Medtronic

Cardiac Rhythm Disease Management

Product Performance Report

Important Patient Management Information for Physicians

2013

First Edition – Issue 68

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 29 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 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

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CRDM Product Performance Report

2013 First Edition
Issue 68

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

Introduction

All product performance reports are not created equal. For 29 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 Product Surveillance Registry.

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 Product Surveillance Registry.

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 and for device and leads still in service. Devices and leads removed for reasons unrelated to performance or are still in service are said to be suspended. Examples of devices and leads removed from service for reasons unrelated to performance include:

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

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

An Example

The following example describes the survival analysis method used to establish the survival probability estimates for Medtronic 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 74)*.

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.

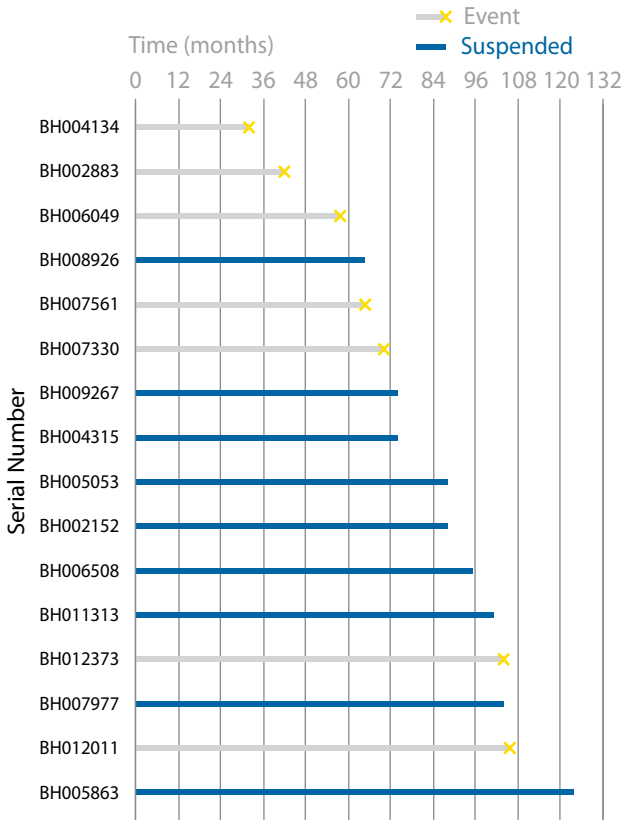


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

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

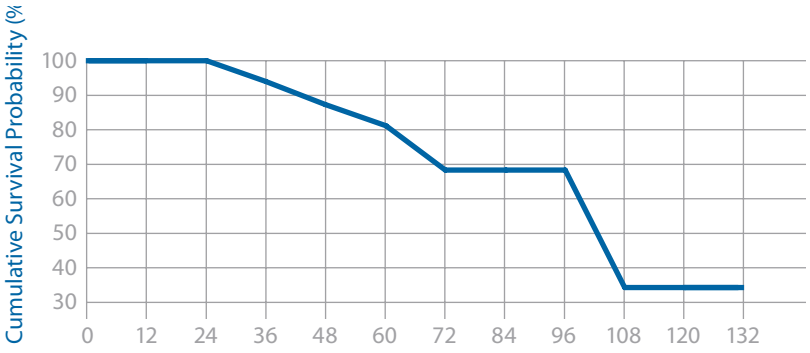
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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.

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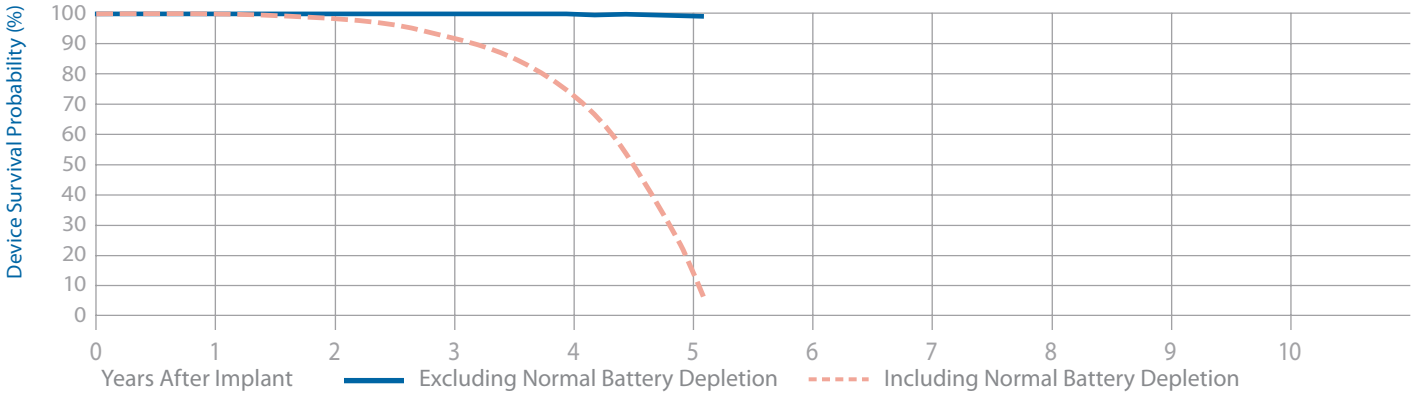
Product Characteristics

US Market Release	Apr-05
Registered US Implants	31,200
Estimated Active US Implants	2,250
Normal Battery Depletions (US)	9,582
Advisories	None

Malfunctions (US)	180
Therapy Function Not Compromised	169
Electrical Component	18
Possible Early Battery Depletion	147
Software Malfunction	2
Other	2
Therapy Function Compromised	11
Electrical Component	10
Other	1

NBD Code	VVED
Serial Number Prefix	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 21



		1 yr	2 yr	3 yr	4 yr	5 yr	at 61 mo
%	———	100.0	99.9	99.7	99.2	99.0	98.9
%	- - - -	99.7	98.1	91.8	71.9	13.1	4.8
#	Effective Sample Size	27,200	23,800	19,000	11,900	1,640	840

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

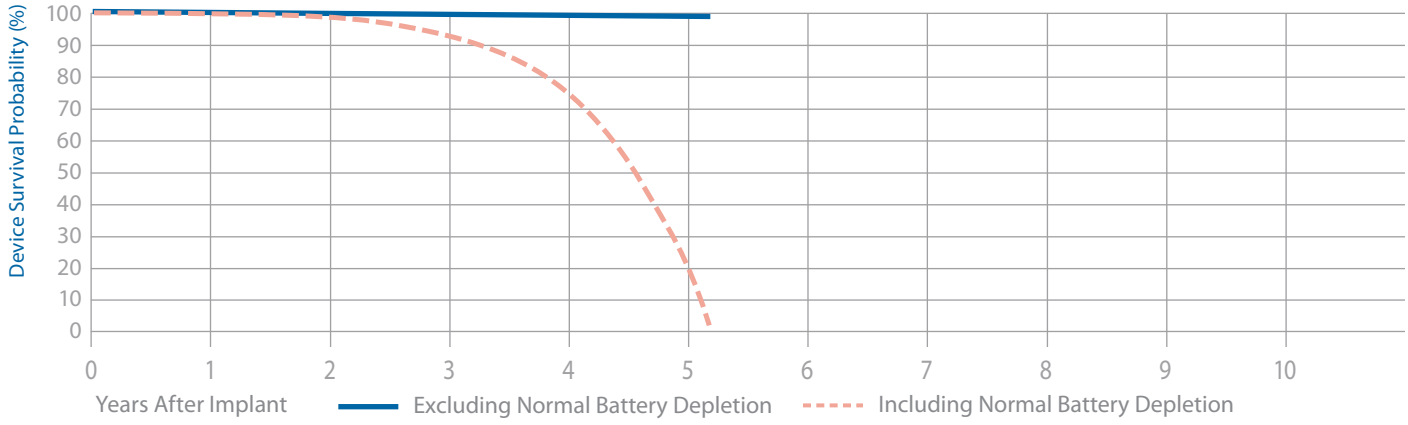
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	19,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	5,150
Advisories	None

Malfunctions (US)	111
Therapy Function Not Compromised	106
Electrical Component	13
Battery Malfunction	1
Possible Early Battery Depletion	89
Other	3
Therapy Function Compromised	5
Electrical Component	4
Other	1

NBD Code	VVED
Serial Number Prefix	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 21



		1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	———	100.0	99.9	99.6	99.2	99.1	99.1
%	- - - -	99.7	98.2	92.5	74.8	19.9	1.8
#		16,900	14,800	11,800	7,490	1,070	260

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

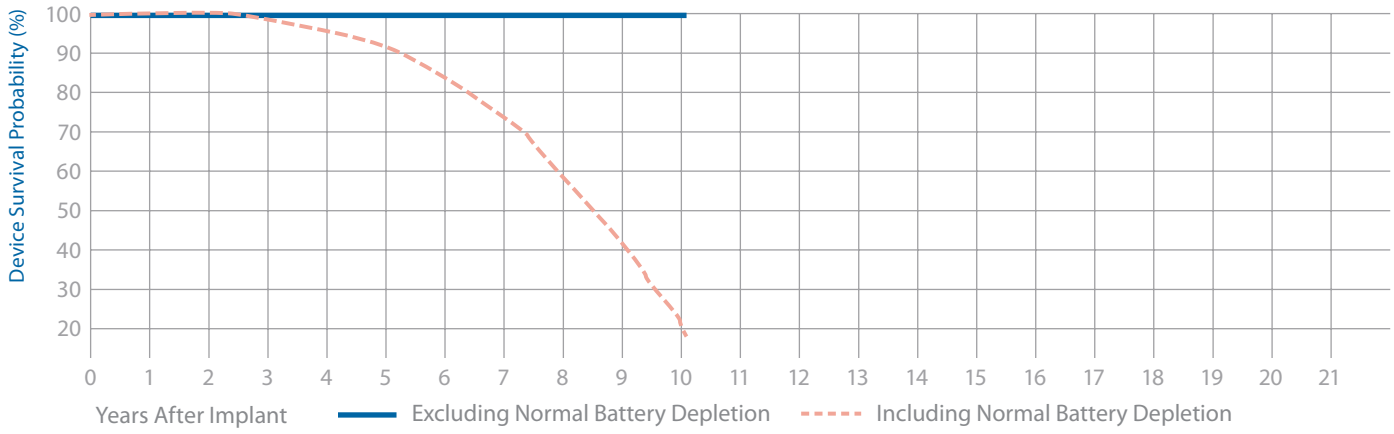
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,300
Estimated Active US Implants	1,370
Normal Battery Depletions (US)	1,346
Advisories	None

Malfunctions (US)	36
Therapy Function Not Compromised	26
Electrical Component	4
Electrical Interconnect	16
Possible Early Battery Depletion	3
Other	3
Therapy Function Compromised	10
Electrical Interconnect	10

NBG Code	DDDR
Serial Number Prefix	PIN
Estimated Longevity	See page 22



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 121 mo
%	100.0	100.0	99.9	99.8	99.7	99.6	99.5	99.5	99.4	99.4	99.4
%	99.8	99.5	98.0	95.7	90.8	83.5	73.1	58.6	40.6	19.8	17.7
#	12,300	10,100	8,110	6,370	4,970	3,720	2,620	1,620	840	240	150

Effective Sample Size

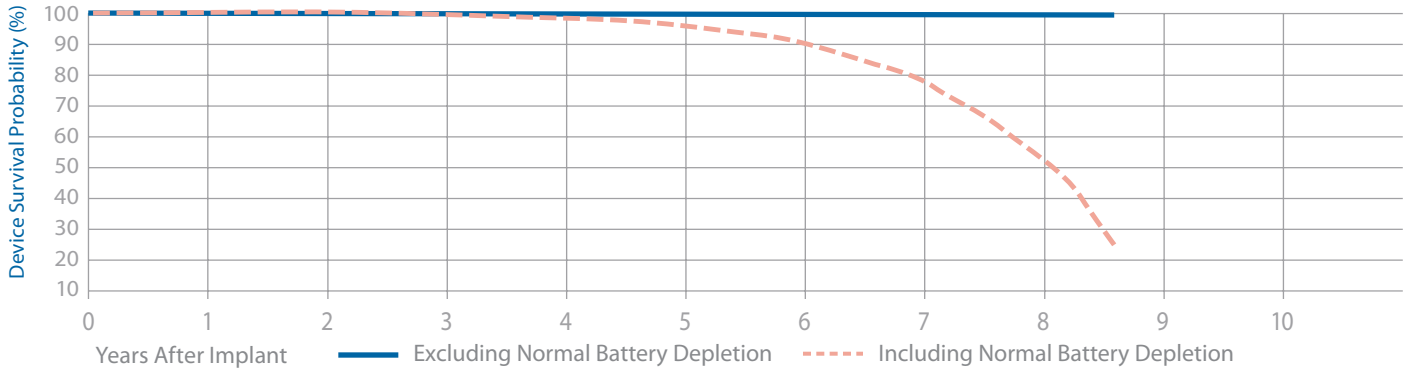
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	39,500
Estimated Active US Implants	14,800
Normal Battery Depletions (US)	1,821
Advisories	None

Malfunctions (US)	24
Therapy Function Not Compromised	14
Electrical Component	2
Electrical Interconnect	3
Possible Early Battery Depletion	1
Other	8
Therapy Function Compromised	10
Electrical Interconnect	10

NBG Code	DDDR
Serial Number Prefix	PKF
Estimated Longevity	See page 22



	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	99.9	99.9	99.9	99.9	99.8	99.8
%	99.9	99.8	99.3	98.0	95.5	90.4	78.1	51.5	24.4
#	34,500	30,100	23,200	16,600	11,600	7,400	3,970	1,370	230

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

C154DWK, C164AWK, C174AWK Concerto

Product Characteristics

	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	81,300	3,500
Estimated Active US Implants	27,000	200
Normal Battery Depletions (US)	13,508	264

Advisories: See page 142 – 2009 Potential Reduced Device Longevity

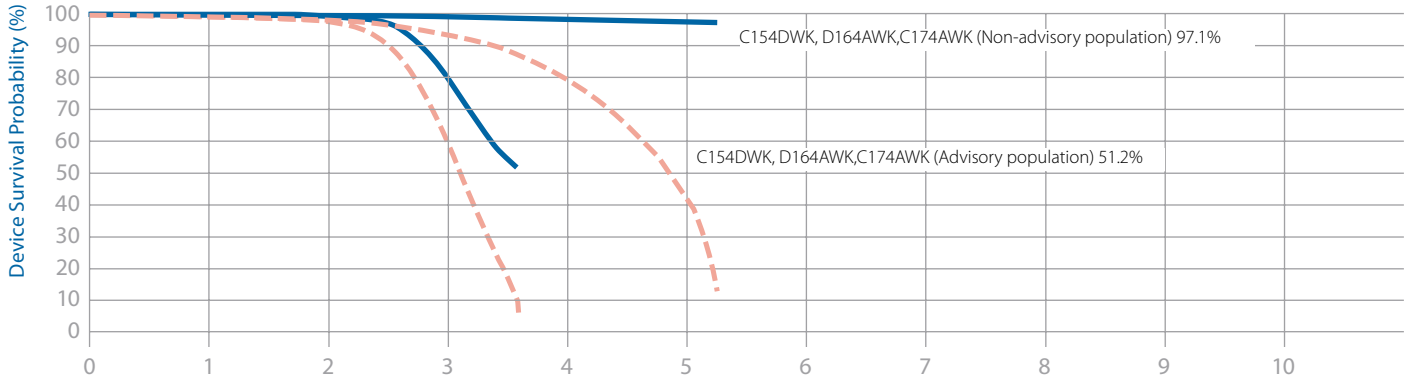
Performance Note: See page 151 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	1,203	1,298
Therapy Function Not Compromised	1,166	1,284
Electrical Component	515	1,280
Electrical Interconnect	2	0
Software/Firmware	3	0
Possible Early Battery Depletion	636	4
Other	10	0
Therapy Function Compromised	37	14
Electrical Component	35	12
Electrical Interconnect	2	1
Other	0	1

NBD Code	DDED
Serial Number Prefix	PVU, PVT, PVR
Max Delivered Energy	35 J
Estimated Longevity	See page 21

(N) = Non-advisory population

(A) = Advisory population



Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	99.8	99.5	98.3	97.1	97.1
%	99.8	98.4	93.5	79.3	41.9	14.1
#	72,800	64,100	53,700	33,600	6,280	860
Effective Sample Size						

Advisory	1 yr	2 yr	3 yr	at 43 mo
%	99.8	99.4	79.1	51.2
%	99.8	97.5	60	8.1
#	3,120	2,710	1,520	200
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

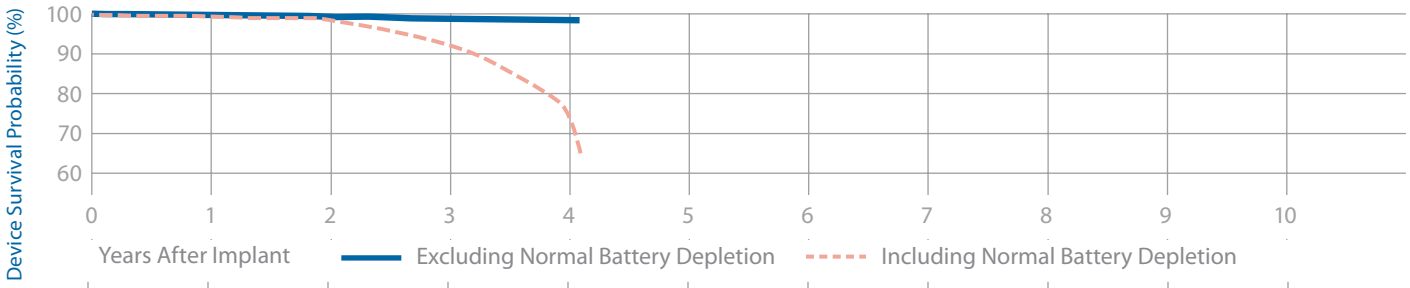
D224TRK, D234TRK, D204TRM, D214TRM Consulta CRT-D/CRT-D M4

Product Characteristics

US Market Release	Sep-08
Registered US Implants	64,700
Estimated Active US Implants	48,770
Normal Battery Depletions (US)	1,568
Advisories	None

Malfunctions (US)	340
Therapy Function Not Compromised	330
Electrical Component	17
Electrical Interconnect	1
Possible Early Battery Depletion	288
Software Malfunction	5
Other	19
Therapy Function Compromised	10
Electrical Component	10

NBD Code	DDED
Serial Number Prefix	PUD
Max Delivered Energy	35 J
Estimated Longevity	See page 21



	1 yr	2 yr	3 yr	4 yr	at 49 mo
%	100.0	99.7	99.2	98.7	98.7
%	99.8	98.3	91.8	72.8	65.4
#	54,200	40,100	16,800	1,160	320

Effective Sample Size

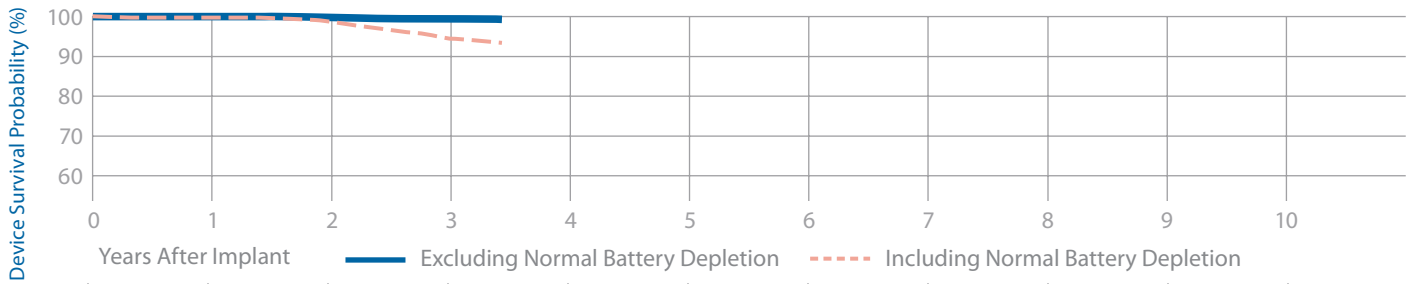
D274TRK, D294TRK Concerto II CRT-D

Product Characteristics

US Market Release	Aug-09
Registered US Implants	30,100
Estimated Active US Implants	24,000
Normal Battery Depletions (US)	332
Advisories	None

Malfunctions (US)	73
Therapy Function Not Compromised	72
Electrical Component	6
Possible Early Battery Depletion	57
Software/Firmware	1
Other	8
Therapy Function Compromised	1
Electrical Component	1

NBD Code	DDED
Serial Number Prefix	PZV
Max Delivered Energy	35 J
Estimated Longevity	See page 21



	1 yr	2 yr	3 yr	at 41 mo
%	100.0	99.8	99.6	99.5
%	99.9	98.6	94.4	93.8
#	27,000	19,000	4,710	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

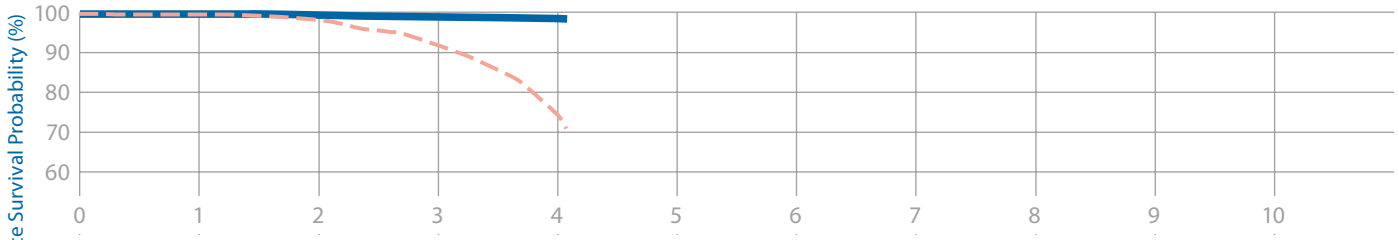
D264TRM, D284TRK Maximo II CRT-D/CRT-D M4

Product Characteristics

US Market Release	Sep-08
Registered US Implants	14,500
Estimated Active US Implants	10,600
Normal Battery Depletions (US)	422
Advisories	None

Malfunctions (US)	86
Therapy Function Not Compromised	84
Electrical Component	3
Possible Early Battery Depletion	75
Other	6
Therapy Function Compromised	2
Electrical Component	2

NBD Code	DDED
Serial Number Prefix	PZP
Max Delivered Energy	35 J
Estimated Longevity	See page 21



	1 yr	2 yr	3 yr	4 yr	at 49 mo
%	100.0	99.6	99.2	98.3	98.3
%	99.8	98.1	91.7	74.5	71.0
#	12,200	8,780	4,510	550	300

Effective Sample Size

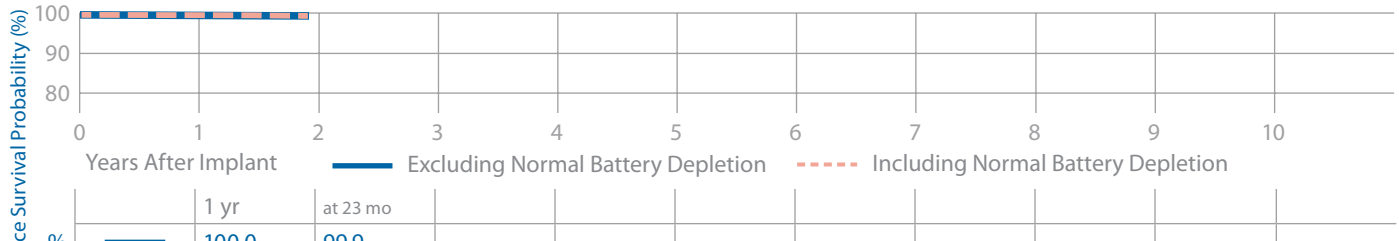
D314TRG, D354TRG, D314TRM, D354TRM Protecta XT CRT-D/CRT-D M4

Product Characteristics

US Market Release	Mar-11
Registered US Implants	39,300
Estimated Active US Implants	37,440
Normal Battery Depletions (US)	21
Advisories	None

Malfunctions (US)	16
Therapy Function Not Compromised	14
Electrical Component	5
Possible Early Battery Depletion	1
Other	8
Therapy Function Compromised	2
Electrical Component	2

NBD Code	DDED
Serial Number Prefix	PFS
Max Delivered Energy	35J
Estimated Longevity	See page 21



	1 yr	at 23 mo
%	100.0	99.9
%	99.9	99.1
#	16,500	190

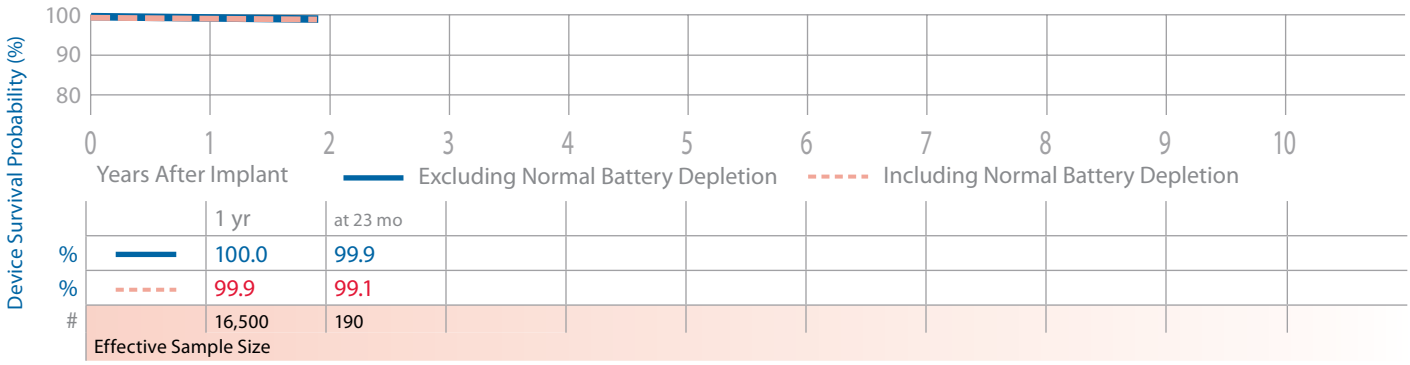
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

D334TRG, D364TRG, D334TRM, D364TRM Protecta CRT-D/CRT-D M4

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	2	NBD Code	DDED
Registered US Implants	6,570	**Therapy Function Not Compromised**	1	Serial Number Prefix	PSO
Estimated Active US Implants	6,240	Other	1	Max Delivered Energy	35J
Normal Battery Depletions (US)	1	**Therapy Function Compromised**	1	Estimated Longevity	See page 21
Advisories	None	Electrical Component	1		

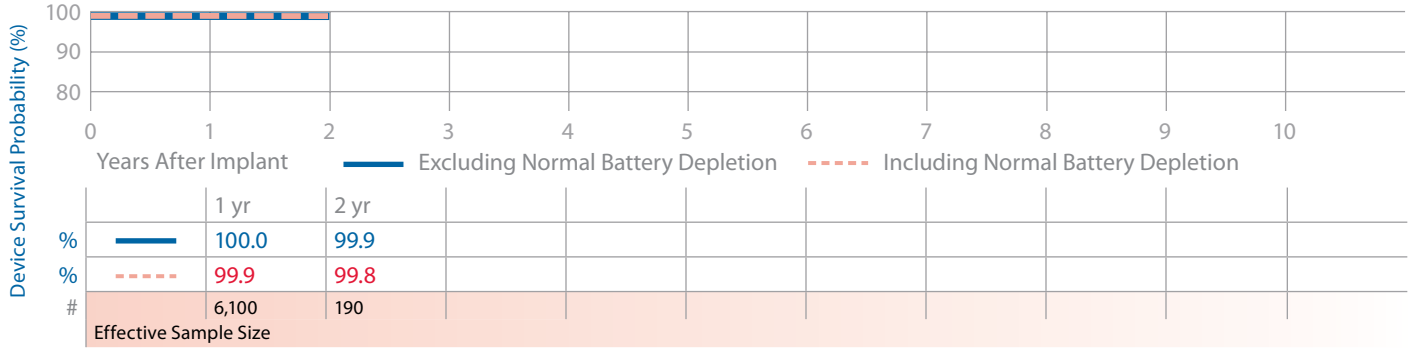


		1 yr	at 23 mo
%	Excluding Normal Battery Depletion	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.1
#	Effective Sample Size	16,500	190

C2TR01 Syncra CRT-P

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	4	NBG Code	OOED
Registered US Implants	5,400	**Therapy Function Not Compromised**	4	Serial Number Prefix	PZX
Estimated Active US Implants	4,990	Other	4	Max Delivered Energy	NA
Normal Battery Depletions (US)	0	**Therapy Function Compromised**	0	Estimated Longevity	See page 22
Advisories	None				



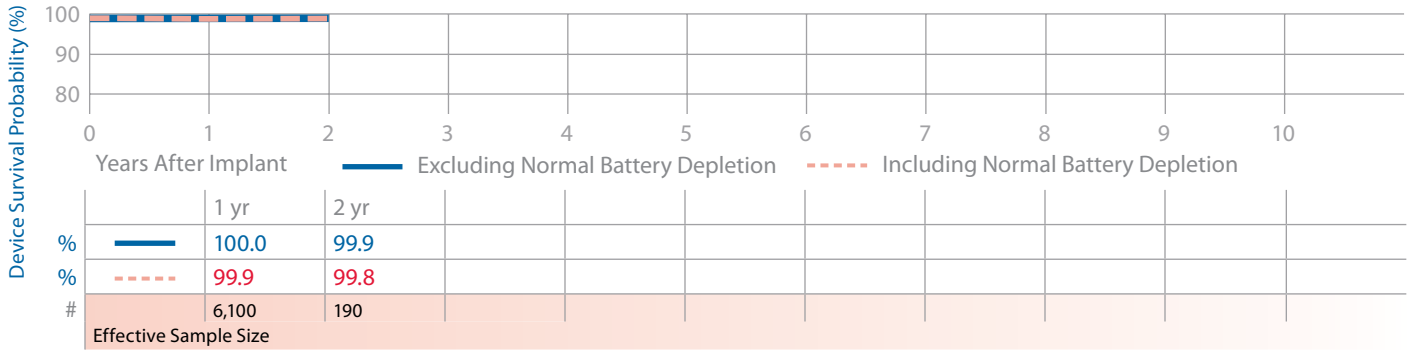
		1 yr	2 yr
%	Excluding Normal Battery Depletion	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.8
#	Effective Sample Size	6,100	190

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

C3TR01, C4TR01 Consulta CRT-P

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	0	NBG Code	OAED
Registered US Implants	6,900	**Therapy Function Not Compromised**	0	Serial Number Prefix	PVX
Estimated Active US Implants	6,450	**Therapy Function Compromised**	0	Max Delivered Energy	NA
Normal Battery Depletions (US)	1			Estimated Longevity	See page 22
Advisories	None				



		1 yr	2 yr
%	Excluding Normal Battery Depletion	100.0	99.9
%	Including Normal Battery Depletion	99.9	99.8
#	Effective Sample Size	6,100	190

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	12 yr
7299	InSync Sentry	Apr-05	31,200	2,250	9,582	11	+	169	=	180	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	98.9 +0.2/-0.2 at 61 mo				
											Including Normal Battery Depletion	99.7 +0.1/-0.1	98.1 +0.2/-0.2	91.8 +0.4/-0.4	71.9 +0.6/-0.7	13.1 +0.7/-0.7	4.8 +0.5/-0.5 at 61 mo				
7304	InSync Maximo	Apr-05	19,000	2,000	5,150	5	+	106	=	111	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	99.1 +0.2/-0.2 at 62 mo				
											Including Normal Battery Depletion	99.7 +0.1/-0.1	98.2 +0.2/-0.2	92.5 +0.4/-0.5	74.8 +0.8/-0.8	19.9 +1.1/-1.0	1.8 +0.6/-0.5 at 62 mo				
8040	InSync	Aug-01	15,300	1,370	1,346	10	+	26	=	36	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	99.4 +0.2/-0.3 at 121 mo
								-			Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.1	98.0 +0.3/-0.3	95.7 +0.4/-0.5	90.8 +0.7/-0.7	83.5 +0.9/-1.0	73.1 +1.2/-1.3	58.6 +1.6/-1.6	19.8 +1.9/-1.9	17.7 +2.0/-1.9 at 121 mo
8042	InSync III	Feb-03	39,500	14,800	1,821	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	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 103 mo	
								-			Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.3 +0.1/-0.1	98.0 +0.2/-0.2	95.5 +0.3/-0.3	90.4 +0.5/-0.6	78.1 +0.9/-1.0	51.5 +1.6/-1.6	24.4 +2.3/-2.2 at 103 mo	
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	81,300	27,000	13,508	37	+	1,166	=	1,203	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.5 +0.1/-0.1	98.3 +0.1/-0.1	97.1 +0.2/-0.2	97.1 +0.2/-0.2 at 63 mo				
	See page 151 – Performance note on Anomalies in MOSFET Integrated Circuit Technology										Including Normal Battery Depletion	99.8 +0.0/-0.0	98.4 +0.1/-0.1	93.5 +0.2/-0.2	79.3 +0.4/-0.4	41.9 +0.6/-0.6	14.1 +1.0/-1.0 at 63 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Device Survival Summary continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	9 yr
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	3,500	200	264	14	+	1,284	=	1,298	Excluding Normal Battery Depletion	99.8 +0.1/-0.2	99.4 +0.2/-0.3	79.1 +1.6/-1.7	51.2 +2.2/-2.2 at 43 mo					
	Advisories: See page 142 – 2009 Potential Reduced Device Longevity See page 151 – Performance note on Anomalies in MOSFET Integrated Circuit Technology										Including Normal Battery Depletion	99.8 +0.1/-0.3	97.5 +0.5/-0.6	60.0 +1.9/-2.0	8.1 +1.5/-1.3 at 43 mo					
D224TRK, D234TRK, D204TRM, D214TRM	Consulta CRT-D/ CRT-D M4	Sep-08	64,700	48,770	1,568	10	+	330	=	340	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.7 +0.0/-0.1	99.2 +0.1/-0.1	98.7 +0.2/-0.2	98.7 +0.2/-0.2 at 49 mo				
											Including Normal Battery Depletion	99.8 +0.0/-0.0	98.3 +0.1/-0.1	91.8 +0.3/-0.3	72.8 +1.3/-1.4	65.4 +2.6/-2.8 at 49 mo				
D274TRK, D294TRK	Concerto II CRT-D	Aug-09	30,100	24,000	332	1	+	72	=	73	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.2 at 41 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.1	98.6 +0.1/-0.2	94.4 +0.4/-0.4	93.8 +0.5/-0.5 at 41 mo					
D264TRM, D284TRK	Maximo II CRT-D/ CRT-D M4	Sep-08	14,500	10,600	422	2	+	84	=	86	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.2/-0.2	98.3 +0.4/-0.5	98.3 +0.4/-0.5 at 49 mo				
											Including Normal Battery Depletion	99.8 +0.1/-0.1	98.1 +0.2/-0.3	91.7 +0.6/-0.7	74.5 +1.9/-2.0	71.0 +2.5/-2.7 at 49 mo				
D314TRG, D354TRG, D314TRM, D354TRM	Protecta XT CRT-D/ CRT-D M4	Mar-11	39,300	37,440	21	2	+	14	=	16	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0 at 23 mo							
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.1 +0.3/-0.6 at 23 mo							

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	9 yr
D334TRG, D364TRG, D334TRM, D364TRM	Protecta CRT-D/ CRT-D M4	Mar-11	6,570	6,240	1	1	+	1	=	2	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0 at 23 mo							
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.1 +0.3/-0.6 at 23 mo							
C2TR01	Syncra CRT-P	Mar-11	5,400	4,990	0	0	+	4	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.1							
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.2							
C3TR01 C4TR01	Consulta CRT-P	Mar-11	6,900	6,450	1	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.1							
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.2							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	
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
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, D234TRK, D204TRM, D214TRM	Consulta CRT-D CRT-D M4	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, D264TRM	Maximo II CRT-D CRT-D M4	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, D354TRG, D314TRM, D354TRM	Protecta XT CRT-D CRT-D M4	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, D364TRG, D334TRM, D364TRM	Protecta CRT-D CRT-D M4	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 March 12, 2013

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	*
C3TR01 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 March 12, 2013

7230Cx, B, E Marquis VR

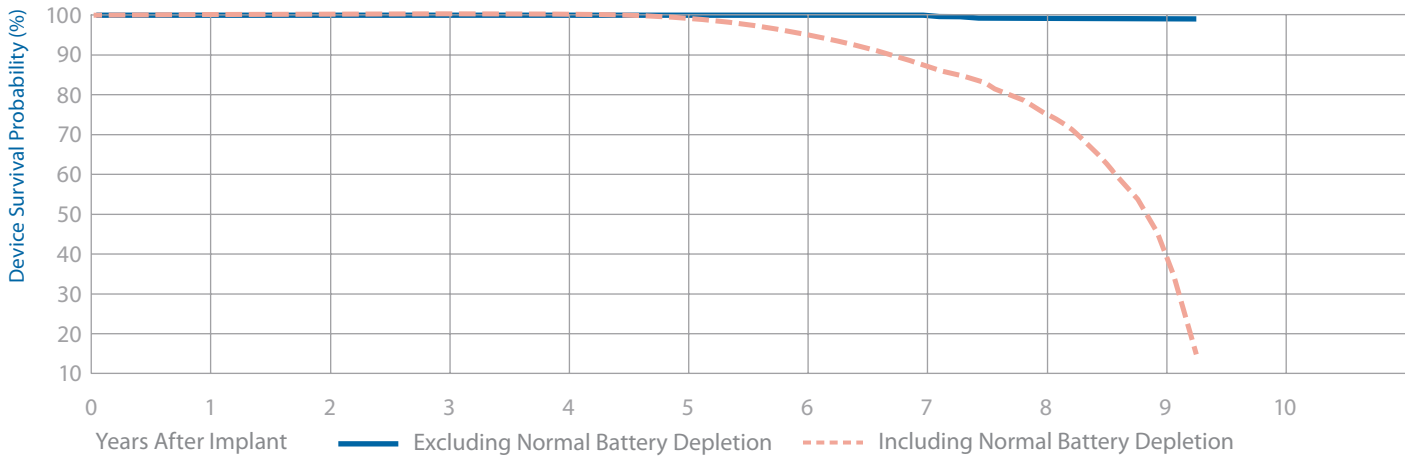
Product Characteristics

US Market Release	Dec-02
Registered US Implants	19,400
Estimated Active US Implants	3,310
Normal Battery Depletions (US)	2,312

Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	62
Therapy Function Not Compromised	33
Electrical Component	14
Battery *(1 malfunction related to advisory)*	1
Software/Firmware	1
Possible Early Battery Depletion	14
Other	3
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	9 yr	at 111 mo
%	———	99.9	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.3
%	- - - -	99.7	99.5	99.1	98.8	98.2	94.7	86.9	75.1	39.9	14.3
#	Effective Sample Size	17,300	13,600	11,300	10,200	9,090	7,920	6,530	4,710	950	180

7231Cx GEM III VR

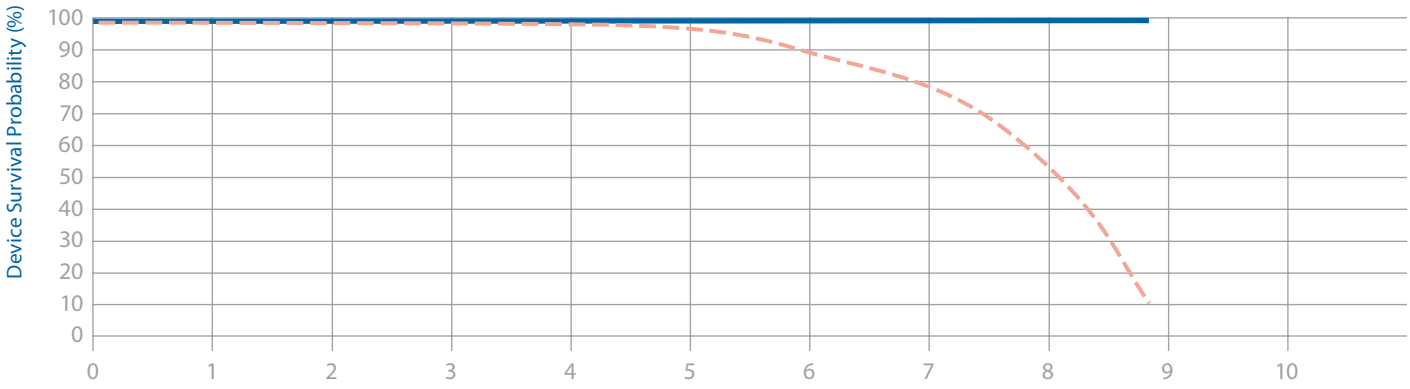
Product Characteristics

US Market Release	Dec-00
Registered US Implants	17,400
Estimated Active US Implants	1,900
Normal Battery Depletions (US)	3,612

Performance Note: See page 156 – Performance note on ICD Battery Discharge Behavior

Malfunctions (US)	40
Therapy Function Not Compromised	30
Electrical Component	22
Battery Malfunction	1
Possible Early Battery Depletion	4
Other	3
Therapy Function Compromised	10
Electrical Component	8
Electrical Interconnect	1
Battery Malfunction	1

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 106 mo
%	———	99.9	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7
%	- - -	99.8	99.5	99.1	98.7	97.3	89.7	78.5	53.3	10.2
#		15,800	14,100	12,500	11,000	9,630	7,910	5,900	3,020	350

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

7232B, Cx, E Maximo VR

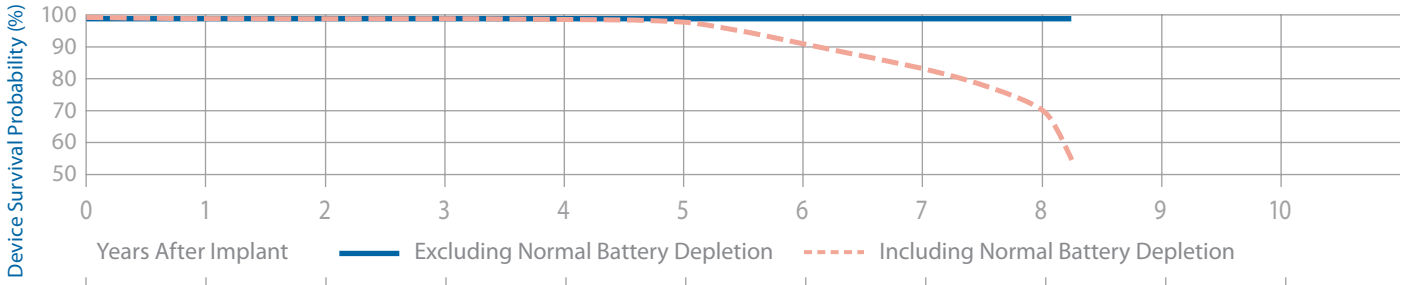
US Market Release	Oct-03
Registered US Implants	44,300
Estimated Active US Implants	18,500
Normal Battery Depletions (US)	2,937

Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	79
Therapy Function Not Compromised	63
Electrical Component	27
Possible Early Battery Depletion	23
Other	13
Therapy Function Compromised	16
Electrical Component	13
Electrical Interconnect	1
Possible Early Battery Depletion	1
Other	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	8 yr	at 99 mo
%	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.7
%	99.9	99.7	99.5	99.1	97.7	91.5	83.2	70.4	53.6
#	40,800	36,700	32,800	28,800	24,300	18,900	11,700	2,090	350

Effective Sample Size

7274 Marquis DR

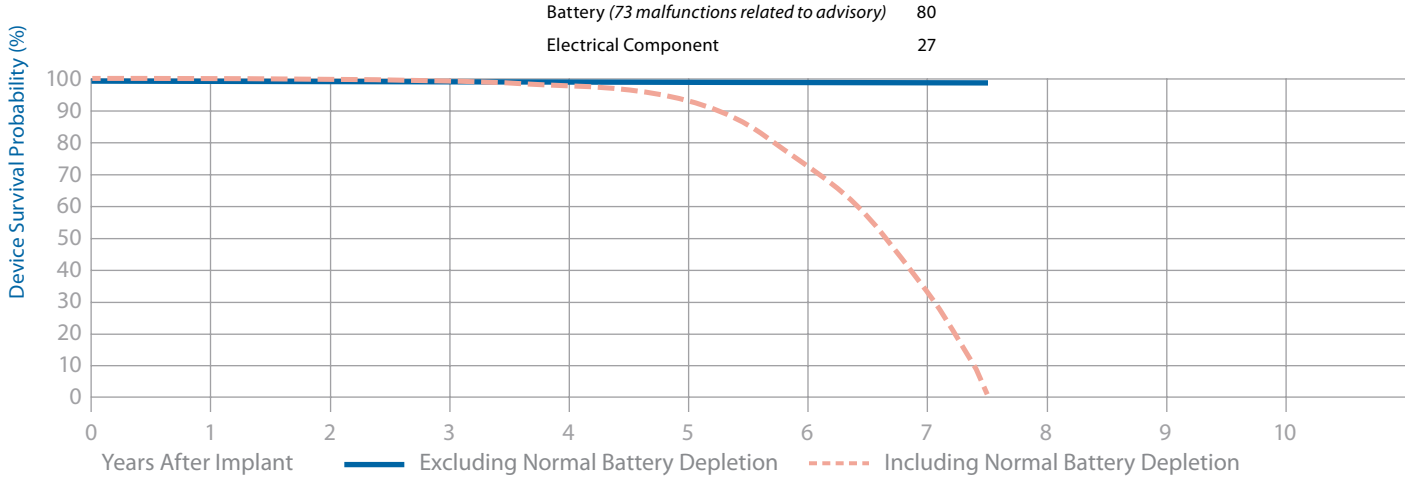
US Market Release	Mar-02
Registered US Implants	48,400
Estimated Active US Implants	2,900
Normal Battery Depletions (US)	8,840

Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	204
Therapy Function Not Compromised	97
Battery *(3 malfunctions related to advisory)*	6
Electrical Component	30
Possible Early Battery Depletion	51
Other	10
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	at 90 mo
%	99.9	99.9	99.8	99.6	99.4	99.3	99.2	99.1
%	99.8	99.5	98.6	97.3	92.1	72.6	34.2	0.8
#	43,000	34,600	26,600	22,500	18,500	12,100	4,130	380

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

7278 Maximo DR

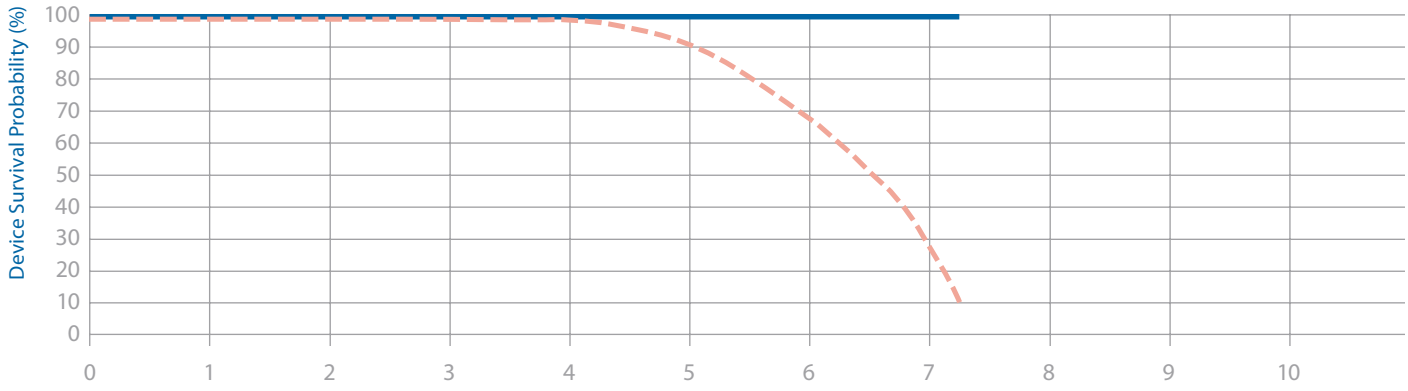
US Market Release	Oct-03
Registered US Implants	37,600
Estimated Active US Implants	7,100
Normal Battery Depletions (US)	8,247

Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	67
Therapy Function Not Compromised	57
Electrical Component	21
Possible Early Battery Depletion	31
Other	5
Therapy Function Compromised	10
Electrical Component	9
Possible Early Battery Depletion	1

Product Characteristics

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	7 yr	at 87 mo
%	———	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.7
%	- - - -	99.9	99.6	99.2	97.7	90.3	67.4	28.7	9.6
#	Effective Sample Size	34,000	30,400	27,200	23,600	18,600	10,900	2,650	730

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

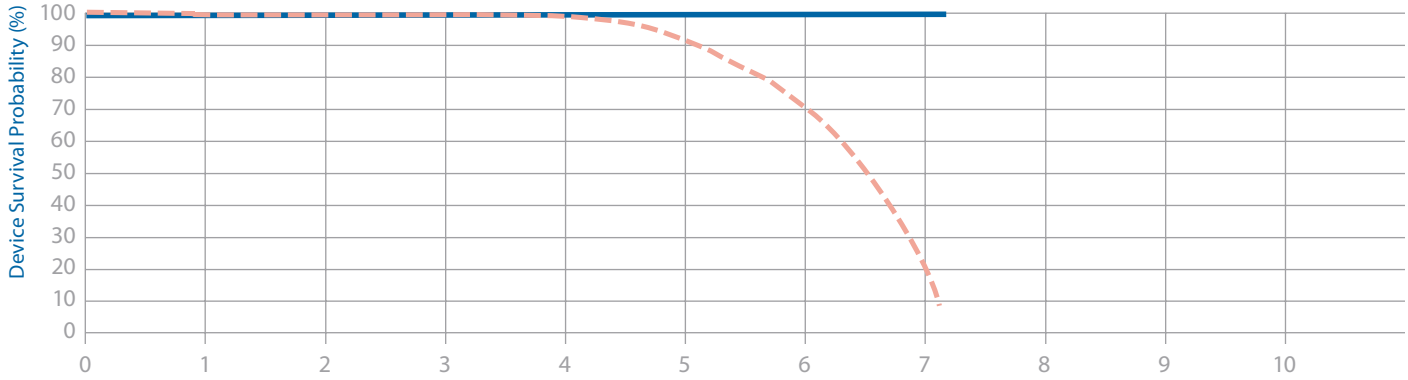
7288 Intrinsic

Product Characteristics

US Market Release	Jun-04
Registered US Implants	30,600
Estimated Active US Implants	5,100
Normal Battery Depletions (US)	8,109
Advisories	None

Malfunctions (US)	70
Therapy Function Not Compromised	63
Electrical Component	26
Battery Malfunction	2
Possible Early Battery Depletion	33
Software Malfunction	1
Other	1
Therapy Function Compromised	7
Electrical Component	5
Other	2

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	7 yr	at 86 mo
%	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	99.9	99.6	99.2	98.3	90.8	70.6	22.2	3.6
#	28,700	26,400	23,800	21,000	17,400	11,300	2,120	530

Effective Sample Size

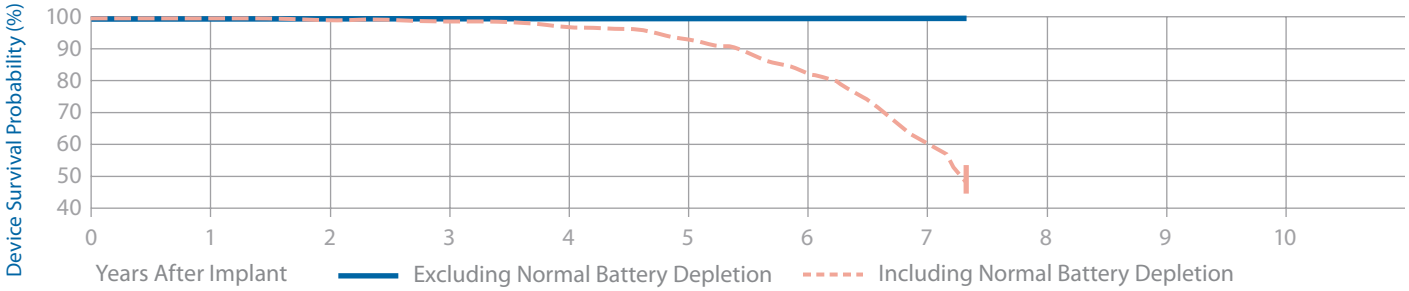
7290Cx Onyx

Product Characteristics

US Market Release	Mar-04
Registered US Implants	950
Estimated Active US Implants	290
Normal Battery Depletions (US)	145
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	7 yr	at 88 mo
%	99.9	99.5	99.5	99.4	99.4	99.4	99.4	99.4
%	99.8	99.0	98.4	97.2	93.4	82.9	60.5	48.2
#	870	790	710	630	540	410	180	100

Effective Sample Size

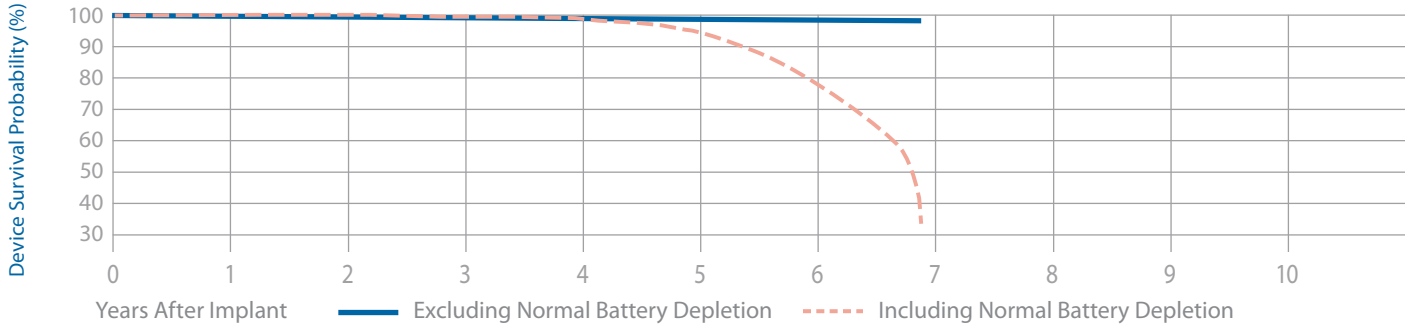
D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	28,200
Estimated Active US Implants	9,040
Normal Battery Depletions (US)	4,524
Advisories: See page 139 – 2012	
Potential Rapid Battery Depletion	

Malfunctions (US)	125
Therapy Function Not Compromised	111
Electrical Component *(9 malfunctions related to advisory)*	28
Electrical Interconnect	1
Software Malfunction	3
Possible Early Battery Depletion *(1 malfunction related to advisory)*	75
Other	4
Therapy Function Compromised	14
Electrical Component *(2 malfunction related to advisory)*	14

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 83 mo
%	100.0	99.9	99.8	99.7	99.4	99.4	99.3
%	99.8	99.6	99.1	97.9	90.7	70.2	34.1
#	26,300	24,100	21,700	19,100	14,900	9,110	790

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

D154AWG, D164AWG Virtuoso DR

Product Characteristics

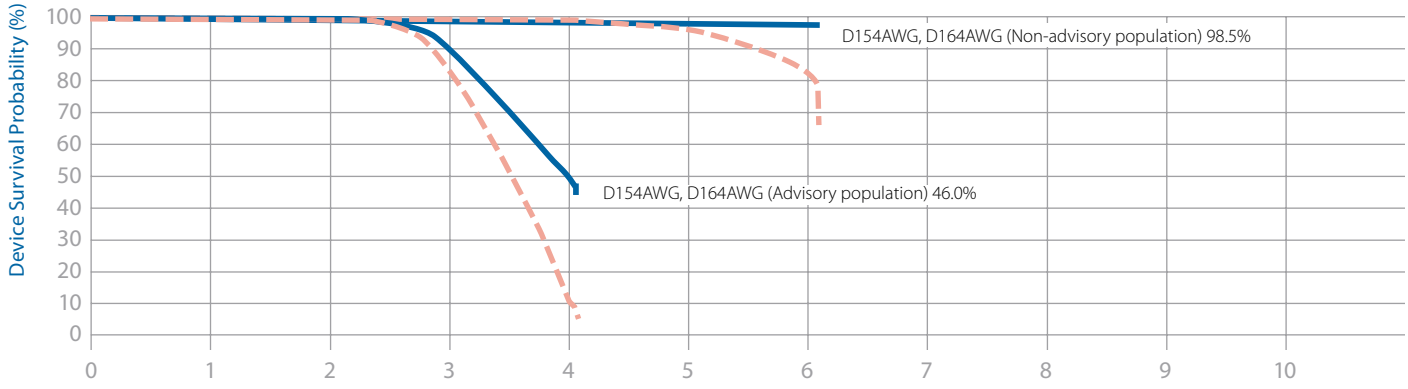
	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	72,700	4,100
Estimated Active US Implants	44,300	300
Normal Battery Depletions (US)	2,496	107

Advisories: See page 142 – 2009 Potential Reduced Device Longevity

Performance Note: See page 151 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	640	1,872
Therapy Function Not Compromised	614	1,859
Electrical Component	465	1,858
Electrical Interconnect	2	0
Possible Early Battery Depletion	117	0
Software Malfunction	1	0
Other	29	1
Therapy Function Compromised	26	13
Electrical Component	24	13
Possible Early Battery Depletion	1	0
Other	1	0

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	6 yr	at 74 mo
%	100.0	99.9	99.9	99.5	98.6	98.5	98.5
%	99.9	99.7	99.4	98.0	93.0	74.7	68.0
#	67,700	62,300	56,600	45,100	23,700	2,920	590
Effective Sample Size							

Advisory	1 yr	2 yr	3 yr	4 yr	at 49 mo
%	100.0	99.9	90.5	49.5	46.0
%	99.9	99.6	84.1	13.9	6.6
#	3,810	3,490	2,760	410	250
Effective Sample Size					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

D154VRC EnTrust VR

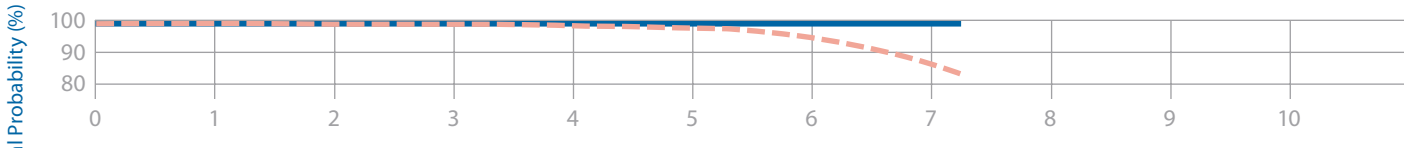
Product Characteristics

US Market Release	Jun-05
Registered US Implants	14,500
Estimated Active US Implants	7,200
Normal Battery Depletions (US)	509

Advisories: See page 139 – 2012 Potential Rapid Battery Depletion

Malfunctions (US)	94
Therapy Function Not Compromised	78
Battery *(2 malfunctions related to advisory)*	2
Electrical Component *(28 malfunctions related to advisory)*	42
Possible Early Battery Depletion *(3 malfunctions related to advisory)*	24
Other *(1 malfunction related to advisory)*	10
Therapy Function Compromised	16
Electrical Component *(8 malfunctions related to advisory)*	16

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	7 yr	at 88 mo
%	100.0	99.9	99.8	99.7	99.4	99.2	98.9	98.8
%	99.9	99.6	99.4	98.9	98.0	92.5	85.4	82.1
#	13,700	12,400	11,200	9,890	8,430	6,410	1,460	180

Effective Sample Size

D154VWC, D164VWC Virtuoso VR

Product Characteristics

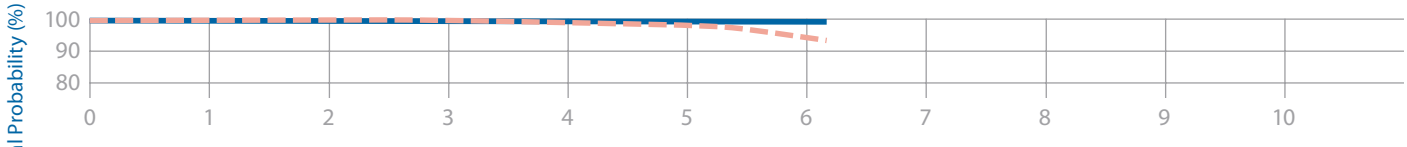
US Market Release	May-06
Registered US Implants	33,100
Estimated Active US Implants	21,600
Normal Battery Depletions (US)	233

Advisories: See page 142– 2009 Potential Reduced Device Longevity

Performance Note: See page 151– Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	138
Therapy Function Not Compromised	126
Electrical Component *(4 malfunctions related to advisory)*	98
Electrical Interconnect	1
Possible Early Battery Depletion	12
Other	15
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	6 yr	at 74 mo
%	100.0	99.9	99.9	99.8	99.4	99.4	99.4
%	99.9	99.8	99.6	99.2	98.1	94.2	93.6
#	30,900	28,300	25,600	20,700	11,000	1,690	490

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

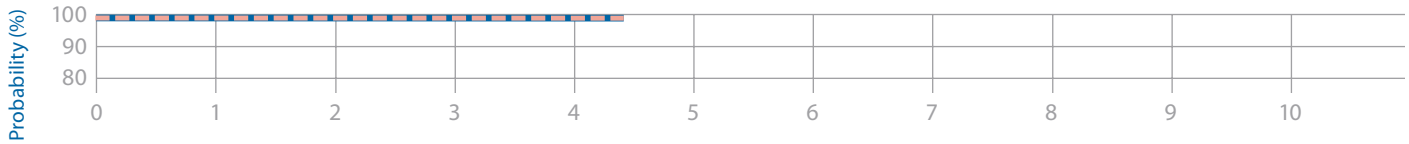
D224DRG, D234DRG, D204DRM, D214DRM Secura DR/DR M4

Product Characteristics

US Market Release	Sep-08
Registered US Implants	49,500
Estimated Active US Implants	41,900
Normal Battery Depletions (US)	127
Advisories	None

Malfunctions (US)	46
Therapy Function Not Compromised	37
Electrical Component	11
Possible Early Battery Depletion	14
Software Malfunction	9
Other	3
Therapy Function Compromised	9
Electrical Component	7
Possible Early Battery Depletion	1
Software Malfunction	1

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



		1 yr	2 yr	3 yr	4 yr	at 53 mo
%	———	100.0	99.9	99.9	99.8	99.8
%	- - - - -	99.8	99.6	99.2	98.4	98.3
#	Effective Sample Size	43,600	33,600	16,000	3,420	240

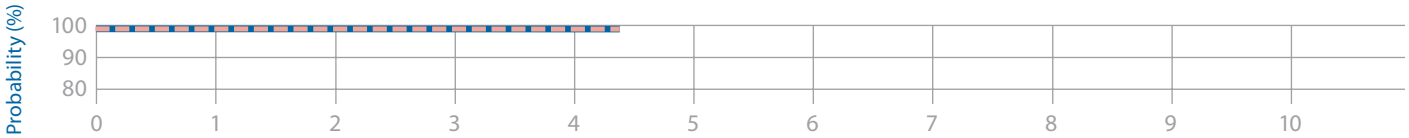
D224VRC, D234VRC, D204VRM, D214VRM Secura VR/VR M4

Product Characteristics

US Market Release	Sep-08
Registered US Implants	19,800
Estimated Active US Implants	16,800
Normal Battery Depletions (US)	27
Advisories	None

Malfunctions (US)	21
Therapy Function Not Compromised	17
Electrical Component	3
Possible Early Battery Depletion	5
Software Malfunction	2
Other	7
Therapy Function Compromised	4
Electrical Component	3
Software/Firmware	1

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

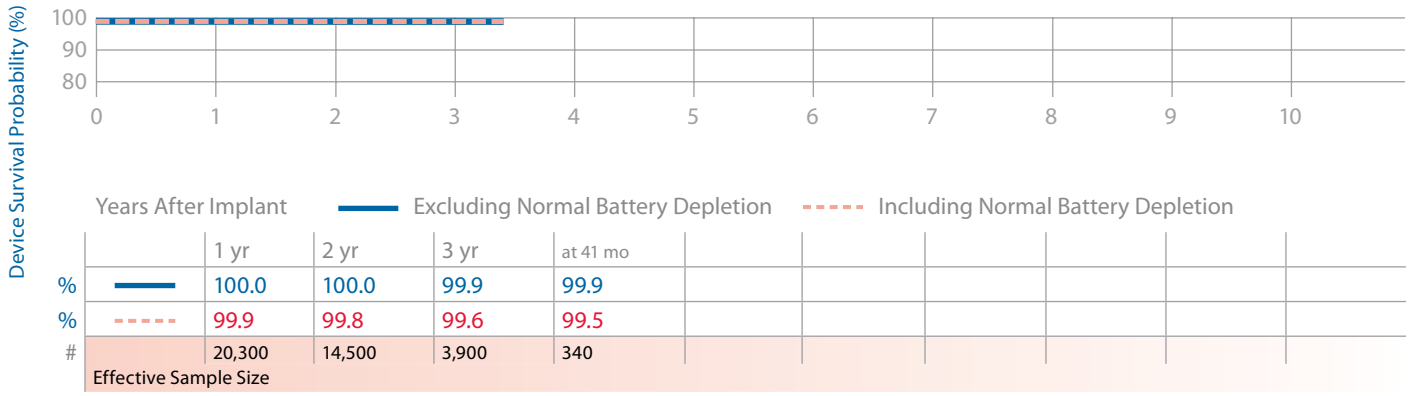


		1 yr	2 yr	3 yr	4 yr	at 53 mo
%	———	100.0	99.9	99.8	99.8	99.8
%	- - - - -	99.9	99.6	99.3	99.3	99.3
#	Effective Sample Size	17,200	13,000	6,680	1,540	130

D274DRG, D294DRG Virtuoso II DR

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	5	NBD Code	VVED
Registered US Implants	22,200	**Therapy Function Not Compromised**	4	Serial Number Prefix	PZT
Estimated Active US Implants	19,100	Battery Malfunction	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	21	Other	3	Estimated Longevity	See page 41
Advisories	None	**Therapy Function Compromised**	1		
		Electrical Component	1		



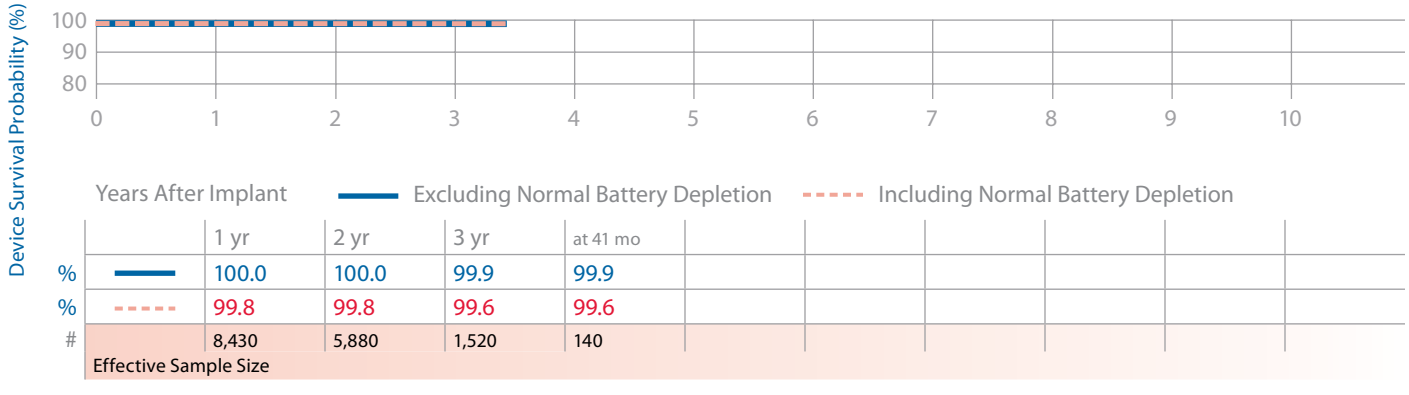
		1 yr	2 yr	3 yr	at 41 mo
%	———	100.0	100.0	99.9	99.9
%	- - - - -	99.9	99.8	99.6	99.5
#		20,300	14,500	3,900	340

Effective Sample Size

D274VRC, D294VRC Virtuoso II VR

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	3	NBD Code	VVEV
Registered US Implants	9,100	**Therapy Function Not Compromised**	3	Serial Number Prefix	PZR
Estimated Active US Implants	8,000	Electrical Component	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	8	Possible Early Battery Depletion	1	Estimated Longevity	See page 41
Advisories	None	Software Malfunction	1		
		Therapy Function Compromised	0		



		1 yr	2 yr	3 yr	at 41 mo
%	———	100.0	100.0	99.9	99.9
%	- - - - -	99.8	99.8	99.6	99.6
#		8,430	5,880	1,520	140

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

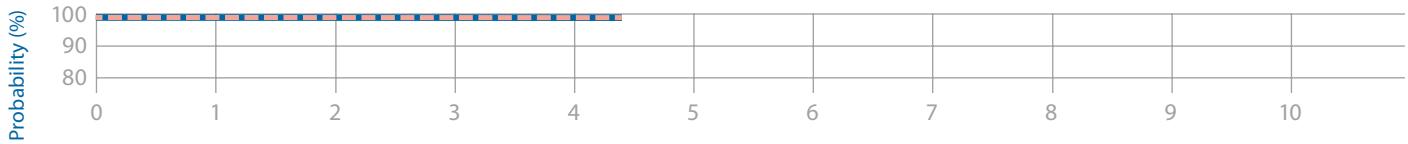
D264DRM, D284DRG Maximo II DR/DR M4

US Market Release	Sep-08
Registered US Implants	19,100
Estimated Active US Implants	16,100
Normal Battery Depletions (US)	45
Advisories	None

Malfunctions (US)	13
Therapy Function Not Compromised	9
Electrical Component	4
Possible Early Battery Depletion	4
Other	1
Therapy Function Compromised	4
Electrical Component	4

Product Characteristics

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



	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	100.0	99.9	99.9	99.9
%	99.9	99.7	99.4	98.5	98.5
#	16,900	12,700	7,290	1,930	190

Effective Sample Size

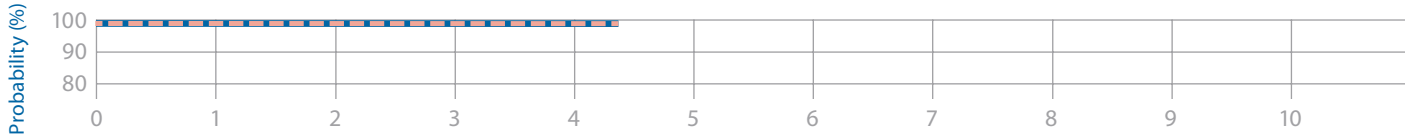
D264VRM, D284VRC Maximo II VR/VR M4

US Market Release	Sep-08
Registered US Implants	12,300
Estimated Active US Implants	10,500
Normal Battery Depletions (US)	25
Advisories	None

Malfunctions (US)	9
Therapy Function Not Compromised	6
Electrical Component	3
Possible Early Battery Depletion	1
Software Malfunctionn	2
Therapy Function Compromised	3
Electrical Component	2
Software Malfunction	1

Product Characteristics

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



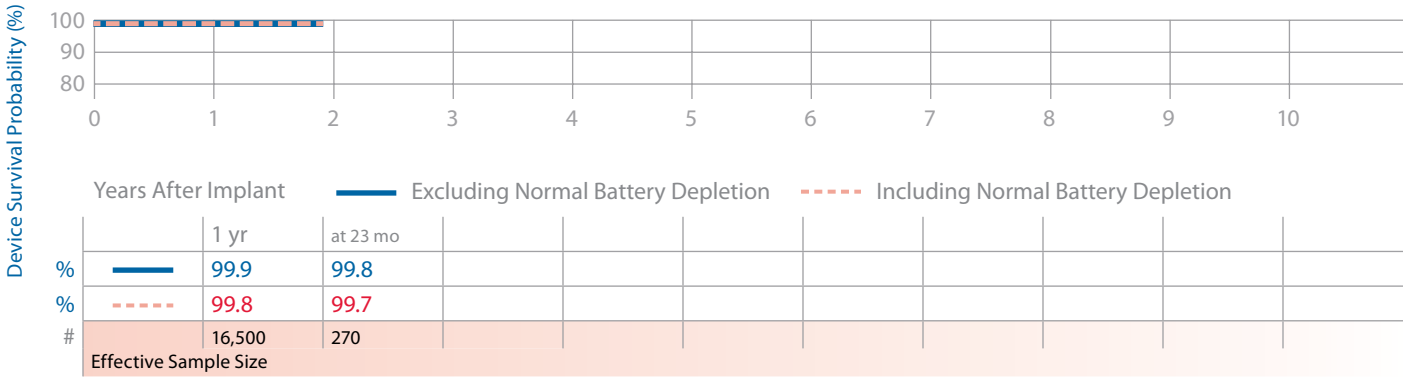
	1 yr	2 yr	3 yr	4 yr	at 52 mo
%	100.0	99.9	99.9	99.9	99.9
%	99.8	99.6	99.3	99.1	99.1
#	11,200	8,350	4,650	1,090	260

Effective Sample Size

D314DRG, D354DRG, D314DRM, D354DRM Protecta XT DR/DR M4

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	15	NBD Code	DDED
Registered US Implants	34,200	**Therapy Function Not Compromised**	13	Serial Number Prefix	PSK
Estimated Active US Implants	32,900	Electrical Component	6	Max Delivered Energy	35 J
Normal Battery Depletions (US)	9	Other	7	Estimated Longevity	See page 41
Advisorie	None	**Therapy Function Compromised**	2		
		Electrical Component	2		

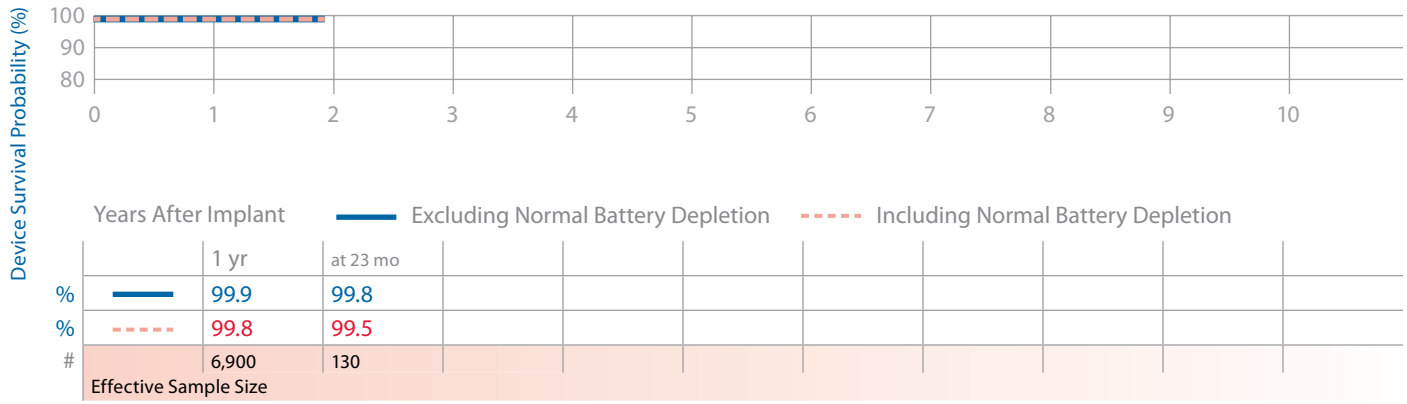


		1 yr	at 23 mo
%	Excluding Normal Battery Depletion	99.9	99.8
%	Including Normal Battery Depletion	99.8	99.7
#	Effective Sample Size	16,500	270

D314VRG, D354VRG, D314VRM, D354VRM Protecta XT VR/VR M4

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	10	NBD Code	VVEV
Registered US Implants	14,200	**Therapy Function Not Compromised**	9	Serial Number Prefix	PSA
Estimated Active US Implants	13,700	Electrical Component	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	5	Other	8	Estimated Longevity	See page 41
Advisories	None	**Therapy Function Compromised**	1		
		Electrical Component	1		



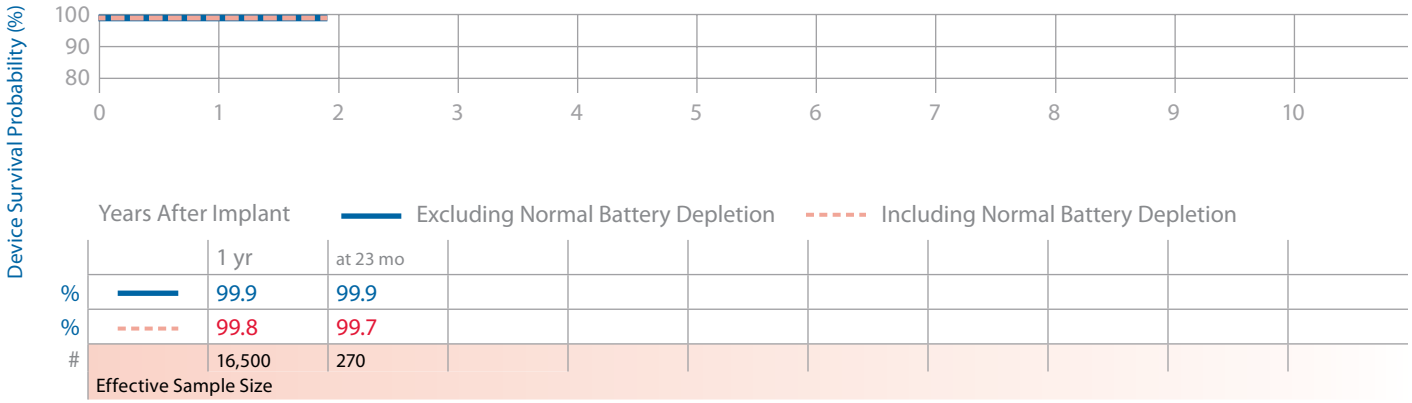
		1 yr	at 23 mo
%	Excluding Normal Battery Depletion	99.9	99.8
%	Including Normal Battery Depletion	99.8	99.5
#	Effective Sample Size	6,900	130

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

D334DRG, D364DRG, D334DRM, D364DRM Protecta DR/DR M4

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	7	NBD Code	DDED
Registered US Implants	9,400	**Therapy Function Not Compromised**	5	Serial Number Prefix	PSP
Estimated Active US Implants	9,000	Electrical Component	3	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2	Other	2	Estimated Longevity	See page 41
Advisories	None	**Therapy Function Compromised**	2		
		Electrical Component	2		

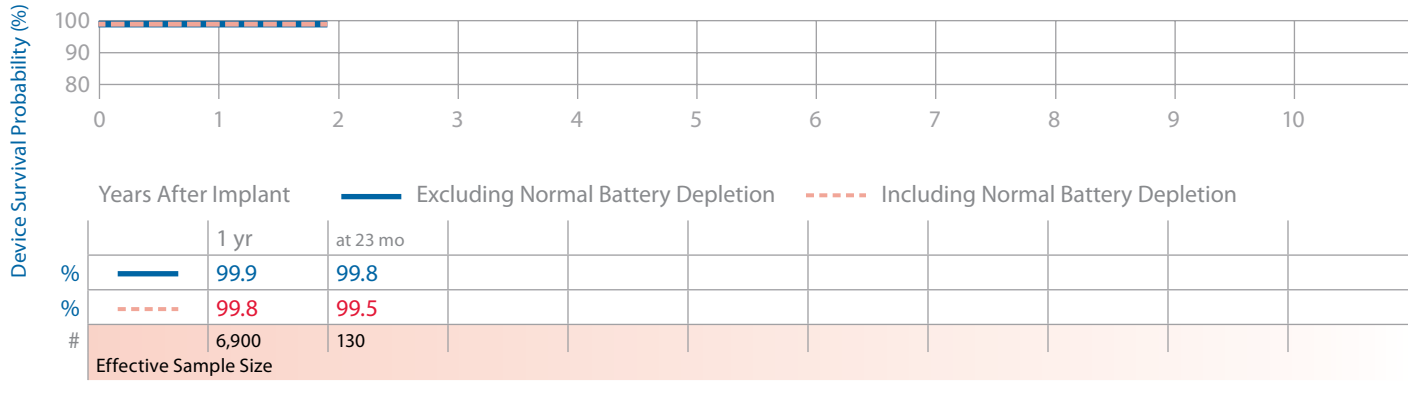


		1 yr	at 23 mo
%	Excluding Normal Battery Depletion	99.9	99.9
%	Including Normal Battery Depletion	99.8	99.7
#	Effective Sample Size	16,500	270

D334VRG, D364VRG, D334VRM, D364VRM Protecta VR/VR M4

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	1	NBD Code	VVEV
Registered US Implants	5,500	**Therapy Function Not Compromised**	0	Serial Number Prefix	PSX
Estimated Active US Implants	5,300	**Therapy Function Compromised**	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	1	Electrical Component	1	Estimated Longevity	See page 41
Advisories	None				



		1 yr	at 23 mo
%	Excluding Normal Battery Depletion	99.9	99.8
%	Including Normal Battery Depletion	99.8	99.5
#	Effective Sample Size	6,900	130

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	+	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
7230Cx B, E	Marquis VR	Dec-02	19,400	3,310	2,312	29	+	33	=	62	Excluding Normal Battery Depletion	99.9 +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 +0.1/-0.2	99.3 +0.2/-0.3 at 111 mo
	Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short					(19) (advisory-related subset)	+	(1)	=	(20)	Including Normal Battery Depletion	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.1 +0.1/-0.2	98.8 +0.2/-0.2	98.2 +0.2/-0.3	94.7 +0.4/-0.5	86.9 +0.7/-0.7	75.1 +1.0/-1.0	14.3 +2.3/-2.1 at 111 mo
7231Cx	GEM III VR	Dec-00	17,400	1,900	3,612	10	+	30	=	40	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 106 mo
	See page 156 – Performance note on ICD Battery Discharge Behavior										Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.1 +0.1/-0.2	98.7 +0.2/-0.2	97.3 +0.3/-0.3	89.7 +0.6/-0.6	78.5 +0.9/-0.9	53.3 +1.2/-1.2	10.2 +1.1/-1.1 at 106 mo
7232Cx B, E	Maximo VR	Oct-03	44,300	18,500	2,937	16	+	63	=	79	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	99.8 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1 at 99 mo
	Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	+	(0)	=	(0)	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	91.5 +0.3/-0.4	83.2 +0.5/-0.5	70.4 +1.0/-1.0	53.6 +2.7/-2.7 at 99 mo
7274	Marquis DR	Mar-02	48,400	2,900	8,840	107	+	97	=	204	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	99.1 +0.1/-0.1 at 90 mo	
	Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short					(73) (advisory-related subset)	+	(3)	=	(76)	Including Normal Battery Depletion	99.8 +0.0/-0.1	99.5 +0.1/-0.1	98.6 +0.1/-0.1	97.3 +0.2/-0.2	92.1 +0.3/-0.4	72.6 +0.6/-0.7	34.2 +0.8/-0.8	0.8 +0.3/-0.2 at 90 mo	
7278	Maximo DR	Oct-03	37,600	7,100	8,247	10	+	57	=	67	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1 at 87 mo	
	Advisories: See page 148 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	+	(0)	=	(0)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.1/-0.1	97.7 +0.2/-0.2	90.3 +0.4/-0.4	67.4 +0.7/-0.7	28.7 +0.8/-0.8	9.6 +0.8/-0.8 at 87 mo	
7288	Intrinsic	Jun-04	30,600	5,100	8,109	7	+	63	=	70	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	99.7 +0.1/-0.1 at 86 mo	
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.3 +0.2/-0.2	90.8 +0.4/-0.4	70.6 +0.7/-0.7	22.2 +0.8/-0.8	3.6 +0.6/-0.5 at 86 mo	
7290Cx	Onyx	Mar-04	950	290	145	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	99.4 +0.4/-0.9 at 88 mo	
											Including Normal Battery Depletion	99.8 +0.1/-0.6	99.0 +0.5/-0.9	98.4 +0.7/-1.1	97.2 +1.0/-1.5	93.4 +1.7/-2.2	82.9 +2.9/-3.4	60.5 +4.5/-4.9	48.2 +5.4/-5.6 at 88 mo	

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	9 yr
D154ATG, D154DRG	EnTrust	Jun-05	28,200	9,040	4,524	14	+	111	=	125	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	99.4 +0.1/-0.1	99.4 +0.1/-0.1	99.3 +0.1/-0.1 at 83 mo		
	Advisories: See page 139 – 2012 Potential Rapid Battery Depletion					(2) (advisory-related subset)	+	(10)	=	(12)	Including Normal Battery Depletion	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.1 +0.1/-0.1	97.9 +0.2/-0.2	90.7 +0.4/-0.4	70.2 +0.7/-0.7	34.1 +1.4/-1.4 at 83 mo		
D154AWG D164AWG (Non-advisory population)	Virtuoso DR	May-06	72,700	44,300	2,496	26	+	614	=	640	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.5 +0.1/-0.1	98.6 +0.1/-0.1	98.5 +0.1/-0.1	98.5 +0.1/-0.2 at 74 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.4 +0.1/-0.1	98.0 +0.1/-0.1	93.0 +0.3/-0.3	74.7 +0.9/-0.9	68.0 +1.6/-1.7 at 74 mo		
D154AWG D164AWG (Advisory population)	Virtuoso DR	May-06	4,100	300	107	13	+	1,859	=	1,872	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.2	90.5 +1.0/-1.1	49.5 +1.9/-1.9	46.0 +1.9/-1.9 at 49 mo				
	Advisories: See page 142 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.9 +0.1/-0.1	99.6 +0.2/-0.3	84.1 +1.2/-1.3	13.9 +1.5/-1.4	6.6 +1.2/-1.0 at 49 mo				
	See page 151 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			
D154VRC	EnTrust VR	Jun-05	14,500	7,200	509	16	+	78	=	94	Excluding Normal Battery Depletion	100.0 +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	98.9 +0.2/-0.3	98.8 +0.3/-0.3 at 88 mo	
	Advisories: See page 139 – 2012 Potential Rapid Battery Depletion					(8) (advisory-related subset)	+	(34)	=	(42)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.2	98.9 +0.2/-0.2	98.0 +0.3/-0.3	92.5 +0.6/-0.6	85.4 +0.9/-1.0	82.1 +2.0/-2.2 at 88 mo	
D154VWC D164VWC (Non-advisory population)	Virtuoso VR	May-06	33,100	21,600	233	12	+	126	=	138	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1 at 74 mo		
	Advisories: See page 142 – 2009 Potential Reduced Device Longevity					(0) (advisory-related subset)	+	(4)	=	(4)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.1 +0.2/-0.2	94.2 +0.6/-0.7	93.6 +0.8/-0.9 at 74 mo		
	See page 151 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D224DRG, D234DRG, D204DRM, D214DRM	Secura DR/ DR M4	Sep-08	49,500	41,900	127	9	+	37	=	46	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 53 mo			
											Including Normal Battery Depletion	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.4 +0.2/-0.2	98.3 +0.3/-0.3 at 53 mo			
D224VRC, D234VRC, D204VRM , D214VRM	Secura VR/ VR M4	Sep-08	19,800	16,800	27	4	+	17	=	21	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 53 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.3 +0.1/-0.2	99.3 +0.1/-0.2	99.3 +0.1/-0.2 at 53 mo			
D274DRG, D294DRG	Virtuoso II DR	Aug-09	22,200	19,100	21	1	+	4	=	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 +0.1/-0.2 at 41 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.2	99.5 +0.2/-0.2 at 41 mo				
D274VRC, D294VRC	Virtuoso II VR	Aug-09	9,100	8,000	8	0	+	3	=	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 41 mo				
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.6 +0.2/-0.3	99.6 +0.2/-0.3 at 41 mo				
D284DRG, D264DRM	Maximo II DR/DR M4	Sep-08	19,100	16,100	45	4	+	9	=	13	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 53 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.2	98.5 +0.3/-0.4	98.5 +0.3/-0.4 at 53 mo			
D284VRC, D264VRM	Maximo II VR/ VR M4	Mar-08	12,300	10,500	25	3	+	6	=	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 52 mo			
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.3 +0.2/-0.2	99.1 +0.2/-0.3	99.1 +0.2/-0.3 at 52 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised		Malfunctions: Therapy Function Not Compromised		Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D314DRG, D354DRG, D314DRM, D354DRM	Protecta XT DR/ DR M4	Mar-11	34,200	32,900	9	2	+	13	=	15	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 23 mo						
											Including Normal Battery Depletion	99.8 +0.0/-0.1	99.7 +0.1/-0.1 at 23 mo						
D314VRG, D354VRG, D314VRM, D354VRM	Protecta XT VR/ VR M4	Mar-11	14,200	13,700	5	1	+	9	=	10	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.4 at 23 mo						
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.2/-0.4 at 23 mo						
D334DRG, D364DRG, D334DRM, D364DRM	Protecta DR/ DR M4	Mar-11	9,400	9,000	2	2	+	5	=	7	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 23 mo						
											Including Normal Battery Depletion	99.8 +0.0/-0.1	99.7 +0.1/-0.1 at 23 mo						
D334VRG, D364VRG, D334VRM, D364VRM	Protecta VR/ VR M4	Mar-11	5,500	5,300	1	1	+	0	=	1	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.4 at 23 mo						
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.2/-0.4 at 23 mo						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	
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 Cx, E	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
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
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 March 12, 2013

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	
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, D234DRG, D204DRM, D214DRM	Secura DR/ DR M4	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, D234VRC, D204VRM, D214VRM	Secura VR/ VR M4	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, D294DRG	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, D294VRC	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, D264DRM	Maximo II DR/DR M4	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, D264VRM	Maximo II VR/ VR M4	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, D354DRG, D314DRM, D354DRM	Protecta XT DR/DR M4	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, D354VRG, D314VRM, D354VRM	Protecta XT VR/VR M4	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, D364DRG, D334DRM, D364DRM	Protecta DR/ DR M4	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, D364VRG, D334VRM, D364VRM	Protecta VR/ VR M4	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.

