List of Titles

American National Standard

ANSI/AAMI/IEC 60601-2-21
& 60601-2-21 Amendment 1:2000

Medical electrical equipment—Part 2: Particular requirements for the safety of infant radiant warmers

AAMI Association for the Advancement of Medical Instrumentation

Medical electrical equipment—Part 2: Particular requirements for the safety of infant radiant warmers

Approved 13 March 2000 by
Association for the Advancement of Medical Instrumentation

Approved 18 July 2000 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum safety, labeling, and performance requirements for infant radiant warmers.

Keywords: control, mode, temperature, test, sensor, stability, strength

List of Titles

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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 this standard does not necessarily imply that all committee members voted for its approval.

At the time this document was balloted, the **Infant Incubator Committee** had the following members:

Cochairs:	Joseph P. Bagnell
	Michael H. LeBlanc, MD
Members:	Joseph P. Bagnell, Hill-Rom Airshields
	Michael Donnelly, University of Cincinnati Medical Center
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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.

Background of AAMI adoption of IEC 60601-2-21, First edition, 1994-02 and IEC 60601-2-21 Amendment 1, 1996-10

As indicated in the foreword to the main body of this document (page vii), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this standard.

International Standard IEC 60601-2-21 and its Amendment 1 were developed by Working Group (WG) 9, Paediatric equipment, of Subcommittee (SC) 62D, Electromedical equipment, to provide minimum safety requirements that will help assure a reasonable level of clinical efficacy and patient safety.

U.S. participation in IEC/SC 62D/WG 9 is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the United States National Committee. AAMI also administers the International Secretariat for IEC/SC 62D on behalf of the United States, and U.S. experts made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international standards as much as possible. The AAMI Infant Incubator Committee, which had initiated the development of an infant simulator as a thermal load to test the servo-control response of an infant radiant warmer as part of its work to develop a U.S. standard, decided to move the development of the simulator to IEC and, pending completion of that work, to adopt IEC 60601-2-21 and its Amendment 1 verbatim. The texts of IEC 60601-2-21 and its Amendment 1 have been integrated into one document in the U.S. version for ease of reference.

The concepts incorporated into this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE 1—This background does not contain provisions of the ANSI/AAMI/IEC standard, *Medical electrical equipment - Part 2: Particular requirements for the safety of infant radiant warmers* (ANSI/AAMI/IEC 60601-2-21 and 60601-2-21 Amendment 1:2000), but it does provide important information about the development and intended use of the document.

NOTE 2—Beginning with the text on page vii, this American National Standard is identical to IEC 60601-2-21, First edition, 1994-02 and IEC 60601-2-21 Amendment 1, 1996-10, as integrated into one document.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of infant radiant warmers

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 60601-2-21 and its amendment have been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard and its amendment is based on the following documents:

DIS/FDIS	Report on voting
62D(CO)71	62D(CO)74
62D/195/FDIS	62D/219/RVD

Full information on the voting for the approval of this Particular Standard can be found in the reports of voting indicated in the above table.

Appendix L is an integral part of this standard. Annexes AA and BB are for information only.

In this Particular Standard, the following print types are used:

— requirements, compliance with which can be tested, and definitions: in roman type;

— notes, explanations, advice, instructions, general statements, exceptions and references: in smaller type;

— *test specifications: in italic type;*

— TERMS USED THROUGHOUT THE PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 60601-1: SMALL CAPITALS.

Introduction

This Particular Standard concerns the safety of INFANT RADIANT WARMERS. It amends and supplements IEC 60601-1 (Second edition, 1988), *Medical electrical equipment—Part 1: General requirements for safety,* with its amendments 1 (1991) and 2 (1995).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a “general guidance and rationale” section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of infant radiant warmers

SECTION ONE—GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies as follows:

1.1 *Scope*

Addition:

This Particular Standard applies to INFANT RADIANT WARMERS as defined in 2.2.101.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of INFANT RADIANT WARMERS as defined in 2.2.101.

1.3 *Particular Standards*

Addition:

With this amendment to the Particular Standard for INFANT RADIANT WARMERS the following documents are to be taken into consideration:

IEC 60601-1:1988, *Medical electrical equipment—Part 1: General requirements for safety*, with its amendments 1 (1991) and 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s).”

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items are designated *aa), bb),* etc.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

1.5 *Collateral Standards*

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment—Part 1: General requirements for safety—1. Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment—Part 1: General requirements for safety—2: Collateral Standard: Electromagnetic compatibility—Requirements and tests*

IEC 60601-1-3:1994, *Medical electrical equipment—Part 1: General requirements for safety—3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-1-4:1996, *Medical electrical equipment—Part 1: General requirements for safety—4. Collateral Standard: Programmable electrical medical systems*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Replacement:

The definition of IEC 60601-1 (see amendment 2) applies.

Additional definitions:

2.1.101 *SKIN TEMPERATURE SENSOR*

A sensing device including the link with the EQUIPMENT intended to measure the infant's skin temperature.

2.1.102 *TEST DEVICE*

A totally mat blackened disc used as a reproducible receiver of radiant energy during testing of the INFANT RADIANT WARMER. (See figure 101.)

2.1.103* *TEST LOAD*

An array of five TEST DEVICES used in a specified configuration (see figure 102) for performance tests of the INFANT RADIANT WARMER.

2.2 *EQUIPMENT types (classification)*

Additional definition:

2.2.101 *INFANT RADIANT WARMER (hereinafter referred to as EQUIPMENT)*

An electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant PATIENT by direct radiation of energy in the infra-red region of the electromagnetic spectrum.

2.10 *Operation of EQUIPMENT*

Addition:

2.10.101 *STEADY TEMPERATURE CONDITION*

A condition which is reached when the temperature, measured at the center of the TEST DEVICE positioned on the mid point of the EQUIPMENT mattress, does not vary by more than 1 ºC over a period of 1 h.

