List of Titles

American National Standard

ANSI/AAMI II:36:1997

Infant incubators

AAMI Association for the Advancement of Medical Instrumentation

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ANSI/AAMI II36—1997
(Revision of ANSI/AAMI II36—1991)

Infant incubators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 15 September 1997 by
American National Standards Institute, Inc.

Abstract: This standard delineates requirements for infant 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: air, alarm, compartment, equilibrium, sensor, temperature

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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. At the time this standard was approved, the committee had the following members:

Cochairs:	Robert H. Stiefel, CCE
	Jeffery Taylor
Members:	Joseph P. Bagnell, Air-Shields Vickers
	Michael M. Donnelly, University of Cincinnati Medical Center
	Joseph F. Dyro, PhD, CCE, Biomedical Resource Group
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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.

Foreword

This standard was developed by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation (AAMI). The objective of this standard is to provide minimum labeling, performance, and safety requirements that will help ensure 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 infant 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 unanticipated hazards.

As with many other medical devices, the design and function of an infant incubator that is effective for one patient may be potentially harmful to another, even when the device is performing to the manufacturer's specifications and is 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 assure 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 underlying these provisions. It is essential that the rationale be read and understood by all who choose to use the standard as a reference.

It should be recognized that an infant incubator currently in use that does not fully comply with all of the labeling, performance, and safety requirements of this standard may still be safe and effective. Nonconformance with the standard should not be the sole basis for a decision to replace an infant incubator.

The decision whether to continue use of an infant incubator should be based on careful consideration of the extent and nature of nonconformance, on how the incubator has been and will be used, and on the costs, risks, and/or benefits that 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 l976. An attempt was also made to achieve harmonization with the standard for infant 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 their work is gratefully acknowledged.

The requirements incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be periodically reviewed and updated to reflect medical and/or technology advances and to address safety and performance issues not previously identified. To remain relevant, the standard must be modified as technological innovation occurs and as new data are brought forward. This 1997 standard is a revision of the original (1991) infant incubator standard. The committee endeavored to "harmonize" the standard with IEC 60601-2-19 (the IEC infant incubator standard). Harmonization of ANSI/AAMI standards with their IEC counterparts is desired by ANSI, AAMI, and FDA. Harmonization resulted in a few minor changes in requirements, the most important being (1) the height of measurement of the alarm sound level was changed from 1.8 to 1.5 m; (2) the minimum alarm sound level was changed from 65 dBA to 50 dBA; and (3) the upper end of the minimum range over which an infant temperature controlled incubator shall be capable of achieving infant temperature equilibrium was changed from 37° C to 37.5° C. Differences remain between the ANSI/AAMI standard and the IEC standard

where the committee felt strongly that the more strict requirement of the ANSI/AAMI standard was appropriate. The biggest change in the 1997 version is the addition of a section (4.2.8.9) on electromagnetic compatibility.

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, Attn: Standards Department.

NOTE—This foreword is not a part of the AAMI standard, *Infant incubators* (ANSI/AAMI II36—1997), but it does provide important information about its development and intended use.

Infant incubators

1 Scope

1.1 General

This standard applies to infant incubators, those electrically powered devices that are intended to assist in the maintenance of the thermal balance of infants, principally by controlling the air temperature in an enclosure.

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

1.2 Inclusions

Infant incubators are divided for purposes of this standard into two classes, on the basis of the temperature variable that is controlled. Included within the scope of this standard are AIR TEMPERATURE CONTROL (ATC) infant incubators and INFANT TEMPERATURE CONTROL (ITC) infant incubators.

1.3 Exclusions

This standard does not cover:

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

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

b) infant incubators specifically intended for use in transporting infants either outside or within the health care facility and including a self-contained power supply; or

c) infant 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.* CSA B96; ANSI/CGA V-1-1987. New York: ANSI, 1987.

2.2 AMERICAN SOCIETY OF HEATING, REFRIGERATING, AND AIR CONDITIONING ENGINEERS, INC. *1995 ASHRAE Handbook¾HVAC 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 (Vir.): AAMI, 1985. American National Standard. ISBN 0-910275-50-5.

2.4 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Electromagnetic compatibility for industrial process measurement and control equipment*, IEC 1000-4 series. Geneva: IEC. (In U.S., 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)

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Part 2: Collateral standard: Electromagnetic compatibility: Requirements and test*, IEC 60601-1-2. Geneva: IEC, 1993. (Available from ANSI.)

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment¾Part 1: General requirements for safety*, IEC 60601-1. Geneva: IEC, 1988.

2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment¾Part 2: Particular requirements for safety of baby incubators*, IEC 60601-2-19. Geneva: IEC, 1990. (Available from ANSI.)

2.8 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. Geneva: CISPR, 1990. (Available from ANSI.)

2.9 NATIONAL FIRE PROTECTION AGENCY. *National electrical code*, No. 70. Boston (Mass.): NFPA, 1993. American National Standard.

2.10 NATIONAL TRUCK EQUIPMENT ASSOCIATION. *Oxygen tank retention system*, AMD Standard 003. Livonia (Mich.): NTEA, 1991.

2.11 UNDERWRITERS LABORATORIES. *Standard for safety, medical and dental equipment*. UL 2601-1. Melville (N.Y.): UL 1994.

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 temperatures taken at regularly spaced sample times not to exceed 1 minute, over a period of 30 minutes (min) (plus the time to complete an integral number of temperature cycles if necessary).

3.3 average incubator temperature: The average temperature at a point 10 cm above and centered over the mattress surface (see figure 1).

3.4 control temperature: The temperature selected at the temperature control (ATC or ITC [see 3.1 and 3.11]).

