

American National Standard



ANSI/AAMI/ IEC 60601- 2-20:2009/ (R)2014 & A1:2016

Medical Electrical
Equipment — Part 2-20:
Particular requirements for
the basic safety and
essential performance of
infant transport 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 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.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended 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.

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 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 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.

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 60601-2-20:2009/(R)2014
(Revision of ANSI/AAMI IIE51:2004)

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

Medical Electrical Equipment — Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

Approved 17 March 2009 by
AAMI

Approved 3 April 2009 and reaffirmed 10 December 2014 by
American National Standards Institute, Inc.

Abstract: This standard applies to the basic safety and essential performance of transport incubators. This standard does not apply to heating devices intended for physiotherapy, baby incubators, radiant warmers.

Keywords: electromedical equipment, medical electrical equipment, infant incubators

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

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

© 2009 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-342-3

CONTENTS

Glossary of equivalent standards	iv
Committee representation.....	vi
Background of AAMI adoption of IEC 60601-2-20:2009.....	vii
FOREWORD	viii
INTRODUCTION	x
201.1 Scope, object and related standards.....	1
201.2 Normative references.....	3
201.3 Terms and definitions.....	3
201.4 General requirements.....	6
201.5 General requirements for testing ME EQUIPMENT	7
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	8
201.7 ME EQUIPMENT identification, marking and documents	8
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	10
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	10
201.10 Protection against unwanted and excessive radiation HAZARDS.....	13
201.11 Protection against excessive temperatures and other HAZARDS	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	15
201.13 HAZARDOUS SITUATIONS and fault conditions	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	23
201.15 Construction of ME EQUIPMENT	23
201.16 ME SYSTEMS	25
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	25
202 Electromagnetic compatibility – Requirements and tests.....	25
210 Requirements for the development of physiologic closed-loop controllers.....	26
Annexes.....	26
Annex AA (informative) Particular guidance and rationale.....	27
Bibliography	36
Index of defined terms used in this particular standard	37
Figure 201.101 – Positioning of air temperature sensors	5
Figure 201.102 – AVERAGE TRANSPORT INCUBATOR TEMPERATURE.....	5
Figure 201.103 – Layout of weight test devices	20
Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements.....	6

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	ANSI/AAMI/IEC TIR62296:2009	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
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
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 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations 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
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	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 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

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

Bryan S. Overton, Draeger Medical Systems Inc.

Andrew Richards, G.E. Healthcare

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.

Background of ANSI/AAMI adoption of IEC 60601-2-20:2009

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 transport incubators. This standard does not apply to heating devices intended for physiotherapy, baby incubators, radiant warmers, 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 60601-2-20:2009, 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 I151:2004, Medical electrical equipment, Part 2: Particular requirements for safety of transport 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, 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 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators* (ANSI/AAMI/IEC 60601-2-20:2009), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the IEC foreword on page viii, this American National Standard is identical to IEC 60601-2-20:2009.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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 IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-20 has been prepared by IEC Subcommittee 62D Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-20 published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. This edition of IEC 60601-2-20 was revised to structurally align with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/731/FDIS	62D/757/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 collateral 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 verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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 TRANSPORT 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.

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators****201.1 Scope, object and related standards**

Clause 1 of the general standard applies, except as follows:

201.1.1 Scope*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.211 of this standard, also referred to as ME EQUIPMENT.

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 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT TRANSPORT 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 [1]¹⁾;
- INFANT INCUBATORS which are not INFANT TRANSPORT INCUBATOR; for information see IEC 60601-2-19 [2];
- INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [3];
- INFANT PHOTOTHERAPY; for information, see IEC 60601-2-50 [4].

¹⁾ Figures between square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT TRANSPORT INCUBATORS as defined in 201.3.211, which minimize HAZARDS to the PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

201.1.3 *Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-10 apply as modified in Clauses 202 and 210 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

NOTE Informative references are listed in the bibliography beginning on page 36.

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

ISO 32, *Gas cylinders for medical use – Marking for identification of content*

ISO 407, *Small medical gas cylinders – Pin-index yoke-type valve connections*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE An index of defined terms is found beginning on page 37.

Addition:

201.3.201

AIR CONTROLLED TRANSPORT INCUBATOR

INCUBATOR in which the air temperature is automatically controlled by an air temperature sensor close to a value set by the OPERATOR

201.3.202

AVERAGE TEMPERATURE

average of temperature readings taken at regular intervals at any specified point in the COMPARTMENT achieved during STEADY TEMPERATURE CONDITION

201.3.203

AVERAGE TRANSPORT INCUBATOR TEMPERATURE

average of the INFANT TRANSPORT INCUBATOR TEMPERATURE readings taken at regular intervals achieved during STEADY TEMPERATURE CONDITION (see Figure 201.102)

201.3.204

BABY CONTROLLED TRANSPORT INCUBATOR

AIR CONTROLLED TRANSPORT INCUBATOR which has the additional capability of automatically controlling the INCUBATOR air temperature in order to maintain the temperature as measured by a SKIN TEMPERATURE SENSOR according to the CONTROL TEMPERATURE set by the OPERATOR

NOTE An INFANT TRANSPORT INCUBATOR operating as a BABY CONTROLLED INCUBATOR is a PHYSIOLOGIC CLOSED-LOOP CONTROLLER as defined in IEC 60601-1-10.