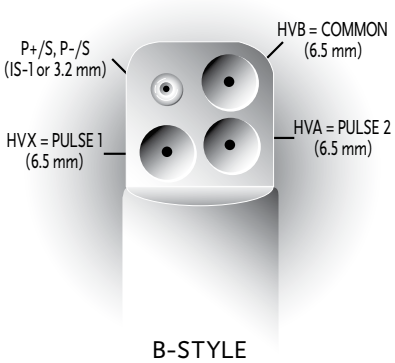
** A full charge is a full energy therapeutic shock or capacitor reformation.

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

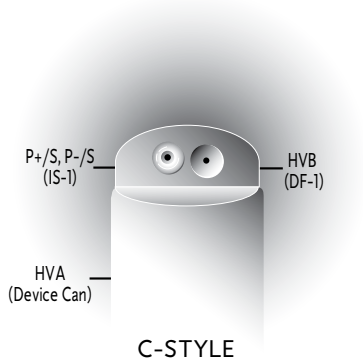
‡ Pacing mode is VVI for single chamber models and DDD for dual chamber models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510-ohm pace load per applicable channel.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

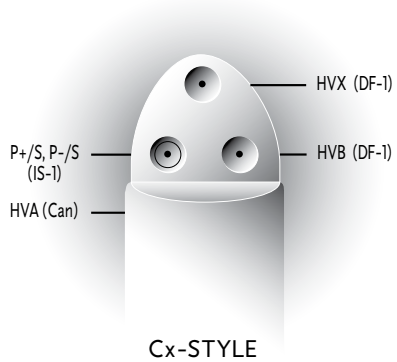
ICD Connector Styles



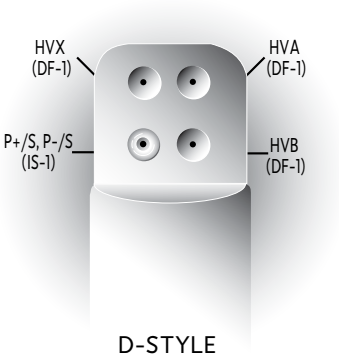
B-STYLE CONNECTOR



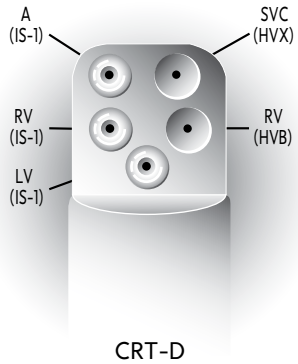
C-STYLE CONNECTOR



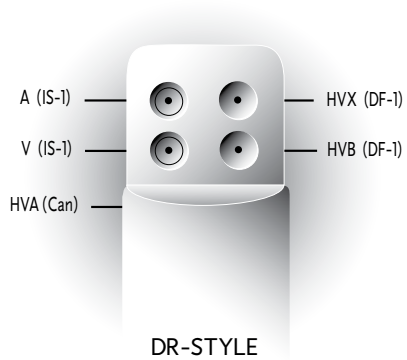
Cx-STYLE CONNECTOR



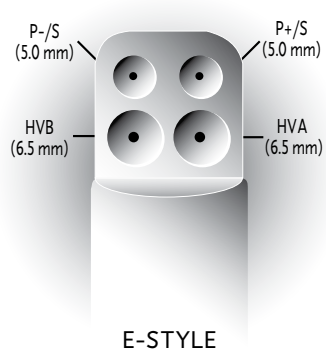
D-STYLE CONNECTOR



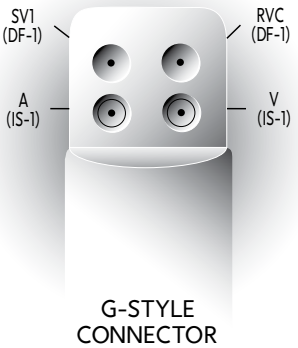
CRT-D CONNECTOR



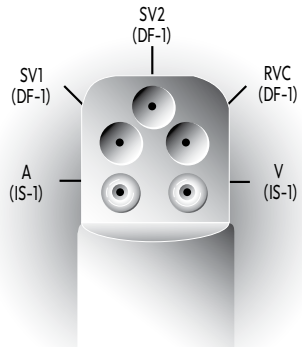
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR



H-STYLE CONNECTOR

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

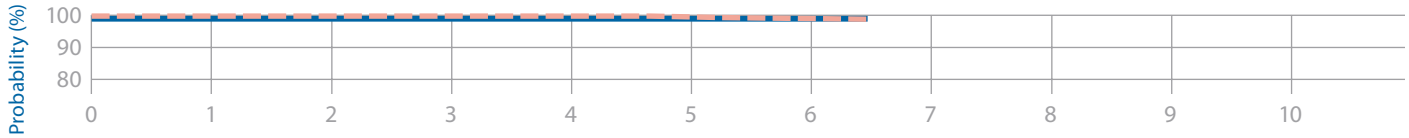
Adapta DR ADDR01, ADDR03, ADDR06, ADD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	342,700
Estimated Active US Implants	281,900
Normal Battery Depletions (US)	375
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	64
Therapy Function Not Compromised	42
Electrical Component	36
Electrical Interconnect	1
Other	5
Therapy Function Compromised	22
Electrical Component	18
Electrical Interconnect	2
Other	2

NBG Code	DDDR, DDD
Serial Number Prefix	PWB, PWD, PWC, PWF, NWB, NWC, NWD, NWF
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.8	99.4	98.8	98.8
#	287,300	225,900	163,000	105,300	55,100	13,500	1,380

Effective Sample Size

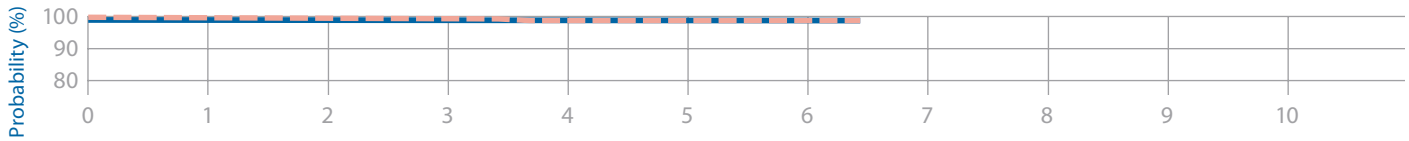
Adapta DR ADDRL1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	73,900
Estimated Active US Implants	66,700
Normal Battery Depletions (US)	23
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	12
Therapy Function Not Compromised	9
Electrical Component	5
Electrical Interconnect	1
Other	3
Therapy Function Compromised	3
Electrical Interconnect	1
Other	2

NBG Code	DDDR
Serial Number Prefix	PWE, NWE
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 76 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.8	99.6	99.4	99.4
#	56,800	39,000	24,000	12,400	4,990	840	170

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

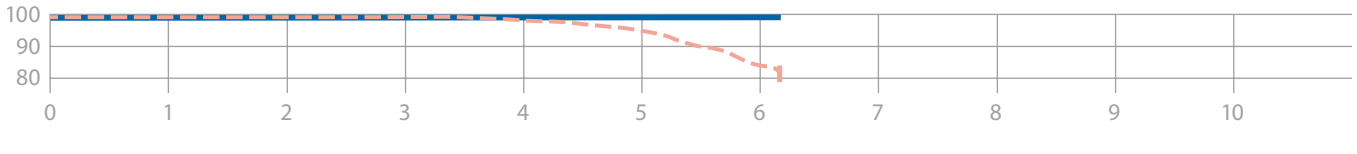
Adapta DR ADDRS1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	33,300
Estimated Active US Implants	24,900
Normal Battery Depletions (US)	274
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	9
Therapy Function Not Compromised	5
Electrical Component	3
Possible Early Battery Depletion	1
Other	1
Therapy Function Compromised	4
Electrical Component	2
Other	2

NBG Code	DDDR
Serial Number Prefix	PWA, NWA
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	99.9	99.8	99.6	98.8	95.6	83.6	81.5
#	26,500	19,700	13,400	8,160	3,790	530	160

Effective Sample Size

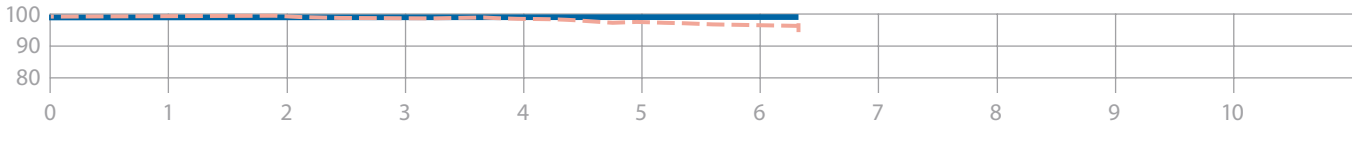
Adapta SR ADSR01, ADSR03, ADSR06

Product Characteristics

US Market Release	Jul-06
Registered US Implants	64,600
Estimated Active US Implants	45,500
Normal Battery Depletions (US)	151
Advisories	None

Malfunctions (US)	8
Therapy Function Not Compromised	4
Electrical Component	2
Electrical Interconnect	1
Possible Early Battery Depletion	1
Therapy Function Compromised	4
Electrical Component	3
Electrical Interconnect	1

NBG Code	SSIR
Serial Number Prefix	NWN, NWM, NWP, PWP, PWM, PWN
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 76 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.4	98.7	97.4	97.3
#	52,800	38,800	27,000	17,000	8,560	1,960	390

Effective Sample Size

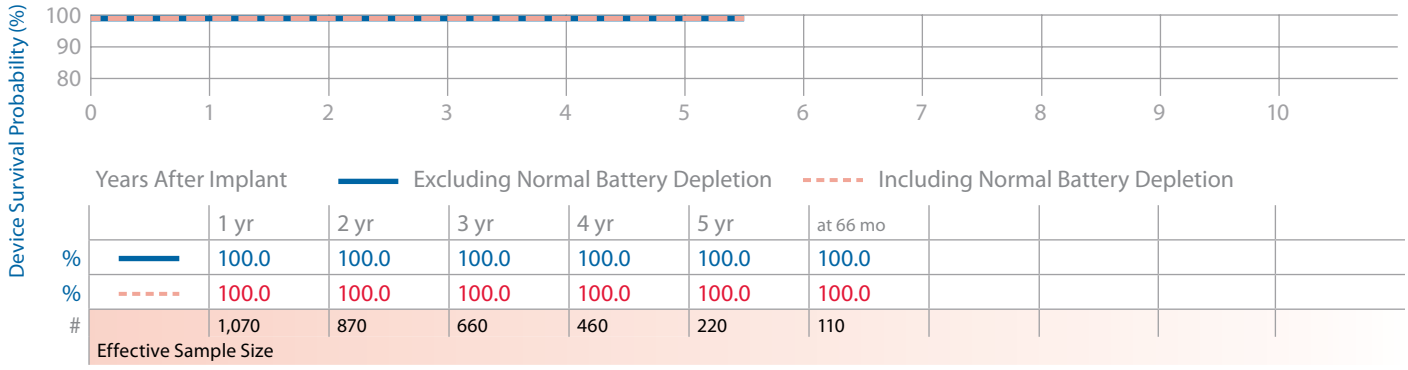
Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Adapta VDD ADVDD01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	0	NBG Code	VDD
Registered US Implants	1,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PWG, NWG
Estimated Active US Implants	760	**Therapy Function Compromised**	0	Estimated Longevity	See page 74
Normal Battery Depletions (US)	1				

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	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
%	100.0	100.0	100.0	100.0	100.0	100.0
#	1,070	870	660	460	220	110

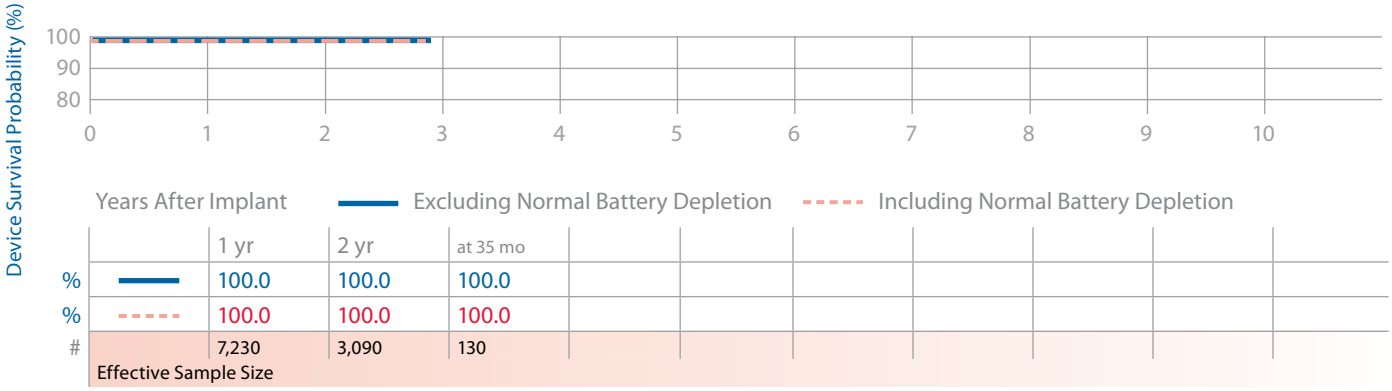
Effective Sample Size

Advisa DR / DR MRI+C82 A2DR01, A3DR01, A4DR01, A5DR01 Ensura MRI EN1DR01

Product Characteristics

US Market Release	Apr-11	Malfunctions (US)	0	NBG Code	OAE - DDDR OOE - DDDR
Registered US Implants	1,120	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZK, PZJ, PZL, PZW
Estimated Active US Implants	1,100	**Therapy Function Compromised**	0	Estimated Longevity	See page 74, 75
Normal Battery Depletions (US)	0				

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



	1 yr	2 yr	at 35 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	7,230	3,090	130

Effective Sample Size

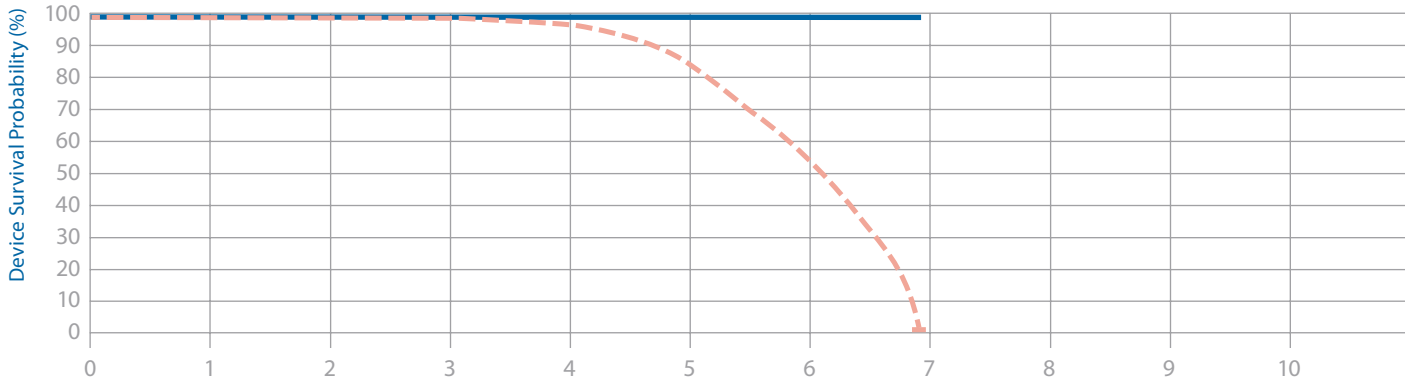
AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03
Registered US Implants	11,100
Estimated Active US Implants	900
Normal Battery Depletions (US)	2,808
Performance Note: See page 154 – 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 74



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 83 mo
%	———	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	- - - -	99.9	99.8	99.4	97.5	85.5	55.2	1.4
#	Effective Sample Size	10,700	9,960	9,150	8,290	6,280	2,880	180

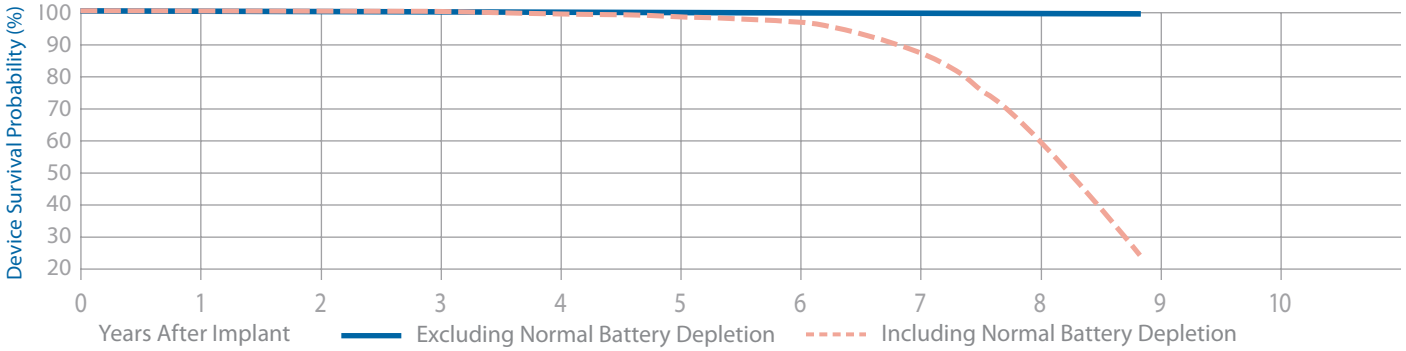
EnPulse DR E1DR01, E1DR03, E1DR06

Product Characteristics

US Market Release	Dec-03
Registered US Implants	6,800
Estimated Active US Implants	1,600
Normal Battery Depletions (US)	1,095
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	1

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

NBG Code	DDDR
Serial Number Prefix	PRA, PRB, PRE
Estimated Longevity	See page 74



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 106 mo
%	———	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	- - - -	100.0	100.0	99.8	99.0	98.1	96.6	86.9	60.1	24.4
#	Effective Sample Size	6,220	5,770	5,330	4,850	4,410	3,950	3,180	1,790	290

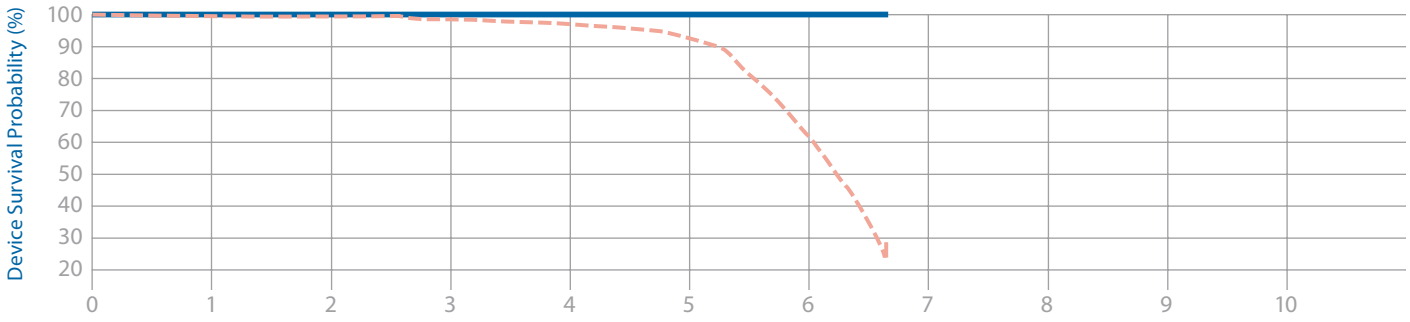
Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

EnPulse DR E1DR21

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	1,900	**Therapy Function Not Compromised**	0	Serial Number Prefix	PPT
Estimated Active US Implants	160	**Therapy Function Compromised**	0	Estimated Longevity	See page 74
Normal Battery Depletions (US)	373				

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



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

		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	99.6	98.6	96.2	91.9	61.3	23.4
#	Effective Sample Size	1,640	1,490	1,330	1,160	970	460	110

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

EnPulse 2 DR E2DR01, E2DR03, E2DR06, E2D01, E2D03

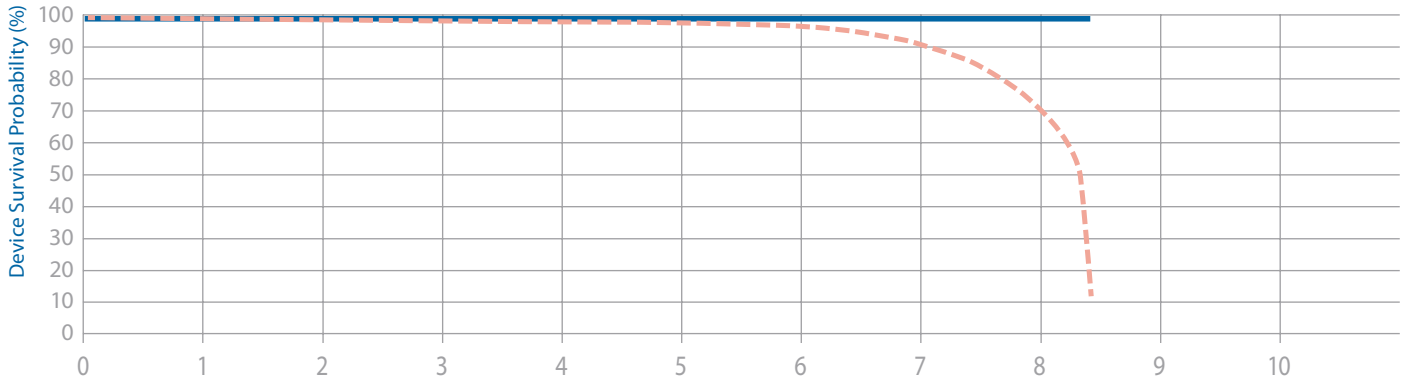
Product Characteristics

US Market Release	Feb-04
Registered US Implants	100,800
Estimated Active US Implants	45,100
Normal Battery Depletions (US)	5,735

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	28
Therapy Function Not Compromised	22
Electrical Component	17
Possible Early Battery Depletion	2
Other	3
Therapy Function Compromised	6
Electrical Component	3
Electrical Interconnect	2
Battery Malfunction	1

NBG Code	DDDR
Serial Number Prefix	PNB, PNC, PNH
Estimated Longevity	See page 74



		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	100.0	100.0	100.0
%	- - - -	99.9	99.9	99.8	99.4	98.7	97.2	91.5	70.5	13.0
#	Effective Sample Size	94,800	87,600	80,500	73,800	67,100	60,300	38,800	9,560	250

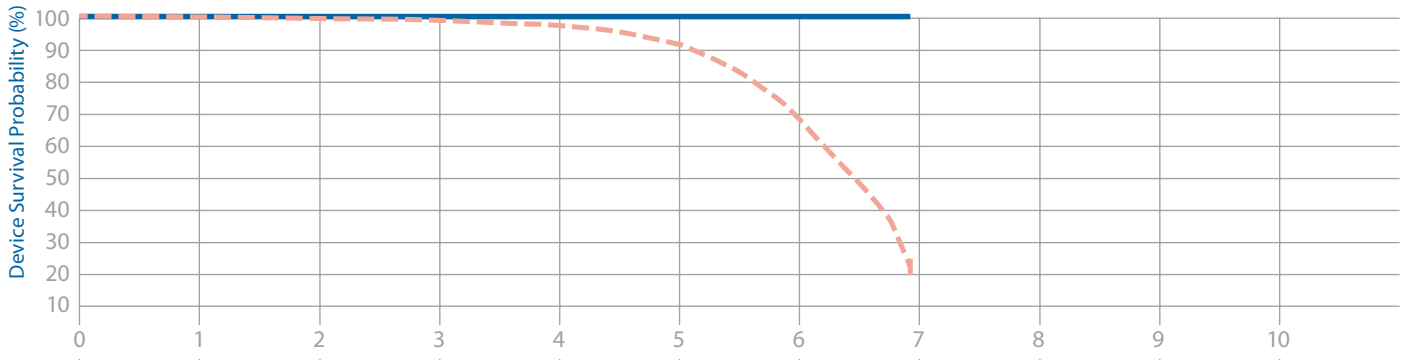
Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

EnPulse 2 DR E2DR21

Product Characteristics

US Market Release	Feb-04	Malfunctions (US)	1	NBG Code	DDDR
Registered US Implants	12,200	**Therapy Function Not Compromised**	0	Serial Number Prefix	PMU
Estimated Active US Implants	2,200	**Therapy Function Compromised**	1	Estimated Longevity	See page 74
Normal Battery Depletions (US)	1,907	Electrical Component	1		

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



		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	100.0	100.0
%	- - - -	99.9	99.5	98.9	97.1	91.0	68.1	21.4
#		10,900	9,740	8,750	7,650	6,290	3,650	310

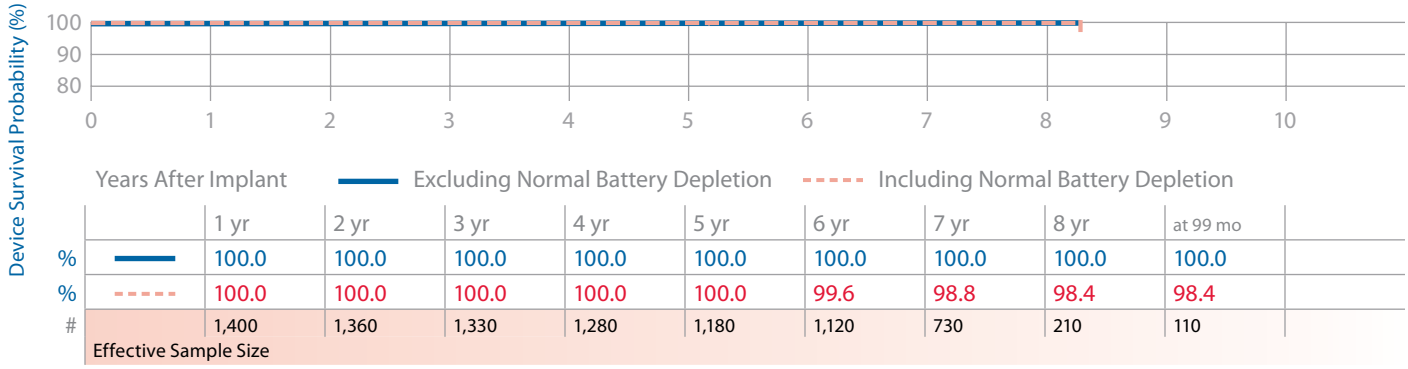
Effective Sample Size

EnPulse 2 DR E2DR31, E2DR33

Product Characteristics

US Market Release	Feb-04	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	590	**Therapy Function Not Compromised**	0	Serial Number Prefix	PNL, PNM
Estimated Active US Implants	400	**Therapy Function Compromised**	0	Estimated Longevity	See page 74
Normal Battery Depletions (US)	8				

Performance Note: See page 149 – 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	at 99 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	99.6	98.8	98.4	98.4
#		1,400	1,360	1,330	1,280	1,180	1,120	730	210	110

Effective Sample Size

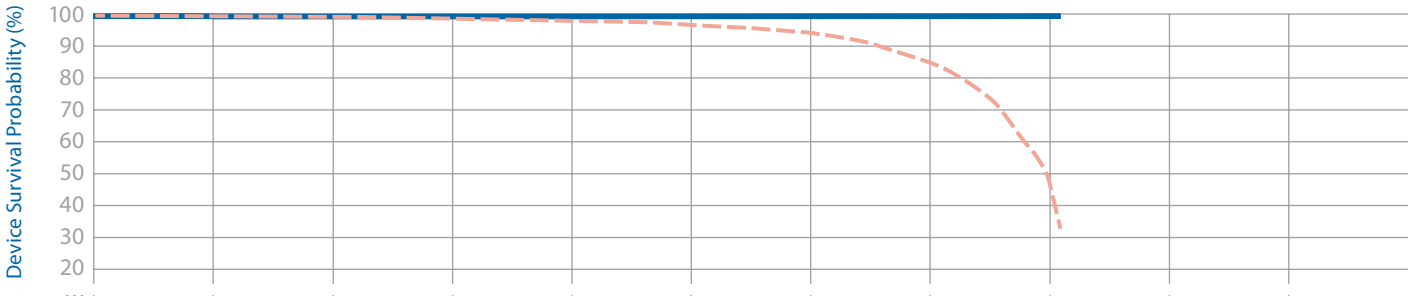
EnPulse 2 SR E2SR01, E2SR03, E2SR06

Product Characteristics

US Market Release	Dec-03
Registered US Implants	25,500
Estimated Active US Implants	7,200
Normal Battery Depletions (US)	1,341
Advisories	None

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

NBG Code	SSIR
Serial Number Prefix	PMW, PMY, PNA
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 97 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9
%	99.9	99.8	99.4	98.8	97.3	94.3	85.0	47.4	32.0
#	22,600	19,600	17,100	15,000	12,800	10,700	5,500	410	130

Effective Sample Size

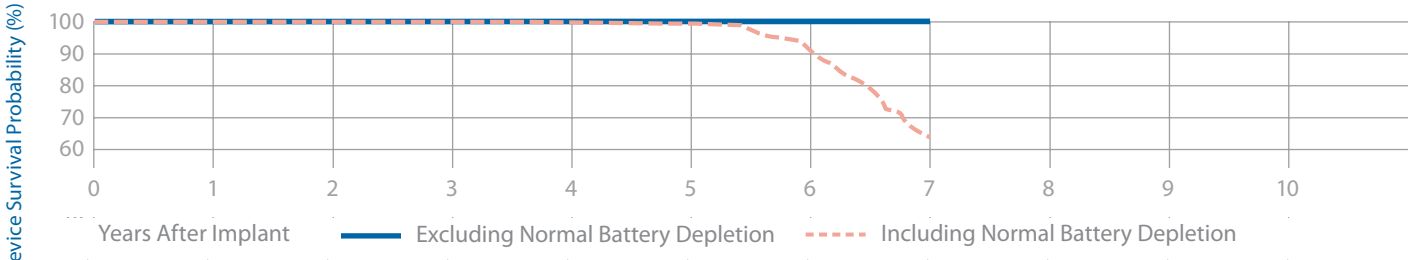
EnPulse 2 VDD E2VDD01

Product Characteristics

US Market Release	Dec-03
Registered US Implants	640
Estimated Active US Implants	190
Normal Battery Depletions (US)	66
Performance Note: See page 149 – 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 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.6	98.5	90.5	63.5
#	710	660	600	550	500	370	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

EnRhythm DR P1501DR

Product Characteristics

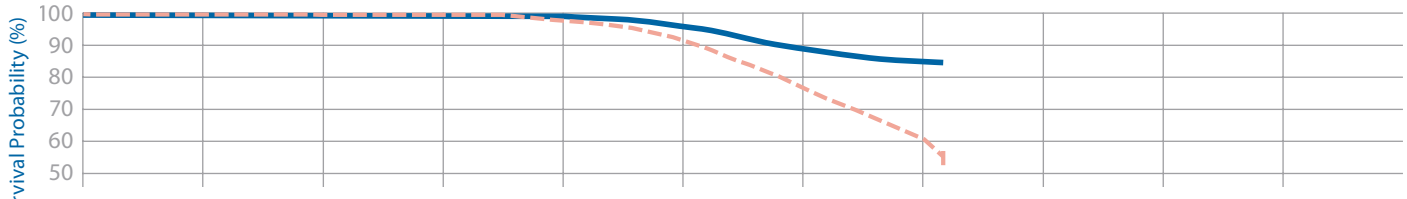
US Market Release	May-05
Registered US Implants	110,100
Estimated Active US Implants	67,300
Normal Battery Depletions (US)	1,013

Advisories: See page 140 – 2010 Low Battery Voltage Displayed at Device Interrogation

Performance Note: See page 151 – Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	5,950
Therapy Function Not Compromised	5,897
Battery *(215 malfunctions related to advisory)*	5,763
Electrical Component *(2 malfunctions related to advisory)*	38
Possible Early Battery Depletion	37
Electrical Interconnect	2
Other	57
Therapy Function Compromised	53
Electrical Component	37
Electrical Interconnect	4
Battery Malfunction	5
Possible Early Battery Depletion	2
Other	5

NBG Code	DDDRP
Serial Number Prefix	PNP
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	100.0	99.9	99.1	96.2	89.4	85.4	85.0
%	99.9	99.9	99.6	97.9	91.8	76.8	61.1	54.6
#	103,900	94,200	78,300	61,600	44,500	25,100	4,460	1,300

Effective Sample Size

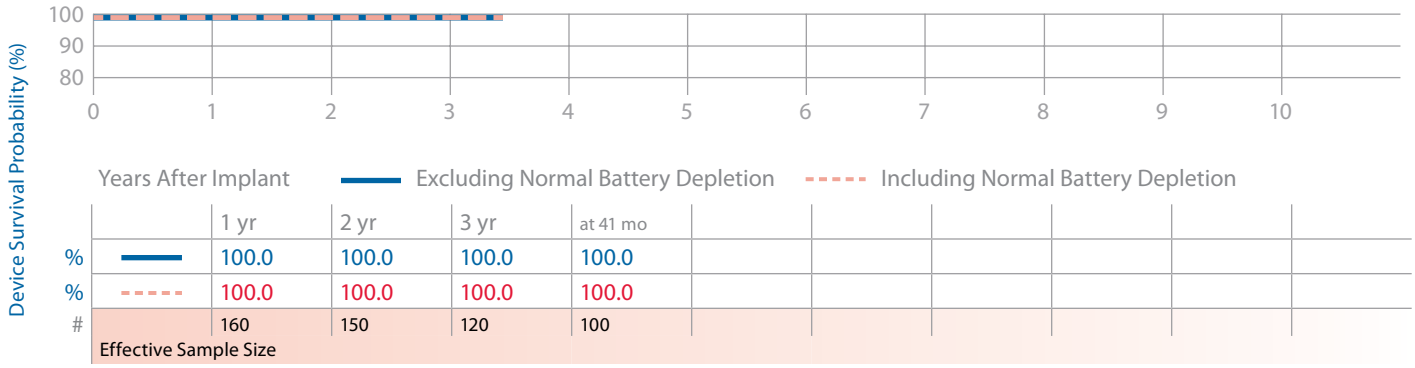
EnRhythm MRI EMDR01

Product Characteristics

US Market Release	N/A
Registered US Implants	110
Estimated Active US Implants	80
Normal Battery Depletions (US)	0
Advisories	None

Malfunctions (US)	6
Therapy Function Not Compromised	6
Battery Malfunction	6
Therapy Function Compromised	0

NBG Code	DDDRP
Serial Number Prefix	PTA
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	at 41 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0
#	160	150	120	100

Effective Sample Size

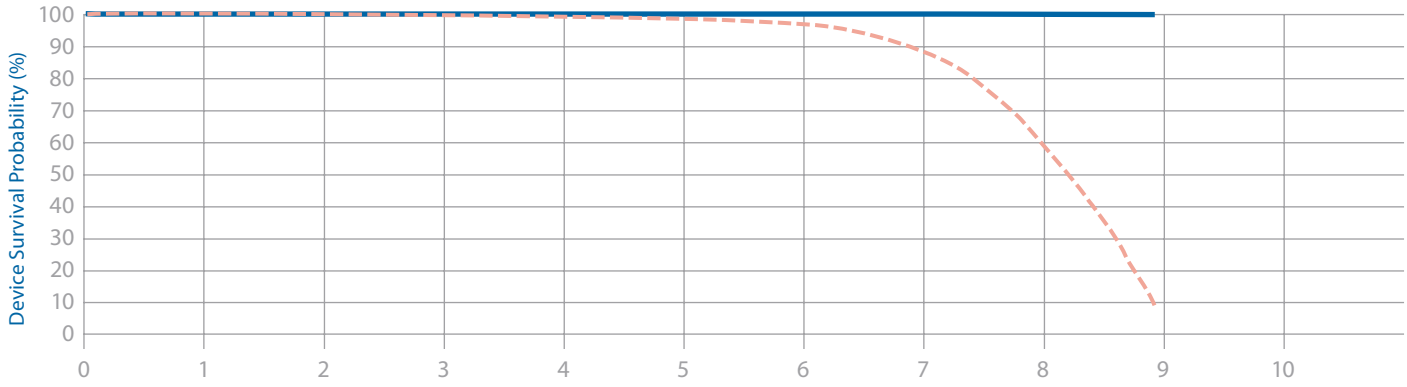
Kappa 400 DR KDR401, KDR403

Product Characteristics

US Market Release	Jan-98
Registered US Implants	46,600
Estimated Active US Implants	4,200
Normal Battery Depletions (US)	7,855
Advisories	None

Malfunctions (US)	27
Therapy Function Not Compromised	15
Electrical Component	10
Electrical Interconnect	1
Possible Early Battery Depletion	2
Other	2
Therapy Function Compromised	12
Electrical Component	6
Electrical Interconnect	6

NBG Code	DDD/RO
Serial Number Prefix	PER, PET
Estimated Longevity	See page 75



	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	99.9	99.9	99.9	99.9	99.9
%	99.9	99.8	99.7	99.4	98.8	97.1	88.1	58.9	8.0
#	44,200	41,100	37,900	34,800	31,400	27,700	21,200	9,730	670

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

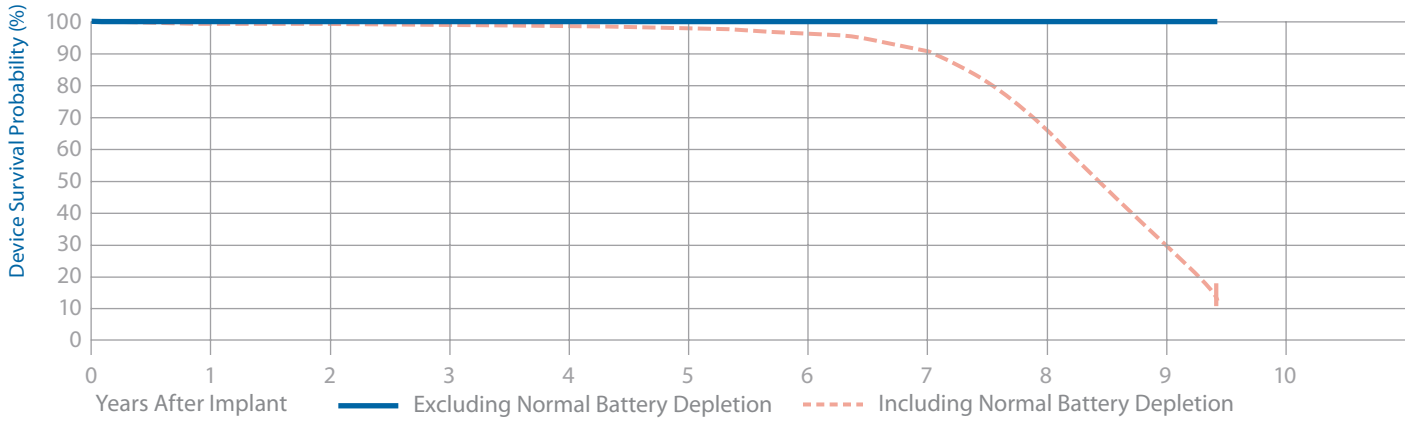
Kappa 400 SR KSR401, KSR403

Product Characteristics

US Market Release	Feb-98
Registered US Implants	15,300
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	1,512
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

NBG Code	SSIR
Serial Number Prefix	PEU, PGD
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.5	99.0	98.4	96.7	90.4	66.2	29.6	14.1
#	13,600	12,000	10,400	9,160	7,910	6,670	5,120	2,580	530	150

Effective Sample Size

Kappa 700 D KD701, KD703, KD706

Product Characteristics

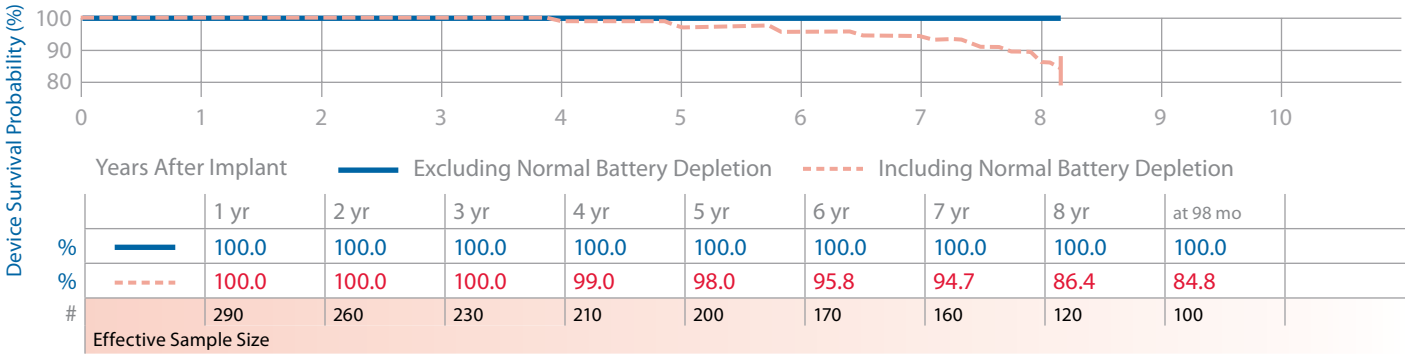
US Market Release	Jan-99
Registered US Implants	320
Estimated Active US Implants	67
Normal Battery Depletions (US)	21

Advisories: See page 143– 2009 Potential Separation of Interconnect Wires

Performance Note: See page 149 – 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 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 98 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.0	98.0	95.8	94.7	86.4	84.8
#	290	260	230	210	200	170	160	120	100

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

Product Characteristics

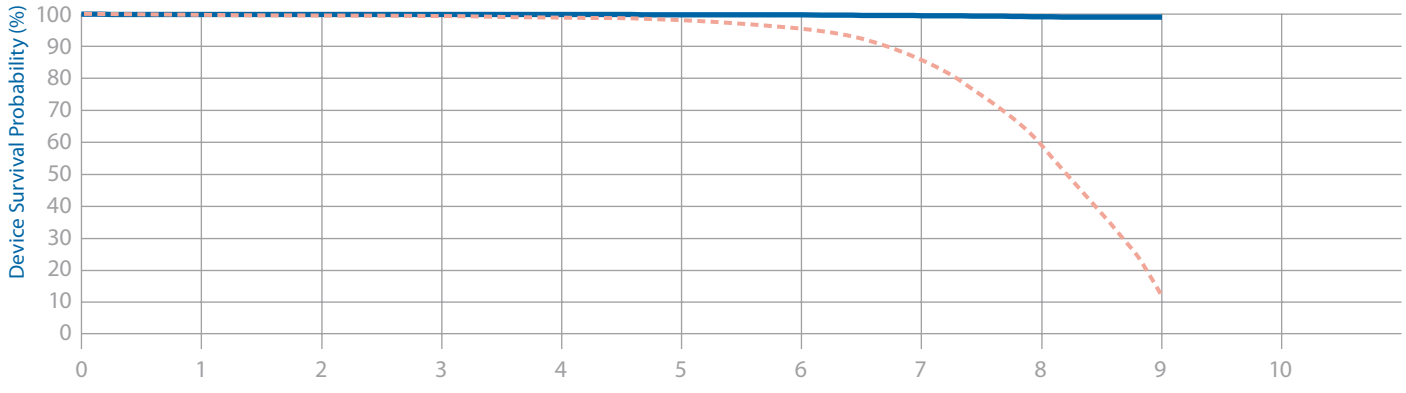
US Market Release	Jan-99
Registered US Implants	205,800
Estimated Active US Implants	23,800
Normal Battery Depletions (US)	34,757

Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	752
Therapy Function Not Compromised	63
Electrical Component	26
Electrical Interconnect	19
Battery Malfunction	1
Possible Early Battery Depletion	4
Other	13
Therapy Function Compromised	689
Electrical Component	17
Electrical Interconnect *(277 malfunctions related to advisory)*	671
Possible Early Battery Depletion	1

NBG Code	DDD/RO
Serial Number Prefix	PGU, PGY, PGW
Estimated Longevity	See page 75



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	———	100.0	99.9	99.9	99.9	99.9	99.9	99.7	99.6	99.4
%	- - - -	99.9	99.8	99.6	99.1	98.0	95.4	85.9	59.3	10.9
#		180,500	165,500	151,000	136,500	122,400	107,000	81,800	40,600	3,060

