Medtronic

Cardiac Rhythm Disease Management

Product Performance Report

Important Patient Management Information for Physicians

2012

First Edition – Issue 66

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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Email: jia.guo@medtronic.com

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

2012 First Edition
Issue 66

Date cutoff for this edition is February 6, 2012 for devices and January 31, 2012 for SLS Leads data

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

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.

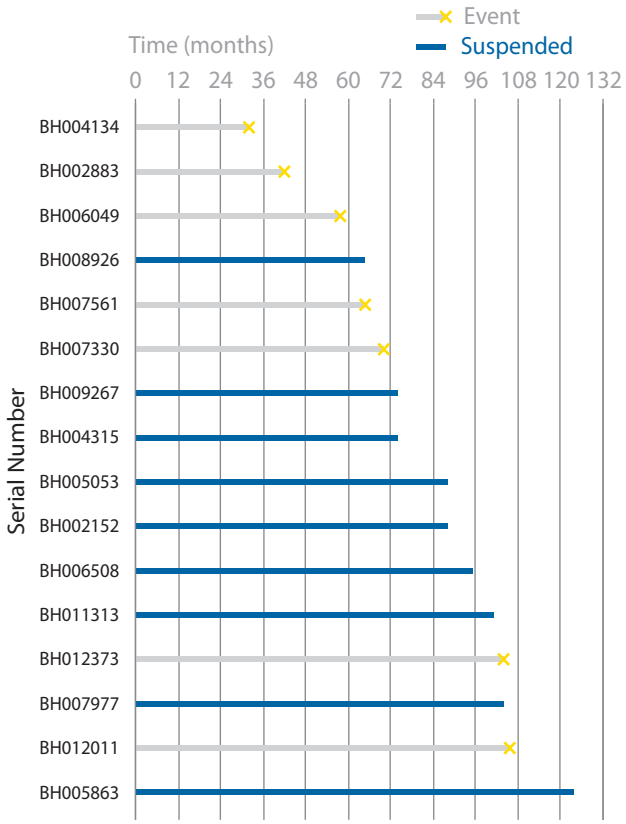


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

B
Number Suspended
Number of devices removed from service for reasons other than an event

C
Number of Events
Number of units removed from service due to an event

D
Effective Sample Size
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.

E
Proportion with Event
Proportion of devices that had an event in the interval. Computed by dividing the Number of Events by the Effective Sample Size.

F
Interval Survival Probability
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.

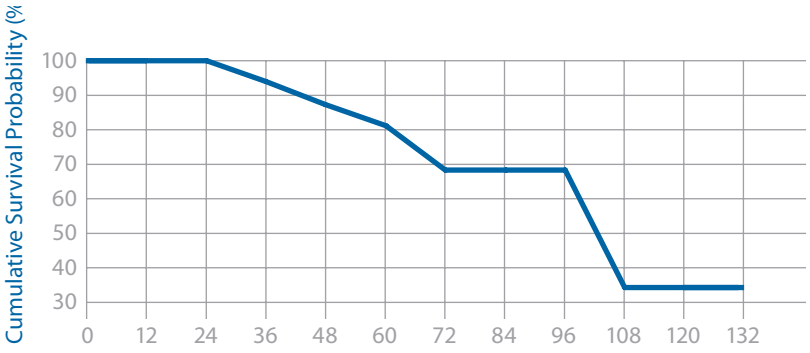
G
Cumulative Survival Probability
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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

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

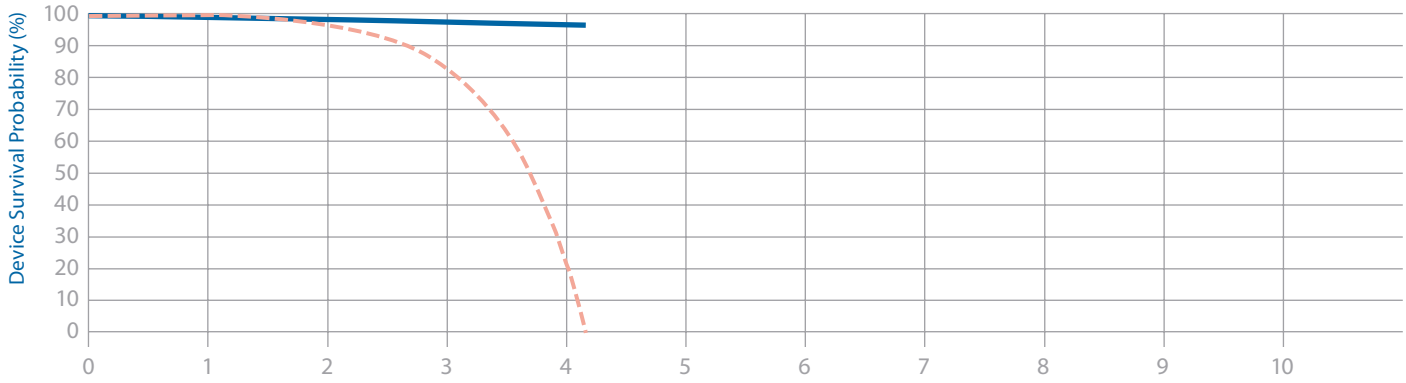
Product Characteristics

US Market Release	Aug-03
Registered US Implants	27,800
Estimated Active US Implants	1,400
Normal Battery Depletions (US)	6,572

Advisories: See page 156 – 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	83.0	23.7	0.4
#	Effective Sample Size	23,800	18,000	12,600	2,350	570

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

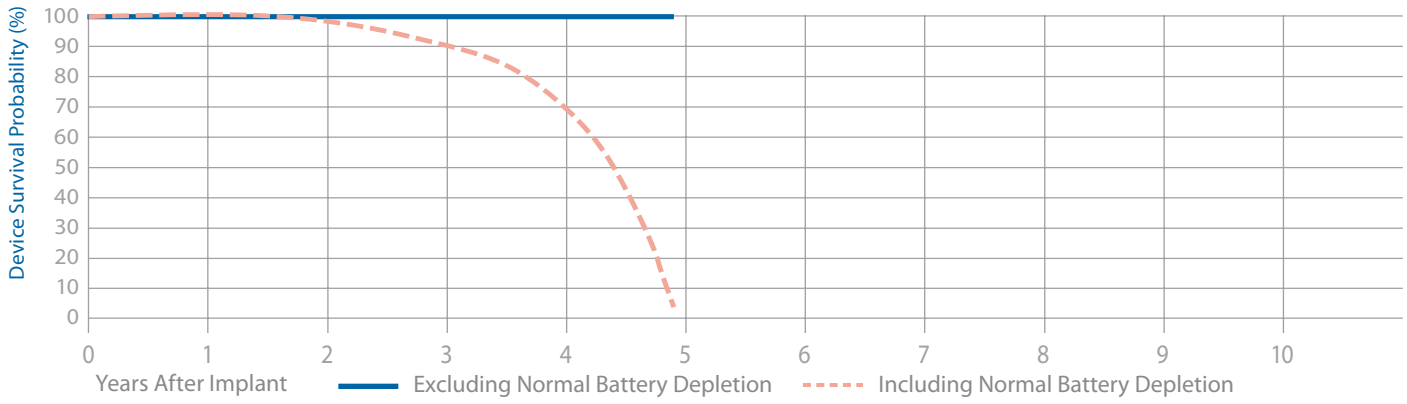
7297 InSync Sentry

Product Characteristics

US Market Release	Nov-04
Registered US Implants	8,800
Estimated Active US Implants	590
Normal Battery Depletions (US)	2,525
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	89.7	70.0	3.4
#	7,680	6,710	5,250	3,260	250

Effective Sample Size

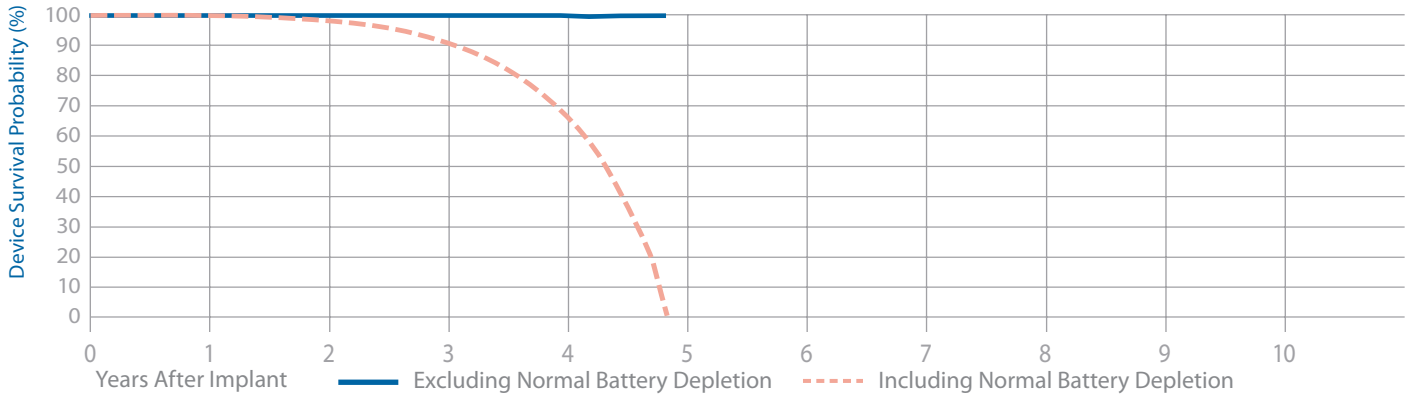
7299 InSync Sentry

Product Characteristics

US Market Release	Apr-05
Registered US Implants	31,100
Estimated Active US Implants	3,070
Normal Battery Depletions (US)	8,973
Advisories	None

Malfunctions (US)	175
Therapy Function Not Compromised	165
Electrical Component	17
Software/Firmware	2
Possible Early Battery Depletion	145
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	99.2	99.0
%	99.8	97.9	90.2	65.7	2.6
#	27,200	23,700	18,600	10,600	900

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

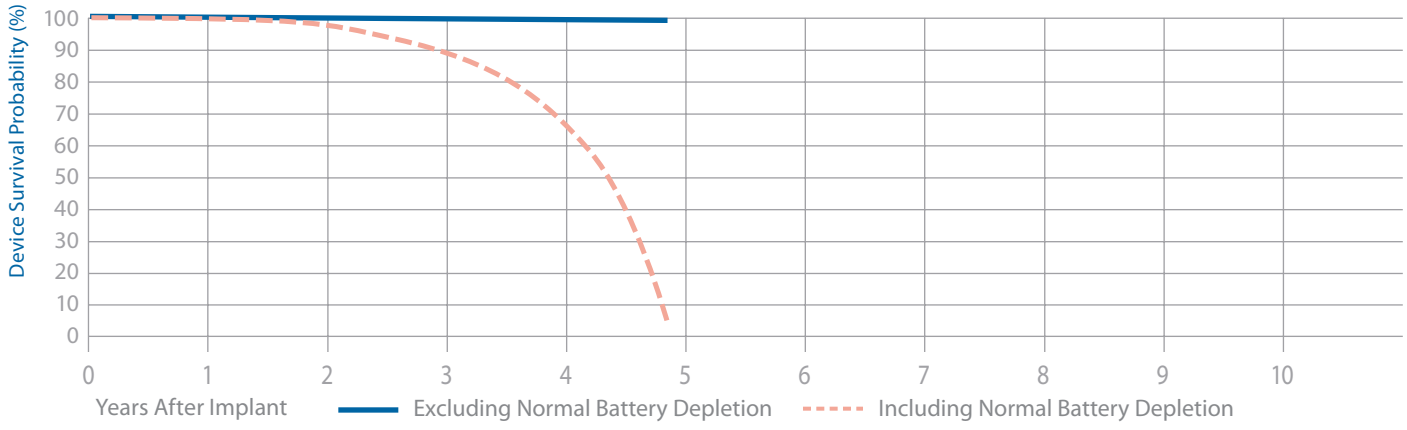
7303 InSync Maximo

Product Characteristics

US Market Release	Jun-04
Registered US Implants	17,300
Estimated Active US Implants	1,090
Normal Battery Depletions (US)	4,797
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	97.8	89.0	66.1	4.2
#		15,000	13,000	10,100	5,760	520

Effective Sample Size

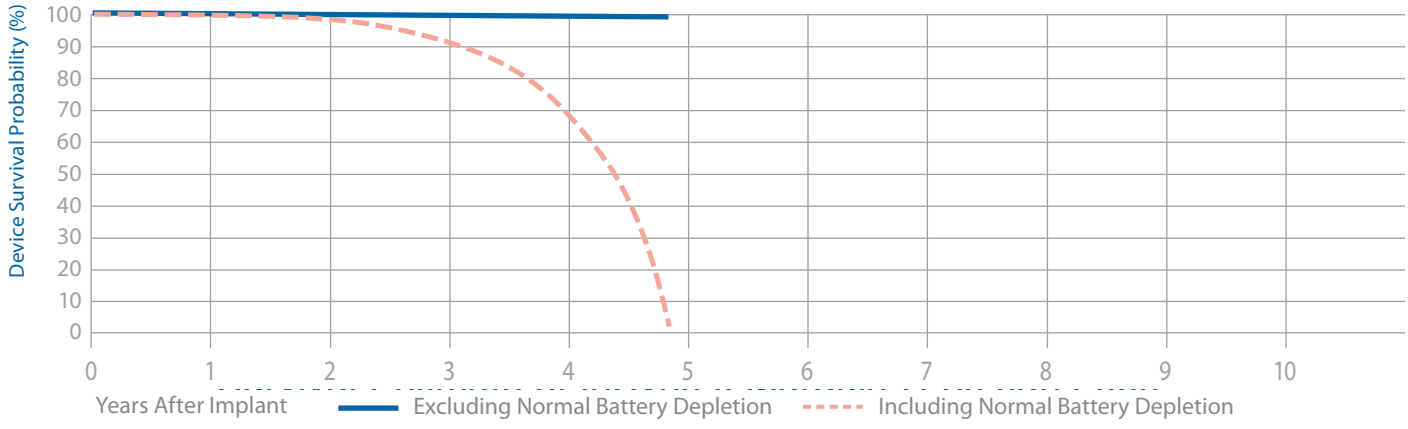
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	19,000
Estimated Active US Implants	2,930
Normal Battery Depletions (US)	4,614
Advisories	None

Malfunctions (US)	100
Therapy Function Not Compromised	96
Battery	1
Electrical Component	12
Possible Early Battery Depletion	83
Therapy Function Compromised	4
Electrical Component	4

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	99.1
%	- - - -	99.8	97.9	90.9	68.8	3.5
#		16,600	14,400	11,100	6,140	420

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

CRT Cardiac Resynchronization Therapy, continued

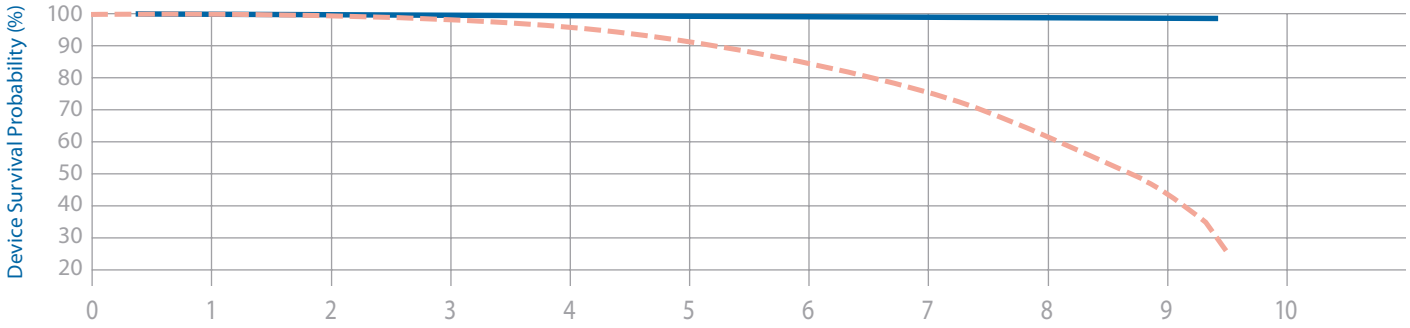
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,300
Estimated Active US Implants	1,690
Normal Battery Depletions (US)	1,189
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	at 112 mo
%	100.0	100.0	99.9	99.8	99.7	99.6	99.5	99.5	99.5	99.4
%	99.9	99.7	98.2	96.1	91.2	84.0	73.6	58.1	38.5	27.4
#	12,100	9,960	7,990	6,280	4,900	3,650	2,560	1,550	670	150

Effective Sample Size

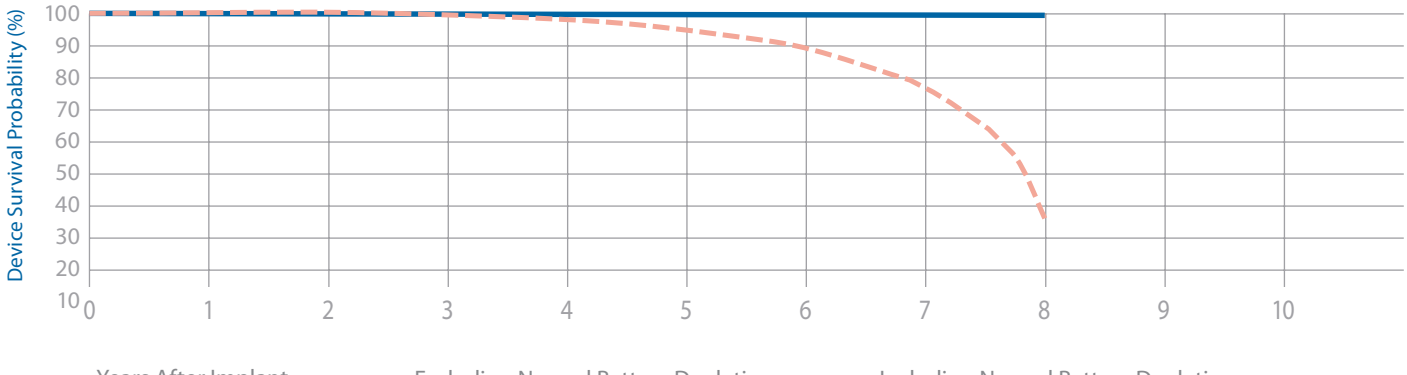
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	39,500
Estimated Active US Implants	17,000
Normal Battery Depletions (US)	1,240
Advisories	None

Malfunctions (US)	18
Therapy Function Not Compromised	9
Electrical Component	5
Electrical Interconnect	1
Possible Early Battery Depletion	1
Other	2
Therapy Function Compromised	9
Electrical Component	3
Electrical Interconnect	6

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	8 yr
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.8
%	99.9	99.9	99.3	97.7	94.7	88.7	75.1	34.3
#	32,800	24,800	17,900	12,700	8,470	5,020	2,460	270

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

C154DWK, C164AWK, C174AWK Concerto

Product Characteristics

	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	81,200	3,500
Estimated Active US Implants	41,700	240
Normal Battery Depletions (US)	6,292	245

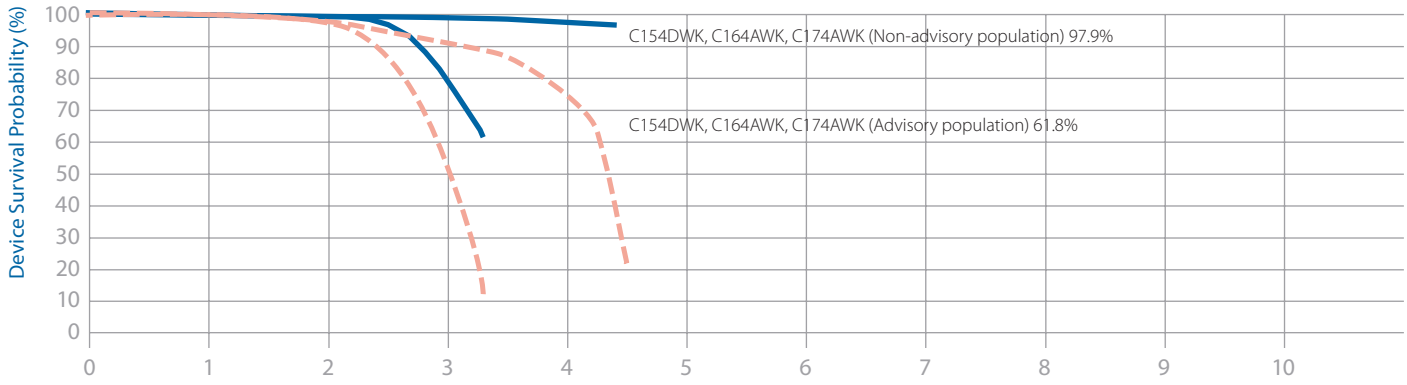
Advisories: See page 150 – 2009 Potential Reduced Device Longevity

Performance Note: See page 161 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	657	1,296
Therapy Function Not Compromised	624	1,281
Electrical Component	100	1,277
Electrical Interconnect	2	
Software/Firmware	2	
Possible Early Battery Depletion	517	4
Other	3	
Therapy Function Compromised	33	15
Electrical Component	31	14
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 56 mo
%	100.0	99.8	99.5	98.7	97.9
%	99.8	98.0	91.9	75.2	23.5
#	71,600	62,500	43,700	15,700	650
Effective Sample Size					

Adv Pop	1 yr	2 yr	3 yr	at 40 mo
%	99.9	99.5	79.2	61.8
%	99.8	97.1	50.5	11.4
#	3,120	2,700	1,350	350
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

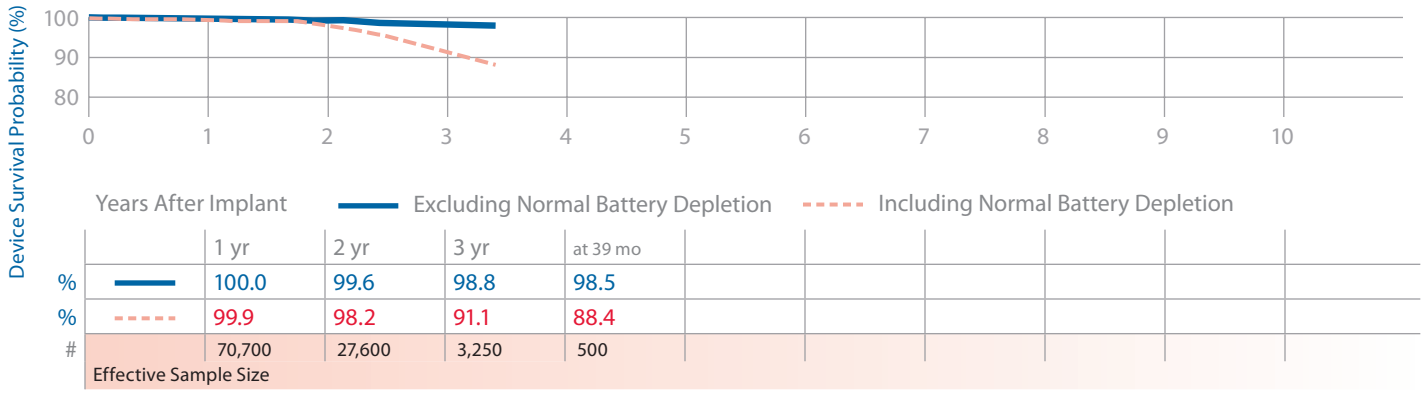
D224TRK Consulta CRT-D

Product Characteristics

US Market Release	Sep-08
Registered US Implants	58,200
Estimated Active US Implants	48,000
Normal Battery Depletions (US)	348
Advisories	None

Malfunctions (US)	221
Therapy Function Not Compromised	215
Electrical Component	9
Software/Firmware	1
Possible Early Battery Depletion	204
Electrical Interconnect	1
Therapy Function Compromised	6
Electrical Component	6

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



	1 yr	2 yr	3 yr	at 39 mo
%	100.0	99.6	98.8	98.5
%	99.9	98.2	91.1	88.4
#	70,700	27,600	3,250	500

Effective Sample Size

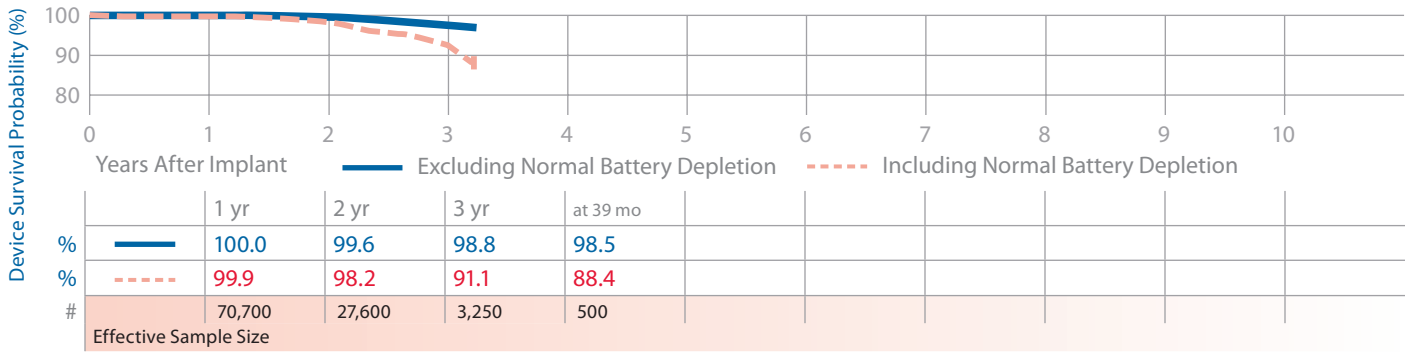
D274TRK, D294TRK Concerto II CRT-D

Product Characteristics

US Market Release	Aug-09
Registered US Implants	29,400
Estimated Active US Implants	25,500
Normal Battery Depletions (US)	55
Advisories	None

Malfunctions (US)	26
Therapy Function Not Compromised	25
Electrical Component	2
Possible Early Battery Depletion	23
Therapy Function Compromised	1
Electrical Component	1

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



	1 yr	2 yr	3 yr	at 39 mo
%	100.0	99.6	98.8	98.5
%	99.9	98.2	91.1	88.4
#	70,700	27,600	3,250	500

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

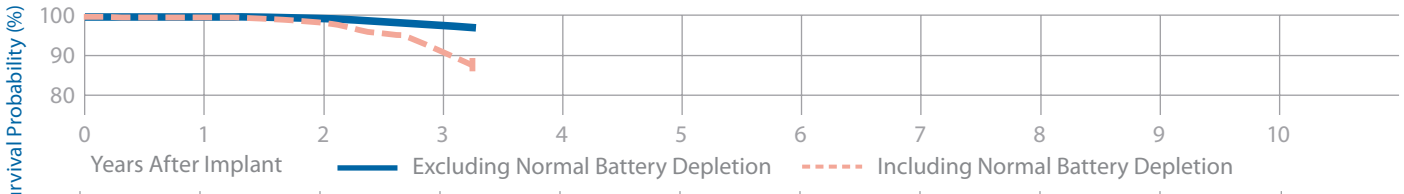
D284TRK Maximo II CRT-D

Product Characteristics

US Market Release	Sep-08
Registered US Implants	13,000
Estimated Active US Implants	10,500
Normal Battery Depletions (US)	116
Advisories	None

Malfunctions (US)	53
Therapy Function Not Compromised	52
Electrical Component	2
Possible Early Battery Depletion	50
Therapy Function Compromised	1
Electrical Component	1

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



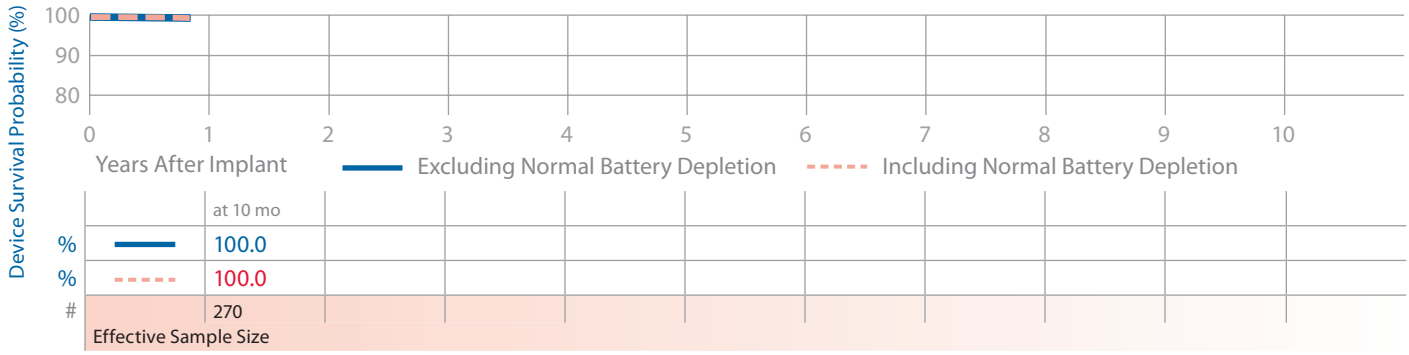
		1 yr	2 yr	3 yr	at 39 mo
%	Excluding Normal Battery Depletion	100.0	99.6	98.8	98.5
%	Including Normal Battery Depletion	99.9	98.2	91.1	88.4
#	Effective Sample Size	70,700	27,600	3,250	500

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D314TRG Protecta XT CRT-D

Product Characteristics

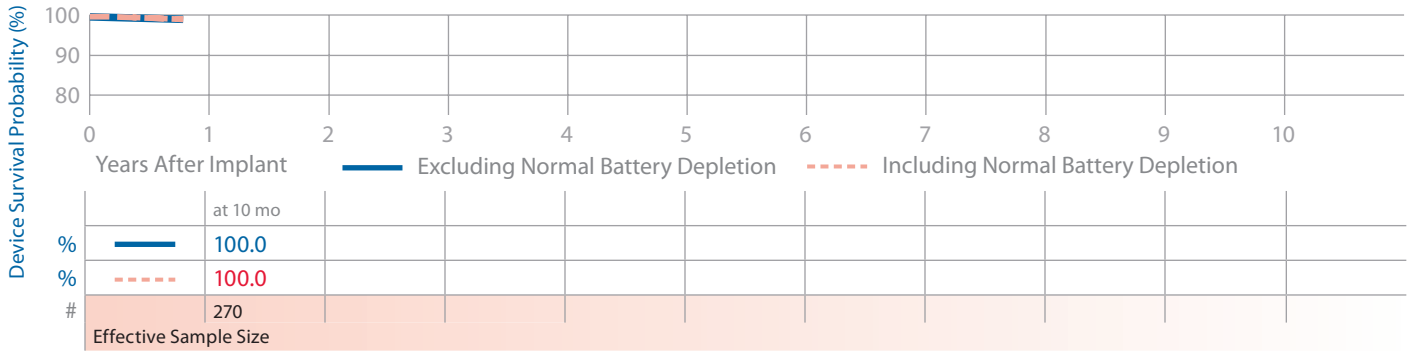
US Market Release	Mar-11	Malfunctions (US)	0	NBD Code	DDED
Registered US Implants	11,400	**Therapy Function Not Compromised**	0	Serial Number Prefix	PFS
Estimated Active US Implants	11,100	Possible Early Battery Depletion	0	Max Delivered Energy	35J
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 22
Advisories	None				



D334TRG Protecta CRT-D

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	0	NBD Code	DDED
Registered US Implants	2,300	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSO
Estimated Active US Implants	2,240	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				

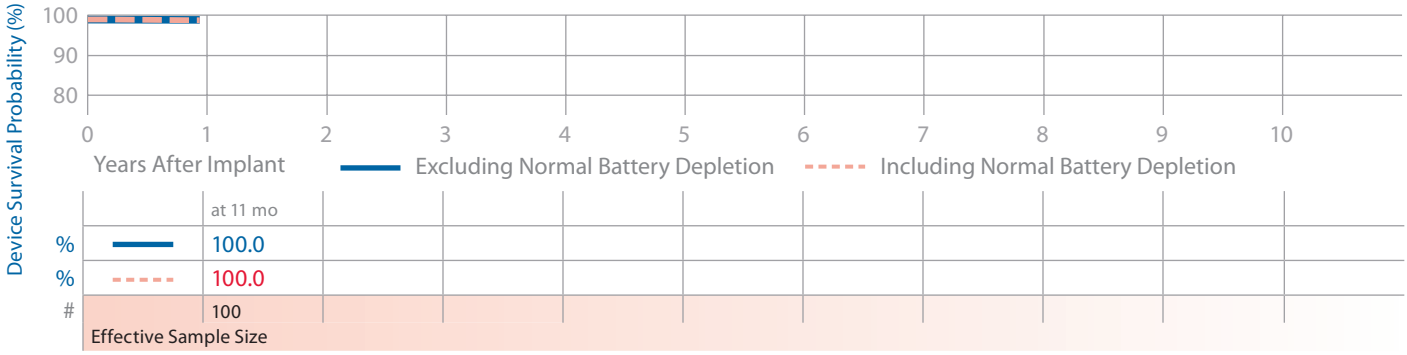


Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

C2TR01 Syncra CRT-P

Product Characteristics

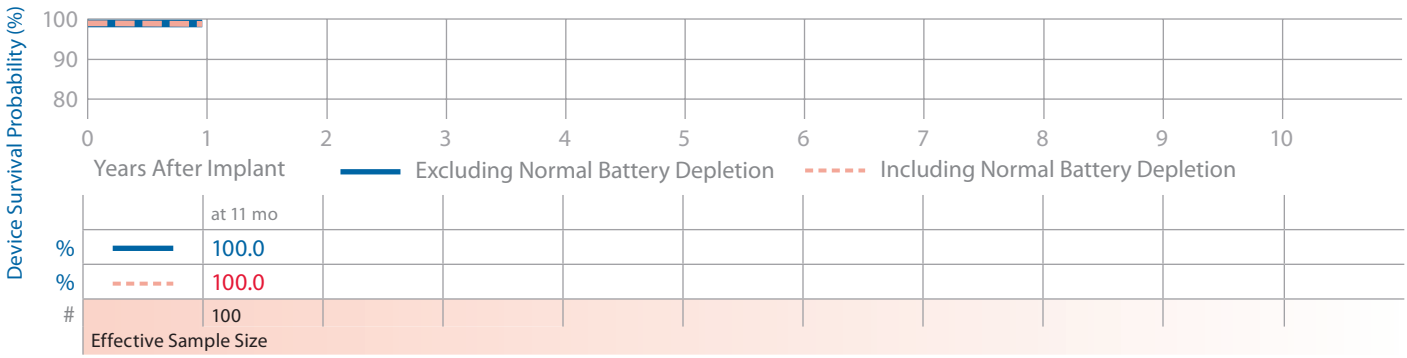
US Market Release	Mar-11	Malfunctions (US)	0	NBG Code	OOED
Registered US Implants	2.900	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZX
Estimated Active US Implants	2,770	Possible Early Battery Depletion	0	Max Delivered Energy	NA
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	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	2,400	**Therapy Function Not Compromised**	0	Serial Number Prefix	PVX
Estimated Active US Implants	2,280	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 February 6, 2012

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): 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
7289	InSync II Marquis	Aug-03	27,800	1,400	6,572	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 156 – 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	83.0 +0.6/-0.6	23.7 +0.9/-0.9	0.4 +0.2/-0.2 at 50 mo				
7297	InSync Sentry	Nov-04	8,800	588	2,525	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	89.7 +0.7/-0.8	70.0 +1.2/-1.3	3.4 +0.9/-0.8 at 59 mo				
7299	InSync Sentry	Apr-05	31,100	3,070	8,973	10	+	165	=	175	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.2 +0.1/-0.1	99.0 +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	65.7 +0.7/-0.7	2.6 +0.4/-0.3 at 58 mo				
7303	InSync Maximo	Jun-04	17,300	1,090	4,797	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	97.8 +0.2/-0.3	89.0 +0.5/-0.6	66.1 +0.9/-0.9	4.2 +0.7/-0.6 at 58 mo				
7304	InSync Maximo	Apr-05	19,000	2,930	4,614	4	+	96	=	100	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.2/-0.2	99.1 +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	68.8 +0.9/-0.9	3.5 +0.7/-0.6 at 58 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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	15,300	1,690	1,189	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 112 mo
								-			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/-0.5	91.2 +0.7/-0.7	84.0 +0.9/-1.0	73.6 +1.3/-1.3	58.1 +1.6/-1.6	27.4 +2.6/-2.5 at 112 mo
8042	InSync III	Feb-03	39,500	17,000	1,240	9	+	9	=	18	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/-0.1	99.9 +0.1/-0.2	99.8 +0.1/-0.2	
								-			Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.3 +0.1/-0.1	97.7 +0.2/-0.2	94.7 +0.4/-0.4	88.7 +0.7/-0.7	75.1 +1.2/-1.2	34.3 +2.8/-2.8	
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	81,200	41,700	6,292	33	+	624	=	657	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.5 +0.1/-0.1	98.7 +0.1/-0.1	97.9 +0.2/-0.2 at 56 mo				
	See page 161 – Performance note on Anomalies in MOSFET Integrated Circuit Technology										Including Normal Battery Depletion	99.8 +0.0/-0.0	98.0 +0.1/-0.1	91.9 +0.2/-0.2	75.2 +0.5/-0.5	23.5 +1.9/-1.8 at 56 mo				
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	3,500	240	245	15	+	1,281	=	1,296	Excluding Normal Battery Depletion	99.9 +0.1/-0.2	99.5 +0.2/-0.4	79.2 +1.6/-1.7	61.8 +2.0/-2.1 at 40 mo					
	Advisories: See page 150– 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.8 +0.1/-0.3	97.1 +0.6/-0.7	50.5 +2.0/-2.0	11.4 +1.5/-1.4 at 40 mo					
	See page 161 – 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	58,200	48,000	348	6	+	215	=	221	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.6 +0.1/-0.1	98.8 +0.2/-0.2	98.5 +0.3/-0.3 at 39 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	98.2 +0.1/-0.1	91.1 +0.6/-0.6	88.4 +1.0/-1.1 at 39 mo					
D274TRK, D294TRK	Concerto II CRT-D	Aug-09	29,400	25,500	55	1	+	25	=	26	Excluding Normal Battery Depletion	100.0 +0.0/-0.1	99.6 +0.1/-0.2	98.8 +0.2/-0.3	98.5 +0.3/-0.3 at 39 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.1	98.2 +0.1/-0.2	91.1 +0.6/-0.7	88.4 +1.0/-1.1 at 39 mo					
D284TRK	Maximo II CRT-D	Sep-08	13,000	10,500	116	1	+	52	=	53	Excluding Normal Battery Depletion	100.0 +0.0/-0.2	99.6 +0.1/-0.3	98.8 +0.2/-0.4	98.5 +0.3/-0.3 at 39 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.2	98.2 +0.1/-0.3	91.1 +0.6/-0.8	88.4 +1.0/-1.1 at 39 mo					
D314TRG	Protecta XT CRT-D	Mar-11	11,400	11,100	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo								
D334TRG	Protecta CRT-D	Mar-11	2,300	2,240	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo								
C2TR01	Syncra CRT-P	Mar-11	2,900	2,770	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 11 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 11 mo								
C4TR01	Consulta CRT-P	Mar-11	2,400	2,280	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 11 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 11 mo								

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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 D294TRK	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 February 6, 2012

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 February 6, 2012

7230 Marquis VR

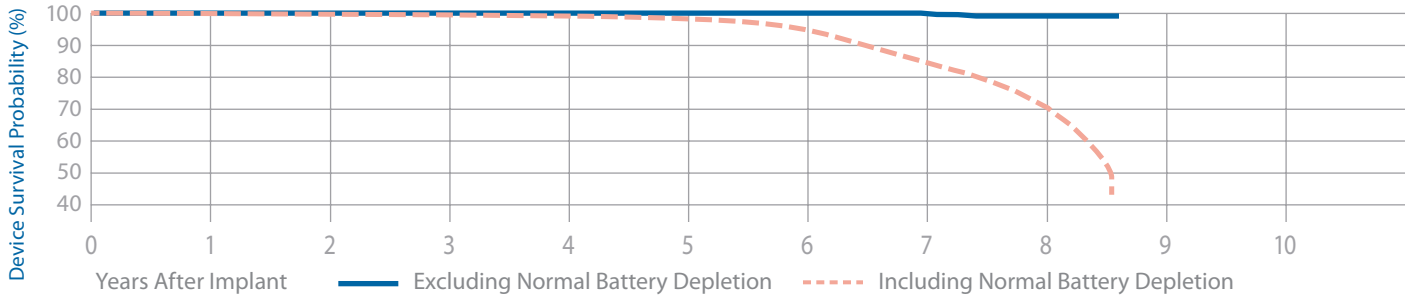
Product Characteristics

US Market Release	Dec-02
Registered US Implants	19,400
Estimated Active US Implants	5,400
Normal Battery Depletions (US)	1,143

Advisories: See page 156 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	58
Therapy Function Not Compromised	29
Electrical Component	12
Battery *(1 malfunction related to advisory)*	1
Software/Firmware	1
Possible Early Battery Depletion	14
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 103 mo
%	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3
%	99.8	99.5	99.3	99.0	98.2	93.9	83.6	69.4	42.0
#	16,900	13,100	10,900	9,780	8,710	7,470	5,490	2,050	180

Effective Sample Size

7231Cx GEM III VR

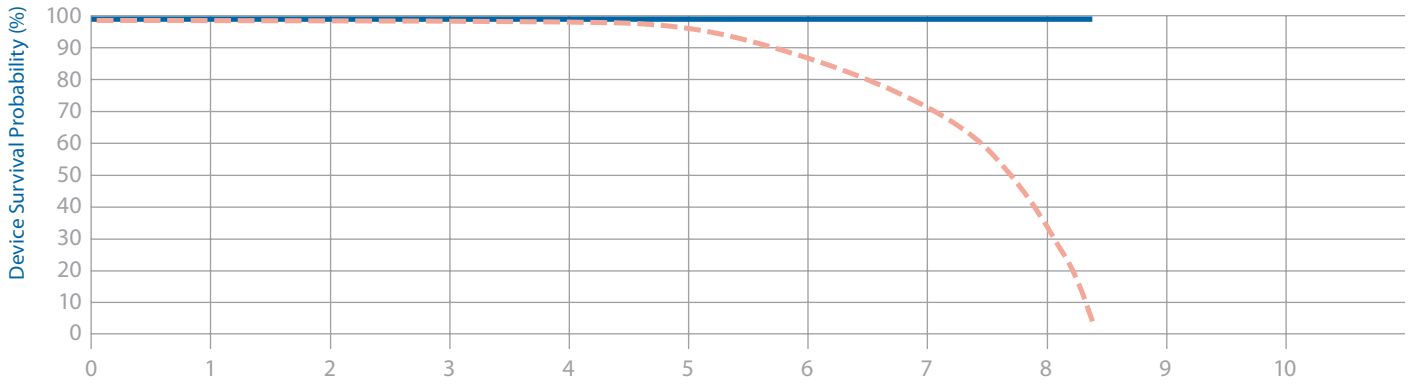
Product Characteristics

US Market Release	Dec-00
Registered US Implants	17,500
Estimated Active US Implants	2,400
Normal Battery Depletions (US)	3,289

Performance Note: See page 166 – 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	98.9	98.4	96.9	87.0	71.9	36.9	5.3
#	15,300	13,600	12,000	10,500	9,100	7,090	4,820	1,740	290

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

7232 Maximo VR

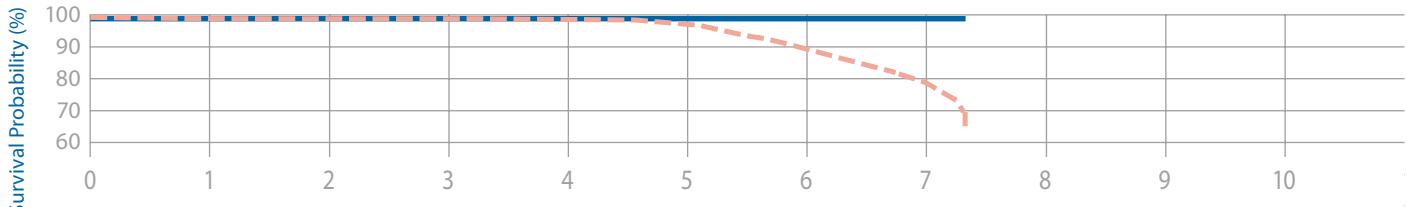
US Market Release	Oct-03
Registered US Implants	44,300
Estimated Active US Implants	21,600
Normal Battery Depletions (US)	1,540

Advisories: See page 156 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	63
Therapy Function Not Compromised	48
Electrical Component	21
Possible Early Battery Depletion	23
Other	4
Therapy Function Compromised	15
Electrical Component	13
Electrical Interconnect	1
Possible Early Battery Depletion	1

Product Characteristics

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 88 mo
%	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.7	99.5	99.1	97.7	89.7	79.1	67.8
#	39,700	35,500	31,500	26,800	21,400	13,400	2,180	410

Effective Sample Size

7274 Marquis DR

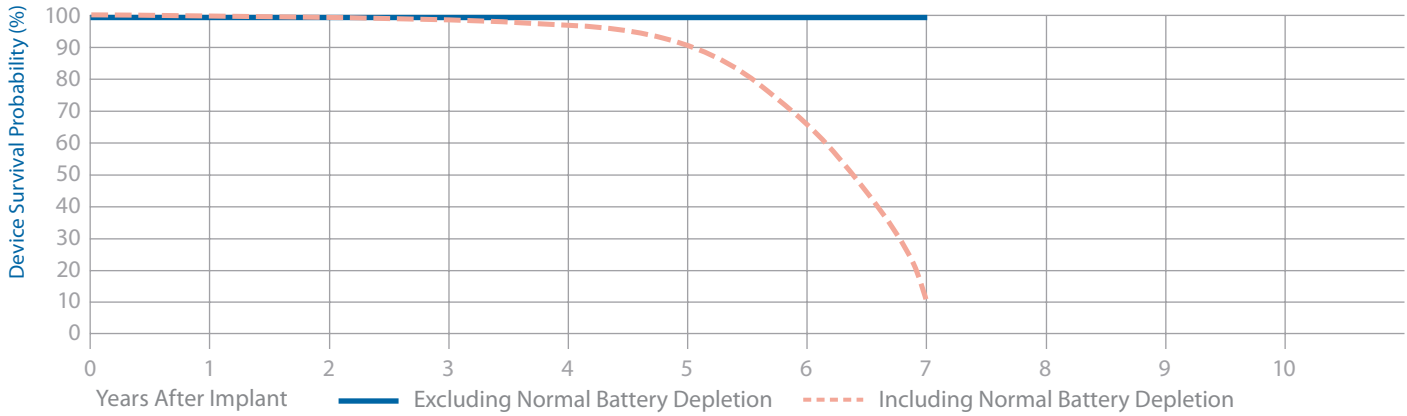
US Market Release	Mar-02
Registered US Implants	48,300
Estimated Active US Implants	3,700
Normal Battery Depletions (US)	8,272

