American National Standard

ANSI/AAMI ID26:2004

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

AAMI
ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

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

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 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 needs of the user.

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

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

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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
(Revision of ANSI/AAMI ID26:1998)

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

Approved 9 December 2004 by
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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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 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical

[1] Currently at FDIS stage

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 22201-4795.

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.

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

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

The term "this Standard" is used to make reference to the General Standard, the Collateral Standard, and this Particular Standard taken together.

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

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

The requirements are followed by specifications for the relevant tests.

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

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

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

1.5 Collateral Standards

Addition:

This Particular Standard also refers to IEC 60601-1-2, which is applicable unless otherwise stated in a particular clause or subclause.

2 Terminology and definitions

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

2.1.3 ACCESSORY

Addition:

separate programmers are regarded as ACCESSORIES and therefore a component part of the EQUIPMENT

2.1.5 APPLIED PART

Replacement:

entirety of all parts of the EQUIPMENT including the infusion liquid pathway that is intentionally in contact with the PATIENT being treated in NORMAL USE

2.2.18 PORTABLE EQUIPMENT

Replacement:

TRANSPORTABLE EQUIPMENT intended to be moved from one location to another while in use or between periods of use by one or more persons or by other means

Additional definitions:

2.101 INFUSION PUMP

EQUIPMENT intended to regulate the flow of liquids into the PATIENT under positive pressure generated by the pump

The INFUSION PUMP may be of:

— type 1: continuous infusion flow only,

— type 2: non-continuous flow only,

— type 3: discrete delivery of a BOLUS,

— type 4: type 1 combined with type 3 and/or type 2 in the same EQUIPMENT,

— type 5: PROFILE PUMP.

2.102 VOLUMETRIC INFUSION PUMP

INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time, but excluding SYRINGE PUMPS

2.103 DRIP-RATE INFUSION PUMP

INFUSION PUMP in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.104 INFUSION CONTROLLER

EQUIPMENT intended to regulate the flow of liquid into the PATIENT under positive pressure generated by gravitational force

2.105 VOLUMETRIC INFUSION CONTROLLER

INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.106 DRIP-RATE INFUSION CONTROLLER

INFUSION CONTROLLER in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT as a number of drops per unit of time

2.107 SPECIAL USE EQUIPMENT

EQUIPMENT in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in units other than those defined in 2.101 to 2.106

2.108 SYRINGE PUMP

EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of one or more single action syringe(s) or similar container(s) (e.g., where the cartridge is emptied by pushing on its plunger) and in which the delivery rate is set by the OPERATOR and indicated by the EQUIPMENT in volume per unit of time

2.109 INFUSION PUMP FOR AMBULATORY USE

EQUIPMENT intended for the controlled infusion of liquids into the PATIENT and intended to be carried continuously by the PATIENT

2.110 PROFILE PUMP

EQUIPMENT intended for controlled infusion of liquids into the PATIENT by means of a programmed sequence of delivery rates

2.111 REGION OF CONTROL

that part of the EQUIPMENT within which flow regulation, flow shut-off, or air detection occurs, within the body of the EQUIPMENT or remotely

2.112 ADMINISTRATION SET

device(s) that convey(s) liquid from the supply via the EQUIPMENT to the PATIENT

2.113 PATIENT LINE

that part of the ADMINISTRATION SET between the EQUIPMENT and the PATIENT

2.114 SUPPLY LINE

that part of the ADMINISTRATION SET between the liquid supply and the EQUIPMENT

2.115 OCCLUSION ALARM THRESHOLD (PRESSURE)

value of the physical quantity at which the occlusion alarm is activated

2.116 KEEP OPEN RATE (KOR)

low predetermined rate(s) to which the EQUIPMENT reverts under specified conditions with the object of keeping the PATIENT LINE open

NOTE—The abbreviation KVO (Keep-Vein-Open Rate) is commonly used as a synonym of KOR.

2.117 FREE FLOW

flow in an ADMINISTRATION SET which is not controlled by the EQUIPMENT; for example, due to the unintended effects of gravity by the removal of the ADMINISTRATION SET from the EQUIPMENT

2.118 ADMINISTRATION SET CHANGE INTERVAL

time recommended by the manufacturer of the EQUIPMENT for using the ADMINISTRATION SET

2.119 BOLUS

discrete quantity of liquid which is delivered in a short time

2.120* INTERMEDIATE RATE defined as follows:

— for VOLUMETRIC INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS, set the rate to 25 mL/h;

— for DRIP-RATE INFUSION PUMPS and DRIP-RATE INFUSION CONTROLLERS, set the rate to 20 drops/minute;

— for SYRINGE PUMPS, set the rate to 5 mL/h;

— for SPECIAL USE EQUIPMENT and INFUSION PUMPS for ambulatory use, set the rate specified by the manufacturer as typical for the EQUIPMENT.

2.121* MINIMUM RATE

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

2.122 MAXIMUM INFUSION PRESSURE

maximum pressure which can be generated by the EQUIPMENT under conditions of total occlusion at the end of the PATIENT LINE

2.123 PATIENT END

that end of the PATIENT LINE where connection to the PATIENT takes place

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

3 General requirements

This clause of the General Standard applies, except as follows:

3.6* *Addition:*

SINGLE FAULT CONDITIONS occurring in those protective systems specified in 51.5 and 51.102 shall become obvious to the OPERATOR within the ADMINISTRATION SET CHANGE INTERVAL. SINGLE FAULT CONDITIONS occurring in the protective system specified in clause 51.103 shall cause the cessation of delivery and the generation of an alarm within a time

interval less than the volume of the ADMINISTRATION SET between the air detector and the venous cannula connected to it divided by the maximum flow rate of the pump.

NOTE—Acceptable methods of complying with this requirement are, for example:

1) a safety system check initiated and controlled by the EQUIPMENT, first at the beginning of the ADMINISTRATION SET CHANGE INTERVAL, and then repeated continuously as warranted;

2) one or more protective systems checks initiated by the OPERATOR and controlled by the EQUIPMENT within the ADMINISTRATION SET CHANGE INTERVAL, with the OPERATOR initiating checks before or during the infusion;

3) a safety system check carried out by the OPERATOR at least once within the ADMINISTRATION SET CHANGE INTERVAL (see 6.8.2 a) 24)).

The following are not regarded as SINGLE FAULT CONDITIONS, but are regarded as NORMAL USE CONDITIONS:

— leakage from the ADMINISTRATION SET and/or the liquid supply;

— depletion of the INTERNAL ELECTRICAL POWER SOURCE;

— mispositioning and/or incorrect filling of a drip chamber;

— air in the SUPPLY LINE or the REGION OF CONTROL;

— pulling on the PATIENT LINE (see ISO 8536-4).

5 Classification

This clause of the General Standard applies, except as follows:

5.2 *Amendment:*

Delete TYPE B APPLIED PART;

5.6 *Amendment:*

Delete all except for CONTINUOUS OPERATION.

6 Identification, marking, and documents

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

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

aa) If detachable liquid reservoirs or PATIENT LINE(S) of specific sizes or brands, or containing specific concentrations of drugs need to be used to maintain safe NORMAL USE of the EQUIPMENT, then relevant markings shall be fixed or indicated in a prominent place on the EQUIPMENT which either identify those conditions or provide location of such information.

Compliance is checked by inspection.

6.1 q) *Physiological effects*

Replacement:

The body of the EQUIPMENT shall be marked with the following:

1) symbol No. 14 of Appendix D of the General Standard or a statement to refer the OPERATOR to the ACCOMPANYING DOCUMENTS;

2) an arrow or other appropriate symbol indicating the correct direction of flow if the ADMINISTRATION SET can be incorrectly loaded;

3) EQUIPMENT as defined in 2.103 and 2.106 shall additionally be marked as follows:

“Caution: this equipment controls the drip rate, not the volume delivered.”

Additional items:

6.1.201 of the Collateral Standard IEC 60601-1-2

Addition:

Compliance is checked by inspection.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

a) *Addition:*

The instructions for use shall also include the following:

1) a list of the recommended ADMINISTRATION SET(S) to be used;

2) a warning of the consequences of the use of unsuitable ADMINISTRATION SET(S);

3) a list of particular ACCESSORIES recommended by the manufacturer for use with the EQUIPMENT;

4) permitted EQUIPMENT orientation and methods and precautions concerning its mounting, for example, stability on a pole;

5) instructions regarding loading, priming, changing, and reloading the ADMINISTRATION SET(S), and the ADMINISTRATION SET CHANGE INTERVAL to maintain the specified performance;

6) instructions regarding the use of clamps on an ADMINISTRATION SET, the avoidance of FREE FLOW conditions, and the procedure to be followed when changing liquid containers;

7) where gravity is relevant to performance, the acceptable height range of the liquid container above the PATIENT's heart;

8) the means provided to protect the PATIENT from air infusion;

9) a statement of the MAXIMUM INFUSION PRESSURE generated and the OCCLUSION ALARM THRESHOLD (PRESSURE)(S) of the EQUIPMENT;

10) a statement of the maximum time for activation of the occlusion alarm when the EQUIPMENT is operating at the MINIMUM RATE and the INTERMEDIATE RATE and at the minimum and maximum selectable OCCLUSION ALARM THRESHOLD (PRESSURE)(S);

11) a statement of the BOLUS volume generated as a result of the EQUIPMENT operating at the INTERMEDIATE RATE and reaching the minimum and maximum OCCLUSION ALARM THRESHOLD (PRESSURE) (see also 51.5 b));

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

13) a statement to indicate to the OPERATOR if the EQUIPMENT cannot be used as PORTABLE EQUIPMENT;

14) precautions required with drop detectors; for example, with respect to placement, cleanliness, liquid level, ambient light;

15) recommendations on any specific method of cleaning and maintaining the EQUIPMENT;

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 min;

17) a statement of KEEP OPEN RATE(S), and when initiated;

18) a list of alarms and their operating conditions;

19) * warning that under certain circumstances the specified accuracy may not be maintained;

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.

20) * reference to a guide on the SAFETY HAZARDS associated with the interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE;

21) the rate obtained when the prime/purge or BOLUS control is operated, and a statement of any alarm disabled;

22) a warning statement on the possible SAFETY HAZARDS associated with external radio frequency interference (RFI) or electromagnetic radiation which may affect the safe operation of the EQUIPMENT. This statement should include examples of typical EQUIPMENT which may generate such radiation;

23) the SELECTABLE RATE range and the increments of selection;

24) guidance on tests to permit the OPERATOR to check the correct functioning of alarm(s) and the operational safety of the EQUIPMENT;

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;

26) the time for which the electronic memory is retained following switch-off;

27) for SPECIAL USE EQUIPMENT, the conversion factor(s) for volume divided by unit of time;

28) * the maximum volume that may be infused under SINGLE FAULT CONDITIONS;

29) guidance on the safe operation of the EQUIPMENT if it is connected operationally to a remote control device;

30) information concerning type(s) of battery to be used and where available;

31) a statement of the meaning of claimed IP-classification;

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;

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

6.8.201 of IEC 60601-1-2

Addition:

6.8.3.201 Technical description

Addition:

The technical description shall additionally include the following:

aa) the sensitivity of the air detector, if included to comply with 51.9, over the specified range of rates for a single bubble;

bb) the units of measurement used for calibration of the EQUIPMENT;

cc) a description of any battery charging system;

dd) a functional description of the means provided to protect the PATIENT from EQUIPMENT error resulting in overinfusion and, where applicable, in underinfusion;

ee) a manufacturer's disclosure of the ADMINISTRATION SET(S) used for all of the tests in this standard;

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

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

SECTION TWO—ENVIRONMENTAL CONDITIONS

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

10 Environmental conditions

This clause of the General Standard applies, except as follows:

Replacement:

10.2.1 a) An ambient temperature between +5 °C and +40 °C.

10.2.1 b) A relative humidity between 20 % and 90 %.

SECTION THREE—PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

14 Requirements related to classification

This clause of the General Standard applies, except as follows:

Replacement:

14.6 b) EQUIPMENT shall be of Type BF or CF.

14.6 d) EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTS OF TYPE CF may have one or more additional APPLIED PARTS OF TYPE BF which may be applied simultaneously if the requirements of 6.1 l) and 19.3 for such EQUIPMENT have been met.

17 Separation

This clause of the General Standard applies, except as follows:

Item c) is not applicable.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies, except as follows:

19.4 Tests:

d) Measuring arrangement

Addition:

3) Measurement of the PATIENT LEAKAGE CURRENT shall be made from the APPLIED PART with the PATIENT LINE filled with saline solution (0.9 % NaCl), and with the PATIENT connection immersed in a container of saline solution (0.9 % NaCl) as indicated in Figures 101 and 102.

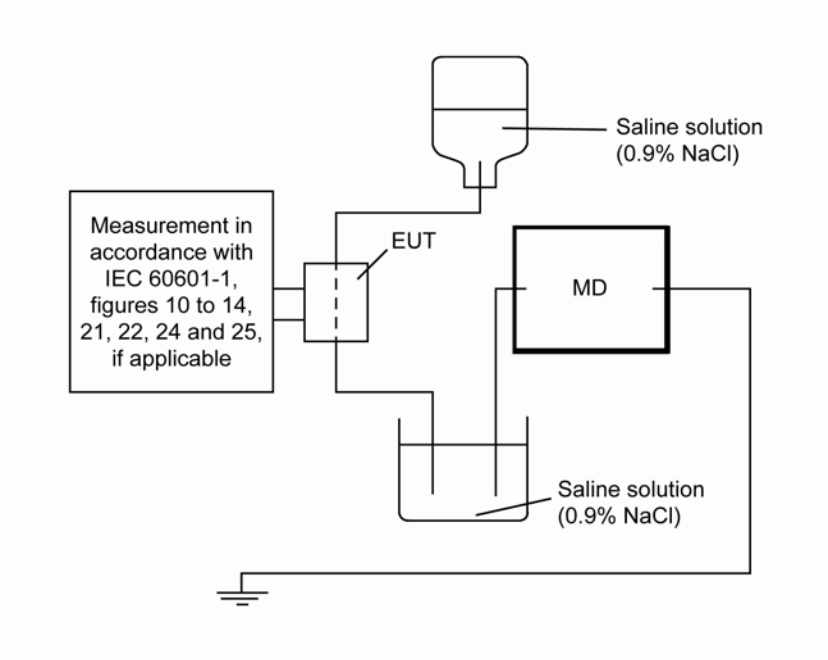

Figure 101—PATIENT LEAKAGE CURRENT external power supply

(MD = measuring device, EUT = equipment under test)

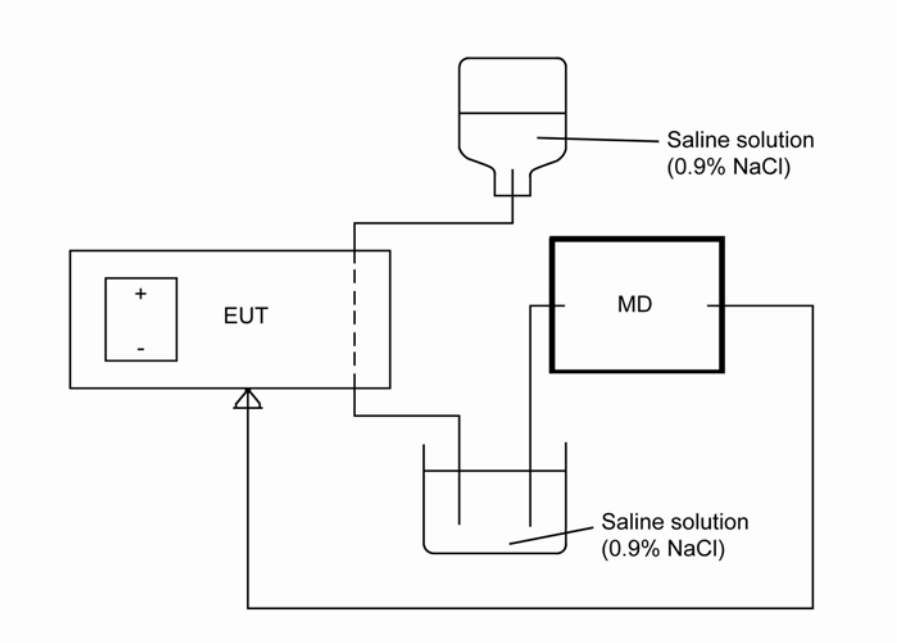

Figure 102—PATIENT LEAKAGE CURRENT—INTERNAL ELECTRICAL POWER SOURCE

h) Measure of PATIENT LEAKAGE CURRENT

Addition:

h) Measurement of PATIENT LEAKAGE CURRENT in a SINGLE FAULT CONDITION shall be performed utilizing the method described in 19.4 d) 3) of this Particular Standard.

