



Designation: F 1456 – 9201

An American National Standard

## Standard Specification for Minimum Performance and Safety Requirements for Capnometers<sup>1</sup>

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, ~~respiratory therapy~~, pediatrics, ~~respiratory care~~, 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~~ uses IEC 601-1:1988 including Amendment 1 and 2 (hereafter referred to as called the General Standard) for many of the general requirements for safety. ~~R~~ 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 The scope given in Clause 1~~

1.1 This clause of the General Standard applies except that 1.1 shall be replaced by the following as follows:

1.1.1 This specification ~~specifies requirements for the safety and performance of capnometers as defined in Subclause 3.5.~~ It applies to capnometers for used 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 Capnometers~~

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 outside the scope of this specification.~~ 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 ~~text~~, specification constitute provisions of this specification. At the time of publication of this specification, the editions indicated were ~~valid~~, current. All standards are subject to revision, and parties ~~to agreements based on~~ using this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed ~~below~~, as follows.

2.2 *ASTM Standards:*

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee ~~F29.03 on Division Three on Ventilators and Ancillary Devices~~, F29.11 on Gas Monitors.

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