3.5 incubator temperature: The air temperature at a point 10 cm above and centered over the mattress surface.

3.6 incubator temperature equilibrium: The condition reached when the average incubator temperature does not vary more than 0.2° C over a period of 1 hour.

3.7 incubator test load: The incubator test load is a 43 cm (16.9 inches) long by 5.4 cm (2.125 inches) diameter copper tube filled with distilled water (see figure 3).

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 of control temperature and infant temperature in ITC mode. It is neither intended nor believed to simulate an infant's thermal response (for example, 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.

3.8 indicated temperature: The temperature displayed by the readout of the incubator temperature or infant temperature.

3.9 infant compartment: That portion of the incubator designed to contain the infant.

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

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

3.12 infant temperature equilibrium: The condition when the incubator test load surface temperature does not vary by more than 0.2° C in 1 hour.

3.13 inspection: Any examination, such as a visual or auditory one, which does not require the use of special laboratory applications or procedures and/or verification of manufacturing and test records.

3.14 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.

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

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

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

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

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

3.20 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, disinfecting, 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 (infant 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 designation;

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;

g) 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 functions that are obvious (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) if applicable, ATC/ITC switch shall produce an auditory, visual, or tactile indication of change of state, and 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. Indicated temperature shall be clearly visible and easily read 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 located to prevent confusion with regard to the position of the control and the indicated value. Any incubator control with 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 of not greater than 0.5° C for ATC settings and not 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 shall also be identified.

4.1.1.5 Overcurrent protection

Overcurrent protection devices shall be clearly and permanently marked as per UL 2601-1 (see 2.11). Circuit breakers should be used if possible. If fuses are used, retainers for spare fuses shall be incorporated. Fuses and spares shall be marked as per UL 2601-1.

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 is being delivered;

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

c) if applicable, a warning of the possible consequences of improper skin attachment or location of the infant temperature sensor;

d) a notice to routinely check infant temperature, incubator temperature, incubator function and, if applicable, infant temperature sensor attachment;

e) a warning if the incubator is not suitable for use in the presence of flammable anesthetics;

f) a warning of the possible adverse consequences to the infant of blankets, diapers, or other objects obstructing or altering airflow patterns.

4.1.2 Operator's manual

Adequate instructions for the installation and proper operation of the incubator shall be provided with each incubator. Instruction 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 shall include a description of the functional characteristics and use of all controls, indicators, displays and alarms, and a procedure for user checks of proper operation, 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. As a minimum the following additional information shall be included:

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 mode only;

5) intervention temperature drop/recovery time for ATC mode 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, specify with mattress in all positions of normal use;

9) incubator test load core temperature vs. incubator temperature;

10) control temperature vs. indicated temperature correlation for both ATC and ITC, and for ATC only, specify correlation with mattress in all positions of normal use;

11) the deviation of indicated temperature from control temperature which will activate the air temperature control alarm for ATC and the infant temperature alarm for ITC;

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 vs. 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 CO_2 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;

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

1) a warning regarding the possible consequences of inadequate skin attachment or location of the infant temperature sensor;

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 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 is being delivered;

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

6) a notice to routinely check infant temperature, 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 of 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 shall be disclosed, giving the relationship between infant temperature, control temperature, and other incubator controlled parameters (e.g., incubator temperature, heater status);

g) a statement of the mass and external dimensions of the infant incubator including oxygen delivery system and trolley, if provided.

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 calibration of controls and for checking alarm systems;

f) recommended intervals for preventive maintenance and skill level required;

g) information on how to obtain authorized repair.

4.2 Performance

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—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 greater than 37° C, this shall require a special action of the operator and 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 control temperature.

b) the air and infant indicated temperature shall be accurate within ± 0.3° 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 over a minimum range of 35° C to 37.5° C. If settings greater than 37.5° 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, this temperature shall not exceed 40° C. For nonmetals, the temperature is derived from

$$TmPt = \frac{0.06\,J / s^{(1/2)} \bullet cm^2}{\sqrt{kr\,c_p}} + 48.9^{o}\,C$$

where: J is Joules, k is thermal conductivity in J/s•cm•° C, ρ is density in g/cm^3, 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 x 10^{-3} J/s•cm^2 after 5s 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) A means shall be provided to activate an alarm and turn off the heater at an incubator temperature not to exceed 40° C. Said means shall activate at an incubator temperature no higher than 40° C if the normal maximum setting is overridden. If an internal adjustment by service personnel is possible, a means to prevent inadvertent changes during preventive maintenance or servicing shall be provided and it shall not be possible to adjust it beyond 40° C.

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

4.2.3.2 Air temperature control alarm

After steady temperature conditions of an air-controlled incubator have been achieved, any sensed temperature deviation of the displayed air temperature exceeding ±3° C compared with the control temperature shall activate an auditory and visual alarm. The equipment heater shall switch off if the displayed air temperature exceeds the control temperature by 3° C.

4.2.3.3 Infant temperature sensor

a) 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 the infant temperature sensor failure when either electrically open- or short-circuited, or if the sensor is improperly connected.

b) Visual and/or auditory indicators should be provided if the skin temperature probe is dislodged.

4.2.3.4 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.

4.2.3.5 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 min.

4.2.3.6 Power failure

The incubator 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 sounding 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 of the incubator.

4.2.3.7 Alarm silencing

Any deliberately silenced auditory alarm shall automatically sound again within 15 min unless the alarm condition has been corrected. 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, during the initial warming of infant or incubator the period of alarm silence may be increased 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 m from the incubator and at a height of 1.5 m as the power-on default. The auditory alarm level may be adjusted downward after power-on by the user to a level not below 50 dBA.