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

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

21 Mechanical strength

This clause of the General Standard applies, except as follows:

21.1 *Replacement:*

EQUIPMENT shall not present a SAFETY HAZARD to the PATIENT as a result of external vibration. This requirement applies only to PORTABLE EQUIPMENT.

Compliance is checked by inspection and the following test:

Fit the EQUIPMENT with the manufacturer's recommended ADMINISTRATION SET and ACCESSORIES. Apply vibrations in a vertical direction and consecutively in two other directions perpendicular to each other in a horizontal plane and in accordance with the values given in Table 101.

Table 101—Vibration value

Frequency range Hz	Displacement or acceleration (peak value)	Number of sweep cycles in each direction
3 to 8	7.5 mm	4
8 to 300	2 g	4

Applied with a sweep rate of 1 octave/min.

21.4 *Replacement:*

REMOTE PARTS including MAINS OPERATED adapters and parts not specified in 21.5 shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface. Subsequent to the fall of the REMOTE PART, when the EQUIPMENT is turned on for use, it shall either:

— function normally, or

— cease delivery and activate an alarm.

Compliance is checked by the following test:

The sample to be tested is allowed to fall freely once from each of three different starting attitudes from a height of l m onto a 50 mm thick hardwood board (e.g., hardwood with a density greater than 700 kg/m^3) which lies flat on a rigid base (concrete block). After this test, no LIVE parts shall become accessible. Cracks not visible to the naked eye and surface cracks in fiber reinforced moldings and the like shall be ignored. If the EQUIPMENT is operational after the test, a dielectric strength test and LEAKAGE CURRENT tests according to clauses 19 and 20 and FUNCTIONAL TESTS at the INTERMEDIATE RATE shall be carried out.

21.6 *Addition:*

INFUSION PUMPS FOR AMBULATORY USE shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.

Compliance is checked by the test of 21.4.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

36* Electromagnetic compatibility

This clause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

36.201* **EMISSIONS**

36.201.1 Radio frequency (RF) EMISSIONS

36.201.1.3* This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.4* This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

Only paragraph 2 of the Collateral Standard IEC 60601-1-2 applies.

36.201.1.5* This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.6 High-frequency surgical EQUIPMENT

This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply.

36.201.1.7*

36.201.2.1* VOLTAGE FLUCTUATIONS and harmonic distortion

36.201.2.2* Magnetic field EMISSIONS

36.202* IMMUNITY

Addition:

The safe functioning of the EQUIPMENT as specified by the manufacturer shall not be impaired by one or more of the IMMUNITY tests, or the EQUIPMENT shall fail without creating a SAFETY HAZARD by these tests. In the latter case, the (non-hazardous) failure mode and the failure level to worst case shall be specified by the manufacturer.

Compliance is checked by the following test:

Set up the EQUIPMENT in NORMAL USE according to the manufacturer's instructions for use. Switch on the EQUIPMENT and select the INTERMEDIATE RATE. Carry out the test as described in this Particular Standard according to the test conditions described in this Particular Standard. By inspection and FUNCTIONAL TESTS, determine compliance with the additional requirement formulated in the previous paragraph. (In case of doubt and if the EQUIPMENT still continues to infuse liquid, carry out a FUNCTIONAL TEST without changing any of the previously selected parameters, for a period of 1 h.) Switch the EQUIPMENT off and then on again. Select the INTERMEDIATE RATE and carry out another FUNCTIONAL TEST for a period of 1 h.

36.202.1* ELECTROSTATIC DISCHARGE

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows (see Annex AA also):

Amendment:

A level of 8 kV shall apply for contact discharge and a level of 15 kV shall apply for air discharge.

36.202.2 Radiated radiofrequency electromagnetic field

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

36.202.2.1 Requirements

a)* This item applies except as follows:

The applicable level is not 3 V/m but 10 V/m.

b)* This item does *not* apply.

c)* This item does *not* apply.

d)*

36.202.2.2* Test conditions

c) This item does *not* apply.

e)* This item does *not* apply.

36.202.4* VOLTAGE DIPS, short interruptions, and voltage variations on power supply input lines

36.202.5* Conducted disturbances, induced by radio-frequency fields above 9 kHz

36.202.6* Magnetic fields

This subclause of the Collateral Standard IEC 60601-1-2 applies, except as follows:

Amendment:

Level: 400 A/m

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

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

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

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

This clause of the General Standard applies, except as follows:

44.3 Spillage

Replacement:

If an IPX1-classification or better is not claimed:

Replacement:

The EQUIPMENT shall be so designed that, taking into consideration aging and rough handling of the EQUIPMENT, in the event of spillage (accidental wetting) no liquid is retained within the EQUIPMENT ENCLOSURE and the EQUIPMENT shall either continue to function normally or cease delivery and activate an alarm.

Compliance is checked by the following test:

Use the test in accordance with IEC 60529 with a test apparatus for DRIP-PROOF EQUIPMENT.

Place the EQUIPMENT in the position of NORMAL USE. Subject the EQUIPMENT to an artificial rainfall of 3 mm/min for 30 s, falling vertically from a height of 0.5 m above the top of the EQUIPMENT. Carry out the test using tap water. Covers and other parts, for example battery compartment covers, which can be removed without the aid of a TOOL are left in position during the test. Where carrying pouches are specified by the manufacturer as forming part of the protection against spillage, then the test is carried out with the EQUIPMENT in the carrying pouch. Where no such specification exists, then the carrying pouch is removed prior to the start of the test. Immediately after the 30 s exposure, remove visible moisture from the body of the EQUIPMENT. Immediately after the above test, determine by inspection that the water has not entered the EQUIPMENT. If water has entered the EQUIPMENT, repeat the test using saline solution (0.9 % NaCl). Carry out a FUNCTIONAL TEST at the INTERMEDIATE RATE for a period of 1 h. Carry out the dielectric strength tests specified in 20.4.

44.4* Leakage

Replacement:

EQUIPMENT shall be so constructed that liquid which might leak from containers, tubing, couplings, and the like does not impair the safe functioning of the EQUIPMENT nor wet uninsulated LIVE parts or electrical insulation which is liable to be adversely affected by such a liquid.

Compliance is checked by the following test:

Set up the EQUIPMENT in NORMAL USE and according to the manufacturer's instructions for use. By means of a pipette, apply drops of the test solution to couplings, tubing connectors, seals, and to parts of the ADMINISTRATION SET which might rupture. Moving parts are in operation or at rest, whichever is the most unfavorable.

Immediately after application of the test solution, carry out the test(s) from 50.102 to 50.108 according to the classification of the EQUIPMENT, at the INTERMEDIATE RATE only. If the EQUIPMENT does not fall into one of the defined categories, then use the appropriate test from 50.102 to 50.108. Carry out the tests of 51.103 and 51.104. Switch off the EQUIPMENT and allow it to stand for a minimum of 12 h under normal conditions (20 °C ± 2 °C, 65 % ± 5 % RH). By means of FUNCTIONAL TESTS, determine that FREE FLOW does not occur. By inspection, check the function of controls and other parts which may have been adversely affected by the test solution.

Carry out the test with a test solution consisting of a 50 % dextrose solution.

44.6 Ingress of liquids

Addition:

If an IPX1-classification is claimed:

Covers and other parts, for example, battery compartment covers, which can be removed without the aid of a TOOL are left in position during the test. Where carrying pouches are specified by the manufacturer as forming part of the protection against ingress of liquids, then the test is carried out with the EQUIPMENT in the carrying pouch. Where no such specification exists, then the carrying pouch is removed prior to the test.

47 Electrostatic charges

Not used. Transferred to clause 36.

49 Interruption of the power supply

This clause of the General Standard applies, except as follows:

49.2

Additions:

EQUIPMENT powered from the SUPPLY MAINS only shall give an audible alarm in the event of an accidental disconnection or a SUPPLY MAINS failure. Under such conditions, the audible alarm shall be maintained for at least 3 min or until power is restored, whichever is less.

Compliance is checked by inspection and FUNCTIONAL TESTS.

EQUIPMENT which utilizes an INTERNAL ELECTRICAL POWER SOURCE either as a primary or standby supply shall give an audible and visible warning 30 min before delivery ceases due to battery exhaustion. During this period, the EQUIPMENT shall give a continuous visible and an intermittent audible warning.

At least 3 min before the end of the battery life, the EQUIPMENT shall give an audible and visible alarm and cease delivery. The alarm shall be maintained for the duration of the remaining battery lifetime.

Compliance is checked by inspection and FUNCTIONAL TESTS when the EQUIPMENT is operated at the INTERMEDIATE RATE and with a fully charged battery.

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

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

50 Accuracy of operating data

This clause of the General Standard applies, except as follows:

Additions:

50.101* The EQUIPMENT shall maintain the manufacturer's stated accuracy or better over the recommended ADMINISTRATION SET CHANGE INTERVAL.

Compliance is checked, using the tests prescribed in 50.102 to 50.108, to verify the accuracy of the EQUIPMENT according to its defined type and the manufacturer's disclosure of accuracy. If the EQUIPMENT does not fall into one of the defined categories, use the appropriate test from 50.102 to 50.108.

Definition of terms given in 50.102 to 50.108:

rate *r*	the delivery rate selected by the OPERATOR
flow	the measured output in volume per unit of time
BOLUS	a discrete quantity of liquid which is delivered in a short time as an infusion but not part of a priming routine
sample interval *S*	the time between successive mass readings or drop counts
test period *T*	the total duration of the test from start to finish
analysis period T_0	designated as the first 2 h of the test period
analysis period T_1	designated as the second hour of the test period
analysis period T_2	designated as the last hour of the test period
analysis period T_X	analysis period specified as T_0, T_1, or T_2
W	the total mass
W_i	the i^{th} mass sample over a specified analysis period
W_j	mass sample at the end of a specified analysis period or test period
W_k	mass sample at the start of a specified analysis period
A	overall mean percentage flow error measured over the analysis period T_1
B	overall mean percentage flow error measured over the analysis period T_2
P	observation window duration
E_p(max.)	maximum measured error in observation window of specified duration
E_p(min.)	minimum measured error in observation window of specified duration
shot pattern	a sequence of BOLUS deliveries which may occur at regular or irregular intervals
shot cycle *I*	the minimum time between successive repetitions of the shot or the shot pattern (from the start of the first shot pattern to the start of the second shot pattern)
density *d*	density of water (0.998 g/mL at 20 °C)

50.102* Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS, and SYRINGE PUMPS

The test apparatus shown in Figures 104a and 104b is used. Carry out the tests using a test solution of ISO class III water for medical use and installing an unused ADMINISTRATION SET. Set up the EQUIPMENT with the test solution in accordance with the manufacturer's instructions for use.

Ensure that EQUIPMENT which has a non-delivery segment within its operating cycle has this segment included in the test.

Set the required rate according to Table 102. Set the sample interval *S* to 1/6 min. Begin the test period simultaneously with starting the EQUIPMENT.

Determine the test period *T*. This test period shall equal the recommended ADMINISTRATION SET CHANGE INTERVAL. Allow the EQUIPMENT to run for the test period *T*.

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).

For VOLUMETRIC INFUSION CONTROLLERS, repeat the test at the INTERMEDIATE RATE for a period of 120 min at a back pressure of −13.33 kPa (−100 mm Hg).

The manufacturer shall disclose the maximum deviation between the results under normal conditions and under back pressure conditions, if applicable.

For VOLUMETRIC INFUSION PUMPS, repeat the test at the INTERMEDIATE RATE for a period of 120 min with the supply container below the pump mechanism at a distance of 0.5 m with the same ADMINISTRATION SET.

The manufacturer shall disclose the maximum deviation between the results under normal condition and under condition of negative head-height, if applicable.

If the EQUIPMENT incorporates a BOLUS facility, carry out the tests specified in 50.106.

If the test of 50.102 cannot be applied because of design features within the EQUIPMENT, apply the most appropriate test from 50.103 to 50.108.

Calculate the actual flow Q_i for each sample interval for the analysis period T_0 (min) from equation (1) (see Figure 103).

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.

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.

Plot the following graphs using a linear scale with scale ratios as follows (see Rationale), where r is the set rate (see Figures AA.3.1 and AA.3.2):

For start-up graph, flow axis is:

maximum = 2 r

minimum = −0.2 r

scale increment = 0.2 r

time = 0 min to 120 min (10 min intervals)

For trumpet graph, flow axis is:

maximum ≥ 15 %

minimum ≥ −15 %

scale increment = 5 %

time = 0 min to 31 min (1 min intervals)

Plot flow Q_i (mL/h) against time T_0 (min) for the first 2 h of the test period (see example in Figure 105). Indicate the rate by means of a broken line. Indicate flow Q_i by means of a solid line.

Plot percentage variation E_p(max.) and E_p(min.) against observation window duration P (min) and the overall mean percentage error A (derived from equation (4)) measured over the analysis period T_1 (min) of the second hour of the test period. See example in Figure 106. Label only data points at 2, 5, 11, 19, and 31 min intervals.

Indicate E_p(max.) and E_p(min.) and the overall mean percentage error A by means of a solid line. Indicate the zero error by means of a dotted line.

Plot percentage variation E_p(max.) and E_p(min.) against observation window duration P (min) and the overall mean percentage error B (derived from equation (5)) measured over the analysis period T_2 (min) of the last hour of the test period. Label only data points at 2, 5, 11, 19, and 31 min intervals.

See example in Figure 107.

Indicate E_p(max.) and E_p(min.) and the overall mean percentage error B by means of a solid line. Indicate the zero error by means of a dotted line. This graph is not applicable to SYRINGE PUMPS.

FORMULAS

Calculate flow using the expression:

$$Q_i = \frac{60\,(W_i - W_{i-1})}{Sd} \text{ (mL/h)} \qquad (1)$$

i = 1, 2,.., T_0/S

where

W_i is the i^{th} mass sample from the analysis period T_0 (g) (corrected for evaporative loss);

T_0 is the analysis period (min);

S is the sample interval (min);

d is the density of water (0.998 g/mL at 20 °C).

Calculate E_p(max.) and E_p(min.) using the trumpet algorithm as follows:

For observation windows of duration P = 2, 5, 11, 19, and 31 min, within the analysis period T_x, there are a maximum of m observation windows, such that:

$$m = \frac{(t_x - P)}{S} + 1$$

where

m is the maximum number of observation windows;

P is the observation window duration;

S is the sample interval (min);

T_x is the analysis period (min).

The maximum E_p(max.) and minimum E_p(min.) percentage variations within an observation window of duration period P min are given by:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \quad (2)$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \quad (3)$$

where

$$Q_i = \frac{60\ (W_i - W_{i-1})}{Sd}\ \text{(mL/h)}$$

W_i is the i^{th} mass sample from the analysis period T_x (g) (corrected for evaporative loss);

r is the rate (mL/h);

S is the sample interval (min);

P is the observation window duration (min);

d is the density of water (0.998 g/mL at 20 °C).

