



Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components¹

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 601-1-1:1992² 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 standard 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 standard 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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SECTION TWO—ENVIRONMENTAL CONDITIONS

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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 MULTIPORT COMMUNICATION DEVICE or another digital source.

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.

³ Available from EIA/TIA, Electronics Industries Association/Telecommunications Industry Association, 2500 Wilson Blvd., Suite 300, Arlington, VA 22201-3834.

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

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 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

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

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-9⁵. (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 “off” 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 3.6).

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:

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

⁶ Available from AAMI, Association for Advancement of Medical Instrumentations, 3330 Washington Blvd., Suite 400, Arlington, VA 22201-4598.

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:

Additions:

43.1 R In 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:

49.5R Means 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.

49.7R When 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.

49.8R There 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 F 1463⁷.

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

⁷ Annual Book of ASTM Standards, Vol 13.01.

condition and functioning automatically whenever the anesthesia gas supply device is in use.

51.8.2.2 For all other specified monitors, means shall be provided to ensure that the monitors and alarms are enabled and functioning prior to use.

NOTE 10—These additional monitors and alarms may be automatically enabled and made to function by turning on the anesthesia gas supply device, or the monitors and the alarms can be manually enabled and made functional by following a pre-use check list. (See Clause 72)

Test for Compliance

51.9.3 Breathing System Pressure (See also Clause 51.8.2)

51.9.3.1 Pressure Monitoring

The ANESTHESIA WORKSTATION shall be provided with a means to display continuously the pressure in the ANESTHESIA BREATHING SYSTEM, or the manufacturer(s) of the ANESTHESIA VENTILATOR and ANESTHESIA BREATHING SYSTEM shall state in the accompanying documents that such a means is required.

51.9.3.2 Pressure Alarm Device

51.9.3.2.1 The pressure monitor shall have associated ALARM DEVICES designed to activate a HIGH PRIORITY ALARM signal when the pressure in the ANESTHESIA BREATHING SYSTEM:

(a) Exceeds the OPERATOR adjustable limit for high pressure;

NOTE 11—This may be coupled to the OPERATOR adjustable pressure limitation device.

(b) Exceeds a OPERATOR adjustable limit for continuing positive pressure for $15 \text{ s} \pm 1.0 \text{ s}$. When PEEP is in use, this alarm shall be OPERATOR adjustable at a level no more than 30 cm H₂O above the set PEEP, or manufacturer preset at a level no more than 10 cm H₂O above the preset PEEP. The manufacturer's preset level above PEEP shall be stated in the accompanying documents:

(c) Is less than negative 10 cm H₂O for greater than 1.0 s.

Test for Compliance

After recommended calibration and warm up procedures have been completed, perform the following tests to ensure that the pressure monitoring and alarms comply with 51.6.3.2.1

Connect the ANESTHESIA BREATHING SYSTEM to a test lung, and induce a pressure rise in the ANESTHESIA BREATHING SYSTEM. Verify that the pressure monitor is functioning. Adjust continuing positive airway pressure alarm limits to the maximum value, if applicable. This alarm shall sound $15 \pm 1 \text{ s}$ after airway pressure reaches this alarm limit. Permit the system pressure to continue to rise until the high pressure alarm limit is reached, at which time this alarm shall sound. Verify the activation of both visual and audible HIGH PRIORITY ALARM signal(s) in both conditions.

Compliance shall be determined by visual inspection, and functional testing by means of simulating the alarm condition in accordance with the accompanying documents.

51.9.3.2.3 When automatic ventilation is in use, there shall be at least a MEDIUM PRIORITY ALARM whenever the breathing system pressure falls below the alarm limit for more than 20 s. This alarm can be preset by the manufacturer, or can

be OPERATOR adjustable. If OPERATOR adjustable, the alarm shall not be capable of being set lower than $5 \pm 0.5 \text{ cm H}_2\text{O}$.

Compliance shall be determined by visual inspection, and functional testing by means of simulating the alarm condition in accordance with the accompanying documents.

51.9.3.3 Pressure Limitation

51.9.3.3.1 The ANESTHESIA WORKSTATION shall be provided with a breathing pressure limiting device which will ensure that the pressure in the ANESTHESIA BREATHING SYSTEM during intended use and under single fault condition shall not exceed 12.5 kPa (125 cm H₂O) or the manufacturer(s) of the ANESTHESIA VENTILATOR and ANESTHESIA BREATHING SYSTEM shall state in the accompanying documents that such a device is required.

An ANESTHESIA VENTILATOR shall be provided with an OPERATOR adjustable pressure limitation to prevent the pressure from exceeding the pressure limit by more than 3 cm H₂O or 15 % of the set value, whichever is the greater, or the manufacturer(s) of the ANESTHESIA VENTILATOR shall state in the accompanying documents that such a device is required.

The range within which the pressure limitation may be adjustable shall be stated by the manufacturer. This range shall include 20 cm H₂O.

NOTE 12—A reservoir bag complying with Specification F 1204⁷ may be considered as a pressure limiting device for an ANESTHESIA WORKSTATION without a ventilator, or when the ventilator module is in the manual or spontaneous breathing mode.

Test for Compliance—Introduce a pressure rise in the ANESTHESIA BREATHING SYSTEM and verify compliance with Clause 51.9.3.3.1.

51.9.3.4 Anesthesia Breathing System Disconnect Alarm

51.9.3.4.1R The ANESTHESIA WORKSTATION shall be provided with at least a MEDIUM PRIORITY ALARM signal that activates in the event of a complete disconnection in the ANESTHESIA BREATHING SYSTEM.

NOTE 13—Alarms considered to comply with the above include, but are not limited to, low pressure, low or zero CO₂, and low volume.

NOTE 14—MONITORING DEVICES indicate specific alarm conditions and do not differentiate between possible causes.

Test for Compliance—Disconnect, in turn, each OPERATOR detachable connection of the ANESTHESIA VENTILATOR or ANESTHESIA BREATHING SYSTEM, or both, recommended by the manufacturer. Use the test method(s) specified by the manufacturer, and verify that the alarm(s) is/are activated.

51.9.4 Exhaled Volume (See also Clause 51.8.2)

51.9.4.1 The ANESTHESIA WORKSTATION shall be provided with a device to monitor the patient's exhaled tidal or minute volume, or both, or the manufacturer(s) of the ANESTHESIA VENTILATOR shall state in the accompanying documents that such a device is required. The accuracy of the displayed value shall be within $\pm 20 \%$ of the actual value above 100 ml tidal volume, or $\pm 20 \%$ of the actual value above 3 L/min minute volume. See Clause 6.8.2 w) for disclosure requirements below 100 mL tidal volume and 3 L/min minute volume.

51.9.4.2 Test for compliance by visual and mechanical inspection. Connect an ANESTHESIA BREATHING SYSTEM to a test lung and adjust the parameters of the test lung and variables of ventilator performance as close as possible to values in Table 4 and in accordance with the intended use. Ventilate the test lung until measured exhaled volumes are stable. Verify compliance with 51.9.4.1.

51.9.4.3 An alarm of at least MEDIUM PRIORITY shall be activated if the patient's exhaled volume falls below an OPERATOR adjustable minimum. If the MEDIUM PRIORITY ALARM can be delayed, the delay shall not exceed 90 s. The delay may be OPERATOR adjustable.

Test for Compliance—Connect the exhaled volume monitor to an ANESTHESIA BREATHING SYSTEM according to the manufacturer's instructions. Set the adjustable alarm delay, if provided, to its maximum setting. Ventilate a test lung until the monitor readings are stable. Reduce the volume of ventilation until the exhaled volume falls below the OPERATOR adjustable low volume alarm setting. Confirm that the MEDIUM PRIORITY ALARM is activated within 90 s.

51.10.5 Ventilatory Carbon Dioxide (See also Clause 51.8.2)

51.10.5.1 The ANESTHESIA WORKSTATION shall be provided with a device to monitor continuously the patient's ventilatory CO₂, or the manufacturer(s) of the ANESTHESIA BREATHING SYSTEM shall state in the accompanying documents that such a means is required.

*Test for Compliance:
Verify by visual inspection.*

51.10.5.2 The CO₂ monitor shall meet the requirements of Specification F 1456⁷.

*Test for Compliance:
Verify by visual inspection.*

51.11 Inspiratory Oxygen Concentration Monitoring (See also Clause 51.8.2)

51.11.1 The ANESTHESIA WORKSTATION shall be provided with an oxygen monitor in compliance with Specification F 1462⁷ for measurement of the O₂ concentration in the inspiratory limb or the Y-piece, or the manufacturer(s) of the ANESTHESIA GAS SUPPLY DEVICE and ANESTHESIA BREATHING SYSTEM shall state in the accompanying documents that such a means is required.

51.11.2 The oxygen monitor shall be provided with an adjustable low O₂ concentration alarm. A HIGH PRIORITY ALARM shall be activated within 30 s after the inspiratory oxygen concentration falls below the low oxygen concentration alarm limit. This 30 s time shall include the delay time of the oxygen monitor and the response time. The low oxygen concentration alarm shall not be adjustable below 18 % volume concentration.

Compliance Test

Compliance shall be tested by visual inspection and functional testing by means of generating an O₂ concentration below the set alarm limit.

NOTE 15—The monitoring of oxygen concentration in the fresh gas is also recommended.

51.12 Oxygen Supply Failure ALARM Protection

51.12.1 The ANESTHESIA GAS SUPPLY DEVICE shall be designed so that whenever the oxygen supply pressure is reduced to below the manufacturer-specified minimum the delivered oxygen concentration shall not decrease below 19 % at the COMMON GAS OUTLET. The performance of the ANESTHESIA GAS SUPPLY DEVICE under these conditions shall be stated in the accompanying documents.

51.12.2 Whenever the oxygen supply pressure falls below the manufacturer-specified threshold, at least a MEDIUM PRIORITY ALARM shall be activated within 5 s. This alarm shall not be capable of being disabled.

Test for Compliance:

51.12.1.1 Test for compliance by visual inspection and by functional testing by simulating the conditions described in Clause 51.12.1 and according to the accompanying documents.

51.12.2.1 Attach a source of oxygen capable of being adjusted to pressures above and below the manufacturer's specified minimum oxygen pressure to the oxygen cylinder attachment of the ANESTHESIA GAS SUPPLY DEVICE,

Adjust the oxygen pressure to below the manufacturer's specified minimum oxygen pressure. Verify that the auditory and visual alarms are activated.

51.13 Protection Against Accidental Delivery of Hypoxic Gas Mixtures

51.13.1 The ANESTHESIA WORKSTATION shall be provided with a device to protect against an OPERATOR selected delivery of a mixture of oxygen and nitrous oxide having an oxygen concentration below 21 % oxygen (V/V) in the fresh gas or in the inspiratory gas. If an override mechanism is provided to permit OPERATOR selection of oxygen concentration below 21 % (V/V), the activation of this mechanism shall be continuously indicated.

Test for Compliance:

Set the machine to deliver 30 % oxygen at the COMMON GAS OUTLET or at the patient connection port, and verify that 30 % oxygen is being delivered in the inspiratory gas or fresh gas.

Attempt to reduce the oxygen concentration below 21 % by any OPERATOR accessible means available on the ANESTHESIA WORKSTATION.

Verify that the oxygen concentration at the COMMON GAS OUTLET or at the patient connection port does not fall below 21 %.

51.14 Agent Concentration Monitor and Alarm

51.14.1 The ANESTHESIA WORKSTATION shall be provided with a device to monitor the concentration of anesthetic vapor in the inspiratory gas, or the manufacturer(s) of the ANESTHETIC VAPOR DELIVERY DEVICE(s) shall state in the accompanying documents that such a means is required. The monitor shall comply with the requirements of Specification F 1452⁷.

NOTE 16—Monitoring of the anesthetic vapor concentration in the fresh gas and the expiratory gas is recommended.

Verify by visual inspection of the accompanying documents.

51.15 Other Monitors

To complete an ANESTHESIA WORKSTATION and comply with the ASA⁸ and AANA⁹ Monitoring Guidelines:

51.15.1 The ANESTHESIA WORKSTATION shall be provided with a device to monitor arterial hemoglobin oxygen saturation, or the manufacturer of the ANESTHESIA WORKSTATION shall state in the accompanying documents that such a means is required. If non-invasive, the monitor shall comply with the requirements of Specification F 1415.⁷

Verify by visual inspection of the accompanying documents.

51.15.2 The ANESTHESIA WORKSTATION shall be provided with a device to monitor the patient's blood pressure, or the manufacturer of the ANESTHESIA WORKSTATION shall state in the accompanying documents that such a means is required. The blood pressure monitor shall comply with the requirements of applicable standards for invasive or non-invasive blood pressure monitoring devices, AAMI BP22⁶ and SP10⁶ respectively.

Verify by visual inspection of the accompanying documents.

