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NSAI Standards

Irish Standard
I.S. EN ISO 9919:2009

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

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EUROPEAN STANDARD

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EN ISO 9919

April 2009

ICS 11.040.10

Supersedes EN ISO 9919:2005

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

Appareils électromédicaux - Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical (ISO 9919:2005)

Medizinische elektrische Geräte Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Pulsoximetriegeräten für den medizinischen Gebrauch (ISO 9919:2005)

This European Standard was approved by CEN on 14 March 2009.

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Contents

Page

Foreword.....3

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC.....4

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Foreword

The text of ISO 9919:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 9919:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9919:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 9919:2005 has been approved by CEN as a EN ISO 9919:2009 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4.101, 4.102	3, 6	
4.103	6, 9.1	
6.1	2,9.1, 13.1	
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 d)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
6.8.2 aa) 21	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3

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Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.1 d) 1st dash	13.1	
6.1 d) 4th dash	12.4	
6.1 f)	9.1, 13.1	
6.1 aa)	10.3	
6.1 bb)	13.3 f), 13.6 h)	
6.1 cc)	13.3 c), 13.3 m)	
6.1 dd)	13.3 e)	
6.8.2	6, 13.6	
6.8.2 aa) 1)	13.6 b)	
6.8.2 aa) 2)	11.4.1, 13.6 j)	
6.8.2 aa) 3)	13.6 b), 13.6 f), 13.6 k), 13.6 l)	
6.8.2 aa) 4)	13.6 b), 13.6 p)	
6.8.2 aa) 5)	13.6 b)	
6.8.2 aa) 7)	13.6 d)	
6.8.2 aa) 11), 6.8.2 aa) 12)	13.6 c)	
6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16), 6.8.2 aa) 17),	13.6 b)	
6.8.2 aa) 19)	13.6 g)	
6.8.2 aa) 20)	13.6 c), 13.6 d)	
6.8.2 aa) 21)	13.4	
6.8.3 aa) 1), 6.8.3 aa) 2)	13.6 d)	
10.1.1	8.3	
19.4	12.6	
20.4	12.6	
21	4, 5, 9.2, 12.7.1	
29, 30, 31	11.2.1	
32	11.1.1, 11.2.1, 11.2.2	
33, 34, 35	11.2.1	
36	9.2, 11.3.1, 12.5	
42	12.7.5, 12.8.2	
42.3	6	
43.101	7.1, 7.3, 9.3	
44.6	7.6	
44.7	8.1, 8.4, 8.6	
46	10.2	
48	7.1, 7.2, 7.5, 8.2	

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Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
48	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
49	4, 12.2, 12.3	
50	6, 10.1, 14	
50.101.2	6a)	This relevant Essential Requirement is not fully addressed in this European Standard
51	6	
51.101	9.1, 10.1 10.2	
52	12.1	
57.3	12.7.4	
101	10.1, 10.2, 12.4	
102.1	2, 3, 4, 5, 6, 7.1, 7.6, 8.3, 9.1, 9.2, 10.1, 11.1.1, 11.2.2, 12.5, 12.6, 12.7.1, 12.7.5, 14	
102.2	9.1, 13.1	
103	10.2	
201	2, 6, 9.1, 10.2, 12.2, 12.3, 12.4	

WARNING - Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 9919:2009

INTERNATIONAL STANDARD

ISO 9919

Second edition
2005-03-15

Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Appareils électromédicaux — Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical

Reference number
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Contents

Page

Foreword vii

Introduction viii

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 General requirements and requirements for tests 7
4.101 Other test methods 7
4.102 Acceptance criteria 8
4.103 Pulse oximeter equipment, parts and accessories 8

5 Classification 8

6 Identification, marking and documents 8
6.1 Marking on the outside of equipment or equipment parts 8
6.8.1 General 9
6.8.2 Instructions for use 9
6.8.3 Technical description 11

7 Power input 11

8 Basic safety categories 11

9 Removable protective means 11

10 Environmental conditions 12
10.1 Transport and storage 12

11 Not used 12

12 Not used 12

13 General 12

14 Requirements related to classification 12
14.6 Types B, BF and CF equipment 12

15 Limitation of voltage and/or energy 12

16 Enclosures and protective covers 12

17 Separation 12

18 Protective earthing, functional earthing and potential equalization 12

19 Continuous leakage currents and patient auxiliary currents 13
19.4 Tests 13

20 Dielectric strength 13
20.4 Tests 13

21 * Mechanical strength 13
21.5 13
21.101 * Shock and vibration 13
21.102 * Shock and vibration for transport 14

