We think 58 years of experience is a good start.

As the specialist in pacemakers, Vitatron is constantly improving its quality standards. A necessity when you know that a patient may have to rely on the same pacemaker for 10 years or more.

We consider your patient to be our patient. That’s how we have worked for the last 58 years. That’s how we have laid the foundation for our reputation as a reliable and committed pacemaker specialist.

We are open and proactive with regard to information on the reliability of our pacemakers and pacing leads.

Have a look for yourself how our pacemakers perform over time.

The Vitatron Quality Assurance Team
Date cutoff for this edition is August 3, 2014 for devices and leads data

This report is available online at www.vitatron.com/ProductPerformance

**IPG Device Performance**
Method for Estimating IPG Device Performance ................................................................. 1
IPG implantable Pulse Generators ................................................................................... 4

**Lead Performance**
Method for Estimating Lead Performance ................................................................. 13
Pacing Leads .................................................................................................................. 16

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The performance of 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. Survival estimates for Vitatron IPGs is based on performance to similar Medtronic IPGs.

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 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

A device is considered as having malfunctioned whenever the analysis shows that any parameter was outside the established performance limits, while implanted and in service. To be considered a malfunction or battery depletion, the device must have been returned 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 and found, through analysis, to actually have performed outside the performance established limits.

Not all malfunctions expose the patient to a loss of pacing therapy. Some malfunctions included in the following survival estimates may not have been detected at all by the physician or the patient. These malfunctions, however, are included in the survival estimates and provide important feedback to our product development organization. To provide insight into the nature of malfunctions, each malfunction is categorized as Malfunction with Compromised Therapy Function or Malfunction without Compromised Therapy Function. For this report, Normal Battery Depletion, Malfunction with Compromised Therapy Function, and Malfunction without Compromised Therapy Function are defined as follows:

Normal Battery Depletion – The condition when:

(a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

(b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information. Expected longevity is established 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.

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.
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.

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 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 includes only malfunctions as events and excludes normal battery depletion.

Since the survival estimate can become very imprecise with small effective sample sizes, the survival curve is truncated when the effective sample size is less than 100 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. 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.

Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion

Not all devices are returned to for analysis. 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.

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 nondevice 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, this underreporting is addressed in two ways. Regular updates obtained from the Social Security Administration about deceased persons is used to update DART data about patients who have died but whose deaths had not been reported. 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.

Footnote:
1: Due to applied methodology, Vitatron CE market approval dates may not coincide with survival curve origins.
Implantable Pulse Generator
A10A1 A10 S

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

Therapy Compromised Malfunctions 0
Battery Malfunction 0
Electrical Component 0
Electrical Interconnect 0
Other Malfunction 0
Poss Early Battery Depltn 0
Software Malfunction 0

CE Market Approval Date 7/18/2013
Normal Battery Depletions (WW) 0

Years 1 2 3 at 44 mo
Excluding NBD 100.0% 100.0% 100.0% 100.0%
Including NBD 100.0% 100.0% 100.0% 100.0%

Effective Sample Size 284 224 161 103

SR01, RS01, Survival Curve
Implantable Pulse Generator

A20A1   A20 SR

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

CE Market Approval Date 7/18/2013
Normal Battery Depletions (WW) 0

<table>
<thead>
<tr>
<th>Years</th>
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<th>2</th>
<th>3</th>
<th>at 44 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding NBD</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Including NBD</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
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</table>

Effective Sample Size

284  224  161  103
Implantable Pulse Generator
A30A1     A30 VDD

<table>
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<tr>
<td>Therapy Not Compromised Malfunctions</td>
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<tr>
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<td>Electrical Component</td>
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</tr>
<tr>
<td>Electrical Interconnect</td>
<td>0</td>
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<tr>
<td>Other Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Therapy Compromised Malfunctions</td>
<td>0</td>
</tr>
<tr>
<td>Battery Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Component</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Interconnect</td>
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<td>Other Malfunction</td>
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<tr>
<td>Poss Early Battery Depltn</td>
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<tr>
<td>Software Malfunction</td>
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CE Market Approval Date: 7/18/2013