51.15.3 The ANESTHESIA WORKSTATION shall be provided with an electrocardiographic monitoring device, or the manufacturer of the ANESTHESIA WORKSTATION shall state in the accompanying documents that such a device is required. This monitor shall comply with the requirements of AAMI EC13.⁶

Verify by visual inspection of the accompanying documents.

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

52. Abnormal Operation and Fault Conditions

Clause 52 of the GENERAL STANDARD applies.

53. Environmental Tests

Clause 53 of the GENERAL STANDARD applies

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

54. General

Clause 54 of the GENERAL STANDARD applies with the following additions.

Additions:

54.4 A single fault condition shall not cause a MONITORING DEVICE or ALARM DEVICE, or both, in accordance with Clause 51 of this standard and its corresponding ANESTHESIA WORKSTATION control function, to fail in such a way that the monitoring or alarm function, or both, becomes ineffective, simultaneous with its corresponding control function (that is, a failure of the ANESTHESIA WORKSTATION function cannot be detected by the corresponding monitoring or alarm function, or both.)

NOTE 17—All manually operated controls should be designed to minimize unintentional change from a set position.

⁸ Available from American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068–2573.

⁹ Available from American Association of Nurse Anesthetists, 222 South Prospect Ave., Park Ridge, IL 60068.

55. Enclosures and Covers

Not Used

56. Components and General Assembly

Clause 56 of the GENERAL STANDARD applies with the following addition:

56.12 This ANESTHESIA WORKSTATION standard supersedes IEC 601-2-13².

57. Mains Parts, Components and Layout

Clause 57 of the GENERAL STANDARD applies with the following additions and amendments:

Amendment:

57.2e) R Auxiliary mains socket outlets on non-permanently installed equipment, intended for the provision of mains supply to other equipment, or to separated parts of equipment, shall be of a type complying with requirements of IEC 320.² (See Fig. 1.)

Such auxiliary mains socket outlets shall be marked in accordance with Clause 6.1k.

NOTE 18—Local codes and requirement may mandate the use of “hospital grade” outlets of NEMA¹⁰ style 5-15.

Compliance is checked by inspection.

Addition

57.3a)R—The mains supply cord of an electrically powered ANESTHESIA WORKSTATION shall be a non-detachable cord or shall be protected against accidental disconnection.

Compliance is checked by inspection and, for equipment when provided with an appliance coupler, by the following test:

The detachable cord is subjected for 1 min to an axial pull of force as shown in Table 5.

During the test, the mains connector shall not become disconnected from the appliance inlet.

57.6 Main Fuses and Over Current Releases

Addition

R— The ANESTHESIA WORKSTATION and each auxiliary mains socket outlet shall be provided with separate fuses or over-current releases as required for a single equipment in sub-clause 57.6.

These fuses or overcurrent releases shall be designed such that the ANESTHESIA WORKSTATION, including the auxiliary mains socket outlets, shall maintain normal function with each auxiliary mains socket outlet, loaded to the maximum.

When each auxiliary mains socket in turn is additionally overloaded by a factor of 7.5 ± 2.5 , all remaining auxiliary mains socket outlets and the ANESTHESIA WORKSTATION shall maintain normal function.

Test for compliance by visual inspection and functional testing.

58. Protective Earthing—Terminals and Connections

Clause 58 of the GENERAL STANDARD applies.

¹⁰ Available from National Electrical Manufacturers Association, NEMA, 1300 North 17th Street, Suite 1847, Rosslyn, VA 22209

59. Construction and Layout

Clause 59 of the GENERAL STANDARD applies.

ADDITIONAL REQUIREMENTS FOR ANESTHESIA WORKSTATIONS

60. Medical Gas Cylinder Attachments

60.1 The ANESTHESIA WORKSTATION shall be provided with at least one attachment for an oxygen cylinder. All medical gas cylinder attachments shall be pin - indexed post - type valves complying with the requirements of CGA V-1-1987.⁵

60.2 All medical gas cylinder attachments shall be provided with a filter (100 μm maximum) for the entrapment of particulate matter prior to delivery of the gas to the GAS PRESSURE REDUCING DEVICE/SYSTEM or FLOW ADJUSTMENT CONTROL(s).

60.3 Each medical gas cylinder attachment shall incorporate a clamping device by which the valve of the cylinder can be adequately forced against a seal to provide a leak resistant gas conduit.

60.4 Each medical gas cylinder attachment shall be designed to prevent tightening of the clamping device until the pins of the pin-indexed safety system are correctly engaged with the appropriate pin-indexed safety system pin-receiving holes of the cylinder valve.

60.5 If two or more interconnected cylinder attachments are provided for the attachment of cylinders of the same gas, a means shall be provided to limit under normal conditions, the leakage from an attached cylinder to either an empty cylinder or to atmosphere, to less than 100 mL/min throughout the pressure range of 1380 kPa to the maximum pressure for the respective gas (that is, N_2O -5168 kPa, O_2 and AIR - 15 180 kPa).

Tests for Compliance:

60.1.1 *Verify by visual inspection.*

60.2.1 *Verify by visual inspection presence of the filter. Confirm that filter size does not exceed 100 μm .*

60.3.1 *Verify by visual inspection.*

60.4.1 *Verify by trying to clamp the post valve of the cylinder to the cylinder attachment without pins being aligned.*

60.5.1 *If two or more interconnected cylinder attachments are provided for the attachment of cylinders of the same gas, pressurize each cylinder attachment inlet with a gas source at varying pressures from 1380 kPa to the maximum pressure for the respective gas (that is, N_2O - 5168 kPa, O_2 and AIR 15 180 kPa). Measure the rate of leakage from the other cylinder attachment.*

If applicable, repeat the above procedure, but measure the rate of leakage to atmosphere.

61. Medical Gas Supply Pressure Indicator(s)

61.1 The ANESTHESIA WORKSTATION shall be equipped with a pressure indicator that indicates the cylinder pressure of each gas. The scale of the pressure indicator shall extend to a pressure at least 33 % greater than the maximum filling pressure of the cylinder, or the full indication position, at a temperature of $20 \pm 3^\circ\text{C}$.

The pressure indicator shall be at least Grade B in accordance with ANSI/ASME B40.1² for indicating dial elastic element pressure gauges, and for other types of pressure indicators, the accuracy shall be at least \pm (4 % of the full scale reading + 8 % of the actual reading).

This pressure indicator shall be LEGIBLE from the front of the ANESTHESIA WORKSTATION.

61.2 When only one pressure indicator is supplied for a specific gas where more than one medical gas cylinder attachment is provided for that gas, it shall be possible to determine the pressures in each of the separate cylinders.

NOTE 19—Pressure indicators cannot accurately indicate the quantitative contents of medical gas cylinders containing liquefied gas.

61.3 The ANESTHESIA WORKSTATION shall be equipped with a means to monitor the pressure for each gas supplied from a MEDICAL GAS PIPELINE SYSTEM. The monitoring point shall be upstream from the unidirectional valve.

This pressure indicator shall be LEGIBLE from the front of the ANESTHESIA WORKSTATION.

61.4 If in a single fault condition the pressure from the pressure sensing element can be conveyed to the gauge case or enclosure, the gauge shall be designed and constructed in such a manner that when a pressure equal to the maximum indicated on the dial or display is applied to a gauge having the pressure sensor removed, no parts shall be expelled free of the gauge enclosure. Gauge cases or enclosures shall have means of venting to prevent internal pressure buildup.

61.5 All elastic element type pressure indicators on the ANESTHESIA WORKSTATION shall be of cleanliness Class IV or higher as outlined for oxygen gauges in ANSI/ASME B40.1.²

61.6 The lowest pressure indication on all analog gauge scales or electronically displayed scales on a ANESTHESIA WORKSTATION shall be:

(a) (a) For dial type gauges, in the lower left quadrant of the dial face (that is, between 6 and 9 of a clock face),

(b) (b) For horizontal gauge faces, at the left of the scale, and

(c) (c) For vertical gauge faces, at the bottom of the scale.

61.7 Mechanical and electronic indicators shall be LEGIBLE.

Tests for Compliance:

61.1 *Verify by visual inspection.*

61.2.1 *Verify by visual inspection and sequential manipulation of cylinder valves.*

61.3.1 *Verify by visual inspection.*

61.4.1 *Verify presence of venting means by visual inspection.*

61.5.1 *Verify by inspection or evidence of certificate of compliance by the manufacturer.*

61.6.1 *Verify by visual inspection.*

61.7.1 *Verify by visual inspection.*

62. Gas Pressure Reducing Device/System

62.1 A GAS PRESSURE REDUCING DEVICE/SYSTEM shall be employed for each gas supplied from cylinders.

62.2 The gas flow from cylinders to the ANESTHESIA GAS SUPPLY DEVICE shall not exceed 10 mL/min when pressure in the MEDICAL GAS PIPELINE SYSTEM is 345 kPa (50 psig).

NOTE 20—Means should be provided to ensure that the ANESTHESIA GAS SUPPLY DEVICE uses gas from the MEDICAL GAS PIPELINE SYSTEM as long as the pressure is 345 kPa (50 psig) or greater.

62.3 An O₂ flow of 2 L/min shall be restored to 2 ± 0.1 L/min within a period of 2 s after operation of the oxygen flush.

62.4 To ensure safety of the ANESTHESIA WORKSTATION, adjacent structures, and personnel, a single GAS PRESSURE REDUCING DEVICE/SYSTEM, or the first of a series of GAS PRESSURE REDUCING DEVICE/SYSTEM in a series, shall meet either of the following requirements:

(a) (a) The GAS PRESSURE REDUCING DEVICE/SYSTEM shall be equipped with a pressure relieving device that opens at not more than four times the normal delivery pressure of that GAS PRESSURE REDUCING DEVICE/SYSTEM and at no more than two-thirds of the minimum burst pressure of the diaphragm. The pressure relieving device shall also be capable of venting the GAS PRESSURE REDUCING DEVICE/SYSTEM at the maximum relief pressure not exceeding the minimum burst pressure of the diaphragm when a pressure 50 % greater than the normal supply pressure of the corresponding gas is applied, or

(b) (b) The GAS PRESSURE REDUCING DEVICE/SYSTEM shall be designed to ensure rupture of its diaphragm, without hazard to its environment due to flying fragments, at a pressure not greater than 2760 kPa (400 psig). The diaphragm shall not rupture at pressures less than 1380 kPa (200 psig).

Tests for Compliance:

62.1.1 Visually inspect the ANESTHESIA WORKSTATION to confirm that each gas circuit where the inlet pressure normally exceeds 345 ± 10 kPa (50 ± 1.5 psig) contains a GAS PRESSURE REDUCING DEVICE/SYSTEM.

62.2.1 Perform the following test to confirm that the GAS PRESSURE REDUCING DEVICE/SYSTEM complies with clause 62.2. These tests must be performed first with oxygen. After completing the test with oxygen, the oxygen supply must be left connected and the oxygen lines pressurized to 345 ± 10 kPa (50 ± 1.5 psig) before proceeding with the tests for other gases.

Close all FLOW ADJUSTMENT CONTROL(s) and flush valves and shut “OFF” all other gases. Connect a compressed gas supply at a pressure of at least 90 % of the maximum cylinder pressure for the respective gas (that is, N₂O - 5168 kPa (750 psig), O₂ and AIR 15 180 kPa (2200 psig)) to one cylinder inlet connection; seal all other cylinder and pipeline inlet connectors for the gas. Verify that there is no leakage by opening the cylinder valve for a few seconds and then reclosing; adjust connections until the cylinder pressure indicator reading does not fall discernibly within 1 min after closing the cylinder valve.

Open the cylinder valve and open the FLOW ADJUSTMENT CONTROL to obtain a flowrate of 1.0 ± 0.05 L/min; record the cylinder pressure, (P₁).

Close the cylinder valve and measure the time (t₁) (in seconds) required for the cylinder pressure to fall to a value (P₂), that is between 10 and 20 % of (P₁).

Connect the pipeline inlet of the ANESTHESIA WORKSTATION to a supply of gas at 345 ± 10 kPa (50 psi) and reset the flowrate to 1.0 ± 0.05 L/min.

Open the cylinder valve and record the cylinder pressure, (P₃).

Close the cylinder valve and record the time (t₂) (in seconds) required for the cylinder pressure to decrease to a value (P₄), that is 75 to 84 % of P₃. Compute the forward flow, (Q), in mL/min according to the following:

$$Q = 16.67 \times [(P_3 - P_4) / (P_1 - P_2)] \times (t_1 / T_2) \quad (1)$$

This shall not exceed 10 mL/min.

62.3.1 Using an indicated oxygen flow of 2.0 L/min, operate the oxygen flush for ten cycles of 10 s duration, with a pause of 5 s between each flush. Check that the flow is restored to 2.0 ± 0.1 L/min within 2 s after each flush.