Calculate the overall mean percentage flow error A using the following expression where A is measured over the analysis period T_1 (the second hour of the test period):

$$A = \frac{100\,(Q - r)}{r} (\%) \quad (4)$$

where

$$Q = \frac{60\,(W_j - W_k)}{T_1 d}\ \text{(mL/h)}$$

r is the rate (mL/h);

W_j is the mass sample at the end of the analysis period T_1 (g) (j = 240);

W_k is the mass sample at the start of the analysis period T_1 (g) (k = 120);

T_1 is the analysis period (min);

d is the density of water (0.998 g/mL at 20 °C).

Calculate the overall mean percentage flow error B using the following expression where B is measured over the analysis period T_2 (the last hour of the test period):

$$B = \frac{100\,(Q - r)}{r}(\%) \qquad (5)$$

where

$$Q = \frac{60\,(W_j - W_k)}{T_2 d}\ \text{(mL/h)}$$

r is the rate (mL/h);

W_j is the mass sample at the end of the test period T_2 (g) (corrected for evaporative loss);

W_k is the mass sample at the start of the analysis period T_2 (g) (corrected for evaporative loss);

T_2 is the analysis period (min);

d is the density of water (0.998 g/mL at 20 °C).

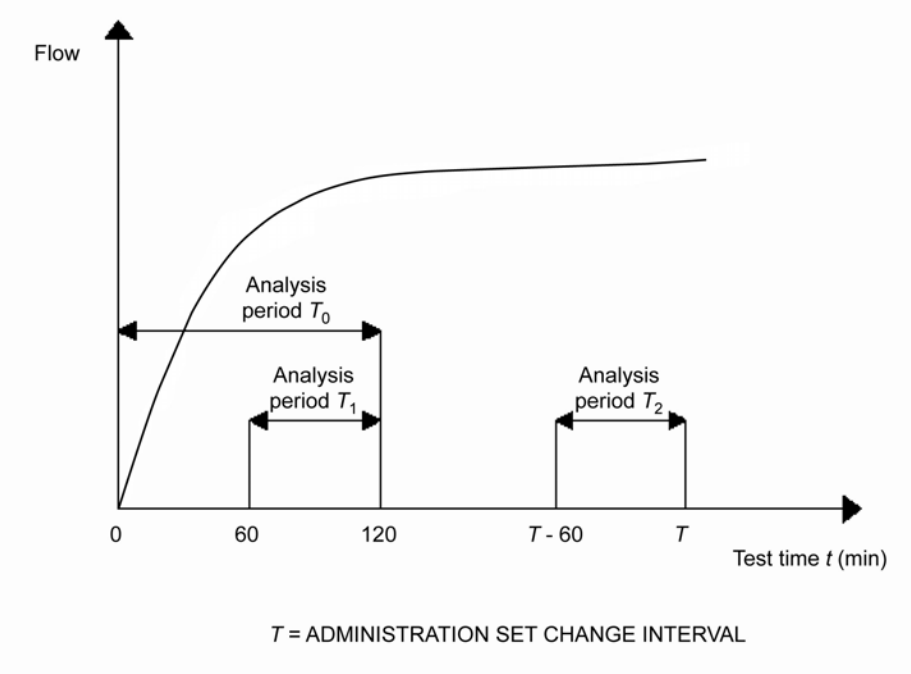

Figure 103—Analysis periods

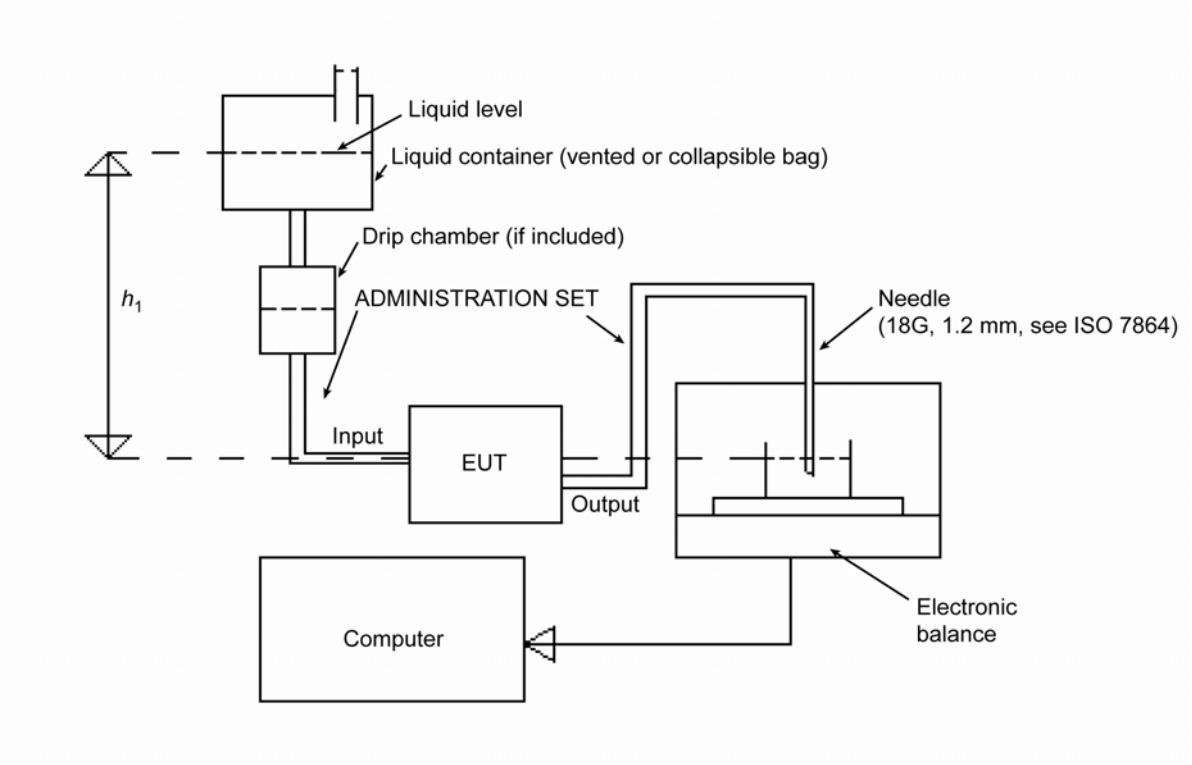

Figure 104a—Test apparatus for VOLUMETRIC INFUSION PUMPS and VOLUMETRIC INFUSION CONTROLLERS

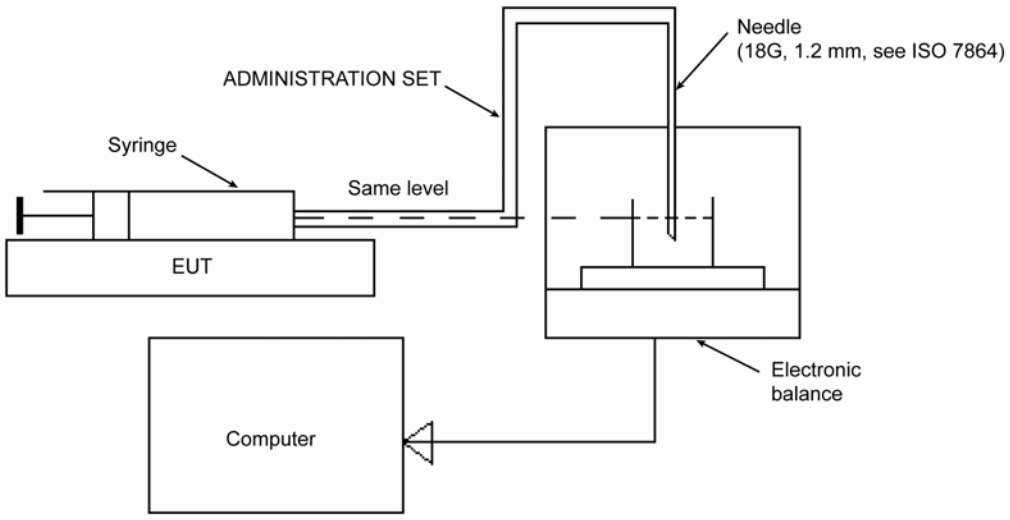

Figure 104b—Test apparatus for SYRINGE PUMPS

NOTE—A balance accurate to five decimal places is required for PUMPS with low MINIMUM RATES.

Set height h_1 (collapsible bag, vented container) in accordance with the manufacturer's instructions for use. The needle (18 G, 1.2 mm, ISO 7864) shall be positioned below the liquid surface.

The mean center line of the pumping chamber to be at the same height as the tip of the needle (18 G, 1.2 mm, ISO 7864).

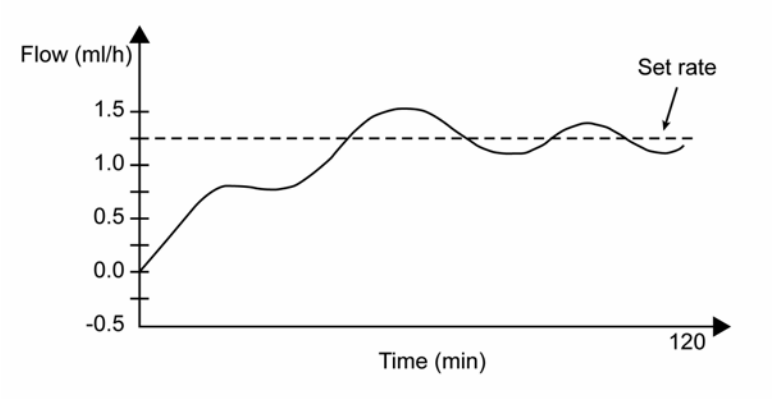

Figure 105—Start-up graph plotted from data gathered during the first 2 h of the test period

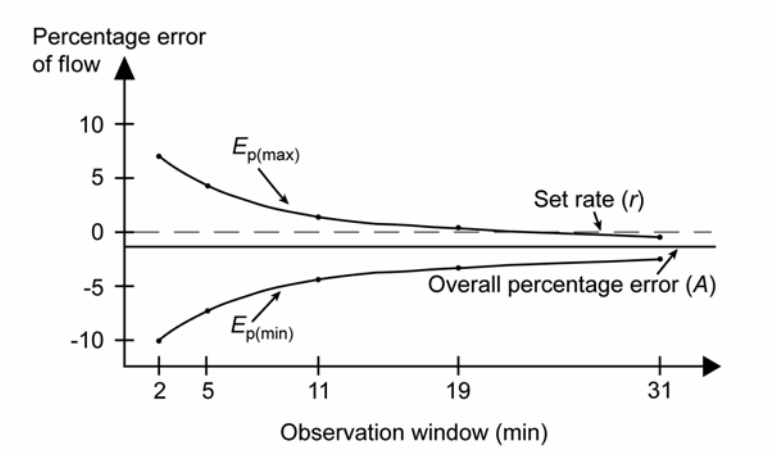

Figure 106—Trumpet curve plotted from data gathered during the second hour of the test period

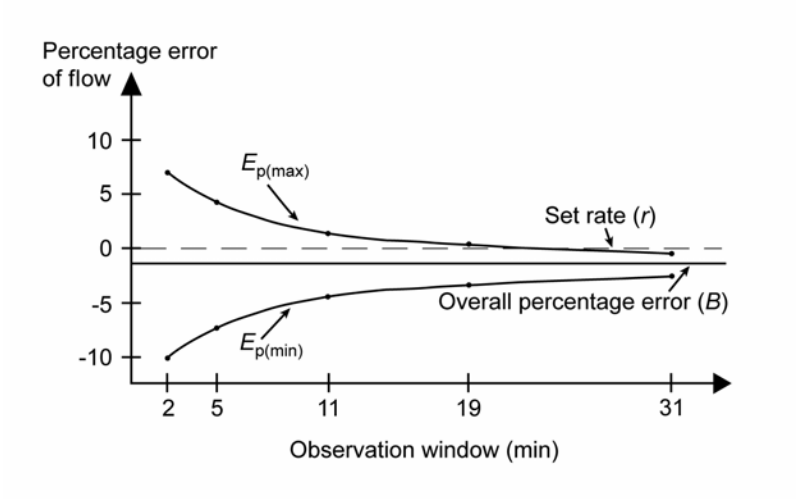

Figure 107—Trumpet curve plotted from data gathered during the last hour of the ADMINISTRATION SET CHANGE INTERVAL

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

The test apparatus shown in Figure 108 is used. Carry out the tests using a test solution of ISO class III water for medical use and installing an unused ADMINISTRATION SET. Set up the EQUIPMENT with the test solution in accordance with the manufacturer's instructions for use. Set the required drip rate according to Table 102. Set the sample interval to 1 min.

Begin the test period simultaneously with starting the EQUIPMENT.

Determine the test period T. If there is sufficient fluid in the container, this test period shall equal the recommended ADMINISTRATION SET CHANGE INTERVAL. If there is insufficient fluid, the duration of the test period shall be calculated by dividing the total fluid volume by the rate. Allow the EQUIPMENT to run for the test period T.

For DRIP-RATE INFUSION CONTROLLERS, repeat the tests at the INTERMEDIATE RATE for a period of 120 min against a back pressure of −13.33 kPa (−100 mm Hg).

Compare the results obtained under back pressure conditions with those obtained previously. If the results show a significant deviation outside the tolerance in the ACCOMPANYING DOCUMENTS, then check that a warning statement is included in the ACCOMPANYING DOCUMENTS.

Calculate the actual drip rate Q_i at each sample interval for the analysis period T_0 from equation (1) (see Figure 103).

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.

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.

For DRIP-RATE INFUSION PUMPS, only repeat the tests at the INTERMEDIATE RATE for a period of 120 min against back pressures of ± 13.33 kPa (± 100 mm Hg).

Plot the following graphs:

a) Drip rate Q_i (drops/min) against time t (min) for the first 2 h of the test period. See example in Figure 109. Indicate the set rate by means of a broken line. Indicate the drip rate Q_i by means of a solid line.

b) Percentage variation E_p(max.) and E_p(min.) against observation window duration P (min) and the overall mean percentage error A (derived from equation (4)) measured over the analysis period T_1 (min) of the second hour of the test period. See example in Figure 106. Indicate E_p(max.) and E_p(min.) and the overall mean percentage error A by means of a solid line. Indicate the zero error by means of a dotted line. Label only data points at 2, 5, 11, 19, and 31 min intervals.

c) Percentage variation E_p(max.) and E_p(min.) against observation window duration P (min) and the overall mean percentage error B (derived from equation (5)) measured over the analysis period T_2 of the last hour of the test period. See example in Figure 107. Indicate E_p(max.) and E_p(min.) and the overall mean percentage error B by means of a solid line. Indicate the zero error by means of a dotted line. Label only data points at 2, 5, 11, 19, and 31 min intervals.

