular Placement

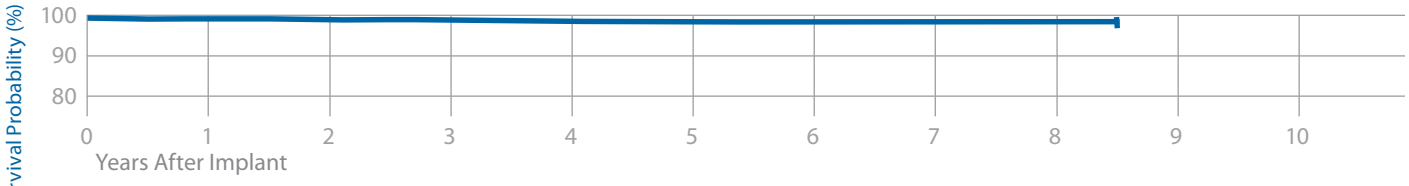
System Longevity Study Results

Number of Leads Enrolled in Study	1,538
Cumulative Months of Follow-Up	64,412
Number of Leads Active in Study	326

Qualifying Complications

10 Total

Lead Dislodgement	2	Failure to Sense	1
Failure to Capture	3	Impedance Out of Range	2
Conductor Fracture	1	Cardiac Perforation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.6	99.4	99.3	99.0	99.0	99.0	99.0	99.0	99.0
#	1,084	897	742	609	472	360	220	124	62

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

5086MRI CapSureFix Novus

Product Characteristics

US Market Release	Feb-11	Serial Number Prefix	LEP
Registered US Implants	17,700	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated Active US Implants	17,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

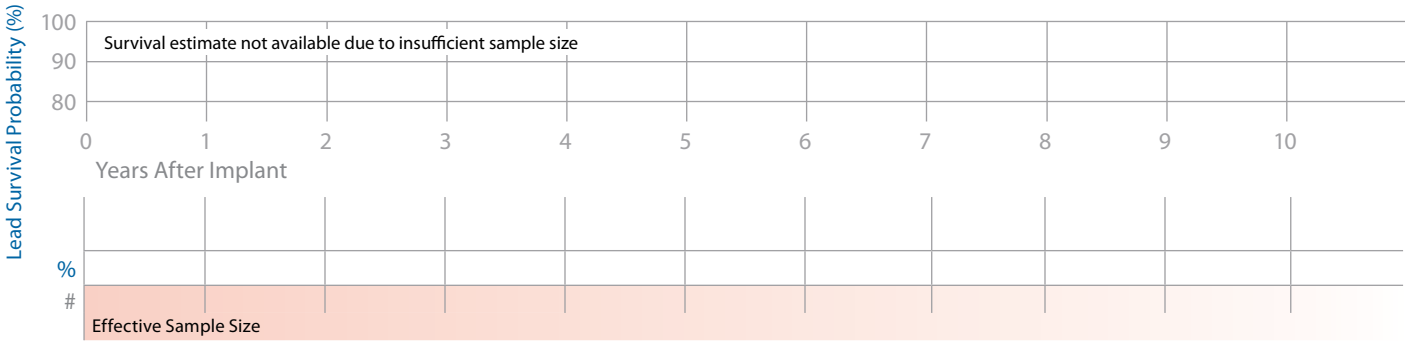
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0
Number of Leads Active in Study	0

Qualifying Complications 0 Total

Lead Dislodgement	0
Failure to Capture	0
Impedance Out of Range	0
Extra Cardiac Stimulation	0



5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Registered US Implants	126,200	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	60,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

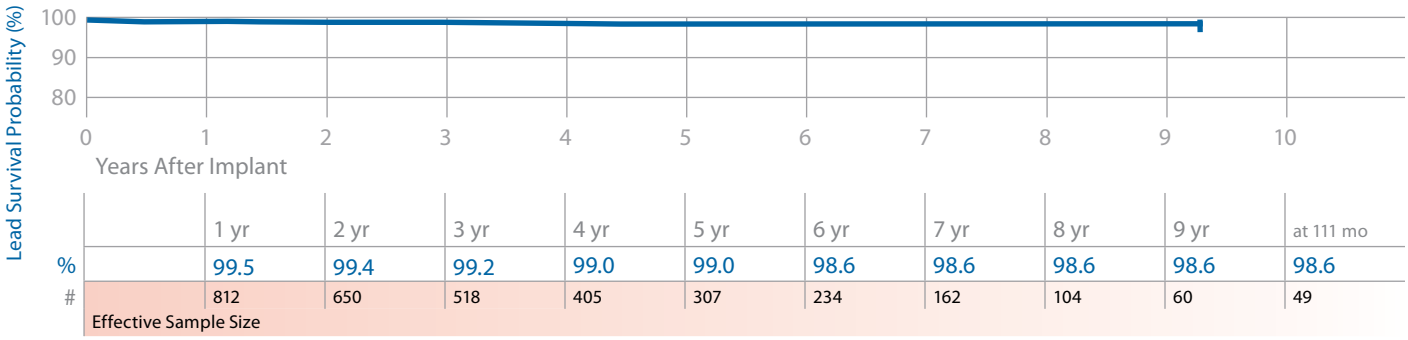
Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	32
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	1,172
Cumulative Months of Follow-Up	46,543
Number of Leads Active in Study	159

Qualifying Complications 9 Total

Lead Dislodgement	5
Failure to Capture	2
Impedance Out of Range	1
Extra Cardiac Stimulation	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.5	99.4	99.2	99.0	99.0	98.6	98.6	98.6	98.6	98.6
#	812	650	518	405	307	234	162	104	60	49

Effective Sample Size

Leads

Pacing Leads continued

5524, 5524M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Registered US Implants	59,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	17,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	11
Crimp/Weld/Bond	1
Insulation Breach	11
Other	2

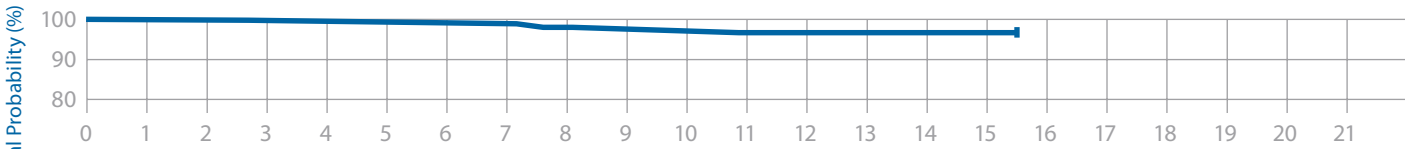
System Longevity Study Results

Number of Leads Enrolled in Study	4,497
Cumulative Months of Follow-Up	252,422
Number of Leads Active in Study	334

Qualifying Complications

39 Total

Lead Dislodgement	4	Insulation (not further defined)	1
Failure to Capture	23	Impedance Out of Range	1
Conductor Fracture	1	Oversensing	4
Failure to Sense	4	Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	at 186 mo
%	99.7	99.7	99.5	99.3	99.2	99.2	98.9	98.4	98.1	97.7	97.5	97.5	97.5	97.5	97.5	97.5
#	3,439	2,965	2,541	2,135	1,780	1,417	1,119	858	675	528	390	286	201	128	68	48

Effective Sample Size

5534 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDG
Registered US Implants	26,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	7,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	5
Other	2

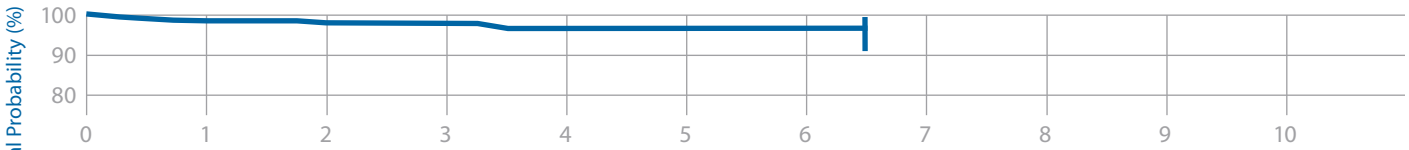
System Longevity Study Results

Number of Leads Enrolled in Study	264
Cumulative Months of Follow-Up	12,959
Number of Leads Active in Study	6

Qualifying Complications

6 Total

Failure to Capture	5		
Impedance Out of Range	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	98.3	97.8	97.8	97.1	97.1	97.1	97.1
#	207	182	155	108	72	56	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Registered US Implants	60,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	30,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

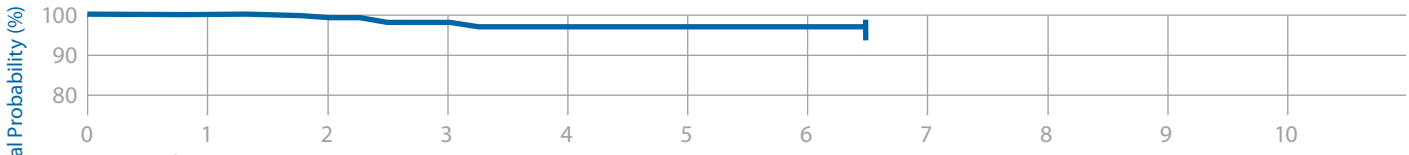
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	15
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	15,325
Number of Leads Active in Study	43

Qualifying Complications 4 Total

Lead Dislodgement	1	Oversensing	1
Failure to Capture	1		
Impedance Out of Range	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	99.2	98.7	98.2	98.2	98.2	98.2
#	273	227	182	156	120	73	50

Effective Sample Size

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Registered US Implants	85,200	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	49,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

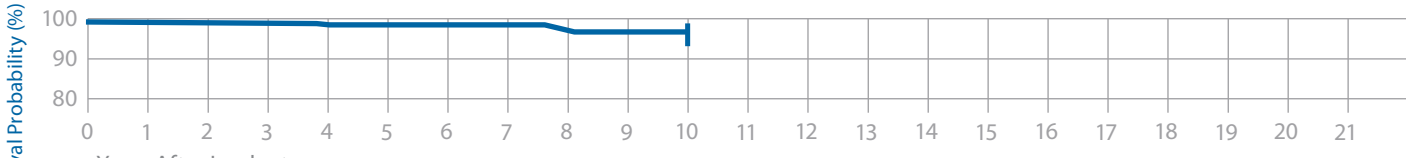
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	24
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	1,053
Cumulative Months of Follow-Up	39,624
Number of Leads Active in Study	146

Qualifying Complications 11 Total

Lead Dislodgement	1	Failure to Sense	2
Failure to Capture	5	Extra Cardiac Stimulation	1
Conductor Fracture	1	Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.8	99.3	99.3	99.3	98.5	97.5	97.5	97.5	97.5	97.5
#	713	528	404	289	214	166	131	110	88	51

Effective Sample Size

Pacing Leads continued

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Registered US Implants	32,400	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	18,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

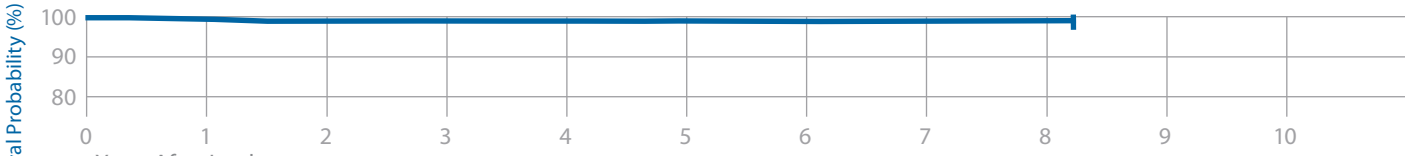
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	672
Cumulative Months of Follow-Up	30,017
Number of Leads Active in Study	129

Qualifying Complications 5 Total

Lead Dislodgement	2
Failure to Capture	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.7	99.3	99.3	98.9	98.9	98.9	98.9	98.9	98.9
#	517	434	347	281	208	149	99	60	51

Effective Sample Size

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Registered US Implants	14,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	9,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

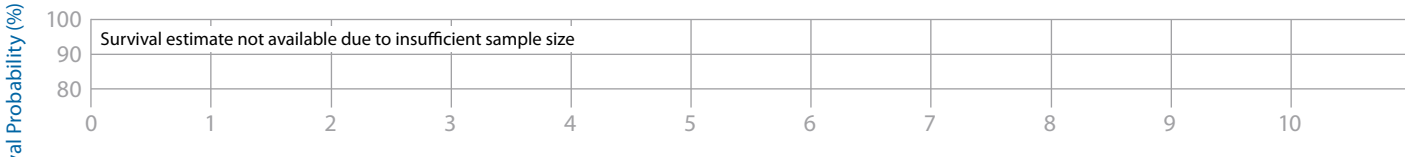
US Returned Product Analysis

Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	6
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	21
Cumulative Months of Follow-Up	1,422
Number of Leads Active in Study	12

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	21

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

6940 CapSureFix

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	TCP
Registered US Implants	25,300	Type and/or Fixation	Transvenous, Atrial-J , Screw-in
Estimated Active US Implants	7,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

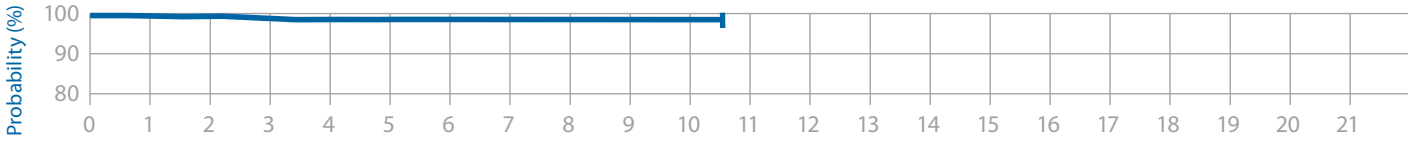
Conductor Fracture	11
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	816
Cumulative Months of Follow-Up	43,112
Number of Leads Active in Study	95

Qualifying Complications 10 Total

Lead Dislodgement	1	Oversensing	5
Conductor Fracture	1		
Failure to Sense	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.7	99.6	98.3	98.1	98.1	98.1	98.1	98.1	98.1	98.1	98.1
#	641	530	441	364	306	255	205	156	122	86	46

