



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 16174.2-2015

Replacing GB 16174.2-2015

**Implants for surgery - Active implantable medical devices - Part
2: Cardiac pacemakers
(English Translation)**

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1.Structure and drafting rules for standardization documents"

Drafting.

This document is Part 2 of GB 16174 "Surgical Implants - Active Implantable Medical Devices". GB 16174 has been published as follows

part.

--- Part 1.General requirements for safety, marking and information to be provided by the manufacturer;

--- Part 2.Cardiac pacemakers.

This document replaces GB 16174.2-2015 "Surgical implants - Active implantable medical devices - Part 2.Cardiac pacemakers" and

Compared with GB 16174.2-2015, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

--- Changed the measurement of pulse amplitude, pulse width, pulse interval and pulse frequency (see 6.1.2, 6.1.1 of the.2015 edition);

--- Deleted the input impedance [see 6.1.4, 28.8.2d of the.2015 edition)];

--- Deleted the electrode lead conductor resistance (Rc) and sensor impedance (ZS) [see 6.2 and 28.8.3d of the.2015 edition)];

- Changed the requirements for electrical neutrality (see 16.2, 16.2 of the.2015 edition);
- Changed the protection of patients from thermal injury (see 17.1, Chapter 17 of the.2015 edition);
- Changed the protection against unintended effects caused by active implantable medical devices (see 19.2, 19.2 of the.2015 edition);
- Changed the protection of active implantable medical devices against damage caused by changes in atmospheric pressure (see Chapter 25, Chapter 25 of the.2015 edition);
- Changed the protection of active implantable medical devices against non-ionizing electromagnetic radiation (see Chapter 27, Chapter 27 of the.2015 edition);
- Added that the accompanying documents should include the URL (see 28.1);
- Deleted the additional clauses in 28.22 (see 28.22 of the.2015 edition).

This document is modified to adopt ISO 14708-2.2019 "Surgical implants - Active implantable medical devices - Part 2.Cardiac pacemakers".

The technical differences between this document and ISO 14708-2.2019 and their reasons are as follows.

- Replace ISO 14708-1.2014 with the normative reference GB 16174.1-2024 (see Chapter 5, Chapter 7 to Chapter 19, Chapter

Chapter 21 to Chapter 26, Chapter 28) to adapt to my country's technical conditions;

- Replace ISO 14117.2019 with the normative reference YY/T 1874-2023 (see Chapter 20, Chapter 21, Chapter 27)

Adapt to my country's technical conditions;

- Replace ISO 11318.2002 with the normative reference YY/T 0946-2014 (see 9.4.1, 11.10, 11.11, 16.2,

23.5) to adapt to my country's technical conditions;

- Replace ISO 27186.2010 with the normative reference ISO 27186.2020 (see 6.2.2, 9.4.1, 11.10, 11.11, 16.2,

23.5), citing the relevant requirements of the latest international standards.

The following editorial changes were made to this document.

- Changed the titles of Chapter 5, Chapter 21, and Chapter 28;
- Deleted Appendix A of ISO 14708-2.2019, which is a comparison table between this document and ISO /T R14283.

The order of appendix numbers is adjusted accordingly.

Introduction

GB 16174 Surgical Implants - Active Implantable Medical Devices specifies the general requirements for active implantable medical devices, providing guidance for patients and

Provide basic security for users. It is planned to include 7 parts.

--- Part 1.General requirements for safety, marking and information to be provided by the manufacturer. The purpose is to specify the requirements for active implantable medical devices.

General requirements for safety, marking and information to be provided by the manufacturer.

--- Part 2.Cardiac pacemakers. The purpose is to specify the specific requirements for cardiac pacemakers.

--- Part 3.Implantable neurostimulators (YY0989.3). The purpose is to specify the specific requirements for implantable neurostimulators.

--- Part 4.Implantable infusion pumps. The purpose is to specify the specific requirements for implantable infusion pumps.

--- Part 5.Circulatory support devices (YY/T 0989.5). The purpose is to specify the special requirements for circulatory support devices.

--- Part 6.Particular requirements for active implantable medical devices (including implantable defibrillators) for the treatment of tachyarrhythmias

(YY0989.6). The purpose is to define active implantable medical devices (including implantable defibrillators) for the treatment of tachyarrhythmias.

Particular requirements for devices).

--- Part 7.Particular requirements for cochlear implant systems (YY0989.7). The purpose is to specify the requirements for cochlear implant systems.

Special requirements.

This document is a revision and supplement to the general standard GB 16174.1-2024.The requirements of this document take precedence over the relevant requirements in Part 1.

Require.

Appendix A provides further explanation of the rationale for each clause of this document.

Appendix B describes a coding system that can be used to specify bradycardia pacing modes.

Appendix C specifies the reference points for measuring pulse amplitude and pulse width,

and the waveform of the test signal used to determine sensitivity.

Any trade names used in this document are provided for the convenience of the user and do not constitute an endorsement.

Surgical Implants Active Implantable Medical Devices

Part 2.Pacemakers

1 Scope

This document specifies requirements specific to cardiac pacemakers.

This document applies to active implantable medical devices for the treatment of bradyarrhythmias and devices that provide cardiac resynchronization therapy, as well as

Certain non-implantable parts and accessories of implantable medical devices.

The tests specified in this document are type tests and compliance is confirmed by testing of samples.

The electrical characteristics of the implantable pulse generator or electrode lead are verified by appropriate methods listed in this document or other methods.

If other methods can be demonstrated to be equal to or superior in accuracy to the method specified, in case of dispute, the method specified in this document shall prevail.

ISO 14708-6 covers all aspects of active implantable medical devices intended for the treatment of tachyarrhythmias.

NOTE: What is often referred to as an "active implantable medical device" may in fact be a single device, a combination of multiple devices, or one or more devices in combination with one or more

A combination of multiple accessories. Not all of these components are partially or fully implantable, but if non-implanted components or accessories may affect the implanted device

To ensure the safety and performance of a device, requirements for non-implanted parts and accessories should be specified.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to

This document.