



Implants for surgery—Active implantable medical devices

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



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 - Australian Society for Biomaterials
 - Medical Technology Association of Australia
 - Neurosurgical Society of Australasia
 - Royal Australasian College of Surgeons
 - Royal Perth Hospital
 - Therapeutic Goods Administration
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Australian Standard[®]

**Implants for surgery—Active
implantable medical devices**

**Part 1: General requirements for safety,
marking and for information to be
provided by the manufacturer**

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-012, Surgical Implants, to supersede AS ISO 14708.1—2003.

The objective of this Standard is to provide general requirements on safety, marking and information to be provided by manufacturers of active implantable medical devices.

This Standard is identical with, and has been reproduced from ISO 14708-1:2014, *Implants for surgery—Active implantable medical devices, Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this part of ISO 14708’ should read ‘this Australian Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>		<i>Australian or Australian/New Zealand Standard</i>	
ISO		AS ISO	
8601	Data elements and interchange formats— —Information interchange— Representation of dates and times	8601	Data elements and interchange formats— Information interchange— Representation of dates and times
		AS/NZS ISO	
11137	Sterilization of health care products— Radiation	11137	Sterilization of health care products— Radiation
11137-1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

CONTENTS

1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Symbols and abbreviations (optional)	7
5	General requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES	7
	5.1 General requirements for non-implantable parts	7
	5.2 General requirements for software	7
	5.3 USABILITY of non-implantable parts	7
	5.4 Data security and protection from HARM caused by unauthorized information tampering	8
	5.5 General requirements for RISK MANAGEMENT	8
	5.6 Misconnection of parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE	9
6	Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES	9
7	General arrangement of the packaging	9
8	General MARKINGS for ACTIVE IMPLANTABLE MEDICAL DEVICES	9
9	MARKINGS on the SALES PACKAGING	10
10	Construction of the SALES PACKAGING	11
11	MARKINGS on the STERILE PACK	12
12	Construction of the NON-REUSABLE PACK	13
13	MARKINGS on the ACTIVE IMPLANTABLE MEDICAL DEVICE	13
14	Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE	14
15	Protection from HARM to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE	16
16	Protection from HARM to the patient caused by electricity	16
17	Protection from HARM to the patient caused by heat	17
	17.1 Protection from HARM to the patient caused by heat	17
	17.2 Active implantable medical device intended to supply heat	17
18	Protection from ionizing radiation released or emitted from the ACTIVE IMPLANTABLE MEDICAL DEVICE	17
19	Protection from unintended effects caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE	17
20	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by external defibrillators	19
21	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by electrical fields applied directly to the patient	23
22	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical treatments	23
23	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces	24
24	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge	26
25	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes	26

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