2.10.102 *TEST DEVICE AVERAGE TEMPERATURE (T_1, T_2, T_3, T_4, or T_M)*

The average temperature reading taken during a STEADY TEMPERATURE CONDITION at regular intervals at the centre of a TEST DEVICE.

* Rationale, see annex AA.

2.10.103 *MID POINT AVERAGE TEMPERATURE (T_M)*

The TEST DEVICE AVERAGE TEMPERATURE of the TEST DEVICE positioned at the mid point of the EQUIPMENT mattress. (See figure 102.)

2.10.104 *CONTROL TEMPERATURE*

The temperature set at the temperature control.

2.10.105 *MANUAL MODE*

A mode of operation in which the heater output is either at a fixed level or a proportion of its maximum output set by the USER.

2.10.106 *BABY CONTROLLED MODE*

A mode of operation in which the power output varies automatically in response to the temperature of the baby, to achieve a temperature close to a value set by the USER.

3 General requirements

This clause of the General Standard applies except as follows:

3.6* *SINGLE FAULT CONDITIONS*

Additional items:

aa) failure of a SKIN TEMPERATURE SENSOR;

bb) disconnection of a SKIN TEMPERATURE SENSOR from the EQUIPMENT;

cc) failure of the heater control circuit.

Additional subclause:

3.101 For EQUIPMENT which combines alternative heat sources, for instance incubators with integrated radiant warmers, heated mattresses, etc., the safety requirements of the Particular Standards for these alternative heat sources, if any, shall be met. The safety requirements of this Particular Standard shall not be altered by such additional heat sources specified by the manufacturer, details of which are provided in the instruction for use.

Compliance is checked by the test of clauses 42 and 56.6 of the relevant standards.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.5* *Ambient temperature, humidity, atmospheric pressure*

*a)** *Amendment:*

In line 3 replace “an ambient temperature within the range 15 ºC to 35 ºC” by “an ambient temperature within the range 18 ºC to 30 ºC”.

4.6 *Other conditions*

Additional item:

aa) During the tests the CONTROL TEMPERATURE shall always exceed the ambient temperature by at least 3 ºC.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

* Rationale, see annex AA.

Additional item:

aa) The EQUIPMENT without integral bed areas shall be permanently and clearly marked with an indication of the permissible distances between the *EQUIPMENT* heating systems and any mattress.

6.3 *Marking of controls and instruments*

Additional item:

aa) Means shall be provided for the clear selection and indication of CONTROL TEMPERATURE on or adjacent to the controls. The means provided shall allow resolution at intervals not greater than 0.2 ºC.

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instruction for use*

Additional item:

aa) The instructions for use shall additionally contain:

1. A statement that independent monitoring of the temperature of the infant by the operator is essential and it is inadvisable to leave an infant unattended under the EQUIPMENT.

2. Recommendations on the permissible distances between the EQUIPMENT heating system and any mattress used with it, and a statement on the effects which any changes in this distance may have.

3. Instructions on the recommended positions and methods of use and attachment of the temperature sensors provided for use with the EQUIPMENT.

4. Details of the EQUIPMENT alarms and methods by which they should be tested routinely.

5. For TYPE B EQUIPMENT in which the infant might not be isolated from earth, a warning that particular care should be taken to ensure that additional equipment connected to the infant is electrically safe.

6. If applicable, a recommendation to the USER to inspect regularly latches and closing devices of barriers to prevent the infant falling out.

7. A statement of the maximum loads which can be applied to all supports and mounting brackets for ACCESSORIES and ancillary equipment.

8.* Information on the effects on the functioning of the EQUIPMENT of detachment of the SKIN TEMPERATURE SENSOR from the PATIENT skin.

9. If applicable, a statement that the tilting of the mattress from its horizontal position relative to the EQUIPMENT heater can affect the performance of the INFANT RADIANT WARMER. (Requirements of 50.102.)

10. A statement that accessories, e.g. for phototherapy or heated mattresses, can affect the performance of the INFANT RADIANT WARMER in respect of the requirements of 50.102.

11. A statement that the INFANT RADIANT WARMER is not suitable for use in the presence of flammable anesthetic gases or other flammable materials, such as some types of cleaning fluids.

12. For INFANT RADIANT WARMERS which are able to be used in the BABY CONTROLLED MODE, a statement describing the method by which the temperature of the baby is maintained.

13. A statement to explain why the USER should use the BABY CONTROLLED MODE.

14. A statement that rectal temperatures are not appropriate for controlling the heater output of the EQUIPMENT.

15. A statement that the EQUIPMENT cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia), and a recommendation to monitor the temperature of the PATIENT.

16. A statement that environmental conditions (e.g. air movement) can affect the thermal balance of the infant.

* Rationale, see annex AA.

17.* If the source of radiation has a limited lifetime, the manufacturer shall state, in the ACCOMPANYING DOCUMENTS, the time after which the source of radiation should be replaced because of aging.

18. A statement that an INFANT RADIANT WARMER should be used only by appropriately trained personnel and under the direction of qualified medical personnel who are familiar with currently known risks and benefits of radiant warmer use.

19. A statement that an INFANT RADIANT WARMER can increase the PATIENTS' insensible water loss.

20. Details of any specified combinations of EQUIPMENT (see 3.101).

SECTION TWO—ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Special environmental conditions

This clause of the General Standard applies except as follows:

10.2.1 *Environment*

a) *Replacement*

An ambient temperature range of +18 ºC to 30 ºC (see 4.5).

Addition:

aa) An ambient air velocity less than 0.3 m/s.

SECTION THREE—PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.2 *Requirements for EQUIPMENT with an APPLIED PART*

Item B-d

Addition:

The reference voltage shall be a minimum of 250 V.

Item B-e

Addition:

The test voltage shall be a minimum of 1500 V.