Normal Battery Depletions (WW): 0

VDD01, Survival Curve

Years After Implant

<table>
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<th>Years</th>
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<tr>
<td>Excluding NBD</td>
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<tr>
<td>Including NBD</td>
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<tr>
<td>Effective Sample Size</td>
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Implantable Pulse Generator
A60A1  A60 DR

CE Market Approval Date  7/18/2013

Normal Battery Depletions (WW)  0

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<tr>
<th>Malfunction</th>
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<th>Therapy Not Compromised Malfunctions</th>
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<tr>
<td>Battery Malfunction</td>
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<tr>
<td>Electrical Component</td>
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<td>Electrical Interconnect</td>
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</tr>
<tr>
<td>Other Malfunction</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Normal Battery Depletions (WW)

Excluding NBD 100.0% 100.0% 100.0% 100.0%
Including NBD 100.0% 100.0% 100.0% 100.0%

Effective Sample Size 271 221 169 105

Years After Implant

Cumulative Survival Probability

Curve Name
- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years at 45 mo

Excluding NBD
- 1 year: 100.0%
- 2 years: 100.0%
- 3 years: 100.0%

Including NBD
- 1 year: 100.0%
- 2 years: 100.0%
- 3 years: 100.0%
## Implantable Pulse Generator

### E10A1  E10 S

<table>
<thead>
<tr>
<th>CE Market Approval Date</th>
<th>12/16/2009</th>
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</thead>
<tbody>
<tr>
<td>Normal Battery Depletions (WW)</td>
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</table>

### Total Malfunctions (WW)

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<thead>
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<th>Malfunction Type</th>
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<tbody>
<tr>
<td>Therapy Not Compromised Malfunctions</td>
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<tr>
<td>Battery Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Component</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Interconnect</td>
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<tr>
<td>Other Malfunction</td>
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<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
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<tr>
<td>Software Malfunction</td>
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### Therapy Compromised Malfunctions

<table>
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<tr>
<th>Malfunction Type</th>
<th>Count</th>
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<tbody>
<tr>
<td>Battery Malfunction</td>
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</tr>
<tr>
<td>Electrical Component</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Interconnect</td>
<td>0</td>
</tr>
<tr>
<td>Other Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
<td>0</td>
</tr>
</tbody>
</table>

### Normal Battery Depletions (WW)

<table>
<thead>
<tr>
<th>Years</th>
<th>Count</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>100.0%</td>
</tr>
<tr>
<td>2</td>
<td>100.0%</td>
</tr>
<tr>
<td>3</td>
<td>100.0%</td>
</tr>
<tr>
<td>4</td>
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</tr>
<tr>
<td>5</td>
<td>100.0%</td>
</tr>
<tr>
<td>6</td>
<td>100.0%</td>
</tr>
<tr>
<td>7</td>
<td>100.0%</td>
</tr>
<tr>
<td>at 94 mo</td>
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### Survival Curve

#### Curve Name
- **SR01, S01, Survival Curve**

#### Years After Implant

<table>
<thead>
<tr>
<th>Years</th>
<th>0</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>at 94 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Excluding NBD</strong></td>
<td>100.0%</td>
<td>99.9%</td>
<td>99.9%</td>
<td>99.6%</td>
<td>99.2%</td>
<td>98.2%</td>
<td>94.5%</td>
<td>82.4%</td>
<td></td>
</tr>
<tr>
<td><strong>Including NBD</strong></td>
<td>99.9%</td>
<td>99.9%</td>
<td>99.9%</td>
<td>99.6%</td>
<td>99.2%</td>
<td>98.2%</td>
<td>94.5%</td>
<td>82.4%</td>
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</tr>
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#### Effective Sample Size

<table>
<thead>
<tr>
<th>Years</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tbody>
<tr>
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Implantable Pulse Generator

