AS ISO 9919—2004
ISO 9919:1992

Australian Standard™

Pulse oximeters for medical use—Requirements

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This Australian Standard was prepared by Committee HE-019, Anaesthetic and Breathing Equipment. It was approved on behalf of the Council of Standards Australia on 18 March 2004 and published on 3 May 2004.

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This Standard was issued in draft form for comment as DR 03502.

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First published as AS ISO 9919—2004.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5883 5

PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-019, Anaesthetic and Breathing Equipment. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 9919:1992, *Pulse oximeters for medical use—Requirements*.

The objective of this Standard is to specify requirements for the safety of pulse oximeters, intended for use in the approximate measurement of the saturation of human arterial haemoglobin, non-invasively.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

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References to International Standards and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
9703	Anaesthesia and respiratory care alarm signals	9703	Anaesthesia and respiratory care alarm signals
9703-1	Part 1: Visual alarm signals	9703.1	Part 1: Visual alarm signals
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard

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INTRODUCTION

The approximate measurement of haemoglobin saturation through the use of pulse oximetry has become an increasingly common practice in many areas of clinical medicine. These include but are not limited to anaesthesia, respiratory therapy, paediatrics and intensive care. This International Standard specifies minimum safety requirements based on parameters that are believed to be achievable within the limits of existing technology.

Annex L contains a rationale for the most important requirements. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard.

AUSTRALIAN STANDARD

Pulse oximeters for medical use — Requirements

Section 1: General

1.1 Scope

ISO 9919 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply except that 1.1 shall be replaced by the following:

This International Standard specifies requirements for the safety of pulse oximeters, as defined in 1.3.12, intended for use in the approximate measurement of the saturation of human arterial haemoglobin, non-invasively.

The field of application includes, but is not limited to

a) perioperative use;

b) adult critical care application;

c) paediatric and neonatal applications;

d) general determination of saturation on hospitalized and non-hospitalized patients.

Pulse oximeters intended for use in laboratory research applications and bench-type oximeters that require a blood sample from the patient are outside the scope of this International Standard.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

IEC 601-1:1988, *Safety of medical electrical equipment — Part 1: General safety requirements.*

IEC 801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

1.3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1:1988 apply, with the following additional definitions.

1.3.1 alarm: Warning signal.

1.3.2 alarm set-point: Setting of the adjustment control or display value which indicates the SpO_2, at or beyond which the alarm is intended to be activated.

NOTE 1 Terms such as "alarm limits" or "alarm threshold" are frequently used to describe the same function.

1.3.3 alarm system: Those parts of the pulse oximeter which

a) establish the alarm set-point(s);

b) activate an alarm when the SpO_2 is less than or equal to the low alarm set-point, if provided, or is equal to or greater than the high alarm set-point, if provided.

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