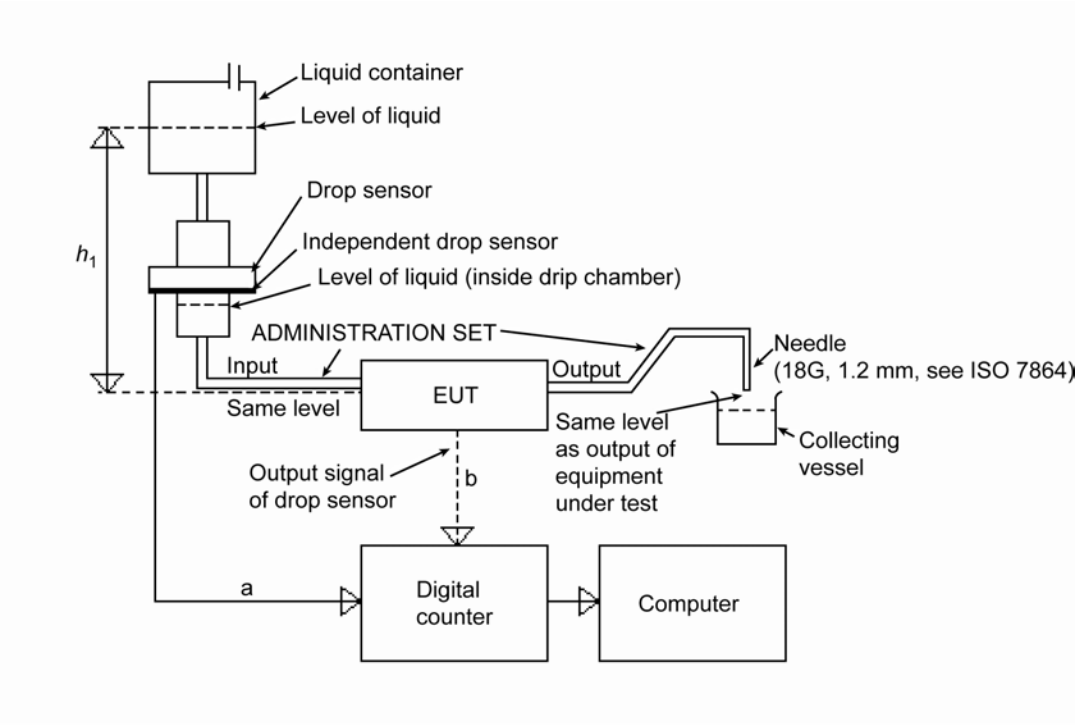

Figure 108—Test apparatus for DRIP-RATE INFUSION PUMPS and DRIP-RATE INFUSION CONTROLLERS

Set height h_1 (collapsible bag or vented container) in accordance with the manufacturer's instructions for use. Mean height of pumping chamber to be at the same height as tip of needle. Use configuration (a) if it is possible to place an independent drop detector on the drop chamber. Use configuration (b) (drop signal extracted from EUT) in other circumstances.

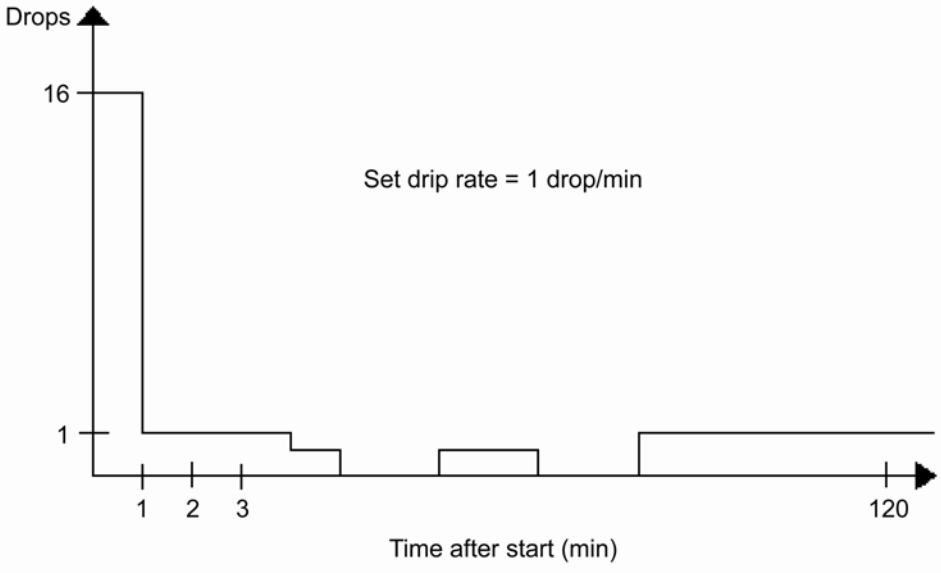

Figure 109—Start-up graph plotted from data gathered during the first 2 h of the test period

FORMULAE

Calculate the drip rate using the expression:

$$Q_i = \frac{(N_i - N_{i-1})}{S} \text{(drops/min)} \tag{6}$$

where

N_i is the i^{th} total drop count sample from the test period;

S is the sample interval (min).

Calculate E_p(max.) and E_p(min.) using the trumpet algorithm as follows:

For observation windows of duration P = 1, 2, 5, 11, 19, and 31 min, within the analysis period T_x, there are a maximum of m observation windows, such that:

$$m = \frac{(T_x - P)}{S} + 1$$

where

m is the maximum number of observation windows;

P is the observation window duration (min);

S is the sample interval (min);

T_x is the analysis period (min).

The maximum E_p(max.) and minimum E_p(min.) percentage variations within an observation window of duration period P (min) are given by:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{7}$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{8}$$

where

$Q_i = \frac{(N_i - N_{i-1})}{S}$ (drops/min)

N_i is the i^{th} total drop count sample from the analysis period T_x;

r is the drip rate (drops/min);

S is the sample interval (min);

P is the observation window duration (min).

Calculate the overall mean percentage drip rate error A using the following expression where A is measured over the analysis period T_1 (the second hour of the test period):

$$A = \frac{100(Q - r)}{r} (\%) \tag{9}$$

where

$$Q = \frac{(N_j - N_k)}{T_1} \text{ (drops/min)}$$

r is the drip rate (drops/min);

N_j is the total drop count at the end of the analysis period T_1 (j = 120);

N_k is the total drop count at the start of the analysis period T_1 (k = 60);

T_1 is the analysis period (min).

Calculate the overall mean percentage drip rate error B using the following expression where B is measured over the analysis period T_2 (the last hour of the test period):

$$B = \frac{100(Q - r)}{r} (\%) \quad (10)$$

where

$$Q = \frac{(N_j - N_k)}{T_2} \text{ (drops/min)}$$

r is the drip rate (drops/min);

N_j is the total drop count at the end of the test period T;

N_k is the total drop count at the start of the analysis period T_2;

T_2 is the analysis period (min).

50.104* Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1

The test apparatus shown in Figure 104b is used. Carry out the tests using a test solution of ISO class III water for medical use or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the EQUIPMENT in accordance with the manufacturer's instructions for use. Prime the ADMINISTRATION SET and set the EQUIPMENT for the INTERMEDIATE RATE. Start the EQUIPMENT. Set the sample interval S to 15 min. Allow the EQUIPMENT to run for a time equivalent to half of the container volume, or 24 h, whichever is the shorter as a stabilization period T_1 (min). Continue the test without stopping the EQUIPMENT for a further 25 h or until the liquid container is depleted. Measure the mass of infusate W_i delivered at each sample interval. Repeat the test at the MINIMUM RATE.

Calculate the mean flow from equation (6) for every two successive samples over the stabilization period T_1.

Calculate E_p(max.) and E_p(min.) for the 15, 60, 150, 330, 570, and 930 min observation windows from equations (7) and (8) over the analysis period T_2 (min) starting from the end of the stabilization period to the end of the test.

Plot the following graphs:

a) Flow Q_i (μL/h) against time (min) over the stabilization period T_1 at 30 min increments. Indicate the rate r (μL/h) by means of a broken line. Indicate flow Q_i by means of a solid line. See Figure 110 as an example.

b) Percentage variation E_p(max.) and E_p(min.) against observation window duration over the analysis period T_2 and the overall mean percentage error A (derived from equation (9)). Indicate the zero error by means of a broken line. Indicate E_p(max.) and E_p(min.) and the overall mean percentage error A by means of solid lines. See Figure 111 as an example.

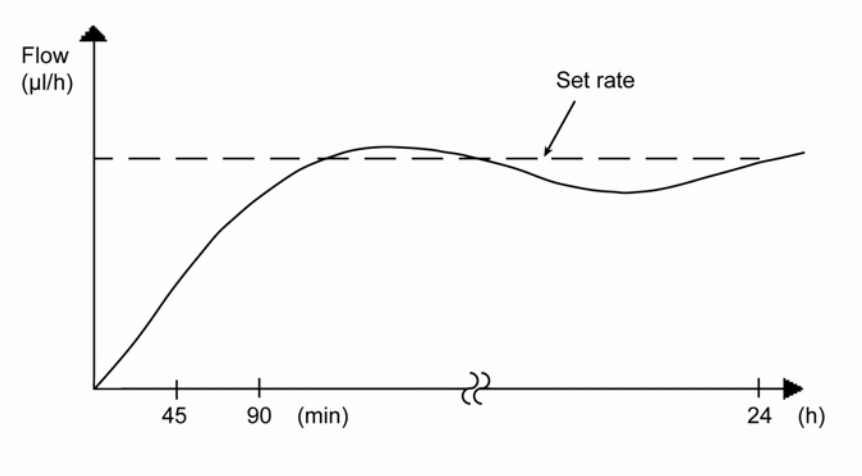

Figure 110—Start-up graph over the stabilization period

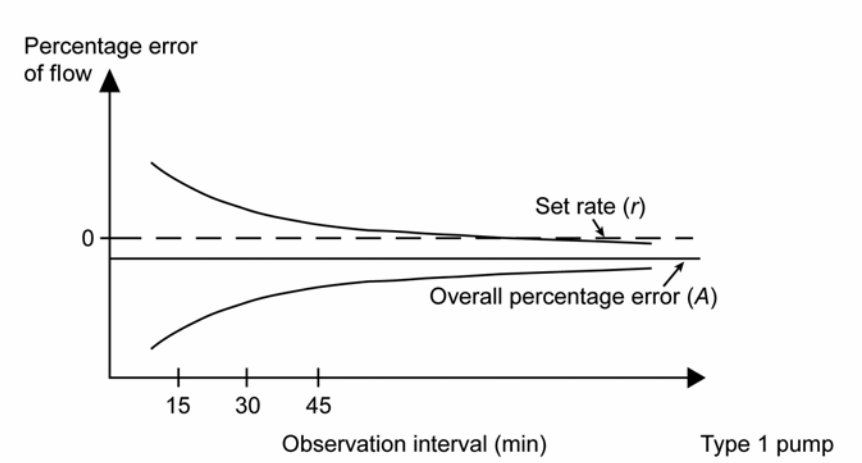

Figure 111—Trumpet curve plotted from data at the end of the stabilization period

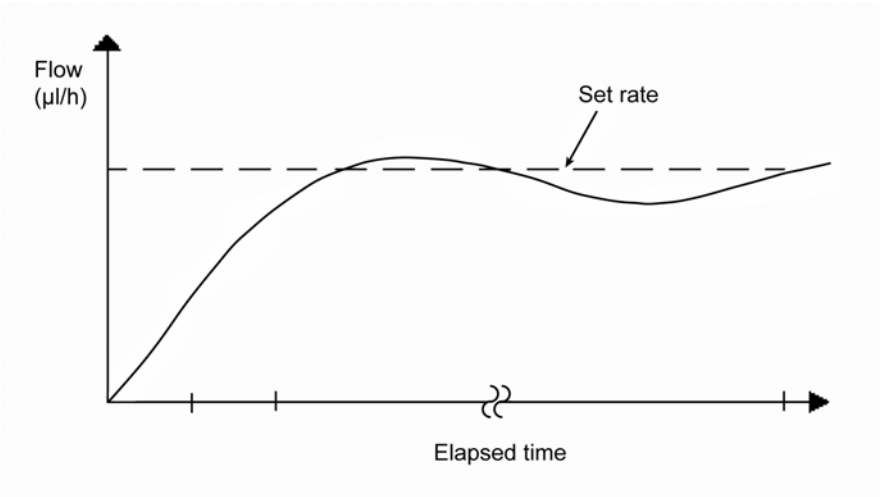

Figure 112—Start-up curve over the stabilization period for quasi-continuous output pumps

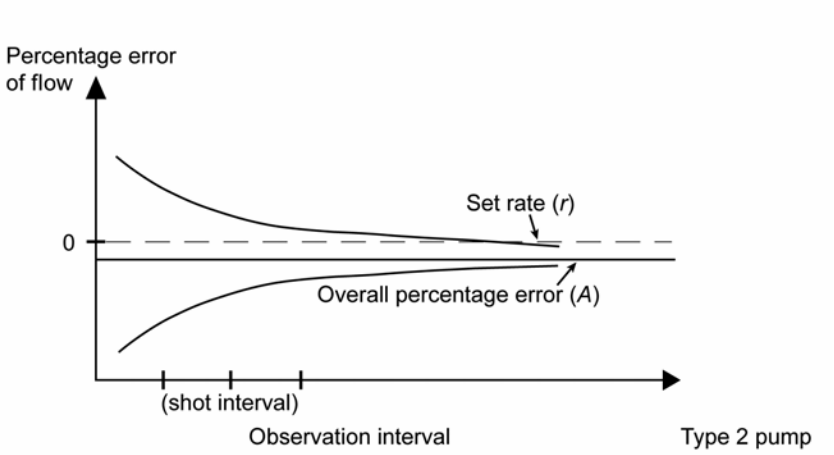

Figure 113—Trumpet curve plotted from data at the end of the stabilization period for quasi-continuous pumps

FORMULAE

Calculate flow using the expression:

$$Q_i = \frac{60\ (W_{2i} - W_{2(i-1)})}{2dS} (\mu L/h) \quad (11)$$

where

i 1, 2,.., T_1 /2S;

W_i is the i^{th} mass sample from the stabilization period T_1 (mg) (corrected for evaporative loss);

T_1 is the stabilization period (min) (≈ 24 h);

S is the sample interval (min) (15 min);

d is the density of test liquid at 20 °C (g/mL).

Calculate E_p(max.) and E_p(min.) using the trumpet algorithm as follows:

For observation windows of duration P = 15, 60, 150, 330, 570, and 930 min, within the analysis period T_2, there are a maximum of m observation windows, such that:

$$m = \frac{(T_2 - P)}{S} + 1$$

where

m is the maximum number of observation windows;

P is the observation window duration (min);

T_2 is the analysis period (min);

S is the sample interval (min) (15 min).

The maximum E_p(max.) and minimum E_p(min.) percentage variations, within an observation window of duration period P (min), are given by:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{12}$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{13}$$

where

$$Q_i = \frac{60\,(W_i - W_{i-1})}{Sd} \text{ (mL/h)}$$

W_i is the i^{th} mass sample from the analysis period T_2 (mg) (corrected for evaporative loss);

r is the set rate (μL/h);

S is the sample interval (min);

P is the observation window duration (min);

d is the density of test liquid at the test temperature (g/mL).

Calculate the overall percentage flow error A using the following expression, where A is measured over the analysis period T_2:

$$A = \frac{100\,(Q - r)}{r} (\%) \tag{14}$$

where

$$Q = \frac{60\,(W_j - W_k)}{T_2 d} (\mu\text{L/h})$$

r is the set rate (μL/h);

W_j is the mass sample at the end of the analysis period T_2 (mg);

W_k is the mass sample at the start of the analysis period T_2 (mg);

T_2 is the analysis period (min);

d is the density of test liquid at the test temperature (g/mL).

50.105* Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 2

The test apparatus shown in Figure 104b is used. Carry out the tests using a test solution of ISO class III water for medical use or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the EQUIPMENT in accordance with the manufacturer's instructions for use. Prime the ADMINISTRATION SET.

Determine the shot pattern of the pump output. Derive the shot cycle. Measure the time taken (in minutes) for 20 successive shot cycles at the INTERMEDIATE RATE (and ensure that there is sufficient liquid in the container for the subsequent 100 shots after the stabilization period).

Calculate the mean duration of the shot cycle *I* (min).

Derive sample interval *S* corresponding to the INTERMEDIATE RATE shot cycle *I*.

If the shot cycle *I* is greater than 0.5 min, then:

$$S = kI$$

where

S is the sample interval;

I is the shot cycle;

k is the integer constant = 1.

If the shot cycle *I* is less than 0.5 min, then

$$S = kI$$

where

S is the sample interval;

I is the shot cycle;

k is the minimum integer constant giving k*I* approximately equal to 0.5 min.

Synchronize the measuring EQUIPMENT to measure the mass of infusate delivered in successive sequences of k shot cycles.