E50A1   E50 D

<table>
<thead>
<tr>
<th>Total Malfunctions (WW)</th>
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<tbody>
<tr>
<td>Therapy Not Compromised Malfunctions</td>
<td>0</td>
</tr>
<tr>
<td>Battery Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Component</td>
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</tr>
<tr>
<td>Electrical Interconnect</td>
<td>0</td>
</tr>
<tr>
<td>Other Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
<td>0</td>
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</tbody>
</table>

| Therapy Compromised Malfunctions | 0 |
| Battery Malfunction | 0 |
| Electrical Component | 0 |
| Electrical Interconnect | 0 |
| Other Malfunction | 0 |
| Poss Early Battery Depltn | 0 |
| Software Malfunction | 0 |

CE Market Approval Date 12/16/2009

Normal Battery Depletions (WW) 0

DR01, D01, Survival Curve

Excluding NBD

Including NBD

Effective Sample Size

<table>
<thead>
<tr>
<th>Years</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>at 95 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding NBD</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Including NBD</td>
<td>100.0%</td>
<td>99.9%</td>
<td>99.9%</td>
<td>99.7%</td>
<td>99.4%</td>
<td>98.5%</td>
<td>95.7%</td>
<td>84.8%</td>
</tr>
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</table>

Effective Sample Size

118676  98412  78432  59140  40826  23312  9060  406
Total Malfunctions (WW) | 1

Therapy Not Compromised Malfunctions | 1

- Battery Malfunction | 0
- Electrical Component | 1
- Electrical Interconnect | 0
- Other Malfunction | 0
- Poss Early Battery Depltn | 0
- Software Malfunction | 0

Therapy Compromised Malfunctions | 0

- Battery Malfunction | 0
- Electrical Component | 0
- Electrical Interconnect | 0
- Other Malfunction | 0
- Poss Early Battery Depltn | 0
- Software Malfunction | 0

CE Market Approval Date | 12/16/2009

Normal Battery Depletions (WW) | 0

Excluding NBD

<table>
<thead>
<tr>
<th>Years</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>at 95 mo</th>
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<tbody>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
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<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Including NBD

| Years | 100.0% | 99.9% | 99.9% | 99.7% | 99.4% | 98.5% | 95.7% | 84.8% |

Effective Sample Size

| Years | 118676 | 98412 | 78432 | 59140 | 40826 | 23312 | 9060 | 406 |

**Implantable Pulse Generator**

**E60A1**

**E60 DR**

**DR01, D01, Survival Curve**

**Curve Name**

- **Excluding Normal Battery Depletion**
- **Including Normal Battery Depletion**

**Years**

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- at 95 mo

**Excluding NBD**

- 100.0%
- 100.0%
- 100.0%
- 100.0%
- 100.0%
- 100.0%
- 100.0%
- 100.0%

**Including NBD**

- 100.0%
- 99.9%
- 99.9%
- 99.7%
- 99.4%
- 98.5%
- 95.7%
- 84.8%

**Effective Sample Size**

- 118676
- 98412
- 78432
- 59140
- 40826
- 23312
- 9060
- 406
## Implantable Pulse Generator

**G20A1**

**G20 SR**

<table>
<thead>
<tr>
<th>CE Market Approval Date</th>
<th>12/16/2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Battery Depletions (WW)</td>
<td>0</td>
</tr>
</tbody>
</table>

### Total Malfunctions (WW)

<table>
<thead>
<tr>
<th>Malfunction Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Component</td>
<td>0</td>
</tr>
<tr>
<td>Electrical Interconnect</td>
<td>0</td>
</tr>
<tr>
<td>Other Malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
<td>0</td>
</tr>
</tbody>
</table>

### Therapy Compromised Malfunctions

<table>
<thead>
<tr>
<th>Malfunction Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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</tr>
<tr>
<td>Poss Early Battery Depltn</td>
<td>0</td>
</tr>
<tr>
<td>Software Malfunction</td>
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</tbody>
</table>