62.4.1 For Option (a) Apply an ever increasing pressure at the outlet of the GAS PRESSURE REDUCING DEVICE/SYSTEM until the relief valve opens. Note this pressure. Continue to increase the pressure until the pressure stops increasing, and note this pressure. Verify that the opening pressure is not greater than four times the normal delivery pressure, and that the maximum pressure measured is less than two-thirds of the minimum burst pressure of the diaphragm.

For Option (b)—Follow the manufacturer’s recommended method for testing rupture of the diaphragm. Verify that the no safety hazard is created as a result of the diaphragm rupture, and that the diaphragm does not rupture at less than 1380 kPa (200 psig).

63. Anesthesia Gas Supply Piping

63.1 There shall be no hazard for patients, OPERATOR(s), or third person(s) arising if the ANESTHESIA GAS SUPPLY PIPING is subjected to the pressure which may occur during any single fault condition

63.2 Except for the venting of air or oxygen from fluidics or pneumatic elements, the leakage from the ANESTHESIA GAS SUPPLY PIPING:

(a) (a) For each gas service between the outlet of the GAS PRESSURE REDUCING DEVICE/SYSTEM and the inlet to the FLOW ADJUSTMENT CONTROL shall not exceed 25 mL/min at the manufacturer’s specified normal working pressure, or

(b) (b) For each gas service between the cylinder attachment and/or pipeline inlet(s), including the GAS PRESSURE REDUCING DEVICE/SYSTEM and the inlet to the FLOW ADJUSTMENT CONTROL, this leakage shall not exceed 150 mL/min (corrected to 20 °C) when pressurized to the maximum and minimum inlet pressures for the respective gas service.

63.3 The leakage rate on each gas service between the FLOW ADJUSTMENT CONTROL and the COMMON GAS OUTLET shall not exceed 50 mL/min at a pressure of 3 kPa (30 cm H₂O). If applicable, this requirement shall be met under each of the following conditions:

(a) (a) With one ANESTHETIC VAPOR DELIVERY DEVICE installed and in the “ON” position;

(b) (b) With one ANESTHETIC VAPOR DELIVERY DEVICE installed and in the “OFF” position; and

(c) (c) With the ANESTHETIC VAPOR DELIVERY DEVICE removed if it is designated by the manufacturer as OPERATOR detachable.

Tests for Compliance

63.1.1 Using oil free air, pressurize the ANESTHESIA GAS SUPPLY PIPING to the maximum pressure obtainable under a single fault condition, and verify that no safety hazard to OPERATOR or third person is created.

63.2.1 Compliance is met by completion of a test in accordance with manufacturer’s instructions.

63.3.1 Compliance is met by completion of a test in accordance with manufacturer’s instructions.

64. Flow Adjustment Control(s)

64.1 When a GAS MIXER is not incorporated into the ANESTHESIA GAS SUPPLY DEVICE, a single FLOW ADJUSTMENT CONTROL shall be provided for each of the different gases supplied to the COMMON GAS OUTLET.

64.2 Each FLOW ADJUSTMENT CONTROL shall maintain for at least 30 min, any set rate of the allowable rates of flow within $\pm 10\%$ of the setting or ± 10 mL/min, whichever is the greater, whenever the supply pressures (pipeline or cylinder) and pressures at the COMMON GAS OUTLET vary within the limits specified by the manufacturer.

64.3 Each FLOW ADJUSTMENT CONTROL shall be adjacent to or identifiable with its associated FLOW INDICATOR.

64.4 FLOW ADJUSTMENT CONTROLS shall be located on the front of the ANESTHESIA WORKSTATION.

64.5 For rotary style FLOW ADJUSTMENT CONTROL(s), the oxygen knob shall have the physically distinguishable profile in accordance with Fig. 2. All other rotary style FLOW ADJUSTMENT CONTROL knobs shall be round. The oxygen knob diameter shall not be less than the diameter of any of the knobs controlling the other gases.

NOTE 21—The oxygen knob may project beyond the knobs controlling other gases when the knobs are grouped together.

Other types of FLOW ADJUSTMENT CONTROL(s) shall be designed so that the oxygen FLOW ADJUSTMENT CONTROL looks and feels different from the FLOW ADJUSTMENT CONTROL(s) for the other gases.

64.6 Where the FLOW ADJUSTMENT CONTROL requires a direct rotational motion by the OPERATOR for flowrate adjustment, the FLOW ADJUSTMENT CONTROL shall be designed so that either:

(1) Continuation of rotation will not cause “disassembly” of the FLOW ADJUSTMENT CONTROL, or

(2) Rotation is prevented prior to the point where “disassembly” would occur, or

(3) The stem of each rotary FLOW ADJUSTMENT CONTROL shall be captive so that it cannot be disengaged from its housing without the use of tools.

Tests for Compliance:

64.1.1 Verify by visual inspection.

64.2.1 Attach a flowmeter to the COMMON GAS OUTLET of the ANESTHESIA WORKSTATION or follow the manufacturer’s instructions for flow rate verification. Select a flow rate of the available flow rates for a specified gas. Vary the supply pressures and the outlet pressures to the extremes specified by the manufacturer, and verify compliance with Clause 64.2.

64.3.1 Verify by visual inspection.

64.4.1 Adjust lighting to a level of 215 lux. From a position 1 m in front of the ANESTHESIA WORKSTATION, verify that all FLOW ADJUSTMENT CONTROL(s) are LEGIBLE.

64.5.1 For rotary style FLOW ADJUSTMENT CONTROL(s), verify by visual inspection that the FLOW ADJUSTMENT CONTROL(s) comply with the requirements of Clause 64.6 and Fig. 2 for the oxygen-FLOW ADJUSTMENT CONTROL.

For other types (non - rotary style) of FLOW ADJUSTMENT CONTROL(s) verify that the oxygen control is different from those of other gases.

64.6.1 Where applicable, verify that when the required rotational motion is applied that the FLOW ADJUSTMENT CONTROL(s) comply with the requirements of Clause 64.6.

65. Flow Indicators

65.1 When the ANESTHESIA WORKSTATION is equipped with FLOW ADJUSTMENT CONTROL(s), it shall be equipped with one or more FLOW INDICATOR(s) for each gas supplied to the ANESTHESIA WORKSTATION from either MEDICAL GAS PIPELINE SYSTEM(s) or cylinder(s).

65.2 If provided, each FLOW INDICATOR shall be graduated in units of liters per minute. For all flows less than 1 L/min, the flow may be expressed either in millilitres per minute or in decimal fractions of a litre per minute (with a zero before the decimal sign), but shall be consistent on any one ANESTHESIA WORKSTATION.

65.3 The manufacturer shall state in the accompanying documents of the ANESTHESIA WORKSTATION the limits of error for each of the FLOW INDICATORS when measured at ambient conditions of 20°C and 760 mm Hg.

65.4 If provided, the oxygen FLOW INDICATOR shall be on the right most extremity of a bank of FLOW INDICATORS as viewed from the front of the ANESTHESIA WORKSTATION.

65.5 FLOW INDICATORS of the tube type shall be separated or shall be designed to avoid confusion. The graduations shall be marked on the tube, or alternatively, a scale with the graduation markings shall be located immediately adjacent to the tube.

65.6 The name or chemical symbol in accordance with CGA V-5⁵ for the gas shall be marked on or adjacent to the FLOW INDICATOR. This marking shall be LEGIBLE. If color coding is used it shall be in conformance with CGA C-9⁵ (See Table 1).

NOTE 22—Where oxygen and other gases are delivered by their respective FLOW INDICATORS into a common manifold, the oxygen should be delivered downstream of all other gases.

Test for Compliance:

65.1.1 Verify by visual inspection.

65.2.1 Verify by visual inspection.

65.3.1 *Verify by reviewing the accompanying documents.*

65.4.1 *Verify by visual inspection.*

65.5.1 *Verify by visual inspection.*

65.6.1 *Verify by visual inspection and review of the accompanying documents.*

66. Gas Mixing System

66.1 When a GAS MIXING SYSTEM is used, there shall be an indication of the gases controlled, the concentration of oxygen (% V/V) in the mixture, and the minimum and maximum oxygen concentrations (% V/V). The range of oxygen concentrations shall be indicated continuously, or on OPERATOR demand.

66.2 At any flow and pressure given in the instructions for use, the oxygen concentration shall be within $\pm 5\%$ (V/V) of the set or indicated value.

66.3 Each GAS MIXING SYSTEM control(s) shall be adjacent to or identifiable with its associated indicator(s). The GAS MIXING SYSTEM control(s) or its surrounding shall be durably marked with the name or chemical formula in accordance with CGA V-5. These and the markings required in clause 66.1 shall be LEGIBLE from the front, and if color coding is used it shall be in accordance with CGA C-9⁵ (See Table 1).

Test for Compliance:

66.1.1 *Test for compliance by visual inspection.*

66.2.1 *Test the GAS MIXING SYSTEM according to the instructions for use provided by the manufacturer. The accuracy of the indicated value shall be within $\pm 5\%$ of the actual value at the minimum indicated O_2 concentration, at 50 % of the maximum indicated O_2 concentration, and at the maximum indicated O_2 concentration for 5 min when tested under the following combinations, (see Table 6) of pressures and flows as specified by the manufacturer.*

66.3.1 *Test for compliance by visual inspection.*

67. Oxygen Flush

67.1 **R** The ANESTHESIA WORKSTATION shall be equipped with a manually operated single purpose flush for the delivery of a limited but unmeasured flow of oxygen directly to the COMMON GAS OUTLET. The ANESTHESIA WORKSTATION shall not be provided with a flush for any other single gas.

67.2 The oxygen flush shall have only one “OFF” position, and should be designed to minimize unintentional operation.

67.3 The oxygen flush shall be operable with one hand, and be self - closing.

67.4 The oxygen flush shall deliver oxygen at a steady flow of not less than 35 L/min and not exceeding 75 L/min to the COMMON GAS OUTLET of the ANESTHESIA WORKSTATION, when oxygen is supplied to the flush at the manufacturer’s specified operating pressure range.

67.5 The flow of oxygen from the oxygen flush shall be delivered to the COMMON GAS OUTLET of the ANESTHESIA WORKSTATION without passing through any ANESTHETIC VAPOR DELIVERY DEVICE(s). Pressure at the outlet of the ANESTHETIC VAPOR DELIVERY DEVICE shall either:

(a) (a) Not increase or decrease by more than 10 kPa (100 cm H_2O) during operation of the oxygen flush, when the COMMON GAS OUTLET is open to atmosphere, or

(b) (b) When tested as described in Annex A2, the output of anesthetic vapor shall not increase by more than 20 %

Tests for Compliance:

67.1.1 *Verify by visual inspection that the ANESTHESIA WORKSTATION is equipped with an oxygen flush and that no other single gas flush is provided.*

67.2.1 *Verify that the oxygen flush has only one “off” position, and that the possibility of accidental operation has been minimized.*

67.3.1 *Operate the oxygen flush to verify compliance.*

67.4.1 *Using a test flowmeter, verify that the flow delivered at the COMMON GAS OUTLET is between 35 L/min and 75 L/min when the pressure to the inlet of the oxygen flush is within the range specified by the manufacturer.*

67.5.1 *Verify by functional testing according to manufacturers instructions, or by following the test methods given in Annex A2.*

68. Anesthetic Vapor Delivery Device(s)

68.1 All ANESTHETIC VAPOR DELIVERY DEVICE(s) to be used with the ANESTHESIA WORKSTATION shall be concentration calibrated.

68.2 The calibrated control of the ANESTHETIC VAPOR DELIVERY DEVICE(s) shall be marked in such a way that it is LEGIBLE from the front of the ANESTHESIA WORKSTATION.

68.3 A system shall be provided that prevents gas from passing through the chamber or reservoir of one ANESTHETIC VAPOR DELIVERY DEVICE(s) to that of another.

68.4 ANESTHETIC VAPOR DELIVERY DEVICE(s) not intended for use in the ANESTHESIA BREATHING SYSTEM shall have non-interchangeable proprietary fittings or shall have 23 mm conical fittings in compliance with Fig. 3. In no case shall male or female 15 or 22 mm conical fittings be used. When 23 mm conical fittings are used, the inlet to the ANESTHETIC VAPOR DELIVERY DEVICE(s) shall be male and the outlet female.

68.5 The direction of gas flow through the ANESTHETIC VAPOR DELIVERY DEVICE shall be marked with arrows. ANESTHETIC VAPOR DELIVERY DEVICE(s) designed solely for use in the ANESTHESIA BREATHING SYSTEM shall be marked “for use only in the breathing system”.

68.6 When tested in accordance with clause 68.6.1, the output of the ANESTHETIC VAPOR DELIVERY DEVICE(s) in the “Off” or “Zero” position, if the “Zero” is also the “Off” position, shall be less than 0.05 %. The control(s) of the ANESTHETIC VAPOR DELIVERY DEVICE(s) shall be designed to prevent unintentional operation from the “Off” position.

