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Technical Information Report

AAMI TIR21:1998

Systems used to forecast remaining pacemaker battery service life

AAMI Association for the Advancement of Medical Instrumentation

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AAMI TIR No. 21—1998

Systems used to forecast remaining pacemaker battery service life

Approved 30 January 1998

Abstract: This report describes the clinical expectations for the performance of systems that use "real-time" measurements telemetered by the pulse generator to forecast remaining battery service life. These systems combine the real-time measurements with assumptions provided by the clinician to forecast the remaining service life of the pacemaker battery. The method described in this report is based on the use of battery voltage measurements. Other methods that use battery impedance or charge measurements can also be used.

Keywords: pacemaker battery, implantable medical device, electromedical device, implants, battery depletion, battery longevity

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COMMITTEE REPRESENTATION

The Algorithm Task Group developed this technical information report under the auspices of the AAMI Pacemaker Committee.

The **AAMI Pacemaker Committee**, which authorized the distribution of this report, has the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

INTRODUCTION

A perceived need exists on the part of clinicians for better tools to forecast the remaining battery service life of implantable cardiac pacemakers. This technical report discusses the clinical expectations for the performance of systems used to develop these predictions. It focuses on those systems that forecast remaining battery service life by combining "real-time" measurements (i.e., battery voltage, impedance, etc.) made by the pulse generator with assumptions provided by the clinician about the future pacing needs of the patient. It does not include those algorithms used by the pacemaker manufacturer for longevity analysis associated with labeling claims.

Ongoing clinical management of a pacemaker patient requires the physician to take into account a number of factors including remaining battery service life in clinical use. Today's pacemaker can have a battery service life, under typical conditions, that can range from 4 to 10+ years depending on a number of factors including:

a) initial battery capacity (milliampere-hours);

b) the output energy programming (amplitude and pulse width) and lead impedance;

c) the patient's demand for pacing (percent paced);

d) the average paced rate;

e) the current consumed by the pulse generator circuitry (quiescent current).

It should be noted that the duration of a pacemaker implant does not always equal battery service life. Sometimes a pacemaker is removed for other reasons before the battery is exhausted. These include upgrading the pacemaker system due to changes in the patient's condition and pulse generator circuit failure.

Most currently manufactured pulse generators are designed to provide a minimum interval between the onset of their recommended replacement time indicator and the point where the manufacturer can no longer assure that the pulse generator will perform according to its specifications. This interval is a minimum of 3 months or 6 months, depending on the manufacturer and the product line.

The frequency of routine follow-ups for the purpose of monitoring for the onset of the recommended replacement time indicator could be reduced if the pacing system provided an early indication that the pulse generator's replacement time is approaching. This could simplify follow-up procedures associated with evaluating remaining battery service life and potentially have a favorable impact on health care costs.

To provide an early warning of onset of the recommended replacement time indicator, it is a common practice to estimate the remaining battery service life based on “real-time” measurements made by the pulse generator combined with assumptions provided by the physician about the future pacing needs of the patient. For this to be effective, there are important issues that need to be discussed between the industry and the clinicians. Manufacturers must understand the clinicians’ needs and expectations. The clinicians, for their part, must understand the practical issues and limitations associated with these systems so the systems can be applied properly in a total program for managing the pacemaker patient.

SYSTEMS USED TO FORECAST REMAINING PACEMAKER BATTERY SERVICE LIFE

1 Scope

This report describes the clinical expectations for the performance of systems that use "real-time" measurements telemetered by the pulse generator to forecast remaining battery service life. These systems combine the real-time measurements with assumptions provided by the clinician to forecast the remaining service life of the pacemaker battery. The method described in this report is based on the use of battery voltage measurements. Other methods that use battery impedance or charge measurements can also be used.

This report discusses the input requirements from both the pulse generator (e.g., battery resistance, etc.) and the clinician regarding usage history and the anticipated use profile.

This report discusses the practical limitations of forecasting remaining pacemaker battery service life using this type of system. These limitations include those inherent in the pacemaker such as (a) battery variability, (b) accuracy of the measurement system, (c) variability in the use profile. The report also discusses the limitations associated with the availability and accuracy of information provided by the clinician.

Guidance on presentation of the resulting information is included to facilitate its use by the clinician as part of a total patient management program.

This report does not cover those algorithms that are used by pacemaker manufacturers for longevity analysis associated with labeling claims. This report is not applicable to implantable cardioverter defibrillators (ICDs).

2 Definitions

For the purposes of this technical information report, the following definitions apply.

2.1 beginning of service (BOS): Time when an individual implantable pulse generator is first released by the manufacturer as fit for placing on the market.

2.2 recommended replacement time (RRT): Time when the battery depletion indicator reaches the value set by the manufacturer of the pulse generator for its recommended replacement.

3 Pulse generator longevity and battery depletion

The normal service life of a pulse generator is usually defined as the expected duration of a pulse generator implant. The normal service life of the pulse generator is dependent on the service life of each of the components of the pacemaker, including the battery. The battery is conceptually different from the other components. In principle, although not always in practice, the other components are designed to last indefinitely. However, the available energy of the battery is consumed during its normal use. The battery has a finite service life because the battery contains a fixed amount of active chemicals. As the pulse generator operates, the battery's active chemicals are depleted Eventually, the battery voltage falls to a level that is insufficient to operate the device within the limits specified by the manufacturer. Before this point is reached, the pulse generator must be replaced. Therefore, the normal service life of a pulse generator is determined, in practice, by the longevity of the battery.

The battery longevity is the interval between implantation of the pulse generator and a manufacturer-defined battery voltage that indicates RRT is reached. Because normal service life can vary dramatically with particular patients, battery longevity is usually stated at a specific set of nominal conditions and programmed parameters. Given a battery with a certain size, design, and chemistry, the battery longevity can be calculated from the average current needed for this nominal set of conditions. Annex A.2.2 describes the method for calculating pulse generator longevity. The nominal pulse generator service life and the conditions under which it is calculated are stated in the labeling. The variety of terminology among the various manufacturers can present a challenge to the physician. Annex D contains a summary of the terms in use at the time of the preparation of this report. The methods used by manufacturers to estimate nominal pulse generator service life are beyond the scope of this report.

The ideal battery for an implantable medical device is one that is highly reliable, can deliver the peak power required by the device over an extended period of time, has an appropriate indication of impending battery depletion, and can be fit into a small package. All of these requirements are intertwined and must be balanced when the battery is designed for an implantable medical device.

There have been several different battery chemistries used to power cardiac pacemakers over the years beginning with nickel-cadmium oxide (nicad) batteries.[1] The zinc-mercuric oxide (or mercury) battery proved to be a more practical battery for powering pacemakers. Typically, mercury batteries provided 1–3-year longevity. The advent of lithium batteries in the early 1970s revolutionized cardiac pacing. In a short time, lithium batteries replaced mercury batteries in most implantable applications. Several different lithium chemistries have been used in implantable medical devices. For cardiac pacemakers, the lithium/iodine chemistry provides a good balance of reliability, energy density, and an indication of impending battery depletion. Consequently, lithium/iodine has emerged as the battery chemistry of

[1] Untereker, DF., Shepard, RB., et al. Power Sources for Implantable Pacemakers. In: Ellenbogen, KA., Kay, GN., Wilkoff, BL., eds. Clinical Cardiac Pacing. Philadelphia: W.B. Saunders, 1995, p. 104.

choice for cardiac pacemakers. An overview of the structure and capacity characteristics of the lithium/iodine battery used in virtually all cardiac pacemakers is given in annex A.2.1.

Because of its inherently high internal impedance, the deliverable capacity of a lithium/iodine battery is a function of the current drain at which the battery is depleted. This relationship is illustrated in figure A.4. This figure illustrates how the deliverable capacity of the battery changes with increased current drain. This characteristic, which is inherent in the lithium/iodine chemistry, is one factor that must be taken into account when estimating battery longevity. This is one reason why nominal pulse generator service life is estimated using an average current associated with a set of nominal conditions over the life of the pulse generator. As the current from the battery increases, the resulting voltage drop further reduces the time period during which the battery can produce current at or above the specified minimum voltage necessary to operate the pulse generator circuitry (see figure A.5).

4 Battery depletion and programming for optimum longevity

Modern pulse generators offer the clinician a wide range of programming options to tailor the therapy to the needs of the individual patient. Virtually all pulse generators allow the clinician to change the amplitude and pulse width of the stimulation pulse to achieve capture of the myocardium. The selection of these parameters has a significant impact on battery longevity because they control how much energy is extracted from the battery by each stimulation pulse.

A pulse generator must be operated within a reasonable safety factor that ensures capture of the myocardium by the stimulation pulse. This safety factor, usually referred to as the “safety margin,” is defined as the ratio of the pacing output voltage divided by the stimulation threshold voltage at the same pulse width. The safety margin is controlled by programming the pulse generator’s output (or the preset back-up pulse for pulse generators with autocapture). Once programmed, the pulse generator’s output is a fixed value for pulse generators without autocapture. Selecting an appropriate programmed output for a patient is based on clinical factors that include:

a) measured threshold for capture;

b) the spontaneous variation in threshold due to sleep, eating, and medications;

c) the expected rise in threshold after implantation with standard and steroid eluding leads.

A common clinical concern is the programming of pacing output for maximum longevity consistent with maintaining the desired safety margin. Some pulse generators offer “regulated” output voltage settings that remain constant throughout the life of the pulse generator despite battery depletion. For the optimal setting of regulated outputs refer to annex A.3. Pulse generators also offer “unregulated” outputs (see the model of annex A.1) that decrease in direct proportion as the battery depletes. During the initial part of the battery discharge, the voltage remains relatively constant. However, towards the “knee” of the discharge curve, the voltage begins to fall rapidly creating a problem with maintaining the desired safety margin. Therefore, with unregulated output settings the output must be programmed high enough to maintain capture despite the anticipated reduction in output voltage as the battery depletes. For unregulated output voltages the minimum pacing current is obtained when the pulse generator is programmed to the voltage/pulse width combination that places the pulse width closest to the “chronaxie” pulse width (refer to annex A.3 for a full discussion).

The clinician can further improve longevity by decreasing the number of output pulses. This can be accomplished by decreasing the escape rate, especially when the patient has an underlying rhythm. Also the A-V interval can be increased when the patient has a long A-V conduction time. Less aggressive rate-responsive programming will also favor native rhythms that inhibit the pulse generator and reduce the average current drain. Rate hysteresis and features that mimic native rate decreases during sleep may also reduce the number of output pulses.

5 The battery depletion curve

The battery capacity data in figure A.4 can be converted into voltage–time curves (see annex A.2.2). Figure 1 illustrates a generic battery depletion curve.

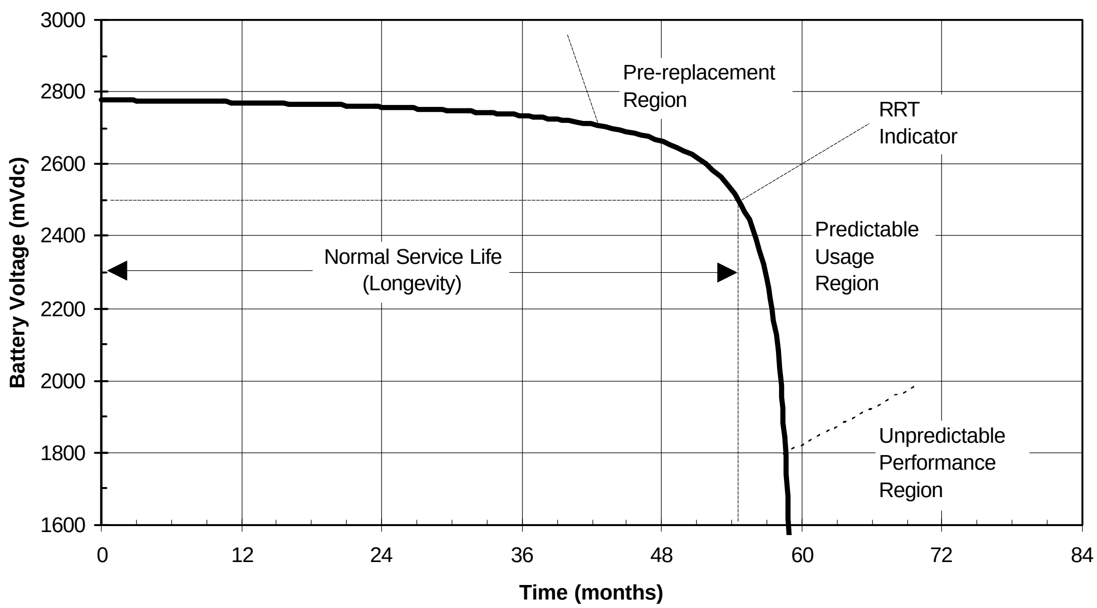


Figure 1—Generic battery depletion curve

For routine follow-up of pacemaker patients, there are three regions on the battery discharge curve that are of particular interest. These regions are illustrated in figure 1.

5.1 The prereplacement region

Some manufacturers have attempted to anticipate RRT by providing an indicator that signals the clinician to intensify follow-up of the pulse generator. These preliminary indicators are set to anticipate RRT by an interval specified by the manufacturer. They vary by manufacturer and product line (see annex D).

The prereplacement region occurs near the end of the normal service life of the pulse generator battery. In this region, the pulse generator continues to operate according to its permanent program settings. Entry into this region can be used to justify an increase in follow-up frequency.

Entry into this region may be signaled by an early indicator from the pulse generator that the battery is approaching RRT. These preliminary indicators are set to anticipate RRT by an interval specified by the manufacturer and are usually based on a measurement by the pulse generator of battery voltage and/or impedance. The manufacturer may employ a variety of ways of communicating the onset of the preliminary indicator to the clinician.

Another method for determining that the pulse generator battery is approaching the end of the normal service life is to forecast remaining longevity. These systems advise the clinician that, given a particular usage pattern, the pulse generator will reach RRT within a certain time period. If pacemaker patients are followed annually, the remaining longevity forecast should begin at least 12 months before the expected onset of the RRT indicator.

5.2 The predictable usage region

In this region, the pulse generator may change its permanent operation (i.e., go to a preset pacing modality and rate) to control energy usage to ensure at least the defined interval before reaching the unpredictable performance region. All pulse generators provide at least one indicator that signals entry into this region. Pacemaker manufacturers use various terms to describe this indicator. In this technical report, it is referred to as the RRT indicator. Once a valid RRT indicator has occurred and the pulse generator is operating in the predictable usage region, the pulse generator should be replaced. Reprogramming that increases output energy (i.e., pacing rate, pulse width, or pulse amplitude) should only be done with extreme caution. Increasing output energy may decrease the duration of the predictable usage region and even abruptly place the pulse generator in the unpredictable performance region leading to reduced or no output.

The requirement for a battery RRT indicator results from the need to signal impending battery depletion in a manner that allows the patient and clinician adequate time to replace the pulse generator. This interval is typically a minimum of 3 months or 6 months, depending on the manufacturer and the product line (see annex D). The duration of the predictable usage region influences the maximum safe interval for following a patient with a particular pulse generator.

In general, this requires a battery to have some measurable characteristics (such as voltage or impedance) that are directly related to its state of discharge. There are three recognized methods for monitoring a battery's state of discharge: (a) measured battery voltage, (b) measured battery resistance, (c) accumulated sum of charge removed. Of these, battery voltage and battery resistance are the most commonly used characteristics. Figure A.7 illustrates the relationship between voltage, internal resistance, and capacity for a typical lithium-iodine battery.

For the lithium-iodine battery, the internal resistance increases gradually during most of the discharge, causing a corresponding decrease in the battery voltage. Near RRT, the battery resistance increases more rapidly, causing a faster decrease in battery voltage. Because the voltage decreases gradually throughout most of the useful life of the pulse generator, battery voltage may not be particularly useful in estimating remaining service life until RRT draws near. However, measured voltage may be useful for determining the battery's ability to support higher current demand or to indicate that RRT is imminent. Most pacemakers incorporate a battery voltage measurement circuit in the form of an analog-to-digital converter. Measured battery impedance is generally less dependent on current drain than is battery voltage and may convey more information about the state of discharge. Some pulse generators incorporate circuitry designed to measure the internal resistance of the battery for determining when RRT is reached and/or as an input to determining remaining service life. This is discussed more fully in annex A.2.2.

When the predetermined RRT value is reached, the pulse generator sets an internal indicator. Thereafter, externally observable changes occur. These changes range from behavior changes that can be observed in an electrocardiogram (ECG), such as increasing the basic escape interval or magnet interval, to telemetering a status flag to the programmer during a follow-up session.

One of the primary purposes of routine follow-up is to monitor for the onset of the RRT indicator. The interval between follow-ups is determined, in part, by the need to make sure that the patient is seen between the time the RRT indicator is set and the pulse generator battery reaches the point on the battery curve where the manufacturer can no longer assure that the pulse generator will perform according to its specifications.

5.3 The unpredictable performance region

This is the region on the battery curve where the manufacturer can no longer assure that the pulse generator will perform according to its specifications. Because the pulse generator is operating on the steep part of the battery depletion curve, loss of capture is imminent. Reprogramming that increases output energy may lead to no output. The pulse generator should always be replaced before it reaches this stage.

6 Patient follow-up and battery depletion

An organized pacemaker follow-up program is important for all pacemaker patients. The primary goal of such a program is to assess the efficacy of the medical intervention and the well-being of the patient. There are many factors that the clinician must take into consideration when determining the frequency of pacemaker follow-up visits. Not the least of these is ensuring the detection of the RRT indicator while the pulse generator is in the predictable use region of the battery depletion curve.