20.3 *Values of test voltages*

Addition:

The reference voltage for the insulation B-d shall be a minimum of 250 V.

The test voltage for the insulation B-e shall be a minimum of 1500 V.

* Rationale, see annex AA.

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

21 Mechanical strength

This clause of the General Standard applies except as follows:

21.3 *Amendment:*

The normal load for an infant PATIENT is reduced to 10 kg.

Additional subclauses:

21.101 Supports and mounting brackets for ACCESSORIES and ancillary equipment shall meet the manufacturer's recommended maximum loads.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the following test:

Apply a gradually increasing force so as to act vertically through the center of supports and mounting brackets. Increase the force from zero to three times the manufacturer's recommended maximum load in a 5 s to 10 s interval and sustain it for a period of 1 min. The supports and mounting brackets shall not be damaged.

21.102 For EQUIPMENT with an integral bed area suitable barriers shall be provided to prevent the PATIENT from falling off the mattress. Such barriers as are intended to be opened or removed to allow access to the PATIENT shall latch in their closed positions and shall remain locked under the test conditions.

Compliance with the requirements is checked by inspection and the following test:

Apply to all the barriers (other than those secured with the use of a TOOL) an outward horizontal force of 20 N to the center of each barrier for 5 s. The barriers shall remain closed.

24 Stability in NORMAL USE

This clause of the General Standard applies except as follows:

24.1 *Addition:*

The EQUIPMENT and the mounting brackets and shelves are provided with the most unfavorable combination of detachable parts and accessories and are loaded with the recommended maximum load.

24.3 This subclause of the General Standard does not apply.

Additional subclause:

24.101 If EQUIPMENT is mounted on wheels, the manufacturer shall provide a means to prevent its inadvertent movement.

Compliance is checked by inspection.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

33* Infra-red radiation

The maximum irradiance level at any point on the mattress shall not exceed 60 mW/cm^2 in the total infra-red spectrum.

The maximum irradiance level shall not exceed 10 mW/cm^2 in the near infra-red spectrum (760 nm to 1400 nm).

Compliance is checked by measurements.

* Rationale, see annex AA.

36 Electromagnetic compatibility

36.202 *IMMUNITY (see IEC 60601-1-2)*

36.202.2.1 *Requirements*

Item *a)* *Replace the text of this subclause by the following:*

For radiated radio-frequency electromagnetic fields the EQUIPMENT and/or SYSTEM shall

- continue to perform its intended function as specified by the manufacturer at a level up to 3 V/m for the frequency range of 26 MHz to 1 GHz;
- continue to perform its intended function as specified by the manufacturer or fail without creating a SAFETY HAZARD at a level less than or equal to 10 V/m for the frequency range of 26 MHz to 1 GHz.

SECTION SIX—PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

42 Excessive temperature

This clause of the General Standard applies except as follows:

42.1 *Amendment:*

Delete from column 1 in table Xa: "EQUIPMENT parts which may in NORMAL USE have a brief contact with a PATIENT". Delete from column 2: "50 ºC".

42.3* *Amendment:*

Replace the first paragraph by the following:

The temperature of surfaces accessible to an infant PATIENT on the mattress shall not exceed 40 ºC for metal surfaces and 42 ºC for other materials when the EQUIPMENT is operating under STEADY TEMPERATURE CONDITION at its maximum CONTROL TEMPERATURE.

Under conditions of warm-up to STEADY TEMPERATURE CONDITION or that of a SINGLE FAULT CONDITION these surfaces shall not exceed 42 ºC for metal or 45 ºC for other materials.

42.5 *Addition:*

If the heater element surface temperature exceeds 85 ºC in NORMAL USE, heater guards which cannot exceed 85 ºC in NORMAL USE shall be fitted.

Compliance is checked by measurement of the temperature and by performing the rigidity test as described in 21 a) of the General Standard. The heater guard shall not touch the heater element.

43 Fire prevention

Add the following new subclauses:

43.101 In order to eliminate the risk of oxygen fires caused by electrical components which can be a source of ignition in enclosed compartments of EQUIPMENT containing an oxygen system, at least one of the following requirements shall apply:

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* Rationale, see annex AA.

- electrical components shall be separated from compartments in which accumulations of oxygen can occur by a barrier complying with the requirements of 43.102;
- compartments containing electrical components shall be ventilated according to the requirements of 43.103;
- electrical components which, in NORMAL USE or SINGLE FAULT CONDITION, can be a source of ignition shall comply with the requirements of 43.103.

43.102 Any barrier required under the provisions of 43.101 shall be sealed at all joints and at any holes for cables or for other purposes.

Compliance is checked by inspection and if applicable by the compliance test described in 40.5 of the General Standard, for enclosures with restricted breathing.

The internal overpressure of 4 mbar specified in subclause 40.5 of the General Standard is not applicable when, in NORMAL CONDITION, a pressure difference exists between the spaces separated by the barrier. In such cases the compliance test of 43.103 of this Particular Standard applies.

43.103 The ventilation required under the provisions of 43.101 shall be such that the oxygen concentration in the compartment containing electrical components shall not exceed 4 vol. % above the ambient level. If this requirement is met by forced ventilation, means for an alarm in the event of malfunction shall be provided.

Compliance is checked by the following test:

The oxygen concentration shall be measured under the following conditions and for such a period that the highest possible concentration of oxygen occurs.

- *SINGLE FAULT CONDITION including possible leakage of oxygen.*
- *Selection of the most unfavorable control settings.*
- *MAINS VOLTAGE deviations of ± 10%.*

The measurements shall be repeated after 4 h during which time the SUPPLY MAINS shall have been switched off and the gas supply remained on.

The rate of air exchange in the test room shall be between 3 volumes and 10 volumes per hour.