### Normal Battery Depletions (WW)

<table>
<thead>
<tr>
<th>Years</th>
<th>Excluding NBD</th>
<th>Including NBD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
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</tr>
<tr>
<td></td>
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**Effective Sample Size**

<table>
<thead>
<tr>
<th>Years</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>at 95mo</th>
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<tbody>
<tr>
<td>Excluding NBD</td>
<td>68632</td>
<td>53485</td>
<td>40367</td>
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<td>133</td>
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<tr>
<td>Including NBD</td>
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<td>99.9%</td>
<td>99.8%</td>
<td>99.4%</td>
<td>98.7%</td>
<td>97.2%</td>
<td>92.5%</td>
<td>76.1%</td>
</tr>
</tbody>
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**Survival Curve**

- SR01, SR03, SR06, Survival Curve
- Including Normal Battery Depletion
- Excluding Normal Battery Depletion

**Years After Implant**

<table>
<thead>
<tr>
<th>Years</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</tr>
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<tbody>
<tr>
<td>Excluding NBD</td>
<td>100.0%</td>
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**Curve Name**

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

### Years After Implant

- Years: 0, 1, 2, 3, 4, 5, 6, 7, at 95mo

**Effective Sample Size**

- 68632, 53485, 40367, 29336, 20058, 11864, 4880, 133
Implantable Pulse Generator

G70A1  G70 DR

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<td>Therapy Not Compromised Malfunctions</td>
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<td>0</td>
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</thead>
<tbody>
<tr>
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Method for Estimating Lead Performance

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 leads cannot be expected to last forever. While IPGs 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 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

Returned leads and lead segments are analyzed to determine whether or not they meet established performance limits. 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.

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

All cardiac rhythm surveillance registries are consolidated into the Product Surveillance Registry (PSR), which is part of the PAN Registry platform. The PAN Registry is a patient centric surveillance platform which follows patients implanted with a Medtronic or Vitatron cardiac rhythm product. The Product Performance Report (PPR) tracks lead survival of PAN Registry enrolled patients. The PAN Registry is designed to record clinical observations representative of the total clinical experience. Lead survival estimates include both lead hardware failure and lead-related complications classified as product performance events, 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.

PAN Registry

Performance of cardiac therapy products has been monitored 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, systems and processes have been continually adapted to more effectively monitor product performance following market release. The following summarizes current registry requirements.

Our 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 market-released cardiac therapy products. Product-related adverse events, indicating the status of the product, are collected to measure product survival probabilities. The data gathered may also be used to support the design and development of new cardiac therapy products. The registry is designed to continue indefinitely, encompassing new products as they become commercially available.

To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria. The number of participants is regularly reviewed to ensure the necessary capacity to meet 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 our cardiac rhythm products are used. Eligible products for enrollment include market-released cardiac rhythm therapy products for which additional information to further characterize product performance following market release is desired. Enrollment may be capped and follow-up discontinued when sufficient duration and precision is achieved to effectively characterize product survivability.

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

Patients are eligible for enrollment if:

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

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

Quality and integrity of the data is continually evaluated 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, perforation, 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. A lead-related event with at least one of the following classifications that is adjudicated by the committee as a complication and occurs more than 30 days after implant is considered a product performance event and will contribute to the survival analysis endpoint. Events with an onset date 30 days or less after the implant are considered procedure related and therefore are not included as lead-related complications.

**Event Classifications**

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

*Note: Lead dislodgment with successful repositioning is not considered a product performance event and will not contribute to the survival analysis endpoint.*

**Data Analysis Methods**

Survival estimates for Vitatron leads is based on performance to similar Medtronic leads. The performance of Vitatron 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.

The survival analysis for left truncated and right-censored data is conducted to estimate the long term product performance for each lead model periodically. The survival functions are estimated using the Kaplan-Meier method. The calculated survival probability at a given time t is an estimator of survival probability beyond t, conditional on survival to the smallest of the entry time (post implant). The 2-sided point-wise confidence limit are calculated.