Effective Sample Size

Leads

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
3830	SelectSecure	Atrial	Aug-05	622	509	2	13,732	99.7 +0.2/-1.0	99.7 +0.2/-1.0	99.7 +0.2/-1.0	99.7 +0.2/-1.0	99.7 +0.2/-1.0	99.7 +0.2/-1.0 at 63 mo								
3830	SelectSecure	Vent	Aug-05	385	282	1	10,756	100.0	100.0	100.0	100.0	100.0	100.0 at 63 mo								
4023	CapSure SP	Vent	Aug-91	1,158	250	22	72,820	99.8 +0.2/-0.6	99.2 +0.4/-0.9	98.7 +0.6/-1.1	98.5 +0.7/-1.1	98.5 +0.7/-1.1	98.1 +0.8/-1.3	97.2 +1.1/-1.8	96.9 +1.2/-1.8	96.3 +1.3/-2.1	95.7 +1.6/-2.6	95.7 +1.6/-2.6 at 159 mo			
4024	CapSure SP	Vent	Oct-91	1,215	18	4	50,877	99.9 +0.1/-0.5	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	98.8 +0.1/-5 .0 at 117 mo					
4033	CapSure Z	Vent	Not US released	539	31	10	29,540	99.4 +0.4/-1.4	99.1 +0.6/-1.5	98.8 +0.7/-1.6	98.5 +0.8/-1.9	98.1 +1/-2.2	97.5 +1.3/-2.7	97.5 +1.3/-2.7	96.6 +1.8/-3.9	95.3 +2.5/-5.1 at 114 mo					
4067	CapSureFix	A or V	Jan-97	171	48	8	11,059	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9 at 78 mo							
4068	CapSureFix	Atrial	Mar-96	2,413	339	69	131,388	98.9 +0.4/-0.5	98.7 +0.4/-0.6	98.2 +0.5/-0.7	98.0 +0.5/-0.8	97.4 +0.7/-0.9	97.2 +0.7/-1	96.9 +0.8/-1.1	95.6 +1.1/-1.6	94.1 +1.6/-2.3	92.0 +2.3/-3.2	91.1 +2.7/-3.9 at 159 mo			
4068	CapSureFix	Vent	Mar-96	1,799	259	44	93,767	99.3 +0.3/-0.6	98.7 +0.5/-0.7	98.7 +0.5/-0.7	98.2 +0.6/-1	97.8 +0.7/-1.1	97.3 +0.9/-1.2	96.2 +1.1/-1.7	95.5 +1.4/-1.9	94.2 +1.8/-2.6	92.6 +3/-4.7 at 138 mo					
4073	CapSure Sense	Vent	Jun-02	102	72	0	6,867	100.0	100.0	100.0	100.0	100.0	100.0	100 .0 at 75 mo							
4074	CapSure Sense	Atrial	Jun-02	214	152	2	13,314	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8							
4074	CapSure Sense	Vent	Jun-02	626	455	3	24,706	99.6 +0.3/-1.1	99.4 +0.4/-1.4	99.4 +0.4/-1.4	99.4 +0.4/-1.4	99.4 +0.4/-1.4	99.4 +0.4/-1.4	99.4 +0.4/-1.4							
4076	CapSureFix Novus	Atrial	Feb-04	1,657	1,280	6	45,725	99.8 +0.1/-0.5	99.6 +0.2/-0.5	99.6 +0.2/-0.5	99.6 +0.2/-0.5	99.6 +0.2/-0.5	99.6 +0.2/-0.5 at 66 mo								
4076	CapSureFix Novus	Vent	Feb-04	1,226	908	3	38,391	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.5 +0.4/-1.6	99.5 +0.4/-1.6 at 69 mo								
4092	CapSure SP Novus	Vent	Sep-98	1,147	402	18	64,757	98.9 +0.5/-0.9	98.8 +0.5/-0.9	98.7 +0.5/-1	98.4 +0.6/-1.1	98.1 +0.7/-1.2	97.9 +0.8/-1.3	97.9 +0.8/-1.3	97.9 +0.8/-1.3	97.9 +0.8/-1.3 at 111 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4523	CapSure SP	Atrial	Aug-91	121	10	4	7,531	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3 at 57 mo									
4524	CapSure SP	Atrial	Oct-91	911	41	6	40,291	99.6 +0.3/-0.7	99.3 +0.4/-1	99.3 +0.4/-1	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2 at 114 mo					
4533	CapSure Z	Atrial	Not US released	206	13	4	11,670	100.0	99.4 +0.5/-3.5	98.8 +0.9/-3.6	97.9 +1.4/-4.2	97.9 +1.4/-4.2	97.9 +1.4/-4.2	97.9 +1.4/-4.2 at 78 mo							
4558M	Screw-In	Atrial	Nov-94	539	22	12	22,993	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	97.6 +1.6/-4.2	96.5 +2.1/-5.2	96.5 +2.1/-5.2	91.8 +4.3/-8.8 at 108 mo					
4568	CapSureFix	Atrial	Jan-97	656	170	33	31,676	96.8 +1.2/-1.8	96.4 +1.3/-1.9	95.3 +1.5/-2.2	94.7 +1.6/-2.5	94.0 +1.8/-2.6	94.0 +1.8/-2.6	93.4 +2.1/-2.9	93.4 +2.1/-2.9	93.4 +2.1/-2.9 at 102 mo					
4574	CapSure Sense	Atrial	Jun-02	200	163	0	2,314	100.0	100.0 at 15 mo												
4592	CapSure SP Novus	Atrial	Oct-98	283	70	5	14,431	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3	97.4 +1.5/-3.8	97.4 +1.5/-3.8	97.4 +1.5/-3.8	97.4 +1.5/-3.8	97.4 +1.5/-3.8 at 102 mo					
5023, 5023M	CapSure SP	Vent	Nov-88	1,354	354	19	82,541	99.7 +0.2/-0.5	99.7 +0.2/-0.6	99.5 +0.3/-0.6	99.4 +0.3/-0.7	99.3 +0.4/-0.9	98.8 +0.5/-1.2	97.6 +0.9/-1.6	97.6 +0.9/-1.6	96.7 +1.4/-2.3	95.9 +1.8/-3 at 141 mo				
5024, 5024M	CapSure SP	Vent	Mar-90	8,153	348	56	441,293	99.6 +0.1/-0.2	99.6 +0.1/-0.2	99.5 +0.1/-0.3	99.4 +0.2/-0.2	99.3 +0.2/-0.2	99.3 +0.2/-0.3	99.1 +0.3/-0.3	99.0 +0.3/-0.4	98.8 +0.3/-0.6	98.5 +0.5/-0.7	98.3 +0.6/-0.9	97.3 +1.2/-2	97.3 +1.2/-2 at 201 mo	
5033	CapSure Z	Vent	Feb-96	1,899	180	28	98,520	99.7 +0.2/-0.4	99.6 +0.2/-0.4	99.1 +0.4/-0.7	99.0 +0.5/-0.7	98.8 +0.5/-0.9	98.3 +0.7/-1.2	97.7 +0.9/-1.3	96.9 +1.1/-1.7	96.0 +1.4/-2.1	95.5 +1.6/-2.5	94.5 +2.2/-3.5 at 165 mo			
5034	CapSure Z	Atrial	Feb-96	386	141	5	43,189	99.5 +0.4/-1.6	99.5 +0.4/-1.6	99.5 +0.4/-1.6	99.5 +0.4/-1.6	99.5 +0.4/-1.6	99.5 +0.4/-1.6	98.8 +0.8/-1.9	98.8 +0.8/-1.9	98.8 +0.8/-1.9	98.8 +0.8/-1.9	98.8 +0.8/-1.9 at 150 mo			
5034	CapSure Z	Vent	Feb-96	1,209	16	11	44,335	99.7 +0.2/-0.6	99.4 +0.3/-0.8	99.1 +0.4/-1	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.1 +1.1/-2.8	96.6 +2.1/-5.7						
5054	CapSure Z Novus	Atrial	Jun-98	424	176	2	31,594	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4 at 111 mo					
5054	CapSure Z Novus	Vent	Jun-98	967	120	9	37,968	99.5 +0.3/-0.8	99.4 +0.3/-0.9	99.4 +0.3/-0.9	99.1 +0.5/-1.2	99.1 +0.5/-1.2	97.8 +1.2/-2.3	97.8 +1.2/-2.3	97.8 +1.2/-2.3	97.8 +1.2/-2.3 at 108 mo					

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
5068	CapSureFix	Atrial	Jan-97	967	42	6	33,537	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.3 +0.5/-1.2	99.3 +0.5/-1.2	99.3 +0.5/-1.2	99.3 +0.5/-1.2	99.3 +0.5/-1.2	97.6 +1.5/-4.2	97.6 +1.5/-4.2	97.6 +1.5/-4.2 at 126 mo				
5068	CapSureFix	Vent	Jan-97	1,362	85	5	39,849	99.9 +0.1/-0.8	99.7 +0.2/-0.9	99.5 +0.3/-1.2	99.2 +0.5/-1.6	99.2 +0.5/-1.6	99.2 +0.5/-1.6	98.5 +1/-2.5	98.5 +1/-2.5	98.5 +1/-2.5					
5072	SureFix	A or V	Jun-98	508	83	3	26,824	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	98.6 +1.0/-3.9					
5076	CapSureFix Novus	Atrial	Aug-00	2,737	833	19	128,187	99.7 +0.1/-0.4	99.6 +0.2/-0.3	99.4 +0.2/-0.5	99.1 +0.3/-0.6	99.1 +0.3/-0.6	99.0 +0.4/-0.6	99.0 +0.4/-0.6	98.7 +0.6/-0.9	98.7 +0.6/-0.9 at 9 yr					
5076	CapSureFix Novus	Vent	Aug-00	1,538	326	10	64,412	99.6 +0.2/-0.5	99.4 +0.3/-0.6	99.3 +0.4/-0.7	99.0 +0.5/-0.9	99.0 +0.5/-0.9	99.0 +0.5/-0.9	99.0 +0.5/-0.9	99 .0 +0.5/-0.9	99.0 +0.5/-0.9 at 102 mo					
5086MRI	CapsureFix Novus	A or V	Feb-11	0	0	0	0	100.0 at 0 mo													
5092	CapSure SP Novus	Vent	Jun-98	1,172	159	9	46,543	99.5 +0.3/-0.7	99.4 +0.3/-0.8	99.2 +0.4/-0.9	99.0 +0.5/-1.2	99.0 +0.5/-1.2	98.6 +0.7/-1.6	98.6 +0.7/-1.6	98.6 +0.7/-1.6	98.6 +0.7/-1.6 at 111 mo					
5524, 5524M	CapSure SP	Atrial	Mar-90	4,497	334	39	252,422	99.7 +0.2/-0.2	99.7 +0.1/-0.2	99.5 +0.2/-0.3	99.3 +0.3/-0.4	99.2 +0.3/-0.4	99.2 +0.2/-0.5	98.9 +0.4/-0.5	98.4 +0.5/-0.7	97.7 +0.8/-1	97.5 +0.8/-1.1	97.5 +0.8/-1.1	97.5 +0.8/-1.1 at 9 yr		
5534	CapSure Z	Atrial	Feb-96	264	6	6	12,959	98.3 +1.1/-2.7	97.8 +1.3/-3	97.8 +1.3/-3	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5 at 78 mo							
5554	CapSure Z Novus	Atrial	Jun-98	344	43	4	15,325	100.0	99.2 +0.6/-2.4	98.7 +0.9/-2.6	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3 at 78 mo							
5568	CapSureFix	Atrial	Jan-97	1,053	146	11	39,624	99.8 +0.1/-0.7	99.3 +0.4/-0.9	99.3 +0.4/-0.9	99.3 +0.4/-0.9	98.5 +0.9/-1.9	97.5 +1.3/-2.8	97.5 +1.3/-2.8	97.5 +1.3/-2.8	97.5 +1.3/-2.8					
5592	CapSure SP Novus	Atrial	Jun-98	672	129	5	30,017	99.7 +0.2/-1.1	99.3 +0.4/-1.3	99.3 +0.4/-1.3	98.9 +0.7/-1.6	98.9 +0.7/-1.6	98.9 +0.7/-1.6	98.9 +0.7/-1.6	98.9 +0.7/-1.6	98.9 +0.7/-1.6 at 99 mo					
5594	CapSure SP Novus	Atrial	Jun-01	21	12	0	1,422	100.0 at 0 mo													
6940	CapSureFix	Atrial	Oct-98	816	95	10	43,112	99.7 +0.2/-0.8	99.6 +0.3/-1	98.3 +0.8/-1.5	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6 at 126 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
3830	SelectSecure	Aug-05	20,100	16,400	2	0	7	3
4023	CapSure SP	Aug-91	41,100	8,000	14	0	4	2
4024	CapSure SP	Oct-91	221,300	45,600	29	0	147	8
4033	CapSure Z	Not US released	NA	NA	0	0	0	0
4067	CapSureFix	Jan-97	1,000	200	1	0	0	0
4068	CapSureFix	Mar-96	124,300	33,700	41	0	125	5
4073	CapSure Sense	Jun-02	700	300	0	0	0	0
4074	CapSure Sense	Jun-02	82,200	52,600	1	0	14	1
4076	CapSureFix Novus	Feb-04	349,100	271,600	17	1	14	16
4092	CapSure SP Novus	Sep-98	169,200	80,900	7	0	31	1
4523	CapSure SP	Aug-91	11,200	2,600	1	0	2	1
4524	CapSure SP	Oct-91	101,300	26,100	1	0	49	3
4533	CapSure Z	Not US released	NA	NA	0	0	0	0
4558M	Screw-in	Nov-94	19,900	4,300	1	0	18	0
4568	CapSureFix	Jan-97	69,600	24,400	3	0	49	1
4574	CapSure Sense	Jun-02	53,900	37,200	5	0	2	0
4592	CapSure SP Novus	Oct-98	82,300	41,700	6	0	11	1
5023, 5023M	CapSure SP	Nov-88	9,800	2,200	5	0	0	0
5024, 5024M	CapSure SP	Mar-90	200,700	46,400	51	1	48	9
5033	CapSure Z	Feb-96	2,300	500	1	0	0	0
5034	CapSure Z	Feb-96	56,000	13,600	12	0	12	3
5054	CapSure Z Novus	Jun-98	93,000	42,200	8	1	17	3
5068	CapSureFix	Jan-97	102,800	32,200	35	2	51	4
5072	SureFix	Jun-98	9,700	4,300	2	0	6	0
5076	CapSureFix Novus	Aug-00	1,349,300	873,500	284	0	291	86
5086MRI	CapSureFix Novus	Feb-11	17,700	17,500	0	0	0	0
5092	CapSure SP Novus	Jun-98	126,200	60,200	6	0	32	1
5524, 5524M	CapSure SP	Mar-90	59,800	17,100	11	1	11	2
5534	CapSure Z	Feb-96	26,200	7,500	3	0	5	2
5554	CapSure Z Novus	Jun-98	60,000	30,000	7	0	15	1
5568	CapSureFix	Jan-97	85,200	49,500	7	0	24	6
5592	CapSure SP Novus	Jun-98	32,400	18,500	3	0	3	0
5594	CapSure SP Novus	Jun-01	14,300	9,700	4	0	6	1
6940	CapSureFix	Oct-98	25,300	7,900	11	0	17	1