Most pulse generators are designed to provide a minimum interval between the onset of their RRT indicator and the point where the manufacturer can no longer assure that the pulse generator will perform according to its specifications. This interval is a minimum of 3 months or 6 months depending on the manufacturer and the product line.

The frequency of patient follow-ups for the purpose of monitoring for the onset of the recommended replacement time indicator could be reduced if the pacing system provided an early indication that the pulse generator's replacement time was approaching. This can simplify follow-up procedures associated with evaluating remaining battery service life. The early indicator would signal entry into the prereplacement region of the battery depletion curve and could be used to justify an increase in follow-up frequency.

The technique discussed in this report would predict that a pulse generator battery was approaching the end of the normal service life by forecasting remaining longevity. Such a system advises the clinician that, given a particular usage pattern, the pulse generator will reach RRT within a certain time period. In this report, it is assumed that pacemaker patients will be scheduled for follow-up visits at least annually. This means that the prereplacement region should begin 12 months before the expected onset of the RRT indicator.

At entry into the prereplacement region, the system should be able to predict the number of months until the expected onset of the RRT indicator. Before entry into the prereplacement region, the estimated remaining longevity can be expressed as a range rather than as a specific number of months remaining. The task group preparing this report considered the appropriate ranges to be: 12 to 24 months, 24 to 36 months, and greater than 36 months.

7 Forecasting remaining longevity

Remaining longevity is defined as the interval between a point in time after implantation of the pulse generator and the onset of the RRT indicator. At any point in the normal service life of the battery, the remaining longevity can be calculated using equation 13. Remaining longevity is a function of the remaining deliverable capacity of the battery and the future average battery current drain. Projecting remaining longevity depends on ability of the system to estimate remaining battery capacity and the factors that contribute to the future average battery current drain.

The accuracy of these estimates is dependent, in large part, on the measurement system employed by the manufacturer in a particular pulse generator. In the absence of a specific product design, one may only draw general conclusions about the accuracy of these measurements. The discussion in this report is based on a hypothetical, but reasonably achievable, measurement technique and on published manufacturer's data.

The clinician wishing to estimate remaining life should be aware of the shape of the voltage-versus-capacity curve (see figure A.7). Today's lithium/iodine batteries have a longer flat portion of the curve than earlier designs. This provides the patient with the programmed pulse amplitude for a longer period of time. However, these newer designs also decrease in voltage more rapidly during the last months of the prereplacement region. The procedure of using voltage to predict capacity is inaccurate when voltage is not significantly decreasing. By the time voltage begins to decrease significantly, the battery may have less than a year of remaining life. Thus, an accurate prediction of remaining life may not be possible until less than a year of life remains.

7.1 Estimating remaining battery capacity

The total deliverable capacity of a lithium/iodine battery is a function of the current drain at which the battery is depleted. At a point on the discharge curve when the voltage begins to change more rapidly there is a direct relationship between remaining deliverable capacity (Q´) and battery voltage or battery resistance (see annex C.1). This discussion assumes that the remaining longevity estimate is based on battery voltage measurements. Use of battery resistance measurements will produce equivalent results.

To determine Q´, the system must measure or calculate the average battery current drain associated with the present condition of the pulse generator. The battery voltage at that current is measured. One then finds the discharge curve representing that battery current and determines the remaining capacity between the measured voltage and the voltage representing RRT (see figure C.1). That capacity is Q´. It should be noted that this method is effective only in that portion of the battery discharge curve that is showing substantial change as a function of capacity.

Each of the measurements associated with determining Q´ has some uncertainty that contributes to the potential error in the value of Q´. The accuracy of the measurements is dependent on the measurement system employed by the manufacturer in a particular pulse generator. In the absence of a specific product design, one may only draw general conclusions about the accuracy of these measurements.

Annex C.1 presents an analysis of the effect of measurement errors on Q´ for a hypothetical pulse generator system. In this hypothetical system, there are three sources of error that impact the estimate of Q´. They are battery variability (described in annex B) and the uncertainties in the measurement of battery voltage and battery current. It can be assumed that the three error sources are independent of each other. Propagation of error theory states that the relative error in the sum of two or more independent error sources will be approximately the square root of the sum of their relative errors squared. Using this process, the uncertainties in the three error sources for the hypothetical system have been combined to produce the curves in figure C.7. Because of the shape of the capacity-discharge curves, a symmetric error battery voltage measurement (i.e., ± 10 mV) produces an asymmetric error in Q´. When dealing with asymmetric error, only error that would result in overestimating the remaining capacity will, in turn, result in overestimating the remaining longevity.

In the previous discussion, it is assumed that the deliverable capacity of a lithium/iodine battery of a certain design is a fixed quantity. Therefore, the battery voltage–time curves in figure A.6 can be derived for any constant current value. Real lithium/iodine batteries, however, are subject to normal statistical variability due to variation in the manufacturing process. While the lithium/iodine battery system has been well characterized and is well understood and the manufacturing process is tightly controlled, the performance of batteries is still subject to statistical variability that cannot be ignored when projecting remaining longevity.

Battery manufacturers characterized the performance of their batteries based on design analysis, accelerated testing, and life testing. Each of these is discussed in annex B. In estimating remaining longevity, it is recommended that a nominal value of ± 5.5% be used as an approximation of the contribution of battery variability.

7.2 Combination of errors

The previous sections have described potential uncertainty in the estimate of remaining battery capacity and the possible error in estimating future average battery current based on “real-time” measurements. It is important to remember that these numbers are dependent on the characteristics of the specific battery used in the pulse generator and on the measurement techniques employed by the manufacturer in a particular pulse generator design. In the absence of a specific design, one may only draw general conclusions about the results.

Remaining longevity can be calculated by dividing Q´ by the average future current drain. In annex C.2, propagation of error theory is used to compute the relative error in the ratio of the two variables (see equation 18). Combining all of the measurement error sources identified in this report produces the curves in figure C.8.

Because of the shape of the battery capacity curves, the system error is not symmetric around the measured battery voltage. As illustrated in figure C.2, a symmetric error in measured battery voltage propagates into an asymmetric error in the remaining battery capacity. In this report, only those error components that contribute to overestimating the remaining life are considered. Overestimating the remaining longevity is significant because this error would lead the onset of RRT before it is expected by the user. However, near RRT the slope of the battery discharge curve is such that the error can be assumed to be symmetric about the measured battery voltage.

Using this model, the percentage error in the remaining battery longevity estimate due to measurement uncertainty ranges from a high of approximately 41% to a low of 36% depending on the measured values. As expected, the percentage error is higher near BOS because the derivative of the battery capacity curve with respect to battery voltage is large. Unless the same capacitor charging current measurement (I_c) is used in the calculation of both Q´ and the future average battery current drain, the uncertainty in the battery current measurement will have a significant impact on the overall potential system error. In this report, the two measurements are assumed to be completely independent.

When evaluating the practical limitations of an algorithm based on "real-time" measurements, it is useful to transform the data in figure C.8 into a plot of the percent uncertainty in the remaining battery longevity estimate (L") as a function of the months remaining to RRT. The results of this transformation are shown in figure 2.

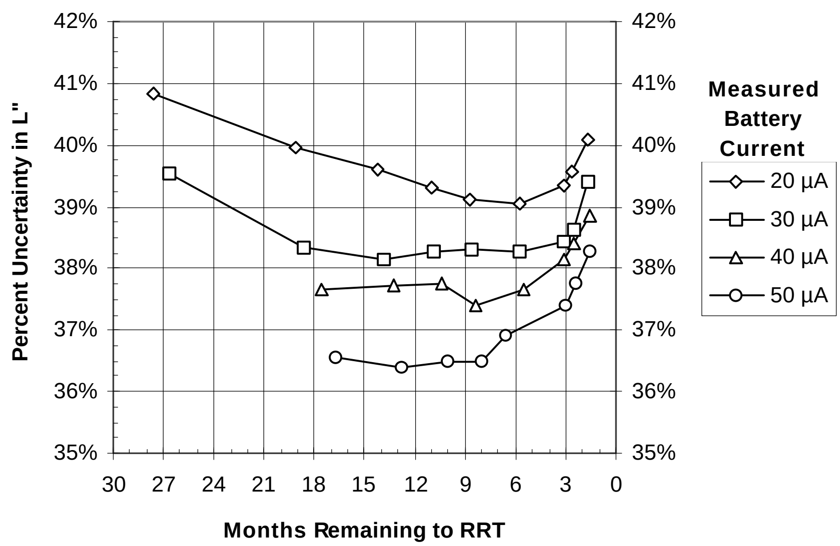


Figure 2—Percent uncertainty in remaining battery longevity (L")

The potential error in the estimate of remaining longevity can be quantified using the graph in figure 2. Consider the following example. The system described in this report measures a battery voltage of 2710 mV and projects a future average battery current drain of 30 µA. With these inputs, the algorithm would estimate the remaining longevity as 13.9 months. From figure 2, the potential error associated with this estimate is approximately 38%, or 5.3 months. Therefore, the real remaining longevity could be as low as

8.6 months.

Some manufacturers include an error estimate in the programmer's remaining life projection routines. This error estimate can be displayed to the clinician as a confidence interval stating that expected remaining life lies between *x* months and *y* months with a given confidence. Here, *x* is smaller than the expected remaining life, and *y* is larger than the expected remaining life. This confidence interval is based on the manufacturer's analysis of error including error in current drain, error in battery impedance, and error in battery capacity. Manufacturers can estimate these errors based on their own measurement and estimation systems. A manufacturer's estimates may be significantly different from the errors presented in this TIR.

7.3 Estimating the future average battery current drain

The future average battery current drain depends on the current delivered to the electrodes and the current used by the circuitry itself. The current used by the circuitry itself may be derived empirically for each pulse generator model or measured and stored in the pacing system, usually in the programmer. The inputs required to assess the battery current are the pacing mode, pulse amplitude (voltage or current), pulse duration, lead impedance, voltage multiplier coefficient, and average pacing rate. These parameters may be measured, may reflect nominal programmed parameters, or may be considered to be constants. The choice varies from manufacturer to manufacturer and may even vary for different product families from one manufacturer. The model for estimating future average battery current drain presented in annex C.2 presupposes that the quiescent current, pacing modality, pulse width, and voltage multiplier coefficients are stored in the system. The pulse amplitude and lead impedance are measured or calculated from "real-time" data collected by the pulse generator. The future average pacing rate is estimated based on the future use profile.

The future use profile is expressed as the average pacing rate over the remainder of the life of the pulse generator. The average pacing rate depends on the percentage of time that the patient is paced (percentage paced) in each channel and on the programmed pacing rate. For some pacing modalities, actual paced rate may be higher than the programmed rate because of tracking of intrinsic atrial activity and/or other physiological or biophysical signals.

Estimating the future average pacing rate based on a prediction of the future use profile can potentially introduce the most uncertainty into the calculation of remaining battery longevity. There is no way to quantify the potential error introduced by the estimate of the average pacing rate. Therefore, for the purpose of calculating the cumulative error, it will be assumed that the uncertainty associated with this estimate is zero.

Instead of assigning a tolerance to this estimate, the system can deal with the uncertainty by calculating the remaining longevity based on the data available and a set of reasonable worst case assumptions. The task group developed the assumptions in table 1 for estimating the future use profile. This table contains guidelines for development of pacing systems that were not generally implemented at the time this report was written. As described in annex C.3, the average pacing rate can be based on historical data accumulated by the pacemaker or on clinician input. If the pulse generator is recording historical usage data, then a minimum of 24 hours of history is thought to be required in order to make a reasonable estimate of average pacing rate based solely on recorded data. If the pulse generator has accumulated less than 24 hours of history, the system should ignore the recorded data.

For those pulse generators that do not have the capability of recording historical usage data, or have accumulated less than 24 hours of history, the clinician should provide an estimate of average pacing rate based on his or her professional assessment of the patient's condition.

For nonrate variable pacing modalities, the sustained pacing rate will be equal to the programmed base rate. The clinician need only provide an estimate of the percentage paced in each active channel. The average pacing rate in each active channel can be calculated using equation 19. If no estimate is provided, the system should assume that the device is pacing 100% of the time in the active channels.

For rate-variable pacing modalities, the clinician must also provide an estimate of the sustained rate in each of the active channels, taking into account those factors that may cause the heart rate to exceed the programmed base rate. In this case, the average pacing rate in each of the active channels can be calculated using equation 20. If no estimates are provided by the clinician, the system should assume that the pacemaker is pacing 100% of the time at 110% of the programmed base rate in each of the active channels.

Table 1—Assumptions for estimating the future use profile

Pacing Modality	**Typical Remaining Longevity**		**Minimum Remaining Longevity**	
Nonrate variable pacing modality	Pacing rate =	Programmed rate	Pacing rate =	Programmed rate
	Percent paced =	Recorded data if $\geq$ 24 hours, or	Percent paced =	100% in active channels
		Clinician estimate if < 24 hours of recorded data, or		
		100% in active channels if no recorded data or clinician estimate.		
Rate-variable pacing modality	Pacing Rate =	Recorded data if $\geq$ 24 hours, or	Pacing rate =	120% of programmed rate
		Clinician estimate if < 24 hours of recorded data, or		
		110% of programmed rate if no recorded data or clinician estimate.		
	Percent paced =	Recorded data if $\geq$ 24 hours, or	Percent paced =	100% in active channels
		Clinician estimate if < 24 hours of recorded data, or		
		100% in active channels if no recorded data or clinician estimate.		

8 Presentation of remaining longevity

To be useful as part of a total patient management protocol, a system for forecasting remaining battery longevity should provide the clinician with an estimate of the typical remaining longevity and the minimum remaining longevity. This is the minimum information that should be provided to facilitate the management of patients. Individual manufacturers may provide additional information based on the capabilities of the pacing system and the design of their individual algorithms.

8.1 Typical remaining longevity

The typical remaining longevity is the average number of months remaining before the predicted onset of the RRT indicator. The typical remaining longevity may be calculated, taking into account the following factors:

a) the measured battery parameters (i.e., battery voltage, battery resistance, and/or accumulated charge delivered), which are used to estimate the remaining deliverable capacity;

b) the pulse generator's permanent programmed settings that determine the current drawn from the battery during each pacing pulse (i.e., pacing pulse amplitude and pulse width) and the measured or calculated system parameters (i.e., lead impedance);

c) the predicted future use profile. The predicted future use profile includes the programmed pacing mode, the expected average pacing rate and, for pacemakers with autocapture, the predicted pacing threshold voltage. The expected average pacing rate and predicted pacing threshold voltage are determined from either the usage history accumulated by the pacemaker or from an estimate provided by the clinician (see table 1 for the assumptions associated with average pacing rate related to computing typical remaining longevity).

d) the current used by the pulse generator's sensing amplifiers, control, and monitoring circuitry. This quiescent current is usually assumed to be a constant value for a given pulse generator model.

The typical remaining longevity represents the most useful estimate of the months of service life remaining in the battery, assuming that the future use is as expected.

Continuing with the example in the previous section, our hypothetical system measures a battery voltage of 2710 mV. If the future average current drain was estimated to be 30 µA based on current output programming and the typical future use profile, the typical remaining longevity estimate would be 13.9 months. Using the chart in figure 2, this estimate could exceed the actual remaining longevity by 38%, or

5.3 months. Looking at the estimate another way, when the algorithm is reporting 13.9 months to RRT, the actual interval under the future use conditions described above could be as short as 8.6 months.

8.2 Minimum remaining longevity

Because of the uncertainty in the estimates used to calculate the typical remaining longevity, the algorithm should also provide the clinician with an estimate of the minimum remaining longevity based on a reasonably severe usage pattern. The minimum remaining longevity is the minimum number of months until the predicted onset of the RRT indicator. The minimum remaining longevity is calculated taking into account the following factors:

a) the measured battery parameters (i.e., battery voltage, battery resistance, and/or accumulated charge delivered), which are used to estimate the remaining deliverable capacity;

b) the pulse generator's permanent programmed settings that determine the current drawn from the battery during each pacing pulse (i.e., pacing pulse amplitude and pulse width) and the measured or calculated system parameters (i.e., lead impedance);

c) the predicted future use profile under reasonably severe conditions. The predicted future use profile includes the programmed pacing mode and the expected average pacing rate under reasonably severe conditions. The expected average pacing rate under reasonably severe conditions is calculated by taking the expected average pacing rate from either the usage history accumulated by the pacemaker or from an estimate provided by the clinician (see table 1 for the assumptions associated with average pacing rate when computing minimum remaining longevity).

d) the current used by the pacemaker's sensing amplifiers, control, and monitoring circuitry. This quiescent current is usually assumed to be a constant value for a given pacemaker model.

The minimum remaining longevity represents a reasonable worst case estimate of the months of service life remaining in the battery. The minimum remaining longevity calculated in this manner provides a lower bound to the actual remaining longevity that compensates for the errors inherent in estimating the nominal longevity as described in section 8.1.

This estimate is subject to the same measurement errors as the typical longevity estimate. For example, assume that the future average battery current associated with the minimum longevity conditions described above is 50 µA. With a measured battery voltage of 2710 mV and a battery current of 50 µA, our hypothetical system would estimate the remaining longevity as 12.8 months. Using figure 2, the uncertainty in this estimate is 36.5%, or 4.7 months. When the algorithm is reporting 12.8 months to RRT, the actual interval under the future use conditions described above could be as short as 8.1 months.

9 Summary

Clinicians perceive a need for better tools to forecast the remaining battery service life of implantable cardiac pacemakers. One such tool is a system that forecasts remaining battery service life by combining "real-time" measurements made by the pulse generator with assumptions provided by the clinician. This report focuses on the limitations of forecasting remaining battery service life using such systems.

