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# American National Standard

Advancing Safety in Health Technology

## ANSI/AAMI/ REVIEWIEC 60601-

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# A1:2016

Medical Electrical Equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators



### Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

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 in Hea 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 AA for establishing the criteria must be documented in the rationale.

and/or processing of a medical device or system A recommended makin Again the crationale accompanying each AAMI standard and practice does not address device performance per se, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare 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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

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.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important reference in responsible decision-making, but it should never replace responsible decision-making.

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 A recommended provides provides guidelines for the ast take, purch a pedific the ast and resources of the individual institution or firm. recommended practice is an excellent guide to the reasoning and data underlying its provision. AAMI at In summary, a standard or recommended practice is truly

Although a device standard is primarily threefed as the Or VISI is the Although a device in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

#### INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the AAMI News. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an official interpretation in the AAMI News.

American National Standard

ANSI/AAMI/IEC 60601-2-19:2009/(R)2014 (Revision of ANSI/AAMI II36:2004)

Corrected 9 April 2012: Includes change to subclauses 201.4.3.101, 201.9.6.2.1.101, and 201.12.1.107



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Approved 17 March 2009 by **AAMI** 

Approved 3 April 2009 and reaffirmed 16 December 2014 by **American National Standards Institute, Inc.** 

**Abstract:** This standard applies to the basic safety and essential performance of baby incubators. This standard can also be applied to baby incubators used for compensation or alleviation of disease, injury or disability. This standard does not apply to heating devices intended for physiotherapy, radiant warmers, and transport incubators.

Keywords: infant incubators, electromedical equipment, medical electrical equipment

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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 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003 Ac	VANSI/AÂMI/IECITIR62296:2009 0gy	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	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 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
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ISO 10993-1.2003 nded to allow	ANST/AAM/ISO/109935220030 evaluate t	haeaatent
ISO 10993-2:2006 of the docum	AN\$1/AAM14SO11:099362:2006.irchasing de	dentical
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1:2006 +1-877	Amendment 1:2006/(R)2009/W aami org	
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment	ANSI/AAMI BE78:2002/(R)2008	Minor technical variations
1:2006	ANSI/AAMI BE78:2002/A1:2006/(R)2008	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
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ISO 11137-2:2006 (2006-08-01      ANSI/AAMI/ISO 11137-2:2006      Identical        ISO 11137-3:2006      ANSI/AAMI/ISO 11138-1:2006      Identical        ISO 11137-3:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11138-1:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11138-2:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11138-5:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11138-5:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11138-5:2006      ANSI/AAMI/ISO 11138-2:2006      Identical        ISO 11140-1:2005      ANSI/AAMI/ISO 11138-5:2007      Identical        ISO 11140-2:2007      ANSI/AAMI/ISO 11140-3:2007      Identical        ISO 11140-2:2007      ANSI/AAMI/ISO 1140-2:2007      Identical        ISO 11140-2:2006      ANSI/AAMI/ISO 11607-1:2006      Identical        ISO 11137-2:2006      ANSI/AAMI/ISO 11607-2:2006      Identical        ISO 11407-2:2006      ANSI/AAMI/ISO 11737-2:1998      Identical        ISO 13408-2:2003      ANSI/AAMI/ISO 11408-3:2006      Identical        ISO 13408-2:2003      ANSI/AAMI/ISO 13408-3:2006      Identical        ISO 13408-2:2003	ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	
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#### **Committee representation**

#### Association for the Advancement of Medical Instrumentation

#### Infant Incubator Committee

This standard was adopted by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this document 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 Systems Inc.
	Joseph F. Dyro, CCE, PhD
	Monica Ferrante, NeoForce Group Inc.
	Gary H. Harding, Greener Pastures
	Michael H. Mackin, G.E. Healthcare
	Nancy A. Pressly, FDA/CDRH 👝 👝 🦲
	Susan E. Reinarz, RNC, MSN, NNP, National Association of Neonatal Nurses
	Richard L. Savoie, Smith Medical
	Robert H. Stiefel, CCE, MS, University of Maryland Medical System
	Robert D. White, MD, American Academy of Pediatrics
Alternates:	William M. Burdick, FDA/CDRH <sup>ety in</sup> Health Technology
	Bryan S. Overton, Draeger Medical Systems Inc.
	Andrew Richards, G.E. Healthcare

DDEV/IEW/CODV

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

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

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#### Background of ANSI/AAMI adoption of IEC 60601-2-19:2009

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.

This standard was developed by the IEC Subcommittee (SC) 62D, Electromedical equipment, maintenance team (MT) 21 on Pediatric equipment. The objective of this standard is to provide the basic safety and essential performance requirements of baby incubators. This standard can also be applied to baby incubators used for compensation or alleviation of disease, injury or disability. This standard does not apply to heating devices intended for physiotherapy, radiant warmers, and transport incubators, which are covered in other documents.

U.S. participation in this IEC SC is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation on behalf of the US National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft International Standard of IEC 60601-2-19:2009, the AAMI Infant Incubator Committee, which serves as the U.S. Technical Advisory sub-Group (sub-TAG) to MT 21 decided to adopt it verbatim as a revision of ANSI/AAMI II36:2004, Medical electrical equipment, Part 2: Particular requirements for safety of baby incubators.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

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 Standards Department, AAMIS 1119 No Glebe Road, Suite 2201 Arlington, VA 22201 4795 document and is

intended to allow potential purchasers to evaluate the content

NOTE—This background does not contain provisions of the American National Standard, Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of baby incubators (ANSI/AAMI/IEC 60601-2-19:2009), but it does provide important information about the development and intended use of the document.

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NOTE—Beginning with the IEC foreword on page viii, this American National Standard is identical to IEC 60601-2-19:2009.

#### INTERNATIONAL ELECTROTECHNICAL COMMISSION

#### MEDICAL ELECTRICAL EQUIPMENT -

#### Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

#### FOREWORD

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International standard IEC 60601-2-19 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. It was revised to structurally align with the third edition (2005) of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/727/FDIS	62D/756/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- Test specifications: italic type.
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
  Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2: For the purposes of this standard, the auxiliary verbument and is

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard of the document before making a purchasing decision.
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard, MI document, contact AAMI at
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

#### INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT INCUBATOR equipment.

This particular standard amends and supplements IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular 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.



### **PREVIEW COPY**

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#### American National Standard

#### ANSI/AAMI/IEC 60601-2-19:2009/(R)2014

#### MEDICAL ELECTRICAL EQUIPMENT -

#### Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

#### 201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT INCUBATORS, as defined in 201.3.209 of this standard, also referred to as ME EQUIPMENT. Advancing Safety in Health Technology

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.4 of the general standard of an AAMI guidance document and is

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NOTE See also 4.2 of the general standard before making a purchasing decision.

This particular standard specifies safety requirements for INFANT INCUBATORS but alternate methods of compliance with a specific clause by demonstrating equivalent safety will not be judged as non-compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information see IEC 80601-2-35 [3]<sup>2</sup>;
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [2];
- INFANT TRANSPORT INCUBATORS, for information, see IEC 60601-2-20 [1];
- INFANT PHOTOTHERAPY EQUIPMENT, for information see IEC 60601-2-50 [4].

<sup>1)</sup> The general standard is IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

<sup>&</sup>lt;sup>2)</sup> Figures in square brackets refer to the Bibliography.