American National Standard

ANSI/AAMI ID26:2004/(R)2013

Medical electrical equipment—Part 2: Particular requirements for the safety of infusion pumps and controllers

AAMI
Advancing Safety in Medical Technology

The 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 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.

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:

1. 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 decisionmaking.

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 need 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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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. 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 ID26:2004/(R)2013
(Revision of ANSI/AAMI ID26:1998)

CORRECTED COPY

Medical electrical equipment—
Part 2: Particular requirements for the safety of infusion pumps and controllers

Approved 2 December 2004 by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: This standard establishes minimum labeling, safety, performance, and testing requirements for electromechanical infusion devices that have a pumping or gravity-feed controlling function, that deliver fluid from either a separate or a self-contained source, and that are intended for use with parenteral fluids for such purposes as parenteral nutrition and administration of drugs and routine fluids.

Keywords: controller, infusion, pump, syringe

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.

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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 judgement 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.

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SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

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 5840:200x	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

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

Committee representation

Association for the Advancement of Medical Instrumentation

Infusion Device Committee

This standard was developed by the Infusion Device Committee of the Association for the Advancement of Medical Instrumentation, which also acts as the U.S. Technical Advisory Subgroup to the relevant work in the International Electrotechnical Commission. Committee approval of this standard does not necessarily imply that all members voted for its approval.

At the time this document was published, the **AAMI Infusion Device Committee** had the following members:

Cochairs:	David Meyers
	Nathaniel M. Sims, MD
Members:	William M. Burdick, U.S. Food and Drug Administration/Center for Devices and Radiological Health
	Allen K. Wong, Abbott Laboratories
	Mark Graber, GE Healthcare
	Bruce R. Horowitz, BS, Advanced Neuromodulations Systems Inc.
	Thomas McGraghan, Baxter Healthcare Corporation
	David Meyers, Alaris Medical Systems, Inc.
	Saul Miodownik, CCE, Memorial Sloan-Kettering Cancer Center
	Gerald Moss, MD, PhD, Rensselaer Polytechnic Institute
	Ziad A. Rouag, Johnson & Johnson
	Philip Schneider, Ohio State University Hospital
	Veronica Ivans, Medtronic Inc.
	Nathaniel M. Sims, MD, Massachusetts General Hospital
	Scott Thiel, Roche Diagnostics Corp.
Alternates:	Ahmad Sajadi, MS.RAC, Alaris Medical Systems
	Tony Varrichio, Advanced Neuromodulations Systems Inc.
	Ramakrishna Venugopalan, Johnson & Johnson

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

Foreword

This AAMI Standard was developed by the AAMI Infusion Device Committee as the result of the five-year review of ANSI/AAMI ID26:1998. The objective is to specify minimum labeling, safety, performance, and testing requirements for mechanical and electromechanical infusion devices that have a pumping or gravity-feed controlling function, that deliver fluid from either a separate or a self-contained source, and that are intended for use with parenteral fluids for such purposes as parenteral nutrition and administration of drugs and routine fluids.

This standard is based on the International Electrotechnical Commission (IEC) standard for infusion pumps and controllers, IEC 60601-2-24:1998, developed by Working Group (WG) 8, Infusion pumps, of IEC/SC 62D, Electromedical equipment. AAMI administers the International Secretariat and the U.S. Technical Advisory Group (TAG) for IEC/SC 62D.

This standard contains significant national deviations from IEC 60601-2-24:1998. These deviations are explained in an informative section, "AAMI deviations from IEC 60601-2-24:1998," which begins on page x.

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 that 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.

Appendix L is an integral part of this standard. IEC and ISO International Standards are available in the United States from the American National Standards Institute.

Annex AA is 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, introductions, general statements, exceptions, and references: in smaller type;

— *test specifications: in italic type*;

— TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, and other health care professionals, working with government representatives and device manufacturers, to define those safety and performance criteria that could reasonably be achieved at this time. Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-3798.