Advisories: See page 156 – 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

Product Characteristics

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
%	99.7	99.4	98.4	96.9	90.4	65.3	10.6
#	42,200	33,900	25,900	21,800	17,700	10,500	1,260

Effective Sample Size

7275 GEM III DR

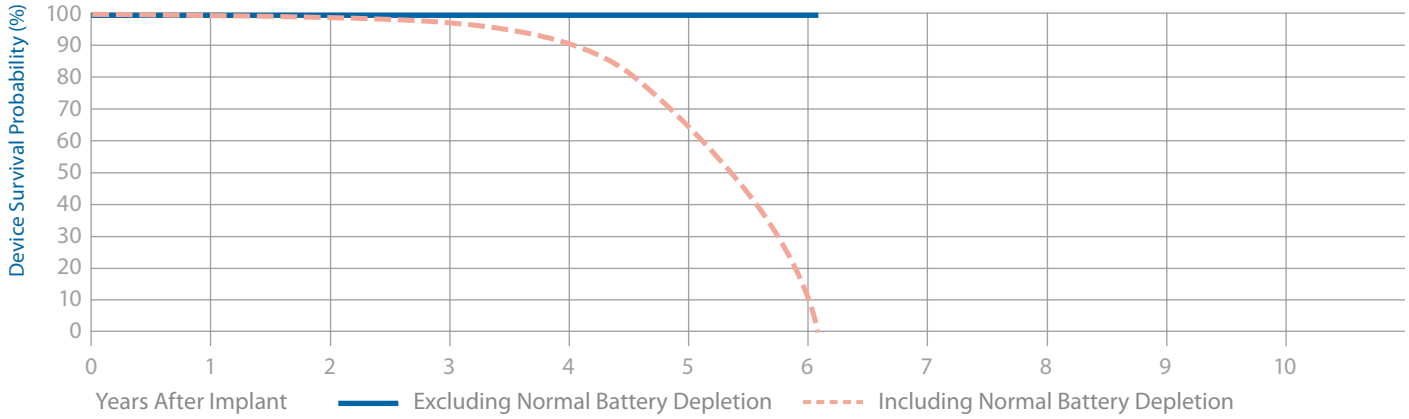
Product Characteristics

US Market Release	Nov-00
Registered US Implants	20,200
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	4,447

Performance Note: See page 166 – 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	64.7	13.2	2.8
#	17,500	15,300	13,100	10,100	5,530	710	350

Effective Sample Size

7278 Maximo DR

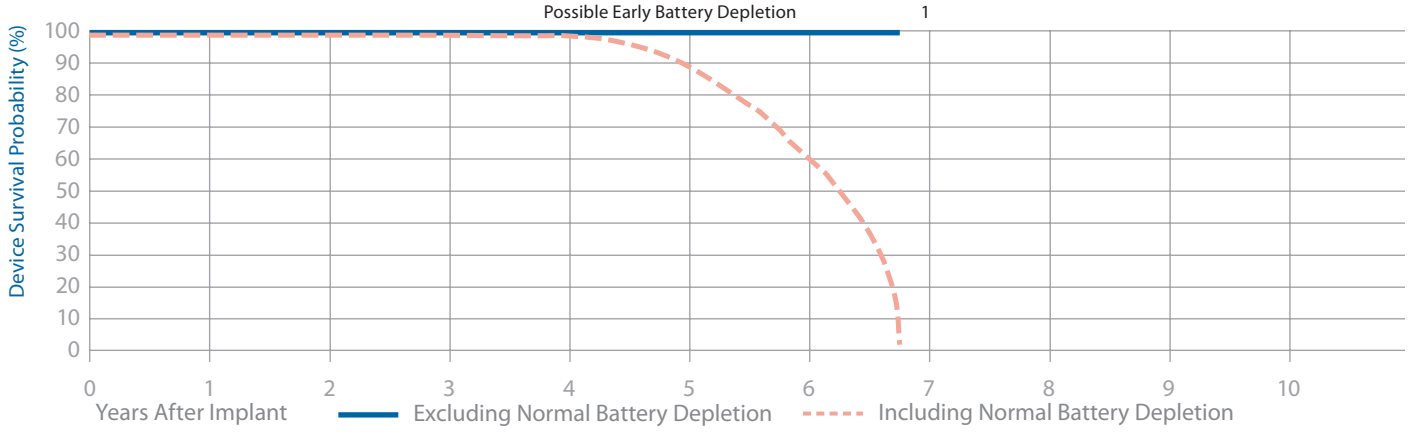
Product Characteristics

US Market Release	Oct-03
Registered US Implants	37,600
Estimated Active US Implants	11,300
Normal Battery Depletions (US)	5,706

Advisories: See page 156 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	56
Therapy Function Not Compromised	47
Electrical Component	19
Possible Early Battery Depletion	26
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 81 mo
%	100.0	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.6	99.1	97.4	88.5	59.9	2.0
#	33,700	30,000	26,500	22,300	16,700	7,730	310

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

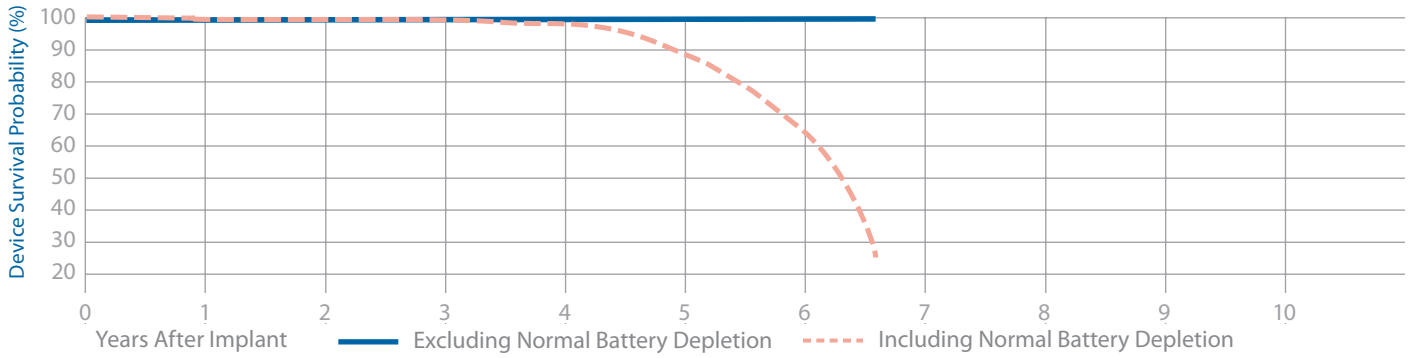
7288 Intrinsic

Product Characteristics

US Market Release	Jun-04
Registered US Implants	30,600
Estimated Active US Implants	10,600
Normal Battery Depletions (US)	4,623
Advisories	None

Malfunctions (US)	63
Therapy Function Not Compromised	56
Battery	2
Electrical Component	20
Software/Firmware	1
Possible Early Battery Depletion	32
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 79 mo
%	100.0	99.9	99.9	99.8	99.8	99.7	99.7
%	99.9	99.7	99.2	98.1	88.9	64.2	26.3
#	28,200	25,900	23,200	20,400	16,200	7,920	1,040

Effective Sample Size

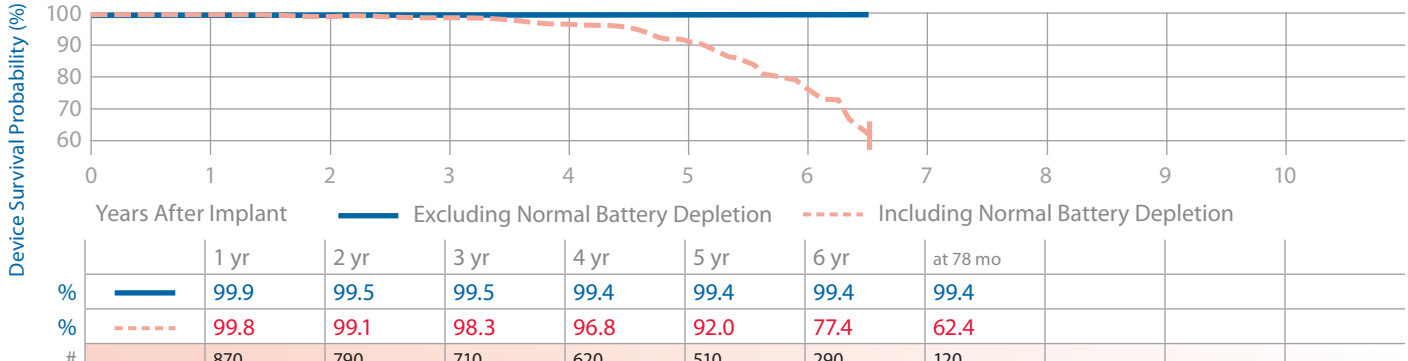
7290Cx Onyx

Product Characteristics

US Market Release	Mar-04
Registered US Implants	950
Estimated Active US Implants	380
Normal Battery Depletions (US)	103
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 78 mo
%	99.9	99.5	99.5	99.4	99.4	99.4	99.4
%	99.8	99.1	98.3	96.8	92.0	77.4	62.4
#	870	790	710	620	510	290	120

Effective Sample Size

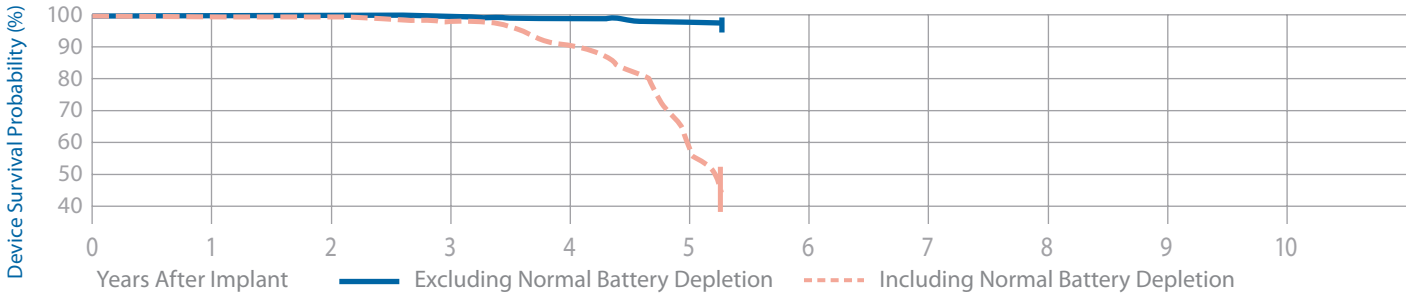
D153ATG, D153DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	460
Estimated Active US Implants	93
Normal Battery Depletions (US)	143
Advisories: See page 147 – 2012 Potential Rapid Battery Depletion	

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

NBD Code	DDED, VVED
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 63 mo
%	99.8	99.8	99.3	98.4	97.6	97.6
%	99.6	99.6	98.0	90.6	56.4	45.7
#	440	400	360	280	160	100

Effective Sample Size

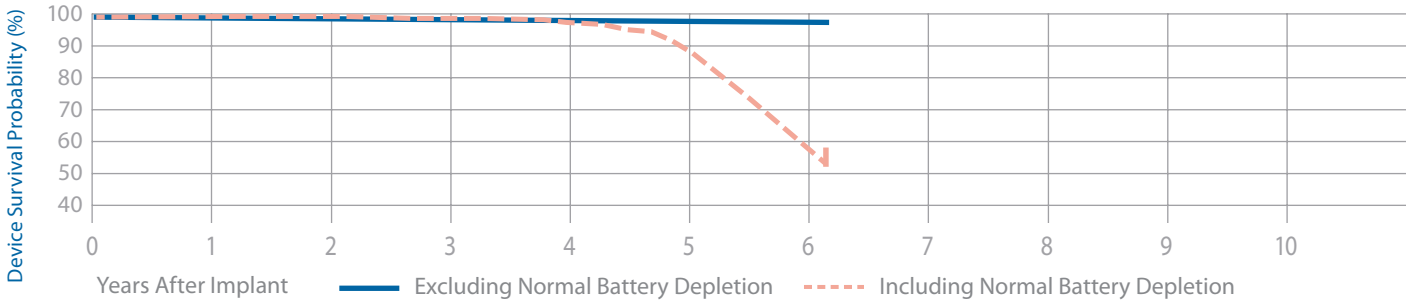
D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	28,100
Estimated Active US Implants	13,700
Normal Battery Depletions (US)	1,813
Advisories: See page 147 – 2012 Potential Rapid Battery Depletion	

Malfunctions (US)	110
Therapy Function Not Compromised	97
Electrical Component	24
Electrical Interconnect	1
Software/Firmware	2
Possible Early Battery Depletion	70
Therapy Function Compromised	13
Electrical Component	13

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	6 yr	at 74 mo
%	100.0	99.9	99.8	99.7	99.5	99.4	99.4
%	99.9	99.7	99.2	97.6	89.3	66.7	51.4
#	25,700	23,500	21,000	17,700	12,800	2,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D154AWG, D164AWG Virtuoso DR

Product Characteristics

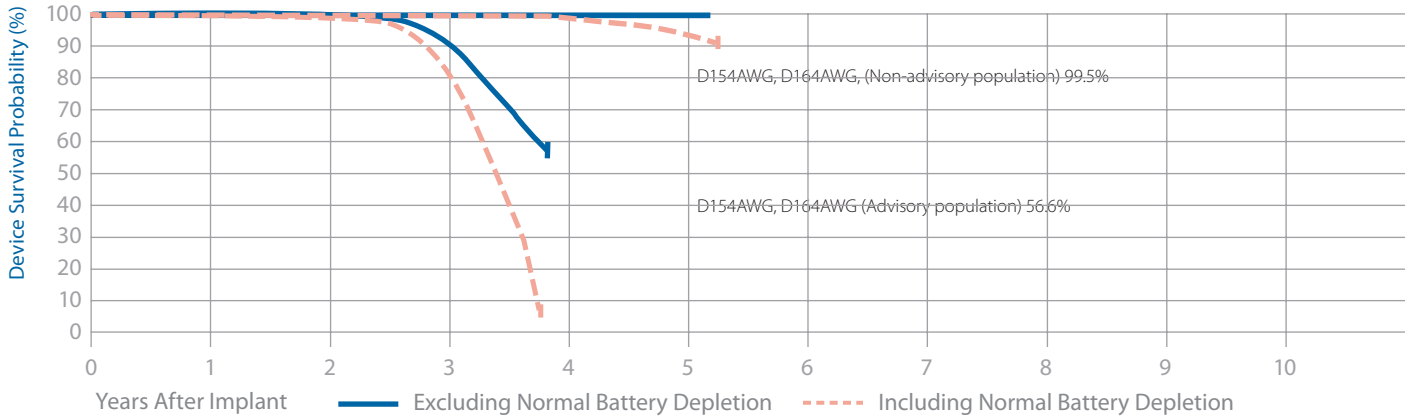
	(N)	(A)
US Market Release	May-06	
Registered US Implants	72,600	4,100
Estimated Active US Implants	51,400	400
Normal Battery Depletions (US)	502	57

Advisories: See page 150 – 2009 Potential Reduced Device Longevity

Performance Note: See page 161 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	163	1,861
Therapy Function Not Compromised	139	1,850
Electrical Component	50	1,849
Electrical Interconnect	1	0
Possible Early Battery Depletion	86	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	5 yr	at 63 mo
%	100.0	99.9	99.9	99.8	99.5	99.5
%	99.9	99.7	99.3	98.3	93.6	91.0
#	66,600	60,700	47,800	25,000	3,930	530
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	7.3
#	3,790	3,480	2,670	290
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D154VRC EnTrust VR

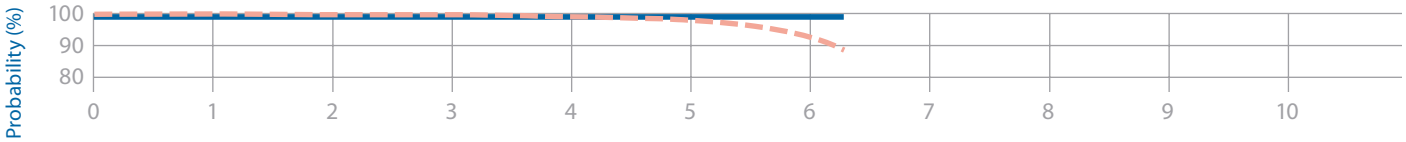
Product Characteristics

US Market Release	Jun-05
Registered US Implants	14,400
Estimated Active US Implants	8,100
Normal Battery Depletions (US)	171

Advisories: See page 147 – 2012
Potential Rapid Battery Depletion

Malfunctions (US)	69
Therapy Function Not Compromised	60
Battery	2
Electrical Component	28
Possible Early Battery Depletion	29
Other	1
Therapy Function Compromised	9
Electrical Component	9

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	6 yr	at 76 mo
%	99.9	99.9	99.8	99.7	99.4	99.2	99.2
%	99.9	99.6	99.3	98.8	97.6	91.4	88.3
#	13,200	12,000	10,700	9,130	7,080	1,410	150

Effective Sample Size

D154VWC, D164VWC Virtuoso VR

Product Characteristics

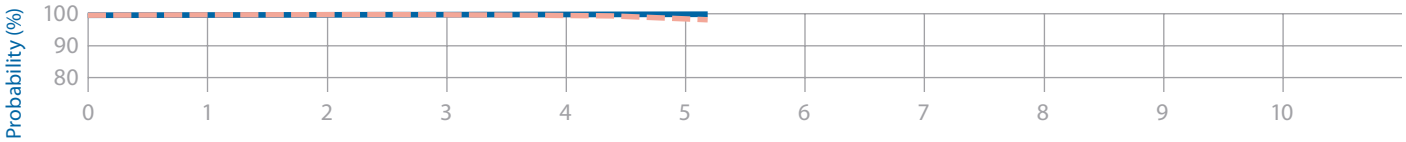
US Market Release	May-06
Registered US Implants	33,100
Estimated Active US Implants	23,400
Normal Battery Depletions (US)	76

Advisories: See page 150– 2009
Potential Reduced Device Longevity

Performance Note: See page 161–
Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	41
Therapy Function Not Compromised	29
Electrical Component *(3 malfunctions related to advisory)*	20
Electrical Interconnect	1
Possible Early Battery Depletion	8
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	5 yr	at 62 mo
%	100.0	100.0	99.9	99.9	99.8	99.8
%	99.9	99.8	99.6	98.4	98.4	98.4
#	30,200	27,300	21,500	10,900	1,270	220

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

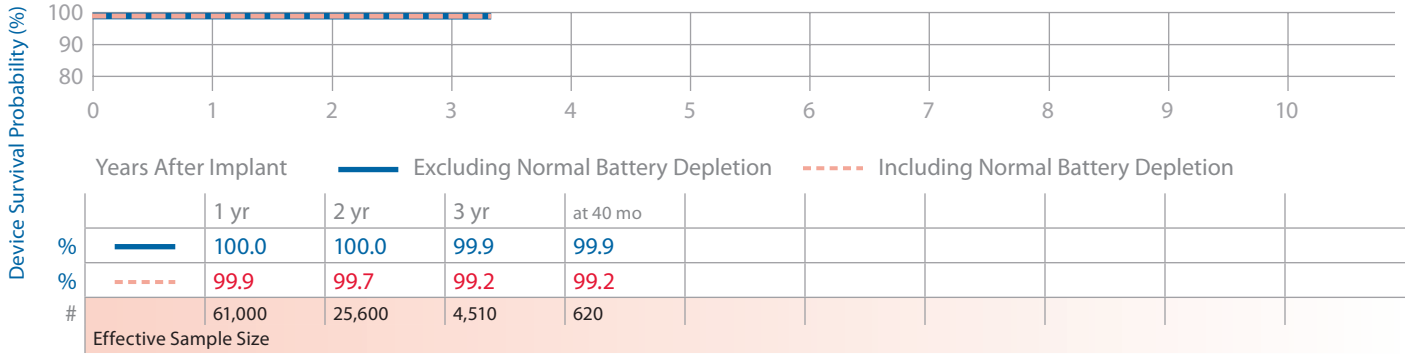
D224DRG Secura DR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	45,300
Estimated Active US Implants	40,000
Normal Battery Depletions (US)	56
Advisories	None

Malfunctions (US)	23
Therapy Function Not Compromised	17
Electrical Component	7
Possible Early Battery Depletion	7
Software/Firmware	3
Therapy Function Compromised	6
Electrical Component	5
Software/Firmware	1

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



	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	99.9	99.9
%	99.9	99.7	99.2	99.2
#	61,000	25,600	4,510	620

Effective Sample Size

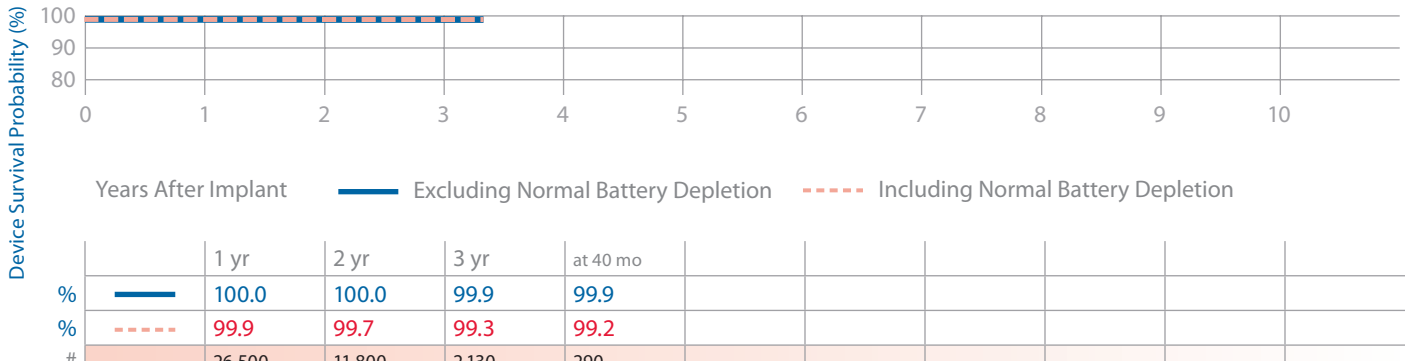
D224VRC Secura VR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	17,600
Estimated Active US Implants	15,500
Normal Battery Depletions (US)	18
Advisories	None

Malfunctions (US)	8
Therapy Function Not Compromised	5
Electrical Component	1
Possible Early Battery Depletion	3
Software/Firmware	1
Therapy Function Compromised	3
Electrical Component	2
Software/Firmware	1

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



	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	99.9	99.9
%	99.9	99.7	99.3	99.2
#	26,500	11,800	2,130	290

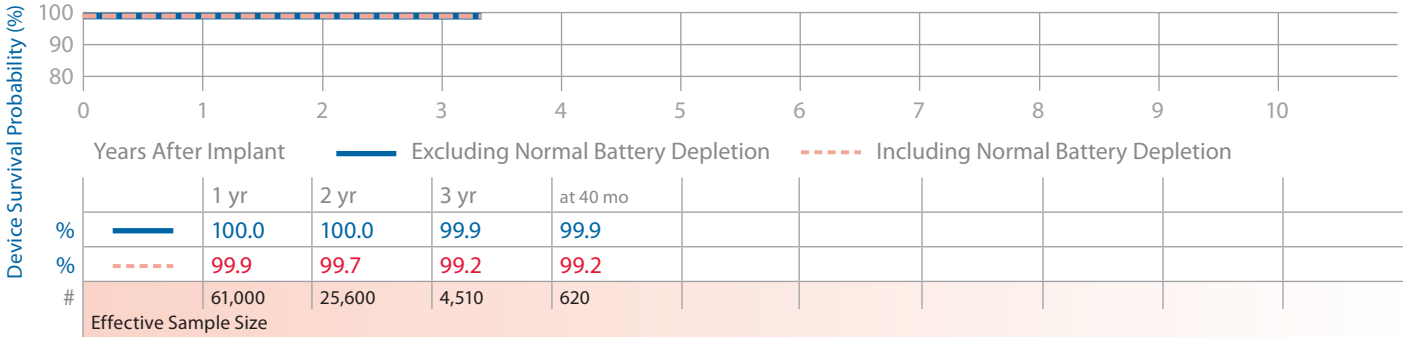
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D274DRG Virtuoso II DR

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVED
Registered US Implants	21,600	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZT
Estimated Active US Implants	19,600	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	6			Estimated Longevity	See page 41
Advisories	None				

Product Characteristics



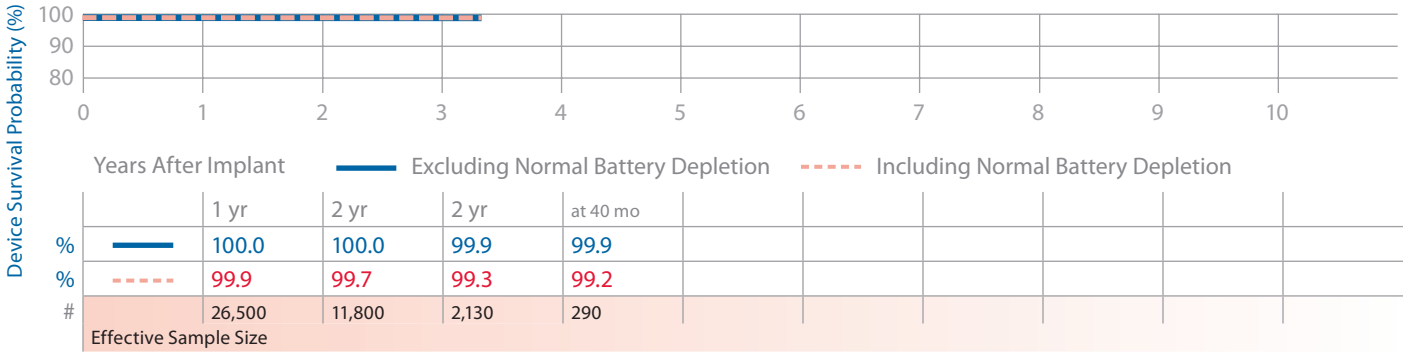
	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	99.9	99.9
%	99.9	99.7	99.2	99.2
#	61,000	25,600	4,510	620

Effective Sample Size

D274VRC Virtuoso II VR

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVEV
Registered US Implants	8,800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZR
Estimated Active US Implants	8,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	3			Estimated Longevity	See page 41
Advisories	None				

Product Characteristics



	1 yr	2 yr	2 yr	at 40 mo
%	100.0	100.0	99.9	99.9
%	99.9	99.7	99.3	99.2
#	26,500	11,800	2,130	290

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

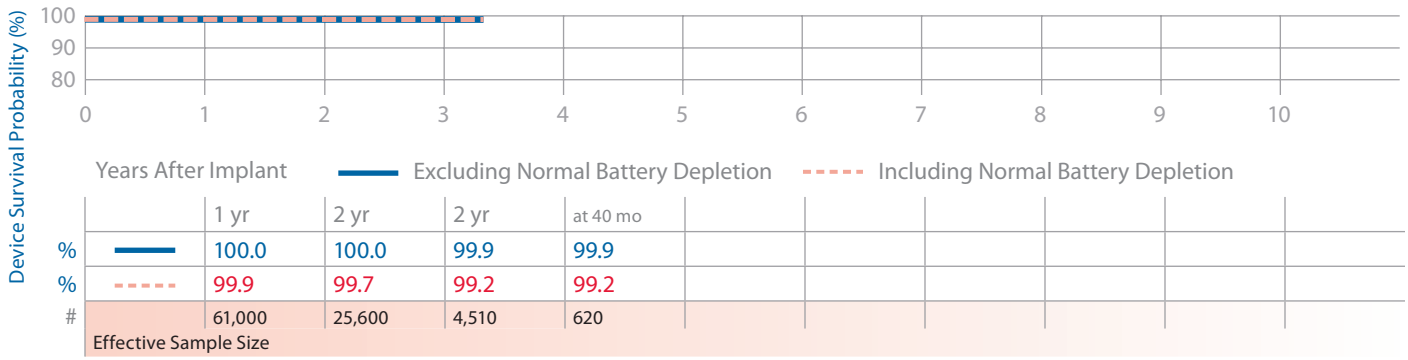
D284DRG Maximo II DR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	17,200
Estimated Active US Implants	15,100
Normal Battery Depletions (US)	21
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

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



		1 yr	2 yr	2 yr	at 40 mo
%	———	100.0	100.0	99.9	99.9
%	- - - - -	99.9	99.7	99.2	99.2
#	Effective Sample Size	61,000	25,600	4,510	620

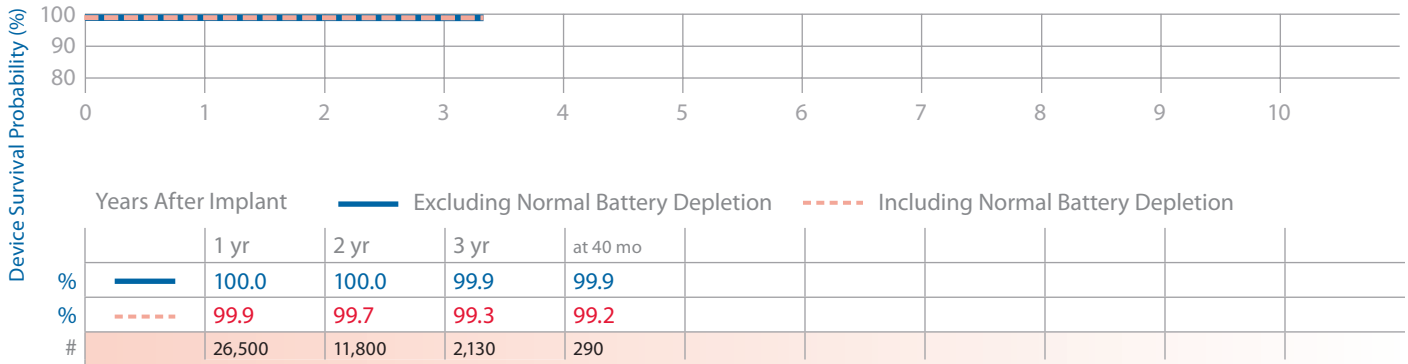
D284VRC Maximo II VR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	10,800
Estimated Active US Implants	9,500
Normal Battery Depletions (US)	14
Advisories	None

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

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



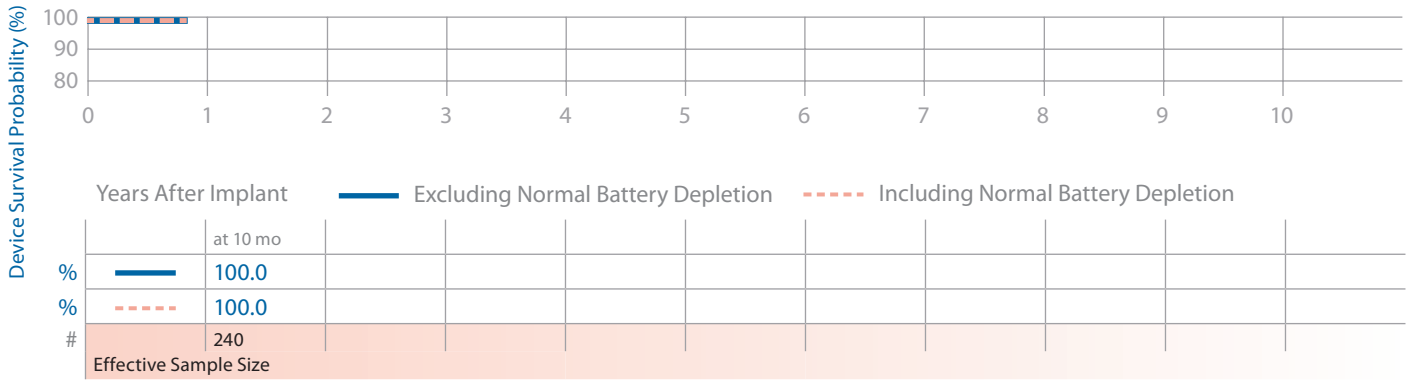
		1 yr	2 yr	3 yr	at 40 mo
%	———	100.0	100.0	99.9	99.9
%	- - - - -	99.9	99.7	99.3	99.2
#	Effective Sample Size	26,500	11,800	2,130	290

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D314DRG Protecta XT DR

Product Characteristics

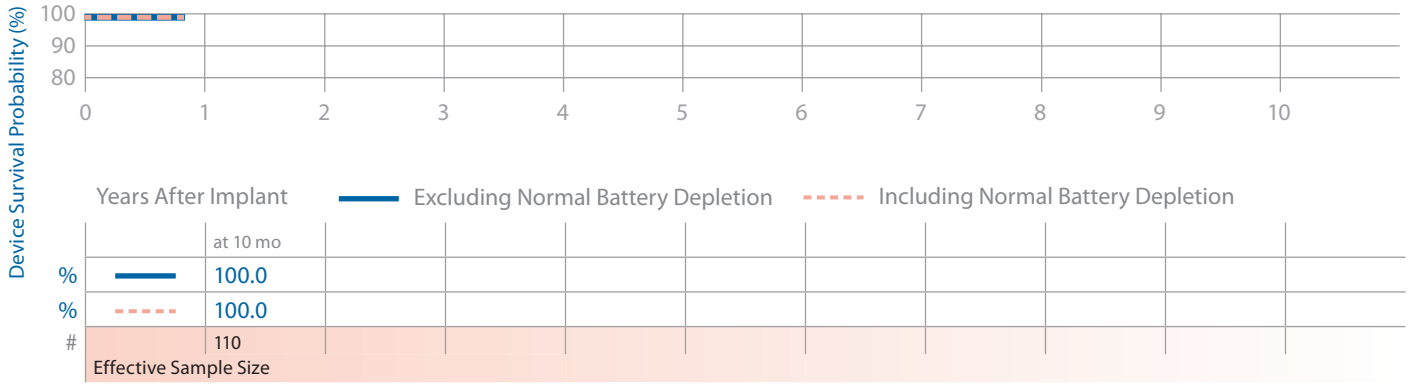
US Market Release	Mar-11	Malfunctions (US)		NBD Code	DDED
Registered US Implants	9,700	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSK
Estimated Active US Implants	9,500	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2	Electrical Component	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	3,700	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSA
Estimated Active US Implants	3,600	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	1	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		

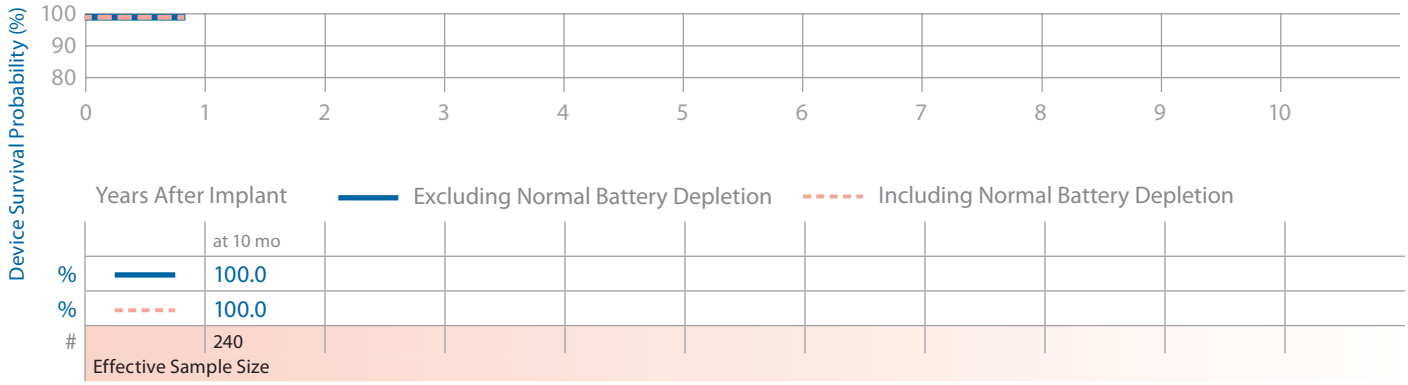


Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

D334DRG Protecta DR

Product Characteristics

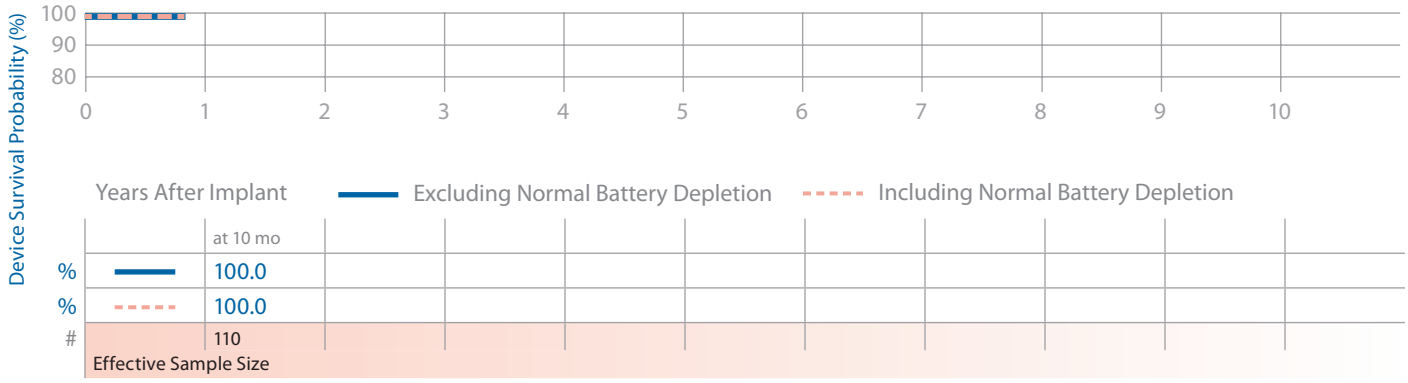
US Market Release	Mar-11	Malfunctions (US)		NBD Code	DDED
Registered US Implants	3,300	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSP
Estimated Active US Implants	3,300	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	0	Estimated Longevity	See page 41
Advisories	None	Software/Firmware	0		



D334VRG Protecta VR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)		NBD Code	VVEV
Registered US Implants	1,800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSX
Estimated Active US Implants	1,800	**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		



Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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	19,400	5,400	1,143	29	+ 29	= 58	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	99.4 +0.2/-0.2	99.3 +0.2/-0.2 at 103 mo
	Advisories: See page 156 – 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	99.5 +0.1/-0.1	99.3 +0.1/-0.2	99.0 +0.2/-0.2	98.2 +0.2/-0.3	93.9 +0.5/-0.5	83.6 +0.8/-0.8	69.4 +1.2/-1.3	42.0 +3.5/-3.5 at 103 mo
7231	GEM III VR	Dec-00	17,500	2,400	3.289	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 166 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.9 +0.2/-0.2	98.4 +0.2/-0.2	96.9 +0.3/-0.3	87.0 +0.7/-0.7	71.9 +1.0/-1.0	36.9 +1.3/-1.3	5.3 +0.9/-0.8 at 101 mo
7232	Maximo VR	Oct-03	44,300	21,600	1,540	15	+ 48	= 63	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 88 mo	
	Advisories: See page 156 – 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	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.1 +0.1/-0.1	97.7 +0.2/-0.2	89.7 +0.4/-0.4	79.1 +0.8/-0.9	67.8 +2.2/-2.3 at 88 mo	
7274	Marquis DR	Mar-02	48,300	3,700	8,272	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 156 – 2005 Potential Premature Battery Depletion Due to Battery Short					(73)	+ (3)	= (76) (advisory-related subset)	Including Normal Battery Depletion	99.7 +0.0/-0.1	99.4 +0.1/-0.1	98.4 +0.1/-0.1	96.9 +0.2/-0.2	90.4 +0.4/-0.4	65.3 +0.7/-0.7	10.6 +0.7/-0.6		
7275	GEM III DR	Nov-00	20,100	1,500	4,447	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 166 – 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	64.7 +0.9/-1.0	13.2 +1.0/-1.0	2.8 +0.7/-0.6 at 73 mo		
7278	Maximo DR	Oct-03	37,600	11,200	5,706	9	+ 47	= 56	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 +0.0/-0.1	99.8 +0.0/-0.1 at 81 mo		
	Advisories: See page 156 – 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	99.1 +0.1/-0.1	97.4 +0.2/-0.2	88.5 +0.4/-0.4	59.9 +0.8/-0.8	2.0 +0.8/-0.6 at 81 mo		
7288	Intrinsic	Jun-04	30,600	10,600	4,623	7	+ 56	= 63	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 79 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	88.9 +0.4/-0.5	64.2 +0.8/-0.8	26.3 +1.3/-1.2 at 79 mo		

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Device Survival Summary continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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	10 yr
7290Cx	Onyx	Mar-04	950	380	103	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 78 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	92.0 +1.9/-2.4	77.4 +3.5/-4.0	62.4 +5.0/-5.5 at 78 mo		
D153ATG, D153DRG	EnTrust	Jun-05	460	93	143	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	98.4 +0.9/-2.0	97.6 +1.2/-2.4	97.6 +1.2/-2.4 at 63 mo			
	Advisories: See page 147 –2012 Potential Rapid Battery Depletion								Including Normal Battery Depletion	99.6 +0.3/-1.5	99.6 +1.3/-1.5	98.0 +1.0/-2.0	90.6 +2.7/-3.7	56.4 +5.8/-6.3	45.7 +6.2/-6.4 at 63 mo			
D154ATG, D154DRG	EnTrust	Jun-05	28,100	13,700	1,813	13	+ 97	= 110	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	99.4 +0.1/-0.1	99.4 +0.1/-0.1 at 74 mo		
	Advisories: See page 147 – 2012 Potential Rapid Battery Depletion								Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.2 +0.1/-0.1	97.6 +0.2/-0.2	89.3 +0.5/-0.5	66.7 +1.1/-1.1	51.4 +2.8/-2.9 at 74 mo		
D154AWG D164AWG (Non-advisory population)	Virtuoso DR	May-06	72,600	51,400	502	24	+ 139	= 163	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	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 63 mo			
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.3 +0.1/-0.1	98.3 +0.1/-0.1	93.6 +0.5/-0.5	91.0 +1.0/-1.1 at 63 mo			
D154AWG D164AWG (Advisory population)	Virtuoso DR	May-06	4,100	400	57	11	+ 1,850	= 1,861	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 150 – 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	7.3 +1.2/-1.1 at 46 mo					
	See page 161 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																	
D154VRC	EnTrust VR	Jun-05	14,400	8,100	171	9	+ 60	= 69	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	99.2 +0.2/-0.2	99.2 +0.2/-0.2 at 76 mo		
	Advisories: See page 147 – 2012 Potential Rapid Battery Depletion								Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.3 +0.1/-0.2	98.8 +0.2/-0.2	97.6 +0.3/-0.3	91.4 +0.9/-1.0	88.3 +2.0/-2.4 at 76 mo		
D154VWC D164VWC (Non-advisory population)	Virtuoso VR	May-06	33,100	23,400	76	12	+ 29	= 41	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/-0.1	99.8 +0.1/-0.1	99.8 +0.0/-0.1 at 62 mo			
	Advisories: See page 150 – 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	99.3 +0.1/-0.1	98.4 +0.3/-0.3	98.4 +0.3/-0.3 at 62 mo			
	See page 161 – 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		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
D224DRG	Secura DR	Sep-08	45,300	40,000	56	6	+	17	=	23	Excluding Normal Battery Depletion	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 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.2 +0.1/-0.2	99.2 +0.1/-0.2 at 40 mo				
D224VRC	Secura VR	Sep-08	17,600	15,500	18	3	+	5	=	8	Excluding Normal Battery Depletion	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 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.3 +0.2/-0.2	99.2 +0.2/-0.3 at 40 mo				
D274DRG	Virtuoso II DR	Aug-09	21,600	19,600	6	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	99.9 +0.0/-0.1 at 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.2 +0.1/-0.2	99.2 +0.1/-0.2 at 40 mo				
D274VRC	Virtuoso II VR	Aug-09	8,800	8,000	3	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	99.9 +0.0/-0.1 at 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.3 +0.2/-0.2	99.2 +0.2/-0.3 at 40 mo				
D284DRG	Maximo II DR	Sep-08	17,200	15,100	21	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	99.9 +0.0/-0.1 at 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.2 +0.1/-0.2	99.2 +0.1/-0.2 at 40 mo				
D284VRC	Maximo II VR	Sep-08	10,800	9,500	14	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	99.9 +0.0/-0.1 at 40 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.3 +0.2/-0.2	99.2 +0.2/-0.3 at 40 mo				

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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
D314DRG	Protecta XT DR	Mar-11	9,700	9,500	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
D314VRG	Protecta XT VR	Mar-11	3,700	3,600	1	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
D334DRG	Protecta DR	Mar-11	3,300	3,300	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
D334VRG	Protecta VR	Mar-11	1,800	1,800	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 10 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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 February 6, 2012

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.

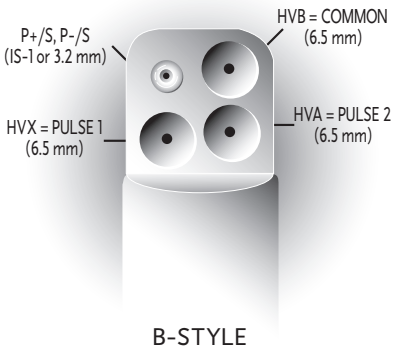
** A full charge is a full energy therapeutic shock or capacitor reformation.

