

Technical Information Report

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Systems used to forecast
remaining pacemaker
battery service life

Systems used to forecast remaining pacemaker battery service life

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Abstract: Discusses clinical expectations for performance of systems used to develop better tools to forecast the remaining battery service life of implantable cardiac pacemakers.

Keywords: battery service life, implants, cardiac pacemakers, pulse generator, labeling

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Glossary of equivalent standards

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Association for the Advancement of Medical Instrumentation

Cardiac Rhythm Management Devices Committee

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Committee approval of this document does not necessarily imply that all committee members voted for its approval. At the time this document was published, the committee had the following members.

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Systems used to forecast remaining pacemaker battery service life

1 Scope

This technical information report describes the clinical expectations for the performance of systems that use “real-time” measurements telemetered by a 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 technical information 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 also 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, and (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 Battery: often used either as a single cell or a group of cells connected in a pack.

2.2 Beginning of service (BOS): time when an individual implantable pulse generator is first released by the manufacturer as fit for placing it on the market.

2.3 End of service (EOS): point (determined by the manufacturer) at which the power source can no longer reliably support the device. A “cut-off” voltage may be provided.

2.4 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 principal, 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. Practically, therefore, the normal service life of a pulse generator is determined 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 one 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.

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- to 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 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 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 the following:

- a) measured threshold for capture;
- b) spontaneous variation in threshold due to sleep, eating, and medications; and
- c) possible rise in threshold after implantation with standard and steroid eluting 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 A.3. Pulse generators also offer “unregulated” outputs (see the model of 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 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 A.2.2). Figure 1 illustrates a generic battery depletion curve.

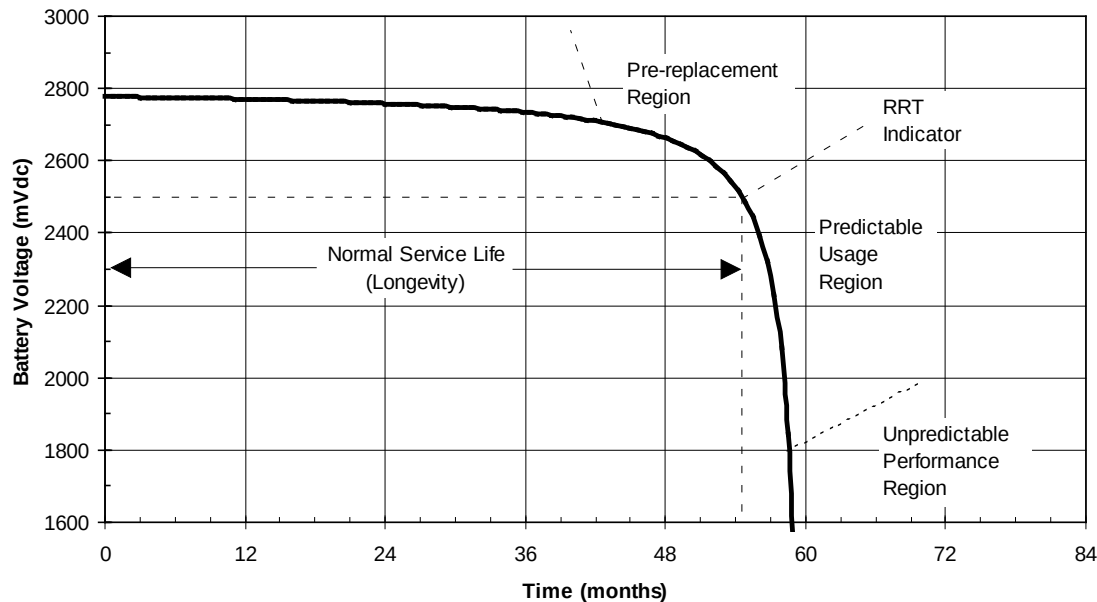


Figure 1 – Generic lithium/iodine battery depletion curve

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 pre-replacement 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.

The prerenplacement 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 could 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 assure 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 information 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 usually 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 a minimum of 3 months as currently specified in ISO 14708-2. 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, and (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 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 almost 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.

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 as currently specified in ISO 14708-2.

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 pre-replacement 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. These systems advise 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 pre-replacement region should begin 12 months before the expected onset of the RRT indicator.

At entry into the pre-replacement region, the system should be able to predict the number of months until the expected onset of the RRT indicator. Before entry into the pre-replacement region, the estimated remaining longevity can optionally 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 16. 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 manufacturers' 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 pre-replacement 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 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 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 $\pm 5.5\%$ 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 C.2, propagation of error theory is used to compute the relative error in the ratio of the two variables (see equation 21). 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 to 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.

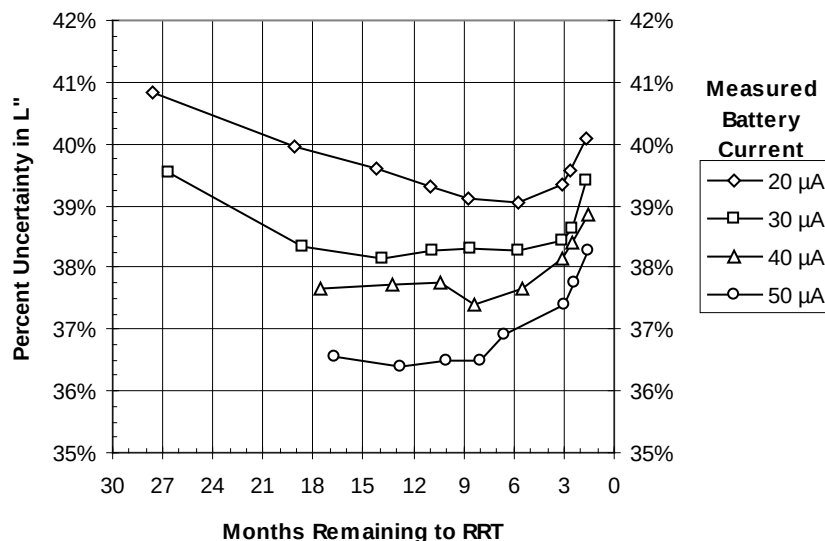


Figure 2—Percent uncertainty in remaining battery longevity (L'')

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 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 C.2, 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 non-rate 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 methodology for determining the average pacing rate in each active channel is presented in Table 1. 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 methodology for determining the average pacing rate in each of the active channels is again presented in Table 1. 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	
Non-rate variable pacing modality	Pacing rate =	Programmed rate	Pacing rate =	Programmed rate
	Percent paced =	Recorded data if ≥ 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 ≥ 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 ≥ 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 optionally 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 algorithm.

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:

- The measured battery parameters (i.e., battery voltage, battery resistance, and/or accumulated charge delivered), which are used to estimate the remaining deliverable capacity.
- 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).
- 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 associated with computing typical remaining longevity).
- 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 continues as expected. However, the clinician needs to be aware of the possible error in the estimate as described in the example in 7.2.

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 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 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 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 get close to EOS. 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