NOTE—This foreword does not contain provisions of the standard, ANSI/AAMI ID26:2004, *Medical electrical equipment—Part 2: Particular requirements for the safety of infusion pumps and controllers*, but it does provide important information about the development and intended use of the document.

Introduction

ANSI/AAMI ID26:2004 (hereinafter referred to as “This Particular Standard”) deals with the safety of INFUSION PUMPS and CONTROLLERS. The relationship between this Particular Standard and IEC General and Collateral Standards in the 60601 series is explained in 1.3.

The safe use of INFUSION PUMPS and CONTROLLERS is primarily the responsibility of the OPERATOR. It is also recognized that OPERATORS should be trained in the operation of MEDICAL ELECTRICAL EQUIPMENT and that safe use of the EQUIPMENT can only be achieved if it is operated in accordance with the manufacturer’s instructions for use. The minimum specified safety requirements are considered to provide a practical degree of safety in operation. It is the responsibility of the manufacturer to ensure that the requirements of this Particular Standard are reliably implemented. This Particular Standard has been developed in accordance with these principles.

Safe use can be ensured only if the associated disposable parts, especially lines and syringes, are consistent with the system. ISO 7886-2:1996, *Sterile hypodermic syringes for single use—Part 2, Syringes for use with power-driven syringe pumps* should be taken into account.

AAMI deviations from IEC 60601-2-24:1998

General

American English spelling is used in the AAMI standard, and periods are used as decimal points.

Subclause 1.1* Scope

The subclause has been changed from:

> This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS and PUMPS FOR AMBULATORY USE, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home PATIENTS as prescribed and medically indicated. These particular requirements do not apply to devices:
>
> 1) specifically intended for diagnostic or similar use (e.g., angiography or other pumps permanently controlled or supervised by the OPERATOR),
>
> 2) enteral infusion,
>
> 3) extracorporeal circulation of blood,
>
> 4) implantable or disposable devices,
>
> 5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water),
>
> 6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

It now reads:

> This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS, and PUMPS FOR AMBULATORY USE, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home PATIENTS as prescribed and medically indicated. These particular requirements do not apply to:
>
> 1) devices specifically intended for diagnostic or similar use (e.g., angiography or other pumps permanently controlled or supervised by the OPERATOR),
>
> 2) devices specifically intended for enteral infusion,
>
> 3) devices specifically intended for extracorporeal circulation of blood,
>
> 4) implantable or disposable devices,
>
> 5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water),
>
> 6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

1.3 Particular Standards

The following sentence has been added to paragraph 1:

> Reference the latest revision of these particular standards for changes after the publishing of this Particular Standard.

Subclause 2.121* minimum rate

This subclause has been changed from:

> lowest rate selectable by the OPERATOR, but not less than 1 mL/h
>
> NOTE—For INFUSION PUMPS FOR AMBULATORY USE it is the LOWEST SELECTABLE RATE

It now reads:

lowest rate selectable by the OPERATOR, but not less than 1 mL/h

The following definitions have been added to clause 2:

2.124* MAXIMUM SELECTABLE RATE

highest rate selectable by the OPERATOR if higher than the INTERMEDIATE RATE

2.125* LOWEST SELECTABLE RATE

lowest rate selectable by the OPERATOR if lower than the INTERMEDIATE RATE

2.126 REMOTE PARTS

attachable ACCESSORIES that are necessary for the proper operation of the EQUIPMENT feature; for example, a drop sensor is a REMOTE PART but a syringe holder is not

Subclause 6.8.2 Instructions for use

Item 12) has been changed from:

12) a statement of the means provided (if any) to manage the BOLUS before occlusion release;

It now reads:

12) a statement regarding management of the entrapped BOLUS before occlusion release;

Item 16) has been changed from:

16) the typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE;

It now reads:

16) the typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at the INTERMEDIATE RATE; and the operating time from the INTERNAL ELECTRICAL POWER SOURCE at the MAXIMUM SELECTABLE RATE if less than 30 minutes;

The NOTE below item 19) has been changed from:

NOTE—The manufacturer must specify the parameters in which the device cannot maintain the specified accuracy; e.g., minimum/maximum viscosity of liquids, reaction time of the safety system, scope of the risk analysis, etc.