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

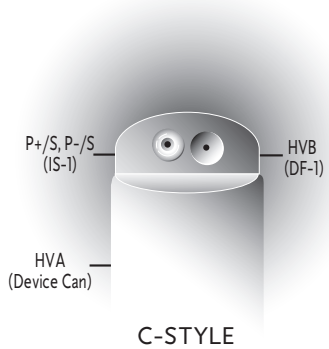
‡ Pacing mode is VVI for single chamber models and DDD for dual chamber models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510-ohm pace load per applicable channel.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

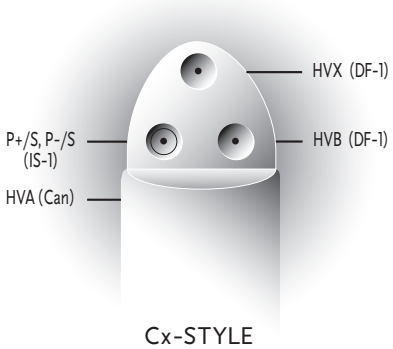
ICD Connector Styles



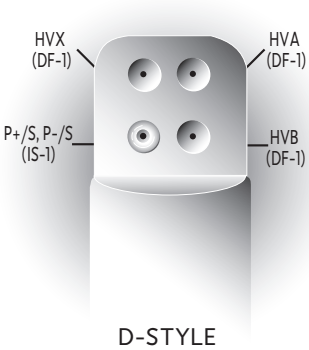
B-STYLE CONNECTOR



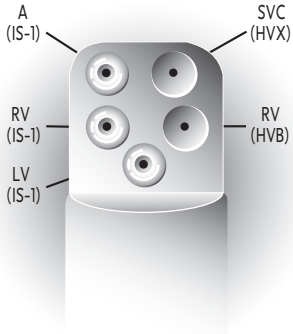
C-STYLE CONNECTOR



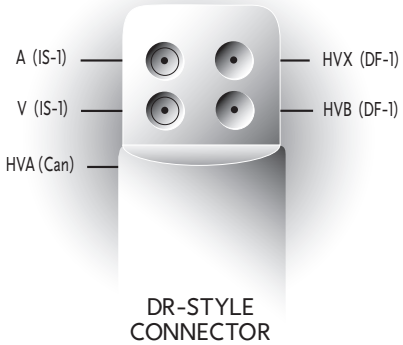
Cx-STYLE CONNECTOR



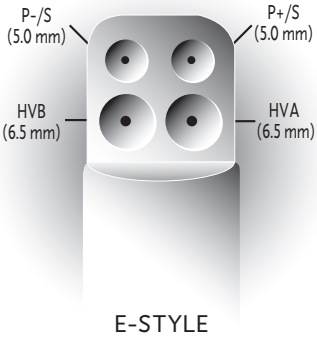
D-STYLE CONNECTOR



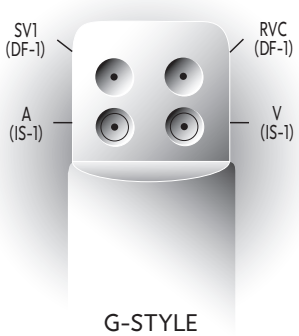
CRT-D CONNECTOR



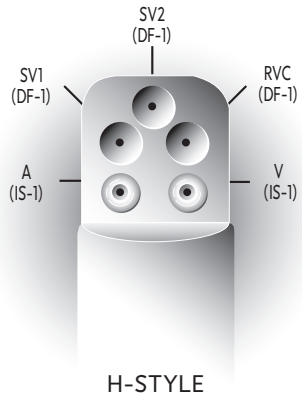
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR



H-STYLE CONNECTOR

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

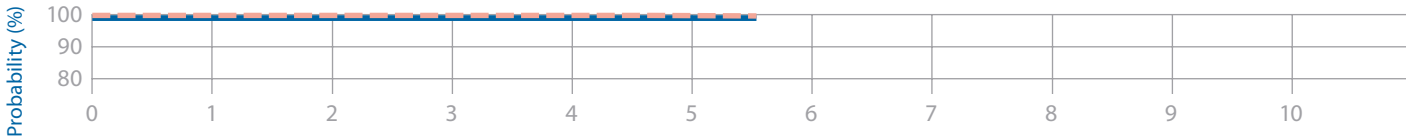
Adapta DR ADDR01, ADDR03, ADDR06, ADD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	291,500
Estimated Active US Implants	242,600
Normal Battery Depletions (US)	155
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	51
Therapy Function Not Compromised	32
Electrical Component	31
Electrical Interconnect	1
Therapy Function Compromised	19
Electrical Component	17
Electrical Interconnect	2

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



	1 yr	2 yr	3 yr	4 yr	5 yr	at 65 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.4	99.2
#	227,600	161,600	103,100	52,100	10,800	380

Effective Sample Size

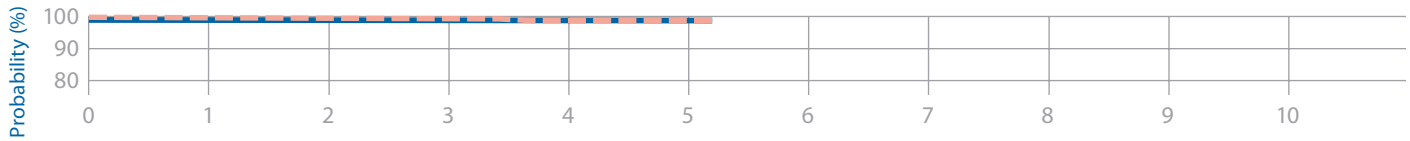
Adapta DR ADDRL1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	53,900
Estimated Active US Implants	48,900
Normal Battery Depletions (US)	9
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

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

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



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.7	99.7
#	36,500	21,300	10,600	3,870	430	190

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Adapta DR ADDRS1

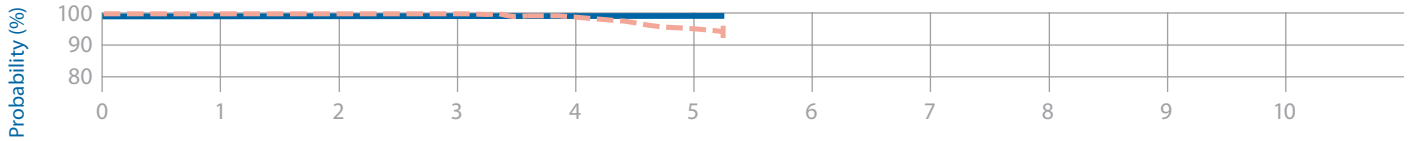
US Market Release	Jul-06
Registered US Implants	28,000
Estimated Active US Implants	21,400
Normal Battery Depletions (US)	84

Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	5
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
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	5 yr	at 63 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.6	98.7	95.0	94.4
#	20,600	13,900	8,310	3,850	670	140

Effective Sample Size

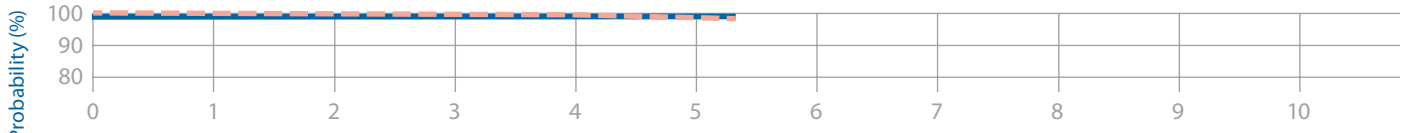
Adapta SR ADSR01, ADSR03, ADSR06

US Market Release	Jul-06
Registered US Implants	54,000
Estimated Active US Implants	38,100
Normal Battery Depletions (US)	72
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	5 yr	at 64 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.7	99.3	98.3	98.3
#	38,500	26,400	16,100	7,690	1,450	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

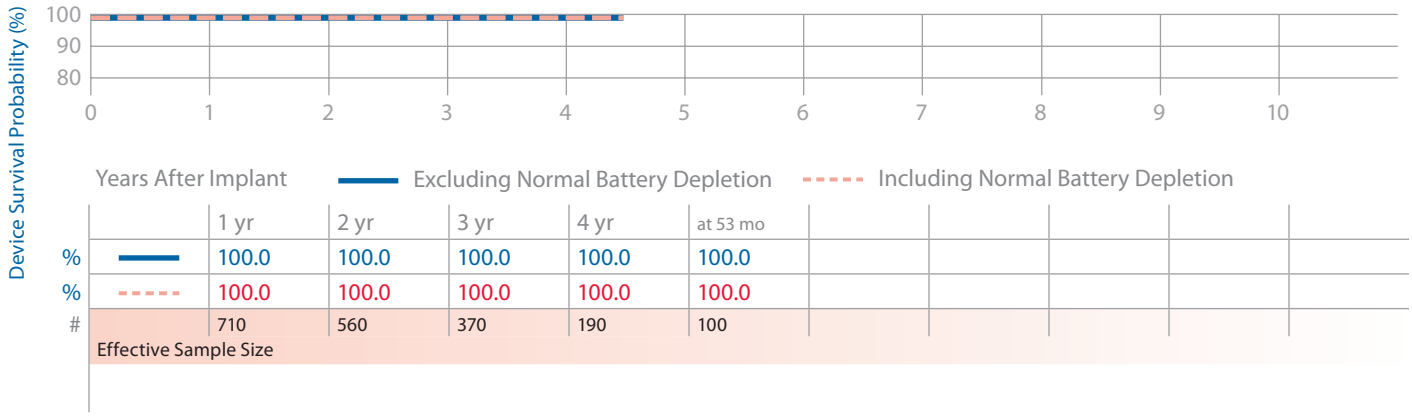
Adapta VDD ADVDD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	890
Estimated Active US Implants	690
Normal Battery Depletions (US)	0
Performance Note: See page 159 – 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	4 yr	at 53 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0
#	710	560	370	190	100

Effective Sample Size

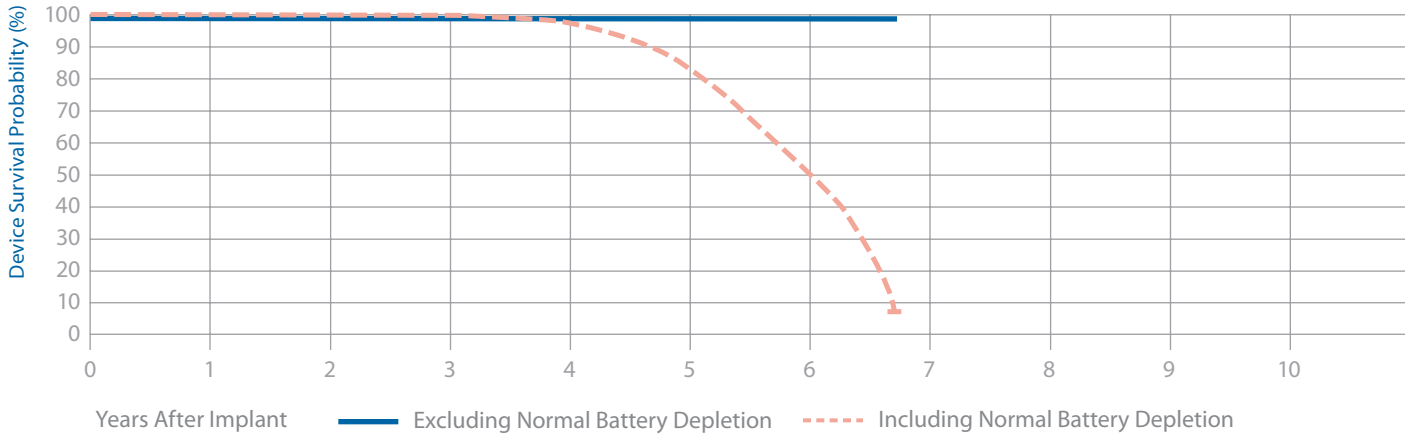
AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03
Registered US Implants	10,800
Estimated Active US Implants	1,140
Normal Battery Depletions (US)	2,658
Performance Note: See page 164 – 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 81 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.8	99.5	97.6	84.3	50.7	9.4
#	9,660	8,920	8,160	7,360	5,540	2,400	300

Effective Sample Size

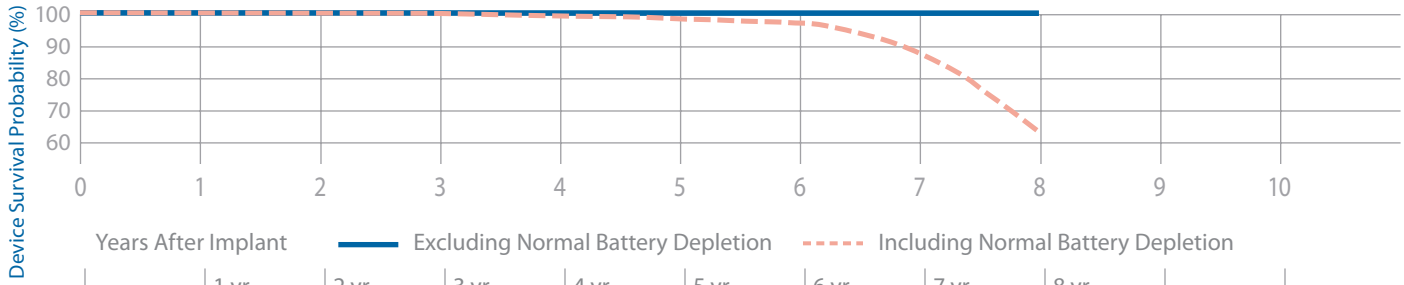
Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

EnPulse DR E1DR01, E1DR03, E1DR06

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	1	NBG Code	DDDR
Registered US Implants	6,820	**Therapy Function Not Compromised**	1	Serial Number Prefix	PRA, PRB, PRE
Estimated Active US Implants	2,630	Electrical Component	1	Estimated Longevity	See page 78
Normal Battery Depletions (US)	550	**Therapy Function Compromised**	0		

Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	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	99.9	99.2	98.4	96.9	87.5	62.7
#	6,210	5,720	5,310	4,840	4,400	3,940	3,130	150

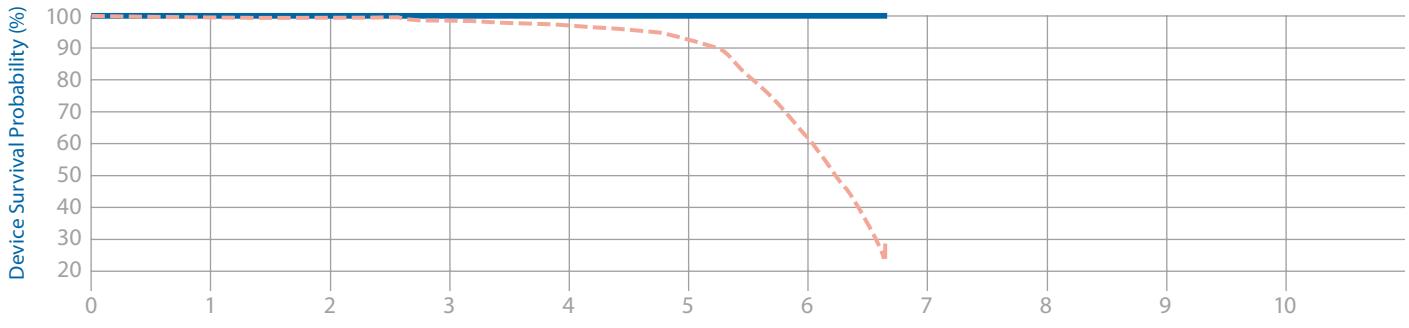
Effective Sample Size

EnPulse DR E1DR21

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	1,850	**Therapy Function Not Compromised**	0	Serial Number Prefix	PPT
Estimated Active US Implants	190	**Therapy Function Compromised**	0	Estimated Longevity	See page 78
Normal Battery Depletions (US)	349				

Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	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	63.6	26.0
#	1,640	1,480	1,320	1,160	970	480	120

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

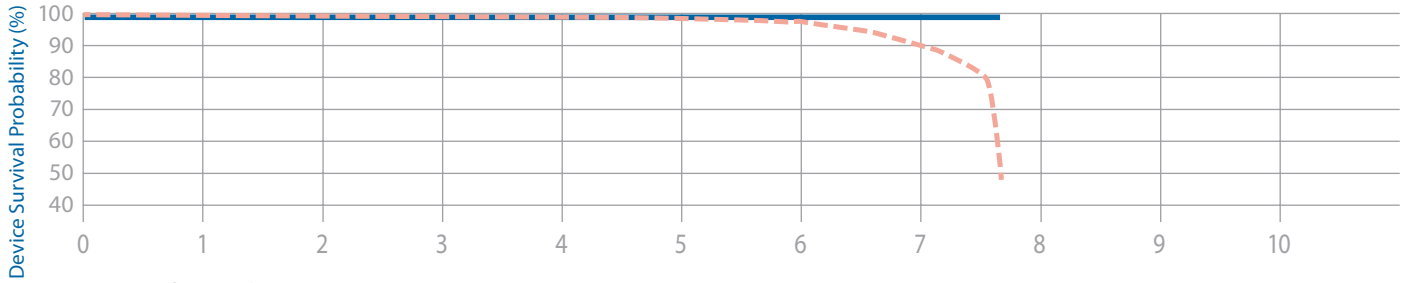
EnPulse 2 DR E2DR01, E2DR03, E2DR06

Product Characteristics

US Market Release	Feb-04
Registered US Implants	100,700
Estimated Active US Implants	54,700
Normal Battery Depletions (US)	2,003
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	23
Therapy Function Not Compromised	17
Electrical Component	15
Electrical Interconnect	2
Therapy Function Compromised	6
Battery	1
Electrical Component	3
Electrical Interconnect	2

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 92 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.5	98.9	97.4	90.8	47.9
#	91,500	84,400	77,400	70,700	63,600	41,500	14,300	110

Effective Sample Size

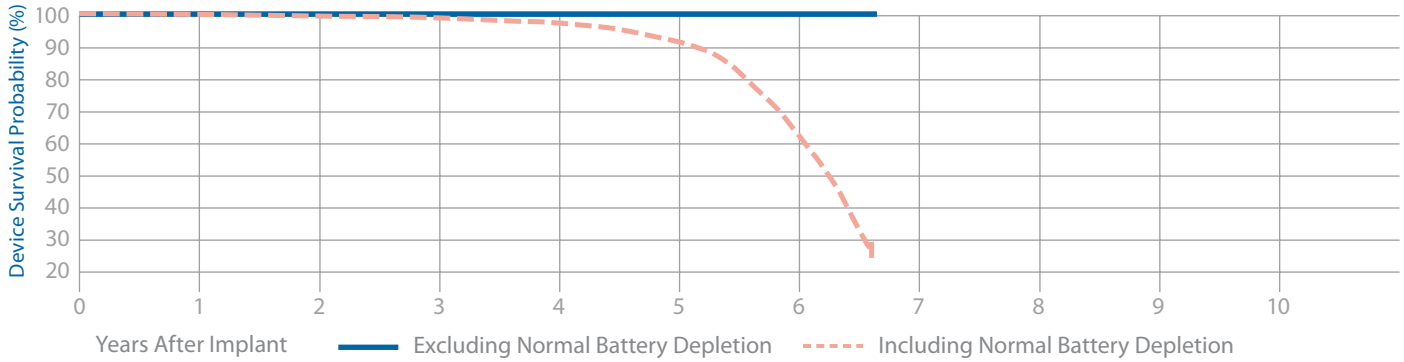
EnPulse 2 DR E2DR21

Product Characteristics

US Market Release	Feb-04
Registered US Implants	12,200
Estimated Active US Implants	3,560
Normal Battery Depletions (US)	1,268
Performance Note: See page 159 – 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



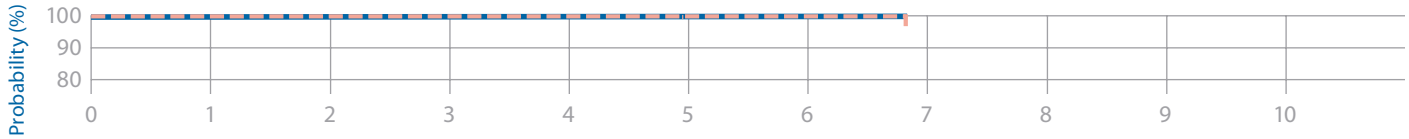
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 79 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.2	97.7	91.7	68.5	29.5
#	10,600	9,520	8,540	7,460	6.020	2,250	230

Effective Sample Size

EnPulse 2 DR E2DR31, E2DR33

Product Characteristics

US Market Release	Feb-04	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	580	**Therapy Function Not Compromised**	0	Serial Number Prefix	PNL, PNM
Estimated Active US Implants	420	**Therapy Function Compromised**	0	Estimated Longevity	See page 78
Normal Battery Depletions (US)	2				
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					



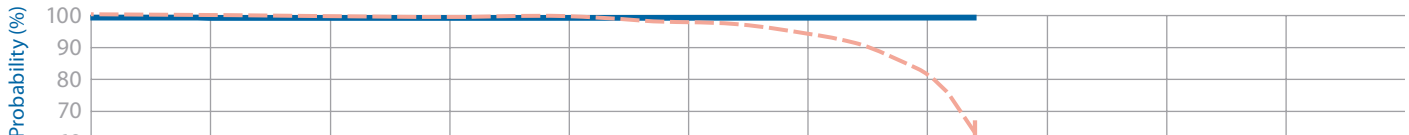
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0	99.5	99.5
#	560	530	500	470	430	240	100

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	25,500	**Therapy Function Not Compromised**	3	Serial Number Prefix	PMW, PMY, PNA
Estimated Active US Implants	9,160	Electrical Component	2		
Normal Battery Depletions (US)	638	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 89 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	97.7	94.3	81.4	61.3
#	21,300	18,300	15,800	13,700	11,300	6,100	1,480	280

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

EnPulse 2 VDD E2VDD01

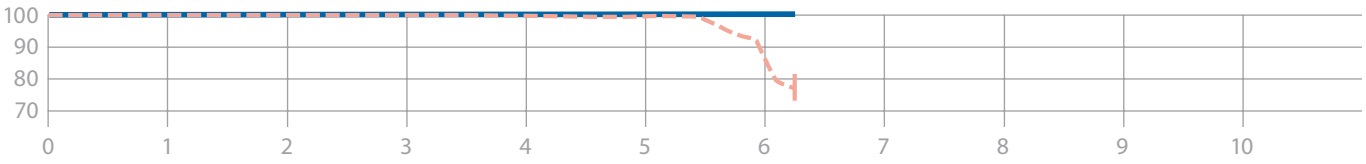
Product Characteristics

US Market Release	Dec-03
Registered US Implants	640
Estimated Active US Implants	260
Normal Battery Depletions (US)	44

Performance Note: See page 159 – 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	at 75 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.5	99.1	86.8	76.6
#	570	520	460	420	350	170	100

Effective Sample Size

EnRhythm DR P1501DR

Product Characteristics

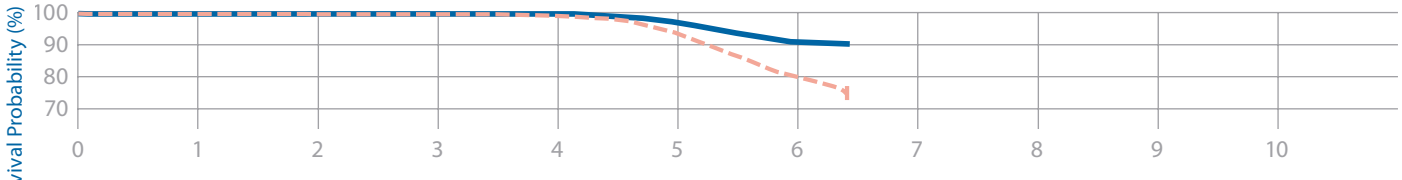
US Market Release	May-05
Registered US Implants	109,700
Estimated Active US Implants	76,300
Normal Battery Depletions (US)	296

Advisories: See page 148 – 2010 Low Battery Voltage Displayed at Device Interrogation

Performance Note: See page 161 – Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	2,898
Therapy Function Not Compromised	2,851
Battery *(183 malfunctions related to advisory)*	2,794
Electrical Component *(1 malfunction related to advisory)*	22
Possible Early Battery Depletion *(1 malfunction related to advisory)*	33
Electrical Interconnect	2
Therapy Function Compromised	47
Battery	5
Electrical Component	36
Electrical Interconnect	4
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 77 mo
%	100.0	100.0	99.9	99.5	97.0	91.1	90.3
%	100.0	99.9	99.7	98.9	93.5	79.8	74.6
#	97,500	80,900	64,600	49,600	33,700	8,740	790

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

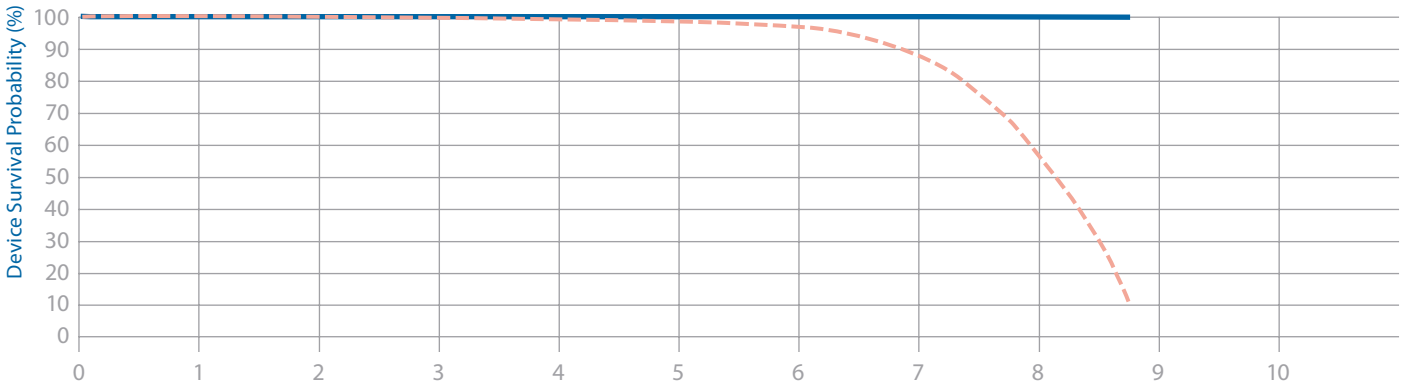
Kappa 400 DR KDR401, KDR403

US Market Release	Jan-98
Registered US Implants	46,800
Estimated Active US Implants	4,820
Normal Battery Depletions (US)	7,619
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



	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	99.9	99.9	99.9	99.9	99.9
%	99.8	99.8	99.6	99.4	98.9	97.2	87.9	56.8	10.8
#	42,500	39,300	36,100	33,000	29,600	25,800	19,400	8,370	850

Effective Sample Size

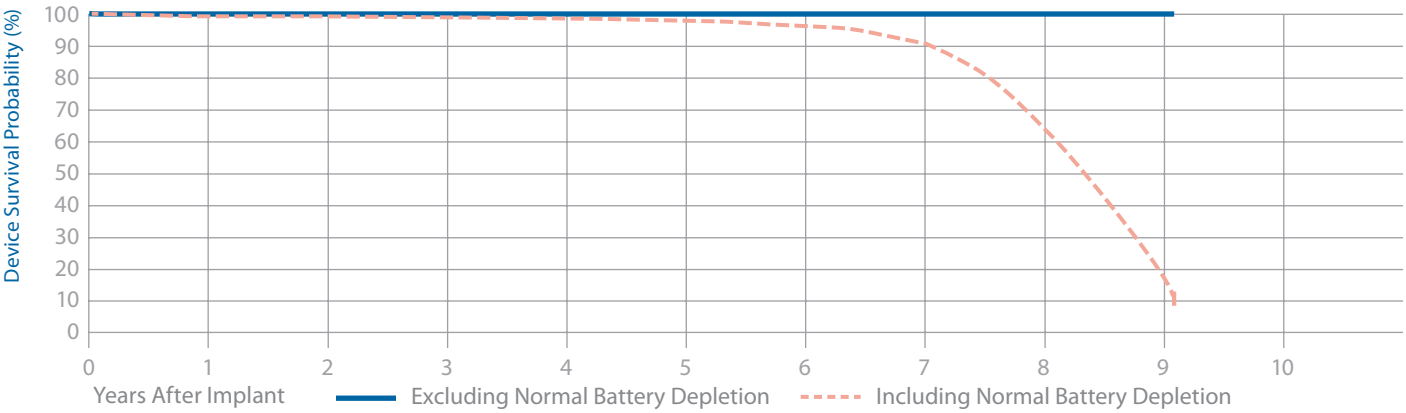
Kappa 400 SR KSR401, KSR403

US Market Release	Feb-98
Registered US Implants	15,400
Estimated Active US Implants	1,710
Normal Battery Depletions (US)	1,435
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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 109 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.7	99.5	99.0	98.5	96.8	90.5	63.9	17.0	10.3
#	13,000	11,300	9,830	8,550	7,290	5,990	4,490	2,070	200	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 600 DR KDR601, KDR603, KDR606

Product Characteristics

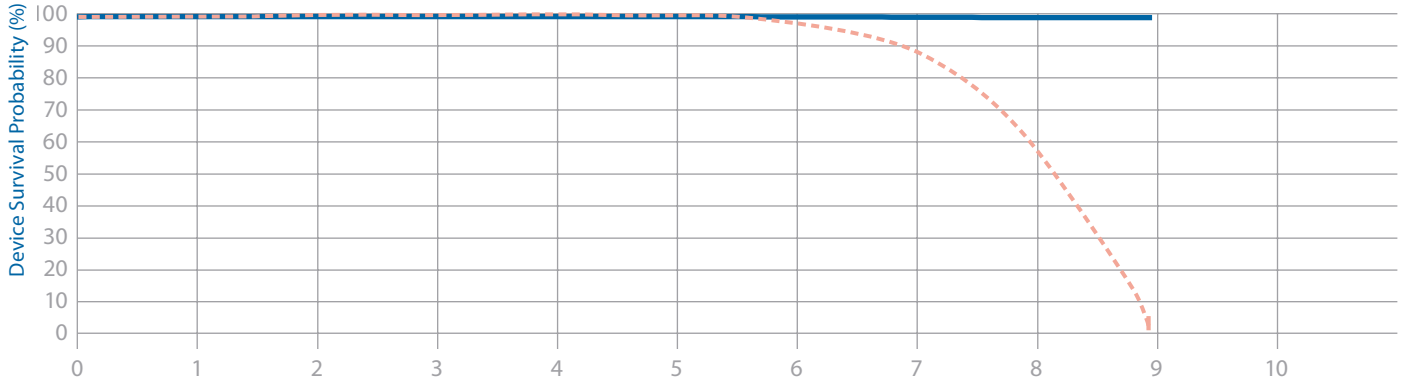
US Market Release	Jan-99
Registered US Implants	25,000
Estimated Active US Implants	1,930
Normal Battery Depletions (US)	3,789

Advisories: See page 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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	57.5	4.9
#		20,900	19,000	17,000	15,200	13,400	11,500	8,790	4,110	240

Effective Sample Size

IPG

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 600 DR KDR651, KDR653

Product Characteristics

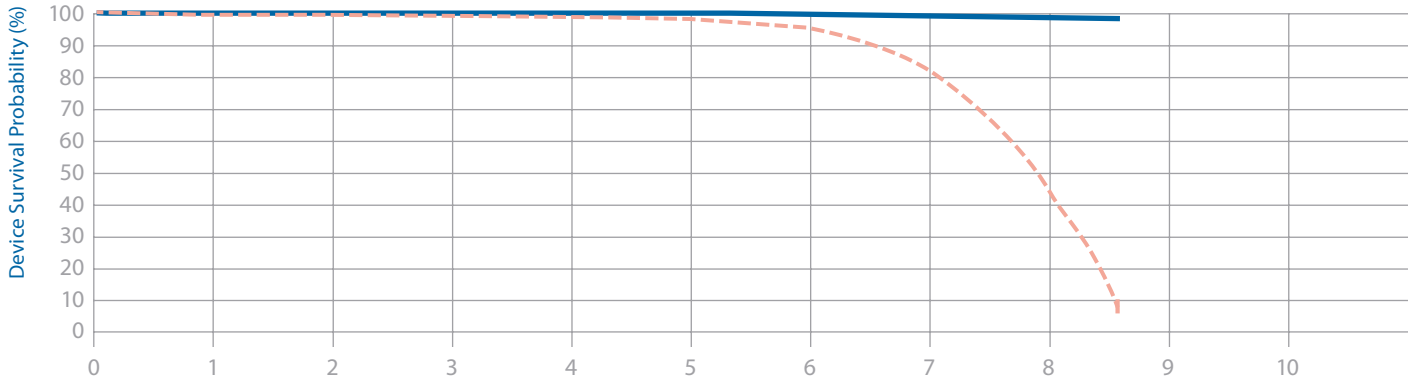
US Market Release	Mar-01
Registered US Implants	16,400
Estimated Active US Implants	1,340
Normal Battery Depletions (US)	2,717

Advisories: See page 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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	81.2	43.7	6.3
#	12,500	11,400	10,300	9,160	8,080	6,960	4,960	1,850	170

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 700 D KD701, KD703, KD706

Product Characteristics

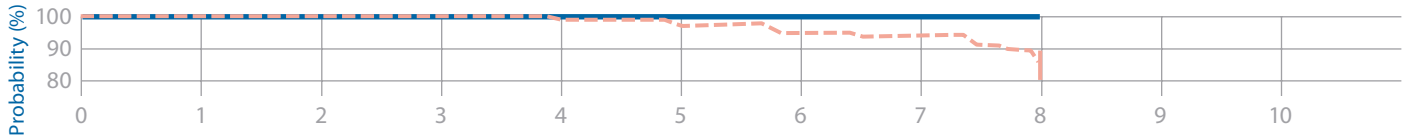
US Market Release	Jan-99
Registered US Implants	310
Estimated Active US Implants	67
Normal Battery Depletions (US)	17

Advisories: See page 157 – 2002 Potential Fractured Power Supply Wires; See also page 151– 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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
#	270	240	210	190	180	160	140	110

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

Product Characteristics

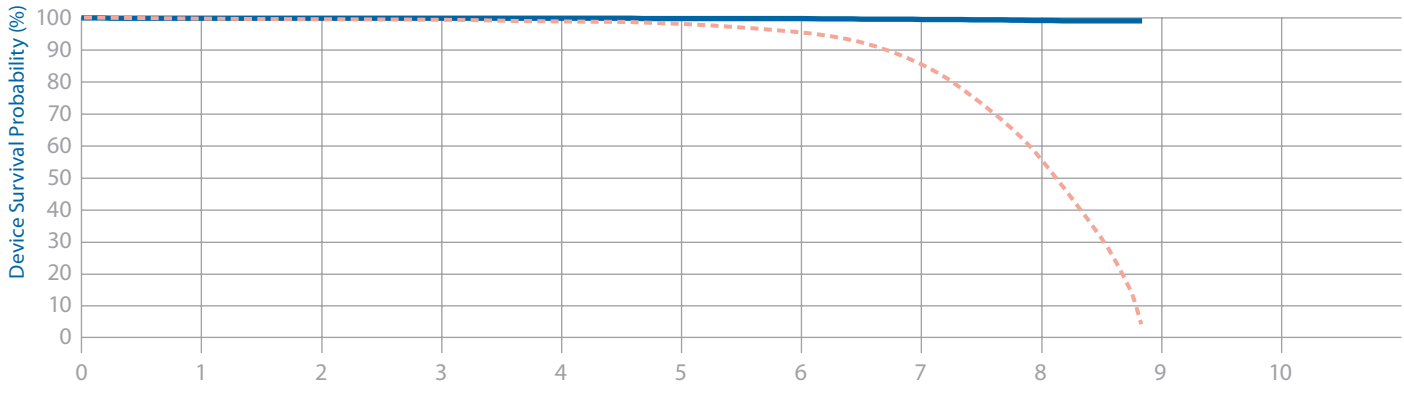
US Market Release	Jan-99
Registered US Implants	206,300
Estimated Active US Implants	30,000
Normal Battery Depletions (US)	32,080

Advisories: See page 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	740
Therapy Function Not Compromised	38
Battery	1
Electrical Component	27
Electrical Interconnect *(1 malfunction related to advisory)*	3
Possible Early Battery Depletion	4
Other	3
Therapy Function Compromised	702
Electrical Component	17
Electrical Interconnect *(416 malfunctions related to advisory)*	684
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	85.4	56.1	4.6
#	172,700	157,800	143,500	129,200	115,200	97,400	70,900	31,600	1,700

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 700 DR KDR721

Product Characteristics

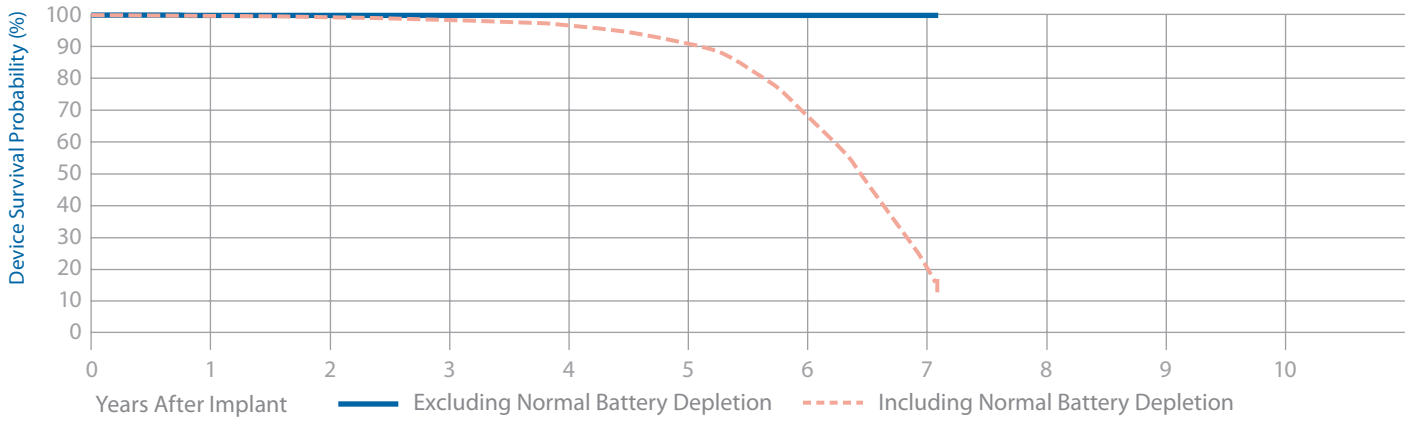
US Market Release	Feb-99
Registered US Implants	9,830
Estimated Active US Implants	780
Normal Battery Depletions (US)	1,342

Advisories: See page 157– 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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	68.9	20.9	14.7
#	Effective Sample Size	8,440	7,440	6,480	5,490	4,330	2,190	280	190

Kappa 700 SR KSR701, KSR703, KSR706

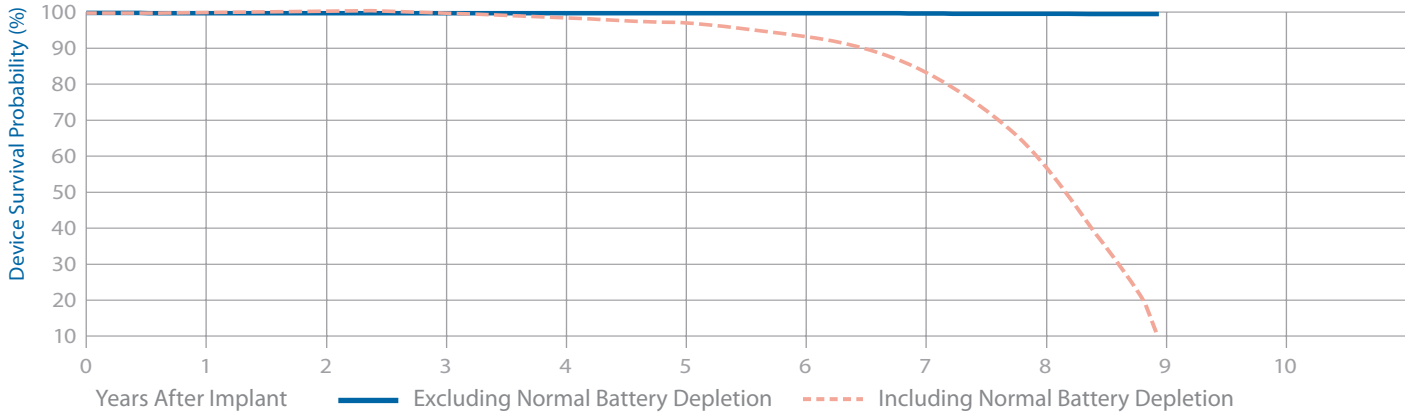
Product Characteristics

US Market Release	Jan-99
Registered US Implants	55,300
Estimated Active US Implants	6,960
Normal Battery Depletions (US)	4,754

Advisories: See page 151 – 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	98.6	97.2	93.6	83.5	56.4	11.2
#		45,500	39,000	33,100	28,100	23,400	18,000	12,200	5,410	360

Effective Sample Size

Kappa 700 VDD KVDD701

Product Characteristics

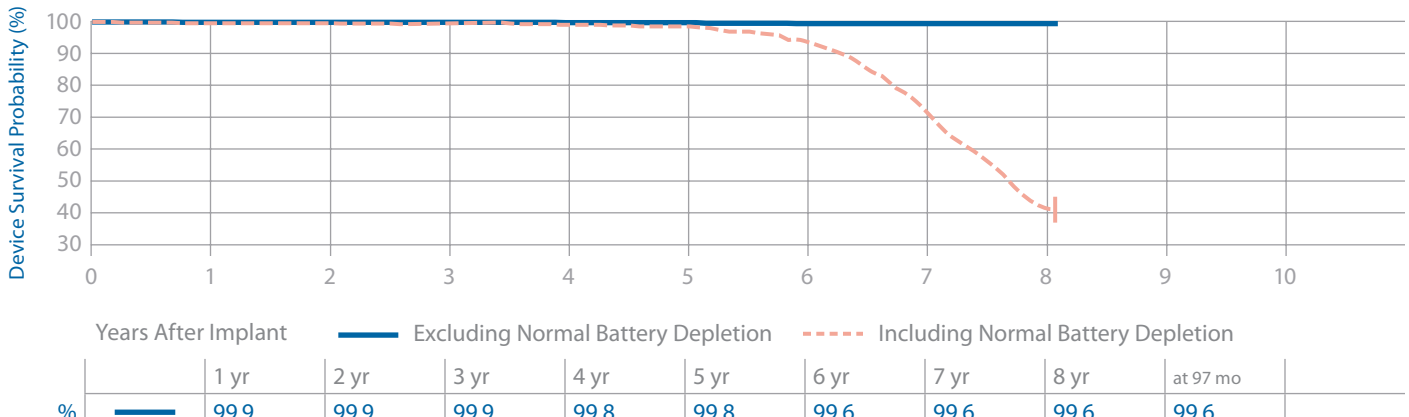
US Market Release	Jan-99
Registered US Implants	1,690
Estimated Active US Implants	210
Normal Battery Depletions (US)	172

Advisories: See page 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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	99.6	99.1	98.6	98.4	94.1	72.7	41.9	41.1
#		1,480	1,320	1,180	1,050	960	790	430	110	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 800 DR KDR801, KDR803

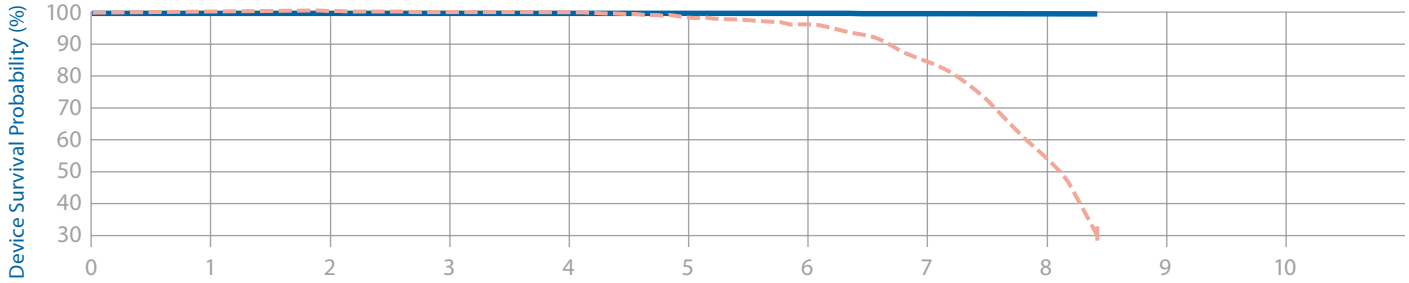
Product Characteristics

US Market Release	Jan-02
Registered US Implants	4,280
Estimated Active US Implants	840
Normal Battery Depletions (US)	592

Performance Note: See page 159 – 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 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	99.5	98.5	96.1	84.4	54.0	29.5
#	3,840	3,510	3,180	2,860	2,540	2,240	1,720	770	180

Effective Sample Size

Kappa 900 DR KDR901, KDR903, KDR906

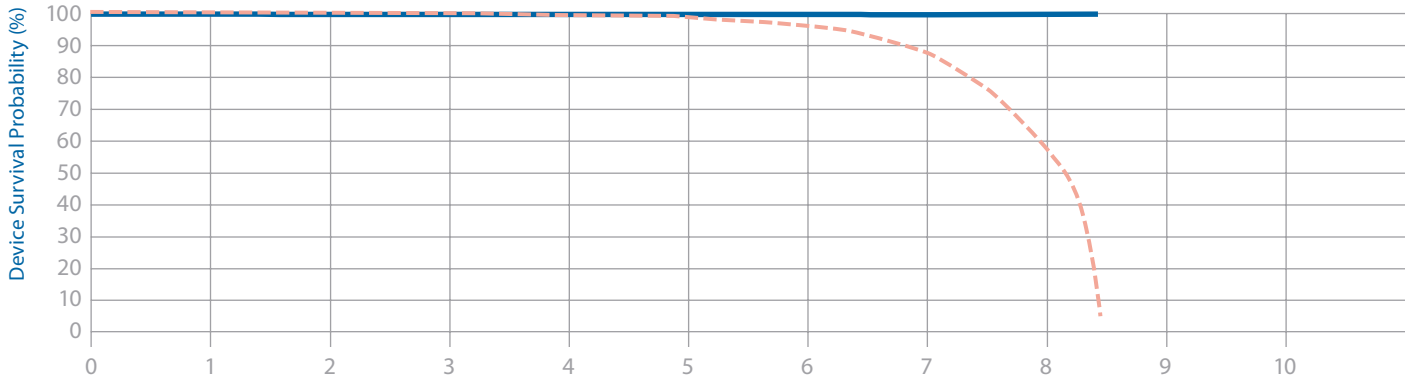
Product Characteristics

US Market Release	Jan-02
Registered US Implants	125,400
Estimated Active US Implants	37,800
Normal Battery Depletions (US)	13,888

Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	74
Therapy Function Not Compromised	18
Electrical Component	16
Electrical Interconnect	1
Other	1
Therapy Function Compromised	56
Electrical Component	11
Electrical Interconnect	45

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 103 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	87.5	57.9	6.8
#	112,800	103,500	94,500	85,800	77,000	63,100	44,200	17,000	900

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 900 SR KSR901, KSR903, KSR906

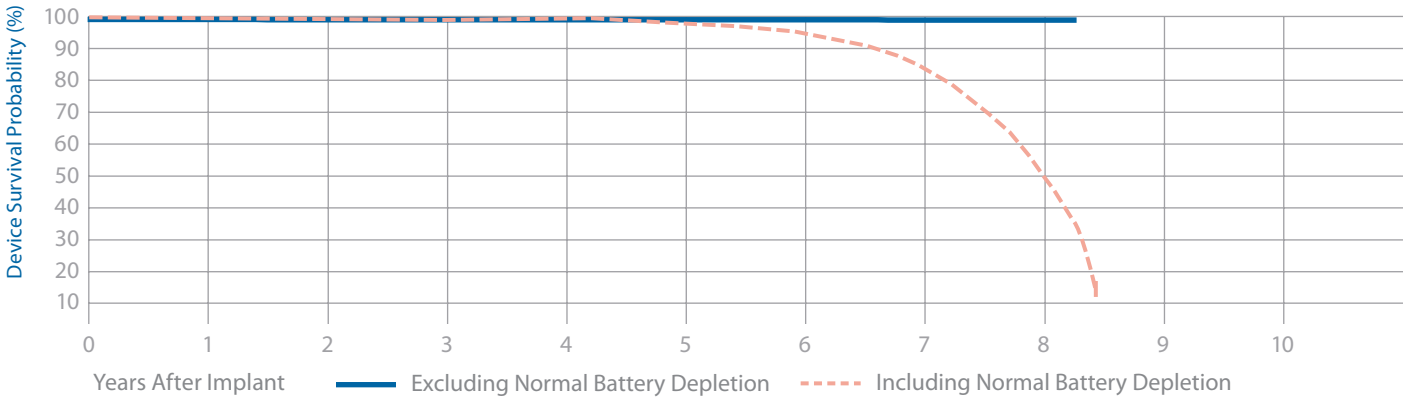
Product Characteristics

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	8,120
Normal Battery Depletions (US)	2,376

Advisories: See page 151 – 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 101 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.8
%	99.9	99.8	99.6	98.9	97.5	94.5	83.9	48.9	13.0
#	30,300	25,900	22,300	19,100	16,100	11,600	6,730	1,890	170

Effective Sample Size

Kappa 900 VDD KVDD901

Product Characteristics

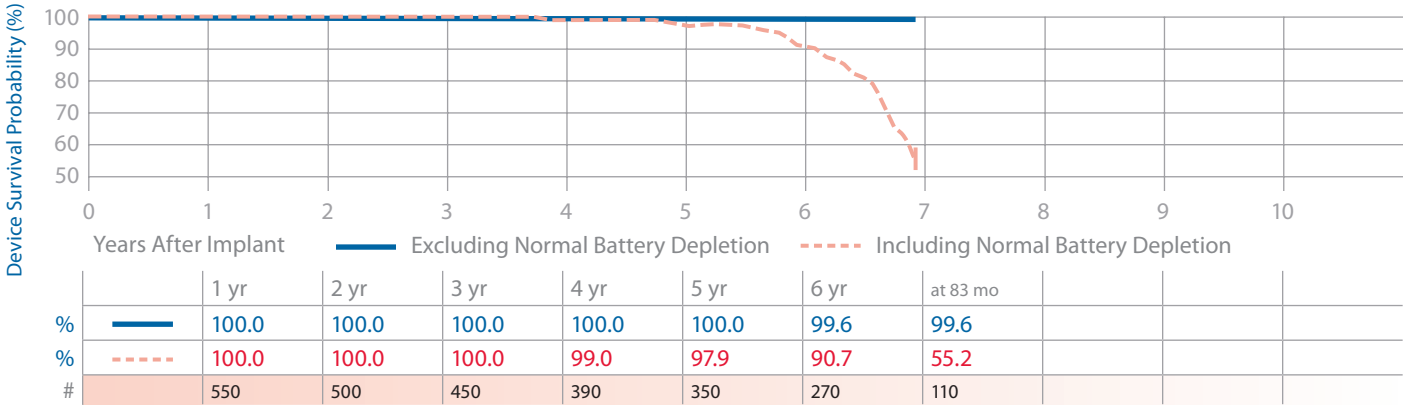
US Market Release	Jan-02
Registered US Implants	650
Estimated Active US Implants	77
Normal Battery Depletions (US)	80

Advisories: See page 151 – 2009
Potential Separation of Interconnect Wires

Performance Note: See page 159 –
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	55.2
#	550	500	450	390	350	270	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Kappa 920 DR KDR921

US Market Release	Jan-02
Registered US Implants	16,300
Estimated Active US Implants	1,860
Normal Battery Depletions (US)	2,633

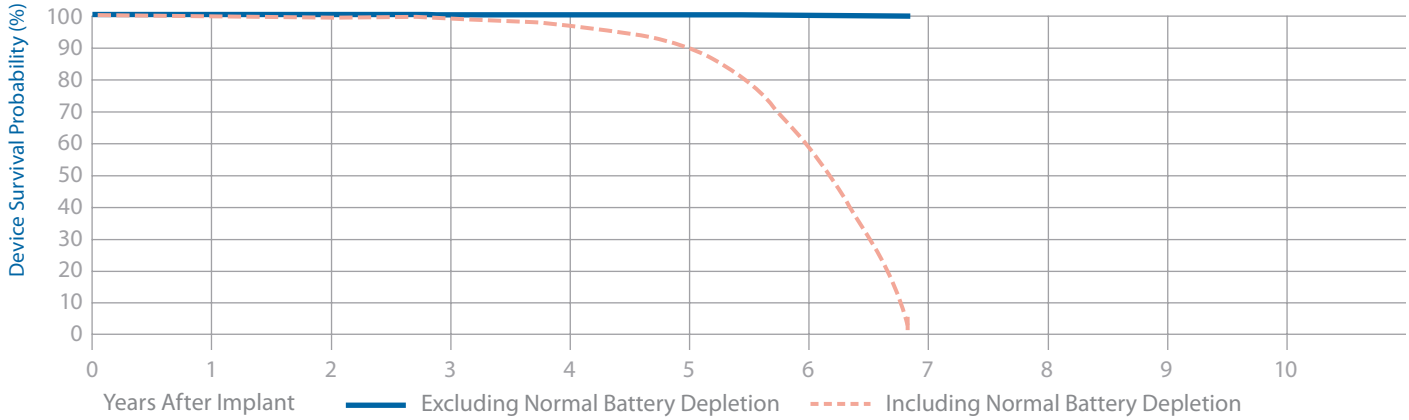
Advisories: See page 151 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 159 – 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 82 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	99.9	99.7	99.2	97.2	90.2	59.6	2.0
#	14,000	12,500	11,100	9,550	7,580	3,220	120

Effective Sample Size

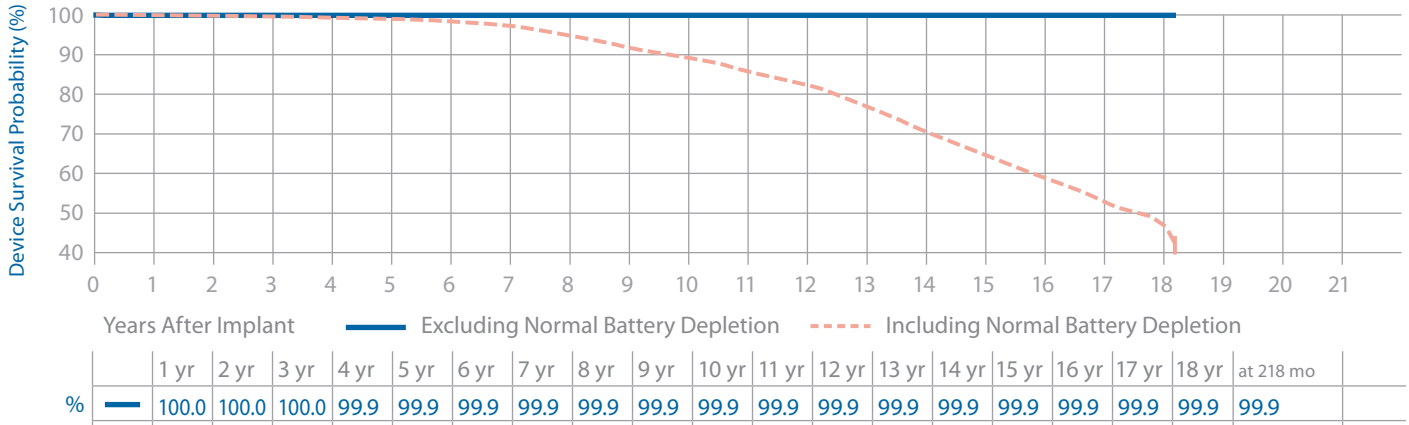
Legend II 8424, 8426, 8427

US Market Release	Nov-91
Registered US Implants	58,600
Estimated Active US Implants	5,830
Normal Battery Depletions (US)	2,611
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	18 yr	at 218 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
%	99.9	99.7	99.5	99.2	98.9	98.2	97.3	94.8	91.6	88.6	85.5	82.2	77.2	70.9	64.4	58.4	53.1	46.5	41.9
#	52,000	46,500	40,900	35,600	31,100	27,300	23,700	19,700	15,700	12,500	10,100	8,180	6,370	4,880	3,780	2,910	1,940	370	130

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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

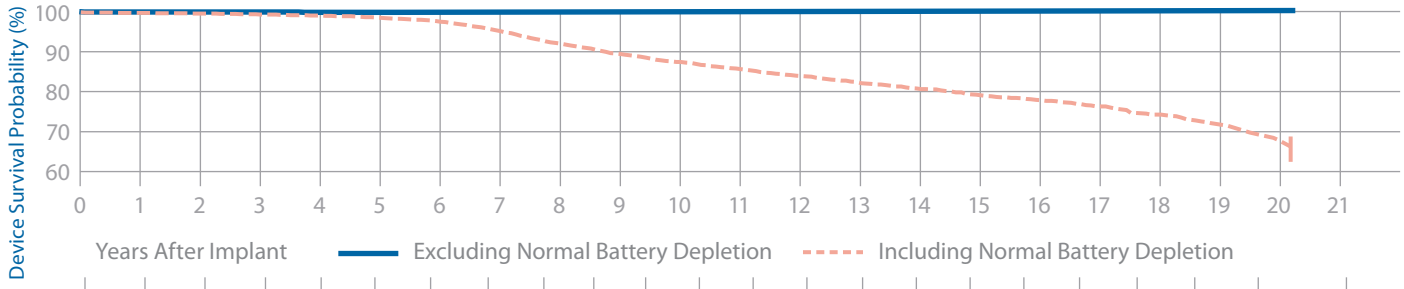
US Market Release	Nov-88
Registered US Implants	58,600
Estimated Active US Implants	7,470
Normal Battery Depletions (US)	1,768

Advisories: See page 158 – 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 247 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	89.5	87.4	85.7	84.0	82.3	80.9	79.3	78.0	76.2	74.3	72.0	69.9	64.0
#	49,900	43,400	37,400	31,800	27,000	22,600	18,600	15,100	12,600	10,700	9,230	8,060	7,120	6,360	5,720	4,930	3,840	2,750	1,690	770	170

Effective Sample Size

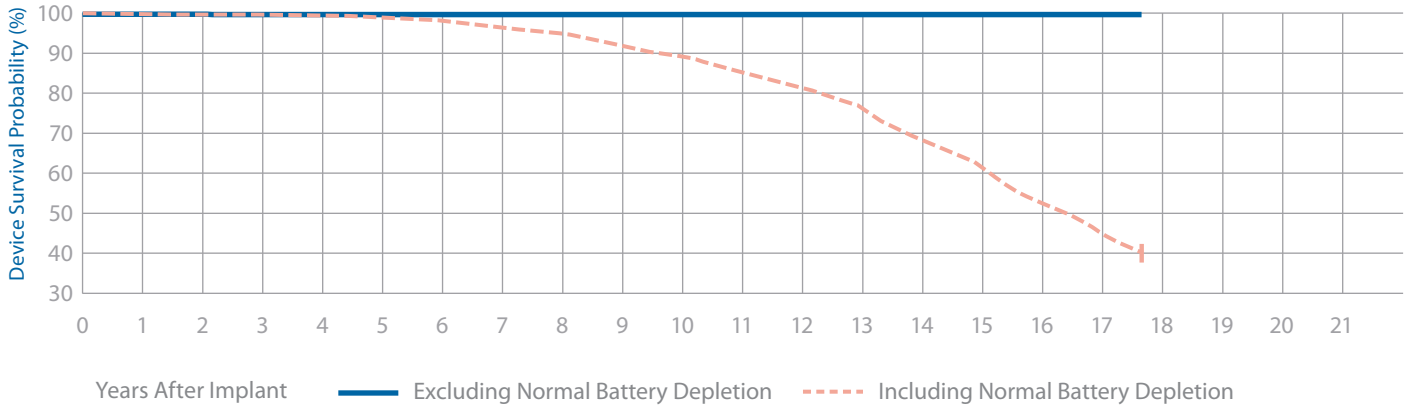
Minuet 7107, 7108

US Market Release	Mar-92
Registered US Implants	16,800
Estimated Active US Implants	1,930
Normal Battery Depletions (US)	973
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 212 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	89.1	85.7	81.9	76.3	68.0	61.0	52.1	44.7	39.7
#	14,800	13,400	12,000	10,700	9,510	8,430	7,340	6,230	5,210	4,310	3,530	2,860	2,290	1,730	1,320	900	470	150

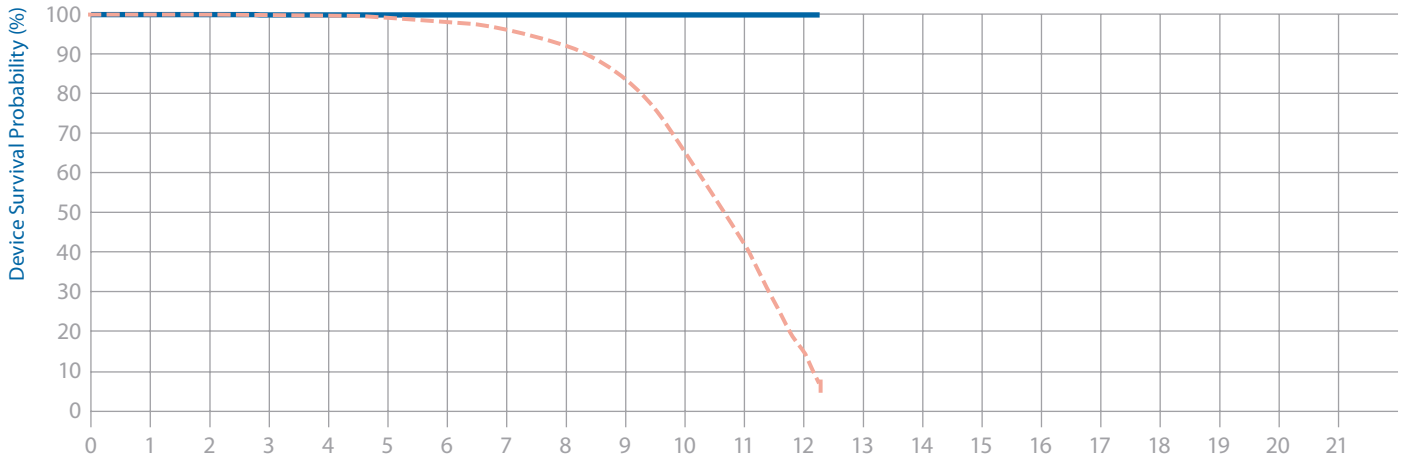
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Preva DR 7088, 7089

Product Characteristics

US Market Release	Jul-96	Malfunctions (US)	4	NBG Code	DDD/RO
Registered US Implants	25,500	**Therapy Function Not Compromised**	0	Serial Number Prefix	PGJ, PGK
Estimated Active US Implants	2,470	**Therapy Function Compromised**	4	Estimated Longevity	See page 79
Normal Battery Depletions (US)	2,886	Electrical Component	2		
Advisories	None	Electrical Interconnect	2		



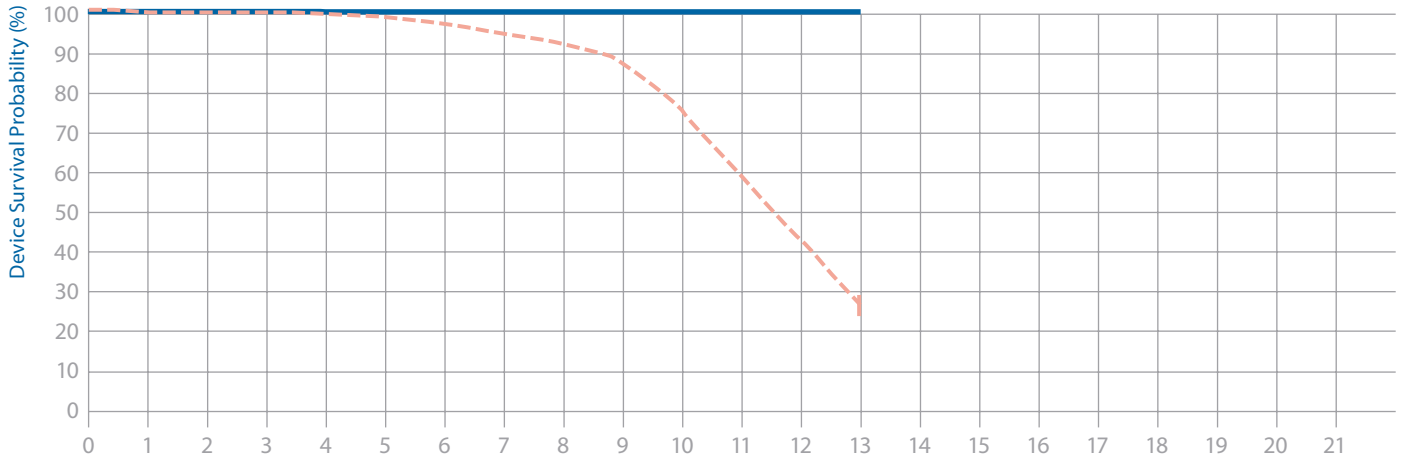
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 147 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.8	99.5	99.3	98.7	97.7	96.2	92.4	84.5	66.4	41.6	14.0	5.5
#	22,200	20,100	18,000	16,000	14,100	12,400	10,700	8,920	6,860	4,330	2,000	390	120

Effective Sample Size

Preva SR 8088, 8089

US Market Release	Jul-96	Malfunctions (US)	1	NBG Code	SSIR
Registered US Implants	17,800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PGL, PGM
Estimated Active US Implants	1,620	**Therapy Function Compromised**	1	Estimated Longevity	See page 79
Normal Battery Depletions (US)	1,089	Possible Early Battery Depletion	1		
Advisories	None				

Product Characteristics



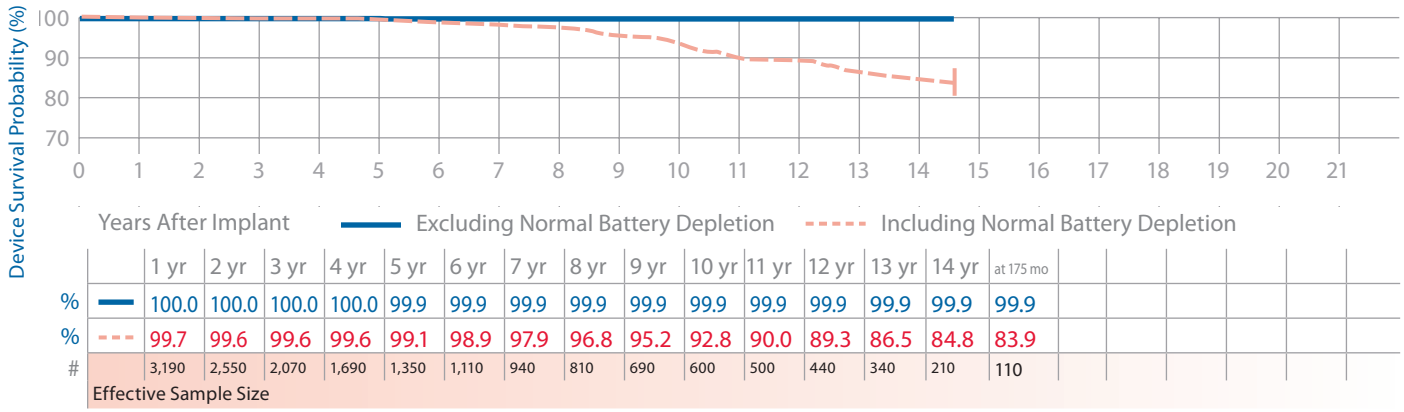
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.8	99.7	99.4	99.0	98.3	97.2	95.0	92.1	87.3	75.2	59.1	43.3	26.3
#	14,600	12,400	10,600	8,910	7,510	6,310	5,240	4,240	3,360	2,350	1,440	820	150

Effective Sample Size

Prevail S 8085, 8086

US Market Release	Oct-95	Malfunctions (US)	1	NBG Code	SSI
Registered US Implants	4,190	**Therapy Function Not Compromised**	0	Serial Number Prefix	PEY, PFA
Estimated Active US Implants	460	**Therapy Function Compromised**	1	Estimated Longevity	See page 79
Normal Battery Depletions (US)	58	Electrical Component	1		
Advisories	None				

Product Characteristics



	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 175 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	90.0	89.3	86.5	84.8	83.9
#	3,190	2,550	2,070	1,690	1,350	1,110	940	810	690	600	500	440	340	210	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

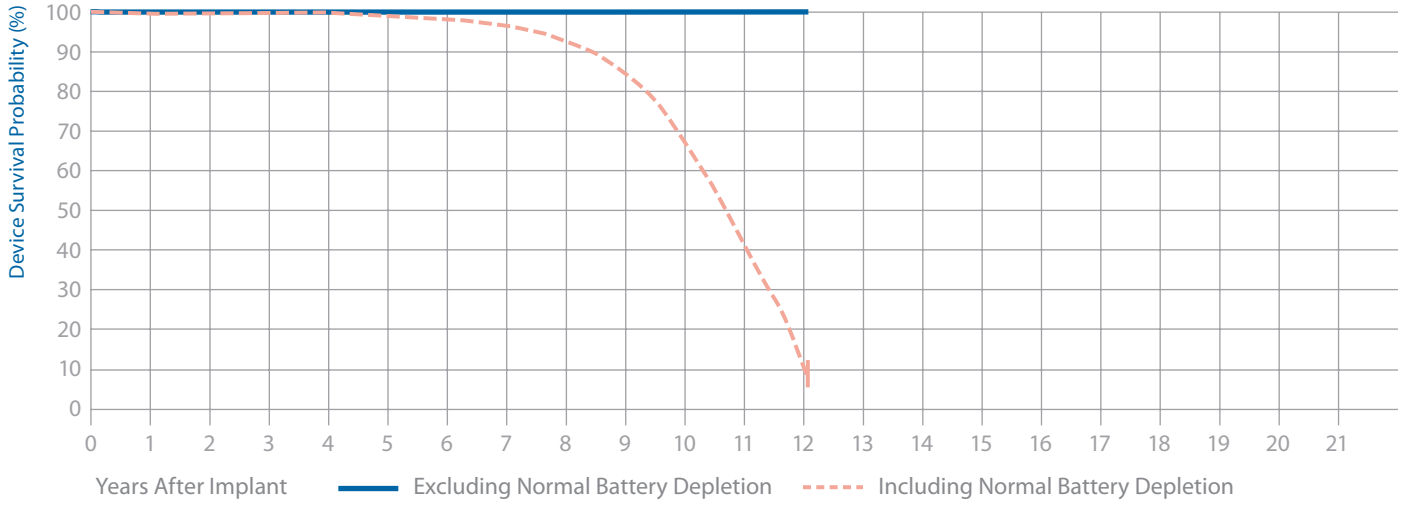
Prodigy DR 7860, 7861, 7862

Product Characteristics

US Market Release	Oct-95
Registered US Implants	37,400
Estimated Active US Implants	3,140
Normal Battery Depletions (US)	3,949
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	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
%	99.9	99.8	99.6	99.3	98.7	97.9	96.3	92.4	84.6	68.4	42.1	10.8	7.8
#	33,000	29,900	27,000	24,100	21,200	18,600	16,000	13,200	9,820	6,220	2,580	340	190

Effective Sample Size

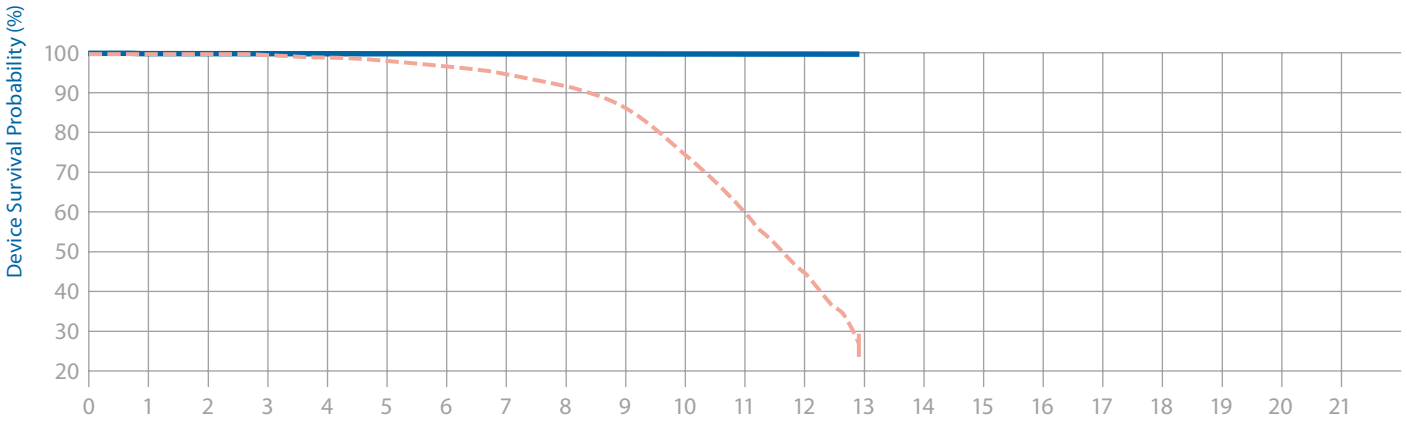
Prodigy SR 8158, 8160, 8161, 8162

US Market Release	Oct-95
Registered US Implants	22,300
Estimated Active US Implants	2,350
Normal Battery Depletions (US)	1,348
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 155 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	91.5	86.1	74.1	60.0	45.0	26.5
#	18,600	16,000	13,700	11,500	9,680	8,080	6,670	5,380	4,110	2,820	1,710	890	160

Effective Sample Size

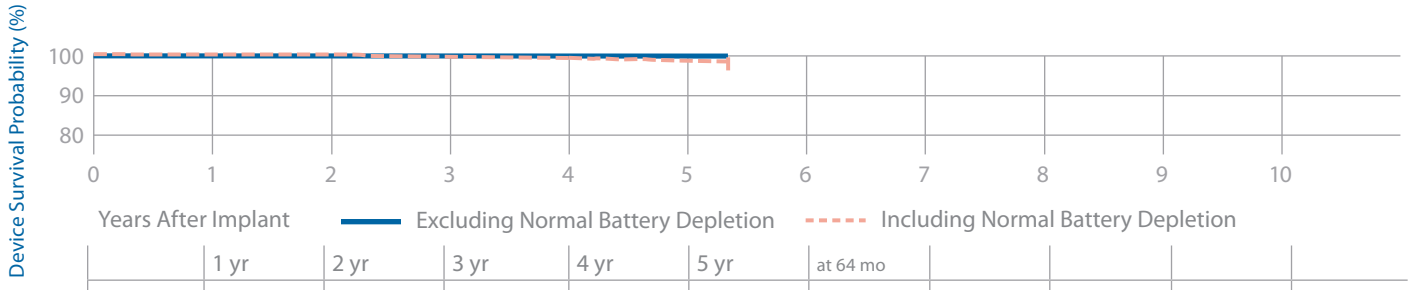
Sensia DR SEDR01, SED01

US Market Release	Jul-06
Registered US Implants	103,500
Estimated Active US Implants	79,900
Normal Battery Depletions (US)	75
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	12
Therapy Function Not Compromised	8
Electrical Component	8
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	5 yr	at 64 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.6	99.1	98.9
#	78,800	56,000	34,300	15,700	2,770	240

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

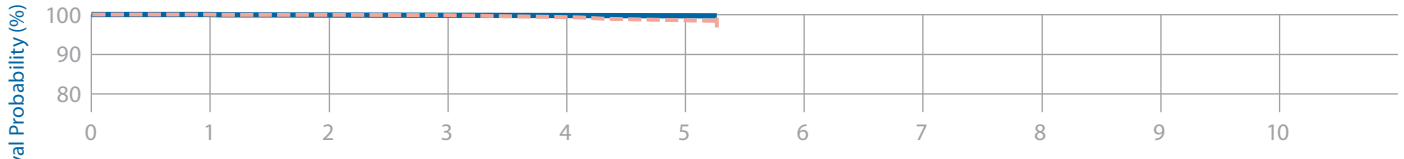
Sensia SR SESR01, SES01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	69,700
Estimated Active US Implants	49,200
Normal Battery Depletions (US)	60
Advisories	None

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

NBG Code	SSIR, SSI
Serial Number Prefix	PWR, PWS, NWR, NWS
Estimated Longevity	See page 80



	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
%	100.0	99.9	99.8	99.5	98.9	98.9
#	48,500	32,300	18,400	7,810	1,300	300

Effective Sample Size

Sigma 100 S SS103, SS106

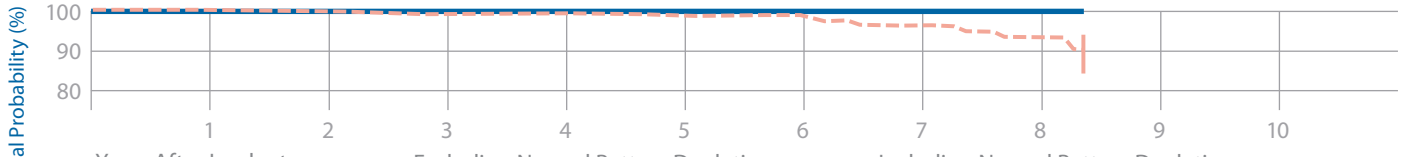
Product Characteristics

US Market Release	Aug-99
Registered US Implants	790
Estimated Active US Implants	100
Normal Battery Depletions (US)	18

Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires

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

NBG Code	SSI
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	at 100 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	93.7	90.3
#	580	450	360	280	220	190	150	120	100

Effective Sample Size

Sigma 200 DR SDR203

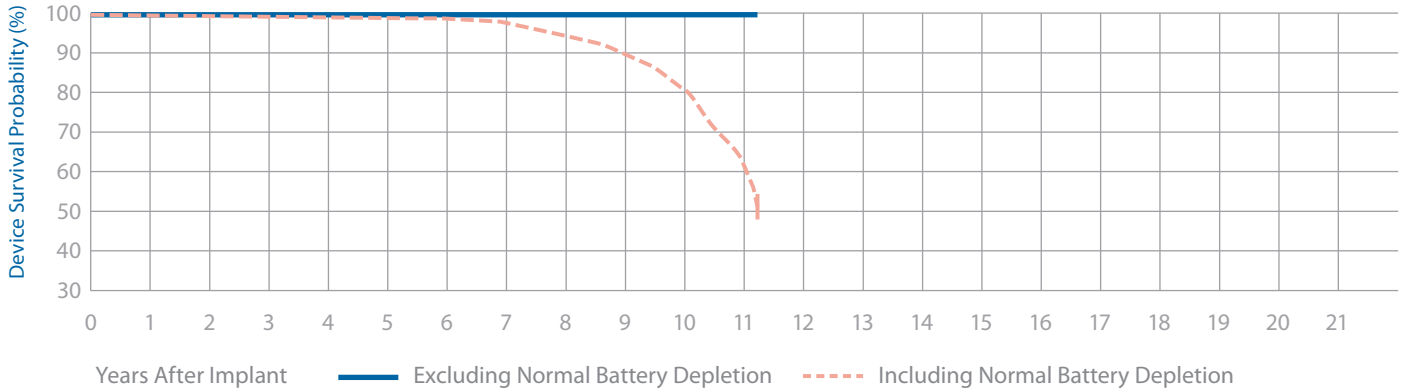
US Market Release	Aug-99
Registered US Implants	15,800
Estimated Active US Implants	3,940
Normal Battery Depletions (US)	599

Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 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	at 135 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.6	99.5	99.5	99.5	99.5
%	100.0	99.9	99.9	99.8	99.5	99.0	97.5	94.1	89.8	81.1	62.5	50.8
#	13,600	12,200	10,700	9,570	8,440	7,430	6,300	4,950	3,560	2,000	490	190

Effective Sample Size

Sigma 200 SR SSR203, SS203

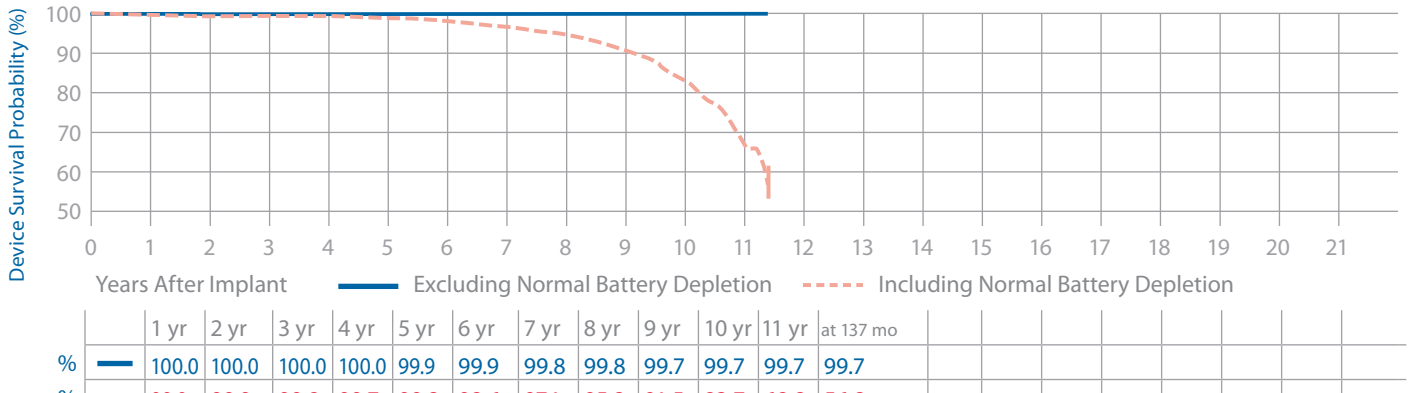
US Market Release	Sep-99
Registered US Implants	12,100
Estimated Active US Implants	2,110
Normal Battery Depletions (US)	285

Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 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 137 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	91.5	83.7	68.2	56.2
#	9,550	7,950	6,650	5,610	4,720	4,000	3,260	2,560	1,800	1,080	380	140

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Sigma 300 DR SDR303, SDR306

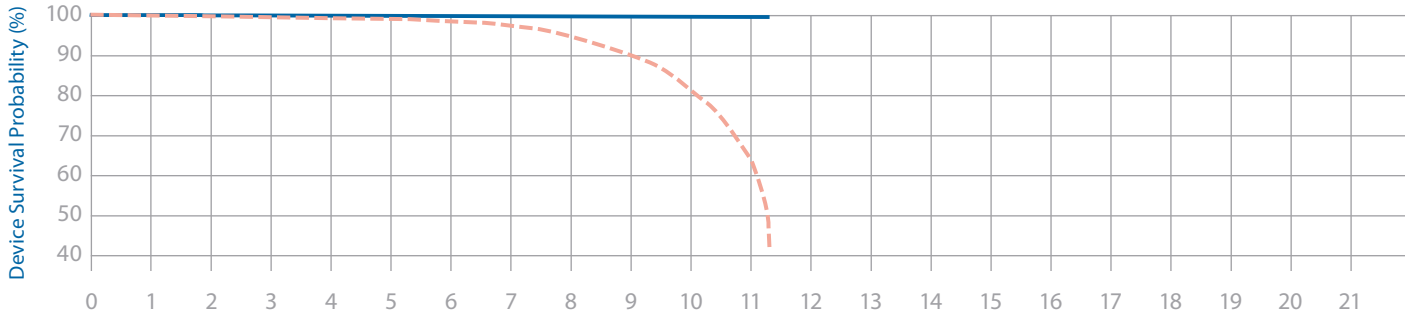
Product Characteristics

US Market Release	Aug-99
Registered US Implants	106,700
Estimated Active US Implants	34,300
Normal Battery Depletions (US)	2,523

Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	208
Therapy Function Not Compromised	10
Electrical Component	5
Electrical Interconnect	4
Possible Early Battery Depletion	1
Therapy Function Compromised	198
Electrical Component	8
Electrical Interconnect	190
(145 malfunctions related to advisory)	

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	at 136 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.6	99.5	99.5	99.5	99.5
%	100.0	99.9	99.9	99.7	99.4	98.9	97.9	95.1	90.4	81.7	63.3	41.0
#	92,300	82,300	73,300	64,800	55,400	45,300	34,900	25,100	15,900	8,190	1,770	180

Effective Sample Size

Sigma 300 SR SSR303, SSR306

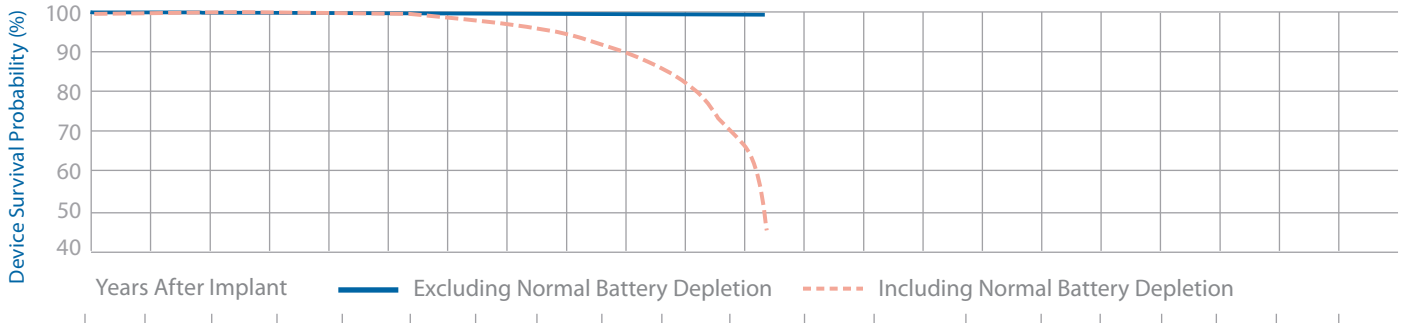
Product Characteristics

US Market Release	Aug-99
Registered US Implants	54,100
Estimated Active US Implants	12,300
Normal Battery Depletions (US)	872

Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	48
Therapy Function Not Compromised	3
Electrical Component	1
Electrical Interconnect	1
Other	1
Therapy Function Compromised	45
Electrical Component	3
Electrical Interconnect	42
(37 malfunctions related to advisory)	

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	11 yr	at 136 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.7	99.7	99.7	99.7	99.7
%	100.0	99.9	99.8	99.6	99.2	98.6	97.2	94.9	90.5	81.8	65.8	46.9
#	43,100	36,000	30,300	25,400	20,400	15,700	11,600	8,190	4,980	2,600	610	110

Effective Sample Size

Sigma 300 VDD SVDD303

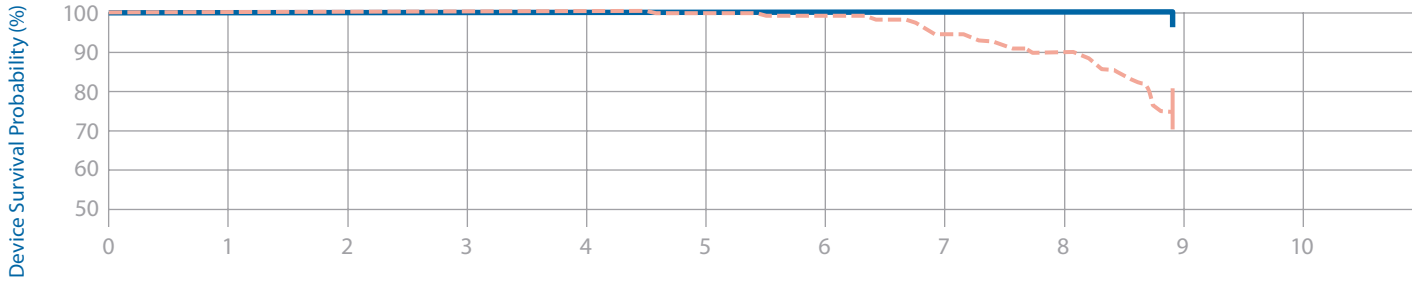
US Market Release	Sep-99
Registered US Implants	640
Estimated Active US Implants	110
Normal Battery Depletions (US)	49

Advisories: See page 155 – 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)	

Product Characteristics

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 107 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	94.2	89.6	74.6
#	550	480	430	380	340	290	230	170	100

Effective Sample Size

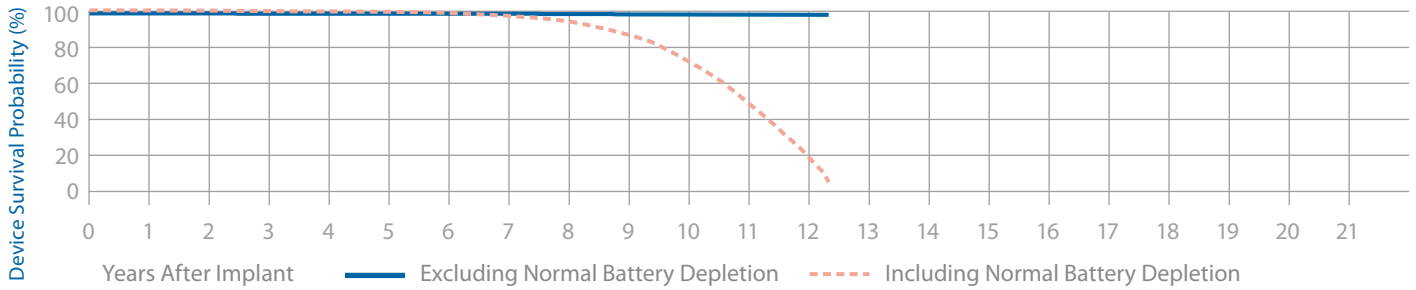
Thera-i DR 7960i, 7961i, 7962i

US Market Release	Oct-95
Registered US Implants	121,300
Estimated Active US Implants	10,400
Normal Battery Depletions (US)	14,029
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

Product Characteristics

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 148 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	98.9	98.1	96.7	93.2	85.8	71.3	48.1	19.7	5.8
#	108,800	99,800	91,600	82,900	74,500	66,100	57,200	47,700	36,600	23,700	11,500	2,580	510

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

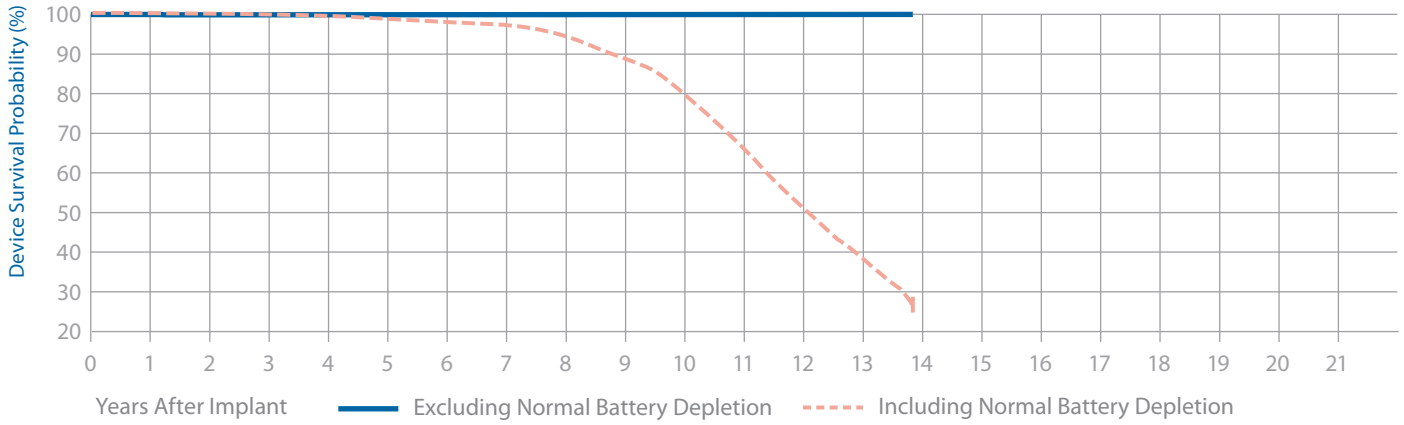
Thera-i SR 8960i, 8961i, 8962i

US Market Release	Oct-95
Registered US Implants	50,000
Estimated Active US Implants	4,520
Normal Battery Depletions (US)	2,884
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 166 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	65.8	51.6	38.4	26.9
#	42,300	36,700	31,900	27,300	23,300	19,800	16,600	13,700	10,700	7,790	5,000	2,990	1,230	170