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Kappa 700 DR KDR721

Product Characteristics

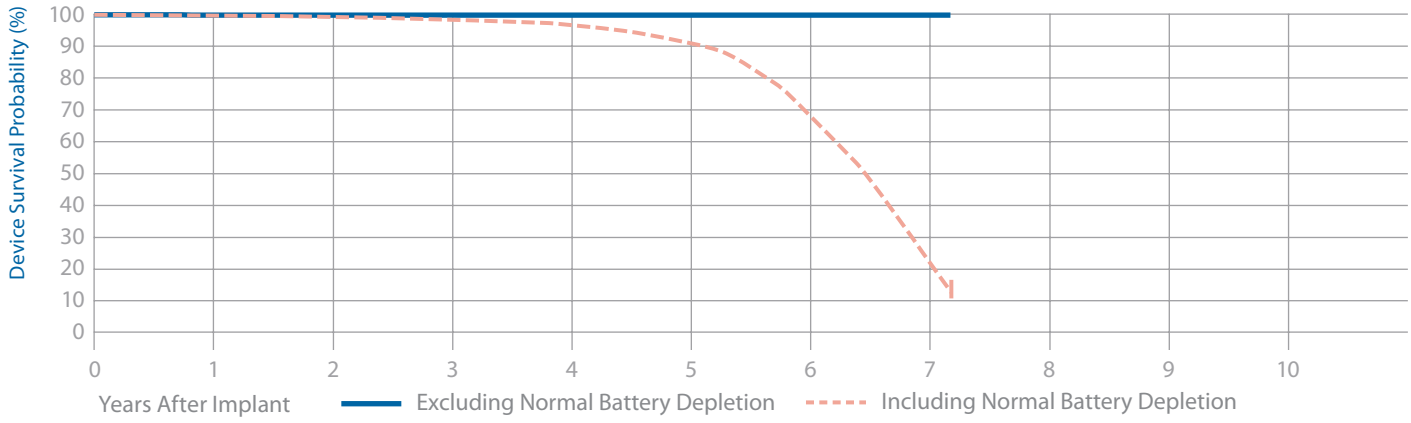
US Market Release	Feb-99
Registered US Implants	9,800
Estimated Active US Implants	750
Normal Battery Depletions (US)	1,346

Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 149 – 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

NBG Code	DDD/RO
Serial Number Prefix	PGR
Estimated Longevity	See page 75



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	———	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	- - - -	99.9	99.5	98.7	96.6	90.7	68.9	22.2	12.3
#		8,630	7,620	6,650	5,640	4,450	2,260	320	120

Effective Sample Size

Kappa 700 SR KSR701, KSR703, KSR706

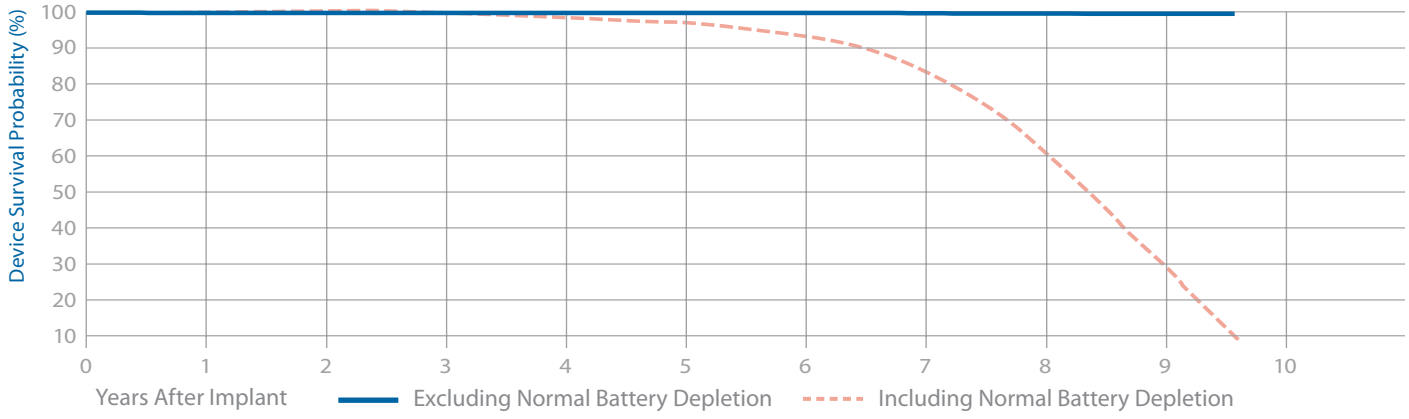
Product Characteristics

US Market Release	Jan-99
Registered US Implants	55,100
Estimated Active US Implants	6,000
Normal Battery Depletions (US)	5,100

Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	30
Therapy Function Not Compromised	6
Electrical Component	2
Electrical Interconnect	1
Possible Early Battery Depletion	1
Other	2
Therapy Function Compromised	24
Electrical Component	4
Electrical Interconnect *(17 malfunctions related to advisory)*	20

NBG Code	SSIR
Serial Number Prefix	PHT, PHW, PHU
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 115 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8
%	99.9	99.7	99.3	98.5	97.0	93.6	84.4	61.5	29.2	9.1
#	48,300	41,700	35,700	30,600	26,000	21,400	15,400	7,640	1,640	150
Effective Sample Size										

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Kappa 800 DR KDR801, KDR803

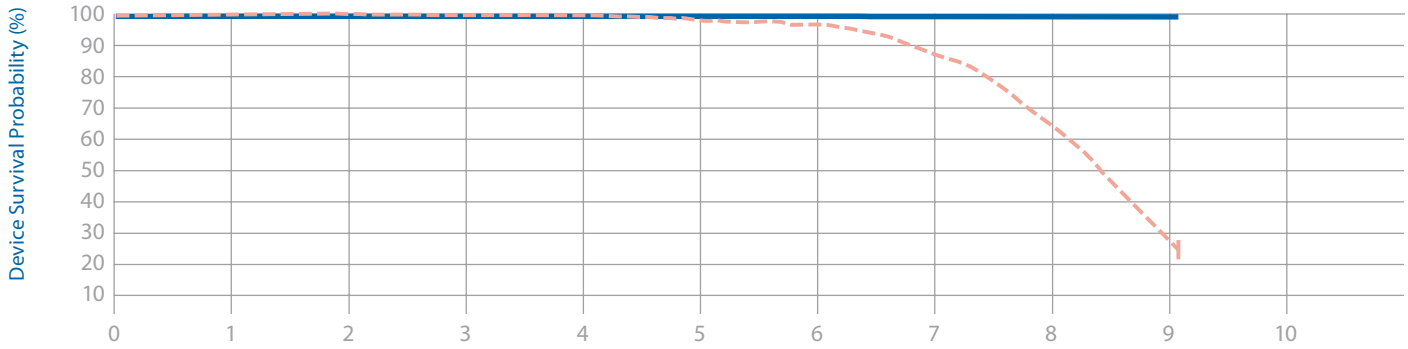
Product Characteristics

US Market Release	Jan-02
Registered US Implants	4,300
Estimated Active US Implants	540
Normal Battery Depletions (US)	736

Performance Note: See page 149 – 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 75



	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	99.9	99.9	99.9	99.9
%	100.0	99.8	99.6	99.4	98.6	96.5	87.6	64.8	28.1	23.8
#	4,580	4,250	3,910	3,590	3,260	2,940	2,390	1,340	220	170

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Kappa 900 DR KDR901, KDR903, KDR906

Product Characteristics

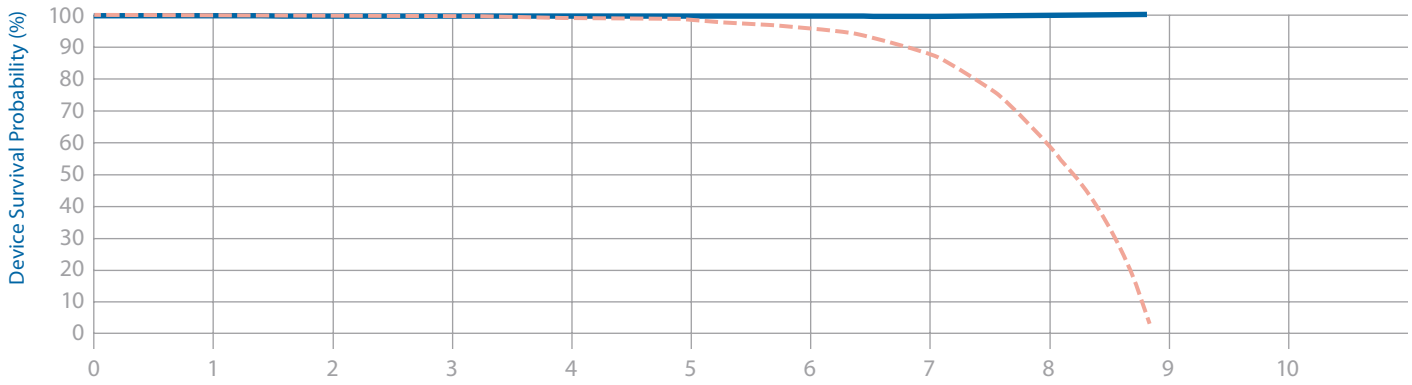
US Market Release	Jan-02
Registered US Implants	125,200
Estimated Active US Implants	26,100
Normal Battery Depletions (US)	19,708

Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	79
Therapy Function Not Compromised	26
Electrical Component	16
Electrical Interconnect	4
Other	6
Therapy Function Compromised	53
Electrical Component	9
Electrical Interconnect	44

NBG Code	DDR/RO
Serial Number Prefix	PKM, PKN, PKP
Estimated Longevity	See page 75



		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	99.9
%	- - - - -	99.9	99.9	99.7	99.3	98.4	96.3	87.9	60.2	4.0
#	Effective Sample Size	117,400	108,000	98,900	90,200	81,500	72,400	55,000	25,800	1,030

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Kappa 900 SR KSR901, KSR903, KSR906

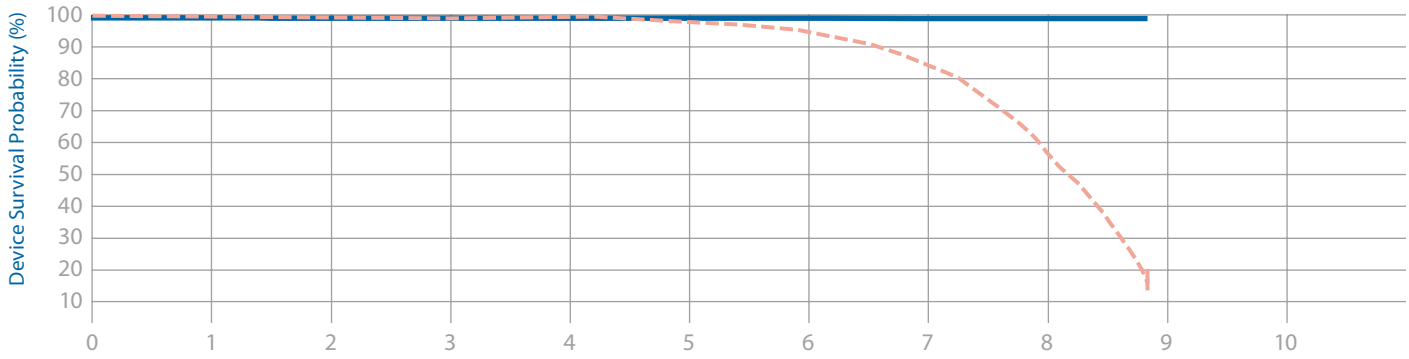
Product Characteristics

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	6,200
Normal Battery Depletions (US)	3,176

Advisories: See page 143 – 2009
Potential Separation of Interconnect Wires

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

NBG Code	SSIR
Serial Number Prefix	PLF, PLG, PLH
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 106 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.7	99.4	98.7	97.4	94.5	85.2	56.3	15.6
#	32,000	27,600	24,000	20,700	17,700	14,900	9,880	3,670	270

Effective Sample Size

Kappa 900 VDD KVDD901

Product Characteristics

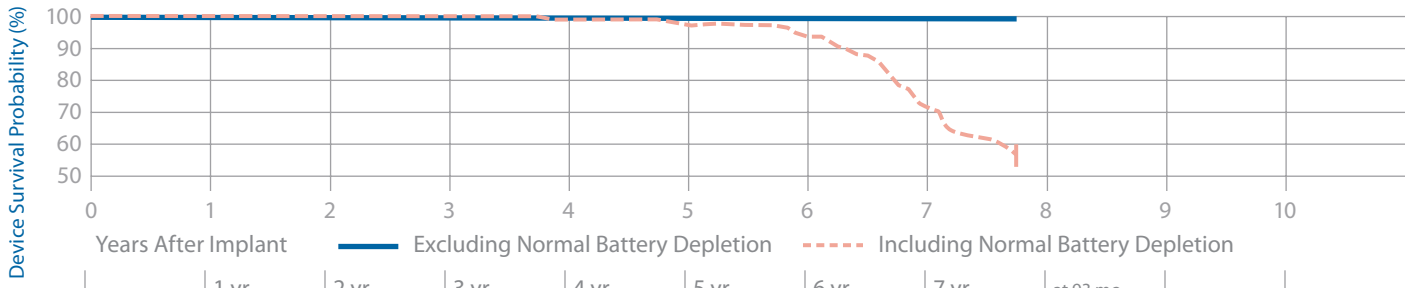
US Market Release	Jan-02
Registered US Implants	650
Estimated Active US Implants	75
Normal Battery Depletions (US)	81

Advisories: See page 143 – 2009
Potential Separation of Interconnect Wires

Performance Note: See page 149 –
Performance note on Dual Chamber
Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	1
Therapy Function Not Compromised	1
Other	1
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PLE
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	100.0	100.0	100.0	100.0	100.0	99.8	99.8	99.8
%	100.0	100.0	100.0	99.3	98.6	93.9	71.1	56.3
#	770	710	660	600	560	460	230	110

Effective Sample Size

Kappa 920 DR KDR921

Product Characteristics

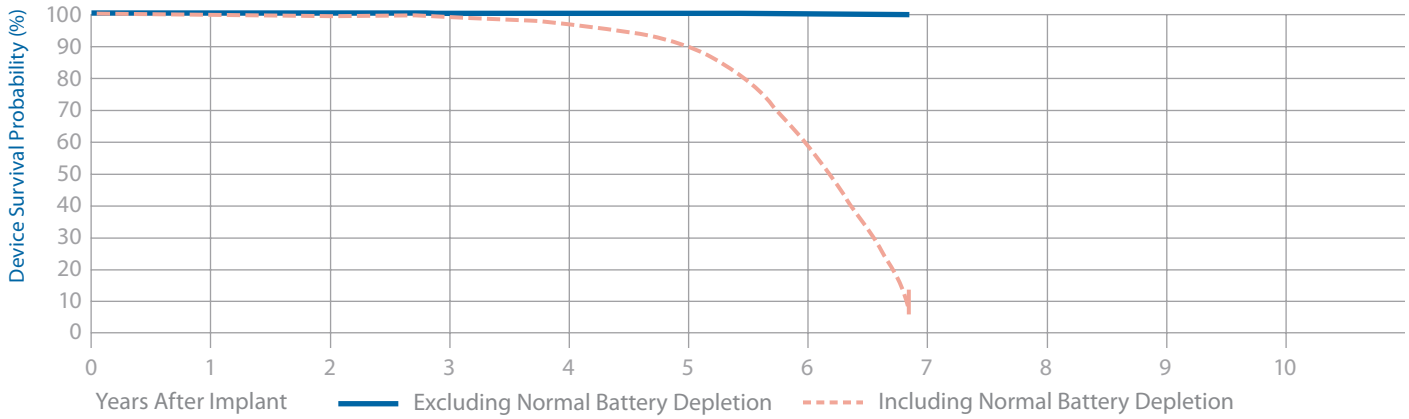
US Market Release	Jan-02
Registered US Implants	16,300
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	2,779

Advisories: See page 143 – 2009
Potential Separation of Interconnect Wires

Performance Note: See page 149 –
Performance note on Dual Chamber
Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	5
Therapy Function Not Compromised	2
Electrical Component	1
Other	1
Therapy Function Compromised	3
Electrical Interconnect *(3 malfunctions related to advisory)*	3

NBG Code	DDD/RO
Serial Number Prefix	PKR
Estimated Longevity	See page 75



	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
%	99.8	99.6	99.0	96.9	89.8	59.7	9.6
#	14,200	12,700	11,200	9,720	7,720	3,520	250

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

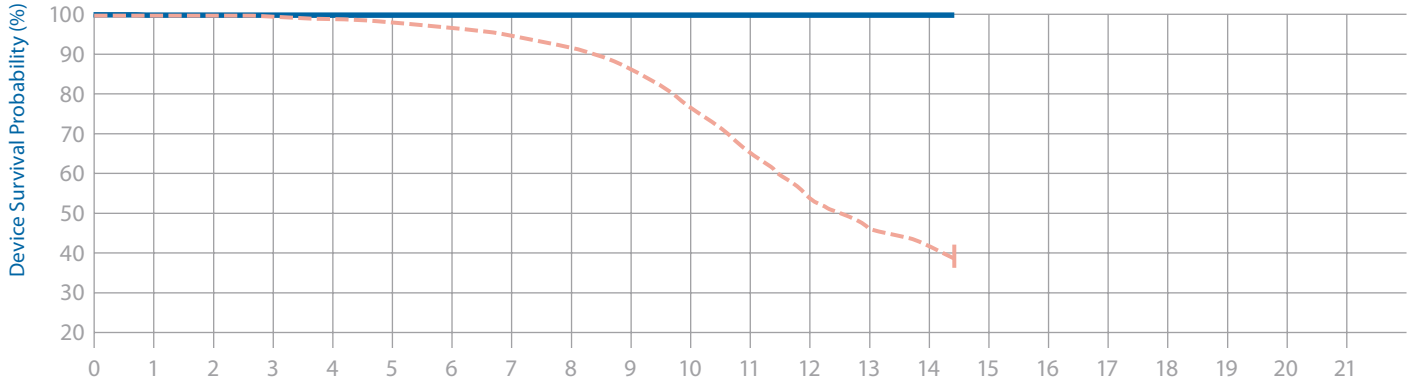
Prodigy SR 8158, 8160, 8161, 8162

Product Characteristics

US Market Release	Oct-95
Registered US Implants	22,200
Estimated Active US Implants	2,200
Normal Battery Depletions (US)	1,396
Advisories	None

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

NBG Code	SSIR
Serial Number Prefix	PEM, PED, PEE, PEF
Estimated Longevity	See page 75



	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 173 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
%	99.8	99.6	99.2	98.6	97.8	96.7	95.0	91.9	87.1	77.1	66.1	55.1	46.1	42.0	38.7
#	19,700	17,000	14,700	12,600	10,700	9,110	7,660	6,330	5,010	3,670	2,530	1,690	1,140	430	110

Effective Sample Size

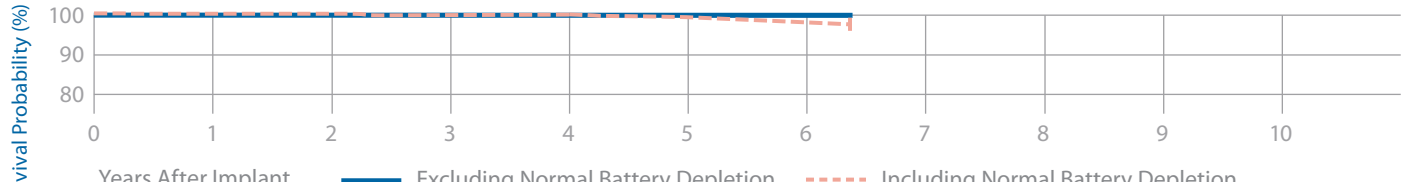
Sensia DR SEDR01, SED01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	119,100
Estimated Active US Implants	90,100
Normal Battery Depletions (US)	171
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ER	

Malfunctions (US)	24
Therapy Function Not Compromised	14
Electrical Component	11
Electrical Interconnect	1
Other	2
Therapy Function Compromised	10
Electrical Component	4
Electrical Interconnect	1
Other	5

NBG Code	DDD, DDDR
Serial Number Prefix	PWL, PWK, NWL, NWK
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 76 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.6	99.1	98.5	98.3
#	97,700	75,200	53,800	33,400	15,900	3,270	540

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

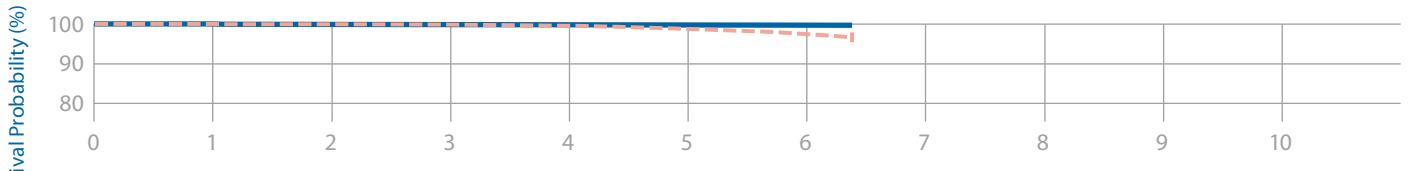
Sensia SR SESR01, SES01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	83,000
Estimated Active US Implants	58,000
Normal Battery Depletions (US)	135
Advisories	None

Malfunctions (US)	7
Therapy Function Not Compromised	6
Electrical Component	4
Other	2
Therapy Function Compromised	1
Electrical Interconnect	1

NBG Code	SSIR, SSI
Serial Number Prefix	PWR, PWS, NWR, NWS
Estimated Longevit	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 76 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.6	99.0	97.6	96.6
#	65,000	47,000	31,700	18,300	8,190	1,550	170

Effective Sample Size

Sigma 100 S SS103, SS106

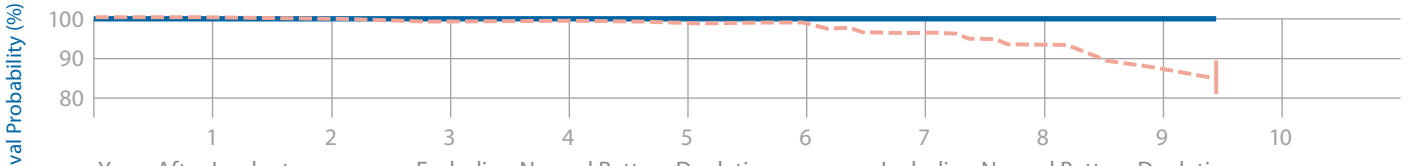
Product Characteristics

US Market Release	Aug-99
Registered US Implants	830
Estimated Active US Implants	110
Normal Battery Depletions (US)	26

Advisories: See page 147 – 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 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 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	99.6	99.6	98.8	98.8	97.0	93.7	85.3	82.2
#	620	490	390	320	250	220	190	150	120	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Sigma 200 DR SDR203

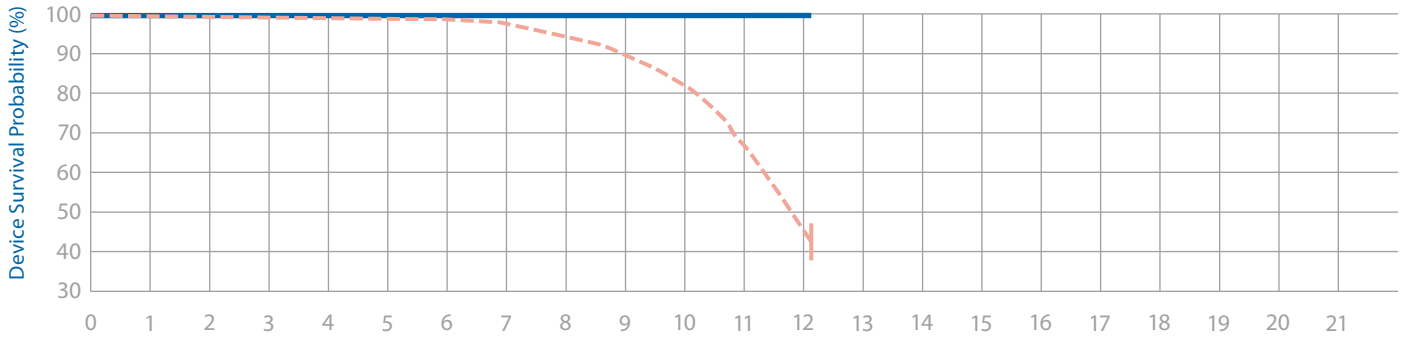
Product Characteristics

US Market Release	Aug-99
Registered US Implants	15,900
Estimated Active US Implants	3,300
Normal Battery Depletions (US)	828

Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	35
Therapy Function Not Compromised	12
Electrical Component	1
Electrical Interconnect *(1 malfunction related to advisory*	10
Other	1
Therapy Function Compromised	23
Electrical Component	1
Electrical Interconnect *(21 malfunctions related to advisory*	21
Other	1

NBG Code	DDD/RO
Serial Number Prefix	PJD
Estimated Longevity	See page 76



	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	99.9	99.9	99.8	99.6	99.5	99.5	99.5	99.5	99.5
%	100.0	99.9	99.9	99.7	99.4	98.8	97.3	94.3	90.5	83.5	69.4	48.8	42.6
#	14,200	12,700	11,300	10,100	9,010	7,970	6,930	5,860	4,670	3,230	1,670	260	170

Effective Sample Size

Sigma 200 SR SSR203, SS203

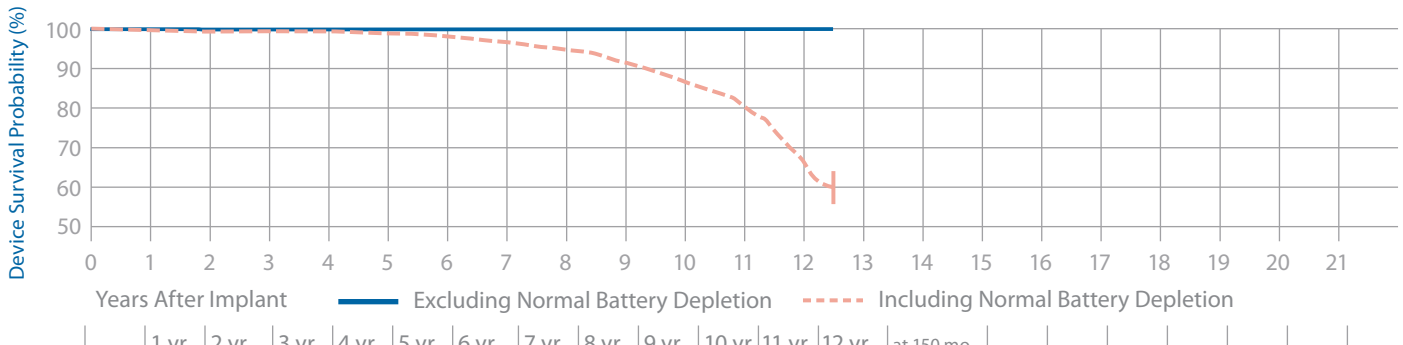
Product Characteristics

US Market Release	Sep-99
Registered US Implants	12,100
Estimated Active US Implants	1,800
Normal Battery Depletions (US)	397

Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	13
Therapy Function Not Compromised	0
Therapy Function Compromised	13
Electrical Interconnect *(13 malfunctions related to advisory)*	13

NBG Code	SSIR
Serial Number Prefix	PJG
Estimated Longevity	See page 76



	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
%	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.7	99.7	99.7	99.7	99.7	99.7
%	99.9	99.9	99.8	99.7	99.2	98.6	97.2	95.2	92.3	86.6	76.2	65.6	59.6
#	10,300	8,740	7,430	6,380	5,480	4,750	4,060	3,510	2,830	2,040	1,250	460	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Sigma 300 DR SDR303, SDR306

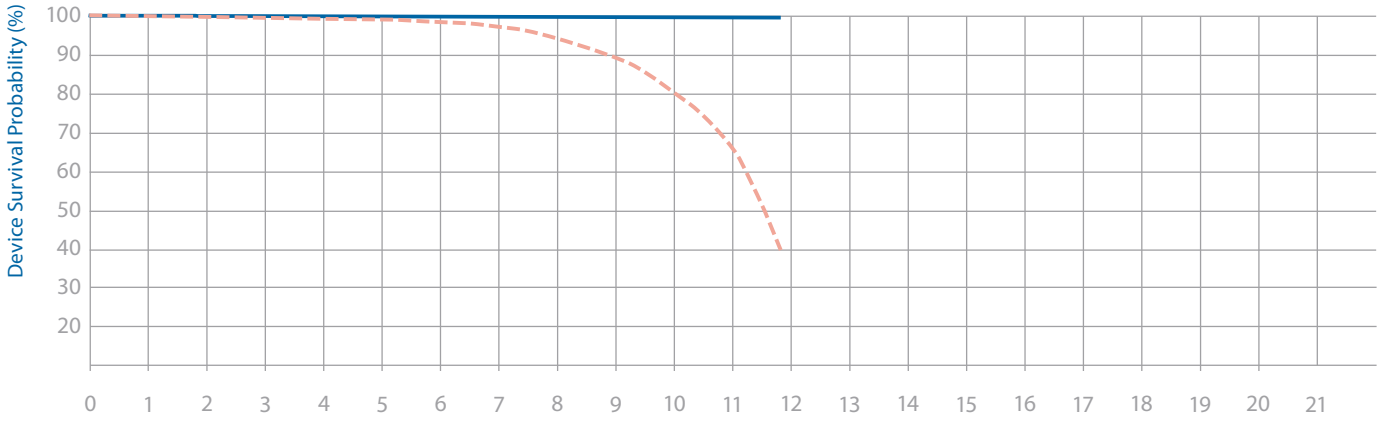
Product Characteristics

US Market Release	Aug-99
Registered US Implants	106,600
Estimated Active US Implants	30,000
Normal Battery Depletions (US)	3,874

Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	245
Therapy Function Not Compromised	58
Electrical Component	6
Electrical Interconnect *(7 malfunctions related to advisory)*	41
Possible Early Battery Depletion	1
Other	10
Therapy Function Compromised	187
Electrical Component	7
Electrical Interconnect *(163 malfunctions related to advisory)*	179
Other	1

NBG Code	DDD/RO
Serial Number Prefix	PJD, PJE
Estimated Longevity	See page 76



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 143 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.7	99.6	99.5	99.4	99.4	99.4
%	99.9	99.9	99.8	99.6	99.3	98.8	97.7	95.1	91.0	83.6	69.4	39.5
#	96,600	86,500	77,400	69,000	61,300	53,000	43,500	33,500	24,000	14,400	6,340	480

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Sigma 300 SR SSR303, SSR306

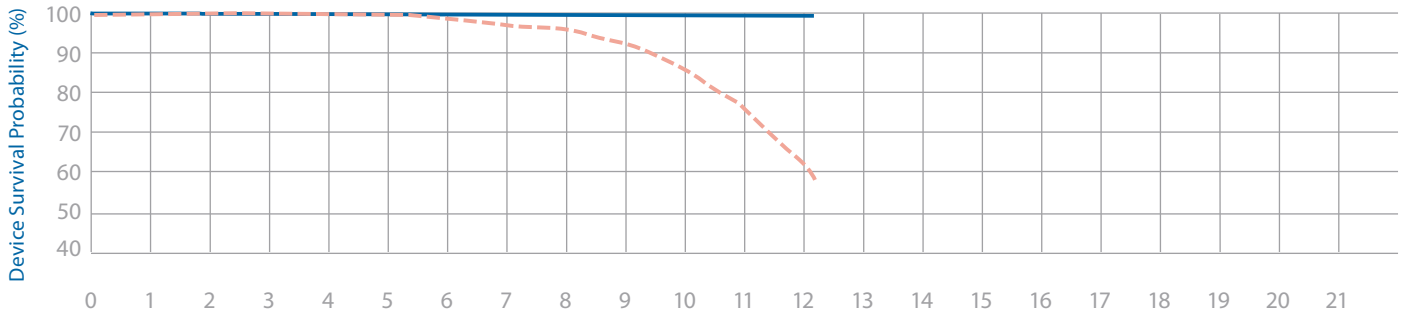
Product Characteristics

US Market Release	Aug-99
Registered US Implants	54,000
Estimated Active US Implants	10,800
Normal Battery Depletions (US)	1,243

Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	52
Therapy Function Not Compromised	11
Electrical Component	1
Electrical Interconnect *(4 malfunctions related to advisory)*	8
Other	2
Therapy Function Compromised	41
Electrical Component	3
Electrical Interconnect *(37 malfunctions related to advisory)*	38

NBG Code	SSIR
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 76



	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 146 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.7	99.7	99.7	99.6	99.6	98.6
%	99.9	99.9	99.7	99.5	99.2	98.6	97.5	95.6	92.1	85.8	76.0	62.7	58.2
#	47,100	40,000	34,100	29,300	25,300	21,000	16,800	13,000	9,320	5,640	2,810	580	250

Effective Sample Size

Sigma 300 VDD SVDD303

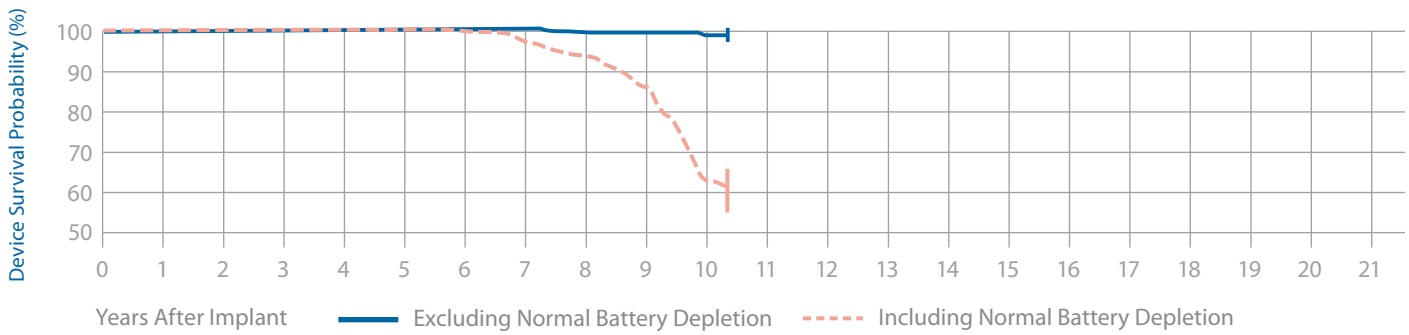
Product Characteristics

US Market Release	Sep-99
Registered US Implants	650
Estimated Active US Implants	81
Normal Battery Depletions (US)	67

Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Interconnect *(1 malfunction related to advisory)*	1

NBG Code	VDDD
Serial Number Prefix	PJD
Estimated Longevity	See page 76



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 124 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.2	99.2	98.8	98.8
%	100.0	100.0	100.0	100.0	99.7	99.1	96.6	93.2	85.8	63.4	61.2
#	890	820	770	720	660	610	540	460	320	140	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

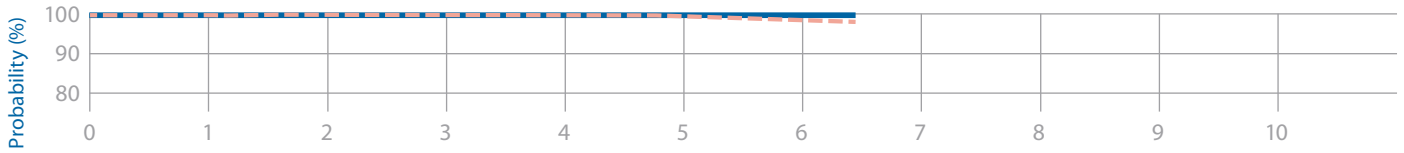
Versa DR VEDR01

US Market Release	Jul-06
Registered US Implants	93,900
Estimated Active US Implants	71,700
Normal Battery Depletions (US)	164
Performance Note: See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	15
Therapy Function Not Compromised	9
Electrical Component	4
Electrical Interconnect	2
Other	3
Therapy Function Compromised	6
Electrical Component	2
Other	4

Product Characteristics

NBG Code	DDDR
Serial Number Prefix	PWH, NWH
Estimated Longevity	See page 76



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.9	99.7	99.2	98.3	98.1
#	81,000	64,400	47,600	31,700	16,900	4,180	160

Effective Sample Size

Revo MRI SureScan RVDR01

US Market Release	Feb-11
Registered US Implants	52,000
Estimated Active US Implants	50,300
Normal Battery Depletions (US)	0
Advisories	None

Malfunctions (US)	17
Therapy Function Not Compromised	16
Electrical Component	3
Other	13
Therapy Function Compromised	1
Electrical Component	1

Product Characteristics

NBG Code	DDDRP
Serial Number Prefix	PTN
Estimated Longevity	See page 76

	1 yr	2 yr	at 25 mo
%	100.0	99.9	100.0
%	99.9	99.8	99.8
#	25,200	1,310	290

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	9 yr	10 yr	11 yr
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Jul-06	342,700	281,900	375	22	+	42	=	64	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 77 mo				
	See page 149 – 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	99.8 +0.0/-0.0	99.4 +0.0/-0.1	98.8 +0.1/-0.1	98.8 +0.1/-0.1 at 77 mo				
Adapta DR	ADDRL1	Jul-06	73,900	66,700	23	3	+	9	=	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	100.0 +0.0/-0.0 at 76 mo				
	See page 149 – 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	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.4 +0.2/-0.3	99.4 +0.2/-0.3 at 76 mo				
Adapta DR	ADDRS1	Jul-06	33,300	24,900	274	4	+	5	=	9	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 74 mo				
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	98.8 +0.2/-0.2	95.6 +0.5/-0.5	83.6 +1.7/-1.9	81.5 +2.5/-2.9 at 74 mo				
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	64,600	45,500	151	4	+	4	=	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 at 76 mo				
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.4 +0.1/-0.1	98.7 +0.2/-0.2	97.4 +0.4/-0.4	97.3 +0.4/-0.5 at 76 mo				
Adapta VDD	ADVDD01	Jul-06	1,000	760	1	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 66 mo					
	See page 149 – 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	100.0 +0.0/-0.0 at 66 mo					
Advisa DR MRI+C82 Ensura	A2DR01, A3DR01, A4DR01, A5DR01, ENDR01	Apr-11	1,120	1,100	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 at 35 mo								
	See page 149 – 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 at 35 mo								
AT500	AT501, 7253	Mar-03	11,100	900	2,808	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 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 83 mo				
	See page 154 – 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	99.4 +0.1/-0.2	97.5 +0.3/-0.3	85.5 +0.8/-0.8	55.2 +1.2/-1.3	1.4 +0.7/-0.5 at 83 mo				

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

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	9 yr	10 yr	11 yr
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	6,800	1,600	1,095	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	100.0 +0.0/-0.0 at 106 mo		
	See page 149 – 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 +0.1/-0.2	99.0 +0.2/-0.3	98.1 +0.3/-0.4	96.6 +0.5/-0.6	86.9 +1.0/-1.1	60.1 +1.7/-1.7	24.4 +2.0/-1.9 at 106 mo		
EnPulse DR	E1DR21	Dec-03	1,900	160	373	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 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.6 +0.2/-0.5	98.6 +0.5/-0.8	96.2 +0.9/-1.2	91.9 +1.4/-1.7	61.3 +3.2/-3.3	23.4 +3.8/-3.6 at 80 mo				
EnPulse 2 DR	E2DR01, E2DR03, E2DR06, E2D01, E2D03	Feb-04	100,800	45,100	5,735	6	+	22	=	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	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 101 mo		
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.1/-0.1	98.7 +0.1/-0.1	97.2 +0.1/-0.1	91.5 +0.2/-0.2	70.5 +0.6/-0.6	13.0 +3.0/-2.7 at 101 mo		
EnPulse 2 DR	E2DR21	Feb-04	12,200	2,200	1,907	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 83 mo				
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.1	99.5 +0.1/-0.2	98.9 +0.2/-0.2	97.1 +0.3/-0.4	91.0 +0.6/-0.7	68.1 +1.2/-1.2	21.4 +2.0/-1.9 at 83 mo				
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	590	400	8	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 99 mo		
	See page 149 – 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	99.6 +0.2/-0.5	98.8 +0.5/-0.9	98.4 +0.7/-1.2	98.4 +0.7/-1.2 at 99 mo		
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,500	7,200	1,341	1	+	5	=	6	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.4 at 97 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.4 +0.1/-0.1	98.8 +0.2/-0.2	97.3 +0.2/-0.3	94.3 +0.4/-0.4	85.0 +0.7/-0.7	47.4 +2.5/-2.5	32.0 +4.2/-4.1 at 97 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	9 yr	10 yr	11 yr
EnPulse 2 VDD	E2VDD01	Dec-03	640	190	66	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				
	See page 149 – 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	99.6 +0.3/-0.9	98.5 +0.7/-1.5	90.5 +2.4/-3.2	63.5 +5.5/-6.2				
EnRhythm DR	P1501DR	May-05	110,100	67,300	1,013	53	+	5,897	=	5,950	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.1 +0.1/-0.1	96.2 +0.2/-0.2	89.4 +0.3/-0.3	85.4 +0.4/-0.4	85.0 +0.4/-0.4 at 86 mo			
	See page 140 – 2010 Low Battery Voltage Displayed at Device Interrogation Advisories:					(0)	+	(217)	=	217 (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.0/-0.0	97.9 +0.1/-0.1	91.8 +0.2/-0.2	76.8 +0.4/-0.4	61.1 +0.6/-0.6	54.6 +1.1/-1.1 at 86 mo			
	See page 151 – Performance note on anomalies in MOSFET Integrated Circuit Technology																					
EnRhythm MRI	EMDR01	N/A	110	80	0	0	+	6	=	6	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 41 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 41 mo							
Kappa 400 DR	KDR401, KDR403	Jan-98	46,600	4,200	7,855	12	+	15	=	27	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 107 mo		
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.7 +0.0/-0.1	99.4 +0.1/-0.1	98.8 +0.1/-0.1	97.1 +0.2/-0.2	88.1 +0.4/-0.4	58.9 +0.7/-0.7	8.0 +0.7/-0.7 at 107 mo		
Kappa 400 SR	KSR401, KSR403	Feb-98	15,300	1,500	1,512	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 113 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.2/-0.2	98.4 +0.2/-0.3	96.7 +0.4/-0.4	90.4 +0.7/-0.7	66.2 +1.3/-1.4	14.1 +1.9/-1.8 at 113 mo		
Kappa 700 DR	KD701, KD703, KD706	Jan-99	320	67	21	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 98 mo		
	See page 143 – 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 +0.7/-2.7	98.0 +1.2/-3.2	95.8 +2.1/-4.0	94.7 +2.4/-4.3	86.4 +4.5/-6.4	84.8 +4.9/-6.8 at 98 mo		
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																					

