Technical Information Report

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Systems used to forecast remaining pacemaker battery service life

AAMI

Advancing Safety in Health Technology

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

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

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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

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