Effective Sample Size

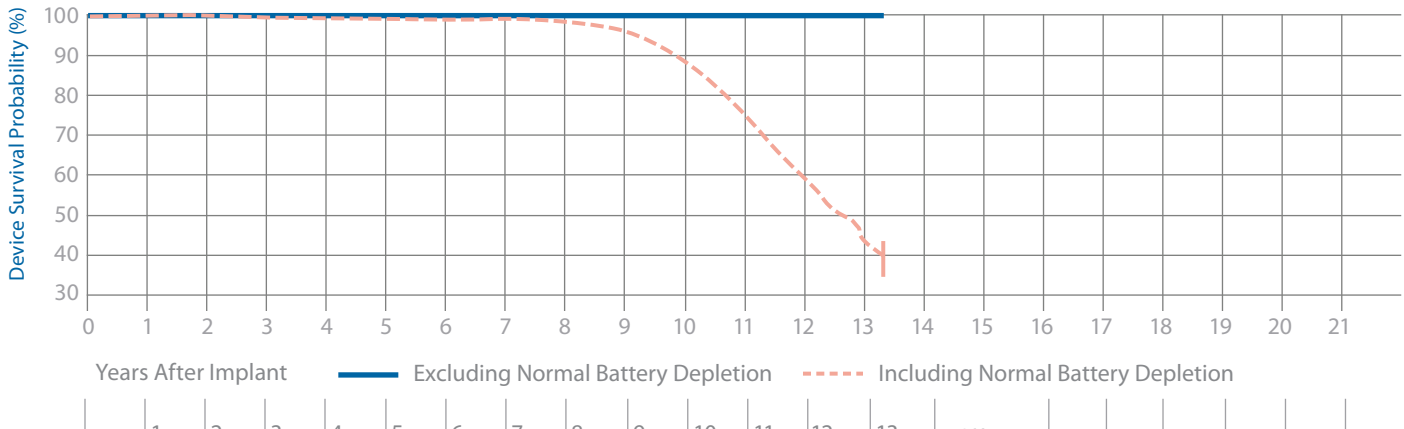
Thera-i VDD 8968i

US Market Release	Mar-95
Registered US Implants	4,860
Estimated Active US Implants	570
Normal Battery Depletions (US)	331
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 160 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	75.3	58.2	43.2	39.7
#	4,220	3,780	3,390	3,010	2,700	2,410	2,140	1,880	1,620	1,270	860	480	210	120

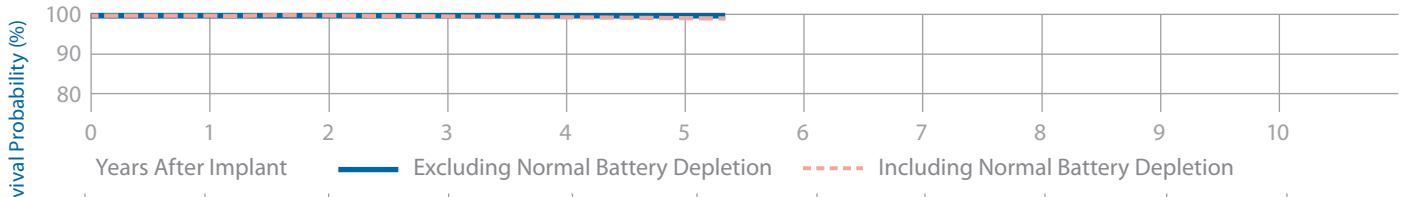
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

Versa DR VEDR01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	8	NBG Code	DDDR
Registered US Implants	83,000	**Therapy Function Not Compromised**	6	Serial Number Prefix	PWH, NWH
Estimated Active US Implants	64,600	Electrical Component	5	Estimated Longevity	See page 80
Normal Battery Depletions (US)	64	Electrical Interconnect	1		
Performance Note: See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI		**Therapy Function Compromised**	2		
		Electrical Component	2		



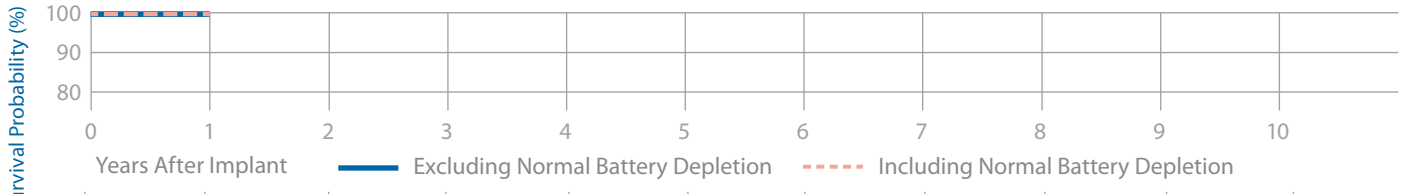
	1 yr	2 yr	3 yr	4 yr	5 yr	at 64 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.7	99.3	99.2
#	65,200	48,200	31,800	16,600	3,480	340

Effective Sample Size

Revo MRI SureScan RVDR01

Product Characteristics

US Market Release	Feb-11	Malfunctions (US)	1	NBG Code	DDDRP
Registered US Implants	22,100	**Therapy Function Not Compromised**	0	Serial Number Prefix	PTN
Estimated Active US Implants	21,700	**Therapy Function Compromised**	1	Estimated Longevity	See page 80
Normal Battery Depletions (US)	0	Electrical Component	1		



	1 yr
%	100.0
%	100.0
#	370

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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	291,500	242,600	155	19	+	32	=	51	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 at 65 mo						
	See page 159 – 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	99.4 +0.1/-0.1	99.2 +0.1/-0.2 at 65 mo						
Adapta DR	ADDRL1	Jul-06	53,900	48,900	9	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 at 62 mo						
	See page 159 – 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/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2 at 62 mo						
Adapta DR	ADDRS1	Jul-06	28,000	21,400	84	2	+	3	=	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 at 63 mo						
	See page 159 – 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/-0.1	99.6 +0.1/-0.1	98.87 +0.3/-0.3	95.0 +0.9/-1.0	94.4 +1.2/-1.5 at 63 mo						
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	54,000	38,100	72	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	100.0 +0.0/-0.0 at 64 mo						
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.7 +0.1/-0.1	99.3 +0.1/-0.2	98.3 +0.3/-0.4	98.3 +0.3/-0.4 at 64 mo						
Adapta VDD	ADVDD01	Jul-06	890	690	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	100.0 +0.0/-0.0 at 53 mo							
	See page 159 – 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 at 53 mo							
AT500	AT501, 7253	Mar-03	10,800	1,140	2,658	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 81 mo					
	See page 164 – 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	84.3 +0.8/-0.9	50.7 +1.3/-1.3	9.4 +1.2/-1.2 at 81 mo					
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	6,820	2,630	550	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				
	See page 159 – 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/-0.5	87.5 +1.0/-1.1	62.7 +2.6/-2.8				
EnPulse DR	E1DR21	Dec-03	1,850	190	349	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 159 – 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	63.6 +3.1/-3.3	26.0 +3.8/-3.7 at 80 mo					

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		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
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	100,700	54,700	2,003	6	+	17	=	23	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 92 mo				
	See page 159 – 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	99.5 +0.0/-0.1	98.9 +0.1/-0.1	97.4 +0.1/-0.1	90.8 +0.3/-0.4	47.9 +7.0/-7.4 at 92 mo				
EnPulse 2 DR	E2DR21	Feb-04	12,200	3,560	1,268	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 79 mo					
	See page 159 – 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	99.2 +0.2/-0.2	97.7 +0.3/-0.3	91.7 +0.6/-0.7	68.5 +1.3/-1.4	29.5 +2.8/-2.8 at 79 mo					
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	580	420	2	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 81 mo					
	See page 159 – 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	99.5 +0.4/-1.7	99.5 +0.4/-1.7 at 81 mo					
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,500	9,160	638	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 89 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	97.7 +0.2/-0.3	94.3 +0.4/-0.5	81.4 +1.3/-1.3	61.3 +3.1/-3.3 at 89 mo				
EnPulse 2 VDD	E2VDD01	Dec-03	640	260	44	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 75 mo					
	See page 159 – 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	99.1 +0.6/-1.6	86.8 +3.9/-5.3	76.6 +5.6/-6.9 at 75 mo					
EnRhythm DR	P1501DR	May-05	109,700	76,300	296	47	+	2,851	=	2,898	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.5 +0.1/-0.1	97.0 +0.2/-0.2	91.1 +0.3/-0.3	90.3 +0.4/-0.4 at 77 mo					
	Advisories: See page 148 – 2010 Low Battery Voltage Displayed at Device Interrogation					(0)	+	(185)	=	185 (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	98.9 +0.1/-0.1	93.5 +0.2/-0.2	79.8 +0.5/-0.5	74.6 +1.0/-1.1 at 77 mo					
	See page 161 – Performance note on anomalies in MOSFET Integrated Circuit Technology																						
Kappa 400 DR	KDR401, KDR403	Jan-98	46,800	4,820	7,619	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 105 mo			
	See page 159 – 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	99.4 +0.1/-0.1	98.9 +0.1/-0.1	97.2 +0.2/-0.2	87.9 +0.4/-0.4	56.8 +0.7/-0.7	10.8 +0.8/-0.8 at 105 mo			
Kappa 400 SR	KSR401, KSR403	Feb-98	15,400	1,710	1,435	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 109 mo			
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.2/-0.2	98.5 +0.2/-0.3	96.8 +0.4/-0.4	90.5 +0.7/-0.8	63.9 +1.5/-1.5	10.3 +2.1/-1.9 at 109 mo			

continued

Device Survival Summary continued

Family	Model Number	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	12 yr	14 yr	16 yr
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	25,000	1,930	3,789	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 157– 2002 Potential Fractured Power Supply Wires; See also page 151 – 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	57.5 +1.1/-1.1	4.9 +0.9/-0.8 at 107 mo			
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																						
Kappa 600 DR	KDR651, KDR653	Mar-01	16,400	1,340	2,717	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 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 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	81.2 +0.9/-1.0	43.7 +1.4/-1.4	6.3 +1.2/-1.1 at 103 mo			
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																						
Kappa 700 D	KD701, KD703, KD706	Jan-99	310	67	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 157– 2002 Potential Fractured Power Supply Wires; See also page 151 – 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 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																						
Kappa 700 DR	KDR701, KDR703, KDR706	Jan-99	206,300	30,000	32,080	702	+	38	=	740	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 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires					(416)	+	(1)	=	(417) (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	85.4 +0.2/-0.2	56.1 +0.4/0.4	4.6 +0.4/-0.3 at 106 mo			
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																						
Kappa 700 DR	KDR721	Feb-99	9,800	780	1,342	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 157– 2002 Potential Fractured Power Supply Wires; See also page 151 – 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	68.9 +1.4/-1.5	20.9 +2.0/-1.9	14.7 +2.0/-1.9 at 85 mo				
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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	55,300	6,960	4,754	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 151 – 2009 Potential Separation of Interconnect Wires					(20)	+ (0)	= (20) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.1/-0.1	98.6 +0.1/-0.1	97.2 +0.2/-0.2	93.6 +0.3/-0.3	83.5 +0.5/-0.6	56.4 +0.9/-0.9	11.2 +1.2/-1.1 at 107 mo			
Kappa 700 VDD	KVDD701	Jan-99	1,690	210	172	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 157 – 2002 Potential Fractured Power Supply Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires					(4)	+ (0)	= (4) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.1/-0.5	99.6 +0.2/-0.5	99.1 +0.4/-0.7	98.6 +0.5/-0.8	98.4 +0.6/-0.9	94.1 +1.3/-1.7	72.7 +3.1/-3.5	41.9 +4.7/-4.7	41.1 +4.7/-4.8 at 97 mo			
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 800 DR	KDR801, KDR803	Jan-02	4,280	840	592	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 101 mo			
	See page 159 – 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	96.1 +0.7/-0.8	84.4 +1.5/-1.6	54.0 +2.3/-2.4	29.5 +3.1/-3.0 at 101 mo			
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,400	37,800	13,888	56	+ 18	= 74	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 103 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/-0.1	98.6 +0.1/-0.1	96.5 +0.1/-0.1	87.5 +0.3/-0.3	57.9 +0.5/-0.5	6.8 +0.8/-0.7 at 103 mo			
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	8,120	2,376	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 +0.0/-0.1	99.8 +0.1/-0.1 at 101 mo			
	Advisories: See page 151 – 2009 Potential Separation of Interconnect Wires					(7)	+ (1)	= (8) (advisory-related subset)	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 +0.3/-0.4	83.9 +0.7/-0.7	48.9 +1.4/-1.4	13.0 +2.3/-2.1 at 101 mo			
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 900 VDD	KVDD901	Jan-02	650	77	80	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 151 – 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/-3.7	55.2 +6.4/-7.0 at 83 mo					

Device Survival Summary continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 6, 2012

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		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 920 DR	KDR921	Jan-02	16,300	1,860	2,633	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 82 mo					
	Advisories: See page 151 – 2009 Potential Separation of Interconnect Wires					(3) (advisory-related subset)	+	(0)	=	3	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	90.2 +0.6/-0.6	59.6 +1.2/-1.2	2.0 +0.0/-0.1 at 82 mo					
	See page 159 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																							
Legend II	8424, 8426, 8427	Nov-91	58,600	5,830	2,611	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 218 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	88.6 +0.4/-0.4	82.2 +0.6/-0.6	70.9 +0.9/-0.9	41.9 +2.5/-2.6 at 218 mo
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Nov-88	58,600	7,470	1,768	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 247 mo
	Advisories: See page 158 – 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	87.4 +0.5/-0.5	84.0 +0.6/-0.6	80.9 +0.7/-0.7	64.0 +2.5/-2.6 at 247 mo
Minuet	7107, 7108	Mar-92	16,800	1,930	973	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 212 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	89.1 +0.7/-0.8	81.9 +1.0/-1.1	68.0 +1.5/-1.5	39.7 +2.6/-2.6 at 212 mo
Preva DR	7088, 7089	Jul-96	25,500	2,470	2,886	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 147 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	66.4 +1.0/-1.1	14.0 +1.2/-1.1	5.5 +1.1/-1.0 at 147 mo	
Preva SR	8088, 8089	Jul-96	17,800	1,620	1,089	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 13 yr	
											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	43.3 +1.9/-1.9	26.3 +2.4/-2.4 at 13 yr	
Prevail S	8085, 8086	Oct-95	4,190	460	58	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 175 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/-1.3	92.8 +1.6/-2.0	89.3 +2.1/-2.5	84.8 +2.7/-3.3	83.9 +2.9/-3.5 at 175 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	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
Prodigy DR	7860, 7861, 7862	Oct-95	37,400	3,140	3,949	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	100.0 +0.0/-0.0 at 145 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	10.8 +1.1/-1.0	7.8 +1.1/-1.0 at 145 mo	
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,300	2,350	1,348	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 155 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	91.5 +0.6/-0.6	74.1 +1.2/-1.2	45.0 +1.8/-1.8	26.5 +2.5/-2.5 at 155 mo	
Sensia DR	SEDR01, SED01	Jul-06	103,500	79,900	75	4	8	12	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 at 64 mo						
	See page 159 – 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	99.1 +0.2/-0.2	98.9 +0.3/-0.4 at 64 mo						
Sensia SR	SESR01, SES01	Jul-06	69,700	49,200	60	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 at 63 mo						
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.3	98.9 +0.2/-0.3 at 63 mo						
Sigma 100 S	SS103, SS106	Aug-99	790	100	18	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 100 mo			
	Advisories: See page 155 – 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	93.7 +2.8/-4.8	90.3 +3.8/-6.1 at 100 mo			
Sigma 200 DR	SDR203	Aug-99	15,800	3,940	599	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 +0.1/-0.2	99.5 +0.1/-0.2 at 135 mo		
	Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 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	97.5 +0.3/-0.4	94.1 +0.6/-0.6	81.1 +1.2/-1.3	50.8 +3.4/-3.5 at 135 mo		
Sigma 200 SR	SSR203, SS203	Sep-99	12,100	2,110	285	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/-0.2	99.7 +0.1/-0.2 at 137 mo		
	Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 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	83.7 +1.6/-1.7	56.2 +4.3/-4.6 at 137 mo		
Sigma 300 DR	SDR303, SDR306	Aug-99	106,700	34,300	2,523	198	10	208	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/-0.0	99.6 +0.1/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 136 mo		
	Advisories: See page 155 – 2005 Potential Separation of Interconnect Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires					(145)	(0)	(145) (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	81.7 +0.6/-0.6	41.0 +3.5/-3.5 at 136 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	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	54,100	12,300	872	45	+ 3	= 48	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 136 mo		
	Advisories: See page 155– 2005 Potential Separation of Interconnect Wires; See also page 151 – 2009 Potential Separation of Interconnect Wires					(37) (advisory-related subset)	+ (0)	= (37)	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	98.6 +0.1/-0.2	97.2 +0.2/-0.3	94.9 +0.4/-0.4	81.8 +1.0/-1.1	46.9 +4.8/-4.9 at 136 mo		
Sigma 300 VDD	SVDD303	Sep-99	640	110	49	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/-2.5	99.5 +0.4/-2.5 at 107 mo			
	Advisories: See page 155– 2005 Potential Separation of Interconnect Wires					(1) (advisory-related subset)	+ 0	= (1)	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	94.2 +2.2/-3.6	89.6 +3.2/-4.6	74.6 +5.7/-7.0 at 107 mo			
Thera-i DR	7960i, 7961i, 7962i	Oct-95	121,300	10,400	14,029	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 148 mo	
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.4 +0.0/-0.1	98.9 +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	19.7 +0.6/-0.6	5.8 +0.6/-0.5 at 148 mo	
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	4,520	2,884	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 166 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	51.6 +1.1/-1.1	26.9 +1.9/-1.8 at 166 mo	
Thera-i VDD	8968i	Mar-95	4,860	570	331	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 160 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	58.2 +2.9/-3.0	39.7 +3.7/-3.8 at 160 mo	
Versa DR	VEDR01	Jul-06	83,000	64,600	64	2	+ 6	= 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 at 64 mo						
	See page 159 – 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	99.3 +0.1/-0.2	99.2 +0.2/-0.2 at 64 mo						
Revo MRI SureScan	RVDR01	Feb-11	22,100	21,700	0	1	+ 0	= 1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0											
									Including Normal Battery Depletion	100.0 +0.0/-0.0											

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.**

Family	Model Number	Estimated Longevity			Elective Replacement Indicators
		Amplitude Setting	500 Lead Ω	1000 Lead Ω	
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 February 6, 2012

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 February 6, 2012

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 February 6, 2012

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	2,900	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

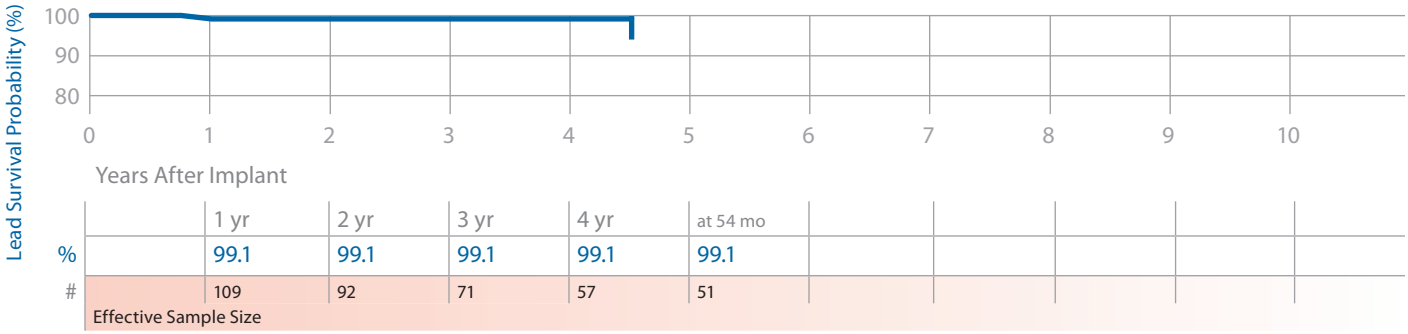
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	134
Cumulative Months of Follow-Up	6,481
Number of Leads Active in Study	21

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

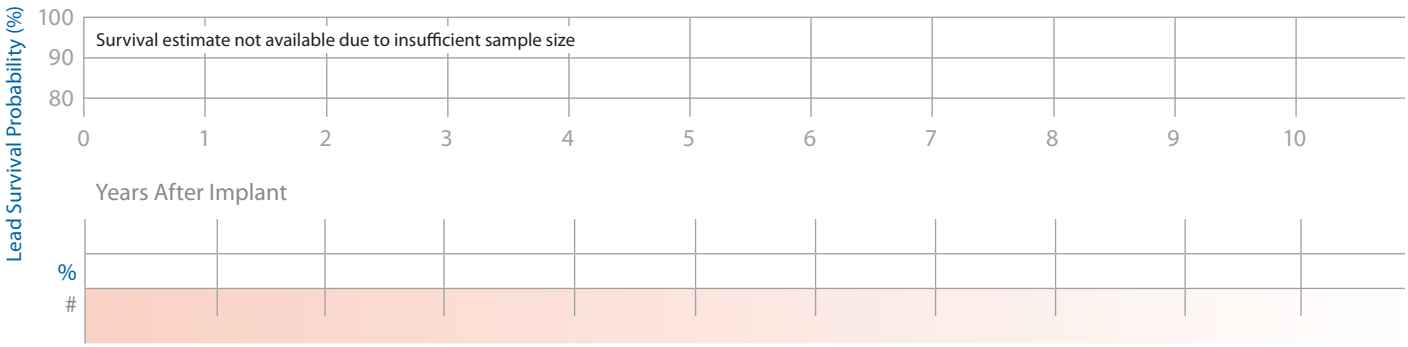
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

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 January 31, 2012

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	37,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

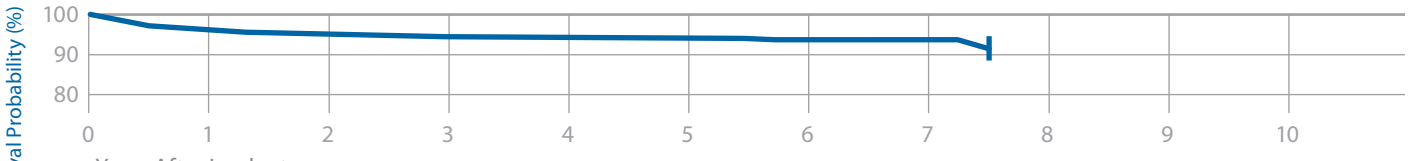
Conductor Fracture	47
Crimp/Weld/Bond	0
Insulation Breach	5
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	675
Cumulative Months of Follow-Up	29,104
Number of Leads Active in Study	156

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 90 mo
%	95.9	95.0	94.3	94.3	94.3	93.2	93.2	91.5
#	545	437	357	274	194	124	66	47

Effective Sample Size

4194 Attain OTW

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Registered US Implants	102,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	63,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

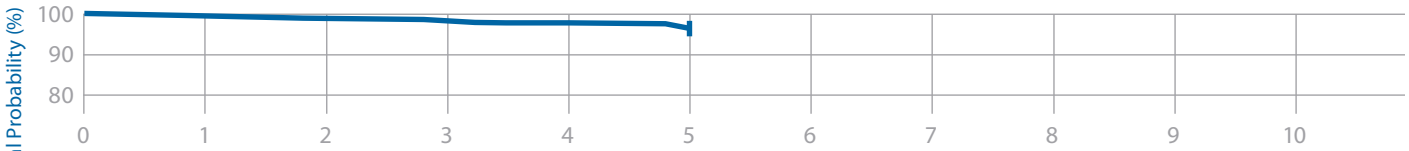
Conductor Fracture	10
Crimp/Weld/Bond	0
Insulation Breach	38
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	1,214
Cumulative Months of Follow-Up	28,024
Number of Leads Active in Study	848

Qualifying Complications 23 Total

Lead Dislodgement	12
Failure to Capture	5
Insulation (ESC)	1
Insulation (not further defined)	2
Extra Cardiac Stimulation	3



	1 yr	2 yr	3 yr	4 yr	5 yr
%	99.0	97.9	97.9	97.5	96.2
#	774	450	262	150	54

Effective Sample Size

Leads

Left-Heart Leads continued

4195 Attain StarFix

Product Characteristics

US Market Release	Aug-08	Serial Number Prefix	AAD
Registered US Implants	12,600	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Deployable Lobe Fixation
Estimated Active US Implants	10,300	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

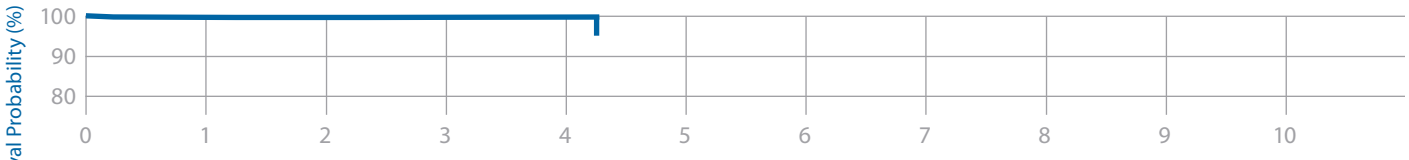
System Longevity Study Results

Number of Leads Enrolled in Study	953
Cumulative Months of Follow-Up	14,826
Number of Leads Active in Study	815

Qualifying Complications

4 Total

Lead Dislodgement	3
Conductor Fracture	1



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	99.6	99.6	98.9	98.9	98.9
#	448	135	67	55	51

Effective Sample Size

4196 Attain Ability

Product Characteristics

US Market Release	May-09	Serial Number Prefix	PVI
Registered US Implants	38,800	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Preformed Body, Double Curve
Estimated Active US Implants	33,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

System Longevity Study Results

Number of Leads Enrolled in Study	1,859
Cumulative Months of Follow-Up	20,670
Number of Leads Active in Study	1,525

Qualifying Complications

17 Total

Lead Dislodgement	7
Failure to Capture	4
Extra Cardiac Stimulation	6

	1 yr	2 yr
%	98.9	98.5
#	665	64

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Left-Heart Leads continued

4296 Attain Ability Plus

Product Characteristics

US Market Release	Apr-11	Serial Number Prefix	RRA
Registered US Implants	3,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	3,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

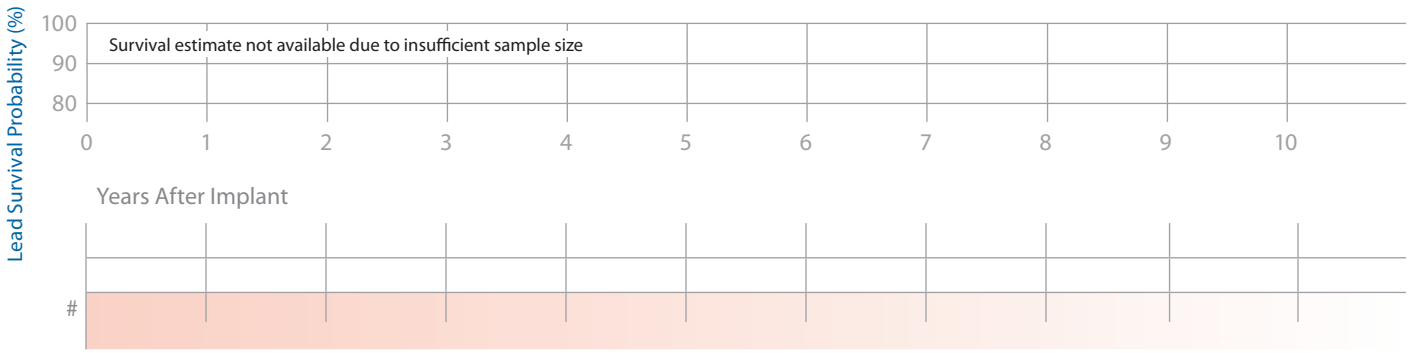
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	151
Cumulative Months of Follow-Up	140
Number of Leads Active in Study	148

Qualifying Complications 0 Total

Lead Dislodgement	0
Conductor Fracture	0
Extra Cardiac Stimulation	0



4396 Attain Ability Straight

Product Characteristics

US Market Release	Mar-11	Serial Number Prefix	RAE
Registered US Implants	1,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Tines
Estimated Active US Implants	1,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

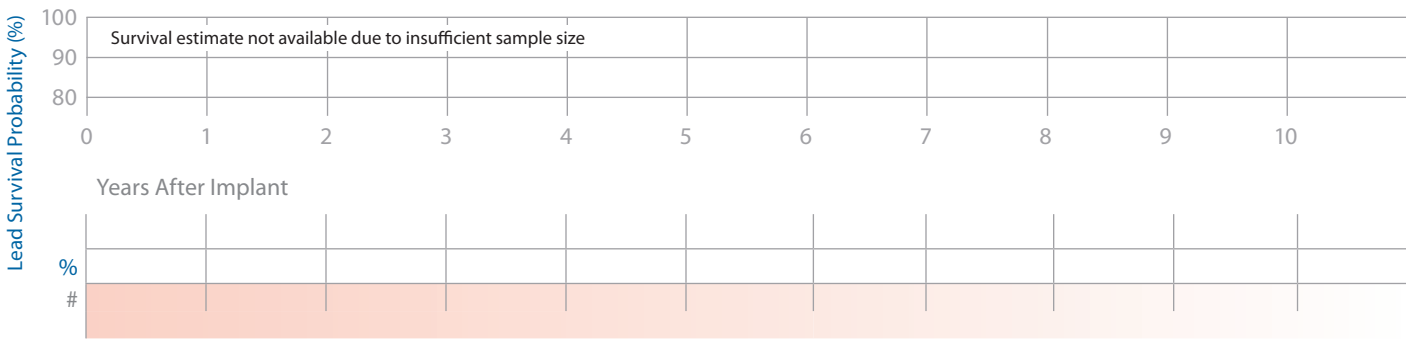
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	54
Cumulative Months of Follow-Up	321
Number of Leads Active in Study	53

Qualifying Complications 0 Total

Lead Dislodgement	0
Failure to Capture	0
Extra Cardiac Stimulation	0



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	21	1	6,481	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	156	37	29,104	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/-2.8	93.2 +2.0/-2.8	91.5 +3.2/-5.0 at 90 mo		
4194	Attain OTW	Aug-04	1,214	848	23	28,024	99.0 +0.4/-0.9	97.9 +0.8/-1.3	97.9 +0.8/-1.3	97.5 +1.0/-1.5	96.2 +2.0/-4.1					
4195	Attain StarFix	Aug-08	953	815	4	14,826	99.6 +0.3/-0.8	99.6 +0.3/-0.8	98.9 +0.8/-3.2	98.9 +0.8/-3.2	98.9 +0.8/-3.2 at 51 mo					
4196	Attain Ability	May-09	1,859	1,525	17	20,670	98.9 +0.4/-0.7	98.5 +0.7/-1.3								
4296	Attain Ability Plus	Apr-11	151	148	0	140	100.0 at 0 mo									
4396	Attain Ability Straight	Mar-11	54	53	0	321	100.0 at 0 mo									

Source: System Longevity Study
Data as of January 31, 2012

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	2,900	0	0	0	1
2188	Attain CS	Aug-01	1,800	300	1	0	0	0
4193	Attain OTW	May-02	100,600	37,900	47	0	5	8
4194	Attain OTW	Aug-04	102,700	63,800	10	0	38	6
4195	Attain StarFix	Aug-08	12,600	10,300	1	0	1	7
4196	Attain Ability	May-09	38,800	33,100	2	0	0	1
4296	Attain Ability Plus	Apr-11	3,700	3,500	0	0	0	0
4396	Attain Ability Straight	Mar-11	1,000	1,000	0	0	0	0

Source: Returned Product Analysis
Data as of January 31, 2012

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	102,700	1	2	92	21	1	0	1	6	25	3
4195	Attain StarFix	12,600	1	0	22	8	0	0	0	0	20	1
4196	Attain Ability	38,800	1	2	90	28	0	0	1	4	37	3
4296	Attain Ability Plus	3,700	0	0	9	2	0	0	0	0	2	0
4396	Attain Ability Straight	1,000	0	1	6	2	0	0	0	0	3	0

Report Cutoff Date: January 31, 2012

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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 January 31, 2012

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

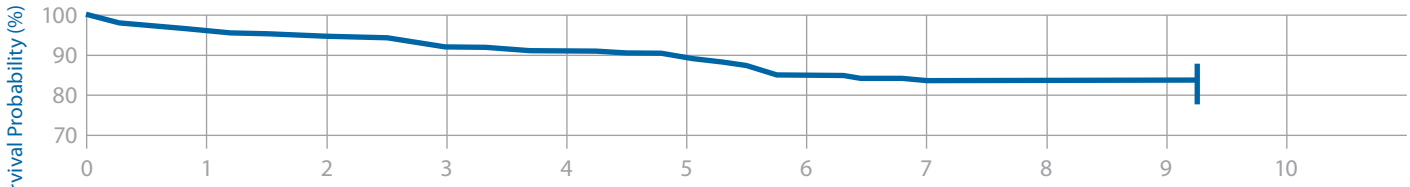
System Longevity Study Results

Number of Leads Enrolled in Study	407
Cumulative Months of Follow-Up	23,303
Number of Leads Active in Study	4

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	66	56	50

Effective Sample Size

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 153 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

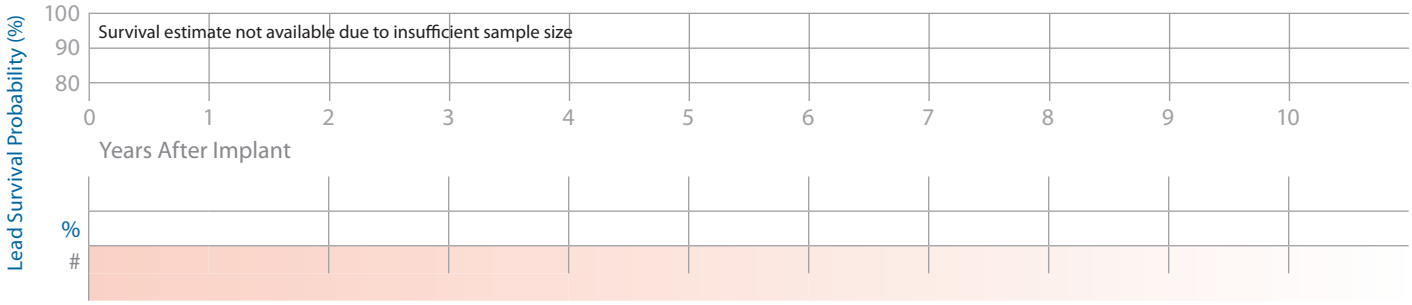
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	151
Number of Leads Active in Study	2

Qualifying Complications

0 Total



Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	4,100	Polarity	True Bipolar/One Coil
Advisories		Steroid	Yes
See page 153 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

Conductor Fracture	450
Crimp/Weld/Bond	0
Insulation Breach	0
Other	5

System Longevity Study Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	11,469
Number of Leads Active in Study	159

Qualifying Complications 18 Total

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

	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	98.2	95.8	94.0	92.9	92.9
#	258	227	185	98	63

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	4,500	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

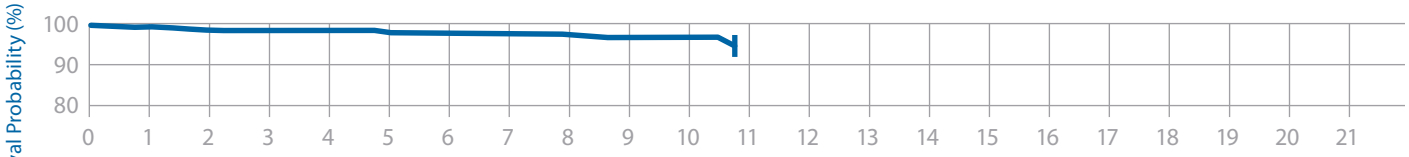
Conductor Fracture	20
Crimp/Weld/Bond	0
Insulation Breach	23
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	411
Cumulative Months of Follow-Up	24,784
Number of Leads Active in Study	51

Qualifying Complications 10 Total

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



	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	81	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	16,200	Type and/or Fixation	Transvenous CS or SVC Defib
Estimated Active US Implants	2,600	Polarity	One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

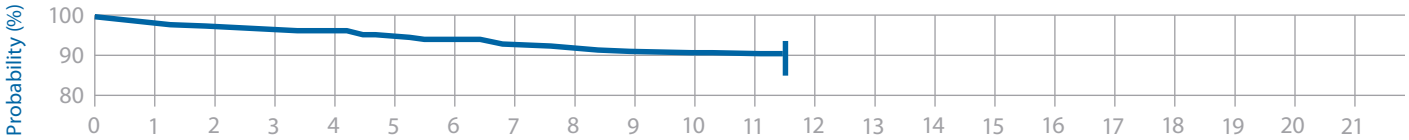
Conductor Fracture	167
Crimp/Weld/Bond	0
Insulation Breach	32
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,359
Number of Leads Active in Study	19

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	50

Effective Sample Size

6935 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-08	Serial Number Prefix	TAU
Registered US Implants	28,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	26,400	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Performance Note: See page 160 –
Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

US Returned Product Analysis

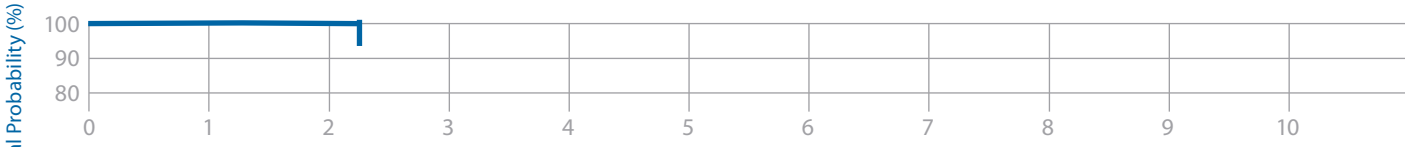
Conductor Fracture	22
Crimp/Weld/Bond	0
Insulation Breach	0
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	1,329
Cumulative Months of Follow-Up	13,473
Number of Leads Active in Study	1,191

Qualifying Complications 4 Total

Conductor Fracture	1
Failure to Sense	1
Oversensing	2



	1 yr	2 yr	at 27 mo
%	99.7	99.1	99.1
#	454	87	44

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	2,400	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

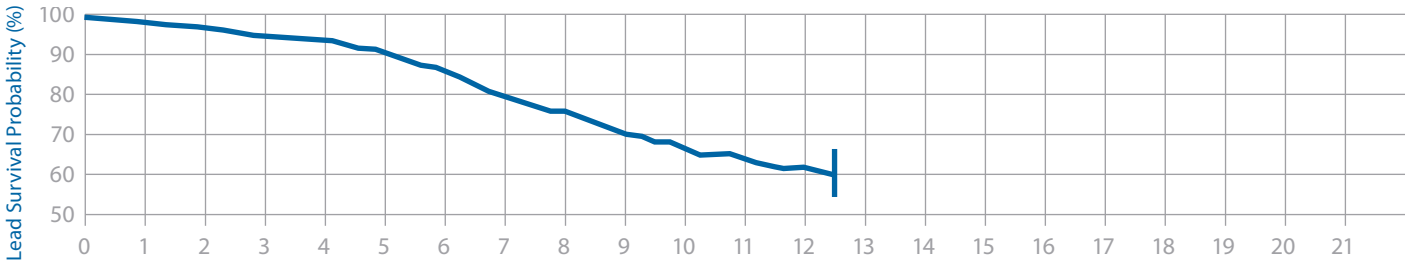
Conductor Fracture	176
Crimp/Weld/Bond	0
Insulation Breach	342
Other	7

System Longevity Study Results

Number of Leads Enrolled in Study	1,349
Cumulative Months of Follow-Up	75,072
Number of Leads Active in Study	19

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

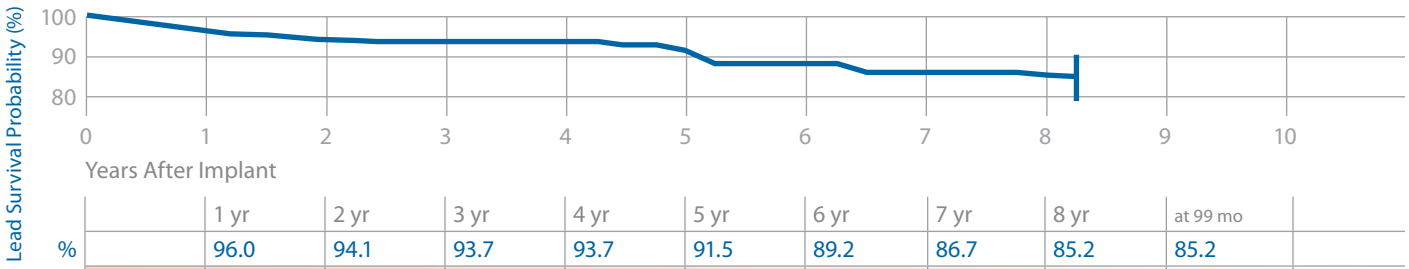
Conductor Fracture	28
Crimp/Weld/Bond	0
Insulation Breach	4
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	384
Cumulative Months of Follow-Up	20,555
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	91.5	89.2	86.7	85.2	85.2
#	312	273	232	188	154	115	78	54	51

Effective Sample Size

Leads

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	5,700	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

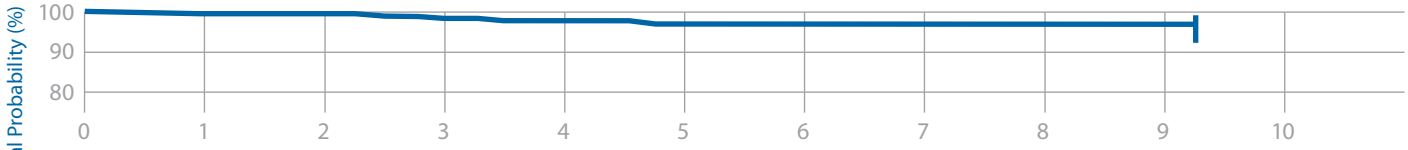
Conductor Fracture	14
Crimp/Weld/Bond	1
Insulation Breach	21
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	18,648
Number of Leads Active in Study	35

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	6,700	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

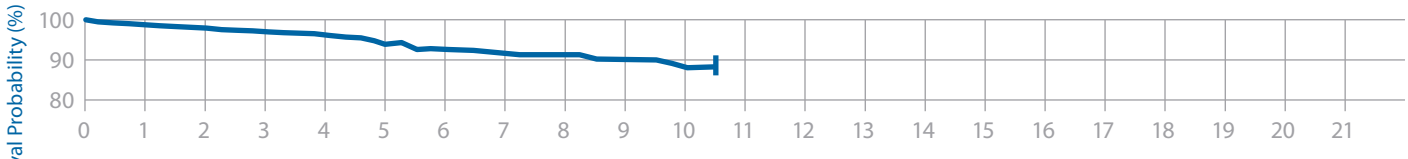
Conductor Fracture	64
Crimp/Weld/Bond	1
Insulation Breach	27
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	1,311
Cumulative Months of Follow-Up	78,866
Number of Leads Active in Study	252

Qualifying Complications 82 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	37
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	91.0	89.8	88.0	88.0
#	1,146	981	874	745	620	491	359	259	160	76	56

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Defibrillation Leads continued

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Registered US Implants	39,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	21,300	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	80
Crimp/Weld/Bond	1
Insulation Breach	2
Other	1

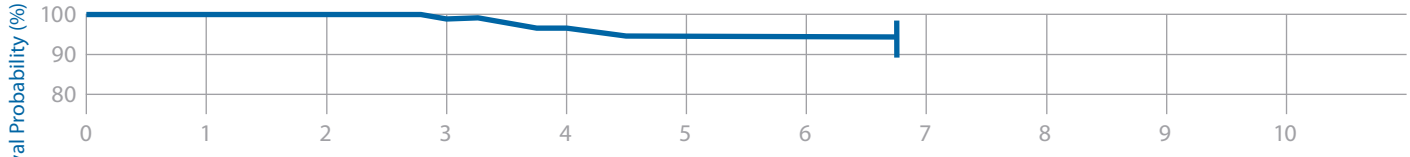
System Longevity Study Results

Number of Leads Enrolled in Study	470
Cumulative Months of Follow-Up	13,369
Number of Leads Active in Study	282

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 81 mo
%	100.0	100.0	99.2	97.2	94.8	94.8	94.8
#	281	164	109	84	63	58	49

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	13,600	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	114
Crimp/Weld/Bond	1
Insulation Breach	32
Other	6

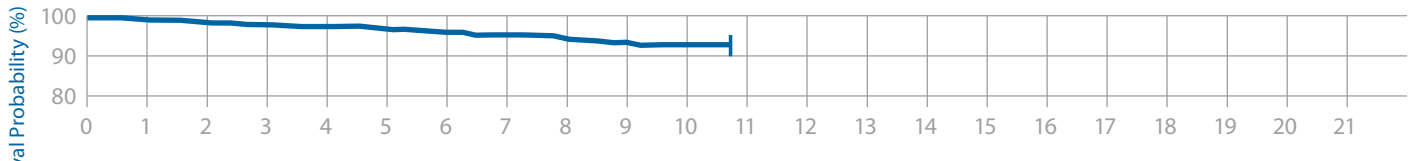
System Longevity Study Results

Number of Leads Enrolled in Study	1,154
Cumulative Months of Follow-Up	65,925
Number of Leads Active in Study	139

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	93.1	93.1
#	996	821	683	565	465	381	314	234	170	108	58

Effective Sample Size

Defibrillation Leads continued

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Registered US Implants	340,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	236,900	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Performance Note: See page 160 – Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

