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Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components¹

This standard is issued under the fixed designation F1850; 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 601-1-1:1992² 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:*

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

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2. Terminology

2.1 Clause 2 of the GENERAL STANDARD applies together with ISO 4135² and the following:

2.13 Terminology and Definitions Related to ANESTHESIA WORKSTATIONS

2.13.1 *accuracy*—the quality that characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

2.13.2 *alarm device*—a device that performs the task of annunciating visual or audible alarm signal(s), or both, when an alarm condition is present. Such devices are, for example, the power failure alarm, and oxygen supply failure alarm.

2.13.3 *anesthesia breathing system*—see ISO 4135 (Rev. 1995).

2.13.4 *anesthesia gas supply device*—an assembly of components that controls and delivers all gas flow and agent concentration in the fresh gas into the ANESTHESIA BREATHING SYSTEM. It may include a FLOW ADJUSTMENT CONTROL(s), a GAS MIXING SYSTEM and an ANESTHETIC VAPOR DELIVERY DEVICE(s)

2.13.5 *anesthesia gas supply piping*—all pipe work, including unions, from the UNIDIRECTIONAL VALVE(s) in the pipeline inlet(s), the piping connecting the high pressure supply to the GAS PRESSURE REDUCING DEVICE/SYSTEM, and from the GAS PRESSURE REDUCING DEVICE/SYSTEM outlet to the FLOW ADJUSTMENT CONTROL(s) and auxiliary gas outlets. It includes piping leading to and from pneumatic ALARM DEVICE(s), pressure indicator(s), oxygen flush, ANESTHETIC VAPOR DELIVERY DEVICE(s), and piping leading to the COMMON GAS OUTLET

2.13.6 *anesthetic vapor delivery device*—device where anesthetic agent is transformed from the liquid to the gaseous phase in a controllable concentration.

2.13.7 *anesthesia ventilator*—see ISO 4135 (Rev. 1995).²

2.13.8 *anesthesia workstation*—a system for administration of anesthesia to patients. It consists of the ANESTHESIA GAS SUPPLY DEVICE, ANESTHESIA VENTILATOR, MONITORING DEVICES and PROTECTION DEVICE(s).

2.13.9 *applied part*—for the purpose of this specification, the APPLIED PART is the COMMON GAS OUTLET (Fresh Gas Outlet) and other parts of the ANESTHESIA WORKSTATION intended to be connected with the patient or with the anesthesia breathing system.

2.13.10 *auxiliary oxygen flowmeter*—a self-contained oxygen flowmeter with its own FLOW ADJUSTMENT CONTROL, FLOW INDICATOR, and outlet, not ordinarily used during the administration of general anesthesia.

2.13.11 *bias*—a constant or systematic error as opposed to a random error. It manifests itself as a persistent positive or negative deviation of the method average from the accepted reference value.

2.13.12 *common gas outlet (fresh gas outlet)*—that port through which the dispensed mixture from the ANESTHESIA GAS SUPPLY DEVICE is delivered to the ANESTHESIA BREATHING SYSTEM.

2.13.13 *delivery system device*—a system/device used as part of an ANESTHESIA WORKSTATION that delivers energy or substances to the patient.

2.13.14 *flow adjustment control*—a device or assembly that controls the flow of gas(es), or gas mixtures.

2.13.15 *flow indicator*—a device that indicates the volume of a specific gas or gas mixture passing through it in a unit of time.

2.13.16 *gas mixing system*—a device or assembly that receives oxygen and other medical gas(es) and delivers a mixture of these gases in controllable concentrations.

2.13.17 *gas pressure reducing device/system*—a single device, or group of devices designed to provide a range of controlled delivery pressure over a specified range of inlet pressures.

2.13.18 *infusion device(s)*—mechanical and electromechanical devices intended to regulate the flow of liquids (parenteral fluids, drugs, and routine fluids) to the patient under positive pressure generated either by a pump, or by gravitational force.

2.13.19 *legible*—displayed qualitative or quantitative information, values, functions, and/or markings shall be discernible or identifiable to an OPERATOR with 6-6 (20/20) vision (corrected if necessary) from a distance of 1 m at a light level of 215 lux, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the normal line of sight of the OPERATOR.

2.13.20 *medical gas pipeline system*—the complete system that comprises a central supply system with control equipment, a pipeline distribution system and terminal units at the points where non-flammable medical gases may be delivered.

2.13.21 *monitoring device*—a device that performs the task of indicating the value of a measured variable to the OPERATOR. Such devices are for example, the airway pressure monitor or the exhaled volume monitor.

2.13.22 *operator*—the clinician (for example anesthesiologist).

