

Exhibit F

CRM Product Performance Report 2006

Q3 Summary Edition

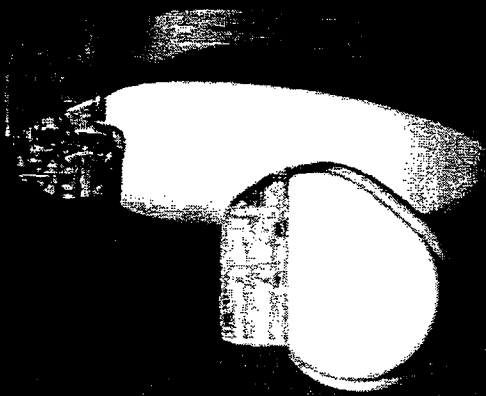
Boston
Scientific

Report elements conform with or surpass current
HRS Draft Recommendations for device manufacturer
product performance reports

NEW

- > Survival probability comparisons across product generations
- > Reported device return rate and reason for out of service
- > Worldwide malfunction details

Data current as of July 7, 2006



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Boston Scientific
Quality Policy

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

It has been more than 100 days since the completion of Boston Scientific's merger with Guidant. As we move forward, quality, reliability, and innovation will remain the keys to our success. Quality and reliability will be the highest priorities for our company, while innovation is the fuel that drives our growth. We are committed to timely, transparent and responsible communications in the interest of achieving the best patient care possible.

The Cardiac Rhythm Management (CRM) division of Boston Scientific is dedicated to publishing product performance reports that meet or exceed the medical community's expectations. The data provided in this report reflect reporting elements that align with or surpass those described in the Draft Recommendations Report by the Heart Rhythm Society (HRS) Task Force on device Performance Policies and Guidelines. The frequency and detail of performance reporting is a demonstration of our commitment to open communication and evidence of the high quality of our medical devices.

As the Vice President of Quality and Reliability Assurance, I am committed to providing even more clarity on an ongoing basis. Elements that are new to this report are listed below.

Q3 2006 Boston Scientific CRM PPR New Reporting Elements

- Survival probability comparisons across product generations
- Worldwide confirmed malfunction details
- Reported device return rate
- Reason for device explant or out of service
- U.S. estimated active implants for each product/product grouping
- All data current as of July 7, 2006

Additionally, we are providing a new communication called *CRM Product News* that includes timely updates to information included in quarterly Product Performance reports, as well as other product performance information. This is available at www.guidant.com/ppr.

Thank you for your continued interest and the important role you play in advancing patient care and facilitating ongoing product improvement. Please contact Boston Scientific CRM at 1.800.CARDIAC (227.3422) to report product observations or to provide comments about ways to improve this report or other communications for the broad array of individuals who benefit from device therapy.



William E. Young
Vice President, Reliability and Quality Assurance
Cardiac Rhythm Management

✓ Comprehensive performance data remain available at www.guidant.com/ppr. To receive print editions, please subscribe online at www.guidant.com/ppr.

✓ To obtain a Return Product Mailing Kit, please complete the online form at www.guidant.com/return.

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Data in this report depict United States (USA) device performance through July 7, 2008. For a list of trademarks, please see page 7. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.