22 Moving parts 15

23 Surfaces, corners and edges 15

24 Stability in normal use 15

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25 Expelled parts 15
26 Vibration and noise 16
27 Pneumatic and hydraulic power 16
28 Suspended masses 16
29 X-Radiation 16
30 Alpha, beta, gamma, neutron radiation and other particle radiation 16
31 Microwave radiation 16
32 Light radiation (including lasers) 16
33 Infra-red radiation 16
34 Ultraviolet radiation 16
35 Acoustical energy (including ultrasonics) 16
36 * Electromagnetic compatibility 17
37 Locations and basic requirements 17
38 Marking, accompanying documents 17
39 Common requirements for category AP and category APG equipment 17
40 Requirements and tests for category AP equipment, parts and components thereof 17
41 Requirements and tests for category APG equipment, parts and components thereof 17
42 Excessive temperatures 18
43 Fire prevention 18
43.101 * Pulse oximeter equipment used in conjunction with oxidants 18
43.101.1 Ignitable material 18
43.101.2 Sparking 19
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility 19
44.6 * Ingress of liquids 19
44.7 Cleaning, sterilization and disinfection 19
45 Pressure vessels and parts subject to pressure 19
46 Human errors 20
47 Electrostatic charges 20
48 Biocompatibility 20
49 Interruption of the power supply 20
49.101 Power-failure alarm condition 20
49.102 Pulse oximeter equipment operation following interruption of the power supply 20
49.102.1 Settings and data storage following short interruptions or automatic switchover 20
49.102.2 Operation following long interruptions 20
50 Accuracy of operating data 21
50.101 * SpO_2 accuracy of pulse oximeter equipment 21
50.101.1 * Specification 21
50.101.2 Determination of SpO_2 accuracy 21
50.102 Accuracy under conditions of motion 22
50.103 Accuracy under conditions of low perfusion 22
50.104 Pulse rate accuracy 23
51 Protection against hazardous output 23
51.101 * Data update period 23
51.102 Detection of pulse oximeter probe and probe cable extender fault 23

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52 Abnormal operation and fault-conditions ... 23

53 Environmental tests ... 24

54 General ... 24

55 Enclosures and covers ... 24

56 Components and general assembly ... 24

57 Mains parts, components and layout ... 24

58 Protective earthing — Terminals and connections ... 24

59 Construction and layout ... 24

101 * Signal inadequacy ... 24

102 * Pulse oximeter probes and probe cable extenders ... 25
102.1 General ... 25
102.2 Labelling ... 25

103 Saturation pulse information signal ... 25

104 Alarm systems ... 25
201.1.2 * Assignment of priority ... 25
201.5.4 * Default alarm preset ... 26
201.8 Alarm signal inactivation states ... 26
201.8.3 Indication and access ... 26

105 Appendices of IEC 60601-1:1988 ... 26

Annex AA (informative) **Rationale** ... 27

Annex BB (informative) **Skin temperature at the pulse oximeter probe** ... 38

Annex CC (informative) **Determination of accuracy** ... 42

Annex DD (informative) **Calibration standards** ... 50

Annex EE (informative) **Guideline for evaluating and documenting SpO_2 accuracy in human subjects** ... 51

Annex FF (informative) **Simulators, calibrators and functional testers for pulse oximeter equipment** ... 58

Annex GG (informative) **Concepts of equipment response time** ... 68

Annex HH (informative) **Reference to the Essential Principles** ... 72

Annex II (informative) **Environmental aspects** ... 74

Annex JJ (informative) **Index of defined terms** ... 76

Bibliography ... 78

Tables

Table AA.1 — Qualitative assessment of pulse oximeter equipment shock and vibration environment ... 28

Table AA.2 — Allowable maximum temperatures for skin contact with medical electrical equipment applied parts (adapted from Table 22, IEC/CDV 60601-1:2004) ... 30

Table BB.1 — Pulse oximeter probe safe application time and source ... 40

Table EE.1 — Example of target plateaus and ranges ... 54

Table HH.1 — Correspondence between this International Standard and the Essential Principles ... 72

Table II.1 — Environmental aspects addressed by clauses of this International Standard ... 75

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Figures

Figure CC.1 — Synthesized calibration data (base case) 43

Figure CC.2 — Constant offset has been added to base case 44

Figure CC.3 — Tilt has been added to base case 45

Figure CC.4 — Graphical representation for the definition of local bias (Test sensor SpO_2 as a function of reference S_R) 46