The programming options that are provided in modern pulse generators can be used to improve battery longevity during the normal service life. However, once the pulse generator battery enters the predictable usage region of the battery depletion curve, the pulse generator may restrict the programming options available to the clinician. The pulse generator may change its permanent operation in order to control energy usage to assure a minimum time interval between RRT and the point in time when the manufacturer can no longer assure that the pulse generator will perform according to its specifications.

The RRT indicator always marks the end of the normal service life of a pulse generator. Although the terminology may vary, all the manufacturers surveyed (see table D.1) provide an RRT indicator. The occurrence of this indicator is followed by a predictable usage region that may vary in duration for each manufacturer and product family. If a pulse generator is operated beyond this region, the manufacturer can no longer assure that it will perform according to its specifications.

With currently available technology, it is possible to construct a system that can forecast remaining longevity using "real-time" measurements made by the pulse generator. The accuracy of forecasting remaining battery longevity is dependent on (a) the accuracy of the estimate of remaining battery capacity, and (b) the accuracy of the estimate of future average battery current drain.

The hypothetical system described in this report is capable of estimating the months remaining to RRT with an error ranging between 36% and 41% (see figure 2). At 12 months before RRT, this is approximately ± 5 months. The measurement-induced error rapidly increases as you move further away from RRT. Depending on the particular battery discharge current level when the measurements are made, the utility of the system as a tool for managing patients becomes marginal between 18 and 24 months prior to RRT. Of course, each manufacturer would estimate the accuracy of a particular implementation, depending on the individual measurement techniques employed in a given pulse generator. However, practical systems should be able to achieve similar, if not better, performance.

Estimating the future average battery current drain based on a prediction of the future use profile can potentially introduce the most uncertainty into the calculation of remaining battery longevity. There is no way to quantify the potential error introduced by the estimate of the average pacing rate. Instead of assigning a tolerance to this estimate, this report proposes dealing with the uncertainty by calculating the remaining longevity based on the data available and a set of reasonable worst case assumptions.

Many modern pacing systems are capable of recording historical usage data that are very useful in estimating the future use profile. The task group concluded that a minimum of 24 hours of accumulated usage history is necessary for the system to make an estimate based solely on accumulated data. If the pulse generator does not have this capability or has accumulated less than 24 hours of history, the clinician should provide an estimate of average pacing rate based on his or her professional assessment of the patient's condition.

The task group developed a set of assumptions for estimating the future use profile under typical and reasonable worst case conditions (see table 1). Using these assumptions, the system can predict the typical remaining longevity and the minimum remaining longevity. Given these two values and an understanding of the accuracy of the measurement system, the clinician can estimate an appropriate interval to the next follow-up for monitoring battery status.

Annex A

Fundamental system model

To understand the performance of systems that use “real-time” measurements telemetered by the pulse generator to forecast the remaining battery service life, it is important to understand the fundamental system model on which these algorithms are based. The purpose of this annex is to communicate background information that may be helpful in understanding the concepts discussed in this report.

A.1 The pulse generator circuit model

A typical pulse generator may perform many different functions. Its primary function, however, is to provide pacing therapy by generating appropriately timed stimulation pulses that are synchronized to intrinsic cardiac activity (if any is present). A rate-adaptive pulse generator will also interpret other physiological or biophysical signals that indicate changes in biological demand. To carry out its primary function, the typical pulse generator uses sophisticated microelectronics that sense cardiac activity and/or other physiological or biophysical signals and implement the algorithms that control the available pacing modalities (e.g., VVI, DDD). The pulse generator may be capable of recording information about its internal operation and/or the interface between the pulse generator and the patient. Also, most pulse generators are capable of communicating with an external instrument for receiving instruction and exporting data stored in the pulse generator. All of these control and monitoring functions require that the pulse generator circuitry draw energy from the battery and thus they affect the service life of the pacemaker.

A.1.1 Stimulation pulse

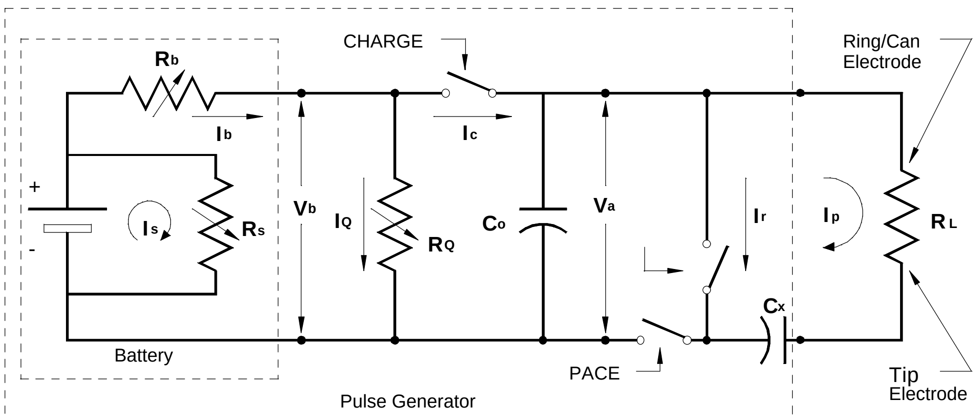
From an energy consumption point of view, the stimulation pulse produced by the output circuit constitutes the most significant drain on the battery. Pulse generator output circuits can be classified into two categories: constant-voltage and constant-current.

A.1.1.1 Constant-voltage output circuit

The constant-voltage output circuit is the most common type of output circuit used in implantable pulse generators. A constant-voltage output circuit applies a voltage pulse to the tip electrode of the lead. A simplified circuit diagram for a constant-voltage type system is shown in figure A.1.

This circuit contains an ideal battery that is connected to the rest of the pulse generator circuitry through a variable series resistor (R_b). This resistor represents the internal impedance of the battery that increases over time as the battery is discharged. A second variable resistor (R_s) is shown in parallel with the ideal battery. This resistor represents the spontaneous self-discharge of the battery by internal chemical reaction. The battery chemistry that produces both of these effects is discussed in A.2.

As energy is withdrawn from the battery, the internal impedance, R_b, increases. As this resistance rises, the battery voltage (V_b) will decline. In the model in figure A.1, the voltage available to the pulse generator circuitry, and consequently the output voltage (V_a) will decline in direct proportion to V_b. This type of power supply is referred to as an “unregulated supply.” Some pulse generators employ circuitry that maintains V_a at a constant value. A supply that maintains a constant V_a is referred to as a “regulated supply.” The remainder of the discussion in this section applies to either type of power supply.



R_b	Internal battery resistance	C_o	Holding capacitor(s)
I_b	Battery current	I_c	Capacitor charging current
V_b	Battery voltage	V_a	Pacing output voltage
R_s	Self-discharge load	R_L	Lead impedance
I_s	Self-discharge current	I_p	Stimulation (pacing) current
R_Q	Quiescent load	I_r	Recharge current
I_Q	Quiescent (static) current	C_x	Blocking capacitor

Figure A.1—Simple constant-voltage output circuit

The output voltage (V_a) is stored on one or more holding capacitors, represented as C_o in figure A.1. Multiple holding capacitors are sometimes used to multiply the battery voltage to a higher amplitude. These “voltage multiplier” circuits necessarily require proportionally more charging current from the battery to deliver a given amount of stimulation current at the higher amplitude, a consequence of the conservation of energy. The capacitor charging current (I_c) required to charge the holding capacitors is given by the equation:

$$I_c = M \times I_p \qquad (1)$$

where I_p is the stimulation (pacing) current delivered by the output circuit and M is a voltage multiplier coefficient associated with the programmed pulse amplitude. In a single holding capacitor system, M =

1.0. When multiple capacitors are used, M can be expected to increase as the efficiency of the charging system declines. As capacitors are switched in and out of the output circuit to achieve the programmed output voltage, the efficiency of the charging circuit will change. Therefore, it is likely that there will be a value of M associated with each programmable pulse amplitude.

Two switches are used to deliver the pacing stimulus to the lead: a PACE switch and a RECHARGE switch that reestablishes the charge equilibrium after the stimulation pulse has been delivered. These switches, however, are not perfect and can cause direct current (DC) to leak from the pulse generator. To prevent DC leakage, a blocking capacitor, C_x, is inserted in the output circuit.

When the pulse generator control circuitry determines that it is time to deliver a stimulation pulse, the PACE switch is closed. When the PACE switch closes, the output voltage (V_a) that is stored on capacitor C_o is applied to the tip electrode of the lead through capacitor C_x. When the programmed pulse width (PW) has been reached, the pulse generator control circuitry opens the PACE switch. While the PACE switch is closed, some of the charge stored on capacitor C_o is transferred to capacitor C_x, and some is delivered to the lead system to stimulate the myocardium. To reestablish equilibrium, the pulse generator circuitry closes the RECHARGE switch, and a “recharge” pulse is delivered. The recharge pulse is intended to remove any residual charge on capacitor C_x, and on the pacing electrodes of the lead (polarization). After sufficient time has passed to allow the residual charge on capacitor C_x to dissipate, the RECHARGE switch is opened. A typical constant-voltage (CV) pulse waveform generated by this procedure is shown in figure A.2. After the CV pulse is delivered, the charge on capacitor C_o is replenished from the power supply by closing the CHARGE switch. Replenishment of the charge on capacitor C_o must be completed before another pacing stimulus can be delivered.

It is important to note that the voltage is actually not constant during the stimulation pulse. The voltage “droops” during the pulse as charge is drained from capacitor C_o. The lower the lead impedance (R_L), the greater the current (I_p) and the greater the magnitude of the voltage droop. The voltage droop is given by the equation:

$$\Delta V = V_a\left(1 - e^{-\frac{PW}{R_L \times C}}\right) \quad (2)$$

where V_a is the pulse amplitude, PW is the pulse width, R_L is the total impedance of the lead and the tissue that completes the circuit, and C is the effective output capacitance. Some manufacturers use the voltage droop during the stimulation pulse to estimate lead impedance. However, such a calculation of lead impedance is an approximation because the true lead impedance is not purely resistive but has some capacitive and inductive components as well.

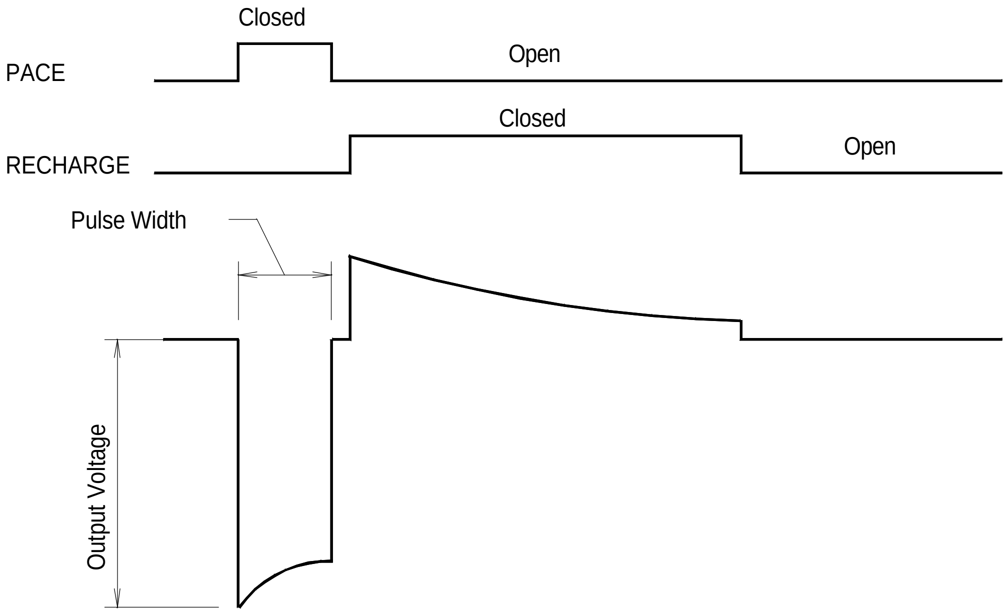


Figure A.2—Typical constant-voltage pulse waveform

The amount of energy expended in the pacing pulse determines, in large part, the battery longevity. The energy in the pulse depends on three primary variables: pulse amplitude, pulse width, and lead impedance. The amount of energy in the pulse can be found by integrating the product of voltage and current over time:

$$E = \int_0^t V \times I dt \qquad (3)$$

Using Ohm's law to solve for current as a function of voltage and resistance, the following equation can be derived:

$$E = V_a^2 \times \left(\frac{C}{2}\right) \times \left(1 - e^{-\frac{2 \times PW}{R_l \times C}}\right) \qquad (4)$$

where V_a is the peak pulse amplitude, R_L is the lead impedance, PW is the pulse width, and C is the effective output capacitance. This is only an approximation of the energy in the stimulation pulse because lead impedance is not purely resistive as is assumed here. Also, lead impedance is not necessarily constant during the pacing stimuli because charge is stored at the pacing electrodes during the pulse (i.e., polarization). However, the approximation is accurate enough for most pacing applications that require estimating the energy in the stimulation pulse.

A.1.1.2 Constant-current output

A constant-current output circuit is designed to deliver a known amount of current to the tip electrode of the lead. Constant-current output circuits are typically no longer used for implantable pacemakers, although they are still popular for external pacemakers. The following is a brief discussion of the constant-current output circuit.

The circuit diagram for a constant-current output circuit is similar to that shown in figure A.1, except that an output current limiting resistor is connected in series with the PACE switch. This internal current limiting resistor has a high resistance in comparison to the lead impedance. The internal resistance limits the output current to a fixed (constant) value during the stimulation pulse, as long as the internal resistance is large in comparison to the lead impedance.

The amount of energy contained in the constant-current output pulse is also dependent on the pulse amplitude, pulse width, and the lead impedance. As with the constant-voltage pulse, the energy can be calculated by integrating the product of voltage and current over time. If the internal limiting resistance is large in comparison to the lead impedance, the current will be constant during the pulse. If we assume that the lead impedance is also constant during the pulse, the energy can be calculated by the equation:

$$E = I_p^2 \times R_L \times PW \qquad (5)$$

A.1.2 Control and monitoring circuits

The control and monitoring circuits of the typical pulse generator include such functional elements as the pacing therapy controller, the sense amplifier(s), the telemetry controller, and the diagnostic subsystem. Each of these functional elements consumes power from the pacemaker battery. Some circuits, such as the pacing therapy controller and the sense amplifier(s), operate continuously and impose a constant current drain on the battery. Others, such as the telemetry controller, impose a more substantial load but operate at such a low duty cycle as to be negligible. Finally, other circuits, such as a diagnostic subsystem, may or may not impose a load on the battery. The pacemaker manufacturer must analyze each of these components and determine how best to account for them when predicting remaining pacemaker battery service life.

In the model shown in figure A.1, the load imposed by the control and monitoring circuitry is represented by a variable resistor (R_Q) that results in a quiescent (static) current (I_Q) flowing inside the pulse generator. In this model, the value of this internal resistor is directly proportional to the battery voltage (V_b), so that I_Q remains constant as V_b declines during the life of the pacemaker. With modern circuit technology, I_Q is a few microamperes. As a first approximation, I_Q can be considered as independent of the programmed settings of the pulse generator.[2]

In the past, quiescent current drain was not a major contributor to total current drain. In today's sophisticated pulse generators, however, the quiescent current drain is a significant and complex contributor to total current drain. Some manufacturers include a model in their programmers to estimate quiescent current drain as a function of operating mode (dual chamber, single chamber), programmed activity levels, programmed diagnostics, battery voltage, pacing rate, and other factors. This quiescent current drain is then added to the estimated pacing current drain to obtain total current estimate that can be used in the remaining life projection.

The inclusion of powerful microprocessors and memory chips has increased quiescent current drain to the point where it is the primary contributor to total current drain in many pacing applications. Therefore, an accurate model of quiescent current drain is needed in remaining life projection algorithms. Assuming a constant quiescent current drain for a given pulse generator can result in unacceptably large error in total current drain estimation.

A.2 The pacemaker battery model

The lithium/iodine battery is the most important implantable battery because it has been used in the great majority of cardiac pulse generators manufactured since 1980 and is used in virtually all cardiac pacemakers manufactured today. Lithium/iodine batteries have a high energy density (1 Wh/cm^3) and low self-discharge, resulting in good longevity and small size.[3] The voltage and impedance characteristics allow for relatively easy monitoring for the approaching end-of-service. The battery system is relatively simple and inherently resistant to many common modes of failure. As a result, lithium/iodine batteries have obtained an enviable record of reliability among electrochemical power sources.

A.2.1 Deliverable battery capacity (Q)

The lithium/iodine-polyvinylpyridine battery consists of a lithium anode, a cathode material comprising iodine (a small portion of which has been reacted with polyvinylpyridine), and a solid electrolyte, lithium iodide, which is formed in situ as the battery is discharged (see figure A.3). The polyvinylpyridine serves to impart an electronic conductivity to the cathode material. This conductivity varies as the elemental iodine is depleted in the battery reaction. As the discharge reaction proceeds, the layer of lithium iodide that forms between the anode and the cathode material increases in thickness, causing the internal resistance of the battery to increase gradually (R_b in figure A.1). The resistance of the cathode material increases in a nonlinear fashion as the battery approaches the end of useful life, resulting in a more

[2] Untereker, DF., Shepard, RB., et al. Power Sources for Implantable Pacemakers. In: Ellenbogen, KA., Kay, GN., Wilkoff, BL., eds. Clinical Cardiac Pacing. Philadelphia: W.B. Saunders, 1995, p. 100.
[3] Ibid, p. 106.

pronounced increase in battery resistance and the indication that the elective replacement point is approaching.