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	9 yr	10 yr	11 yr
Kappa 700 DR	KDR701, KDR703, KDR706	Jan-99	205,800	23,800	34,757	689	+ 63	= 752	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	99.7 +0.0/-0.0	99.6 +0.0/-0.0	99.4 +0.1/-0.1		
	See page 143 – 2009 Potential Separation of Interconnect Wires					(277)	+ (0)	= (277) (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	99.1 +0.0/-0.0	98.0 +0.1/-0.1	95.4 +0.1/-0.1	85.9 +0.2/-0.2	59.3 +0.3/-0.3	10.9 +0.4/-0.4		
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																			
Kappa 700 DR	KDR721	Feb-99	9,800	750	1,346	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 86 mo			
	See page 143 – 2009 Potential Separation of Interconnect Wires					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.1/-0.1	99.5 +0.1/-0.2	98.7 +0.2/-0.3	96.6 +0.4/-0.5	90.7 +0.7/-0.8	68.9 +1.4/-1.5	22.2 +2.0/-1.9	12.3 +2.0/-1.9 at 86 mo			
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																			
Kappa 700 SR	KSR701, KSR703, KSR706	Jan-99	55,100	6,000	5,100	24	+ 6	= 30	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 115 mo		
	See page 143 – 2009 Potential Separation of Interconnect Wires					(17)	+ (0)	= (17) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.3 +0.1/-0.1	98.5 +0.1/-0.1	97.0 +0.2/-0.2	93.6 +0.3/-0.3	84.4 +0.5/-0.5	61.5 +0.8/-0.8	9.1 +1.3/-1.2 at 115 mo		
Kappa 800 DR	KDR801, KDR803	Jan-02	4,300	540	736	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/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 109 mo		
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI								Including Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.2	99.6 +0.1/-0.2	99.4 +0.2/-0.3	98.6 +0.3/-0.4	96.5 +0.6/-0.7	87.6 +1.1/-1.2	64.8 +1.9/-1.9	23.8 +2.7/-2.6 at 109 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
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,200	26,100	19,708	53	26	79	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 at 107 mo			
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.3 +0.0/-0.1	98.4 +0.1/-0.1	96.3 +0.1/-0.1	87.9 +0.2/-0.2	60.2 +0.4/-0.4	4.0 +0.5/-0.4 at 107 mo			
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	6,200	3,176	9	8	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	99.9 +0.0/-0.1 at 106 mo			
	Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires					(8) (advisory-related subset)	(0)	(8)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.7 +0.1/-0.2	97.4 +0.2/-0.2	94.5 +0.3/-0.3	85.2 +0.6/-0.6	56.3 +1.0/-1.1	15.6 +1.6/-1.5 at 106 mo			
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 900 VDD	KVDD901	Jan-02	650	75	81	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	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4 at 93 mo				
	Advisories: See page 143 – 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	99.3 +0.4/-1.0	98.6 +0.7/-1.3	93.9 +1.8/-2.4	71.1 +4.3/-4.8	56.3 +5.5/-5.9 at 93 mo				
Kappa 920 DR	KDR921	Jan-02	16,300	1,500	2,779	3	2	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	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 82 mo					
	Advisories: See page 143 – 2009 Potential Separation of Interconnect Wires					(3) (advisory-related subset)	(0)	3	Including Normal Battery Depletion	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.0 +0.2/-0.2	96.9 +0.3/-0.3	89.8 +0.6/-0.6	59.7 +1.1/-1.2	9.6 +1.4/-1.2 at 82 mo					
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,200	2,200	1,396	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	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 173 mo
									Including Normal Battery Depletion	99.8 +0.1/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.6 +0.2/-0.2	97.8 +0.2/-0.3	96.7 +0.3/-0.3	95.0 +0.4/-0.4	91.9 +0.5/-0.6	77.1 +1.0/-1.1	55.1 +1.5/-1.5	42.0 +1.8/-1.8	38.7 +2.3/-2.3 at 173 mo
Sensia DR	SEDR01, SED01	Jul-06	119,100	90,100	171	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	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 76 mo					
	See page 149 – 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 +0.1/-0.1	98.5 +0.2/-0.2	98.3 +0.2/-0.3 at 76 mo					
Sensia SR	SESR01, SES01	Jul-06	83,000	58,000	135	1	6	7	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 76 mo					
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.0 +0.1/-0.2	97.6 +0.4/-0.5	96.6 +0.8/-1.0 at 76 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
Sigma 100 S	SS103, SS106	Aug-99	830	110	26	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/-0.1	100.0 +0.0/-0.1	100.0 +0.1/-0.1	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 113 mo		
	Advisories: See page 147 – 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	99.6 +0.3/-1.3	99.6 +0.3/-1.3	98.8 +0.8/-2.0	98.8 +0.8/-2.0	97.0 +1.5/-3.1	93.7 +2.6/-4.3	82.2 +5.2/-7.0 at 113 mo		
Sigma 200 DR	SDR203	Aug-99	15,900	3,300	828	23	+ 12	= 35	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	99.6 +0.1/-0.2	99.5 +0.1/-0.2	99.5 +0.1/-0.2	99.5 +0.1/-0.2 at 145 mo
	Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 144 – 2009 Potential Separation of Interconnect Wires					(21)	+ (1)	= (22) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.2	98.8 +0.2/-0.2	97.3 +0.3/-0.4	94.3 +0.5/-0.6	83.5 +1.0/-1.0	48.8 +2.6/-2.6	42.6 +3.3/-3.4 at 145 mo
Sigma 200 SR	SSR203, SS203	Sep-99	12,100	1,800	397	13	+ 0	= 13	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	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2 at 150 mo
	Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires					(13)	+ (0)	= (13) (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 +0.2/-0.2	99.2 +0.2/-0.2	98.6 +0.3/-0.3	97.2 +0.4/-0.5	95.2 +0.6/-0.7	86.6 +1.1/-1.2	65.6 +2.3/-2.4	59.6 +3.2/-3.4 at 150 mo
Sigma 300 DR	SDR303, SDR306	Aug-99	106,600	30,000	3,874	187	+ 58	= 245	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	99.7 +0.0/-0.0	99.6 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1 at 143 mo	
	Advisories: See page 147 – 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires					(163)	+ (7)	= (170) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	99.3 +0.1/-0.1	98.8 +0.1/-0.1	97.7 +0.1/-0.1	95.1 +0.2/-0.2	83.6 +0.4/-0.5	39.5 +1.9/-1.9 at 143 mo	
Sigma 300 SR	SSR303, SSR306	Aug-99	54,000	10,800	1,243	41	+ 11	= 52	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	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1 at 146 mo
	Advisories: See page 147– 2005 Potential Separation of Interconnect Wires; See also page 143 – 2009 Potential Separation of Interconnect Wires					(37)	+ (4)	= (41) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.6 +0.1/-0.1	97.5 +0.2/-0.2	95.6 +0.3/-0.3	85.8 +0.7/-0.7	62.7 +1.7/-1.8	58.2 +2.4/-2.5 at 146 mo

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Sigma 300 VDD	SVDD303	Sep-99	650	81	67	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	99.8 +0.2/-0.9	99.2 +0.5/-1.2	98.8 +0.7/-2.0	98.8 +0.7/-2.0 at 124 mo		
	Advisories: See page 147– 2005 Potential Separation of Interconnect Wires					(1)	+	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	99.7 +0.2/-0.9	99.1 +0.5/-1.1	96.6 +1.2/-1.8	93.2 +1.8/-2.4	63.4 +5.1/-5.6	61.2 +5.3/-5.9 at 124 mo		
Versa DR	VEDR01	Jul-06	93,900	71,700	164	6	+	9	=	15	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 77 mo					
	See page 149 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					(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/-0.1	99.2 +0.1/-0.1	98.3 +0.2/-0.2	98.1 +0.3/-0.3 at 77 mo					
Revo MRI SureScan	RVDR01	Feb-11	52,000	50,300	0	1	+	16	=	17	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 25 mo									
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 25 mo									

Source: Medtronic Device Registration and Returned Product Analysis
Data as of March 12, 2013

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. The longevity estimates shown here assume a lower rate of 60 ppm, 100% pacing, and pulse width of 0.4 ms unless noted otherwise. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from these estimates. **The elective replacement time is indicated via telemetry indication, and rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet), unless noted otherwise.**

		Estimated Longevity			
Family	Model Number	Amplitude Setting	500 Lead Ω	1000 Lead Ω	Elective Replacement Indicators
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.4 6.0	**
Adapta DR	ADDRS1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.3 3.2	6.1 5.4 4.4	**
Adapta DR	ADDRL1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.0 7.3 5.4	10.0 8.9 7.2	**
Adapta SR	ADSR01, ADSR03, ADSR06	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 5.1	7.9 7.5 6.3	**
Adapta VDD	ADVDD01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.5 4.4	6.5 6.2 5.4	**
AT500	AT501, 7253	Low 2.0 V (A, RV) Nominal 3.0 V (A, RV) High 5.0 V (A, RV)	7.7 5.8 3.7	8.3 7.0 5.2	Telemetry indication. Pacing mode and rate (magnet and non-magnet) as programmed.
Advisa DR	A4DR01, A5DR01	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	**
Advisa DR MRI+C82	A3DR01	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 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, E2D01, E2D03	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	**
EnRhythm MRI	EMDR01	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	**

**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 March 12, 2013

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
Ensura MRI	EN1DR01	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	**
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 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 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 920 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	**
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	**

**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 March 12, 2013

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
Sigma 200 DR	SDR203	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 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	**
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 March 12, 2013

Method for Estimating Lead Performance

Medtronic CRDM has tracked lead survival for over 29 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.

Shortfalls of Using Returned Product and Complaints to Estimate Lead Performance

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.

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

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

Medtronic tracks lead survival through its Product Surveillance Registry. The registry 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 lead need not be returned to Medtronic.

Product Surveillance Registry (PSR)

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

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

To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria. The number of participants is regularly reviewed to ensure the necessary capacity to meet Medtronic's ongoing prospective post-market surveillance needs is available. Every effort is made to ensure participants are representative of the range of clinical environments in which Medtronic cardiac rhythm products are used. Eligible products for enrollment include Medtronic market-released cardiac rhythm therapy products for which additional information to further characterize product performance following market release is desired. Enrollment may be capped at a product when the number enrolled ensures sufficient precision to effectively characterize product survivability.

continued

Method for Estimating Lead Performance continued

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

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

Patients are eligible for enrollment if:

- They are intended to be implanted or are within 30 days 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
- They participated in a qualifying investigational study of a Medtronic cardiac therapy product that is now market-released; complete implant and follow-up data are available; and the data can be appropriately and legally released.

Each site must inform Medtronic whenever a lead complication has occurred or when a patient is no longer participating. Chronic product performance is analyzed as a function of time using the survival analysis method.

Medtronic continually evaluates the quality and integrity of the data through a combination of on-site and centralized monitoring activities.

Lead Complications

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

All reported lead-related adverse events are classified by the reporting investigator and are adjudicated by an independent event adjudication committee.[1] A lead-related complication is considered to have occurred if a clinical observation occurs more than 30 days after implant, is adjudicated with at least one of the following event classifications and at least one of the following clinical actions is made. Events with an onset date 30 days or less after the implant are considered procedure-related and therefore not included as chronic lead-related complications.

Event Classifications

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

Clinical Actions

- Lead surgically abandoned/capped
- Lead electrically abandoned
- Lead explanted
- Lead replaced
- Lead conductor taken out of service (polarity reprogrammed to remove defective conductor, e.g., bipolar to unipolar)

continued

[1] During the evolution of PSR, event adjudication was transitioned from a Medtronic technical review committee to an independent event adjudication committee in 2011. Data analyses include adjudication using both methods.

- 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.

Data Analysis Methods

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

Survival times are calculated from the implant date to the earliest of the complication date, out-of-service date (for example, subject leaves the study or the lead is no longer being used) or the last follow-up date. If a lead experiences more than one complication, the first is used to calculate survival time; although all complications associated with a lead are included in the summary tables.

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.

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.

Although tabular data is provided 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 the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the number of leads entering an interval is less than 50 leads. When the number of leads entering an interval reaches 50, the next data point is added to the survival curve. For those lead models that do not have sufficient sample size, a survival curve will not be presented.

Definition of Analysis Dataset

The survival estimates are derived from all device components successfully enrolled as of the data cutoff date. The number of enrollments is listed for each lead model.

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

Criteria for Model Inclusion

Performance information for a model or model family will be published when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Models will continue to be published 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.

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.

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 PSR 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, clinical conditions and/or varying implant conditions/techniques. After a period of time, the implant and the lead performance stabilizes. It is for this reason that the Product Surveillance Registry results, which are intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

Information about the clinical experience in the first month of service is included in 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 PSR , 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 Product Surveillance Registry. 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	12,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Estimated Active US Implants	2,700	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

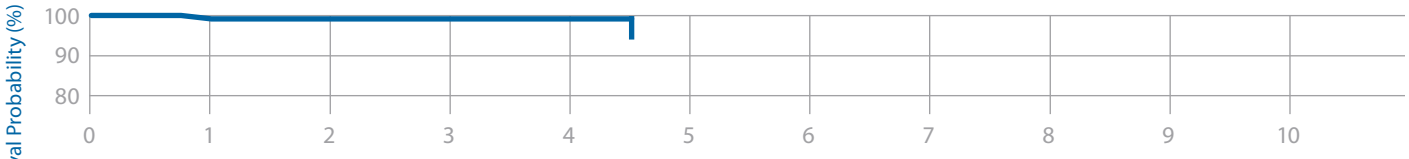
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	134
Cumulative Months of Follow-Up	6,667
Number of Leads Active in Study	14

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

4193 Attain OTW

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Registered US Implants	100,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	35,000	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

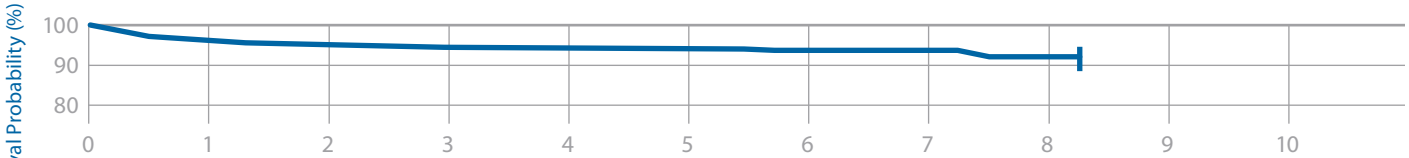
Conductor Fracture	52
Crimp/Weld/Bond	0
Insulation Breach	8
Other	51

Product Surveillance Registry Results

Number of Leads Enrolled in Study	675
Cumulative Months of Follow-Up	30,442
Number of Leads Active in Study	123

Qualifying Complications 38 Total

Conductor Fracture	1	Lead Dislodgement	14
Extra Cardiac Stimulation	8	Unspecified Clinical Failure	3
Failure to Capture	12		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	95.9	95.0	94.3	94.3	93.8	93.3	93.3	92.3	92.3
#	545	437	358	275	203	145	99	57	44

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Left-Heart Leads

4194 Attain OTW

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Registered US Implants	108,200	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	64,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	53
Other	10

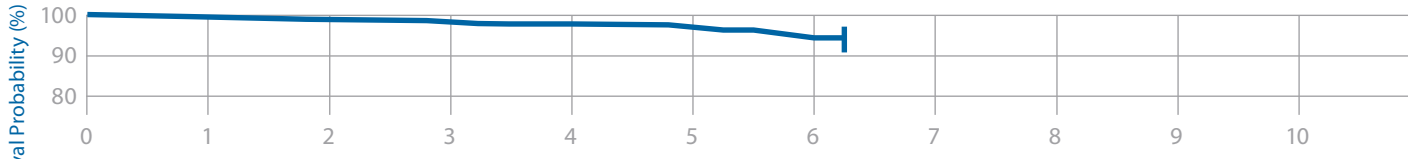
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,222
Cumulative Months of Follow-Up	36,808
Number of Leads Active in Study	731

Qualifying Complications

28 Total

Extra Cardiac Stimulation	4
Failure to Capture	7
Insulation (ESC)	1
Insulation (not further defined)	2
Lead Dislodgement	14



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	98.7	97.7	97.7	97.4	96.8	94.2	94.2
#	934	611	372	222	141	68	52

Effective Sample Size

4195 Attain StarFix

Product Characteristics

US Market Release	Aug-08	Serial Number Prefix	AAD
Registered US Implants	14,500	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Deployable Lobe Fixation
Estimated Active US Implants	11,500	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

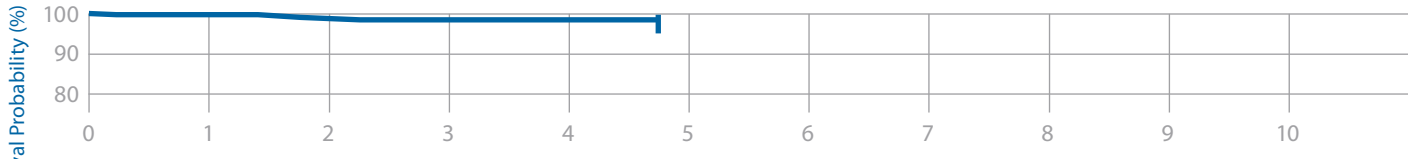
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,231
Cumulative Months of Follow-Up	23,520
Number of Leads Active in Study	963

Qualifying Complications

12 Total

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



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	99.2	98.6	98.3	98.3	98.3
#	723	346	110	59	50

Effective Sample Size

Left-Heart Leads continued

4196 Attain Ability

Product Characteristics

US Market Release	May-09	Serial Number Prefix	PVI
Registered US Implants	48,600	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Preformed Body, Double Curve
Estimated Active US Implants	40,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

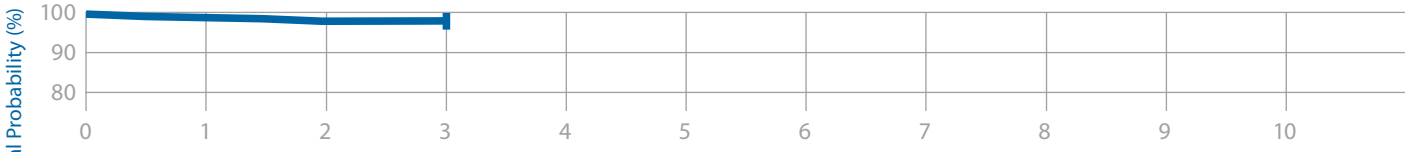
Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	0
Other	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,876
Cumulative Months of Follow-Up	34,965
Number of Leads Active in Study	1,300

Qualifying Complications 38 Total

Conductor Fracture	1	Lead Dislodgement	14
Extra Cardiac Stimulation	12		
Failure to Capture	11		



	1 yr	2 yr	3 yr
%	98.3	97.5	97.0
#	1,266	488	61

Effective Sample Size

4296 Attain Ability Plus

Product Characteristics

US Market Release	Apr-11	Serial Number Prefix	RRA
Registered US Implants	12,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	11,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

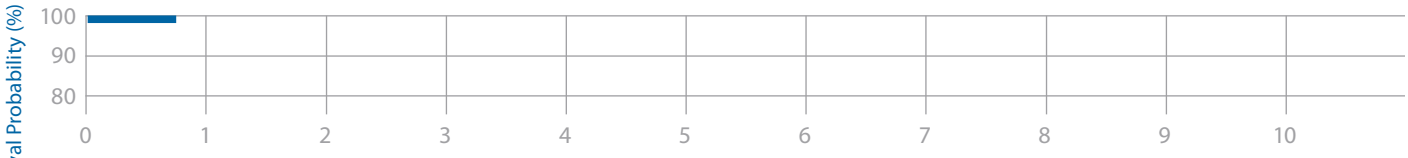
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	672
Cumulative Months of Follow-Up	2,876
Number of Leads Active in Study	618

Qualifying Complications 2 Total

Lead Dislodgement	2



	at 9 mo
	99.5
#	87

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

4396 Attain Ability Straight

Product Characteristics

US Market Release	Mar-11	Serial Number Prefix	RAE
Registered US Implants	2,800	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Tines
Estimated Active US Implants	2,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

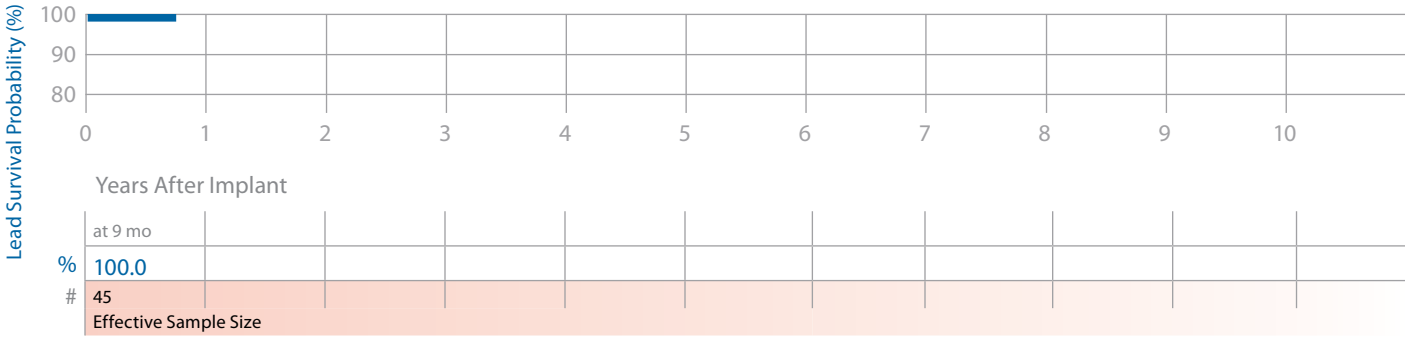
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	178
Cumulative Months of Follow-Up	1,517
Number of Leads Active in Study	161

Qualifying Complications

0 Total



Leads

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	14	1	6,667	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					
4193	Attain OTW	May-02	675	123	38	30,442	95.9 +1.3/-1.8	95.0 +1.4/-2.1	94.3 +1.6/-2.3	94.3 +1.6/-2.3	93.8 +1.8/-2.4	93.3 +2.0/-2.7	93.3 +2.0/-2.7	92.3 +2.5/-3.7	92.3 +2.5/-3.7 at 99 mo	
4194	Attain OTW	Aug-04	1,222	731	28	36,808	98.7 +0.6/-0.8	97.7 +0.8/-1.2	97.7 +0.8/-1.2	97.4 +0.9/-1.3	96.8 +1.3/-2.1	94.2 +2.6/-4.4	94.2 +2.6/-4.4 at 75mo			
4195	Attain StarFix	Aug-08	1,231	963	12	23,520	99.2 +0.4/-0.9	98.6 +0.7/-1.1	98.3 +0.8/-1.4	98.3 +0.8/-1.4	98.3 +0.8/-1.4 at 57 mo					
4196	Attain Ability	May-09	1,876	1,300	38	34,965	98.3 +0.5/-0.8	97.5 +0.7/-1.0	97.0 +0.9/-1.3							
4296	Attain Ability Plus	Apr-11	672	618	2	2,876	99.5 +0.4/-1.8 at 9 mo									
4396	Attain Ability Straight	Mar-11	178	161	0	1,517	100 .0 at 9 mo									

US Returned Product Analysis Summary

Source: Product Surveillance Registry
Data as of February 1, 2013

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	12,000	2,700	1	0	0	4
4193	Attain OTW	May-02	100,700	35,000	52	0	8	51
4194	Attain OTW	Aug-04	108,200	64,800	12	0	53	10
4195	Attain StarFix	Aug-08	14,500	11,500	1	0	1	4
4196	Attain Ability	May-09	48,600	40,500	5	0	0	6
4296	Attain Ability Plus	Apr-11	12,000	11,300	0	0	0	0
4396	Attain Ability Straight	Mar-11	2,800	2,600	0	0	0	0

Source: Returned Product Analysis
Data as of February 1, 2013

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	12,000	0	0	9	3	0	1	0	0	1	0
4193	Attain OTW	100,700	0	0	44	11	1	0	0	0	16	2
4194	Attain OTW	108,200	2	2	114	34	2	0	0	6	28	5
4195	Attain StarFix	14,500	0	0	21	11	0	0	0	1	18	1
4196	Attain Ability	48,600	0	1	117	34	1	0	1	5	56	3
4296	Attain Ability Plus	12,000	0	0	35	5	0	0	1	0	8	0
4396	Attain Ability Straight	2,800	0	1	13	2	0	0	0	0	5	0

Report Cutoff Date: February 1, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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
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 February 1, 2013

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	8,800	Type and/or Fixation	Epicardial Defib Patch, Suture
Estimated Active US Implants	1,500	Polarity	Defib Electrode only
Advisories	None	Steroid	No

US Returned Product Analysis

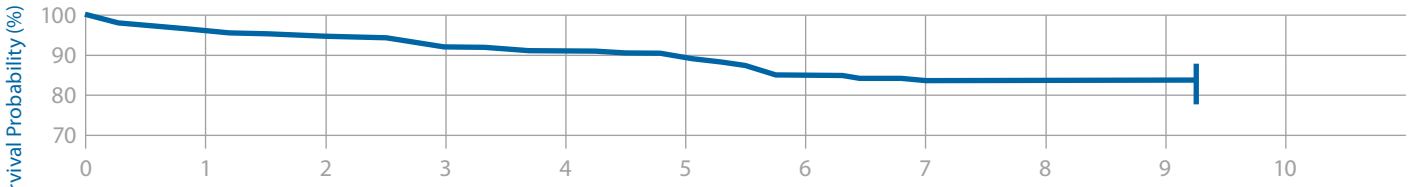
Conductor Fracture	25
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

Product Surveillance Registry 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

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



	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: See page 145– 2007 Potential Conductor Wire Fracture		Steroid	Yes

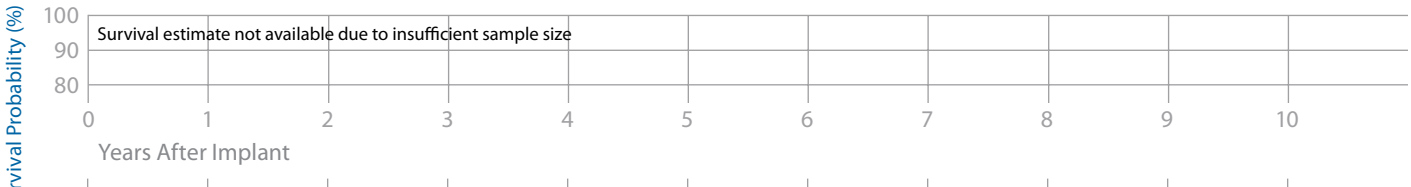
US Returned Product Analysis

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	174
Number of Leads Active in Study	2

Qualifying Complications 0 Total



	at 0 mo
%	100.00
#	4

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	3,600	Polarity	True Bipolar/One Coil
Advisories		Steroid	Yes
See page 145 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

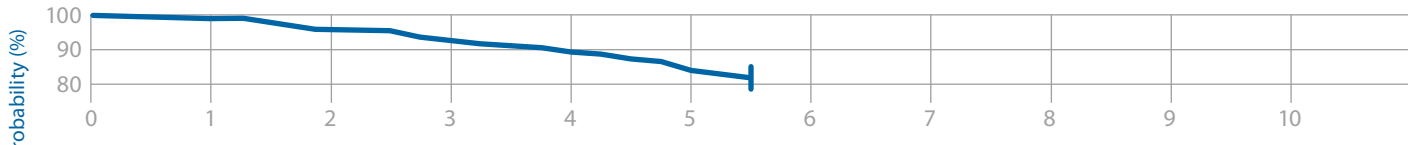
Conductor Fracture	504
Crimp/Weld/Bond	0
Insulation Breach	1
Other	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	13,106
Number of Leads Active in Study	119

Qualifying Complications 37 Total

Conductor Fracture	19
Failure to Capture	3
Failure to Sense	1
Impedance Out of Range	7
Lead Dislodgement	2
Oversensing	5



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	98.2	96.2	93.0	89.2	83.8	81.6
#	257	226	192	139	85	47

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	4,300	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

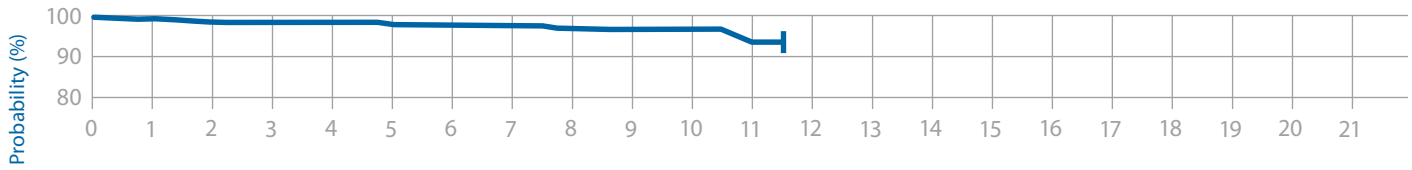
Conductor Fracture	22
Crimp/Weld/Bond	0
Insulation Breach	23
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	412
Cumulative Months of Follow-Up	25,610
Number of Leads Active in Study	41

Qualifying Complications 10 Total

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



	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
%	99.2	98.3	98.3	98.3	97.8	97.8	97.8	96.8	96.8	96.8	93.6	93.6
#	356	297	240	199	161	129	110	95	83	69	53	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	14,400	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

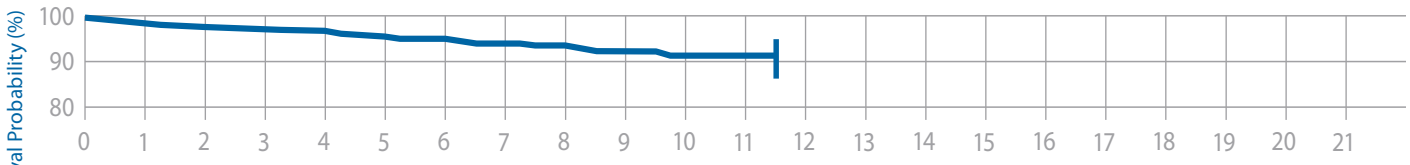
Conductor Fracture	170
Crimp/Weld/Bond	0
Insulation Breach	32
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,382
Number of Leads Active in Study	13

Qualifying Complications 47 Total

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



	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	108	77	57	50

Effective Sample Size

6935 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-08	Serial Number Prefix	TAU
Registered US Implants	40,200	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	36,600	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Performance Note: See page 150 – Helix Retraction of the Sprint Quattro Secure S 6935 and Sprint Quattro Secure 6947

US Returned Product Analysis

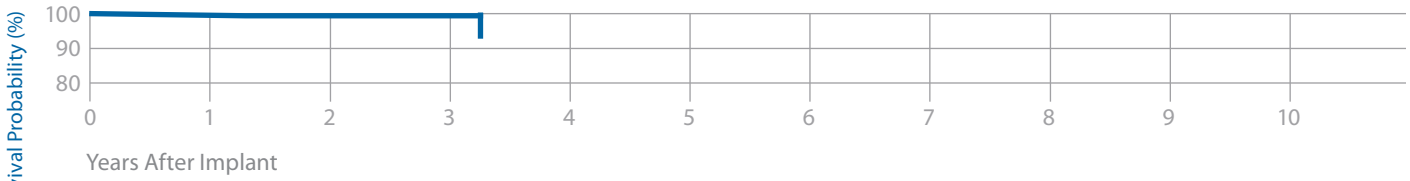
Conductor Fracture	46
Crimp/Weld/Bond	0
Insulation Breach	2
Other	42

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,886
Cumulative Months of Follow-Up	25,696
Number of Leads Active in Study	1,610

Qualifying Complications 8 Total

Conductor Fracture	1
Failure to Sense	1
Lead Dislodgement	4
Oversensing	2



	1 yr	2 yr	3 yr	at 39 mo
%	99.5	99.2	99.2	99.2
#	846	353	81	44

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Defibrillation Leads continued

6936, 6966 Transvene

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAV, TAL
Registered US Implants	23,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	2,200	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

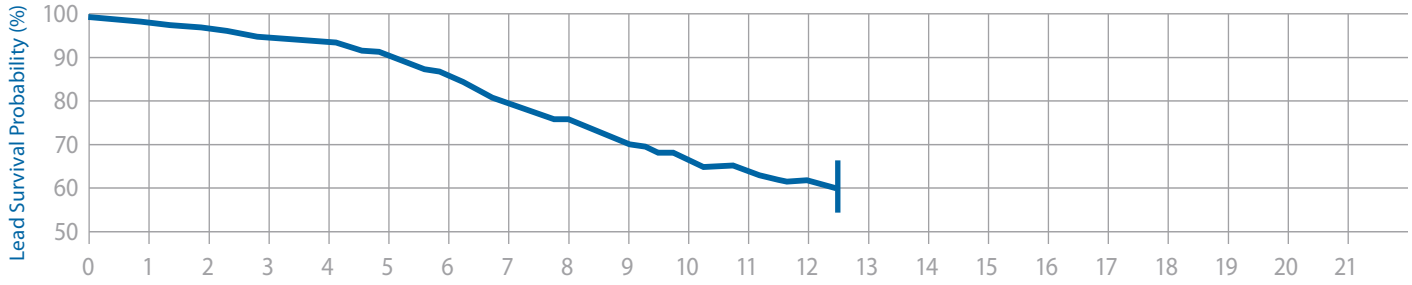
Conductor Fracture	177
Crimp/Weld/Bond	0
Insulation Breach	348
Other	15

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,349
Cumulative Months of Follow-Up	75,241
Number of Leads Active in Study	13

Qualifying Complications 188 Total

Conductor Fracture	22	Impedance Out of Range	7
Extra Cardiac Stimulation	6	Insulation (not further defined)	14
Failure to Capture	15	Oversensing	112
Failure to Sense	7	Unspecified Clinical Failure	5



	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	59.6
#	1,140	956	807	659	530	414	284	210	142	104	75	56	50

Effective Sample Size

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	5,400	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

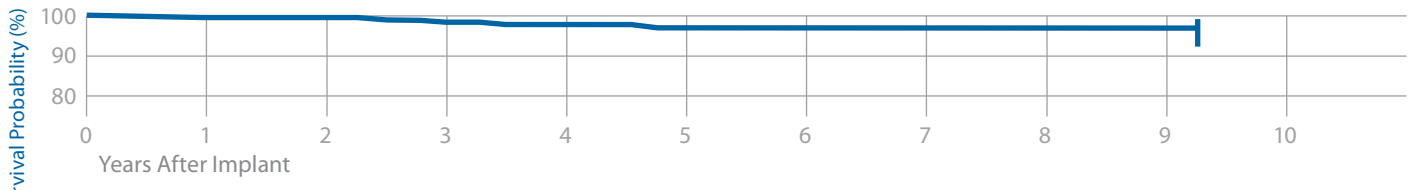
Conductor Fracture	14
Crimp/Weld/Bond	1
Insulation Breach	22
Other	7

Product Surveillance Registry Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	19,099
Number of Leads Active in Study	29

Qualifying Complications 7 Total

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



	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	96.8	96.8	96.8	96.8	96.8	96.8
#	294	231	179	141	118	100	78	67	53	49

Effective Sample Size

Defibrillation Leads continued

6943 Sprint

Product Characteristics

US Market Release	Oct-97	Serial Number Prefix	TCE
Registered US Implants	20,500	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	6,300	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

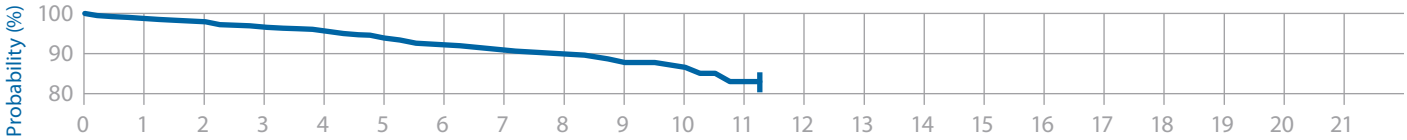
Conductor Fracture	71
Crimp/Weld/Bond	1
Insulation Breach	28
Other	7

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,311
Cumulative Months of Follow-Up	81,556
Number of Leads Active in Study	220

Qualifying Complications 94 Total

Conductor Fracture	24	Insulation (not further defined)	1
Failure to Capture	8	Lead Dislodgement	2
Failure to Sense	7	Other	1
Impedance Out of Range	8	Oversensing	40
		Unspecified Clinical Failure	3



	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
%	98.6	97.7	96.5	95.6	93.7	92.1	90.9	89.9	87.8	86.6	83.1	83.1
#	1,146	981	874	745	628	511	399	293	196	116	65	53

Effective Sample Size

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Registered US Implants	41,400	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	21,800	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

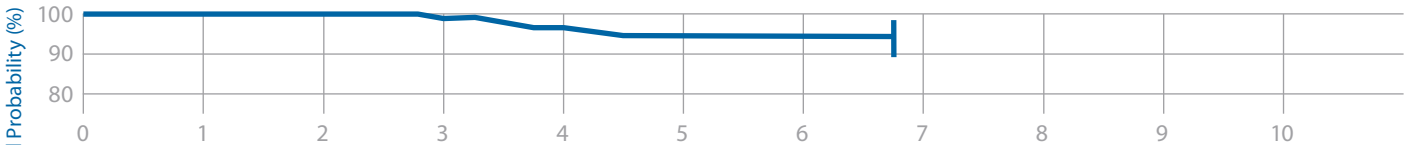
Conductor Fracture	93
Crimp/Weld/Bond	1
Insulation Breach	2
Other	31

Product Surveillance Registry Results

Number of Leads Enrolled in Study	509
Cumulative Months of Follow-Up	16,123
Number of Leads Active in Study	283

Qualifying Complications 6 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	99.3	97.5	95.1	95.1	95.1
#	356	217	128	85	66	58	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Defibrillation Leads continued

6945 Sprint

Product Characteristics

US Market Release	Sep-97	Serial Number Prefix	TDA
Registered US Implants	42,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	12,800	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

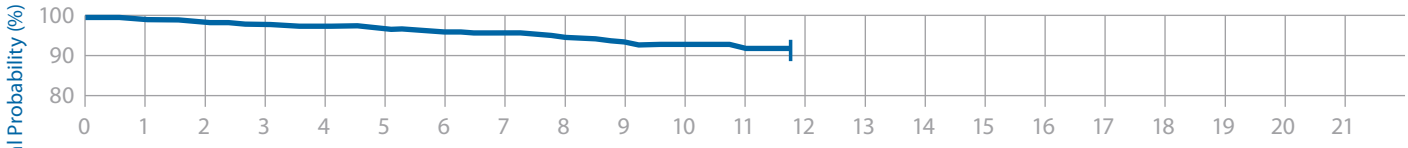
Conductor Fracture	121
Crimp/Weld/Bond	1
Insulation Breach	35
Other	13

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,155
Cumulative Months of Follow-Up	67,487
Number of Leads Active in Study	125

Qualifying Complications 38 Total

Conductor Fracture	8	Impedance Out of Range	5
Extra Cardiac Stimulation	1	Oversensing	17
Failure to Capture	2	Unspecified Clinical Failure	1
Failure to Sense	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 141 mo
%	99.4	98.7	98.2	97.6	96.8	96.1	95.6	94.5	93.2	92.7	91.7	91.7
#	997	822	684	566	466	382	315	239	183	137	86	49

Effective Sample Size

6947M Sprint Quattro Secure

Product Characteristics

US Market Release	Feb-12	Serial Number Prefix	TDK
Registered US Implants	21,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	20,600	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Performance Note: See page 150 – Helix Retraction of the Sprint Quattro Secure S 6935and Sprint Quattro Secure 6947

US Returned Product Analysis

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	994
Cumulative Months of Follow-Up	2,540
Number of Leads Active in Study	961

Qualifying Complications 2 Total

Failure to Capture	2

	at 6 mo
%	99.5
#	78

Effective Sample Size

Leads

Defibrillation Leads continued

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Registered US Implants	358,900	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	243,700	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Performance Note: See page 150 – Helix Retraction of the Sprint Quattro Secure S 6935and Sprint Quattro Secure 6947

US Returned Product Analysis

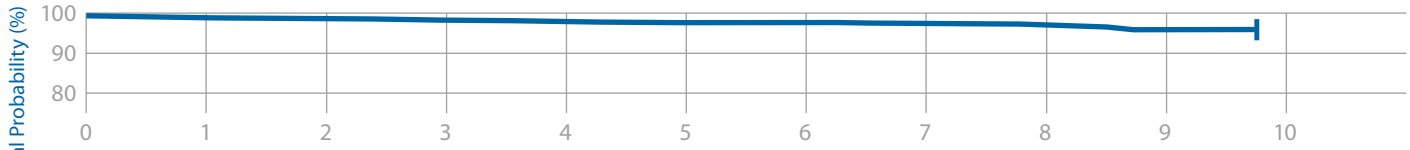
Conductor Fracture	436
Crimp/Weld/Bond	4
Insulation Breach	32
Other	272

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,715
Cumulative Months of Follow-Up	115,003
Number of Leads Active in Study	1,151

Qualifying Complications 37 Total

Conductor Fracture	7	Lead Dislodgement	4
Failure to Capture	1	Oversensing	11
Failure to Sense	2	Unspecified Clinical Failure	2
Impedance Out of Range	7		
Insulation (not further defined)	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	99.5	99.2	98.9	98.6	98.2	97.8	97.3	96.9	95.8	95.8
#	2,395	1,900	1,176	745	582	437	327	223	105	48

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	4,900	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes

See page 146 – 2007 Potential Conductor Wire Fracture

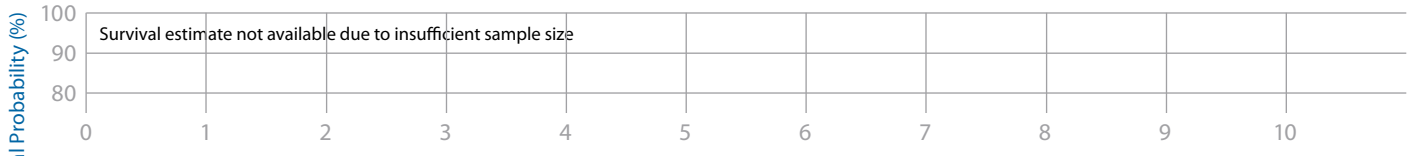
US Returned Product Analysis

Conductor Fracture	141
Crimp/Weld/Bond	0
Insulation Breach	2
Other	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	30
Cumulative Months of Follow-Up	1,413
Number of Leads Active in Study	15

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	30

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Defibrillation Leads continued

6949 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFJ
Registered US Implants	186,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	79,600	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes
See page 146 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

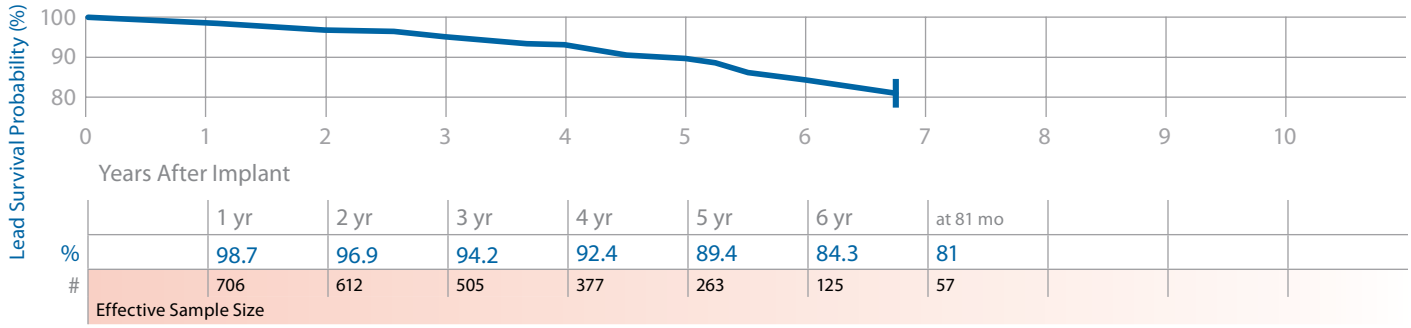
Conductor Fracture	5,977
Crimp/Weld/Bond	3
Insulation Breach	29
Other	196

Product Surveillance Registry Results

Number of Leads Enrolled in Study	795
Cumulative Months of Follow-Up	37,326
Number of Leads Active in Study	241

Qualifying Complications 75 Total

Conductor Fracture	36	Insulation (not further defined)	2
Failure to Capture	2	Lead Dislodgement	1
Failure to Sense	4	Oversensing	15
Impedance Out of Range	14	Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	98.7	96.9	94.2	92.4	89.4	84.3	81
#	706	612	505	377	263	125	57

Effective Sample Size

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Registered US Implants	3,800	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated Active US Implants	2,200	Polarity	One Defib Coil
Advisories	None	Steroid	No

US Returned Product Analysis

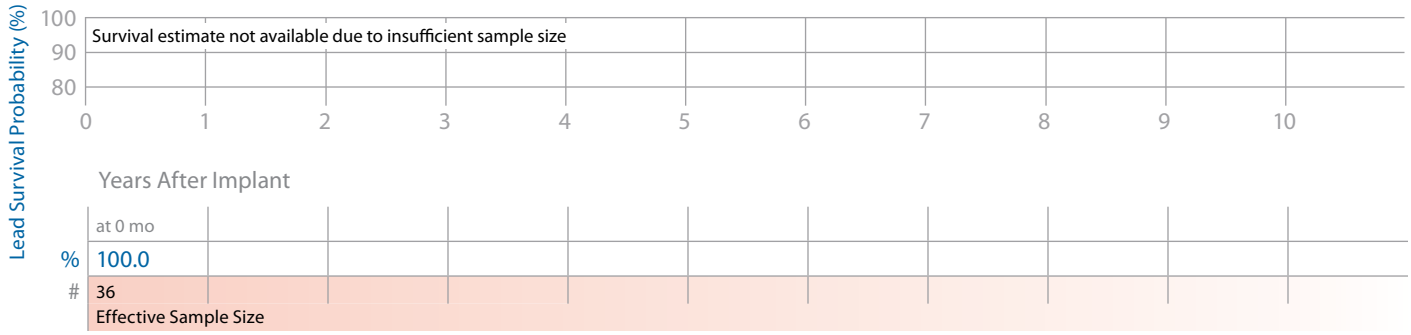
Conductor Fracture	19
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	41
Cumulative Months of Follow-Up	1,087
Number of Leads Active in Study	20