US Returned Product Analysis

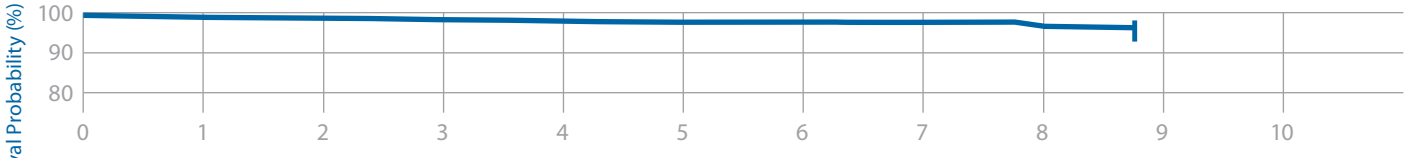
Conductor Fracture	328
Crimp/Weld/Bond	4
Insulation Breach	21
Other	58

System Longevity Study Results

Number of Leads Enrolled in Study	2,708
Cumulative Months of Follow-Up	100,486
Number of Leads Active in Study	1,406

Qualifying Complications 31 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.5	99.3	99.0	98.7	98.2	97.9	97.6	96.9	96.0
#	2,324	1,395	913	733	577	413	235	111	40

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	5,500	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes

See page 153 – 2007 Potential Conductor Wire Fracture

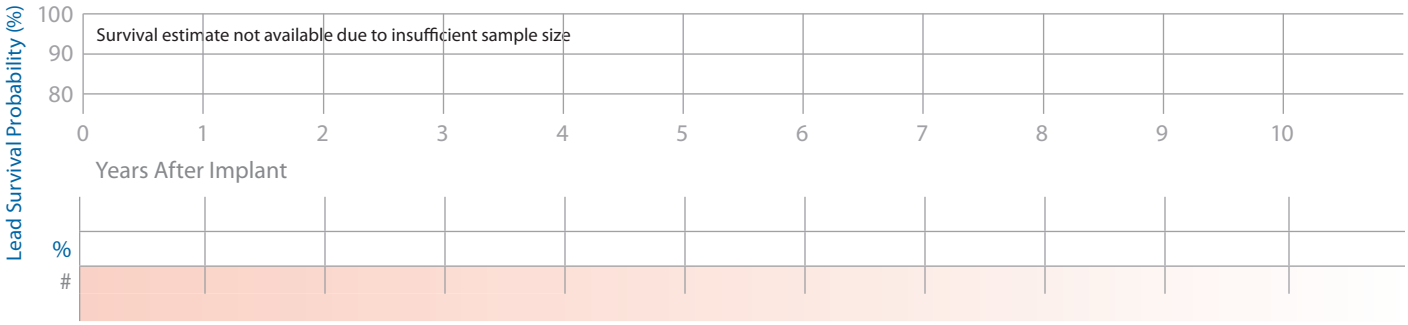
US Returned Product Analysis

Conductor Fracture	120
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 January 31, 2012

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	90,600	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes
See page 153 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

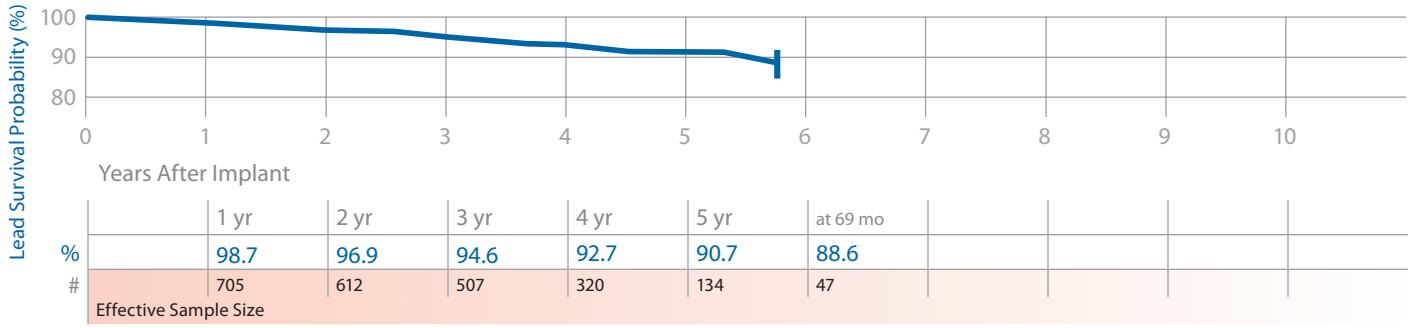
Conductor Fracture	5,244
Crimp/Weld/Bond	2
Insulation Breach	12
Other	60

System Longevity Study Results

Number of Leads Enrolled in Study	794
Cumulative Months of Follow-Up	33,520
Number of Leads Active in Study	364

Qualifying Complications 54 Total

Lead Dislodgement	1	Insulation (not further defined)	1
Failure to Capture	2	Impedance Out of Range	10
Conductor Fracture	22	Unspecified Clinical Failure	1
Failure to Sense	2	Oversensing	14
		Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	98.7	96.9	94.6	92.7	90.7	88.6
#	705	612	507	320	134	47

Effective Sample Size

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Registered US Implants	3,400	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated Active US Implants	2,000	Polarity	One Defib Coil
Advisories	None	Steroid	No

US Returned Product Analysis

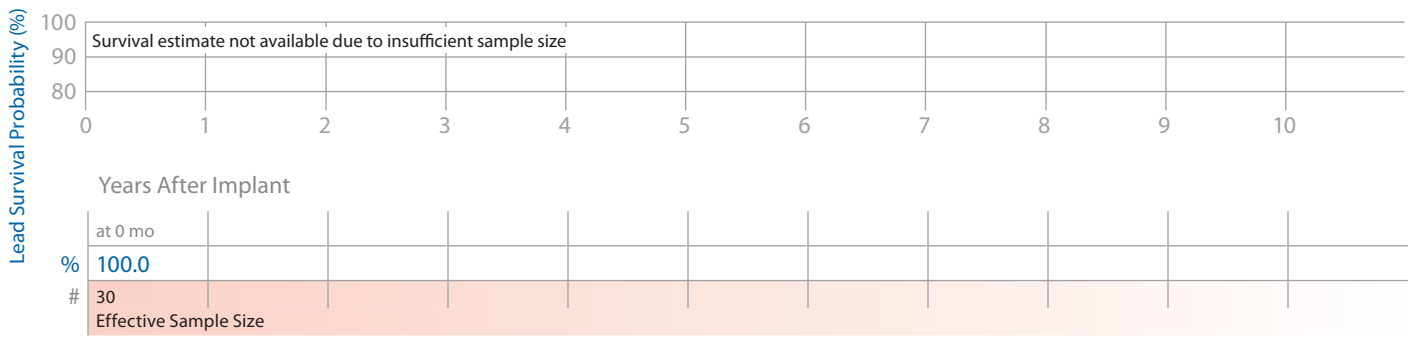
Conductor Fracture	15
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	32
Cumulative Months of Follow-Up	864
Number of Leads Active in Study	17

Qualifying Complications 1 Total

Conductor Fracture	1



	at 0 mo
%	100.0
#	30

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	4	47	23,303	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	151	100.0 at 0 mo												
	Advisories: See page 153 – 2007 Potential Conductor Wire Fracture																		
6931	Sprint Fidelis	Sep-04	294	159	18	11,469	98.2 +1.0/-2.5	95.8 +1.9/-3.2	94.0 +2.3/-3.9	92.9 +2.6/-4.2	92.9 +2.6/-4.2 at 51 mo								
	Advisories: See page 153 – 2007 Potential Conductor Wire Fracture																		
6932	Sprint	Aug-96	411	51	10	24,784	99.2 +0.5/-1.7	98.3 +0.9/-2.0	98.3 +0.9/-2.0	98.3 +0.9/-2.0	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	19	47	54,359	98.4 +0.7/-1.0	97.5 +0.9/-1.3	97.2 +0.9/-1.4	96.7 +1.0/-1.6	95.4 +1.4/-2.0	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	1,329	1,191	4	13,473	99.7 +0.2/-0.9	99.1 +0.6/-1.9	99.1 +0.6/-1.9 at 27 mo										
	See page 160 – Performance note on Helix Retraction 6935 and 6947																		
6936, 6966	Transvene	Dec-93	1,349	19	187	75,072	98.2 +0.6/-1.0	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/-4.0	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	20,555	96.0 +1.6/-2.7	94.1 +2.0/-3.1	93.7 +2.2/-3.2	93.7 +2.2/-3.2	91.5 +2.8/-4.0	89.2 +3.3/-4.8	86.7 +4.0/-5.6	85.2 +4.6/-6.4	85.2 +4.6/-6.4 at 99 mo				
6942	Sprint	Jul-97	351	35	7	18,648	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	252	82	78,866	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 +1.9/-2.3	88.0 +3.0/-3.8	88.0 +3.0/-3.8 at 126 mo			
6944	Sprint Quattro	Dec-00	470	282	5	13,369	100.0	100.0	99.2 +0.7/-5.1	97.2 +1.9/-5.7	94.8 +3.0/-7.0	94.8 +3.0/-7.0	94.8 +3.0/-7.0 at 81 mo						
6945	Sprint	Sep-97	1,154	139	37	65,925	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/-2.0	94.5 +1.7/-2.5	93.1 +2.1/-3.1	93.1 +2.1/-3.1 at 129 mo			
6947	Sprint Quattro Secure	Nov-01	2,708	1,406	31	100,486	99.5 +0.2/-0.4	99.3 +0.3/-0.4	99.0 +0.4/-0.5	98.7 +0.5/-0.8	98.2 +0.7/-1.0	97.9 +0.7/-1.2	97.6 +0.9/-1.4	96.9 +1.3/-2.3	96.0 +1.8/-3.3 at 105 mo				
	See page 160 – 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 153 – 2007 Potential Conductor Wire Fracture																		
6949	Sprint Fidelis	Sep-04	794	364	54	33,520	98.7 +0.6/-1.2	96.9 +1.1/-1.5	94.6 +1.5/-2.1	92.7 +1.8/-2.4	90.7 +2.3/-2.9	88.6 +3.3/-4.5 at 69 mo							
	Advisories: See page 153 – 2007 Potential Conductor Wire Fracture																		
6996	Sub-Q Lead	Jun-01	32	17	1	864	100.0 at 0 mo												

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	4,100	450	0	0	5
6932	Sprint	Aug-96	14,900	4,500	20	0	23	3
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	16,200	2,600	167	0	32	3
6935	Sprint Quattro Secure	Nov-08	28,700	26,400	22	0	0	6
6936, 6966	Transvene	Dec-93	23,600	2,400	176	0	342	7
6939, 6999	Sub-Q Patch	Dec-93	3,700	300	28	0	4	1
6942	Sprint	Jul-97	17,700	5,700	14	1	21	2
6943	Sprint	Oct-97	20,700	6,700	64	1	27	3
6944	Sprint Quattro	Dec-00	39,700	21,300	80	1	2	1
6945	Sprint	Sep-97	42,600	13,600	114	1	32	6
6947	Sprint Quattro Secure	Nov-01	340,700	236,900	328	4	21	58
6948	Sprint Fidelis	Sep-04	10,400	5,500	120	0	1	0
6949	Sprint Fidelis	Sep-04	186,600	90,600	5,244	2	12	60
6996	Sub-Q Lead	Jun-01	3,400	2,000	15	0	0	0

Source: Returned Product Analysis
Data as of January 31, 2012

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	5	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	16,200	0	0	1	2	1	0	1	0	0	5
6935	Sprint Quattro Secure	28,700	6	3	19	14	19	5	1	13	1	1
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	39,700	0	3	12	11	12	3	0	6	0	6
6945	Sprint	42,600	0	1	4	7	9	1	2	1	1	1
6947	Sprint Quattro Secure	340,700	22	19	92	64	101	22	4	56	2	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	17	0	19
6996	SubQ	3,400	0	0	1	0	1	0	0	2	0	0

Report Cutoff Date: January 31, 2012

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 January 31, 2012

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Registered US Implants	20,800	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	16,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	10
Other	3

Atrial Placement

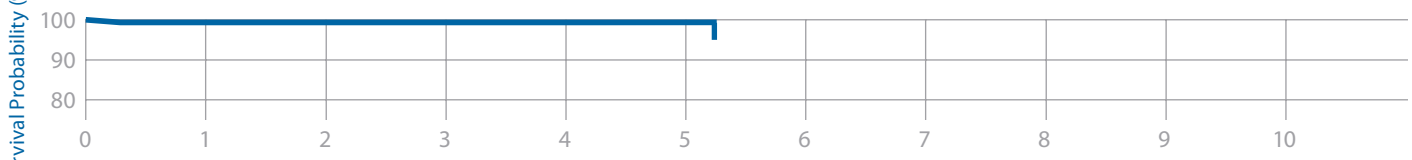
System Longevity Study Results

Number of Leads Enrolled in Study	766
Cumulative Months of Follow-Up	16,060
Number of Leads Active in Study	591

Qualifying Complications

4 Total

Failure to Sense	1
Cardiac Perforation	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.4	99.4	99.4	99.4	99.4	99.4
#	402	188	133	85	57	51

Effective Sample Size

Ventricular Placement

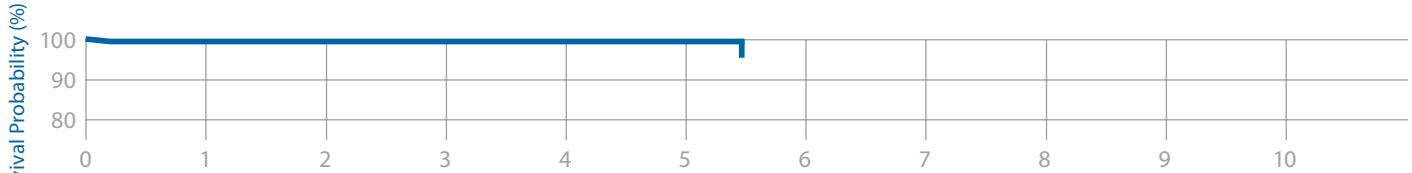
System Longevity Study Results

Number of Leads Enrolled in Study	472
Cumulative Months of Follow-Up	12,042
Number of Leads Active in Study	333

Qualifying Complications

1 Total

Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
#	269	152	123	87	61	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	7,700	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

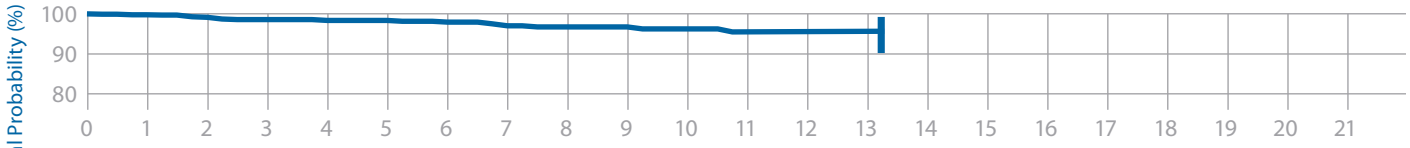
Conductor Fracture	14
Crimp/Weld/Bond	0
Insulation Breach	4
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	73,316
Number of Leads Active in Study	216

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	279	196	141	99	57	50

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	43,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	29
Crimp/Weld/Bond	0
Insulation Breach	159
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	50,855
Number of Leads Active in Study	17

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	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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

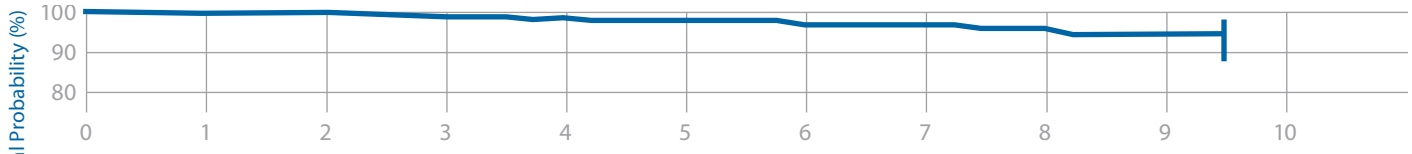
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	29,793
Number of Leads Active in Study	3

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	79	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

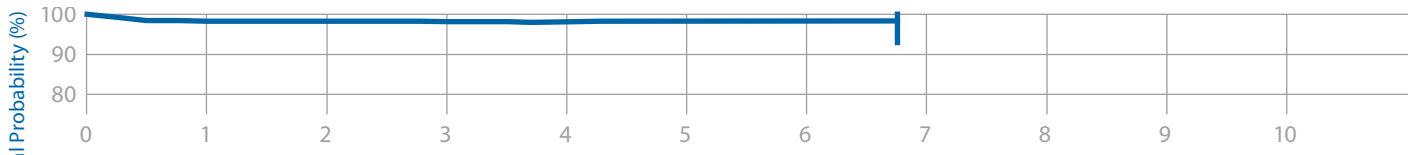
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	171
Cumulative Months of Follow-Up	11,097
Number of Leads Active in Study	44

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 81 mo
%	98.1	98.1	98.1	98.1	98.1	98.1	98.1
#	131	119	107	90	82	73	52

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	32,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	44
Crimp/Weld/Bond	0
Insulation Breach	147
Other	5

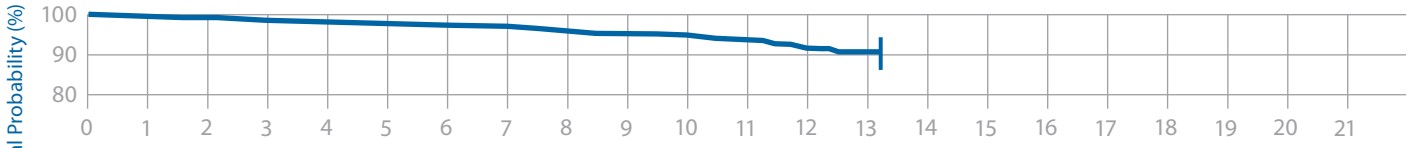
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,413
Cumulative Months of Follow-Up	131,591
Number of Leads Active in Study	301

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	92.0	91.1	91.1
#	1,907	1,637	1,370	1,116	897	734	567	450	324	235	174	120	68	52

Effective Sample Size

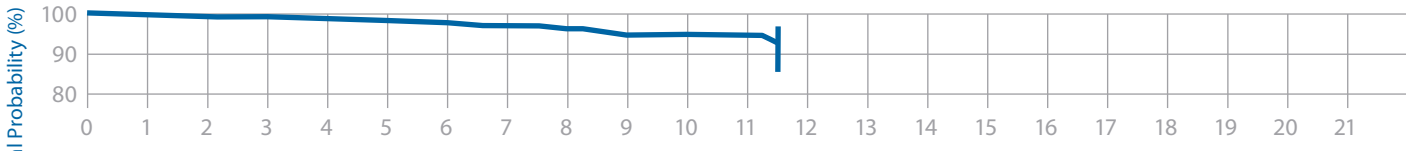
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	94,169
Number of Leads Active in Study	208

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	92.7
#	1,426	1,218	1,031	831	684	541	394	268	178	114	64	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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

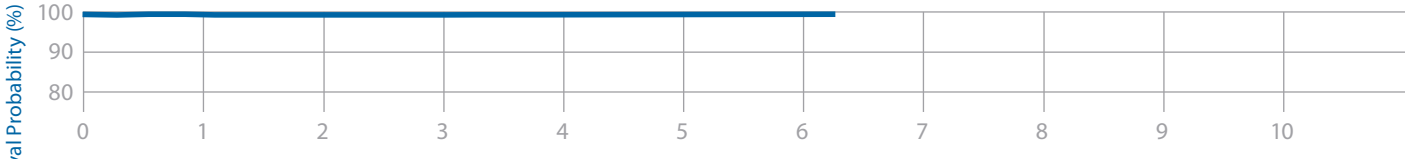
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	102
Cumulative Months of Follow-Up	7,095
Number of Leads Active in Study	71

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	93	85	84	81	67	53

Effective Sample Size

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Registered US Implants	85,400	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	53,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	16
Other	1

Atrial Placement

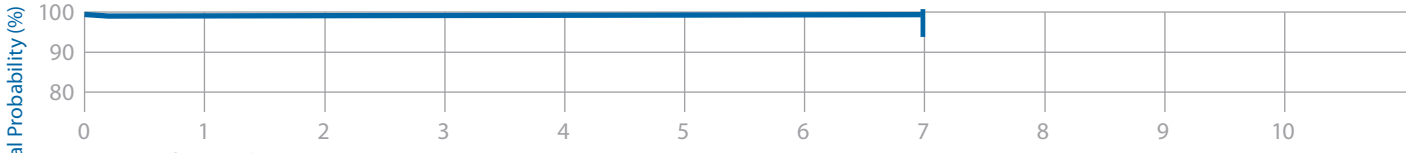
System Longevity Study Results

Number of Leads Enrolled in Study	215
Cumulative Months of Follow-Up	13,875
Number of Leads Active in Study	151

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	169	126	86	54

Effective Sample Size

Ventricular Placement

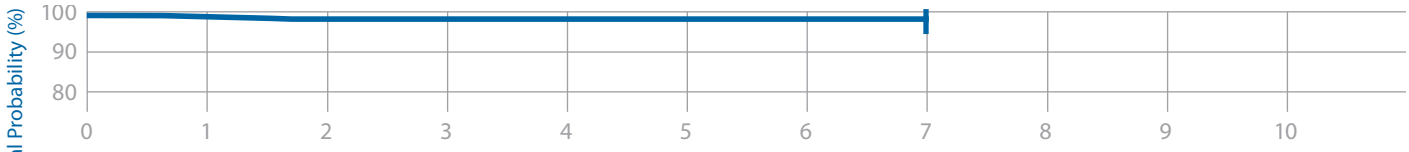
System Longevity Study Results

Number of Leads Enrolled in Study	799
Cumulative Months of Follow-Up	26,337
Number of Leads Active in Study	598

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
%	99.7	99.4	99.4	99.4	99.4	99.4	99.4
#	443	357	327	290	191	108	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Registered US Implants	376,400	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	289,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	22
Crimp/Weld/Bond	1
Insulation Breach	21
Other	16

Atrial Placement

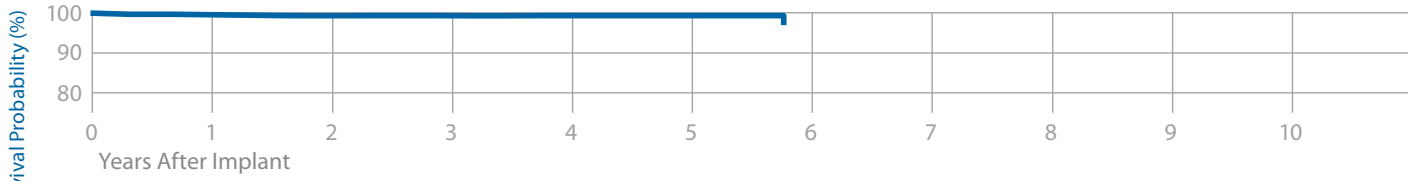
System Longevity Study Results

Number of Leads Enrolled in Study	1,657
Cumulative Months of Follow-Up	48,631
Number of Leads Active in Study	1,190

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 69 mo
%	99.8	99.6	99.6	99.6	99.6	99.6
#	1,415	775	448	249	110	49

Effective Sample Size

Ventricular Placement

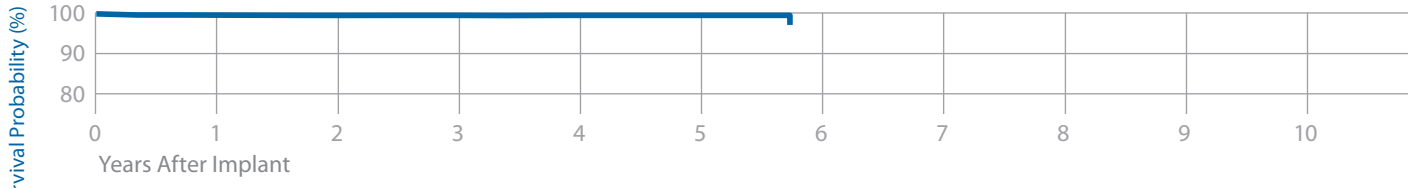
System Longevity Study Results

Number of Leads Enrolled in Study	1,227
Cumulative Months of Follow-Up	40,162
Number of Leads Active in Study	848

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
#	1,055	637	429	286	139	58

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Pacing Leads continued

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Registered US Implants	172,100	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	80,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

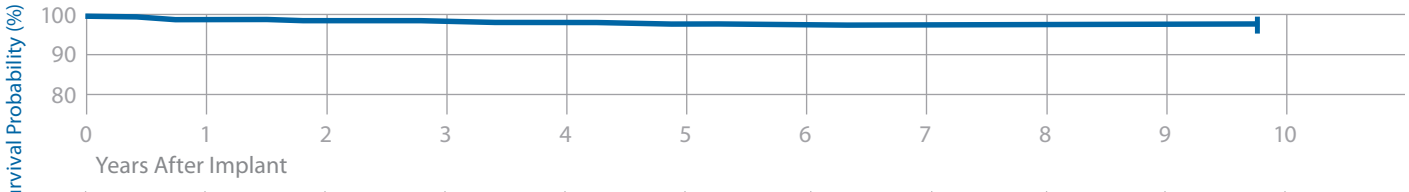
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	35
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	1,147
Cumulative Months of Follow-Up	65,267
Number of Leads Active in Study	299

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 117 mo
%	98.9	98.8	98.7	98.4	98.1	97.9	97.9	97.9	97.9	97.9
#	928	830	733	636	551	449	315	198	107	43

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	2,500	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

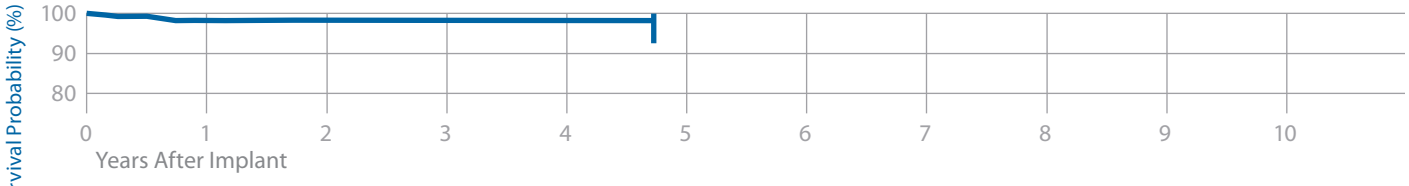
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	2
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	7,588
Number of Leads Active in Study	4

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 January 31, 2012

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	25,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

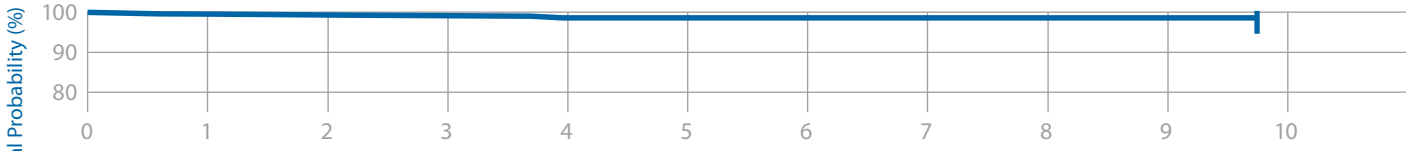
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	53
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	40,433
Number of Leads Active in Study	39

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 117 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	64	51

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

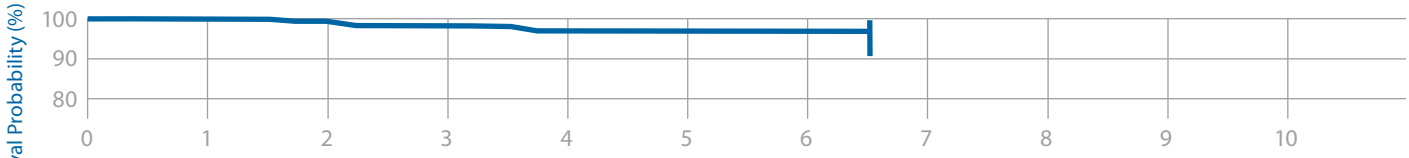
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	206
Cumulative Months of Follow-Up	11,767
Number of Leads Active in Study	0

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	4,100	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

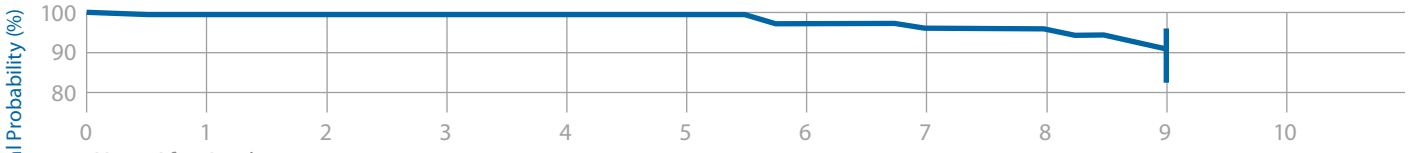
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	18
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	22,997
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	69,500	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	23,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

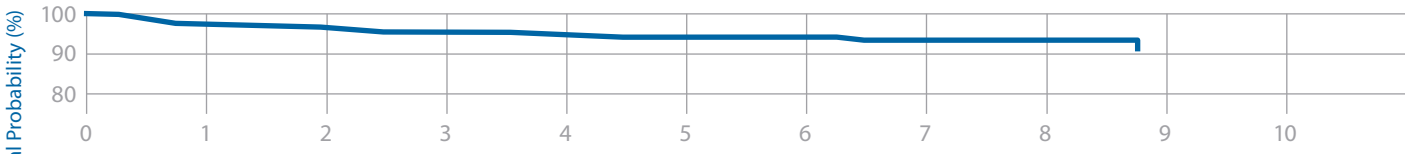
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	57
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	656
Cumulative Months of Follow-Up	31,758
Number of Leads Active in Study	151

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 105 mo
%	96.8	96.4	95.3	94.7	94.0	94.0	93.4	93.4	93.4
#	495	431	349	291	242	187	134	75	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Pacing Leads continued

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Registered US Implants	56,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	38,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

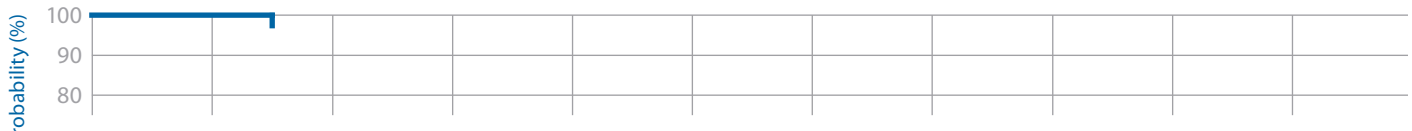
US Returned Product Analysis

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

System Longevity Study Results

Qualifying Complications 0 Total

Number of Leads Enrolled in Study	319
Cumulative Months of Follow-Up	3,076
Number of Leads Active in Study	271



	1 yr	at 18 mo
%	100.0	100 .0
#	73	49

Effective Sample Size

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Registered US Implants	83,500	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	41,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

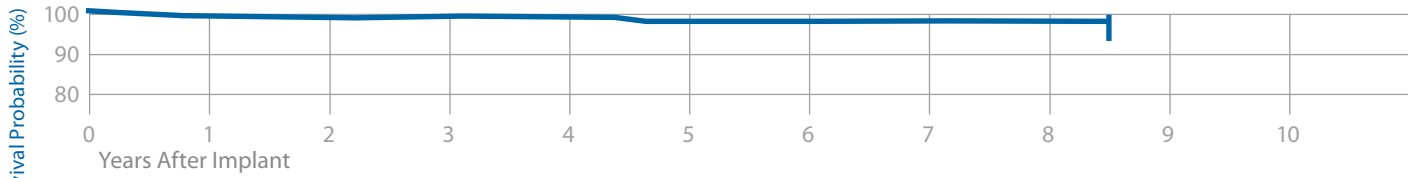
US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	12
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	14,531	Failure to Capture	2
Number of Leads Active in Study	63	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
#	193	171	153	130	111	101	80	63	52

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

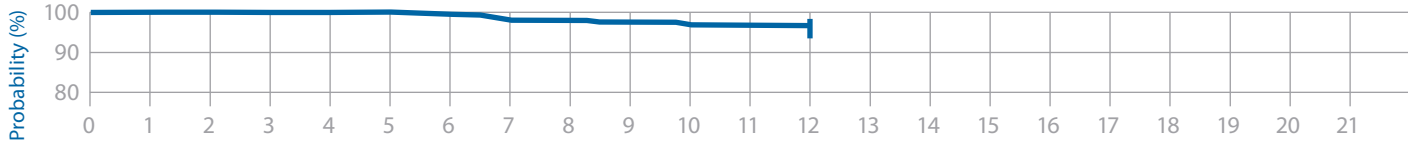
Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1,354
Cumulative Months of Follow-Up	83,694
Number of Leads Active in Study	335

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	12 yr
%	99.7	99.7	99.5	99.4	99.3	98.8	97.6	97.6	97.3	96.8	96.1	96.1
#	1,076	942	833	731	636	557	456	358	255	170	104	51

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	44,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

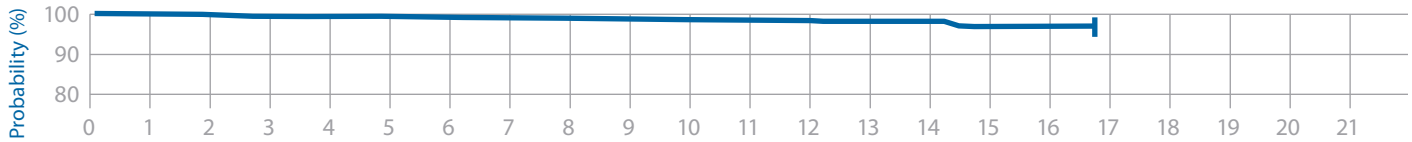
Conductor Fracture	51
Crimp/Weld/Bond	1
Insulation Breach	50
Other	9

System Longevity Study Results

Number of Leads Enrolled in Study	8,153
Cumulative Months of Follow-Up	441,672
Number of Leads Active in Study	321

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	1,096	823	612	440	321	224	140	82	55

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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

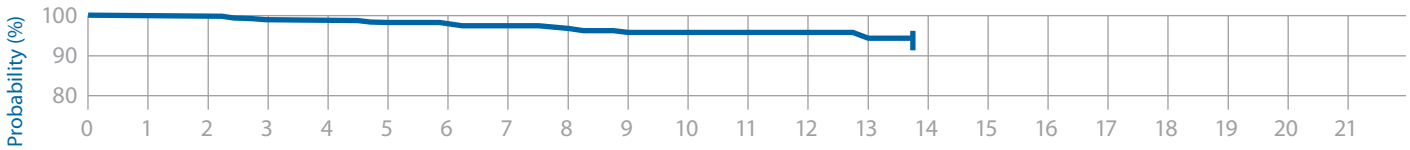
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	99,245
Number of Leads Active in Study	171

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	94.7	94.7
#	1,416	1,144	945	796	659	527	416	345	283	223	171	135	103	60

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	13,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

Atrial Placement

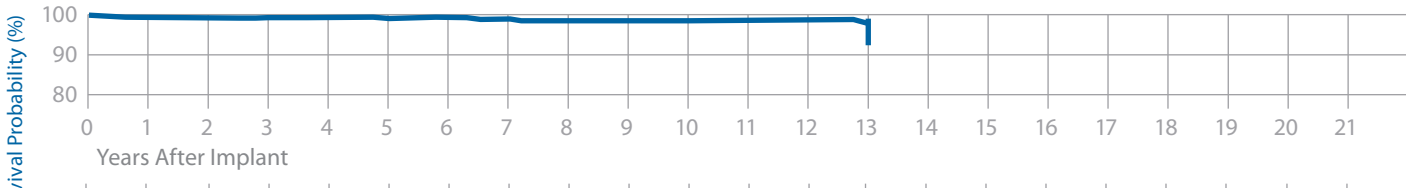
System Longevity Study Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	43,665
Number of Leads Active in Study	135

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	13 yr
%	99.5	99.5	99.5	99.5	99.5	99.5	98.8	98.8	98.8	98.8	98.8	98.8	97.1
#	383	382	379	373	355	330	294	250	207	179	125	80	49

Effective Sample Size

Ventricular Placement

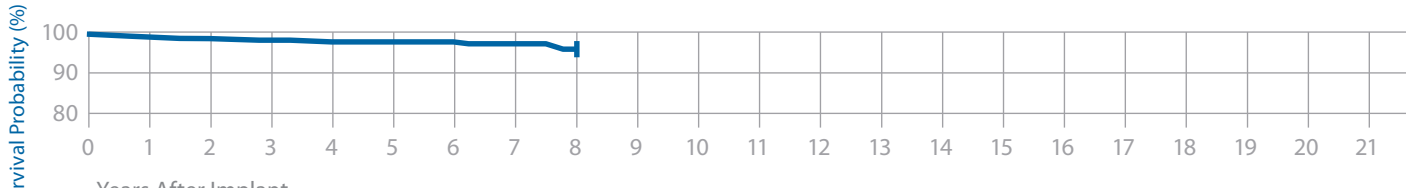
System Longevity Study Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Follow-Up	44,323
Number of Leads Active in Study	15

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 January 31, 2012

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Registered US Implants	94,000	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	41,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	1
Insulation Breach	21
Other	3

Atrial Placement

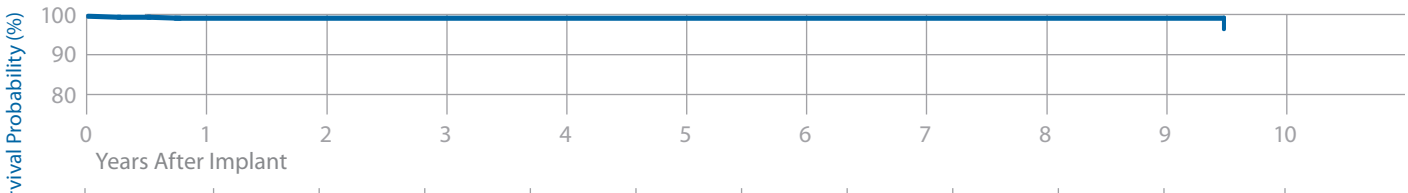
Longevity Study Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	32,186
Number of Leads Active in Study	169

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 114 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	197	131	72	44

Effective Sample Size

Ventricular Placement

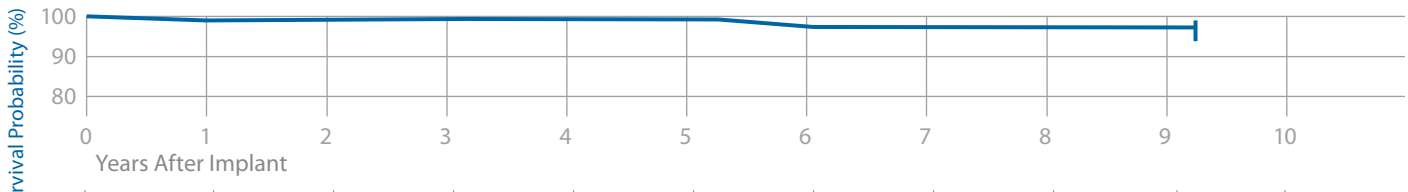
System Longevity Study Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	38,256
Number of Leads Active in Study	113

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	at 111 mo
%	99.5	99.4	99.4	99.1	99.1	97.9	97.9	97.9	97.9	97.9
#	656	513	387	318	273	197	149	107	60	50

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	30,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	36
Crimp/Weld/Bond	2
Insulation Breach	53
Other	4

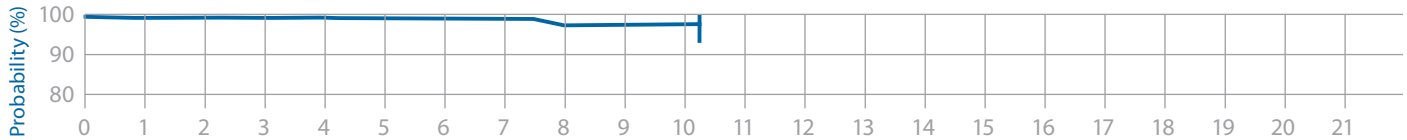
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	968
Cumulative Months of Follow-Up	33,708
Number of Leads Active in Study	37

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 123 mo
%	99.6	99.6	99.3	99.3	99.3	99.3	99.3	97.6	97.6	97.6	97.6
#	553	425	322	254	211	160	131	104	77	60	53

Effective Sample Size

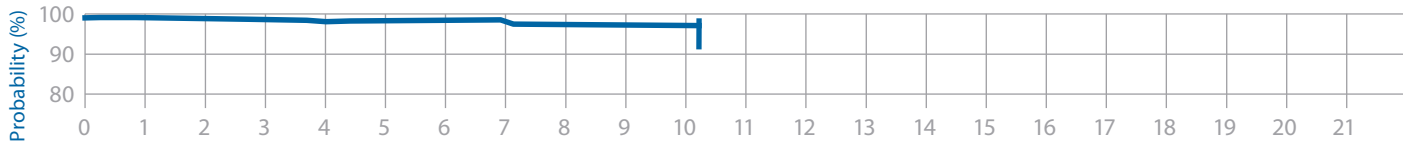
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,362
Cumulative Months of Follow-Up	39,929
Number of Leads Active in Study	78

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	at 123 mo
%	99.9	99.7	99.5	92.2	99.2	99.2	98.5	98.5	98.5	98.5	98.5
#	700	499	363	268	227	189	152	129	95	59	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Registered US Implants	9,800	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

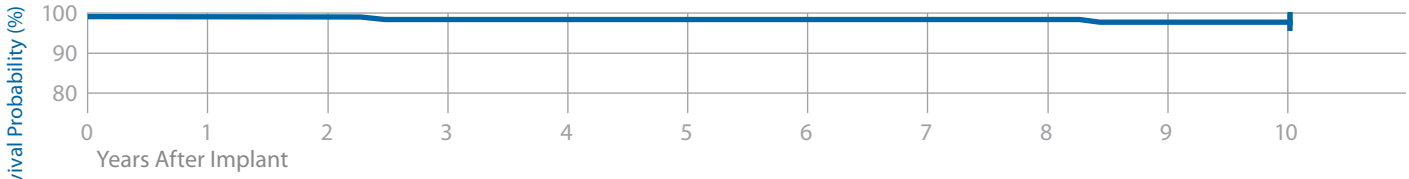
System Longevity Study Results

Number of Leads Enrolled in Study	508
Cumulative Months of Follow-Up	27,043
Number of Leads Active in Study	72

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	98.5	98.5
#	376	316	268	222	187	164	136	114	91	53

Effective Sample Size

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Registered US Implants	1,402,900	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	894,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	322
Crimp/Weld/Bond	0
Insulation Breach	333
Other	97

Atrial Placement

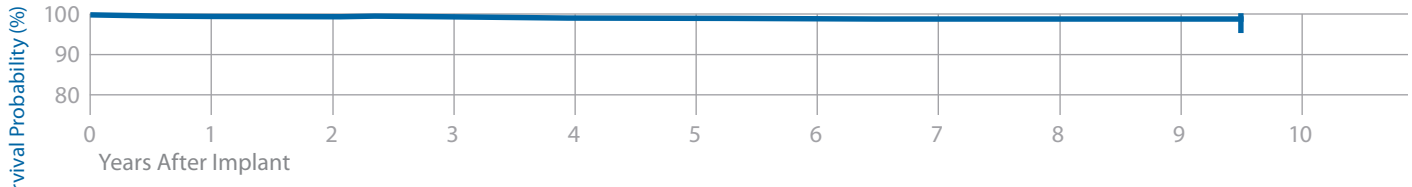
System Longevity Study Results

Number of Leads Enrolled in Study	2,740
Cumulative Months of Follow-Up	129,717
Number of Leads Active in Study	755

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	at 114 mo
%	99.7	99.6	99.4	99.1	99.1	99.0	99.0	98.7	98.7	98.7
#	2,077	1,771	1,512	1,304	1,044	725	445	273	101	56

Effective Sample Size

Ventricular Placement

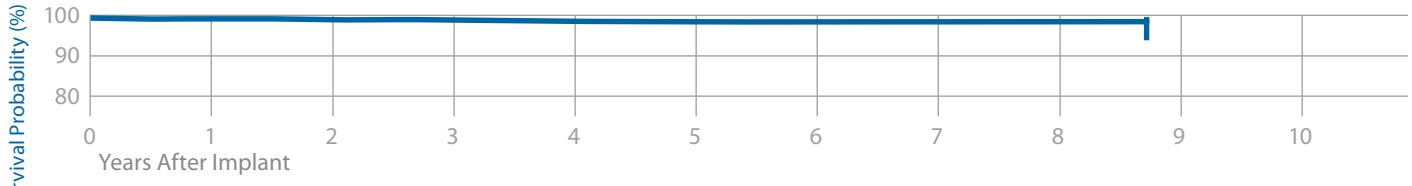
System Longevity Study Results

Number of Leads Enrolled in Study	1,538
Cumulative Months of Follow-Up	64,681
Number of Leads Active in Study	308

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 105 mo
%	99.6	99.4	99.3	99.0	99.0	99.0	99.0	99.0	99.0
#	1,081	898	742	607	475	362	227	134	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

Pacing Leads continued

5086MRI CapSureFix Novus

Product Characteristics

US Market Release	Feb-11	Serial Number Prefix	LFP
Registered US Implants	44,300	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated Active US Implants	43,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