The deliverable capacity of a lithium/iodine battery is a function of the current drain at which the battery is depleted. At high current drains, the capacity is reduced because of a phenomenon known as "polarization." The internal resistance of the battery causes the voltage under load to drop more rapidly, resulting in a lower delivered capacity. At very low current drains, the capacity can be reduced by self-discharge (I_s in figure A.1). Self-discharge occurs early in battery life, when the lithium iodide layer being formed between anode and cathode is thin enough to allow iodine molecules to migrate directly to the lithium, reacting internally. Once an appreciable amount of lithium iodide is formed, the self-discharge rate diminishes to nearly zero. However, under very low current discharge, this initial self-discharge is not negligible and must be accounted for in projecting battery longevity as a function of current drain.

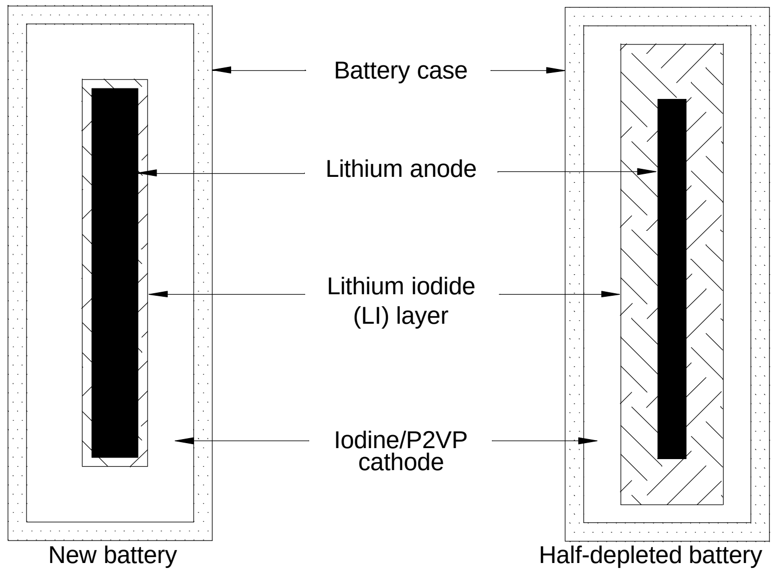


Figure A.3—Cross-section of new and partially depleted lithium/iodine pulse generator batteries[4]

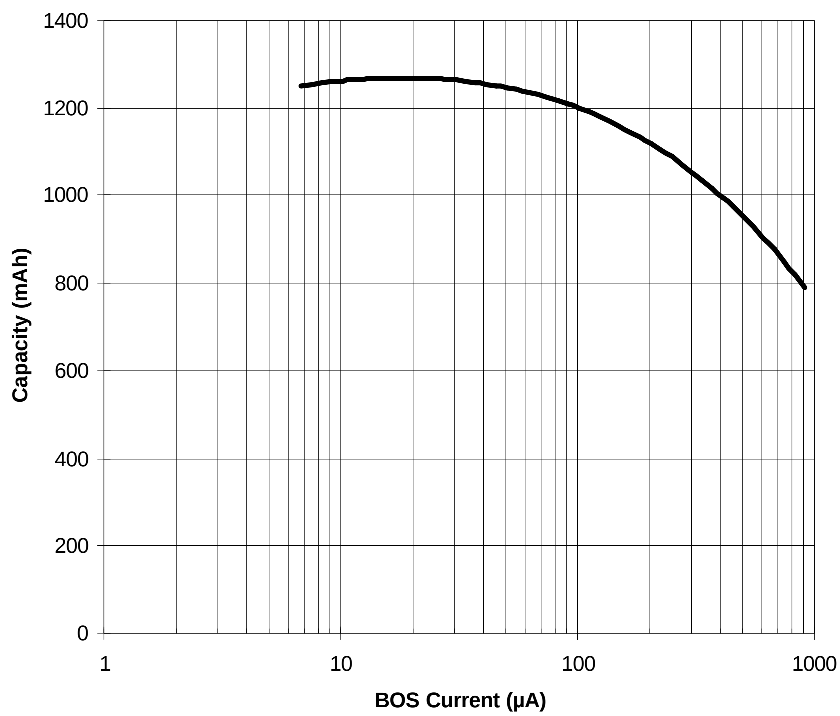
A common method for representing the capacity of a battery as a function of current drain is the "Selim-Bro" plot.[5] This representation plots the capacity of a battery as a function of the current drain, shown on a logarithmic scale. The Selim-Bro plot for a typical lithium/iodine battery is shown in figure A.4. The particular battery model described by this curve is a half-round battery of nominal dimensions—45 mm by 23 mm by 5 mm.

The data in figure A.4 can be translated into a curve showing battery longevity as a function of current drain. This is shown in figure A.5.

Figure A.5 demonstrates that even though the capacity of the battery diminishes as current drain decreases, the longevity increases, although not as much as would be the case were the capacity constant as a function of current drain.

[4] Fester, K., Schmidt C. Impact of Battery Technology on Pacemaker Design, Size, and Longevity. Medtronic Technical Concept Paper. Minneapolis, MN: Medtronic, 1990, p. 2.
[5] Selim, R., Bro, P. Performance domain analysis of primary batteries. J. Electrochemical Society, 118: 829, 1971.

The above discussion demonstrates that the performance of a battery as a function of current drain must be taken into account in the development of a longevity algorithm.



NOTE—BOS current refers to the current drain at the beginning of battery discharge. A cutoff voltage of 1.8 volts is assumed.

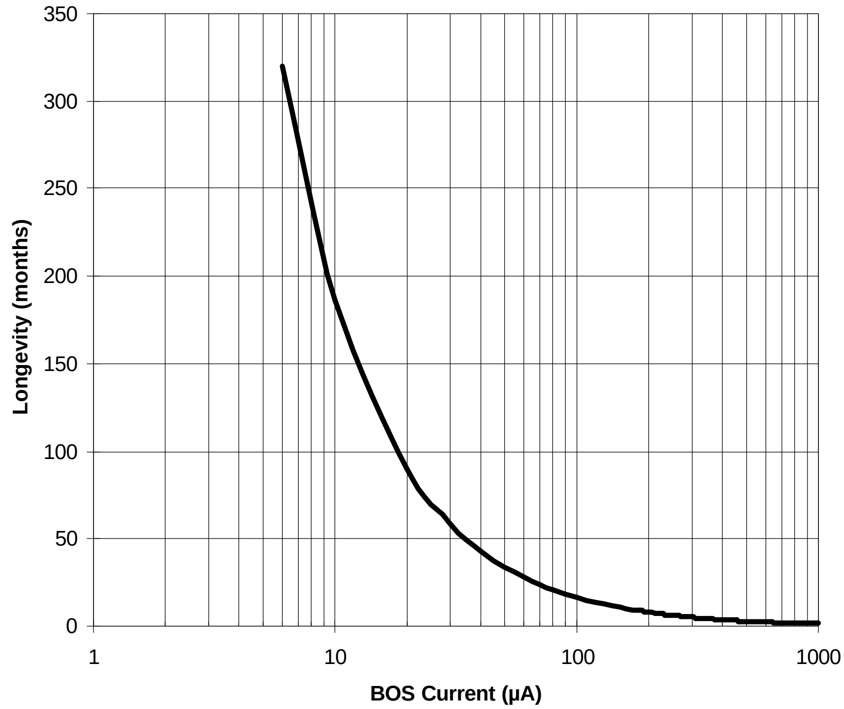
Figure A.4—The capacity as a function of current drain for a typical lithium/iodine battery

A.2.2 Battery longevity

Battery longevity of a pulse generator is typically defined as the interval between the implantation of the device and onset of the recommended replacement time (RRT) indicator. Given a battery of a certain deliverable capacity (Q), the longevity of the pulse generator in years (L) can be calculated using the equation:

$$L = \frac{Q}{8.766 \times 10^6 \times \overline{I_b}} \quad (6)$$

where $\overline{I_b}$ is the average battery current drain. Q is expressed in milliampere-hours (mAh) and $\overline{I_b}$ in microamperes (µA). The conversion factor of 8.766×10^6 converts mAh per microampere to years. In



NOTE—A cutoff voltage of 1.8 volts is assumed.

Figure A.5—Battery longevity as a function of current drain

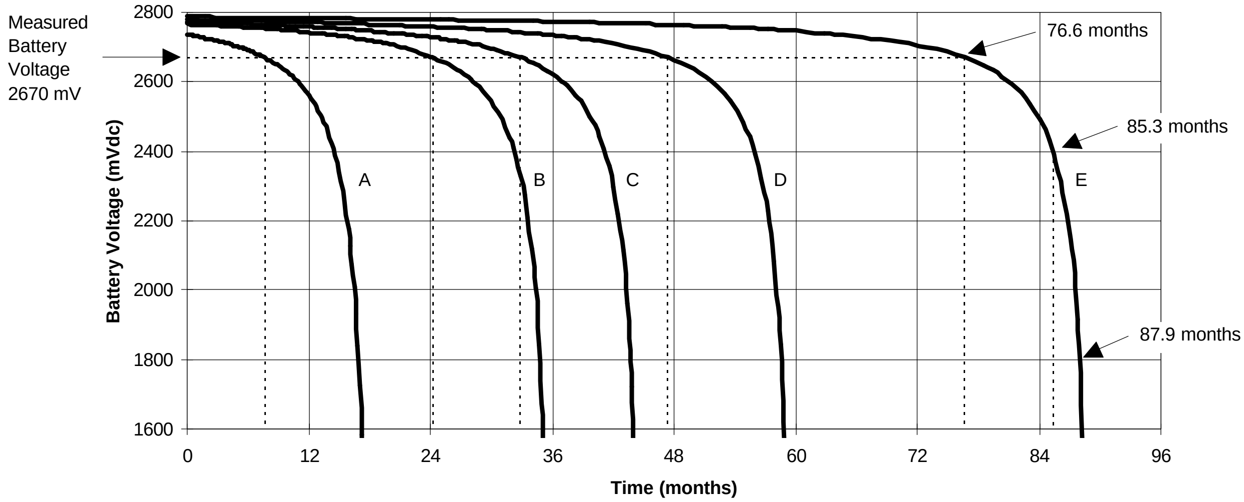
the circuit shown in figure A.1, the average battery current drain, $\overline{I_b}$, is calculated using the equation:

$$\overline{I_b} = \overline{I_c} + I_Q \quad (7)$$

where $\overline{I_c}$ is the average current from the battery to charge the output capacitors expressed in µA, and I_Q is the quiescent current flowing inside the pulse generator circuitry expressed in µA.

Using equation 6, the battery capacity data described in the previous section can be converted into the family of battery voltage versus time curves in figure A.6. Each curve represents terminal voltage of the battery over time when discharged at a constant current.

It must be noted that there is an inherent statistical variability in the delivered capacity of a lithium/iodine battery. This means that the voltage–time curves in figure A.6 are nominal discharge curves. The statistical variability in the delivered capacity is discussed in annex B.



NOTE—Curve A = 100 µA , curve B = 50 µA, curve C = 40µA, curve D = 30 µA, and curve E = 20 µA.

Figure A.6—Battery voltage–time for a specific lithium/iodine battery discharged at constant currents

The total deliverable capacity of the lithium/iodine battery is a function of the current drain at which the battery is depleted. Therefore, determining the total deliverable capacity requires knowledge of how the energy was drained from the battery. This requires that the battery have some measurable characteristics that are directly related to its state of discharge. There are three recognized methods for monitoring a battery's state of discharge: battery voltage, battery resistance, and accumulated charge removed. Of the three, battery voltage and battery resistance are the most commonly used characteristics.

The analysis in this report assumes that the remaining-longevity estimate is based on battery voltage measurements. Use of resistance measurements will produce equivalent results because of the relationship between battery voltage and battery resistance (see figure A.7).

Once the RRT threshold voltage is established for a pulse generator, the longevity can be calculated. When discharged at a constant current of 20 µA, the typical battery in figure A.6 will reach an RRT voltage of 2.4 V in 85.3 months (7.1 years). If the discharge current remains the same, the battery will reach a 1.8 V cut-off voltage in 87.9 months (7.3 years).

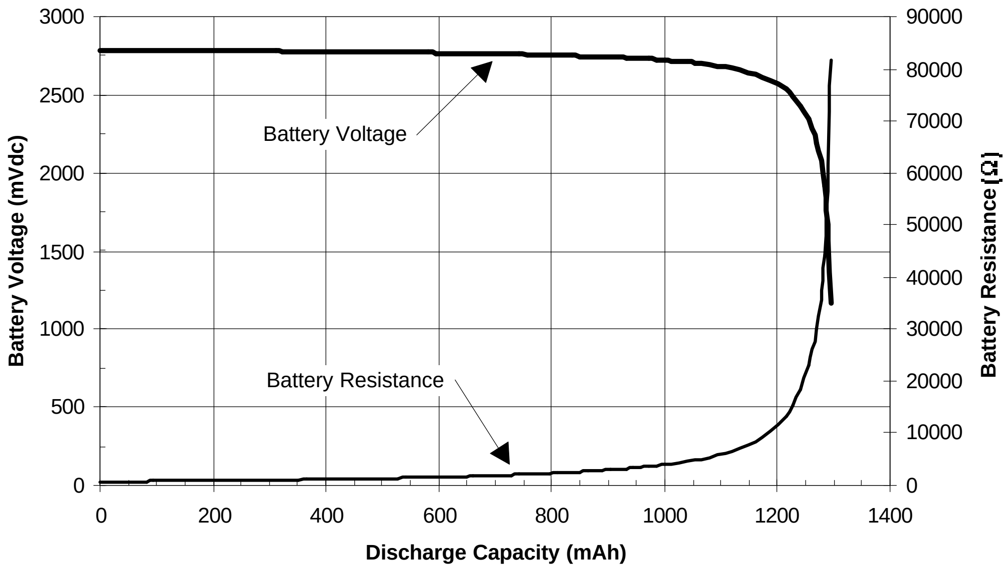


Figure A.7—Relationship between voltage, internal resistance, and capacity for a specific lithium/iodine battery at a constant discharge current

A.3 Programming pacing output for maximum longevity consistent with adequate safety margin

A.3.1 Introduction

Safety margin and longevity are related by the following three physician requirements.

a) The projected pulse generator longevity must be determinable with an error that is small enough to allow scheduling of follow-ups and elective replacement in a nonemergent fashion.

b) The pacing threshold must be determined so that an adequate output safety margin can be programmed, ensuring that capture is maintained despite variations in threshold due to the activities of daily living.

c) The physician should be guided in the selection of efficient output settings that maximize longevity consistent with the selected safety margin.

A.3.2 Forecasting pulse generator longevity

This requires knowledge of the average pulse generator current and remaining cell capacity. Remaining capacity can be estimated from battery measurements (voltage and/or impedance) or by subtracting the capacity consumed from the initial cell capacity.

Total current is the sum of "housekeeping" current and pacing current. Pacing current will depend on (among other things) the pacing rate, percent paced, output voltage, pulse width, and lead impedance. Note that although total current can be estimated from the telemetered battery current during a follow-up session, it may not be representative of the average current drawn. More elaborate schemes may store current consumption data or pace/sense counter information (from which current consumption can be calculated). The longevity forecast is then made with the presumption that future usage will be similar to past usage.

A.3.3 Programming of pacing safety margin

The stimulation threshold must be determined before a safety margin can be programmed. The concept of the strength-duration (SD) curve is fundamental to electrostimulation. The widely accepted Lapique equation relates pacing voltage (V) to stimulus pulse width (PW) via the following equation:

$$V = Rb \times \left(1 + \frac{tc}{PW}\right) \tag{8}$$

Rb (rheobase) is the minimum voltage regardless of pulse width that can cause stimulation, and tc (chronaxie) is the pulse width at twice rheobase. Refer to the lower trace of figure A.8, which shows the shape of the curve. Typical values of rheobase and chronaxie for modern pacing leads are 0.25 V and 0.5 ms respectively. Most pulse generators have stimulus voltage programmable from 0.5 V to approximately 8 V and pulse width programmable from 0.03 ms to 1.5 ms.

A pacing pulse whose voltage and pulse width falls below the SD curve will result in a failure to capture the myocardium. Generally, a "safety margin" is included so that all stimuli will be superthreshold even if the SD curve moves up (due to an increase in rheobase, for example). The simplest safety margin is defined in terms of voltage. For a given pulse width the voltage safety margin is defined as a multiple of the voltage pacing threshold at that pulse width:

$$V_{sm} = V_{th} \times SM \text{ at each pulse width} \tag{9}$$

NOTE—Minimum pulse energy occurs at chronaxie even with the application of the voltage safety margin.

A.3.4 Selection of efficient output settings

Only certain voltage and pulse width settings may be programmed in the pulse generator. Output voltages may be unregulated (i.e., be derived directly from the battery and therefore vary in proportion with battery voltage) or regulated (i.e., remain constant despite battery depletion).

For unregulated modes, the output voltages are defined as multiples and submultiples of the battery voltage. Typical multiplier settings are 0.5, 1.0, 1.5, 2.0, and 3.0, which result in beginning of life output voltages of 1.3, 2.7, 4.1, 5.4, and 8.1 V respectively when used with a lithium/iodine cell (the standard cell used in implantable pacemaker systems) that has a beginning of life output voltage of 2.7 V.

Some manufacturers offer regulated output voltage settings such as 0.5 V to 4.0 or 5.0 V in 0.5 V steps in addition to the unregulated voltages.

Pulse width programmability is typically programmable over the range 0.03 ms to 1.5 ms. One manufacturer allows programming in 0.01 ms steps over the whole range, although 0.03 ms steps are more typical.

