

**American
National
Standard**

ANSI/AAMI II51:1996

Transport infant incubators



**Association for the Advancement
of Medical Instrumentation**

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II51 Transport infant incubators

American National Standard

ANSI/AAMI II51—1996

Transport infant incubators

Developed by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract:

This standard delineates requirements for transport incubator labeling and performance, which are intended to minimize risks to patient and user, and establishes referee tests by which the requirements can be verified.

Keywords:

compartment, environment, temperature, thermal, transportation

Committee representation

Association for the Advancement of Medical Instrumentation

Infant Incubator Committee

This standard was developed by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

The **AAMI Infant Incubator Committee** currently has the following members:

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Members: Joseph P. Bagnell, Air-Shields Vickers
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Devices and Radiological Health

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Acknowledgment

The AAMI Infant Incubator Committee wishes to acknowledge the contribution of Mr. Otho Boone of Ohmeda, who served as cochair of the committee during much of the development of this standard.

Foreword

This standard was developed by the AAMI Infant Incubator Committee. The objective of this standard is to provide minimum labeling, performance, and safety requirements that will help assure a reasonable level of clinical efficacy and patient safety. The standard is not intended to address matters of medical management and/or prescription, which are the responsibility of the medical personnel.

No standard can fully assure that a device will be totally safe and effective. Known risks associated with the use of transport incubators are addressed in this standard, but this does not preclude the possibility of harm as a result of improper use, random component failures, or other unanticipated hazards.

As with many other medical devices, it is inherent in the design and function of transport incubators that to be effective for one patient a device may be potentially harmful to another, even when the device is performing to the manufacturer's specifications and in conformance with a published standard. It is possible that an absolutely "safe" device would be ineffective for at least a portion of the patient population for which its use is intended.

Performance requirements have been established in this standard where a parameter is known to affect safety and efficacy and where sufficient data are available to establish specific performance criteria. Technological feasibility alone has not been considered a valid basis for establishing performance requirements.

Disclosure requirements have been established in this standard where a parameter is known to affect safety and efficacy, but where sufficient data are not available to permit the establishment of performance criteria. Where disclosure requirements have been defined, sufficient information has been provided to permit the user to knowledgeably compare and evaluate the parameters on available incubators when disclosure is made.

Referee test methods have been made part of the standard to ensure that a valid comparison of information required for disclosure can be made and that conformance with the performance requirements can be verified.

The rationale statement of [annex A](#), while not an "official" part of the standard, explains the committee's reasons for establishing the disclosure and performance requirements and provides important technical and clinical data to support these provisions. It is essential that the rationale be read and understood by all who use the standard as a reference.

It should be recognized that because a transport incubator currently in use does not fully comply with all of the labeling, performance, and safety requirements of this standard, it does not necessarily mean that the device cannot be used safely and effectively. Nonconformance with the standard should not be the sole basis for a decision to replace a transport incubator.

The decision on whether to continue use of a transport incubator should be based on careful consideration of the extent and nature of nonconformance, on how it has been and will continue to be used, and on what costs, risks, and/or benefits will result from the decision.

In the development of this standard, the committee has drawn extensively on the work performed by ECRI (formerly the Emergency Care Research Institute) under contract with the U.S. Food and Drug Administration (FDA). The final report on this work, "The Development of a Standard for Infant Warmers and Incubators" (NTIS document No. PB-263 250/3WV), was published in 1976. An attempt was also made to achieve harmonization with the draft standard for transport incubators which has been completed by Subcommittee SC62 (Electromedical Equipment) of the International Electrotechnical Commission (IEC). Lastly, to ascertain the current clinical consensus on many of the safety and performance issues that required resolution, the committee relied heavily on the recommendations of the Infant Incubator Advisory Task Force of the American Academy of Pediatrics (AAP). The assistance of the AAP Task Force and FDA's support of the Task Force's work are gratefully acknowledged.

The requirements in this standard should be considered flexible and dynamic. Like any other standard, it must be periodically reviewed and updated to reflect medical and/or technology advances and to address safety and performance issues not previously identified. It must be modified as technological innovation occurs and as new data are brought forward.

As used within the context of this standard, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is discouraged but not prohibited; "may" is used to indicate a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations.

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, and other health care professionals, working with government representatives and device manufacturers, to define those safety and performance criteria that could reasonably be achieved at this time. Suggestions for improving the standard are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA, 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI standard, *Transport infant incubators* (ANSI/AAMI II51—1996), but it does provide important information about the development and intended use of the document.

Transport infant incubators

1 Scope

1.1 General

This standard applies to transport incubators, those electrically powered devices that are intended to assist in maintaining the thermal balance of infants, principally by controlling the air temperature in an enclosure, and also are suitable for transporting an infant inside and/or outside a hospital. Transport infant incubators have a self-contained electric power supply for use when an external supply is not available.

NOTE—All references to transport incubators in this document refer to transport infant incubators.

1.2 Inclusions

Transport incubators are classified for purposes of this standard into two classes, on the basis of the temperature

variable which is controlled. Included within the scope of this standard are air temperature control (ATC) transport infant incubators and infant temperature control (ITC) transport infant incubators.

At the time of this writing, we are aware of two Federal Aviation Administration guidelines (see [annex B](#), references).

1.3 Exclusions

This standard does not cover

- a) radiant warmers, i.e., devices that primarily utilize radiant energy to maintain the thermal balance of an infant;

NOTE—The applicability of future standards for radiant warmers to a transport incubator incorporating radiant heat must be addressed when such standards are issued.

- b) incubators not specifically intended for use in transporting infants either outside or within the health care facility and not including a self-contained power supply; or
- c) transport incubators intended for use in anesthetic environments.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to use the most recent editions of the documents indicated below.

2.1 AMERICAN NATIONAL STANDARDS INSTITUTE, CANADIAN STANDARDS ASSOCIATION AND COMPRESSED GAS ASSOCIATION. *Compressed gas cylinder valve outlet and inlet connections*. ANSI B57.1; CSA B96; CGA V-1-1987.

2.2 AMERICAN SOCIETY OF HEATING, REFRIGERATING, AND AIR CONDITIONING ENGINEERS, INC. *1995 ASHRAE handbook—HVAC systems and applications*. Atlanta (GA): ASHRAE, 1995.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus*. ANSI/AAMI ES1–1985. Arlington (VA): AAMI, 1985. American National Standard. ISBN 0-910275-50-5.

2.4 GENERAL SERVICES ADMINISTRATION, FEDERAL SUPPLY SERVICE. *Federal specification for ambulances*. KKK-A-1822C. Washington (DC); January 1990.

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Electro- magnetic compatibility for industrial process measurement and control equipment*. IEC 1000-4 series. Geneva: IEC. (In the United States, available from ANSI.)

IEC 1000-4-2:1995, Electrostatic discharges requirements

IEC 1000-4-3:1995, (ENV 50140); Immunity to radiated radio frequency electromagnetic fields

IEC 1000-4-4:1995, Electrical fast transient burst requirements

IEC 1000-4-5:1995, (ENV 50142); Voltage surge immunity requirements

IEC 1000-4-6:199x, (ENV 50141); Currently document 77B/144/DIS, Immunity to conducted disturbances induced by RF fields (draft International Standard)

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Part 2: Collateral standard: Electromagnetic compatibility: Requirements and test* IEC 601-1-2, 1993 (available from ANSI).

- 2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION.** *Medical electrical equipment— Part 1: General requirements for safety* IEC 601-1, 1988 (available from ANSI).
- 2.8 INTERNATIONAL ELECTROTECHNICAL COMMISSION.** *Medical electrical equipment—Part 2: Particular requirements for safety of transport incubators* IEC-601-2-20, 1990 (available from ANSI).
- 2.9 INTERNATIONAL SPECIAL COMMITTEE ON RADIO INTERFERENCE.** *Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific, and medical (ISM) radio frequency equipment* CISPR 11, 2nd edition. 1990 (available from ANSI).
- 2.10 NATIONAL FIRE PROTECTION AGENCY.** *National electrical code*, No. 70. Boston: NFPA, 1993. American National Standard.
- 2.11 NATIONAL TRUCK EQUIPMENT ASSOCIATION.** *Litter retention system* AMD Standard 004. Livonia (MI): NTEA, 1991.
- 2.12 NATIONAL TRUCK EQUIPMENT ASSOCIATION.** *Oxygen tank retention system* AMD Standard 003. Livonia (MI): NTEA, 1991.
- 2.13 UNDERWRITERS LABORATORIES.** *Standard for safety, medical and dental equipment*. UL 544. Melville (NY): UL, 1988.

NOTE—UL 2601-1 is available.

3 Definitions

For the purposes of this standard, the following definitions apply.

- 3.1 air temperature controlled (ATC) incubator:** An incubator in which the incubator temperature is maintained at a value set by the user.
- 3.2 average temperature:** The arithmetic mean of the temperatures measured over a cycle of temperature variation caused by the operation of the temperature controller.
- 3.3 charge time:** Time required to charge the alternative power source from 80% of its rated voltage to a level that meets the specified operating time.
- 3.4 control temperature:** The temperature selected at the temperature control (ATC or ITC).
- 3.5 high temperature thermostat:** A non-operator-adjustable or a fixed means, independent of the primary incubator temperature control system, which activates an auditory and visual alarm and turns off the heat source.
- 3.6 incubator temperature:** The air temperature at a point 10 centimeters (cm) above and centered over the mattress surface.
- 3.7 incubator temperature equilibrium:** The condition reached when the average incubator temperature varies no more than 0.2° C over a period of 1 hour (h).
- 3.8 incubator test load:** The incubator test load is a 43-centimeters- (16.9 inches [in]) long by 5.4-centimeters- (2.125 in) diameter copper tube filled with distilled water (see [figure 2](#), page 32).

NOTE—The incubator test load is intended for use in comparing and validating incubator performance. It provides an indication of the partitioning of heat loss (or gain) between convective/conductive and radiative heat transfer and acts as a thermal load during testing of the correlation between control temperature and infant temperature in ITC mode. It is neither intended nor believed to simulate an infant's thermal response (e.g., an incubator test load has no evaporative heat loss, circulation, or internal heat generation), and is therefore used only during tests at infant temperature equilibrium.

- 3.9 indicated temperature:** The temperature displayed by the readout of the incubator temperature or infant temperature.

3.10 infant: That portion of the incubator designed to contain the infant.

3.11 infant temperature: Skin temperature of the infant as measured by manufacturer's specified means and location.

3.12 infant temperature controlled (ITC) incubator: An incubator in which the infant temperature is maintained at a value set by the operator.

3.13 infant temperature equilibrium: The condition when the incubator test load surface temperature varies by no more than 0.2° C in 1 h.

3.14 inspection: Any examination (e.g., visual or auditory) that does not require the use of special laboratory applications or procedures and/or verification of manufacturing and test records.

3.15 operating time: Time period during which the alternate internal battery power source will maintain the incubator temperature within 1° C of the control temperature.

3.16 overshoot: The amount by which the incubator temperature exceeds the average incubator temperature at incubator temperature equilibrium as a result of an increase in control temperature.

3.17 risk current: Any current, including capacitively coupled currents, that may be conveyed from accessible conductive parts of the incubator or its accessories to ground or other accessible parts, that is not intended to be applied to the patient, attending personnel, or bystanders.

3.18 single fault: Condition in which a single means for protection against a safety hazard in the equipment fails.

3.19 temperature rise time: The time required for the incubator temperature to rise 10° C.

3.20 temperature uniformity: The amount by which the average temperature at each of four points 10 cm (4 in) above the mattress surface, in an array as specified in [5.1.2\(b\)\(7\)](#), differs from the average incubator temperature at incubator temperature equilibrium.

3.21 temperature variability: The range of the incubator temperature that will be observed over a 1-hour period after incubator temperature equilibrium has been reached.

3.22 undershoot: The amount by which the incubator temperature falls below the average incubator temperature at incubator temperature equilibrium as a result of a decrease in control temperature.

4 Requirements

4.1 Labeling

In addition to the information required by applicable federal regulations, the device or its accompanying documentation shall provide the information specified in [4.1.1](#), [4.1.2](#), and [4.1.3](#).

4.1.1 Device markings

4.1.1.1 General

Device markings shall withstand the cleaning, disinfection, and sterilization procedures recommended by the manufacturer and shall not peel or wear off during normal use.

4.1.1.2 Product identification

Each device shall be plainly marked in a place where the following information will be visible or readily accessible for reference by the user:

- a) type of product (transport incubator) and trademark name if applicable;

- b) name and location of manufacturer or first importer of an incubator of foreign manufacture;
- c) model number, catalogue number, part number, or other unique identifying information;
- d) serial number, lot number, or other unique traceability identification;
- e) nominal voltages, frequencies, and wattages or currents;
- f) abbreviated instructions as required for correct operation.

In addition, any attachable accessories intended for use with the device shall identify the model of the incubator(s) with which they may be used.

4.1.1.3 Controls, displays, and switches

Connectors with obvious functions (e.g., the power cord) are exempt from this labeling requirement. In addition, the following requirements shall apply:

- a) All switches and controls shall be clearly labeled to identify their functions.
- b) The ATC/ITC switch, if applicable, shall produce an auditory, visual, or tactile indication of change of state, and appropriate means shall be provided to unambiguously indicate which control mode is operational.
- c) An indication of incubator temperature shall be provided by a separate temperature sensor that is independent of any temperature sensor used for control of the incubator temperature. Indicator temperature shall be clearly visible and read easily without opening the incubator, even under conditions of high relative humidity in a cool environment. The indication may be intermittent, continuous, or user-actuated.
- d) The direction of control(s) adjustment shall be clearly indicated. Minimum and maximum markings shall be provided and identified to prevent confusion with regard to the position of the control and the indicated value. Any incubator control, if it has a rotary action, shall be arranged so that a clockwise rotation produces an increase in output.
- e) Temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals no greater than 0.5° C for ATC settings and no greater than 0.25° C for ITC settings.

4.1.1.4 Infant temperature sensors

If applicable, identification of the manufacturer's recommended sensor shall be posted at the sensor's point of connection. Both the sensor and the device shall be labeled to identify the sensor intended for use with the device. Sensors used to indicate rather than control temperature also shall be identified.

4.1.1.5 Overcurrent protection

Overcurrent protection devices shall be clearly and permanently marked as per UL 544 (see [2.13](#)). Circuit breakers should be used if possible. If a fuse or fuses are used, retainers for spare fuses shall be incorporated. Fuses and spares shall be marked as per UL 544.