4.2.4.3 Infant compartment alarm

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

4.2.5 CO_2 concentration

In normal use, the CO_2 concentration in the infant compartment shall not exceed 0.5%.

4.2.6 Fire prevention

4.2.6.1 Electronics compartment oxygen concentration

Components which in normal use or in a single fault condition may be a source of ignition shall be separated from any oxygen-enriched environments by a barrier which will prevent the O_2 concentration from exceeding ambient by no more than 4%. Alternatively, if the O_2 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 within the oxygen-enriched environment which could be a source of ignition (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 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 using a 20-newton test force to simulate normal use or infant activity;

d) be constructed so that means of access to the infant shall not appear to be latched when it is not actually latched;

e) be designed to minimize the likelihood of inadvertent obstruction or alteration of airflow patterns, which would affect performance;

f) the 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 similar equipment 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 10º from the vertical in normal use, 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 a 100-newton load.

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 2.10).

b) Gauges shall be clearly visible, and valves and regulators which are 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) if any incubator controls rotate, a clockwise direction shall increase the value of the settings.

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 penetrate to electrical components during normal use.

4.2.7.7 Mercury thermometers and thermostats

Thermometers or thermostats containing 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 degrade safety or performance if it enters the electrical compartment(s);

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.

4.2.8 Electrical characteristics

4.2.8.1 Risk current

The device shall meet the applicable requirements as 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 of a type 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 cord shall be used for equipment subject to operation in such conditions.

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

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 ac 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 ± 10 percent 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 a number, which is 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 60601-1 requirements (see 2.6).

4.2.8.9 Electromagnetic compatibility (EMC) requirements

These EMC requirements were developed on the basis of reference standards 2.4, 2.5, and 2.8.

4.2.8.9.1 Electromagnetic (EM) emissions

4.2.8.9.1.1 Radiated and conducted electromagnetic emissions

The 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 incubator shall not exceed 30 dB µV from 30 to 230 MHz and shall not exceed 37 dB µV from 230 to 1000 MHz.

4.2.8.9.1.2 Magnetic field emissions

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

4.2.8.9.2 Electromagnetic immunity

4.2.8.9.2.1 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. The equipment shall continue to meet its specifications or fail in such a way that all high and low temperature alarms and thermal cutouts continue to function according to the requirements of this standard, and the incubator settings shall be maintained.

4.2.8.9.2.2 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.

4.2.8.9.2.3 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.

4.2.8.9.2.4 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.

4.2.8.9.2.5 Power line transients

Only transient loss of functionality is allowed when the equipment is subjected to fast transient/bursts (1 kV) at the main 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 subjected 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	UNITS	MIN/MAX VALUE
4.2.1	Environmental performance			
	a) Temperature;	range	° C	20 to 30
	b) Barometric pressure;	range	kPa	86 to 106
	c) Relative humidity;	range	%	0 to 95
	d) Air velocity.	range	cm/s	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
		max	° C	± 0.7
	c) air and infant control temperature/indicated temperature correlation;	range	° C	35 to 37.5
		max	° C	38
	d) infant temperature equilibrium during ITC;			
	— override allowed;	max	° C	40
		max	° C	derive TmPt
	e) infant accessible maximum temperature			
	— metals;	max	° C	60
	— nonmetals;	max	° C	70
	f) user accessible maximum temperature			
	— metals;			
	— nonmetals.			
4.2.3	Alarms	--	--	--
4.2.3.1	High temperature			
	a) means provided activates alarm and turns off heater	max	° C	40
	— override allowed;	max	° C	40
		max	° C	40
	— not possible to adjust higher;	NA	NA	NA
	b) verify or assure function during normal operation.			
4.2.3.2	Air temperature control alarm			
	— sensed temperature deviation between the displayed air temperature and the control temperature causes an auditory and visual alarm to operate;	range	° C	±3
	— heater switches off if the displayed air temperature exceeds the control temperature.	max	° C	3
4.2.3.3	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
4.2.3.4	Infant temperature			
	— auditory and visual alarms if infant's indicated temperature differs from control temperature by more than manufacturer's specification.	max	° C	1

Table 1—Summary of performance requirements

SECTION	REQUIREMENT DESCRIPTION	MIN/MAX	UNITS	MIN/MAX VALUE
4.2.3.5	Air circulation failure — auditory and visual alarms if air circulation fails.	max	minutes	15
4.2.3.6	Power failure — auditory and visual alarms if loss of power; — auditory alarm sustained; — mode of operation unchanged upon power restoration.	NA min min	NA minutes minutes	NA 3 5
4.2.3.7	Alarm silencing — any silenced alarm shall sound again unless condition corrected; — silencing one alarm won't affect others; — visual alarms not extinguished until condition corrected; — alarm silence period may be longer during initial warm-up.	max NA NA max	minutes NA NA minutes	15 NA NA 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 1.5 m.	min	dBA	65 initial; may be adjusted to 50
4.2.4.3	Infant compartment 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	Electronics compartment oxygen concentration — components which may be a source of ignition must be separated from oxygen-enriched environments to prevent excessive O_2 concentration above ambient; — alternatively, limit product of voltage and short circuit current.	max max	% VA	4 10
4.2.6.2	Maximum temperatures of components exposed to oxygen — limit surface temperature of components in oxygen-enriched atmosphere	max	° C	300
4.2.7	Mechanical/construction requirements	--	--	--

