SLOVENSKI STANDARD
SIST EN 864:2000

01-januar-2000

Elektromedicinska oprema - Merilniki CO2 (kapnometri) za uporabo pri ljudeh - Posebne zahteve

Medical electrical equipment - Capnometers for use with humans - Particular requirements

Medizinische elektrische Geräte - Kapnometer für die Anwendung am Menschen - Besondere Anforderungen

Appareils électromédicaux - Capnometres pour utilisation chez l'homme - Prescriptions particulieres

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ICS:

11.040.50	Radiografska oprema	Radiographic equipment

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English version

Medical electrical equipment - Capnometers for use with humans - Particular requirements

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Medizinische elektrische Geräte - Kapnometer für die Anwendung am Menschen - Besondere Anforderungen

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive (s).

For relationship with EU Directives, see informative annex ZA, which is an integral part of this standard.

Annexes AA,BB and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is one of a series based on European Standard EN 60601-1:1990.

In EN 60601-1 this type of European Standard is referred to as a "Particular Standard". As stated in 1.3 of EN 60601-1:1990, the requirements of this European Standard take precedence over those of EN 60601-1:1990. Clauses and subclauses additional to those in EN 60601-1:1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional figures are numbered beginning '101' and additional tables are numbered beginning '101'. Additional items in lettered lists are lettered beginning 'aa)' .

The measurement of carbon dioxide in a gaseous mixture has become an increasingly common practice in many areas of clinical medicine, such as anaesthesia, respiratory therapy, paediatrics and intensive care. The minimum safety requirements given in this European Standard are based on parameters that are achievable within the limits of existing technology.

Annex AA 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 standard. Clauses and subclauses marked with R after their number have corresponding rationales contained in annex AA.

Section one. General

1 Scope

Clause 1 of EN 60601-1:1990 applies except that 1.1. is replaced by the following:

1.1 This European Standard specifies requirements for the safety of capnometers as defined in 3.6 of this standard.

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 standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1 : 1990 applies with the following additions:

EN 475	Medical devices. Electrically-generated alarm signals.
prEN 737-3	Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements
prEN 740:1992	Medical electrical equipment - Anaesthetic workstations and their modules - Particular requirements
prEN 1281-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1 : Cones and sockets

EN 1281-2	Anaesthetic and respiratory equipment - Conical connectors - Part 2 : Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)
EN 60601-1 : 1990	Medical electrical equipment - Part 1 : General requirements for safety
EN 60601-1-2	Medical electrical equipment - Part 1 : General requirements for safety - Collateral standard : Electromagnetic compatibility - Requirements and tests
EN ISO 3744	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially freefield over a reflecting plane (ISO 3744:1994)
IEC 79-4	Electrical apparatus for explosive gas atmospheres - Part 4 : Method of test for ignition temperature
IEC 651	Sound level meters
IEC 801-2	Electromagnetic compatibility for industrial-process measurement and control equipment - Part 2 : Electrostatic discharge requirements

3 Terminology and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions:

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

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

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

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: Terms such as "alarm limits" or "alarm threshold" are frequently used to described the same function.

3.5 alarm system: Those parts of the capnometer which:

a) establish the alarm limit(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.

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

NOTE: 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.

3.7 carbon dioxide level: Concentration of carbon dioxide expressed in % (V/V) or the partial pressure in kPa (or mmHg) in a gaseous mixture.

