American National Standard

ANSI/AAMI II36:2004

Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

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A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

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Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI II36:2004
(Revision of ANSI/AAMI II36:1997)

Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 9 December 2004 by
American National Standards Institute, Inc.

Abstract: This standard establishes safety requirements for baby incubators with the view to minimizing hazards to the patient and user. It also specifies tests by which compliance requirements can be verified. It does not apply to transport incubators or infant radiant warmers, which are covered in other publications.

Keywords: air, alarm, compartment, equilibrium, sensor, temperature

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

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Printed in the United States of America

ISBN 1–57020–232–X

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:200x[1]	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical

[1] Currently at FDIS stage

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International designation	U.S. designation	Equivalency
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

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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 document was published, the **AAMI Infant Incubator Committee** had the following members:

Cochairs:
Joseph P. Bagnell
Nancy A. Pressly

Members:
Joseph P. Bagnell, Draeger Medical Infant Care
Joseph F. Dyro, PhD
Gary H. Harding, Greener Pastures
Robert J. Kopotic, ConMed Corporation
Michael H. Mackin, Ohmeda Medical
Julie R. Parnell, PhD, Olympic Medical Corporation
Nancy A. Pressly, U.S. Food and Drug Administration
Alexander S. Sinclair, PhD, Health Canada Medical Devices Bureau
Robert H. Stiefel, University of Maryland Medical Systems

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.

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Background of ANSI/AAMI combined adoption of IEC 60601-2-19:1990 and IEC 60601-2-19/A1:1996

This standard was developed by the AAMI Infant Incubator Committee. This standard establishes safety requirements for baby incubators with the view to minimizing hazards to the patient and user. It also specifies tests by which compliance requirements can be verified. It does not apply to transport incubators nor infant radiant warmers, which are covered in other publications.

During the course of putting this document together, the AAMI Infant Incubator Committee first decided on an identical adoption of IEC 60601-2-19, Medical electrical equipment—Part 2-19: Particular requirements for safety of baby incubators, which is based in large part on the AAMI II36, Infant incubators. During the first committee ballot of this document, however, a couple of issues were raised which are covered in the AAMI II36 standard but not in the IEC 60601-2-19 standard. Although the IEC document addressed most of the issues that the committee members felt were important, there were a couple of areas covered in the II36 standard that had been omitted by the IEC. Hence, this AAMI standard includes all of the requirements from IEC 60601-2-19:1990 and 60601-2-19/A1:1996 (amendment) as well as deviations that are applicable only to the AAMI standard.

The U.S. deviations are explained in an informative section, "AAMI deviations from IEC 60601-2-19:1990 and IEC 60601-2-19/A1:1996," which begins on the following page.

IEC 60601-2-19:1990 as well as the Amendment, 60601-2-19/A1:1996, were developed by IEC Subcommittee (SC) 62D, Electromedical Equipment, which is administered by AAMI on behalf of International Electrotechnical Commission (IEC), a worldwide organization for standardization. As previously noted, AAMI standards served as the basis of the international standard. In addition, the AAMI Infant Incubator Committee, working as the U.S. Technical Advisory Sub-Group for IEC SC 62D/MT 21, was responsible for developing the U.S. consensus on the international standard and otherwise participated in the drafting of that document.

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.

The concepts incorporated in 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 comes to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

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

NOTE—This background does not contain provisions of the American National Standard *Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators* (ANSI/AAMI II36:2004), but it does provide important information about the development and intended use of the document.

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AAMI deviations from IEC 60601-2-19:1990 and IEC 60601-2-19/A1:1996

Sub-clause 50.101

The following item has been added to this clause:

> The manufacturer shall disclose the temperature variation from AVERAGE INCUBATOR TEMPERATURE to INCUBATOR TEMPERATURE during STEADY TEMPERATURE CONDITION in the ACCOMPANYING DOCUMENTS.

Clause 105* Concentration of carbon dioxide (CO_2)

Sub-clause 105.1

The requirement (first paragraph in this section) has been changed from:

> The manufacturer shall specify in the ACCOMPANIYNG DOCUMENTS the maximum CO_2 concentration which will occur in the BABY COMPARTMENT during the following test under NORMAL CONDITIONS.

to:

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

Appendix L

The following references have been added to this list:

> AMERICAN ACADEMY OF PEDIATRICS. *Safety and performance of infant incubators.* A report to the Food and Drug Administration, Bureau of Medical Devices, by the Infant Incubator Advisory Task Force of the American Academy of Pediatrics. AAP, 1983.
>
> RAHILLY, PM. Effects of 2 % carbon dioxide, 0.5 % carbon dioxide, and 100 % oxygen on cranial blood flow of the human neonate. *Pediatrics*, 1980, vol. 66, pp. 685–689.

Annex AA, Clause 105.1

The following paragraph has been added to this clause as a second paragraph:

> An inspired CO_2 concentration of 4 % or less can produce major physiologic changes in newborn infants (American Academy of Pediatrics, 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 American Academy of Pediatrics Task Force subsequent to its meeting resulted in an agreement that 0.5 % would be acceptable because of limitations on the accuracy of measurement and the fact that the test method represented a large infant (5–6 kg), and therefore a margin of safety is provided for the smaller, more susceptible infant where CO_2 production is lower.

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MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of baby incubators

FOREWORD

1) 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.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

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PREFACE

This Particular Standard has been prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this Standard is based upon the following documents:

Six Months' Rule	Report on Voting
62D(CO)38	62D(CO)43

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

The text of this amendment is based on the following documents:

FDIS	Report on Voting
62D/193/FDIS	62D/216/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The following IEC publications are quoted in this Standard:

Publications Nos. 601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.

601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.

601-2-20 (1990): Medical electrical equipment. Part 2: Particular requirements for safety of transport incubators.

651 (1979): Sound level meters.

Other publications:

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.

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