Table 1—Summary of performance requirements

SECTION	REQUIREMENT DESCRIPTION	MIN/MAX	UNITS	MIN/MAX VALUE
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 min	NA N	NA 20
	c) ensure that means of access cannot be inadvertently opened during use or by infant activity	NA	NA	NA
	d) ensure that 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.			
4.2.7.2	Stability and transportability:			
	a) Tip-over:			
	— Angle from vertical in normal use;	min min	degrees N	10 100
	— force in worst-case configuration	NA	NA	NA
	b) Thresholds: Latches and doors remain closed and manufacturer supplied auxiliary equipment remains attached after impact	min	N	100
	c) Mattress tray: If extended outside enclosure with infant remains secure; doesn't tip under weight			
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

Table 1—Summary of performance requirements

SECTION	REQUIREMENT DESCRIPTION	MIN/MAX	UNITS	MIN/MAX VALUE
4.2.7.8	Incubator humidifying system: (if provided) a) leakage or spillage due to overfilling or tilting shall not enter electrical compartment, affecting performance b) can be cleaned and sterilized between uses c) water level indication should be provided d) can be emptied without tilting	NA NA NA NA	NA NA NA NA	A NA NA NA
4.2.7.9	Infant temperature sensors — shall be designed to prevent use 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
4.2.8	Electrical characteristics	--	--	--
4.2.8.1	Risk current — shall meet ANSI/AAMI Safe current limits for electromedical apparatus.	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; — hospital grade AC power plug; — strain relief shall prevent stress on terminals, splices, or wiring;	NA NA NA	NA NA NA	NA NA NA
4.2.8.5	Power indicator (shall) — show when power is 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 ±10% of rated voltage; not damaged by 95 to 135 V_{rms}.	NA	NA	NA
4.2.8.7	Dielectric withstand — of 1 minute at 1000 V plus twice rated voltage or 1 second at 1200 V plus 2.4 times rated voltage.	NA	NA	NA
4.2.8.8	Grounding impedance — per IEC 60601-1.	NA	NA	NA
4.2.8.9	Electromagnetic compatibility requirements	--	--	--
4.2.8.9.1	Electromagnetic emissions	--	--	--
4.2.8.9.1.1	Radiated and conducted EM emissions: — comply with CISPR 11 Group 1 Level B; — emissions at 10 m from 30 Hz to 230 MHz, and — from 230 to 1000 MHz.	NA max max	NA dBµV dBµV	NA 30 37

Table 1—Summary of performance requirements

SECTION	REQUIREMENT DESCRIPTION	MIN/MAX	UNITS	MIN/MAX VALUE
4.2.8.9.1.2	Magnetic field emission — from surface.	max	millitesla	0.5
4.2.8.9.2	Electromagnetic immunity.	--	--	--
4.2.8.9.2.1	Immunity to radiated RF EM fields — per IEC 1000-4-3, level 2 field, no change of state.	NA	NA	NA
4.2.8.9.2.2	Immunity to conducted EM fields — per IEC 1000-4-6, no change of state or performance degradation.	NA	NA	NA
4.2.8.9.2.3	Immunity to magnetic fields — no change of state.	NA	NA	NA
4.2.8.9.2.4	Immunity to ESD (per IEC 1000-4-2): — for open air, discharges up to 4 kV or direct discharges up to 2 kV, no change in operation; — 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.	NA max	NA seconds	NA 2
4.2.8.9.2.5	Power, line transients: a) fast transients/bursts, per IEC 1000-4-4, with only transient loss of function allowed; b) surge immunity, per IEC 1000-4-5, with no change of state allowed.	NA NA	NA NA	NA NA

5 Tests

This section provides all of the inspections, examinations, and tests to be performed in order 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: ≤ 15cm/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 with calibration that is traceable where possible 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, disinfecting, and sterilizing 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), the required measurements are to be reported under the test conditions specified. The results should also 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 5.1.2b(b)(6), (9), (10), and (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 ± 1.0° 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 ± 1.0° 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° C 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, with the incubator in an ambient temperature of 25 ± 1.0° C, allow the incubator test load to reach infant temperature equilibrium 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. If an override mechanism is provided (see 4.2.2[d]), the maximum control temperature settings for default and override conditions shall be tested.

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 dividing the length and width in half, and at center mattress (see figure 4). During incubator temperature equilibrium at control temperatures of both 32° C 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 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 its horizontal position and in the maximum tilt positions.

   ii) ITC operation—If applicable, see 5.2.2(b).

9) Incubator test load core temperature vs. 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 its horizontal position and in 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 3), 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. 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.

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 its horizontal position, in the

maximum mattress tilt positions, and during other conditions of normal use (e.g., with and without inner walls).

13) Air circulation alarm—See 5.2.3.5.

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

15) CO_2 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.

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) Mass and dimensions—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 ± 0.1° 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 an internal adjustment is possible, compliance with the requirement that means to prevent inadvertent changes shall be provided. Compliance with the requirement that said means cannot be set over 40° C can be verified by adjusting the thermostat to its maximum setting and repeating the test.

b) Verify conformance by the method recommended by the manufacturer in the operator's manual.

5.2.3.2 Air temperature control alarm

Compliance is checked by inspection and the following two tests:

a) Test 1—Set the control temperature to 32° C. After the temperature indication has not varied by more than ±0.5° C for at least 10 min, increase the displayed air temperature. Report whether the auditory and visual alarms operate when the requirement is met and whether the equipment heater switches off.

b) Test 2—As for test 1, but in this instance the control temperature is set to 35° C. After the temperature indication has not varied by more than ±0.5° C for at least 10 min, decrease the displayed air temperature. Report whether the auditory and visual alarms operate if the requirement is met. The equipment heater remains in operation.

5.2.3.3 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.

5.2.3.4 Infant temperature

See 5.1.2(b)(11).