201.3.205

COMPARTMENT

environmentally-controlled enclosure intended to contain an INFANT and with transparent section(s) which allows for viewing of the INFANT

201.3.206

CONTROL TEMPERATURE

temperature selected at the temperature control

201.3.207

INFANT

PATIENT up to the age of three months and a weight less than 10 kg

***201.3.208**

INFANT TRANSPORT INCUBATOR

TRANSPORTABLE ME EQUIPMENT that is equipped with a COMPARTMENT and a TRANSPORTABLE electrical power source with the means to control the environment of the INFANT primarily by heated air within the COMPARTMENT

201.3.209

SKIN TEMPERATURE

temperature of the skin of the INFANT at a point on which the SKIN TEMPERATURE SENSOR is placed

201.3.210

SKIN TEMPERATURE SENSOR

sensing device intended to measure the INFANT'S SKIN TEMPERATURE

201.3.211

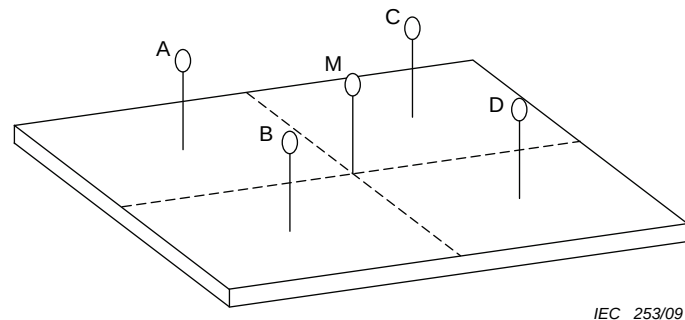
STEADY TEMPERATURE CONDITION

condition reached when the TRANSPORT INCUBATOR TEMPERATURE does not vary by more than 1 °C over a period of 1 h (see Figure 201.102)

201.3.212

TRANSPORT INCUBATOR TEMPERATURE

temperature of the air at a point 10 cm above the center of the MATTRESS surface in the COMPARTMENT (see Figure 201.101, point M)



Key

M = INCUBATOR TEMPERATURE sensor

A, B, C, D = Air temperature sensor

The measuring points A to D and M are in a plane parallel to and at a distance of 10 cm from the MATTRESS.

Figure 201.101 – Positioning of air temperature sensors

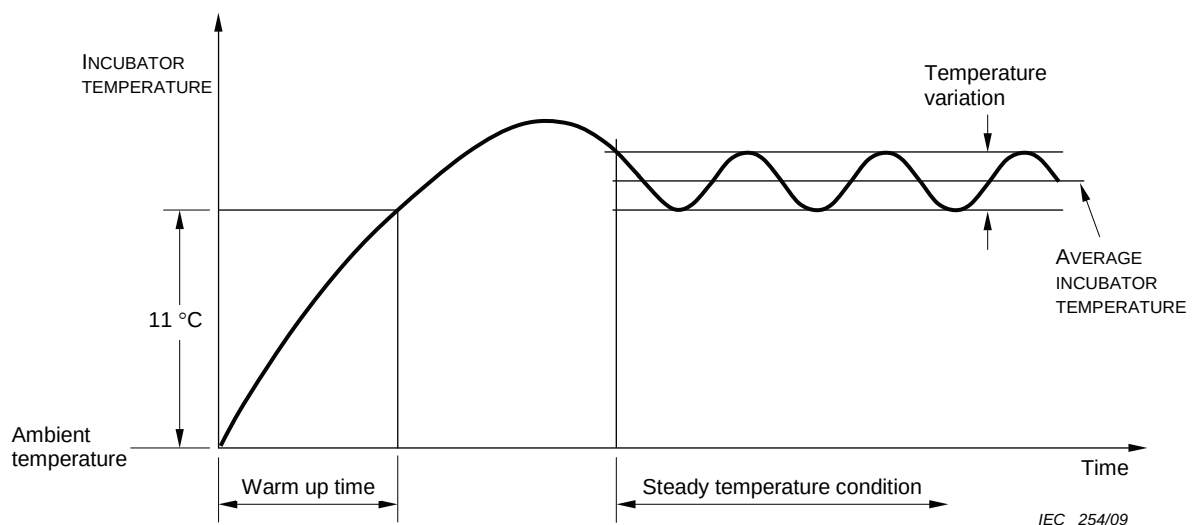


Figure 201.102 – Variation of INCUBATOR TEMPERATURE

201.3.213

TRANSPORTABLE ELECTRICAL POWER SOURCE

rechargeable battery and battery charger intended to provide the electrical power necessary to operate the INFANT TRANSPORT INCUBATOR

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

For ME EQUIPMENT which combines alternative heat sources, for instance INCUBATORS with integrated INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or 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 tests of clause 201.11 and subclause 201.15.4.2.1 of the relevant particular standards.