68.7 The ANESTHETIC VAPOR DELIVERY DEVICE(s) shall be equipped with a liquid level indicator visible from the front of the ANESTHESIA WORKSTATION. The ANESTHETIC VAPOR DELIVERY DEVICE(s) shall be designed so that it cannot be overfilled when in the normal operating position.

NOTE 23—If applicable, the ANESTHETIC VAPOR DELIVERY DEVICE(s) should be designed so that substantially all liquid but that contained in the wick (if present) can be drained when the ANESTHETIC VAPOR DELIVERY DEVICE(s) is emptied in accordance with the manufacturer's instructions. These requirements apply regardless of whether the agent bottle is being used as the agent reservoir.

NOTE 24—The filling mechanism(s) of the ANESTHETIC VAPOR DELIVERY DEVICE(s) should be fitted with a permanently attached AGENT SPECIFIC FILLING DEVICE to help prevent accidental filling with the wrong agent. It is recommended that this AGENT SPECIFIC FILLING DEVICE be either a manufacturer's proprietary device, or be in compliance with the requirements of ISO 5360².

68.8 When used, and mounted (if applicable), in accordance with the manufacturer's instructions, and filled to the maximum safe indicated level, the ANESTHETIC VAPOR DELIVERY DEVICE shall permit the use of maximum calibrated flows of O₂ and N₂O simultaneously in the "on" and in the "off" positions, without discharging liquid anesthetic through its outlet.

68.9 The average delivered concentration (volume percent or partial pressure) from the ANESTHETIC VAPOR DELIVERY DEVICE(s) shall not deviate from the set value by more than +30 % or -20 % or by more than +7.5 % or -5 % of the maximum setting, whichever is greater, under the following test conditions at an ambient temperature of 23°C ± 1°C at one standard atmosphere (1013 mbar):

(a) (a) The ANESTHETIC VAPOR DELIVERY DEVICE(s) is filled with the appropriate agent to approximately one quarter of the way between the minimum and maximum fill marks.

(b) (b) The pressure fluctuation is introduced at the COMMON GAS OUTLET of 15 ± 2 cycles per minute at an I:E ratio of 1:2 ± 20 %.

(c) (c) Condition 1: the pressure produced at the COMMON GAS OUTLET is 2 ± 0.3 kPa above ambient. The total gas flow is 2 ± 0.2 L/min.

(d) (d) Condition 2: the pressure produced at the COMMON GAS OUTLET is 5 ± 0.4 kPa above ambient. The total gas flow is 8 ± 0.8 L/min.

(e) (e) The pressure falls from 100 % to 33 % in less than 0.6 seconds.

NOTE 25—When fresh gas flow is determined by ventilator settings, they are set for a minute volume of 2 L/min and 8 L/min.

Tests for Compliance:

68.1.1 Verify by visual inspection.

68.2.1 Verify by visual inspection.

68.3.1 Verify by inspection of accompanying documents.

68.4.1 Verify by visual inspection and review of the accompanying documents. Details of a test to determine conformance to the requirement in clause 68.4 shall be furnished by the manufacturer upon request by the USER.

68.5.1 Test for compliance by visual inspection and functional testing.

68.6.1 Verify by visual inspection and functional testing using the carrier gas and analytic technique recommended by the manufacturer.

68.7.1 Verify by visual inspection and functional testing using the carrier gas and analytic technique recommended by the manufacturer.

68.8.1 Mount the ANESTHETIC VAPOR DELIVERY DEVICE(s) according to the manufacturers' instructions. Turn "On" the maximum calibrated flows of nitrous oxide and oxygen and inspect for liquid anesthetic at the ANESTHETIC VAPOR DELIVERY DEVICE(s) outlet.

68.9.1 Using the settings specified in Table 7, verify by functional testing by adhering to the temperature stabilization method, carrier gas, and analytic technique recommended by the manufacturer.

68.10 Without back pressure produced at the COMMON GAS OUTLET, all other conditions being the same as specified in clause 68.9, the average delivered concentration (volume percent or partial pressure) from the ANESTHETIC VAPOR DELIVERY DEVICE shall not deviate from the set value by more than ± 20 % or ± 5 % of the maximum setting, whichever is greater, when the pressure at the COMMON GAS OUTLET is within the range of ± 0.5 kPa of ambient.

68.10.1 Using the settings specified in Table 7, verify by functional testing by adhering to the temperature stabilization method, carrier gas, and analytic technique recommended by the manufacturer.

69. Common Gas Outlet

69.1 If an OPERATOR accessible COMMON GAS OUTLET is provided, it shall be in compliance with one of the following: a 22 mm male conical fitting with a coaxial 15 mm female connector in accordance with Specification F 1054,⁷ or a manufacturer's specific fitting.

There shall be only one functional COMMON GAS OUTLET at a time.

69.2 For manufacturer - specific fittings, the connector shall remain engaged after an axial pull of 35 N maintained for 30 s.

NOTE 26—The COMMON GAS OUTLET may also incorporate a load bearing fitting for secure attachment of accessory devices. If the COMMON GAS OUTLET is OPERATOR accessible, it should be provided with means to prevent unintentional disconnects.

69.3 For conical fittings, the supporting structure of the COMMON GAS OUTLET shall permit the simultaneous application of a bending moment of 3 Nm on, and a torque of 3 Nm around, the axis without permanent deformation or displacement of the mountings of the COMMON GAS OUTLET.

Tests for Compliance:

69.1.1 Visually inspect the ANESTHESIA WORKSTATION and determine that if more than one OPERATOR accessible COMMON GAS OUTLET is provided, only one COMMON GAS OUTLET is functional at a time.

69.2.1 Verify that the COMMON GAS OUTLET is equipped with a retaining device, and that it is in compliance with the appropriate standard.

69.3.1 For manufacturer specific fittings, confirm that after an axial pull of 35 N maintained for 30 s the connector remains engaged, and then can be disengaged. Reconnect and disconnect the connector to ensure that its retaining ability remains.

Test the structural integrity of the supporting structure of the COMMON GAS OUTLET with a torque wrench and special adapters to ensure compliance.

70. Pipeline Inlet Connections

70.1 The ANESTHESIA WORKSTATION shall be provided with pipeline inlet connectors for both oxygen and nitrous oxide. These connections as well as MEDICAL GAS PIPELINE SYSTEM connections for other gases (if provided) shall be DISS threaded body fittings in compliance with the applicable requirements of CGA V-5.⁵ The attachment of these fittings to the ANESTHESIA WORKSTATION shall be such that they cannot be interchanged.

70.2 Each pipeline inlet shall be provided with a filter having a pore size not exceeding 100 micrometers.

70.3 When both pipeline inlet fittings and a medical gas cylinder attachment are present for the same gas, unidirectional valve(s) shall be provided to prevent the reverse flow of gas, from the ANESTHESIA GAS SUPPLY DEVICE to the MEDICAL GAS PIPELINE SYSTEM, or to atmosphere, from exceeding 50 mL/min at the manufacturer's specified working pressure.

Tests for Compliance:

70.1.1 *Verify by visual inspection that the ANESTHESIA WORKSTATION is equipped with pipeline inlet connections for both oxygen and nitrous oxide.*

Verify by inspection that all pipeline inlet connectors of the ANESTHESIA WORKSTATION are in compliance with the applicable requirements of CGA V-5.⁵

Verify that the pipeline inlet connectors are not interchangeable.

70.2.1 *Verify that a filter with a pore size less than 100 μ m is present in all pipeline inlet connectors.*

70.3.1 *Attach a suitable test flowmeter to the pipeline inlet connector. Pressurize the system as specified by the manufacturer. The flow measured by the flowmeter is the leakage past the unidirectional valve and shall not exceed 50 mL/min.*

71. Gas Power Outlet(s)

71.1 Gas power outlet(s), if provided, shall be gas specific, and shall be durably marked with the name or symbol of the gas in accordance with CGA V-5⁵, and the nominal output pressure. These markings shall be LEGIBLE. Where color coding is used, it shall be in accordance with CGA C-9.⁵ (See Table 1.)

71.2 Test for Compliance:

71.2.1 *Verify by visual inspection, that if gas power outlet(s) are provided, that they are gas specific and marked in accordance with 71.1.*

72. Checklist

72.1 Each ANESTHESIA WORKSTATION shall be provided with a checklist(s) of the procedures recommended by the manufacturer to be performed prior to each use of the ANESTHESIA WORKSTATION.

Manufacturers of DELIVERY SYSTEM/DEVICE(s), MONITORING DEVICE(s), ALARM DEVICE(s) and PROTECTION DEVICE(s) intended for use in an ANESTHESIA WORKSTATION shall state in the instructions for use that whoever assembles an ANESTHESIA WORKSTATION from individual devices or systems shall provide the checklist for the ANESTHESIA WORKSTATION.

The USER who assembles an ANESTHESIA WORKSTATION from separate DELIVERY SYSTEM/DEVICE(s), MONITORING DEVICE(s), ALARM DEVICE(s) and PROTECTION DEVICE(s) shall provide a checklist comprising the procedures which shall be incorporated into the checklist for the ANESTHESIA WORKSTATION.

NOTE 27—These procedures may be performed automatically, in whole or in part, or by the OPERATOR. Attention is drawn to additional check lists established by regional or national medical associations, or government agencies. The use of electronic displays (for example, a CRT) integral to, or provided with the ANESTHESIA WORKSTATION or the module, to provide such a checklist is permitted.

SECTION ELEVEN—BREATHING SYSTEM, AND ANESTHETIC GAS SCAVENGING SYSTEM

73. Breathing Systems

NOTE 28—Different types of breathing systems may be used with the ANESTHESIA WORKSTATION. Attention is drawn to Specification F 1208⁷ for requirements pertaining mainly to circle breathing systems.

74. Anesthetic Gas Scavenging Systems

74.1 The gas scavenging port and hoses shall comply with the requirements in Specification F 1343.⁷

SECTION TWELVE—AUXILIARY EQUIPMENT

75. Suction Equipment

75.1 Suction equipment provided as part of the ANESTHESIA WORKSTATION shall conform to the requirements of Specification F 960.⁷

76. Auxiliary Oxygen Flowmeter

NOTE 29—The presence of an AUXILIARY OXYGEN FLOWMETER is strongly recommended. Such a flowmeter is self contained usually with a maximum flow of 10 L/min and with a barbed fitting on the outlet (so that the oxygen that it delivers is not connected in any way to the COMMON GAS OUTLET of the ANESTHESIA WORKSTATION). It is usually mounted on the left side of the ANESTHESIA WORKSTATION, and may be used to provide supplemental inspired oxygenation (for example, via a nasal canula) to a patient under spinal, epidural, or other regional anesthesia. It may also be used to enrich the inspired gas mixture provided by a manually powered self-inflating resuscitator bag, which is called for on the pre-use checklist for emergency applications.

77. Other Auxiliary Equipment

All other auxiliary equipment provided with the ANESTHESIA WORKSTATION shall conform to the requirements of the appropriate ASTM Standard.

SECTION THIRTEEN—DATA INTERFACES

78. Data Interfaces

78.1 The ANESTHESIA WORKSTATION shall provide at least one DIGITAL INTERFACE.

78.2 DIGITAL INTERFACES of devices marketed as compatible with this ANESTHESIA WORKSTATION standard shall comply with one of the specified published communication standards. (See Clause 2.16.3)

NOTE 30—Some devices (for example, mechanical vaporizers, PROTECTION DEVICES) may not provide DIGITAL INTERFACES. Legacy

devices with RS-232³ interfaces may have only rudimentary communication capabilities inadequate for use as DIGITAL INTERFACES as defined in this standard.

NOTE 31—Devices having waveform output may offer an analog format (NTE ± 10 V) or a digital format. If digital, it may offer selectable output of one or more waveforms at a time (ideally, all waveforms should be available at all times). This waveform output feature may occur via the same DIGITAL INTERFACE used for parameter values and alarms. Optionally, a product may offer its waveform output via one or more additional DIGITAL INTERFACES. Transmitted waveform data should comply with suitable published standards (for example, Specification E 1467¹¹ or Guide E 1763¹²).

78.3 If a device has more than one DIGITAL INTERFACE, only one DIGITAL INTERFACE shall be used for control of the device's alarm parameters or annunciation.

78.4 If a DIGITAL INTERFACE employs the RS-232 standards³, the manufacturer shall document the transmission protocol, data format, and hardware connector pinout as implemented to allow another party to implement a working DIGITAL INTERFACE. (See Appendix X1).

NOTE 32—RS-232 default parameters should include 9600 baud, 8 data bits, no parity, and 1 stop bit.

