ISO 80601-2-56:2009-10 (E)

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

Contents

Page

Foreword v

Introduction vi

201.1 * Scope, object and related standards 1
201.1. 1 Scope 1
201.1. 2 Object 2
201.1. 3 Collateral standards 2
201.1. 4 Particular standards 2
201.2 Normative references 3
201.3 Terminology and definitions 3
201.4 General requirements 6
201.4. 2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 6
201.4. 2.101 Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 7
201.4. 3 ESSENTIAL PERFORMANCE 7
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE 7
201.4. 101 Environmental conditions of use 7
201.5 General requirements for testing of ME EQUIPMENT 7
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 7
201.7 ME EQUIPMENT identification, marking and documents 7
201.7. 2.1 Minimum requirements for marking on ME EQUIPMENT and interchangeable parts 8
201.7. 2.1.101 Additional requirements for minimum requirements for marking on ME EQUIPMENT and interchangeable parts, marking of the packaging 8
201.7. 2.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 8
201.7. 2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 8
201.7. 4.3 Unit of measure 8
201.7. 4.3.101 Additional requirements for unit of measure 8
201.7. 9 ACCOMPANYING DOCUMENT 9
201.7. 9.1 Additional general requirements 9
201.7. 9.2 Additional requirements for instructions for use 9
201.7. 9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material 9
201.7. 9.2.101 Instructions for use 9
201.7. 9.101 Additional requirements for ACCOMPANYING DOCUMENT 10
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 10
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 10
201.10 Protection against unwanted and excessive radiation HAZARDs 10
201.11 Protection against excessive temperatures and other HAZARDS 10
201.12 Accuracy of controls and instruments and protection against hazardous outputs 10
201.12. 1 Accuracy of controls and instruments 10
201.12. 1.101 Additional requirements for accuracy of controls and instruments 10
201.12. 2 USABILITY 11
201.12. 2.101 * Additional requirements for USABILITY 11
201.13 HAZARDOUS SITUATIONS and fault conditions 11
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 11
201.15 Construction of ME EQUIPMENT 11
201.16 ME SYSTEMS 11
201.17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 11
201.101 Laboratory performance requirements 11

201.101. 1 * General test requirements 11
201.101. 2 * Laboratory accuracy 12
201.101. 3 * Time response for a continuous clinical thermometer 13
201.102 * Clinical accuracy validation 13
201.102. 1 Method 13
201.102. 2 * Human subject population requirements 14
201.102. 3 * Clinical bias calculation 15
201.102. 4 * Limits of agreement calculation 15
201.102. 5 * Clinical repeatability calculation 16
201.103 * Probes, probe cable extenders and probe covers 16
201.103. 1 General 16
201.103. 2 Labeling 17
202 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic compatibility -- Requirements and tests 17
202.6.2.1.10 ..... Compliance criteria 17

Annexes

Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 19

Annex D (informative) Symbols on Marking 22

Annex AA (informative) Particular Guidance and rationale 24

Annex BB (informative) REFERENCE TEMPERATURE SOURCE 37

Annex CC (informative) Environmental aspects 39

Annex DD (informative) Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142 40

Bibliography 42

Alphabetized index of defined terms used in this particular standard 45