Qualifying Complications 2 Total

Conductor Fracture	1
Impedance Out of Range	1



	at 0 mo
%	100.0
#	36

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	174	100.0 at 0 mo												
	Advisories: See page 146 – 2007 Potential Conductor Wire Fracture																		
6931	Sprint Fidelis	Sep-04	294	119	37	13,106	98.2 +1.0/-2.5	96.2 +1.7/-3.2	93.0 +2.6/-4.1	89.2 +3.5/-4.9	83.8 +4.8/-6.4	81.6 +5.3/-7.1 at 66 mo							
	Advisories: See page 146 – 2007 Potential Conductor Wire Fracture																		
6932	Sprint	Aug-96	412	41	10	25,610	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/-2.5	97.8 +1.2/-2.5	97.8 +1.2/-2.5	96.8 +1.8/-3.7	96.8 +1.8/-3.7	93.6 +3.5/-7.5 at 138 mo			
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	966	13	47	54,382	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/-4.1	91.2 +2.8/-4.1 at 138 mo			
6935	Sprint Quattro Secure	Nov-08	1,886	1,610	8	25,696	99.5 +0.3/-0.6	99.2 +0.4/-0.8	99.2 +0.4/-0.8	99.2 +0.4/-0.8 at 39 mo									
	See page 150 – Performance note on Helix Retraction 6935 and 6947																		
6936, 6966	Transvene	Dec-93	1,349	13	188	75,241	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	59.6 +6.1/-6.9 at 150 mo		
6942	Sprint	Jul-97	351	29	7	19,099	99.1 +0.6/-1.9	99.1 +0.6/-1.9	98.1 +1.1/-2.7	97.5 +1.4/-3.1	96.8 +1.7/-3.8	96.8 +1.7/-3.8	96.8 +1.7/-3.8	96.8 +1.7/-3.8	96.8 +1.7/-3.8 at 111 mo				
6943	Sprint	Oct-97	1,311	220	94	81,556	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	92.1 +1.6/-2.0	90.9 +1.9/-2.2	89.9 +2.1/-2.4	86.6 +2.8/-3.6	83.1 +4.0/-5.2 at 135 mo			
6944	Sprint Quattro	Dec-00	509	283	6	16,123	100.0	100.0	99.3 +0.6/-4.1	97.5 +1.7/-5.1	95.1 +2.9/-6.6	95.1 +2.9/-6.6	95.1 +2.9/-6.6 at 81 mo						
6945	Sprint	Sep-97	1,155	125	38	67,487	99.4 +0.4/-0.6	98.7 +0.5/-1.0	98.2 +0.7/-1.1	97.6 +0.8/-1.3	96.8 +1.1/-1.6	96.1 +1.3/-1.8	95.6 +1.4/-2.0	94.5 +1.7/-2.4	92.7 +2.2/-3.2	91.7 +2.7/-3.9 at 141 mo			
6947	Sprint Quattro Secure	Nov-01	2,715	1,151	37	115,003	99.5 +0.2/-0.4	99.2 +0.3/-0.4	98.9 +0.4/-0.5	98.6 +0.5/-0.7	98.2 +0.6/-1.0	97.8 +0.7/-1.1	97.3 +0.9/-1.5	96.9 +1.1/-1.7	95.8 +1.6/-2.5 at 117 mo				
	See page 150 – Performance note on Helix Retraction 6935 and 6947																		
6947M	Sprint Quattro Secure	Feb-12	994	961	2	2,540	99.5 +0.4/-1.7 at 6 mo												
	See page 150 – Performance note on Helix Retraction 6935 and 6947																		
6948	Sprint Fidelis	Sep-04	30	15	0	1,413	100.0 at 0 mo												
	Advisories: See page 146 – 2007 Potential Conductor Wire Fracture																		
6949	Sprint Fidelis	Sep-04	795	241	75	37,326	98.7 +0.6/-1.2	96.9 +1.1/-1.6	94.2 +1.6/-2.1	92.4 +1.8/-2.5	89.4 +2.4/-3	84.3 +3.3/-4.2	81.0 +4.3/-5.4 at 81 mo						
	Advisories: See page 146 – 2007 Potential Conductor Wire Fracture																		
6996	Sub-Q Lead	Jun-01	41	20	2	1,087	100.0 at 0 mo												

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Defibrillation Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
6721, 6921	Epicardial Patch	Feb-93	8,800	1,500	25	2	0	0
6930	Sprint Fidelis	Sep-04	400	200	3	0	0	0
6931	Sprint Fidelis	Sep-04	8,100	3,600	504	1	0	8
6932	Sprint	Aug-96	14,900	4,300	22	23	0	4
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	14,400	2,600	170	32	0	4
6935	Sprint Quattro Secure	Nov-08	40,200	36,600	46	2	0	42
6936, 6966	Transvene	Dec-93	23,100	2,200	177	348	0	15
6942	Sprint	Jul-97	17,700	5,400	14	22	1	7
6943	Sprint	Oct-97	20,500	6,300	71	28	1	7
6944	Sprint Quattro	Dec-00	41,400	21,800	93	2	1	31
6945	Sprint	Sep-97	42,700	12,800	121	35	1	13
6947	Sprint Quattro Secure	Nov-01	358,900	243,700	436	32	4	272
6947M	Sprint Quattro Secure	Feb-12	21,100	20,600	1	0	0	6
6948	Sprint Fidelis	Sep-04	10,400	4,900	141	2	0	5
6949	Sprint Fidelis	Sep-04	186,700	79,600	5,977	29	3	196
6996	Sub-Q Lead	Jun-01	3,800	2,200	19	0	0	0

Source: Returned Product Analysis
Data as of February 1, 2013

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	8,800	1	2	0	0	1	1	0	3	0	0
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	1
6932	Sprint	14,900	0	0	4	2	0	2	0	1	0	2
6933, 6937, 6937A, 6963	SVC/CS	14,400	0	0	1	2	0	0	1	0	0	6
6935	Sprint Quattro Secure	40,200	10	0	26	15	23	5	1	10	0	5
6936, 6966	Transvene	23,100	5	2	1	5	3	2	1	1	0	4
6942	Sprint	17,700	0	1	1	4	0	0	0	2	0	1
6943	Sprint	20,500	1	0	0	1	1	1	1	2	0	0
6944	Sprint Quattro	41,400	0	2	16	11	11	3	0	8	0	6
6945	Sprint	42,700	1	1	4	6	7	2	2	0	1	2
6947	Sprint Quattro Secure	358,900	22	18	99	66	109	28	4	45	2	22
6947M	Sprint Quattro Secure	21,100	2	1	22	12	3	1	0	2	0	0
6948	Sprint Fidelis	10,400	0	2	7	6	1	0	0	0	0	3
6949	Sprint Fidelis	186,700	10	40	23	32	30	19	6	17	0	25
6996	SubQ	3,800	0	0	1	1	0	0	0	2	0	0

Report Cutoff Date: February 1, 2013

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
6935	Sprint Quattro Secure	Endo RV True Bipolar Sensing	IS-1	DF-1	8.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
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
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	8.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6947M	Sprint Quattro Secure	Endo RV/SVC True Bipolar Sensing	DF4	DF4	8.6 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

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Registered US Implants	20,900	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	15,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	12
Other	4

Atrial Placement

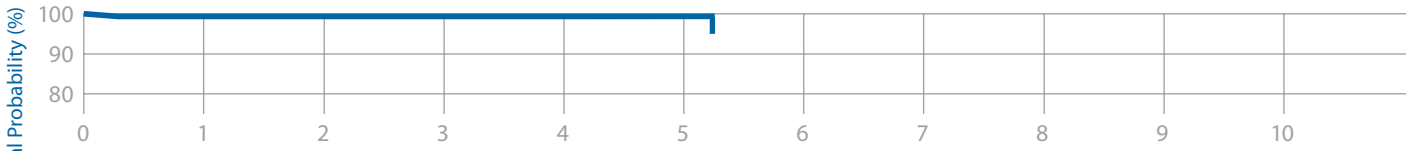
Product Surveillance Registry Results

Number of Leads Enrolled in Study	769
Cumulative Months of Follow-Up	22,098
Number of Leads Active in Study	509

Qualifying Complications

6 Total

Cardiac Perforation	1
Extra Cardiac Stimulation	1
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.2	99.2	99.2	99.2	99.2	99.2
#	612	337	173	98	63	54

Effective Sample Size

Ventricular Placement

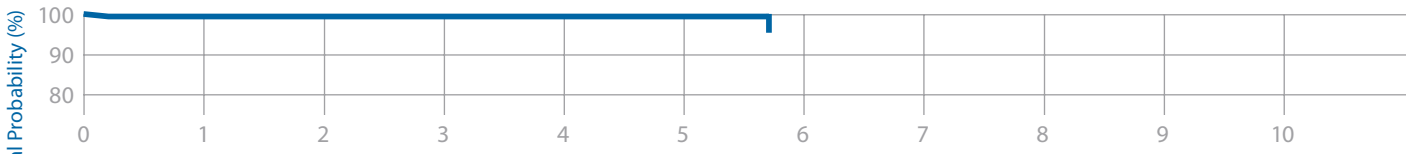
Product Surveillance Registry Results

Number of Leads Enrolled in Study	475
Cumulative Months of Follow-Up	15,455
Number of Leads Active in Study	290

Qualifying Complications

3 Total

Impedance Out of Range	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.5	99.5	99.5	99.5	99.5	99.5
#	388	229	142	90	63	49

Effective Sample Size

Pacing Leads continued

4024 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAJ
Registered US Implants	217,500	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	41,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	27
Crimp/Weld/Bond	0
Insulation Breach	178
Other	16

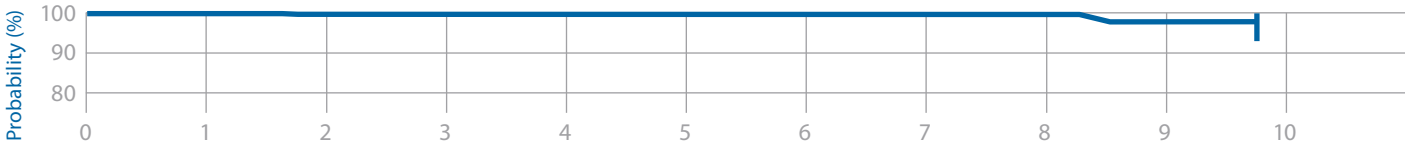
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	50,928
Number of Leads Active in Study	13

Qualifying Complications

4 Total

Failure to Capture	3
Insulation (not further defined)	1



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

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4068 CapSureFix

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCE
Registered US Implants	123,800	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	30,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	50
Crimp/Weld/Bond	0
Insulation Breach	163
Other	95

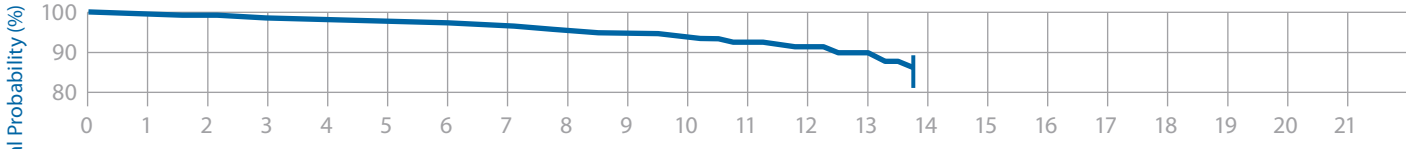
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,413
Cumulative Months of Follow-Up	133,591
Number of Leads Active in Study	266

Qualifying Complications 77 Total

Conductor Fracture	3	Insulation (ESC)	2
Extra Cardiac Stimulation	2	Insulation (MIO)	2
Failure to Capture	22	Insulation (not further defined)	2
Failure to Sense	13	Lead Dislodgement	8
Impedance Out of Range	9	Oversensing	11
		Unspecified Clinical Failure	3



	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
%	98.9	98.7	98.2	98.0	97.4	97.2	96.7	95.3	94.6	93.7	92.5	91.4	89.9	86.2
#	1,907	1,637	1,370	1,116	897	737	577	472	358	256	189	135	84	43

Effective Sample Size

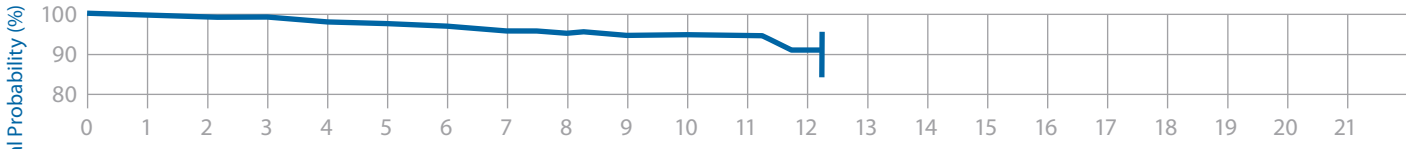
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	95,888
Number of Leads Active in Study	162

Qualifying Complications 51 Total

Conductor Fracture	3	Impedance Out of Range	11
Extra Cardiac Stimulation	2	Insulation (not further defined)	1
Failure to Capture	22	Oversensing	7
Failure to Sense	3	Unspecified Clinical Failure	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
%	99.3	98.7	98.7	98.2	97.8	97.2	95.8	95.0	93.5	93.1	92.4	89.7	89.7
#	1.427	1,219	1,032	832	685	539	405	300	213	133	77	52	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Registered US Implants	91,300	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	57,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	20
Other	1

Atrial Placement

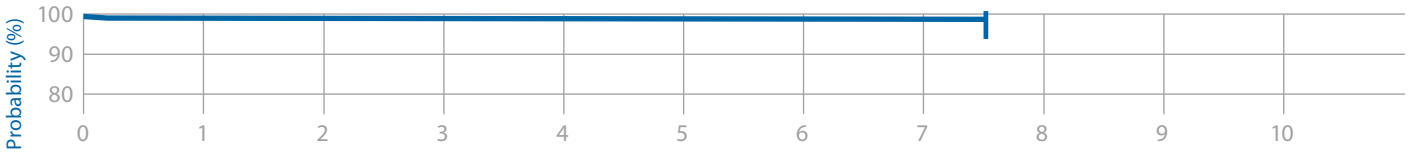
Product Surveillance Registry Results

Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	14,960
Number of Leads Active in Study	137

Qualifying Complications

2 Total

Failure to Sense	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1
#	200	189	183	171	146	112	73	52

Effective Sample Size

Ventricular Placement

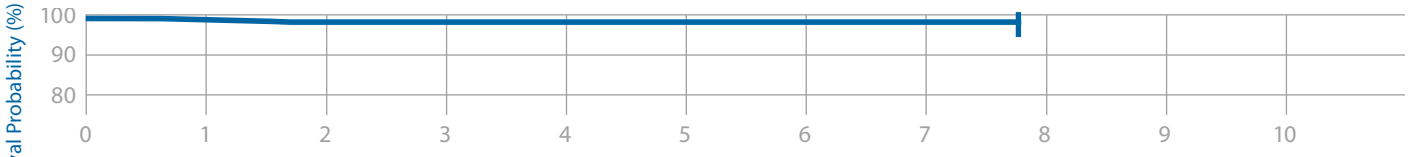
Product Surveillance Registry Results

Number of Leads Enrolled in Study	956
Cumulative Months of Follow-Up	30,769
Number of Leads Active in Study	691

Qualifying Complications

3 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	99.7	99.5	99.5	99.5	99.5	99.5	99.5	99.5
#	541	388	329	304	242	154	85	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Registered US Implants	432,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	332,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	33
Crimp/Weld/Bond	1
Insulation Breach	33
Other	24

Atrial Placement

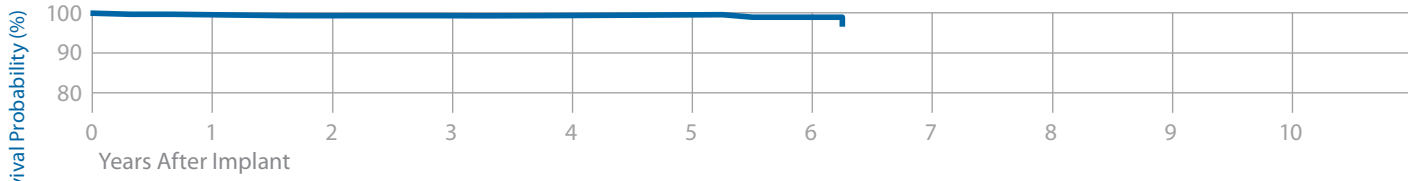
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,662
Cumulative Months of Follow-Up	59,076
Number of Leads Active in Study	1,017

Qualifying Complications

8 Total

Conductor Fracture	1
Failure to Capture	2
Failure to Sense	1
Insulation (not further defined)	1
Lead Dislodgement	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	99.8	99.6	99.5	99.5	99.5	98.9	98.9
#	1,471	1,112	642	370	208	68	48

Effective Sample Size

Ventricular Placement

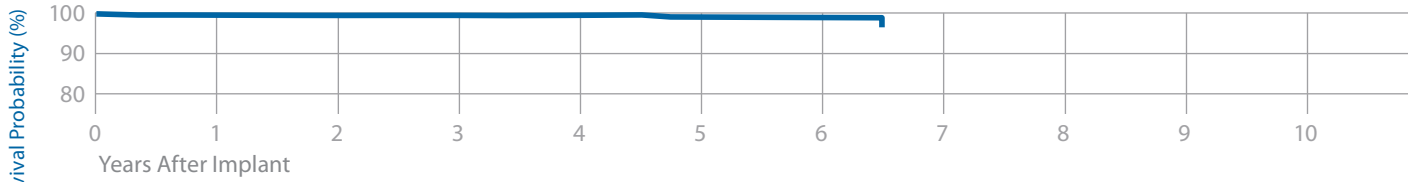
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,229
Cumulative Months of Follow-Up	46,434
Number of Leads Active in Study	744

Qualifying Complications

5 Total

Extra Cardiac Stimulation	1
Failure to Capture	3
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	99.8	99.8	99.7	99.7	99.0	99.0	99.0
#	1,087	829	534	353	200	76	44

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Registered US Implants	177,000	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	80,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

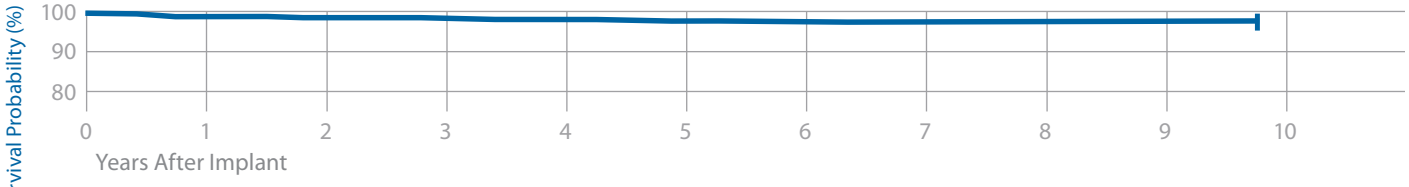
Conductor Fracture	9
Crimp/Weld/Bond	0
Insulation Breach	48
Other	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,147
Cumulative Months of Follow-Up	65,701
Number of Leads Active in Study	293

Qualifying Complications 19 Total

Conductor Fracture	3	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Lead Dislodgement	4
Failure to Capture	9		



	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	97.7	97.7	97.7	97.7	97.7
#	929	831	734	637	553	449	320	206	117	47

Effective Sample Size

4524 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAR
Registered US Implants	99,500	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	23,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

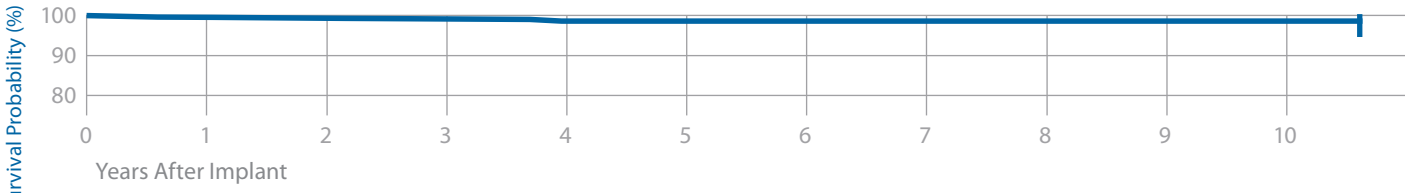
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	64
Other	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	40,725
Number of Leads Active in Study	35

Qualifying Complications 6 Total

Failure to Capture	3
Failure to Sense	2
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0	99.0	99.0	99.0
#	682	537	427	329	251	182	133	87	65	55	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4558M Screw-In

Product Characteristics

US Market Release	Nov-94	Serial Number Prefix	LDC
Registered US Implants	19,400	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	3,800	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

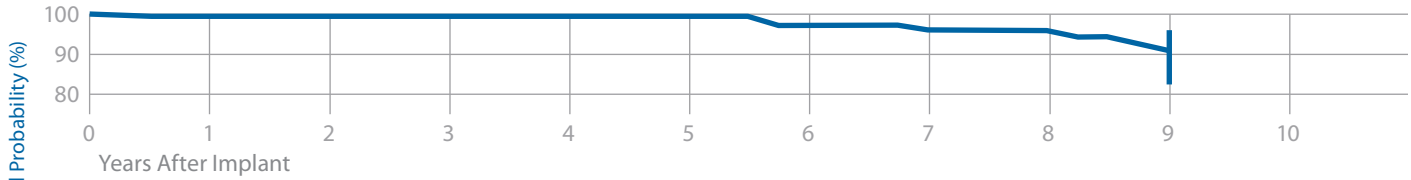
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	18
Other	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	23,289
Number of Leads Active in Study	6

Qualifying Complications 12 Total

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

Pacing Leads continued

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Registered US Implants	69,100	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	21,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

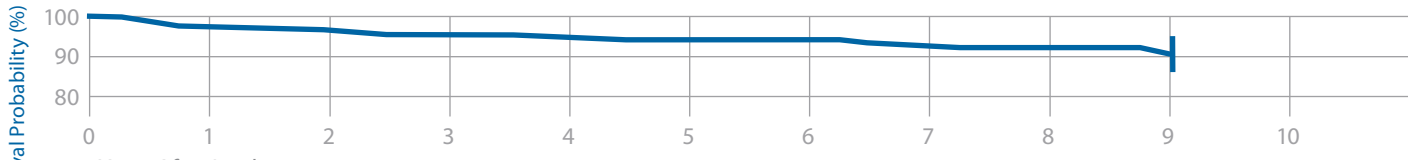
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	81
Other	53

Product Surveillance Registry Results

Number of Leads Enrolled in Study	656
Cumulative Months of Follow-Up	32,177
Number of Leads Active in Study	133

Qualifying Complications 35 Total

Failure to Capture	18	Lead Dislodgement	9
Failure to Sense	4	Medical Judgment	1
Impedance Out of Range	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	96.8	96.4	95.3	94.7	94.0	94.0	92.8	92.1	90.5
#	495	431	350	292	242	187	134	80	51

Effective Sample Size

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Registered US Implants	61,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	41,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

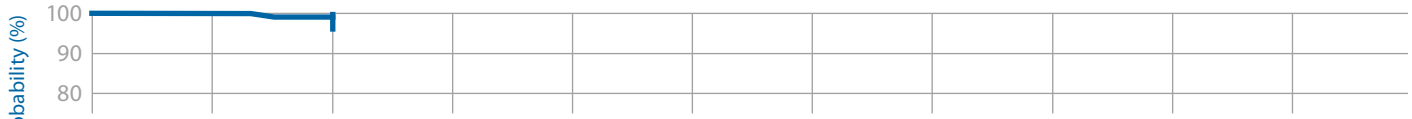
Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	490
Cumulative Months of Follow-Up	5,514
Number of Leads Active in Study	382

Qualifying Complications 2 Total

Lead Dislodgment	2		



	1 yr	2 yr
%	99.5	99.5
#	156	57

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Registered US Implants	85,400	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	40,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

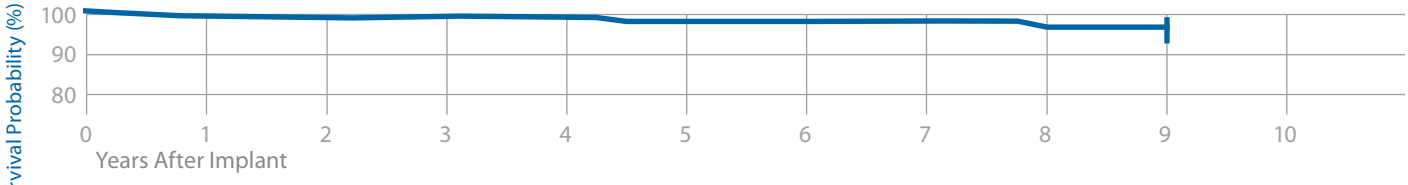
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	283
Cumulative Months of Follow-Up	14,710
Number of Leads Active in Study	61

Qualifying Complications 6 Total

Failure to Capture	3
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	98.2	98.2	98.2	98.2	97.4	97.4	97.4	96.0	96.0
#	193	171	153	130	112	101	81	66	48

Effective Sample Size

5024, 5024M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	SY or LAT
Registered US Implants	197,800	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	42,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

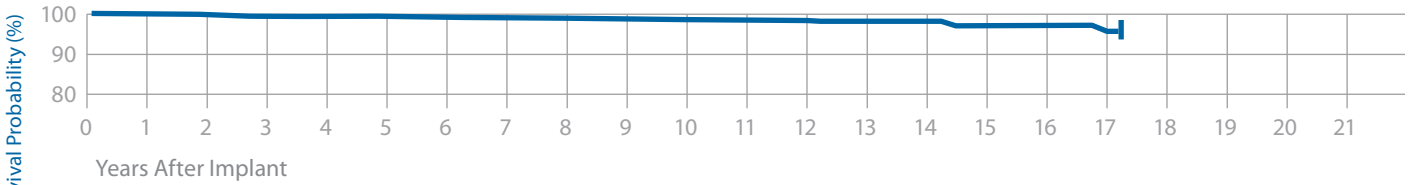
Conductor Fracture	53
Crimp/Weld/Bond	1
Insulation Breach	56
Other	17

Product Surveillance Registry Results

Number of Leads Enrolled in Study	8,153
Cumulative Months of Follow-Up	444,024
Number of Leads Active in Study	262

Qualifying Complications 57 Total

Conductor Fracture	3	Insulation (not further defined)	5
Extra Cardiac Stimulation	2	Lead Dislodgement	6
Failure to Capture	27	Other	2
Failure to Sense	2	Oversensing	5
Impedance Out of Range	3	Unspecified Clinical Failure	1
Insulation (ESC)	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	16 yr	17 yr	at 207 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	97.9	97.1	97.1	95.6	95.6
#	6,128	5,277	4,477	3,747	3,113	2,460	1,927	1,457	1,103	837	636	466	348	250	163	102	56	48

Effective Sample Size

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

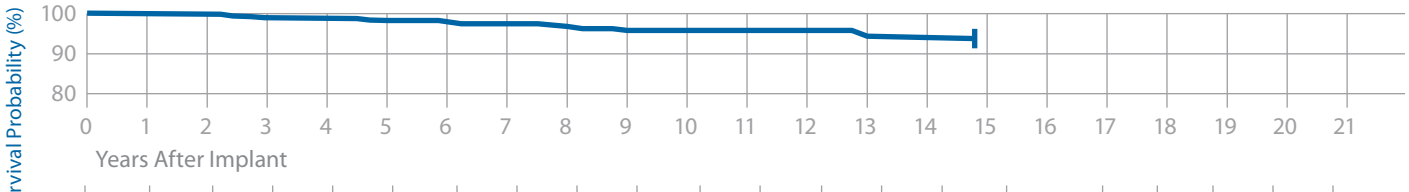
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	100,842
Number of Leads Active in Study	148

Qualifying Complications 29 Total

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	8	Insulation (not further defined)	1
Failure to Capture	13	Lead Dislodgement	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	at 177 mo
%	99.7	99.6	99.1	99.0	98.8	98.3	97.7	96.9	96.0	96.0	95.6	95.6	94.9	93.9	93.9
#	1,415	1,143	944	795	658	527	416	347	290	240	188	153	126	78	45

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5034 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDF
Registered US Implants	55,200	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	12,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	14
Other	7

Atrial Placement

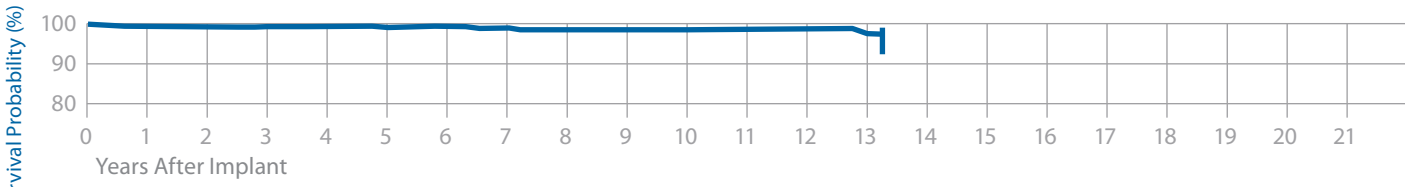
Product Surveillance Registry Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	44,637
Number of Leads Active in Study	130

Qualifying Complications

5 Total

Conductor Fracture	1
Failure to Capture	2
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	at 159 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	98.8	98.8	98.8	98.8	98.8	98.8	97.5	97.5
#	383	382	379	373	355	330	294	250	207	183	147	102	61	50

Effective Sample Size

Ventricular Placement

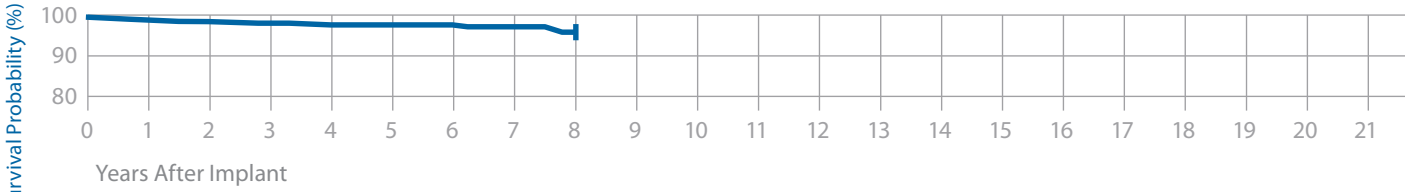
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Follow-Up	44,496
Number of Leads Active in Study	12

Qualifying Complications

11 Total

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



	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

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Registered US Implants	95,900	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	41,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	1
Insulation Breach	24
Other	6

Atrial Placement

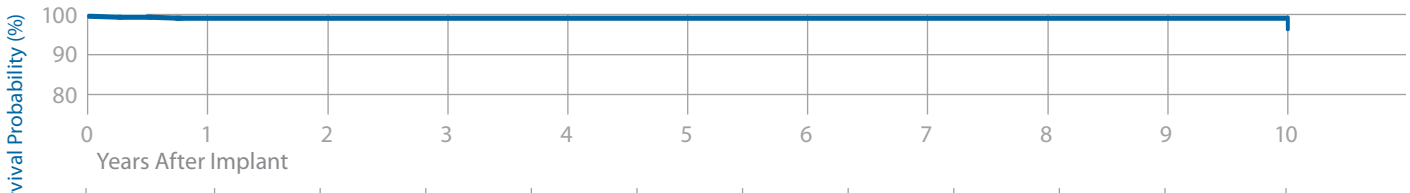
Product Surveillance Registry Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	33,362
Number of Leads Active in Study	156

Qualifying Complications

2 Total

Failure to Capture	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	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	208	155	93	50

Effective Sample Size

Ventricular Placement

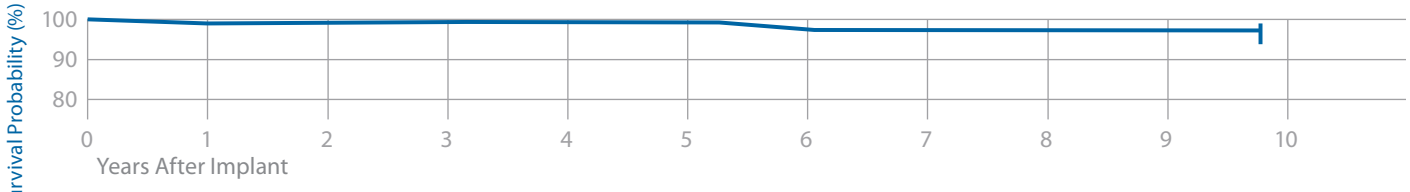
Product Surveillance Registry Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	39,207
Number of Leads Active in Study	92

Qualifying Complications

9 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 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	274	202	157	116	76	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5068 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDJ
Registered US Implants	102,400	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	29,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	40
Crimp/Weld/Bond	2
Insulation Breach	56
Other	83

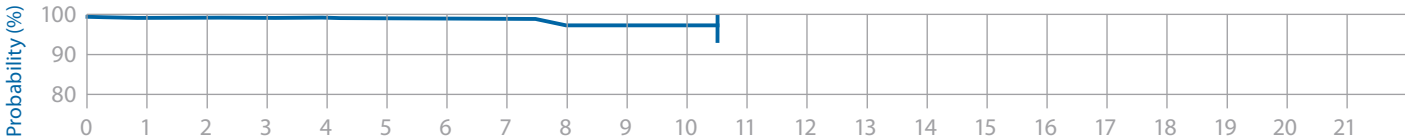
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	968
Cumulative Months of Follow-Up	34,032
Number of Leads Active in Study	31

Qualifying Complications 6 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.6	99.6	99.3	99.3	99.3	99.3	99.3	97.6	97.6	97.6	97.6
#	553	425	322	254	211	160	131	104	78	62	47

Effective Sample Size

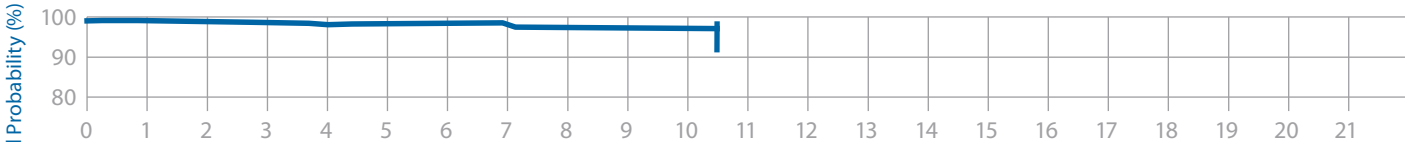
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,362
Cumulative Months of Follow-Up	40,437
Number of Leads Active in Study	65

Qualifying Complications 5 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.9	99.7	99.5	99.2	99.2	99.2	98.5	98.5	98.5	98.5	98.5
#	700	499	363	268	227	189	152	128	102	70	51

Effective Sample Size

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Registered US Implants	10,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	4,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

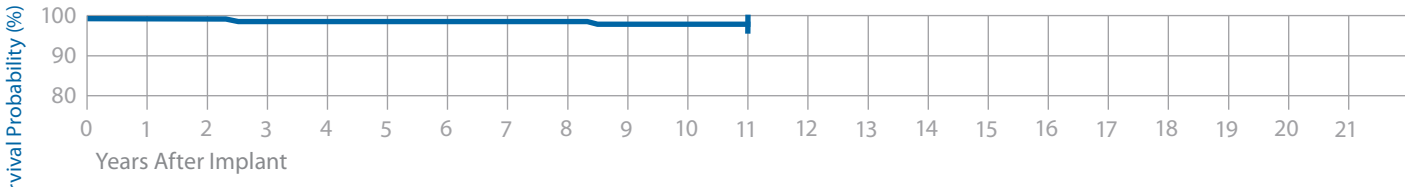
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	6
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	508
Cumulative Months of Follow-Up	27,962
Number of Leads Active in Study	55

Qualifying Complications 3 Total

Cardiac Perforation	1
Failure to Capture	1
Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.8	99.8	99.4	99.4	99.4	99.4	99.4	99.4	98.5	98.5	98.5
#	376	316	268	222	187	164	134	112	93	75	54

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Registered US Implants	1,511,200	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	956,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	404
Crimp/Weld/Bond	0
Insulation Breach	422
Other	204

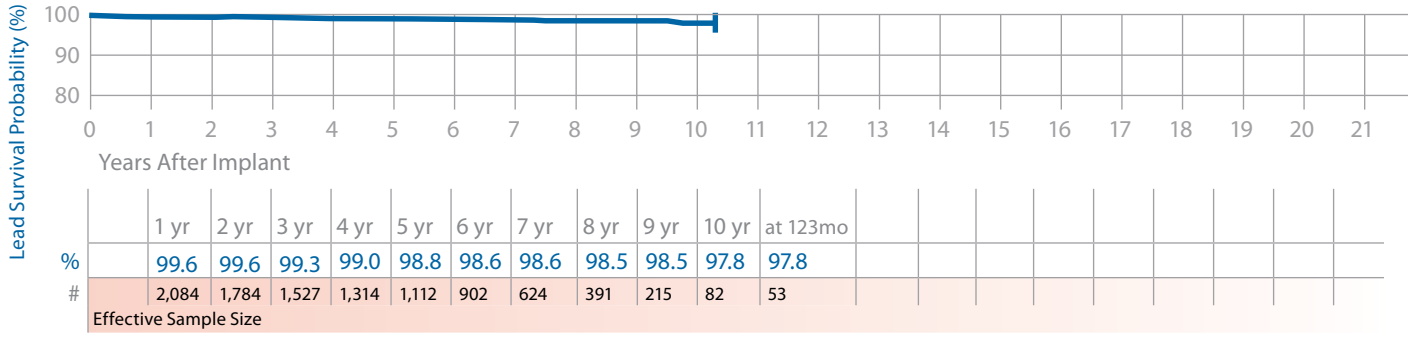
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,744
Cumulative Months of Follow-Up	139,060
Number of Leads Active in Study	648

Qualifying Complications 26 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123mo
%	99.6	99.6	99.3	99.0	98.8	98.6	98.6	98.5	98.5	97.8	97.8
#	2,084	1,784	1,527	1,314	1,112	902	624	391	215	82	53

Effective Sample Size

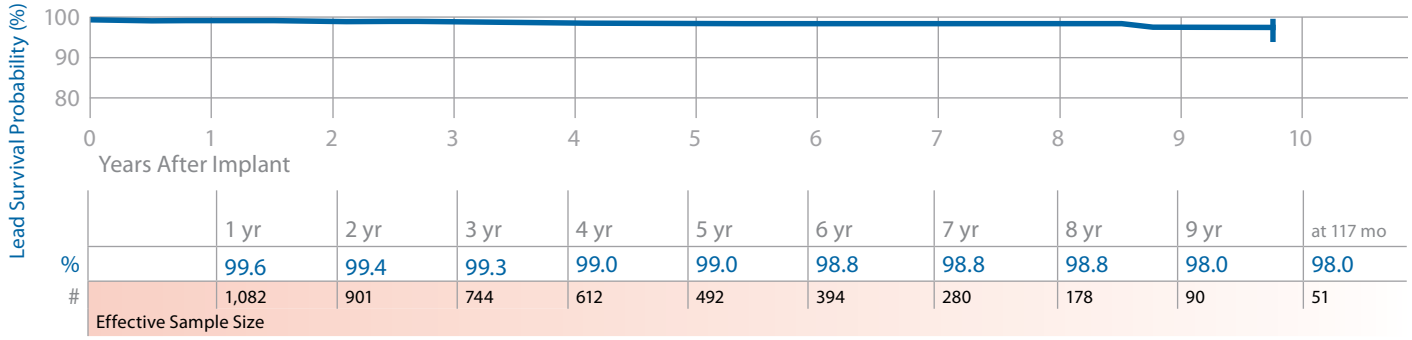
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,539
Cumulative Months of Follow-Up	67,711
Number of Leads Active in Study	276

Qualifying Complications 12 Total

Cardiac Perforation	1	Failure to Sense	1
Conductor Fracture	1	Impedance Out of Range	2
Failure to Capture	5	Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	99.6	99.4	99.3	99.0	99.0	98.8	98.8	98.8	98.0	98.0
#	1,082	901	744	612	492	394	280	178	90	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5086MRI CapSureFix Novus

Product Characteristics

US Market Release	Feb-11	Serial Number Prefix	LFP
Registered US Implants	102,900	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated Active US Implants	99,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

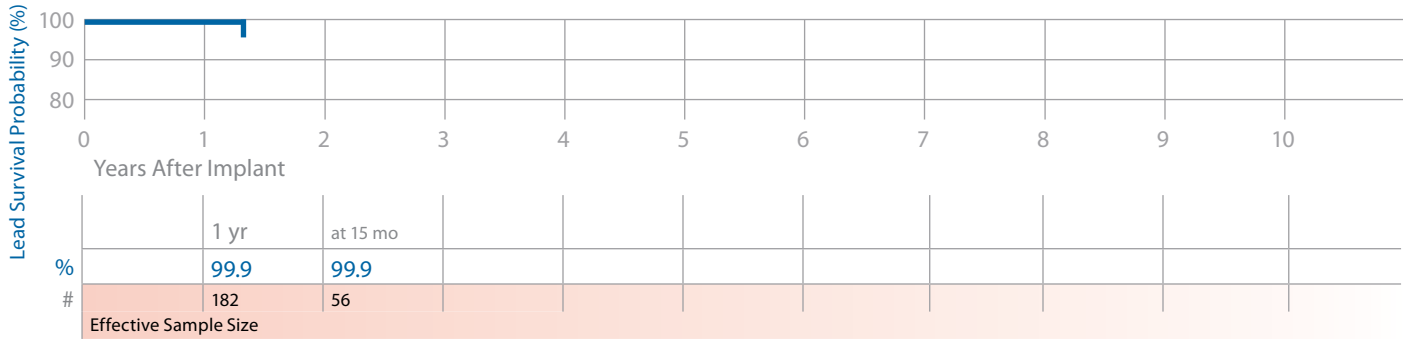
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	3
Other	12

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,406
Cumulative Months of Follow-Up	13,080
Number of Leads Active in Study	2,225

Qualifying Complications 1 Total

Lead Dislodgement	1



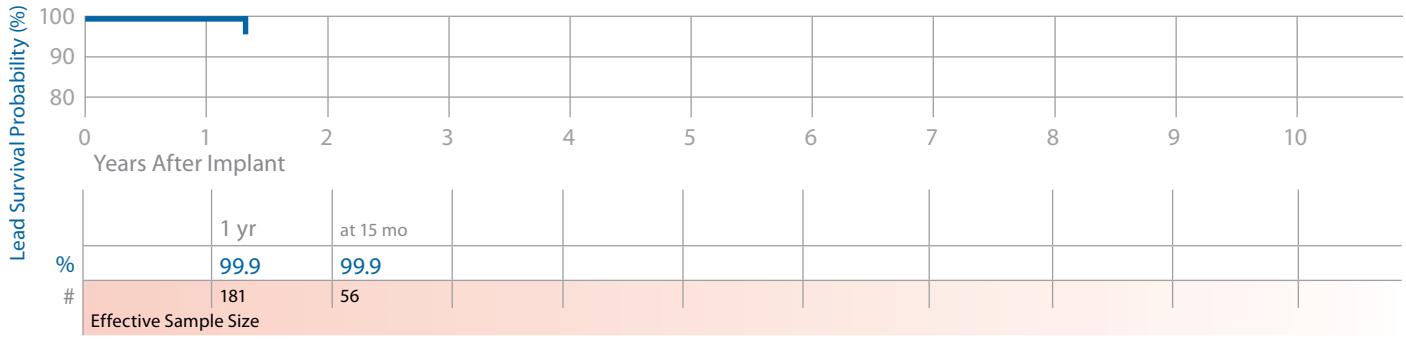
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,397
Cumulative Months of Follow-Up	13,008
Number of Leads Active in Study	2,220

Qualifying Complications 2 Total

Failure to Capture	1
Lead Dislodgement	1



Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Registered US Implants	132,700	Type and/or Fixation	Transvenous, Vent, Tines
Estimated Active US Implants	60,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	0
Insulation Breach	38
Other	5

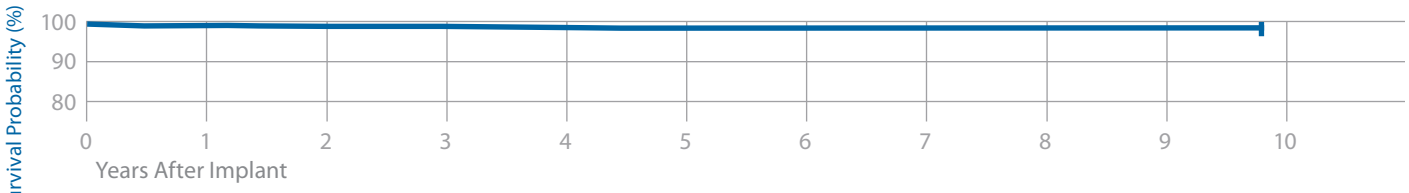
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,172
Cumulative Months of Follow-Up	47,860
Number of Leads Active in Study	130

Qualifying Complications

9 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	99.5	99.4	99.2	99.0	99.0	98.6	98.6	98.6	98.6	98.6
#	812	650	518	407	316	240	179	123	79	52

Effective Sample Size

5524, 5524M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Registered US Implants	59,400	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	15,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	11
Crimp/Weld/Bond	2
Insulation Breach	11
Other	3

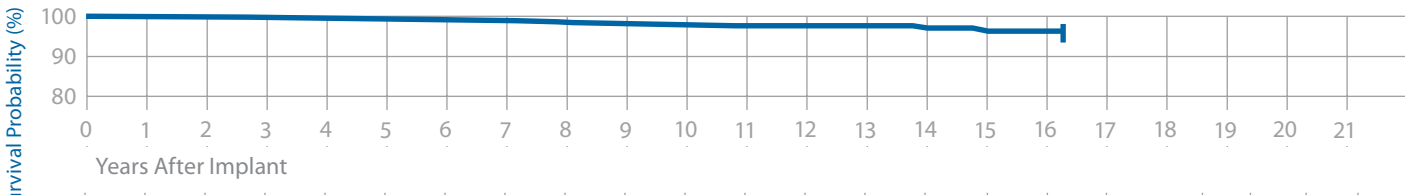
Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,496
Cumulative Months of Follow-Up	255,338
Number of Leads Active in Study	233