It now reads:

NOTE—The manufacturer must specify the parameters in which the device cannot maintain the specified accuracy; e.g., minimum/maximum viscosity of liquids, minimum/maximum back pressure, minimum/maximum infusion rates, reaction time of the safety system, scope of the risk analysis, etc.

Item 25) has been changed from:

25) data as evaluated by the test methods of 50.101 to 50.108 at the rates indicated in Table 102, including an explanation for the OPERATOR of the data presentation;

It now reads:

25) a) a mean rate accuracy at the INTERMEDIATE RATE under standard conditions of: 1 hour, ambient back pressure, manufacturer's recommended container height, ISO class III water, and standard atmospheric condition;

b) rate accuracy data as evaluated by the test methods of 50.101 to 50.108 at the rates indicated in Table 102, including an explanation for the OPERATOR of the data presentation;

A new item 32) has been added to this subclause. It reads:

32) a warning statement on the possible SAFETY HAZARDS associated with Magnetic Resonance Imaging (MRI) which may affect the safe operation of the EQUIPMENT, if applicable;

A new item 33) has been added to this subclause. It reads:

33) a warning statement on the possible SAFETY HAZARDS associated with hyperbaric chambers which may affect the safe operation of the EQUIPMENT, if applicable.

Subclause 6.8.3 Technical description

The following item has been added to this clause:

ff)* a manufacturer's disclosure of the PROFILE PUMP characteristics of delivery change during transition interval.

Subclause 50.102*

The phrase, "interval S + to 0.5" in the third paragraph has been changed. It now reads:

interval *S* to 1/6 min

The second sentence of the fourth paragraph has been changed from:

This test period shall equal the recommended ADMINISTRATION SET CHANGE INTERVAL if there is sufficient fluid in the container.

It now reads:

This test period shall equal the recommended ADMINISTRATION SET CHANGE INTERVAL.

The third sentence of the fourth paragraph has been deleted. The sentence read:

If not, calculate the duration of the test period by dividing the total fluid volume by the rate.

The fifth paragraph has been changed from:

For VOLUMETRIC INFUSION PUMPS and SYRINGE PUMPS repeat the test at the INTERMEDIATE RATE for a period of 120 min at back pressures of ± 13.33 kPa (± 100 mm Hg).

It now reads:

For VOLUMETRIC INFUSION PUMPS and SYRINGE PUMPS repeat the test at the INTERMEDIATE RATE for a period of 120 min at back pressures of +39.9 kPa (+300 mm Hg) and −13.3 kPa (−100 mm Hg).

The scale of the Trumpet Graph in paragraph 17 has been changed from:

maximum = 15 %

minimum = −15 %

It now reads:

maximum ≥ 15 %

minimum ≥ −15 %

The thirteenth paragraph has been changed from:

Calculate E_p(max.) and E_p(min.) for the 2, 5, 11, 19, and 31 min observation windows from equations (2) and (3) over the analysis period T_1 (min) of the second hour of the test period.

It now reads:

Calculate E_p(max.) and E_p(min.) for all available observation windows from 1 min to 31 min, using equations (2) and (3), over the analysis period T_1 (min) of the second hour of the test period.

The fourteenth paragraph has been changed from:

Except for SYRINGE PUMPS calculate E_p(max.) and E_p(min.) for the 2, 5, 11, 19, and 31 min observation windows from equations (2) and (3) over the analysis period T_2 (min) of the last hour of the test period.

It now reads:

> Except for SYRINGE PUMPS, calculate E_p(max.) and E_p(min.) for all available observation windows from 1 min to 31 min, using equations (2) and (3), over the analysis period T_2 (min) of the last hour of the test period.

The following sentence has been added to paragraph 19:

> Label only data points at 2, 5, 11, 19, and 31 min intervals.

The following has been added to paragraph 21:

> Label only data points at 2, 5, 11, 19, and 31 min intervals.