2.13.23 *peep (positive end expiratory pressure)*—the positive pressure within the airway at the end of expiratory flow.

2.13.24 *precision*—the quality that characterizes the ability of a device to give for the same value of the quantity measured, indications that agree amongst themselves, not taking into consideration the systematic errors associated with variations of the indications

2.13.25 *protection device(s)*—a device that, without intervention of the OPERATOR, performs the task of protecting the patient from hazardous output due to incorrect delivery of energy or substances. Such devices are for example, the oxygen supply failure device or the maximum pressure limitation device.

2.13.26 *reserve electrical power supply*—that portion of the equipment that supplies temporary power to the electrical system in the event of interruption of the normal electrical supply.

2.13.27 *user*—the owner of the ANESTHESIA WORKSTATION (for example, hospital).

2.14 Terminology and Definitions Related to Alarms (see Clause 51)

2.14.1 *disable*—to prevent an otherwise enabling condition from initiating a function.

2.14.1.1 *Discussion*—For the purpose of this specification, to **DISABLE** an alarm means to prevent the annunciation of the auditory alarm signal. Optionally, the visual component may be prevented.

2.14.2 *high priority alarm*—a signal that indicates a condition requiring immediate action.

2.14.3 *low priority alarm*—a signal that indicates a condition that requires **OPERATOR** awareness, but not necessarily action.

2.14.4 *medium priority alarm*—a signal that indicates a condition requiring prompt action.

2.14.5 *silencing*—to temporarily stop the annunciation of an audible alarm.

2.15 Terminology and Definitions Related to AARK's (Automated Anesthesia Record Keepers)

2.15.1 *artifact*—data that is not a true representation of the patient condition.

2.15.2 *back-up*—an electronic copy of an anesthetic record or collection of anesthetic records made for the purpose of securing the data for retrieval at a later time.

2.15.3 *editing*—changing a recorded value, comment, annotation, or event in the anesthetic record, whether stored automatically or entered manually, at any time after it has been made part of the record.

2.15.4 *input device*—a device connected to the AARK that is used to manually enter data or control the AARK. These may include, but are not limited to, keyboards, mice, trackballs, light-pens, bar code scanners, microphones, etc.

2.15.5 *network*—the connection between the AARK and another computer or another AARK, or both, for the purpose of transferring data.

2.15.6 *non-volatile*—stored electronically in such a way that the loss of all electric power (normal and reserve) to the system or storage device will not alter the data stored on the media.

2.15.7 *output devices*—a device that presents data from a computer system to an **OPERATOR** or **USER** for viewing or storage. Examples include printers and screens.

2.15.8 *recorded data*—captured data that is stored by the AARK.

2.16 Terminology and Definitions Related to Digital Communication and Information Systems

2.16.1 *control center (of an anesthesia workstation)*—the **INFORMATION SYSTEM** component of an **ANESTHESIA WORKSTATION** mediating the centralized alarm prioritization and management strategy, and possibly other functions.

2.16.2 *decision support system*—an **INFORMATION SYSTEM** intended to automatically process data from one or more sources, providing output information to assist the **OPERATOR**.

2.16.3 *digital interface*—hardware and protocol supporting bidirectional digital serial data communication complying with one of the following published data communication standards (see also Clause 85, Annex A, and Appendix B):

- A. RS-232.³
- B. IEEE 1073.⁴

2.16.4 *IEEE 1073*—Serial digital data communication complying with the signal characteristics, transport, protocol, and data formats defined by members of the IEEE 1073⁴ family of standards. These standards are also widely known by the names **MIB**, or medical information bus.

2.16.5 *information system*—a digital system collecting, displaying, or processing information from other **PRIMARY** or **SECONDARY DATA SOURCES**. Digital data may be transferred through **DIGITAL INTERFACES** or **NETWORKS**. Examples include AARK's and **DECISION SUPPORT SYSTEMS**.

2.16.6 *network*—a connection between digital systems (computers or AARK's) for transmission of data over a communication medium using a common protocol.

2.16.7 *operator input*—data provided by various interactions of the **OPERATOR** with the **ANESTHESIA WORKSTATION** controls or record keeping components that can be stored and transmitted in digital form.

2.16.8 *primary data source*—a **MONITORING DEVICE** or **DELIVERY DEVICE** providing functional or measured data via **DIGITAL INTERFACES** or **OPERATOR INPUT**.

2.16.9 *RS-232*³—serial digital data communication complying with the electrical characteristics and cable connectors defined by EIA/TIA standard RS-232-C-1969³ or its successors (EIA/TIA-232-D-1987, EIA/TIA-232-E-1991³).