43.104* Electrical circuits which can produce sparks or generate increased surface temperatures and which might otherwise be a source of ignition shall be so designed that no ignition occurs. At least both of the following requirements shall be satisfied in NORMAL CONDITION and SINGLE FAULT CONDITION:

- the product of the r.m.s. value of the no load voltage and the r.m.s. value of the short circuit current shall not exceed 10 VA.
- The surface temperature of components shall not exceed 300 ºC.

Compliance is checked by the following test:

Voltages and currents shall be measured or calculated and surface temperatures shall be measured in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

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

This clause of the General Standard applies except as follows:

44.3 *Spillage*

Replacement:

The EQUIPMENT shall be so constructed that in the event of spillage of water (accidental wetting) no safety hazard shall result from the ingress of water, the equipment shall meet the dielectric strength requirements specified in 20.1 to 20.4 of the General Standard and the EQUIPMENT shall function normally.

* Rationale, see annex AA.

Compliance is checked by the following tests:

Position the EQUIPMENT in the least favorable position of NORMAL USE. In the case of EQUIPMENT with BABY CONTROLLED MODE, the SKIN TEMPERATURE SENSOR shall be placed at the center of the upper surface of the mattress.

Pour 200 ml of isotonic water (0.9% saline) steadily on the center of the mattress over a period of 15 s.

After this test, the EQUIPMENT shall comply with the requirements of this Standard.

46 Human errors

This clause of the General Standard applies except as follows:

Additional subclauses:

46.101 Each temperature control, if it has a rotary action, shall be so arranged that a clockwise rotation produces an increase in temperature.

Compliance is checked by inspection.

46.102 It shall not be possible to connect a sensor intended for use with the EQUIPMENT to an inappropriate socket on the EQUIPMENT.

Compliance is checked by inspection.

46.103 In the case of an INFANT RADIANT WARMER which can be operated in various modes of operation the mode of operation shall be clearly displayed.

Compliance is checked by inspection.

46.104* In the case of INFANT RADIANT WARMERS which are operated in the MANUAL MODE an auditory and visual alarm shall be given at least every 15 min and the heater deactivated if the maximum irradiance at any point of the mattress area exceeds a net irradiance level of 10 mW/cm^2 at an ambient temperature of 25 ºC. The heater can be reactivated and the alarm can be reset in compliance with 102.2 (see section 101).

Compliance is checked by inspection and measurements.

49 Interruption of the power supply

Clause 49 of the General Standard applies except as follows:

49.2 *Addition:*

The EQUIPMENT shall be so designed that an interruption and restoration of the power supply does not change the CONTROL TEMPERATURE or other preset values.

Compliance is checked by switching the SUPPLY MAINS off and then switching on within 1 min, and inspecting the EQUIPMENT.

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

The clauses and subclauses of this section of the General Standard apply except as follows:

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

Additional subclauses:

50.101 The temperature measured by the SKIN TEMPERATURE SENSOR shall be continuously displayed and clearly visible. The temperature displayed shall have an accuracy of ± 0.3 ºC. If the display is used to present any other parameter, this shall only be obtained on demand, using a momentary action switch. The range of displayed temperature shall be at least 30 ºC to 40 ºC.

* Rationale, see annex AA.

Compliance is checked by inspection and the following test:

Immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 ºC ± 0.1 ºC. Position a calibrated thermometer, accurate to within ± 0.05 ºC, with its bulb adjacent to the SKIN TEMPERATURE SENSOR. The reading of the standard thermometer shall be compared with the displayed temperature and their difference shall not exceed 0.3 ºC less the calibrated thermometer error.

50.102* The difference between the MID POINT AVERAGE TEMPERATURE and the TEST DEVICE AVERAGE TEMPERATURE of any of the other devices comprising the TEST LOAD shall not exceed 2 ºC.

Compliance is checked by the following test:

Prepare five TEST DEVICES consisting of aluminum discs each with a mass of 500 g ± 10 g and a diameter of 100 mm ± 2 mm.

Drill 5 mm diameter holes 50 mm ± 2 mm deep as shown in figure 101 and coat the entire disc surface with non-reflective black paint.

NOTE—The disc thickness will be approximately 23 mm.

Subject EQUIPMENT to the following test in a room in which the maximum air velocity is 0.1 m/s and the ambient temperature is maintained at 23 ºC ± 2 ºC.

Place four individually identified TEST DEVICES, marked 1, 2, 3 and 4 on the horizontal mattress at the centers of each of four rectangles formed by bisecting the length and width of the mattress as shown in figure 102. Place a fifth TEST DEVICE marked "M" on the mid point of the mattress. Insert a temperature sensor in each of the five TEST DEVICE centers and, in the case of an EQUIPMENT with a BABY CONTROLLED MODE, attach the SKIN TEMPERATURE SENSOR to the center of the upper surface of the TEST DEVICE "M", assuring a good thermal conductive contact (e.g. thermal paste). In the case of an EQUIPMENT with a BABY CONTROLLED MODE, set the temperature control to a CONTROL TEMPERATURE of 36 ºC ± 0.1 ºC and operate the EQUIPMENT until a STEADY TEMPERATURE CONDITION is obtained. In the case of an EQUIPMENT with only a MANUAL MODE, set the heater output so that the TEST DEVICE will warm up to approximately 36 ºC under STEADY TEMPERATURE CONDITION. Take at least 20 readings of temperature of each TEST DEVICE at regular intervals over a 60 min period.

Calculate the five values of the TEST DEVICE AVERAGE TEMPERATURE for each TEST DEVICE as follows:

$$T_1 = (t_{11} + t_{12} + t_{13} + t_{14} + \ldots t_{1n}) / n$$

where

T_1 is the TEST DEVICE AVERAGE TEMPERATURE for TEST DEVICE No. 1

$t_{11} \ldots t_{1n}$ are the individual temperature readings taken of TEST DEVICE No. 1 at regular intervals during the STEADY TEMPERATURE CONDITION

n is the number of readings during the STEADY TEMPERATURE CONDITION

Calculate the remaining TEST DEVICE AVERAGE TEMPERATURES T_2, T_3, T_4 AND T_M in the same way.