Subclause 50.103* Accuracy tests for DRIP RATE INFUSION CONTROLLERS and DRIP RATE INFUSION PUMPS

Paragraph 7 has been changed from:

> Calculate E_p(max.) and E_p(min.) for the 1, 2, 5, 11, 19, and 31 min observation windows from equations (2) and (3) over the analysis period T_1 (min) of the second hour of the test period.

It now reads:

> Calculate E_p(max.) and E_p(min.) for all available observation windows from 1 min to 31 min, using equations (2) and (3), over the analysis period T_1 (min) of the second hour of the test period.

Paragraph 8 has been changed from:

> Calculate E_p(max.) and E_p(min.) for the 1, 2, 5, 11, 19, and 31 min observation windows from equations (2) and (3) over the analysis period T_2 (min) of the last hour of the test period.

It now reads:

> Calculate E_p(max.) and E_p(min.) for all available observation windows from 1 min to 31 min, using equations (2) and (3), over the analysis period T_2 (min) of the last hour of the test period.

The following has been added to paragraph 10 b):

> Label only data points at 2, 5, 11, 19, and 31 min intervals.

The following has been added to paragraph 10 c)

> Label only data points at 2, 5, 11, 19, and 31 min intervals.

Figure 104a

The value “0.0000 g” has been deleted from the “Electronic balance” box.

Figure 104b

The value “0.0000 g” has been deleted from the “Electronic balance” box.

Table 102—Set rates, BOLUS volumes and test apparatus for the accuracy tests of 50.102 to 50.108

Two columns have been added to Table 102 under the heading “Set rates.” They are:

“LOWEST SELECTABLE RATE (for rates less than 1 mL/h, alternate test methodologies may be used)”

and

“MAXIMUM SELECTABLE RATE (limited to 24 hours at maximum rate).”

Descriptions in the leftmost column of the table have been changed from:

INFUSION PUMP FOR AMBULATORY USE								
Type 1	*	*		*			104b)	50.104
Type 2		*		*			104b)	50.105

and

DRIP-RATE, VOLUMETRIC, INFUSION PUMP, or SYRINGE PUMP or INFUSION PUMP FOR AMBULATORY USE								
Type 3					*	*	104a), 104b)	50.106
Type 4	*	*	*	*	*	*	104a), 104b)	50.104 & 50.106
Type 5	*	*	*	*	*	*	104a), 104b), 108	50.104 & 50.106

They now read:

INFUSION PUMP FOR AMBULATORY USE								
Type 1 (continuous infusion flow only)	*	*		*			104b)	50.104
Type 2 (non-continuous flow only)		*		*			104b)	50.105

and

SINGLE CATEGORY INFUSION PUMPS: VOLUMETRIC, DRIP-RATE, SYRINGE FOR AMBULATORY USE AND NOT TYPE 1 (CONTINUOUS INFUSION FLOW ONLY) OR TYPE 2 (NON-CONTINUOUS FLOW ONLY)								
Type 3 (discrete delivery of a BOLUS)					*	*	104a), 104b)	50.106
Type 4 (type 1 combined with type 3 and/or type 2 in the same EQUIPMENT)	*	*	*	*	*	*	104a), 104b)	50.104, 50.106
Type 5 (PROFILE PUMP)	*	*	*	*	*	*	104a), 104b), 108	50.104, 50.106

The following footnotes are added:

[1] For rates less than 1 mL/h, alternate methodologies may be used.

[2] Limited to 24 hours at maximum rate.

[3] For discrete delivery of bolus volume test.

Subclause 51.106 Audible and visual alarms

The second sentence of this subclause has been deleted. The sentence read:

This requirement does not apply to INFUSION PUMPS FOR AMBULATORY USE.

Subclause 51.107

Item b) of this subclause has been changed from:

b) the audible alarm silence period of the EQUIPMENT in stand-alone operation shall not exceed 2 min;

It now reads:

b) the audible alarm silence period of the EQUIPMENT in operation shall not exceed 2 min;

Subclause 51.108

This first sentence of this subclause has been changed from:

51.108 INFUSION PUMPS FOR AMBULATORY USE shall additionally include an alarm, if the EQUIPMENT is switched to a standby mode of operation for more than 1 h.