2.16.10 *secondary data source*—an **INFORMATION SYSTEM** that re-transmits data collected from **PRIMARY DATA SOURCES** and other **SECONDARY DATA SOURCES**. A **SECONDARY DATA SOURCE** may have modular **PRIMARY DATA SOURCES** as components. Digital data may be primary or secondary due to origination either from within a **MULTIPOINT COMMUNICATION DEVICE** or another digital source.

³ Available from EIA/TIA, Electronics Industries Association/Telecommunications Industry Association, 2500 Wilson Blvd., Arlington, VA 22201.

⁴ Available from IEEE, Institute of Electrical and Electronics Engineers, 445 Hoes Ln., PO Box 1331, Piscataway, NJ 08854-1331.

3. General Requirements

Clause 3 of the GENERAL STANDARD applies with the following additions:

Additions:

3.6j) Applicable single fault conditions are short and open circuits of components or wiring that can increase temperatures. (See SECTION SEVEN.)

3.6 k An oxidant leak which is not detected by an ALARM DEVICE or inspection procedures recommended by the manufacturer shall be considered a normal condition and not a single fault condition.

Test for compliance by simulation of a single fault condition.

4. General Requirements for Tests

Clause 4 of the GENERAL STANDARD applies with the following addition:

Addition:

4.12 Type testing of components of ANESTHESIA WORKSTATIONS

For type testing components of the ANESTHESIA WORKSTATION the requirements of the appropriate section(s), of this specification, including the referenced additional standards as stated in the appropriate section, apply. The manufacturer of components for ANESTHESIA WORKSTATIONS shall specify in the instructions for use the ANESTHESIA WORKSTATION(S) configuration(s) for which the compatibility and compliance with this specification have been established.

The manufacturer may use type tests different from those detailed within this specification, if an equivalent degree of safety is obtained.

5. Classification

Clause 5 of the GENERAL STANDARD applies.

6. Identification, Marking and Documents

Clause 6 of the GENERAL STANDARD applies with the following additions and amendments:

Amendment:

6.1j) R The input marking required in Sub-clause 6.1j of the GENERAL STANDARD shall be given in amperes for the ANESTHESIA WORKSTATION and for the sum of the allowed maximum current ratings for the ANESTHESIA WORKSTATION and the auxiliary mains socket outlets.

Amendment:

6.1k) R The requirement on marking of auxiliary mains socket outlets of Sub-clause 6.1k in the GENERAL STANDARD shall apply to each auxiliary mains socket outlet and shall be given in amperes.

NOTE 2—Marking should be provided to indicate the location of fuses or overcurrent release for the auxiliary mains socket outlet(s).

Auxiliary mains socket outlet(s) shall be marked with a warning to the effect that:

Equipment connected to auxiliary mains socket outlets must comply with IEC 601-1-1² and the total sum of the system leakage current shall not exceed 300 microamps (See Clause 19.4h). It is the USER'S responsibility to ensure compliance

with the above standard and that the leakage current limits are not exceeded.

Additional Clauses:

6.1 aa) Device packaging or labeling, or both, shall distinguish between identical or similar products in both the sterile and non-sterile state from the same manufacturer.

6.1 bb) Each gas specific inlet shall be durably marked with either the gas name or chemical symbol in accordance with CGA V-5.⁵ This marking shall be LEGIBLE, and if color coding is used, it shall be in accordance with CGA C-9.⁵ (See Table 1.)

6.1 cc) The COMMON GAS OUTLET (Fresh Gas Outlet), if OPERATOR accessible, shall be durably marked. This marking shall be LEGIBLE.

6.1 dd) Controls for gas flow or agent output shall be durably marked with a LEGIBLE indication to inform the OPERATOR which action(s) is (are) required to increase/decrease the gas flow or agent output.

6.1 ee) For the ANESTHESIA VENTILATOR, all ports shall be durably marked. These markings shall be LEGIBLE. Symbols may be used, and when symbols are used, they shall be explained in the instructions for use.

6.1 ff) The ANESTHESIA WORKSTATION or its components, or both, shall be durably marked with the rated supply pressure(s) to which the equipment can be connected. These markings shall be LEGIBLE.

6.3g All OPERATOR interchangeable components, including ANESTHESIA VENTILATOR, ANESTHETIC AGENT DELIVERY SYSTEM(s), and recommended accessory components that are flow direction sensitive, and that can be misconnected, shall be durably marked with a LEGIBLE arrow showing the correct direction of flow.

6.3h The auxiliary gas outlet(s), if provided, shall be durably marked with either the gas-name or chemical symbol in accordance with CGA V-5.⁵ This marking shall be LEGIBLE, and if color coding is used, it shall be in accordance with CGA C-9.⁵ (See Table 1.)

