

Australian Standard™

Capnometers for use with humans— Requirements

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.

The following are represented on Committee HE-019:

- 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
- Australian Industry Group
- Australian Society of Anaesthetists
- College of Biomedical Engineering Institution of Engineers Australia
- Commonwealth Department of Health and Ageing
- Department of Human Services (South Australia)
- Health Department of Western Australia
- Medical Industry Association of Australia Inc
- NSW Health Department

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Web Shop at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

Australian Standards™ and other products and services developed by Standards Australia are published and distributed under contract by SAI Global, which operates the Standards Web Shop.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 03501.

Australian Standard™

Capnometers for use with humans— Requirements

First published as AS ISO 9918—2004.

COPYRIGHT

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

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

ISBN 0 7337 5804 5

 **Documents**
Document Sharing Hub

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:

<i>Reference to International Standard</i>		<i>Australian or Australian/New Zealand Standard</i>	
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

Section 1 General	1
1.1 Scope	1
1.2 Normative references	1
1.3 Definitions	1
1.4 General requirements	3
1.5 General requirements for tests	3
1.6 Classification	3
1.7 Identification marking and documents	3
1.8 Power point	5
Section 2 Environmental conditions	6
2.1 Basic safety categories	6
2.2 Removable protective means	6
2.3 Environmental conditions	6
2.4 Special measures with respect to safety	6
2.5 Single fault condition	6
Section 3 Protection against electric shock hazards	7
3.1 General	7
3.2 Requirements related to classification	7
3.3 Limitation of voltage and/or energy	7
3.4 Enclosures and protective covers	7
3.5 Separation	7
3.6 Protective earthing, functional earthing and potential equalization	7
3.7 Continuous leakage currents and patient auxiliary currents	7
3.8 Dielectric strength	7

Section 4 Protection against mechanical hazards	8
4.1 Mechanical strength	8
4.2 Moving parts	8
4.3 Surfaces, corners and edges	8
4.4 Stability in normal use	8
4.5 Expelled parts	8
4.6 Vibration and noise	9
4.7 Pneumatic and hydraulic power	10
4.8 Suspended masses	10
Section 5 Protection against hazards from unwanted or excessive radiation	11
5.1 X-radiation	11
5.2 Alpha, beta, gamma, neutron radiation and other particle radiation	11
5.3 Microwave radiation	11
5.4 Light radiation (including lasers)	11
5.5 Infrared radiation	11
5.6 Ultraviolet radiation	11
5.7 Acoustical energy (including ultrasonics)	11
5.8 Electromagnetic compatibility	11
Section 6 Protection against hazards of ignition of flammable anaesthetic mixtures	12
6.1 Locations and basic requirements	12
6.2 Marking, accompanying documents	12
6.3 Common requirements for category AP and category APG equipment	12
6.4 Requirements and tests for category AP equipment, and parts and components	12
6.5 Requirements and tests for category APG equipment, and parts and components	12
Section 7 Protection against excessive temperatures and other safety hazards	13
7.1 Excessive temperatures	13
7.2 Fire prevention	13

7.3	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	13
7.4	Pressure vessels and parts subject to pressure	14
7.5	Human error	14
7.6	Electrostatic charges	14
7.7	Materials in applied parts in contact with the body of the patient	14
7.8	Interruption of power supply	14
Section 8	Accuracy of operating data and protection against hazardous output	15
8.1	Accuracy of operating data	15
Section 9	Abnormal operation and fault conditions; environmental tests	19
9.1	Abnormal operation and fault conditions	19
9.2	Environmental tests	19
Section 10	Constructional requirements	20
10.1	General	20
10.2	Enclosures and covers	20
10.3	Components and general assembly	20
10.4	Mains parts, components and layout	20
10.5	Protective earthing — Terminals and connections	20
10.6	Construction and layout	20
Section 11	Additional requirements specific to capnometers	21

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 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 3744:—¹⁾, *Acoustics — Determination of sound power levels of noise sources using sound pressure*

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

— *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 9703-1:1992, *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.

1.3.3 alarm limit: Reading of a monitored variable at which the alarm is first activated.

1.3.4 alarm set-point: Setting of the adjustment control or display value which indicates the monitored variable's reading 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.

1.3.5 alarm system: Those parts of the capnometer which

- a) establish the alarm set-point(s);
- b) activate an alarm when the carbon dioxide reading 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.

1.3.6 capnometer: Device for the measurement of carbon dioxide concentration or partial pressure in ventilatory gases.