Compare TEST DEVICE AVERAGE TEMPERATURES T_1, T_2, T_3, T_4 with T_M and verify the maximum difference does not exceed 2.0 ºC.

50.103* With the EQUIPMENT working in the BABY CONTROLLED MODE with horizontal mattress orientation, the temperature as measured by the SKIN TEMPERATURE SENSOR shall not differ from the CONTROL TEMPERATURE by more than 0.5 ºC.

Compliance is checked during the tests of 50.102.

50.104 If an oxygen monitor is supplied as an integral part of the INFANT RADIANT WARMER, this shall be in accordance with ISO 7767.

50.105* If an oxygen controller forms an integral part of the INFANT RADIANT WARMER, then there shall be independent sensors for monitoring and control of O_2.

* Rationale, see annex AA.

A visual and auditory alarm shall be given if the displayed oxygen concentration deviates from the set level by more than ± 5 vol. % O_2.

Compliance is checked by the following test:

Set the oxygen concentration to the level of 35 vol. %. When steady condition has been reached, decrease the concentration quickly to less than 29 vol. %. Verify that the alarm activates at a displayed oxygen concentration no less than 30 vol. %.

Restore to the level of 35 vol. % O_2. When steady condition has been reached, increase the concentration quickly to more than 41 vol. %. Verify that the alarm activates at a displayed oxygen concentration no more than 40 vol. %.

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

54 General

This clause of the General Standard applies except as follows:

Additional subclause:

54.101 The range of the CONTROL TEMPERATURE in the BABY CONTROLLED MODE of an INFANT RADIANT WARMER shall be from 36 ºC or less to not more than 38 ºC.

Compliance is checked by inspection.

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.6 *Temperature and overload control devices*

a) Application

Amendment:

Delete dashes 3 and 4.

Addition (preceding paragraph 1):

aa) After STEADY TEMPERATURE CONDITIONS have been achieved, any sensed temperature deviation exceeding ± 1 ºC compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate, and the EQUIPMENT heater shall switch off when the sensed temperature exceeds the CONTROL TEMPERATURE by 1 ºC.

Compliance is checked by inspection and both of the following tests:

Test 1

Set the CONTROL TEMPERATURE to 36 ºC and immerse the SKIN TEMPERATURE SENSOR in a water bath maintained at 36 ºC ± 0.1 ºC. Position a calibrated thermometer accurate to within ± 0.05 ºC with its bulb adjacent to the SKIN TEMPERATURE SENSOR. After a steady temperature indication is achieved and maintained for at least 10 min, increase the water bath temperature control setting to 38 ºC. Report whether the auditory and visual alarms operate at a water bath temperature not exceeding 37 ºC ± 0.3 ºC and whether the EQUIPMENT heater switches off.

Test 2

As for test 1, but in this instance the temperature control setting of the water bath is reduced from 36 ºC ± 0.1 ºC to 34 ºC ± 0.1 ºC. Report whether the auditory and visual alarms operate above 35 ºC ± 0.3 ºC and the EQUIPMENT heater remains in operation.

bb) *The EQUIPMENT shall not* permit the skin temperature of the PATIENT to exceed 40 ºC under NORMAL CONDITION and each SINGLE FAULT CONDITION.

Compliance is checked by the following test:

Place a TEST DEVICE at the center of the mattress, with the EQUIPMENT operating under STEADY TEMPERATURE CONDITIONS at the maximum CONTROL TEMPERATURE, and under any SINGLE FAULT CONDITION.

The test device shall not exceed 40 ºC without the auditory and visual alarms operating and the heater being disconnected.

56.10 *Actuating parts of controls*

Item *b)* *Fixing, prevention of maladjustment*

Addition:

If the relative movement of any control knob and its actuating mechanism can affect the indication of the CONTROL TEMPERATURE, they shall be secured together so as to prevent the possibility of misalignment.

Item *c)* *Limitation of movement*

Addition (after paragraph 1):

If rotating knobs are provided for the change of CONTROL TEMPERATURE, the stops provided shall withstand the torques specified in Table XIII of the General Standard.

Additional section:

SECTION 101—ADDITIONAL REQUIREMENTS

101 Alarms

101.1 *Failure of the supply mains*

Auditory alarm and visual indication shall be provided to give warning for a minimum of 10 min in the event of failure of the SUPPLY MAINS to the EQUIPMENT or until the main supply is restored.

Compliance is checked by disconnecting from the SUPPLY MAINS while the EQUIPMENT is switched on.

Report whether the alarm operates for a minimum of 10 min.

101.2 *Open and short circuit of the SKIN TEMPERATURE SENSOR in a BABY CONTROLLED MODE*

The EQUIPMENT shall be provided with an auditory and visual alarm which operates in the event of the SKIN TEMPERATURE SENSOR having open circuit or short circuit leads in the BABY CONTROLLED MODE.

Both open and short circuit leads shall disconnect the supply to the heater.

Compliance is checked by simulating both fault conditions and observing the effect.

102 Sound pressure level

102.1* Auditory alarms shall produce an A-weighted sound pressure level of at least 65 dB at a distance of 3 m from the front of the EQUIPMENT. Other than the muting specified in 102.3, the auditory alarm may be adjusted by the OPERATOR to a minimum lower level of 50 dB measured with the range setting of an A-weighted scale.

The A-weighted sound pressure level of the alarm shall not exceed 80 dB on the mattress.

Compliance of the minimum level is checked by measurement of the auditory alarm sound pressure level in accordance with ISO 3743 (reflecting room) using a sound level meter complying with the requirements for type III specified in IEC 60651 placed 1.5 m above the floor and 3 m from the front of the EQUIPMENT.

* Rationale, see annex AA.