6.3j Pressure Indicators All medical gas cylinder and pipeline pressure indicators shall be graduated and marked in units of kPa times 100. The markings and graduations shall be clearly identified with the pressure indicator(s) with which they are associated, and shall be LEGIBLE.

NOTE 3—Pressure indicators additionally may be marked in units of PSIG.

Each gas specific pressure indicator shall be identified by DURABLE and LEGIBLE marking using gas-name or chemical symbol in accordance with CGA V-5.⁵ If color coding is used in addition, it shall be in accordance with CGA C-9.⁵ (See Table 1.)

ANESTHESIA BREATHING SYSTEM pressure indicators shall be graduated and durably marked in units of kPa or cm H₂O, or both. These markings shall be LEGIBLE.

6.3.k FLOW ADJUSTMENT CONTROL(s)

Each FLOW ADJUSTMENT CONTROL or its surroundings shall be identified by a DURABLE and LEGIBLE marking

⁵ Available from CGA, Compressed Gas Association, 1725 Jefferson Davis Hwy., Suite 10004, Arlington, VA 22202-4102.

using gas name or chemical symbol in accordance with CGA V-5.⁵ If color coding is used in addition it shall be in accordance with CGA C-9.⁵ (See [Table 1.](#))

If applicable the point of reference for reading the FLOW INDICATOR shall be readily identifiable with the associated FLOW INDICATOR.

6.3.L ANESTHETIC AGENT DELIVERY DEVICE(s)

The maximum and minimum filling levels shall be marked on the liquid level indicator. These markings shall be DURABLE and LEGIBLE. As an alternative the actual usable volume and capacity shall be displayed.

Each OPERATOR-detachable ANESTHETIC AGENT DELIVERY DEVICE(s) shall be durably marked, either with the words “See Accompanying Documents” or symbol #14 from Table D1 of the GENERAL STANDARD.

If OPERATOR accessible, the agent reservoir or filling port, or both, shall be durably marked with the generic name of the anesthetic agent. The control(s) activating the delivery shall be durably marked, with the generic name in full spelling, or the abbreviated form, of the anesthetic agent being administered, or the same information shall be displayed.

If color coding is used in addition, it shall be in accordance with [Table 2.](#)

The units for which the control of the ANESTHETIC AGENT DELIVERY DEVICE(s) is graduated shall be LEGIBLE and durably marked either on the control or shall be displayed continuously or on OPERATOR demand.

Graduated controls, if provided, shall be marked with “zero” or “off,” or with both if the zero-position is not also the off-position.

6.3m The oxygen flush control shall be located on the front of the equipment, and shall be durably marked with one of the following:

OXYGEN FLUSH

O₂ FLUSH

O₂ +

These markings shall be LEGIBLE. If color coding is used in addition, it shall be in accordance with CGA C-9.⁵ (See [Table 1.](#))

6.8 Accompanying Documents

Clause 6.8 of the GENERAL STANDARD applies with the following additions and or amendments.

Amendment:

6.8.2a Manufacturers/suppliers of complete ANESTHESIA WORKSTATION(s) or ANESTHESIA GAS SUPPLY DEVICE(s) shall provide a listing of the applicable means for monitoring, alarm and protection against hazards from delivery of energy or substances to the patient. These are specified in [Clause 51](#) of this specification and summarized in [Table 3](#). The instructions for use shall state that the ANESTHESIA WORKSTATION or ANESTHESIA GAS SUPPLY DEVICE shall not be operated without the applicable MONITORING, ALARM and PROTECTION DEVICE(s).

Additional Clauses:

6.8.2j) The instructions for use shall describe methods of verifying alarm functions.

6.8.2k) If applicable, the instructions for use shall contain a warning to the effect that:

The connection of equipment to the auxiliary mains socket outlet(s) may increase the leakage currents to values exceeding the allowable limits in the event of a defective protective earth conductor. If multiple pieces of equipment are connected together, and one power cord supplies power, the leakage current of the whole assembled system should be measured.

6.8.2L) Instructions for use shall include testing for correct assembly and connection of each device supplying gas to the equipment and any ANESTHETIC VAPOR DELIVERY DEVICE(s) fitted to the equipment.

6.8.2m) The instructions for use shall include the operating characteristics of any pressure relieving device(s) fitted to the equipment.

6.8.2n) The instructions for use shall include the pressure and flow characteristics of any auxiliary gas outlet(s) when the pipeline supply pressure is 50 + 5 / – 0 psig. The manufacturer shall indicate the effects of variations in pipeline supply pressures on these pressure and flow characteristics.

6.8.2o) The instructions for use shall include the operating characteristics of the oxygen supply failure alarm system(s) and if provided, the associated cut-off devices.