5.2.3.5 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.

5.2.3.6 Power failure

With the incubator turned on, disconnect the power cord from the 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 temperatures are unchanged.

5.2.3.7 Alarm 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 to 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 sound level of the equipment being tested.

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 1.5 m and at a distance 3 m from the front of the incubator. If more than one alarm sound level or 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 to15 cm above the center of the mattress. The alarm sound level shall be adjusted to maximum, if user adjustable.

5.2.5 CO_2 concentration

A 4% mixture of CO_2 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 be vertically upwards at a rate of 750 ml/min (or equivalent CO_2 minute volume). Measure CO_2 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 O_2 concentration, measure the O_2 concentration in all compartments, which may be a source of ignition. Alternatively, if the O_2 concentration can exceed 4% above ambient, measure the no-load voltage and short-circuit current of components which 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, which may be a source of ignition during conditions, which 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 to 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 manufacturer's maximum recommendations, which positions the incubator to minimize stability,

   1) the incubator shall not tip over at an angle of 10° from the vertical;

   2) the incubator shall not tip over with an applied force of 100 newtons at the highest point of the incubator or 1.5 m from the floor (whichever is lower).

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 2). The two types of movement are repeated two times with each pair of wheels first. 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 that is 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 to 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.

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, gradually increasing over a period of 5 to 10 s to a maximum equal to three 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 2.10).

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 one 1 m long, along the side(s) of the incubator where the control(s) are accessible. There shall not be contact with switches, controls, or knobs, which 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) 200 ml of water shall be sprayed on all inner surfaces of the infant compartment such that drops coalesce and flow down the walls. In addition, 200 ml of water shall be poured steadily on the infant tray. After 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 Incubator 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.

5.2.8 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 2.11) and the International Standard for Medical Electrical Equipment, Part 1, IEC 60601-1 (see 2.6).

Any strain relief shall be tested by the application of a 35-pound 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.

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 one minute between the ground plug and phase/neutral via the incubator's power cord. The resulting current as measured by a hi-pot tester must not be greater than 12 mA.

Connect the 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 Electromagnetic compatibility (EMC) requirements

Infant 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.

5.2.8.9.1 Electromagnetic (EM) emissions

5.2.8.9.1.1 Radiated and conducted electromagnetic emissions

The instrument shall comply with CISPR 11 Group 1 Level B (see 2.8). 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 a patient simulated (incubator test load) terminated mode.

5.2.8.9.1.2 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.

5.2.8.9.2 Electromagnetic immunity

5.2.8.9.2.1 Immunity to RF electromagnetic fields

The test methods and instruments specified in IEC 1000-4-3 (see 2.4) apply.

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

a) Field strength: 3 V/m (Level 2); 10 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 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, which are met.

5.2.8.9.2.2 Immunity to conducted electromagnetic fields

The test methods and instruments specified in the current draft of IEC 1000-4-6 (see 2.4) apply.

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) 10 Vrms (roughly corresponds to a radiated field strength of 10 V/m).

b) Carrier frequency: 150 kHz to 230 MHz

c) AM modulation, 80% index, at 1, 5, and 20 Hz.

5.2.8.9.2.3 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 ± 1° C at the instrument.

5.2.8.9.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in IEC 1000-4-2 (see 2.4) apply.

The 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.

5.2.8.9.2.5 Power line transients

a) Fast transients/burst—The test methods and instruments of IEC 1000-4-4 (see 2.4) 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 2.4) 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 infant 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 infant 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) 60601-2-19, *Particular Requirements for the Safety of Baby 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

Infant 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 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 for means of 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 infant incubators must comply with these regulations.

In addition, there are other critical facts which must be set forth in the labeling in order 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 that 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 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, 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 an 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.

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, 1981; 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, 1981; 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, 1981; 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, 1965).

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 airflow characteristics of the incubator. Since the location of the infant on the mattress can vary, nonuniformity should be minimized in order to maintain the infant as close to the prescribed incubator temperature as possible (Adamsons, *et al.*, 1969; Avery, 1981; 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 (4.2.2b)) (Adamsons, *et al.*, 1965; Avery, 1981; Day, 1941; Perlstein, *et al.*, 1976).

9) Incubator test load core temperature vs. 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 Moyt, 1967; Scopes and Ahmed, 1966; Sauer, Dane, *et al.*, 1984).

10) Control temperature vs. indicated temperature correlation—This information enables the user to determine whether the difference between the prescribed temperature (control temperature) and the indicated temperature are suitable for the intended application and within the performance requirements of this standard (4.2.2c)) (Adamsons, *et al.*, 1965; Avery, 1981; 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 is 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) CO_2 concentration—This information enables the user to determine whether the maximum CO_2 concentration in the infant compartment as a result of the infant's exhaled CO_2 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.

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 which 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. (Mendenhall, *et al.*, 1960)

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 assure an effective cleaning method which 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) Mass and dimensions—This information is required for clinicians to provide proper facilities to situate and use the incubator.

A.4.1.3 Service manual

This 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 in order 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.*, 1981; 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 the skin temperature measurements. Small changes in skin temperature have been shown to affect O_2 consumption (LeBlanc, 1983; Silverman, *et al.*, 1966). An accuracy of ± 0.3° 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 ± 1.0° 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 ± 0.7° 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 to 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 to 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.

