Technical Information Report

AAMI TIR21: 2017
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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Figure A.15 — SVO- carbon monofluoride hybrid cathode mode – compared to 90 month discharge data

Figure A.16 — Relationship between voltage, impedance and capacity for a lithium/manganese dioxide battery at a constant discharge current

Figure A.17 — Capacity as a function of current drain for a lithium/manganese dioxide battery

Figure A.18 — Longevity as a function of average discharge current (cutoff voltage 2.2 V)

Figure A.19 — Threshold, safety margin, and pacing current

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

Figure B.2 — Example of projected longevity variability of a lithium/hybrid cathode battery

Figure B.3 — Discharge curves of a group of lithium iodine batteries discharged under a 12.5 KΩ load (results are converted to 140 KΩ load) [18-20]

Figure B.4 — Scaled discharge curves of a group of lithium hybrid cathode batteries discharged under a 1 mA constant current compared to discharge curves collected at 30 µA [4]

Figure B.5 — Life test results for a group of 77 lithium/iodine batteries discharged under 100 KΩ constant resistive load [15]

Figure B.6 — Life test results for lithium/hybrid cathode batteries discharged at 30 µA [15]

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

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

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

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

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

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

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

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

Tables

Table 1 — Assumptions for estimating the future use profile

Table A.1 — Current taken from the battery
Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation
Cardiac Rhythm Management Devices Committee

This AAMI Technical Information Report was developed by the Cardiac Rhythm Management Devices Committee. 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...