Set the EQUIPMENT for the INTERMEDIATE RATE.

Start the EQUIPMENT. Allow the EQUIPMENT to run for a time equivalent to half of the container volume or 24 h, whichever is the shorter, as a stabilization period T_1 (min). Continue the test without stopping the EQUIPMENT for a further 100 sample intervals.

Measure the mass of infusate W_i delivered at each sample interval.

Choose any integer n such that:

$$nS \approx 30 \text{ (min)}$$

where

S is the sample interval (k*I*) (min);

n is the integer constant.

Calculate the mean flow from equation (15) for every successive n*S* sample, over the stabilization period T_1.

Calculate E_p(max.) and E_p(min.) for $P = S$, $2S$, $5S$, $11S$, $19S$, and $31S$ min observation windows from equations (16) and (17) over the analysis period T_2 starting from the end of the stabilization period to the end of the test.

Plot flow as a function of elapsed time over the stabilization period T_1 defined above. Indicate the rate on the graph by means of a broken line. See Figure 112 as an example.

Plot percentage variation E_p(max.) and E_p(min.) against observation window duration, over the analysis period T_2 and the overall mean percentage error *A* (derived from equation (18)).

Indicate the zero error by means of a broken line. Indicate E_p(max.) and E_p(min.) and the overall mean percentage error A by means of solid lines. See Figure 113 as an example.

FORMULAE

Calculate flow using the expression:

$$Q_i = \frac{60\,(W_{ni} - W_{n(i-1)})}{ndS}\ (\mu L/h) \tag{15}$$

where

I = 1,2,.., T_1/nS;

W_i is the i^{th} mass sample from the stabilization period T_1 (mg) (corrected for evaporative loss);

T_1 is the stabilization period (min) (≈ 24 h);

S is the sample interval (min) (kI min);

n is the integer constant (nS ≈ 30 min);

d is the density of test liquid at the test temperature (g/mL).

Calculate E_p(max.) and E_p(min.) using the trumpet algorithm as follows:

For consecutive observation windows P = S, 2S, 5S, 11S, 19S, and 31S min, within the analysis period T_2, there are a maximum of m successive samples such that:

$$m = \frac{(T_2 - P)}{S} + 1$$

where

m is the maximum number of observation windows;

P is the observation window duration (min);

T_2 is the analysis period (min);

S is the sample interval (min).

The maximum E_p(max.) and minimum E_p(min.) percentage variations, within an observation window of duration period P (min), are given by:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{16}$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \times \sum_{i=j}^{j+\frac{P}{S}-1} 100 \times \left(\frac{Q_i - r}{r} \right) \right] (\%) \tag{17}$$

where

$$Q_i = \frac{60\,(W_i - W_{i-1})}{Sd}\ (\mu L/h)$$

W_i is the i^{th} mass sample from the analysis period T_2 (mg) (corrected for evaporative loss);

r is the set rate (μL/h);

S is the sample interval (min);

P is the observation window duration (min);

d is the density of test liquid at the test temperature (g/mL).

Calculate the overall percentage flow error A using the following expression, where A is measured over the analysis period T_2:

$$A = \frac{100\,(Q - r)}{r}(\%) \tag{18}$$

where

$$Q = \frac{60\,(W_j - W_k)}{T_2 d}(\mu L/h)$$

r is the set rate (μL/h);

W is the total mass (mg) (corrected for evaporative loss);

W_j is the mass sample at the end of the analysis period T_2 (mg);

W_k is the mass sample at the start of the analysis period T_2 (mg);

T_2 is the analysis period (min);

d is the density of test liquid at the test temperature (g/mL).

50.106* Accuracy tests for pumps type 3

The test apparatus shown in Figure 104a or 104b is used (as appropriate) using a test solution of ISO class III water for medical use or a liquid which can be expected to give similar test results and installing an unused ADMINISTRATION SET. Set up the EQUIPMENT with the recommended ADMINISTRATION SET in accordance with the manufacturer's instructions for use. Set the EQUIPMENT to supply a BOLUS at the minimum setting. Start the EQUIPMENT and weigh 25 successive BOLUS deliveries either demanded manually or by program.

Calculate the mean and the percentage deviation from the set value. Select the deliveries with the maximum positive and maximum negative deviations from the set value. Express these as percentage deviations from the set value. Repeat the test with the EQUIPMENT at the maximum BOLUS setting.

50.107* Accuracy tests for pumps type 4

Pumps type 4 shall be tested according to 50.104, 50.105, and 50.106, as appropriate.

NOTE—Correction factors may be applicable to PUMPS FOR AMBULATORY USE type 4 where a continuous or quasi-continuous flow is maintained throughout the BOLUS delivery. These factors are disclosed in the ACCOMPANYING DOCUMENTS.

50.108* Accuracy tests for pumps type 5

Pumps type 5 shall be tested according to 50.102 to 50.106, as appropriate.

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

EQUIPMENT	Set rates				BOLUS		Test	
	Minimum	Inter-mediate	Lowest selectable[1]	Maximum selectable[2]	Minimum	Maximum	Apparatus (figure)	Sub-clause
DRIP-RATE INFUSION CONTROLLER	*	*	*	*			108	50.103
DRIP-RATE INFUSION PUMP	*	*	*	*			108	50.103
VOLUMETRIC INFUSION CONTROLLER	*	*	*	*			104a), 104b)	50.102
VOLUMETRIC INFUSION PUMP	*	*	*	*	*	*	104a), 104b)	50.102, (50.106)[3]
SYRINGE PUMP	*	*	*	*	*	*	104b)	50.102, (50.106)[3]
INFUSION PUMP FOR AMBULATORY USE								
Type 1 (continuous infusion flow only)	*	*		*			104b)	50.104
Type 2 (non-continuous flow only)		*		*			104b)	50.105
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

[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

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

51.1 Intentional exceeding of safety limits

Addition:

An example would be the priming/purge control of the EQUIPMENT.

Compliance is checked by inspection.

51.5 Incorrect output

Replacement:

a) Protection against overinfusion

Means shall be provided to prevent overinfusion under SINGLE FAULT CONDITIONS. An audible alarm shall be initiated in the event of overinfusion and the EQUIPMENT shall either cease delivery of infusion liquid or reduce the delivery rate to the KEEP OPEN RATE or less.

Compliance is checked by inspection and FUNCTIONAL TESTS.

b)* Protection against overinfusion FREE FLOW conditions

Means shall be provided to protect the PATIENT from overinfusion as a result of FREE FLOW conditions. This requirement applies as soon as the ADMINISTRATION SET is installed in the EQUIPMENT in accordance with the manufacturer's instructions for use.

Remark: Refer also to 54.102 and 54.103.

Compliance is checked by inspection and FUNCTIONAL TESTS, including, but not limited to, allowing the flow to stabilize the quick lowering of the collecting vessel by 50 cm and checking for evidence of FREE FLOW.

Additions:

51.101

a) *maximum infusion pressure*

The EQUIPMENT shall not produce a MAXIMUM INFUSION PRESSURE capable of causing a rupture or a leak in the ADMINISTRATION SET.

Compliance is checked by inspection and FUNCTIONAL TESTS.

b)* *Protection against BOLUS volumes and occlusion*

Means shall be provided to protect the PATIENT from BOLUS and underinfusion resulting from occlusion following activation of the occlusion alarm.

NOTE—An acceptable method of complying with this requirement is to activate an audible alarm and terminate the infusion liquid flow at the OCCLUSION ALARM THRESHOLD (PRESSURE).

Compliance is checked by the following test:

This test applies only to INFUSION PUMPS, VOLUMETRIC INFUSION PUMPS, DRIP-RATE INFUSION PUMPS, SPECIAL USE EQUIPMENT, and SYRINGE PUMPS.

The test apparatus shown in Figure 114 is used. Carry out the tests using a test solution of ISO class III water for medical use. Perform the test under normal conditions (20 °C ± 2 °C, 65 % ± 5 % RH). Operate the EQUIPMENT in NORMAL USE according to the manufacturer's instructions for use. Prime the ADMINISTRATION SET and the tubing connected to the pressure transducer.

Select the INTERMEDIATE RATE and the OCCLUSION ALARM THRESHOLD (PRESSURE) specified by the manufacturer. If the OCCLUSION ALARM THRESHOLD (PRESSURE) can be selected, set it to minimum. Connect the PATIENT END of the PATIENT LINE to the stopcock. Open the stopcock to the collecting vessel. Start the EQUIPMENT and allow the flow to become constant. Switch the stopcock and detect the OCCLUSION ALARM THRESHOLD (PRESSURE). Measure the time taken from switching the stopcock to activation of the occlusion alarm.

Inspect the ADMINISTRATION SET for ruptures or leaks. Empty the collecting vessel. Switch the stopcock and collect the BOLUS volume generated as a result of the occlusion until the pressure is reduced to atmospheric.

If the OCCLUSION ALARM THRESHOLD (PRESSURE) can be selected, repeat the test with it set to maximum.

If any OPERATOR action is given for 6.8.2 a) 12), a test shall be conducted of the means provided by the EQUIPMENT to release the BOLUS. This consists of performing the release as described before measuring the amount of the BOLUS remaining.

Verify by volume or mass that the result of the test is in accordance with the requirements of 51.5 a) and 51.5 b) and the disclosure statement in the ACCOMPANYING DOCUMENTS required by 6.8.2 a) 9) to 6.8.2 a) 12).

For INFUSION PUMPS FOR AMBULATORY USE, carry out the following test:

The test apparatus shown in Figure 114 is used. Carry out the tests using a test solution of ISO class III water for medical use. Perform the test under normal conditions (20 °C ± 2 °C, 65 % ± 5 % RH). Operate the EQUIPMENT in

NORMAL USE according to the manufacturer's instructions for use. Prime the ADMINISTRATION SET and the tubing connected to the pressure transducer.

Select the INTERMEDIATE RATE. Connect the PATIENT END of the PATIENT LINE to the pressure measuring system. Start the EQUIPMENT and detect the OCCLUSION ALARM THRESHOLD (PRESSURE).

Inspect the ADMINISTRATION SET for ruptures or leaks.

Stop the EQUIPMENT and disconnect the pressure measuring system. Vent the ADMINISTRATION SET to atmosphere. Close the PATIENT END of the PATIENT LINE. If the OCCLUSION ALARM THRESHOLD (PRESSURE) can be selected, set it to minimum. Restart the EQUIPMENT and wait until an occlusion alarm occurs or the EQUIPMENT stops. Collect the BOLUS volume generated as a result of the occlusion. If the OCCLUSION ALARM THRESHOLD (PRESSURE) can be selected, then repeat the test with it set to maximum. If any OPERATOR action is given for 6.8.2 a) 12), a test shall be conducted of the means provided by the EQUIPMENT to release the BOLUS. This consists of performing the release as described before measuring the amount of the BOLUS remaining. Verify by volume or mass that the result of the test is in accordance with the requirements of 51.101 a) and 51.101 b) and the disclosure statement in the ACCOMPANYING DOCUMENTS required by 6.8.2 a) 9) to 6.8.2 a) 12).

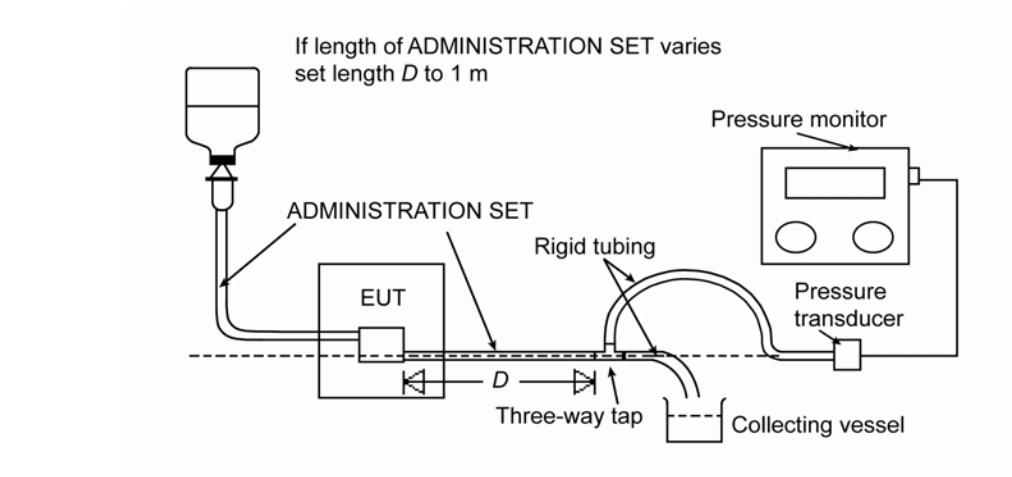

Figure 114—Test apparatus to determine the OCCLUSION ALARM THRESHOLD (PRESSURE) and BOLUS volumes

51.102 Reverse delivery

During NORMAL USE and/or SINGLE FAULT CONDITION of the EQUIPMENT, continuous reverse delivery, which may cause a SAFETY HAZARD, shall not be possible.

Compliance is checked by inspection.

51.103 EQUIPMENT and drop sensor orientation

Safe operation of the EQUIPMENT shall not be affected by:

— the mispositioning or removal of a drop sensor, and

— operating the EQUIPMENT with a tilted or incorrectly filled drip chamber.

Under these conditions, the EQUIPMENT shall either:

— maintain the accuracy of delivery, or

— stop the flow and generate an audible alarm.

Compliance is checked by the following FUNCTIONAL TEST:

Operate the EQUIPMENT in NORMAL USE according to the manufacturer's instructions for use. Select any rate. Tilt the drip chamber from the vertical to a maximum of 20° in two orthogonal planes. By inspection, determine the result of the test. By inspection, determine the effects of mispositioning, removal, or overfilling of a drip chamber.

51.104* Protection against air infusion

This requirement does not apply to SYRINGE PUMPS.

The EQUIPMENT shall protect the PATIENT from air infusion which may cause a SAFETY HAZARD due to air embolism.

Compliance is checked by inspection and FUNCTIONAL TESTS in accordance with the manufacturer's specification (see 6.8.3 e)).

After the initiation of an air detection alarm, it shall not be possible to recommence liquid delivery by a single action.

Compliance is checked by inspection and FUNCTIONAL TEST.

51.105 ADMINISTRATION SETS—Operational characteristics

Should the manufacturer allow the use of a range of ADMINISTRATION SETS with different operational characteristics, then automatic means shall be provided or manual action(s) shall be necessary to prevent incorrect output.

Compliance is checked by inspection and FUNCTIONAL TEST.

51.106 Audible and visual alarms

Unless specified elsewhere, the alarms required by this Particular Standard shall be so arranged that an audible alarm shall occur in all alarm situations.

Compliance is checked by inspection and FUNCTIONAL TEST.

51.107 Alarms required by clause 51 of this Particular Standard shall comply with the following. This requirement does not apply to INFUSION PUMPS FOR AMBULATORY USE:

a) the audible alarm shall be able to produce a sound-pressure level (or, if adjustable, a maximum level) of at least 65 dB(A) at 1 m, and shall not be by the OPERATOR externally adjustable below 45 dB(A) at 1 m;

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

c) the visual alarm shall continue to operate during the audible alarm silence period;

d) means shall be provided to enable the OPERATOR to check the operation of audible and visual alarms.

Compliance is checked by measuring the A-weighted sound pressure level, with an instrument complying with the requirements for a type 1 instrument laid down in IEC 60651 or IEC 60804, as follows:

The pump and the microphone are placed in free-field conditions (according to ISO 3744), at a height of 1.5 m from the reflecting plane. The distance between the pump and the microphone shall be 1 m. The background noise level shall be at least 10 dB(A) below the sound pressure level to be measured. During the test, microphone orientation should be toward, but in the lowest horizontal sound power direction from, the pump.

