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Standard Specification for Capnometers¹

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INTRODUCTION

The measurement of carbon dioxide in a gaseous mixture has become a common practice in many areas of clinical medicine, such as anesthesia, respiratory therapy, pediatrics, and intensive care. This draft specification establishes minimum safety and performance requirements for capnometers based on parameters that are achievable within the limits of existing technology.

Appendix X1 contains a rationale for the most important requirements. It is included to provide additional insight for the reasoning that led to the requirements and recommendations that have been incorporated into this draft specification.

This draft specification references IEC 601-1:1988 (hereafter referred to as the General Standard) for many of the general requirements for safety. Requirements specific to capnometers begin at Clause 60.

1. Scope

1.1 The scope given in Clause 1 of the General Standard applies except that 1.1 shall be replaced by the following:

1.1.1 This specification specifies requirements for the safety and performance of capnometers as defined in Subclause 3.5. It applies to capnometers used with adults, children, and neonates.

1.1.2 It does not apply to devices solely intended for use as cutaneous monitors.

1.1.3 Capnometers intended for use in laboratory research applications are outside the scope of this specification.

2. Referenced Documents

2.1 The following standards contain provisions which, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

2.2 ASTM Standards:

F 1054 Specification for Conical Fittings of 15 mm and 22 mm sizes²

F 1463 Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care³

2.3 ISO Standards:³

ISO 32:1977 Gas Cylinders for Medical Use—Marking for Identification of Contents

ISO 5356/1:1987 Anaesthetic and Respiratory Equipment—Connectors, Part I: Cones and Sockets

ISO 5356/2:1987 Anaesthetic and Respiratory Equipment—Connectors, Part II: Screw-Threaded-Weight-Bearing Connectors

ISO 7249 Controls—Terms, Suitability, Design Requirements

ISO 7250 Basic List of Anthropomorphic Measurements

2.4 IEC Standards:³

IEC 65:1985 Safety Requirements for Mains Operated Electronic and Related Apparatus for Household and Similar Use

IEC 79-3:1972 Electrical Apparatus for Explosive Atmospheres—Part III: Spark Test Apparatus for Intrinsically Safe Units

IEC 79-4:1975 Electrical Apparatus for Explosive Gas Atmospheres—Part IV: Method of Test for Ignition Temperature

IEC 601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements

IEC 801-2:1991 Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment—Part 2: Electrostatic Discharge Requirements

3. Terminology

3.1 **Definitions**—For the purposes of this specification, the definitions given in Clause 2 of the General Standard apply, along with the following definitions:

3.1.1 **accuracy**—the quality that characterizes the ability of a device to give indications approximating to the true value of

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² *Annual Book of ASTM Standards*, Vol 13.01.

³ Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

the quantity measured.

3.1.2 *alarm*—a warning signal.

3.1.3 *alarm set point*—the setting of the adjustment control, or display value, which indicates the carbon dioxide reading, at or beyond which the alarm is intended to be activated.

3.1.3.1 *Discussion*—Terms such as “alarm limits” or “alarm threshold” are frequently used to describe the same function.

3.1.4 *alarm system*—those parts of the capnometer which: (1) establish the alarm set point(s); and (2) 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.

3.1.5 *capnometer*—a device for the measurement of carbon dioxide concentration or partial pressure in ventilatory gases.

3.1.5.1 *Discussion*—The capnometer consists of all equipment including accessories, sensor, and sampling tubing (if a diverting capnometer) specified by the manufacturer for the intended use of the capnometer.

3.1.6 *carbon dioxide level*—the concentration of carbon dioxide in gaseous mixture.

3.1.6.1 *Discussion*—This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mm Hg).

3.1.7 *carbon dioxide reading*—the measured carbon dioxide level as indicated by the capnometer display.

3.1.8 *cutaneous oxygen and carbon dioxide partial pressure monitoring equipment*—equipment or associated transducers, or both, for the monitoring or recording, or both, of partial pressures of oxygen and carbon dioxide at the skin surface.