Qualifying Complications

41 Total

Conductor Fracture	1	Insulation (not further defined)	1
Failure to Capture	23	Lead Dislodgement	4
Failure to Sense	4	Other	1
Impedance Out of Range	1	Oversensing	6



	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 195 mo
%	99.7	99.7	99.5	99.3	99.2	99.2	98.9	98.4	98.1	97.8	97.6	97.6	97.6	97.0	96.2	96.2	96.2
#	3,438	2,964	2,541	2,136	1,781	1,418	1,120	862	691	556	422	311	233	170	102	53	49

Effective Sample Size

Leads

Pacing Leads continued

5534 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDG
Registered US Implants	25,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	6,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

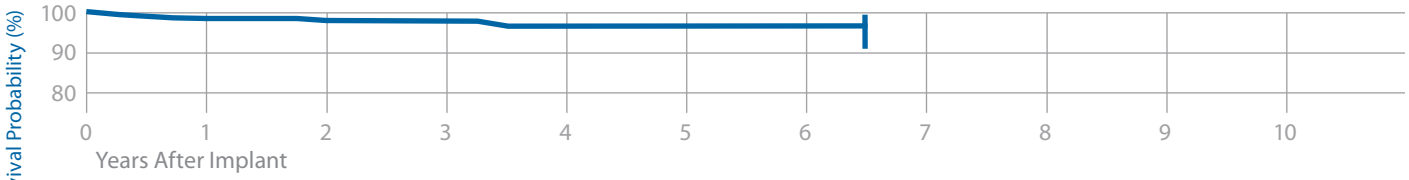
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	4
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	264
Cumulative Months of Follow-Up	13,009
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

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Registered US Implants	62,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	29,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

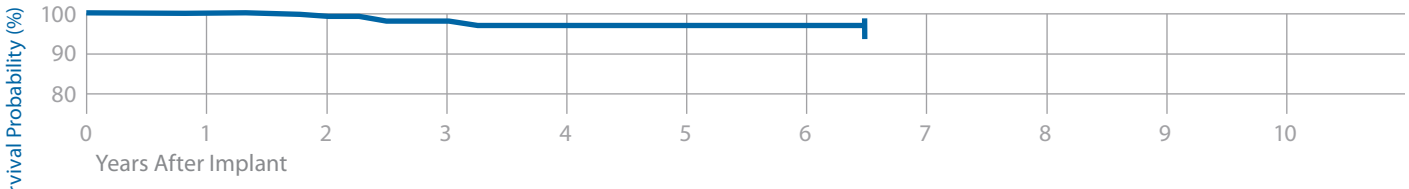
Conductor Fracture	9
Crimp/Weld/Bond	0
Insulation Breach	18
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	15,784
Number of Leads Active in Study	35

Qualifying Complications 4 Total

Failure to Capture	1
Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	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	159	137	80	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Registered US Implants	90,900	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	50,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

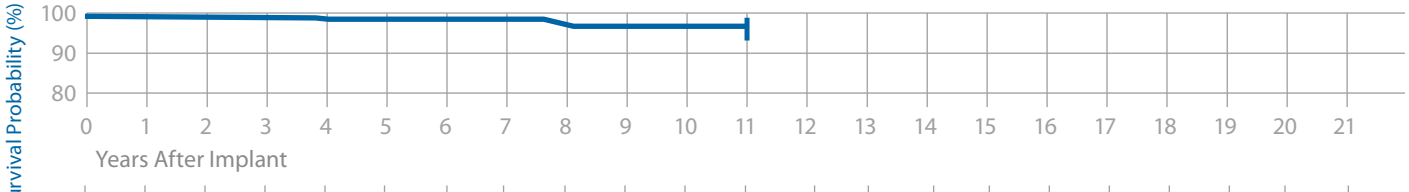
Conductor Fracture	13
Crimp/Weld/Bond	0
Insulation Breach	28
Other	38

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,053
Cumulative Months of Follow-Up	40,661
Number of Leads Active in Study	99

Qualifying Complications 11 Total

Conductor Fracture	1	Failure to Sense	2
Extra Cardiac Stimulation	1	Lead Dislodgement	1
Failure to Capture	5	Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.7	99.2	99.2	99.2	98.8	97.8	97.8	97.8	97.8	97.8	97.8
#	712	526	402	287	222	170	136	114	95	72	45

Effective Sample Size

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Registered US Implants	34,500	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	18,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

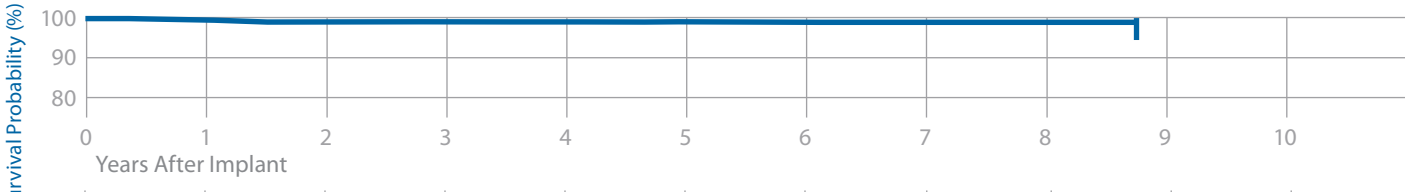
Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	4
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	672
Cumulative Months of Follow-Up	31,062
Number of Leads Active in Study	112

Qualifying Complications 5 Total

Failure to Capture	3		
Lead Dislodgement	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.7	99.3	99.3	98.9	98.9	98.9	98.9	98.9	98.9
#	517	434	347	283	219	153	111	81	54

Effective Sample Size

Leads

Pacing Leads continued

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Registered US Implants	15,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	10,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

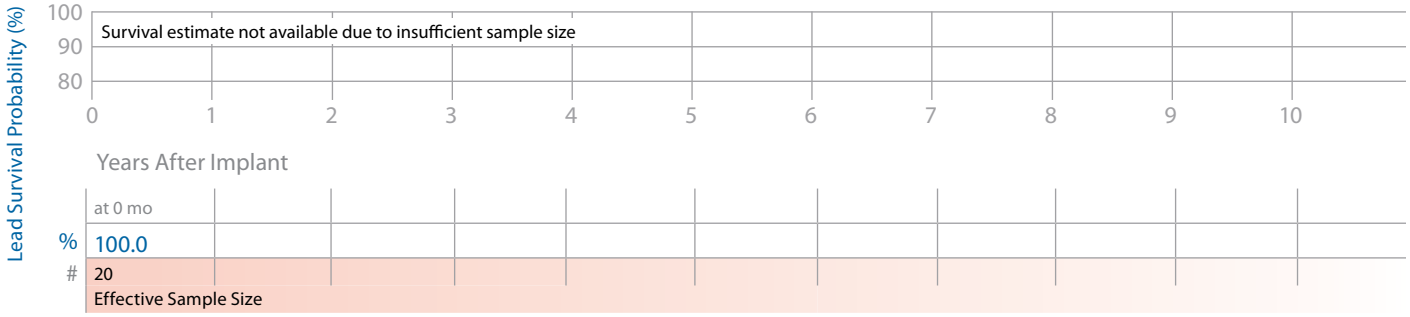
US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	7
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	20
Cumulative Months of Follow-Up	1,515
Number of Leads Active in Study	10

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	20

Effective Sample Size

6940 CapSureFix

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	TCP
Registered US Implants	25,400	Type and/or Fixation	Transvenous, Atrial-J , Screw-in
Estimated Active US Implants	7,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

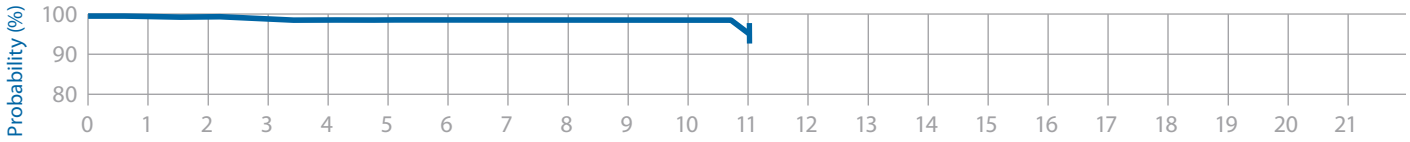
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	17
Other	15

Product Surveillance Registry Results

Number of Leads Enrolled in Study	816
Cumulative Months of Follow-Up	43,939
Number of Leads Active in Study	80

Qualifying Complications 12 Total

Conductor Fracture	1
Failure to Sense	3
Lead Dislodgement	3
Oversensing	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.7	99.6	98.3	98.1	98.1	98.1	98.1	98.1	98.1	98.1	94.8
#	641	530	441	364	306	254	205	157	125	95	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	769	509	6	22,098	99.2 +0.4/-1.1	99.2 +0.4/-1.1	99.2 +0.4/-1.1	99.2 +0.4/-1.1	99.2 +0.4/-1.1	99.2 +0.4/-1.1 at 63 mo								
3830	SelectSecure	Vent	Aug-05	475	290	3	15,455	99.5 +0.4/-1.3	99.5 +0.4/-1.3	99.5 +0.4/-1.3	99.5 +0.4/-1.3	99.5 +0.4/-1.3	99.5 +0.4/-1.3 at 69 mo								
4024	CapSure SP	Vent	Oct-91	1,215	13	4	50,928	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/-5.0 at 117 mo					
4068	CapSureFix	Atrial	Mar-96	2,413	266	77	133,591	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	96.7 +0.9/-1.2	95.3 +1.2/-1.6	93.7 +1.6/-2.1	91.4 +2.3/-3.2	86.2 +4.4/-6.3 at 165 mo			
4068	CapSureFix	Vent	Mar-96	1,799	162	51	95,888	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	97.2 +0.8/-1.3	95.8 +1.2/-1.7	95.0 +1.4/-2.0	93.1 +2.0/-2.8	89.7 +3.7/-5.6	89.7 +3.7/-5.6 at 147 mo			
4074	CapSure Sense	Atrial	Jun-02	214	137	2	14,960	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	99.1 +0.7/-2.8 at 90 mo						
4074	CapSure Sense	Vent	Jun-02	956	691	3	30,769	99.7 +0.2/-0.8	99.5 +0.3/-1.1	99.5 +0.3/-1.1	99.5 +0.3/-1.1	99.5 +0.3/-1.1	99.5 +0.3/-1.1	99.5 +0.3/-1.1	99.5 +0.3/-1.1 at 93 mo						
4076	CapSureFix Novus	Atrial	Feb-04	1,662	1,017	8	59,076	99.8 +0.1/-0.5	99.6 +0.2/-0.5	99.5 +0.3/-0.6	99.5 +0.3/-0.6	99.5 +0.3/-0.6	98.9 +0.7/-2.3	98.9 +0.7/-2.3 at 75 mo							
4076	CapSureFix Novus	Vent	Feb-04	1,229	744	5	46,434	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.7 +0.2/-0.7	99.7 +0.2/-0.7	99.0 +0.7/-1.6	99.0 +0.7/-1.6	99.0 +0.7/-1.6 at 78 mo							
4092	CapSure SP Novus	Vent	Sep-98	1,147	293	19	65,701	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	97.7 +0.8/-1.3	97.7 +0.8/-1.3	97.7 +0.8/-1.3	97.7 +0.8/-1.3 at 117 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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
4524	CapSure SP	Atrial	Oct-91	911	35	6	40,725	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	99.0 +0.6/-1.2 at 126 mo				
4558M	Screw-In	Atrial	Nov-94	539	6	12	23,289	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 9 yr					
4568	CapSureFix	Atrial	Jan-97	656	133	35	32,177	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	92.8 +2.3/-3.2	92.1 +2.5/-3.6	90.5 +3.5/-5.4 at 9 yr					
4574	CapSure Sense	Atrial	Jun-02	490	382	2	5,514	99.5 +0.4/-1.5	99.5 +0.4/-1.5												
4592	CapSure SP Novus	Atrial	Oct-98	283	61	6	14,710	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	96.0 +2.4/-5.7	96.0 +2.4/-5.7 at 9 yr					
5024, 5024M	CapSure SP	Vent	Mar-90	8,153	262	57	444,024	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	97.9 +0.8/-1.2	97.1 +1.2/-2.1	95.6 +2.3/-4.6 at 207 mo	
5033	CapSure Z	Vent	Feb-96	1,899	148	29	100,842	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	95.6 +1.5/-2.4	93.9 +2.4/-3.7	93.9 +2.4/-3.7 at 177 mo		
5034	CapSure Z	Atrial	Feb-96	386	130	5	44,637	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	97.5 +1.7/-5.4 at 159 mo			
5034	CapSure Z	Vent	Feb-96	1,209	12	11	44,496	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	156	2	33,362	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					
5054	CapSure Z Novus	Vent	Jun-98	967	92	9	39,207	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 117 mo					

continued

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	31	6	34,032	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 126 mo				
5068	CapSureFix	Vent	Jan-97	1,362	65	5	40,437	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 126 mo				
5072	SureFix	A or V	Jun-98	508	55	3	27,962	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	98.5 +1.1/-4 at 11 yr				
5076	CapSureFix Novus	Atrial	Aug-00	2,744	648	26	139,060	99.6 +0.2/-0.3	99.6 +0.2/-0.4	99.3 +0.3/-0.4	99.0 +0.4/-0.6	98.8 +0.4/-0.6	98.6 +0.5/-0.7	98.6 +0.5/-0.7	98.5 +0.5/-0.9	97.8 +1.1/-1.9	97.8 +1.1/-1.9 at 123 mo				
5076	CapSureFix Novus	Vent	Aug-00	1,539	276	12	67,711	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	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.0 +1.2/-2.5 at 117 mo					
5086MRI	CapSureFix Novus	Atrial	Feb-11	2,406	2,225	1	13,080	99.9 +0.1/-0.4	99.9 +0.1/-0.4 at 15 mo												
5086MRI	CapSureFix Novus	Vent	Feb-11	2,397	2,220	2	13,008	99.9 +0.1/-0.3	99.9 +0.1/-0.3 at 15 mo												
5092	CapSure SP Novus	Vent	Jun-98	1,172	130	9	47,860	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 117 mo					
5524, 5524M	CapSure SP	Atrial	Mar-90	4,496	233	41	255,338	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	97.8 +0.7/-1.1	97.6 +0.7/-1.2	97.0 +1.1/-1.7	96.2 +1.6/-2.7	96.2 +1.6/-2.7 at 195 mo	
5534	CapSure Z	Atrial	Feb-96	264	6	6	13,009	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	35	4	15,784	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	99	11	40,661	99.7 +0.2/-0.7	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0	98.8 +0.7/-1.6	97.8 +1.2/-2.6	97.8 +1.2/-2.6	97.8 +1.2/-2.6	97.8 +1.2/-2.6	97.8 +1.2/-2.6 at 11 yr				
5592	CapSure SP Novus	Atrial	Jun-98	672	112	5	31,062	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 105 mo					
5594	CapSure SP Novus	Atrial	Jun-01	20	10	0	1,515	100.0 at 0 mo													
6940	CapSureFix	Atrial	Oct-98	816	80	12	43,939	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	94.8 +3.1/-7.5 at 11 yr				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
3830	SelectSecure	Aug-05	20,900	15,900	4	12	0	4
4024	CapSure SP	Oct-91	217,500	41,100	27	178	0	16
4068	CapSureFix	Mar-96	123,800	30,300	50	163	0	95
4074	CapSure Sense	Jun-02	91,300	57,100	2	20	0	1
4076	CapSureFix Novus	Feb-04	432,000	332,400	33	33	1	24
4092	CapSure SP Novus	Sep-98	177,000	80,400	9	48	0	3
4524	CapSure SP	Oct-91	99,500	23,400	1	64	0	6
4558M	Screw-in	Nov-94	19,400	3,800	1	18	0	20
4568	CapSureFix	Jan-97	69,100	21,500	3	81	0	53
4574	CapSure Sense	Jun-02	61,000	41,100	5	3	0	0
4592	CapSure SP Novus	Oct-98	85,400	40,800	7	17	0	1
5024, 5024M	CapSure SP	Mar-90	197,800	42,400	53	56	1	17
5033	CapSure Z	Feb-96	2,300	500	1	0	0	3
5034	CapSure Z	Feb-96	55,200	12,300	12	14	0	7
5054	CapSure Z Novus	Jun-98	95,900	41,100	10	24	1	6
5068	CapSureFix	Jan-97	102,400	29,300	40	56	2	83
5072	SureFix	Jun-98	10,000	4,200	3	6	0	0
5076	CapSureFix Novus	Aug-00	1,511,200	956,100	404	422	0	204
5086MRI	CapSureFix Novus MRI	Feb-11	102,900	99,700	3	3	0	12
5092	CapSure SP Novus	Jun-98	132,700	60,800	10	38	0	5
5524, 5524M	CapSure SP	Mar-90	59,400	15,800	11	11	2	3
5534	CapSure Z	Feb-96	25,800	6,800	3	4	0	4
5554	CapSure Z Novus	Jun-98	62,000	29,200	9	18	0	1
5568	CapSureFix	Jan-97	90,900	50,500	13	28	0	38
5592	CapSure SP Novus	Jun-98	34,500	18,900	4	4	0	0
5594	CapSure SP Novus	Jun-01	15,800	10,300	5	7	0	1
6940	CapSureFix	Oct-98	25,400	7,200	12	17	0	15

Source: Returned Product Analysis
Data as of February 1, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	20,900	5	1	27	14	3	1	1	0	0	2
4024	CapSure SP	217,500	12	11	48	103	1	15	1	2	6	20
4068	CapSureFix	123,800	5	3	31	23	0	5	1	1	2	4
4074	CapSure Sense	91,300	10	1	24	28	0	1	0	0	2	0
4076	CapSureFix Novus	432,000	46	4	116	63	6	14	1	8	11	12
4092	CapSure SP Novus	177,000	1	4	21	28	0	0	1	0	2	2
4524	CapSure SP	99,500	2	2	23	15	0	4	2	0	1	12
4558M	Screw-in	19,400	2	0	2	2	0	1	0	1	1	1
4568	CapSureFix	69,100	3	1	4	6	1	1	0	0	2	1
4574	CapSure Sense	61,000	0	1	33	14	1	8	0	0	0	4
4592	CapSure SP Novus	85,400	0	0	26	8	1	1	1	0	0	2
5024, 5024M	CapSure SP	197,800	9	8	30	49	1	9	6	3	3	16
5033	CapSure Z	2,300	0	0	0	0	0	0	0	0	0	1
5034	CapSure Z	55,200	2	2	14	28	0	3	3	0	0	12
5054	CapSure Z Novus	95,900	1	1	22	22	0	0	1	0	2	9
5068	CapSureFix	102,400	16	4	20	31	1	5	1	0	1	6
5072	SureFix	10,000	0	0	2	2	0	0	0	0	0	0
5076	CapSureFix Novus	1,511,200	150	11	470	227	27	35	8	13	12	31
5086MRI	CapsureFix Novus	102,900	99	2	112	55	13	11	1	9	2	0
5092	CapSure SP Novus	132,700	4	1	43	30	1	6	3	3	0	9
5524, 5524M	CapSure SP	59,400	0	0	0	0	0	0	0	0	0	0
5534	CapSure Z	25,800	0	0	6	3	0	1	0	1	0	4
5554	CapSure Z Novus	62,000	0	1	29	25	0	2	0	0	0	3
5568	CapSureFix	90,900	7	0	30	19	2	2	1	2	2	4
5592	CapSure SP Novus	34,500	1	0	24	4	0	2	0	0	0	1
5594	CapSure SP Novus	15,800	0	0	8	0	0	0	0	0	0	2
6940	CapSureFix	25,400	0	1	6	1	0	0	0	0	1	0

Report Cutoff Date: February 1, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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
4024	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4068	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
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
4524	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
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
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)
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 February 1, 2013

Epi/Myocardial Pacing Leads

4951, 4951M Spectraflex

Product Characteristics

US Market Release	Oct-81	Serial Number Prefix	TF or LBJ
Registered US Implants	11,600	Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Estimated Active US Implants	2,500	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

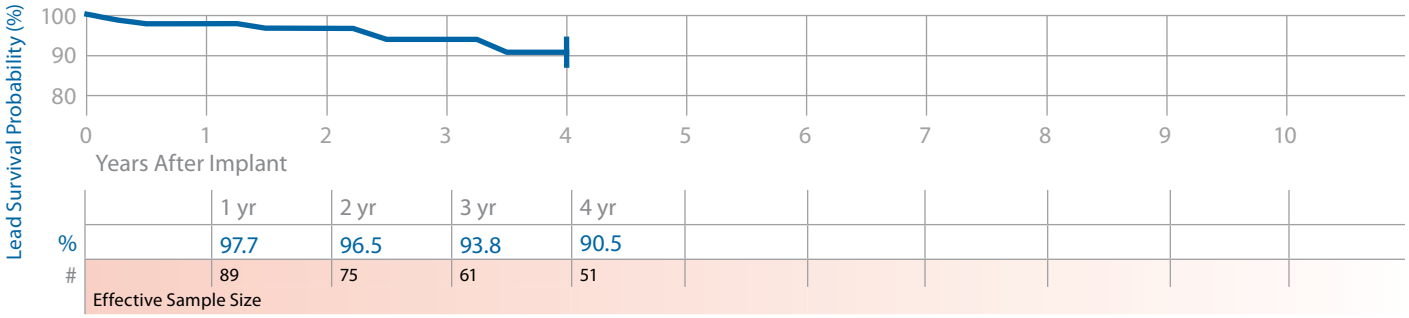
Conductor Fracture	36
Crimp/Weld/Bond	0
Insulation Breach	9
Other	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	179
Cumulative Months of Follow-Up	5,953
Number of Leads Active in Study	4

Qualifying Complications 14 Total

Conductor Fracture	1	Impedance Out of Range	1
Failure to Capture	7	Insulation (ESC)	1
Failure to Sense	3	Insulation (not further defined)	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	20,900	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	9,400	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

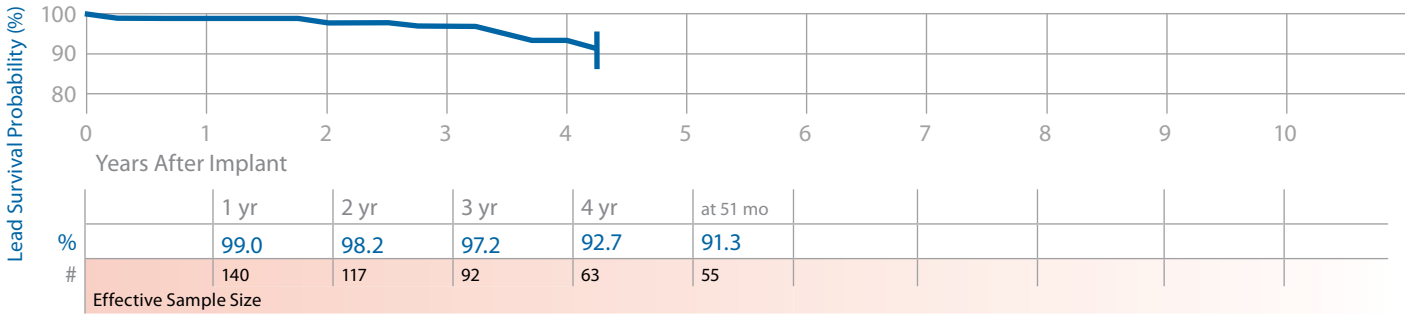
Conductor Fracture	163
Crimp/Weld/Bond	1
Insulation Breach	34
Other	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	219
Cumulative Months of Follow-Up	7,617
Number of Leads Active in Study	25

Qualifying Complications 12 Total

Conductor Fracture	5	Insulation (not further defined)	1
Failure to Capture	3	Oversensing	2
Failure to Sense	1		



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	99.0	98.2	97.2	92.7	91.3
#	140	117	92	63	55

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

Product Characteristics

US Market Release	Sep-99	Serial Number Prefix	LEN
Registered US Implants	27,800	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	17,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

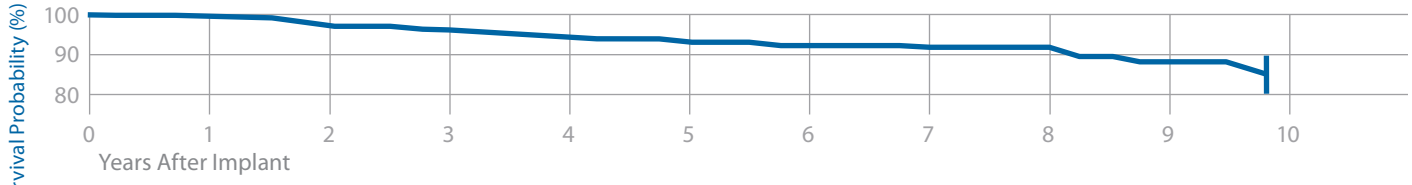
Conductor Fracture	33
Crimp/Weld/Bond	0
Insulation Breach	12
Other	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	816
Cumulative Months of Follow-Up	39,078
Number of Leads Active in Study	334

Qualifying Complications 61 Total

Conductor Fracture	12		Impedance Out of Range	5
Extra Cardiac Stimulation	2		Insulation (not further defined)	3
Failure to Capture	20		Other	7
Failure to Sense	4		Oversensing	8



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	98.6	96.7	95.1	93.0	92.1	91.2	89.2	89.2	86.4	84.7
#	618	525	428	342	266	195	142	99	66	47

Effective Sample Size

5071 Screw-in

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Registered US Implants	44,300	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated Active US Implants	15,200	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

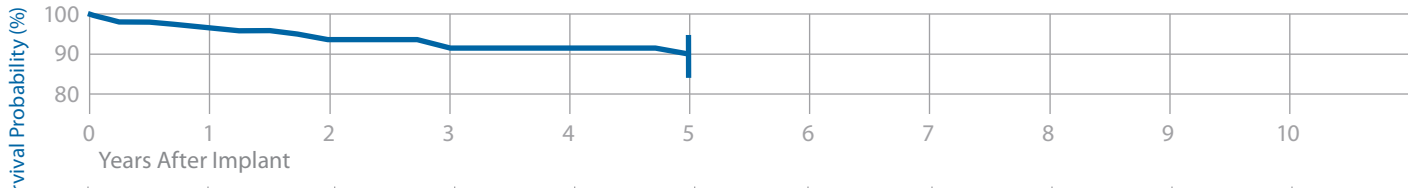
Conductor Fracture	13
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	295
Cumulative Months of Follow-Up	8,171
Number of Leads Active in Study	60

Qualifying Complications 14 Total

Failure to Capture	11		
Impedance Out of Range	1		
Oversensing	2		



	1 yr	2 yr	3 yr	4 yr	5 yr
%	97.3	94.2	92.0	92.0	90.3
#	147	102	75	64	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

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	5,953	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	25	12	7,617	99 .0 +0.7/-3.0	98.2 +1.2/-4.0	97.2 +1.8/-4.7	92.7 +3.7/-7.1	91.3 +4.2/-8.0 at 51 mo							
4968	CapSure Epi	Sep-99	816	334	61	39,078	98.6 +0.6/-1.2	96.7 +1.1/-1.7	95.1 +1.5/-2.1	93.0 +1.9/-2.5	92.1 +2.0/-2.8	91.2 +2.3/-3.0	89.2 +2.8/-3.8	89.2 +2.8/-3.8	84.7 +4.6/-6.3 at 117 mo			
5071	Screw -in	Dec-92	295	60	14	8,171	97.3 +1.5/-3.2	94.2 +2.8/-4.9	92.0 +3.6/-6.2	92.0 +3.6/-6.2	90.3 +4.3/-7.5							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

Epi/Myocardial Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
4951, 4951M	Spectraflex	Oct-81	11,600	2,500	36	9	0	5
4965	CapSure Epi	Sep-96	20,900	9,400	163	34	1	2
4968	CapSure Epi	Sep-99	27,800	17,200	33	12	0	2
5071	Screw-in	Dec-92	44,300	15,200	13	2	0	0

Source: Returned Product Analysis
Data as of February 1, 2013

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	11,600	0	1	0	8	0	0	0	0
4965	CapSure Epi	20,900	0	1	0	4	1	4	3	0
4968	CapSure Epi	27,800	0	0	3	11	2	0	2	0
5071	Screw-in	44,300	1	0	0	32	0	2	2	3

Model Number	Family	Estimated US Implants	Insulation Breach	Unspecified
4951, 4951M	Spectraflex	11,600	0	1
4965	CapSure Epi	20,900	0	3
4968	CapSure Epi	27,800	1	0
5071	Screw-in	44,300	0	1

Report Cutoff Date: Data as of February 1, 2013

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 February 1, 2013

VDD Single Pass Pacing Leads

5032 CapSure VDD

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCL, LCN, LCM
Registered US Implants	5,300	Type and/or Fixation	Transvenous, Atr-Vent,Tines
Estimated Active US Implants	1,200	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	6
Other	0

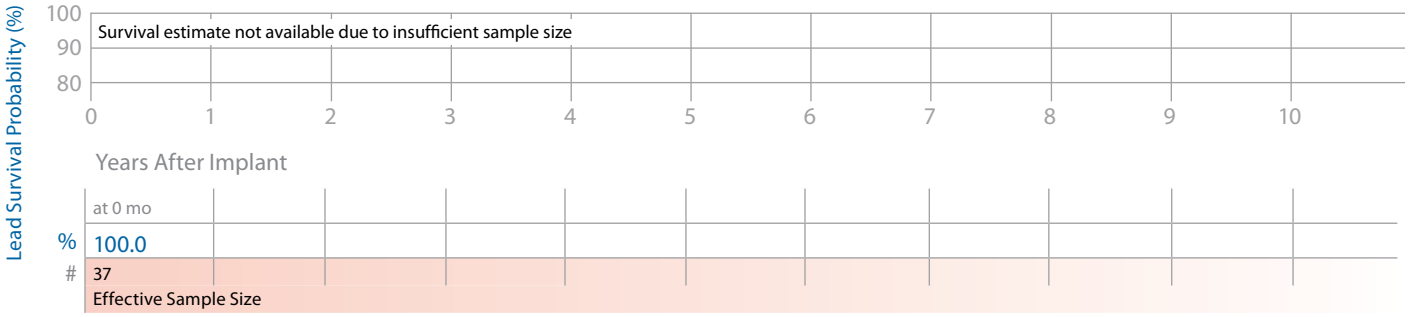
Product Surveillance Registry Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,683
Number of Leads Active in Study	0

Qualifying Complications

1 Total

Failure to Sense	1



	at 0 mo
%	100.0
#	37

Effective Sample Size

5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Registered US Implants	9,100	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

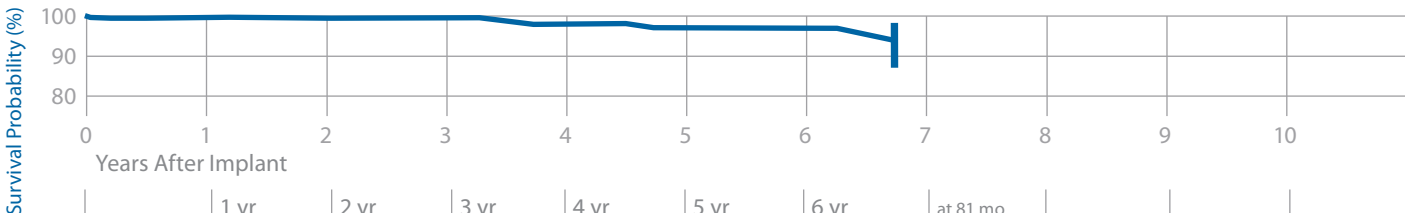
Product Surveillance Registry Results

Number of Leads Enrolled in Study	558
Cumulative Months of Follow-Up	20,718
Number of Leads Active in Study	51

Qualifying Complications

6 Total

Conductor Fracture	3
Failure to Capture	1
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	98.2	98.2	95.2
#	420	308	220	176	135	83	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of February 1, 2013

VDD Single Pass Pacing 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	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	558	51	6	20,718	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4	98.8 +0.8/-2.8	98.2 +1.2/-3.2	98.2 +1.2/-3.2	95.2 +3.0/-7.3 at 81 mo			

Source: Product Surveillance Registry
Data as of February 1, 2013

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	5,300	1,200	7	0	6	0
5038	CapSure VDD-2	Sep-98	9,100	3,500	4	0	1	0

Source: Returned Product Analysis
Data as of February 1, 2013

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Lead Dislodgement	Failure to Capture	Failure to Sense	Extracardiac Stimulation	Unspecified
5032	CapSure VDD	5,400	1	1	1	0	1
5038	CapSure VDD-2	9,000	2	1	1	1	0

Report Cutoff Date: February 1, 2013

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 February 1, 2013

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 Product Surveillance Registry. The study protocol requests device data be routinely taken and sent to Medtronic at no more than 6-month intervals.

In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available in a 6-month interval, a conservative approach has been adopted whereby only the maximum charge time in each 6-month interval is reported. As charge time is directly proportional to the time elapsed since the last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.

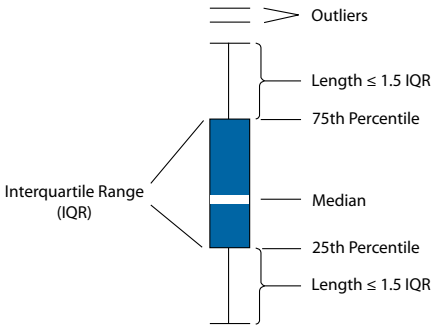
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

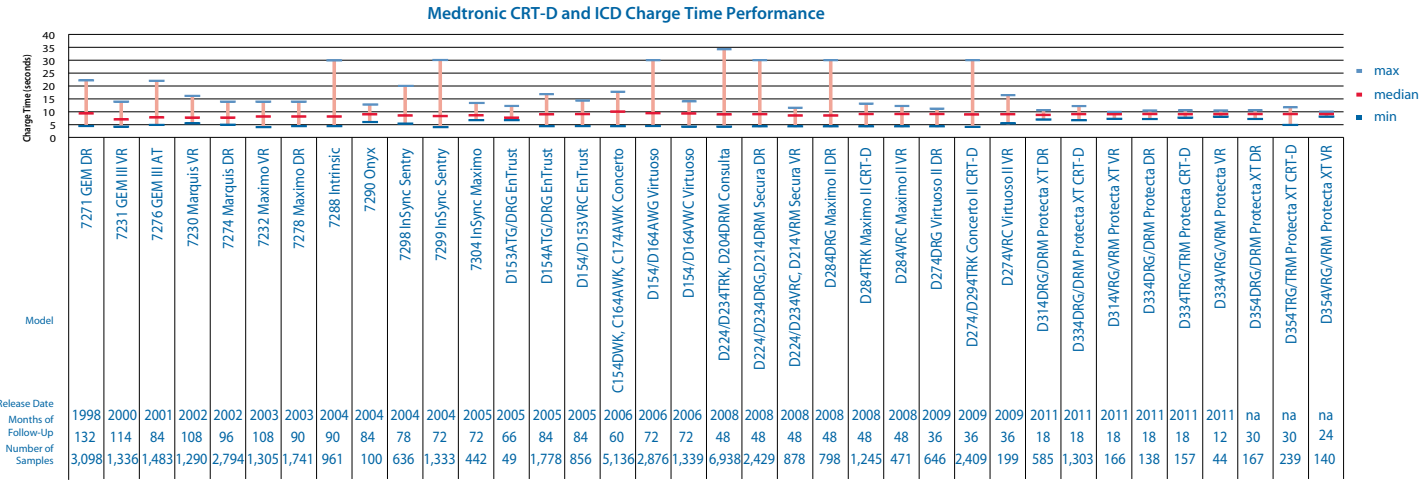
Data Presentation

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 7271 GEM DR.

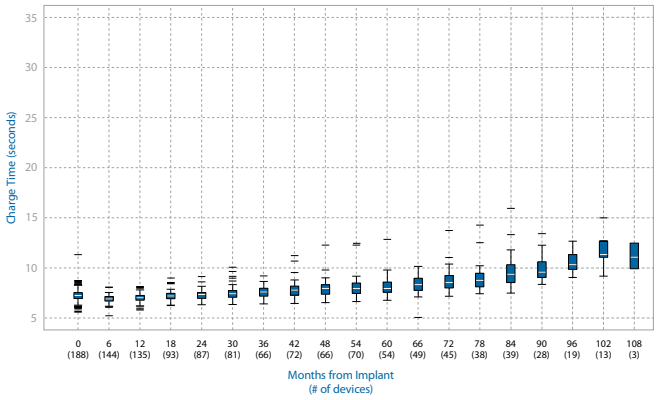




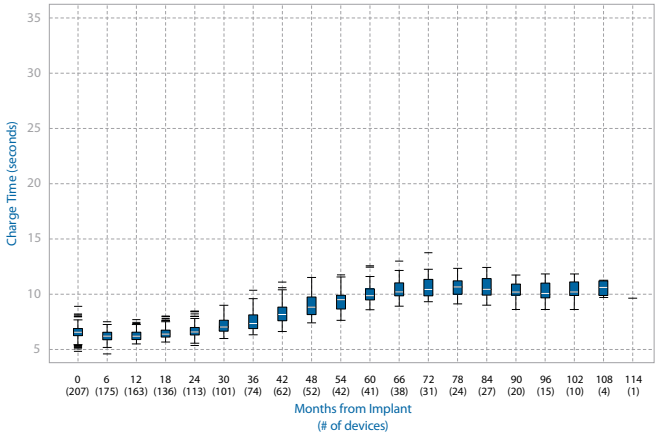
Source: Product Surveillance Registry
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

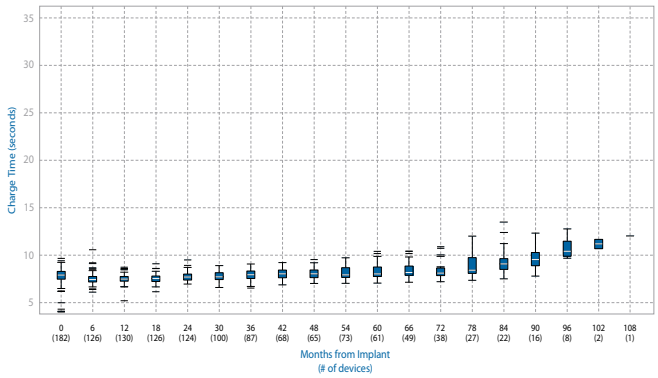
7230 Marquis VR Charge Time



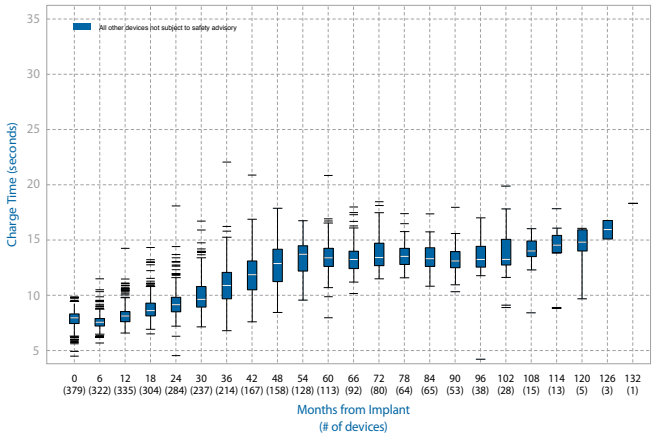
7231 GEM III VR Charge Time



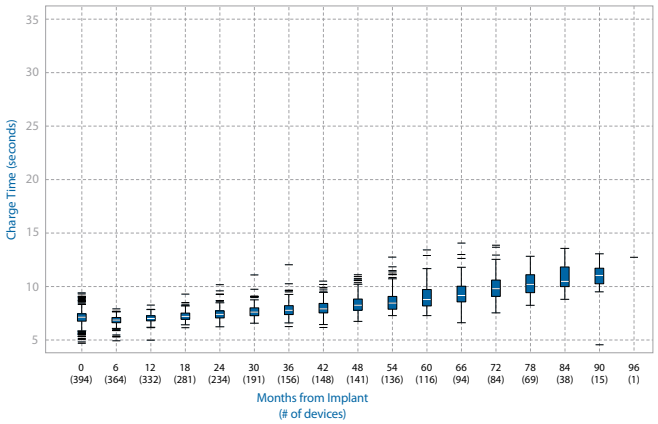
7232 Maximo VR Charge Time



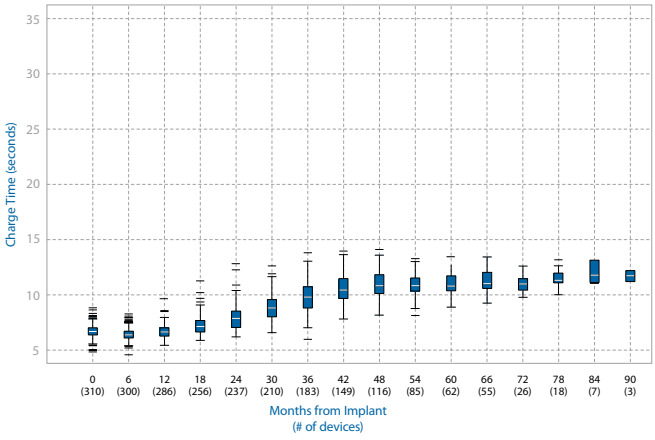
7271 GEM DR Charge Time



7274 Marquis DR Charge Time



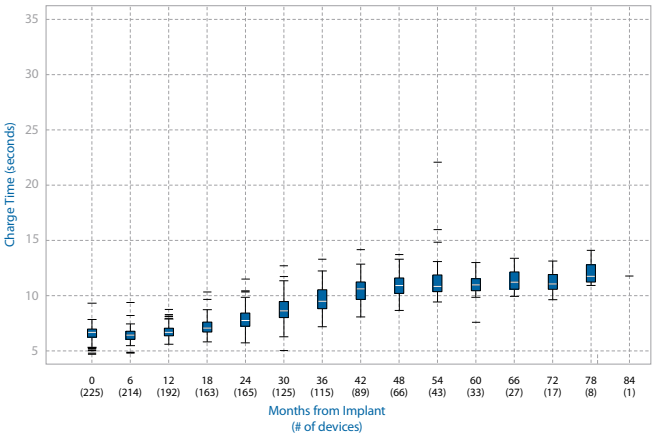
7275 GEM III DR Charge Time



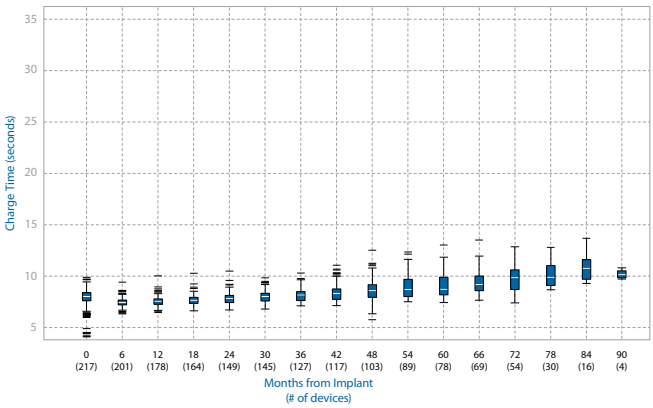
Source: System Longevity Study
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