78.5 If a DIGITAL INTERFACE employing the RS-232 standards⁴ operates at no more than 19.2 Kbaud, the product may operate in either a broadcast mode or a polling mode. If an RS-232³ interface operates at more than 19.2 Kbaud, the product shall not operate in a broadcast mode.

NOTE 33—A polling protocol should minimally provide: a means of asking what data is available; selecting any component of that data for one time or continuing output; identifying when or if new data becomes available; and a means of stopping any portion or all outputs. Requests for output of specific data should be available as both one time requests as well as continuing requests. The DIGITAL INTERFACE definition still requires bidirectional communication capability even if broadcast mode is employed (see Clause 79).

78.6 A SECONDARY DATA SOURCE shall provide an indication whether data originating from a PRIMARY DATA SOURCE have been modified before re-transmission.

79. Data Interface Requirements for Infusion Devices

79.1 INFUSION DEVICES marketed as compatible with this ANESTHESIA WORKSTATION standard shall comply with the requirements of ANSI/AAMI ID 26.²

79.2 INFUSION DEVICES shall accept a command from the ANESTHESIA WORKSTATION CONTROL CENTER to disable INFUSION DEVICE audible alarms.

79.3 INFUSION DEVICES shall respond to queries from the ANESTHESIA WORKSTATION CONTROL CENTER for identification and status. The INFUSION DEVICE shall be identified to the ANESTHESIA WORKSTATION CONTROL CENTER by one of the following: a unique identifier of the INFUSION DEVICE, a logical identifier, corresponding to the fluid being delivered, and the INFUSION DEVICE'S DIGITAL INTERFACE port location on the ANESTHESIA WORKSTATION.

NOTE 34—An INFUSION DEVICE should provide a minimum set of

responses including: "not granted," "feature not available," and "unknown request."

79.4 Information transmitted to the ANESTHESIA WORKSTATION shall as a minimum include the information required for the anesthesia record.

79.5 Communication interfaces shall support a centralized alarm management strategy, accomplished in the following manner (also see Appendix X1):

The ANESTHESIA WORKSTATION CONTROL CENTER shall send a command to an INFUSION DEVICE instructing it to DISABLE its audible alarms. The command shall be transmitted using a predetermined rate and protocol. If an INFUSION DEVICE does not receive this command under the predetermined conditions, it shall enable audible alarms.

HIGH PRIORITY alarms shall be visually presented at the INFUSION DEVICE, periodically transmitted to the ANESTHESIA WORKSTATION CONTROL CENTER, and transmitted as a part of each query response until the condition is corrected at the INFUSION DEVICE.

MEDIUM PRIORITY and LOW PRIORITY ALARMS shall be visually presented at the INFUSION DEVICE and transmitted to the ANESTHESIA WORKSTATION CONTROL CENTER as part of each query response until the condition is corrected at the INFUSION DEVICE.

The ANESTHESIA WORKSTATION CONTROL CENTER shall present device alarm conditions to the OPERATOR in accordance with the centralized management prioritization scheme.

80. Data Interface Requirements for an Automated Anesthesia Record Keeper (AARK)

80.1 This section defines physical, functional, and electrical integration of an AARK with other components of an ANESTHESIA WORKSTATION.

NOTE 35—An AARK typically consists of a central processing unit, one or more data entry mechanisms, a MULTIPORT COMMUNICATION DEVICE, and a visual display. The AARK records data at defined intervals from other components of the ANESTHESIA WORKSTATION and may accept data from other sources. RECORDED DATA is typically displayed in a tabular or graphical format that emulates the traditional anesthesia record. The AARK also provides methods for entry of patient demographics, drugs, and clinical notes and events. Data are saved on removable or non-removable storage media (for example, computer disks or paper).

The AARK may be part of a NETWORK that communicates with other INFORMATION SYSTEMS (for example, BACK-UP servers, other AARKs, hospital or laboratory information systems).

80.2 Requirements

80.2.1 The AARK shall be capable of automatically acquiring electronically monitored physiological parameters from patient monitoring components for the ANESTHESIA WORKSTATION. At a minimum the AARK shall provide a means of acquiring all mandatory patient parameters specified in the Standard for Basic Anesthetic Monitoring published by the American Society of Anesthesiologists⁸ and the American Association of Nurse Anesthetists⁹.

NOTE 36—Input data may include, but are not limited to, the following sources: ECG, pulse rate, temperature, blood pressure, end-tidal CO₂, pulse oximetry, cardiac output, airway gas, airway pressure and flow, other

¹¹ Annual Book of ASTM Standards, Vol 14.01.

¹² Annual Book of ASTM Standards, Vol 03.06.

oxygen saturation, EMG, alarm status and combinations of these.

NOTE 37—In addition, the AARK should be capable of automatically acquiring data from the DELIVERY DEVICES that may be components of the ANESTHESIA WORKSTATION.

NOTE 38—The AARK may be capable of automatically generating, acquiring, or synchronizing additional data such as date, time, status, etc. among the ANESTHESIA WORKSTATION components.

NOTE 39—The AARK should be capable of communicating with other INFORMATION SYSTEMS that could contribute to the AUTOMATED ANESTHESIA RECORD. Interfaces should include but are not limited to, inputs from hospital information systems (for example, laboratory, pharmacy, DECISION SUPPORT, perioperative systems, or archived patient records).

NOTE 40—The AARK should be capable of sending the electronic anesthetic record to other medical record systems employing suitable standard methods.

80.2.2 The AARK shall have means for allowing OPERATOR INPUT of data that have not been acquired automatically.

NOTE 41—Data that may be entered manually include but are not limited to patient demographics, clinical notes, events, ARTIFACT indication, comments, personnel, equipment utilized, etc.

80.2.3 AARK devices marketed as compatible with the ANESTHESIA WORKSTATION shall provide DIGITAL INTERFACES capable of receiving measurement and status data from devices conforming to the data interface specification of Clause 78.

The AARK shall be capable of communicating via DIGITAL INTERFACES with patient monitoring and other digitally interfaced equipment configured as components of the ANESTHESIA WORKSTATION, utilizing applicable published standards whenever possible, and other means when necessary.

NOTE 42—The DIGITAL INTERFACES provided by the AARK may be configurable such that they can operate at different data rates, parity types, and framing types. Also, the AARK may employ other electronic interfaces to other types of non-medical electronic equipment such as various INPUT DEVICES, OUTPUT DEVICES, or a combination of both (for example, local area NETWORK, data storage media). Such additional electronic interface connections should not affect the operation of the data interfaces or the integrity of the data collected.

NOTE 43—The AARK may transform or process data from various sources.

NOTE 44—An AARK should be capable of transmitting and receiving data on a NETWORK. Data should comply with appropriate standards for health information exchange (for example, Specification E 1238¹¹, HL7 v2.3¹³). The data collected should be in a form that can be stored in a database or exported.

NOTE 45—The AARK should provide means to prevent loss of data, including: means to automatically and securely BACK-UP or archive all data stored by the AARK; an operational power supply even when the ANESTHESIA WORKSTATION power is “off”; and incorporation of an auxiliary RESERVE ELECTRICAL POWER SUPPLY enabling the AARK to continue to function in the event of low power or power interruptions or disturbances. (See Clause 80.4.2)

80.3 Specific Requirements

80.3.1 The AARK shall produce at least an acceptable perianesthetic record as defined by the ASA Standards, Guidelines and Statements (October 1996).⁸

80.3.2 The AARK shall provide means of EDITING the data that has been entered into the record.

80.3.3 A NON-VOLATILE audit trail of alterations (the original and modified) shall be generated, including the time of change and who made the change.

NOTE 46—If an AARK can place an electronic signature on the anesthetic record, it should comply with Guide E 1762.¹¹

NOTE 47—The AARK should provide means to prevent unauthorized access to patient or provider data from the electronic record. The AARK may make data contained in the anesthesia record available to other INFORMATION SYSTEMS.

80.3.4 There shall be a means to display the data that comprises the anesthetic record. The AARK shall be capable of displaying this or other data as it is acquired.

NOTE 48—Not all of the data needs to be displayed simultaneously.

80.4 Physical & Technical Documentation

80.4.1 AARK devices marketed as compatible with the ANESTHESIA WORKSTATION shall have available technical documentation defining the physical dimensions and weight of the equipment as defined in 6.8 of this specification.

NOTE 49—Attachment of an AARK to an ANESTHESIA WORKSTATION should not cause the ANESTHESIA WORKSTATION to be out of compliance with the requirements of Section 4 of this specification.

NOTE 50—The ANESTHESIA WORKSTATION should accommodate the physical attachment of an AARK.

80.4.2 AARK devices marketed as compatible with the ANESTHESIA WORKSTATION shall have technical documentation defining the electrical specifications of the equipment. These specifications must at the minimum include voltage and current requirements of the equipment under operating conditions with applicable environmental specifications for the equipment under operating and non-operating conditions. This technical documentation shall be provided as part of the accompanying documents of the ANESTHESIA WORKSTATION as defined in 6.7 of this specification.

NOTE 51—Electrical power for the AARK may be provided by either an independent power outlet, or by the main power source within the ANESTHESIA WORKSTATION. If power for the AARK is provided by the main power source within the ANESTHESIA WORKSTATION, the AARK should be able to remain in an “ON” mode and not be affected by the ANESTHESIA WORKSTATION when the main power switch is in power “Off” mode. This will prevent possible loss of data should the operator accidentally switch off the power mains to the ANESTHESIA WORKSTATION prior to the complete writing of RECORDED DATA to a NON-VOLATILE storage media by the AARK.

NOTE 52—AARK devices should incorporate an auxiliary RESERVE ELECTRICAL POWER SUPPLY enabling the AARK to continue to function in the event of low power or power interruptions or disturbances. The inclusion of such a capability shall be documented in the appropriate accompanying documents as defined in 6.8 of this specification.

80.4.3 If the AARK transforms or processes data, the processes or transformations shall be described in the technical documentation.

80.4.4 If the AARK generates data elements, such as date, time, status, etc. the methods utilized shall be specified in the technical documentation.

¹³ Available from Health Level Headquarters, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104.

ANNEXES

(Mandatory Information)

A1. REFERENCES

A1.1 AAMI Documents⁶:

- AAMI HE-48 Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices
- AAMI ES-1 Safe Current Limits for Electromedical Apparatus
- AAMI EC-11 Electrocardiographic Devices
- AAMI SP-10 Electronic or Automated Sphygmomanometers

A1.2 ASME Standard¹⁴:

- ASME B40.1 Gauges - Pressure Indicating Dial Type - Elastic Element

A1.3 ASTM Standards:

- D 3670 Guide for Determination of Precision and Bias of Methods of Committee D-22¹⁵
- E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems¹¹
- E 1467 Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems⁹
- E 1713 Specification for Transferring Digital Waveform Data Between Independent Computer Systems¹¹
- E 1762 Guide for Electronic Authentication of Health Care Information¹¹
- F 960 Specification for Medical Surgical Suction and Drainage Systems⁸
- F 1054 Specification for Conical Fittings of 15 mm and 22 mm Size
- F 1161 Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines⁷
- F 1204 Specification for Anesthesia Reservoir Bags⁷
- F 1208 Specification for Performance and Safety Requirements for Anesthesia Breathing Systems⁷
- F 1343 Specification for Scavenging Systems for Anesthetic Gases⁷
- F 1415 Specification for Pulse Oximeters⁷
- F 1456 Specification for Capnometers⁷
- F 1452 Specification for Minimum Performance and Safety Requirements for Anesthetic Gas Monitors⁷
- F 1462 Specification for Oxygen Analyzers⁷
- F 1463 Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care⁷

A1.4 CGA Standards⁵:

- CGA C-9-1993 Standard Color Marking of Compressed Gas Cylinders Intended for Medical Use
- CGA V-1-1994 Compressed Gas Cylinder Valve Outlet and Inlet Connections
- CGA V-5-1989 Non-Interchangeable Low Pressure Connections for Medical Gas Applications
- CGA G-7-1997 Commodity Specification for Air

A1.5 EIA/TIA Documents³:

- EIA RS-232-C 1969 Interface between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange
- EIA/TIA-232-D 1987 Interface between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange
- EIA/TIA-232-E 1991 Interface between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data

A1.6 HL7 Document¹³

- HL7 An Application Protocol for Electronic Data Exchange in Healthcare Environments

A1.7 IEC Standards²:

- IEC 601-1 Safety for Medical Electrical Equipment Part 1: General requirements (2nd Ed. - 1988)
- IEC 601-1-1 Medical Electrical Equipment: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 601-1-2 Medical Electrical Equipment: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

A1.8 IEEE Standards⁴:

- IEEE STD 1073 IEEE Standard for Medical Device Communications—Transport Profile—Overview and Framework
- IEEE STD 1073.3.1 IEEE Standard for Medical Device Communications—Transport Profile—Connection Mode (ANSI)
- IEEE STD 1073.4.1 IEEE Standard for Medical Device Communications—Physical Layer Interface—Cable Connected (ANSI)

A1.9 ISO Standards²:

- ISO/IEC 7498-1: Information Technology—Open Systems Interconnection—Basic Reference Model: The Basic Model (for many related references, see citations in IEEE STD 1073-1996)
- ISO 4135 Anesthesiology Vocabulary

¹⁴ Available from American Society of Mechanical Engineers, ASME, 345 East 47th Street, New York, NY 10017.