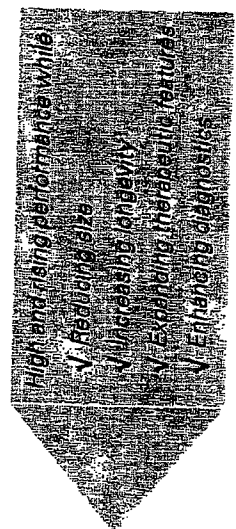
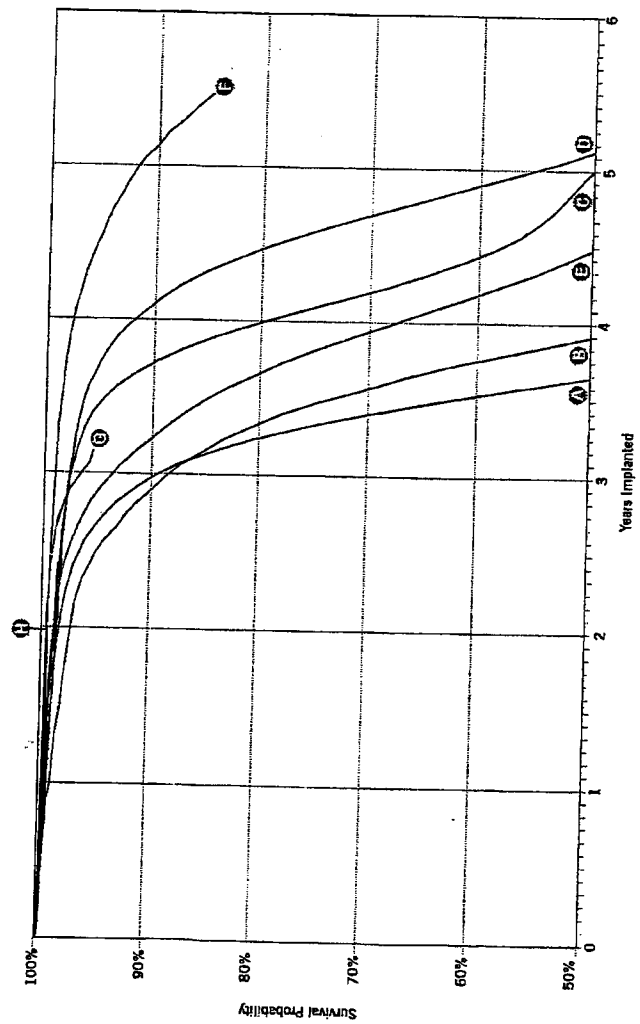
Generation-to-Generation Product Comparisons

GENERATION-TO-GENERATION PRODUCT COMPARISONS

A fundamental goal of the Boston Scientific CRM Quality System is to demonstrate performance improvement with each successive product introduction. As part of our Corrective and Preventive Actions (CAPA) system, data from field performance, suppliers, and manufacturing operations are monitored to identify opportunities for improvements in existing products or subsequent generations. While not the case

in every generation, the net result is high and improving performance in successive product generations. Shown below are survival probability comparisons between older and newer product generations, for ICDs. This graph demonstrates Boston Scientific's ability to maintain high performance while simultaneously reducing device size, increasing longevity, and providing enhanced diagnostic and therapeutic features.

ICD Evolution



1991

VENTAK P/PRX
146 EC
A

VENTAK P/PRX
97/142 80
B

VENTAK MINI
AM/AM
C

VENTAK VAV/AV
AM/AM
D

VENTAK VAV/AV
AM/AM
E

VENTAK VAV/AV
AM/AM
F

VENTAK VAV/AV
AM/AM
G

VENTAK VAV/AV
AM/AM
H

Decreasing Size while Increasing Longevity and Enhanced Diagnostic and Therapeutic Features

2004

H

Statistical Methodology

What is Device Survival Probability?

Medical journals have traditionally used patient survival probability to display information on treatment option effectiveness. In this report, **pulse generator and lead survival probabilities** convey information about long-term performance of implantable cardiac rhythm management products.

Survival probability shows the percentage of implanted devices that remain implanted and in service at various points in a product's service life, in the absence of competing risks, such as natural mortality or voluntary explants. Conceptually, a pulse generator of high reliability and large battery capacity or low current drain remains near 100% survival until eventually, normal battery depletion begins to cause significant numbers of devices to be removed, and the device survival probability drops rapidly. For example, a device survival probability of 99% indicates that within the stated implant duration, the pulse generator had a 1% risk of removal for battery depletion or for incurring a malfunction that required replacement. Survival probabilities are provided with and without normal battery depletions (depicted as "Battery Depletions and Malfunctions" and "Malfunctions Only," respectively).

Boston Scientific estimates survival probability at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in a new report section entitled, "Reported Device Return Rate and Reason for Out of Service."

Survival probabilities are statistical estimates subject to uncertainty. To quantify this uncertainty, 95% confidence intervals of survival probabilities are computed. Greenwood's formula is used to estimate the standard error of the calculated survival probabilities, and confidence intervals are constructed using a logit transformation, assuming the transformed values are normally distributed. For example, 99.36% (-0.3/+0.2) represents an interval of 99.06% to 99.56%, and these intervals are constructed such that 95% of the time they will contain the true survival probability. These confidence intervals are not symmetric due to the transformation method described previously.