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

On the following pages, each graph includes a survival curve 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.
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, survival curves are truncated 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 received cut-off date (e.g., date of data entry at a study site). The number of enrollments is listed for each lead model.

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

**Returned Product Analysis Results**

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

For reporting returned product analysis results, a lead is considered as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits while implanted and in service. To be considered a malfunction for returned product analysis reporting, the lead must have been returned 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 and found, through analysis, to actually have performed outside established performance limits.

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

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

**Footnotes**:

2: During the evolution of SLS, event adjudication was transitioned from a technical review committee to an independent event adjudication committee in 2011. Data analyses include adjudication using both methods.

3: Due to applied methodology, Vitatron CE market approval dates may not coincide with survival curve origins.

### Distribution Data

- **CE Approval Date:** 4/1/2001
- **WW Distribution:** 176,817

### Product Characteristics

<table>
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<th>Feature</th>
<th>Value</th>
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<tr>
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<td>Active Screw In</td>
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<tr>
<td>Lead Function</td>
<td>Pacing/Sensing</td>
</tr>
<tr>
<td>Steroid Indicator</td>
<td>Yes</td>
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<tr>
<td>Lead Placement</td>
<td>Transvenous</td>
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<tr>
<td>Lead Tip Location</td>
<td>Atrium or Right Ventricle</td>
</tr>
<tr>
<td>Pace/Sense Polarit</td>
<td>Bipolar</td>
</tr>
</tbody>
</table>

### WW Acute Lead Observations

- **Cardiac Perforation:** 1
- **Conductor Fracture:** 0
- **Extracardiac Stimulation:** 1
- **Failure To Capture:** 5
- **Failure To Sense:** 3
- **Impedance Abnormal:** 1
- **Insulation Breach:** 1
- **Lead Dislodgement:** 5
- **Oversensing:** 0
- **Unspecified:** 0

### WW Returned Product Analysis

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<tr>
<th>Issue</th>
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<td>Crimp Weld Bond</td>
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<td>Insulation Breach</td>
<td>12</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
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### VENTRICULAR PLACEMENT

#### Survival Curve (in months)

- **Survival Curve**
  - Cumulative Survival Probability Graph
  - Lower 95 Pct Confidence Graph
  - Upper 95 Pct Confidence Graph

### Graph Name

- **Years**
  - **%:** 99.5% 99.3% 99.1% 98.8% 98.8% 98.4% 98.1% 97.5% 96.7% 96.7%
  - **#:** 1,129 864 712 568 485 412 341 264 172 115 67

- **Months After Implant**
**PACING LEAD**

**ICM09JB**

**Distribution Data**
- CE Approval Date: 4/1/2001
- WW Distribution: 24,970

**Product Characteristics**
- Fixation Type: J-shape, tines
- Lead Function: Pacing/Sensing
- Steroid Indicator: Yes
- Lead Placement: Transvenous
- Lead Tip Location: Atrium
- Pace/Sense Polarit: Bipolar

**WW Acute Lead Observations**
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 0
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

**WW Returned Product Analysis**
- Conductor Fracture: 0
- Crimp Weld Bond: 0
- Insulation Breach: 0
- Other: 0

**Graph Name**
- Cumulative Survival Probability Graph
- Lower 95 Pct Confidence Graph
- Upper 95 Pct Confidence Graph

<table>
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**Survival Curve**

**Cumulative Survival Probability**

**Months After Implant**

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<td>Extracardiac Stimulation</td>
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<td>Failure To Capture</td>
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<td>0</td>
</tr>
<tr>
<td>Insulation Breach</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>

### ATRIAL PLACEMENT

#### ATR, Survival Curve

- **Cumulative Survival Probability Graph**
- **Lower 95% Pct Confidence Graph**
- **Upper 95% Pct Confidence Graph**