6.8.2p) If the ANESTHESIA GAS SUPPLY DEVICE is fitted with a GAS MIXING SYSTEM, the instructions for use shall specify the leakage from one gas inlet to the other. The instructions for use shall also include the design pressure(s) and the recommended range of flows from the GAS MIXING SYSTEM.

6.8.2q) The instructions for use shall include the recommended service interval.

6.8.2r) If appropriate, the instructions for use shall include the operational characteristics of ANESTHESIA VENTILATOR(s) recommended for use with the ANESTHESIA WORKSTATION, including a pneumatic diagram.

6.8.2s) If appropriate, the instructions for use shall include the operational characteristics of ANESTHESIA BREATHING SYSTEM(s) and anesthetic gas scavenging system(s) recommended for use with the ANESTHESIA WORKSTATION.

6.8.2t) If the ANESTHESIA GAS SUPPLY DEVICE is fitted with an ANESTHETIC VAPOR DELIVERY DEVICE(s) by the manufacturer or it is intended that a recommended ANESTHETIC VAPOR DELIVERY DEVICE(s) is to be fitted according to the instructions for use, the following shall be provided in the instructions for use:

Details of the ANESTHETIC VAPOR DELIVERY DEVICE(s) performance, including the effects of variation in ambient temperature, ambient pressure, tilting, back pressure, input flow and gas mixture composition;

If applicable, a warning that the performance of the ANESTHESIA WORKSTATION or ANESTHETIC VAPOR DELIVERY DEVICE(s), or both, may be degraded if the two are mismatched;

Instructions for the use of any filling device(s) with which the ANESTHETIC VAPOR DELIVERY DEVICE(s) is fitted;

The carrier gas, gas flow(s) and analytical technique recommended for testing the ANESTHETIC VAPOR DELIVERY DEVICE(s).

A statement that the ANESTHETIC VAPOR DELIVERY DEVICE(s) should not be used between  and the first

graduation above zero, if the ANESTHETIC VAPOR DELIVERY DEVICE(s) cannot be calibrated in this range.

If applicable, the volume of agent required to fill the agent reservoir from the minimum to the maximum filling level, and the total capacity.

6.8.2u) The instructions for use shall include information about disinfection or sterilization of reusable components, or both;

6.8.2v) The instructions for use shall include information about the cleanliness and sterility of respiratory gas conducting components upon delivery;

6.8.2w) The manufacturer shall disclose in the instructions for use the minimum detectable exhaled volume, the accuracy of the indicated exhaled volumes and the resolution of the exhaled volume monitor when tested according to method in Clause 51.6.4.2.

6.8.2x) The instructions for use shall include a statement that an alternative means of ventilation should be available whenever the ANESTHESIA WORKSTATION is in use.

6.8.2y) If alarm limits are preset by the manufacturer the limits shall be disclosed in the instructions for use.

6.8.2z) The instructions for use shall include a description of the functioning of the ANESTHESIA WORKSTATION or its individual devices, or both, after an interruption of the mains electrical power and/or a switch-over to a RESERVE ELECTRICAL POWER SUPPLY.

6.8.2aa) The instructions for use shall state the recommended applications (neonatal, pediatric, adult) for the ANESTHESIA VENTILATOR.

6.8.2bb) The manufacturer/supplier of the ANESTHESIA WORKSTATION shall disclose in the instructions for use the location of latex based components.

6.8.2cc) The location and instructions relevant to any filter elements recommended by the manufacturer shall be disclosed in the instructions for use.

6.8.2dd) The instructions for use shall state whether or not the ANESTHESIA WORKSTATION is suitable for use in a magnetic resonance imaging (MRI) environment.

6.8.3 Technical Descriptions

Clause 6.8.3 of the GENERAL STANDARD applies with the following additions.

6.8.3a) Disclosure of accuracies (including BIAS and PRECISION), display resolutions and range of each calibrated control, and for each monitored variable that is displayed.

Disclosure of interdependence of controls, if applicable.

Disclosure of all information necessary to check that an ANESTHESIA WORKSTATION or its devices, or both, is/are installed correctly and is/are in safe and correct working order, and on the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation.

6.8.3b) The manufacturer of the ANESTHESIA VENTILATOR shall include:

A listing of the following:

- (a) Maximum limited pressure, $P_{lim,max}$;
- (b) Range of values to which the maximum working pressure can be set and the means by which the maximum is ensured (for example, pressure cycling, pressure limiting, pressure generation);

(c) A statement whether subatmospheric pressure is available in the expiratory phase,

(d) Minimum (most subatmospheric) limited pressure; and

(e) Range of values to which the minimum (most subatmospheric) working pressure can be set and the means by which the minimum is ensured.