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
3830	SelectSecure	20,100	6	1	26	12	1	1	1	0	0	2
4023	CapSure SP	41,100	0	1	3	4	1	1	3	0	1	2
4024	CapSure SP	221,300	12	11	50	108	0	15	1	7	2	21
4033	CapSure Z	2,300	0	0	0	0	0	0	0	0	0	0
4067	CapSure Fix	1,000	1	0	0	0	0	0	0	0	0	0
4068	CapSure Fix	124,300	4	3	31	25	0	5	1	4	1	4
4073	CapSure Sense	700	0	0	0	0	0	0	0	0	0	0
4074	CapSure Sense	82,200	5	1	17	22	0	1	0	3	0	1
4076	CapSure Fix Novus	349,100	30	4	98	53	5	15	1	6	4	8
4092	CapSure SP Novus	169,200	2	4	18	24	0	0	1	3	0	2
4523	CapSure SP	11,200	0	0	2	2	0	1	0	0	0	0
4524	CapSure SP	101,300	0	2	24	17	0	4	2	1	0	14
4533	CapSure Z	NA	0	0	0	0	0	0	0	0	0	0
4558M	Screw-in	19,900	2	0	2	2	0	1	0	2	1	1
4568	CapSure Fix	69,600	3	1	4	7	0	0	0	3	0	1
4574	CapSure Sense	53,900	0	2	19	9	1	4	0	0	0	3
4592	CapSure SP Novus	82,300	0	0	22	7	2	1	0	0	0	2
5023, 5023M	CapSure SP	9,800	0	1	2	0	0	0	0	0	0	0
5024, 5024M	CapSure SP	200,700	10	9	33	49	1	9	6	3	3	14
5033	CapSure Z	2,300	0	0	1	0	0	0	0	0	0	0
5034	CapSure Z	56,000	3	3	16	32	0	3	2	0	0	12
5054	CapSure Z Novus	93,000	1	2	12	20	0	0	1	0	0	8
5068	CapSure Fix	102,800	13	4	22	34	1	5	1	1	0	6
5072	SureFix	9,700	0	0	2	1	0	0	0	0	0	1
5076	CapSure Fix Novus	1,349,300	120	9	399	179	21	36	5	14	12	29
5086MRI	CapsureFix Novus	17,700	25	0	28	9	1	4	1	0	3	0
5092	CapSure SP Novus	126,200	5	1	29	25	1	5	4	0	3	9
5524, 5524M	CapSure SP	59,800	1	3	20	13	0	9	2	0	0	10
5534	CapSure Z	26,200	0	0	6	3	0	2	0	0	2	4
5554	CapSure Z Novus	60,000	0	1	30	22	0	1	0	0	0	3
5568	CapSure Fix	85,200	6	0	23	16	1	4	1	1	1	3
5592	CapSure SP Novus	32,400	0	0	20	4	0	1	0	0	0	2
5594	CapSure SP Novus	14,300	0	1	6	0	1	0	0	0	0	2
6940	CapSure Fix	25,300	0	1	6	1	0	0	0	1	0	0

Report Cutoff Date: July 31, 2011

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
3830	SelectSecure	Transvenous V or A Screw-In	Polyurethane/Silicone (55D,4719)	MP35N 5 Filars/ Cable	1.8 mm Helix/Steroid	IS-1 BI
4023	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4 Filars	Porous Platinized/ Steroid	IS-1 UNI
4024	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4033	CapSure Z	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4067	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
4068	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4073	CapSure Sense	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 5 Filars	TiN Coated Platinum Iridium/Steroid	IS-1 UNI
4074	CapSure Sense	Transvenous Ventricular Tines	Polyurethane/Silicone (55D, 4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium/ Steroid	IS-1 BI
4076	CapSureFix Novus	Transvenous V or A Screw-In	Polyurethane/Silicone (55D, 4719)	MP35N 4/6 Filars	TiN Coated Platinum Alloy/Steroid	IS-1 BI
4092	CapSure SP Novus	Transvenous Ventricular Tines	Polyurethane/Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/ Steroid	IS-1 BI
4523	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	Porous Platinized/ Steroid	IS-1 UNI
4524	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4533	CapSure Z	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4558M	Screw-In	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4568	CapSureFix	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4574	CapSure Sense	Transvenous Atrial -J Tines	Polyurethane/Silicone (55D,4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium	IS-1 BI
4592	CapSure SP Novus	Transvenous Atrial-J Tines	Polyurethane/Silicone (55D/4719)	MP35N 6/3 Filars	Porous Platinized/ Steroid	IS-1 BI
5023, 5023M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm (5023) IS-1 UNI (5023M)
5024, 5024M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile (5024) IS-1 BI (5024M)
5033	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
5034	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5054	CapSure Z Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	CapSure Z Porous/Platinized/ Steroid	IS-1 BI
5068	CapSureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5072	SureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/5 Filars	1.8 mm Helix/Steroid	IS-1 BI
5076	CapSureFix Novus	Transvenous V or A Screw-In	Silicone (4719)	MP35N 4/6 Filars	Porous Platinized/ Steroid	IS-1 BI
5086MRI	CapsureFix Novus	Transvenous A or V Screw-in	Silicone	MP35N	Titanium nitride coated platinum alloy	IS-1 BI
5092	CapSure SP Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5524, 5524M	CapSure SP	Transvenous Atrial-J Tines	Silicone	MP35N 6/5 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile (5524) IS-1 BI (5524M)

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Pacing Leads continued

Reference Chart continued

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
5534	CapSure Z	Transvenous Atrial-J Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	CapSure Z Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	CapSure Z Porous Platinized/ Steroid	IS-1 BI
5568	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5592	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5594	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Platinized Platinum/ Steroid	IS-1 BI
6940	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Epi/Myocardial Pacing Leads

4951, 4951M Spectraflex

Product Characteristics

US Market Release	Oct-81	Serial Number Prefix	TF or LBJ
Registered US Implants	11,700	Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Estimated Active US Implants	2,600	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

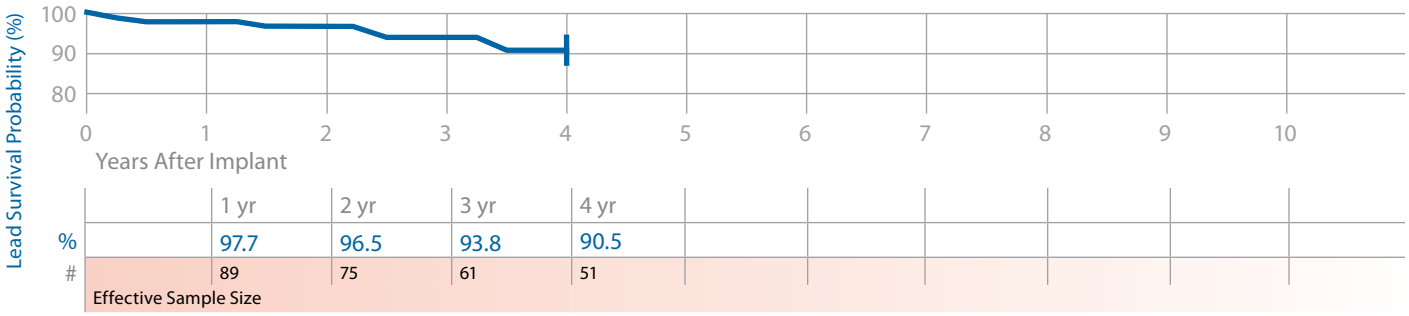
Conductor Fracture	36
Crimp/Weld/Bond	0
Insulation Breach	8
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	179
Cumulative Months of Follow-Up	5,924
Number of Leads Active in Study	4

Qualifying Complications 14 Total

Failure to Capture	7	Insulation (not further defined)	1
Conductor Fracture	1	Insulation (ESC)	1
Failure to Sense	3	Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr
%	97.7	96.5	93.8	90.5
#	89	75	61	51

Effective Sample Size

4965 CapSure Epi

Product Characteristics

US Market Release	Sep-96	Serial Number Prefix	LBT
Registered US Implants	19,700	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	9,300	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

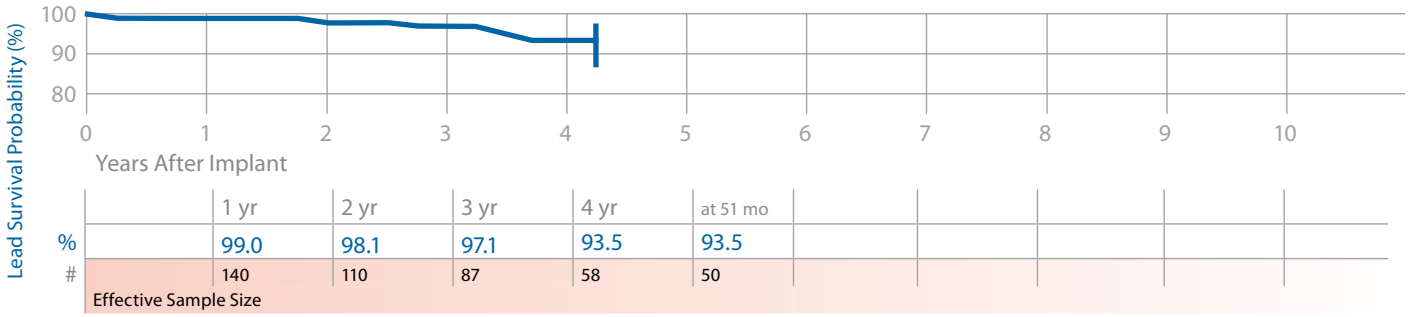
Conductor Fracture	126
Crimp/Weld/Bond	1
Insulation Breach	31
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	219
Cumulative Months of Follow-Up	7,190
Number of Leads Active in Study	35

Qualifying Complications 8 Total

Failure to Capture	2	Oversensing	2
Conductor Fracture	3		
Failure to Sense	1		



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	99.0	98.1	97.1	93.5	93.5
#	140	110	87	58	50

Effective Sample Size

Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

Product Characteristics

US Market Release	Sep-99	Serial Number Prefix	LEN
Registered US Implants	22,800	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	14,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

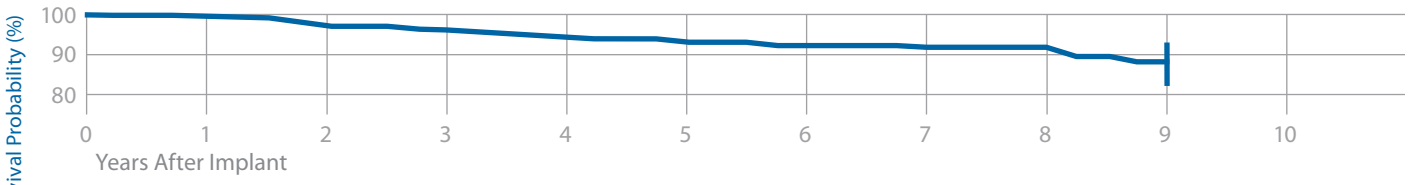
Conductor Fracture	19
Crimp/Weld/Bond	0
Insulation Breach	6
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	716
Cumulative Months of Follow-Up	33,110
Number of Leads Active in Study	386

Qualifying Complications 43 Total

Failure to Capture	18
Conductor Fracture	9
Failure to Sense	3
Insulation (not further defined)	2
Impedance Out of Range	3
Oversensing	7
Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.4	97.4	96.3	94.3	93.1	92.6	91.8	91.8	88.2
#	555	449	371	275	203	150	115	80	47

Effective Sample Size

5071 Screw-in

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Registered US Implants	40,700	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated Active US Implants	14,500	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

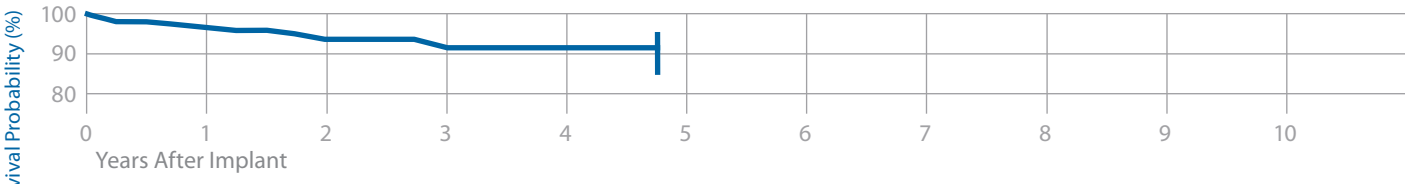
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	272
Cumulative Months of Follow-Up	7,533
Number of Leads Active in Study	54

Qualifying Complications 13 Total

Failure to Capture	11
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	96.6	94.1	91.7	91.7	91.7
#	134	91	72	63	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
4951, 4951M	Spectraflex	Oct-81	179	4	14	5,924	97.7 +1.6/-4.8	96.5 +2.2/-5.8	93.8 +3.5/-7.5	90.5 +4.8/-9.1								
4965	CapSure Epi	Sep-96	219	35	8	7,190	99.0 +0.7/-3.0	98.1 +1.3/-4.0	97.1 +1.9/-4.9	93.5 +3.5/-7.2	93.5 +3.5/-7.2 at 51 mo							
4968	CapSure Epi	Sep-99	716	386	43	33,110	99.4 +0.4/-1.0	97.4 +1.1/-1.7	96.3 +1.3/-2.1	94.3 +1.8/-2.6	93.1 +2.2/-3.0	92.6 +2.3/-3.3	91.8 +2.6/-3.7	91.8 +2.6/-3.7	88.2 +4.1/-6.2 at 9 yr			
5071	Screw -in	Dec-92	272	54	13	7,533	96.6 +1.8/-3.6	94.1 +2.8/-5.1	91.7 +3.7/-6.5	91.7 +3.7/-6.5	91.7 +3.7/-6.5 at 57 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

Epi/Myocardial Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
4951, 4951M	Spectraflex	Oct-81	11,700	2,600	36	0	8	6
4965	CapSure Epi	Sep-96	19,700	9,300	126	1	31	0
4968	CapSure Epi	Sep-99	22,800	14,300	19	0	6	1
5071	Screw-in	Dec-92	40,700	14,500	12	0	2	0

Source: Returned Product Analysis
Data as of July 31, 2011

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure To Sense	Impedance Abnormal	Extracardiac Stimulation
4951, 4951M	Spectraflex	11,700	0	1	0	8	0	0	0	0
4965	CapSure Epi	19,700	0	1	0	4	0	2	3	0
4968	CapSure Epi	22,800	1	0	3	9	1	0	1	0
5071	Screw-in	40,700	1	0	1	22	0	0	2	1

Model Number	Family	Estimated US Implants	Insulation Breach	Unspecified
4951, 4951M	Spectraflex	11,700	0	1
4965	CapSure Epi	19,700	0	3
4968	CapSure Epi	22,800	1	0
5071	Screw-in	40,700	0	1

Report Cutoff Date: July 31, 2011

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4951, 4951M	Spectraflex	Myocardial Stab-In V or A/Peds	Polyurethane (80A)	MP35N 4 Filars	Barb	5 mm (4951) IS-1 UNI (4951M)
4965	CapSure Epi	Epicardial Suture V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 UNI
4968	CapSure Epi	Epicardial Suture V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 B1
5071	Screw-in	Myocardial Screw-In Ventricular	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI

Report Cutoff Date: July 31, 2011

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

VDD Single Pass Pacing Leads

5032 CapSure VDD

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCL, LCN, LCM
Registered US Implants	5,400	Type and/or Fixation	Transvenous, Atr-Vent,Tines
Estimated Active US Implants	1,300	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	7
Other	0

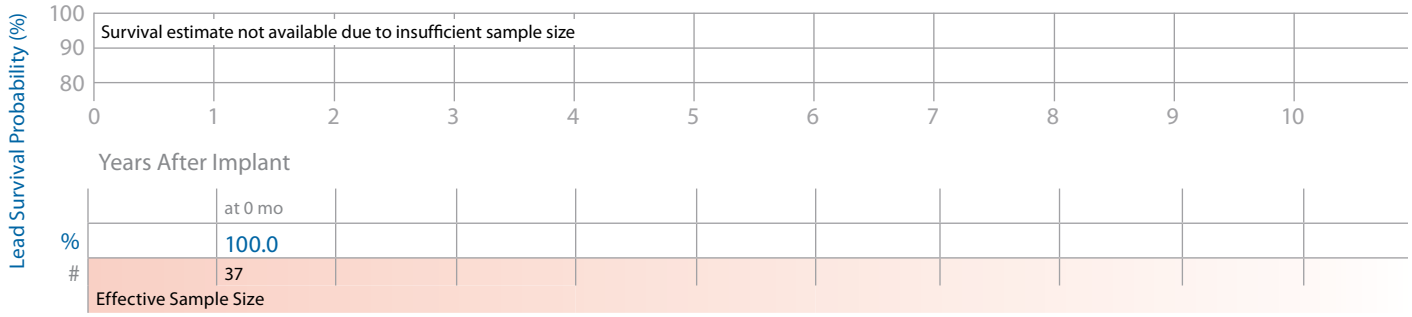
System Longevity Study Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,683
Number of Leads Active in Study	0

