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

(ISO 9919:2005, IDT)

医用电气设备 医用脉搏血氧仪设备

基本安全和主要性能专用要求

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Table of Contents

Foreword.....	5
Introduction	6
1 Scope.....	8
2 Normative references.....	8
3 Terms and definitions	10
4 General requirements and requirements for tests.....	16
5 Classification.....	17
6 Identification, marking and documents.....	17
7 Power input.....	22
8 Basic safety categories	22
9 Removable protective means.....	22
10 Environmental conditions	22
11 Not used.....	22
12 Not used.....	22
13 General	22
14 Requirements related to classification	22
15 Limitation of voltage and/or energy	23
16 Enclosures and protective covers	23
17 Separation.....	23
18 Protective earthing, functional earthing and potential equalization	23
19 Continuous leakage currents and patient auxiliary currents.....	23
20 Dielectric strength	24
21* Mechanical strength	24
22 Moving parts	26
23 Surfaces, corners and edges	26
24 Stability in normal use	27
25 Expelled parts	27
26 Vibration and noise	27

27 Pneumatic and hydraulic power	27
28 Suspended masses	27
29 X-Radiation	27
30 Alpha, beta, gamma, neutron radiation and other particle radiation	27
31 Microwave radiation	27
32 Light radiation (including lasers)	27
33 Infra-red radiation.....	28
34 Ultraviolet radiation	28
35 Acoustical energy (including ultrasonic).....	28
36* Electromagnetic compatibility	28
37 Locations and basic requirements	29
38 Marking, accompanying documents.....	29
39 Common requirements for category AP and category APG equipment	29
40 Requirements and tests for category AP equipment, parts and components thereof	29
41 Requirements and tests for category APG equipment, parts and components thereof	29
42 Excessive temperatures.....	29
43 Fire prevention	30
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	31
45 Pressure vessels and parts subject to pressure.....	32
46 Human errors	32
47 Electrostatic charges.....	32
48 Biocompatibility	32
49 Interruption of the power supply.....	33
50 Accuracy of operating data.....	34
51 Protection against hazardous output.....	37
52 Abnormal operation and fault-conditions	38
53 Environmental tests	38

54 General	38
55 Enclosures and covers.....	38
56 Components and general assembly.....	38
57 Mains parts, components and layout	38
58 Protective earthing - Terminals and connections.....	38
59 Construction and layout	38
101* Signal inadequacy	39
102* Pulse oximeter probes and probe cable extenders.....	39
103 Saturation pulse information signal	40
104 Alarm systems.....	40
105 Appendices of the general standard.....	41
Annex AA (Informative) Rationale	42
Annex BB (Informative) Skin temperature at the pulse oximeter probe	58
Annex CC (Informative) Determination of accuracy	63
Annex DD (Informative) Calibration standards.....	75
Annex EE (Informative) Guideline for evaluating and documenting SpO ₂ accuracy in human subjects.....	77
Annex FF (Informative) Simulators, calibrators and functional testers for pulse oximeter equipment	87
Annex GG (Informative) Concepts of equipment response time	99
Annex HH (Informative) Reference to the essential principles	104
Annex II (Informative) Environmental aspects	107
Bibliography	109
Index	113

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This Standard identically uses ISO 9919:2005, covering 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 accuracy of pulse oximeter equipment measurements, and the names that are assigned to those formulas.

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 tutorial introduction to several kinds of testers used in pulse oximetry.

Annex GG describes the concept of pulse oximeter equipment response time.

This Standard is a particular standard based on GB 9706.1-2007. GB 9706.1-2007 is hereafter designated as a 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.

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

1 Scope

GB 9706.1-2007, Clause 1 applies, except as follows.

Amendment (add at the end of 1.1):

This 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 monitor, 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 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 Standard is not applicable to pulse oximeter equipment solely intended for foetal use.

This Standard is not applicable to remote or slave (secondary) devices that display SpO₂ values that are located outside of the patient environment.

The requirements of this Standard which replace or modify requirements of GB 9706.1-2007 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.

GB/T 2423.5-1995, *Environmental testing for electric and electronic products Part 2: Test methods Test Ea and guidance: Shock* (IEC 68-2-27:1987, IDT)

GB/T 2423.8-1995, *Environmental testing for electric and electronic products Part 2: Test methods Test Ed: Free fall* (IEC 68-2-32:1990, IDT)

GB/T 2423.10-2008, *Environmental testing for electric and electronic products - Part 2: Tests methods - Test Fc: Vibration (sinusoidal)* (IEC 60068-2-6:1995, IDT)

GB/T 2423.56-2006, *Environmental testing for electric and electronic products - Part 2: Test methods - Test Fh: Vibration, broad-band random (digital control) and guidance* (IEC 60068-2-64:1993, IDT)

GB 4208-2008, *Degrees of Protection Provided by Enclosure (IP Code)* (IEC 60529:2001, IDT)

GB/T 5332-2007, *Method of test for ignition temperature of flammable liquids and gases* (IEC 60079-4:1975, IDT)

GB/T 5465.2-2008, *Graphical Symbols for Use on Electrical Equipment - Part 2: Graphical Symbols* (IEC 60417DB:2007, IDT)

GB 7247.1-2001, *Safety of laser products - Part 1: Equipment classification, requirements and users guide* (IEC 60825-1:1993, IDT)

GB 9706.1-2007, *Medical electrical equipment - Part 1: General requirements for safety* (GB 9706.1-2007, IDT)

GB 9706.15-2008, *Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems* (IEC 60601-1-1:2000, IDT)

GB/T 19974-2005, *Sterilization of health care products - General requirement for characterization of a sterilization agent and the development, validation and routine control of a sterilization process* (ISO 14937:2000, IDT)

YY 0466-2003, *Medical devices - Symbols to be used with medical device labels labelling and information to be supplied* (ISO 15223-2000, IDT)

YY 0505-2005, *Medical electrical equipment - Part 1-2: General*

requirements for safety - Collateral standards: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001, IDT)

YY/T 0708-2009, Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: programmable electrical medical systems (IEC 60601-4:2000, IDT)

YY 0709-2009, 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 60601-1-8:2006, IDT)

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

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

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

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in GB 9706.1-2007, Clause 2, as amended by the collateral Standards, and the following apply.

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

3.1 accuracy

closeness of agreement between a test result and an accepted reference value

NOTE 1: See 50.101.2.2 for the method of calculating the SpO₂ accuracy of pulse oximeter equipment.

NOTE 2: See also discussion in Annex CC.

NOTE 3: Adapted from GB/T 3358.1.

3.2 controlled desaturation study

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