A listing of the ranges of the following parameters:

(a) Cycling pressure,

(b) End-expiratory pressure, and

(c) The limiting pressure and generated pressure shall be listed if a facility for subatmospheric pressure in the expiratory phase is available,

A technical description of the means of triggering shall be provided.

The purpose, type, range and sensing position of all measuring and display devices either incorporated into the ventilator or recommended by the manufacturer.

The internal volume of any breathing attachments or other components or subassemblies recommended by the manufacturer to be placed between the patient connection port and the patient. The manufacturer shall disclose the test method on request.

Details of any restrictions on the location or sequence of components, or both, within the ventilator breathing system for example where such components are flow-direction-sensitive.

7. Power Input:

Clause 7 of the GENERAL STANDARD applies.

SECTION TWO—ENVIRONMENTAL CONDITIONS

8. Basic Safety Categories

Appendix A1.2 of the GENERAL STANDARD applies.

9. Removable Protective Means

Not used, Replaced by subclause 6.1z).

10. Environmental Conditions

Clause 10 of the GENERAL STANDARD applies with the following additions:

10.2.3 Pneumatic Power—The ANESTHESIA GAS SUPPLY DEVICE and ANESTHESIA VENTILATOR shall continue to function within the specified tolerance throughout the specified range of pressure variation.

The time weighted average input flow required by the ANESTHESIA GAS SUPPLY DEVICE and ANESTHESIA VENTILATOR shall not exceed 60 L/min at a pressure of 50 +0/−5 psig measured at the gas inlet connector.

Test for compliance by simulating a pressure variation throughout the range specified by the manufacturer, while confirming that the ANESTHESIA GAS SUPPLY DEVICE and ANESTHESIA VENTILATOR continue to perform according to specification.

11. (Previous Title): Special Measures with Respect to Safety

Not used.

12. (Previous Title): Single Fault Condition

Not used. (Transferred to Sub-Clause 6.1z)



SECTION THREE—PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

13. General

Clause 13 of the GENERAL STANDARD applies.

14. Requirements Related to Classification

Clause 14 of the GENERAL STANDARD applies.

15. Limitation of Voltage and/or Energy

Clause 15 of the GENERAL STANDARD applies.

16. ENCLOSURES and PROTECTIVE COVERS

Clause 16 of the GENERAL STANDARD applies.

17. Separation (Previous Title: Insulation and Protective Impedances)

Clause 17 of the GENERAL STANDARD applies.

18. Protective Earthing, Functional Earthing and Potential Equalization

Clause 18 of the GENERAL STANDARD applies.

19. Continuous Leakage Current and Patient Auxiliary Current

Clause 19 of the GENERAL STANDARD applies with the following amendment:

Amendment:

19.4 h) R Measurement of the patient leakage current.

The patient leakage current shall be measured from all APPLIED PARTS classified as the same type (See clause 14.6 of the GENERAL STANDARD). These parts shall be connected together electrically. Parts connected to the protective earth terminal shall be tested separately.

The leakage current limits specified in AAMI ES-1⁶ apply.

20. Dielectric Strength

Clause 20 of the GENERAL STANDARD applies.

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

21. Mechanical Strength

Clause 21 of the GENERAL STANDARD applies.

22. Moving Parts

Clause 22 of the GENERAL STANDARD applies.

23. Surfaces, Corners, and Edges

Clause 23 of the GENERAL STANDARD applies.

24. Stability in NORMAL USE

Clause 24 of the GENERAL STANDARD applies with the following addition.

Addition:

⁶ Available from AAMI, Association for Advancement of Medical Instrumentations, 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201-4795.

The manufacturer shall specify any weight limits or placement restrictions, or both, under which Clause 24 of the GENERAL STANDARD is met.

25. Expelled Parts

Clause 25 of the GENERAL STANDARD applies.

26. Vibration and Noise

Not used.

27. Pneumatic and Hydraulic Power

Under consideration.

28. Suspended Masses

Clause 28 of the GENERAL STANDARD applies.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29. X-Radiation

Clause 29 of the GENERAL STANDARD applies.

30. Alpha, Beta, Gamma, Neutron Radiation and Other Particle Radiation

Under consideration.

31. Microwave Radiation

Under consideration.

32. Light Radiation (Including Lasers)

Under consideration.

33. Infra-Red Radiation

Under consideration.

34. Ultra-Violet Radiation

Under consideration.

35. Acoustical Energy (Including Ultrasonics)

Under consideration.

36. Electromagnetic Compatibility

The requirements in Clause 36 of the GENERAL STANDARD apply with the following additions.

