ISO 14708-6:2010-03 (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

Page

Foreword v

Introduction vii

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Symbols and abbreviated terms (optional) 6

5 General requirements for non-implantable parts 6

6 Measurement of implantable pulse generator and lead characteristics 6
6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics 6
6.2 Measurement of the electrical characteristic of a sensing/pacing LEAD 9

7 General arrangement of the packaging 9

8 General markings for active implantable medical devices 9

9 Markings on the sales packaging 9

10 Construction of the SALES PACKAGING 10

11 Markings on the STERILE PACK 10

12 Construction of the NON-REUSABLE PACK 11

13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE 11

14 Protection from unintended biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE 12

15 Protection from HARM to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE 12

16 Protection from HARM to the patient caused by electricity 12

17 Protection from HARM to the patient caused by heat 15

18 Protection from ionizing radiation released or emitted from the ACTIVE IMPLANTABLE MEDICAL DEVICE 15

19 Protection from unintended effects caused by the device 15

20 Protection of the device from damage caused by external defibrillators 17

21 Protection of the device from changes caused by high power electrical fields applied directly to the patient 21
21.2 Protection of the device from damage caused by HF surgical exposure 21

22 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical instruments 22

23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces 22

24 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge 27

25 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes 27

26 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by temperature changes 27

27 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from electromagnetic non-ionizing radiation 27

28 Accompanying documentation 49

Annex A (informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this standard 55

Annex B (informative) Relationship between the clauses of this standard and the fundamental principles listed in Annex A 77

Annex D (informative) Code for describing modes of IMPLANTABLE PULSE GENERATORS 99

Annex E (normative) Interface circuits 101

Annex F (informative) Selection of capacitor Cx 105

Annex G (normative) Calibration of injection network (Figure E.105); Test signal of inhibition generator (Figure G.101) 106

Annex H (informative) Defined terms 108

Bibliography 110