4.1.1.6 Important notices, cautions, and warnings

The following statements should be clearly displayed on the exterior of each device:

- a) a warning that the oxygen concentration should be routinely analyzed whenever oxygen is administered to ensure that the prescribed concentration continues to be delivered accurately;
- b) a warning about the possible effects of external radiant heat sources on infant temperature, temperature

control, alarm functions, and equipment;

- c) if applicable, a warning as to the possible consequences of inadequately attaching the infant temperature sensor to the skin and of improperly locating it on the infant;
- d) a notice that the temperature of the infant, incubator temperature, incubator function and, if applicable, infant temperature sensor attachment should be routinely checked.
- e) if applicable, a warning that the incubator is not suitable for use in the presence of flammable anesthetics;
- f) a warning about the possible adverse consequences to the infant from blankets, diapers, or other objects that obstruct or alter air flow patterns;
- g) if applicable, a warning that the transport incubator is not suitable for use outside the hospital.

4.1.2 Operator's manual

Adequate instructions for the installation and proper operation of the incubator shall be provided with each incubator. Instructions for the installation and proper operation of accessories intended for use with the incubator shall be provided and may be included in the operator's manual for the incubator or in the operator's manual for the accessory. These instructions shall include a description of the functional characteristics and use of all controls, indicators, displays, and alarms, and a procedure for the user to check on the proper operation of components, including visual and auditory alarms. For incubators that control temperatures other than, or in addition to, incubator temperature, an explanation of the temperature control methodology, how and where these temperatures are measured, and how they relate to indicated temperature, control temperature, and incubator temperature during incubator or infant temperature equilibrium shall also be provided. A glossary of the applicable terms as defined in this standard shall be included. The following additional information shall be included at a minimum:

- a) a statement of the device's intended application;
- b) the following performance specifications (with tolerances as appropriate), as determined in accordance with the tests of section 5.1.2(b):
 - 1) temperature rise time for ATC only;
 - 2) overshoot and undershoot for ATC only;
 - 3) time required to reach incubator temperature equilibrium for ATC only;
 - 4) temperature variability for ATC only;
 - 5) intervention temperature drop/recovery time for ATC only;
 - 6) control temperature range for ATC and, if applicable, ITC;
 - 7) temperature uniformity with mattress in all positions of normal use for ATC only;
 - 8) indicated temperature accuracy for both ATC and ITC, and for ATC only, with mattress in all positions of normal use;
 - 9) incubator test load core temperature versus incubator temperature;
 - 10) control temperature versus indicated temperature correlation for both ATC and ITC and for ATC only, correlated with mattress in all positions of normal use;
 - 11) the deviation of indicated temperature from control temperature that will activate the infant temperature alarm, for ITC only;
 - 12) range of air velocity over the mattress during normal use in ATC mode. If air velocity is changed

under other conditions (e.g., control temperature, mattress tilt, ATC versus ITC), specify the conditions and air velocities;

13) the time to alarm upon occurrence of air circulation failure for both ATC and ITC;

14) range, accuracy, and other pertinent functional characteristics of other controls, alarms, and indicators, for both ATC and ITC;

15) maximum CO₂ concentration;

16) maximum infant compartment sound level produced by the incubator during normal use with no alarm activated, for both ATC and ITC;

17) maximum auditory sound level with alarm(s) activated, for both ATC and ITC;

18) maximum infant compartment sound level with alarms activated, for both ATC and ITC;

19) maximum recommended loads on shelves and mounting brackets;

20) battery performance specifications, including re charge time, operating time, alternate power sources, low battery condition, and shelf-life;

21) a statement of the ranges of ambient temperature, humidity, and atmospheric pressure to which the transport incubator can be exposed and still meet the requirements of this standard.

c) the following notices, cautions, and warnings, if applicable:

1) a warning regarding the possible consequences of inadequately attaching the infant temperature sensor to the skin and of improperly locating it on the infant;

2) a warning that infant temperature sensors should not be used to control rectal temperature;

3) if the heater temperature exceeds 147° C and the incubator air is recirculated past the heater, a warning that ether exhaled by an infant can produce levels of formaldehyde that can be potentially toxic to the infant;

4) a warning that the oxygen concentration should be routinely analyzed whenever oxygen is administered to ensure that the prescribed concentration continues to be delivered;

5) a warning about the possible effects of external radiant heat sources on infant temperature, temperature control, alarm functions, and equipment;

6) a reminder to routinely check the temperature of the infant, incubator temperature, incubator function and, if applicable, infant temperature sensor placement;

7) a notice that incubators conforming only to this standard are not suitable for use in the presence of flammable anesthetics.

d) cleaning, disinfection, and sterilization methods and materials suitable for use on the incubator and, if separate instructions are not provided, for its accessories;

e) the method and recommended frequency for verifying the integrity of the high temperature alarm sensor if integrity verification is not an automatic or continuous function;

f) if applicable, an explanation of the control methodology for ITC mode, giving the relationship between infant temperature, control temperature and other incubator controlled parameters (e.g., incubator temperature, heater status);

g) instructions and warning for systems, if any, that limit the infant's movement;

- h) the intended power sources with which the transport incubator can be operated according to section 4.2.8.9, and the polarity of the electrical connections as necessary;
- i) a statement of the mass and external dimensions of the transport incubator, including that of the specified transportable external power source, with oxygen delivery system and trolley, if any;
- j) a statement on how to achieve a fixation of the transport incubator in an emergency vehicle.

4.1.3 Service manual

A service manual shall be available from the manufacturer and shall include:

- a) care, preventive maintenance, and repair instructions for the equipment;
- b) theory of operation;
- c) schematics and wiring diagrams;
- d) complete parts lists;
- e) procedures for calibrating the controls and for checking alarm systems;
- f) recommended intervals for preventive maintenance (including the recommended interval for battery replacement) and required skill level;
- g) information on how to obtain authorized repair.

4.2 Performance

For transport incubators that are limited to intrahospital use, specifications will be listed in [brackets] in the sections that follow (i.e., in this standard, not in the manufacturer's literature).

4.2.1 Environmental performance

The incubator shall meet the requirements of this standard when operated over the following range of ambient conditions:

- a) temperature: 10 to 30° C [20 to 30° C];

NOTE—Ambient temperature must be at least 3° C less than control temperature.

- b) barometric pressure: 86 to 106 kPa (645 to 795 millimeters [mm] Hg);
- c) relative humidity: 0 to 95%, noncondensing;
- d) air velocity: 10 to 15 cm/second(s).

4.2.2 Thermal characteristics

The incubator shall exhibit the following thermal characteristics:

- a) During ATC, the incubator shall be capable of achieving incubator temperature equilibrium from a control temperature of at least 23° C to no more than 39° C. If the maximum control temperature is set to a temperature over 37° C, this shall be indicated with an easily recognizable yellow warning light including or combined with relevant temperature range indication.

NOTE—Ambient temperature must be at least 3° C less than the control temperature.

- b) The air and infant indicated temperature shall be accurate within $\pm 0.3^{\circ}$ C of the calibrated standard.
- c) The air and infant control temperature/indicated temperature correlation shall be within 0.7° C.

- d) During ITC the incubator shall be capable of achieving infant temperature equilibrium at a control temperature from 35° C or less to 37° C or more; if settings over 37° C are provided, an override mechanism shall be required to achieve such settings; the upper limit shall not exceed 38° C.
- e) No object in the infant accessible compartment shall exceed the temperature for the threshold of pain (TmPt). For metal objects, it shall not exceed 40° C.

For nonmetals, the temperature is derived from

$$T_{mPt} = \frac{00.06 J / s^{(1/2)} \cdot cm^2}{\sqrt{k\rho c_p}} + 48.9^\circ C$$

where: J is joules, k is thermal conductivity in J/s • cm • °C, ρ is density in g/cm³, and c_p is heat capacity in J/g • °C.

The heat flow to a 37° C heat sink from any point in the infant accessible compartment shall not exceed 6.3 • 10⁻³ J/s • cm² after 5 s for stabilization; and

- f) the temperature of surfaces that a user may contact during normal operation of the device shall not exceed 60° C if a high thermal-conductivity (e.g., metal) surface is used, and 70° C if a low thermal-conductivity (e.g., some plastics or wood) surface is used.

4.2.3 Alarms

4.2.3.1 High temperature

A high temperature thermostat shall be provided that activates an alarm and turns off the heater at an incubator temperature not to exceed 40° C. The high temperature thermostat shall activate at an incubator temperature no higher than 40° C if the normal maximum setting is overridden. If a high temperature thermostat is internally adjustable by service personnel, means to prevent inadvertent changes during preventive maintenance or servicing shall be provided, and the high temperature thermostat shall not be adjustable beyond 40° C.

Means shall be provided to verify or assure the function of the high temperature alarm sensor during normal use without interrupting therapy.

4.2.3.2 Infant temperature sensor

For all ITC devices, an auditory and visual alarm shall operate if the infant temperature sensor fails electrically open- or short-circuited, or if the sensor is improperly connected to the control circuit. ATC devices that have a means to indicate the infant temperature shall provide a visual indication of infant temperature sensor failure when either electrically open- or short-circuited, or if the sensor is improperly connected.

4.2.3.3 Infant temperature

For ITC devices, auditory and visual alarms shall be activated if the infant's indicated temperature differs from the control temperature by more than the preset amount specified by the manufacturer.

4.2.3.4 Air circulation failure

An auditory and visual alarm shall be activated in the event of air circulation failure. The time to alarm upon occurrence of this condition shall be disclosed by the manufacturer. The maximum time to alarm shall not exceed 15 minutes (min).

4.2.3.5 External power failure

If the incubator does not incorporate a method to automatically switch to its internal power source upon the loss of external power (ac or dc), it shall incorporate an auditory alarm and visual indicator to signal complete failure

of the input electrical power or inadvertent disconnection from the power source. The auditory alarm shall be capable of being sustained for at least 3 min. A 5-min or shorter interruption and subsequent restoration of input electrical power shall change neither the mode of operation nor the control temperature.

4.2.3.6 Low battery

A low battery alarm shall be provided. The manufacturer shall describe its operation. The alarm shall be auditory and visual, and shall be silenceable (but the visual indicator shall not be extinguishable). The auditory alarm shall be capable of being sustained for at least 5 min. Normal operation shall be maintained for at least 5 min after the alarm.

4.2.3.7 Silencing

Unless the alarm condition has been corrected, any deliberately silenced auditory alarm shall automatically sound again within 15 min. The silencing of one alarm shall not disable or in any way inactivate any other alarm. Visual alarms shall not be extinguished until the alarm condition has been corrected. This requirement applies only to alarms covered in this standard. For ITC devices only, the period of alarm silence may be increased during the initial warming of infant or incubator to a time specified by the manufacturer. The maximum time to alarm during initial warming shall not exceed 30 min.

4.2.4 Sound levels

4.2.4.1 Infant compartment

The sound level in the infant compartment shall not exceed 60 dBA during normal use.

4.2.4.2 Auditory alarm

Auditory alarm indications required by this standard shall have a sound level of at least 65 dBA measured 3 meters (m) from the incubator and at a height of 1.8 m.

4.2.4.3 Infant compartment alarm

Alarm sound levels in the infant compartment shall not exceed 80 dBA.

4.2.5 CO₂ concentration

In normal use, the CO₂ concentration in the infant compartment shall not exceed 0.5%.

4.2.6 Fire prevention

4.2.6.1 Electronics compartment oxygen concentration

Components that may be a source of ignition in normal use or in a single fault condition shall be separated from any oxygen-enriched environments by a barrier that will prevent the O₂ concentration from exceeding ambient by no more than 4%. Alternatively, if the O₂ concentration can exceed 4% above ambient, the product of load voltage and short circuit current shall not exceed 10 volt amperes.

4.2.6.2 Maximum temperatures of components exposed to oxygen

The surface temperature of components that could be a source of ignition within the oxygen-enriched environment (e.g., heater) shall not exceed 300° C.

4.2.7 Mechanical/construction requirements

4.2.7.1 Infant compartment

The infant compartment shall:

- a) protect the infant from the generally cooler ambient air circulation and be constructed to facilitate

observation of the infant;

- b) provide a means of access for handling the infant and for the introduction of tubes, cords, leads, and similar equipment;
- c) be constructed such that the means of access to the infant shall not be capable of being inadvertently opened or disengaged during normal use or as a result of infant activity;
- d) be constructed so that the means of access to the infant shall not appear to be latched when it is not latched;
- e) be designed to minimize the likelihood of inadvertent obstruction or alteration of air flow patterns that would affect performance;
- f) the transport incubator shall have means by which the baby can be taken in and out without the need to remove the canopy completely or to disconnect tubes, cords, leads and the like from the infant.

4.2.7.2 Stability and transportability

The incubator shall meet the following requirements:

- a) **Tip-over:** The tip-over angle shall be at least 10° from the vertical in normal use and at least 20° during transportation, and the tip-over force shall be at least 100 newtons while in the worst-case configuration of parts and loaded accessories recommended by the manufacturer.
- b) **Thresholds:** Latches and doors shall remain closed and ancillary equipment supplied by or available from the manufacturer shall remain secure after impact with thresholds typically found in a hospital.
- c) **Mattress tray:** If the mattress tray can be extended outside the enclosure to improve access to the infant, the tray shall remain securely retained, shall be firmly supported, and shall not tip under the weight of the infant.
- d) **Restraining systems:** A means shall be provided to limit the infant's movement to a defined area within the infant compartment during normal use.
- e) **Incubator retention in ground vehicle:** The incubator's retention system shall be capable of sustaining 1500 lbs of force applied in the longitudinal, lateral, and vertical directions without separation of the incubator's mount from the retention system (see [2.11](#)).

4.2.7.3 Shelves and mounting brackets

Shelves and mounting brackets shall withstand 3 times the manufacturer's recommended load without evidence of damage to the shelf or mounting bracket.

4.2.7.4 Supplementary gas supply

- a) If the device is designed to hold a supplementary air, oxygen, or other gas supply, each supply shall be capable of being firmly secured to the unit (see [2.12](#)).
- b) Gauges shall be clearly visible, and valves and regulators intended to be adjusted shall be readily accessible. If attached to a medical gas system, these shall conform to [2.1](#).

4.2.7.5 Switches, controls, and knobs

The following requirements shall apply:

- a) Indicating knobs shall incorporate means to provide reasonable protection against inadvertent readjustment of the knob.
- b) All switches and controls accessible to the user under normal conditions shall be securely fastened to

prevent inadvertent repositioning

- c) A clockwise direction shall increase the value of the settings of any incubator control that rotates.