<table>
<thead>
<tr>
<th>Years</th>
<th>at 90 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>99.7%</td>
</tr>
<tr>
<td></td>
<td>99.6%</td>
</tr>
<tr>
<td></td>
<td>99.4%</td>
</tr>
<tr>
<td></td>
<td>99.3%</td>
</tr>
<tr>
<td></td>
<td>99.1%</td>
</tr>
<tr>
<td></td>
<td>98.8%</td>
</tr>
<tr>
<td></td>
<td>98.3%</td>
</tr>
<tr>
<td></td>
<td>98.3%</td>
</tr>
</tbody>
</table>

**Graph Name**

- Cumulative Survival Probability Graph
- Lower 95 Pct Confidence Graph
- Upper 95 Pct Confidence Graph

**Graph Data**

- 120 Months After Implant
- 100% Survival
- 50% Survival
**PACING LEAD**

**ICQ09B**

**VENTRICULAR PLACEMENT**

**Distribution Data**
- CE Approval Date: 4/1/2001
- WW Distribution: 65,841

**Product Characteristics**
- Fixation Type: Active Screw In
- Lead Function: Pacing/Sensing
- Steroid Indicator: Yes
- Lead Placement: Transvenous
- Lead Tip Location: Atrium or Right Ventricle
- Pace/Sense Polar: Bipolar

**WW Acute Lead Observations**
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 0
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

**WW Returned Product Analysis**
- Conductor Fracture: 2
- Crimp Weld Bond: 0
- Insulation Breach: 0
- Other: 1

**Graph Name**
- **Cumulative Survival Probability Graph**
- **Lower 95 Pct Confidence Graph**
- **Upper 95 Pct Confidence Graph**

<table>
<thead>
<tr>
<th>Years</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>99.8%</td>
<td>1,079</td>
</tr>
<tr>
<td>2</td>
<td>99.8%</td>
<td>943</td>
</tr>
<tr>
<td>3</td>
<td>99.8%</td>
<td>792</td>
</tr>
<tr>
<td>4</td>
<td>99.7%</td>
<td>569</td>
</tr>
<tr>
<td>5</td>
<td>99.3%</td>
<td>343</td>
</tr>
<tr>
<td>6</td>
<td>99.3%</td>
<td>228</td>
</tr>
<tr>
<td>7</td>
<td>98.6%</td>
<td>101</td>
</tr>
<tr>
<td>at 90 mo</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**VEN, Survival Curve**

**Cumulative Survival Probability**

**Graph**

- **Graph Name**
  - Cumulative Survival Probability Graph
  - Lower 95 Pct Confidence Graph
  - Upper 95 Pct Confidence Graph

- **Graph Data**
  - **Years**
    - 1
    - 2
    - 3
    - 4
    - 5
    - 6
    - 7

- **Percentage**
  - 99.8%

- **Number**
  - 1,079
  - 943
  - 792
  - 569
  - 343
  - 228
  - 101
  - 75
## PACING LEAD

### Distribution Data
- **CE Approval Date**: 12/15/2000
- **WW Distribution**: 13,687

### Product Characteristics
- **Fixation Type**: Tines
- **Lead Function**: Pacing/Sensing
- **Steroid Indicator**: Yes
- **Lead Placement**: Transvenous
- **Lead Tip Location**: Atrium or Right Ventricle
- **Pace/Sense Polarit**: Bipolar

## IHP09B

### WW Acute Lead Observations
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 0
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