Figure CC.5 — Graphical representation for the definition of local bias and mean bias (Test sensor SpO_2 as a function of reference S_R) 46

Figure EE.1 — Example of desaturation-time profile 54

Figure FF.1 — Sample calibration curve for pulse oximeter equipment 60

Figure FF.2 — Interface of a functional tester that uses a photodiode and LED to interact with a pulse oximeter probe 61

Figure FF.3 — Interface of a functional tester that uses a dye mixture 62

Figure FF.4 — Interface of a functional tester that uses a liquid crystal modulator 63

Figure FF.5 — Absorbency of blue bandage material (measured in reflection) used in a special test pulse oximeter probe with great patient-to-patient variability of calibration 65

Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects 66

Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects (*continued*) 67

Figure GG.1 — Illustration of fidelity of pulse oximeter equipment performance in tracking saturation changes 68

Figure GG.2 — Illustration of effect of different averaging times on fidelity 69

Figure GG.3 — Graphic representation of components of alarm system delay 70

Figure GG.4 — Illustration of the effects of different averaging times on a more rapid and noisier desaturation signal 71

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9919 (IEC 60601-2-54) was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 9919:1992), which has been technically revised.

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Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This International Standard covers basic safety and essential performance requirements achievable within the limits of existing technology.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a requirement and identifying the hazards that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a **pulse oximeter probe** and a **patient's** tissue.

Annex CC discusses both the formulae used to evaluate the **SpO_2 accuracy** of **pulse oximeter equipment** measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when *in vitro* blood calibration of **pulse oximeter equipment** is needed.

Annex EE presents a guideline for **controlled desaturation study** for the calibration of **pulse oximeter equipment**.

Annex FF is a tutorial introduction to several kinds of testers used in pulse oximetry.

Annex GG describes concepts of **pulse oximeter equipment** response time.

This International Standard is a Particular Standard, based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— "Replacement" means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— "Addition" means that the relevant text of this Particular Standard is a new element (e.g. subclause, list element, note, table, figure) additional to the General Standard.

— "Amendment" means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

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To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change, and test specifications*: italic type*;

— terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold type.**

Throughout this Particular Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

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Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

1 Scope

IEC 60601-1:1988, Clause 1 applies, except as follows.

Amendment (add at the end of 1.1):

This International Standard specifies particular requirements for the basic safety and essential performance of **pulse oximeter equipment** intended for use on humans. This includes any part necessary for **normal use**, e.g. the **pulse oximeter monitor**, **pulse oximeter probe**, **probe cable extender**.

These requirements also apply to **pulse oximeter equipment,** including **pulse oximeter monitors**, **pulse oximeter probes** and **probe cable extenders,** that has been **reprocessed**.

The intended use of **pulse oximeter equipment** includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate on **patients** in healthcare institutions as well as on **patients** in home care.

* This International Standard is not applicable to **pulse oximeter equipment** intended for use in laboratory research applications nor to oximeters that requires a blood sample from the **patient**.

This International Standard is not applicable to **pulse oximeter equipment** solely intended for foetal use.

This International Standard is not applicable to remote or slave (secondary) devices that display $\mathbf{SpO_2}$ values that are located outside of the **patient environment**.

The requirements of this International Standard which replace or modify requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000/IEC 60417:2004, *Graphical symbols for use on equipment — Index and synopsis*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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ISO 14937:2000, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*
Amendment 1:2002.
Amendment 2:2004.

IEC 60068-2-6:1995, *Environmental testing — Part 2-6: Tests — Test Fc. Vibration (sinusoidal)*

IEC 60068-2-27:1987, *Environmental testing — Part 2-27: Tests — Test Ea and guidance. Shock*

IEC 60068-2-32:1975, *Environmental testing — Part 2-32: Tests — Test Ed. Free fall*
Amendment 1:1982
Amendment 2:1990

IEC 60068-2-64:1993, *Environmental testing — Part 2-64: Test methods — Test Fh. Vibration, broad-band random (digital control) and guidance*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*
Amendment 1:1995

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1:1988[1)], *Medical electrical equipment — Part 1: General requirements for safety*
Amendment 1:1991
Amendment 2:1995

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral Standard: Programmable electrical medical systems*
Amendment 1:1999

IEC 60601-1-6:2004, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

IEC 60825-2:2000, *Safety of laser products — Part 2: Safety of optical fibre communication systems* (OFCS)

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in IEC 60601-1:1988, Clause 2, as amended by the Collateral Standards, and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex JJ.

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