4.2.7.6 Ingress of liquids

The following requirements shall apply:

- a) The incubator shall be constructed so that liquids cannot enter the electrical compartment of the device to the detriment of its performance or safety.
- b) The infant compartment shall be constructed so that liquid deposited on its inside surface cannot come into contact with electrical components during normal use.

4.2.7.7 Mercury thermometers and thermostats

Thermometers or thermostats using mercury shall not be used.

4.2.7.8 Incubator humidifying system

Means for humidification should be provided. If humidification is provided, the following requirements shall be met:

- a) Leakage or spillage due to overfilling or tilting during transport shall not come into contact with the electrical compartment(s) to the degradation of the safety or performance of the device.
- b) The humidifying system shall be capable of being cleaned and disinfected or sterilized between patient uses.
- c) An indication of water level should be provided for systems with fillable water tanks.
- d) The humidifying system shall be capable of being emptied without tilting the incubator.

4.2.7.9 Infant temperature sensors

Sensors intended for different functions in the same device shall be designed to prevent use in incorrect receptacles.

4.2.7.10 Wheels

If an incubator is equipped with wheels for transportation, at least two of them shall be capable of being locked by the user.

4.2.7.11 Infant compartment illumination

A means for illumination of the infant compartment should be provided. If provided, it shall have a minimum of 35 foot candles of normal white illumination (see 2.4). Using a light meter sensitive to visual light range, measure the light intensity at five specified locations (see figure 3, page 32) and disclose the individual values. If the light source is movable, the manufacturer must disclose the location(s) used for test.

4.2.8 Electrical characteristics

4.2.8.1 Risk current

The device shall meet the applicable requirements specified in the American National Standard, *Safe current limits for electromedical apparatus* (see 2.3).

4.2.8.2 Overcurrent protection

Overcurrent protection shall be provided.

4.2.8.3 Power switch

Any power control switch shall simultaneously interrupt all power conductors of their source.

4.2.8.4 Power cord, plug, and strain relief

Flexible cords shall be suitable for the intended application. Voltage and current ratings for the cords shall not be less than the rating of the appliance. Cords shall be of Type SJE, SJO, SJT, SJTO, or another jacketed cord that is at least as serviceable. Oil resistant cords shall be used for equipment subject to operation in such conditions.

Alternating current power plugs shall be of the conventional two (2) blade with grounding pin construction, be designated "Hospital Grade," and be marked accordingly.

A strain relief shall be provided on an appliance with an integral power supply cord. The strain relief shall prevent mechanical stress from being transmitted to terminals, splices, or internal wiring.

A clamp may be used to provide strain relief but additional insulation may be required if damage to the cord can result. Additionally, means shall be provided to prevent a flexible cord from being pushed into an appliance through the cord entry hole if this can result in mechanical damage to the cord or exposure of the cord to temperatures higher than acceptable for the cord type.

A transport incubator intended for use in an ambulance shall be operable from an external 12 Vdc power source. A dc power cord, including a power plug of type MS3116F12-3P or its interchangeable commercial equivalent, shall be provided. The polarity of the plug shall be: pin A, +12V; pin B, ground; pin C, not used (see 2.4).

4.2.8.5 Power indicator

There shall be a visual indication when the power switch is on and electrical power is being delivered to the incubator.

4.2.8.6 Supply voltage variation

Devices with rated nameplate alternating current voltages between 115 to 120 V root mean square (rms) shall meet all requirements of this standard, except for 4.1.2(b)(1), (3), (4), (6), (12), and (13) at line voltages $\pm 10\%$ of the rated voltage. These devices shall not be damaged by operation on input voltages from 95 to 135 V_{rms}.

Where the nameplate voltage is other than the range specified, the voltage limits shall be the limits specified above, multiplied by the ratio of the device nameplate voltage to 120 V.

4.2.8.7 Dielectric withstand

The insulation and spacing shall be capable of withstanding, without breakdown, the application for 1 min of 1000 V plus twice the maximum rated voltage, or the application for 1 s of 1200 V plus 2.4 times the rated voltage.

4.2.8.8 Grounding impedance

The impedance between the point of any connection grounding means and any other metal part required to be grounded shall comply with IEC 601-1 requirements (see 2.7).

4.2.8.9 Transportable electrical power source

The transport incubator shall have a transportable electrical power source.

- a) The transportable electrical power source shall consist of a rechargeable battery and battery charger. It shall also be designed to operate from at least one external direct and one external alternating current electrical supply, as specified in the instructions for use. All requirements of this standard shall continue to be met. There shall be a visual indication when the battery is being used to power the incubator, and a visual indication when the battery is being charged.

- b) The capacity of the transportable electrical power source shall be sufficient to maintain the transport incubator at a control temperature of 36° C for at least 90 min in an ambient temperature of 15° C (control temperature of 36° C for at least 30 min in an ambient temperature of 20° C).
- c) The capacity of the transportable electrical power source shall be sufficient to maintain the transport incubator at a control temperature of 36° C for at least 15 min in an ambient temperature of –5° C, and continue to maintain this control temperature when returned to an ambient temperature of 20–25° C (not required for intrahospital transport incubators).
- d) It shall not be possible to overcharge and damage the transportable electrical power source, even if the equipment is left connected to the charging power source for an indefinite period. Controls that affect the rate of recharge or the final battery voltage level shall not be accessible to the user without the aid of a tool. The battery shall also comply with the requirements of UL 544 (see 2.13).

4.2.8.10 Electromagnetic compatibility (EMC) requirements

These EMC requirements were developed on the basis of reference standards [2.5](#), [2.6](#), and [2.9](#).

4.2.8.10.1 Electromagnetic emissions

4.2.8.10.1.1 Radiated and conducted electromagnetic emissions

The transport incubator shall comply with the requirements of CISPR 11 Group 1 Level B in the worst case configuration and operating mode.

Emission levels measured 10 m from the transport incubator shall not exceed 30 dB µV from 30 MHz to 230 MHz and shall not exceed 37 dB µV from 230 MHz to 1000 MHz.

4.2.8.10.1.2 Magnetic field emissions

The unit shall not emit a magnetic field greater than 0.5 millitesla (5 gauss) from 30 Hertz (Hz) to 250 kHz at any point on the surface of the transport incubator under normal operating conditions.

4.2.8.10.2 Electromagnetic immunity

4.2.8.10.2.1 Immunity to radiated RF electromagnetic fields

All requirements of this standard shall be verified over the entire range of carrier and modulation frequencies specified for the level 2 tests (3 V/m), when all faces of the instrument are sequentially exposed to a modulated RF electromagnetic field. For the level 3 tests, field strength of 20 V/m shall be used (rather than 10 V/m). The equipment shall continue to meet its specifications or fail in such a way that all high and low temperature alarms and thermal cutouts (e.g., high temperature thermostat) continue to function according to the requirements of this standard, and the incubator settings shall be maintained.

4.2.8.10.2.2 Immunity to conducted electromagnetic fields

No unintentional change of state shall occur when an RF field is injected into the line cord. No degradation of system performance or loss of functionality shall occur.

4.2.8.10.2.3 Immunity to magnetic fields

No unintentional change of state shall occur when the equipment is exposed on all faces to an ac magnetic field. Some display jitter is allowed; however, the displayed information must be readable.

4.2.8.10.2.4 Immunity to electrostatic discharge (ESD)

There shall be no noticeable change in equipment operation for open air discharges or direct contact discharges

of test condition 1 (4 kV and 2 kV respectively). The equipment shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is allowed. However, display glitches or momentary LED flashes are acceptable during an ESD. For open air discharges or direct contact discharges of test condition 2 (8 kV and 4 kV respectively), the equipment may exhibit momentary loss of functionality, but shall recover within 2 s without user intervention.

4.2.8.10.2.5 Power line transients

Only transient loss of functionality is allowed when the equipment is subjected to fast transient/bursts (1 kV) at the mains plug. The device shall return to its condition just prior to the burst without operator intervention. No unintentional change of state is allowed when the equipment is subject to surges line to line (1 kV) and line to ground (2 kV). The device shall return to its prior condition without operator intervention.

4.2.9 Summary

Table 1—Summary of performance requirements

Section	Requirement description	Min/max	Unit	Min/max value
4.2.1	Environmental performance			
	a) temperature;	range	°C	10-30[20-30]*
	* for transport incubators limited to intrahospital use			
	b) barometric pressure;	range	kPa	86 to 106
	c) relative humidity;	range	%	0 to 95
	d) air velocity.	range	cm/sec	10 to 15
4.2.2	Thermal characteristics			
	a) incubator temperature equilibrium during ATC;	range	°C	23 to 39
	b) air and infant indicated temperature accuracy;	range	°C	± 0.3
	c) air and infant control temperature/indicated temperature correlation;	max	°C	± 0.7
	d) infant temperature equilibrium during ITC;	range	°C	≤35 to 37
	override allowed;	max	°C	38
	e) infant accessible maximum temperature			
	— metals	max	°C	40
	— nonmetals;	max	°C	derive TmPt
	f) user accessible maximum temperature			
	— metals	max	°C	60
	— nonmetals.	max	°C	70
4.2.3	Alarms			
4.2.3.1	High temperature			
	a) thermostat activates alarm and			
	— turns off heater	max	°C	40
	— override allowed	max	°C	40
	— not possible to adjust higher;	max	°C	40

	b) verify or assure function during normal operation.	NA	NA	NA
4.2.3.2	Infant temperature sensor			
	—ITC devices: auditory and visual alarm for open or short-circuit or improper connection;	NA	NA	NA
	—ATC devices with means to indicate infant temperature: visual alarm for same conditions.	NA	NA	NA
4.2.3.3	Infant temperature: auditory and visual alarms if infant's indicated temperature differs from control temperature by more than manufacturer's specification	max	°C	manufacturer's specifications
4.2.3.4	Air circulation: auditory and visual alarms if air circulation fails.	max	minutes	15
4.2.3.5	External power failure:			
	— auditory and visual alarms if loss of power (unless automatic switch to internal power);	NA	NA	NA
	— auditory alarm sustained;	min	minutes	3
	— mode of operation unchanged upon power restoration.	min	minutes	5
4.2.3.6	Low battery			
	— auditory and visual alarms;	NA	NA	NA
	— silenceable;	NA	NA	NA
	— auditory alarm sustained;	min	minutes	5
	— normal operation maintained.	min	minutes	5
4.2.3.7	Silencing			
	— any silenced alarm shall sound again unless condition corrected;	max	minutes	15
	— silencing one alarm won't affect others;	NA	NA	NA
	— visual alarms not extinguished until condition corrected;	NA	NA	NA
	— alarm silence period may be longer during initial warm-up.	max	minutes	30
4.2.4	Sound levels.	--	--	--
4.2.4.1	Infant compartment, during normal use.	max	dBA	60
4.2.4.2	Auditory alarms, at distance of 3 m and height of 1.8 m.	min	dBA	65
4.2.4.3	Infant compartment during alarm.	max	dBA	80
4.2.5	CO ₂ concentration, during normal use.	max	%	0.5
4.2.6	Fire prevention.	--	--	--

4.2.6.1	Components that may be a source of ignition must be separated from oxygen-enriched environments to prevent excessive O ₂ concentration above ambient;	max	%	4
	— alternatively, limit product of voltage and short circuit current.	max	VA	10
4.2.6.2	Limit surface temperature of component oxygen-enriched atmosphere.	max	°C	300 in
4.2.7	Mechanical/construction requirements.	--	--	--
4.2.7.1	Infant compartment shall			
	a) protect infant from ambient air circulation and facilitate observation;	NA	NA	NA
	b) provide access to infant and for tubes, cords, leads, etc.;	NA	NA	NA
	c) means of access cannot be inadvertently opened during use or by infant activity;	NA	NA	NA
	d) means of access cannot appear latched when not latched;	NA	NA	NA
	e) minimize likelihood of obstructing or altering air flow, affecting performance;	NA	NA	NA
	f) allow moving infant in or out without removing canopy completely or disconnecting tubes, cords, leads, etc.	NA	NA	NA
4.2.7.2	Stability and transportability			
	a) tip-over			
	— angle from vertical in normal use	min	degrees	10
	— angle during transport	min	degrees	20
	— force in worst-case configuration;	min	N	100
	b) thresholds: latches and doors remain closed and manufacturer supplied auxiliary equipment remains attached after impact;	NA	NA	NA
	c) mattress tray: if extended outside enclosure with infant remains secure	min	N	100
	— doesn't tip under weight;	max	degrees	5
	d) infant's movement limited within infant compartment;	NA	NA	NA
	e) incubator retention in ground vehicle, per AMD standard 004.	NA	NA	NA
4.2.7.3	Shelves and mounting brackets shall withstand 3 times manufacturer's recommended load.	NA	NA	NA
4.2.7.4	Supplementary gas supply			

	a) if designed to hold gases, they shall be held securely, per AMD standard 003;	NA	NA	NA
	b) gauges shall be visible; valves and regulators accessible.	NA	NA	NA
4.2.7.5	Switches, controls, and knobs			
	a) indicating knobs shall be reasonably protected from inadvertent readjustment;	NA	NA	NA
	b) switches and knobs securely fastened to prevent inadvertent repositioning;	NA	NA	NA
	c) if any control rotates, clockwise shall increase value of settings.	NA	NA	NA
4.2.7.6	Ingress of liquids			
	a) liquids shall not enter electrical compartment to the detriment of device;	NA	NA	NA
	b) liquid inside infant compartment cannot penetrate to electrical components.	NA	NA	NA
4.2.7.7	Mercury thermometers and thermostats shall not be used.	NA	NA	NA
4.2.7.8	Incubator humidifying system, if provided			
	a) leakage or spilling due to overfilling or tilting shall not enter electrical compartment, affecting performance;	NA	NA	NA
	b) can be cleaned and sterilized between uses;	NA	NA	NA
	c) water level indication should be provided;	NA	NA	NA
	d) can be emptied without tilting.	NA	NA	NA
4.2.7.9	Infant temperature sensors cannot be used in incorrect receptacles if intended for different functions.	NA	NA	NA
4.2.7.10	Wheels, if provided, at least two can be locked.	NA	NA	NA
4.2.7.11	Patient compartment illumination, if provided.	min	ft-candle	35
4.2.8	Electrical characteristics.	--	--	--
4.2.8.1	Risk current shall meet ANSI/AAMI <i>Safe current limits for electromedical apparatus</i> .	NA	NA	NA
4.2.8.2	Overcurrent protection shall be provided.	NA	NA	NA
4.2.8.3	Power switch shall interrupt all conductors.	NA	NA	NA
4.2.8.4	Power cord, plug, and strain relief			
	— suitable power cord, including voltage and current rating, and type;	NA	NA	NA