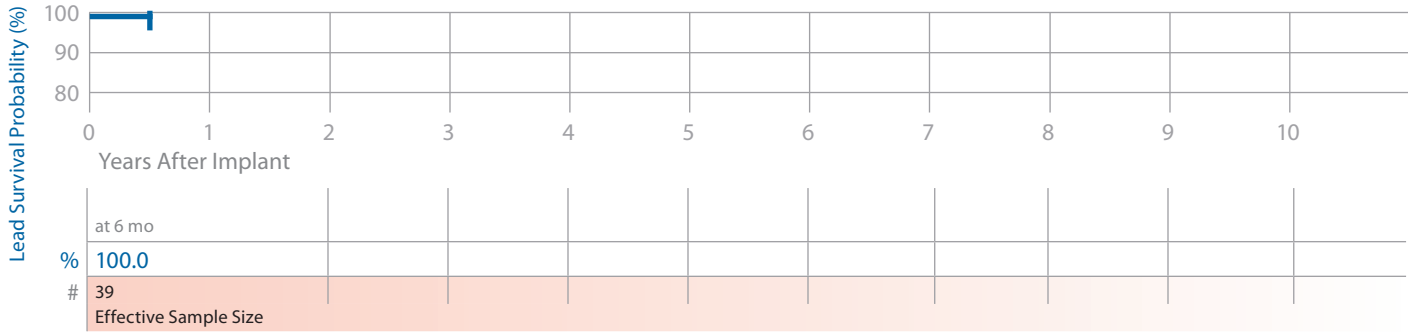
US Returned Product Analysis

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

System Longevity Study Results

Number of Leads Enrolled in Study	1,592
Cumulative Months of Follow-Up	1,413
Number of Leads Active in Study	1,552

Qualifying Complications 0 Total



	at 6 mo
%	100.0
#	39
Effective Sample Size	

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Registered US Implants	128,400	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	59,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

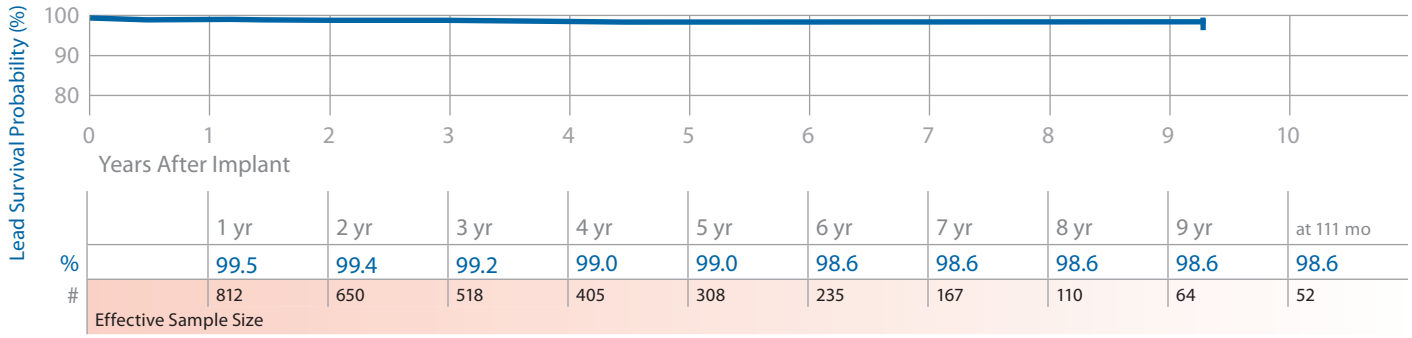
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	33
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	1,172
Cumulative Months of Follow-Up	46,803
Number of Leads Active in Study	150

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	308	235	167	110	64	52
Effective Sample Size										

Pacing Leads continued

5524, 5524M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Registered US Implants	60,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	16,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

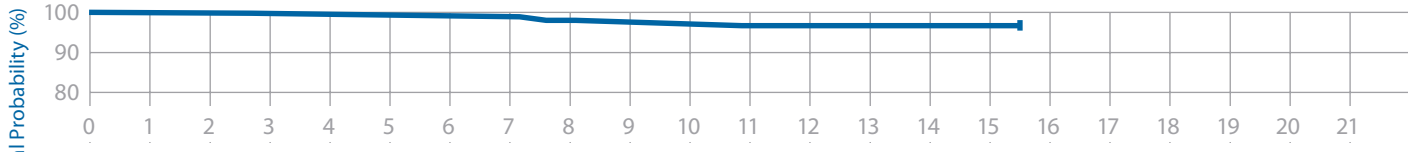
Conductor Fracture	11
Crimp/Weld/Bond	1
Insulation Breach	11
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	4,496
Cumulative Months of Follow-Up	252,709
Number of Leads Active in Study	307

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
#	3,438	2,964	2,540	2,134	1,779	1,416	1,118	857	677	533	397	286	207	133	72	50

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	7,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

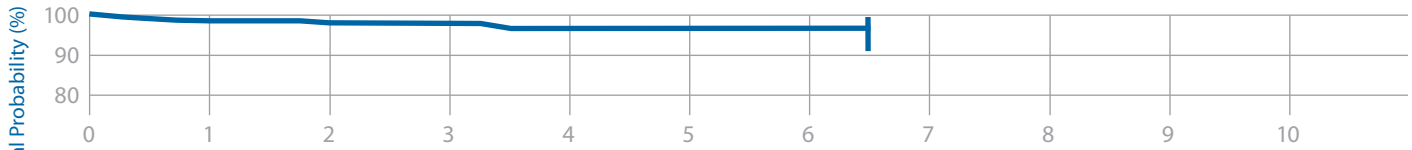
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	5
Other	2

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 January 31, 2012

Pacing Leads continued

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Registered US Implants	60,700	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	29,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

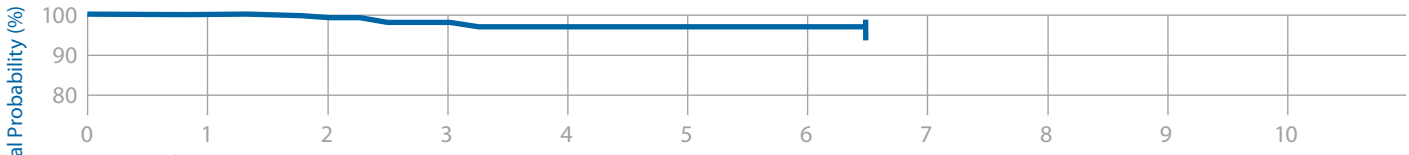
Conductor Fracture	9
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	15,449
Number of Leads Active in Study	39

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	126	73	50

Effective Sample Size

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Registered US Implants	87,200	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

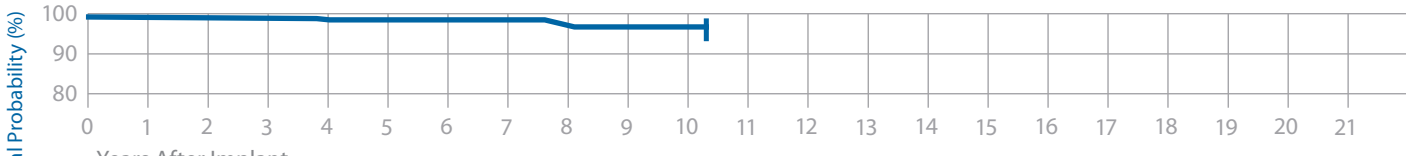
Conductor Fracture	8
Crimp/Weld/Bond	0
Insulation Breach	27
Other	7

System Longevity Study Results

Number of Leads Enrolled in Study	1,053
Cumulative Months of Follow-Up	39,855
Number of Leads Active in Study	133

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	at 123 mo
%	99.8	99.3	99.3	99.3	98.6	97.5	97.5	97.5	97.5	97.5	97.5
#	713	528	404	290	215	168	132	110	91	55	48

Effective Sample Size

Leads

Pacing Leads continued

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Registered US Implants	33,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	18,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

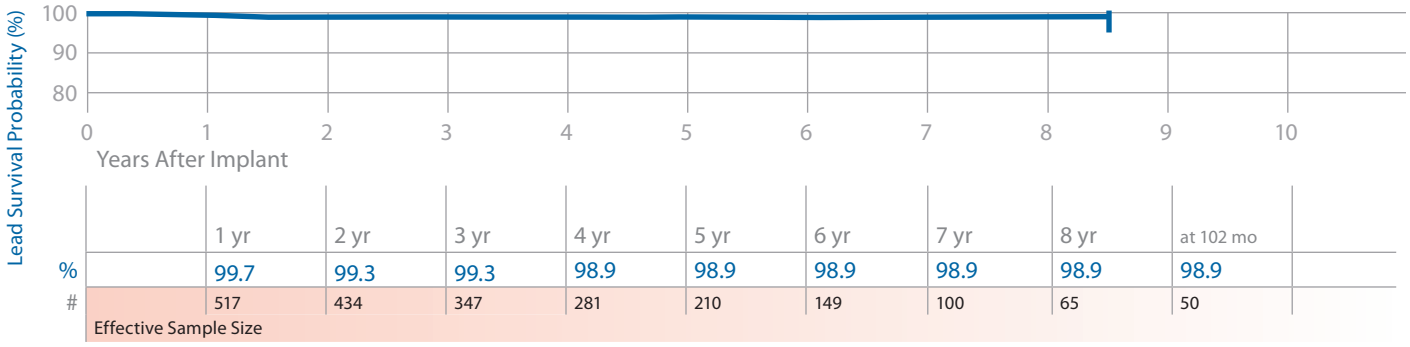
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	672
Cumulative Months of Follow-Up	30,202
Number of Leads Active in Study	123

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 102 mo
%	99.7	99.3	99.3	98.9	98.9	98.9	98.9	98.9	98.9
#	517	434	347	281	210	149	100	65	50

Effective Sample Size

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Registered US Implants	14,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	9,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

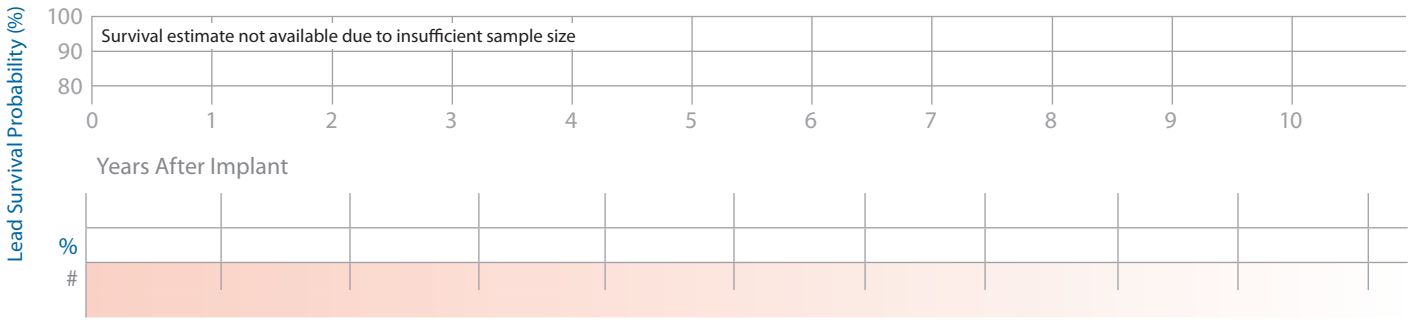
US Returned Product Analysis

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	1,452
Number of Leads Active in Study	11

Qualifying Complications 0 Total



Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	7,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

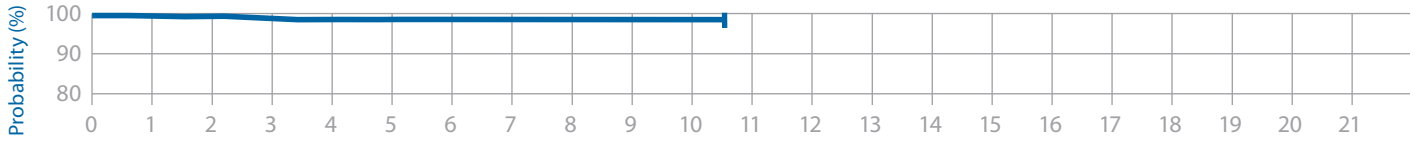
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	816
Cumulative Months of Follow-Up	43,292
Number of Leads Active in Study	86

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	206	157	123	89	56

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	766	591	4	16,060	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1 at 63 mo								
3830	SelectSecure	Vent	Aug-05	472	333	1	12,042	100.0	100.0	100.0	100.0	100.0	100.0 at 66 mo								
4023	CapSure SP	Vent	Aug-91	1,158	216	22	73,316	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	17	4	50,855	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 +1.0/-5 .0 at 117 mo					
4033	CapSure Z	Vent	Not US released	539	3	10	29,793	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 +1.0/-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	44	8	11,097	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 81 mo							
4068	CapSureFix	Atrial	Mar-96	2,413	301	69	131,591	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/-1.0	96.9 +0.8/-1.1	95.6 +1.1/-1.6	94.1 +1.6/-2.2	92.0 +2.3/-3.3	91.1 +2.7/-3.9 at 159 mo		
4068	CapSureFix	Vent	Mar-96	1,799	208	44	94,169	99.3 +0.3/-0.6	98.7 +0.5/-0.7	98.7 +0.5/-0.7	98.2 +0.6/-1.0	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	92.7 +2.9/-4.8 at 138 mo				
4073	CapSure Sense	Vent	Jun-02	102	71	0	7,095	100.0	100.0	100.0	100.0	100.0	100.0	100 .0 at 75 mo							
4074	CapSure Sense	Atrial	Jun-02	215	151	2	13,875	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	799	598	3	26,337	99.7 +0.2/-1.1	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3							
4076	CapSureFix Novus	Atrial	Feb-04	1,657	1,190	6	48,631	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 69 mo								
4076	CapSureFix Novus	Vent	Feb-04	1,227	848	3	40,162	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	299	18	65,267	98.9 +0.5/-0.9	98.8 +0.5/-0.9	98.7 +0.5/-1.0	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 117 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	4	4	7,588	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	39	6	40,433	99.6 +0.3/-0.7	99.3 +0.4/-1.0	99.3 +0.4/-1.0	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 117 mo					
4533	CapSure Z	Atrial	Not US released	206	0	4	11,767	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	22,997	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	151	33	31,758	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 105 mo					
4574	CapSure Sense	Atrial	Jun-02	319	271	0	3,076	100.0	100.0 at 18 mo												
4592	CapSure SP Novus	Atrial	Oct-98	283	63	5	14,531	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	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	335	19	83,694	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 +1.0/-1.6	97.6 +1.0/-1.6	96.8 +1.3/-2.2	96.1 +1.6/-2.8				
5024, 5024M	CapSure SP	Vent	Mar-90	8,153	321	56	441,672	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/-2.0	97.3 +1.2/-2.0 at 201 mo	
5033	CapSure Z	Vent	Feb-96	1,899	171	28	99,245	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	94.7 +2.0/-3.3 at 165 mo			
5034	CapSure Z	Atrial	Feb-96	386	135	5	43,665	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	97.1 +2.1/-6.7 at 156 mo			
5034	CapSure Z	Vent	Feb-96	1,209	15	11	44,323	99.7 +0.2/-0.6	99.4 +0.3/-0.8	99.1 +0.4/-1.0	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	169	2	32,186	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 114 mo					
5054	CapSure Z Novus	Vent	Jun-98	967	113	9	38,256	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	97.9 +1.1/-2.4	97.9 +1.1/-2.4	97.9 +1.1/-2.4	97.9 +1.1/-2.4 at 111 mo					

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	968	37	6	33,708	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 +1.6/-4.2	97.6 +1.6/-4.2	97.6 +1.6/-4.2 at 123 mo				
5068	CapSureFix	Vent	Jan-97	1,362	78	5	39,929	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 +1.0/-2.5	98.5 +1.0/-2.5	98.5 +1.0/-2.5	98.5 +1.0/-2.5 at 123 mo				
5072	SureFix	A or V	Jun-98	508	72	3	27,043	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	98.5 +1.1/-4.0					
5076	CapSureFix Novus	Atrial	Aug-00	2,740	755	19	129,717	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 114 mo					
5076	CapSureFix Novus	Vent	Aug-00	1,538	308	10	64,681	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 105 mo					
5086MRI	CapsureFix Novus	A or V	Feb-11	1,592	1,552	0	1,413	100.0 at 6 mo													
5092	CapSure SP Novus	Vent	Jun-98	1,172	150	9	46,803	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	4,496	307	39	252,709	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/-1.0	97.5 +0.8/-1.1	97.5 +0.8/-1.1	97.5 +0.8/-1.1 at 186 mo	
5534	CapSure Z	Atrial	Feb-96	264	6	6	12,959	98.3 +1.1/-2.7	97.8 +1.3/-3.0	97.8 +1.3/-3.0	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	39	4	15,449	100.0	99.2 +0.6/-2.4	98.7 +0.9/-2.6	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0 at 78 mo							
5568	CapSureFix	Atrial	Jan-97	1,053	133	11	39,855	99.8 +0.1/-0.7	99.3 +0.4/-0.9	99.3 +0.4/-0.9	99.3 +0.4/-0.9	98.6 +0.8/-2.0	97.5 +1.3/-2.8	97.5 +1.3/-2.8	97.5 +1.3/-2.8	97.5 +1.3/-2.8	97.5 +1.3/-2.8 at 123 mo				
5592	CapSure SP Novus	Atrial	Jun-98	672	123	5	30,202	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 102 mo					
5594	CapSure SP Novus	Atrial	Jun-01	21	11	0	1,452	100.0 at 0 mo													
6940	CapSureFix	Atrial	Oct-98	816	86	10	43,292	99.7 +0.2/-0.8	99.6 +0.3/-1.0	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 January 31, 2012

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	20,800	16,500	3	0	10	3
4023	CapSure SP	Aug-91	41,100	7,700	14	0	4	2
4024	CapSure SP	Oct-91	221,300	43,800	29	0	159	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	32,200	44	0	147	5
4073	CapSure Sense	Jun-02	700	300	0	0	0	0
4074	CapSure Sense	Jun-02	85,400	53,700	1	0	16	1
4076	CapSureFix Novus	Feb-04	376,400	289,700	22	1	21	16
4092	CapSure SP Novus	Sep-98	172,100	80,000	7	0	35	2
4523	CapSure SP	Aug-91	11,200	2,500	1	0	2	1
4524	CapSure SP	Oct-91	101,300	25,100	1	0	53	3
4533	CapSure Z	Not US released	NA	NA	0	0	0	0
4558M	Screw-in	Nov-94	19,900	4,100	1	0	18	0
4568	CapSureFix	Jan-97	69,500	23,200	3	0	57	1
4574	CapSure Sense	Jun-02	56,200	38,200	5	0	3	0
4592	CapSure SP Novus	Oct-98	83,500	41,100	6	0	12	1
5023, 5023M	CapSure SP	Nov-88	9,800	2,200	5	0	0	0
5024, 5024M	CapSure SP	Mar-90	200,700	44,700	51	1	50	9
5033	CapSure Z	Feb-96	2,300	500	1	0	0	0
5034	CapSure Z	Feb-96	56,000	13,100	12	0	12	3
5054	CapSure Z Novus	Jun-98	94,000	41,500	10	1	21	3
5068	CapSureFix	Jan-97	102,800	30,900	36	2	53	4
5072	SureFix	Jun-98	9,800	4,300	2	0	6	0
5076	CapSureFix Novus	Aug-00	1,402,900	894,200	322	0	333	97
5086MRI	CapSureFix Novus	Feb-11	44,300	43,300	0	0	1	2
5092	CapSure SP Novus	Jun-98	128,400	59,800	7	0	33	1
5524, 5524M	CapSure SP	Mar-90	60,300	16,600	11	1	11	2
5534	CapSure Z	Feb-96	26,200	7,200	3	0	5	2
5554	CapSure Z Novus	Jun-98	60,700	29,500	9	0	17	1
5568	CapSureFix	Jan-97	87,200	49,500	8	0	27	7
5592	CapSure SP Novus	Jun-98	33,200	18,600	3	0	3	0
5594	CapSure SP Novus	Jun-01	14,800	9,900	4	0	6	1
6940	CapSureFix	Oct-98	25,300	7,600	12	0	17	1

Source: Returned Product Analysis
Data as of January 31, 2012

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	Extracardiac Stimulation	Impedance Abnormal	Unspecified
3830	SelectSecure	20,800	6	1	26	14	1	1	1	1	0	2
4023	CapSure SP	41,100	0	1	3	4	1	1	3	1	0	2
4024	CapSure SP	221,300	12	11	50	109	0	15	1	2	7	21
4033	CapSure Z	Not US Released	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	1	4	4
4073	CapSure Sense	700	0	0	0	0	0	0	0	0	0	0
4074	CapSure Sense	85,400	8	1	25	25	0	1	0	0	3	1
4076	CapSure Fix Novus	376,400	37	4	121	66	6	17	1	5	8	8
4092	CapSure SP Novus	172,100	2	4	19	25	0	0	1	0	3	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	0	1	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	1	2	1
4568	CapSure Fix	69,500	3	1	4	7	0	1	0	0	3	1
4574	CapSure Sense	56,200	0	2	25	11	1	4	0	0	0	3
4592	CapSure SP Novus	83,500	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	50	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	94,000	2	2	17	20	0	0	1	0	0	8
5068	CapSure Fix	102,800	13	4	22	34	1	5	1	0	1	6
5072	SureFix	9,800	0	0	2	1	0	0	0	0	0	1
5076	CapSure Fix Novus	1,402,900	137	9	447	214	24	38	7	13	15	31
5086MRI	CapsureFix Novus	44,300	67	0	92	46	7	16	1	10	3	5
5092	CapSure SP Novus	128,400	5	1	36	27	1	6	4	3	0	9
5524, 5524M	CapSure SP	60,300	1	3	20	13	0	9	2	0	0	10
5534	CapSure Z	26,200	0	0	6	3	0	2	0	2	0	4
5554	CapSure Z Novus	60,700	0	1	31	23	0	2	0	0	0	3
5568	CapSure Fix	87,200	6	0	26	18	2	4	1	1	1	5
5592	CapSure SP Novus	33,200	0	0	21	4	0	2	0	0	0	2
5594	CapSure SP Novus	14,800	0	1	7	0	0	0	0	0	0	2
6940	CapSure Fix	25,300	0	1	6	1	0	0	0	0	1	0

Report Cutoff Date: January 31, 2012

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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 January 31, 2012

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 January 31, 2012

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

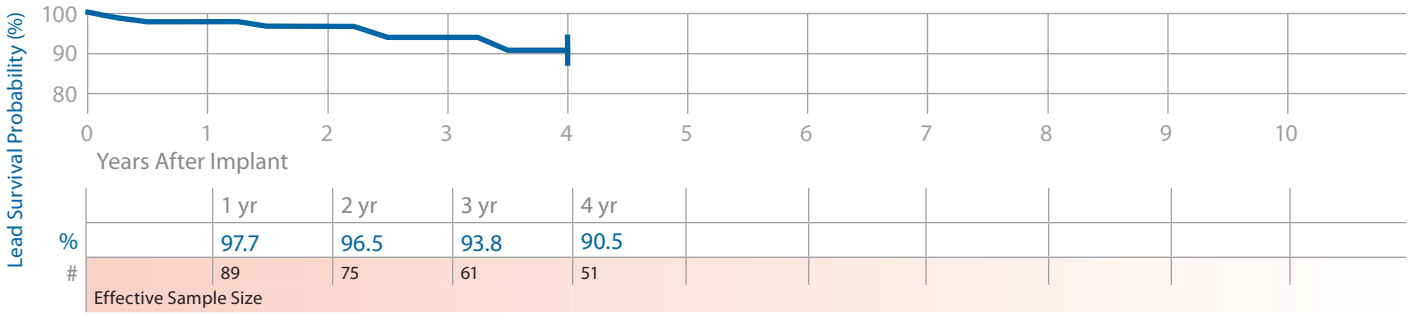
System Longevity Study Results

Number of Leads Enrolled in Study	179
Cumulative Months of Follow-Up	5,929
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	20,100	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	136
Crimp/Weld/Bond	1
Insulation Breach	32
Other	0

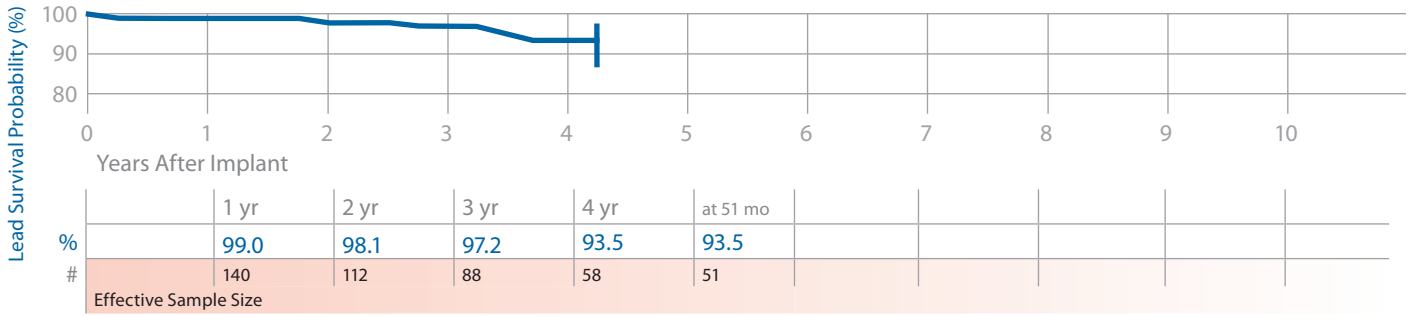
System Longevity Study Results

Number of Leads Enrolled in Study	219
Cumulative Months of Follow-Up	7,274
Number of Leads Active in Study	34

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	97.2	93.5	93.5
#	140	112	88	58	51

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	24,400	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	15,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

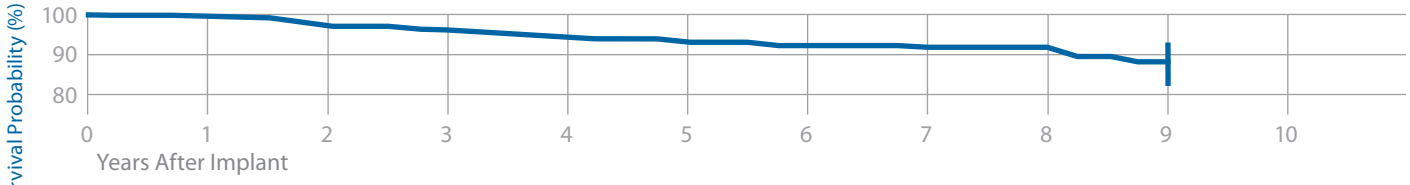
Conductor Fracture	23
Crimp/Weld/Bond	0
Insulation Breach	8
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	736
Cumulative Months of Follow-Up	34,073
Number of Leads Active in Study	385

Qualifying Complications 41 Total

Failure to Capture	17	Insulation (not further defined)	2
Conductor Fracture	8	Impedance Out of Range	3
Failure to Sense	3	Oversensing	7
		Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.6	97.6	96.7	94.8	93.7	93.2	92.5	92.5	88.9
#	564	460	376	287	218	159	121	84	48

Effective Sample Size

5071 Screw-in

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Registered US Implants	41,800	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated Active US Implants	14,500	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

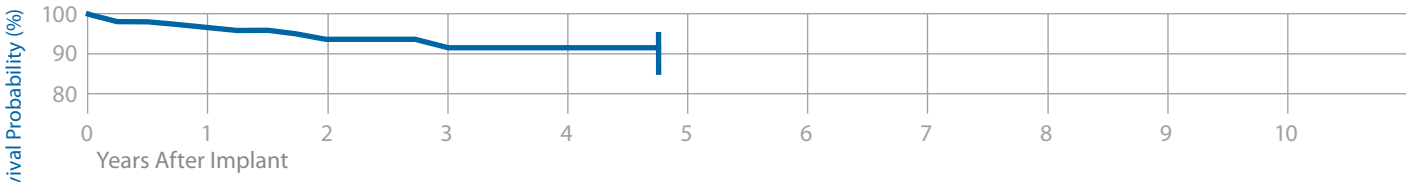
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	281
Cumulative Months of Follow-Up	7,684
Number of Leads Active in Study	59

Qualifying Complications 12 Total

Failure to Capture	10
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	97.2	94.7	92.3	92.3	92.3
#	138	92	73	63	53

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of Januray 31, 2012

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	5,929	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	34	8	7,274	99.0 +0.7/-3.0	98.1 +1.3/-4.0	97.2 +1.8/-4.9	93.5 +3.5/-7.1	93.5 +3.5/-7.1 at 51 mo							
4968	CapSure Epi	Sep-99	736	385	41	34,073	99.6 +0.3/-1.0	97.6 +1.0/-1.7	96.7 +1.2/-2.0	94.8 +1.7/-2.5	93.7 +2.0/-2.9	93.2 +2.1/-3.1	92.5 +2.4/-3.6	92.5 +2.4/-3.6	88.9 +4.0/-6.0 at 108 mo			
5071	Screw-in	Dec-92	281	59	12	7,684	97.2 +1.5/-3.5	94.7 +2.6/-4.9	92.3 +3.6/-6.4	92.3 +3.6/-6.4	92.3 +3.6/-6.4 at 57 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	20,100	9,300	126	1	32	0
4968	CapSure Epi	Sep-99	24,400	15,200	23	0	8	1
5071	Screw-in	Dec-92	41,800	14,500	12	0	2	0

Source: Returned Product Analysis
Data as of January 31, 2012

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	20,100	0	1	0	4	0	2	3	0
4968	CapSure Epi	24,400	1	0	3	9	2	0	1	0
5071	Screw-in	41,800	1	0	1	26	0	0	2	3

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: Data as of January 31, 2012

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

Source: Medtronic Device Registration and Returned Product Analysis
Data as of Januray 31, 2012

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

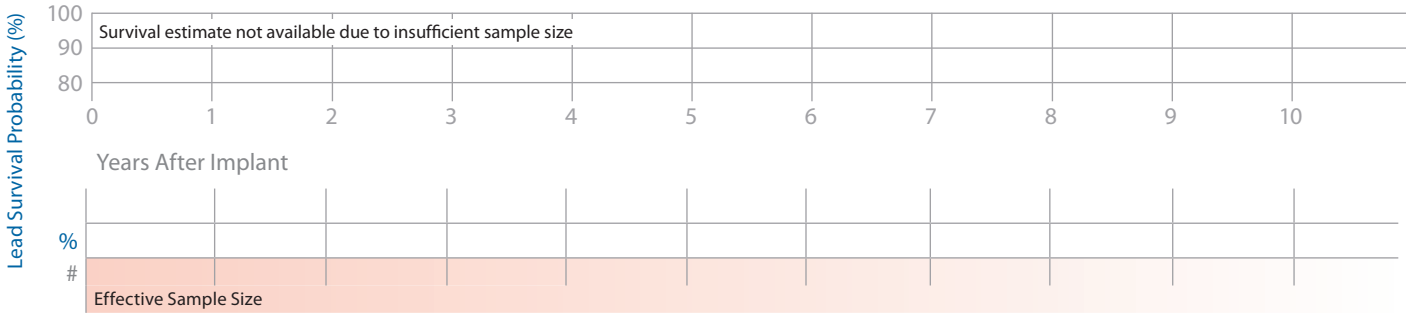
System Longevity Study Results

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



5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Registered US Implants	8,900	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated Active US Implants	3,500	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

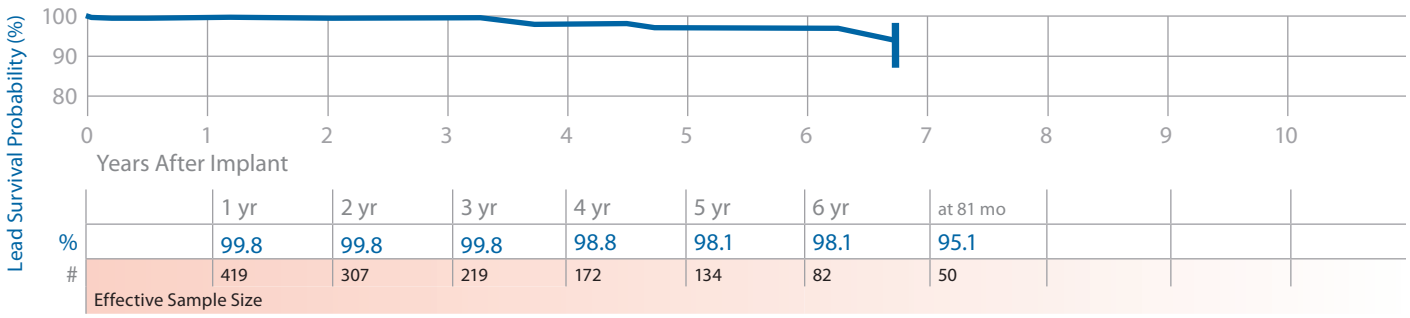
System Longevity Study Results

Number of Leads Enrolled in Study	553
Cumulative Months of Follow-Up	20,562
Number of Leads Active in Study	48

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	95.1
#	419	307	219	172	134	82	50

Effective Sample Size

Leads

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2012

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	48	6	20,562	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	95.1 +3.0/-7.4 at 81 mo			

Source: System Longevity Study
Data as of January 31, 2012

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	8,900	3,500	4	0	1	0

Source: Returned Product Analysis
Data as of January 31, 2012

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	8,900	1	1	0	1

Report Cutoff Date: January 31, 2012

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 January 31, 2012

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.

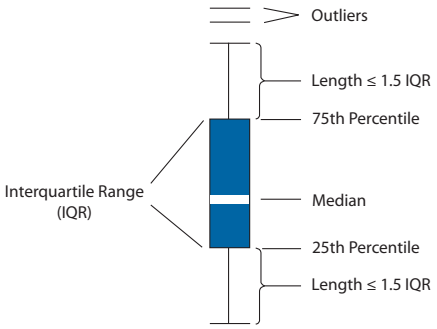
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide charge times that are short and consistent over the life of the product.

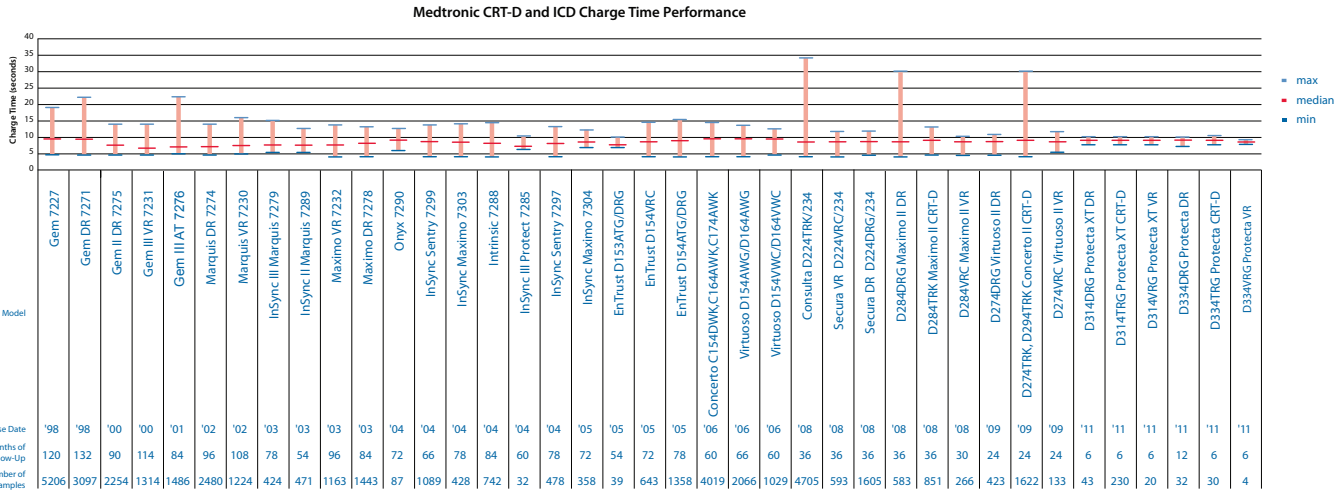
Data Presentation

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.

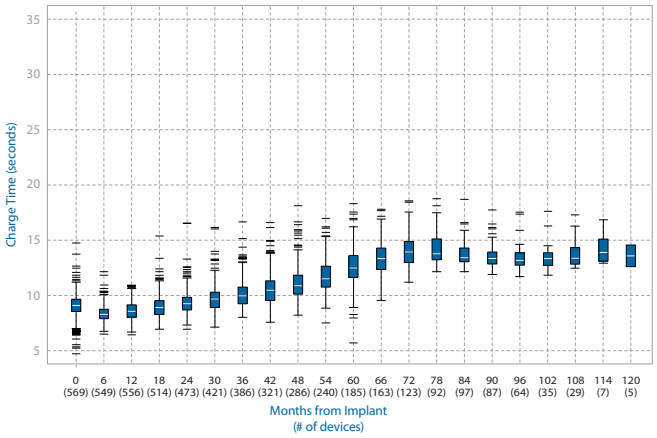




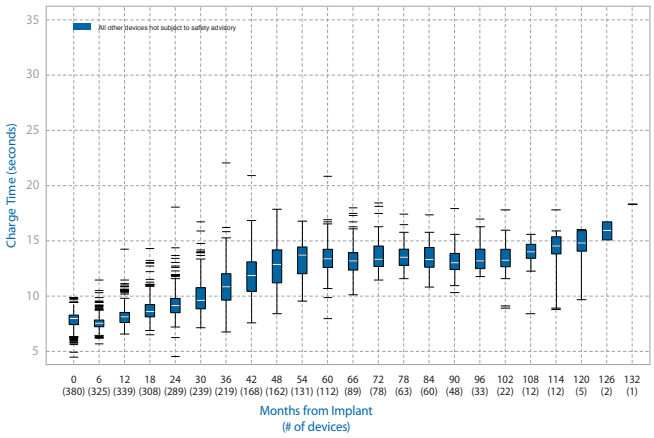
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

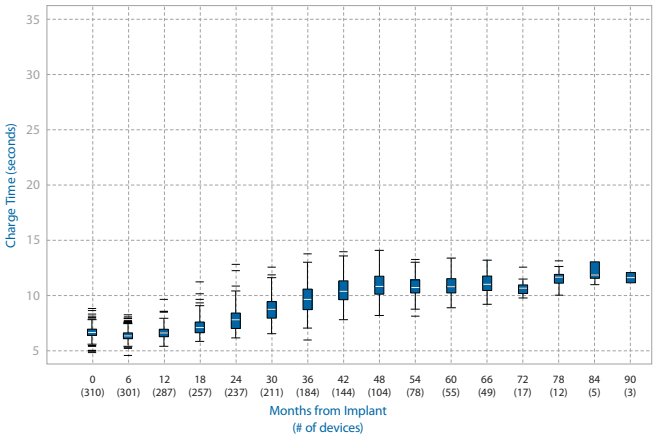
7227 GEM Charge Time



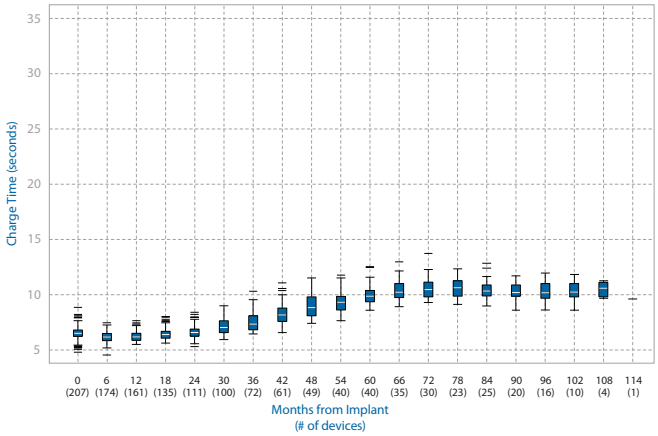
7271 GEM DR Charge Time



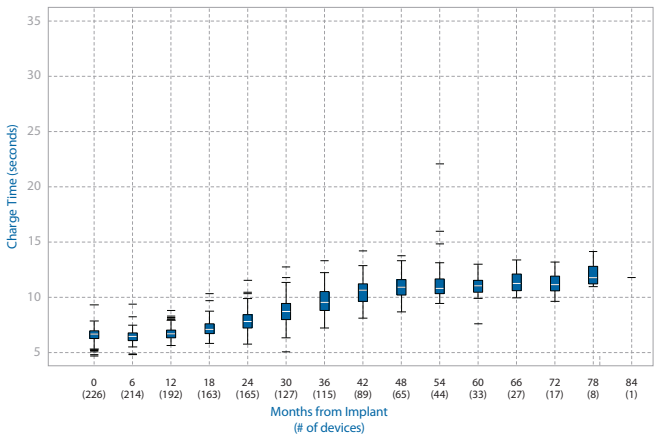
7275 GEM III DR Charge Time



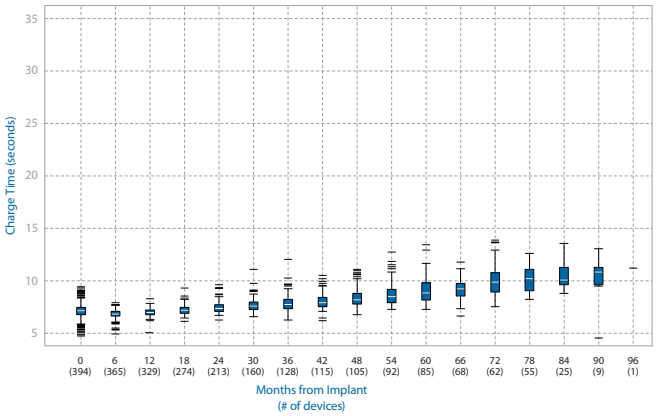
7231 GEM III VR Charge Time



7276 GEM III AT Charge Time



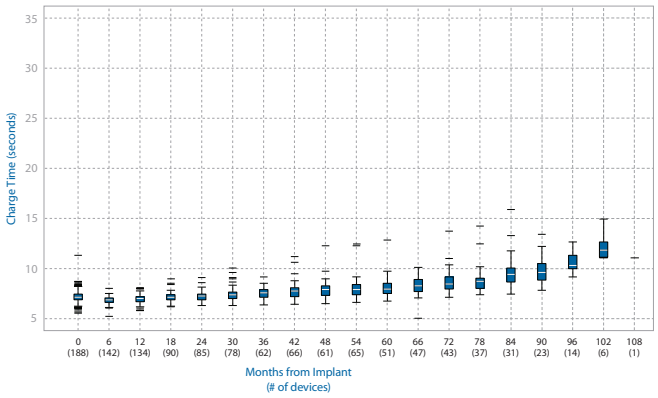
7274 Marquis DR Charge Time



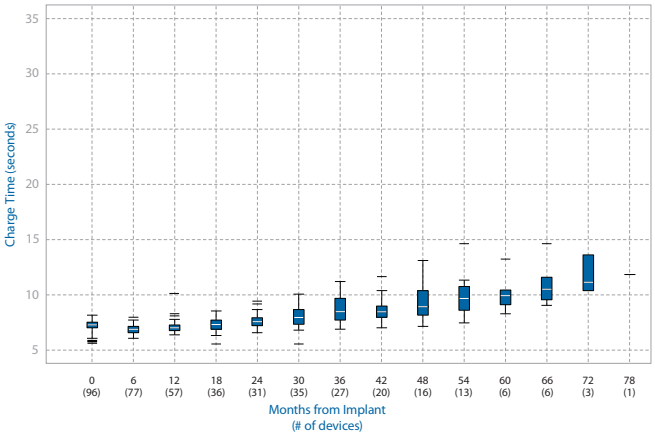
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

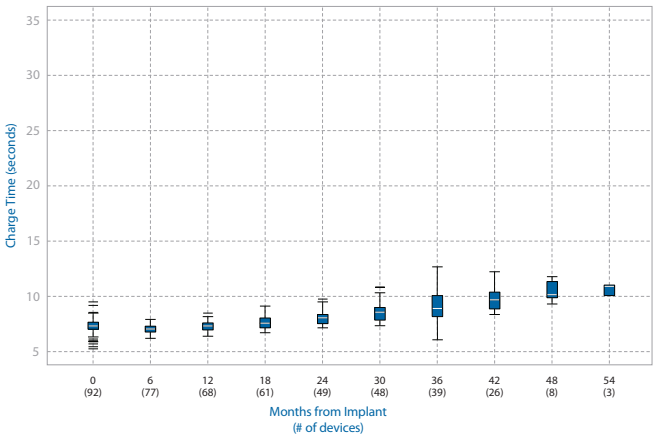
7230 Marquis VR Charge Time



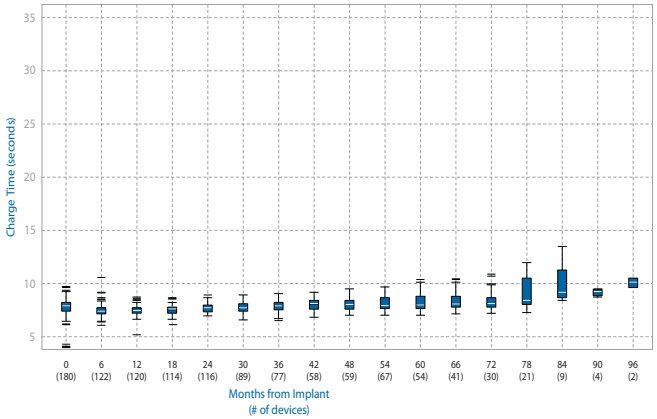
7279 InSync III Marquis Charge Time



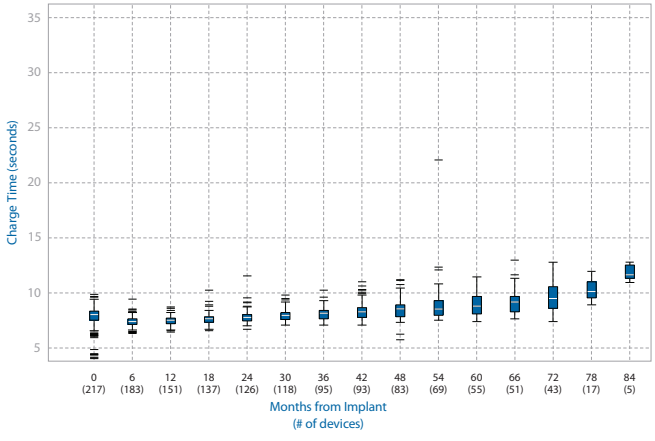
7289 InSync II Marquis Charge Time



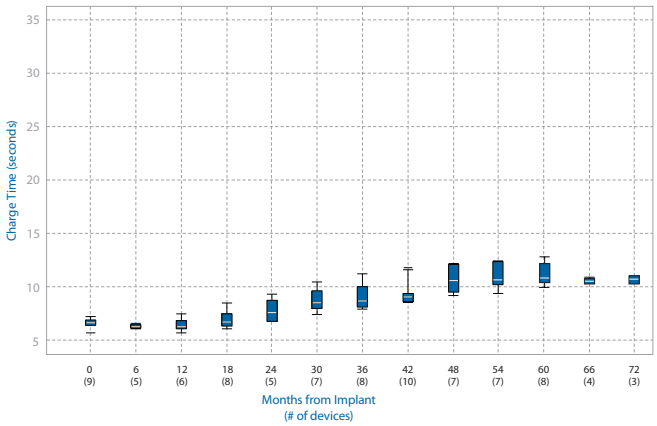
7232 Maximo VR Charge Time



7278 Maximo DR Charge Time



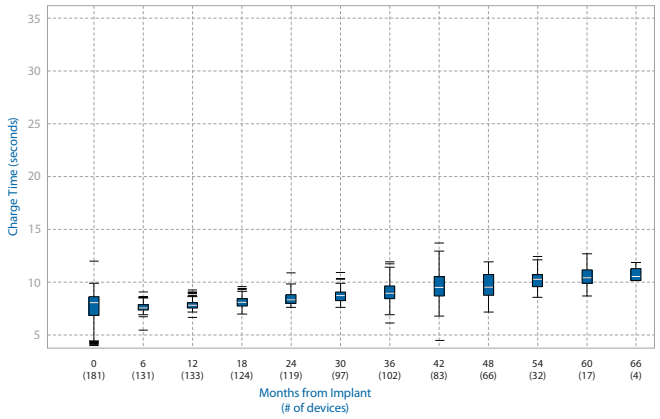
7290 Onyx Charge Time



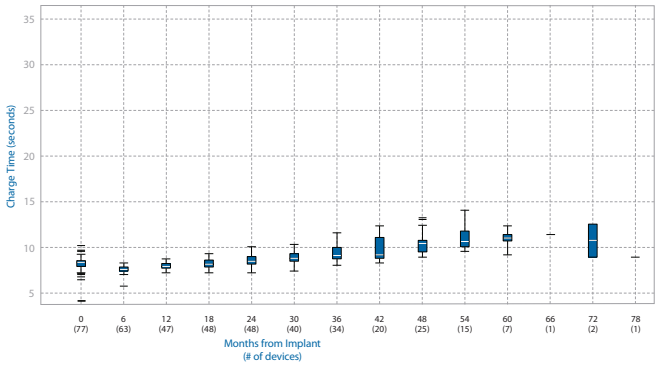
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