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 of operation for more than 1 h.

Compliance is checked by inspection and FUNCTIONAL TEST.

51.109 Alarms required by 51.108, 51.110, and 49.2 shall comply with the following:

a) the audible alarm shall produce a sound pressure level of at least 50 dB(A) at 1 m;

b) the audible alarm output shall not be adjustable without either the use of a TOOL or by special means (e.g., pressing a sequence of switches);

c) means shall be provided to enable the OPERATOR to check the operation of the alarms.

Compliance is checked by measuring the A-weighted sound power level, with an instrument complying with the requirements for a type 1 instrument laid down in IEC 60651 or IEC 60804, as follows.

The pump and the microphone are placed in free-field conditions (according to ISO 3744), at a height of 1.5 m from the reflecting plane. The distance between the pump and the microphone shall be 1 m. The background noise level shall be at least 10 dB(A) below the sound pressure level to be measured. During the test, microphone orientation should be toward, but in the lowest horizontal sound power direction from, the pump.

51.110 *Audible means shall be provided to indicate to the OPERATOR the end of infusion.*

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

Compliance is checked by inspection and by FUNCTIONAL TEST.

51.111 *An audible warning shall be provided prior to the end of the infusion alarm.*

This requirement applies only to SYRINGE PUMPS.

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS

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

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

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

54 General

This clause of the General Standard applies, except as follows:

54.3 Inadvertent changing of settings

Replacement:

Means shall be provided to prevent accidental or unintended changes in rate settings.

Compliance is checked by inspection.

If manual means for priming/purging are provided, no single action by the OPERATOR shall initiate priming/purging to comply with the requirement of 51.1.

Compliance is checked by inspection and FUNCTIONAL TEST.

Additions:

54.101 Fitting of the syringe

Means shall be provided to ensure correct clamping and location of a syringe barrel and plunger in the SYRINGE PUMP.

In the event of incorrect location of the plunger, the SYRINGE PUMP shall not start.

Means shall be provided to prevent syphoning under SINGLE FAULT CONDITIONS.

An alarm shall be activated if an attempt is made to remove the syringe while the SYRINGE PUMP is running.

EQUIPMENT shall be so designed that no SAFETY HAZARD to the PATIENT can occur due to pulling force on the PATIENT LINE.

Compliance is checked by inspection.

54.102 Fitting of the ADMINISTRATION SET

Where applicable, means shall be provided to ensure correct fitting of the ADMINISTRATION SET into the EQUIPMENT.

An alarm shall be activated if an attempt is made to remove the ADMINISTRATION SET while the pump is running.

EQUIPMENT shall be so designed that no SAFETY HAZARD to the PATIENT can occur due to pulling force on the PATIENT LINE.

Compliance is checked by inspection.

54.103* Human errors

At least two distinctive and separate actions shall be required before FREE FLOW can occur in NORMAL USE. The first action shall stop the flow and initiate an audible alarm. This requirement does not apply to SYRINGE PUMPS and INFUSION PUMPS FOR AMBULATORY USE which use syringes.

Remark: Refer also to 51.5 b).

Compliance is checked by inspection and FUNCTIONAL TEST.

54.104 EQUIPMENT shall be so designed that, if it is accidentally switched off and then switched on again by means of a functional control, the safety of the PATIENT shall be maintained.

Compliance is checked by inspection and FUNCTIONAL TEST.

56 Components and general assembly

This clause of the General Standard applies, except as follows:

56.8 Indicators

Addition:

An indicator lamp (or means other than marking) shall be provided to indicate that the SUPPLY MAINS is on.

Compliance is checked by inspection.

Annexes

The appendices of the General Standard apply, except as follows:

Appendix L

References—Publications mentioned in this standard

Appendix L of the General Standard applies, except as follows:

Addition:

IEC 60521:1988, *Class 0.5, 1, and 2 alternating-current watthour meters*

IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety*

Amendment 1 (1991)

Amendment 2 (1995)

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

IEC 60651:1979, *Sound level meters*

Amendment 1 (1993)

IEC 60801-1:1984, *Electromagnetic compatibility for industrial-process measurement and control equipment—Part 1: General introduction*

IEC 60801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment—Part 2: Electrostatic discharge requirements*

IEC 60804:1985, *Integrating-averaging sound level meters*

Amendment 1 (1989)

Amendment 2 (1993)

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 3: Radiated radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4:1995, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 4: Electrical fast transient/burst immunity test*

ISO 3696:1987, *Water for analytical laboratory use—Specification and test methods*

ISO 3744:1994, *Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 7886-2:1996, *Sterile hypodermic syringes for single use—Part 2: Syringes for use with power-driven syringe pumps*

ISO 8536-4:1987, *Infusion equipment for medical use—Part 4: Infusion sets for single use*

The following Collateral Standards quoted in Amendment 2 of IEC 60601-1 do not apply:

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

Amendment 1 (1995)

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

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

Annex AA
(informative)

General guidance and rationale

AA.1 Rationale for the requirements of this Particular Standard

1.1 ADMINISTRATION SETS are not fully tested by this Particular Standard because they are outside its scope, but it is recognized that INFUSION PUMPS and CONTROLLERS can comply with this Particular Standard only if they are used together with compatible ADMINISTRATION SETS such as those recommended by the manufacturer. It is the responsibility of the OPERATOR to use such ADMINISTRATION SETS in order to avoid a SAFETY HAZARD resulting from the use of unsuitable ADMINISTRATION SETS. It is the responsibility of the manufacturer to recommend ADMINISTRATION SETS which comply with functional safety aspects.

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

3.6 In order to protect the PATIENT from a SAFETY HAZARD due to failure of the protective systems specified in clause 51, subclause 3.6 of this standard requires that SINGLE FAULT CONDITIONS occurring in these protective systems become immediately obvious to the OPERATOR while the EQUIPMENT is operational.

One method of implementing this would be for the EQUIPMENT to continuously carry out self-check routines and alarm and stop infusing if a SINGLE FAULT CONDITION occurs (see example 3 of 3.6). However, it is recognized that this method might require expensive technology. Two other methods are, therefore, allowed. Example 2 allows the OPERATOR to initiate an automatic self-check procedure at any time before, during, or after the infusion. Example 1 allows the OPERATOR to participate in an interactive procedure by following a safety check list described in the ACCOMPANYING DOCUMENTS.

It is intended that, whichever method is employed, all primary sensors in the protective system should be included so that a true functional check is carried out.

6.8.2 a) 19) Examples of conditions under which the EQUIPMENT may fail to maintain the specified accuracy include short time periods, unusual infusion liquid characteristics, the use of excessively fine bore needles, inadequate protection against the extremes of environmental conditions, occlusion of the ADMINISTRATION SET upstream of the EQUIPMENT.

6.8.2 a) 20) Examples of a SAFETY HAZARD associated with interconnection of the infusion system or ACCESSORIES to the PATIENT LINE include the possible change in infusion rate due to such interconnections and the increased possibility of air infusion to the PATIENT, especially with gravity feed systems.

6.8.2 a) 28) The maximum infusion that may occur under SINGLE FAULT CONDITIONS may be declared as a percentage of the set rate or the BOLUS volume delivered before the EQUIPMENT stops.

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

44.4 Attention is drawn to the fact that leakage may occur from liquid reservoirs, ADMINISTRATION SETS, and connectors above and in the EQUIPMENT, and that the liquid may be a viscous 50 % dextrose solution. Impairment of safety features due to leakage of this liquid may only occur after a period of time as the solution dries.

50.101 The ability of the EQUIPMENT to maintain the manufacturer's stated accuracy is the essential safety component of this requirement. This requirement for the EQUIPMENT does not take into account clinical criteria of the PATIENT, for example, age, weight, drugs used, etc.

Accuracy of these devices may be affected by extremes of back pressure.

50.102 to 50.108 Accuracy tests for INFUSION PUMPS and INFUSION CONTROLLERS

Data on performance following the start of infusion is important and must be shown by an unambiguous method so that the OPERATOR can select the appropriate EQUIPMENT to suit the clinical application. Graphs of the type shown in Figures 105, 109, and 110 should be included in the INSTRUCTIONS OF USE. These graphs also give a good indication of the nature of the short-term flow fluctuations and are considered self-explanatory when studied with 50.102 to 50.105, as appropriate.

The type of presentation adopted enables OPERATORS to determine the start-up performance of the pump and the nature of its output, be it continuous, discontinuous, cyclical, or otherwise. It is a matter of safety whether delivery starts in a reasonable time. OPERATORS will wish to be aware of likely delays in start-up and whether there are long periods of zero flow (or even reverse flow) during the pumping cycle.

Delays following start-up will vary greatly with:

a) correct priming;

b) backlash in the mechanism;

c) the point at which a leadscrew is engaged (for SYRINGE PUMPS);

d) set delivery rate;

e) compliances within the syringe.

Following the attainment of the normal set delivery rate, it is important for OPERATORS to be aware of the short-term fluctuations in flow which may be expected from EQUIPMENT. Tests for this are conducted as described in 50.102 to 50.105 and example graphs are shown in Figures 106, 107, and 111.

If these tests were carried out before delivery had stabilized, the results would normally be completely dependent on the first few minutes after start-up, and would give no useful information on expected performance at other times.

In establishing the accuracy of various pumps, the flow over a given period of time is measured. Parameters have been set to provide a safe standard to which the EQUIPMENT should comply. However, when the time interval over which the accuracy is measured is shortened, all pumps show considerable variations of flow pattern, for instance, on a minute to minute basis. This applies to all currently available EQUIPMENT: rotary and linear peristaltic, diaphragm and piston types, and even SYRINGE PUMPS. With certain EQUIPMENT, it is possible to show errors of flow of ± 75 % over a 1 min cycle, and errors of ± 30 % over a 5 min cycle are not uncommon.

At the present time, certain drugs infused by such EQUIPMENT have a pharmacological and biological half-life of less than 5 min. For example, one of the agents commonly used to support the cardiac output in a severely ill PATIENT has a half-life of approximately 2.5 min. It is obvious that the use of such agents in concentrations which require low rates and where such demonstrated fluctuations occur may lead to alarming and potentially dangerous responses by the PATIENT. It is therefore of vital importance that the OPERATOR

is made aware that such fluctuations can occur so that he can make the necessary adjustments in both concentration and set delivery rate.

DRIP-RATE INFUSION CONTROLLERS are used only for intravenous infusions. They operate because the pressure created by the height of the liquid level in the container above the infusion site (usually about 90 cm H_20 = 8.83 kPa) is greater than the maximum venous pressure likely to be encountered in clinical practice (approximately 2.67 kPa (20 mm Hg)).

The maximum drip rate available with these devices is usually 100 drops per minute which, when using a 20 drops/ml set, is equivalent to a set rate of 300 mL/h. 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). With higher viscosity liquids, such as dextrose (50 %), these figures increase to 0.43 kPa (3.2 mm Hg) (with an 18 G, 1.2 mm needle 40 mm long) and 2.86 kPa (21.4 mm Hg) (with a 21 G, 0.8 mm needle 40 mm long), respectively.

In clinical practice, it would be inadvisable to attempt to use higher viscosity liquids or smaller gauge needles. Thus, the tests specified will allow realistic testing of the performance of the EQUIPMENT.

VOLUMETRIC INFUSION CONTROLLERS are similar to DRIP-RATE INFUSION CONTROLLERS in that they use gravity to supply the required infusion pressure. However, these devices are calibrated in volumetric units, for example, milliliters per hour (mL/h), and, although they count drops, they attempt to convert drops to volumes. This may be accomplished by the use of a special drop-forming orifice in the drip chamber and/or the use of liquid codes (programmed by the OPERATOR) to take account of the different characteristics of various solutions used in intravenous therapy. The volume of a drop is dependent on a number of factors which include drip rate, temperature, pressure, the materials and condition of the drop-forming orifice, viscosity, and surface tension of the liquid used. However, as the purpose of the test is to ensure that the infusion output is consistent with the selected value, tests carried out using ISO class III water for medical use and at the extremes of back pressure (negative back pressure only) are satisfactory.

VOLUMETRIC INFUSION PUMPS are designed to deliver precise volumes of liquids at medium and high set rates and shall be capable of pumping intravenously and using various sizes of needle, and all types of liquids.

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 fluids. Testing at −13.3 kPa (−100 mm Hg) is to simulate the negative back pressures that are sometimes encountered in clinical usage.

51.5 b) PATIENT movement has been known to cause FREE FLOW. During testing, this may be investigated by allowing the flow to stabilize, then quickly lowering the collecting vessel 50 cm and checking for evidence of FREE FLOW. The above simulates PATIENT movement.

51.101 b) IEC 60601-1 allows testing to be carried out at temperatures between +10 °C and +40 °C. Test houses should be aware of the effects of the extremes of temperature on BOLUS volumes generated as a result of this test.

51.104 Infusion of 1 ml of air within 15 min is not considered to be a SAFETY HAZARD. Bubbles of less than 50 µL of air each are omitted in summing up the 1 mL.

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

54.103 Acceptable methods of maintaining PATIENT safety are either to maintain the previously selected mode of operation and set rate, or to cease delivery and initiate an audible alarm.

A functional control is one which is designed to either start or stop infusion, and may be separate from or combined with the mains switch.

The quality of insulation is investigated in clauses 17, 19, 20, and subclause 57.10.

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

36 It is well known that strong electromagnetic fields can interfere with electronic EQUIPMENT. INFUSION PUMPS and CONTROLLERS are known to be affected in the same way. In particular, there have been reports of interference from radio transmitters in ambulances and from electromagnetic fields generated by diathermy EQUIPMENT. The increased use of mobile telephones, particularly those operating at frequencies of 450 MHz and 900 MHz, has likewise been shown to cause problems with the operation of INFUSION PUMPS and CONTROLLERS.

As the use of automatic INFUSION PUMPS escalates in new environments which are often alien to the sensitive electronic circuitry employed, it is important for the OPERATOR to be aware of the possible hazards which may arise. Examples of such SAFETY HAZARDS include unpredictable cessation of infusion and reversion to a purge mode of operation.

It is also important that the manufacturer is aware that external interference may also change or destroy internal or external feedback loops that regulate various physical variables within the EQUIPMENT. A known example of this is an oscillating action of the infusion mechanism due to such external interference. Generally, the EQUIPMENT reacts in an unpredictable manner.

36.201.1.3 This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply because INFUSION PUMPS and CONTROLLERS do *not* intentionally apply RF energy for diagnosis or treatment.

36.201.1.4 The first paragraph of this subclause of the Collateral Standard IEC 60601-1-2 does *not* apply because INFUSION PUMPS and CONTROLLERS are *not* radiology EQUIPMENT.

36.201.1.5 This subclause of the Collateral Standard IEC 60601-1-2 does *not* apply because INFUSION PUMPS and CONTROLLERS are *not* PERMANENTLY INSTALLED EQUIPMENT.

36.201.1.7 This subclause of the Collateral Standard IEC 60601-1-2 applies.

The Collateral Standard IEC 60601-1-2 states that manufacturers shall state the test procedure used for PATIENT COUPLED EQUIPMENT and/or SYSTEMS. INFUSION PUMPS and CONTROLLERS are PATIENT COUPLED EQUIPMENT as defined in the Collateral Standard, because the ADMINISTRATION SET is considered as a “path for ... electromagnetic energy” (see last two lines of the definition in 2.202 in the Collateral Standard IEC 60601-1-2).

36.201.2.1 This subclause states that fluctuations or distortion caused by EQUIPMENT are *not* tested. In Annex AAA of the Collateral Standard IEC 60601-1-2, it is stated that “EQUIPMENT and/or SYSTEMS are an insignificant load factor on the power network, and do not create daily peak power demands as do consumer products (e.g., TV sets). Moreover, most EQUIPMENT and/or SYSTEMS are not connected to the public low-voltage supply systems.” This statement, which is meant for all MEDICAL ELECTRICAL EQUIPMENT together and not for individual apparatus, clarifies why fluctuations and distortions do not need to be measured.