¹⁵ Annual Book of ASTM Standards, Vol 11.03.

A2. METHOD OF TEST FOR THE ACCURACY OF DELIVERED VAPOR CONCENTRATION DURING OXYGEN FLUSH

A2.1 Test the ANESTHETIC VAPOR DELIVERY DEVICE on the ANESTHESIA WORKSTATION with a ANESTHESIA BREATHING SYSTEM recommended by the manufacturer or supplier (see 6.8.2).

A2.1.1 Connect an anesthetic vapor analyser to the COMMON GAS OUTLET of the ANESTHESIA WORKSTATION or, if applicable, to the inspiratory port of the ANESTHESIA VENTILATOR.

A2.1.2 Check to ensure that the components downstream of the ANESTHETIC VAPOR DELIVERY DEVICE will not affect the test results, for example by absorbing the volatile agents, by imposing time delays on response, or by leakage.

A2.2 Place the ANESTHESIA WORKSTATION with the specified test equipment and anesthetic agent in the test room for at least 3 h at $20 \pm 3^\circ \text{C}$ and maintain this temperature throughout the test procedure.

A2.3 Fill the ANESTHETIC VAPOR DELIVERY DEVICE with the appropriate anesthetic agent to approximately half of the maximum usable volume, and let it stand for at least 45 min.

NOTE A2.1—These 45 min may be within the 3 h period specified in A2.2.

A2.3.1 If the manufacturer recommends that when power is applied to the ANESTHETIC VAPOR DELIVERY DEVICE, a

warm up period be allowed before use, power shall be applied for at least that period before testing. This period may be within the 45 min.

A2.4 Set the ANESTHETIC VAPOR DELIVERY DEVICE to the “on” position at the maximum concentration setting. Purge the ANESTHETIC VAPOR DELIVERY DEVICE for 3 min at a flow of 2 L/min.

A2.5 With the ANESTHETIC VAPOR DELIVERY DEVICE in the “off,” “zero” or, if applicable, the “standby” position, set the gas flow through the ANESTHESIA WORKSTATION to $2 \pm 0.2 \text{ L/min}$ and adjust the ventilator to give 15 ± 2 breaths/min at an I:E ratio of $1:2 \pm 20\%$ with the inspiratory flow control set to maximum.

NOTE A2.2—For an ANESTHESIA WORKSTATION in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of $2 \pm 0.2 \text{ L}$.

A2.6 Measure the output of anesthetic vapor (concentration of vapor \times volume of gas) for 1 min before and then during a 10 s operation of the oxygen flush.

A2.6.1 Compare these two measurements expressed as volume of vapor per unit of time.

NOTE A2.3—The volume of gas may be determined for example, by integrating flow or by collecting the gas during the specified period.

APPENDIXES

(Nonmandatory Information)

X1. COMMUNICATION INTERFACE: DOCUMENTATION AND SUPPORT

X1.1 Devices marketed as compatible with this specification should provide the following:

X1.1.1 Documentation of the DIGITAL INTERFACE (that is, by including the protocol in the USER’s Manual for the device). The seven-layer ISO communications model may be useful for this purpose. Some layers may have null implementations or cite appropriate published standards. Unique characteristics not defined by cited standards should be adequately disclosed by the manufacturer so that another party (for example, USER, manufacturer) may establish successful digital data transmission.

X1.1.1.1 Layer 1—Physical—Connector, pinouts, voltages, cable requirements, etc.,

X1.1.1.2 Layer 2—Data Link—Control information, frame length, etc.,

X1.1.1.3 Layer 3—Network—Address definition, etc.,

X1.1.1.4 Layer 4—Transport—Acknowledgment messages, sequence numbers, flow control, etc.,

X1.1.1.5 Layer 5—Session—Connection establishment and teardown, control mechanisms, remote procedure calls, etc.,

X1.1.1.6 Layer 6—Presentation—Transformation, formats, compression, expansion, encryption, decryption, etc., and

X1.1.1.7 Layer 7—Application—File access/transfer, virtual terminal information transfer, network management, directory services, etc.

X1.1.2 Appropriate supplemental support mechanisms for DIGITAL INTERFACES in addition to documentation (that is, technical support services, or provision of equipment by temporary arrangement).

X1.1.3 In cases where operation of special device options (for example, control) require a DIGITAL INTERFACE, manufacturers should/may negotiate appropriate agreements to ensure safe and predictable behavior of devices when integrated to function as parts of a system.

X2. COMMUNICATION INTERFACE: CONTROL OF ALARMS

X2.1 A product may allow another (controlling) product to remotely control its alarms. This control should at least affect the controlled product's visual and audible alarm notifications. Specific control of the controlled product's alarm "definitions" may also be provided.

X2.2 Devices that permit modification of their alarm state by another controlling device should revert to default behavior with auditory and visual alarms enabled when valid communication to verify continuation of a controlling relationship of one device over another is not periodically transmitted and acknowledged.

X2.3 If remote control over alarms is provided, it should be provided via a DIGITAL INTERFACE using a standard communication protocol. Ideally, this DIGITAL INTERFACE would also be used for communication of parameter values.

X2.4 An INFUSION PUMP should allow a potential controller to request control over the controlled product's alarm notification or definition functions, or both. Control of alarm functions may affect definitions and notification of alarm

conditions. The controlled product should not grant this control request unless the request for control was preceded by a continuous output request for alarm and alert status information. It should allow the controlling product to request control over the controlled product's alarm notification or definition functions, or both.

X2.5 If control over alarm notification is provided, after control is adequately requested and granted, the controlled device may initiate a visual alarm indication, but should not initiate any audible alarm indications, if so configured by the USER. The controlling device should visually and audibly indicate the alarm condition.

X2.6 If control over alarm "definition" (for example, alarm enabled (ON) or disabled (OFF), alarm limit value, etc.) is provided, the controlled device should identify which alarm definitions may be modified, which definitions are to be affected, and what values are acceptable. There should be a mechanism to permit the controlling device to verify that requested changes have been made or refused.

X3. RATIONALE

X3.1 Clause 6.1j—The marking of the ANESTHESIA WORKSTATION power input and the sum of the power input in amperes, gives information on the minimum mains fuses or OVER CURRENT RELEASES needed in different situations.

X3.2 Clause 6.1k—The marking of each auxiliary mains socket outlet with its output in amperes, gives information on the current ratings of the fuses or OVER CURRENT RELEASES of each auxiliary mains socket outlet.

X3.2.1 Note 2—Ideally, the fuses or OVER CURRENT RELEASES for these auxiliary mains socket outlet would always be immediately adjacent. However, this is not always the case; therefore this requirement that marking be provided to indicate the location of the fuses or OVER CURRENT RELEASES was felt to be justified.

X3.3 Clause 6.8.2k—The higher the leakage current the greater the risk for the patient or operator to suffer electrical shock. Leakage current of multiple devices connected together will be greater than that of any single device. Therefore, the connected devices should be tested for leakage current as a single assembled system.

X3.4 Clause 19.4h—The definition of the APPLIED PART in this specification is the basis for, and clarification of, the requirements for and measurement of patient leakage current.

X3.4.1 It is not possible, however, to include any requirements in this Particular Standard for leakage currents from electrically operated attachments such as humidifiers and heating elements which may be connected in the ANESTHE-

SIA BREATHING SYSTEM because the types of such attachments which will be used in clinical work with a specific type of ANESTHESIA WORKSTATION cannot be anticipated by the manufacturer or by a test house.

X3.4.2 However, parts integrated with the ANESTHESIA WORKSTATION such as temperature and carbon dioxide sensors that are intended to come into contact with the ANESTHESIA BREATHING SYSTEM and that are electrically connected to the ANESTHESIA WORKSTATION are considered as parts for which requirements for leakage currents can be specified in this specification. Such parts are therefore included in the definition of APPLIED PART. (See Fig. 1 of the General Standard.)

X3.4.3 The U.S. national standard, AAMI ES-1, states the allowable limits for leakage current.

X3.5 Clause 37—Equipment that can be used with flammable anesthetic agents is not covered by this specification.

X3.6 Clause 38—Equipment that can be used with flammable anesthetic agents is not covered by this specification.

X3.7 Clause 39—Equipment that can be used with flammable anesthetic agents is not covered by this specification.

X3.8 Clause 40—Equipment that can be used with flammable anesthetic agents is not covered by this specification.

X3.9 Clause 41—Equipment that can be used with flammable anesthetic agents is not covered by this specification.

X3.10 Clause 43—Reports of fire caused by medical

devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of fire is fundamentally determined by the three elements that are necessary in order to start a fire:

Ignitable material (fuel),

Temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials, and

An oxidant.

Therefore, following the basic safety concepts of the General Standard, the objective in the design of the equipment must be to ensure that under both normal and single fault conditions, and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur, provided it is self-limiting (e.g., a fuse or a resistor within a sealed compartment) so that no hazard is created.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required these may be determined using the methods and apparatus described in IEC 79-4².

In considering the ignitable materials particular attention should be paid to materials that may accumulate during prolonged use, for example, airborne particles of paper or cotton.

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures whilst in environments containing oxidants thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs; but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. Where the potential spark power dissipations deviate from the well established safe practice, therefore, specific spark tests should be conducted simulating the most unfavorable environment which can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use the requirements to minimize fire risk are based on limitation of temperature and electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen,

which is given in the American NFPA Publication 53M¹⁶ as 310°C. The assumption was therefore made that 300°C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. Simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any “fuel” present.

It is therefore, now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety may only be possible with the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, that is, material, temperature, and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments, or add forced ventilation, to ensure that the oxygen content does not exceed that of ambient air under single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under single fault conditions.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

X3.11 Clause 49.5—During committee deliberations it was decided that fresh gas flow and automatic ventilation were the minimum performance characteristics that needed to be retained by the ANESTHESIA WORKSTATION, so as to permit the OPERATOR a period of at least 30 min to either correct the power failure or have the surgery completed and the patient moved to a safer location.

X3.12 Clause 49.6—The committee felt that going to reserve electrical power did not require an immediate OPERATOR response, but merely awareness. Accepting this premise,

¹⁶ Available from National Fire Protection Association, NFPA 7 Batterymarch Park, Quincy, MA 02209-9101.

which is also based on a 30 min period during which the ANESTHESIA WORKSTATION will provide automatic ventilation and continuous fresh gas flow, a LOW PRIORITY ALARM which could not be disabled was provided for.

X3.13 Clause 49.7—The committee felt that the OPERATOR, having already been alerted by a LOW PRIORITY ALARM to the fact that the workstation was operating on RESERVE ELECTRICAL POWER SUPPLY, needed nothing more than a MEDIUM PRIORITY ALARM to indicate that the RESERVE ELECTRICAL POWER SUPPLY was approaching imminent failure. For obvious reasons they felt that this alarm should not be capable of being disabled.

X3.14 Clause 49.8—The committee after extensive deliberations felt that a means must be provided to the OPERATOR to determine the status of the RESERVE ELECTRICAL POWER SUPPLY and in some fashion to permit the OPERATOR to estimate how much time remained before complete failure of the RESERVE ELECTRICAL POWER SUPPLY.

X3.15 Clause 51.7.7—The first paragraph in this clause intends to avoid excessive noise in the operating room by having the HIGH PRIORITY ALARM stop as soon as possible, that is, as soon as the condition causing the alarm's activation stops. There are many alarm activating conditions that are frequently very brief, for example, as patient's cough during a ventilator inspiratory flow, a breathing tube compressed by a surgical assistant leaning on it, or more insidious still, an intermittent malfunction in a ventilator.

X3.15.1 For these, and similar situations that are very brief, or that occur while the anesthetist is otherwise occupied and not looking at the central display, or alarm panel, the committee felt that a "flight recorder" or more probably the AARK should store the event (not necessarily displaying or recording it on the anesthesia record). The practice of recording all events whether they are incorporated in the clinical record or not may assist detection and documentation of rare or intermittent events that are otherwise very resistant to diagnosis.

X3.16 Clause 51.9.3.4.1—The committee generally agreed that currently there is no way to indicate reliably the failure of breathing system integrity (for example, partial or even complete disconnection of the breathing system). Under certain specific circumstances, CO₂ monitoring, (low) pressure monitoring, (low) volume monitoring, anaesthetic vapor monitoring, or O₂ monitoring may indicate, or contribute to, the detection of loss of breathing system integrity. It is for these reasons that a medium priority alarm have been provided for the monitors mentioned. The manufacturer, in the accompanying documents, shall indicate which monitor, or combination of monitors, is most likely to indicate disconnection may have occurred.