Qualifying Complications

1 Total

Failure to Sense	1



	at 0 mo
%	100.0
#	37

Effective Sample Size

5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Registered US Implants	8,800	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated Active US Implants	3,600	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	1
Other	0

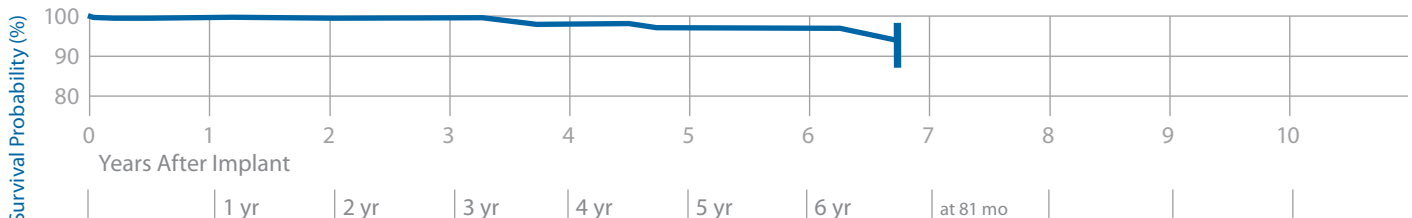
System Longevity Study Results

Number of Leads Enrolled in Study	553
Cumulative Months of Follow-Up	20,512
Number of Leads Active in Study	50

Qualifying Complications

6 Total

Failure to Capture	1
Conductor Fracture	3
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	99.8	99.8	99.8	98.8	98.1	98.1	94.9
#	419	307	218	172	134	81	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

VDD Single Pass Pacing Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	Qualifying Complications	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
5032	CapSure VDD	Mar-96	38	0	1	1,683	100.0 at 0 mo									
5038	CapSure VDD-2	Sep-98	553	50	6	20,512	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4	98.8 +0.8/-2.8	98.1 +1.2/-3.3	98.1 +1.2/-3.3	94.9 +3.1/-7.5 at 81 mo			

Source: System Longevity Study
Data as of July 31, 2011

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
5032	CapSure VDD	Mar-96	5,400	1,300	7	0	7	0
5038	CapSure VDD-2	Sep-98	8,800	3,600	4	0	1	0

Source: Returned Product Analysis
Data as of July 31, 2011

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Lead Dislodgement	Failure to Capture	Failure to Sense	Extracardiac Stimulation
5032	CapSure VDD	5,400	1	3	1	0
5038	CapSure VDD-2	8,800	1	1	0	1

Report Cutoff Date: July 31, 2011

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
5032	CapSure VDD	Transvenous V and A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI
5038	CapSure VDD-2	Transvenous V and A Tines	Silicone	MP35N	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2011

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 CRDM 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 System Longevity Study. 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.

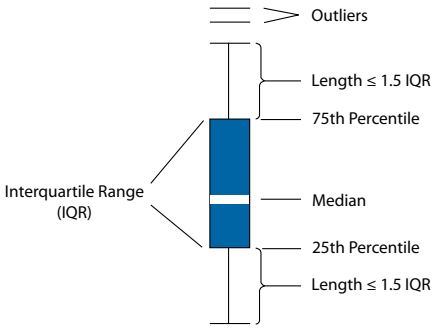
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide charge times that are short and consistent over the life of the product.

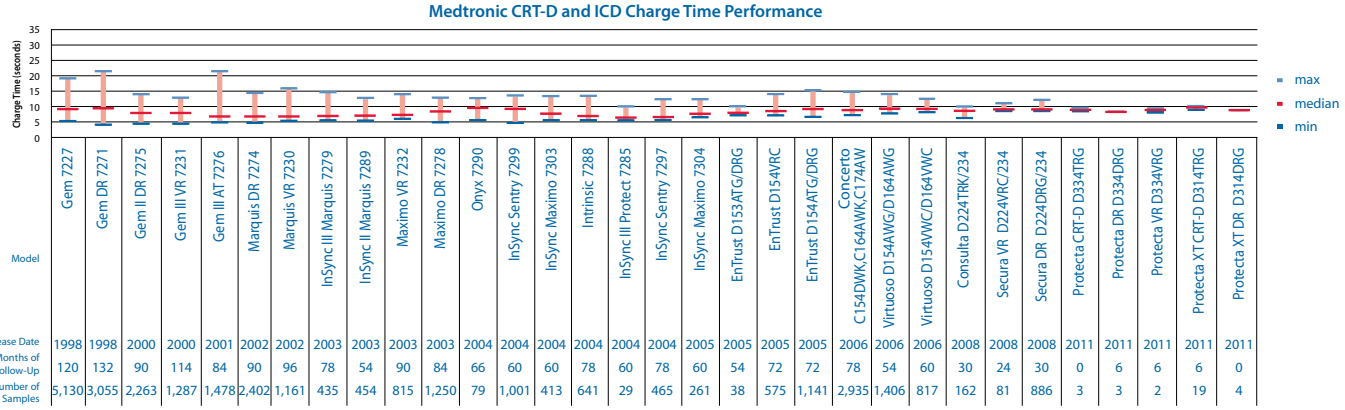
Data Presentation

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.

Results

The graph below shows the overall maximums, minimums, and medians for Medtronic ICD and CRT-D products, beginning with the 7221 Micro Jewel.

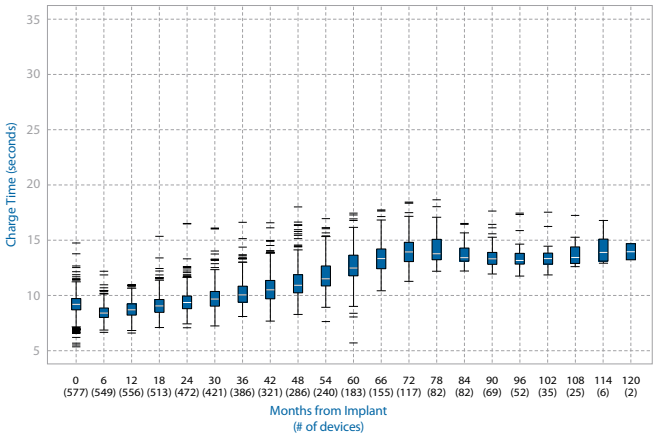




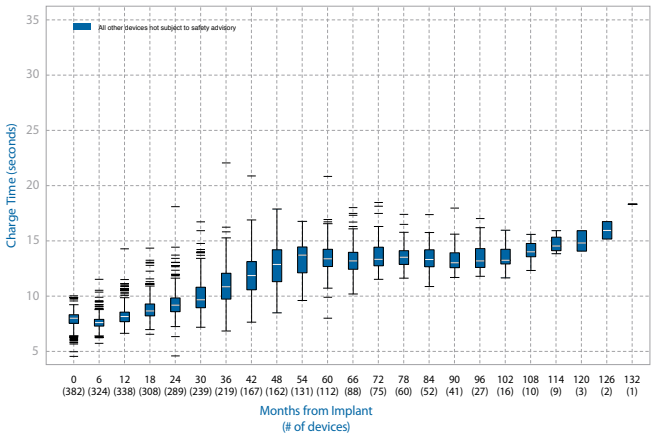
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

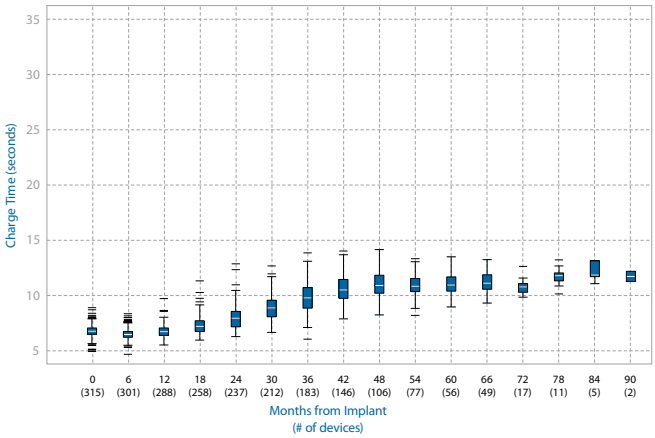
7227 GEM Charge Time



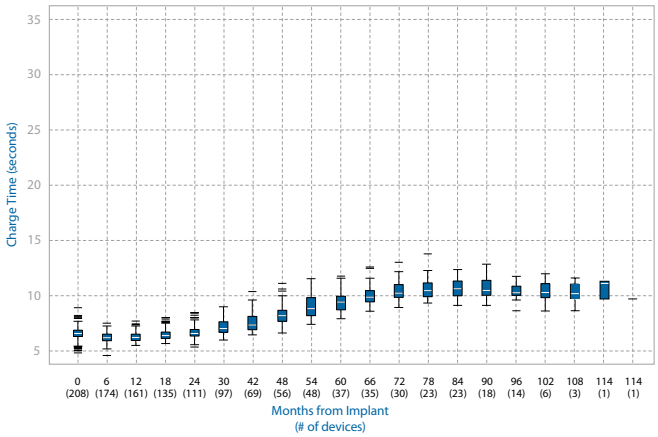
7271 GEM DR Charge Time



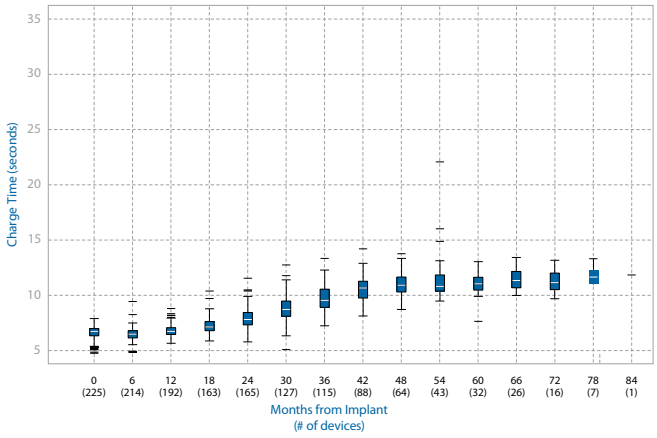
7275 GEM III DR Charge Time



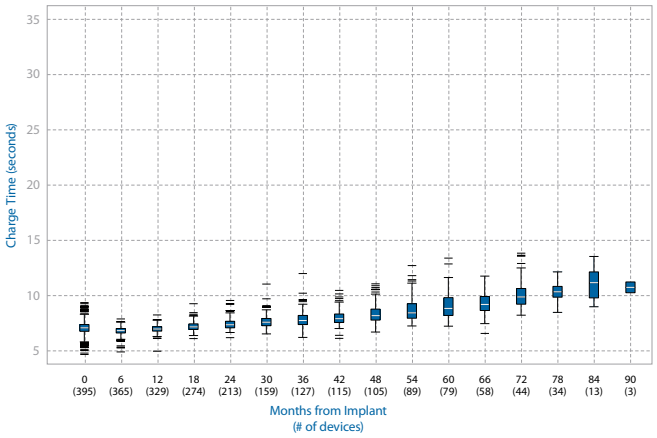
7231 GEM III VR Charge Time



7276 GEM III AT Charge Time



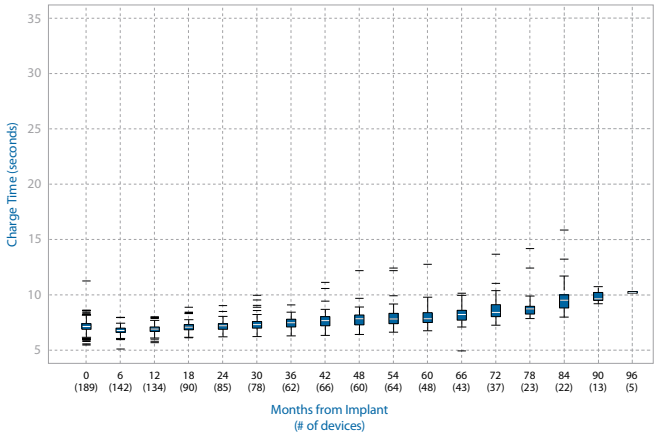
7274 Marquis DR Charge Time



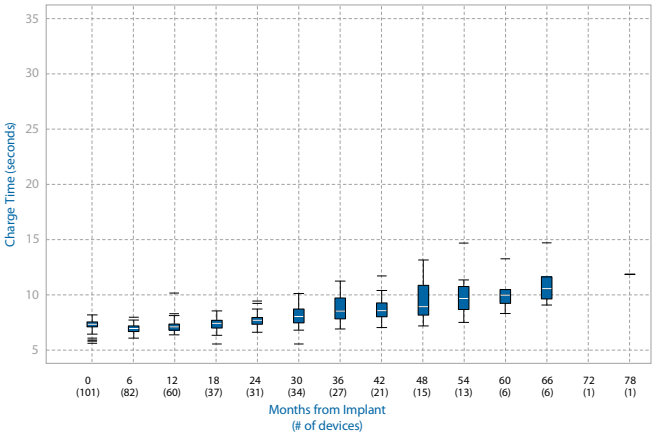
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

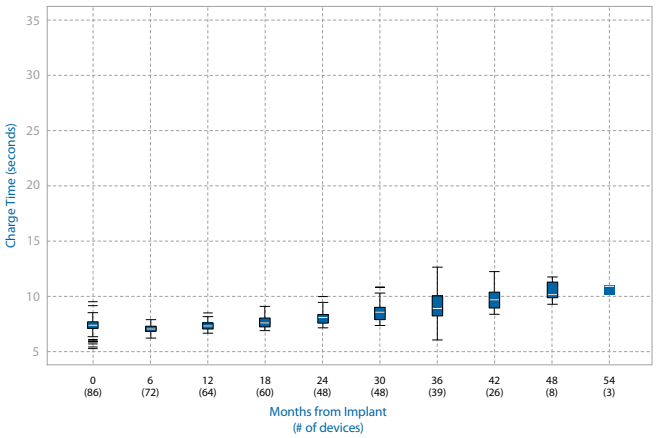
7230 Marquis VR Charge Time



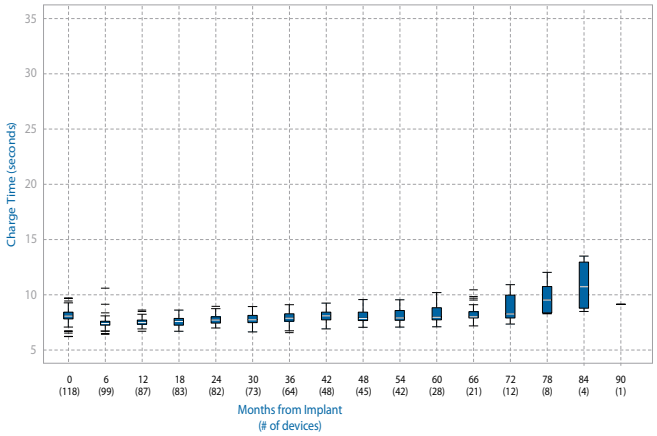
7279 InSync III Marquis Charge Time



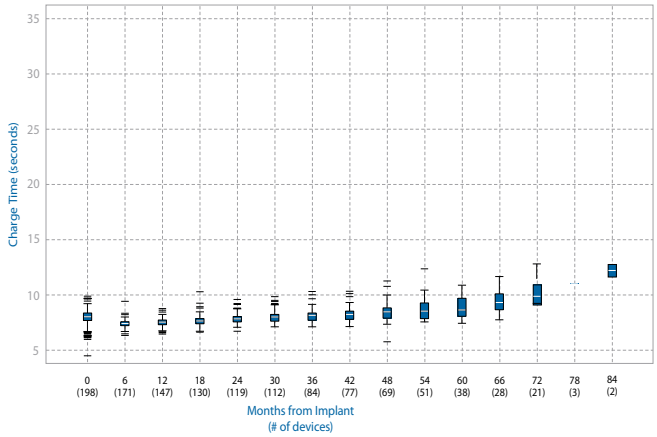
7289 InSync II Marquis Charge Time



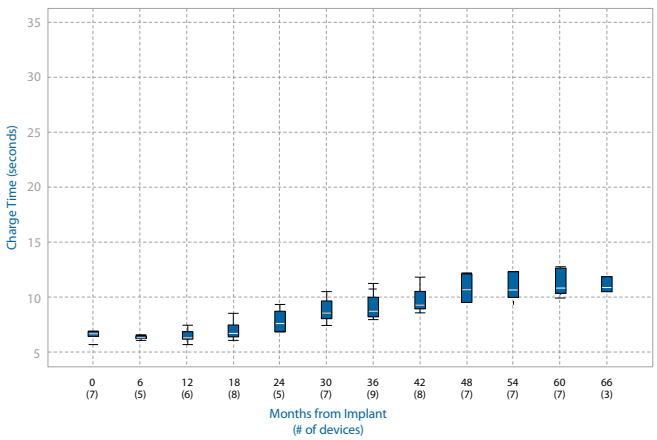
7232 Maximo VR Charge Time



7278 Maximo DR Charge Time



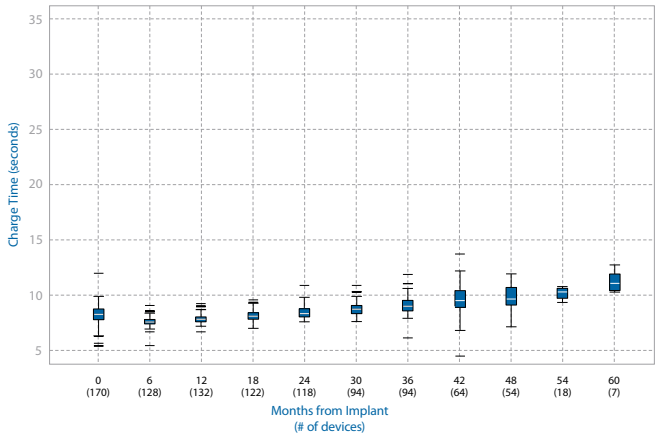
7290 Onyx Charge Time



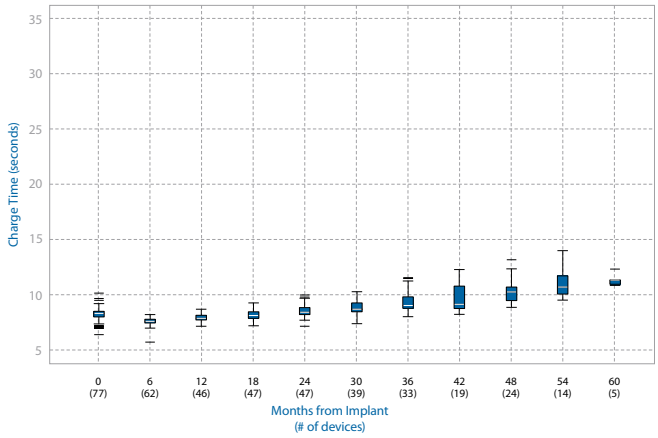
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

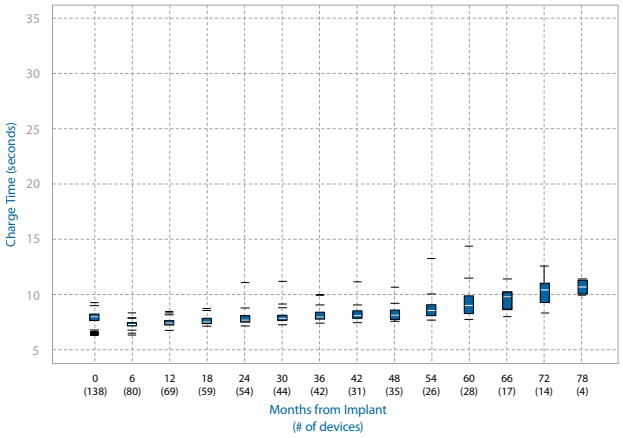
7299 InSync Sentry Charge Time



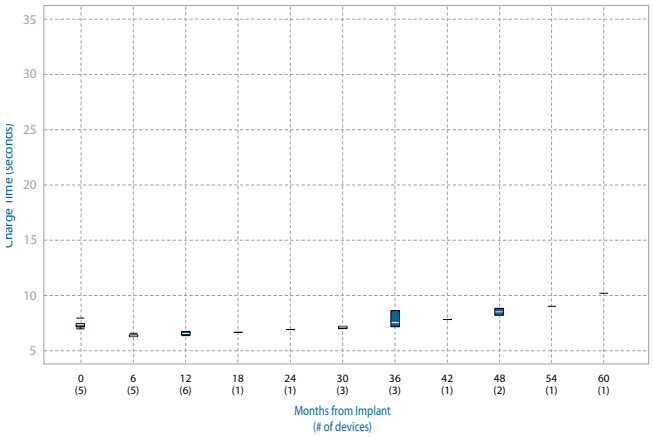
7303 InSync Maximo Charge Time



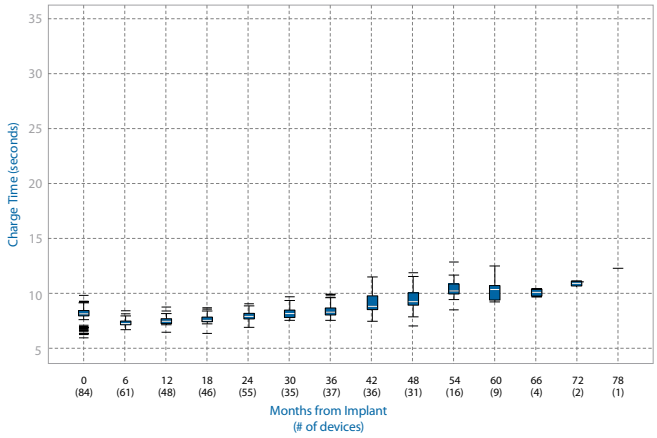
7288 Intrinsic Charge Time



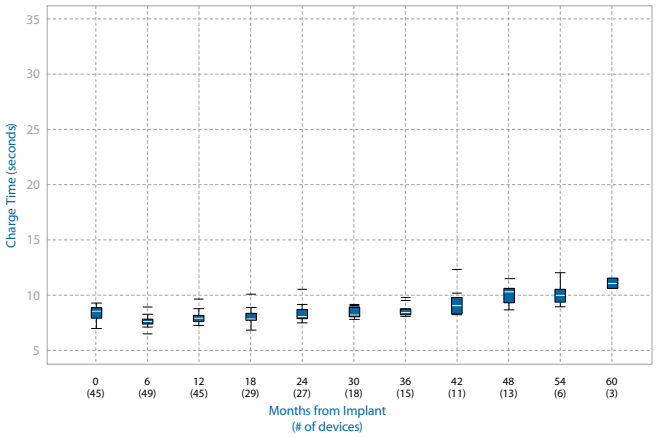
7285 InSync III Protect Charge Time



7297 InSync Sentry Charge Time



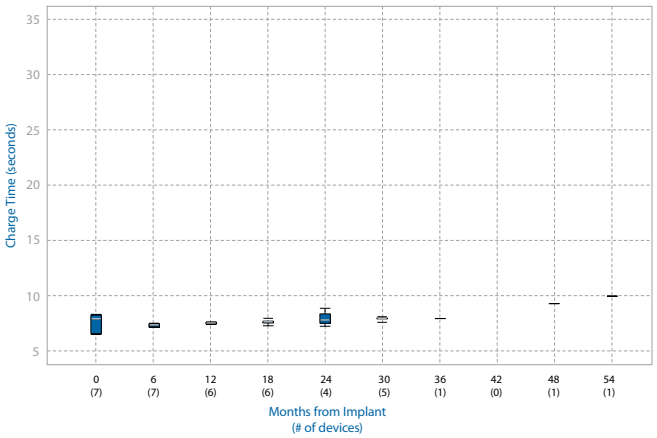
7304 InSync Maximo Charge Time



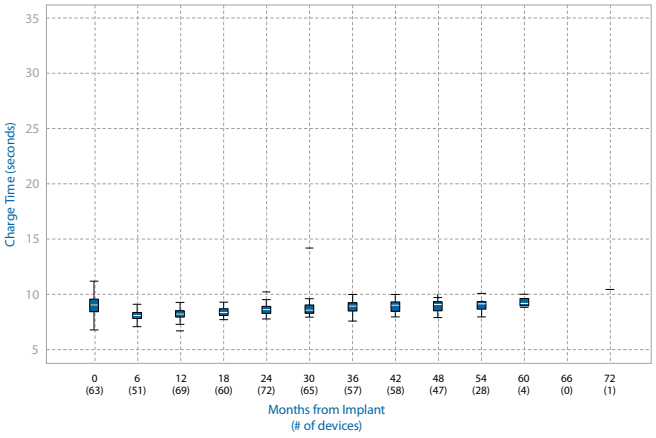
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

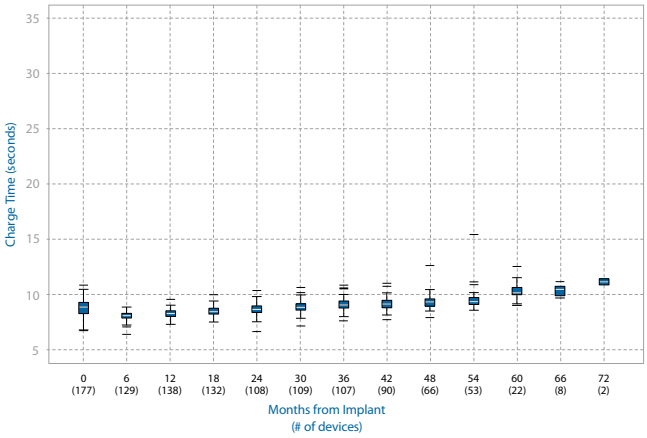
D153ATG, DRG EnTrust Charge Time



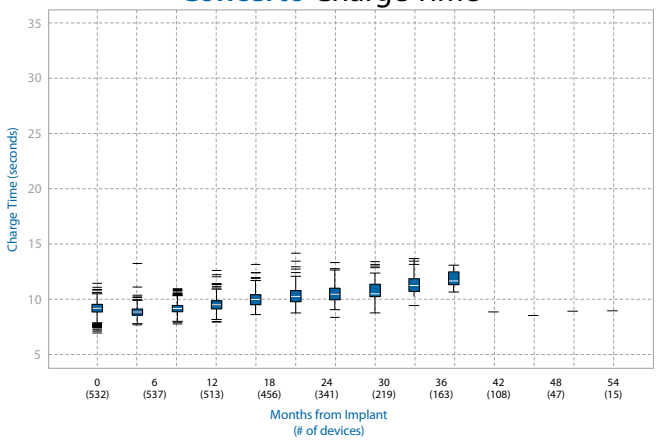
D154VRC EnTrust Charge Time



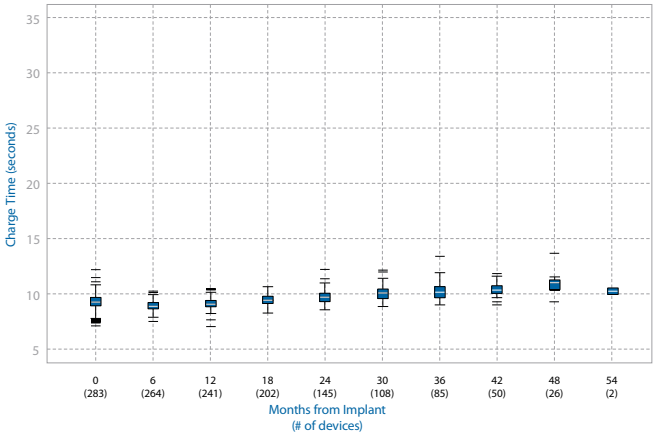
D154ATG, DRG EnTrust Charge Time



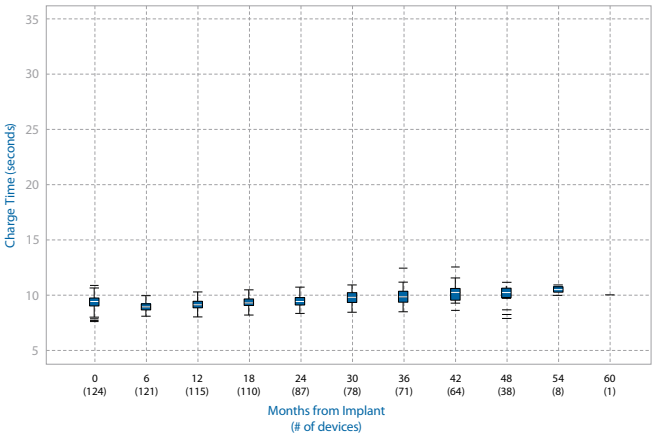
C154DWK, C164AWK, C174AWK Concerto Charge Time



D154AWG, D164AWG Virtuoso Charge Time



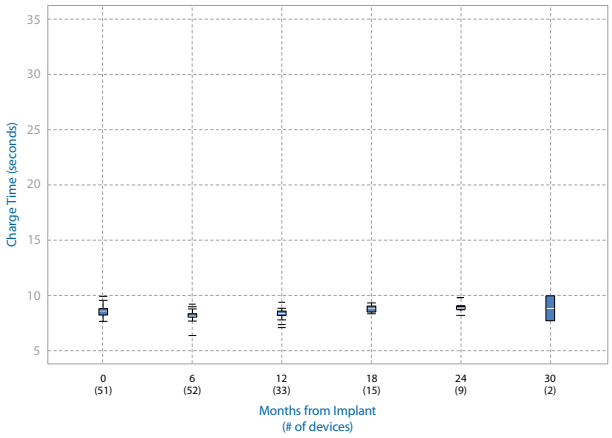
D154VWC, D164AWG Virtuoso Charge Time



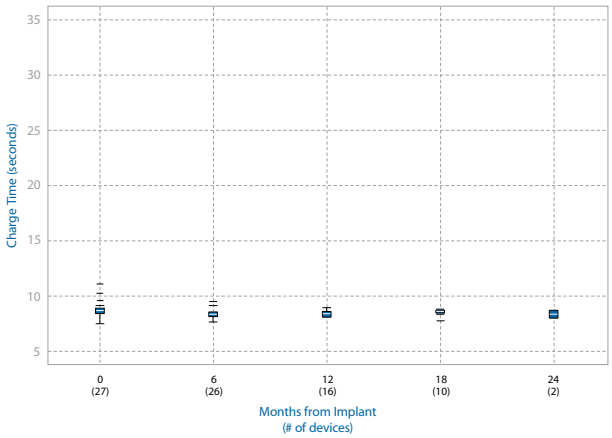
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