It now reads:

51.108 INFUSION PUMPS shall additionally include an audible and/or visible alarm, if the EQUIPMENT is switched to a standby mode of operation. INFUSION PUMPS FOR AMBULATORY USE shall include an alarm if the EQUIPMENT is switched to a standby mode for more than 1 h.

Annex AA (informative) General guidance and rationale

AA.1 Rationale for the requirements of this Particular Standard

The following has been added:

2.120 to 2.125 Rate definitions used in this standard are defined in a manner that utilizes the rate definitions of MINIMUM RATE and INTERMEDIATE RATE from IEC 60601-2-24:1998, and adds new definitions of MAXIMUM SELECTABLE RATE and MINIMUM SELECTABLE RATE. The new definitions were added to include requirements for performance testing at rates lower than the MINIMUM RATE and higher than the INTERMEDIATE RATE.

The following example is provided to demonstrate use of these definitions when executing accuracy testing per section 50. Refer to Table 102. If the device under test were a VOLUMETRIC INFUSION PUMP with a range of operation of 0.1 mL/h to 999 mL/h, then accuracy tests would be conducted at:

LOWEST SELECTABLE RATE	0.1 mL/h
MINIMUM RATE	1.0 mL/h
INTERMEDIATE RATE	25 mL/h (for VOLUMETRIC INFUSION PUMP)
MAXIMUM SELECTABLE RATE	999 mL/h

Rationale for 6.8.3 ff) has been added, which reads:

6.8.3 ff) Since there are many possible configurations for PROFILE PUMPS, the manufacturer is required to characterize a typical performance during transition intervals.

Subclauses 50.102 to 50.108

Sentence two of the ninth paragraph has been changed. The sentence has been changed from:

With an 18 G, 1.2 mm needle 40 mm long, the pressure drop across the needle at 300 mL/h using water is approximately 3.3 kPa (2.5 mm Hg).

It now reads:

With an 18 G, 1.2 mm needle 40 mm long, the pressure drop across the needle at 300 mL/h using water is approximately 0.33 kPa (2.5 mm Hg).

The eleventh paragraph has been deleted. The paragraph read:

With DRIP-RATE INFUSION PUMPS it is necessary to investigate the effects of liquid viscosities on drip-rate accuracy as DRIP-RATE INFUSION PUMPS will be expected to pump a range of fluids of differing viscosities. The most viscous fluid, dextrose 50 %, will be pumped at drip rates not greater than an equivalent flow of 150 mL/h. If a 20 drops per ml ADMINISTRATION SET is used, this is a drip-rate of 50 drops per min. In order to simplify the test procedure

and obviate the use of different infusion liquids, it has been decided to reproduce the additional back pressure that high viscosity liquids (such as dextrose 50 %) would produce by the use of fine gauge needles. Testing is carried out at the two extremes of back pressures, −13.33 kPa (−100 mm Hg) and +13.33 kPa (+100 mm Hg). An 18 G, 1.2 mm needle of 40 mm long (which produces no significant additional back pressure at any flow likely to be encountered) is used at −13.33 kPa (−100 mm Hg) and a 21 G, 0.8 mm needle 40 mm long, at +13.33 kPa (+100 mm Hg). The use of a 21G, 0.8 mm needle 40 mm long produces additional back pressure that can be calculated by the Hagen-Poinseuille formula.

The fourteenth paragraph has been deleted. The paragraph read:

Variants of these pumps to cater for paediatric applications are designed to deliver precise volumes at low set rates (between 1 mL/h and 10 mL/h) and are calibrated in 0.1 mL/h increments. It is not considered necessary to test these pumps for accuracy of delivery below 1 mL/h because clinical applications would call for the use of a SYRINGE PUMP in these circumstances.

