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Capnometers for use with humans — Requirements

Capnomètres pour utilisation chez l'homme — Prescriptions

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9918 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 3, *Lung ventilators and related equipment*.

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.

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

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 CO_2 concentration or partial pressure at the sampling site to the achievement of 10 % of final CO_2 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 CO_2 value in the capnometer when a step function change in CO_2 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).

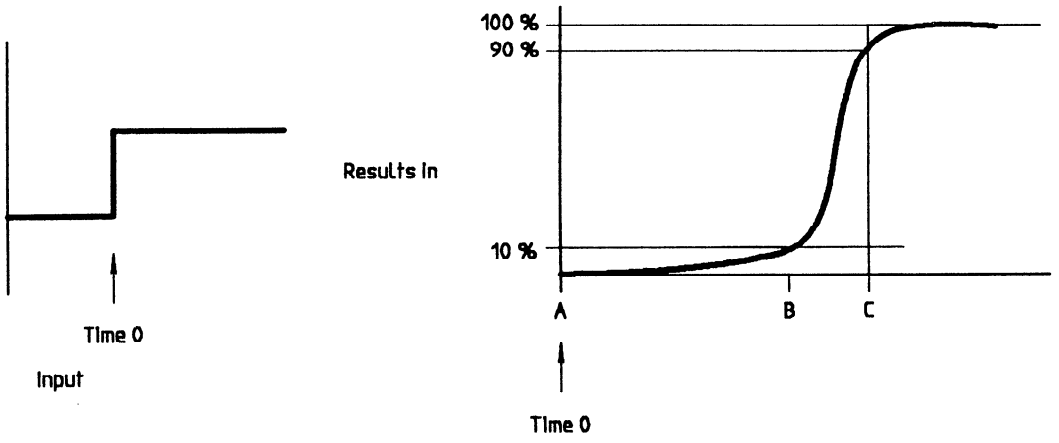

Figure 1 — Response time (total system response)

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

vapours; mechanical shock; cyclic pressure; barometric pressure or pressure at the site of use of the capnometer; fluctuation in line or battery voltage; if automatic compensation for barometric pressure is not provided, then the accompanying documents shall contain an explanation that readings in concentration units are correct only under the pressure at which the capnometer is calibrated;

5) an illustration of the features of the capnometer indicating the location of all operating controls, adjustments, and system components necessary for correct operation;

6) instructions for operation of the capnometer including the following:

   — checking and calibration before use; routine inspection and testing,

   — recommended methods for cleaning and disinfection or sterilization. If accessories are delivered in sterile packaging the instructions shall contain the necessary information regarding re-sterilization or disposal of such items in the event of damage to the sterile packaging and/or the items;

7) a description of the correct installation of the capnometer and a detailed description of sampling arrangements and any connecting tubing;

8) the manufacturer shall provide information regarding the expected adverse effects on 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. Additionally the manufacturer shall provide a warning that pump motors in the capnometer may adversely affect other medical equipment e.g. ECG tracings;

9) the instruction for use shall include all necessary information about materials which the patient or user may come into contact with, as regards toxicity and/or action on tissues;

10) the characteristics of alarms provided;

11) if unusual risks are related to the disposal of the equipment or parts thereof including batteries and/or rechargeable batteries, the manufacturer shall specify those items in the instructions for use. There will be an additional statement as to whether the manufacturer is able to dispose of the listed items;

12) if applicable, the manufacturer shall list relevant certifications and state the date of their authorizations.

1.8 Power point

The requirements given in clause 7 of IEC 601-1:1988 apply.

Section 2: Environmental conditions

2.1 Basic safety categories

Not used.

2.2 Removable protective means

Not used.

2.3 Environmental conditions

The requirements given in clause 10 of IEC 601-1:1988 apply.

2.4 Special measures with respect to safety

Not used.

2.5 Single fault condition

Not used.