	— hospital grade ac power plug;	NA	NA	NA
	— strain relief shall prevent stress on terminals, splices, or wiring;	NA	NA	NA
	— operable from external 12 Vdc, with standard plug and wiring.	NA	NA	NA
4.2.8.5	Power indicator shall show when power on and being delivered to incubator.	NA	NA	NA
4.2.8.6	Supply voltage variation			
	— meet requirements (except 4.1.2[b][1], [3], [4], [6], [12], and [13]) at $\pm 10\%$ of rated voltage;	NA	NA	NA
	— not damaged by 95 to 135 V _{rms} .	NA	NA	NA
4.2.8.7	Dielectric withstand of 1 min at 1000 V plus twice rated voltage or 1 s at 1200 V plus 2.4 times rated voltage.	NA	NA	NA
4.2.8.8	Grounding impedance per IEC 601-1.	NA	NA	NA
4.2.8.9	Transportable electrical power source			
	a) charger and battery that operate from ac and at least one external dc and one external ac source;	NA	NA	NA
	visual indicators of battery operation and battery charging;	NA	NA	NA
	b) battery capacity to maintain 36° C in 15° C ambient [36° C in 20° C ambient intrahospital models];	min	minutes	90
	c) battery capacity to maintain 36° C in -5° C ambient [not required for intrahospital models];	min	minutes	30
	d) not possible to overcharge and damage transportable electrical power source, no matter how long connected; battery complies with UL 544.	min	minutes	15
4.2.8.10	Electromagnetic compatibility.	--	--	--
4.2.8.10.1	Electromagnetic emissions.	--	--	--
4.2.8.10.1.1	Radiated and conducted EM emissions comply with CISPR 11 Group 1 Level B;	NA	NA	NA
	— emissions at 10 m from 30 MHz to 230 MHz; and	max	dBμV	30
	— from 230 MHz to 1000 MHz.	max	dBμV	37
4.2.8.10.1.2	Magnetic field emission from surface.	max	millitesla	0.5
4.2.8.10.2	Electromagnetic immunity.	--	--	--
4.2.8.10.2.1	Immunity to radiated RF EM fields, per IEC 1000-4-3, level 2 or level 3 field, no change of state.	NA	NA	NA
	NOTE—20 V/m used for level 3 field strength			
4.2.8.10.2.2	Immunity to conducted EM fields, per IEC 1000-4-6, no change of state			

	or performance degradation.	NA	NA	NA
4.2.8.10.2.3	Immunity to magnetic fields, no change of state.	NA	NA	NA
4.2.8.10.2.4	Immunity to electrostatic discharge, per IEC 1000-4-2			
	—for open air, discharges up to 4 kV or direct discharges up to 2 kV, no change in operation;	NA	NA	NA
	—for open air discharges up to 8 kV or direct discharges up to 4 kV, there may be momentary loss of function, but must recover, without intervention.	max	seconds	2
4.2.8.10.2.5	Power, line transients			
	— fast transients/bursts, per IEC 1000-4-4, with only transient loss of function allowed;	NA	NA	NA
	— surge immunity, per IEC 1000-4-5, with no change of state allowed.	NA	NA	NA

5 Tests

This section details all of the inspections, examinations, and tests to be performed to ascertain that the device conforms with the requirements of section 4. Except for the first digit, the paragraph numbers of requirements and tests are identical; for example, compliance with the requirement of 4.2.2 can be verified by the test of 5.2.2.

Test conditions

Unless otherwise indicated, all measurements and tests shall be made at the following ambient conditions and in normal operating position:

- a) temperature: 20 to 24° C, where the control temperature is at least 3° C above ambient;
- b) relative humidity: 50 ± 5%;
- c) barometric pressure: 86 to 106 kPa (645 to 795 mm Hg);
- d) ac supply voltage: nameplate voltage ± 2 volts;
- e) air velocity: ≤ 15 cm/s.

The ambient sound level must be at least 10 dBA lower than the measured sound level of the alarm.

Accuracy of instruments and test apparatus

The equipment used to test the requirements of section 4 shall be verified within the manufacturer's specified calibration period. All instruments and test equipment shall

- a) be appropriate for measuring the test parameter;
- b) have an accuracy with a tolerance of at least one-third that of the last significant digit of the variable being measured;
- c) conform to laboratory standards whose calibration, where possible, is traceable to the primary standards at the National Institute of Standards and Technology;
- d) all disclosure requirement measurement accuracies will have the accuracy of the test instrument added to the measurement. All performance requirement measurement accuracies will have the accuracy of the

test instrument subtracted from the measurement.

NOTE—Temperature sensors shall have a time constant not to exceed 10 s.

5.1 Labeling

5.1.1 Device markings

5.1.1.1 General

Conformance can be determined by performing the cleaning, disinfection, and sterilization procedures recommended by the manufacturer, and subsequent inspection of device markings.

5.1.1.2 Product identification

Conformance can be verified by inspection.

5.1.1.3 Controls, displays, and switches

Conformance can be verified by inspection.

5.1.1.4 Infant temperature sensors

Conformance can be verified by inspection.

5.1.1.5 Overcurrent protection

Conformance can be verified by inspection.

5.1.1.6 Important notices, cautions, and warnings

Conformance can be verified by inspection.

5.1.2 Operator's manual

a) Conformance can be verified by inspection.

b) Performance specifications:

NOTE—For sections (1) through (5) below, the required measurements are to be reported under the test conditions specified. The results also should be reported in the form of a graph of incubator temperature versus time. Any worst-case measurements over the entire range of ambient conditions in section 4.2.1, which deviate by more than 20% from the required measurements, must also be reported. Tests 5.1.2(b)(6), 5.1.2(b)(9), 5.1.2(b)(10), and 5.1.2(b)(11), if applicable, require the use of an incubator test load (see Definitions) with the infant temperature sensor of the incubator attached to the surface of the load using the manufacturer's recommended method.

1) **Temperature rise time.** With the incubator at an ambient temperature of $20 \pm 1.0^\circ \text{C}$, set the control temperature to its maximum setting. Measure the time required for the incubator temperature to increase 10°C .

2) **Overshoot and undershoot.** With the incubator in an ambient temperature of $25 \pm 1.0^\circ \text{C}$, allow the incubator to reach incubator temperature equilibrium at an ATC control temperature setting of 36°C . Reset and allow the incubator to reach incubator temperature equilibrium at an ATC control temperature setting of 32°C and then 36°C . Measure to the nearest 0.1°C the difference between the average incubator temperature and the minimum incubator temperature at the 32°C setting, and the difference between the average incubator temperature and the maximum incubator temperature at the subsequent 36°C setting.

3) **Time required to reach incubator temperature equilibrium.** Measure to the nearest minute the

time required to decrease from incubator temperature equilibrium at 36° C to the start of incubator temperature equilibrium at 32° C, and the time required to increase from incubator temperature equilibrium at 32° to the start of incubator temperature equilibrium at the subsequent 36°C setting during the ATC operation test procedure of 2) above.

4) **Temperature variability.** Measure the maximum and minimum incubator temperature to the nearest 0.1° C during incubator temperature equilibrium at 32° C and 36° C control temperature settings.

5) **Intervention temperature drop/recovery time.** Operating at incubator temperature equilibrium at a control temperature of 36° C, open the ports or doors provided for two-handed access to the infant (the manufacturer's recommended means by which an infant can be treated without removing the infant from the infant compartment). Leave ports or doors open for 15 min, and then close. If removable access port cuffs are provided, also conduct this test with the cuffs removed. Allow the incubator to again reach incubator temperature equilibrium. Leave the main access door (the manufacturer's recommended means by which an infant can be placed into or removed from the infant compartment) open for 15 min, and then close. Allow the incubator to again reach incubator temperature equilibrium. Measure the minimum incubator temperature to the nearest 0.1° C, and the recovery time to the start of the subsequent incubator temperature equilibrium after closing the incubator. Measure both interventions to the nearest minute.

6) **Control temperature range:**

i) **ATC operation.** Allow the incubator to reach incubator temperature equilibrium first at the maximum and then at the minimum ATC control temperature settings. Measure the average incubator temperature at each setting to the nearest 0.1° C.

ii) **ITC operation.** If applicable, allow the incubator test load to reach infant temperature equilibrium with the incubator in an ambient temperature of $25 \pm 1.0^{\circ}\text{C}$, first at the maximum and then at the minimum control temperature settings. Measure the average infant indicated temperature and incubator temperature at each setting to the nearest 0.1° C.

7) **Temperature uniformity.** Five calibrated temperature sensors shall be located in a plane parallel to and 10 cm above the mattress at the center of each of four areas defined by lines that divide the length and width in half, and at center mattress (see [figure 3](#), page 32). During incubator temperature equilibrium at control temperatures of both 32° and 36 °C, measure to within 0.1° C the incubator temperature and the temperature at each of the other defined locations with the mattress in its horizontal position and with the mattress in the maximum tilt positions recommended by the manufacturer.

8) **Indicated temperature accuracy**

i) **ATC operation.** During incubator temperature equilibrium at ATC control temperatures of 32° C and 36° C, note the indicated temperature and measure the incubator temperature to within 0.1° C with the mattress in the horizontal and the maximum tilt positions.

ii) **ITC operation.** If applicable, see [5.2.2\(b\)](#).

9) **Incubator test load core temperature versus incubator temperature.** During incubator temperature equilibrium at ATC control temperatures of 32° C, 36° C, and maximum, measure the incubator test load core temperature and corresponding incubator temperature to within 0.1° C.

10) **Control temperature/indicated temperature correlation:**

i) **ATC operation.** During incubator temperature equilibrium at control temperatures of 32° C and 36° C, note the maximum difference between the indicated temperature and the control temperature with the mattress in the horizontal and the maximum tilt positions.

ii) **ITC operation.** Note the difference between infant indicated temperature and control temperature during infant temperature equilibrium at a 36° C setting. If it can be demonstrated that an alternative test method is as relevant for this test, the manufacturer may use this method to verify the performance requirement; disclosure of this shall be made.

11) **Infant temperature alarm.** If applicable, during infant temperature equilibrium at a control temperature of 36° C (i.e., ITC mode, infant temperature sensor attached to the incubator test load per [figure 2](#), page 32), gradually increase the control temperature until the low temperature alarm is activated and note the difference between the indicated temperature and the control temperature to the nearest 0.1° C. For high temperature alarm activation repeat while gradually decreasing the control temperature.

12) **Air velocity.** At an ATC control temperature of 36° C measure the maximum and minimum air velocity at each of the five locations identified in [5.1.2\(b\)\(7\)](#) with the mattress in both the horizontal and the maximum tilt positions, and during other conditions of normal use (e.g., with and without inner walls).

13) **Air circulation alarm.** See [5.2.3.4](#).

14) **Other controls/alarms.** The manufacturer's specified values are verified by test methods provided by the manufacturer in the service manual.

15) **CO₂ concentration.** See [5.2.5](#).

16) **Infant compartment sound level.** See [5.2.4.1](#).

17) **Auditory alarm sound level.** See [5.2.4.2](#).

18) **Infant compartment alarm sound level.** See [5.2.4.3](#).

19) **Shelf loading.** Conformance can be verified by inspection. See [5.2.7.3](#).

20) **Battery performance**

i) Recharge time. With the incubator off and the battery fully discharged, as specified by the manufacturer, measure the time for the battery to reach 90% of full charge. Repeat with the incubator on and set at 36° C (starting from ambient temperature). Repeat both tests with the incubator connected to any specified alternative electrical supplies that charge the battery.

ii) Operating time. Perform the test specified in [5.2.8.9\(b\)](#), but let the transport incubator operate from its battery until the transport incubator no longer maintains an average incubator temperature within 1.0° C of the setting. Report the time that the transport incubator maintains the incubator temperature.

iii) Alternate power sources. Compliance can be verified by inspection

iv) Low battery condition. Under the test conditions of (ii), above, measure the time and temperature when the low battery condition occurs, as specified by the manufacturer. Do not change any control settings. After 10 min, return the incubator to room ambient conditions (if applicable), and plug it into the specified alternating current electrical supply. Describe the performance of the incubator supply. Describe the performance of the incubator (mode of operation, control temperature settings, alarm conditions, etc.) and anything that has changed.

v) Shelf life. Compliance can be verified by inspection.

21) **Statement of minimum ambient temperature, humidity, and atmospheric pressure.** Compliance can be verified by inspection.

- c) **Important notices, cautions, and warnings.** Compliance can be verified by inspection.
- d) **Cleaning, disinfection, and sterilization.** Compliance can be verified by inspection.
- e) **High temperature alarm sensor.** Compliance can be verified by inspection. See [5.2.3.1](#).
- f) **ITC control methodology.** Compliance can be verified by inspection.
- g) **Limiting infant's movements.** Compliance can be verified by inspection.
- h) **Transportable electrical power source.** Compliance can be verified by inspection.
- i) **Mass and dimensions.** Compliance can be verified by inspection.
- j) **Fixation in vehicle.** Compliance can be verified by inspection.

5.1.3 Service manual

Conformance can be verified by inspection.

5.2 Performance

5.2.1 Environmental performance

The manufacturer is to certify compliance.

5.2.2 Thermal characteristics

- a) Incubator temperature control range. See [5.1.2\(b\)\(6\)\(i\)](#).
- b) Air and infant indicated temperature accuracy. With a calibrated temperature sensor and the air temperature sensor immersed in a temperature controlled bath at $36 \pm 0.1^{\circ} \text{C}$, measure the bath temperature to within 0.05°C and note the indicated temperature; repeat the test with the infant temperature sensor in place of the air temperature sensor.
- c) Air and infant control temperature/indicated temperature correlation See [5.1.2\(b\)\(10\)\(i\)](#) and (ii).
- d) Infant control temperature range. See [5.1.2\(b\)\(6\)\(ii\)](#).
- e) Surface temperatures. Compliance shall be verified by surface temperature measurements and calculations, based on characteristics of materials.
- f) Maximum user contact temperature. With ATC control temperature set at maximum incubator temperature and supply voltage at 110% of the nominal rated voltage, locate and measure the maximum surface temperature the user can contact in normal use.