## ATRIAL PLACEMENT

### WW Returned Product Analysis
- Conductor Fracture: 0
- Crimp Weld Bond: 0
- Insulation Breach: 0
- Other: 0

## ATR, Survival Curve

### Cumulative Survival Probability

<table>
<thead>
<tr>
<th>Years</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>99.5%</td>
<td>410</td>
</tr>
<tr>
<td>2</td>
<td>99.5%</td>
<td>390</td>
</tr>
<tr>
<td>3</td>
<td>99.5%</td>
<td>357</td>
</tr>
<tr>
<td>4</td>
<td>99.5%</td>
<td>321</td>
</tr>
<tr>
<td>5</td>
<td>99.5%</td>
<td>288</td>
</tr>
<tr>
<td>6</td>
<td>99.5%</td>
<td>251</td>
</tr>
<tr>
<td>7</td>
<td>99.5%</td>
<td>218</td>
</tr>
<tr>
<td>8</td>
<td>99.5%</td>
<td>184</td>
</tr>
<tr>
<td>9</td>
<td>99.5%</td>
<td>147</td>
</tr>
<tr>
<td>10</td>
<td>99.5%</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>at 132 mo</td>
<td>66</td>
</tr>
</tbody>
</table>
PACING LEAD  |  IHP09B  |  VENTRICULAR PLACEMENT

**Product Characteristics**
- **Fixation Type**: Tines
- **Lead Function**: Pacing/Sensing
- **Steroid Indicator**: Yes
- **Lead Placement**: Transvenous
- **Lead Tip Location**: Atrium or Right Ventricle
- **Pace/Sense Polarit**: Bipolar

**Distribution Data**
- **CE Approval Date**: 12/15/2000
- **WW Distribution**: 13,687

**WW Acute Lead Observations**
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 0
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

**WW Returned Product Analysis**
- Conductor Fracture: 0
- Crimp Weld Bond: 0
- Insulation Breach: 0
- Other: 0

**VENTRICULAR PLACEMENT**

**Graph Name**
- Cumulative Survival Probability Graph
- Lower 95 Pct Confidence Graph
- Upper 95 Pct Confidence Graph

**Years**
- %: 99.3% 99.1% 99.1% 98.7% 98.7% 97.3% 97.3% 97.3% 97.3% 97.3%
- #: 471 385 300 260 225 187 162 131 90 64 56

**Cumulative Survival Probability**

- Months After Implant
- Years: 1 2 3 4 5 6 7 8 9 10
- % at 126 mo
**PACING LEAD**

**IHP09JB**

### Distribution Data
- CE Approval Date: 12/15/2000
- WW Distribution: 5,284

### Product Characteristics
- **Fixation Type**: Tines
- **Lead Function**: Pacing/Sensing
- **Steroid Indicator**: Yes
- **Lead Placement**: Transvenous
- **Lead Tip Location**: Atrium - J
- **Pace/Sense Polarit**: Bipolar

### WW Acute Lead Observations
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 0
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

### WW Returned Product Analysis
- Conductor Fracture: 0
- Crimp Weld Bond: 0
- Insulation Breach: 1
- Other: 0

---

### Survival Curve

Graph Name:
- **Cumulative Survival Probability Graph**
- **Lower 95 Pct Confidence Graph**
- **Upper 95 Pct Confidence Graph**

<table>
<thead>
<tr>
<th>Years</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100.0%</td>
<td>142</td>
</tr>
<tr>
<td>2</td>
<td>98.2%</td>
<td>105</td>
</tr>
<tr>
<td>3</td>
<td>97.1%</td>
<td>82</td>
</tr>
<tr>
<td>4</td>
<td>95.9%</td>
<td>74</td>
</tr>
<tr>
<td>5</td>
<td>95.9%</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>95.9%</td>
<td>50</td>
</tr>
</tbody>
</table>

*at 72 mo*
**PACING LEAD**

**IMK49B**

### Distribution Data
- **CE Approval Date**: 4/1/2001
- **WW Distribution**: 60,552

### Product Characteristics
- **Fixation Type**: Tines
- **Lead Function**: Pacing/Sensing
- **Steroid Indicator**: Yes
- **Lead Placement**: Transvenous
- **Lead Tip Location**: Right Ventricle
- **Pace/Sense Polarit**: Bipolar

### WW Acute Lead Observations
- **Cardiac Perforation**: 0
- **Conductor Fracture**: 0
- **Extracardiac Stimulation**: 0
- **Failure To Capture**: 2
- **Failure To Sense**: 0
- **Impedance Abnormal**: 0
- **Insulation Breach**: 1
- **Lead Dislodgement**: 1
- **Oversensing**: 0
- **Unspecified**: 0

