ISO 14708-6:2019 (E)

Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

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 Measurement 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 the bradyarrhythmia characteristics
6.1.3 Measurement of ICD output voltage
6.1.4 Measurement of delivered CD pulse energy
6.1.5 Measurement of the antitachyarrhythmia pacing pulse amplitude
6.1.6 Measurement of the sensitivity of an implantable pulse generator with automatic sensitivity control
6.1.7 Charge time
6.1.8 Capacitor formation (capacitor maintenance)
6.2 Measurement of the electrical characteristic of a sensing/pacing lead

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 unintended 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

17.1 Protection from harm to the patient caused by heat
17.2 Active implantable medical device intended to supply 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) Notes on ISO 14708-6

B.1 General
B.2 Notes on specific clauses and subclauses

Annex C (informative) Code for describing modes of implantable pulse generators

C.1 General
C.2 The code
C.3 Usage

Page count: 66