201.4.3 *ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATORS

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
ESSENTIAL PERFORMANCE requirement 1	201.12.1.105 or generation of a visual and audible alarm in compliance with 201.9.6.2.1.102 201.15.4.2.1
ESSENTIAL PERFORMANCE requirement 2	201.12.1.107 or generation of a visual and audible alarm in compliance with 201.9.6.2.1.102 201.15.4.2.1

201.4.10 Power supply

Additional subclauses:

201.4.10.101 *Ability to operate with different power supply sources

The INFANT TRANSPORT INCUBATOR shall have a TRANSPORTABLE ELECTRICAL POWER SOURCE consisting of a rechargeable battery and battery charger designed to operate from an alternating current supply voltage. It shall also be designed to operate from at least one external direct and

one external alternating current SUPPLY MAINS as specified in the instructions for use. All requirements of the general standard and this particular standard shall continue to be met.

Compliance is checked by repeating the tests in subclauses 201.12.1.101, 201.12.1.102, 201.12.1.105 and 201.12.1.107 with the INFANT TRANSPORT INCUBATOR operating at an ambient temperature of $15\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ when supplied from each of its SUPPLY MAINS in turn. This also includes the TRANSPORTABLE ELECTRICAL POWER SOURCE.

201.4.10.102 Capacity of TRANSPORTABLE ELECTRICAL POWER SOURCE

The capacity of any TRANSPORTABLE ELECTRICAL POWER SOURCE shall be sufficient to maintain the INFANT TRANSPORT INCUBATOR at a temperature in accordance with the following test during at least 90 min.

Compliance is checked by inspection and the following test:

The INFANT TRANSPORT INCUBATOR with a fully charged battery shall be placed in an environment with an ambient temperature of $15\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$. It shall be operated from the SUPPLY MAINS until a STEADY TEMPERATURE CONDITION has been established at a CONTROL TEMPERATURE of $36\text{ }^{\circ}\text{C}$ and then set to operate from any TRANSPORTABLE ELECTRICAL POWER SOURCE. The INFANT TRANSPORT INCUBATOR TEMPERATURE shall be maintained within $2\text{ }^{\circ}\text{C}$ of the CONTROL TEMPERATURE.

This test shall be conducted while all the electrical powered ACCESSORIES, as specified by the MANUFACTURER, are in operation and making the maximum demand upon the external TRANSPORTABLE ELECTRICAL POWER SOURCE.

201.4.10.103 Overcharge of TRANSPORTABLE ELECTRICAL POWER SOURCE

It shall not be possible to overcharge and damage the TRANSPORTABLE ELECTRICAL POWER SOURCE even if the ME EQUIPMENT is left connected to the a.c. electrical power source for an indefinite period. Controls which affect the rate of recharge or the final battery voltage level shall not be accessible to the OPERATOR without the aid of a TOOL.

Compliance is checked by inspection.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 *Ambient temperature, humidity, atmospheric pressure

Addition to a):

The ME EQUIPMENT shall comply with the requirements of this standard when operating within the following conditions:

- an ambient temperature between $+10\text{ }^{\circ}\text{C}$ and $+30\text{ }^{\circ}\text{C}$.

If not otherwise specified in this particular standard, all tests shall be carried out at an ambient temperature within the range of $21\text{ }^{\circ}\text{C}$ to $26\text{ }^{\circ}\text{C}$ and an ambient air velocity less than 1.0 m/s and greater than 0.3 m/s .

201.5.4 Other conditions

Addition:

If not otherwise specified, the CONTROL TEMPERATURE shall be 36 °C and shall always exceed the ambient temperature by at least 3 °C.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

(see also Table C.1)

Additional subclauses:

201.7.2.101 *Oxygen monitor

An INFANT TRANSPORT INCUBATOR not equipped with an integral oxygen monitor and which provides means for oxygen administration shall be marked in a prominent position with a text which states: "Use an oxygen monitor when oxygen is administered".

NOTE See also 7.5 of the general standard.

201.7.2.102 Heater surface temperature

If a heater is accessible without the use of a TOOL a notice, symbol (see 7.5 of the general standard) or marking shall be displayed adjacent to the heater giving warning of high surface temperature.

201.7.4 Marking of controls and instruments (see also Table C.3)

201.7.4.2 *Control devices

Addition:

Temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals of not greater than 1 °C for AIR CONTROLLED TRANSPORT INCUBATORS and not greater than 0.5 °C for BABY CONTROLLED TRANSPORT INCUBATORS.

Marking of the maximum and the minimum values of controls and-indicators shall be such that no confusion can arise with regard to the position of the control and/or the indicated values.

201.7.9.2.2 Warning and safety notices

Addition: