Longevity Estimation in IPG Devices

Overview and Objectives:
Over the years, Medtronic has continued to refine the way it provides and displays estimated remaining longevity for its Implantable Pulse Generators (IPGs). This document clarifies the historical and current implementation of time to replacement estimates for the following device families: Thera®, Thera-i, Prodigy®, EnPulse® I/II, InSync® III, Kappa® 400-900 families, Sigma®, Adapta®, Versa® and Sensia® pacemakers.1

Software Release Update for Longevity Projection, Version 1.1
In January 2007 (U.S. release) the longevity estimation feature was standardized for the devices listed above. The presentation of “Estimated Time to Replacement” or “Remaining Longevity” was changed to improve the usability and clinical accuracy of the longevity projections.

In addition, updates for certain product battery life terms were made (summarized in the table below). This new nomenclature ensures compliance with new CENELEC standards for implantable devices published in December 2003.

<table>
<thead>
<tr>
<th>New Nomenclature</th>
<th>Old Nomenclature</th>
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<tr>
<td>BOS</td>
<td>Beginning of Service</td>
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<tr>
<td>EOS</td>
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<tr>
<td>RRT/ERI</td>
<td>Recommended Replacement Time (RRT/ERI)</td>
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<td>Prolonged service period</td>
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<td>Projected service life</td>
<td>Longevity</td>
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Current Overview of Longevity Estimation
Remaining longevity is a calculated estimate of the time remaining until pacemaker replacement will be required.

Displayed Minimum, Average, and Maximum Longevity estimates are computed such that 95% of devices will meet the minimum longevity projection, and 90% will fall within the Min-Max boundaries (5th percentile minimum, 95th percentile maximum).

There is a 5% probability that the implanted device will reach the recommended replacement time sooner than the displayed minimum due to battery variation.

Wide differences between minimum and maximum are sometimes computed and are attributable to the variability in lithium-iodine battery resistance that occurs as it nears end-of-service. This type of variability is more typical of pacemaker batteries.

Sufficient IPG pacing history (at least 24 hours) must be available to successfully estimate remaining longevity.2 This calculated estimate is based on programmed parameter settings and event data accumulated by the pacemaker since the previous follow-up session. This event data includes things such as (but not limited to):

- Pacing sequences (AS-VS, AS-VP, AP-VS, AP-VP)
- Measured battery voltage and battery impedance
- Lead impedances and polarities
- Pulse width, amplitude, mode and lower rate

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1 The following are trademarks of Medtronic: Thera, Prodigy, EnPulse, InSync, Kappa, Sigma, Adapta, Versa, Sensia.
2 When sufficient pacing history is available, Kappa, EnPulse, and Adapta/Versa/Sensia devices will include the label “Based on Past History” in their Battery/Lead data screens and reports.
If less than 24 hours of pacing history has been collected, or if one of the event sequence counters has reached its maximum value, or the mode has been reprogrammed such that the paced chamber(s) are different than the chamber(s) paced during the time of event counter data collection, the device will conservatively estimate longevity assuming 100% pacing.3

Upon successful measurement and interrogation of the device, average longevity, maximum longevity and minimum longevity values are calculated. The following rules are applied for displaying these calculated values:

1. If the calculated minimum longevity ≥ 1 year, all values are displayed in years. The minimum longevity is rounded down, and the average and maximum values are rounded to the nearest half-year.

2. If the calculated minimum longevity is < 1 year, all values are displayed in months. The minimum longevity is rounded down, and the average and maximum values are rounded to the nearest month.

3. If the calculated minimum longevity is ≤ 6 months, all values are displayed in months and the minimum longevity will be prefixed with a “less than” symbol (<). The minimum longevity is rounded down, and the average and maximum values are rounded to the nearest month.

4. If any of the calculated longevity values are < 1 month, that value will be displayed as “< 1 months.”

For Thera/Thera-i/Prodigy/InSync:

- The Battery/Lead data screen will calculate and display Estimated Time to Replacement as a single average value (based on the 5-95% bell curve) and will also display the minimum value.
- The “More Info” screen will calculate and display three values: Maximum, Average, and Minimum in years or months depending upon the remaining longevity of the device.

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3 When any of these conditions are satisfied, Kappa, EnPulse, and Adapta/Versa/Sensia devices will include the label “Based on 100% Pacing” in their Battery/Lead data screens and reports.
For Kappa, EnPulse, and Adapta/Versa/Sensia:

- The Quick Look™ screen will use the average value (based on the 5-95% bell curve) as the estimated “Remaining Longevity” and will also display the minimum value.
- All printed reports that contain longevity data and the Battery/Lead data screen will report the Minimum, Average, (remaining longevity) and Maximum range of values.

Patient Management Considerations Using Remaining Longevity Estimates

Consider the following when using the displayed remaining longevity to determine follow-up frequency:

- Always review the Minimum Longevity from the Battery/Lead data. If this value is less than 12 months, consider increasing the follow-up frequency, especially for patients who are pacemaker dependent or who do not tolerate VVI pacing.
- Per device manual labeling, remaining longevity estimates are not intended as a determination of elective replacement. Use only labeled RRT/ERI indicators or battery status message for this decision.
- There is a 5% probability that an implanted device will reach RRT/ERI sooner than the displayed minimum (i.e., one out of every 20 devices will under-achieve the minimum value displayed). This should be taken into consideration when determining follow-up frequency for patients as their devices near their recommended replacement time intervals.
- When the device reaches RRT/ERI, the patient should be scheduled for immediate pacemaker replacement. The device will automatically change certain parameter settings to the RRT/ERI operating values. At most output settings, at least 95% of pacemakers will achieve a prolonged service period of at least 3 months after RRT/ERI is set. At the end of 3 months, erratic pacing may occur. Refer to the appropriate device reference manuals for complete details on RRT/ERI and prolonged service life expectations.