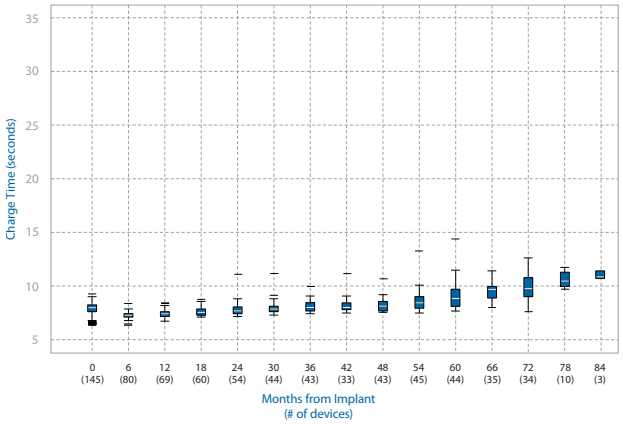
7299 InSync Sentry Charge Time



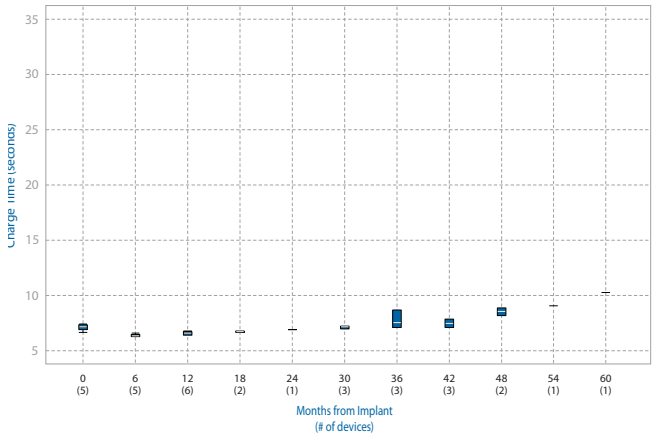
7303 InSync Maximo Charge Time



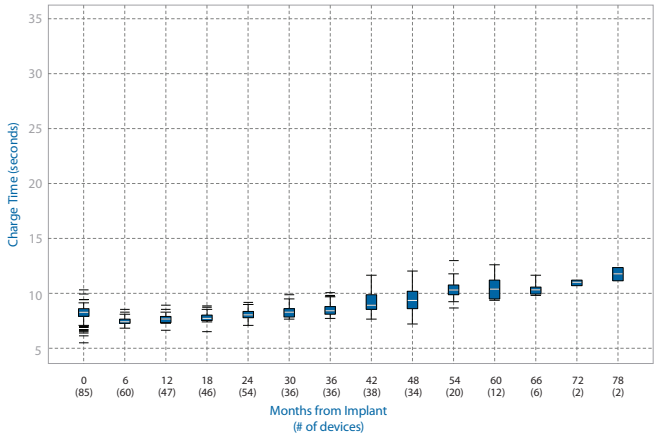
7288 Intrinsic Charge Time



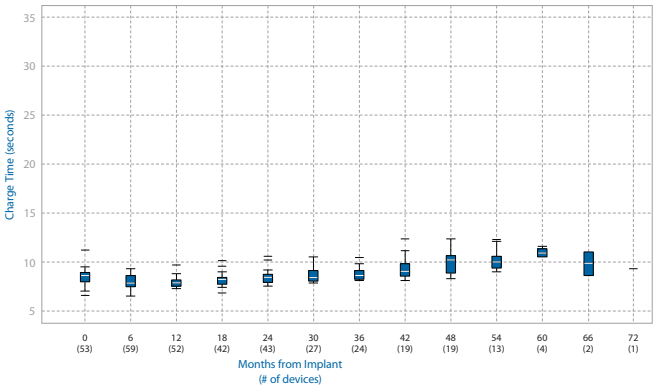
7285 InSync III Protect Charge Time



7297 InSync Sentry Charge Time



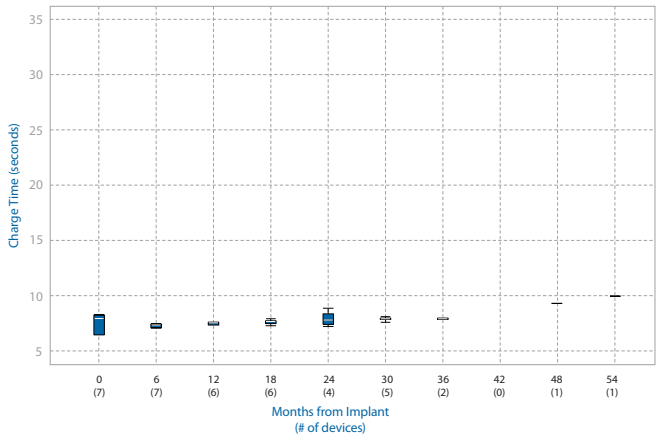
7304 InSync Maximo Charge Time



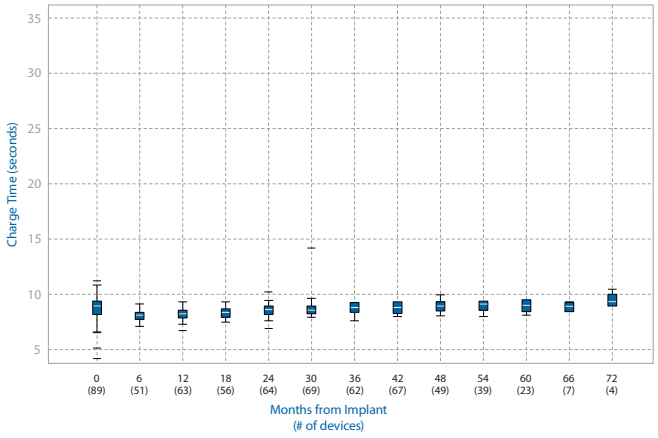
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

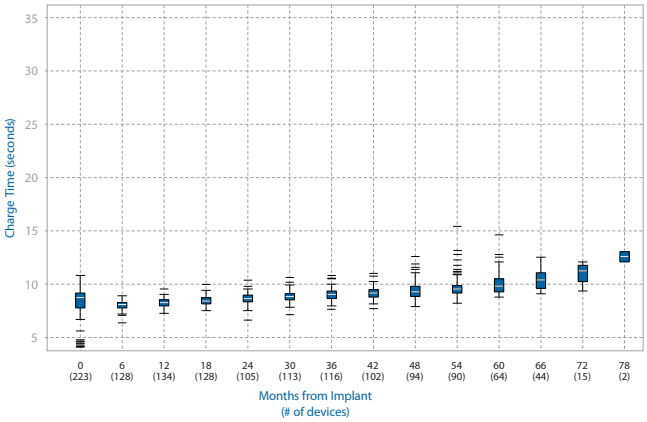
D153ATG, DRG EnTrust Charge Time



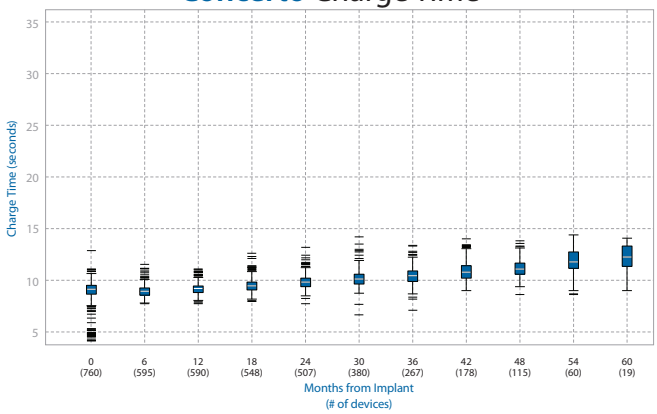
D154VRC EnTrust Charge Time



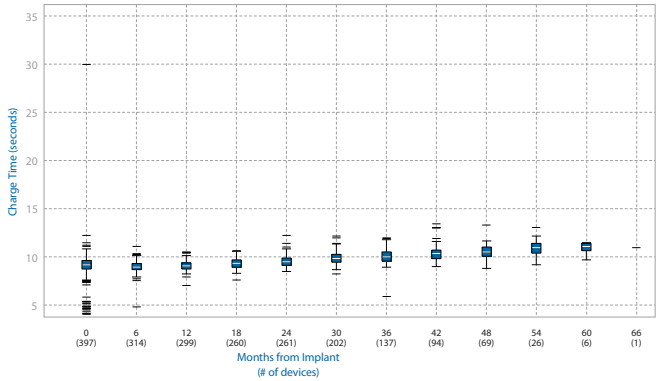
D154ATG, DRG EnTrust Charge Time



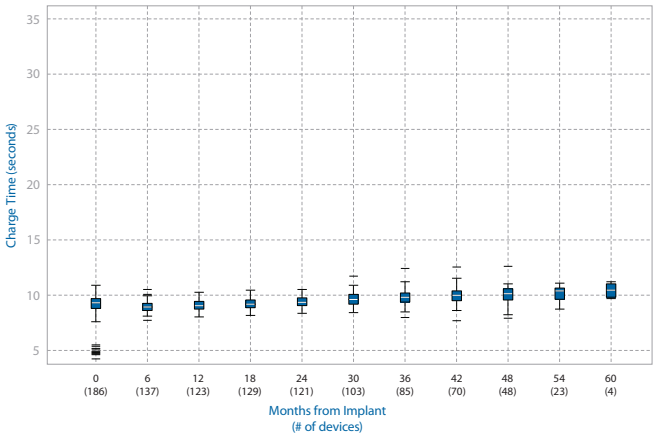
C154DWK, C164AWK, C174AWK Concerto Charge Time



D154AWG, D164AWG Virtuoso Charge Time



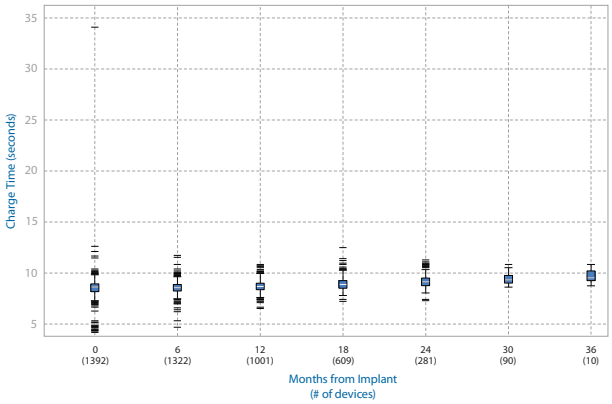
D154VWC, D164VWC Virtuoso Charge Time



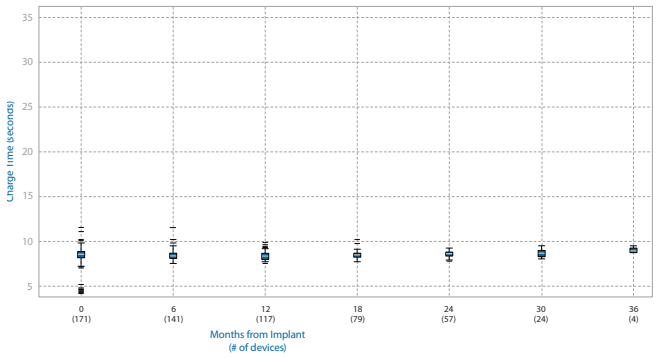
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

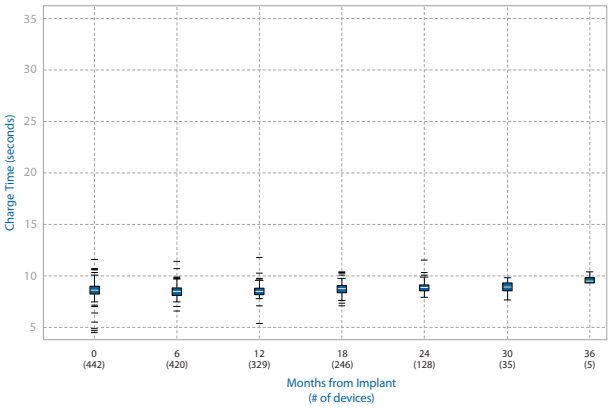
D224TRK/234 Consulta Charge Time



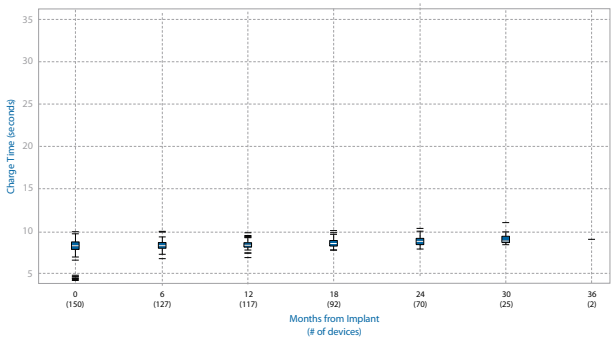
D224VRC/234 Secura VR Charge Time



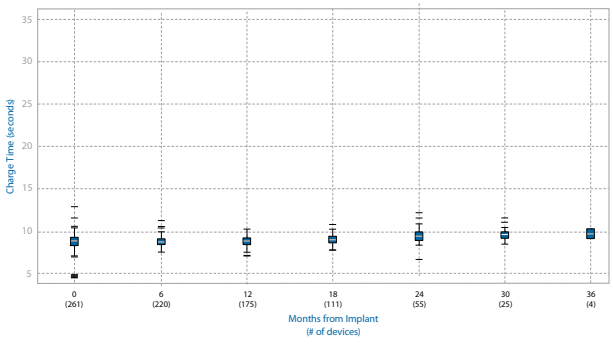
D224DRG/234 Secura DR Charge Time



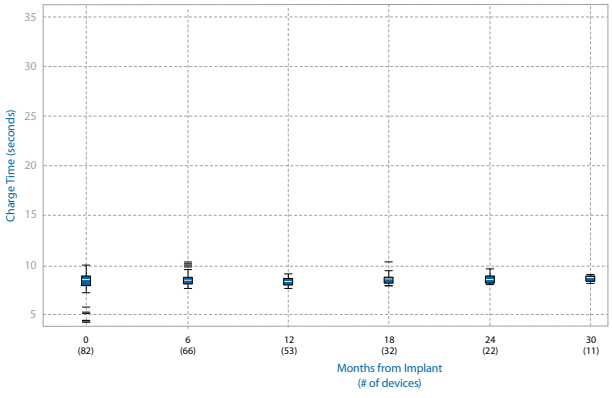
D284DRG Maximo II DR Charge Time



D284TRK Maximo II CRT-D Charge Time



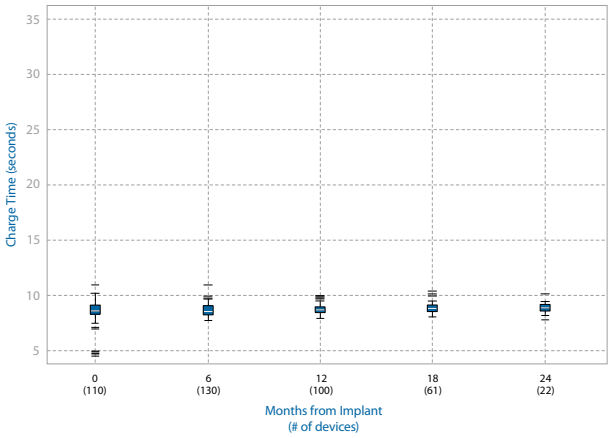
D284VRC Maximo II VR Charge Time



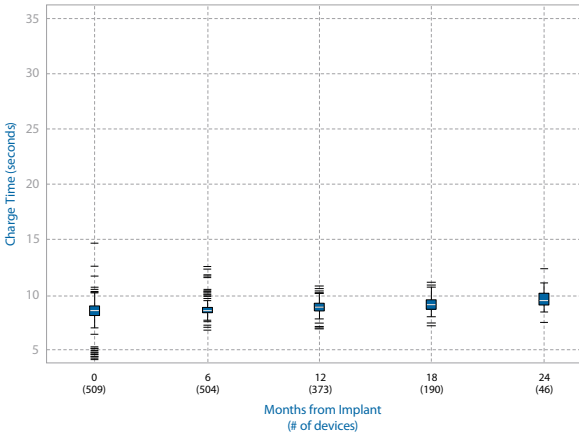
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

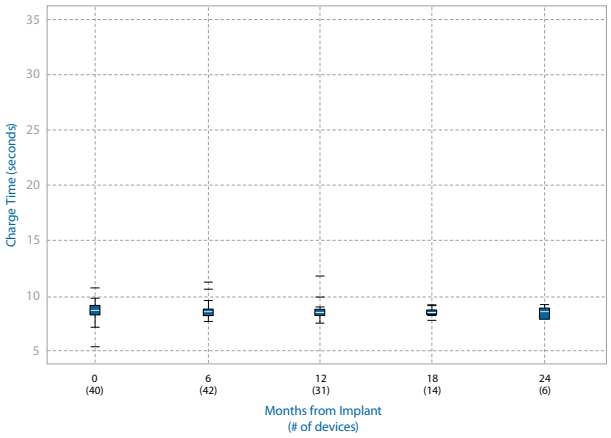
D274DRG Virtuoso II DR Charge Time



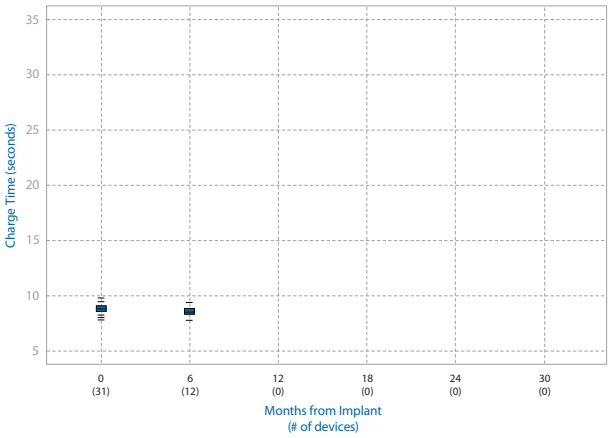
D274TRK, D294TRK Concerto II CRT-D Charge Time



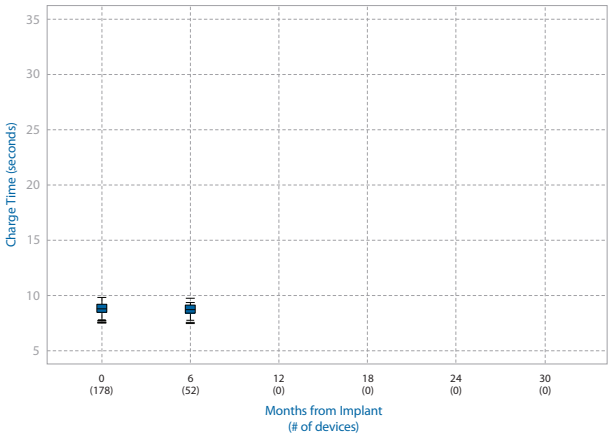
D274VRC Virtuoso II VR Charge Time



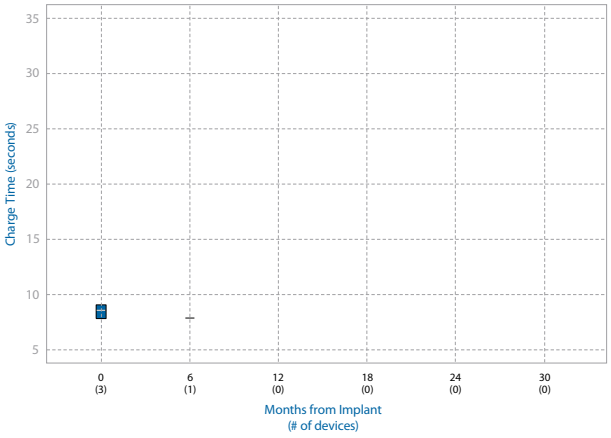
XT DR D314DRG Protecta Charge Time



XT CRT-D D314TRG Protecta Charge Time



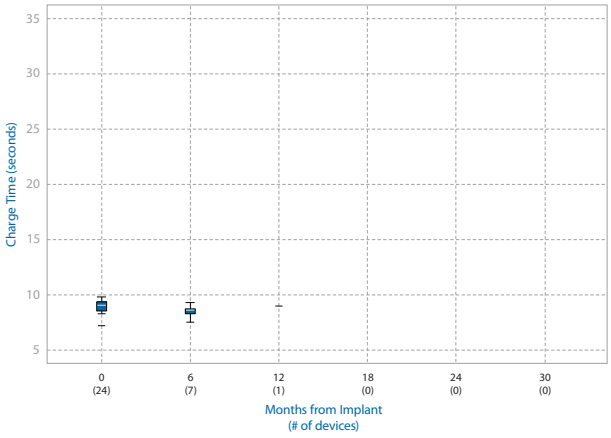
D334VRG Protecta VR Charge Time



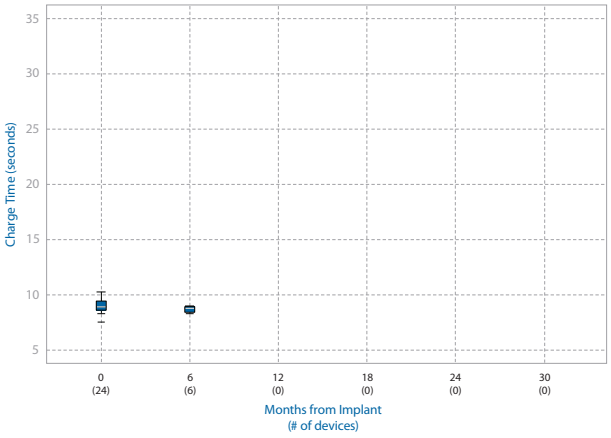
Source: System Longevity Study
Data as of February 6, 2012

ICD and CRT-D Charge Time Performance continued

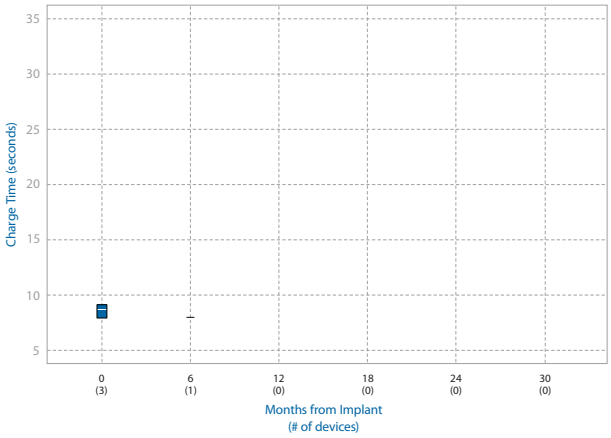
DR D334DRG Protecta Charge Time



CRT-D D334TRG Protecta Charge Time



VR D334VRG Protecta Charge Time



Source: System Longevity Study
Data as of February 6, 2012

Advisories

EnTrust ICDs

Original Date of Advisory: March 2012

Potential Rapid Battery Depletion

Product

All EnTrust ICDs.

Advisory

A small percentage of EnTrust ICDs may not meet expected longevity or provide at least three months of device operation between the Elective Replacement Indicator (ERI) and End of Life (EOL) due to a more-rapid-than-expected drop in battery voltage. An estimated 39,000 EnTrust ICDs are currently implanted worldwide. No patient deaths or serious injuries have been reported as a result of this issue.

The reported events have involved a drop in battery voltage from ~3.0 V to ERI (2.61 V) over a time period ranging from approximately one week to six months. All reported events have occurred at least 30 months after implant.

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed. The exact sequence of events and use conditions that lead to the battery short is still being investigated.

Patient Management Recommendations (As of March 2012)

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient management recommendations:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.
- Physicians should program the audible patient alerts for "Low Battery Voltage ERI" and "Excessive Charge Time EOL" to ON.
- Physicians should replace devices promptly after they reach ERI if the decline in voltage is more rapid than expected.
- Prophylactic replacement of EnTrust ICDs is not recommended.

Status Update

As of February 20, 2012, there have been 60 confirmed events. No patient deaths or serious injuries have been reported. No reports have been made of a failure to deliver high voltage therapy.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)
69,000 Worldwide (**42,600** United States)	**60** Worldwide (**44** United States)	**39,000** Worldwide (**23,100** United States)	**0.09%** Worldwide (**0.10%** United States)

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.

Software Update (As of October 2010)

The battery issues described above and subsequent software update are summarized in the table below. When a device receives the software update, if battery impedance is greater than the new ERI threshold ERI will be triggered shortly thereafter. Therefore, clinicians may observe an ERI/EOL indicator at the next patient follow-up. When ERI is triggered by battery impedance, additional battery capacity remains and can support device function at ERI parameters for at least one year. Medtronic is not aware of any reports of loss of therapy due to this issue.

As a reminder, when ERI is triggered, EnRhythm devices revert to VVI pacing at 65 ppm at the programmed output settings. EOL is declared 90 days after ERI or at a battery voltage of 2.69 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.

continued

EnRhythm Pacemakers

Original Date of Advisory: February 2010

Low Battery Voltage Displayed at Device Interrogation, continued

If an unanticipated ERI/EOL is declared, it is likely due to battery impedance. In such cases, additional battery capacity remains and can support device function at ERI parameters for at least one year. However, when ERI or EOL (typically 90 days after ERI) declaration is seen, schedule device replacement.

Status Update

As of February 24, 2012, 342 devices out of approximately 146,500 devices worldwide have been confirmed as having exhibited an advisory event related to the original advisory, in which higher than expected battery impedance caused a drop in battery voltage at interrogation. Approximately 103,000 remain implanted.

Included in the August 2011 Performance Update was information about the projected percentage of devices that would encounter an early ERI due to unexpected high battery impedance. As of January 2012, analysis of over 16,000 US CareLink patients whose devices reached ERI continues to occur with the rate of 6-10% within 5 years post-implant as communicated with our August 2011 Performance Update.

[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 **(146,500** Worldwide)	**342** Worldwide	**103,000** Worldwide	**0.23%**	

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 February 27, 2012, 3,668 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 800 remain implanted. Approximately 600 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)	**3,668** Worldwide (**3,154** United States)	**800** Worldwide (**600** United States)	**41%** Worldwide (**45%** 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 February 27, 2012, Medtronic has observed 458 Kappa devices and 281 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.79% (Kappa) and 1.89% (Sigma) of the original affected implant population.

Four hundred twenty-one (421) of the Kappa devices (0.72%) and 218 of the Sigma devices (1.46%) 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 3,600 Kappa devices and 2,800 Sigma devices remain implanted. Of these, approximately 1,100 Kappa and 700 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 16,000 devices of this subset remain active. We have observed a failure rate of approximately 0.094% 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)	**421** 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.	**3,600** Worldwide (**1,100** United States)	**0.79%** Worldwide **1.40%** (United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**218** 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.	**2,800** Worldwide (**700** United States)	**1.89%** 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 February 1, 2012, of the initial implant population of 205,600 in the United States, approximately 100,400 remain implanted. According to System Longevity Study results, lead survival is estimated to be 88.6% (+3.3/-4.5) at 69 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)	**5,355** (United States)	**100,400** (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 February 27, 2012, 731 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Three hundred seventy-four (374) of the Sigma devices (0.94%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 357 Sigma devices (0.89%) 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 7,700 remain implanted. Approximately 1,900 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)	**374** Worldwide (**74** United States) with information indicating a clinical presentation.An additional **357** Worldwide (**63** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**7,700** Worldwide (**1,900** United States)	**1.83%** Worldwide **1.38%** (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 February 27, 2012, 192 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 8,000 remain implanted. Approximately 7,000 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)	**192** Worldwide (**115** United States)	**8,000** Worldwide (**7,000** 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 February 27, 2012, 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 2,000 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	**2,000**	

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.

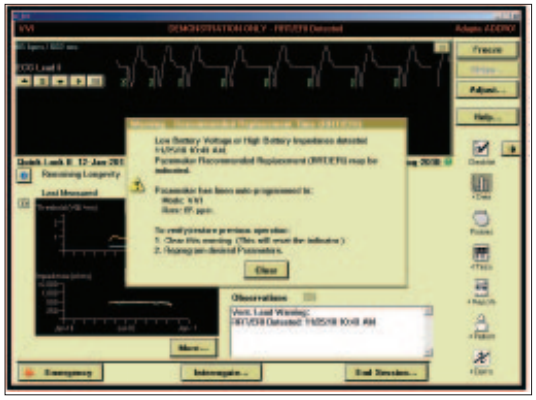
Background

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.

Programmer Software Reset Method (Adapta, Versa, Sensia, Relia, Vitatron Series E and G)

Programmer software is available which can differentiate a regular ERI and an ERI caused by the measurement lock-up issue. Upon interrogation of a device with the measurement lock-up ERI, the programmer software recognizes the issue and guides the clinician to clear the ERI (Example 1). Following an ERI reset, the device parameters should be reviewed and reprogrammed to clinician specifications.

Example 1 – Programmer Software Detects Measurement Lock-up ERI

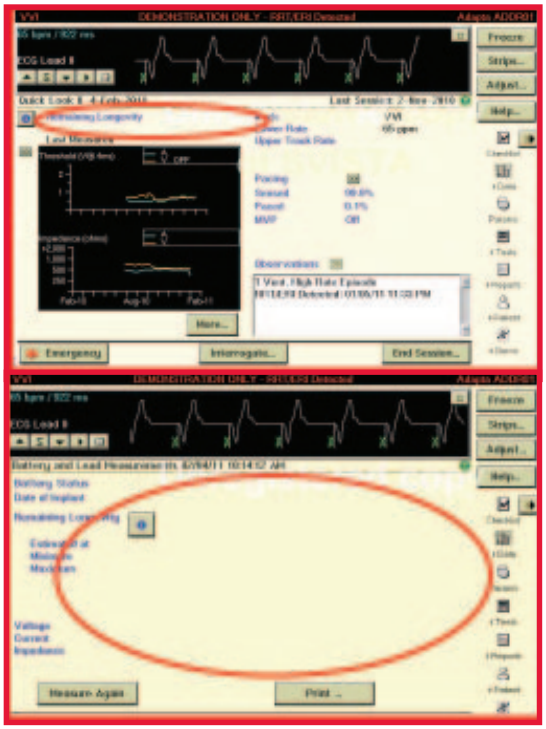


Reset Method for Kappa and EnPulse

A service tool continues to be available through Medtronic Technical Services to clear the measurement lock-up issue for Kappa and EnPulse devices.

The issue can be identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values (Example 2). If this measurement lock-up occurs, contact Medtronic Brady Technical Services at 1-800-505-4636 for assistance.

Example 2 – Programmer Screens for Measurement Lock-up ERI (Kappa and EnPulse)



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

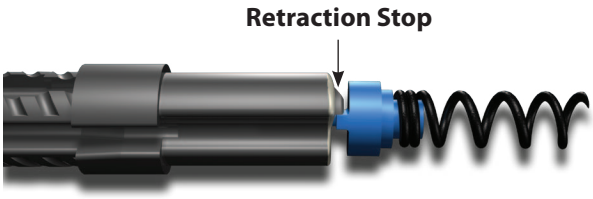
In certain cases, over-retraction of the helix, during initial implant or subsequent repositioning, may result in the inability to extend the helix. This does not impact acute or chronic performance of successfully implanted leads.

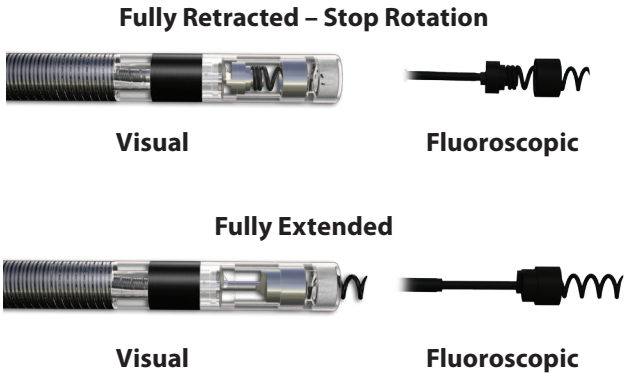
The root cause is over-retraction of the helix mechanism beyond the retraction stop, resulting in the inability to extend the helix in a subsequent attempt.

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

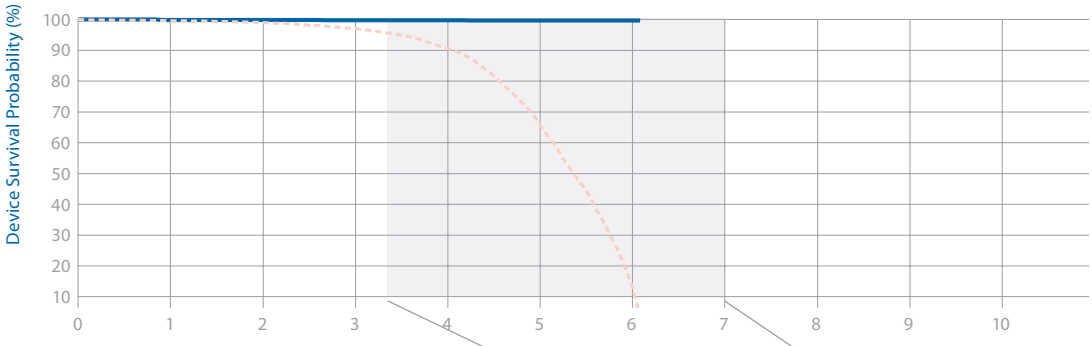
The survival curves in the Product Performance Report represent the composite experience of thousands of devices over a wide range of programming options and patient use conditions. While the curves are useful for understanding the overall performance of a population of devices, they cannot be used to 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
#	Effective Sample Size	18,000	15,000	13,000	10,000	5,000	300

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.

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.

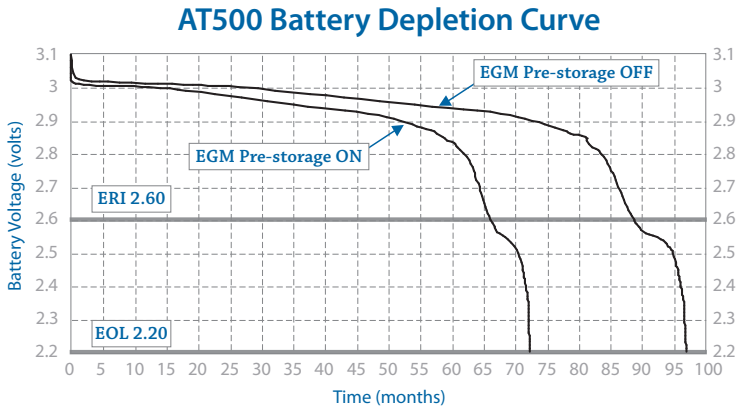


Figure 1

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.

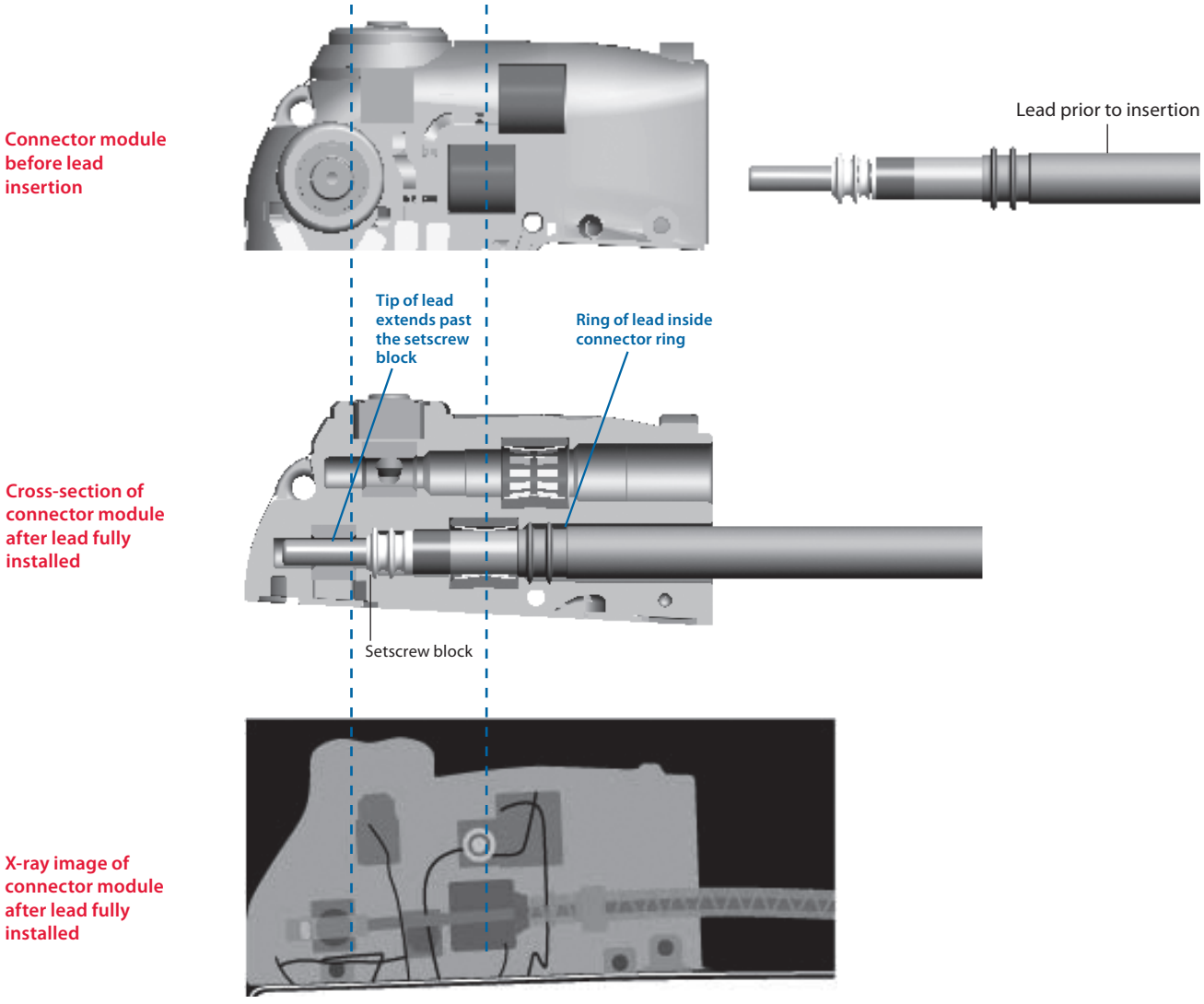
If the lead connector is not fully installed, oversensing may result as described in the connector problems section of the performance note, "Clinical Management of High Voltage Lead System Oversensing."

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.

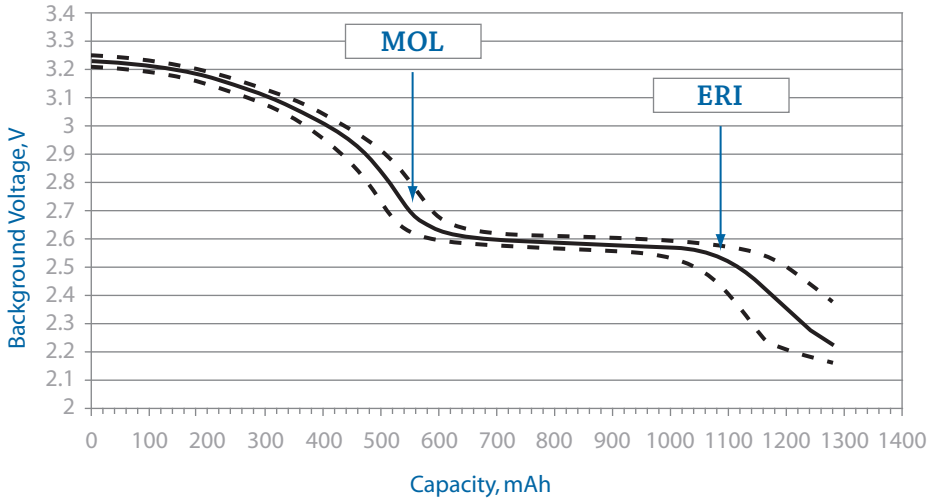
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

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.

[1] Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE*. June 2002;25(6):879-882.

[2] Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol*. January 1, 2003;41(1):73-80.

[3] Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. July 2007;4(7):892-896.

Clinical Management of High-Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus, ICD systems attempt to dynamically adjust sensing of electrical events and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T and far-field P waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high-voltage therapies. This is due, in part, to the desire to err on the side of delivering lifesaving high voltage therapy rather than withholding it. Thus, an ICD system that is experiencing oversensing issues will continue to deliver therapeutic shocks as required, but may also subject the patient to unnecessary shocks.

Oversensing can be difficult to manage, in that the precipitating cause of the oversensing can be problematic to isolate. Oversensing can be caused by many factors, including myopotentials/far-field sensing, electromagnetic interference, T wave sensing, connector issues, incomplete or complete conductor fractures, and insulation breaches. While the individual physician must exercise medical judgment in determination of appropriate clinical management of ICD systems, the chart below may assist in the process of causal factor differentiation and possible intervention.

Phenomenon	Causal Factors	Characteristics	Management/Comments
Myopotentials/ Far-field sensing	Diaphragmatic muscle potentials in breathing, wide tip-to-ring (coil on integrated bipolar leads) spacing	Nonphysiological sensed event on EGM, which may confuse detection potentially resulting in false positive shocks	Check R waves for deterioration. Reprogram sensitivity. Try repositioning lead. Consider change-out to true bipolar lead, or if true bipolar lead in use, one with closer tip-to-ring spacing than current lead.
EMI (Electro-Magnetic Interference)	Arc welders, electrical generators, store walk-through security scanners, poorly insulated electrical equipment	Multiple and consecutive short intervals (< 140 ms) independent of underlying sinus beats. Associated with proximity to the EMI source.	Avoid EMI areas. True bipolar leads less susceptible.
T-wave sensing	Drugs, ischemic tissue, exercise, Long QT syndrome, electrolyte imbalance	Sense markers seen on EGM related to T wave. False positive detection.	Check for R wave deterioration and characteristics. If R wave > 3.0 mV, reprogram sensitivity. If R wave < 3.0 mV, reposition/replace lead. Address causal factor (e.g., drugs [if appropriate/medically viable]).
Connector problems	Loose setscrew, cross-threaded setscrew, incomplete lead insertion into header	This is an acute phenomenon seen within 6 months of implant (usually sooner)	Requires invasive check of connections. May be reproducible with pocket manipulation.
Incomplete conductor fracture	One or more filars of a multifilar conductor fracturing while leaving enough filars intact to provide a conduction circuit	Characterized by chaotic oversensing related to motion of the fracture site	Check EGMs and x-rays. Manipulate lead at suspected fracture site if possible as a provocative test. If confirmed, replace lead.
Lead insulation breach	Cuts, tears, metal ion oxidization, abrasion, cold flow, environmental stress cracking	Characterized by cyclical and/or erratic, intermittent, spontaneous oversensing; often post-pace or post-shock can cause false positives	Replace lead. If acute, usually secondary to implant damage/replacement damage. If late, material characteristic.
Oversensing during interrogation with programming head (not wireless telemetry) with complete lead fracture	Interrogation with a programming head in combination with complete lead fracture that creates an open circuit can induce noise on the sensing circuitry inside the ICD can	Nonphysiologic sensed event on EGM. If detection is enabled during interrogation, oversensing may result in inappropriate therapy.	Quickly remove the programming head. CANCEL the interrupted interrogation and manually load the software for the specific device model. Reposition the programmer head over the device and immediately select SUSPEND. Device will resume detection when programming head is removed, or when RESUME is selected. Replace lead.

Technical Services is available at all times to advise clinicians in the troubleshooting and management of Medtronic products. For assistance in the United States, please call 1 (800) 723-4636. In other countries, please contact your local Medtronic representative.

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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