Additions:

36.1 IEC 601-1-2² applies with the following additions:

Addition:

36.2 Clause 36 of IEC 601-1-2² applies with the following addition:

If an anomaly occurs, such as display interrupt, alarm activation, etc., it shall be possible to restore normal operation within 30 s after the electrostatic discharges have been applied. (SILENCING of an activated alarm shall not be considered a failure.)

SECTION SIX — PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE MIXTURES

37. Locations and Basic Requirements

R This clause of the GENERAL STANDARD does not apply.



38. Marking and Accompanying Documents

R This clause of the GENERAL STANDARD does not apply

39. Common Requirements for CATEGORY AP and CATEGORY EQUIPMENT

R This clause of the GENERAL STANDARD does not apply

40. Requirements and Tests for CATEGORY AP EQUIPMENT, Parts and Components Thereof

R This clause of the GENERAL STANDARD does not apply

41. Requirements and Test for CATEGORY APG EQUIPMENT, Parts and Components Thereof

R This clause of the GENERAL STANDARD does not apply

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES, AND OTHER SAFETY HAZARDS

42. Excessive Temperatures

Clause 42 of the GENERAL STANDARD applies.

43. Fire Prevention

Clause 43 of the GENERAL STANDARD applies with the following additions:

43.1 RIn order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault condition, shall not at the same time be subjected to conditions in which:

The temperature of the material is raised to its minimum ignition temperature, and

An oxidant is present.

The minimum ignition temperature is determined in accordance with IEC 79-4² using the oxidizing conditions present under normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under normal and single fault condition.

If sparking can occur under normal or single fault condition(s), the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavorable combination of normal condition(s) with a single fault.

44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

Clause 44 of the GENERAL STANDARD applies with the following additions:

Additions:

44.3 The ANESTHESIA WORKSTATION and its components shall be so constructed that spillage does not wet component parts which when wetted can cause a safety hazard.

Test for Compliance

Test in accordance with Clause 44.3 of the GENERAL STANDARD.

44.7 All components not specified by the manufacturer as single patient use, which come into contact with exhaled patient gas that may be rebreathed, shall be capable of being sterilized or disinfected unless means are provided for bacterial/viral filtration between the components and the patient.

Verify by visual inspection of the accompanying documents.

45. Pressure Vessels and Parts Subject to PRESSURE

Clause 45 of the GENERAL STANDARD applies.

46. Human Errors

Clause 46 of the General Standard applies with the following addition:

NOTE 4—In order to minimize OPERATOR errors and consider human factors in the design of ANESTHESIA WORKSTATIONS, monitors and controls that merit the OPERATOR's close attention should be arranged close to the OPERATOR's line of sight when observing the patient. It is also recommended that the contents of AAMI HE-48⁶ be reviewed. While general guidance may be obtained from AAMI HE-48⁶, the involvement in the device's design of individuals with human factors expertise is strongly urged.

47. Electrostatic Charges

Not used.

48. Materials in APPLIED PARTS in Contact with the Body of the Patient

Not used.

49. Interruption of the Power Supply

Clause 49 of the GENERAL STANDARD applies with the following additions:

Additions:

49.5RMeans shall be provided to ensure continuous fresh gas flow and automatic ventilation during an interruption of the mains electrical power up to 30 min in duration.

49.6R There shall be at least a LOW PRIORITY ALARM when there is an automatic switch over to a RESERVE ELECTRICAL POWER SUPPLY. This alarm shall not be capable of being disabled.

49.7RWhen the RESERVE ELECTRICAL POWER SUPPLY reaches a level specified by the manufacturer to be such that failure of the RESERVE ELECTRICAL POWER SUPPLY is imminent, there shall be a MEDIUM PRIORITY ALARM. This alarm shall not be capable of being disabled.

49.8RThere shall be a means for the OPERATOR to determine that the output of the RESERVE ELECTRICAL POWER SUPPLY is within the manufacturer's specified range.

Tests for Compliance:

49.5.1 Verify by functional testing according to the manufacturer's instructions.

49.6.1 Verify that a LOW PRIORITY ALARM is activated upon the automatic switch over to the RESERVE ELECTRICAL POWER SUPPLY, and that this alarm cannot be disabled.

49.7.1 Verify by functional testing according to the manufacturer's instructions, that the *MEDIUM PRIORITY ALARM* is activated, and that this alarm cannot be disabled.

49.8.1 Verify by visual inspection.

SECTION EIGHT—ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

50. Accuracy of Operating Data

Clause 50 of the GENERAL STANDARD applies.

51. Protection Against Hazardous Output

Clause 51 of the GENERAL STANDARD applies with the following additions:

Additions:

51.5 The particular requirements of MONITORING, ALARM, and PROTECTION DEVICE(s) apply when the ANESTHESIA WORKSTATION is under normal power supply condition.