Additional Considerations regarding Remaining Longevity Estimates

Longevity estimates are based on the assumption that current drain will remain relatively stable. Any feature that modifies the current drain of the device can potentially invalidate the longevity calculation. The most common of these features includes:

- Adaptation of output settings via Capture Management
- Lead Impedance changes
- Electrical Resets
- Sustained periods of Rate Responsive pacing

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4 Nonmagnet Mode = VVI at 65 ppm, Magnet Mode = VOO at 65 ppm, Battery/Lead information display replacement message.
Background:

Right Ventricular Capture Management and Longevity – Past versus Present

One of the key contributors to maximizing longevity is to program the device to the lowest possible output settings while still maintaining an appropriate safety margin. Capture Management options provide automatic daily adaptation of output settings to help ensure that patients are receiving the longest possible life from their devices. In Medtronic pacemakers, two methods are used when measuring thresholds to determine if capture or loss-of-capture occurs: 1) Evoked response or 2) Algorithmic methods based on inter-chamber or intra-chamber timing relationships.

- Right Ventricular Capture Management (RVCM) – Uses “evoked response” sensing\(^5\)
- Atrial Capture Management (ACM – Uses an algorithmic approach to detecting captured events based upon intrinsic timing or AV conduction timing

Evoked response can be affected by lead/tissue interface, polarization effects, tip-to-ring spacing, and lead design. If this signal is not sensed due to any of these factors, the RVCM feature records a loss-of-capture condition and can report a “high threshold” condition. This is particularly true for older pacemakers (Kappa 700 models) that did not provide automatic RVCM options to correct for inadvertent high threshold measurements that have since been implemented in Kappa 900 and subsequent generations of pacemakers.

The following table summarizes the operation of RVCM as it has continued to be enhanced and improved from its initial Kappa 700 implementation. Refer to Medtronic’s semi-annual Product Performance Report – Performance Note section on “Clinical Management of VCM near Elective Replacement” for additional details.

<table>
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<tr>
<th>Right Ventricular Capture Management</th>
<th>Kappa 700 Original Implementation</th>
<th>Kappa 900 Enhancements</th>
<th>EnPulse Enhancements</th>
<th>Adapta/Versa/Sensia and Vision 3D Enhancements</th>
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<tr>
<td>How pacing thresholds are measured</td>
<td>Measures “evoked response” of pacing pulse using Strength-Duration algorithm</td>
<td>Rheobase (amplitude threshold) measured at 0.4 ms pulse width; reduces lead polarization effect seen at 1.0 ms and provides more clinically-relevant value</td>
<td>Same as Kappa 900</td>
<td>Adapta family is the same as Kappa 900 and EnPulse Vision 3D enhancement:</td>
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<tr>
<td></td>
<td>Initial measurements made using programmed Sensing Polarity (e.g., Bipolar)</td>
<td>Chronaxie (pulse width threshold) measured at double the amplitude threshold</td>
<td>- Measure “evoked response” of only the Amplitude pacing threshold at 0.4 ms (no pulse width threshold measurement taken)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rheobase (amplitude threshold) measured at 1.0 ms pulse width</td>
<td>Programmed safety margin applied to the measured Amp and PW</td>
<td>- Programmed safety margin applied to the amplitude threshold value</td>
<td></td>
</tr>
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<td>Chronaxie (pulse width threshold) measured at double the amplitude threshold</td>
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\(^5\) Evoked response is the electrical signal sensed by the device when the myocardium has been captured by the pacing stimulus.
## Right Ventricular Capture Management and Longevity – Past versus Present (continued)

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| **What happens if a high threshold (> 2.5 V) is measured** | No secondary measurement occurs; Amplitude set to 5.0 V, Pulse Width set to 1.0 ms | If pacing threshold search (PTS) results in an amplitude threshold of > 2.5 V:  
- Ventricular sensing polarity changes (only for the duration of the test, pacing polarity unaffected)  
- The pacing threshold search is repeated  
- If threshold is acceptable, subsequent PTS repeated in this polarity  
- May improve evoked response sensing by increasing the "tip-to-ring" spacing for the test (for example: Bipolar to Unipolar) | Same as Kappa 900 | Same as Kappa 900 and EnPulse |
| **How the device recovers from a high threshold measurement** | Outputs remain fixed at 5 V, 1.0 ms until programmable “Acute Phase” time period expires (typically 120 days post-implant)  
After Acute Phase expires, output settings can be automatically adapted downward again based on measured thresholds and safety margin  
At anytime, if patient is seen at clinic – physician can confirm or deny high threshold and reprogram to lower settings as necessary | Same as Kappa 700 | Same as Kappa 700 and Kappa 900 | During “Acute Phase”, if high threshold measured (> 2.5 V), device is allowed to decrease amplitude back down to the original programmed (or shipped) value if thresholds decrease |
Brief Statement: IPGs

Indications
Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and increases in activity and/or minute ventilation. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm. For the MR Conditional IPG, a complete pacing system consisting of either an Advisa DR MRI™ SureScan® Model A2DR01 IPG or Revo MRI SureScan® Model RVDR01 IPG and 2 CapSure Fix MRI® SureScan 5086MRI leads is required for use in the MR environment.

Contraindications
IPGs are contraindicated for dual chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms; unipolar pacing for patients with an implanted cardioverter defibrillator because it may cause unwanted delivery or inhibition of ICD therapy; and certain IPGs are contraindicated for use with epicardial leads and with abdominal implantation.

Warnings/Precautions
Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Potential complications
Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.