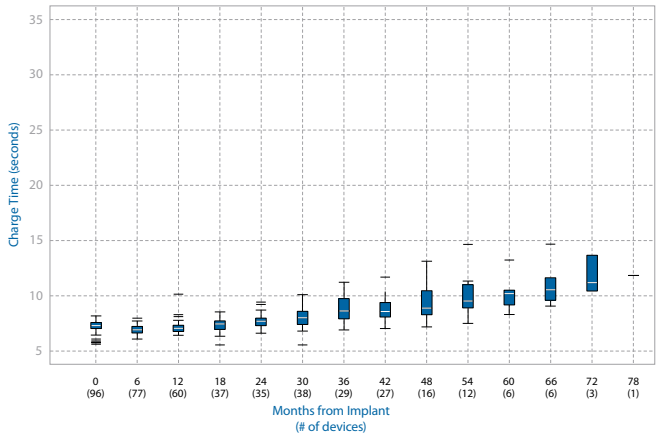
7276 GEM III AT Charge Time



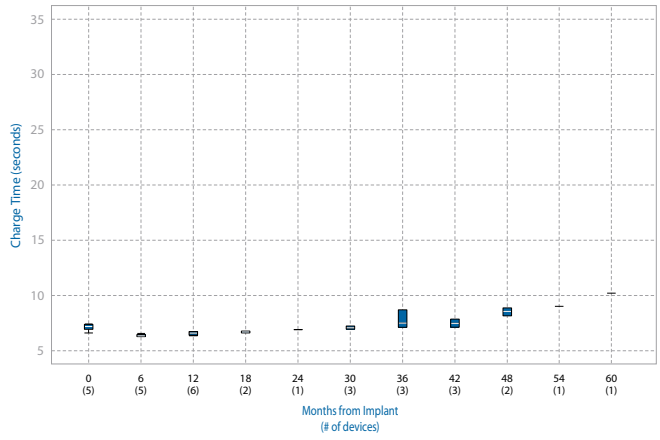
7278 Maximo DR Charge Time



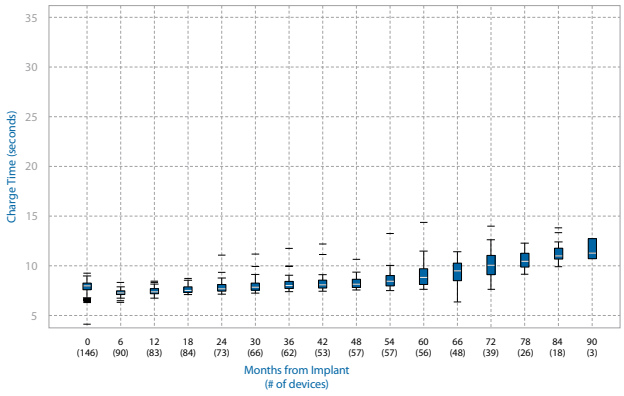
7279 InSync III Marquis Charge Time



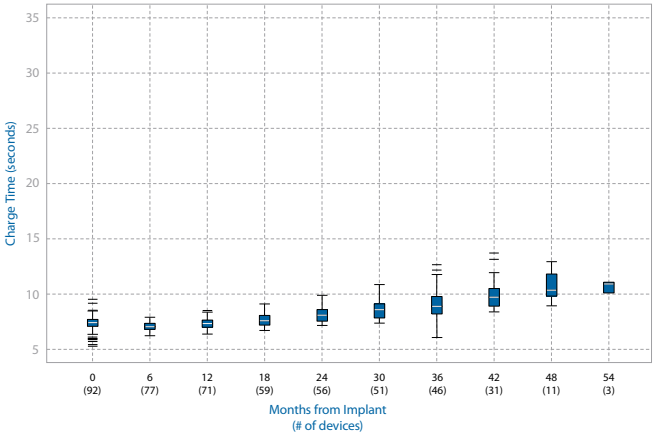
7285 InSync III Protect Charge Time



7288 Intrinsic Charge Time



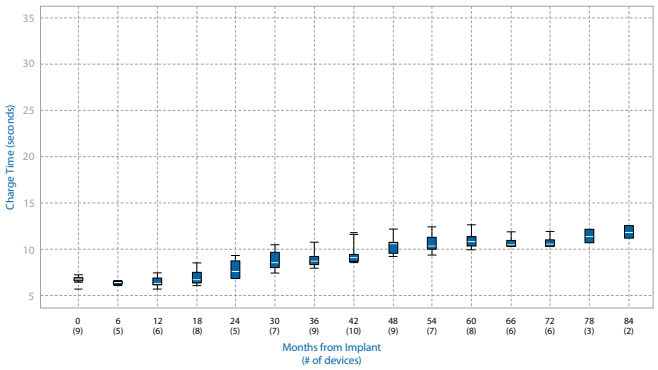
7289 InSync II Marquis Charge Time



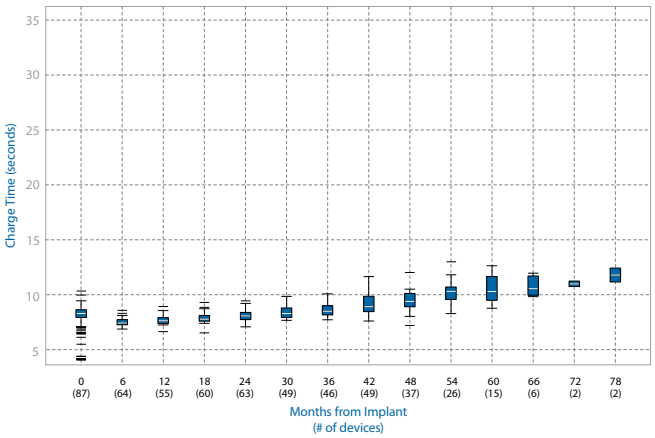
Source: Product Surveillance Registry
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

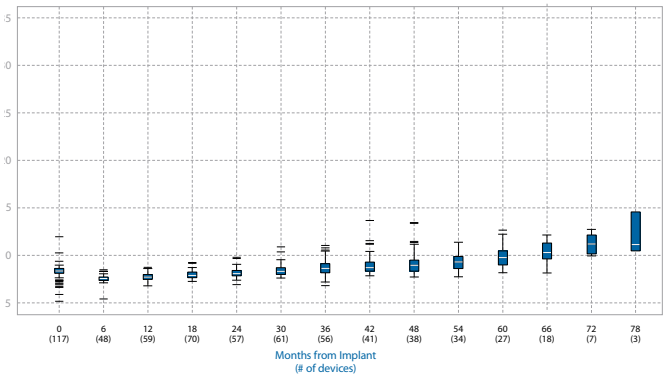
7290 Onyx Charge Time



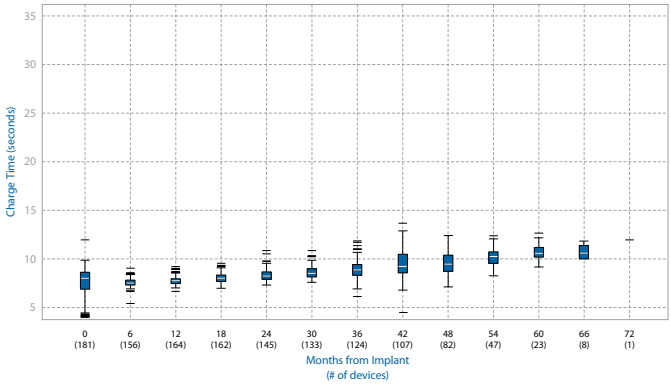
7297 InSync Sentry Charge Time



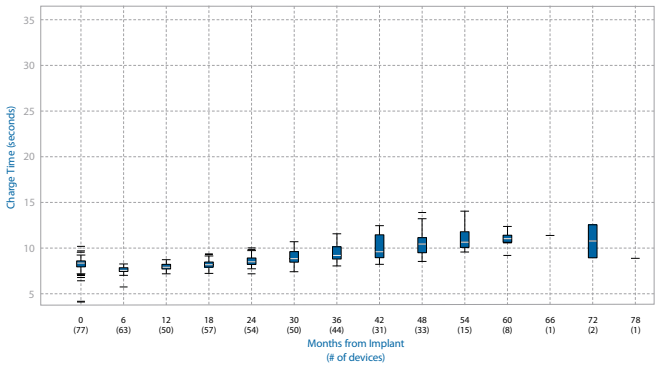
7298 InSync Sentry Charge Time



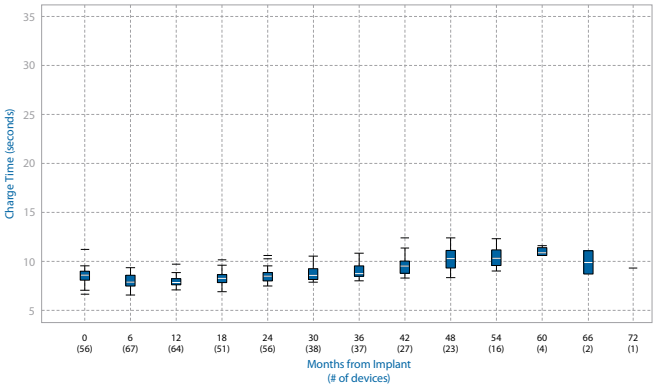
7299 InSync Sentry Charge Time



7303 InSync Maximo Charge Time



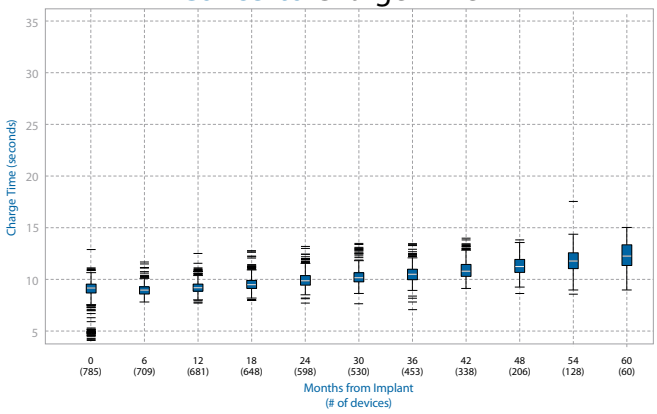
7304 InSync Maximo Charge Time



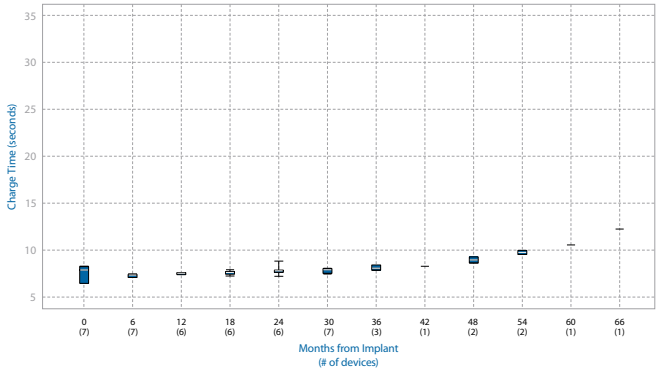
Source: System Longevity Study
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

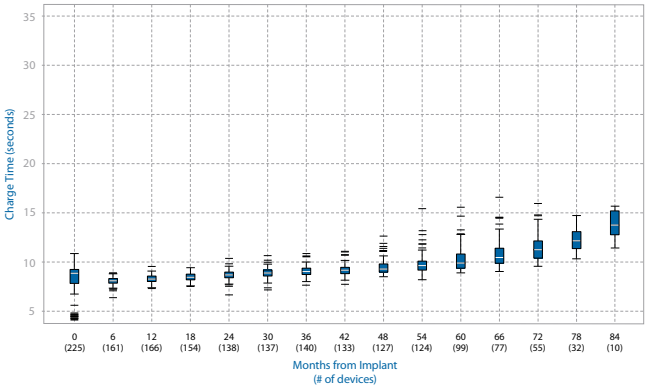
C154DWK, C164AWK, C174AWK Concerto Charge Time



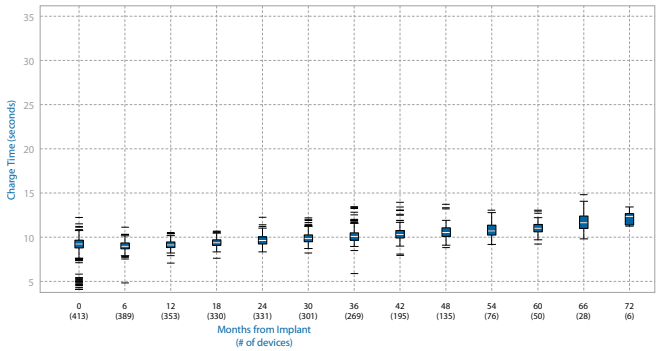
D153ATG/DRG EnTrust Charge Time



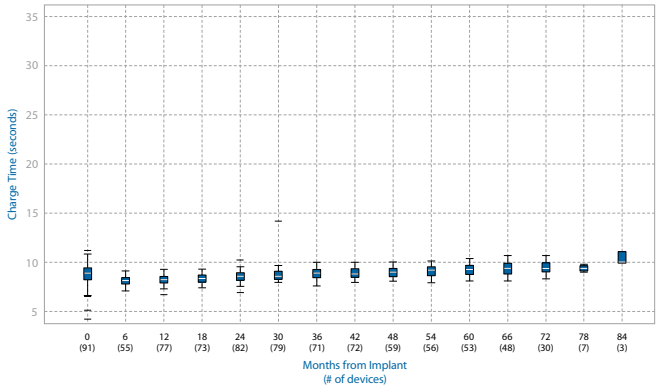
D154ATG/DRG EnTrust Charge Time



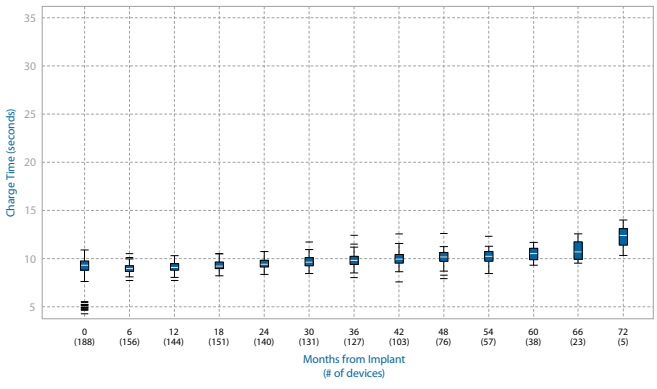
D154AWG/164 Virtuoso Charge Time



D154VRC EnTrust Charge Time



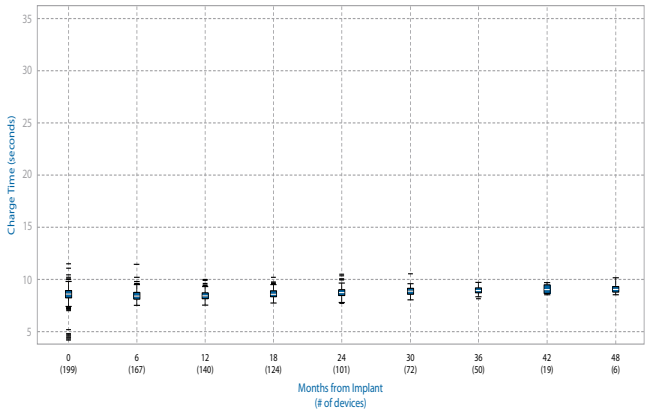
D154VWC/164 Virtuoso Charge Time



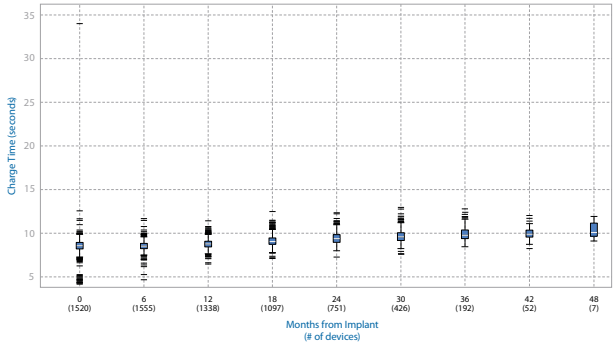
Source: Product Surveillance Registry
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

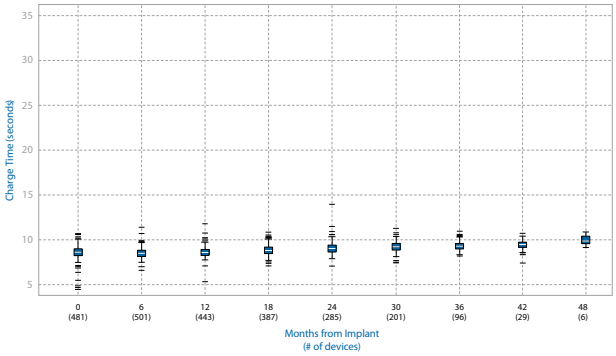
D224VRC/234 Secura VR Charge Time



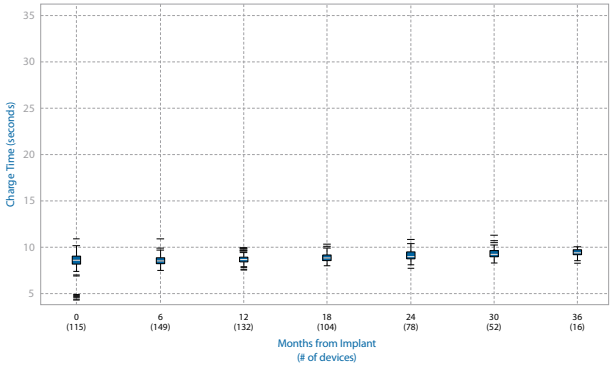
D224TRK/234 Consulta Charge Time



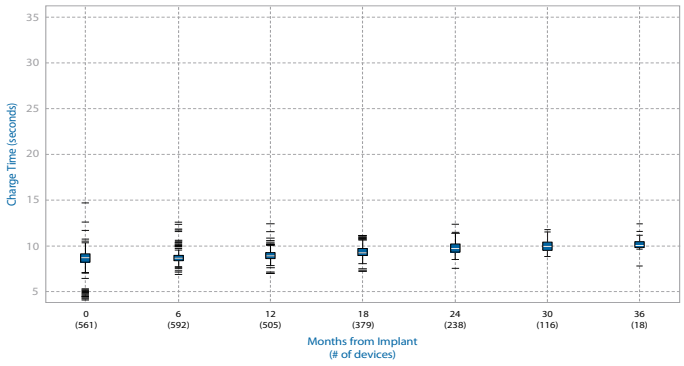
D224DRG/234 Secura DR Charge Time



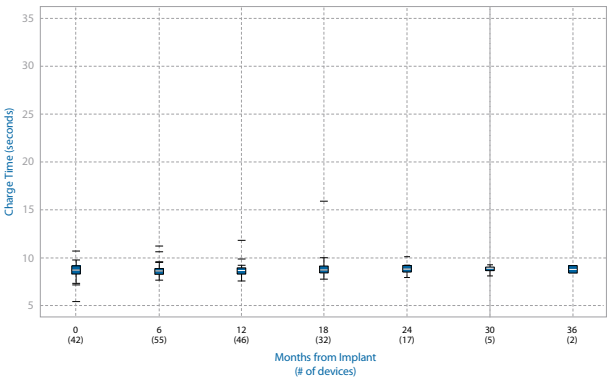
D274DRG Virtuoso II DR Charge Time



D274TRK/294 Concerto II CRT-D Charge Time



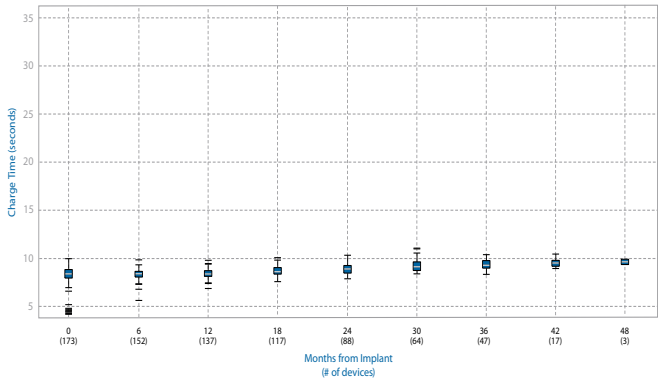
D274VRC Virtuoso II VR Charge Time



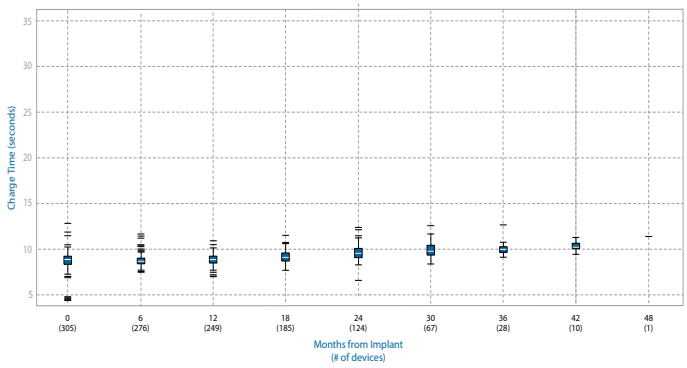
Source: System Longevity Study
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

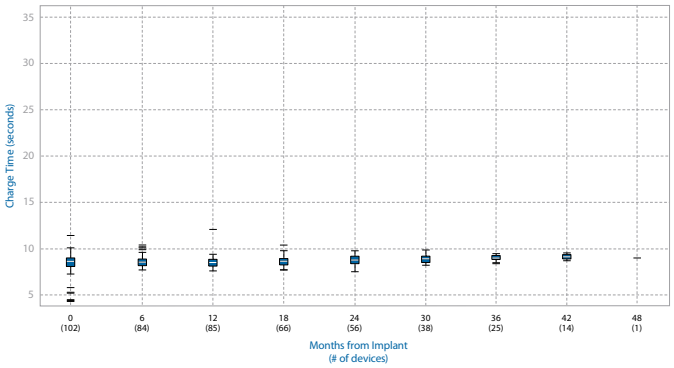
D284DRG Maximo II DR Charge Time



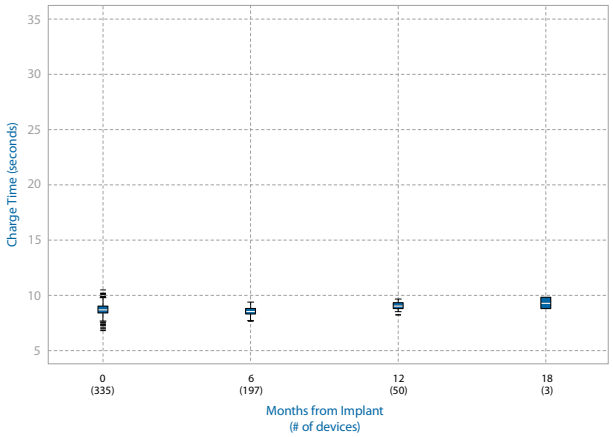
D284TRK Maximo II CRT-D Charge Time



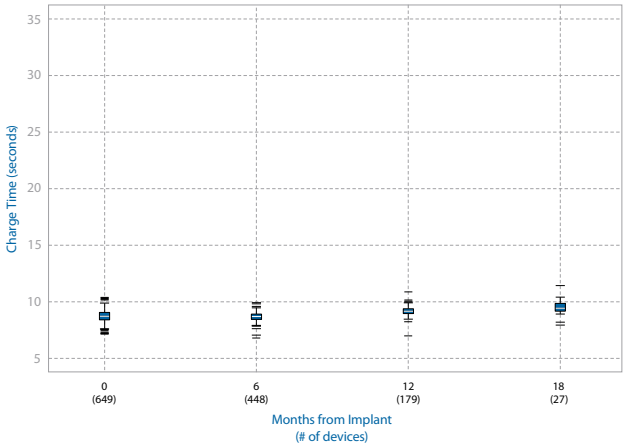
D284VRC Maximo II VR Charge Time



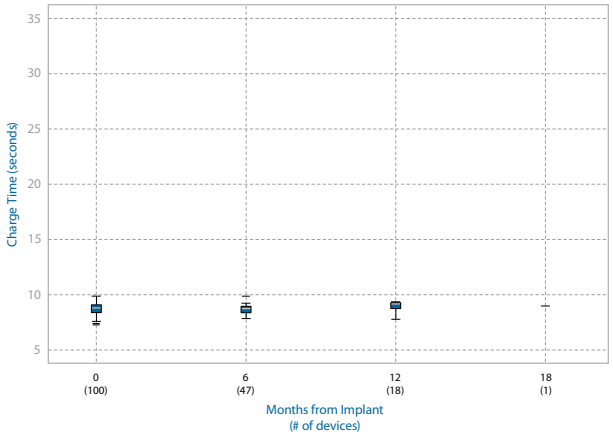
D314DRG/DRM Protecta XT DR Charge Time



D314TRG/TRM Protecta XT CRT-D Charge Time



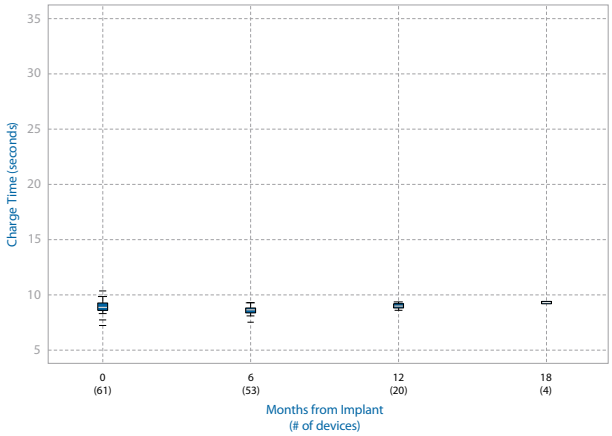
D314VRG/VRM Protecta XT VR Charge Time



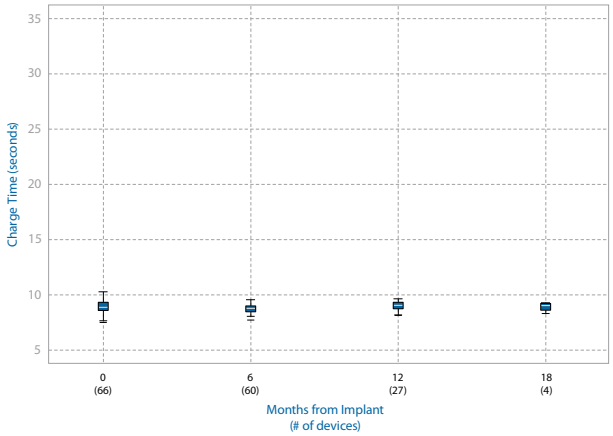
Source: Product Surveillance Registry
Data as of February 1, 2013

ICD and CRT-D Charge Time Performance continued

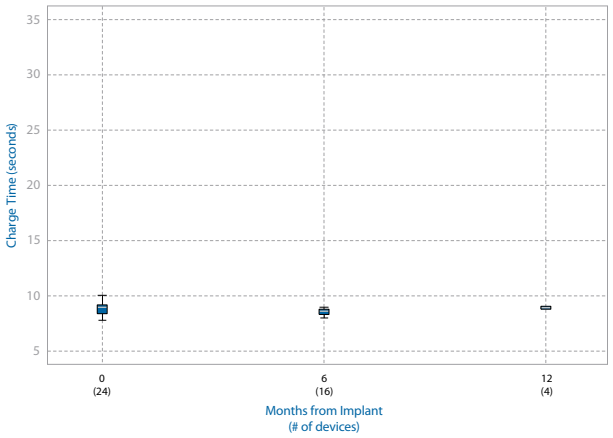
D334DRG/DRM Protecta DR Charge Time



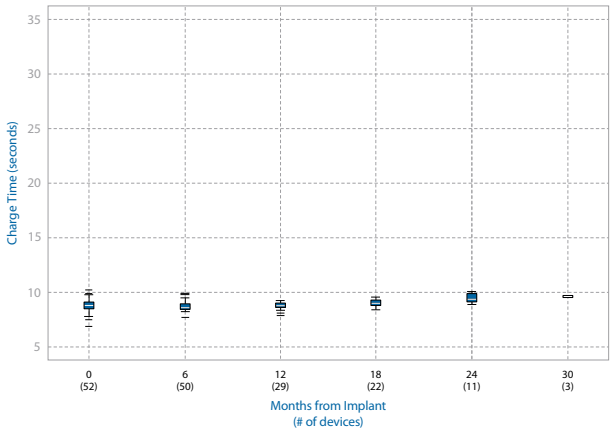
D334TRG/TRM Protecta CRT-D Charge Time



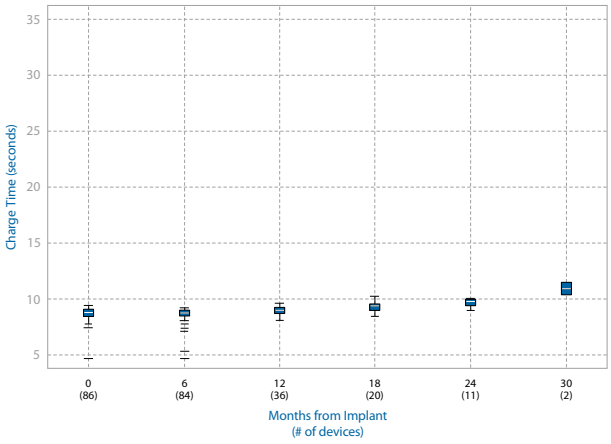
D334VRG/VRM Protecta VR Charge Time



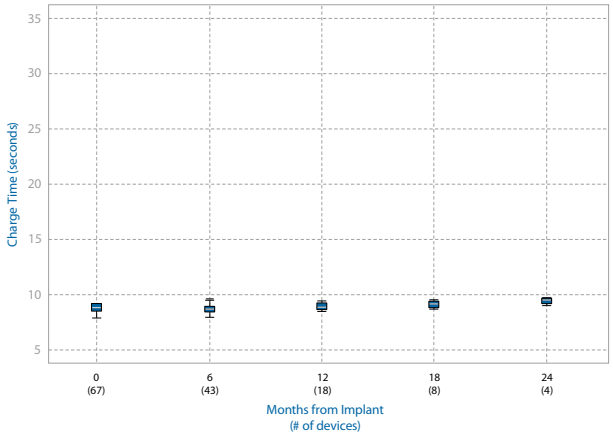
D354DRG/DRM Protecta XT DR Charge Time



D354TRG/TRM Protecta XT CRT-D Charge Time



D354VRG/VRM Protecta XT VR Charge Time



Source: System Longevity Study
Data as of February 1, 2013

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 11, 2013, there have been 74 confirmed events. No patient deaths have been reported due to this issue. No reports have been made of a failure to deliver high voltage therapy.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)
69,000 Worldwide (**43,200** United States)	**74** Worldwide (**56** United States)	**30,600** Worldwide (**19,400** United States)	**0.10%** Worldwide (**0.12%** 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.

[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.

Status Update

As of February 25, 2013, 364 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 96,100 remain implanted.

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)	**364** Worldwide	**88,800** Worldwide	**0.25%**	

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 February 25, 2013, percentage of devices that have encountered ERI due to battery impedance has not exceeded the rate of 6-10% within 5 years post-implant as communicated with our August 2011 Performance Update.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Only devices using the updated software can trigger ERI due to impedance.
All EnRhythm pacemakers (**146,500** Worldwide)	**6,698** Worldwide	**88,800** Worldwide	

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 11, 2013, 3,681 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, less than 500 remain implanted worldwide.

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)	**3,681** Worldwide (**3,165** United States)	**< 500** Worldwide (**< 500** 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 25, 2013, Medtronic has observed 458 Kappa devices and 294 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.79% (Kappa) and 1.97% (Sigma) of the original affected implant population.

Four hundred twenty-one (421) of the Kappa devices (0.72%) and 229 of the Sigma devices (1.53%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 37 Kappa devices (0.06%) and 65 Sigma devices (0.44%) 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, less than 500 Kappa devices remain implanted worldwide and 2,400 Sigma devices remain implanted worldwide. Of these, 600 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 17,000 devices of this subset remain active. We have observed a failure rate of approximately 0.096% 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 and Unconfirmed 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.	**< 400** Worldwide (**< 100** United States)	**0.79%** Worldwide **1.40%** (United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**229** Worldwide (**47** United States) with information indicating a clinical presentation. An additional **65** worldwide (**16** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**2,400** Worldwide (**600** United States)	**1.97%** Worldwide **1.70%** (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 11, 2013, of the initial implant population of 205,600 in the United States, approximately 90,800 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 81.0% (+4.3/-5.4) at 81 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.
279,500 Worldwide (**205,600** United States)	**5,992** Worldwide (**4,174** United States)	**125,000** Worldwide (**90,800** 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 25, 2013, 796 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred twenty-three (423) of the Sigma devices (1.01%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 363 Sigma devices (0.90%) were returned with no information indicating a potential malfunction while implanted or with insufficient information to determine the state of the device at explant. Lacking definite information indicating proper operation until explant, these remaining devices are conservatively categorized as having experienced interconnect wire separation while implanted.

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 7,200 remain implanted. Approximately 1,700 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed and Unconfirmed 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)	**423** Worldwide (**82** United States) with information indicating a clinical presentation.An additional **363** Worldwide (**66** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**7,200** Worldwide (**1,700** United States)	**2.00%** Worldwide **1.49%** (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 11, 2013, 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 2,700 remain implanted. Approximately 2,400 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)	**2,700** Worldwide (**2,400** 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.

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.

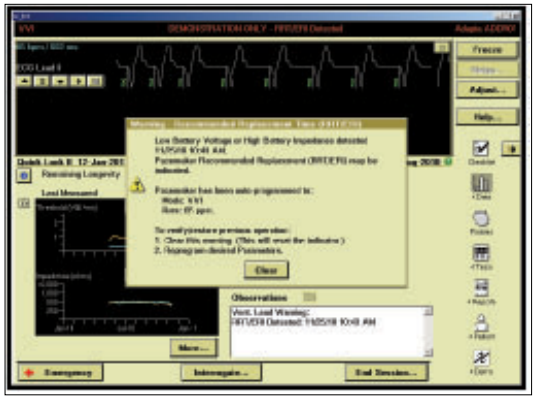
Background

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

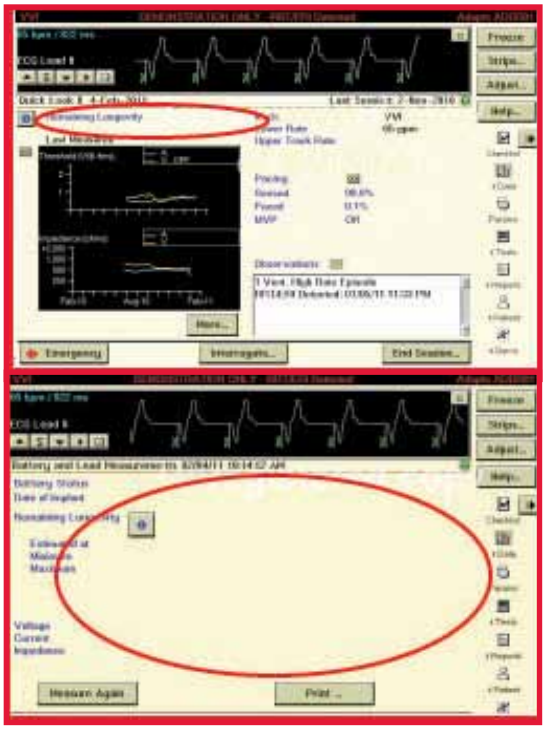


Reset Method for Kappa and EnPulse

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

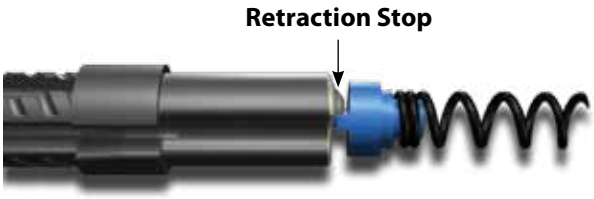
In certain cases, over-retraction of the helix, during initial implant or subsequent repositioning, may result in the inability to extend the helix. This does not impact acute or chronic performance of successfully implanted leads.

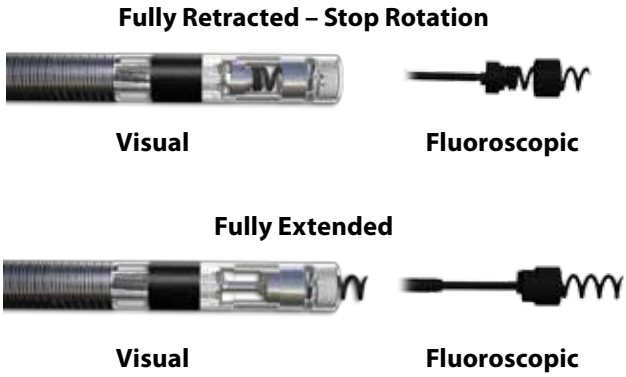
The root cause is over-retraction of the helix mechanism beyond the retraction stop, resulting in the inability to extend the helix in a subsequent attempt.

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

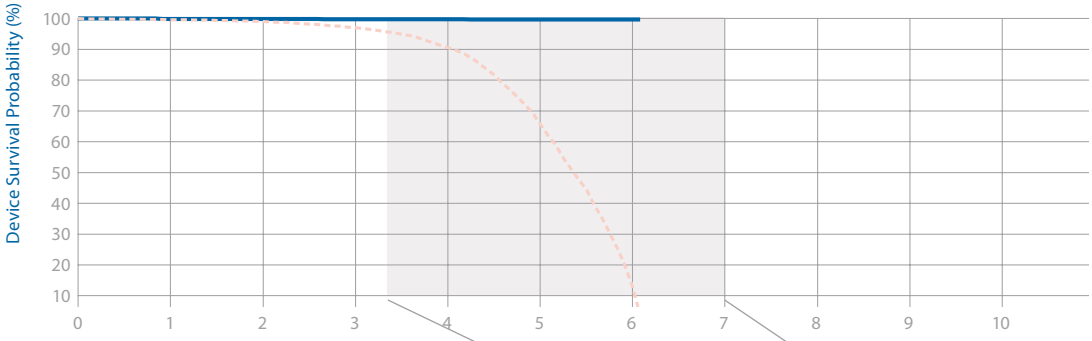
The survival curves in the Product Performance Report represent the composite experience of thousands of devices over a wide range of programming options and patient use conditions. While the curves are useful for understanding the overall performance of a population of devices, they cannot be used to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

Effective Sample Size

Estimated Longevity

Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing
Monthly	3.3	3.8	4.3	4.4
Quarterly	4.2	5.0	5.8	6.3
Semiannual	4.5	5.5	6.5	7.0

This figure shows the range of the estimated longevity values given in the reference chart in relation to the survival curve. The range of longevity is representative of a typical range of use values, not the absolute minimum or maximum longevities possible. In this example, the survival curve including normal battery depletion is approaching 50% at approximately the mid-point of the range of longevity values.

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.

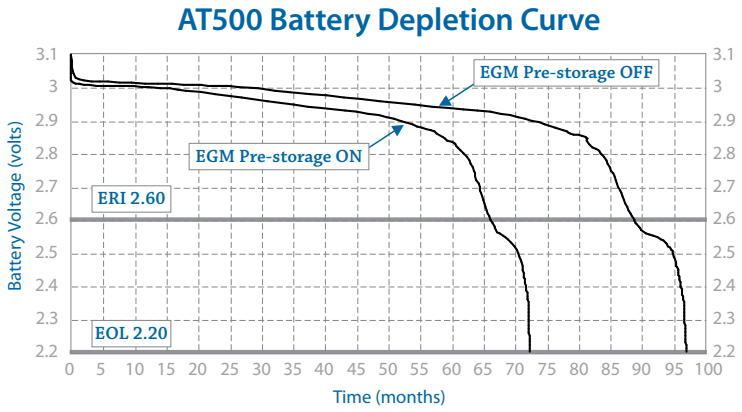


Figure 1

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.

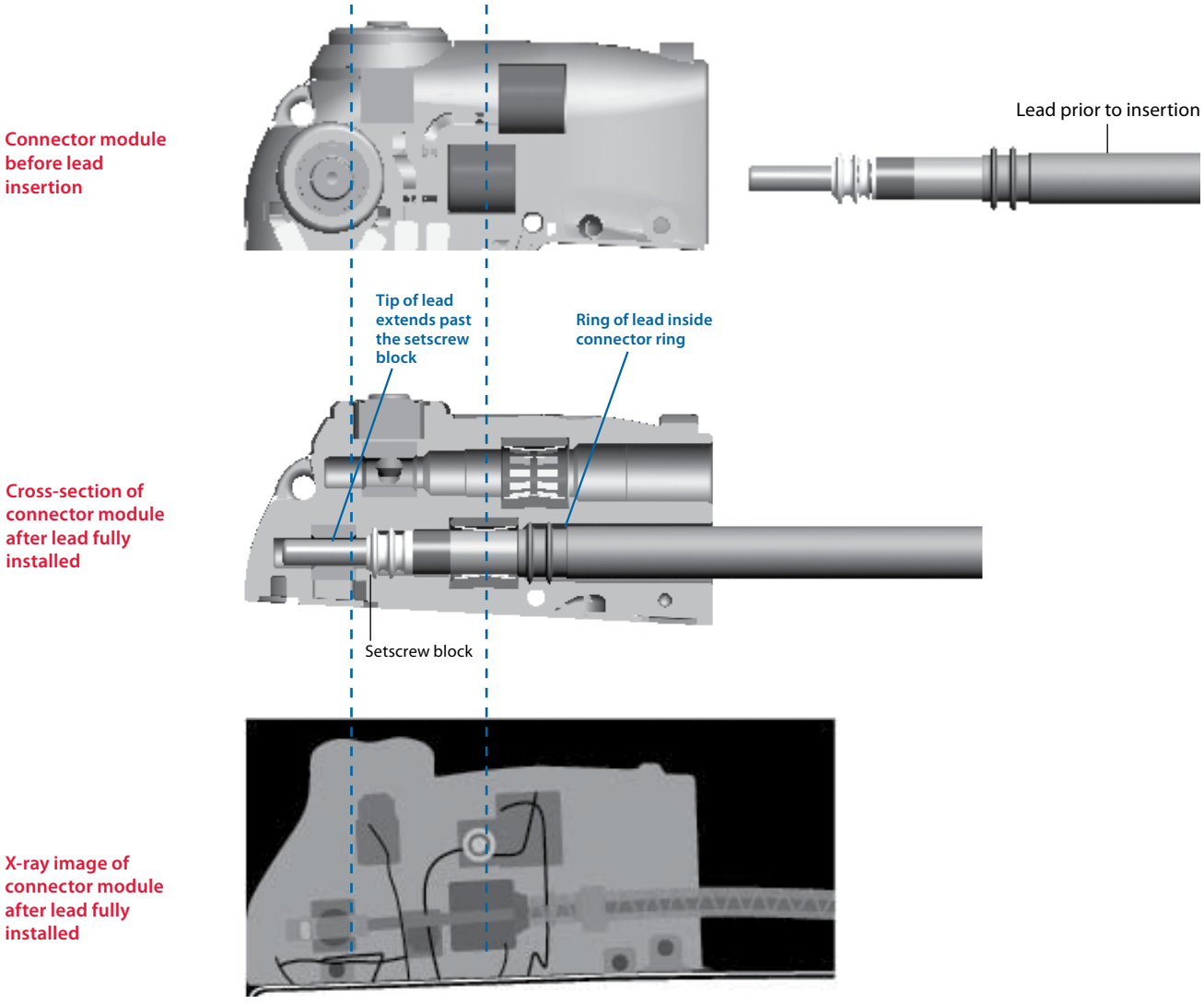
If the lead connector is not fully installed, oversensing may result as described in the connector problems section of the performance note, "Clinical Management of High Voltage Lead System Oversensing."

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.

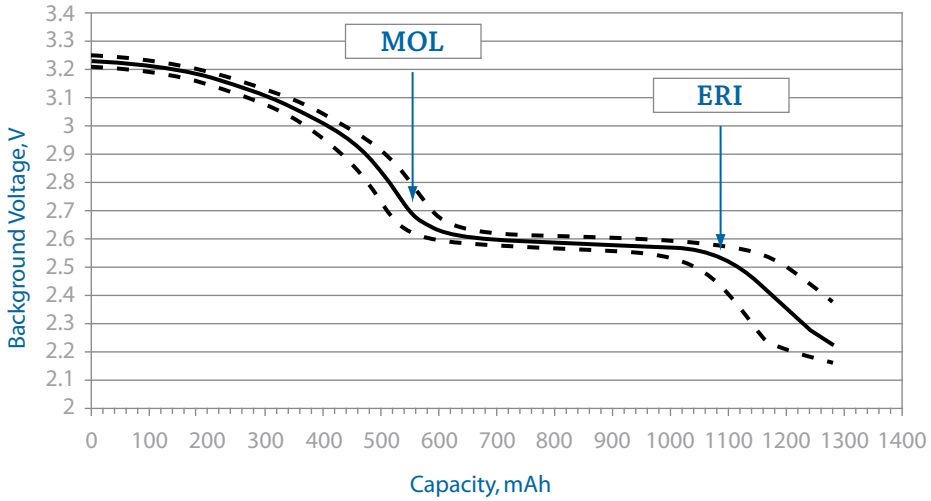
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

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 Product Surveillance Registry (PSR).

The final decision on the functional integrity and continued use of an implanted lead must be a matter of medical judgment based on these factors as well as specific patient conditions.

General Criteria for Lead Replacement

The evaluation of a chronically implanted lead is an important part of the decision to continue to use the lead with a new ICD. However, these results alone do not necessarily predict the future integrity of that lead. With the expected longevity of today's ICDs varying between approximately 5 and 10 years, a physician replacing a device should consider a number of factors, including those listed below.

Factors that should be considered in a decision to replace or continue to use include:

- Pacing and sensing thresholds should be evaluated for the potential to maintain acceptable levels
- Pacing impedance should be measured. Bear in mind that pacing impedance below 250 ohms results in excessive battery current drain, which may seriously compromise ICD longevity, regardless of lead integrity.
- The physical appearance of the lead should be examined for insulation cracks, breaches, or other indications of lead wear or degradation
- Medtronic System Longevity Study data should be referenced. Actuarial survival of the lead and the observed lead failure mechanisms are specific factors to consider. Use of a new lead should be considered if failure mechanisms suggest an increased time dependency as suggested in the shape of performance curve for the specific lead model.
- Current publications may provide additional information on the clinical management of leads.[1-3] Ultimately, the decision to replace an implanted lead involves medical judgment.

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

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

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

Clinical Management of High-Voltage Lead System Oversensing

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

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

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

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

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

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
Email: crdm.returnedproduct@medtronic.com

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