Inclusion Criteria for Lead and Pulse Generator Survival Probability Datasets To be included in survival probability statistics, a device must first be successfully implanted (defined in this report as occurring upon pocket closure). Prophylactic device removals are tracked as part of the active population up until the time the device is removed from service; devices removed prophylactically that function per manufacturer's specification at the time of explant are not counted as malfunctions for purposes of survival probability. Reasons for device explant or out of service, if known, are provided in this report for each pulse generator product/product grouping.

Data in this report depict U.S. device performance through July 7, 2006. Survival probabilities are based on devices registered as implanted in the United States. Privacy laws in many other geographies preclude manufacturers from obtaining specific patient implant and explant information, thus device survival probabilities cannot be constructed from these data. Boston Scientific believes, however, that U.S. experience is generally representative of worldwide performance. The Confirmed Malfunction Details for leads and pulse generators reflect worldwide confirmed malfunctions, inclusive of U.S. data.

Survival estimates are provided for product families that have accumulated at least 10,000 cumulative implant months. The minimum interval sample size is 200 implanted units. For older, select pacemaker models, survival probability data were truncated to more realistically depict device longevity. Older-generation pacemakers that have lasted beyond the specified warranty period tend to be underreported to Boston Scientific when removed from service.

Survival probability data are presented in tabular format in print, and in tabular and graphical formats online at www.guidant.com. Performance data for Intermedics products may also be found on www.guidant.com. Specific inclusion criteria for pulse generator and lead survival probability datasets are described here. Not all products may be approved for use in all geographies, as product approval is geography specific.

Worldwide distribution and U.S. registered implant numbers have been rounded to provide population size context. A U.S. confirmed malfunction count and percentage are displayed for each product/product grouping within each U.S. Summary table. The malfunction percentage shown is not intended to facilitate comparison of Boston Scientific device performance to that of competitive

devices, nor is it intended to facilitate generation-to-generation reliability comparisons. The information shown is intended to put the malfunctions in context, relative to overall product performance. Cumulative survival probability is a more accurate representation of overall product performance.

To convey implant experience for a product family, average device age and U.S. approval date are provided. The U.S. approval date listed is the earliest date Boston Scientific received approval for one or more of the models in the family.

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)
Reduction in survival probability for **pulse generators** is due to:

- Devices removed for normal battery depletion
- Device malfunctions occurring while implanted, as confirmed by returned product analysis
- Devices removed from service and reported to have exhibited premature battery depletion, but not confirmed by laboratory analysis, whether returned or not—also known as “unconfirmed reports of premature battery depletions”

Survival Probability – Malfunctions Only (Pulse Generators)

Reduction in survival probability for **pulse generators** is due only to:

- Device malfunctions occurring while implanted, as confirmed by returned product analysis; premature battery depletions are considered device malfunctions

In this case, normal battery depletions do NOT contribute to the reduction in survival probability; rather, reduction in survival probability is due only to confirmed pulse generator malfunctions. Furthermore, unconfirmed reports of premature battery depletions do not reduce “Malfunctions Only” survival probability. Put another way, this information depicts the percentage of malfunction-free devices remaining in service at various intervals in the product’s service life, based on returned product analysis.

Survival Probability – Complications and Malfunctions (Leads)

Reduction in survival probability for **leads** is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads not returned for laboratory analysis but reported to have discrepancy with mechanical integrity and/or impedance measurement 30 days or more post-implant

Approximately one-fifth of leads involved in a complication are returned for laboratory analysis. To provide more meaningful survival information, lead failures are combined with unconfirmed reports of product complications as defined in the U.S.

Food and Drug Administration (FDA) post-market surveillance guidance document originally dated February 15, 1992; revised November 16, 1992 and June 9, 1993.

Further Adjustments for Device and Lead Survival

Because underreporting of patient deaths unrelated to device function would result in overestimation of pulse generator or lead survival by overstating the number of devices in service, Boston Scientific addresses this underreporting in two ways. First, quarterly updates are obtained from the Social Security Administration about deceased persons and compared to Boston Scientific patient data to learn about patients who have died but whose deaths had not been reported to Boston Scientific. Second, Boston Scientific uses 10% annual patient mortality as a baseline and adjusts reported patient deaths in any interval for which reports are less than the baseline rate. No adjustment is applied to account for underreporting of malfunctions, as the rate of underreporting is unknown.

