Designation: F 1456 – 01

Standard Specification for Minimum Performance and Safety Requirements for Capnometers[1]

This standard is issued under the fixed designation F 1456; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The measurement of carbon dioxide in a gaseous mixture has become a common practice in many areas of clinical medicine, such as anesthesia, pediatrics, respiratory care, and intensive care. This 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 specification.

This specification uses IEC 601-1:1988 including Amendment 1 and 2 (hereafter called the General Standard) for many of the general requirements for safety. Additional requirements specific to capnometers begin at Clause 60.

SECTION ONE—GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1. Scope

1.1 This clause of the General Standard applies except as follows:

1.1.1 This specification applies to capnometers for use with adults, children, and neonates.

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

1.1.3 It does not apply to devices intended for use in laboratory research applications or nonhuman applications.

1.1.4 This specification does not apply to capnometers intended for use with flammable anesthetic mixtures.

1.1.5 This specification does not apply to devices that are intended for use in single-breath, spot-check, or noncontinuous monitoring applications.

2. Referenced Documents

2.1 The following standards contain provisions, which through reference in this specification constitute provisions of this specification. At the time of publication of this specification, the editions indicated were current. All standards are subject to revision, and parties using this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed as follows.

2.2 *ASTM Standards:*

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes[2]

F 1463 Specification for Alarm Signals in Medical Equipment Used in Anethesia and Respiratory Care[2]

2.3 *IEC Standards:*

IEC 60079-4:1975 Electrical Apparatus for Explosive Gas Atmospheres—Part 4: Method of Test for Ignition Temperature[3]

IEC 60601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements Including Amendment 1 and Amendment 2[3]

IEC 60601-1-2:1992 Medical Electrical Equipment: Collateral Requirements Electromagnetic Compatibility[3]

2.4 *ISO Standards:*

ISO 4135:1995 Anaesthesiology—Vocabulary[3]

ISO 7000-1989 Graphical Symbols for Use on Equipment-Index and Synopsis[3]

ISO 7504:1984 Gas Analysis—Vocabulary[3]

2.5 *Other Standards:*

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.11 on Gas Monitors.

Current edition approved April 10, 2001. Published December 2001. Originally published as F 1456 – 92. Last previous edition F 1456 – 92.

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

[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

This document is now PUBLIC

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States.