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

where: TmPt 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•cm•° C), ρ is the density of the material (gm/cm^3), and c_p is the specific heat of the material (J/gm•° 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 TmPt is:

$$TmPt = 0.494\,(5)^{-.412}\left(\frac{0.239}{\sqrt{kr\,c_p}} + 31.5\right) + 41^{o}C$$

$$TmPt = 0.25\left(\frac{0.239}{\sqrt{kr\,c_p}} + 31.5\right) + 41^{o}C$$

$$TmPt = \frac{0.06}{\sqrt{kr\,c_p}} + 48.9^{o}C$$

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 2.1×10^{-3} J/s•cm•° C (Cohen, 1973), 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

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

$$X_{skin} = 1\ cm$$

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* 6.3×10^{-3} *J/s•cm*^{2}.

Example:

For Teflon, $k = 2.42 \times 10^{-3}$ *J/s•cm•° C,* $r = 2.15$ *gm/cm*^{3}, *Cp = 1.05 J/gm•° C*.

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

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

For acute exposure of 5 s, the allowable surface temperature TmPt shall be:

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

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 6.3×10^{-3} J/s•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.

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 Air temperature control

Deviation of the air temperature from the control setting may indicate that the incubator is not controlling the air temperature. If this situation were to continue, hypothermia or hyperthermia might result. Causes of deviation include open doors, blocked airflow, or external heat sources.

A.4.2.3.3 Infant temperature sensor

A failed sensor or one that is not properly connected to its receptacle could cause the infant to be exposed to high operative temperatures. A failed sensor alarm provides a rapid alert to prevent this occurrence. Deviation of the indicated temperature from the control temperature may indicate that the incubator is not appropriately controlling the baby's temperature. Were this situation allowed to continue, hypothermia or hyperthermia might result. Causes of deviation of the indicated temperature from the controlled temperature include dislodgment of the skin probe (Mayock, 1976), the placement of the skin probe on the infant after it has become dislodged and the infant has become overheated, malfunctioning of the incubator or probe, and warming of a cold baby or cooling of an overheated baby. In practice, this provides the only alarm for probe dislodgment. The most common fault condition in caring for babies in infant incubators is the detached skin probe. If the skin probe becomes detached and the user does not become aware of the detached probe in a timely fashion, the infant can be overheated. Although the alarm for deviation of the indicated temperature from the control point picks up most of the skin probe dislodgment, if the probe becomes dislodged gradually so that the temperature changes gradually, it will not be picked up by this particular alarm system. Similarly, if the probe falls to a region that has a temperature similar to that of the infant, its dislodgment will not be picked up. This has the potential to result in hyperthermia of the infant and frequently does in clinical practice. Thus, if a better means becomes available to detect skin probe dislodgment directly incorporating it into the device design of the infant incubator will result in a safer and more effective device. Although several such devices have been designed, none had been tested in a practical environment at the time this standard was written.

A.4.2.3.4 Infant temperature

The dislodging of infant temperature sensors can occur causing 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 O_2 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.4.2.3.5 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 build-up of CO_2 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.4.2.3.6 Power failure

To help assure that personnel will be alerted when the incubator is not being powered, due to dislodgment of the power cord plug or to a general power outage, incubators should incorporate an audible alarm to signal complete failure of input electrical power. Inadvertent power loss for any reason should not alter the operating mode or settings when power is restored.

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 warm-up of the device, since warm-up time commonly exceeds 15 min. There is no data to support a specific value for the time to allow alarm silencing during initial warm-up. The maximum allowable value, 30 min, was selected as a reasonable value for safety and for the warm-up time of currently available infant 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 a synergism between incubator noise and kanamycin, or a correlation 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 instead that the maximum alarm sound level should simply be disclosed by the manufacturer for the information of the clinician. Recent improvements in nursing care practices reduce noise levels and patient disturbances to a minimum. Allowance is provided to start alarms at a lower level to accommodate customer requests.

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 CO_2 concentration

An inspired CO_2 concentration of 4% or even less can produce major physiologic changes in newborn infants (AAP, 1983; Rahilly, 1980). The magnitude of these changes varies directly with the CO_2 concentration, and some changes are still detectable at a CO_2 concentration of 0.5%. Extrapolation from the available data suggests that there will be no significant effect at inspired CO_2 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 to 6 kg) and therefore a margin of safety is provided for the smaller, more susceptible infant where CO_2 production is lower.

A.4.2.6 Fire prevention

A.4.2.6.1 Electronics compartment oxygen concentration

The increase in flammability which could occur at oxygen concentrations of 4% or less above ambient was considered acceptable in terms of safety. At O_2 concentrations greater than 4% above ambient, a barrier is needed to minimize fire hazard. An energy level of 10 VA is sufficiently low that ignition will not occur in high O_2 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 that may affect temperature and oxygen control. An incubator that

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 2601-1).

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.

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.4.2.8 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 2.3 for devices with non-isolated 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 assure that primary power will be interrupted if used on isolated power source or if polarity is reversed.

A.4.2.8.4 Power cord and strain relief

The requirements of UL 2601-1 and IEC 60601-1 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 assure normal operation of the incubator 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 assure 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 Electromagnetic compatibility requirements

With the proliferation of digital and computer instruments working at close range in the hospital, for instance in the ICU, 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 infant incubator standard a stand-alone 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 that 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. 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 60601-1-2 on EMC in medical devices recognizes that measurement and control of EMC is particularly difficult for patient coupled devices, such as infant incubators, where the infant temperature sensor acts as an antenna which both emits and receives rf signals, with an antenna gain which 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 infant incubator design state-of-the-art and the almost infinite variety of EM environments that a portable device might encounter. The general documents quoted in reference (CISPR, IEC) have standardized on approximately four levels that 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) and it is important to indicate the performance of the instrument in a Level 3 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 which differ from the standardized environments covered in this standard, they 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 infant incubators standard is likely to be revised and improved in the future.

