

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 1 Scope	1
201.1.1 2 Object	2
201.1.1 3 Collateral standards	2
201.1.1 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	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