NOTE 2 The capnometer consists of all equipment including accessories, sensor, and sampling tube (in the case of a diverting capnometer) specified by the manufacturer for the intended use of the capnometer.

1.3.7 carbon dioxide level: Concentration of carbon dioxide in a gaseous mixture.

NOTE 3 This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mmHg).

1.3.8 carbon dioxide reading: Measured carbon dioxide level as indicated by the capnometer display.

1.3.9 default setting; default limits: Parameters first active on power-up of the device.

1.3.10 manufacturer's default setting [limits]: Parameters first active on power-up of the device as configured by the manufacturer or distributor.

1.3.11 delay time: Time from a step function change in CO₂ concentration or partial pressure at the sampling site to the achievement of 10 % of final CO₂ value in the capnometer (time A-B in figure 1).

1.3.12 display: Visual representation of output data.

1.3.13 diverting capnometer: Capnometer which transports a portion of the respired gases from the

sampling site, through a sampling tube, to the sensor.

1.3.14 high priority [warning] alarm: Signal indicating that immediate user response is required.

1.3.15 Interference with measurement accuracy: Difference between the carbon dioxide reading in a corresponding mixture in which the interfering gas or vapour fraction has been replaced by nitrogen.

1.3.16 low priority [advisory] alarm: Signal indicating that user awareness is required.

1.3.17 medium priority [cautionary] alarm: Signal indicating that prompt user response is required.

1.3.18 non-diverting capnometer: Capnometer that does not transport gas away from the sampling site.

1.3.19 oxygen level: Concentration of oxygen in a gaseous mixture.

NOTE 4 This may be expressed in any suitable unit such as by percent volume or partial pressure in kPa (or mmHg).

1.3.20 partial pressure: Pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature.

1.3.21 percent V/V carbon dioxide [other gas]: Level of carbon dioxide (or other gas) in a mixture, expressed as a percentage volume fraction.

1.3.22 rise time: Time required to achieve a rise from 10 % to 90 % of final CO₂ value in the capnometer when a step function change in CO₂ concentration or partial pressure occurs at the sampling site (segment B-C in figure 1).

1.3.23 sampling site: Location at which respiratory gases are diverted for measurement to a remote sensor in a diverting capnometer or the location of the sensor area in a non-diverting capnometer.

1.3.24 sampling tubing: Conduit for transfer of ventilatory gases from the sampling site to the sensor in a diverting capnometer.

1.3.25 sensor: Part of the capnometer which is sensitive to the presence of carbon dioxide.

1.3.26 sensor area: Part of the sensor at which carbon dioxide is detected.

1.3.27 total system response time: Sum of the delay time and rise time (segment A-C in figure 1).

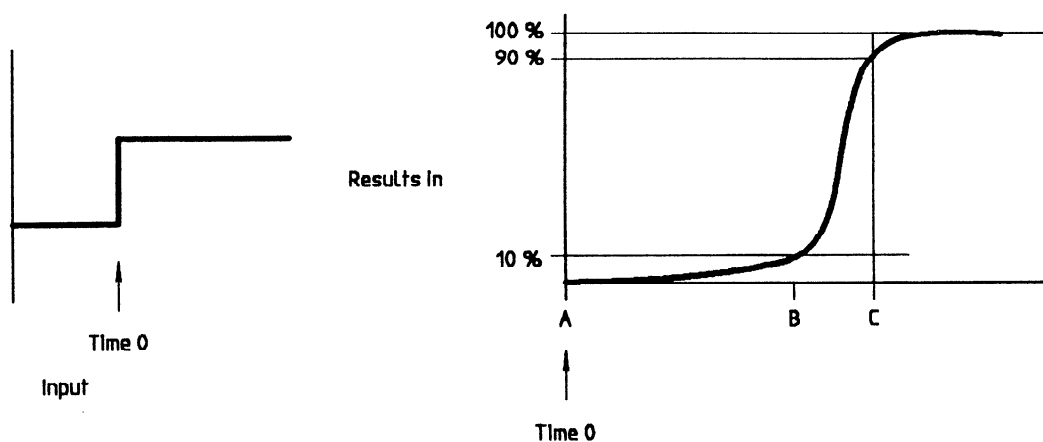


Figure 1 — Response time (total system response)

1.3.28 transcutaneous monitoring equipment: Equipment and/or associated transducers for the monitoring and/or recording of partial pressures of oxygen and carbon dioxide at the skin surface.