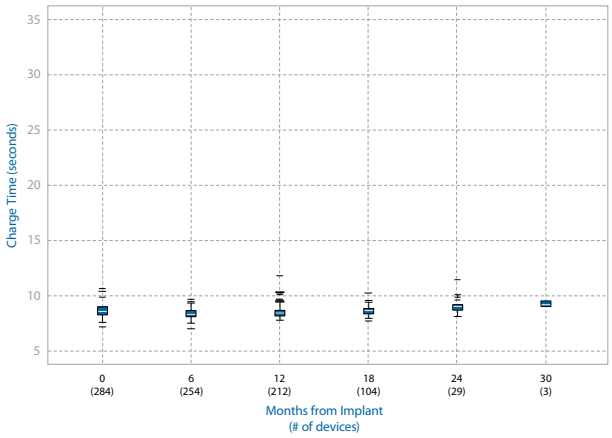
D224TRK/234 Consulta Charge Time



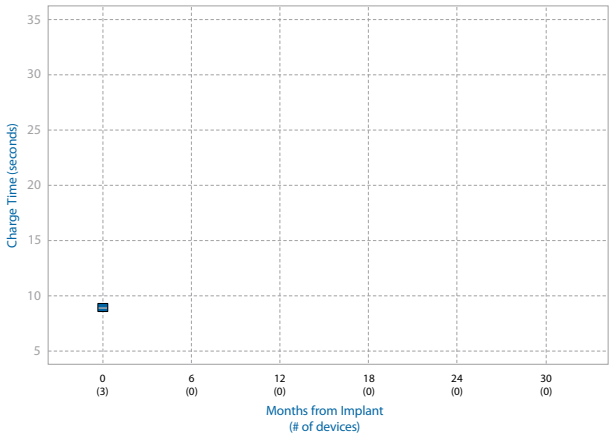
D224VRC/234 Secura VR Charge Time



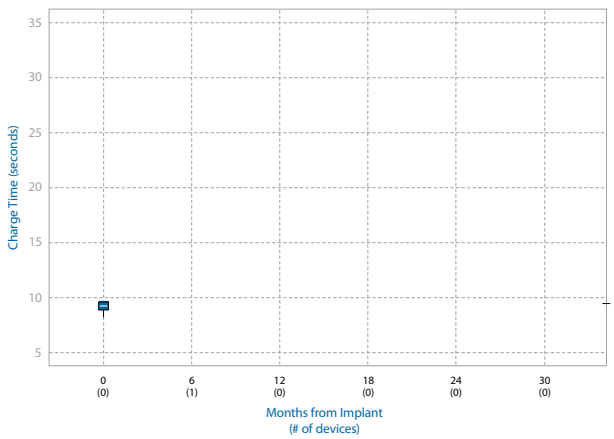
D224DRG/234 Secura DR Charge Time



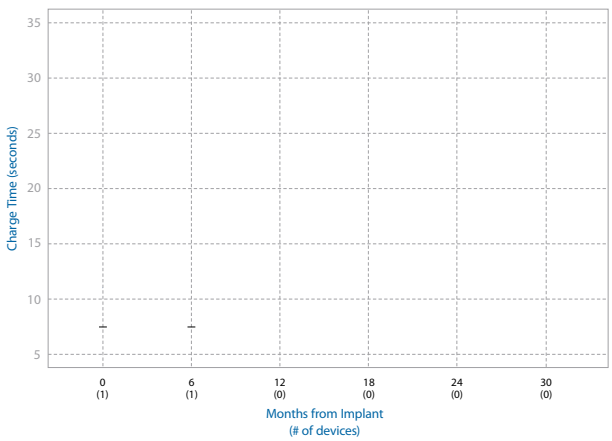
CRT-D D334TRG Protecta Charge Time



DR D334DRG Protecta Charge Time



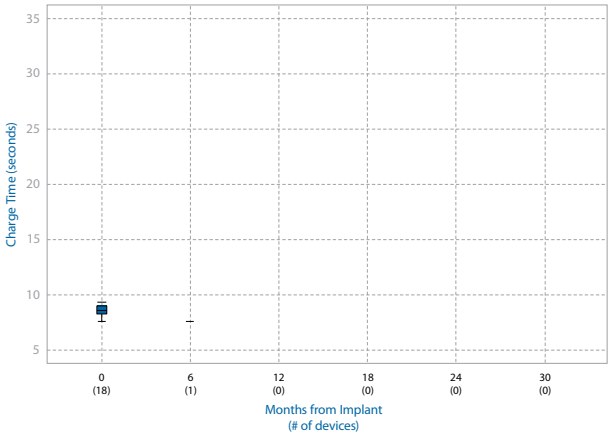
VR D334VRG Protecta Charge Time



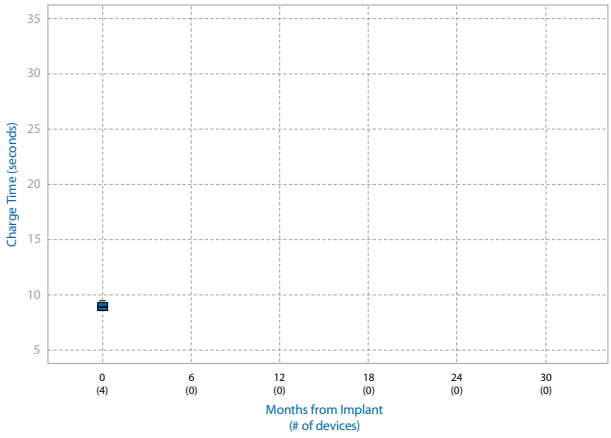
Source: System Longevity Study
Data as of July 31, 2011

ICD and CRT-D Charge Time Performance continued

XT CRT-D D314TRG Protecta Charge Time



XT DR D314DRG Protecta Charge Time



ICD Charge Times

Source: System Longevity Study
Data as of July 31, 2011

Advisories

EnRhythm Pacemakers

Original Date of Advisory: February 2010

Low Battery Voltage Displayed at Device Interrogation

Product

All EnRhythm pacemakers.

Advisory

Two specific battery issues with EnRhythm pacemakers have been identified and both are addressed by a Medtronic software update.

First Issue
As of 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. The lower voltage measurement caused confusion and occasionally resulted in unnecessary explants.

Medtronic's investigation has shown that none of these reports resulted in loss of therapy. Importantly, the ERI notification, which uses the nightly battery measurement, is unaffected and accurate. Medtronic has identified the root cause as higher than expected battery resistance.

Medtronic's internal testing has shown that there is 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 eliminates this risk.

Second Issue
Through internal accelerated testing, Medtronic has identified a second issue that projects battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion. 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 will eliminate this issue by changing ERI criteria.

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 2.69 V, whichever comes sooner.

Battery Issue	Software Update
Battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion	Changed ERI battery voltage threshold from 2.59 V to 2.81 V 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 5,000 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.

EnRhythm Pacemakers
Original Date of Advisory: February 2010

continued

Status Update

As of August 18, 2011, 334 devices out of approximately 142,000 devices worldwide have been confirmed as having exhibited an advisory related event. Approximately 106,000 remain implanted.

[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.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)	The software update eliminates any potential future risk of the two battery issues described above by changing the ERI criteria.
All EnRhythm pacemakers (**142,000** Worldwide).	**334** Worldwide	**106,000** Worldwide	**0.24%**	

Concerto CRT-D and Virtuoso ICD

Original Date of Advisory: September 2009

Potential Reduced Device Longevity

Product

A subset of Concerto CRT-D and Virtuoso ICD devices may not meet expected device longevity. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

Advisory

A subset of Concerto CRT-D and Virtuoso ICD devices may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation. This issue may present in the affected devices as reaching the Recommended Replacement Time (RRT) earlier than projected. This issue does not compromise device functionality or affect therapy delivery.

Based on information from returned devices, Medtronic expects that affected devices will continue to provide at least 3 months of normal device function between RRT and End of Service (EOS) as described in device labeling.

A total of 8,900 devices worldwide are affected by this advisory. An estimated 6,300 of these devices were active at the time of the original advisory communication.

Concerto and Virtuoso devices in the affected subset were manufactured primarily in 2006 and can be traced to a specific subset of low voltage capacitors.

Patient Management Recommendations

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients with devices in the affected subset:

Physicians should continue routine follow-up sessions at least every 3 months in accordance with product labeling.

Physicians should verify that the Low Battery Voltage RRT alert is programmed to "On-High." This provides an audible, alternating tone when the device reaches RRT. These devices are shipped with this alert programmed nominally to "On-High."

Physicians may consider monitoring patients through CareLink. The CareLink home monitor can be used to automatically notify the clinician when the device reaches RRT.

Status Update

As of August 18, 2011, 3,601 devices out of approximately 8,900 devices in this subset worldwide have been confirmed as having exhibited this capacitor degradation. Out of the initial advisory population of 8,900 worldwide, approximately 1,000 remain implanted. Approximately 800 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)
8,900 Implanted Worldwide (**7,000** United States)	**3,601** Worldwide (**3,097** United States)	**1,000** Worldwide (**800** United States)	**40%** Worldwide (**44%** United States)

Kappa 600/700/900 Pacemakers
Sigma 100/200/300 Pacemakers

Original Date of Advisory: May 2009

Potential Separation of Interconnect Wires (2009)

Product

A specific subset of Kappa and Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

Advisory Population

Specific subsets of Kappa and Sigma series pacemakers may fail at a higher than expected rate due to separation of wires that connect the electronic circuit to other pacemaker components (e.g., battery, connector). This may present clinically as loss of rate response, premature battery depletion, loss of telemetry, or no output.

Some patients, whose devices experience a wire separation resulting in a loss of pacing output, will experience a return of bradycardia symptoms (e.g., fainting or lightheadedness). In rare cases involving pacemaker dependent patients, loss of pacing output may result in death or serious injury.

Since 1997, there have been over 1.7 million Kappa and Sigma devices implanted worldwide. At the time of the original advisory communication, an estimated 15,200 Kappa and 6,100 Sigma devices affected by the advisory remained implanted and active. These devices were manufactured primarily between November 2000 and November 2002. Most of these devices have been implanted in patients for five years or longer and may be nearing normal elective replacement time.

There is no provocative testing that can predict which specific devices may fail, and no device programming can mitigate this issue if it occurs.

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 recommendations for patients:

- 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

Advisory Population

Patient management recommendations remain unchanged. As of August 18, 2011, Medtronic has observed 456 Kappa devices and 269 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.78% (Kappa) and 1.81% (Sigma) of the original affected implant population.

Four hundred nineteen (419) of the Kappa devices (0.72%) and 206 of the Sigma devices (1.38%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 37 Kappa devices (0.06%) and 63 Sigma devices (0.42%) 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.

As of May 2009, our modeling predicts failure rates due to this issue of 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime of those pacemakers still in service at that time.

Out of the initial advisory population of 58,300 Kappa devices and 14,900 Sigma devices worldwide, approximately 4,100 Kappa devices and 3,000 Sigma devices remain implanted. Of these, approximately 1,200 Kappa and 800 Sigma devices are in the United States.

Continued Vigilance

Included in the advisory communication was information about an additional subset of Kappa devices where we have observed a much lower rate of occurrence of this issue. Approximately 44,000 devices of this subset remain active. We have observed a failure rate of approximately 0.082% in this subset and our May 2009 modeling predicts a failure rate of 0.12% over the remaining device life of those pacemakers still in service at that time. After review with our Independent Physician Quality Panel, we do not recommend any specific actions for this group of devices. We will continue to monitor performance and inform you if any specific patient management recommendations are warranted.

continued

Kappa 600/700/900 Pacemakers

Sigma 100/200/300 Pacemakers
Original Date of Advisory: May 2009

Potential Separation of Interconnect Wires, continued

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 Population
Kappa Pacemakers				
58,300 Implanted Worldwide (est.) (**17,600** United States)	**419** Worldwide (**221** United States) with information indicating a clinical presentation. An additional **37** worldwide (**25** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**4,100** Worldwide (**1,200** United States)	**0.78%** Worldwide **1.40%** (United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**206** Worldwide (**43** United States) with information indicating a clinical presentation. An additional **63** worldwide (**15** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**3,000** Worldwide (**800** United States)	**1.81%** Worldwide **1.57%** (United States)	**4.8%**

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Potential Conductor Wire Fracture

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 www.medtronic.com/fidelis
  - 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]

Status Update

As of August 1, 2011, of the initial implant population of 205,600 in the United States, approximately 108,000 remain implanted. According to System Longevity Study results, lead survival is estimated to be 90.6% (+2.6/-3.6) at 66 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.

[1] Swerdlow C, Gunderson B, Ousdigian K, et al. Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads, *Circulation*. November 2008; 118:2122-2129.

[2] Wilkoff B, Love C, Byrd C, et al. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. *Heart Rhythm*. July 2009;6:1085-1104.

continued

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Potential Conductor Wire Fracture, continued

Keeping Physicians Informed

The most recent Sprint Fidelis lead performance information, including survival curves, physician letters, and subpopulation data, can be found at www.medtronic.com/fidelis and will be updated semi-annually. Medtronic's website also has a selected list of peer-reviewed publications related to Fidelis lead performance and extraction. Medtronic is committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1 (800) 723-4636 (US).

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Additional information about the Sprint Fidelis lead is available at: www.medtronic.com/fidelis.
205,600 (United States)	**4,868** (United States)	**108,000** (United States)	

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires (2005)

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Go to www.medtronic.com/CRDMProductPerformance 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 August 18, 2011, 694 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Three hundred forty-one (341) of the Sigma devices (0.85%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 353 Sigma devices (0.88%) 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.

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 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 9,000 remain implanted. Approximately 2,100 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 in Service as of May 2009
40,000 Implanted Worldwide (est.) (**9,900** United States)	**341** Worldwide (**69** United States) with information indicating a clinical presentation.An additional **353** Worldwide (**63** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**9,000** Worldwide (**2,100** United States)	**1.73%** Worldwide **1.30%** (United States)	**3.9%**

7274 Marquis DR **7278 Maximo DR** **7277 InSync Marquis** **7279 InSync III Marquis**
7230 Marquis VR **7232 Maximo VR** **7289 InSync II Marquis** **7285 InSync III Protect**

Original Date of Advisory: February 2005

Potential Premature Battery Depletion Due to Battery Short

Product

The specific subset of Marquis family ICD and CRT-D devices having batteries manufactured prior to December 2003 is affected. Devices manufactured with batteries produced after December 2003 are not affected. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

Advisory

Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. Battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism.

Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. As of February 2005, the rate of shorting was approximately 1 in 10,000 (0.01%); bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.

No provocative testing can predict which of these devices will experience this issue. Once a short occurs, battery depletion can take place within a few hours to a few days. After depletion the device ceases to function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

Patient Management Recommendations

We recommend you consider the following patient management options:

- Conduct quarterly (i.e., every 3 months) follow-up procedures
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care promptly
- Program Low Battery Voltage ERI Patient Alert to "On-High." This will result in an audible, alternating tone in the limited circumstances where a battery depletes slowly over a number of days. Data indicates most shorts will occur rapidly and will not be detected by this feature.
- Provide a hand-held magnet to patients to check device status and program the Low Battery Voltage ERI Patient Alert to "On-High." Device operation may be monitored periodically (e.g., daily) by patients placing the magnet over the device for 1-2 seconds. If the device is functional, a steady tone will sound for approximately 20 seconds. If no tone is heard, follow-up care should be sought promptly.