X3.17 Clause 51.12.1—As defined in CGA standard G 7.1⁶, "medical air" is permitted to have an oxygen concentration between 19.5 and 23.5 %. Allowing a minimum concentration of 19 % at the fresh gas outlet, permits the manufacturer to offer the OPERATOR to deliver air from the

ANESTHESIA GAS SUPPLY DEVICE in the event of an oxygen supply failure.

X3.18 Clause 57.2e—In order to assist the USER/OPERATOR in managing total system leakage current, the committee agreed to require the auxiliary mains socket outlets, when provided, to be a specific type that will not accept a standard mains plug. The committee agreed that requiring these non-standard outlets will make it inconvenient to attach non-medical equipment (for example, vacuum cleaners), or inappropriate devices (for example, high current drawing devices such as a heating blanket) to the ANESTHESIA WORKSTATION.

X3.18.1 The committee also decided against limiting the number of these outlets to a small specific quantity (that is, four) since the number of outlets is by itself no guarantee that leakage current limits will not be exceeded.

X3.19 Clause 57.3a—Accidental disconnection of the mains supply cord could be hazardous to the patient.

X3.20 Clause 57.6aa—A short circuit of another equipment connected to the auxiliary mains socket outlet must not affect the normal function of the life support function of the ANESTHESIA WORKSTATION.

X3.21 Clause 64.2—This is a test for the stability of flow as adjusted by a flow control and is designed to determine the preset allowable flow shall be within $\pm 10\%$ of the setting chosen by the OPERATOR or within ± 10 mL/min for a 30 min period, whichever is greater; this to occur under normal operating conditions as described by the manufacturer. It is reasonable to expect that the ANESTHESIA WORKSTATION, once set, will not need checking every 10, 20, 30, 60 s or every 2 to 3 min. Traditionally, and commonly, anesthetists record blood pressure and pulse values at 5 min intervals. It is common to record the gas flows from the machine at 15 to 30 min intervals. Therefore, it was elected to use a 30 min period in which to assume that the OPERATOR would not have to pay close attention to the flows being delivered by the ANESTHESIA WORKSTATION. It was felt unreasonable, due to potential variations in piped gas pressures within a large hospital and operating room suite, or possible variations within the pressures of the gas machine piping due to power on, turn off, or change in settings of a gas powered ventilator, to demand beyond a 30 min period of stability.

X3.22 Clause 78—Communication Interface: Rationale

X3.22.1 Prologue:

X3.22.1.1 Digital technologies open new design alternatives for anesthetic delivery systems, while digital communication technologies may facilitate better integration of traditionally independent monitors and delivery devices used for monitoring and administration of anesthesia to patients. Integration of formerly independent devices into systems opens opportunities that were formerly unachievable. A relatively simple example is prioritization and presentation of alarms at a central location, dealing with one of the critical human factors and safety issues

during anesthetics. Clinical DECISION SUPPORT and apparatus fault diagnosis are more sophisticated examples drawing on information from multiple sources.

X3.22.1.2 Many considerations pertaining to the use of digital communications as a core technology have arisen during the development of this ANESTHESIA WORKSTATION standard. This appendix attempts to distill the most important rationales and issues from many discussions. Different issues and significance depend on whether one is considering passive data collection and display, centralized management of alarms, modification of alarm annunciation, or feedback control of delivery systems.

X3.22.1.3 Other issues arise when considering the flow of data and its availability according to need. In systems using serial digital interfaces to transmit information, one device may potentially intercept data destined for another. In such cases a mechanism to pass the data to the needful recipient should exist. In contrast, on a data network broadcast data can be collected by any able recipient. However data transmission within this standard for an ANESTHESIA WORKSTATION does not employ a broadcast NETWORK model.

X3.22.2 *Necessity:*

X3.22.2.1 It is one of the intentions of this specification to enable assembly of well-integrated ANESTHESIA WORKSTATIONS employing modular components that may originate from different manufacturers.

X3.22.2.2 This specification on one hand recognizes changes in ANESTHESIA DELIVERY SYSTEM technology that may provide alternatives to previously standardized anesthesia gas delivery systems based on mechanical technology (Specification F1161⁸). An additional motivation for the creation of this standard is the rapid advance of information technologies in the last several years. Successful communication, presentation, and storage of digital data is essential to developing a systematically integrated ANESTHESIA WORKSTATION that improves upon prevailing haphazard associations of independent ANESTHESIA DELIVERY SYSTEMS, MONITORS, and recordkeeping devices (AARKs). Poor integration and harmonization create a confusing working environment for the OPERATOR, especially regarding alarms; that is a widely recognized factor degrading human performance. Therefore it is a significant patient safety issue.

X3.22.3 *Framework:*

X3.22.3.1 The perioperative period has a uniquely high information density that is rarely integrated with other evolving medical INFORMATION SYSTEMS. This specification attempts to define a suitable framework for acquisition, use, and storage of the perianesthetic portion of that information.

X3.22.3.2 The remainder of this appendix will focus on important considerations too diverse to standardize affecting integration of ANESTHESIA WORKSTATIONS. Restrictions imposed by this standard are explained, and pivotal issues are identified to assist manufacturers and USERS.

X3.22.4 *Safety:*

X3.22.4.1 Not all types of data that may be transmitted have the same implications for patient safety. For instance, failed transmission of monitor data or alarm status information is unlikely to be a critical problem if the primary monitors are

still functioning properly and independently. However, improperly managed control of alarms, indication of alarms in a centralized alarm management scheme, or control of AGENT DELIVERY SYSTEMS could produce critical or life-threatening situations.

X3.22.4.2 When pertinent standards are mute, and because of the potentially critical safety considerations involved when one device exerts control over another, vendors may choose to negotiate agreements regarding control functions mediated by digital interfaces.

X3.22.5 *Digital Interfaces:*

X3.22.5.1 Communication interfaces should be defined by published, public digital communication standards whenever possible. All control functions, if implemented, should be transmitted through a compliant digital serial interface. Types of data that may be transmitted using a DIGITAL INTERFACE include: device connection and status, protocol negotiation, parameter values, alarm status and current limits, and control signals, for example, to alter alarm settings, delivery device control, etc.

X3.22.5.2 Numerous standard and proprietary data communication mechanisms are possible. The committee resolved after many discussions that the number of acceptable communication standards should be restricted to improve the likelihood of successful integration of modular components possibly provided by several manufacturers. EIA RS-232-C⁴ and its successors (EIA/TIA-232-D and E)⁴ are permitted because of the widespread use of these interfaces in clinical devices, computers, and computer peripherals. Because many elements of protocol, data format, assured connection, etc. are not specified by the RS-232⁴ standards, a burden of documentation is placed on the manufacturer to facilitate coherent communication between devices employed in an ANESTHESIA WORKSTATION system. Since RS-232⁴ does not provide a “reliable” transport protocol, precautions should be taken to ensure robust and reliable communication when using RS-232⁴ interfaces, especially detection of lost connections and corruption of data (for example, checksums, connection queries).

X3.22.5.3 Other related serial communication standards were considered (for example, RS-422, RS-423, RS-449, RS-485⁴). While these have specific advantages, none holds a dominant position or special suitability for medical purposes, and all suffer significant limitations since they were not designed with clinically motivated design requirements.

X3.22.5.4 IEEE-1073 (MIB, Medical Information Bus) standards are cited because they are designed for the unusual requirements of the clinical arena. The requirements include patient safety, electrical suitability, robust interface reliability, timing synchronization, and consistency of DIGITAL INTERFACES across the spectrum of medical devices. A primary purpose is that connection and configuration of a bedside data network be no more difficult for a primary clinician than plugging the devices into their mains power supplies. Manufacturers should document which members of the IEEE 1073⁵ family of standards are employed. Deviations from the published standards should be noted as necessary.

X3.22.5.5 Not all modular components of an integrated anesthesia workstation system will have DIGITAL INTERFACES. For instance, ANESTHETIC AGENT DELIVERY DEVICES (vaporizers) do not now routinely have DIGITAL INTERFACES, while future electronic vapor delivery devices may be designed with DIGITAL INTERFACES.

X3.22.5.6 Access to unmodified data from PRIMARY DATA SOURCES should be unrestricted since it is not possible to completely anticipate all purposes for which ANESTHESIA WORKSTATION INFORMATION SYSTEMS may need to employ digitally transmitted data. When it is necessary for digital data to pass through another device's DIGITAL INTERFACES it should be made available by retransmission. Retransmitted data should be annotated if the original data or format were modified. A possible solution to this dilemma is provision of a MULTIPORT COMMUNICATION DEVICE to accumulate digital data from all available PRIMARY DATA SOURCES, making all data available to any number of potential INFORMATION SYSTEM consumers. A MULTIPORT COMMUNICATION DEVICE may also need to be able to "patch" digital communication between specific ports (for example, between a central alarm controller and alarm-controlled devices).

X3.22.6 Non-Serial Data Interfaces:

X3.22.6.1 Use of other communication mechanisms in addition to acceptable standard DIGITAL INTERFACES in the context of this standard are permitted. Use of alternate communication mechanisms (for example, analog voltages, SCSI (Small Computer System Interface), IEEE-488)⁵ should be disclosed by the manufacturer.

X3.22.6.2 More advanced interfaces, protocols, and formats may be used as technology advances.

X3.22.7 Centralized Alarm Strategy:

X3.22.7.1 Control over alarms is necessary for implementation of a centralized alarm strategy. Centralization of alarm management is one of the least complex INFORMATION SYSTEMS contemplated by this standard, yet it still requires a thorough analysis of the ramifications of centralized alarm management. The analysis should include possible information requirements of the INFORMATION SYSTEMS that might communicate with the AARK, yet also need data, alarm status or limit settings from devices communicating primarily with the alarm centralization or AARK modules of the anesthetic workstation. Examples of systems potentially needing access to primary data passed through by another intermediate system include clinical data repositories and DECISION SUPPORT

SYSTEMS. Time limits for annunciation of specified conditions may constrain the tolerable delay for data being received from an intermediate system.

X3.22.8 Control, Main Power:

X3.22.8.1 A product may allow another (controlling) product to remotely control its main power state. The controlling product may exercise this control as means of ensuring that the controlled product is operational when the controlling device is turned on. Alternatively, a controlled product may allow remote control of "standby" versus "active" modes using commands from the controlling device transmitted via a DIGITAL INTERFACE.

X3.22.9 Multiple Device Digital Interfaces:

There is a potential hazard that requests for control of alarms or other device features via DIGITAL INTERFACES may be received from more than one potential controller over different interfaces. Should multiple control be granted, none of the controllers would actually know the state of the controlled device, since its state may have been changed by a different controller on another interface. Therefore, if a device has more than one DIGITAL INTERFACE and control is granted via a DIGITAL INTERFACE between a controller and device accepting external control instructions, such control should only be granted over the first interface where it is granted.

X3.22.9.1 This feature, if provided, should be hardware selectable, so that it may be DISABLED at the discretion of the USER. A controlled device should not be required to respond in such a manner as to grant control to more than one potential controller at any time.

X3.22.9.2 The USER or OPERATOR should ensure that the controlled device is set up correctly and that requests for control will only originate at one device DIGITAL INTERFACE.

X3.22.10 Control of Power or Standby Status:

X3.22.10.1 This type of control requires that the product include special hardware if it cannot be or is not plugged directly into the controlling product to obtain its main electrical power. This type of control may require a product to support a special "shut-down" mode of operation. In this mode, the controlled product may appear to be "off," but still accepts specific commands received through its DIGITAL INTERFACE. This control should occur after the complete system (for example, controlling product with controlled product) has been configured by the USER or OPERATOR to enable this special operational mode of the controlled product.