36.201.2.2 No requirements in the first edition of the Collateral Standard IEC 60601-1-2 apply. Requirements in later editions automatically apply.

36.202 Subclause 36.202 of the first edition of the Collateral Standard IEC 60601-1-2 states that “Compliance with the requirements given in 36.202.1 to 36.202.6 shall be checked by verifiying that, under the specified conditions the EQUIPMENT and/or SYSTEM continues to perform its intended function as specified by the manufacturer or fails without creating a SAFETY HAZARD” (e.g., cease delivery and alarm). The additional requirement in this Particular Standard specifies more precisely what this means for INFUSION PUMPS and CONTROLLERS.

36.202.1 Annex AAA of the first edition of the Collateral Standard IEC 60601-1-2 states that levels in the Collateral Standard IEC 60601-1-2 are chosen to harmonize with ITE limits. This Particular Standard prescribes higher levels because of the life supporting character of INFUSION PUMPS and because of the type of application of them.

The Collateral Standard IEC 60601-1-2 specifies no special test method for MEDICAL ELECTRICAL EQUIPMENT which is not mains connected. If this kind of EQUIPMENT is placed on an isolating support 0.5 mm thick as required by IEC 60801-2, it is charged by subsequent ESDs and no further ESD testing is possible until its EUT is fully discharged again. It is

noted here that discharging of an EUT can be accomplished by using air-ionizers which locally produce ionized air around the EUT.

36.202.2.1 a) The Collateral Standard IEC 60601-1-2 specifies a test level of 3 V/m. Because INFUSION PUMPS and CONTROLLERS are LIFE SUPPORTING EQUIPMENT, this Particular Standard specifies a test level of 10 V/m.

36.202.2.1 b) and c) These items of the Collateral Standard do not apply because INFUSION PUMPS and CONTROLLERS are not for use in X-ray or other shielded locations only.

36.202.2.1 d) Annex AAA of the first edition of the Collateral Standard IEC 60601-1-2 explains that the physiological signals measured can be substantially below those induced by a field strength of 3 V/m (see also rationale to 36.202.2.2 d) below).

36.202.2.2 b) INFUSION PUMPS and CONTROLLERS are LIFE SUPPORTING EQUIPMENT according to the definition 2.201 in the Collateral Standard IEC 60601-1-2, and therefore the test frequency shall be swept from 26 MHz to 1 GHz (for other than LIFE SUPPORTING EQUIPMENT, only a few frequencies have to be tested).

36.202.2.2 d) Annex AAA of the first edition of the Collateral Standard IEC 60601-1-2 explains that the PATIENT may function as an antenna. For the time being, this Particular Standard gives no solution to this problem, but this is no reason not to perform the IMMUNITY test with radiated electromagnetic fields on INFUSION PUMPS and CONTROLLERS.

36.202.2.2 e) This item e) does *not* apply because it covers PERMANENTLY INSTALLED EQUIPMENT and "other than LIFE SUPPORTING EQUIPMENT."

36.202.4 Annex AAA of first edition of the Collateral Standard IEC 60601-1-2 states that applicable IMMUNITY levels are under consideration by Technical Committee 77 and Working Group 13 of Subcommittee 62A. For the time being, this Particular Standard refers to the rather old EEC Recommendation number C42/9 in which dips, interruptions, and variations are specified.

36.202.5 Annex AAA of the first edition of the Collateral Standard IEC 60601-1-2 states that limits and test methodology are under consideration by Working Group 13 of Subcommittee 62A, Subcommittee 65A, and Subcommittee 77B. This Particular Standard contains no requirements for the time being.

36.202.6 Annex AAA of the Collateral Standard IEC 60601-1-2 states that limits and methodology are under consideration by Technical Committee 77. This Particular Standard, however, refers for the time being to IEC 60521 in which 400 A/m is required.

AA.3 Rationale for the algorithm for this Particular Standard

Tests

Accuracy tests for PUMPS FOR AMBULATORY USE

Devices for continuous drug infusion may be required to deliver at a mean set rate which is adjustable over a range of 25–50 times, and with a minimum setting as low as 10 μL/h. The most practical method of controlling to such a limit is to operate quasi-continuously by delivering a discrete small volume increment *v* ("shot") at predetermined intervals *t*, to give a mean set rate of *v*/*t*. The shot frequency can be hundreds of shots per hour, or only a few per 24 h. In some pumps, both the shot interval and the shot volume are changed when a new set rate is selected.

For the subcutaneous delivery route, various pharmacokinetic delay mechanisms smooth the effect of the discontinuous flow, and the amplitude of consequential physiological excursions may thereby be limited.

In the case of insulin where physiological considerations would predicate truly continuous infusion, it has been shown that intermittent subcutaneous delivery within a period of 2 h has no observable clinical disadvantage. Even at this low shot frequency, delivery may be defined as quasi-continuous.

For luteinizing hormone, on the other hand, intermittent delivery of the hormone with a period of around 90 min mimicking the normal pituitary release pattern seems to be clinically optimal. In this application, delivery might be defined as programmed BOLUS, and the pump might incorporate controls for BOLUS volume and for interval between BOLUSES. Insulin pumps generally provide a variable continuous basal infusion, and a variable volume BOLUS on demand. Certain pumps synthesize the BOLUS by an increase in infusion rate over a preset time.

Each clinical application should be considered on its merits and it shall be the responsibility of the OPERATOR to confirm the suitability of a pump for the intended application, taking into consideration the performance and the required delivery protocol.

Types of pumps

Pumps for drug delivery may be categorized into five subgroups on the basis of the mode of delivery:

— type 1: continuous infusion flow only;

— type 2: non-continuous flow only;

— type 3: discrete delivery of a BOLUS;

— type 4: type 1 combined with type 3 and/or type 2 in the same EQUIPMENT;

— type 5: PROFILE PUMP.

Flow errors

Flow errors and variations occur generally because of error or variation in the controlled variables *v* or *t*. Systematic error (error in the mean) occurs when the values of *v* and *t* are incorrect (inherently, or because an unsuitable syringe or other component is in use). Adventitious variation or error is most likely in *v* (shot-to-shot variation, cyclic and random mechanical variability, or tolerances in a syringe or other component).

The OPERATOR of an ambulatory pump will not normally consult the physician more than once a day, and therefore manual resetting of the set rate will not normally occur within a 24 h period. Test protocols should operate on a similar cycle.

Ambulatory pumps are primed before use. Nevertheless, flow on start-up may remain erratic for some time, and a stabilization period prior to testing for errors is therefore included in the test protocol.

Flow testing

The test protocols are devised to characterize the steady-state flow and to identify errors both in the mean and in variations about the mean. Flow is measured by weighing the infusate delivered in a defined observation period, which would ideally be specifically related to the pharmacokinetics of the application for which the device is intended. This is clearly impractical, not least because clinical data for many potential infusates are not available.

A graph of flow versus time (Figure AA.3.1) gives a clear and simple picture of the general stability with time. This is generated during the stabilization period and produces the so-called “start-up curve.”

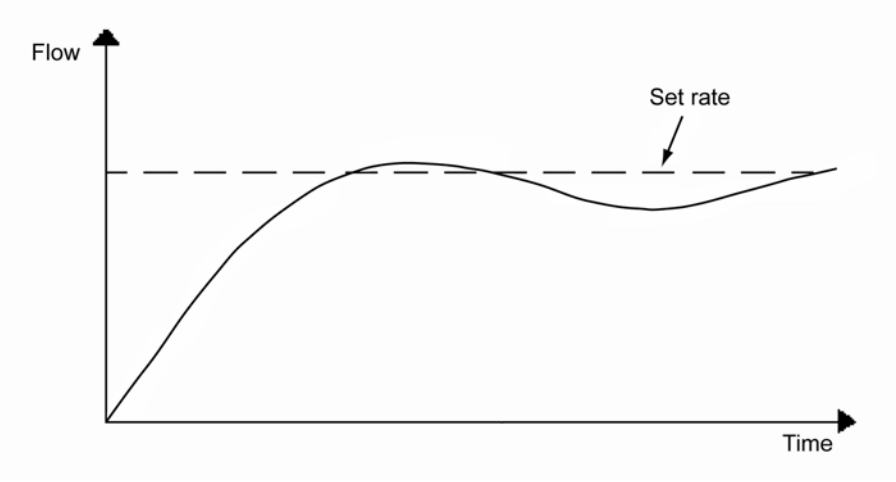

Figure AA.3.1—Start-up graph

After stabilization, data is processed to integrate flow over a range of time periods. The maximum positive and negative errors occurring within these time periods are plotted, to give the so-called “trumpet” profile (Figure AA.3.2).

The performance may thereby be compared with the manufacturer's data, and the plot allows the clinician to match the device to the pharmacokinetics of the application.

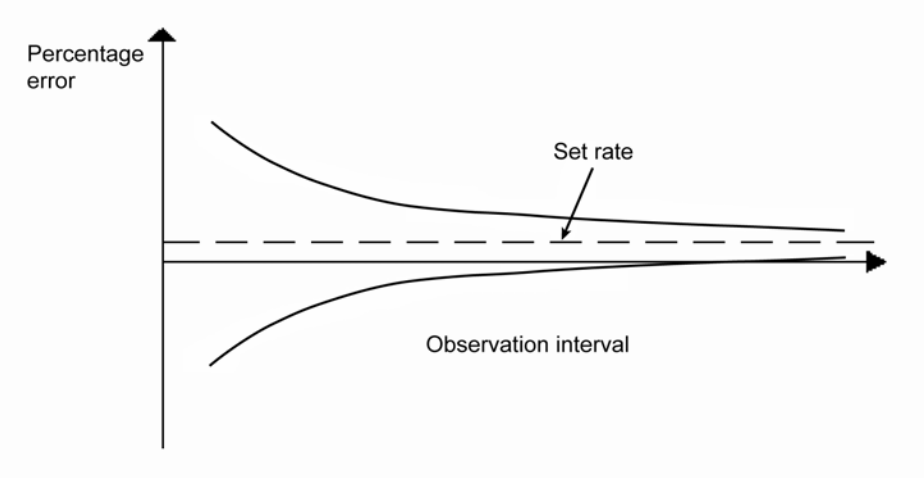

Figure AA.3.2—Trumpet curve

For type 2 (quasi-continuous) pumps, with a fixed shot volume, the interrogation interval is a simple multiple of the shot interval. In such pumps, the technique of flow measurement and the characteristics of the pumps are such that the validity of tests is not dependent on the setting of the pumps. Thus, the curve derived at a convenient INTERMEDIATE RATE setting may be applied to higher and lower rate settings by appropriate scaling of the ordinate.

BOLUS setting

BOLUS delivery is measured by direct weighing of the infusate delivered.

Scaling of graphs (with reference to the tests of 50.102 to 50.108)

It may be necessary to produce different scales of percentage variation in flow or drip rate depending on the type of EQUIPMENT tested. It is important that OPERATORS are able to assess the accuracy characteristics of devices on a comparable basis and that the data presented are easily understood.

Rationale for an algorithm to calculate E_p(max.) and E_p(min.)

The algorithm to calculate the maximum E_p(max.) and minimum E_p(min.) percentage variations within the observation window of duration P (min) over an analysis period T may be divided into four component stages.

The first stage calculates the maximum number of observation windows of duration P (min) over the analysis period T. There are a maximum number m of such observation windows. Consider, first, the smallest observation window of duration S (min), up to the largest observation window of duration T (min):

For the smallest observation window	$P = S$	$m = T/S$
For the second smallest observation window	$P = 2S$	$m = T/S - 1$
For the k^{th} smallest observation window	$P = kS$	$m = T/S - k + 1$
For the largest observation window	$P = T$	$m = 1$
Substituting	$k = P/S$	$m = T/S - P/S + 1$

Hence, for any observation window of duration P, where P is a multiple of S, there are a maximum of m observation windows given by the following equation:

$$m = \frac{(T - P)}{S} + 1 \qquad \text{(AA.3.1)}$$

The second stage calculates the flow error E_i for each successive sample over the analysis period T. Since E_p(max.) and E_p(min.) are expressed as a percentage, Q_i shall also be expressed as a percentage error from rate r. Figure AA.3.3 shows that for W_0 to W_n mass samples, there are Q_1 to Q_n flows, and consequently e_1 to e_n flow errors. Note that W_i is the i^{th} mass sample of the analysis period T, not the i^{th} mass sample of the test period. Any e_i is calculated from the following equation:

$$Q_i = \frac{60\,(W_i - W_{i-1})}{Sd}$$

$$e_i = 100(Q_i - r)/r \qquad \text{(AA.3.2)}$$

The third stage calculates the mean flow error over any observation window of duration P. An average is achieved by summing the individual flow errors over each observation window and dividing the result by their total number (see Figure AA.3.3).

This calculation is repeated for all m observation windows determined from equation AA.3.1. Equation AA.3.3 calculates the mean flow error E_p for all observation windows of duration P.

For the first window

$$E_p(1) = \frac{e_1 + e_2 + .. + e_{P/S}}{P/S}$$

For the second window

$$E_p(1) = \frac{e_2 + .. + e_{P/S+1}}{P/S}$$

For the m^{th} window

$$E_p(1) = \frac{e_m + e_{m+1} + ... + e_{P/S} + e_{P/S+m-1}}{P/S}$$

Hence, for any window j from one to a maximum of m windows

$$E_p(j) = \frac{S}{P} \sum_{i=j}^{j+\frac{P}{S}-1} e_i \qquad \text{(AA.3.3)}$$

The final calculation stage is to determine the maximum E_p(max.) and minimum E_p(min.) percentage variations within the observation window of duration P. These parameters are simply the maxima of the $E_p(j)$ calculated from equation AA.3.3. Hence:

For the maximum

$$E_p(\text{max.}) = \text{Maximum}\ (\ E_p(1),\ E_p(2),\ ..,\ E_p(m)\ )$$

or

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{MAX}}\ (E_p(j)) \qquad \text{(AA.3.4)}$$

Similarly, for the minimum

$$E_p(\text{min.}) = \text{Minimum}\ (\ E_p(1),\ E_p(2),\ ..,\ E_p(m))$$

or

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}}\ (E_p(j)) \qquad \text{(AA.3.5)}$$

All four calculation stages may be combined into a single equation for E_p(max.) and E_p(min.), respectively:

$$E_p(\text{max.}) = \underset{j=1}{\overset{m}{\text{MAX}}} \left[\frac{S}{P} \cdot \sum_{i=j}^{j+\frac{P}{S}-1} 100 \left[\frac{Q_i - r}{r} \right] \right] \quad \text{(AA.3.6)}$$

$$E_p(\text{min.}) = \underset{j=1}{\overset{m}{\text{MIN}}} \left[\frac{S}{P} \cdot \sum_{i=j}^{j+\frac{P}{S}-1} 100 \left[\frac{Q_i - r}{r} \right] \right] \quad \text{(AA.3.7)}$$

where

$$m = \frac{(T-P)}{S} + 1$$

In order to determine the maximum E_p(max.) and minimum E_p(min.) percentage variations within each observation window of duration P, equations AA.3.1 to AA.3.7 should be recalculated for each new value of P = 1, 2, 5, 11, 19, and 31 min.