3.1.9 *delay time*—the 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 (see Fig. 1).

3.1.10 *display*—the visual representative of output data.

3.1.11 *diverting capnometer*—a capnometer that transports a portion of respired gases from the sampling site through a sampling tube to the sensor, which is remote from the patient.

3.1.12 *high-priority alarm*—an indication of danger and meaning that immediate action on the part of the operator is required.

3.1.13 *interference with measurement accuracy*—the difference between the carbon dioxide reading in the presence of an interfering gas mixture and the carbon dioxide reading in a corresponding mixture in which the interfering gas or vapor fraction has been replaced by nitrogen.

3.1.14 *low-priority alarm*—an indication of a condition that

requires awareness on the part of the operator, but not necessarily action.

3.1.15 *medium-priority alarm*—an indication meaning that prompt action on the part of the operator is required.

3.1.16 *non-diverting capnometer*—a capnometer that uses a sensor at the sampling site.

3.1.17 *oxygen level*—the concentration of oxygen in a gaseous mixture.

3.1.17.1 *Discussion*—This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mm Hg).

3.1.18 *partial pressure*—the pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature.

3.1.19 *percent (%) v/v carbon dioxide (or other gases)*—the level of carbon dioxide (or other gas) in a mixture, expressed as a percent volume fraction.

3.1.20 *rise time*—the time required to achieve a rise from 10 to 90 % of the final CO₂ value in the capnometer when a step function change in CO₂ concentration or partial pressure occurs at the sampling site (see Fig. 1).

3.1.21 *sampling site*—the 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.

3.1.22 *sampling tubing*—the conduit for transfer of respiratory gases from the sampling site to the sensor in a diverting capnometer.

3.1.23 *sensor*—the part of the capnometer that is sensitive to the presence of carbon dioxide.

3.1.24 *sensor area*—the part of the sensor at which carbon dioxide is detected.

3.1.25 *total system response time*—the sum of the delay time and the rise time (see Fig. 1).

3.1.26 *transducer*—a device for converting the partial pressure or concentration of a gas into a signal for monitoring or recording.

4. Relationship of This Specification to the General Standard

Section One—General

	(A)	(NA)	(AM/R) ⁴
1. Scope and object			X
2. Terminology and definitions			X
3. General requirements			X
4. General requirements for tests			X
5. Classification	X		
6. Identification, marking and documents			X
7. Power input	X		

Section Two—Environmental Conditions

8. Basic safety requirements (not used)	
9. Removable protective means (not used)	
10. Environmental conditions	X
11. Special measures with respect to safety (not used)	
12. SINGLE FAULT CONDITION (not used)	

Section Three—Protection Against Electric Shock Hazards

13. General	X
14. Requirements related to classification	X
15. Limitation of voltage and/or energy	X

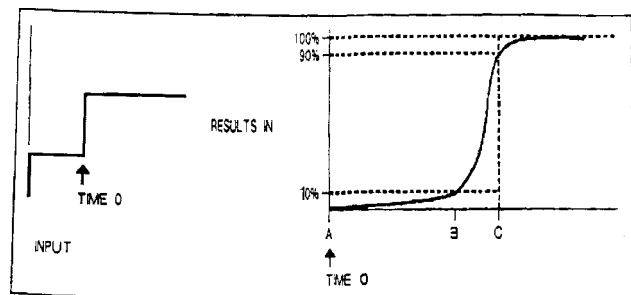


FIG. 1 Response Time (Total System Response)

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16. Enclosures and PROTECTIVE COVERS	X	
17. Separation	X	
18. Protective earthing, functional earthing, and potential equalization	X	
19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		X
20. Dielectric strength	X	

Section Four—Protection Against Mechanical Hazard

21. Mechanical strength		X
22. Moving parts	X	
23. Surfaces, corners, and edges	X	
24. Stability in NORMAL USE	X	
25. Expelled parts	X	
26. Vibration and noise (not used)		
27. Pneumatic and hydraulic power	X	
28. Suspended masses	X	