Boston Scientific does not make statistical adjustments to account for underreporting of battery depletion. However, as mentioned earlier, Boston Scientific includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions, which results in inclusion of many more devices than would be included based only on the AdvaMed proposal.

Categorization of Normal Battery Depletions and Malfunctions for Survival Probability Reporting

Malfunctions represent devices removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (such as ionizing therapeutic radiation), are not reported as device malfunctions in survival data. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction. Malfunctions are further classified according to their impact on therapy, as follows:

Malfunction With Compromised Therapy – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

Malfunction Without Compromised Therapy – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Per the Advamed proposal, **Normal Battery Depletion** is defined as the condition when

- 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
- A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings

Boston Scientific has traditionally included within this count both returned and non-returned devices removed from service for battery depletion with no associated complaint. Additionally, while overall device function has been assessed for all returned devices, status of the elective replacement indicator has not been required. In conformance with the Advamed proposal, Boston Scientific has transitioned to performing battery usage analysis, including battery status verification, on all devices returned without a complaint. We continue to include non-returned devices reported by our customers as being removed from service due to normal battery depletion within this count, as it serves as an adjustment for underreporting of normal battery depletions.

U.S. Reports of Acute Lead Observations

Because acute lead performance contributes to overall clinical experience, Boston Scientific provides a summary of U.S. reports of lead observations occurring in the first month of service. Acute lead performance may be subject to a number of factors, including patient-specific clinical conditions and/or varying implant conditions/techniques. Some examples of lead observations include, but are not limited to: dislodgement, muscle stimulation, noisy signal observed, etc. To be included in this summary of observations, a lead must first be successfully implanted. These reported observations may or may not have resulted in clinical action and/or product return to Boston Scientific. Multiple observations are possible for any given lead.

Reported Device Return Rate and Reason for Out of Service

In accordance with Heart Rhythm Society-draft recommended elements in manufacturer product performance reports, Boston Scientific now provides reason for U.S. device explant or out of service if known, for all pulse generator products/product groupings for which U.S. survival probability data are reported. The number of Boston Scientific devices reported to have been explanted in the U.S. and the number and percentage of reported, explanted devices returned to Boston Scientific are also provided. The reasons for out of service include normal battery depletion, device upgrade, complication related to another system component or clinical conditions such as infection, device malfunction (which includes devices under advisory that have experienced a malfunction), or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown. It should be noted that the reason for a device explant or out of service may either be confirmed through laboratory analysis (as in the case of normal battery depletion) or it may be reported to Boston Scientific with no associated returned device or laboratory analysis. Additionally, there may be more than one reason listed for why a device was explanted or taken out of service.

Boston Scientific's CRM Corrective and Preventive Actions (CAPA) System

Boston Scientific strives to provide implantable devices of high quality and reliability. However, these devices are not perfect and may exhibit malfunctions at a low rate of occurrence. Device performance information is received from many sources through various channels. Boston Scientific monitors information from many sources including suppliers, testing, manufacturing and field performance to identify opportunities for improvement.

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples.

Improvement implementation may vary by geography due to various factors including regulatory review timing, and, in some cases, improvements may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

Improvements are closely monitored for effectiveness. Boston Scientific informs regulatory bodies of each significant event that poses potential risk to patient health to meet regulatory obligations, and shares returned product investigation findings with physicians. The confirmed malfunction details section for pulse generators and leads includes a summary of these findings.

In summary, thorough investigation of internal and external data coupled with low trigger levels for improvements creates a continuous product improvement system that is very responsive to patient and physician needs. Boston Scientific is committed to characterizing and presenting to our customers an accurate picture of product performance and addressing identified issues in a timely fashion.

Help Us Provide You With More Complete Product Performance Data Reporting Adverse Events

The data presented reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department at:

United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.
International: Please refer to the back page of this report for local contact information.
E-mail: crmevent@guidant.com

Returning Products to Boston Scientific

Boston Scientific provides a **Returned Products Kit** (Model 6499) that includes proper forms, shipping/packaging (biohazard bags), and a prepaid shipping label. It can be ordered at no charge through Boston Scientific's Customer Service department at 1.800.CARDIAC (227.3422) or 651.582.2698. The kit should be returned to:

Guidant Corporation
Cardiac Rhythm Management
Attn: Returned Products
4100 Hamline Ave North
St. Paul, MN 55112-5798

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