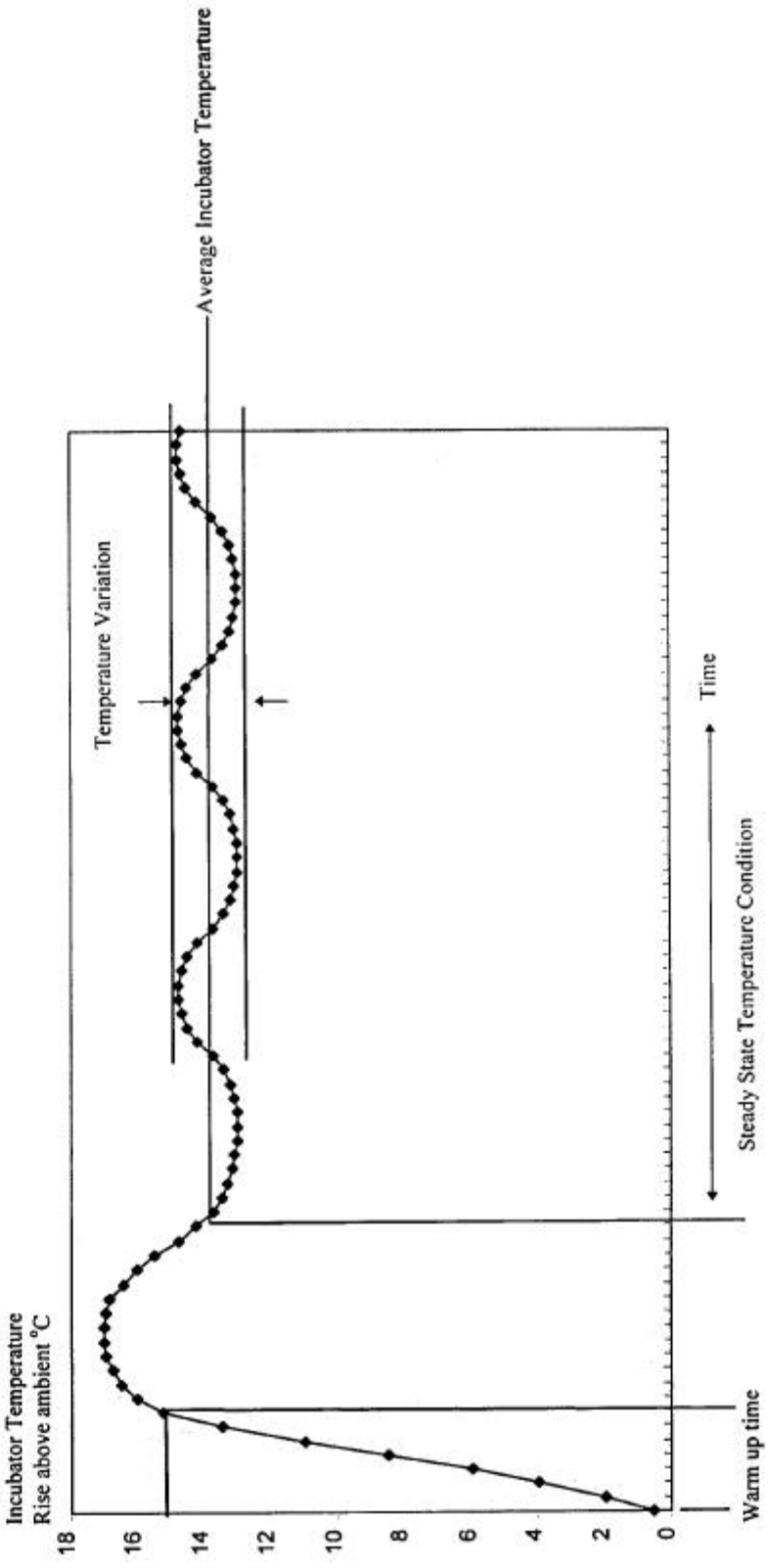


Figure 1 -- Average incubator temperature

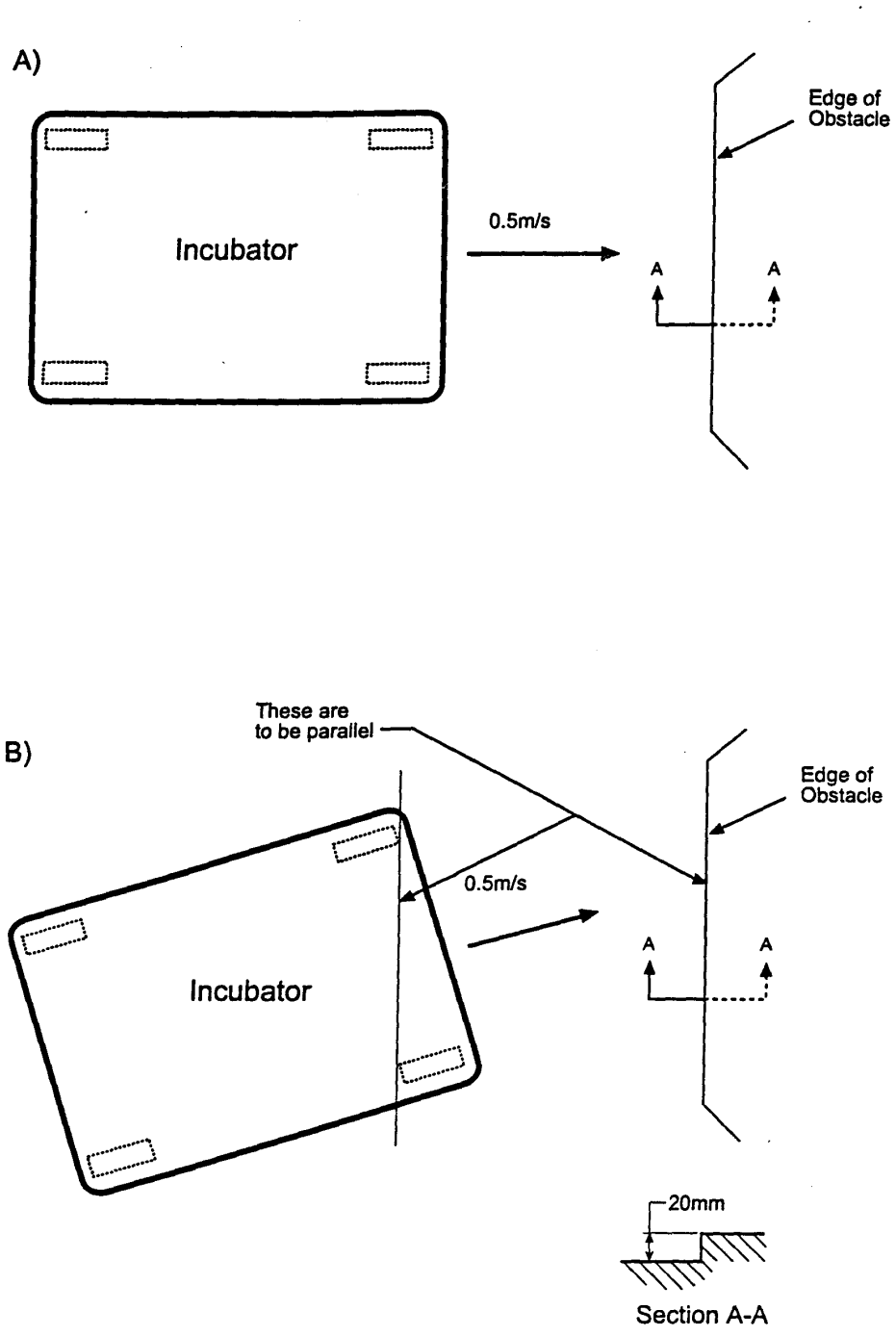
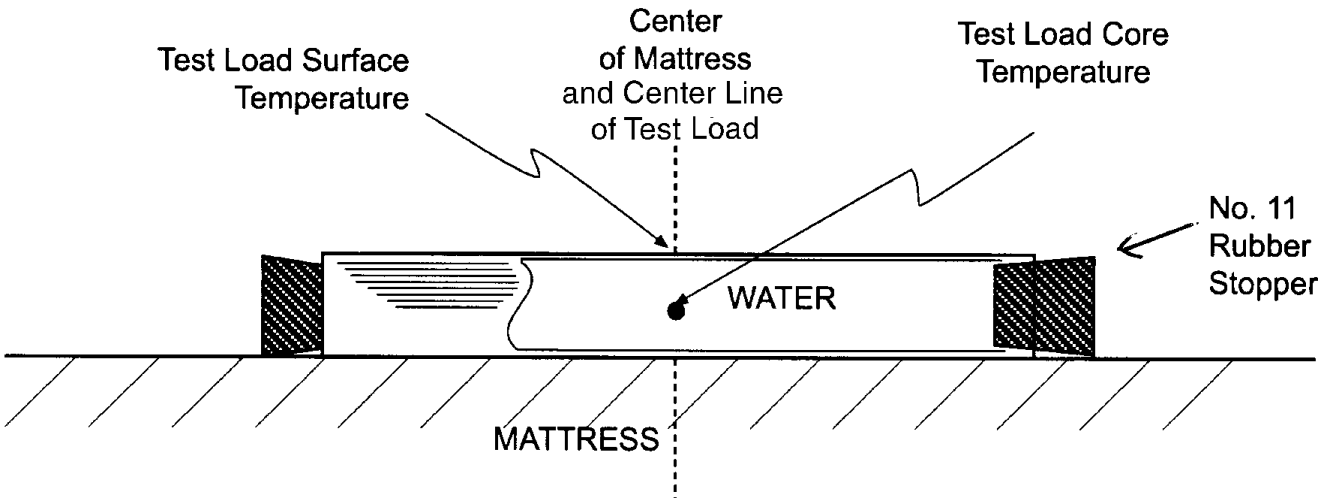


Figure 2 -- Threshold test



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 3—Incubator test load

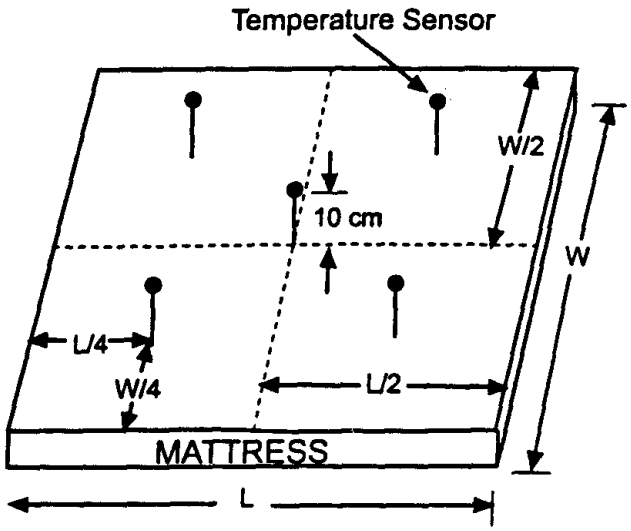


Figure 4 -- Temperature sensor locations

Annex B

(informative)

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