51.6 Each ANESTHESIA WORKSTATION or individual DELIVERY SYSTEM/DEVICE intended for use in a ANESTHESIA WORKSTATION shall either:

(a) Be provided with MONITORING, ALARM and PROTECTION DEVICE(s) specified in this specification, or,

(b) If such devices are not provided with the ANESTHESIA WORKSTATION, the manufacturer of the individual DELIVERY SYSTEM/DEVICE shall provide information about the MONITORING, ALARM and PROTECTION devices required.

Test for compliance by examination of the ANESTHESIA WORKSTATION, or by examination of the accompanying documents of the individual device(s) or system(s).

NOTE 5—The particular requirements for these PROTECTION DEVICE(s) are specified in Clause 51 of this specification. A tabulation of the different DELIVERY SYSTEM/DEVICE(s) and their associated MONITORING, ALARM and PROTECTION DEVICE(s) is summarized in Table 3.

NOTE 6—National or regional regulatory bodies may determine which PROTECTION DEVICE(s) shall be used with specific delivery devices in addition to the essential ones listed in this specification.

51.7 ALARM DEVICES

51.7.1 ALARM DEVICE(S) specified in this specification shall be grouped into one or more of three categories—HIGH PRIORITY, MEDIUM PRIORITY, LOW PRIORITY. These alarms shall comply with the requirements of Specification F1463.

NOTE 7—The audible alarm signals should allow DISABLING by the OPERATOR during the administration of anesthesia, and should be capable of being disabled until the ANESTHESIA WORKSTATION is connected to the patient in order to prevent nuisance alarms unless otherwise specified by this standard.

51.7.2 If an alarm can be disabled by the OPERATOR, there shall be a visual indication that it has been disabled.

51.7.3 Audible alarm SILENCING by the OPERATOR shall not prevent the audible alarm from being activated by a new or different alarm condition.

51.7.4 The set points of adjustable alarms shall be indicated continuously, or on OPERATOR demand.

51.7.5 If either automatic change or OPERATOR adjustable change of alarm priority is provided it shall not be to a lower priority level than that specified in this specification.

51.7.6 If an interface for a remote alarm is provided, the interface shall be designed so that a failure in the remote alarm will not affect the correct functioning of the ANESTHESIA WORKSTATION.

51.7.7 R When a HIGH PRIORITY ALARM is activated and when the condition causing the alarm has cleared, the auditory signal shall reset automatically.

When an alarm that is specified as HIGH PRIORITY ALARM in this specification is activated and when the condition causing the alarm has cleared, it shall be possible for the OPERATOR to determine the alarm variable that caused the alarm, and that a HIGH PRIORITY ALARM had been activated.

The maximum time for which a HIGH PRIORITY ALARM can be silenced shall be 120 s.

Alarms specified as HIGH PRIORITY ALARM(s) in this specification shall not be capable of being disabled.

51.7.8 When a MEDIUM PRIORITY ALARM is activated and when the condition causing the alarm has cleared, the auditory signal shall reset automatically. The maximum time for which the MEDIUM PRIORITY ALARM can be silenced shall be 120 s.

51.8 Ventilatory Monitoring, Alarm, and Protection

51.8.1 The ANESTHESIA WORKSTATION shall be provided with the MONITORING, ALARM and PROTECTION DEVICE(s) as specified in Clause 51, or the manufacturer of the ANESTHESIA WORKSTATION shall state in the accompanying documents that such device(s) is/are required. The characteristics associated with each of these monitors and alarms are also specified in Clause 51.

NOTE 8—The displays of these monitors should be updated according to clinical needs and the risks associated with the variable being monitored.

Test for Compliance

Examine the ANESTHESIA WORKSTATION and the accompanying documents to verify compliance with Clause 51.

51.8.2 Operating Requirements

Means shall be provided to ensure that the specified monitors and alarms are enabled and functioning prior to use. (See Clause 72)

NOTE 9—These monitors and alarms may be automatically enabled and made to function by turning on the ANESTHESIA WORKSTATION, or the monitors and alarms can be manually enabled and made functional by following a pre-use check list.

Verify that all monitors and alarms are either enabled and functioning automatically, or by following the pre-use check list procedure in Clause 72.

51.8.2.1 Automatic Enabling

Means shall be provided that the monitor and alarms mentioned in clauses 51.9.3 (breathing system pressure), and 51.11 (oxygen concentration) shall be in the enabled condition and functioning automatically whenever the anesthesia gas supply device is in use. In addition, either the exhaled volume monitor (Clause 51.9.4) or the ventilatory Carbon Dioxide Monitor, or both, (Clause 51.10.5) shall be in the enabled