The current taken from the battery for pacing at a pacing rate of one pulse per second (i.e., 60 ppm) is:

$$I = M \times C \times V \times \left(1 - e^{-\frac{PW}{R \times C}}\right) \tag{10}$$

where M is the battery voltage multiplier associated with the specific output voltage, V. Note that for regulated output voltages $M \times V_{bat}$ must be larger than V by at least the dropout voltage of the voltage regulator. C is the equivalent capacitance of the output circuit (the series equivalent capacitance of C_o and C_x in figure A.1 of annex A.1). PW is the output pulse width. R is the lead impedance (assumed to be resistive), which is the sum of the lead ohmic resistance and the lead-tissue interfacial impedance.

The exponential term can be expanded as a Taylor Series. The convergence of the series and the point at which it can be truncated depends on the criteria for an acceptable error and the value of the negative exponent. For most practical clinical situations the equation:

$$I = M \times V \times \frac{PW}{R} \tag{11}$$

is a reasonable approximation. For example, with PW = 0.45 ms and R = 500 Ω, the equation overestimates the current by 9.3%.

For unregulated output settings, as M is equal to the output voltage divided by the battery voltage, the equation can be expressed as:

$$I = V^2 \times \left(\frac{PW}{R \times V_{bat}}\right) \tag{12}$$

For unregulated voltages, it is most efficient to pace at the pulse width closest to chronaxie at a voltage that achieves the desired safety margin. The disadvantage of unregulated output settings is that the output voltage (and the safety margin) decrease as the battery depletes. Unregulated output pacing is more efficient than regulated as there is no voltage drop across the output regulator.

For regulated output voltages it is always more efficient to use the highest regulated voltage within a given multiplier setting (i.e., lowest voltage drop across the output regulator). For example, suppose that a lead had a rheobase of 0.75 V and a chronaxie of 0.5 ms. Consider a safety margin of 2. Assume that the pulse generator used a multiplier setting of 1.5 for regulated voltages of 2.5, 3.0, and 3.5 V (see table A.1).

Table A.1—Current taken from the battery

M	SM	V_{sm}	V_{th}	PW	I (Equation 10)	I (Equation 11)
1.5	2.0	2.5	1.25	0.750	4.86	5.63
1.5	2.0	3.0	1.50	0.500	4.08	4.50
1.5	2.0	3.5	1.75	0.375	3.66	3.94

Note that the approximation of equation 11 approaches the result given by equation 10 as the pulse width narrows. The pacing current at an output setting of 3.5 V/0.375 ms is actually lower than for 3.0 V/0.5 ms (the chronaxie pulse width) or 2.5 V/0.75 ms.

The lower curve of figure A.8 is the pacing threshold curve for a pacing lead that has a rheobase of 0.5 V and a chronaxie of 0.6 ms. The smooth curve above and to the right is the 2X safety margin curve with the regulated output voltage points marked. The irregular plot is the current corresponding to each voltage-pulse width pair (assuming a lead impedance of 500 Ω). The pacing current at 2.0 V is lower than at 1.5 V. Similarly, the pacing current at 3.5 V is lower than at either 2.5 V or 3.0 V.

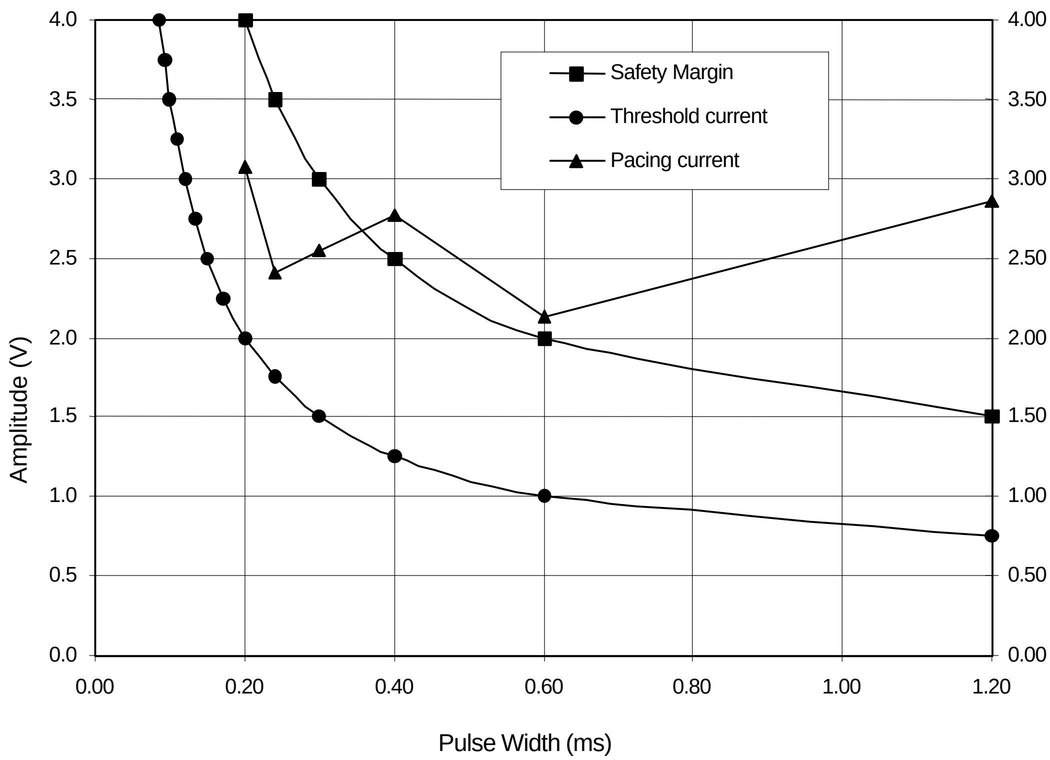


Figure A.8—Threshold, safety margin, and pacing current

Annex B

Battery variability

Among the limitations to be considered in developing a longevity algorithm is the variability inherent in the capacity of the battery itself. Since virtually 100% of all pacemakers use the lithium/iodine battery system today, this discussion will be restricted to that particular battery chemistry.

The lithium/iodine system has been used in cardiac pacemakers since 1972, and many years of data have been accumulated on the reliability, longevity, and variability of this battery system. There is an inherent statistical variability in the delivered capacity of this battery system that has been well characterized and is well understood at this point. The reasons for this variability are beyond the scope of this document.

This section will address the “normal” variability inherent in the lithium/iodine system. It will not consider abnormal behavior or catastrophic failures due to defects in a particular battery. Such defects are extremely rare and need not be considered in analyzing the effects of battery variability on the overall limitations of the longevity algorithm. The analysis presented below will be restricted to “state-of-the-art” batteries, i.e., batteries incorporating design features in place today rather than batteries used in the past.

The following paragraphs provide variability data as presented to pacemaker manufacturers and incorporated into the data used to project performance of individual pacemaker models. Accelerated test data will be presented that will illustrate variability of batteries produced over a 4-year time frame. Finally, data from life testing of batteries under carefully controlled test conditions will be presented.

Although many different battery models are in use today, they share the same general chemical features and show reasonably equivalent statistical variability. Therefore, data for three specific battery models will be used to illustrate the variability inherent in the lithium/iodine system.

B.1 Projection of battery variability

As new battery models are designed and produced for pacemakers, an estimate of the nominal longevity and statistical variability is presented to the pacemaker manufacturer for incorporation into manuals and submission to regulatory agencies. These projections are typically presented as nominal discharge curves (battery voltage and/or internal resistance plotted versus capacity and/or time).

Considering historical data available from previous battery models, estimates of the statistical variability about this nominal discharge curve are generated. These are presented as additional discharge curves illustrating the plus and minus three sigma limits to be expected in the performance of the battery in real time. A series of such curves can be generated for specific current drains at which the battery will be discharged in clinical use. The projections presented at this point are intended to be "worst case" variability projections and are therefore intentionally pessimistic.

Figure B.1 presents a typical projection of battery variability. This graph shows the nominal performance and the three sigma curves for a battery of nominal dimensions (33 mm by 26 mm by 8.6 mm) discharged under a 22-microampere load at body temperature.

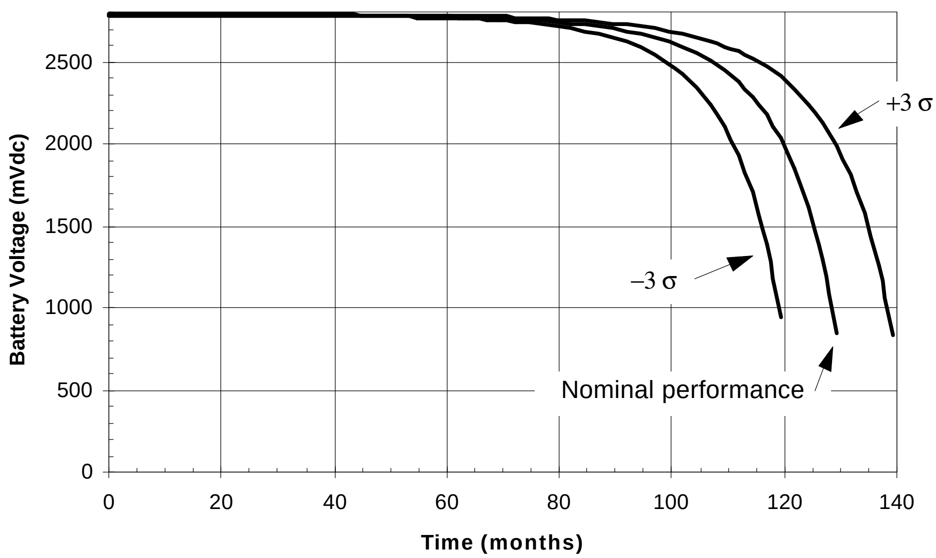


Figure B.1—Example of projected longevity variability of a lithium/iodine battery

B.2 Variability from accelerated testing

Among the routine test programs used by battery manufacturers is a quarterly sampling of typical production batteries. A group of 12 batteries per model are taken from production and placed under a constant resistive load of 12.4 KΩ. The results of this test can be translated into performance under typical pacemaker loads by well-established algorithms. The variability can therefore be assessed over the manufacturing lifetime of the battery.

Figure B.2 presents the results of over 4 years of such testing for a battery model used by several pacemaker manufacturers. This battery is a half-round model of nominal dimensions (45 mm by 23 mm by 5 mm). The nominal capacity of this battery is 1200 mAh. The total number of batteries shown in this graph is 155 batteries. The average longevity to a 1.8 V cutoff voltage was 85.37 months. The standard deviation was 1.22 months. The three sigma limits were +89.01 months and -81.72 months.

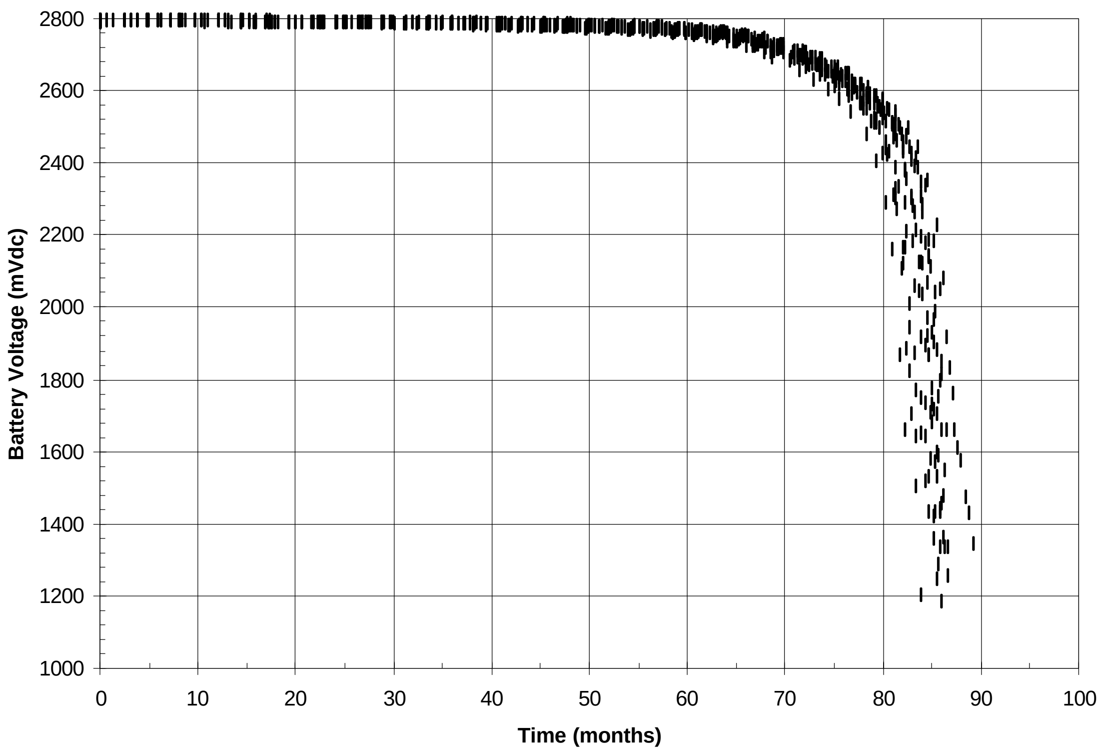


Figure B.2—Discharge curves of a group of batteries discharged under a 12.5 KΩ load.

NOTE — Results are converted to 140 KΩ load.

B.3 Variability from life testing

A running sample of 1% of all batteries is selected for a life test program. The batteries are discharged under a constant resistive load of 100 KΩ, and their performance is monitored every 2 months. As batteries reach the elective replacement voltage (defined in this test as 1.8 volts), an assessment of the statistical variability can be made.

Figure B.3 is a histogram showing the variability in longevity of a group of 77 batteries that have completed the life testing. The battery model is a rather small battery of nominal dimensions (27 mm by 22 mm by 5 mm) and a rated capacity of 0.82 ampere hours.

The nominal longevity of this group of batteries was 44.2 months, with a standard deviation of 0.87 months. The three sigma limits were +46.8 months and -41.6 months.

An additional measure of battery longevity is available from life tables (also called cumulative survival curves), based on the manufacturer's database of implants' subsequent case histories for each model. Such tables have the additional advantage that they reflect actual usage without recourse to theoretical assumptions or laboratory conditions. Either life tables will confirm the life testing results mentioned above, or their conflicting results will occasion an evaluation of laboratory conditions and assumptions. Both the Cutler-Ederer and Kaplan-Meier life table methods can be used. Traditionally, the Cutler-Ederer method is more manageable since it groups cases into intervals containing, at times, many failures.

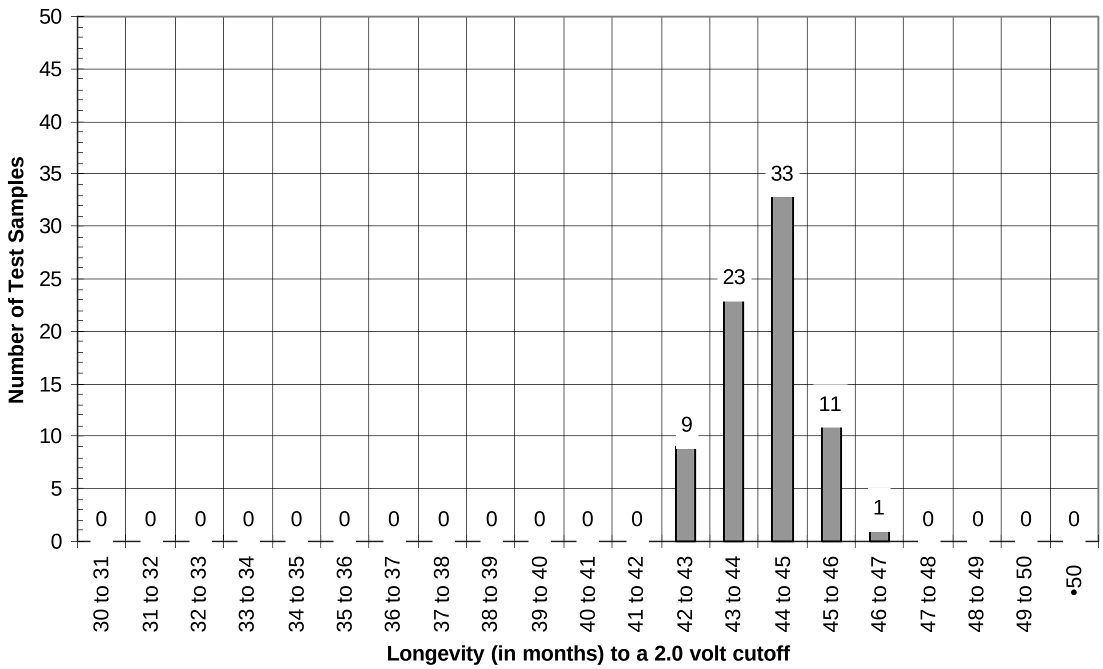


Figure B.3—Life test results for a group of 77 batteries discharged under 100 KΩ constant resistive load

B.4 System error contribution due to battery variability

If the battery (usually one battery in a pacemaker) has less than its nominal capacity, the remaining longevity at any time in the device's service life will be in error by that amount, other things being perfect. For example, it is entirely possible that a battery rated at 1,000 mAh is actually 980 mAh, i.e., 2% below nominal. If the nominal pacemaker longevity calculated using equation 6 is 7 years, the actual will be 0.98 × 7.0, or 6.86 years (51 days less than 7 years). If the remaining longevity is estimated by integrating the current used throughout the device lifetime, this error remains the same size, i.e., 51 days. When the estimated remaining life is 51 days, the actual will be 0 days! Analysis of the test data presented above shows that a statistical variability of approximately 9% to 11% (± 4.3% to ± 5.5% around a nominal value) can be expected from a "normal" population of typical lithium/iodine batteries. It should be understood that this variability is a function of current drain, storage conditions, and the particular battery model. In developing the pacemaker longevity algorithm, it is recommended that a nominal value for three sigma limits of ± 5.5% be used as an approximation of the contribution of battery variability to the overall variability in pacemaker longevity.