Compliance of the maximum level is checked with each alarm sound means activated, the sound level being measured at a point 5 cm above the center of the mattress.

Ensure that the background A-weighted sound pressure level is at least 10 dB below the measured levels.

102.2* If EQUIPMENT incorporate a manual control the auditory and visual alarms (see 46.104) shall operate within 15 min of commencement of use in this mode. The auditory alarm shall be mutable. Following any muting the auditory alarm shall operate again within 15 min. This sequence shall continue until the manual control mode is changed.

Compliance is checked by inspection, operating the EQUIPMENT and timing the alarm.

102.3 *Silencing*

With the exception of the alarm specified in 101.1, it is allowable for the auditory alarm to be silenced or switched to a lower sound pressure level by the OPERATOR, but it shall revert automatically to a full value after not more than 15 min. The visual indication shall continue after the alarm has been silenced until the alarm conditions have been corrected.

Compliance is checked by inspection, operating the EQUIPMENT and timing the alarm.

102.4 *Alarm function test*

Means shall be provided to allow the OPERATOR to verify the operation of auditory and visual alarms. Such means may consist of information given in the instruction for use.

Compliance is checked by operation.

102.5* If the frequency of the auditory alarms is adjustable by the OPERATOR, the subclause 102.1 shall apply to all the individual selectable frequencies.

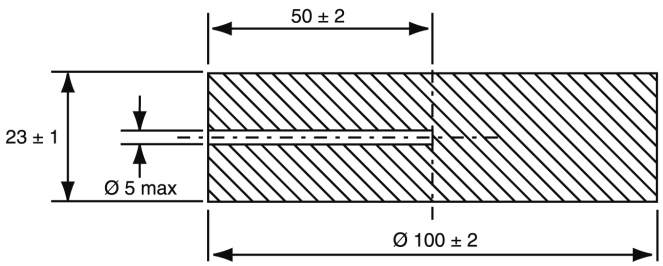
103 Concentration of carbon dioxide (CO_2)

If the mattress of an INFANT RADIANT WARMER is fitted with a compartment which encloses the baby, the manufacturer shall specify in the ACCOMPANYING DOCUMENTS the maximum CO_2 concentration which will occur in the compartment during the following test under NORMAL CONDITIONS.

Compliance is checked by the following test:

A 4% mixture of CO_2 in air shall be administered at a rate of 750 ml/min at a point 10 cm above the center of the mattress (see figure 102, middle point) through an 8 mm diameter tube in vertical direction from the mattress to the top. CO_2 concentration at a point 15 cm from the middle point shall be measured after 1 h.

* Rationale, see annex AA.

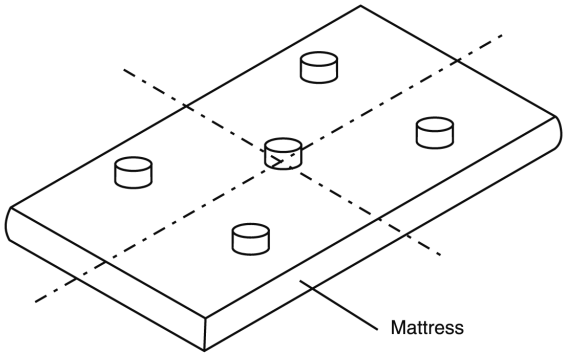


CEI-IEC 142/94

Surface finish: non-reflective black paint
Disc mass: 500 g ± 10 g
Disc material: aluminum of density within the range 2.6 g/cm^3 and 2.9 g/cm^3

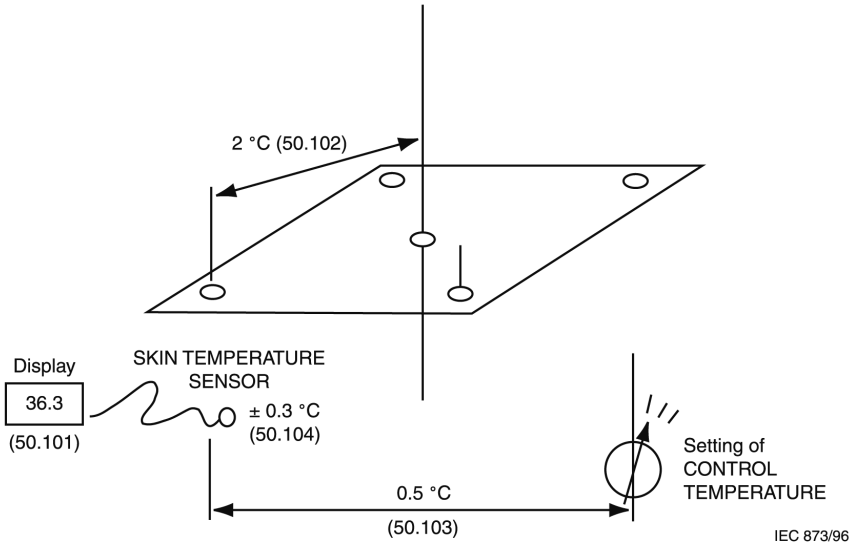
All dimensions are in millimeters

Figure 101—Test device



CEI-IEC 143/94

Figure 102—Layout of test devices



Temperature alarm ± 1 °C	(56.6) *aa)*
Overtemperature alarm 40 °C	(56.6) *bb)*
Main failure alarm	(101.1)
Maximum surface temperature 42 °C	(42.3)
Manual mode 10 mW/cm^2 and 15 min alarm	(46.104) (102.2)

NOTE—Numbers in brackets indicate the relevant subclause

Figure 103—Illustration of the main requirements of this standard

Appendix/Annexes

The appendices of the General Standard apply except as follows:

Appendix L

References—Publications mentioned in this standard

Add the following to the list of IEC Standards:

IEC 60651:1979, *Sound level meters.*

Add the following to the list of ISO Standards:

ISO 3743:1988, *Acoustics—Determination of sound power levels of noise sources—Engineering methods for special reverberation test rooms.*

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures—Safety requirements.*

Add the following new annexes:

Annex AA
(informative)

General guidance and rationale

The numbering of the following reasons corresponds to the numbering of this Standard.

