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PHARMACEUTICAL INDUSTRY STANDARD

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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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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 SpO_2 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 SpO_2 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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