5.2.3 Alarms

5.2.3.1 High temperature

- a) At temperature equilibrium with the ATC control temperature at 36°C , disable the primary thermostat to turn the heater output to maximum. At the time the alarm is activated, measure the incubator temperature using a calibrated sensor. The means for accomplishing this should be specified by the manufacturer in the service manual. If the incubator control temperature limit of 37°C can be overridden, do so per the instructions in the operator's manual and repeat this test. If a high temperature thermostat is internally adjustable, compliance with the requirement that means to prevent inadvertent changes can be verified by inspection. That the high temperature thermostat cannot be set over 40°C can be verified by adjusting the thermostat to its maximum setting and repeating the test.
- (b) Verify conformance with the method recommended by the manufacturer in the operator's manual.

5.2.3.2 Infant temperature sensor

The manufacturer shall certify that a shorted (<5 ohm) or open (>1 megohm) sensor will sound an alarm. Slowly insert connector into its receptacle to determine if any intermediate positions will inhibit alarm activation.

5.2.3.3 Infant temperature

See 5.1.2(b)(11).

5.2.3.4 Air circulation failure

With the incubator turned on and the air circulation fan removed or disabled, a visual and auditory alarm shall be activated according to the manufacturer's specifications.

5.2.3.5 External power failure

With the incubator turned on, disconnect the power cord from the external power source and verify that the auditory alarm is activated for at least 3 min. After being disconnected for 5 min, the power cord shall be reconnected to verify that the operating mode and control temperature are unchanged.

NOTE—This test does not have to be performed if the incubator automatically switches over to internal power upon the loss of external power.

5.2.3.6 Low battery

Operate the incubator from the battery power until a low battery condition is reached. The functioning of the auditory and visual alarms, and that the incubator can continue to operate for 5 minutes, can be verified by inspection.

5.2.3.7 Silencing

An alarm condition is simulated for all alarm functions as recommended by the manufacturer. The time(s) for the alarm(s) to reactivate after silencing is measured with a stopwatch. Proper functioning of visual alarms can be verified by inspection.

5.2.4 Sound levels

5.2.4.1 Infant compartment

With the incubator turned on, measure the sound level at a point 10-15 cm above the center of the mattress.

NOTE—With the incubator turned off, this sound level must be at least 10 dBA lower than with the incubator turned on or appropriate ambient sound level correction must be made. This is required to obtain an accurate reading of the equipment's sound level.

5.2.4.2 Auditory alarm

With the alarm sound level adjusted to minimum (if user adjustable), measure the sound level at a height of 1.8 m and a distance of 3 m from the front of the incubator. If more than one alarm sound means is provided, each must be checked.

5.2.4.3 Infant compartment alarm

With each alarm sound means activated, measure the sound level at a point 10-15 cm above the center of the mattress. The alarm sound level shall be adjusted to the maximum, if user adjustable.

5.2.5 CO₂ concentration

A 4% mixture of CO₂ in air shall be administered through an 8 mm diameter tube at a point 10 cm above the center of the mattress. This flow shall move vertically upwards at a rate of 750 milliliters (ml)/min (or

equivalent CO₂ min volume). Measure CO₂ concentration at a point 15 cm from this point when stability is achieved.

5.2.6 Fire prevention

5.2.6.1 Electronics compartment oxygen concentration

With incubator operating as recommended by the manufacturer for highest O₂ concentration, measure the O₂ concentration in all compartments that may be a source of ignition. Alternatively, if the O₂ concentration can exceed 4% above ambient, measure the no-load voltage and short-circuit current of the components that may be a source of ignition under normal use or single fault conditions.

5.2.6.2 Maximum temperatures of components exposed to oxygen

Locate and measure the maximum temperature of components in the oxygen enriched environment that may be a source of ignition during conditions that will result in the maximum temperature of these components.

5.2.7 Mechanical/construction requirements

5.2.7.1 Infant compartment

- a) Conformance can be verified by inspection.
- b) Conformance can be verified by inspection.
- c) With ports and/or doors latched, apply at the center of each door and/or port, a horizontal outward force gradually increasing over a period of 5–10 s to a maximum of 20 newtons. Maintain for 5 s.
- d) Conformance can be verified by inspection.
- e) Conformance can be verified by inspection.
- f) Conformance can be verified by inspection.

5.2.7.2 Stability and transportability

- a) **Tip-over.** With the casters in the worst-case position and prevented from rolling with all movable parts, doors, supports, and accessories loaded to the manufacturer's maximum recommendation positioned to minimize the incubator's stability, apply at the highest point of the incubator or 1.5 m from the floor (whichever is lower), a horizontal force great enough to tip the incubator. The horizontal force shall be greater than 100 newtons and the incubator shall not tip over at an angle of 10° from the vertical.

The test shall be repeated with the transport incubator in its transport position on a plane inclined at an angle of 20°.

- b) **Thresholds.** Pull the incubator in the direction of its long axis at a constant velocity of 0.5 ± 0.1 m/s until its leading wheels meet a 20 mm thick plate. The test shall be carried out (1) with the incubator's long, axis at right angles to the edge of the plate, and (2) with the edge of the plate parallel to a line from the leading edge of one front wheel to the trailing edge of the other front wheel (see [figure 1](#), page 31). The two types of movement are repeated 2 times with each pair of wheels. Following these tests, the incubator shall perform to manufacturer's specifications. The incubator's mechanical and structural integrity shall be verified, e.g., latches and doors shall remain closed and ancillary equipment recommended by the manufacturer for use during transport shall remain secure.
- c) **Mattress tray.** With the mattress tray fully extended, apply at the midpoint of its outermost edge, a vertically downward force gradually increasing over a period of 5-10 s to a maximum of 100 newtons. Maintain for 1 min. The tray shall not tilt more than 5° and its structural integrity shall not be adversely affected.

d) Conformance can be verified by inspection.

e) The incubator's retention system is to be attached to a platform able to sustain without deformation the following loads. A force of 1500 lbs is to be applied to a point 15 in above the platform and in the center of the incubator's mount. The force shall be applied by a means that does not place stress on any single component, unless that component is solely responsible for holding the incubator's mount in the retention system. Otherwise, the force is to be distributed among all components responsible for holding the incubator's mount in the retention system in the applied direction of force. The incubator may be separated from its mount if the incubator and mount separate.

The force shall be applied in the longitudinal, lateral, and vertical directions as quickly as possible. The retention system shall not release the incubator's mount. If any deformation has occurred after application of force, the damaged parts shall be replaced before further testing. Deformation of parts does not constitute failure.

5.2.7.3 Shelves and mounting brackets

With each support and/or mounting bracket in its worst case configuration, apply at its center a vertically downward force that increases gradually over a period of 5 to 10 s to a maximum equal to 3 times the manufacturer's recommended maximum weight. Maintain for 1 min. The tray or bracket shall not tilt more than 5° and its structural integrity shall not be adversely affected.

5.2.7.4 Supplementary gas supply

- a) Test the capability of the supplementary air, oxygen, or other gas supply to be firmly secured to the unit according to AMD Standard 003 (see [2.12](#)).
- b) Conformance with the requirement for indexing, visibility and accessibility of gauges, valves, and regulators can be verified by inspection. If attached to medical gas systems, these shall conform to the requirements of [2.1](#).

5.2.7.5 Switches, controls, and knobs

- a) Brush a vertically held straight edge, which should be 1 meter long, along the side(s) of the incubator where the control(s) are accessible. There shall be no contact with switches, controls, or knobs that could result in a change in setting.
- b) Conformance can be verified by inspection.
- c) Conformance can be verified by inspection.

5.2.7.6 Ingress of liquids

- a) The incubator shall be positioned as for normal use with the hood in the normal position. Steadily pour 200 ml of water on the most vulnerable point of the top surface of the incubator. Upon completion of this test, the incubator shall comply with the requirements of this standard.
- b) Spray 200 ml of water on all inner surfaces of the infant compartment such that drops coalesce and flow down the walls. In addition, pour 200 ml of water steadily on the infant tray. Upon completion of this test, the incubator shall satisfy all requirements of this standard.

5.2.7.7 Mercury thermometers and thermostats

Conformance can be verified by inspection.

5.2.7.8 Humidifying system

- a) Fill the humidity reservoir to the maximum level recommended by the manufacturer. Perform the test

described in [5.2.7.2\(b\)](#). Verify that no liquids have entered any electrical compartments and that the device continues to function normally.

b)–d) Conformance can be verified by inspection.

5.2.7.9 Infant temperature sensors

Compliance can be verified by trial and inspection.

5.2.7.10 Wheels

Compliance can be verified by inspection.

5.2.7.11 Patient compartment illumination

Prepare the transport incubator by

- a) placing it in a room with a background illumination of no more than 20 foot candles;
- b) locating the five test points as described in [figure 3](#);
- c) setting the incubator so that the heater is fully on;
- d) positioning the light source, if adjustable, according to the manufacturer's suggestions.

Disclose the illumination recordings at the five test points.

5.2.8 Electrical characteristics

5.2.8.1 Risk current

Risk current levels can be determined by the methods provided in [2.3](#) for verifying conformance with the requirements for devices with isolated or nonisolated patient connections, as applicable.

5.2.8.2 Overcurrent protection

Conformance can be verified by inspection.

5.2.8.3 Power switch

Conformance can be verified by inspection.

5.2.8.4 Power cord, plug, and strain relief

Any flexible power supply cord and/or attachment plug shall meet all requirements of the Underwriters Laboratories, Inc. Standard for Medical and Dental Equipment, UL 544 (see [2.13](#)) and the International Standard for Medical Electrical Equipment, Part 1, IEC 601-1 (see [2.7](#)).

Any strain relief shall be tested by the application of a 35 lb pull such that the strain relief is stressed from any angle that the construction of the appliance allows. All cord connections within the appliance shall be disconnected. The pull shall be applied to the cord and be maintained for 1 min. There shall be no displacement of the strain relief. Further, the strain relief shall be considered unacceptable if, at the point of disconnection of the conductors, there is such movement of the cord as to indicate that stress would have resulted on the connections. Compliance with the requirement for the dc power cord and plug can be verified by inspection.

5.2.8.5 Power indicator

Conformance can be verified by inspection.

5.2.8.6 Supply voltage variation

The effects of input voltage variation can be determined by using a variable transformer and verifying the

performance and operation of alarms, temperature indicators, and controls.

5.2.8.7 Dielectric withstand

Dielectric tests are to be performed by application of high voltage for 1 min between the ground plug and phase/neutral via the transport incubator's power cord. The resulting current as measured by a hi-pot tester must not be greater than 12 mA.

Connect the transport incubator to the hi-pot tester according to the manufacturer's specification. Set the hi-pot tester for either:

- a) 1000 V plus 2x the maximum rated voltage for 1 min, or
- b) 1200 V plus 2.4x the maximum rated voltage for 1 s.

Breakdown shall be defined as an abrupt change in current or any current in excess of 12 mA.

5.2.8.8 Grounding impedance

The voltage is measured when a current of 25 A, derived from a 60-Hz source with no load voltage not exceeding 6 V, is placed for 1 min between the grounding connection and any exposed metal part that is likely to be energized due to an electrical fault. The measured voltage shall not exceed 2.5 V.

5.2.8.9 Transportable electrical power source

- a) The transport incubator shall be connected in turn to all specified transportable electrical power sources set to their rated values at an ambient temperature of $15^{\circ}\text{C} \pm 1^{\circ}\text{C}$. Verify the performance and operation of alarms, temperature indicators, and controls. Visual indications of battery operation and battery charging can be verified by inspection.
- b) The transport incubator with a fully charged battery shall be placed in an environment with an ambient temperature of $15^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ($20^{\circ}\text{C} \pm 1^{\circ}\text{C}$). It shall be operated from the supply mains until a steady temperature condition has been established at a control temperature of 36°C and then set to operate from any transportable external electrical power source. The incubator temperature shall be maintained within 2.0°C of the control temperature for 90 (30) min.

This test shall be conducted while all the electrical powered accessories, as specified, are in operation and making their maximum demand upon the transportable external electrical power source.

- c) For interhospital transport incubators only, the transport incubator is operated as an air controlled incubator connected to an external power source. When the steady temperature condition is established at an ambient temperature within the range of 21°C to 25°C and at a control temperature of 36°C , it shall be set to operate in accordance with the accompanying documents without a supply mains and transferred into an environment where the ambient temperature is being kept at -5°C ($\pm 2^{\circ}\text{C}$) and the wind velocity is not more than 1 m/s. After 15 min it shall be returned into an environment where the ambient temperature lies within the range of 20°C to 25°C and reconnected to an external supply and operated for a further 30 mins. The incubator temperature shall be maintained within 0.7°C of the control temperature for the entire 45 min test time period. The deviation of the incubator temperature from the controlled temperature shall be recorded.

If the accompanying documents specify to meet this requirement at a lower ambient temperature than -5°C ($\pm 2^{\circ}\text{C}$) or for a longer period than 15 min the transport incubator shall be additionally tested for compliance with those claims as indicated.

- d) Conformance can be verified by inspection. The transportable electrical power source will continue to meet manufacturer's specifications.

5.2.8.10 Electromagnetic compatibility (EMC) requirements

Transport incubators are complex instruments because they use patient-coupled devices that markedly affect electromagnetic emissions and immunity. Equipment configurations for the tests will be determined by the manufacturer, but the equipment shall be tested in a sufficient variety of configurations and operating modes that might be encountered in normal operation, so that the worst case may be determined and successfully tested. The infant temperature sensor cables shall be tested both in an unterminated mode and in a patient simulated (incubator test load) terminated mode.

5.2.8.10.1 Electromagnetic emissions

5.2.8.10.1.1 Radiated and conducted electromagnetic emissions

The instrument shall comply with CISPR 11 Group 1 Level B (see 2.9). The detailed test methods are outlined in CISPR 11 and CISPR 16.

The equipment shall be tested on all faces in all expected configurations and operating states. The infant temperature sensor shall be tested in both an unterminated and in a patient simulated (incubator test load) terminated mode.

5.2.8.10.1.2 Magnetic field emissions

Use a gauss meter probe to verify that the instrument does not emit a magnetic field greater than 0.5 millitesla (5 gauss) from 30 Hz to 250 kHz at any point on the surface of the instrument under normal operating conditions.

5.2.8.10.2 Electromagnetic immunity

5.2.8.10.2.1 Immunity to RF electromagnetic fields

The test methods and instruments specified in IEC 1000-4-3 (see 2.5) apply.

The transport incubator is exposed to a modulated RF field with the following characteristics:

- a) Field strength: 3 V/m (Level 2); 20 V/m (Level 3);
- b) Carrier frequency range: 26 MHz to 1 GHz;
- c) AM modulation, 80% index, at 3 frequencies: 1, 5, and 20 Hz.

The infant temperature sensor is attached to an incubator test load. The transport incubator is tested with all its faces sequentially exposed to the RF field.