Status Update

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections. As of August 18, 2011, 191 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. One hundred fifteen (115) of these devices were returned from the United States.

Out of the initial advisory population of 87,000 worldwide, approximately 9,500 remain implanted. Approximately 8,300 of these are in the United States.

The Patient Management Recommendations set forth in the advisory remain unchanged.

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 Population
87,000 Implanted Worldwide (**76,000** United States)	**191** Worldwide (**115** United States)	**9,500** Worldwide (**8,300** United States)	**0.22%** Worldwide (**0.15%** United States)	Consistent with Medtronic projections, the observed rate of shorting may increase to between **0.2%** and **1.5%** over the second half of device life.

Kappa 600, 700 Dual Chamber (D, DR, and VDD) IPGs

Original Date of Advisory: March 15, 2002

Potential Fractured Power Supply Wires

Product

A specific subset of Kappa 700/600 dual chamber (D, DR, and VDD) implantable pulse generators has been identified by serial numbers. Hospitals and Physicians were notified. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

Advisory

As of March 15, 2002, Medtronic observed 53 related failures (0.02%) in over 255,000 Kappa 700/600 dual chamber (D, DR, and VDD) series devices sold worldwide. Medtronic voluntarily communicated this information to physicians because these failures had been observed in patients having submuscular implants.

These devices have presented with an electrical reset, intermittent output, or no output. Our investigation identified the root cause as fractured wires supplying power to the pacemaker. This has been directly correlated to submuscular placement of these devices. Submuscular implant locations (e.g., subpectoral, abdominal, etc.) can result in additional stress and repetitive flexing on the implanted device causing excessive fatigue on these wires. Of the estimated 4,000 devices implanted submuscular, approximately 200 (5%) may experience this failure. These stresses on the implanted device are unique to submuscular implant sites and do not exist with subcutaneous implants.

Patient Management Recommendations

While there is no provocative testing or time dependency that will predict which submuscular placed device will fail, certain electrical resets may be an indicator that a wire fracture has occurred. Normal electrical resets can occur as a result of electrosurgical procedures such as cautery and ablation or from defibrillation therapy. If none of the normal causes of electrical reset can be confirmed, or if a device serial number presents as "000000" following an electrical reset, this may be an indicator of a wire fracture.

For patients who have submuscular implants of devices within the designated serial number range and who are pacemaker dependent with no underlying rhythm, replacement of the device should be considered. Medtronic will provide the replacement device free of charge under the terms of its warranty program if a device is replaced in these patients.

For patients having subcutaneous implants, no change to your current patient care and follow-up is advised.

Status Update

Patient management recommendations remain unchanged. As of August 18, 2011, 337 out of approximately 180,000 distributed (0.18% incidence) Kappa family devices worldwide have been confirmed as having fractured power supply wires. One hundred seventy (170) of these devices were returned from the United States. Out of the initial implant population of 121,000 in the United States, less than 500 remain implanted.

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 Population
180,000 Active Worldwide at time of advisory (**121,000** United States)	**337** Worldwide (**170** United States)	**< 500** Worldwide (**< 500** United States)	**0.19%** Worldwide (**0.14%** United States)	**0.03%**

Minix and Minix ST IPGs

Original Date of Advisory: May 6, 1991

Potential Delayed Restoration of Permanent Settings

Product

All Models of the Minix and Minix ST families of implantable pulse generators

Advisory

Possibility of delayed restoration of permanent pacing mode and parameters, after the magnet or programming head is removed under certain conditions.

Patient Management Recommendations

To eliminate any potential risk associated with temporary programming, depress the INTERROGATE key and verify successful interrogation before moving the programming head away from the pulse generator. The delay condition can also be terminated by repositioning the programming head and depressing the EMERGENCY VVI key.

Status Update

Device performance related to this advisory continues to be within Medtronic's engineering projections. Patient management recommendations remain unchanged. Out of the initial implant population of 65,000 in the United States, approximately 3,000 remain implanted. The devices affected by this advisory are nearing the end of their expected longevity.

Initial Affected Population	Estimated Remaining Active Population	To eliminate any potential risk associated with temporary programming, depress the INTERROGATE key and verify successful interrogation before moving the programming head away from the pulse generator.
All Minix and Minix ST implantable pulse generators	**3,000**	

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.

The issue can be uniquely identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values. Medtronic has developed a method for clearing the ERI condition through the use of a specially configured programmer. There is no impact to the device functionality or longevity after this reset is complete.

Example

Two examples of images from the Medtronic 2090 Programmer are shown below. Example 1 shows what a normal ERI condition looks like. Example 2 shows what will be displayed if the ERI is triggered due to the measurement lock-up condition.

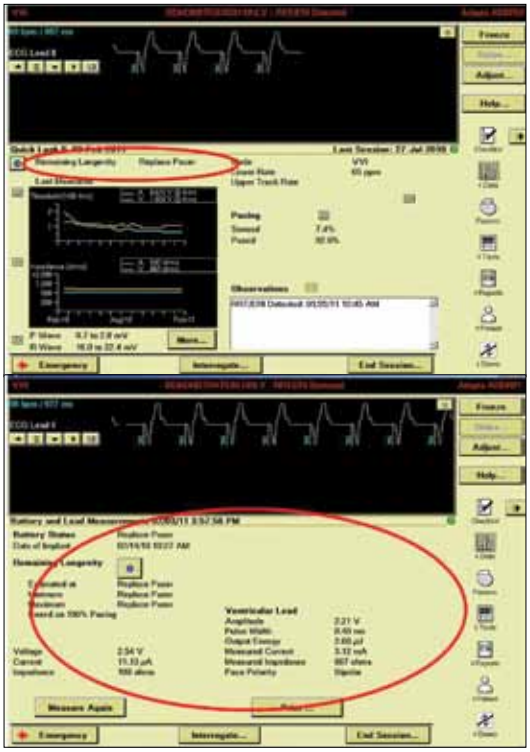
A device that has experienced a measurement lock-up ERI will present ALL of the following symptoms:

- Device declaring ERI/RRT
- Remaining Longevity = <Blank> on the programmer (and CareLink where available)
- Battery Voltage = <Blank> on the programmer (and CareLink where available)
- If the user attempts to take a Battery and Lead Measurement, a pop-up window will indicate that it cannot estimate remaining battery life.

Recommendation

This condition can be reset and does not require device explant. If this measurement lock-up occurs, obtain a save-to-disk file and contact Medtronic Brady Technical Services at 1 (800) 505-4636 for assistance. Reset devices are no more likely to experience a recurrence of this issue.

Example 1 – Programmer Screen for Typical Pacemaker at ERI



Example 2 – Programmer Screen for Measurement Lock-up ERI

Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

Purpose of this Information

This performance note is intended to provide guidance regarding retraction of the helix of Sprint Quattro Model 6935 or 6947 leads.

Background

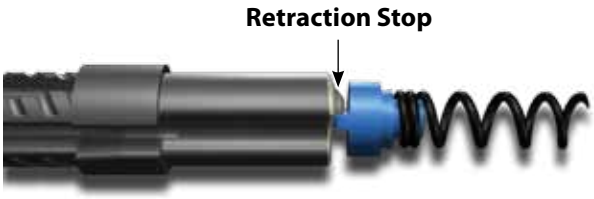
In certain cases, over-retraction of the helix, during initial implant or subsequent repositioning, may result in the inability to extend the helix. This does not impact acute or chronic performance of successfully implanted leads.

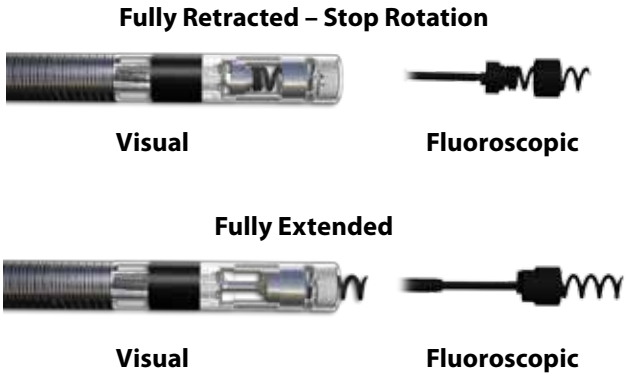
The root cause is over-retraction of the helix mechanism beyond the retraction stop, resulting in the inability to extend the helix in a subsequent attempt.

Recommendations

Consistent with the Technical Manual, the following steps can be used to mitigate this issue.

- Fluoroscopy should be used to confirm when the helix is fully retracted.
- Rotation of fixation tool should be stopped once full helix retraction is visually verified.
- If helix is unable to extend, replace with a new lead and report the issue to Medtronic.





Potential Malfunction of CRT, ICD, and IPG Products due to Anomalies in MOSFET Integrated Circuit Technology

Medtronic has detected a specific pattern of MOSFET IC malfunctions in its Concerto, Virtuoso and EnRhythm family of devices. As of July 2009, Medtronic has confirmed twenty-eight (28) malfunctions related to this pattern out of 115,000 EnRhythm and 233,000 Concerto/Virtuoso products distributed worldwide. Reliability analysis of this pattern shows the probability of occurrence decreases with time and over 90% of the malfunctions related to the pattern had occurred within the first twelve months after implant. With process improvements in place, Medtronic expects few additional malfunctions related to this pattern.

The pattern involves metal-oxide-semiconductor field-effect transistors (MOSFET). A MOSFET is an electronic circuit used to amplify or switch electronic signals. MOSFETs have been used in the electronics industries for decades and MOSFET technology is the most widely used type of integrated circuit. Medtronic uses this technology in the circuitry of its CRT, ICD, and IPG products. Each product contains thousands of MOSFETs in its electronic circuitry.

Each MOSFET depends on a layer of insulating material to electrically isolate its components. The integrity of this insulating layer is important to the operation of the MOSFET. Variation in the thickness of the insulating layer can cause the MOSFET to operate in an undesirable manner. Process variations for electronic circuits can affect the integrity of the insulating material, and can lead to MOSFET malfunction. Medtronic's quality system strives to control process variation and detect undesired anomalies that are characteristic of all MOSFET manufacturing. In addition, Medtronic's post-market vigilance activities monitor malfunctions and may implement screening and testing improvements when a pattern of related malfunctions is identified.

The pattern with the Concerto, Virtuoso and EnRhythm models has presented clinically as high lead impedance, sensing difficulty, loss of pacing therapy and/or early battery depletion due to higher than normal battery drain. The degree of battery drain varies case by case, such that the time from the onset to battery depletion has ranged from several days to several months. If not detected by normal patient follow-up procedures, the use of patient alerts or CareLink remote monitoring, the battery will fully deplete, leaving the patient without therapy.

As of March 2009, Medtronic has implemented additional electrical screening and stress tests to address this specific pattern for products being sold.

Since these rates of malfunction are low and the probability of occurrence decreases with time, Medtronic recommends physicians continue following patients in accordance with standard practice.

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 management of the device and follow-up visits as VCM equipped IPGs near the end of their expected longevity.

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.

Ensuring the Accuracy of Battery Longevity Estimates

Purpose of This Information

This article is intended to help the clinician understand how Medtronic estimates CRT-D, ICD, and IPG device longevity and Medtronic's performance against these estimates.

Device Longevity and Battery Depletion

The device service life ends when the usable battery capacity is depleted. The time to battery depletion depends on three factors:

- The amount of electrical energy expended in providing therapy to the patient
- The amount of energy consumed by the electronic circuitry to perform the functions of the device (e.g., operating the microprocessor, telemetry, memory, and charging component)
- The energy capacity of the battery

Medtronic has developed a statistical model for device longevity that accounts for each of these factors, and has validated the model with real time clinical performance. During the development of its products, Medtronic engineers characterize device longevity using this model. Testing begins during development and continues after market release to ensure the accuracy of device longevity estimates.

Using Survival Curves to Assess Longevity

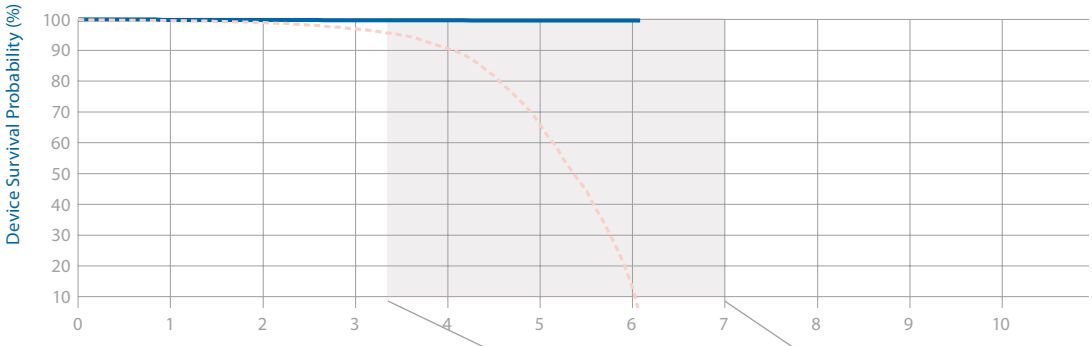
The survival curves in the Product Performance Report represent the composite experience of thousands of devices over a wide range of programming options and patient use conditions. While the curves are useful for understanding the overall performance of a population of devices, they cannot be used to accurately predict the longevity of a specific device in a specific patient. To get a longevity prediction for a specific device, the longevity model must be used. The model is available by contacting Medtronic's Technical Services Department.

Because the survival curves are an aggregate result, the Reference pages in the Product Performance Report include several longevity estimates for a range of use conditions. These longevity estimates are mean values calculated for the parameters given. This range of longevity estimates can be compared to the survival curve including normal battery depletion to assess the overall clinical performance of a device model against the original longevity estimates.

If most of a device model's population is being used at nominal parameters and conditions, the time at which the survival curve including normal battery depletion equals 50% should approximate the midpoint in the range of longevity estimates.

If devices tend to be used at conditions that consume more or less energy than nominal, then the time at which the survival curve equals 50% should tend toward the lower or higher end of the range of longevity estimates, respectively.

EXAMPLE



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	———	99.9	99.9	99.8	99.7	99.7	99.7
%	- - - -	99.6	99.0	96.9	90.1	64.5	8.8
#		18,000	15,000	13,000	10,000	5,000	300

Effective Sample Size

Estimated Longevity

Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing
Monthly	3.3	3.8	4.3	4.4
Quarterly	4.2	5.0	5.8	6.3
Semiannual	4.5	5.5	6.5	7.0

This figure shows the range of the estimated longevity values given in the reference chart in relation to the survival curve. The range of longevity is representative of a typical range of use values, not the absolute minimum or maximum longevities possible. In this example, the survival curve including normal battery depletion is approaching 50% at approximately the mid-point of the range of longevity values.

Interactions between Cardiac Pacing and Ventricular Arrhythmia Initiation

Purpose of this Information

This article is intended to provide information for consideration when programming pacemaker operation in ICDs and pacemakers.