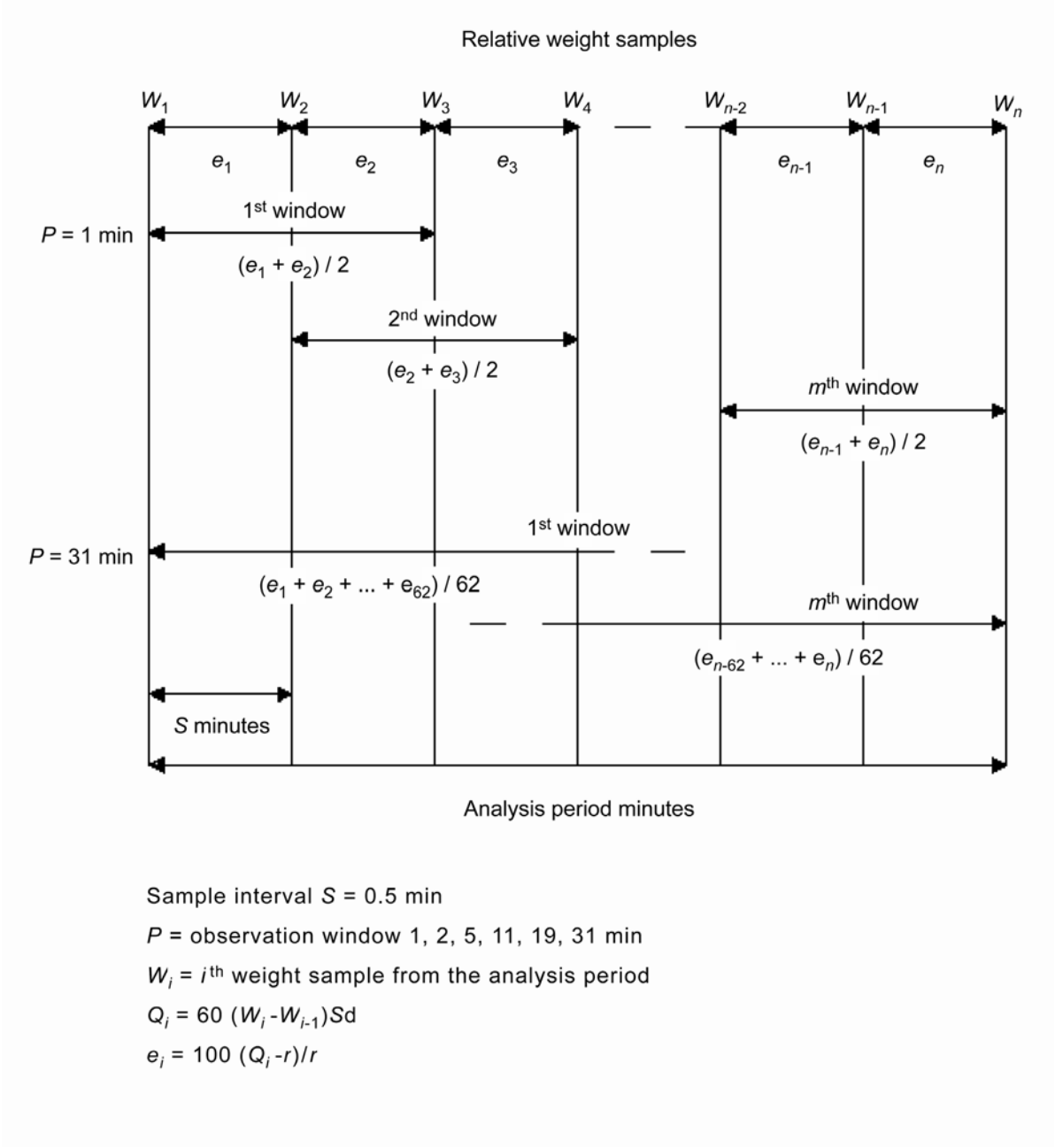

Figure AA.3.3—Calculation for E_p(max.) and E_p(min.)

AA.4 Rationale for development of a "statistical" trumpet graph

The maxima trumpet graph is formulated to quantify the variations in mean flow accuracy over specific observation periods or windows. The variations are presented only as maximum and minimum deviations from the overall mean flow within the observation window.

When the quality of sampled flow data is good, then the maxima trumpet graph is an accurate indicator of the INFUSION PUMP short-term performance. However, the sampled flow data can be susceptible to measurement anomalies. Obvious anomalies may include the formation of air bubbles from dissolved gas or environmental influences on the measurement system, but more complicated interactions such as sampling aliasing or disposable batch performance variations also reduce the quality of sampled data. When the quality of sampled data is reduced, the reliability and reproducibility of the "maxima" trumpet performance is similarly reduced. This is because the maxima trumpet methodology qualifies only the maximum and minimum mean flow variations.

A methodology is required which can meet two primary objectives. First, it should identify the variation in the mean flow over a specific measurement interval. Second, it should be able to produce data that is both reliable and reproducible. Both of these primary objectives shall be achieved when applied to the general case of any arbitrary infusion device.

The remainder of this proposal attempts to define a methodology for testing which meets the stated primary objectives, based on statistical knowledge of the flow performance characteristics of the infusion device.

Statistical analysis on flow performance

Summary

Consider an arbitrary pump which has been infusing for a length of time sufficient to exclude start-up anomalies from the analysis. The rate measured from such an infusion device is then characterized only by the mean flow and variation about the mean flow. The probability density function (pdf) of the long-term flow is also characterized by these statistics of mean flow and variance.

By determining the pdf of each short-term observation window, the short-term performance of the infusion device is characterized statistically. This may be simplified since any observation window may be represented as a sequence of the mean of successive individual data samples over the observation window length. Since the pdf of individual samples can be determined from the long-term flow statistics, a method is required to determine the pdf of successive sample means also from the long-term flow statistics. This can be achieved with the application of the central limit theorem.

Definition of parameters

Consider, once again, an arbitrary pump which has been infusing for a given length of time. With reference to Figure AA.4.1, the flow is measured with a sample interval of T_s (min) over the total duration of the test. This yields a maximum of *i* data samples or interrogation points. To eliminate the start-up anomalies, a continuous analysis period is selected from the *i* data samples.

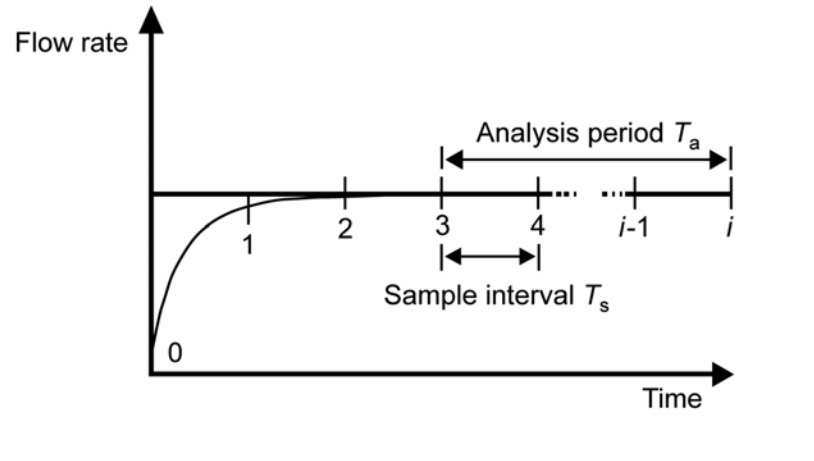

Figure AA.4.1—Sampling protocol

With reference to Figure AA.4.2, The analysis period is of duration T_a (min) and contains *n* data samples. The analysis period T_a may be subdivided into observation windows of lengths 1 to *l* (min), where the maximum window length *l* may be arbitrarily assigned. The maximum number of observation windows *m*, of length *l*, is not significant in the analysis.

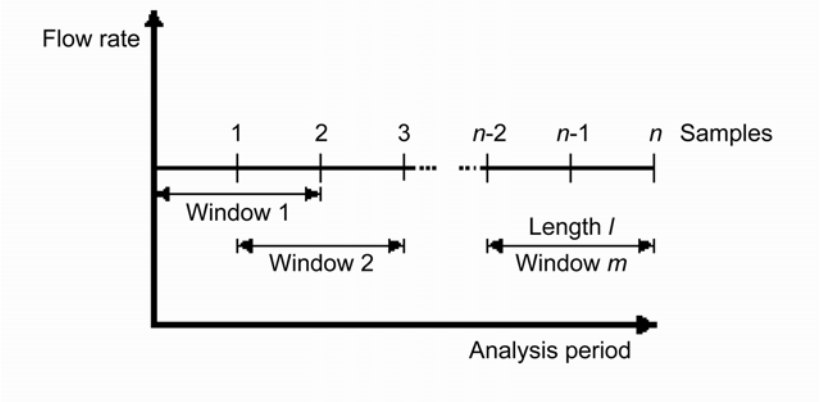

Figure AA.4.2—Observation windows

These parameter definitions are well established for the calculation of maxima trumpet curves.

Mathematical analysis of the flow

The flow output within the analysis period is considered as the parent variate X and will be characterized by some probability density function (pdf), from which the n samples are taken. The population sample mean and sample standard deviation of the parent variate X can be approximated from the n data samples, using the following formulae:

Sample mean

$$X = \frac{1}{n} \cdot \sum_{i=1}^{n} X_i \qquad \text{(AA.4.1)}$$

Sample standard deviation

$$s = \sqrt{\frac{1}{n} \cdot \sum_{i=1}^{n} (X_i - X)^2} \qquad \text{(AA.4.2)}$$

Providing the sampled data size n is large, then equations AA.4.1 and AA.4.2 provide good approximation to the population mean and population standard deviation of the parent distribution (see Figure AA.4.3).

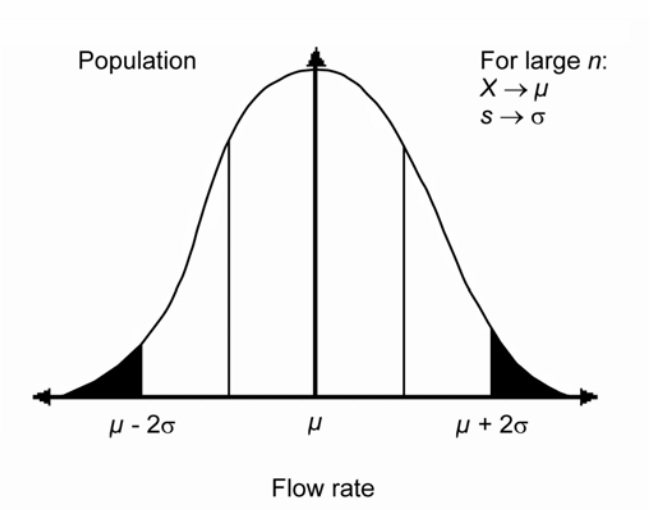

Figure AA.4.3—Distribution of parent variate *X*

The probability distribution of the parent population defines the probability distribution of individual samples. The pdf of successive sample means may be determined by the central limit theorem.

Definition: Central limit theorem

> If variate *X* has mean μ and standard deviation σ, and successive independent samples *n* are taken, the distribution of the sample mean *X* tends, as *n* increases, to that of the normal variate $N(\mu,\sigma 2/n)$.

So the theorem predicts that the distribution of the mean of successive samples will be approximately normal, with mean equivalent to that of the parent distribution, and standard deviation equivalent to the standard deviation of the parent distribution divided by the square root of the successive sample size.

Application of the central limit theorem

The distribution of sample means for all observation windows can be calculated theoretically, yielding probability density functions derived from the distribution of the parent variate *X*, and the central limit theorem. Hence, the pdf of each observation window may be determined.

Observation window	**Mean**	**Standard deviation**
1 min	μ	$\sigma \cdot \sqrt{Ts}$
2 min	μ	$\sigma \cdot \sqrt{Ts/2}$
l min	μ	$\sigma \cdot \sqrt{Ts/l}$

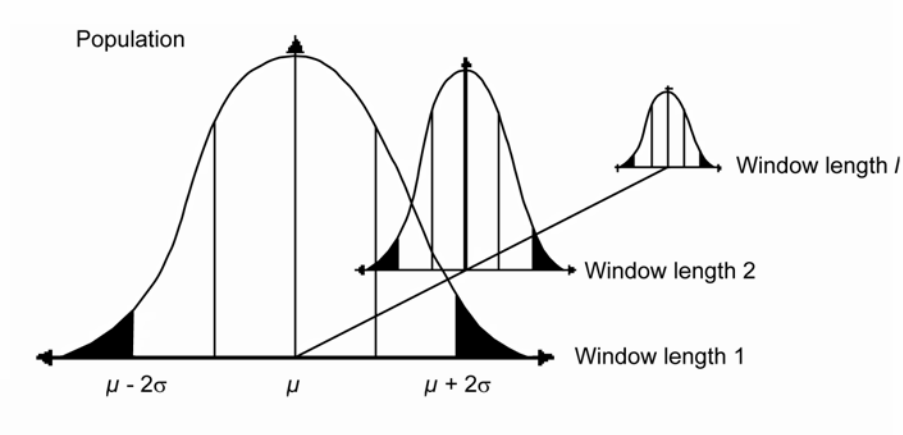

Figure AA.4.4—Distribution of observation windows

Each pdf is approximately normally distributed, and by selecting a nominal confidence limit of ± 2 standard deviations, the statistical trumpet profile can be produced and displayed in a form similar to the “maxima” trumpet graph.

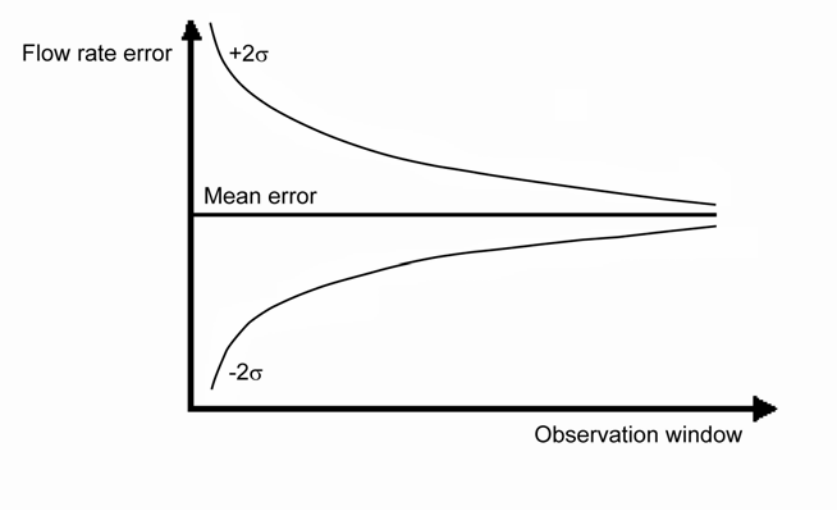

Figure AA.4.5—The statistical trumpet graph

Summary of the validation studies

Two studies were undertaken in order to attempt to validate the suitability of the statistical trumpet proposal as a type test protocol for INFUSION PUMPS.

The first study examined the accuracy of the central limit theorem in predicting the pdf of each observation window, and compared this directly at ± 3 standard deviations with the results obtained from the maxima trumpet algorithm. This study concluded that, while the standard deviations of statistically predicted probability distributions compared well on a qualitative basis (i.e., the characteristic trumpet curve profiles matched), on a quantitative basis significant variations between the measured maxima and the predicted ± 3σ limits for each observation window existed. The uncertainty of the statistical independence of each flow sample and the consequent effect on the central limit theorem are thought to contribute to the errors observed.

The second study examined the ability of the central limit theorem to predict the pdf of each observation windows for a larger sample population of INFUSION PUMPS, based only on a type test of one INFUSION PUMP. Measurements were undertaken using a sample population of ten identical SYRINGE PUMPS from varying batches. Comparisons were made over each observation window to determine whether the mean maxima trumpet values averaged over all ten devices could be predicted by the statistical trumpet ± 3σ limits from one INFUSION PUMP. The study concluded that a greater statistical trumpet prediction accuracy could be attained if the population of devices used to obtain the prediction increased, i.e., a type test of one sample is not appropriate.

The studies have demonstrated that the results of the statistical trumpet algorithm using the central limit theorem yield a good approximation to the results from the maxima trumpet algorithm. However, the approximation is not reliable enough.