2.1.103 The aluminum 500 g TEST DEVICES were developed in 1984 on the basis that they were simple to reproduce to specific dimensions, and they respond to temperature changes due to variations in warmer output. Different manufacturers of infant warmers have considered them to be a suitable reference for tests of their products. Other test devices of this nature tended to be more complicated to reproduce and more expensive.

This TEST LOAD configuration is not intended to represent a specific infant size, but only to test the operation of a radiant warmer.

This TEST LOAD configuration is intended to demonstrate the radiant warmer temperature control mechanism, and indicates the uniformity of heating across the mattress.

A mat black finish of the TEST LOADS should provide a high emissivity value for consistent test data reproduction.

3.6 The additional specified SINGLE FAULT CONDITIONS apply specially to this PARTICULAR STANDARD.

4.5 INFANT RADIANT WARMERS are intended for use in nurseries as well as in labor and delivery rooms; the latter could be cooler than nurseries.

6.8.2 *aa)* 8) It is desirable that the EQUIPMENT should be provided with an auditory alarm and visual indication which operates when the SKIN TEMPERATURE SENSOR is detached from the infant's skin. Technically this has not been reliably achieved and has therefore not been made a requirement of this Standard.

6.8.2 *aa)* 13) An INFANT RADIANT WARMER in the MANUAL MODE of operation emits a preset amount of energy to the child continuously, regardless of the temperature of the infant. If the heater is set at the maximum in order to warm up the infant rapidly, the skin of the infant can become dangerously hot. It is therefore essential to attend to EQUIPMENT operation and infant condition at frequent intervals. It is recommended that the PATIENT under the INFANT RADIANT WARMER be supervised.

6.8.2 *aa)* 15) The EQUIPMENT cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia). Therefore in all situations it is recommended that the temperature of the PATIENT be monitored separately.

6.8.2 *aa)* 17) There have been reports of hot fragments (e.g., metal oxide particles) from aged warmer heaters falling onto the mattress.

33 INFANT RADIANT WARMERS provide thermal support by directing invisible infra-red light to the infant's body. The source of this infra-red light is an overhead heater whose electrical power input is limited by design, thereby limiting the amount of infra-red energy output that can be directed at the infant.

The limits proposed in this standard are based upon a review of literature regarding the effect of infra-red radiation upon the eyes and skin of humans [1 to 14].

Infra-red measurements can be made in both the 760 nm to 1400 nm wavelength (IR-A region) as well as the 1400 nm to 4500 nm segment of the wavelength IR-B and IR-C regions.

The IR-A region is associated with potential for damage to the crystalline lens of the eye which may lead to a cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea (the outermost layer of the eyes) with a resulting potential for burn.

From a review of the literature the following statements can be made:

a) There have been no reports from any sources describing any harmful effects of infra-red radiant energy on either the eyes or skin in infants nursed under INFANT RADIANT WARMERS. Retrospective examinations specifically looking for any eye effects have produced no evidence of harmful effects for either short-term or long-term evaluations. The long-term evaluations were performed from 30 days to 6 years after the infants were nursed under radiant warmers.

b) Spectral irradiance measurements on several commercially available radiant warmers show the absolute peak irradiance that the infant could be exposed to is less than 60 mW/cm^2 across the entire electromagnetic spectrum, with less than 10 mW/cm^2 in the IR-A wavelength region. The irradiance the infant would normally be exposed to at maintenance heat levels is much less than these levels. Clinical reports have documented that the mean radiant flux density needed to maintain a stable skin temperature could be anywhere from 12 mW/cm^2 to approximately 25 mW/cm^2 for very small infants. Higher levels would be needed routinely during warming of cold infants and/or warming newly born infants with skin still wet with amniotic fluid. Generally, the smaller premature infants require more radiant flux density to maintain their skin temperature because they have a relatively larger surface-area-to-mass ratio that permits larger heat losses per unit weight.

c) Wheldon and Rutter [24] accurately report absolute irradiance levels, observing a maintenance irradiance level of (58 ± 3) mW/cm^2 for infants averaging 1.6 kg.

Similar levels of irradiance have been used in neonatal intensive care units for at least the last 15 years to provide thermal support to premature infants.

No reports have identified a corneal opacity or skin inflammation caused by the nursing of the infant under a radiant warmer.

d) The recommendation of AAMI is 60 mW/cm^2.

Both cataracts and retinal lesions have been documented as being caused by IR-A wavelengths. Absorption of the infra-red energy by the iris, which indirectly heats the lens (and forms opacities), has been identified as the most likely cause of infra-red induced cataracts. INFANT RADIANT WARMERS possess very little IR-A energy when compared to sources that have caused cataract formation.

Retinal lesions have been reported to be caused primarily by shorter visible light wavelengths and the actual IR-A component may be a negligible contributor to any retinal damage that could occur.

The proposed radiant warmer threshold values put forth by the Emergency Care Research Institute in 1973 have been observed and maintained by manufacturers of radiant warmers on the market today. These limits of less than 300 mW/cm^2 for the IR-B and IR-C regions and less than 40 mW/cm^2 for the IR-A region are based on data that have since been updated and re-evaluated and confirm their appropriateness.

Photobiologists have not yet determined absolute minimum safe levels of incoherent infra-red light in the IR-A, B and C regions. It has been proposed that for IR-A wavelengths, a safe, chronic exposure level probably is in the order of 10 mW/cm^2 with allowances for incidental exposures for several minutes up to 100 mW/cm^2. In a 1980 publication from one of these same authors [15, 16, 17], it was concluded that 100 mW/cm^2 for IR-B and IR-C regions is the safe threshold limit for chronic exposure of the cornea. Since the time these limits were proposed, these authors have documented that more recent investigations indicate that infra-red radiation may not be as hazardous as was once thought.

