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# Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components[1]

This standard is issued under the fixed designation F 1850; 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

This specification covers minimum safety requirements for an ANESTHESIA WORKSTATION. It applies in addition to IEC Publication 601-1 (ed. 2 1988),[2] hereafter called the GENERAL STANDARD, and to IEC 601-1-1:1992[2] as amended, hereafter called the SYSTEMS STANDARD.

It is recognized that from time to time innovations and designs will appear that offer advantages and yet are not covered by specific safety related design or performance aspects of this specification; such innovations are not to be discouraged. If the techniques and technologies in these innovations advance beyond those described in this specification, then they must meet the safety objectives of this specification.

This specification also describes referee test methods necessary to ensure compliance with the performance and safety requirements described herein. While qualification test procedures to determine compliance are described and specified, equivalent or superior qualification test procedures to determine compliance with the requirements may be used.

## SECTION ONE—GENERAL

### 1. Scope

This clause of the GENERAL STANDARD applies with the following amendment:

**1.5** This specification presents particular requirements for an ANESTHESIA WORKSTATION when supplied as a complete unit, as well as particular requirements for individual devices which together make up a complete ANESTHESIA WORKSTATION.

It is the intent of this specification that both complete ANESTHESIA WORKSTATIONS and the individual devices be commercially available to allow USERS to configure an ANESTHESIA WORKSTATION to meet the needs of their clinical practice in conformance with their national regulations or guidelines, or both. To this end the standard has been structured in such a way as to clearly identify particular requirements pertinent to specific devices currently available.

NOTE 1—Although this specification does not mandate the use of a single communication protocol, the purpose of digital data communication in this specification is to facilitate transfer of data between devices. Possible uses of data from multiple sources include integrated data display and alarm annunciation, and aiding DECISION SUPPORT SYSTEMS. Centralized display integration and functional integration are the hallmarks differentiating this specification from previous anesthesia gas machine standards. Digital communication makes possible integration among workstation devices that may be modular, or interact only through communication interfaces. Documentation and disclosure requirements vary because of expected variations in implementation permitted by the specified standards. Additional documentation requirements are imposed when interface methods not included in the specified DIGITAL INTERFACE standards are encountered.

Equipment that can be used with flammable anesthetic agents, intermittent flow machines, that only deliver gas to the patient at varying rates in response to the patient's inspiratory efforts, and dental nitrous oxide - oxygen machines are not covered by this specification.

1.5.1 *This guide is arranged as follows:*



[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.10 on Anesthesia Workstations.

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