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**