Background

Right ventricular pacing has been associated with increased risk of appropriate therapy for ventricular tachycardia (VT) and ventricular fibrillation (VF) in ICD patients.[1] Abrupt changes in ventricular cycle lengths (short-long-short, S-L-S) may precede initiation of VT/VF in some instances. S-L-S sequences may be permitted in all forms of cardiac pacing. The pause lengths depend upon pacing mode and lower rate programming.[2-4] Because pauses may be associated with VT/VF initiation, pause suppression algorithms have been developed in ICDs. Although pause suppression may have utility in specific patients with repolarization abnormalities and pause dependent VT, it has not been shown to reduce arrhythmia incidence in the general ICD population.[5] Conversely, S-L-S sequences may occur with ventricular pacing in a variety of ways, including atrial tracking of premature atrial contractions (PACs) or by terminating pauses with ventricular paced beats.[6] In some patients, the ectopic depolarization pattern of a ventricular paced beat may be pro-arrhythmic, independent of pause timing. These observations have further enforced the desire to reduce unnecessary ventricular pacing.

Clinical Trial Observations

Medtronic-sponsored clinical trials were retrospectively analyzed to further understand pause-mediated (i.e., S-L-S) scenarios prior to VT/VF. S-L-S onset scenarios were observed in a minority of patients in all pacing modes. Pacemaker interactions prior to VT/VF are dependent on patient conditions, as well as the technical aspects of pacing operation (i.e., pacing mode, lower rate, and AV interval). Because a very low frequency of ventricular pacing is observed during Managed Ventricular Pacing (MVP)[7-9] or VVI 40 pacing modes,[10] the long interval tended to terminate with a ventricular sense. In DDD mode, the long interval tended to be terminated by a ventricular pace. Long intervals of > 1,000 ms prior to VT/VF were rare in MVP mode. In these analyses, only an association between cardiac pacing and VT/VF initiation can be observed, causality cannot be established. The ongoing MVP (Managed Ventricular Pacing vs. VVI 40 Pacing) Trial, a 2-year, 1,000-patient prospective, randomized trial in ICD patients may offer more insight into the frequency of VT/VF across pacing modes.[11]

Pacemaker Patients

In pacemaker patients, ventricular pacing has been associated with higher incidence of AT/AF and heart failure hospitalization.[12,13] MVP provides atrial rate support while dramatically reducing ventricular pacing in patients with sinus node dysfunction and transient AV block.[9] However, as stated in Medtronic reference manuals, depending upon the patient's intrinsic rhythm and conduction, MVP may allow ventricular cycle variation and occasional pauses of up to twice the lower rate.

DDD pacing with long AV intervals may reduce ventricular pacing and may decrease the potential length of pauses compared to MVP. However, DDD with long AV interval programming does not appear to be as effective as AAI-based pacing modes at reducing ventricular pacing,[13,14] may lead to endless loop tachycardia,[14,15] and does not completely eliminate pauses. Also, in DDD mode, a higher programmed lower rate or activation of rate response can lead to an increase in AV conduction times and a higher percentage of ventricular pacing. The potential benefits of reducing ventricular pacing must be weighed against the potential for longer ventricular pauses. Therefore, careful consideration should be given to pacemaker mode and lower rate programming, particularly in the setting of frequent AV block and repolarization abnormalities due to congenital Long QT, electrolyte imbalances, and some medications that prolong QT.

Conclusion

Pacemaker operation may interact with VT/VF initiation in a variety of ways. The patient's heart failure status, arrhythmia substrate, medications, and the relative importance of maintaining ventricular synchrony versus ensuring ventricular rate support must be weighed when choosing optimal hardware (ICD vs. pacemaker) and pacemaker programming (pacing mode, lower rate, etc.).

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[6] Himmrich E, Przibille O, Zellerhoff C, et al. Proarrhythmic effect of pacemaker stimulation in patients with implanted cardioverter-defibrillators. *Circulation*. July 15, 2003;108(2):192-197.

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[9] Gillis AM, Pürerfellner H, Israel CW, et al. Reducing unnecessary right ventricular pacing with the managed ventricular pacing mode in patients with sinus node disease and AV block. *PACE*. July 2006; 29(7):697-705.

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AT500 Pacing System Follow-Up Protocol

Purpose of This Information

This article is intended to provide clinical guidance regarding follow-up practice and patient management when the AT500 battery voltage approaches the Elective Replacement Indicator (ERI) level of 2.6 volts.

Background

Many AT500 pacing systems are now reaching their ERI voltage level (2.6 volts). This is expected since the battery used has an approximate longevity of 5-6 years under normal conditions (100% DDD pacing, 3 volts, 0.4 ms).

Technical Services has received reports of battery voltage levels below end of life (EOL of 2.2 volts) where EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary. It is important for physicians and allied professionals to understand battery depletion characteristics between ERI and EOL so that they, in turn, can understand how this affects management of follow-up visits for the AT500 as this device nears the end of its expected longevity.

AT500 Battery and Longevity Information

In contrast to other IPGs, the AT500 does not change its mode, stimulation rate, or any other parameter when the battery voltage drops below the ERI level of 2.6 volts (with or without magnet applied). The Threshold Margin Test (TMT) is also not available.

Therefore, it is not possible to perform transtelephonic assessment of AT500 battery status. This must be done during an in-clinic follow-up session. A warning will be displayed on the Quick Look screen at the beginning of a programmer (follow-up) session when the ERI battery level occurs. The measured battery voltage will also appear on the programmer display and on printouts.

Battery depletion curves are shown in Figure 1, with special focus on device longevity when programming EGM pre-storage ON or OFF.

Medtronic's review of ongoing AT500 battery life test data matches our original longevity modeling and so meets our expectations. However, when using longer durations between follow-up periods (> 3 months), clinicians should consider the following in setting their remaining longevity expectations.

- Enabling the "EGM Pre-storage On" capability will increase current and reduce device longevity by approximately 9 days for each month pre-storage is ON
- Longevity decreases with an increase in pacing rate, an increase in pacing amplitude or pulse width, a decrease in pacing impedance, a higher ratio of paced to sensed events, or extended use of the Atrial Preference Pacing, EGM pre-storage, or Holter Telemetry features

Recommendations

Follow-up frequency should always be accelerated as devices reach ERI voltage levels to ensure device explant/replacement occurs prior to end of life voltage levels. With the wide variety of follow-up schedules being used, Medtronic recommends a 3-month follow-up frequency for the AT500 pacing systems. This is particularly important for patients in whom EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary.

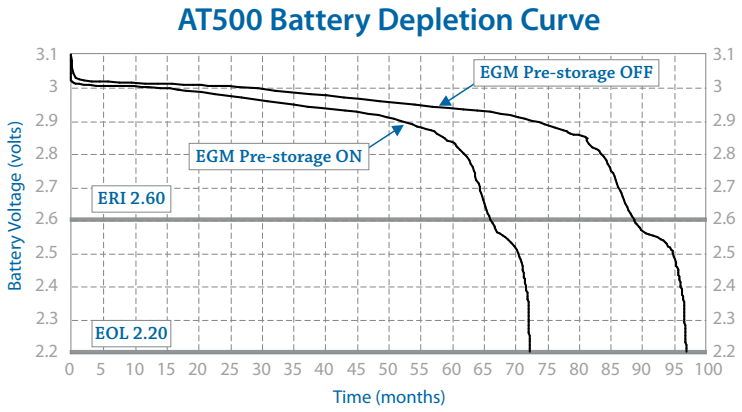


Figure 1

AT500 battery depletion curve for common parameter settings of DDDR, LR 70 ppm, UR 120 ppm, 100% pacing, Atrial – 2 V, 0.4 ms, 600 ohms, Ventricle – 2 V, 0.6 ms, 900 ohms, and EGM Pre-storage ON versus OFF.

Insertion of the Lead into the Device

The implantable system consists of a pulse generator and at least one lead. The system operation depends on proper electrical and mechanical operation. With the advent of internationally recognized connector standards, the challenge of ensuring proper mechanical fit between the lead and device connectors has been simplified, although the international connector standard does not address all aspects of the procedure for connecting a lead to the device.

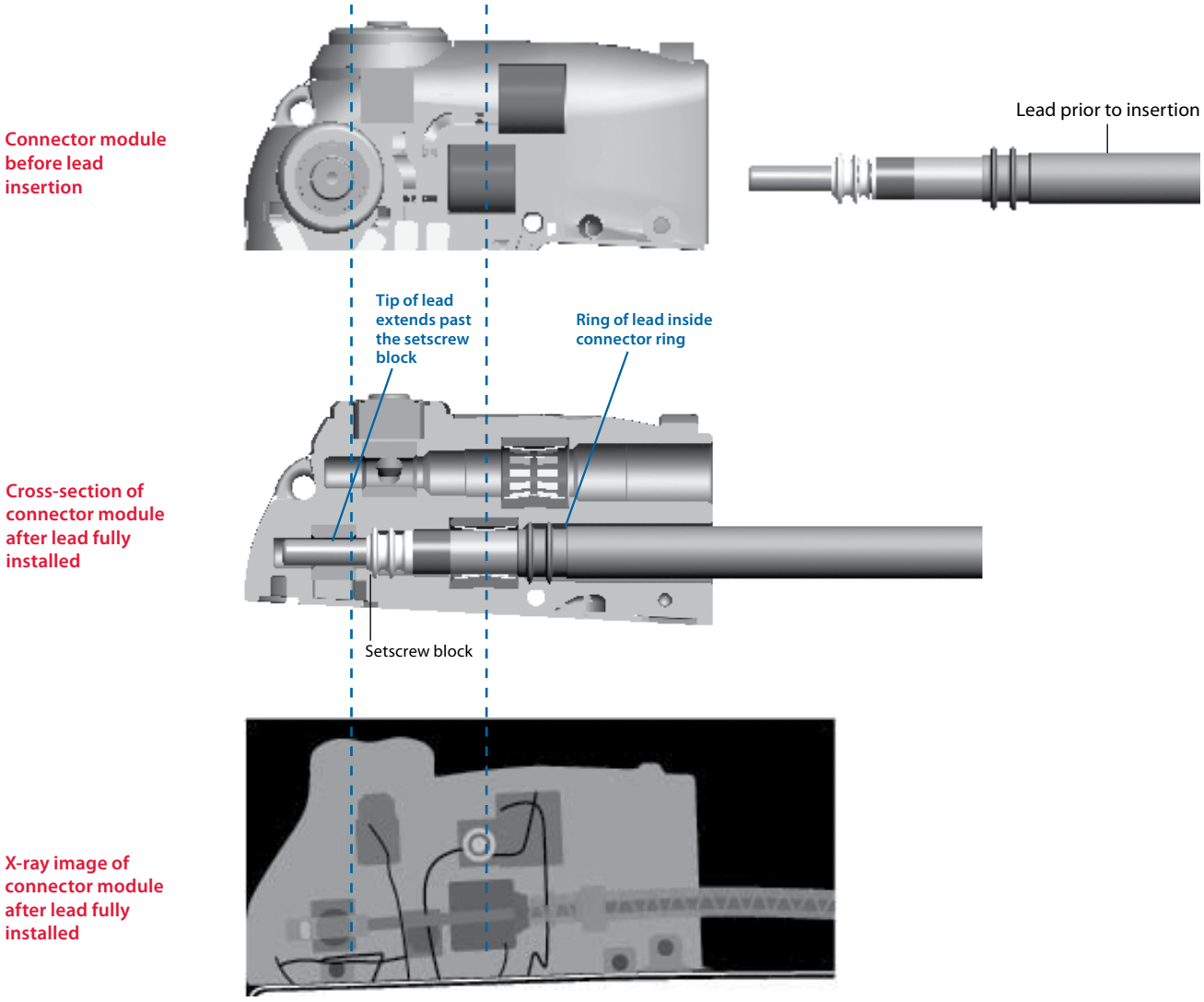
If the lead connector is not fully installed, oversensing may result as described in the connector problems section of the performance note, "Clinical Management of High Voltage Lead System Oversensing."

Performing the following steps can be used for each lead connection during the implant procedure:

1. Insert the torque wrench into the appropriate setscrew. For easier lead insertion, insert the lead closest to the device first.
2. Look down the connector port to verify that the port is not obstructed. If the port is obstructed, retract the setscrew to clear the bore. Take care not to disengage the setscrew from the connector block.
3. Push the lead into the connector port until the lead pin is clearly visible beyond the setscrew block.
4. Hold the lead in position while tightening the setscrew until the torque wrench clicks.
5. Tug gently on the lead to confirm a secure fit.

Current publications may provide additional information on implant procedures used by others, e.g., radiographic evaluation of the terminal pin beyond the terminal post.[1]

[1] Pickett RA III, Saavedra P, Ali MF, Darbar D, Rottman JN. Implantable cardioverter-defibrillator malfunction due to mechanical failure of the header connection. *J Cardiovasc Electrophysiol.* September 2004;15(9):1095-1099.



GEM II DR/VR and GEM III DR/VR/AT ICD Battery Discharge Behavior

Medtronic manufactured and utilized a unique lithium/silver vanadium oxide battery in the GEM II/III family of ICDs. This battery has a distinctive voltage discharge with two regions of constant voltage at 3.2 volts and 2.6 volts.

The battery discharge curve (see curve below) is characterized by a significant decrease in the battery voltage approaching middle of life (MOL), followed by a plateau (MOL to ERI) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily misinterpreted as the battery rapidly approaches ERI, which occurs at 2.55 volts, when the battery may in fact have several years remaining until ERI.

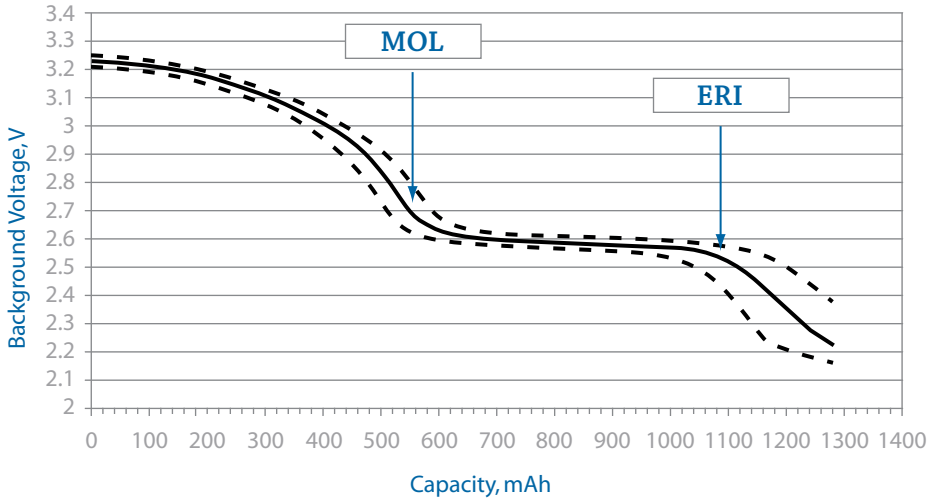
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

As a general rule of thumb, the longevity from implant to MOL = MOL to ERI.

The design of the battery in subsequently released models has been modified to present a more linear battery discharge curve.

If you are concerned about early ERI in your patient's device, you can utilize the battery trend measurements stored in the save-to-disk file, which can be accessed and interpreted through the Medtronic Technical Services at 1 (800) 723-4636.

GEM II/III Battery Discharge Curve



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 System Longevity Study (SLS).

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.

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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 continued

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 CRDM 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.

CRDM Returned Product Analysis Laboratory

Phone: 1 (800) 328-2518, ext. 44800
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