

DIN EN ISO 80601-2-56:2020-08 (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 -56:2017 + Amd1:2018)

Contents	Page
European foreword.....	4
[A1] European foreword to Amendment [A1]	6
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	7
Foreword.....	12
[A1] Foreword to Amendment [A1]	13
Introduction.....	14
201.1 * Scope, object and related standards	16
201.1.1 Scope	16
201.1.2 Object	16
201.1.3 Collateral standards	17
201.1.4 Particular standards	17
201.2 Normative references	18
201.3 Terms and definitions	19
201.4 General requirements	22
201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	22
201.4.3 ESSENTIAL PERFORMANCE	23
Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements	23
201.5 General requirements for testing of ME EQUIPMENT	23
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	23
201.7 ME EQUIPMENT identification, marking and documents	23
201.7.9 ACCOMPANYING DOCUMENT	24
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	25
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	25
201.10 Protection against unwanted and excessive radiation HAZARDS	25
201.11 Protection against excessive temperatures and other HAZARDS	26
201.11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS	26
201.12 Accuracy of controls and instruments and protection against hazardous outputs	27
201.12.1 Accuracy of controls and instruments	27
201.12.2 [A1] USABILITY [A1]	27
201.13 HAZARDOUS SITUATIONS and fault conditions	27
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	27
201.15 Construction of ME EQUIPMENT	27
201.16 ME SYSTEMS	28

201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	28
201.101	Laboratory performance requirements.....	28
201.101.1	* General test requirements	28
201.101.2	* LABORATORY ACCURACY.....	28
201.101.3	* Time response for a DIRECT MODE CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER	29
201.102	* CLINICAL ACCURACY VALIDATION	30
201.102.1	Method	30
201.102.2	* Human subject population requirements.....	31
Table 201.102	— Subject age groups	31
201.102.3	* CLINICAL BIAS calculation	32
201.102.4	* LIMITS OF AGREEMENT calculation	32
201.102.5	* CLINICAL REPEATABILITY calculation	33
201.103	* PROBES, PROBE CABLE EXTENDERS and PROBE COVERS	33
201.103.1	General.....	33
201.103.2	Labelling.....	34
202	Electromagnetic disturbances — Requirements and tests.....	34
206	Usability.....	35
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	35
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	36
212	Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.....	36
Annex C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	37
Annex D (informative)	Symbols on marking.....	40
Annex AA (informative)	Particular guidance and rationale.....	42
Figure AA.101	— Example of temperature time adjustment for a predictive intermittent CLINICAL THERMOMETER.....	44
Figure AA.102	— General structure of a CLINICAL THERMOMETER.....	45
Table AA.101	— Required tests for CLINICAL THERMOMETERS	48
Table AA.102	— Example combinations of operating conditions and REFERENCE temperature for testing the LABORATORY ACCURACY	49
Figure AA.103	— Example of a comparison plot for DUT and RCT	51
Figure AA.104	— Example of a Bland-Altman Plot [18] of the temperature difference (DUT minus RCT) versus the average OUTPUT TEMPERATURES of two thermometers.....	52
Table AA.103	— Example of CLINICAL ACCURACY VALIDATION test results.....	53
Annex BB (informative)	REFERENCE TEMPERATURE SOURCE	54
Annex CC (informative)	Reference to the essential principles of safety and performance of medical devices in accordance with ISO 16142-1 [24]	56
Table CC.1	— Correspondence between the essential principles and this document.....	56
Annex DD (informative)	Terminology — Alphabetized index of defined terms.....	59
Bibliography	62