The fifteenth paragraph has been changed from:

Because high-viscosity liquids may be used, these pumps are tested over the full range of set rates using water at a test back pressure of +13.33 kPa (+100 mm Hg) with a 21 G, 0.8 mm needle 40 mm long to simulate the additional back pressure caused by the use of a high viscosity liquid such as dextrose 50 % (see Hagen-Poinseuille formula and calculations). Testing at −13.33 kPa (−100 mm Hg) is to simulate the negative back pressures that are sometimes encountered in clinical usage.

It now reads:

These pumps are tested over the full range of set rates using water at a back pressure of +39.9 kPa (+300 mm Hg) to simulate the back pressure that can be encountered during arterial infusion or during infusion of viscous liquids. Testing at −13.3 kPa (−100 mm Hg) is to simulate the negative back pressures that are sometimes encountered in clinical usage.

Rationale for 51.108 has been added, which reads:

51.108 This provision is intended to address the occurrence of failure to restart the device after a temporary suspension of operation such as changing an IV bag or adjustment of delivery rate.

AA.2 Rationale for the requirements of IEC 60601-1-2

Rationale for 36.201 has been deleted. The rationale read:

36.201 It is important to realise that for emissions not only CISPR 11 is required by the Collateral Standard IEC 60601-1-2, but also CISPR 14. CISPR 14 is mandatory because it is mentioned in the list with normative references in Annex BBB of the Collateral Standard.

AA.3 Rationale for the algorithm for this Particular Standard

The subheading and text on “Accuracy tests for SYRINGE PUMPS” has been deleted. The text read:

Accuracy tests for SYRINGE PUMPS

In general, the flow from SYRINGE PUMPS tends to be more continuous than most other types of INFUSION PUMP. However, even with SYRINGE PUMPS, the flow can vary considerably over short periods of typically 1 min or less.

Since SYRINGE PUMPS in general do not use flow control methods which depend on the optical properties of the infusion fluid, it is considered necessary only to investigate the effects of liquid viscosity on flow accuracy. In order to simplify the test procedure and obviate the use of different infusion liquids it has been decided to reproduce the additional pressure that high viscosity liquids (such as dextrose 50 %) would produce by the use of fine gauge needles.

Testing is carried out at the extremes of back pressures, −13.33 kPa (−100 mm Hg) and +13.33 kPa (+100 mm Hg).

The word “subcutaneous” has been deleted from the first sentence under “**Types of pumps**.”

Medical electrical equipment—Part 2: Particular requirements for the safety of infusion pumps and controllers

SECTION ONE—GENERAL

The clauses and subclauses of this section of the General Standard (see 1.3) and of this section of the Collateral Standard, IEC 60601-1-2 apply, except as follows:

1 Scope and object

This clause of the General Standard and this clause of the Collateral Standard IEC 60601-1-2 apply, except as follows:

1.1* Scope

Addition:

This Particular Standard specifies the requirement for INFUSION PUMPS, INFUSION CONTROLLERS, SYRINGE PUMPS, and PUMPS FOR AMBULATORY USE, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home PATIENTS as prescribed and medically indicated. These particular requirements do not apply to:

1) devices specifically intended for diagnostic or similar use (e.g., angiography or other pumps permanently controlled or supervised by the OPERATOR),

2) devices specifically intended for diagnostic enteral infusion,

3) devices specifically intended for diagnostic extracorporeal circulation of blood,

4) implantable or disposable devices,

5) EQUIPMENT specifically intended for diagnostic use within urodynamics (measurement of pressure volume relationship of the urinary bladder when filled through a catheter with water),

6) EQUIPMENT specifically intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain a preset pressure level for maintaining penile erection: cavernosometry, cavernosography).

1.3 Particular standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment—Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995) and to the Collateral Standard IEC 60601-1-2:2001, *Medical electrical equipment—Part 1: General requirements for safety, 2. Collateral Standard: Electromagnetic compatibility—Requirements and tests*. Reference the latest revision of these particular standards for changes after the publishing of this Particular Standard.

For brevity, Part 1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s), and IEC 60601-1-2 as the Collateral Standard.

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.