1.3.29 [carbon dioxide gas] transducer: Device for converting the carbon dioxide partial pressure or concentration into a signal for monitoring or recording.

1.4 General requirements

The requirements given in clause 3 of IEC 601-1:1988 apply with the following addition.

3.1.1 Packaging of equipment shall be of sufficient strength to ensure the intended use of the equipment.

3.1.2 For sterile equipment, packaging shall ensure sterile conditions until opened, damaged or until its expiration date is reached or exceeded.

3.10 Devices dependent on software shall be designed in such a way as to minimize the risks arising from errors in the program.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply with the following addition.

4.12 Test methods other than those specified in this International Standard but of equal or greater accuracy may be used to verify compliance with the requirements of this International Standard. However, in the event of dispute, the methods specified in this International Standard shall be used as the reference methods.

1.6 Classification

The requirements given in clause 5 of IEC 601-1:1988 apply.

1.7 Identification marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply with the following additions and modifications.

- a) In the preamble to clause 6, replace second dash first bullet by the following: warning statements, instructive statements or drawings, affixed in a permanent location and legible to an operator with a visual acuity of 1,0 (corrected if necessary) from a distance of 1 m at an illuminance level of 215 lx.

NOTE 5 Operating instructions may be given on the display of the equipment.

- b) In 6.1, replace item d) by the following.

If the size of the capnometer does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the capnometer:

- the name of the manufacturer;
- a serial or lot or batch identifying number;
- the symbol 14 in table DI of IEC 601-1:1988.

- c) In 6.1, add the following to item f): a serial number or other lot or batch identifier.
- d) In 6.1, add the following to item q): the words "not for use in breathing systems", if applicable.
- e) In 6.1, add additional items as follows:

aa) Marking on the capnometer shall additionally include the following: for capnometers not for use with inhalation anaesthetic agents, the phrase “not for use with inhalation anaesthetic agents”.

If moisture has an adverse effect on performance, either a statement that the operator shall see the accompanying documents for the effect of moisture on accuracy, or symbol 14 in table DI of IEC 601-1:1988.

ab) Abridged operating instructions for those capnometers that are intended as “free-standing” types of devices.

ac) Other sources of interference — The manufacturer shall mark the device with a warning to refer to the accompanying documents for the expected adverse effects on the performance of the capnometer when exposed to electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transients, magnetic fields (i.e., Magnetic Resonance Imaging), and radio-frequency interference known at the time of preparation of the accompanying documents. The manufacturer shall also mark the capnometer with a warning that pump motors in the capnometer may adversely affect other medical equipment e.g., ECG tracings.

It is recommended that illustrated service information be provided to include: instructions for preventive maintenance and service calibration, and those adjustments that are necessary to maintain the capnometer in the correct operating condition, as well as a description of those adjustments and replacements that can be performed by the operator.

ad) All displayed measured values shall be marked in appropriate units.

ae) Packages shall be marked with the word “sterile” where appropriate.

af) Detachable applied parts shall be marked with a type number or serial number on them or on the packaging as appropriate.

ag) Where appropriate an indication of the time limit for completely safe use, expressed as the year and month.

f) In 6.7 amend item a) as follows:

a) Colours of indicator lights.

On equipment, the colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action. Dot matrix,

alphanumeric displays, and computer-generated graphics are not considered to be indicator lights.

Compliance shall be checked by functional tests and inspection.

g) In 6.8.2, add the following to item a):

The instructions for use shall additionally include the following information:

- 1) a description of the purpose and intended use of the capnometer;
- 2) a description of the principles of operation of the capnometer, including the relationship between gas concentration and its partial pressure, and the quantitative effects of humidity;
- 3) a detailed specification including the following:
 - the carbon dioxide measurement range and the accuracy of measurement,
 - the stability of measurement accuracy,
 - the rise time,
 - the delay time,
 - the total system response time,
 - the carbon dioxide level alarm range and its accuracy,
 - the operating and non-operating storage temperature ranges,
 - power requirements,
 - time from switching on to obtaining specified operating performance,
 - the priority or category assigned to each alarm,
 - results of sound pressure testing in accordance with subclause 26.2,
 - if gas diversion occurs, the gas diversion flow;
- 4) details of any adverse effect on stated function due to the following: humidity or condensate, including, for example, any adverse effects if an adaptor is provided to improve the function of the sensor in the presence of condensation or particulate water; interfering gases (see subclause 60.1) or