AS ISO 9918—2004
ISO 9918:1993

Australian Standard™

Capnometers for use with humans—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 20 February 2004 and published on 29 March 2004.

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Australasian Society of Anaesthesia Paramedical Officers
Australian and New Zealand College of Anaesthetists
Australian and New Zealand Intensive Care Society
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
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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 9918:1993, *Capnometers for use with humans - Requirements.*

The objective of this Standard is to specify requirements for the safety of capnometers used with adults, children and neonates.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas 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'.

(c) A full point substitutes for a comma when referring to a decimal marker.

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

Reference to International Standard		*Australian or Australian/New Zealand 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	
601	Medical electrical equipment	3200	Medical electrical equipment
601-1	Part 1: General requirements for safety	3200.1	Part 1.0: General requirements for safety - Parent Standard

Only international references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

CONTENTS

INTRODUCTION

The measurement of carbon dioxide in a gaseous mixture has become a common practice in many areas of clinical medicine, such as anaesthesia, respiratory therapy, paediatrics and intensive care. This International Standard specifies minimum safety requirements based on parameters that are 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

Capnometers for use with humans — Requirements

Section 1: General

1.1 Scope

ISO 9918 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 capnometers, as defined in 1.3.6.

It applies to capnometers used with adults, children and neonates. It does not apply to devices intended for use as transcutaneous monitors.

Capnometers intended for use in laboratory research applications are outside the scope of this International Standard.

1.2 Normative reference

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 3744:—[1], *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors.*

ISO 7000:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

IEC 65:1985, *Safety requirements for mains operated electronic and related apparatus for household and similar general use.*

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

IEC 651:1979, *Sound level meters.*

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 accuracy: Quality which characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

1.3.2 alarm: Signal that is activated when a monitored variable equals or crosses the alarm limit.

1) To be published. (Revision of ISO 3744:1981)