NOTE—Certain temperature sensor cable configurations may cause failure to meet these immunity requirements. In such a case, the manufacturer shall disclose the reduced immunity levels that are met.

5.2.8.10.2.2 Immunity to conducted electromagnetic fields

The test methods and instruments specified in the current draft of IEC 1000-4-6 (see 2.5) apply.

When a transport incubator can be operated from line power as well as battery, an RF noise voltage with the following characteristics is injected into the input power cord:

- a) Noise voltage amplitude
 - 1) 3 Vrms (roughly corresponds to a radiated field strength of 3 V/m)
 - 2) 20 Vrms (roughly corresponds to a radiated field strength of 20 V/m);
- b) Carrier frequency: 150 kHz to 230 MHz;
- c) AM modulation, 80% index, at 1, 5, and 20 Hz.

5.2.8.10.2.3 Immunity to magnetic fields

The equipment is exposed on all faces to an external ac magnetic field with the following characteristics:

- a) Magnetic field strength: 10^{-4} tesla peak to peak (1 gauss);
- b) Frequency range: 47.5 to 1320 Hz.

The equipment is exposed on all faces. The infant temperature sensor is replaced with a resistive load that simulates a temperature of $36 \pm 1^\circ \text{C}$ at the instrument.

5.2.8.10.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in [IEC 1000-4-2](#) (see 2.5) apply.

The transport incubator is exposed, at any point on its surface accessible to the operator or patient, to open air discharges or direct contact discharges, both positive and negative.

Condition 1. Open air discharges up to 4 kV and direct contact discharges up to 2 kV.

Condition 2. Open air discharges up to 8 kV or direct contact discharges up to 4 kV.

5.2.8.10.2.5 Power line transients

- a) fast transients/burst: the test methods and instruments of [IEC 1000-4-4](#) (see 2.5) apply. Instruments shall meet a 1 kV immunity level at the mains plug.
- b) surge immunity: the test methods and instruments of [IEC 1000-4-5](#) (see 2.5) apply. Instruments shall meet an immunity level of 1 kV line to line and 2 kV line to ground.

Annex A (informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This appendix provides the rationale for the development of a standard for transport incubators, as well as the rationale for each of the specific provisions of the standard.

The findings of an ECRI (originally Emergency Care Research Institute) study on transport incubators and radiant warmers, carried out under contract with the Food and Drug Administration ([Dyro, 1977](#)), served as the basis for this standard. Additionally, various drafts of the International Electrotechnical Commission's (IEC) 601-2-20, *Particular requirements for the safety of transport incubators*, were also considered during the AAMI Infant Incubator Committee's deliberations. Lastly, to ascertain the current clinical consensus on many of the safety and performance issues that required resolution, the AAMI committee referred to the recommendations of the Infant Incubator Advisory Task Force of the American Academy of Pediatrics ([AAP, 1983](#)).

A.2 Need for the standard

Transport incubators have been successfully used in infant care for many years. In appropriate applications, the benefits of the use of this device are numerous. Sufficient scientific and medical data exist to establish a standard to provide reasonable assurance of the safety and effectiveness of the device and to help control the risks associated with the use of the device. These risks include:

- a) hypothermia or hyperthermia if the temperature level in the device is not adequately controlled or maintained;
- b) electrical shock from improper design and/or construction or device malfunction;

- c) failure to provide heat due to poor reliability of the internal incubator electrical power source;
- d) failure to readily access and assess the infant in an emergency.

The provisions of this standard reflect the committee's effort to address these potential risks and to provide mechanisms for minimizing or eliminating these risks.

A.3 Definitions

A.4 Requirements

A.4.1 Labeling requirements

There are basically two factors that control the label content of a medical device. First, there are the requirements defined in Part 810, Chapter 1, Title 21, of the *Code of Federal Regulations—Good Manufacturing Practice for Medical Devices*—specifically Sections 820.120, 820.121, and 820.130. These regulations establish requirements for proper handling, legibility, expiration dating, and many other aspects of labeling as they pertain to good manufacturing practices. Second, part 201, Chapter 1, Title 21, of the *Code of Federal Regulations*, and Section 502 of the Federal Food, Drug and Cosmetic Act (as amended October 1976) specifically state what constitutes adequate labeling and misbranding for a drug or device. These two groups of requirements comprise the Federal Regulations referred to in [4.1](#) of this standard. All labeling pertaining to transport incubators must comply with these regulations.

In addition, there are other critical facts that must be set forth in the labeling to assure that the device is used safely and effectively in controlling the thermal environment of the infant, and to assist the user in selecting a device most appropriate for the intended use. The provision of this additional information is specified in [4.1.1](#), [4.1.2](#), and [4.1.3](#) of this standard.

A.4.1.1 Device markings

All requirements concerned with markings or labels on the device ensure that important identification information, warnings, and instructions are displayed on the incubator and/or its accessories to minimize hazards and promote proper operation, and that functional detachable components and accessories are used with the incubator(s) for which they are intended.

A.4.1.1.1 General

Normal use and cleaning should not destroy labels and control markings, which could result in operator errors and inappropriate settings.

A.4.1.1.2 Product identification

Permits the user to obtain service, order parts and/or accessories, and identify the device in case of problems. Identification of electrical specifications is essential to the safe and effective use of the device.

A.4.1.1.3 Controls, displays, and switches

Permanent identification of all controls, connectors, alarms, and indicators is necessary to avoid improper use and to alert the user to operating conditions and control settings.

A.4.1.1.4 Infant temperature sensors

Use of a sensor for purposes other than those recommended by the manufacturer could result in incorrect patient temperature indication and/or control and hazardous operating conditions ([Freeman and Linder, 1934](#)).

A.4.1.1.5 Overcurrent protection

The recommendation for circuit breakers is based on the need for restoring power during emergency transport conditions. Also, the use of improper fuses could result in unsafe operating conditions and/or damage to the

incubator.

A.4.1.1.6 Important notices, cautions, and warnings

The inclusion of important labeling will promote proper use of the incubator and related instrumentation (e.g., oxygen delivery and control systems), and make the user aware of outside factors that may affect patient care and safety:

- a) The oxygen concentration in an incubator is subject to a number of variables. Use of an oxygen analyzer to routinely monitor oxygen concentration will provide verification that the prescribed oxygen concentration is achieved. Use of an oxygen analyzer is strongly recommended whenever oxygen is being administered to the infant.
- b) External radiant heat sources, (e.g., the sun, infant radiant warmers, and phototherapy lights) can affect the temperature control and alarm functions of the incubator (Hey and Mount, 1967). Patient temperature and insensible water loss may also be affected by external radiant heat sources ([Bell and Rios, 1983 \(a\), 1983\(b\)](#); [Bell, Gray, et al. 1980](#); [Bell, Weinstein, et al., 1980](#)).
- c) Improper placement of the patient probe (e.g., under the infant) can result in uncontrolled warming. If the patient probe is not placed and does not remain in adequate contact with the patient's skin, the probe can sense the temperature of the cooler surroundings and cause the infant's temperature to rise above the desired level.
- d) Many factors which can influence thermal warming may not be readily apparent to the user ([Adamsons et al., 1965](#); [Bell and Rios, 1983\(a\)](#); [Bell, Gray, et al., 1980](#)). Frequent checks of infant temperature, incubator temperature, and incubator function can help detect unwanted temperature fluctuations from misuse or outside interference and allow users to take corrective action before those fluctuations become hazardous.
- e) Special requirements with respect to electrical safety and explosion hazards are necessary for safe use because of the possible use of flammable anesthetics.
- f) The proper performance of a transport incubator is dependent upon the airflow pattern within the infant compartment. Objects obstructing or altering the airflow pattern could affect the thermal performance of the incubator, and thus, the infant temperature.
- g) Transport incubators not designed or intended for use outside of the hospital could prove unsafe for such use, e.g., not mechanically strong enough, not having sufficient heat generating capacity, or having a limited battery operating time.

A.4.1.2 Operator's manual

It is necessary that the user be provided with adequate instructions for proper use, user maintenance, and cleaning/disinfecting/sterilizing, and that the performance characteristics and specifications disclosed by the manufacturer are adequate to permit user evaluation of the appropriateness of a particular device for the intended application. The parameters called out in [4.1.2\(b\)](#) are generally recognized as important variables in defining incubator performance. However, clinical evidence to support the establishment of specific numerical values for these parameters is lacking. The inclusion of these parameters in the labeling/disclosure section of the standard, rather than in the performance requirements section, allows the manufacturer to state in numerical terms the performance of the device and, in the absence of clinical consensus on what this performance should be, allows the user to evaluate the appropriateness of a particular device for the intended application. At such time as clinical evidence dictates specific performance levels, the standard will be amended accordingly.

- a) **Intended application.** Needed to help prevent unintentional misuse.
- b) **Performance specifications:**

- 1) **Temperature rise time.** This information provides a measure of the time required for an incubator to warm up prior to use or to respond to a need for increased heat to compensate for abnormal heat loss, e.g., from opening of an access port or door.
- 2) **Overshoot and undershoot.** Excessive air and/or skin temperature changes can adversely affect infant metabolism and may induce apnea (Avery, 1993; Daily et al., 1969; Silverman et al., 1966).
- 3) **Incubator temperature equilibrium.** This information enables the user to determine whether the time to respond to an increase or decrease in control temperature is suitable for the intended application. There is no consensus as to what the optimum time should be.
- 4) **Temperature variability.** Excessive air and/or skin temperature changes can adversely affect infant metabolism and may induce apnea (Avery, 1993; Daily, et al., 1969; Perlstein, et al., 1976; Silverman et al., 1966).
- 5) **Intervention temperature drop/recovery time.** This information enables the user to determine whether the incubator response to typical means of access to the infant is suitable for the intended application (Adamsons, et al., 1965; Avery, 1993; Bell, Gray, et al., 1980; Daily et al., 1969).
- 6) **Control temperature range.** Enables the user to determine whether the control temperature range is suitable for the intended application (Hey, 1975; Sauer, Dane, et al., 1984; Scopes and Ahmed, 1966).
- 7) **Temperature uniformity.** During temperature equilibrium the incubator temperature can be expected to differ from the temperature at other sites across the mattress due to the air flow characteristics of the incubator. Since the location of the infant on the mattress can vary, nonuniformity should be minimized to maintain the infant as close to the prescribed incubator temperature as possible (Adamsons, et al., 1965; Avery, 1993; Bell and Rios, 1983 [b]).
- 8) **Indicated temperature accuracy.** This information enables the user to determine whether the maximum difference which can exist between the indicated temperature and the actual temperature is suitable for the intended application and within the performance requirements of this standard (4.2.2 [b]) (Adamsons et al., 1965; Avery, 1993; Day, 1941; Perlstein et al., 1976).
- 9) **Incubator test load core temperature versus incubator temperature.** The incubator test load core temperature gives an approximation of operative temperature, defined as the temperature of a uniform (isothermal) "black" enclosure in which a solid body or occupant would exchange the same amount of heat by radiation and convection as in the actual nonuniform environment (Bligh and Johnson, 1973). Operative temperature is useful for comparing the thermal performance of incubators, e.g., different partitioning of convective and radiative heat transfer or relative ability to keep infants warm (Bell and Rios, 1983 [a], 1983 [b]; Bell, Gray, et al., 1980; Bell, Weinstein, et al., 1980; Wheldon, 1982). Very low birthweight infants require higher operative temperatures (Hardy, 1939; Hey and Katz, 1970; Hey and Mount, 1967; Scopes and Ahmed, 1966; Sauer, Dane et al., 1984).
- 10) **Control temperature versus indicated temperature correlation.** This information enables the user to determine whether the difference between the prescribed temperature (control temperature) and the indicated temperature is suitable for the intended application and within the performance requirements of this standard (4.2.2 [c]) (Adamsons et al., 1965; Avery, 1993; Perlstein et al., 1976).
- 11) **Infant temperature alarm.** This information enables the user to determine whether the temperature deviation from the ITC control temperature which will activate a high or low temperature alarm is suitable for the intended application (Bell, Weinstein et al., 1980; Hey and Katz, 1970; Scopes and Ahmed, 1966; Silverman et al., 1966).
- 12) **Air velocity.** This information enables the user to determine whether the incubator air velocity and its possible effect on the infant's evaporative and convective heat loss are suitable for the intended

application ([Okken et al., 1979](#)).

13) **Air circulation alarm.** This information enables the user to determine whether the time within which the alarm will sound is suitable for the intended application.

14) **Other controls/alarms.** This information enables the user to determine whether the performance characteristics not specified in this standard are suitable for the intended application.

15) **CO₂ concentration.** This information enables the user to determine whether the maximum CO₂ concentration in the infant compartment as a result of the infant's exhaled CO₂ is suitable for the intended application.

16) **Infant compartment sound level.** This information enables the user to determine whether the maximum incubator sound level is suitable for the intended application.

17) **Auditory alarm sound level.** This information enables the user to determine whether the maximum alarm sound level is suitable for the intended use environment.

18) **Infant compartment alarm sound level.** This information enables the user to determine whether the maximum alarm sound level in the incubator is suitable for the intended application.

19) **Shelf loading.** This information enables the user to determine whether the maximum shelf loading recommended by the manufacturer is suitable for the intended application.

20) **Battery performance.** This information enables the user to determine whether the battery performance is suitable for the intended applications.

21) **Ambient conditions.** This information is required for clinicians to determine whether the incubator can be expected to operate properly under different ambient conditions.

c) **Important notices, cautions, and warnings.** The rationale for these requirements is as follows:

1) and 2): Controlling infant temperature with a rectal probe or a skin temperature sensor that is not accurately sensing the skin temperature (loose or misplaced probe) can result in adverse effects on oxygen consumption ([Silverman et al., 1966](#)).

3) Pyrolysis of ether in an infant's exhaled gas to form formaldehyde has been reported. Formaldehyde can be toxic when inhaled.

4) See [A.4.1.1.6\(a\)](#).

5) See [A.4.1.1.6\(b\)](#).

6) See [A.4.1.1.6\(c\)](#) and [A.4.1.1.6\(d\)](#).

7) See [A.4.1.1.6\(e\)](#).

d) **Cleaning, disinfection, and sterilization.** Provision of recommended sterilization/disinfection procedures will help ensure that there is an effective cleaning method that will not degrade device performance.

e) **High temperature alarm sensor.** The high temperature alarm sensor can fail or be damaged due to shock or impact damage during use or cleaning. Verification of its integrity during normal use can be achieved by test means as determined by the manufacturer. Assurance can be achieved by redundancy. The risk of damage and/or failure of other components of the high temperature alarm system is considered slight. Periodic testing of the proper functioning of the entire system is required as part of the recommended preventive maintenance procedure ([4.1.3](#)).

f) **ITC control methodology.** This information is required to provide clinicians with an understanding of

the interrelation of the various parameters controlled and affected by the incubator in ITC mode.

