Technical Information Report

AAMI TIR107: 2026

Cardiovascular implantable electronic devices—Battery longevity management and reporting and prolonged service period behavior

AAMI

Advancing Safety in Health Technology

Cardiovascular implantable electronic devices—Battery longevity management and reporting and prolonged service period behavior

Approved 10 April 2026 by
AAMI

Abstract: This document is limited to implantable cardiac pacemakers, implantable devices intended to treat tachyarrhythmia (including implantable defibrillators), and implantable cardiac resynchronization devices that use primary cell (non-rechargeable) battery technology and report battery status in conformance with ISO 14708-2:2019 or ISO 14708-6:2019, as applicable.

Keywords: cardiac implantable electronic devices, active implants, cardiac rhythm management device, battery, longevity management, reporting, prolonged service period behavior

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

Cardiac Rhythm Management Device Committee

This AAMI Technical Information Report (TIR) was developed and approved by the AAMI Cardiac Rhythm Management Device Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

At the time this document was approved, the **AAMI Cardiac Rhythm Management Device Committee** had the following members:

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Foreword

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- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
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- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall”.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of AAMI TIR107; *Cardiovascular implantable electronic devices—Battery longevity management and reporting and prolonged service period behavior* (AAMI TIR107:2026), but it does provide important information about the development and intended use of the document.

Introduction

This technical information report (TIR) was developed by the AAMI Cardiac Rhythm Management Device Committee in response to requests from committee clinicians. Current cardiovascular implantable electronic device safety standards require that an indicator be provided when a device reaches its recommended replacement time (RRT). These standards also require a minimum time between RRT and end of service (EOS) for implantable pacemakers, implantable cardioverter defibrillators, and implantable cardiac resynchronization devices under stated conditions. These standards do not currently give any guidance concerning means to observe the remaining longevity until RRT nor required behavior of the device once it enters the prolonged service period (PSP; the period between RRT and EOS).

As a result, there are significant variations between different devices and between device manufacturer designs for providing remaining longevity information to clinicians. There is also a lack of consistency in whether devices automatically change their programmed settings during the PSP. Due to this lack of consistency, it can be difficult to properly manage patient risk as devices approach EOS.

In order to solicit broader clinician input concerning these areas of concern, the Cardiac Rhythm Management Committee collaborated with the Heart Rhythm Society to do an online survey of cardiologists and electrophysiologists, which was entitled “AAMI Cardiac Device Safety Standards Survey—Longevity Indications and End of Service Behavior.” The survey was available to Heart Rhythm Society clinicians for five weeks and 103 clinicians returned surveys. The objective of this document is to present and summarize the clinician input in these areas obtained from the survey which will inform medical device manufacturers and provide input for the design of future systems.

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Cardiovascular implantable electronic devices— Battery longevity management and reporting and prolonged service period behavior

1 Scope

The scope of this document is limited to implantable cardiac pacemakers, implantable devices intended to treat tachyarrhythmia (including implantable defibrillators), and implantable cardiac resynchronization devices that use primary cell (non-rechargeable) battery technology and report battery status in conformance with ISO 14708-2:2019 or ISO 14708-6:2019, as applicable.

Devices that are not included in the scope of ISO 14708-2:2019 or ISO 14708-6:2019 (e.g., implantable cardiac monitors, intracardiac/leadless pacemakers, extravascular defibrillators) are not included in the scope of this TIR.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-2:2019, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO 14708-6:2019, *Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-2:2019 and ISO 14708-6:2019 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at www.iso.org/obp/ui

— IEC Electropedia: available at www.electropedia.org

4 Clinician input on the duration of the prolonged service period

See Table 1 for survey question 1 and response choices.

Table 1 — Survey question 1 and response choices

Survey Question 1	Response Choices
What is your feedback on the current ISO requirements for minimum power source depletion indications (to warn of the onset of recommended replacement time [RRT]) that are needed to ensure that clinicians can safely manage the device end of life/replacement phase of implanted devices? (pick one option)	a) Keep the current ISO requirements for an RRT indicator at 6 months prior to end of service ("EOS") for bradyarrhythmia (low power) devices and 3 months prior to end of service ("EOS") for tachyarrhythmia (high power) devices
	b) Require a different "prolonged service period (PSP)"
	c) Other

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