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

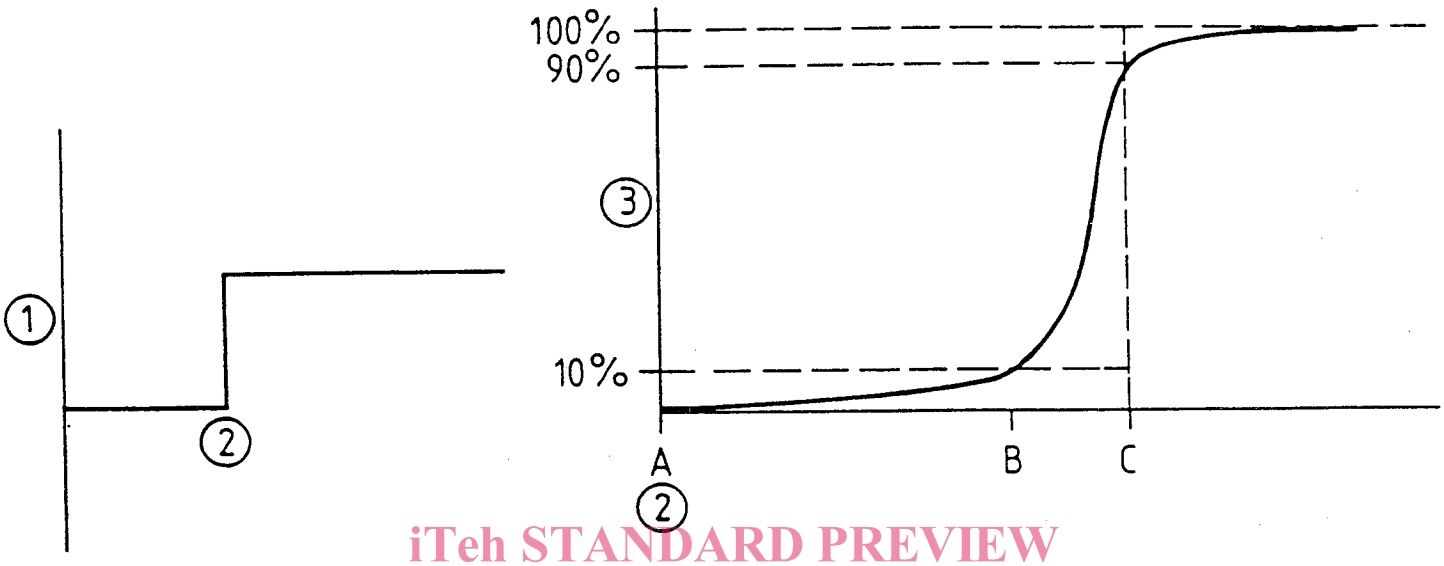
3.9 default setting; default limits: Parameters first active on power up of the device.

3.10 manufacturer's default setting; manufacturer's default limits: Parameters first active on power up of the device as configured by the manufacturer or distributor.

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 displayed by the capnometer (time A-B in figure 101).

3.12 display: Visual representation of output data.

3.13 diverting capnometer; side stream capnometer: Capnometer which transports a portion of the respired gases from the sampling site, through a sampling tube, to the sensor.



1. Input
2. Time 0
3. Response

Figure 101: Response time (total system response)

3.14 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.

3.15 non-diverting capnometer; non-side stream capnometer: Capnometer that does not transport gas away from the sampling site.

3.16 oxygen level: Concentration of oxygen expressed in % (V/V) or the partial pressure in kPa (or mm Hg) in a gaseous mixture.

3.17 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.

3.18 STPD (Standard Temperature and Pressure Dry): Conditions of 273 K, ambient pressure 760 mm Hg (101,3 kPa), no steam.

3.19 BTPS (Body Temperature and Pressure, saturated): Conditions of 37 °C or 310 K, ambient pressure 750 mm Hg, 100 % humidity.

3.20 ATPS (Ambient Temperature and Pressure saturated): Conditions of 21 °C or 294 K, 750 mm Hg, 100 % humidity.

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

3.22 rise time: Time required to achieve a rise from 10 % to 90 % of final CO_2 value displayed by the capnometer when a step function change in CO_2 concentration or partial pressure occurs at the sampling site (segment B-C in figure 101).

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.

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

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

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

3.27 total system response time: Sum of the delay time and rise time (segment A-C in figure 101).

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.

3.29 (carbon dioxide gas) transducer: Device for converting the carbon dioxide partial pressure or concentration into a signal for monitoring or recording.

4 General requirements and general requirements for test

4.1 Modifications to clause 3 of EN 60601-1:1990

Clause 3 of EN 60601-1 : 1990 applies with the following additions:

3.1 Add the following to 3.1:

Packaging of equipment shall be of sufficient strength to ensure integrity of the equipment during storage and transport.

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

3.6 Add the following items:

3.6 aa) Applicable single fault conditions are:

- short and open circuits of components or wiring which can:
    - cause sparks to occur; or
    - increase the energy of sparks; or
    - increase temperature (see section 7);
- incorrect output resulting from software errors

3.6 bb) R An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

4.2 Modification to clause 4 of EN 60601-1:1990

Clause 4 of EN 60601-1:1990 applies with the following addition:

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

5 Classification

Clause 5 of EN 60601-1 : 1990 applies.