Annex C

Remaining battery longevity

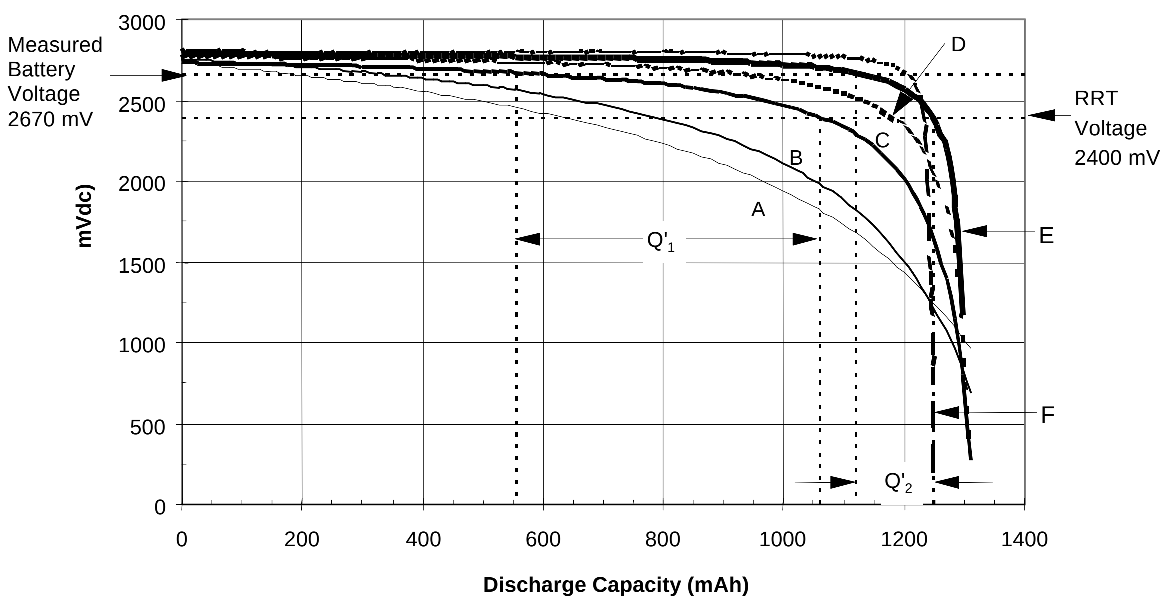
The normal service life of a pulse generator is defined as the time between implant and the onset of the RRT indicator. At any point in time during the normal service life of the pulse generator battery, the remaining battery longevity (L") in months can be estimated using the equation:

$$L'' = \frac{Q'}{7.305 \times 10^5 \times \overline{I_b}''} \qquad (13)$$

if the remaining deliverable capacity of the battery (Q´) in mAh can be estimated and the future average battery current drain ($\overline{I_b}''$) in µA can be predicted. The conversion factor of 7.305 x 10^5 converts mAh per microampere to months.

C.1 Remaining deliverable battery capacity (Q´)

The remaining deliverable battery capacity (Q´) refers to the charge that can actually be used, i.e., the total remaining charge at that instant minus the charge remaining when the RRT indicator will be activated (see figure C.1).



NOTE—Curve A = 800 µA, B = 400 µA, C = 100 µA, D = 50 µA, E = 20 µA, and F = 5 µA.

Figure C.1—Load voltage-capacity for a specific lithium/iodine battery discharged at constant currents

The total deliverable capacity of the lithium/iodine battery is a function of the current drain at which the battery is depleted. Therefore, determining the total deliverable capacity, which is shown on the X-axis of figure C.1, requires knowledge of how the energy was drained from the battery. However, at a point on the discharge curve where the voltage begins to change more rapidly there is a direct relationship between Q´ and battery voltage or battery resistance (see figure A.7).

It must be noted that capacity lost due to self-discharge is an important consideration when estimating remaining deliverable capacity. Lithium/iodine batteries lose capacity that is not available for pacing. This capacity loss (self-discharge) is a function of time and current drain. At very high current drain, self-discharge is negligible. However, at low current drains, self-discharge can account for more than 10% of total capacity.

Self-discharge plays two roles in remaining deliverable capacity projections:

a) determining Q´, the projected remaining deliverable capacity, given voltage and current drain. To calculate the capacity deliverable to pacing, the self-discharge capacity loss is subtracted from the total remaining capacity. This self-discharge can be successfully modeled for lithium/iodine batteries.

b) determining voltage-versus-capacity curves based on accelerated current drain testing (see annex B.2). Battery manufacturers test batteries at very high current drains to accelerate the test time required to achieve a characterization of the voltage-versus-capacity curves. At this high current drain and short test time, capacity lost due to self-discharge is negligible. If the high current drain testing results are translated directly to low current drain, then the self-discharge component of capacity has been ignored and the deliverable capacity is overestimated. The final deliverable capacity curve for a given current drain is obtained by subtracting the calculated self-discharge from the translated total capacity curve.

The effect of self-discharge on remaining capacity can be seen by examining the 5 µA constant current discharge (curve F) in figure C.1. Curve F shows that the maximum deliverable capacity is less than for higher current drain. This reduction in deliverable capacity is the direct result of self-discharge.

C.1.1 Estimating remaining deliverable battery capacity

To determine the remaining deliverable battery capacity (Q´), the system must measure or calculate the average battery current drain associated with the present condition of the pulse generator. The battery voltage at that current is measured. One then finds the discharge curve representing that battery current and determines the remaining capacity between the measured voltage and the voltage representing RRT. That capacity is Q´.

For example, if the current being drawn from the battery depicted in figure C.1 is 100 μA and the measured voltage is 2670 mV, curve C in figure C.1 applies, and the remaining capacity (i.e., the capacity between the measured voltage and the voltage representing RRT) is Q'_1. In this example, Q'_1 is 503.8 mAh. If the current drain remains constant at 100 μA, L" is 6.9 months.

If the current being drawn from the battery is 20 μA and the voltage is 2670 mV, curve E of figure C.1 applies and the remaining capacity to RRT is Q'_2, or 127.6 mAh. If the future drain remains constant at 20 μA, L" is 8.7 months.

It should be noted that this method is effective only in that portion of the battery discharge curve that is showing substantial change as a function of capacity.

The accuracy of the estimate of Q´ depends on the accuracy of the estimate of total remaining charge at the time of measurement and the capacity corresponding to RRT. The capacity corresponding to RRT is a function of battery variability that is discussed in annex B. The accuracy of the total remaining battery capacity estimate is a function of the accuracy of the battery voltage and the battery current measurements.

The accuracy of both the battery voltage and battery current measurements is dependent on the measurement system employed by the manufacturer in a particular pulse generator. In the absence of a specific product design, one may only draw general conclusions about the accuracy of these measurements.

Some manufacturers believe that measuring the battery's AC ohmic impedance is a more accurate estimator of capacity than is measuring voltage. In the flatter regions of the voltage-versus-capacity curve, variation in voltage may be more indicative of factors unrelated to capacity than is AC ohmic impedance. Therefore a remaining life algorithm based on AC ohmic impedance may improve on one of the most difficult aspects of the projection process—accurately estimating remaining life when a significant capacity remains.

C.1.2 Effect of battery voltage measurement error on remaining capacity (Q´)

The following discussion addresses the sensitivity of the remaining battery capacity calculation to the measurement of battery voltage (V_b) and is based on a hypothetical, but reasonably achievable, measurement technique.

Most of the usable life of a lithium/iodine battery is realized at a V_b between 2.8 V at beginning of service (BOS) and the RRT voltage (e.g., 2.4 V). If, for example, the granularity of the voltage measurement is 20 millivolts (mV), there will be 20 distinguishable voltage levels [i.e., (2.8 – 2.4)/0.020] during the normal service life. The measurement will be accurate to ±10 mV. The impact of the measurement error is not uniform over the life of the pulse generator as can be seen in the following example.

The pulse generator manufacturer converts the battery capacity to a family of voltage versus discharge capacity curves (see figure C.1). The slope of the discharge curve is much less near 2.8 V than it is later, near 2.4 V. Each 20 mV change near BOS represents much more of the total device life than does a 20 mV change near RRT. Therefore, a measurement uncertainty of ±10 mV near 2.8 V causes a much larger potential error in computing the remaining capacity than does a ±10 mV uncertainty on the steeper part of the curve. Using the 20 μA constant current curve for the battery depicted in figure C.2, a measured battery voltage of 2770 mV has a potential remaining-capacity uncertainty of $^{+270.5}_{-162}$ mAh. This uncertainty translates into a potential error in the remaining longevity calculation of $^{+18.51}_{-11.09}$ months. Because the slope of the battery capacity curve is not uniform, the predicted remaining capacity is not centered in the interval.

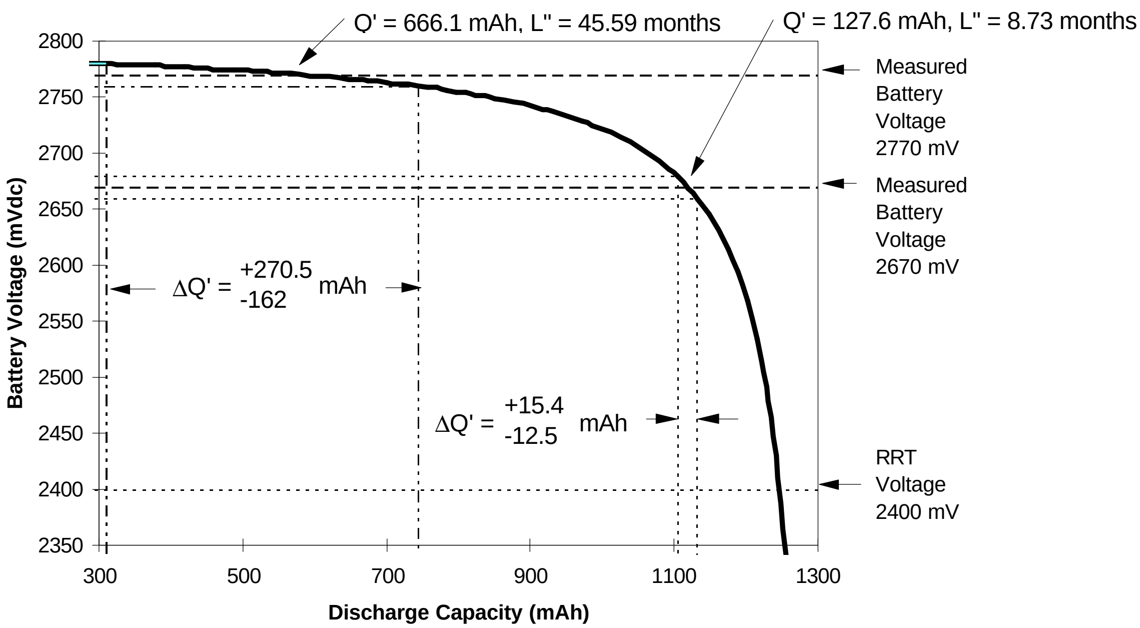


Figure C.2—Load voltage–capacity for a specific lithium/iodine battery discharged at 20 μA

At 2670 mV, however, the measurement uncertainty gives a potential error in the remaining capacity of only $^{+15.4}_{-12.5}$ mAh, which translates into an uncertainty in the remaining longevity calculation of $^{+1.05}_{-0.86}$ months. Expressed as a percentage of the predicted remaining capacity of 127.6 mAh, the uncertainty is $^{+12}_{-10}$ percent at a measured voltage of 2670 mV.

The impact of the measurement uncertainty is not the same for each of the constant voltage-capacity curves. While each of the constant-current capacity curves will have a similar shape, each has a different slope at any given point. This affects the potential error caused by the voltage measurement uncertainty.

For the 30 µA constant-current curve in figure C.3, the potential remaining capacity at a measured V_b of 2670 mV is $^{+22.5}_{-19}$ mAh. This translates into an uncertainty in the remaining longevity calculation of $^{+1.03}_{-0.87}$ months. When expressed as a percentage of the predicted remaining capacity of 183.4 mAh, however, the uncertainty remains approximately $^{+12}_{-10}$ percent at a measured voltage of 2670 mV.

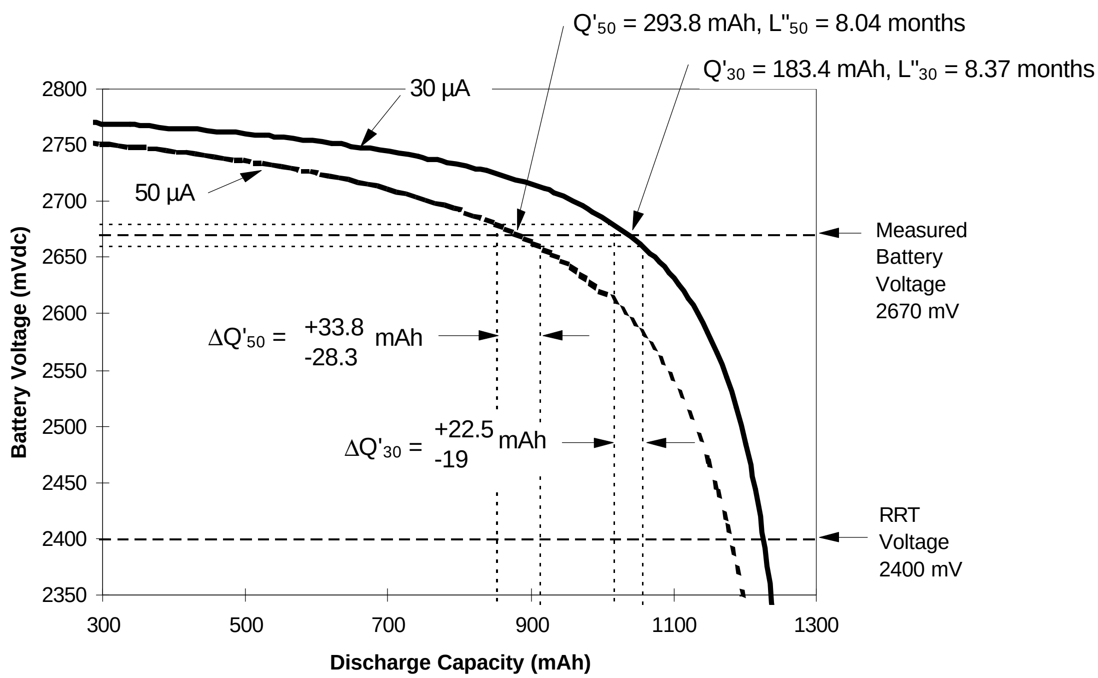


Figure C.3—Load voltage-capacity for a specific lithium/iodine battery discharged at 30 µA and 50 µA

Similarly, the potential uncertainty in the remaining capacity for the 50 µA constant-current curve in figure C.3 can be calculated. The potential uncertainty in the remaining capacity at a measured V_b of 2670 mV is $^{+33.8}_{-28.3}$ mAh. This translates into an uncertainty in the remaining longevity calculation of $^{+0.93}_{-0.77}$ months. When expressed as a percentage of the predicted remaining capacity, however, the uncertainty remains approximately $^{+12}_{-10}$ percent.

Figure C.4 contains a plot of the maximum negative percent uncertainty in Q´ as a function of months remaining to RRT for constant currents of 20 µA, 30 µA, 40 µA, and 50 µA. The negative uncertainty is important because it results in overestimating the remaining capacity based on the measured battery voltage. During the 24-month period preceding RRT, the maximum negative error is 17.31%. This error would result in overestimating the remaining longevity by 4.62 months. At 12 months, the maximum negative error that can be extrapolated from the data in figure C.4 is 12%. This error would result in overestimating the remaining longevity by 1.3 months.

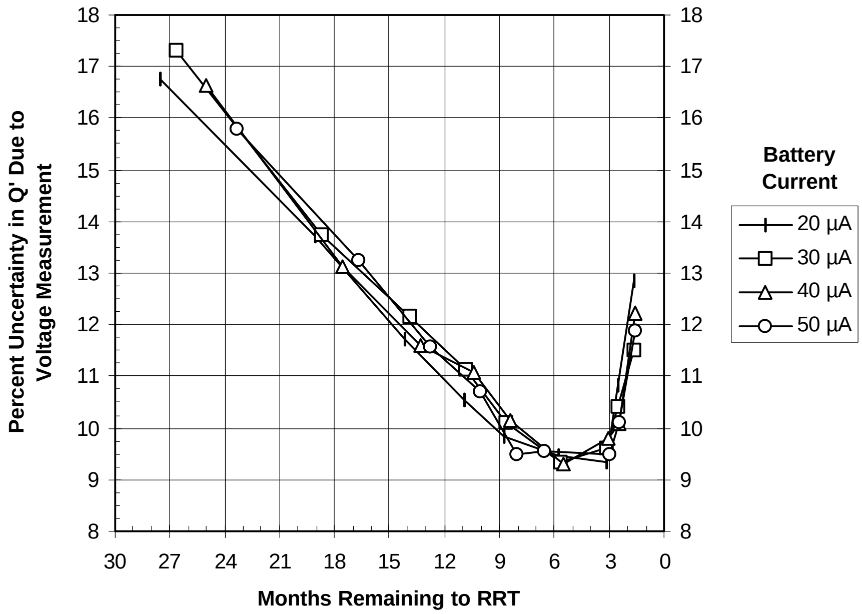


Figure C.4—Percent uncertainty in Q´ due to voltage measurement

Within the operating range of 20 µA to 50 µA, any error as a result of the battery voltage measurement is largely unaffected by an error in battery current measurement. In this report, the 30 µA constant current curve in figure C.4 will be used to estimate the effect of the voltage measurement uncertainty on predicting remaining battery longevity.