- g) **Limiting infant's movements.** This information is required to provide clinicians with the proper means to help avoid physical injury to the infant during transport.
- h) **Transportable electrical power source.** This information is required to provide clinicians with the proper instructions to connect and operate the alternate electrical power sources for use during transport.
- i) **Mass and dimensions.** This information is required for clinicians to provide proper means to transport the incubator in a vehicle.
- j) **Fixation in vehicle.** This information is required for clinicians to provide proper means to transport the incubator in a vehicle.

A.4.1.3 Service manual

A service manual is necessary to enable service personnel to perform preventive maintenance, calibration and repairs in conformance with the manufacturer's recommended procedures.

A.4.2 Performance requirements

A.4.2.1 Environmental performance

This requirement exceeds the limits of the range of ambient environmental conditions required of a ground ambulance environment.

A.4.2.2 Thermal characteristics

- a) **Incubator temperature control range.** It is necessary that an incubator be able to provide a stable thermal environment for an unclothed infant over a wide range of air temperatures to satisfy varying thermal requirements based on many variables (e.g., gestational age, weight, pathology, therapy) (Buetow and Klein, 1964; Day et al., 1964; Hey and Katz, 1970; Marks et al., 1980; Silverman et al., 1966; Sauer et al., 1984). The AAP Task Force recommended a minimum temperature of 20° C based on the specified environmental requirement (4.2.1). A temperature of 23° C is specified based on the need for a differential between the incubator temperature and the ambient temperature in order to achieve stable control. The AAP Task Force (AAP, 1983) also recommended a maximum control temperature of 39° C based on data that show that temperatures above 39° C increase the metabolic rate of an infant in order to maintain normal body temperature. However, with large (term) infants, temperatures over 37° C can be dangerous, while with small (premature) infants, temperatures over 37° C may be required (Hey, 1975; Hey and Katz, 1970; Sauer et al., 1984).
- b) **Air and infant indicated temperature accuracy.** Clinical judgments concerning the adequacy of thermal control and infant well being are based, in great part, on skin temperature measurements. Small changes in skin temperature have been shown to affect O₂ consumption (LeBlanc, 1983; Silverman et al., 1966). An accuracy of $\pm 0.3^{\circ}$ C is considered clinically acceptable and is attainable with current technology. This applies only to this hardware capability. There may be additional variance between actual skin temperature and that measured by the sensor caused by the site and method used for attaching the sensor to the skin.
- c) **Air and infant control temperature/indicated temperature correlation.** The normal range of expected variability in infant body temperature during wake/sleep cycles where body temperatures are not constrained by external temperature control can be up to $\pm 1.0^{\circ}$ C (Day, 1941). A similar range of variability in an incubator control system has been reported to enhance the survival of premature infants (Perlstein et al., 1976). The AAP Task Force (AAP, 1983) recommended a $\pm 0.7^{\circ}$ C variance.
- d) **Infant control temperature range.** There is a strong association between maintaining the abdominal

skin temperature of newborn premature infants and their survival (Buetow and Klein, 1964; Day et al., 1964). A "neutral thermal state" for small neonates has been shown with abdominal skin temperature maintained within 36-37° C (Oliver, 1965; Scopes and Ahmed, 1966; Silverman et al., 1966). Other investigations have confirmed the relationship of basal metabolism and maintenance of skin temperature between 35.5 and 36.5° C (LeBlanc, 1983). A range of 35-37° C is considered to cover the clinically required range. A wider range is allowed to permit greater flexibility in managing extraordinary patient needs.

e) Maximum infant contact temperature.

Potential damage to human skin from hot surfaces can be divided into two parts. Acute changes due to thermal transfers of heat already stored in the material to the skin and chronic changes due to the conduction of heat from the heat source to the infant's core. Safe levels of acute exposure can be calculated from the equation of Stoll (1979, 1982) assuming skin thickness approaches 0.

$$T_{mPt} = .494(t)^{-.412} \left(\frac{0.239}{\sqrt{kr c_p}} + 31.5 \right) + 41^\circ C$$

where: T_{mPt} is the temperature of a material at the pain threshold, t is the time of exposure, k is the thermal conductivity of the material ($J/s \cdot cm \cdot ^\circ C$), ρ is the density of the material (gm/cm^3), and c_p is the specific heat of the material ($J/gm \cdot ^\circ C$). The time to produce skin damage is approximately 2.5 times that to produce pain. Five s is chosen for the end of acute events. Thus, the allowable temperature of the surface T_{mPt} is

$$T_{mPt} = 0.494(5)^{-.412} \left(\frac{0.239}{\sqrt{k\rho c_p}} + 31.5 \right) + 41^\circ C$$

$$T_{mPt} = 0.25 \left(\frac{0.239}{\sqrt{kr c_p}} + 31.5 \right) + 41^\circ C$$

$$T_{mPt} = \frac{0.06}{\sqrt{kr c_p}} + 48.9^\circ C$$

For chronic exposure the skin temperature must exceed 43° C to produce damage. Forty degrees is used for the standard to provide a margin of safety. We use the equation for heat flow by conduction, $(T_1 - T_2)k/X$, where k is the thermal conductivity and X is thickness. If the thermal conductivity of skin is $2.1 \times 10^{-3} J/s \cdot cm \cdot ^\circ C$ (Cohen, 1977), and the effective thickness from skin to core is 1 cm (Bruck, 1992), and if the thermal conductivity of the material is k , and its thickness is X , then

$$(T_{skin} - T_{core}) k_{skin}/X_{skin} = (T_{source} - T_{skin}) k/X,$$

and if

$$T_{core} = 37^\circ C, T_{skin} < 40^\circ C, k_{skin} = 2.1 \times 10^{-3} J/s \cdot cm \cdot ^\circ C,$$

$X_{skin} = 1 \text{ cm}$, then

$$T_{source} < \frac{6.3 \times 10^{-3} X}{k} + 40$$

Or looking only at the right side of the equation, the heat flow to a 37° C heat sink shall not exceed $(T_{skin} - T_{core}) k_{skin}/X_{skin}$ or $6.3 \times 10^{-3} \text{ J/s} \cdot \text{cm}^2$.

Example:

For Teflon, $k = 2.42 \times 10^{-3} \text{ J/s} \cdot \text{cm} \cdot ^\circ\text{C}$, $\rho = 2.15 \text{ gm/cm}^3$,
 $C_p = 1.05 \text{ J/gm} \cdot ^\circ\text{C}$.

$$k r c_p = 5.46 \times 10^3 \text{ J}^2 / \text{cm}^4 \text{ C}$$

$$\sqrt{k r c_p} = 0.0739 \text{ J} / \text{cm}^2 \text{ C}$$

For acute exposure of 5 s, the allowable surface temperature T_{mPt} shall be:

$$\frac{0.06}{0.0739} + 48.9^\circ \text{ C} = 49.7^\circ \text{ C}$$

If the heat source is not directly on the other side of the Teflon and a more complicated geometry exists, the heat flow to a 37° C heat sink shall not exceed $6.3 \times 10^{-3} \text{ J/s} \cdot \text{cm}^2$, after a 5-s stabilization.

f) **Maximum user contact temperature.** A 3- to 5-s exposure to a metal surface at 60° C or to a plastic surface at 70° C will result in a tissue contact temperature of between 45 and 50° C, the pain threshold. Quick removal of the tissue from the heated surface in response to the pain sensation can prevent irreversible injury to the skin ([Moritz and Henriques, 1947](#); [Dussan and Weiner, 1971](#); [Stoll, Chianta, and Piergallini, 1979](#); [Cohen, 1977](#); [Bruck, 1992](#)).

A.4.2.3 Alarms

A.4.2.3.1 High temperature

- a) Failure of the primary incubator temperature control system could cause the infant to be exposed to dangerously high air temperatures. A high temperature alarm will minimize the degree and duration of exposure of the infant to high temperature in the event of such failure. Experience has shown that adjustable high temperature thermostats are misadjusted to their maximum position, and that such adjustments have resulted in excessively high incubator temperatures without an alarm.
- b) The intent of this requirement is to verify that the high temperature alarm sensor is operational during normal use, not to test its calibration.

A.4.2.3.2 Infant temperature sensor

A failed sensor or one that is not properly connected to its receptacle could cause the infant to be exposed to dangerously high air temperatures. A failed sensor alarm provides a rapid alert to prevent this occurrence.

A.4.2.3.3 Infant temperature

The dislodging of infant temperature sensors can occur, which causes the sensor to measure and attempt to control air temperature rather than skin temperature. If the air temperature is significantly different than the skin temperature desired, the infant could be exposed to air temperatures beyond the range of thermal neutrality,

resulting in a potentially harmful effect on O₂ consumption if the user is not alerted to the occurrence (Hey, 1975; Sauer et al., 1984). Available data was not considered adequate to establish specific alarm limits. If the difference is too small, there will be excessive false alarms due to normal infant temperature variability. If the difference is too great, it will be dangerous to the infant. The maximum allowable value, 1° C, was suggested because it has been in common use for many years and appears to be reasonable.

A.4.2.3.4 Air circulation failure

A locked rotor of a fan motor, or failure to replace a fan removed for cleaning, may not be readily detected and could result in the incorrect indication of incubator temperature, the development of hazardous temperatures, or an excessive buildup of CO₂ in the infant compartment with no warning to the user. There is no data to support a specific value for the time to alarm. The maximum allowable value, 15 min, was selected as a reasonable value for safety and for currently available detection mechanisms.

A.4.2.3.5 External power failure alarm

Since transport incubators typically automatically switch to their internal power source when external power is interrupted, it is only important to have an external power failure alarm if the switchover to internal power is not automatic. Inadvertent power loss for any reason should not alter the operating mode or settings when power is restored.

A.4.2.3.6 Low battery alarm

Transport incubators depend on batteries as an emergency source of power. It is important to know when the batteries have approached the end of their useful charge. It is felt that 5 min is an adequate warning to find an alternative power source.

A.4.2.3.7 Alarm silencing

A 15-min alarm silence will provide for reactivation of the alarm in a reasonable period of time, without creating such an annoyance that the attending personnel will be disposed to permanently disable the alarm. The visual indication that an auditory alarm is disabled serves as a reminder to personnel that an alarm condition which is potentially harmful to the infant may exist and may require resolution. An exception was allowed for initial warmup of the device, since warmup time commonly exceeds 15 min. There is no data to support a specific value for the time to allow alarm silencing during initial warmup. The maximum allowable value, 30 min, was selected as a reasonable value for safety and for the warmup time of currently available transport incubators.

A.4.2.4 Sound levels

A.4.2.4.1 Infant compartment

In a number of studies, incubator noise levels have been measured and potentially harmful effects on the hearing of prematurely born infants have been suggested. Studies demonstrating a harmful synergistic effect of continued noise and ototoxic drugs in guinea pigs have added to concern about potential risks to infants (Dayal et al., 1971). However, the only studies involving infants nursed in conventionally available incubators have failed to establish correlations between incubator noise and Kanamycin, or between deafness and duration of noise exposure (Winkel et al., 1978; Abramovich et al., 1979; Stennert et al., 1978). Based on the available evidence, the committee judged that a maximum interior sound level of 60 dBa, which represents performance met by currently available incubators, provided reasonable assurance of safety.

A.4.2.4.2 Auditory alarm

A minimum alarm sound level is necessary to reasonably assure that an alarm will be heard in a typical nursery environment. The establishment of a requirement for maximum sound level was considered by the committee, but, in the absence of documentation to support a specific criterion, it was decided that the maximum alarm

sound level should simply be disclosed by the manufacturer for the information of the clinician.

A.4.2.4.3 Infant compartment alarm

Temporary threshold shifts of hearing in adults have been associated with 8 hour exposures at significantly higher sound levels. While data on premature infants is not available, a lower value was chosen to provide an added margin of safety.

A.4.2.5 CO₂ concentration

An inspired CO₂ concentration of 4% or less can produce major physiologic changes in newborn infants ([AAP](#), 1983; [Rahilly, 1980](#)). The magnitude of these changes varies directly with the CO₂ concentration, and some changes are still detectable at a CO₂ concentration of 0.5%. Extrapolation from the available data suggests that there will be no significant effect at inspired CO₂ concentrations of 0.2% or less. Communications among some members of the AAP Task Force subsequent to its meeting resulted in an agreement that 0.5% would be acceptable because of limitations on the accuracy of measurement and the fact that the test method represented a large infant (5-6 kg), and therefore a margin of safety is provided for the smaller, more susceptible infant where CO₂ production is lower.

A.4.2.6 Fire prevention

A.4.2.6.1 Electronics compartment oxygen concentration

The increase in flammability that could occur at oxygen concentrations of 4% or less was considered acceptable in terms of safety. At O₂ concentrations greater than 4%, a barrier is needed to minimize fire hazard. An energy level of 10 VA is sufficiently low that ignition will not occur in high O₂ concentrations.

A.4.2.6.2 Maximum temperatures of components exposed to oxygen

The temperature specified is low enough to prevent auto-ignition of cotton lint in an oxygen enriched environment.

A.4.2.7 Mechanical/construction requirements

A.4.2.7.1 Infant compartment

The device must contain the infant within the infant compartment in such a way as to prevent the infant from falling and to prevent accidental opening of ports which may affect temperature and oxygen control. A transport incubator, which assists in maintaining an infant's thermal balance primarily by convective heating, must provide a means for isolating the infant from ambient temperatures, while also providing a means for observation and ready access for medical and nursing management ([Hey, 1975](#); [Sauer et al., 1984](#)).

A.4.2.7.2 Stability

- a) **Tip-over.** The required values for tip-over angle and force to tip are based on a survey of existing incubators. The requirements of [4.2.7.2](#) are intended to assure mechanical stability and are consistent with accepted industry practice for evaluation of stability (UL 544).
- b) **Thresholds.** It is important that the device continue to function and/or be suitable for use following the impact of obstacles which might normally be encountered, e.g., room or elevator thresholds.
- c) **Mattress tray.** It is important that pull-out mattress trays be secure under an infant's weight.
- d) **Restraining system.** It is important that an infant be protected from movements that could cause physical injury. The committee had discussions on the possibility of requiring restraints for infants, but at the time no practical and proven devices or technology for achieving this goal were available, as far as the

committee knew. Regarding ambulance and helicopter mishaps, there are no references or standards for mishaps available, thus there is no practical way to address them.

