American National Standard

ANSI/AAMI PC76:2021

Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging

AAMI
Advancing Safety in Health Technology

Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging

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Abstract: Provides requirements and test protocols for implantable pacemakers and ICDs exposed to magnetic resonance imaging. Physicians are increasingly using magnetic resonance imaging as tool for differential diagnostic, thus exposing pacemakers and ICD patients to such equipment. Current product standards for implantable pacemakers and ICDs do not include requirements and test protocols for implantable pacemakers and ICDs, which would ensure patient safety during such procedures.

Keywords: implantable medical devices, testing, pacemakers, ICDs, magnetic resonance, imaging

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Pacemaker & MRI Compatibility Working Group

This AAMI American National Standard (ANS) was developed and approved by the AAMI Pacemaker & ICD MRI Compatibility Working Group.

At the time this document was published, the **AAMI Pacemaker & MRI Compatibility Working Group** had the following members:

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

Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “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 recommended practice 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 the AAMI PC76, *Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging* (AAMI PC76:2021), but it does provide important information about the development and intended use of the document.

Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging

1 Scope

This document is applicable to transvenous pacemaker, ICD, and CRT systems intended to be used in patients who undergo a magnetic resonance scan in 1.5 T, cylindrical (circular or elliptical cross-section) bore, whole body magnetic resonance (MR) scanners operating at approximately 64 MHz with whole body coil excitation.

The tests that are specified in this document characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. The tests can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products. Some of the tests are type tests whereas others require sample size justification.

The scope of this document is limited to:

- systems that do not use sensing functions or that are programmed not to use sensing functions to affect therapy delivery during an MR scan;
- systems which have high voltage therapy disabled during an MR scan;
- devices which are implanted in the pectoral region of patients.

Requirements for non-implantable parts are outside the scope of this document.

The requirements of this document supplement or modify those of AAMI/ISO TIR10974.

NOTE 1 The document might provide useful guidance for newer therapies such as subcutaneous ICD systems, leadless pacemakers, and loop recorders, but their requirements are outside the scope of this document.

NOTE 2 Safety requirements for MR scanners can be found in IEC 60601-2-33.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AAMI/ISO TIR10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

IEC 60601-2-33, *Medical electrical equipment — Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

ASTM F2052-15, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