Section Five—Protection Against Hazards from Unwanted or Excessive Radiation

29. X-radiation	X	
30. Alpha, beta, gamma, neutron radiation and other particle radiation	X	
31. Microwave radiation	X	
32. Light radiation (including lasers)	X	
33. Infra-red radiation	X	
34. Ultra-violet radiation	X	
35. Acoustical energy (including ultrasonics)	X	
36. Electromagnetic compatibility		X

Section Six—Protection Against Hazards of Ignition of Flammable Anaesthetic Mixtures

37. General	X	
38. Marking, ACCOMPANYING DOCUMENTS	X	
39. Common requirements for Category AP and Category APG EQUIPMENT	X	
40. Requirements and tests for Category AP EQUIPMENT, parts or components thereof	X	
41. Requirements and tests for Category APG EQUIPMENT, parts or components thereof	X	

Section Seven—Protection Against Excessive Temperatures and Other Safety Hazards

42. Excessive temperatures	X	
43. Fire prevention		X
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection		X
45. Pressure vessels and parts subject to pressure	X	
46. Human errors		X
47. Electrostatic charges	X	
48. Materials in APPLIED PARTS in contact with the body of the PATIENT	X	
49. Interruption of the power supply	X	

Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output

50. Accuracy of operating data (not used)		
51. Protection against hazardous output		X

Section Nine—Abnormal Operation and Fault Conditions; Environmental Tests

52. Abnormal operation and fault conditions	X	
53. Environmental tests	X	

Section Ten—Constructional Requirements

54. General	X	
55. ENCLOSURES and covers	X	
56. Components and general assembly	X	
57. MAIN PARTS, components and layout	X	
58. Protective earthing—terminals and connections	X	
59. Construction and layout	X	

Additional Clauses

60. Interfering gas and vapor effects other than water vapor	X	
61. Sustained pressure	X	
62. Gas leakage and sampling loss	X	
63. Connectors	X	

^A A = applies, NA = not applicable, and AM/R = applies with an amendment, addition, or revision to the requirement in the General Standard.

5. Clauses Containing Amendments, Additions, or Replacements to the Text in IEC 601-1:1988

NOTE 1—The clause numbers used reference the specific section in the General Standard.

4. *General Requirements and General Requirements for Tests*—Clauses 3 and 4 of the General Standard apply together with the following additions:

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

4.13 Components of the capnometer should be made of materials that are compatible with the gases and agents with which those components are designed to come into contact.

6. *Identification, Marking, and Documents*—The requirements given in Clause 6 of the General Standard apply together with the following additions and modifications:

(1) In the preamble to Clause 6, replace the first item under “clearly legible” by the following:

Warning statements, instructive statements, or drawings: affixed in a permanent location and legible to a user with a visual acuity of 1.0 (corrected if necessary) from a distance of 1 m at an illuminance level of 215 lx.

(2) 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, and Symbol 14 in Table D1 of the General Standard.

(3) In 6.1, add the following to item (f): a serial number or other lot or batch identifier.

(4) In 6.1, add the following to item (q): the words “not for use in breathing systems,” if applicable.

(5) In 6.1, add additional items as follows:

(zz) Marking on the capnometer shall additionally include the following:

(a) For capnometers not for use with inhalational anesthetic agents, the phrase “not for use with inhalation anesthetic agents,” if applicable.

(b) If moisture has an adverse effect on performance, either a statement that the operator or user shall see the accompanying documents for the effect of moisture on accuracy, or Symbol 14 in Table D1.

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

(d) *Other Sources of Interference*—The manufacturer shall mark the device with a warning to refer to the accompanying documents or Symbol 14 in Table D1 of the General Standard for the expected adverse effects on the performance of the capnometer when exposed to electrocautery, electrosurgery,