TABLE 1 Assigned Color Codes and Gas Symbols (See Clauses 6.1.b.b: 6.3.h: 6.3.J: 6.3.k: 6.3.m: 65.6: 66.3: 71)

Intended Gases	CGA Color Code	Pantone Color Numbers	Munsell Color Designations	Federal Std 595a Color Numbers	Gas Symbol
Oxygen	Green	363	10G5/10	14187	O ₂
Nitrous Oxide	Blue	292	2.5PB 4/8	Not specified	N ₂ O
Medical Air	Yellow	Yellow	6.25Y 8.5/12	23655	MED AIR
Carbon Dioxide	Grey	428	7.5GY 6/1	26492	CO ₂
Helium	Brown	470	7.5YR 3/4	Not Specified	He
Nitrogen	Black	Black	5 Y 1/0	37038 (Lusterless) 27038 (Semigloss)	N ₂
Mixtures - Except mixtures of Oxygen and Nitrogen	Color markings of mixtures shall be a combination of colors corresponding to each component gas.	Combinations of the above	Combinations of the above	Combinations of the above	He-O ₂ (He > 80 %) O ₂ -He (He < 80 %) CO ₂ -O ₂ (CO ₂ > 7 %) O ₂ -CO ₂ (CO ₂ < 7 %) O ₂ -AIR
Mixtures - Oxygen and Nitrogen					
- 19.5 % - 23.5 % Oxygen	Yellow	Yellow	6.25Y 8.5/12		O ₂ - N ₂
- All other Oxygen concentrations	Black and Green	Black & 363	5 Y 1/0& 10G5/10		O ₂ - N ₂

TABLE 2 Recommended Colors for Color Coding of Vaporizers^{A, B} (See Clause 6.3.L)

Agent	Color	USA Federal Standard	Pantone	Munsell
Desflurane	Blue	N.A. ^C	3015C	10B4/10
Enflurane	Orange	22510	151C	2.5YR 6/16
Halothane	Red	11105	200C	5R4/14
Isoflurane	Purple	N.A. ^C	254C	7.5P 4/12
Methoxyflurane	Green	14187	334C	10G 5/10
Sevoflurane	Yellow	13655	108C	6.25Y 8.5/12

^A Colors for color coding of vaporizers and appropriate color samples extracted from the following documents or standards: Munsell Book of Color¹²; USA Federal Standard 594a¹³; and Pantone Color Standard.¹⁴

^B Recommended abbreviations for anesthetic agents:

Desflurane – DES or D
 Enflurane– ENF or E
 Halothane – HAL or H
 Isoflurane– ISO or I
 Methoxyflurane– MET or M
 Sevoflurane – SEV or S

^C N.A. = Not Available

TABLE 3 Summary of ALARM, MONITORING, and PROTECTION DEVICES(S)

Delivery System/Device	Alarm Device	Monitoring Device	Protection Device
Electric power supply:			
a) Mains power supply	Clause 49.6	N/A ^A	Clause 49.5
b) Reserve power supply	Clause 49.6 and 49.7	Clause 49.8	N/A ^A
Pneumatic power supply:			
a) Cylinder pressure	N/A ^A	Clause 61.1	N/A ^A
b) Pipeline pressure	N/A ^A	Clause 61.1 and 61.3	N/A ^A
Gas delivery device:			
a) Oxygen supply failure	Clause 51.12.2	Clause 61.1 and 61.3	Clause 51.12.1
b) Other gases supply failure	N/A ^A	Clause 61.1 and 61.3	N/A ^A
c) Hypoxic mixture	N/A ^A	Clause 61.1 and 61.3	Clause 51.13.1
Agent Delivery Device	Clause 51.14.1	Clause 51.14.1	N/A ^A
Anesthesia Ventilator			
- VBS pressure ^B	Clause 51.9.3.2.1	Clause 51.9.3.1	Clause 51.9.3.1
- Exhaled volume	Clause 51.9.4.3	Clause 51.9.4.1	N/A ^A
Anesthesia Breathing System			
- VBS pressure ^B	Clause 51.9.3.2.1	Clause 51.9.3.1	51.9.3.1
- Carbon Dioxide	Clause 51.10.5.2	Clause 51.10.5.1	N/A
- Oxygen concentration	Clause 51.11.1	Clause 51.11.1	N/A
- Exhaled volume	Clause 51.9.4.3	Clause 51.9.4.1	N/A
	Clause 51.15.1 SpO2	Clause 51.15.1 SpO2	N/A
	Clause 51.15.2 BP	Clause 51.15.2 BP	N/A
	Clause 51.15.3 ECG	Clause 51.15.3 ECG	N/A

^AN/A = Not Applicable
^BVBS = Ventilator Breathing System

TABLE 4 Test Conditions for Determining Compliance of an Exhaled Volumeter in accordance with Clause 51.9.4.2

Variables or Parameters	Test Conditions		
	Adult Use	Pediatric Use	Neonatal Use
Tidal Volume V_T (mL) derived from pressure sensor on test lung ($V_T = C$ multiplied by P_{max})	500	300	30
Frequency	10	20	30
I/E Ratio	1:1.5 to 1:2.5	1:1.0 to 1:1.5	1:1.0 to 1:1.5
Resistance (R) kPa/L/s	0.5 ± 10 %	2.0 ± 10 %	5.0 ± 10 %
Isothermal Compliance (C) (mL/kPa)	500 ± 10 %	200 ± 10 %	10 ± 10 %

TABLE 5 Axial Pull Force Test (In Accordance with Clause 57.3.a)

Mass of Equipment (kg)	Pull(N)
Up to and including 1	30
Over 1 up to and including 4	60
Over 4	100

TABLE 6 Gas Mixing System Test (In Accordance with Clause 66.2.1)

		Oxygen		2nd Gas	
		Inlet Pressure minimum	Inlet Pressure Maximum	Inlet Pressure minimum	Inlet Pressure Maximum
Total Flow	Minimum	X	...	X	...
	Maximum	...	X	...	X

TABLE 7 Settings to be Used for Testing Accuracy of Delivered Concentration

Order of Test	Setting (% v/v of Anesthetic Vapor)
1	off, standby, and zero, if separately marked
2 ^A	lowest graduation above zero
3 ^B	10 % FS
4 ^B	20 % FS
5 ^B	50 % FS
6 ^B	75 % FS
7	maximum graduation (full scale)

^AIf 10 % of Full Scale (FS) is the lowest graduation, step 2 is omitted.
^BIf the percentages of Full Scale (FS) do not coincide with a marked setting, use the nearest lower marked setting.

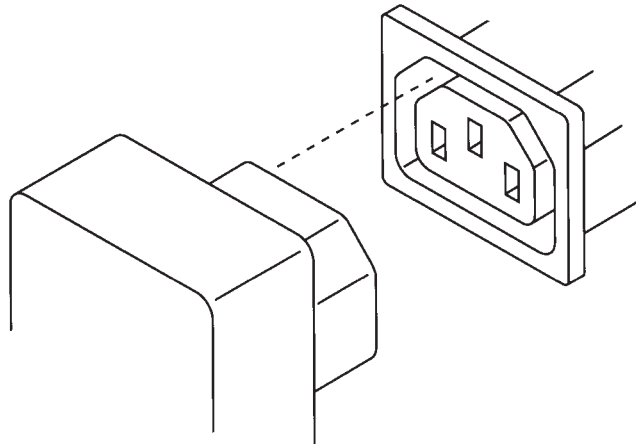
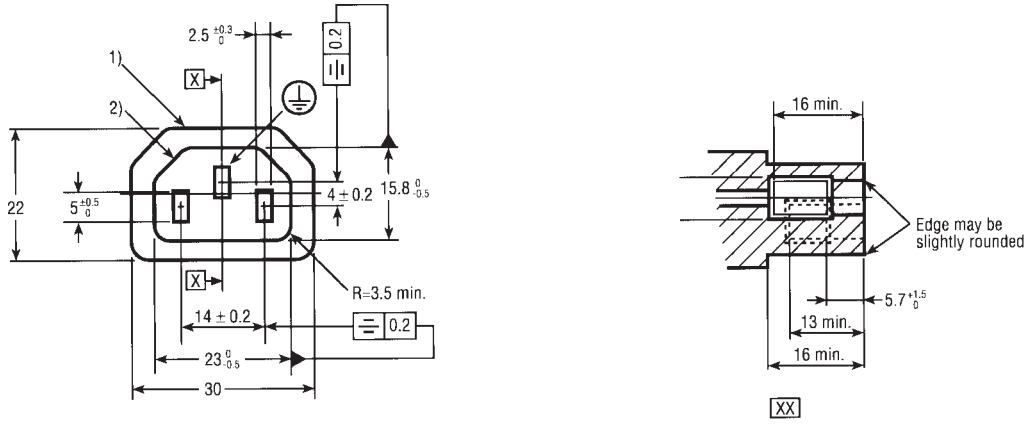


FIG. 1 IEC 320—Appliance Couplers

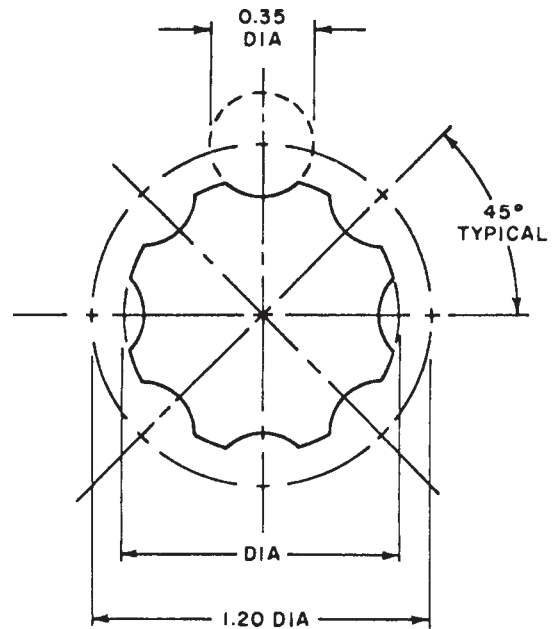
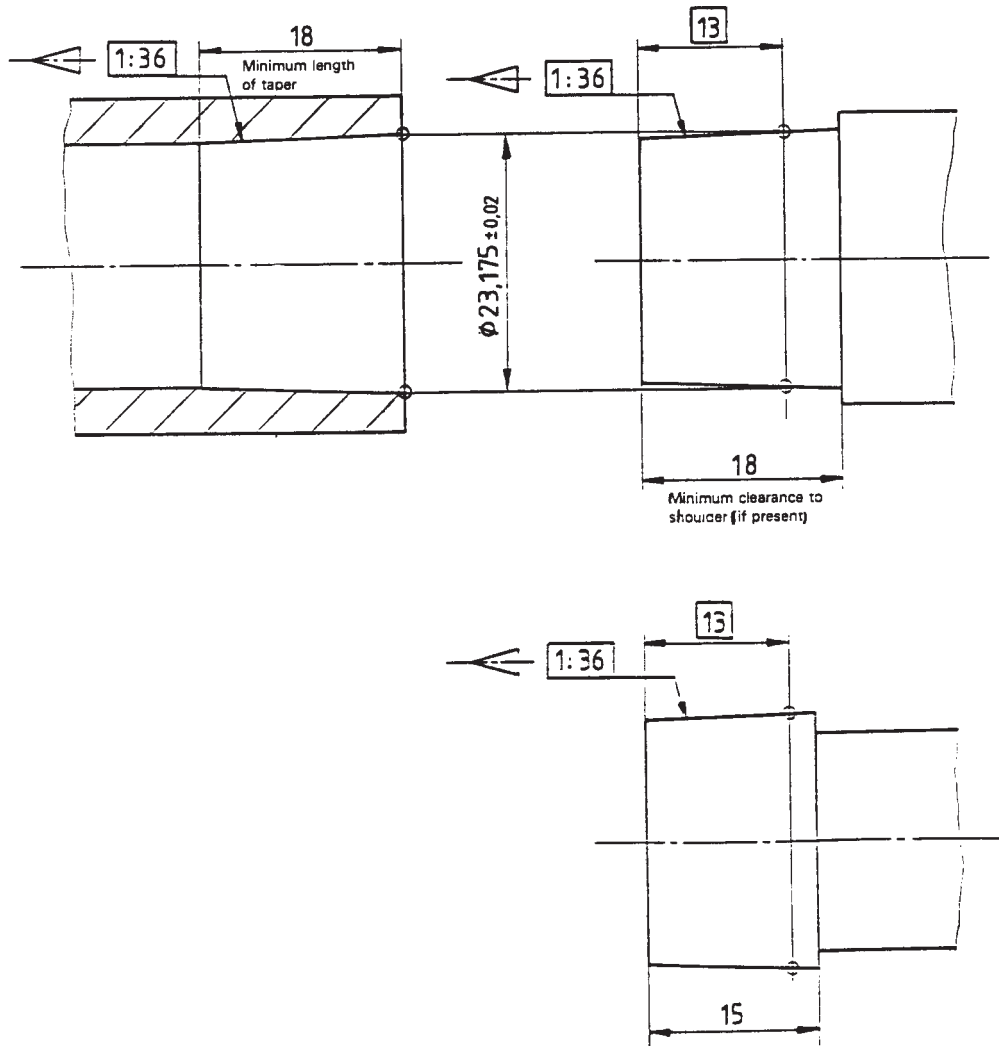


FIG. 2 Oxygen FLOW ADJUSTMENT CONTROL



Notes:

- (1) Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.
- (2) Dimensions in millimetres.

NOTE 1—Maximum radius on the entrance to the female connector and on the leading edge of the male cone should be not less than 0.5 mm and not more than 0.8 mm.

NOTE 2—All dimensions in millimetres.

FIG. 3 Conical Fittings of 23 mm Size

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