DIN EN ISO 80601-2-56:2013-02 (E)

Medical electrical equipment - Part 2- 56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

Contents

Page

Foreword 4

Introduction 5

201.1 * Scope, object and related standards 7
201.1. 1 Scope 7
201.1. 2 Object 8
201.1. 3 Collateral standards 8
201.1. 4 Particular standards 8
201.2 Normative references 9
201.3 Terminology and definitions 9
201.4 General requirements 12
201.4. 2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 12
201.4. 2.101 Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 13
201.4. 3 ESSENTIAL PERFORMANCE 13
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE 13
201.4. 101 Environmental conditions of use 13
201.5 General requirements for testing of ME EQUIPMENT 13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 13
201.7 ME EQUIPMENT identification, marking and documents 13
201.7. 2.1 Minimum requirements for marking on ME EQUIPMENT and interchangeable parts 14
201.7. 2.1.101 Additional requirements for minimum requirements for marking on ME EQUIPMENT and interchangeable parts, marking of the packaging 14
201.7. 2.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 14
201.7. 2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 14
201.7. 4.3 Unit of measure 14
201.7. 4.3.101 Additional requirements for unit of measure 14
201.7. 9 ACCOMPANYING DOCUMENT 15
201.7. 9.1 Additional general requirements 15
201.7. 9.2 Additional requirements for instructions for use 15
201.7. 9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material 15
201.7. 9.2.101 Instructions for use 15
201.7. 9.101 Additional requirements for ACCOMPANYING DOCUMENT 16
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 16
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 16
201.10 Protection against unwanted and excessive radiation HAZARDs 16
201.11 Protection against excessive temperatures and other HAZARDS 16
201.12 Accuracy of controls and instruments and protection against hazardous outputs 16
201.12. 1 Accuracy of controls and instruments 16
201.12. 1.101 Additional requirements for accuracy of controls and instruments 16
201.12. 2 USABILITY 17
201.12. 2.101 * Additional requirements for USABILITY 17
201.13 HAZARDOUS SITUATIONS and fault conditions 17
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 17
201.15 Construction of ME EQUIPMENT 17
201.16 ME SYSTEMS 17

201.17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 17
201.101 Laboratory performance requirements 17
201.101. 1 * General test requirements 17
201.101. 2 * Laboratory accuracy 18
201.101. 3 * Time response for a continuous clinical thermometer 19
201.102 * Clinical accuracy validation 19
201.102. 1 Method 19
201.102. 2 * Human subject population requirements 20
201.102. 3 * Clinical bias calculation 21
201.102. 4 * Limits of agreement calculation 21
201.102. 5 * Clinical repeatability calculation 22
201.103 * Probes, probe cable extenders and probe covers 22
201.103. 1 General 22
201.103. 2 Labeling 23

202 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic compatibility -- Requirements and tests 23
202.6.2.1.10 ..... Compliance criteria 23

Annexes Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 25

Annex D (informative) Symbols on Marking 28

Annex AA (informative) Particular Guidance and rationale 30

Annex BB (informative) REFERENCE TEMPERATURE SOURCE 43

Annex CC (informative) Environmental aspects 45

Annex DD (informative) Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142 46

Bibliography 48

Alphabetized index of defined terms used in this particular standard 51

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices 53