

# ISO 14708-2:2019 (E)

## Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Symbols and abbreviated terms
5	General requirements for non-implantable parts
5.1	General requirements for non-implantable parts
5.2	General requirements for software
5.3	Usability of non-implantable parts
5.4	Data security and protection from harm caused by unauthorized information tampering
5.5	General requirements for risk management
5.6	Misconnection of parts of the active implantable medical device
6	Measurements of implantable pulse generator and lead characteristics
6.1	Measurement of implantable pulse generator characteristics
6.1.1	General considerations
6.1.2	Measurement of pulse amplitude, pulse duration, pulse interval, and pulse rate
6.1.3	Measurement of sensitivity (epos and eneg)
6.1.4	Measurement of input impedance ( $Z_{in}$ )
6.1.5	Measurement of escape interval ( $t_e$ )
6.1.6	Measurement of sensing refractory period ( $t_{sr}$ )
6.1.7	Measurement of pacing refractory period ( $t_{pr}$ ) (applicable only to inhibited implantable pulse generators)
6.1.8	Measurement of AV interval (applicable only to dual-chamber implantable pulse generators)
6.1.9	Measurement of the post-ventricular atrial refractory period (PVARP) (applicable only to implantable pulse generators with atrial sensing and ventricular pacing)
6.1.10	Measurement of the atrial-ventricular (AV) interval after sensing (applicable only to implantable pulse generators with atrial sensing and ventricular pacing)
6.2	Measurement of the lead pacing impedance ( $Z_p$ )
6.2.1	Measurement equipment accuracy
6.2.2	Methods of measuring lead pacing impedance
6.2.3	In vitro method for measurement of lead pacing impedance
7	General arrangement of the packaging
8	General markings for active implantable medical devices
9	Markings on the sales packaging
10	Construction of the sales packaging
11	Markings on the sterile pack
12	Construction of the non-reusable pack

- 13        **Markings on the active implantable medical device**
- 14        **Protection from unintentional biological effects being caused by the active implantable medical device**
- 15        **Protection from harm to the patient or user caused by external physical features of the active implantable medical device**
- 16        **Protection from harm to the patient caused by electricity**
- 17        **Protection from harm to the patient caused by heat**
- 18        **Protection from ionizing radiation released or emitted from the active implantable medical device**
- 19        **Protection from unintended effects caused by the device**
- 20        **Protection of the device from damage caused by external defibrillators**
- 21        **Protection of the device from changes caused by high power electrical fields applied directly to the patient**
- 22        **Protection of the active implantable medical device from changes caused by miscellaneous medical treatments**
- 23        **Protection of the active implantable medical device from mechanical forces**
- 24        **Protection of the active implantable medical device from damage caused by electrostatic discharge**
- 25        **Protection of the active implantable medical device from damage caused by atmospheric pressure changes**
- 26        **Protection of the active implantable medical device from damage caused by temperature changes**
- 27        **Protection of the active implantable medical device from electromagnetic non-ionizing radiation**
- 28        **Accompanying documentation**
- Annex A    (informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document**
- Annex B    (informative) Rationale**
  - B.1        General**
  - B.2        Notes on specific subclauses**
- Annex C    (informative) Code for describing modes of implantable pulse generators**
  - C.1        General**
  - C.2        The code**
  - C.3        Modes of implantable pulse generators**
- Annex D    (normative) Pulse forms**