### WW Returned Product Analysis
- **Conductor Fracture**: 0
- **Crimp Weld Bond**: 0
- **Insulation Breach**: 4
- **Other**: 1

---

**Survival Curve**

- **Cumulative Survival Probability Graph**
- **Lower 95 Pct Confidence Graph**
- **Upper 95 Pct Confidence Graph**

<table>
<thead>
<tr>
<th>Years</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>98.9%</td>
<td>913</td>
</tr>
<tr>
<td>2</td>
<td>98.8%</td>
<td>811</td>
</tr>
<tr>
<td>3</td>
<td>98.6%</td>
<td>723</td>
</tr>
<tr>
<td>4</td>
<td>98.3%</td>
<td>620</td>
</tr>
<tr>
<td>5</td>
<td>98.0%</td>
<td>506</td>
</tr>
<tr>
<td>6</td>
<td>97.8%</td>
<td>394</td>
</tr>
<tr>
<td>7</td>
<td>97.8%</td>
<td>321</td>
</tr>
<tr>
<td>8</td>
<td>97.8%</td>
<td>259</td>
</tr>
<tr>
<td>9</td>
<td>97.8%</td>
<td>210</td>
</tr>
<tr>
<td>10</td>
<td>97.8%</td>
<td>126</td>
</tr>
<tr>
<td></td>
<td></td>
<td>59</td>
</tr>
</tbody>
</table>

**Months After Implant**: at 132 mo
**PACING LEAD**

**IMK49JB**

**Distribution Data**
- CE Approval Date: 4/1/2001
- WW Distribution: 32,243

**Product Characteristics**
- Fixation Type: J-shape, tines
- Lead Function: Pacing/Sensing
- Steroid Indicator: Yes
- Lead Placement: Transvenous
- Lead Tip Location: Atrium - J
- Pace/Sense Polarit: Bipolar

**WW Acute Lead Observations**
- Cardiac Perforation: 0
- Conductor Fracture: 0
- Extracardiac Stimulation: 0
- Failure To Capture: 1
- Failure To Sense: 0
- Impedance Abnormal: 0
- Insulation Breach: 0
- Lead Dislodgement: 0
- Oversensing: 0
- Unspecified: 0

**WW Returned Product Analysis**
- Conductor Fracture: 0
- Crimp Weld Bond: 0
- Insulation Breach: 1
- Other: 0

**Survival Curve**
- Cumulative Survival Probability Graph
- Lower 95 Pct Confidence Graph
- Upper 95 Pct Confidence Graph

**Graph Name**
- Cumulative Survival Probability Graph
- Lower 95 Pct Confidence Graph
- Upper 95 Pct Confidence Graph

**Years**
- %: 97.5% 97.5% 97.5% 96.7% 96.7% 96.7% 95.4% 95.4% 95.4%
- #: 189 166 148 134 110 100 79 71 59 51

**Months After Implant**
- 0 10 20 30 40 50 60 70 80 90 100 110 120
Contact Information

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

International Technical Services Department
Europe (Heerlen NL) +31-45-566-8844

For questions related to this CRDM Product Performance Report, please call International Technical Services at the number above, or write to:

Vitatron Holding BV
Endepolsdomein 5
6229 GW Maastricht
The Netherlands
www.vitatron.com

For questions related to returning explanted product or returning product that shows signs of malfunction, please contact:

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

Within the United States:
Your Medtronic representative or CRDM Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com
Vitatron - based in Europe - is the only medical device company that specializes exclusively in pacemakers. Since 1962, Vitatron pacemakers have helped restore more than 900,000 patients in more than 60 countries to a full life. We strive to achieve perfection in everything we do. This results in unique patient-focused therapies, as well as highly cost-effective pacemakers that are smart & easy to use.

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www.vitatron.com

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