C.1.3 Effect of battery current measurement error on remaining capacity (Q´)

The following discussion addresses the sensitivity of the remaining battery capacity calculation to the battery current measurement.

The average battery current ($\overline{I_b}$) is a function of the quiescent current flowing in the pulse generator circuit and the average current required to charge the output capacitors. The average capacitor charging current is equal to the average stimulation current delivered by the output circuit multiplied by a voltage multiplier coefficient (see equation 1).

Using Ohm's law, the following equation for the capacitor charging current (I_c) resulting from pacing in either the ventricular or atrial channel can be derived:

$$I_c = M \times I_p = M \times \left(\frac{V_a}{R_L} e^{-\frac{PW}{R_L \times C}} \right) \tag{14}$$

where C is the effective output capacitance and M is the voltage multiplier coefficient associated with the programmed pulse amplitude. V_a can be measured by the circuitry in the pulse generator in “real time.” In a similar manner, the voltage drop during the stimulation pulse can be measured. The voltage drop can be used to estimate R_L (see equation 2). Knowing the pacing rate and pulse width at the time the measurement was made, the average charging current can be calculated using the following equation:

$$\overline{I_c} = \frac{I_{cv} \times PW_v \times PR_v}{60000} + \frac{I_{ca} \times PW_a \times PR_a}{60000} \qquad (15)$$

where I_c is the delivered current in each channel in µA, PW is the pulse width in each channel in milliseconds (ms), and PR is the pacing rate in each channel expressed in pulses per minute. The conversion factor of 60,000 converts minutes to milliseconds.

The accuracy of the measurements of the parameters used to calculate I_c is dependent on the measurement system employed by the manufacturer in a particular pulse generator. In the absence of a specific product design, one may only draw general conclusions about the accuracy of these measurements.

If it is assumed that the error in PW and PR are small, then the accuracy of the calculated value of $\overline{I_c}$ will depend on the accuracy of I_C. In most pulse generators, the PW is tightly controlled by the circuitry in the pulse generator. Given current technology, the error in the PW is expected to be ± 1% or less. Therefore, the error introduced by the “jitter” in PW can be ignored. PR at the instant the current measurement is made is accurately known. The error in PR is expected to be ± 1% or less. Therefore, the error introduced by the “jitter” in PR can be ignored.

Practically, it can be assumed that the error in $\overline{I_c}$ is directly related to the uncertainty in measurement of V_a and the measurements (possibly the voltage droop during the stimulation pulse) used in the calculation of R_L.

The manufacturer must analyze the load imposed on the battery by the control and monitoring circuits and account for them in I_Q. However, I_Q is not the same from one pulse generator circuit to another. The variability in I_Q may be determined by measuring the quiescent current on a large sample of devices at various sets of programmable parameters.

Based on manufacturer’s published data, it is assumed for this report that I_b can be calculated to an accuracy of ± 30% for a programmed V_a and PW pair.

Because of the shape of the battery capacity curve (see figure A.4), a ± 30% uncertainty in the measurement of $\overline{I_b}$ does not translate into a ± 30% error in Q´. To determine the impact of the uncertainty in $\overline{I_b}$, the load voltage-capacity curves in figure C.1 are converted into the battery current-capacity curves shown in figure C.5. The currents are plotted along lines of constant battery voltage and produce curves that appear nearly linear. Linear interpolation is used to determine the maximum error in Q´ resulting for the uncertainty in $\overline{I_b}$. In this case, the positive error is considered because this will result in overestimating the remaining longevity because the actual Q´ will be less than the estimated Q´. In figure C.6, the percentage uncertainty is plotted for constant discharge currents of 20 µA, 30 µA, 40 µA, and 50 µA as a function of battery voltage.

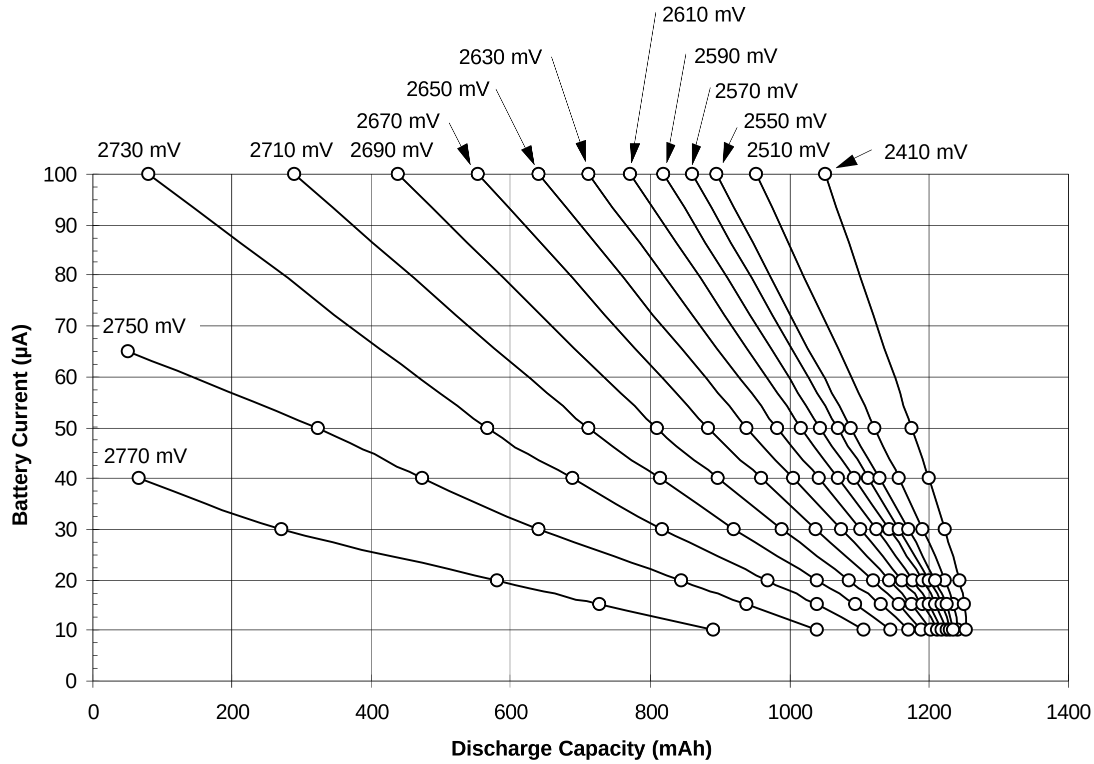


Figure C.5—Battery current-capacity for a specific lithium/iodine battery

The uncertainty in Q´ as a function measured current is nearly constant at approximately 20%. The spread between curves in figure C.6 is believed to be the result of the linear approximation used to interpolate between the data points in figure C.5.

For consistency with the previous section, the 30 µA constant-current curve in figure C.6 will be used to estimate the effect of the current measurement uncertainty on predicting remaining battery longevity.

C.1.4 Combination of errors impacting remaining capacity (Q´)

There are three sources of error that impact the estimate of Q´. They are battery variability, the uncertainties in the measurement of battery voltage, and battery current. Battery variability is discussed in annex B and is estimated at ± 5.5%. The potential error associated with the real-time measurements are described in the previous sections. If it is assumed that the three sources of error are independent of each

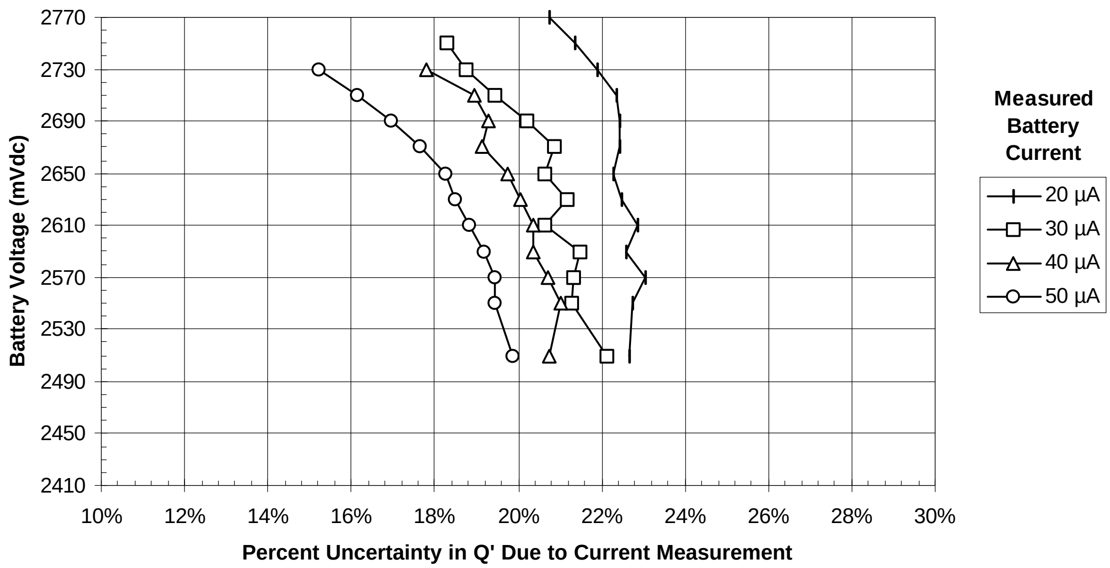


Figure C.6—Percent uncertainty in Q´ due to current measurement

other, then the errors can be combined using the method of propagation of relative errors[6] using the following equation:

$$\varepsilon_{Q'} = \sqrt{\sum_{i=1`}^{N} \varepsilon_i^2} \tag{16}$$

where $\varepsilon_i = \frac{\sigma_i}{x_i}$, and is the relative error component from each of the independent error sources. Combining the three error sources produces the curves in figure C.7.

C.2 Future average battery current drain ($\overline{I_b}''$)

Using equation 7, the future average battery current drain, $\overline{I_b}''$, can be estimated by summing the future average current from the battery to provide stimulation pulses ($\overline{I_c}''$) and the quiescent current (I_Q). $\overline{I_c}''$ is a function of the pacing modalities (i.e., VVI, DDD), the average pacing rate, pulse amplitude(s), pulse width(s), lead impedance(s), and a voltage multiplier coefficient (M) associated with the pulse

[6] Meyer, SL. Data Analysis for Scientists and Engineers. New York: John Wiley & Sons, 1975, pp. 40–41.

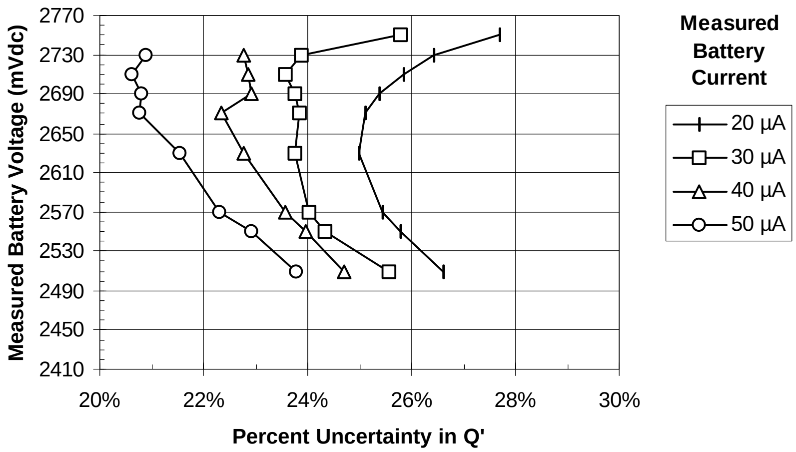


Figure C.7—Percent uncertainty in Q´ due to measurement error sources

amplitude(s). Using equation 14, the capacitor charging current (I_c) resulting from pacing in either the ventricular or atrial channel can be derived.

The future average stimulation current, $\overline{I_c}''$, is a function of the pacing modality and the average pacing rate in each channel, and is given by the equation:

$$\overline{I_c}'' = \frac{I_{cv} \times PW_v \times \overline{PR_v}}{60000} + \frac{I_{ca} \times PW_a \times \overline{PR_a}}{60000} \tag{17}$$

where I_c is the capacity charging current in each channel in µA, PW is the pulse width in each channel in milliseconds (ms), and $\overline{PR}$ is the average pacing rate in each channel expressed in pulses per minute. The conversion factor of 60000 converts minutes to milliseconds. The average pacing rate, $\overline{PR}$, depends on the percentage of time the patient is paced (percentage paced) and on the programmed pacing rate. For certain pacing modalities (i.e., DDD, VVIR, etc.), $\overline{PR}$ will be probably be higher than the programmed rate because of tracking of intrinsic atrial activity and/or other physiological or biophysical signals.

If it is assumed that the error in PW and $\overline{PR}$ are small, then the accuracy of the calculated value of $\overline{I_c}''$ depends on the accuracy of I_c. In most pulse generators, the PW is tightly controlled by the circuitry in the pulse generator. Given current technology, the error in the PW is expected to be ± 1% or less. Therefore, the error introduced by the "jitter" in PW can be ignored. $\overline{PR}$, on the other hand, is based on assumptions that are subject to enormous error. However, for a given set of assumptions, the value of $\overline{PR}$ can be precisely calculated. If it is further assumed that the quiescent current for a given set of conditions is known, then the accuracy of the estimate of $\overline{I_b}''$ approximately equals the accuracy of the calculated I_b and is ± 30%.

From equation 13, L" is estimated by dividing Q´ by $\overline{I_b}''$. The propagation of error in the quotient Z = X/Y is given by the following equation:[7]

$$\varepsilon_z^2 = \varepsilon_x^2 + \varepsilon_y^2 - 2\frac{\sigma_{xy}}{\overline{xy}} \qquad (18)$$

If X and Y are independent variables, then the covariance (s_{XY}) is zero and equation 18 takes on the same form as equation 16. Depending on the measurement system employed by a manufacturer, there might be some correlation between the estimates of Q´ and $\overline{I_b}''$. The greater the positive correlation, the more the overall system error is reduced. However, for this report it is assumed that estimates of Q´ and $\overline{I_b}''$ are independent and the errors can be combined using equation 16.

Combining all of the measurement error sources identified in the previous sections produces the curves in figure C.8.

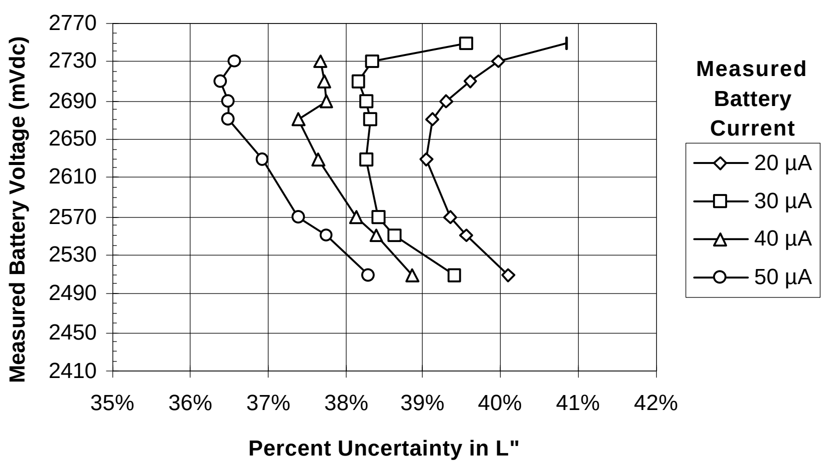


Figure C.8—Percent uncertainty in L" **due to measurement error sources**

Using the model described in this report, the percent error in L" due to measurement uncertainty ranges from a high of approximately 41% to a low of 36.5% depending on the measured values. As expected, the percentage error is higher near BOS because the derivative of the function with respect to battery voltage is large. If the same capacitor charging current measurement (I_c) is used in the calculation of

[7] Meyer, SL. Data Analysis for Scientists and Engineers. New York: John Wiley & Sons. (1975), p. 44.

both Q´ and $\overline{I_b}''$, then the covariance between the terms will increase, and the total system error will be reduced.

C.3 Predicting the future use profile

The average pacing rate ($\overline{PR}$) depends on the percentage of time that the patient is paced (percentage paced) in each channel and on the programmed pacing rate. For some pacing modalities, actual paced rate may be higher than the programmed rate because of tracking of intrinsic atrial activity and/or other physiological or biophysical signals.

C.3.1 Estimating $\overline{PR}$ based on historical data accumulated by the pacemaker

Some pacemakers are capable of recording data on both the percentage paced and the patient's actual heart rate. For many patients, this historical usage data can provide a reasonable estimate of future demand if the data have been accumulated over a sufficient time period.

C.3.2 Estimating $\overline{PR}$ based on clinician input

For those pacemakers that do not have the capability of recording historical usage data or have accumulated insufficient history, the clinician should provide an estimate of $\overline{PR}$ based on his or her professional assessment of the patient's condition.

For nonrate variable pacing modalities, the sustained pacing rate will be equal to the programmed base rate (R_b). The clinician need only provide an estimate of the percentage paced ($P_{\%}$) in each active channel. $\overline{PR}$ in each active channel can be calculated using the equation:

$$\overline{PR_v} = R_b \times P_{\%v} \text{ and/or } \overline{PR_a} = R_b \times P_{\%a} \tag{19}$$

For rate-variable pacing modalities, the clinician must also provide an estimate of the sustained rate (R_s) in each of the active channels, taking into account those factors that may cause the heart rate to exceed the programmed base rate. In this case, $\overline{PR}$ in each of the active channels can be calculated using the equation:

$$\overline{PR_v} = R_{sv} \times P_{\%v} \text{ and/or } \overline{PR_a} = R_{sa} \times P_{\%a} \tag{20}$$

Annex D

Manufacturer’s terminology for battery depletion regions

This annex contains a summary of the terminology in use by various manufacturers to describe the various regions of the generic battery depletion curve shown in figure 1. Table D.1, which begins on the following page, also indicates the variety of methods employed by the various manufacturers to indicate entry into a particular region.