Since no harmful effects from the irradiance levels now present in radiant warmers have been reported, these levels can serve as a maximum threshold limit until further data are made available.

Although further study of threshold levels could be useful to further define limits, the actual benefits derived from the use of radiant warmers far outweigh the potential, unreported, and theoretical risks associated with radiant infra-red energy from INFANT RADIANT WARMERS. No reports of any harmful infra-red energy induced effects have been documented in the medical literature after nearly 15 years of clinical use.

e) The spectral characteristics for human eye and skin media have been documented in the literature. No studies of the neonatal eye spectral characteristics have been reported. Only the spectral characteristics of neonatal skin with respect to visible light have been reported.

Although the neonatal eye is not completely developed at birth, the spectral characteristics are believed to be similar to those of an adult. Examinations of neonatal eyes after being nursed in radiant warmers have not shown any harmful effects from the level of IR-A delivered by the radiant warmers.

Neonatal excised skin specimens have been shown to have similar spectral absorption characteristics to adult skin in the visible light regions. However, for the IR-A regions the skin absorption can vary with the skin thickness.

Since the skin's reflectance is greatest in the IR-A regions, much of the incident light will be reflected away, and only a small portion of the total incident light would actually penetrate the skin.

Most infra-red energy is in the IR-B and IR-C regions and is absorbed by the top 1 mm to 2 mm of skin. No harmful effect from absorption of the radiant energy from a radiant warmer has been reported. Since infra-red energy is not energetic enough to enter into photochemical reactions with skin components, the only effect of the absorption of the energy is heating, which is the primary reason the infant is under a radiant warmer.

f) The associated hazards from exposure to infra-red energy for humans and animals, using both coherent and incoherent light have been documented in the literature [18 to 22]. The hazards, reported in the literature, from exposure of humans to incoherent infra-red light are cutaneous skin burns, corneal opacities and inflammation, lenticular opacities (cataracts), retinal lesions, and skin inflammation. Recent reports have shown that the cutaneous skin burns, corneal opacities and inflammation, and skin inflammation are due entirely to the IR-B and IR-C portions of the infra-red spectrum; because the outermost layer of the skin and eye absorb all of the incident radiation in the wavelength regions, they do not transmit any significant portion of incident energy below this outermost layer. Skin pain thresholds have been documented at approximately 45 ºC.

Several commercially available radiant warmers have skin temperature limits to prevent the skin temperature from exceeding 40 ºC. Corneal opacities have been reported in neonates, but usually are associated with other pathological conditions (in association with congenital glaucoma, or as a result of an infection from either congenital rubella or herpes virus).

42.3 The requirements of this clause can be based upon the BSI publication [23], and the drafting committee having noted the potential risk of babies under warmers coming into contact with hot metallic or other surface; hence the stated limits.

43.104 The hazards of ignition caused by electrical sparks increase

- in purely resistive circuits by electrical power of the spark;
- in inductive and capacitive circuits with the stored energy which is transferred to the spark.

Because of the great variety of ignitable materials and designs of EQUIPMENT, it is not possible to specify uniquely the maximum power and/or energy of electrical circuits which will not cause fires in oxygen.

For guidance see: National Fire Protection Association (NFPA); USA, Publication 53M, "Fire hazards in oxygen enriched atmospheres."

The requirement that the product of open-circuit voltage and short-circuit current should not exceed the value 10 VA does not have complete experimental basis, but is specified in the German Standard VDE 0750, Teil 1, 1977 (see item 34 of this Standard). In EQUIPMENT made to this German Standard, this requirement has proved to minimize the risk of oxygen fires without being too onerous for manufacturers.

The maximum surface temperature of 300 ºC corresponds to the maximum surface temperatures specified in NFPA Publication 53M, table 5-2.

46.104 It is necessary to have in the MANUAL MODE a mode of operation without alarm function on a low heater output level to keep the EQUIPMENT previously warmed (as a stand-by function) or to provide only a small proportion of heat to the baby (usually bigger babies). The experts of this working group and the pediatric doctors from the German National Committee are of the opinion that at a level of 10 mW/cm^2 there is no risk to babies under radiant warmers. Long experience with the use of radiant warmers with low output levels confirms this statement. There are no known safety hazards.

50.102 Long experience of both the medical and technical requirements for INFANT RADIANT WARMERS has shown that this level of performance (2 ºC) is satisfactory in maintaining the temperature of the baby, and readily achievable technically.

50.103 The USER of the EQUIPMENT must be confident that the temperature that is set will be the actual temperature achieved within ± 0.5 ºC.

50.105 Relatively low oxygen concentrations for the PATIENT may cause a brain damage. Relatively high oxygen concentrations for the PATIENT may cause a retrolental fibroplasia. In SINGLE FAULT CONDITION the use of one sensor may cause a SAFETY HAZARD for the baby, therefore for this operation the sensors are required to operate independently.

102.1 65 dB(A) is a rather high noise level in an intensive care nursery. Recent improvements in nursing care practices reduce noise levels and PATIENT disturbances to a minimum. Therefore the OPERATOR should have the option to reduce this sound level.

102.2 An INFANT RADIANT WARMER operating in the MANUAL MODE continuously emits a preset amount of energy to the infant regardless of his/her temperature. If this energy is at a maximum in order to rapidly warm up the infant, the infant's skin can become dangerously hot. A considerable source of risk is that there is not necessarily an automatic monitoring of the infant's temperature. It is therefore essential to have a periodic alarm operation and the condition of the infant under the warmer assessed at frequent intervals.

102.5 OPERATORS have requested the option for adjusting frequency of auditory alarms for better identification of the particular radiant warmer which is sounding the alarm.

Annex BB
(informative)

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