- e) **Incubator retention in ground vehicle.** This requirement is included to provide a reasonable level of retention capability in the event of vehicular accident. This level of retention capability is thought to be adequate since other patient transport cots/litters must comply with similar requirements for ground vehicle transportation throughout the United States. The test is intended to test the incubator's mounting system in the retention system. It is not intended to test the overall structural strength of the incubator. The test is based on normative reference 2.11 for testing retention systems. The force is applied in a similar location as in normative reference 2.11 to approximate rotational forces.

A.4.2.7.3 Shelves and mounting brackets

The requirements of 4.2.7.3 are intended to assure safe mechanical construction under conditions of accidental overloading.

A.4.2.7.4 Supplementary gas supply

Extreme mechanical shock presents a hazard due to the nature of compressed gases. Visible and accessible gauges and controls are essential for safe and proper use.

A.4.2.7.5 Switches, controls, and knobs

- a) Inadvertent changes in control settings, that might result from personnel brushing against the controls, can be detrimental to infant safety.
- b) Slipping of controls and switches on the panel could result in improper calibration of a control.
- c) By convention, incubator controls that rotate increase their setting in a clockwise direction.

A.4.2.7.6 Ingress of liquids

Contact of electrical circuitry with water or other liquids normally used for treatment or cleaning can degrade electrical performance and, in some cases, cause electrical failure or other hazards.

A.4.2.7.7 Mercury thermometers and thermostats

The exposure of infants to the potential toxicity of mercury vapor was judged by the committee's clinician participants to represent an unnecessary risk, even if the potential hazard is reduced by improved housing (McLaughlin et al., 1980; Waffarn and Hodgman, 1979). Alternate means of temperature measurement are readily available.

A.4.2.7.8 Humidifying system

- a) Isolation of liquid containers from electrical compartments is essential to minimize electrical hazard.
- b) Any liquid container is necessarily subject to growth of bacteria and should be capable of being disinfected or sterilized.
- c) A water level indicator is necessary so the user will know when to refill the reservoir.
- d) It is generally accepted good practice with humidifying systems that the reservoir be filled and drained between each patient use. It would be a problem for the personnel attempting to drain a reservoir if this could not be accomplished without tilting the incubator.

A.4.2.7.9 Infant temperature sensors

A rectal probe if improperly used to control an infant's temperature could result in unstable skin temperatures at undesirable levels because of the difference in rectal thermal response time compared to that of the skin (Silverman et al., 1966).

A.4.2.7.10 Wheels

Means to allow the user to prevent the incubator from rolling are necessary for the safety of the infant, user, and equipment.

A.4.2.7.11 Infant compartment illumination

In cases where no other source of light is available, illumination of the patient compartment should be provided.

A.4.2.8 Electrical characteristics

A.4.2.8.1 Risk current

Limiting risk current reduces the potential for inadvertent electric shock from the device. The rationale for the specific risk current limits recommended in normative reference 2.3 for devices with nonisolated patient connection is provided in that standard.

A.4.2.8.2 Overcurrent protection

Overcurrent protection minimizes electrical and fire hazard and/or damage to other components, and reduces the possibility of the interruption of power to other equipment.

A.4.2.8.3 Power switch

This requirement helps ensure that primary power will be interrupted if used on an isolated power source or if polarity is reversed.

A.4.2.8.4 Power cord and strain relief

The requirements of UL 544 and IEC 601-1 are industry standards and are considered appropriate.

A.4.2.8.5 Power indicator

An illuminated indicator provides a visual indication to attending personnel that the switch is on and power is being delivered to the incubator.

A.4.2.8.6 Supply voltage variation

This requirement helps ensure that the incubator operates normally over the range of supply voltage fluctuations commonly encountered in health care facilities and air and land converter systems. Voltage variations beyond the normal range should not damage the device.

A.4.2.8.7 Dielectric withstand

This requirement provides assurance that typical high voltage transients will not cause electrical breakdown.

A.4.2.8.8 Grounding impedance

Low impedance is required to ensure that the path to ground is adequate to handle large currents that may occur due to electrical faults and, thus, to prevent electrical hazard to patients or attending personnel.

A.4.2.8.9 Transportable electrical power source

A transportable electrical power source is required to operate the incubator during transport.

A.4.2.8.10 Electromagnetic compatibility requirements

With the proliferation of digital and computer instruments working at close range in the hospital, e.g., in the intensive care unit (ICU) or in the ambulance, there are a growing number of instances where one instrument emits radiation that interferes with the performance of another instrument. EMC must therefore be considered, in the expectation that compliance with EMC standards, on both emission and immunity, will minimize

detrimental interferences between instruments.

EMC performance and validation tests are very complex and require sophisticated instrumentation. It is not practical to make the transport infant incubator standard a standalone document by including all the pertinent information, particularly concerning test methods and instrumentation. Instead, we reference a number of IEC documents that specify in detail the appropriate EMC test methods and instruments. Two of these documents are still in draft stage and hence are subject to possible change. However, drafts of these documents are available and are routinely used by development and test engineers; it is therefore reasonable to reference and use these documents, particularly since we have no alternative at this time. Clearly, if the final documents differ from the current drafts, the committee will have to examine the impact on the present standard and consider possible revisions.

The standard addresses two complementary subjects: emission, which is the intensity and characteristics of electromagnetic radiation emitted or conducted by an operating device, and immunity, which is the ability of an instrument to perform satisfactorily while exposed to external electromagnetic radiation. The standard sets maximum levels on electromagnetic emission and defines the levels of external radiation that the device must tolerate and still perform satisfactorily.

The maximum levels of emission stated in the general standards have been adjusted to the specific device considered, i.e., transport infant incubator, and require a design effort by the manufacturer. At the same time, the levels are achievable with good design, may be different for different operating modes, and may also be waived when they cannot be achieved during certain operating modes.

The IEC collateral standard 601-1-2 on EMC in medical devices recognizes that measurement and control of EMC is particularly difficult for patient coupled devices, such as transport infant incubators, where the infant temperature sensor acts as an antenna which both emits and receives RF signals, with an antenna gain that depends on the layout of the infant temperature sensor. The IEC standard makes allowance for this situation by providing limited exemptions from the immunity requirements. These exemptions are extended to the present standard, on condition that the reduced immunity levels be measured and disclosed by the manufacturer.

The EM levels stated in the immunity subsection represent a compromise between the transport infant incubator design state-of-the-art and the almost infinite variety of EM environments that a portable device may encounter. The general documents quoted in reference (CISPR, IEC) have standardized on approximately four levels which represent increasingly harsh environments. Level 2 environments are commonly encountered, hence full immunity to Level 2 fields is required. Level 3 environments are rare but may be found (e.g., in the OR or near power lines, etc.) and it is important to indicate the performance of the instrument in a Level 3 environment. However, based on FDA test data for EMI in ambulances ([FDA, 1995](#)), a field strength of 20 V/m (corresponding to “level x” in the reference document) is more representative of the use environment.

For EMC requirements, it is a generally accepted practice to define standardized and progressively more severe EM environments and specify the device response to these standardized environments. There is, of course, an almost infinite variety of field environments that differ from the standardized environments covered in this document. Readers are asked to test their devices in these environments, seek to achieve the highest possible immunity and disclose any observed degradation in performance, so that the user will have appropriate warnings.

Finally, EMC is a rapidly developing subject where standards are evolving. This section of the transport infant incubators standard is likely to be revised and improved in the future.

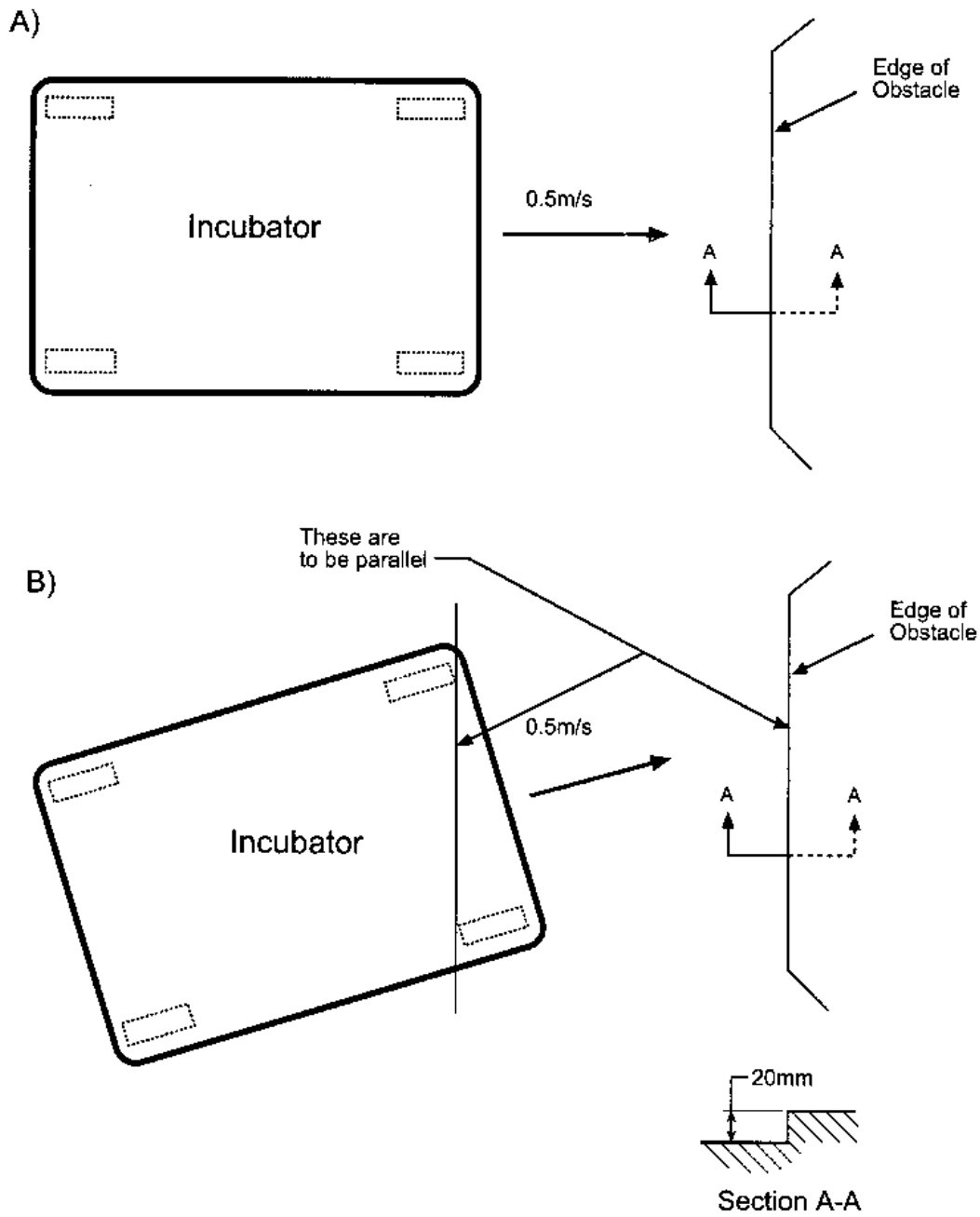
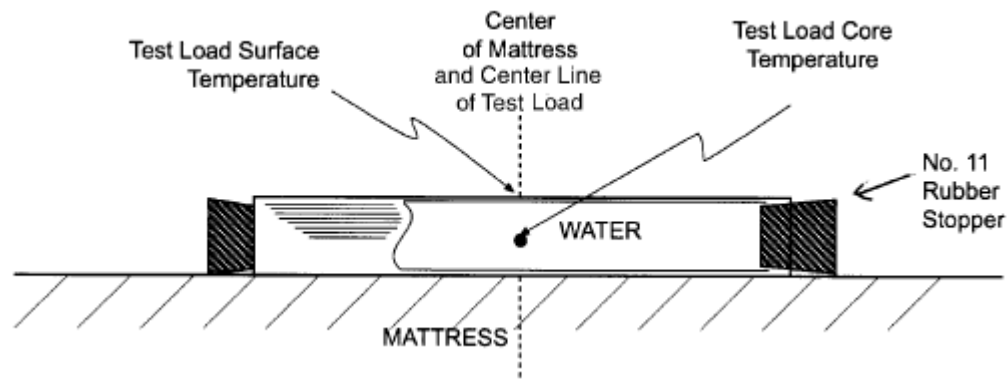


Figure 1—Threshold test



TEST LOAD SPECIFICATIONS:

- BODY** —OUTSIDE DIAMETER = 5.4 ± 0.16 cm (2.125 ± 0.06 in)
 —WALL THICKNESS = 0.18 ± 0.005 cm (0.070 ± 0.002 in)
 —LENGTH = 43 ± 1.3 cm (16.9 ± 0.51 in)
- FINISH** —MATTE BLACK (KRYLON FLAT BLACK SPRAY PAINT)
 —EMISSIVITY = 0.95 -0.99
- ENDS** —NO. 11 RUBBER STOPPER, BLACK
- CORE** —FILLED WITH DISTILLED WATER

NOTE—SURFACE TEMPERATURE SENSOR TO BE ATTACHED ACCORDING TO INCUBATOR MANUFACTURER'S RECOMMENDATIONS.

Figure 2—Incubator test load

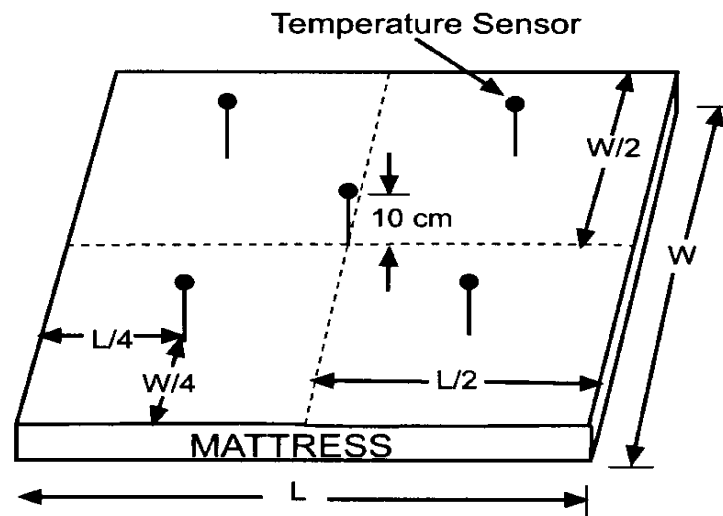


Figure 3—Temperature sensor locations

Annex B (informative)

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