The data in table D.1 were supplied by various manufacturers for models sold within the 10 years prior to the preparation of this report. These manufacturers confirmed the accuracy of the data before going to press. Data that were not confirmed were not included in the table.

The data presented in table D.1 are for general information only. The table contains a summary of the information provided by the manufacturers in the technical literature provided with each pacemaker. The estimation of the time interval between RRT and the point in time when the manufacturer can no longer assure that the pulse generator will perform according to its specifications (column 9) is based on assumptions documented in the manufacturer’s technical literature. These assumptions often vary among manufacturers and may vary among pacemaker models from an individual manufacturer. Therefore, the information presented in this table is not to be used to compare the performance of different models of pacemakers.

NOTE—The reader must consult the manufacturer’s technical literature for questions regarding the performance of a specific pacemaker model.

Table D.1—Manufacturer's terminology for battery depletion regions

COMPANY[1]	MODEL	NORMAL SERVICE LIFE	PREREPLACEMENT REGION	METHOD	RRT INDICATOR	METHOD	PREDICTABLE USAGE REGION	TIME RRT-UPR (MONTHS)[3]
BIOTRONIK	ALL MODELS - SEE MANUALS FOR DETAILS	BEGIN OF SERVICE	ANTICIPATED REPLACEMENT REGION	MR[2] DECREASE BY 11%	ERI	MR DECREASE BY 11%	ERI INDICATION	6 (GENERALLY)
CCC URUGUAY	8307	LONGEVITY			EOL	RATE DECREASE > 5 P.P.M.	EOL REGION	6 MINIMUM
CCC URUGUAY	OMEGA 3000	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	6 MINIMUM
CCC URUGUAY	OMEGA 4000	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	4 MINIMUM
CCC URUGUAY	APEX 3000	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	3 MINIMUM
CCC URUGUAY	APEX 4000	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	3 MINIMUM
CCC URUGUAY	LD PACE	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	4 MINIMUM
CCC URUGUAY	APEX 3143	LONGEVITY	ERI	MR-INCREMENT OF 80MS	EOL	INCREMENTS OF 120MS	EOL REGION	3 MINIMUM
CPI GUIDANT	VIGOR 460/465	LONGEVITY	ELECTIVE REPLACEMENT NEAR	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	ELECTIVE REPLACEMENT PAST	14.8
CPI GUIDANT	VIGOR 950/955	LONGEVITY	ELECTIVE REPLACEMENT NEAR	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	ELECTIVE REPLACEMENT PAST	4.2(DDD),14.8(SSI)
CPI GUIDANT	VIGOR 1130/1135	LONGEVITY	ELECTIVE REPLACEMENT NEAR	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	ELECTIVE REPLACEMENT PAST	13.8
CPI GUIDANT	VIGOR 1230/1235	LONGEVITY	ELECTIVE REPLACEMENT NEAR	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	ELECTIVE REPLACEMENT PAST	4.3(DDD), 12.2(SSI)
CPI GUIDANT	VISTA-4-6,-T(443-447)	LONGEVITY	ELECTIVE REPLACEMENT NEAR	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	POST ERT OPERATING PERIOD	3.2
CPI GUIDANT	VISTA DDD 940-941	LONGEVITY	NEARING ERT	MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	POST ERT OPERATING PERIOD	4.5
CPI GUIDANT	DELTA TRS, 927, 928, 937, 938	LONGEVITY		MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	POST ERT OPERATING PERIOD	3.9
CPI GUIDANT	DELTA T 926, 936	LONGEVITY		MR=90, PROG. IND.	ERT	MR=85, PROG. MESSAGE	POST ERT OPERATING PERIOD	3.9
INTERMEDICS	THINLITH II 227-05	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	THINLITH III 229-05	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	PRIMA 235-01, 236-02	LONGEVITY			ERI	MR DECREASE BY 5	ERI TO EOL REGION	~6

Note 1: All known pacemaker manufacturers were contacted. This table includes data from those who were able to respond.

Note 2: MR = magnet rate.

Note 3: The estimation the time interval between RRT and the point in time when the manufacturer can no longer assure that the pulse generator will perform according to its specifications is based on assumptions documented in the manufacturer's technical literature. These assumptions often vary between manufacturers and may vary between pacemaker models from an individual manufacturer. Therefore, the information presented in this table is not to be used to compare the performance of different models of pacemakers.

Table D.1—Manufacturer's terminology for battery depletion regions (cont.)

COMPANY	MODEL	NORMAL SERVICE LIFE	PREREPLACEMENT REGION	METHOD	RRT INDICATOR	METHOD	PREDICTABLE USAGE REGION	TIME RRT-UPR (MONTHS)
INTERMEDICS	SIRIUS 246-02	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 85	ERI	MR 80	ERI TO EOL REGION	NA
INTERMEDICS	INTERLITH RP 251-02	LONGEVITY			ERI	MR DECREASE BY 5	ERI TO EOL REGION	NA
INTERMEDICS	CYBERLITH 253-02, 04, 06	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	CYBERLITH 253-07, 254-07	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	QUANTUM 253-09, 254-09, 10	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	~6
INTERMEDICS	QUANTUM 253-18, 19, 254-20, 20V	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	~6
INTERMEDICS	SUPRIMA 253-21, 22, 24	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	SUPRIMA II 253-23, 254-26,28	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	~6
INTERMEDICS	QUANTUM II 253-25, 03	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	NA
INTERMEDICS	QUANTUM III 254-27	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	SUPRIMA III 254-31	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	CYBERLITH 259-01	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	CYBERTACH 60 262-01	LONGEVITY			ERI	MR DECREASE BY 4.5	ERI TO EOL REGION	~6
INTERMEDICS	INTERTACH 262-12, 14	LONGEVITY			ERI	MR 90	ERI TO EOL REGION	NA
INTERMEDICS	INTERTACH II 262-16, 16R, 18, 18R	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	11
INTERMEDICS	AVIUS 263-01	LONGEVITY			ERI	MR DECREASE BY 7	ERI TO EOL REGION	NA
INTERMEDICS	GALAXY 271-03	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	NOVA 281-01, 202-02	LONGEVITY			ERI	RATE CHANGE TO 65	ERI TO EOL REGION	4 MINIMUM
INTERMEDICS	NOVA II 281-03, 05, 05S, 282-04, 04R, 04Y	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	NOVA III 281-07, 282-07, 09	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	COSMOS 283-01, 01S, 01V, 284-02, 02V	LONGEVITY			ERI	MR 65	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	COSMOS II 283-03, 284-05	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	NOVA MR 291-01	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	15 MINIMUM
INTERMEDICS	DASH 291-03, 292-03, 03R	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	MARATHON SR 291-09, 292-09, 09E, 09R, 09X, 09Z	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	292-09, 09Z, 09E 12.4Avg 291-09, 292-09, 09R 7.9Avg
INTERMEDICS	DART 292-05	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM

Table D.1—Manufacturer's terminology for battery depletion regions (cont.)

COMPANY	MODEL	NORMAL SERVICE LIFE	PREREPLACEMENT REGION	METHOD	RRT INDICATOR	METHOD	PREDICTABLE USAGE REGION	TIME RRT-UPR (MONTHS)
INTERMEDICS	UNITY C 292-06	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	MARATHON DR 293-09, 294-09, 09E, 09R, 09Z, 294-10	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	18 AVERAGE
INTERMEDICS	COSMOS 3 283-09, 284-09, 09R	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	18 AVERAGE
INTERMEDICS	MOMENTUM 293-23, 294-23, 23E, 23Z	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	18 AVERAGE
INTERMEDICS	UNITY 292-07	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	CIRCADIA 293-01	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	NA
INTERMEDICS	RELAY 293-03, 03E, 294-03, 03R, 03E	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
INTERMEDICS	STRIDE 294-05	LONGEVITY	INTENSIFIED FOLLOW-UP REGION	MR 90	ERI	MR 80	ERI TO EOL REGION	6 MINIMUM
MEDTRONIC	7001/02	PROJECTED LONGEVITY	IMMINENT ELECTIVE REPLACEMENT		ERI	65 PPM (VVI/VOO)	ELECTIVE REPLACEMENT	4 MINIMUM
MEDTRONIC	ELITE 7074, 75, 76,77	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	4 MINIMUM
MEDTRONIC	ELITE II 7084, 85, 86	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	2.9 MINIMUM
MEDTRONIC	KAPPA DR KDR401, 403	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	IMPLANT TO ERI	3 MINIMUM
MEDTRONIC	MINUET 7107, 7108	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO CESSATION OF PACING	3 MINIMUM
MEDTRONIC	SYMBIOS 7005, 05C, 06	PROJECTED LONGEVITY	IMMINENT ELECTIVE REPLACEMENT	MR 75	ERI	65 PPM (VVI/VOO)	ELECTIVE REPLACEMENT	3 MINIMUM
MEDTRONIC	SYMBIOS 7007/7008	PROJECTED LONGEVITY	IMMINENT ELECTIVE REPLACEMENT	MR 75	ERI	65 PPM (VVI/VOO)	ELECTIVE REPLACEMENT	3 MINIMUM
MEDTRONIC	SYNERGYST 7026,27	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO CESSATION OF PACING	5 MINIMUM
MEDTRONIC	SYNERGIST II 7070, 71	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO CESSATION OF PACING	5 MINIMUM
MEDTRONIC	THERA DR 7940, 41, 42, 50, 51,52	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	$THERA_i$ DR 7960_i, 61_i, 62_i	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	THERA D 7944, 45, 46	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	$THERA_i$ D 7964_i, 65_i, 66_i	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	ACTIVITRAX 8400, 02, 03	PROJECTED LONGEVITY	INTENSIFY FOLLOW-UP INDICATOR	20% PULSE STRETCH	ERI	65 PPM (SSI/SOO)	ERI TO ERRATIC	2 MINIMUM
MEDTRONIC	ACTIVITRAX II 8412, 13, 14	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	ELECTIVE REPLACEMENT	4 MINIMUM
MEDTRONIC	KAPPA SR KSR401, 403	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	IMPLANT TO ERI	3 MINIMUM
MEDTRONIC	LEGEND 8416, 17, 18, 19	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	ERI TO CESSATION OF PACING	2.9 MINIMUM
MEDTRONIC	LEGEND II 8424,26, 27, 30	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	ERI TO CESSATION OF PACING	3 MINIMUM

Table D.1—Manufacturer's terminology for battery depletion regions (cont.)

COMPANY	MODEL	NORMAL SERVICE LIFE	PREREPLACEMENT REGION	METHOD	RRT INDICATOR	METHOD	PREDICTABLE USAGE REGION	TIME RRT-UPR (MONTHS)
MEDTRONIC	THERA SR 8940, 41, 42	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	THERA$_i$ SR 8960$_i$, 65$_i$, 62$_i$	PROJECTED LONGEVITY			ERI	65 PPM (SSI/SOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	CLASIX 8436, 37, 38	PROJECTED LONGEVITY			ERI	PR-10%(SOO)	ELECTIVE REPLACEMENT TIME	3 MINIMUM
MEDTRONIC	MICRO MINIX 8360	PROJECTED LONGEVITY			ERI	PR-10%(SSI),-20%(SOO)	ERI TO ERRATIC	<3 MINIMUM
MEDTRONIC	MINIX 8340, 41, 42	PROJECTED LONGEVITY			ERI	PR-10%(SSII),-20%(SOO)	ERI TO ERRATIC	2.3 MINIMUM
MEDTRONIC	MINIX ST 8330, 31	PROJECTED LONGEVITY			ERI	PR -10%(VVI),-20%(VOO)	ERI TO ERRATIC	2.3 MINIMUM
MEDTRONIC	PASYS 8320, 22, 29	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	REPLACEMENT TIME	3 MINIMUM
MEDTRONIC	PASYS ST 8316, 17, 18	PROJECTED LONGEVITY			ERI	PR -10%(VOO)	REPLACEMENT TIME	3 MINIMUM
MEDTRONIC	SPECTRAX S 5940, 40LP, 41	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	EOL TO CESSATION OF PACEMAKER FUNCTION	3 MINIMUM
MEDTRONIC	SPECTRAX SX 5984, 84LP, 85	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	SPECTRAX SX-HT 5976, 77	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	SPEXTRAX SXT 8420, 22, 23	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	SPECTRAX VL 5966, 67, 68	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	SPECTRAX VM 5922, 23	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	SPECTRAX VS 5920, 21	PROJECTED LONGEVITY			ERI	PR -10%(SOO)	ERI TO POWER SOURCE DEPLETION	3 MINIMUM
MEDTRONIC	THERA S 8944, 45, 46	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
MEDTRONIC	THERA$_i$ S 8964$_i$, 65$_i$, 66$_i$	PROJECTED LONGEVITY			ERI	65 PPM (VVI/VOO)	ERI TO ERRATIC	3 MINIMUM
PACESETTER	TRILOGY DR 2350	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	SYNCHRONY III 2028, 29	LONGEVITY			RRT INDICATOR	MR +100 ms or 200 ms	RRT TO EOL	MINIMUM 3
PACESETTER	SYNCHRONY II 2022, 23	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	SYNCHRONY 2020	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	TRILOGY SR 2250	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	SOLUS II 2006, 07	LONGEVITY			RRT INDICATOR	MR +100 ms or 200 ms	RRT TO EOL	MINIMUM 3
PACESETTER	SOLUS 2002, 03	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3

Table D.1—Manufacturer's terminology for battery depletion regions (cont.)

COMPANY	MODEL	NORMAL SERVICE LIFE	PREREPLACEMENT REGION	METHOD	RRT INDICATOR	METHOD	PREDICTABLE USAGE REGION	TIME RRT-UPR (MONTHS)
PACESETTER	TRILOGY DC 2308	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	PARAGON III 2304, 05, 2314, 15	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	PARAGON II 2016	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	PARAGON 2010, 11, 12	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	PHOENIX III 2204, 05	LONGEVITY			RRT INDICATOR	MR +100 ms or 200 ms	RRT TO EOL	MINIMUM 3
PACESETTER	PHOENIX 250, 251	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	5 - 6
PACESETTER	PHOENIX 2 2005, 08, 09	LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	TRILOGY DR+ 2360/2364	PROJECTED LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	TRILOGY SR+ 2260/2264	PROJECTED LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	TRILOGY DC+ 2318	PROJECTED LONGEVITY			RRT INDICATOR	MR +100 ms	RRT TO EOL	MINIMUM 3
PACESETTER	TEMPO DR/D 2102/2902	PROJECTED LONGEVITY			EOL INDICATOR	PROGRAMMER MESSAGE 80	EOL	6 MONTHS
PACESETTER	TEMPO SR/S 1102/2902	PROJECTED LONGEVITY			EOL INDICATOR	PROGRAMMER MESSAGE 80	EOL	6 MONTHS
PACESETTER	REGENCY SC/SC+ 2406/2402	PROJECTED LONGEVITY			RRT INDICATOR	MAGNET RATE < 85	RRT	2-11 MONTHS
TELECTRONICS	META II 1204, 1204H	LONGEVITY	ERI REGION	MR 82.5	EOL INDICATOR	PROGRAMMER MESSAGE MR 80	EOL REGION	6
TELECTRONICS	META III 1206, 1206E, 1206M, 1206C	LONGEVITY	ERI REGION	MR 82.5	EOL INDICATOR	PROGRAMMER MESSAGE MR 80	EOL REGION	6
TELECTRONICS	META DDDR 1256, 1256D	LONGEVITY	ERI REGION	MR 82.5	EOL INDICATOR	PROGRAMMER MESSAGE MR 80	EOL REGION	6
TELECTRONICS	META DDD 1230	LONGEVITY	ERI REGION	MR 78	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	6
TELECTRONICS	META DDDR 1250, 1250H, 1254	LONGEVITY	ERI REGION	MR 78	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	6
TELECTRONICS	AURORA 6291, 6292	LONGEVITY	ERI REGION	MR 80.3	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	6
TELECTRONICS	SIMPLEX 8232, 8230	LONGEVITY	ERI REGION	MR 83	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	2.2
TELECTRONICS	REFLEX 8218, 8220E, 8220	LONGEVITY	ERI REGION	MR 83	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	2
TELECTRONICS	REFLEX DDD 8224, 8223E, 8222	LONGEVITY	ERI REGION	MR 83	EOL INDICATOR	PROGRAMMER MESSAGE MR 63	EOL REGION	9
TELECTRONICS	AUTIMA II 2291	LONGEVITY		NA	EOL INDICATOR	PROGRAMMER MESSAGE MR 80	EOL REGION	3
TELECTRONICS	OPTIMA MPT 5281, 5282	LONGEVITY		NA	PRIMARY EOL INDICATOR	PROGRAMMER MESSAGE MR 85	PRIMARY, SECONDARY EOL	
TELECTRONICS	OPTIMA MPT II 5281A, B, C, 5282A, C	LONGEVITY		NA	PRIMARY EOL INDICATOR	PROGRAMMER MESSAGE MR 85	PRIMARY, SECONDARY EOL	
TELECTRONICS	OPTIMA MPT III 5281D, 5282D, 5281E, 5282E	LONGEVITY		NA	PRIMARY EOL INDICATOR	PROGRAMMER MESSAGE MR 95	PRIMARY, SECONDARY EOL	